To openEHR is Human

A Clinician's perspective

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A dissertation submitted to the University of Dublin, in partial fulfilment of the requirements for the degree of Master of Science in Health Informatics

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Declaration

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work, and has not been submitted as an exercise for a degree at this or any other university.

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09/07/2015

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Dmitri Wall

09/07/2015

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This thesis was as much an adventure as it was a piece of research. It resulted in the acquisition of new knowledge on the part of the author, but more importantly, new connections and new friendships. Many people, in many ways, sometimes unknowingly, shaped my understanding of health informatics, openEHR, research design and human interaction; thank you to each and every one of you.

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Summary

OpenEHR promises an approach to information modeling that places domain experts in a position of influence, enabling the incorporation of their knowledge in health information systems in a flexible manner that can be adapted as medical knowledge changes, while promoting interoperability.

The technical aspects of openEHR and need to engage clinical modelers are well described. However, there has been less focus on the clinical perspective of learning to model. Limited evidence raises concerns regarding the ease with which busy clinicians can develop clinical modeling skills, and practical guidance relating to it is sparse.

This thesis describes a project, facilitated by an action research methodology, to enable a clinician to develop as a clinical modeler in the context of the creation of two real-world patient registries. The development of a number of artifacts by the author, used to develop these registries, is described, as is engagement with expert clinicians, the openEHR clinical modeling community and expert clinical modelers to validate the author's work.

Outputs include observations made by the author during the learning process, proposed amendments of artifact development methodologies, a Clinical Modeling Development Strategy and identification of resources of value to novice clinical modelers. Patient registries are identified as opportunities to engage clinical networks, facilitating the creation of highly interoperable openEHR artifacts, in turn enabling patient registries to meet best-practice guidance.

Medical information is complex and mercurial, making efforts to describe it with information systems challenging. The openEHR model, however, is detailed and flexible enough to meet these challenges. It also recognises that "to err is human", as is diversity of behaviour, and that both must be catered for. (O)penEHR meets these challenges through the community that has evolved around it, collaboratively working to identify as broad a range of perspectives on medical concepts as possible, while iteratively designing out error in the information models that can describe them. While learning to become a clinical modeler is challenging and error laden, the most significant finding of this thesis

is that engagement with this human community enables clinical modelers at all competency levels to make valuable contributions, creating a sense that clinical modeling is achievable and rewarding. For all these reasons the author claims that “to openEHR is human”.

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ABBREVIATIONS

Abbreviation	Full name
AD	Atopic Dermatitis
ADL	Archetype Definition Language
AHRQ	Agency for Healthcare Research and Quality
ATC/DDD	The Anatomical Therapeutic Chemical Classification System with Defined Daily Doses
BPMN	Business Process Model and Notation
CKM	Clinical Knowledge Manager
DEBRA	Dystrophic Epidermolysis Bullosa Research Association
DLQI	Dermatology Life Quality Index
EASI	Eczema Area and Severity Index
EB	Epidermolysis Bullosa
EB-CLINET	Is a "clinical network of EB centres and experts"
EHR	Electronic Health Record
EMA	European Medicines Agency
EPIRARE	European Platform for Rare Disease Registries
EU	European Union
EU SPC ADR database	European Union Summary of Product Characteristics Adverse Drug Reaction database
GEHR	Good European Health Record
GMDN	Global Medical Device Nomenclature
GUI	Graphical User Interface
HGNC	HUGO Gene Nomenclature Committee
HUGO	Human Genome Organisation
ICD	International Classification of Diseases
ICF	International Classification of Functioning, Disability and Health
IGA	Investigator Global Assessment
ISF	Irish Skin Foundation
LOINC	Logical Observation Identifiers Names and Codes
MedDRA	Medical Dictionary for Regulatory Activities
MScHIT	Master of Science in Health Informatics
OMIM	Online Mendelian Inheritance in Man
PARENT JA	PAtient REgistries iNiTiative Joint Action
PGA	Patient Global Assessment
POEM	Patient Orientated Eczema Measure
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
UMDNS	Universal Medical Device Nomenclature System
UML	Unified Medical Language
UMLS	Unified Medical Language System
WHO	World Health Organisation
WHO-ART	WHO Adverse Reactions Terminology

PROLOGUE

GUIDE TO THE STRUCTURE AND PROGRESSION OF THIS THESIS

When the author was identifying possible topics for a thesis, openEHR became an obvious choice, for reasons elaborated in this thesis. (O)penEHR is a complicated solution for a complicated problem. It is therefore unsurprising that the documents that describe openEHR are….complicated! As the author conducted preliminary reading, it seemed that the basic level of knowledge required to understand significant parts of these documents was substantial and a large quantity of knowledge was assumed.

What the author sought, more than anything else, was advice regarding the steps that a novice might take to develop an understanding of openEHR. It struck the author that perhaps the best solution would be for a novice to undertake a project to learn to model and document that journey.

This thesis is deliberately written in a style that recapitulates the chronological sequence in which the project unfolded; it is, therefore, forward-looking in its account of the events rather than retrospective. It begins, by setting the context for the project, in a relative information void. An action research methodology is then used to progress the project, helping the author to navigate through the unknown, towards a position of better understanding. The author's hope is that this approach will provide other novice modelers an opportunity to "walk in my shoes" and enable them to experience how someone at a similar level of understanding progressed. For this reason, the journey is described honestly and all artifacts produced by the author are made available in the compact disc accompanying this thesis. There are occasions, such as at the outset, where the information may seem incomplete. This is precisely because it was incomplete at that time for the author. It is hoped that any confusion that might arise from this atypical approach is offset by the potential help an honest account might provide to other potential clinical modelers searching for a guinea pig!

CHAPTER 1. INTRODUCTION

1.1. BACKGROUND AND MOTIVATION

Until 2014, the author's understanding of openEHR had been limited to fragments of information read intermittently over the preceding years. Described on the openEHR website as "an open domain-driven platform for developing flexible e-health systems" (The openEHR Foundation, 2015), it appeared to be a solution that could be extremely significant to the author, as a physician with an interest in developing user-centred clinical information systems, but appeared so impenetrably complex and time consuming, that that concept was repeatedly pushed aside.

The motivation to push beyond this barrier and adopt this area for a dissertation came from three sources:

1. **Master of Science in Health Informatics (MScHIT) Classwork**
   A class dedicated to understanding openEHR culminated in groups of two classmates, one with a clinical and one with a technical background, producing an openEHR artifact. The author provided clinical context and his technical classmate produced an apparently perfect archetype. The author remained confused, stimulating a number of questions:

   - What would it take to understand openEHR?
   - How difficult would it be for a clinician to learn to model?
   - Are resources available to answer these questions?

2. **The author's work and research**
   The author, a qualified physician, in the latter stages of training to become a consultant dermatologist in Ireland, was employed by a charity, the Irish Skin Foundation (ISF), in the capacity of a research fellow. The author's initial role was to assess the need for, and feasibility of, developing a national registry of skin diseases and this was to progress to become a role that would involve direction of the development of an information technology platform to support a number of key clinical domain areas.
   Work with the ISF project had led to the author being invited to write a subchapter regarding the planning of patient registries for "Methodological

guidelines and recommendations for efficient and rational governance of patient registries" being developed by a European Joint action project PARENT JA (PAtient REgistries iNiTiative Joint Action, henceforth referred to as PARENT). PARENT's aim was to support the development of "comparable and interoperable patient registries with the aim to rationalise and harmonise their development and governance" (Meglič et al., 2012).

The PARENT project identified openEHR as a healthcare information modeling processes that is of significant relevance to enabling the development of state-of-the-art interoperable registries.

3. **Dr Damon Berry**

   Dr Berry's doctoral thesis was entitled "Towards the use of Archetypes to Ensure the Quality of Data in Electronic Health Records" (Berry, 2011). He has a degree in electrical engineering and is a Lecturer in Computing in School of Electrical Engineering Systems in Dublin Institute of Technology. Dr Berry provided exceptionally helpful insights into the world of openEHR, before ultimately becoming the author's thesis supervisor, spending countless hours discussing all aspects of the author's project and thesis, helping to shape the evolution of this project from abstract ideas, to completed thesis.

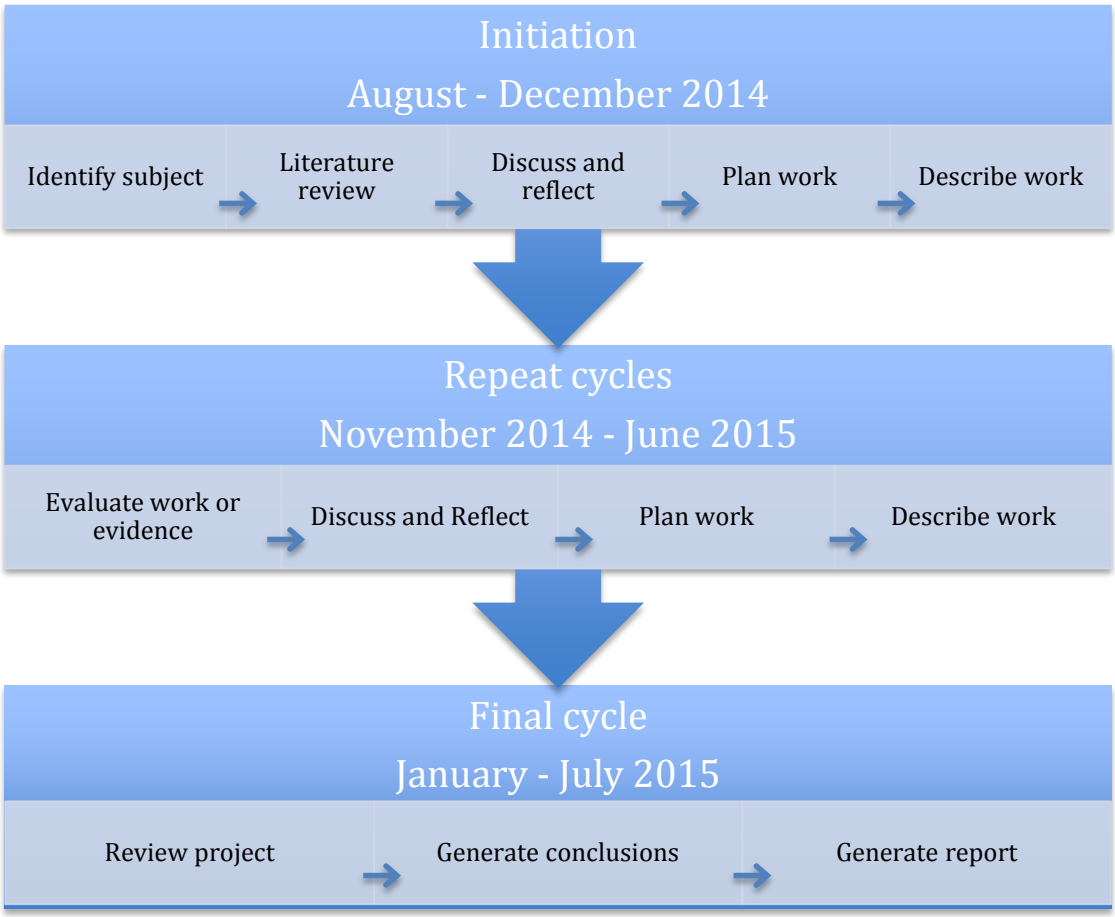
This set of circumstances provided a real-life opportunity and motivation for the author to advance work objectives while developing a skillset that could provide insights into an area of interest, potentially at an interesting intersection of evolving areas: electronic health records and patient registries, focused on the author's professional domain of dermatology.

1.2. METHODOLOGY

The manner in which this thesis is structured is somewhat different to what might be expected in a classic thesis. This structure was adopted after an initial literature review, detailed in the next chapter, was conducted to identify how the author might conduct a project in his areas of interest. It would emerge that the most suitable means of completing this thesis was to focus on the process of a clinician learning to model, utilising the openEHR methodology.

Multiple methodologies were considered, and ultimately used, to enable this, however, action research emerged as the most appropriate overarching methodology. It can be described as "critical and (self-critical) collaborative inquiry by reflective practitioners who are accountable and must make the results of their inquiry public, as well as self-evaluating their practice and being engaged in participatory problem solving and continual professional development" (Zuber-Skerritt, 1996, Koshy et al., 2010). This approach enabled the author to identify a problem and then, through iterative, collaborative cycles of evidence gathering and evaluation, discussion, reflection, planning and implementation, flexibly negotiate an unpredictable pathway to become a novice clinical modeler (Figure 1). This also provided a means to present this process prospectively, in the sequence it occurred, rather than retrospectively, in a potentially more coherent, but idealised manner. The author believed this to be vital to honestly demonstrate to potential modelers the formidable complexities that they may face.

Figure 1 Action Research methodology used in the author's project



In view of this iterative process, the subsequent literature review and methodology chapter are intentionally brief. Their purpose is to orientate the reader with the key

information available to the author at the time of planning this project so that it is clear why subsequent cycles were undertaken.

1.3. LIMITATIONS

The author, while planning this project, identified the limitations imposed as a result of drawing conclusions based on one person's experience of learning to model. Ideally, a number of clinicians would be followed to assess their development. However, opportunities to engage with clinical modelers in the real world, as they begin their modeling journey, is a rare occurrence and would have been particularly difficult to arrange by the author, himself new to the openEHR community. In a preprint abstract, Sundvall (2013), suggests that efforts have been made to achieve this. The author could not locate the promising paper described:

> *"A problem with these approaches is that parts of them currently are rather difficult to learn". "This paper reports findings from a survey among openEHR learners and educators combined with observations of related openEHR mailing list discussions. The paper ends with an opinion piece, where we discuss potentially fruitful ways to learn, explore, and extend archetype-based EHR systems using visualization and examples. The findings highlight potential stumble blocks and solutions and should be of interest for both educators and self-learners".*

To attempt to counteract bias introduced by adopting a study that focuses on one person's perspective, the author has involved a number of relevant groups in studies and mentorship from openEHR experts from both a clinical and technical background.

While it might also be argued that the study of established modelers could produce more powerful results, it was the author's experience from engagement with openEHR, that it is difficult to adequately capture a novice modeler's perspective in retrospect, as experience is gained.

Finally, the premise on which this project and thesis is based is that clinician engagement is a significant challenge, but it is also the key to the success of openEHR. The aim of this project is therefore to capture the perspective of the developing, novice clinician modeler. This is reminiscent of the manner in which patient registries aim to capture patient information in a real-world, real-time manner, accepting that such information can introduce bias, but that this is more reflective of the real-world scenario in which patients live, than the tightly controlled environment of a clinical trial. The author believes that a similar strategy is best suited to this project. By using an action research methodology, it enables the author to examine the novice clinician modeler's perspective in a real-world scenario. This presents certain unpredictable challenges, such as project deadlines, but it also presents equally unpredictable opportunities, that

could not be embraced by a rigid research methodology. It could be argued that the author's context might not be representative of a typical clinician, but the long struggle that health informatics has undergone to develop appropriate solutions has taught us that there is no such thing as a generic healthcare professional, which the author believes is captured to beautifully by Norman (1998):

> *"We are analog beings trapped in a digital world… We are compliant, flexible, tolerant. Yet we have constructed a world of machines that requires us to be rigid, fixed, intolerant*"

1.4. STATEMENT OF INTENT

This thesis is not intended to be a definitive guide to openEHR, nor an instruction manual for clinical modelers. It is intended to describe a project undertaken by one clinician so that he could describe his experience of becoming a clinical modeler. It is hoped that by so doing, potential clinical modelers might discover a resource that will enable them to make a more informed decision regarding whether openEHR is something that they should commit to. It is also hoped that by describing this voice to the openEHR community, that they may be able to gain insights into how more potential clinical modelers might be attracted into, and facilitated to become valuable contributors to, the world of openEHR.

CHAPTER 2. LITERATURE REVIEW AND THESIS RATIONALE

2.1. AIM

This literature review was conducted to gain a basic understanding of openEHR, and use this to examine what elements of the author's work could be used to develop practical modeling skills. It is also intended to facilitate the reader's understanding of the area and the context in which this thesis is conducted. There are two sections:

- A **technical section** was conducted so that the author could understand the basic concepts of openEHR and to identify what work had previously been undertaken with respect to clinical modeling, so that a work plan relevant to the author's circumstances could be developed in a manner supportive of the development of a thesis. This is not intended to be a definitive overview of each area, but a narrative that explains the author's subsequent strategy. It will cover:
    - The principle of openEHR
    - Artifact development
    - The feasibility of clinical modeling
- A **clinical section** was conducted to identify strands of the author's work to which openEHR could be applied in a manner that would enable the author to learn to become a clinical modeler. It is also to present the reader with a sufficient understanding of the clinical domains discussed during this thesis:
    - Patient Registries
    - Atopic dermatitis
    - Epidermolysis Bullosa & Rare Diseases

2.2. TECHNICAL SECTION

2.2.1. OPENEHR

2.2.1.1. DIRECTION

A key phrase, at the core of the openEHR methodology, helped to cement the author's direction towards a dissertation focused on investigating the role of clinicians in the modeling process:

"It is important to involve clinicians in the work of requirements setting. Evaluations of electronic health record systems show consequently that this is a core part for success" (Van Gennip and Talmon, 1995, Hovenga, 2010)

2.2.1.2. PRINCIPLE

OpenEHR developed as a result of more than 20 years of international research, implementations and projects such as the Good European Health Record (GEHR) (Leslie, 2014). The GEHR aimed to develop: ((Ingram, 1995, Kalra, 1994)

- "a modeI architecture for computerised health records across Europe"
- "capable of operating on a wide variety of computer hardwares"
- "able to communicate with many different information systems"

A fundamental principle on which openEHR has been established is that the "core component: 'clinical information' must be developed with clinician involvement" (Hovenga, 2010). Though debate exists as to the capacity of clinicians to contribute to this process, some, central to the openEHR movement, have stated that the openEHR approach is founded on the principle that "domain specialists can model their own information and workflows" (Heard and Beale, 2014).

The two-level approach to modeling underpins the means by which openEHR can enable clinicians to model. This approach, which emerged from the work of a number of authors (Johnson, 1996, Beale, 2002, Beale, 2003), separates the "knowledge and information levels in information systems" (Beale, 2002). This creates a technical layer, called the Reference model, which can be largely ignored by the clinician, who instead needs only focus on creating models of the clinical concepts with which they are familiar. An overarching reference model "guides system development" while "archetypes define clinical content" (Goossen et al., 2010). Rather than constantly defining clinical information for a particular circumstance, archetypes enable the description of clinical concepts that "you only want to define once" (Beale, 2013).

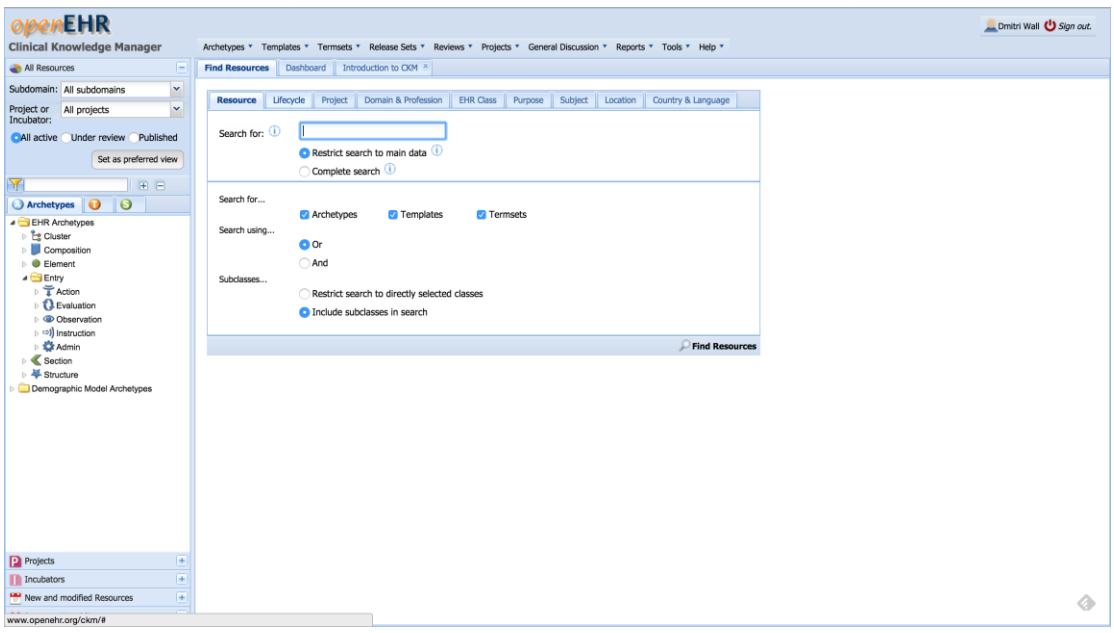
In practical terms, an archetype is a maximal dataset that describes all the components of one clinical concept, for example blood pressure, that might ever be required to

describe that clinical concept, from any clinical point-of-view (Madsen et al., 2010, Ingram and Arikan, 2013). It is imagined that a large library of archetypes will be required to describe all of medicine and that these would be provided by the clinicians who engage directly in the domains that utilise those concepts (Freriks, 2009).

Templates are a means of capturing constrained elements of multiple archetypes in a manner required to suit a particular situation. By combining archetypes and templates, widespread standardisation is enabled in a manner that "has specifically been designed for clinicians to create the archetypes that capture their clinical recording requirements and workflow – effectively shaping their own EHR systems" (Madsen et al., 2010).

Archetypes and templates are stored in a repository called the Clinical Knowledge Manager (Beale, 2013) (Figure 2) that is linked to a social network of clinical modelers. This is openly available and creates an environment that enables re-use of conceptual models or adaptation of existing content for differing circumstances. It also enables online collaboration to curate content, to share experience and improve quality of clinical content models" (openEHR organisation, 2014).

Figure 2 A screenshot of the openEHR Clinical Knowledge Manager



2.2.1.3. THE PROBLEM

While there are numerous descriptions of the conceptual model that openEHR enables, "not many publications focus on the development of archetypes" (Braun et al., 2014,

Santos et al., 2012). Furthermore, the description of real-world implementations of openEHR in the literature suggests that the process is burdensome:

- It required 10 months to create 20 archetypes "by a clinical team coordinated by three health professionals and one systems analyst" who were "supported by around 30 health professionals" "and 5 systems analysts" (Santos et al., 2012).
- "Archetype design and validation can be time-consuming due to the lack of both domain expertise and modelling experience" (Braun et al., 2014).
- "immature modelling support tools, difficulties in defining high-quality archetypes and the problem of overlapping archetypes" in a process that is "time-consuming" (Späth and Grimson, 2011).

One source proposed an extremely useful guide to archetype development, including how they should be validated by the wider CKM community (reproduced in Figure 3) (Leslie, 2008), in addition to providing an excellent archetype review checklist (reproduced in Table 1) (Leslie, 2010) however, the focus did not include how a clinician might gather information to inform the development of an archetype, or how they might practically build that archetype once the appropriate information had been collected. The same author, at a later stage, does, however, describe the need to "engage broadly with a wide range of domain experts - especially clinicians and any individuals or organisations who might potentially use the data for secondary purpose - at the time of reviewing and agreeing that an archetype is ready for use and publication to be inclusive of all requirements" (Leslie, 2012).

Figure 3 Archetype Authoring Process and Lifecycle developed by (Leslie, 2008)

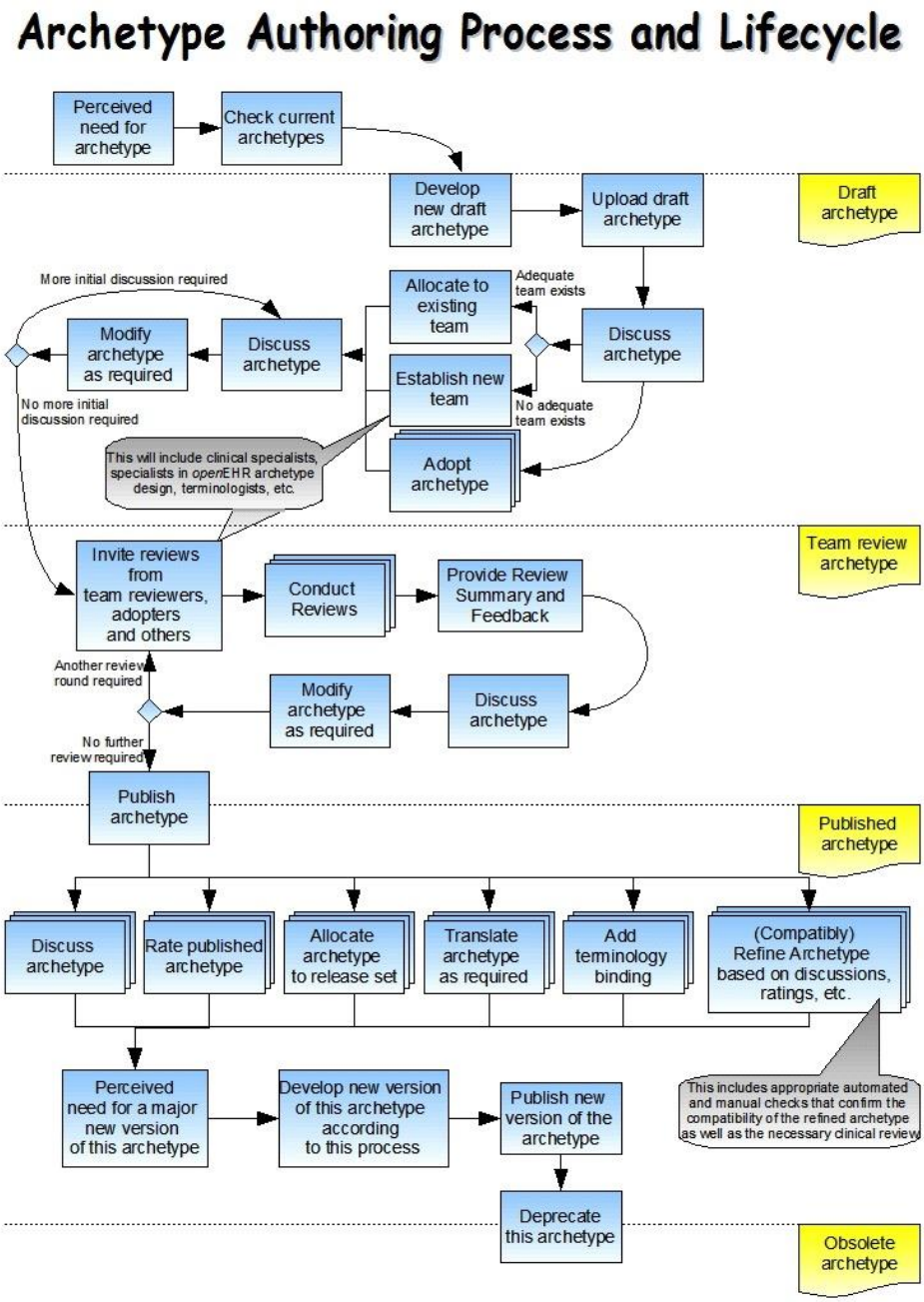


Table 1 Archetype review checklist developed by (Leslie, 2010)

Archetype Detail	Check for:
Cardinality	Check that cardinality is correct for Compositions, Sections, Clusters and Slots
Comments	Check the correctness of any comments per data element
Concept name	Is this appropriate?
Data - data elements	Are these complete? Is there any content missing? Are the datatypes appropriate?
Data - normal statements	Should normal statements be included in this archetype? If present, are the normal statements appropriate? What normal statements should be added?
Events	Should any event be available? Are the specific point-in-time or interval events appropriate? What specific events should be added? Are events present that only apply in limited use cases and should be left to a template?
Metadata	Check completion and correctness of: • Concept Description - a definition of the clinical concept being modelled. • Purpose - the aim and intent of this archetype. What are the key aspects about this concept that will be covered by the scope of the archetype? For example, the adverse reaction EVALUATION will include both data elements that support the documentation of both the propensity of future reactions plus recording summary information about adverse reaction events that have occurred. • Use - description of how this archetype might be used in implementations. • Misuse - description about how this archetype should not be used in implementations. • References • Keywords • Primary Author • Contributors
Occurrences	Check the occurrences of data elements is correct
Phrasing and expression	Check for consistency of phrasing and expression, especially in data element naming and descriptions
Protocol	Are the Protocol data elements appropriate? What other data elements should be added?
Punctuation and spelling	Check for correctness and consistency of punctuation and spelling. Data element names - no full stop All descriptions require a full stop at the end of the sentence.
Slots	Are the slots named appropriately? Are the ITEM archetypes selected as inclusions correct? Are the ITEM archetypes selected as exclusions correct?
State	Are the State data elements appropriate? Are the assumed values correct? What other data elements should be added?

In his thesis, (Corrigan, 2010) proposes an extremely useful archetype and template design methodologies that takes into account a number of other methodologies described in the literature, in addition to his own research. The summarised versions of these are replicated in (Figure 4Figure 5Figure 6).

Figure 4 Summarised archetype design methodology developed by (Corrigan, 2010)

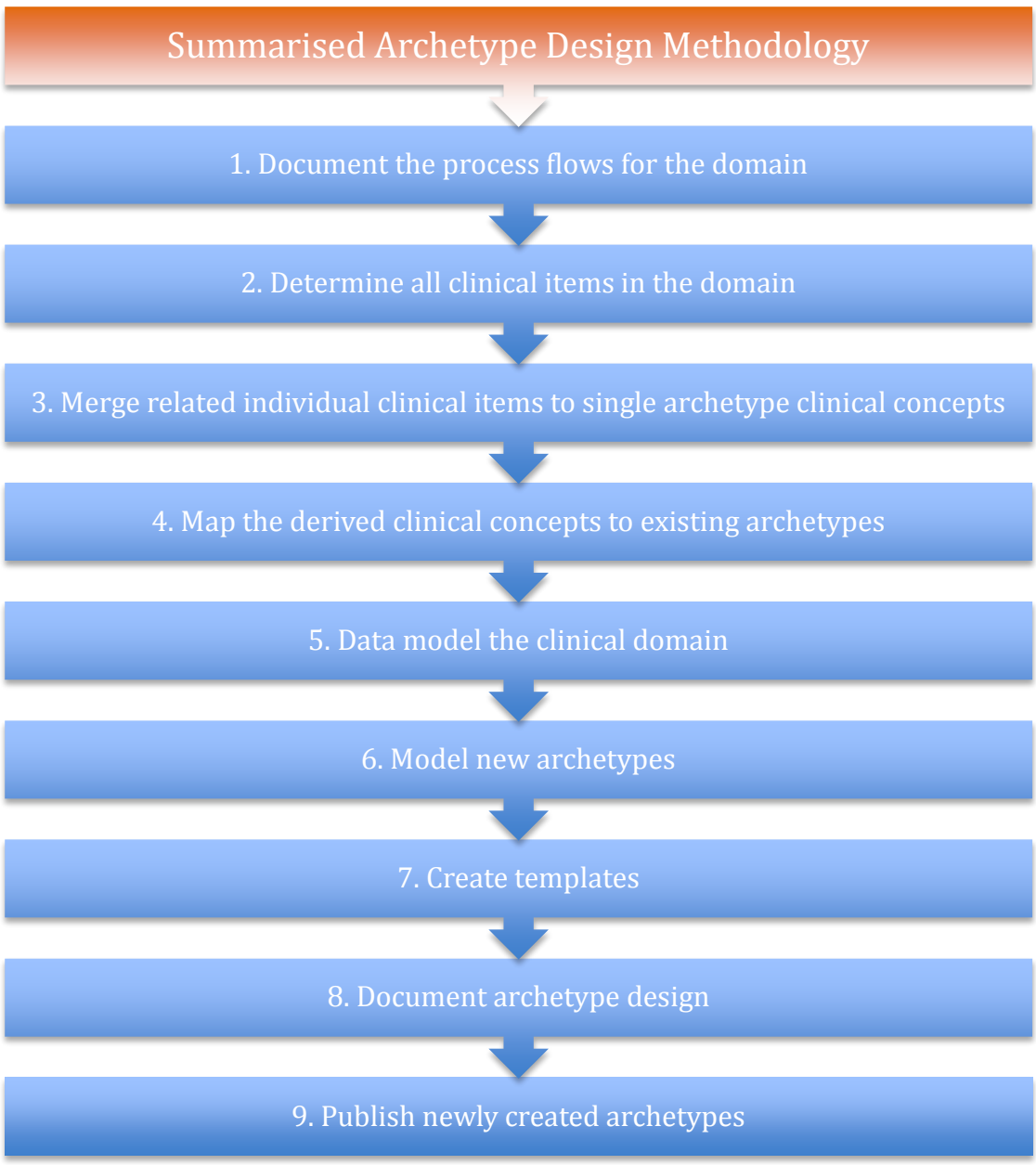


Figure 5 Detail of Step 6 In the summarised archetype design methodology (Corrigan, 2010)

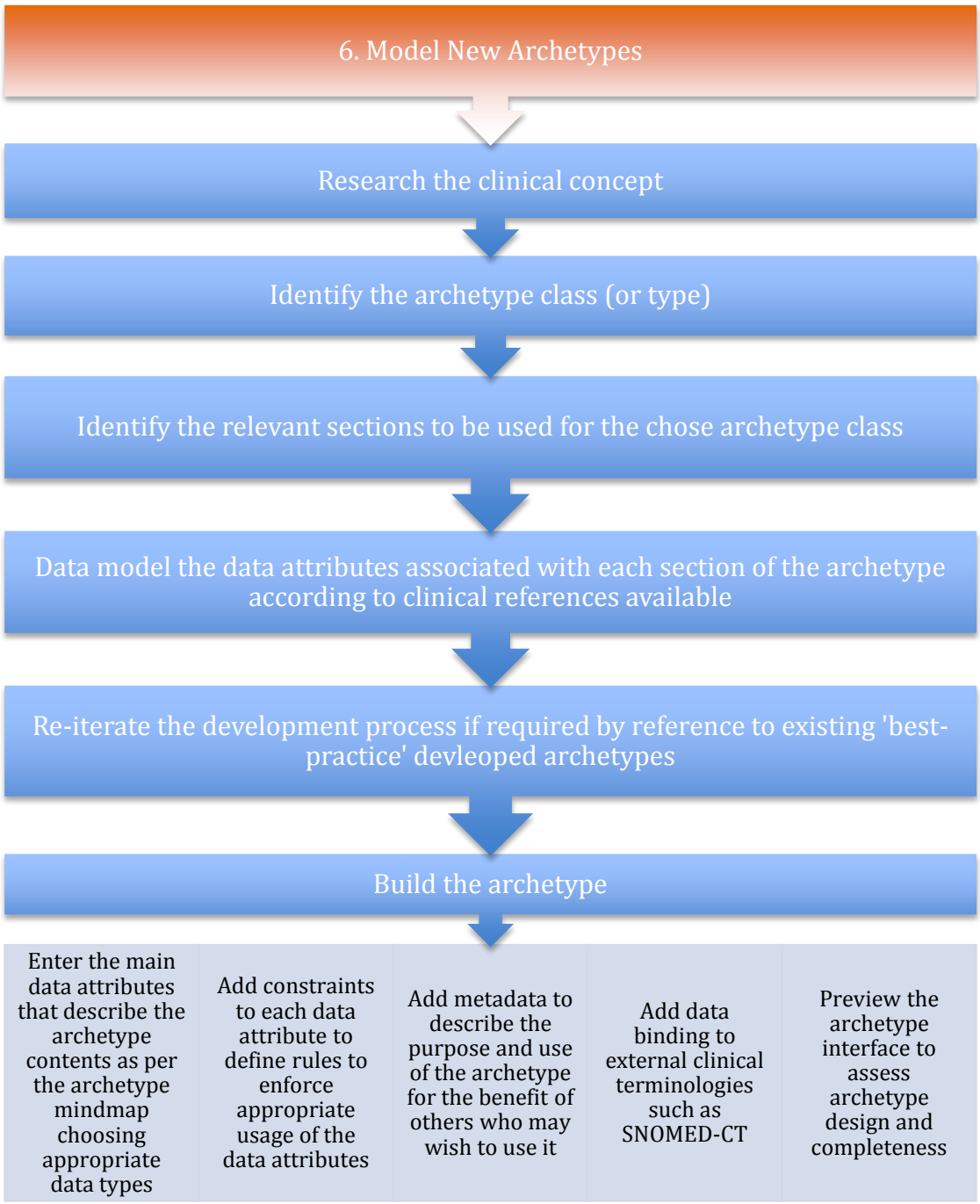


Figure 6 Summarised template design methodology (Corrigan, 2010)

Corrigan, (2010), despite successfully generating these methodologies from practical implementations of openEHR, raises 2 significant points:

- "It is a fundamental question as to whether working clinicians have the time, the data modeling skills and the wish or desire to be involved in an area that has traditionally been an IT skills area."

- "The design methodologies for archetypes and templates suggested in this study are only a starting point for consolidating the multiple sources of information currently available in a more coherent manner."

2.2.1.4. OPENEHR REFLECTION

The literature review confirmed that openEHR is a promising methodology that could facilitate the development of clinically focused information models. However, the complexity of the methodologies raised significant concerns in the author's mind regarding the feasibility of developing the skills to become a clinical modeler, particularly in the context of a real-world scenario. To assess how the author might investigate this further, the author's professional work was examined from the perspective of whether projects could be utilised as use cases to investigate this in practice.

2.3. CLINICAL SECTION

2.3.1. CLINICAL BACKGROUND

The author is in the latter stages of training to become a consultant dermatologist. During training the author developed a significant interest in health information technology, initially with a focus on the development of modular electronic health records for dermatology. Limited satisfaction with existing systems prompted the author to focus on dermatology user expectations and requirements (Wall et al., 2014). The author also developed an interest in medical error and how systems might be developed to protect against this (Wall et al., 2015). Both interests ultimately lead the author towards the area of patient registries.

2.3.2. PATIENT REGISTRIES

Patient registries are best defined by (Gliklich et al., 2014) in their comprehensive guidance document, "Registries for Evaluating Patient Outcomes: A User's Guide":

> *"a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry"*

Patient registries are increasingly being viewed as a valuable means of capturing accurate health information that can facilitate the delivery of effective health care. In Sweden, for example, the establishment of a hip and arthroplasty registry resulted in the avoidance of 7,500 revisions between 2000-2009, with a saving of $140 million in costs (The Lancet, 2011).

Such success has resulted in considerable investment in ensuring the development of high-quality and interoperable registries. In the US, for example, the Agency for Healthcare Research and Quality (AHRQ) have produced the guidance document noted above (Gliklich et al., 2014) with respect to registry best practice, in addition to creating a Registry of Patient Registries (Agency for Healthcare Research and Quality, 2014).

In the EU, the previously noted PARENT is "a joint EU and Member States response to poor cross-border availability of health data for public health and research". It aims to deliver "recommendations and tools for implementation of interoperable and cross-border enables patient registries" (PARENT, 2015) with the aim "to rationalize and harmonize their development and governance" (Meglič et al., 2012). This group has created a pilot Registry of Registries, similar to the AHRQ (PARENT (PAtient REgistries iNiTiative), 2014).

Within "methodological guidelines and recommendations for efficient and rational governance of patient registries", that PARENT are producing, currently in advanced draft format to which the author is contributing, openEHR has been identified as a healthcare information modeling process that is of significant relevance to enabling the development of state-of-the-art interoperable registries.

In the area of rare disease, patient registries have been described as "the best way of pooling data to achieve a sufficient sample size for epidemiological and/or clinical research" (Posada et al., 2014). As a result, the EU has funded the EPIRARE project "to improve standardisation and data comparability among patient registries and to support new registries and data collections" (Taruscio et al., 2014) within the rare disease domain.

2.3.3. CLINICAL BACKGROUND CONTINUED

Patient organisations have also recognised the value of supporting patient registries. One such group is the Irish Skin Foundation, a charity formed in 2011, with a mission "to support in all ways possible, to advocate on behalf of, to educate all involved with, and

to bring comfort to those affected by skin disease in Ireland, their families and their carers" (Irish Skin Foundation, 2015). A two-year research fellowship was offered to the author, to assess:

- Whether the establishment of a national registry of skin disease was advisable in Ireland
- If advisable, how development should proceed

The author conducted an extensive literature review and an on-going stakeholder consultation that has involved in excess of 200 individuals and groups (Figure 7), across more than 15 countries.

Based on this consultation, a number of clinical domains were established as most appropriate in which to establish patient registries. Though these will be developed to create a national registry, they are being developed with international input as they aim to establish the basis of international patient registry collaborations.

The two domains, which are the initial focus from the perspective of development, are:

- Atopic dermatitis
- Epidermolysis Bullosa

2.3.4. ATOPIC DERMATITIS

Atopic dermatitis (AD), also known as eczema, is a common, chronic, itchy, inflammatory skin condition, that is particularly common within the paediatric population (Watson and Kapur, 2011). It has been estimated that approximately 165 million children are affected worldwide (Hay et al., 2015) and the global prevalence in all age groups has been estimated to be in the order of 230 million. Significantly, in many areas of the world the incidence is rising (Williams et al., 2008). Considerable itching can result in atopic dermatitis, resulting in a significant impact on quality of life (Hay et al., 2015), resulting in eczema being the "leading cause of skin condition disability-adjusted life years" (Hay et al., 2014). In fact, the economic burden associated with eczema is "comparable with that of asthma" (Williams et al., 2008, Verboom et al., 2002) and, in the case of moderate to severe disease in children, it "is greater than that of the care of children with type 1 diabetes mellitus" (Williams et al., 2008, Kemp, 2003).

While the author's research supervisor, Professor Alan Irvine, is a well-recognised expert in the field of atopic dermatitis internationally, and AD was to represent the main

focus of the ISF's initial skin disease registry project, the project required the coordination of a number of work streams and groups. This complexity introduced significant uncertainty and risk, considered too great to rely on for the purpose of supporting the author's project. As such, an additional domain area and project were considered.

Figure 7 Groups involved in the Irish Skin Foundation stakeholder evaluation

2.3.5. EPIDERMOLYSIS BULLOSA AND RARE DISEASES

The term epidermolysis bullosa (EB) encompasses a group of predominantly genetically inherited, blistering skin conditions (Fine, 2010). Blistering results from mechanical fragility of the skin and other tissues lined by epithelium (Fine et al., 2009). This can range from clinically imperceptible disease to a severity that has resulted in one physician who cares for EB patients describing it as "easily the most debilitating and devastating disease I have ever seen" (DEBRA Ireland, 2014).

A rare disease is defined, in the European Union, as a disease with an incidence of no more than 1 in 2000 people (Schieppati et al., 2008). Though this might suggest rare diseases are rare occurrences, the total number of distinct rare diseases numbers in the order of 5000 – 8000, meaning that it is estimated that between 27-36 million, or 6-5% of the population of Europe are affected (Commission of the European Communities, 2008, European Commission, 2014, The European Conference on Rare Diseases, 2014).

As a group, rare disease organisations have been extraordinarily well organised, and have achieved significant representation at an EU level (Commission of the European Communities, 2008, European Commission, 2009). This has culminated in a number of actions designed to promote rare disease research and improve patient care. A core focus of these policies is the improvement of data collection and utilisation. Registries are an essential means to realise this, as is evident in a number of documents, including in the "National Rare Disease Plan for Ireland" (Department of Health, 2014).

A literature review identified that a number of registries and databases have been developed in the area of EB. These are listed in Appendix A. While this might suggests that the development of a further patient registry in this field might be superfluous, the significant focus that has occurred in the area of patient registries in the area of rare skin disease, has provided new insights into best practice. The EPIRARE (European Platform for Rare Disease Registries) project was established by the European Union who acknowledged "the relevance of registries as key instruments for developing rare disease (RD) clinical research, improving patient care and health service (HS) planning" (Taruscio et al., 2014). The EPIRARE project aimed to "improve standardization and data comparability among patient registries and to support new registries and data collections" (Taruscio et al., 2014)

As a result of this available guidance, in addition to the PARENT project recommendations, and in the context of the significant efforts that have previously

occurred, the author proposed that a new registry with interoperability at its core, may be an ideal way to facilitate collaboration and enable prospective sharing of EB data internationally, in addition to providing an opportunity to incorporate findings from two European projects in the context of the global openEHR movement.

The value in following this path was strengthened by prior research and professional links that the author had developed with two charities, the DEBRA Ireland (Dystrophic Epidermolysis Bullosa Research Association Ireland) and DEBRA International. Excellent support was offered to support the author's and the ISF's plans through the facilitation of the development of networks and relationships with key EB figures and the provision of resources in the form of advice and assistance.

2.4. SUMMARY (DISCUSSION AND REFLECTION)

(O)penEHR demonstrated a remarkable opportunity to enable a clinician to develop information models, however, how realistic it was to expect clinicians to engage in this process was in question. The author's background presented a significant opportunity to explore how one clinician might, facilitated by opportunities that had arisen from his professional and research background, learn to become a clinical modeler. In addition, the context in which the author would do so; the development of a patient registry to be designed to be used internationally, provided a further opportunity to examine the use of openEHR in the developing field of patient registries that incorporated guidance from a number of significant EU projects and the involvement of an international rare disease community.

Although the author's knowledge and the literature review conducted during this project suggested that development of a patient registry would be a difficult and risky use case, the author believed that it was vital to conduct this project in a real world setting. Though many of the requirements of a clinical modeler can be simulated, the author contends that openEHR will need to demonstrate an ability to engage with clinicians involved in real world projects.

By embedding this research in a real-world example, the author believed that his research was more likely to encounter the demands that other potential clinical modelers interested in becoming involved with openEHR might expect to encounter.

2.5. PLAN

The next chapter identifies how a methodology was chosen that enabled the author to conduct research, while learning to become a clinical modeler in a real-world environment.

CHAPTER 3. METHODOLOGY & PRELIMINARY PLAN

3.1. AIMS AND REQUIREMENTS

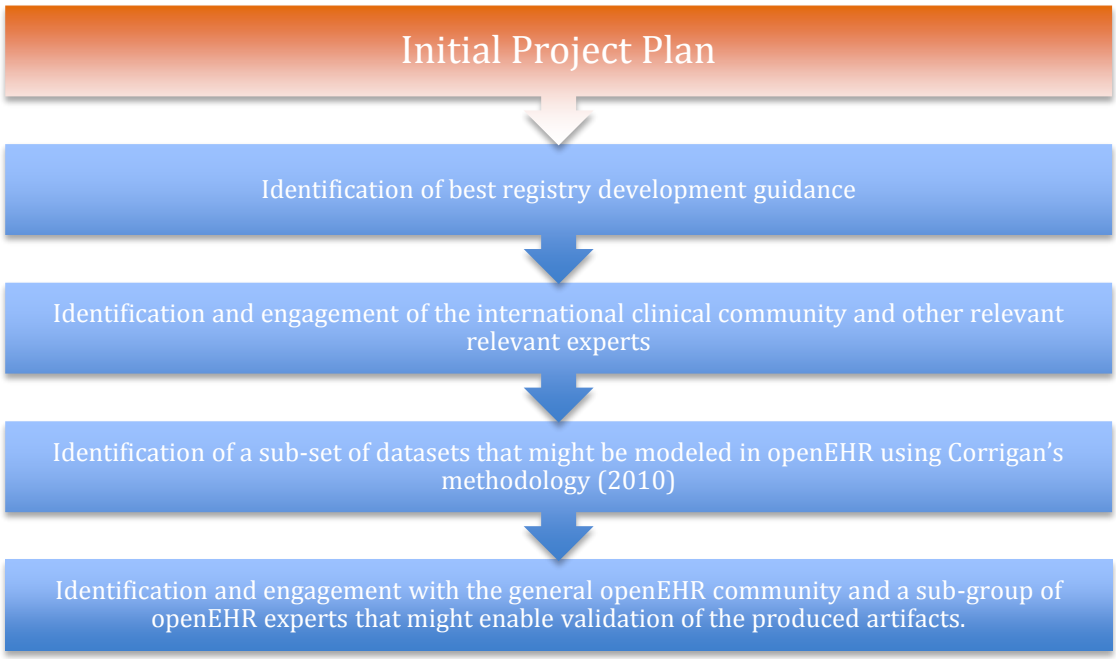
The general research concept underlying this thesis is whether it is feasible to expect a clinician to learn to use the openEHR approach to successfully model artifacts in a manner that can make a meaningful contribution to the development of a real-world system; in this case, the development of a patient registry.

To meet the aims of this study, two main requirements were required of a suitable clinical domain area:

1. A patient registry in the early stages of its development. This would enable the author to identify and develop datasets that could be modeled using an openEHR methodology.
2. A domain with sufficient scope to enable the breadth of skills required by a clinical modeler to be experienced. The literature and the author's experience recognise that the creation of all artifacts required to develop a fully implemented registry is unfeasible in the context of this project. Similar to Corrigan's (2010) thesis approach, the author will therefore aim to model a selection of artifacts. The reasoning behind the selection of these artifacts is explained at the relevant stages of this thesis.

To achieve this, a considerable degree of practical work and network building was expected to be required, which facilitated the development of an initial project plan (Figure 8).

Figure 8 Initial project plan



3.2. EXPLORATION OF POSSIBLE METHODOLOGIES

To conduct this process, the author expected that a number of methodologies were expected to be required:

3.2.1. QUANTITATIVE AND QUALITATIVE SURVEYS

These would facilitate engagement with the EB expert community, openEHR community and expert openEHR clinical modelers to identify datasets that could be developed into artifacts by the author and then validated by experts.

3.2.2. PROTOTYPE METHODOLOGY:

An element of a rapid application development methodology (Beynon-Davies et al., 1999, Martin, 1991) was expected to be required to facilitate creation of openEHR artifacts with graphical user interface (GUI) tools.

3.2.3. OVERARCHING METHDOLOGY

Ultimately, however, an overarching methodology was felt to be required that would enable the author to develop a skill set in:

- An area he has relatively little experience with,

- A use case that may be subject to the significant unpredictability expected as new networks are formed.

As such, the methodology needed to be flexible and afford the author an ability to iteratively evaluate the evolution of the project and make changes to the research plan as required.

3.2.3.1. ACTION-RESEARCH

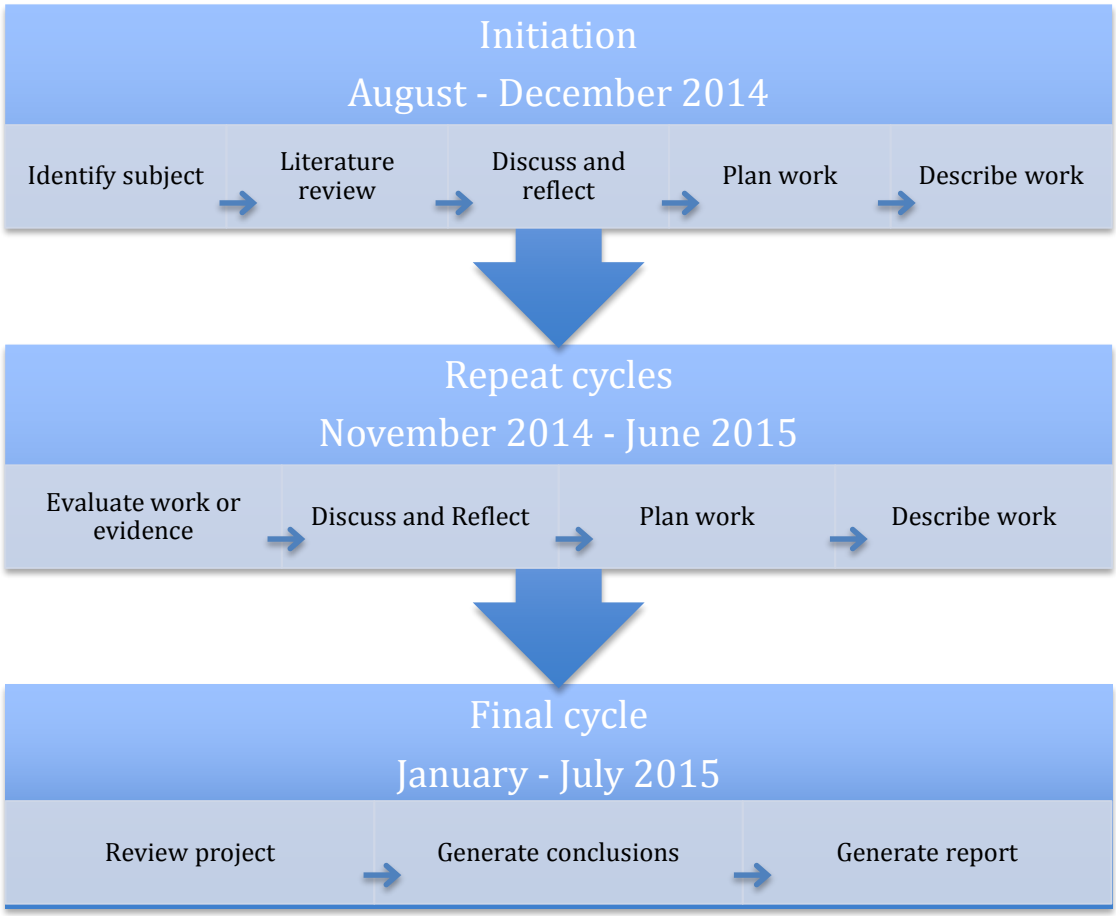
Action research is described as "critical and (self-critical) collaborative inquiry by reflective practitioners who are accountable and must make the results of their inquiry public, as well as self-evaluating their practice and being engaged in participatory problem solving and continual professional development" (Zuber-Skerritt, 1996, Koshy et al., 2010)

Action research was chosen as the research methodology for this project as the author believes that the concept of problem solving through collaborative practical exploration and critical reflection mirrors the question posed in this project, which is fundamentally one of understanding how a clinician might become a practical implementer. As action research methodology is adaptable, it also introduces a flexibility that is required where the road ahead is unclear and, with limited guidance, might result in the need for rapidly developed solutions and deviations from a proposed plan.

The author combined aspects of Stinger's Look, Think, Act Framework (Stringer, 2013) and a methodology presented by (Koshy et al., 2010) to develop the approach outlined in the introduction of this thesis, which is repeated here for convenience (Figure 9).

While this cycle of actions was followed throughout this project, it is noted that steps are combined or omitted in some cycles where required.

Figure 9 Action Research methodology used in the author's project



As a means to clarify this process, an Action Research Planning Sheet (Koshy et al., 2010) was adapted and utilised to facilitate aspects of this project. An example is presented in Appendix B. In addition, a reflective journal was kept to assist in the process of reflective learning. This included multiple components including:

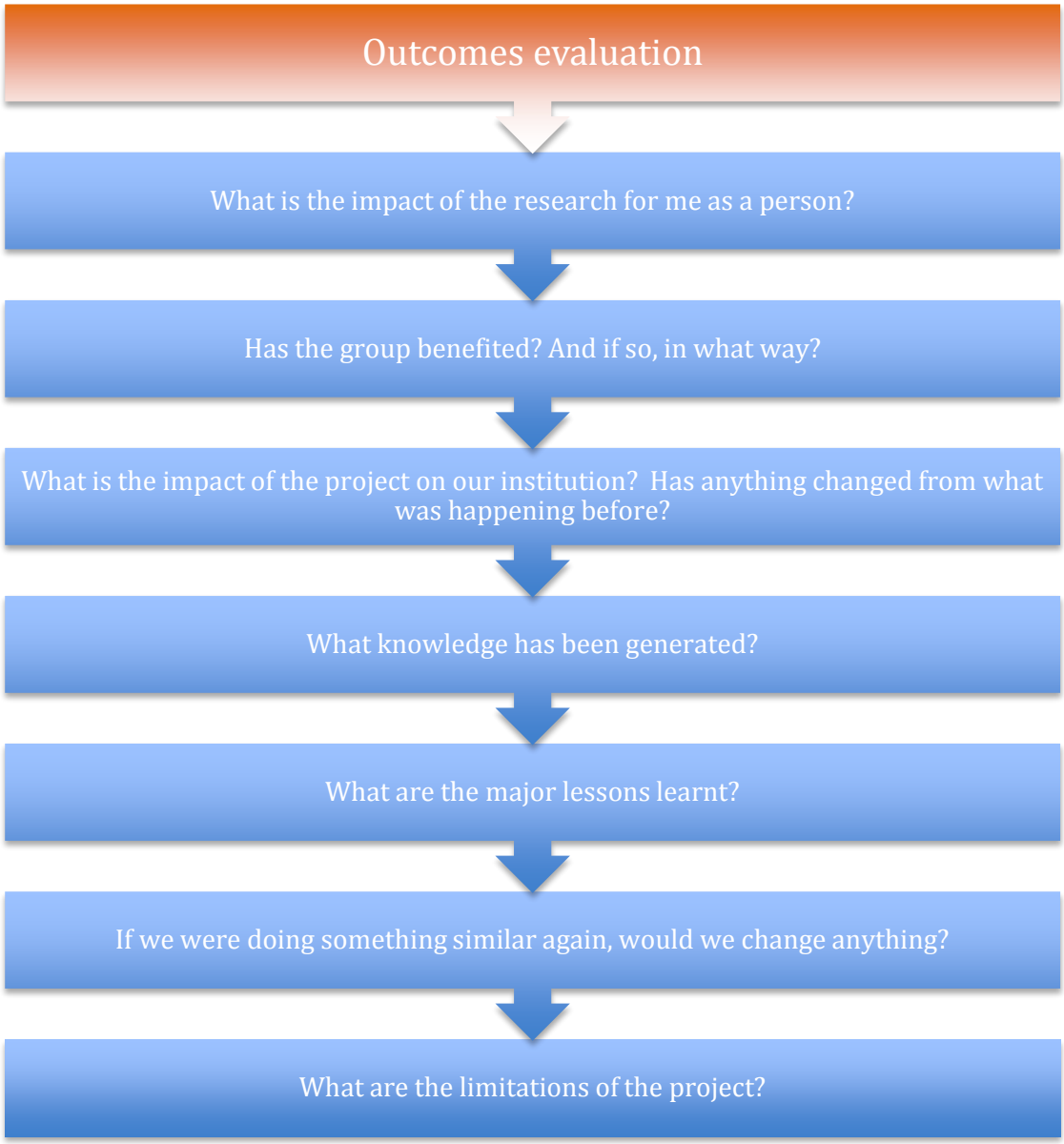
- A reflective diary relating to work conducted kept in Word format (no example given due to considerable quantity of material that would require anonymisation).
- A reflective log kept in Excel format (example included in Appendix B)
- Notes of conversations and meetings relating to the project using online note taking software.

Guidance was taken following a review of the literature in this regard (Janesick, 1999, Study and Learning Centre, 2012, Koshy et al., 2010). Templates suggested for developing a reflective journal were also adapted for the author's purposes (Jepson,

2013, Selvester and Rich, 2008). While it was initially the author's intention to code the materials, the quantity of materials generated made this unfeasible as the project progressed.

Finally, the author identified questions proposed by Koshy et al (2010) that could be used to conduct an action research reflective discussion in the evaluation of the project outcomes (Chapter 5.2) (Figure 10).

Figure 10 Action research reflective discussion questions to facilitate project outcomes evaluation



3.3. INITIAL PROJECT PLAN

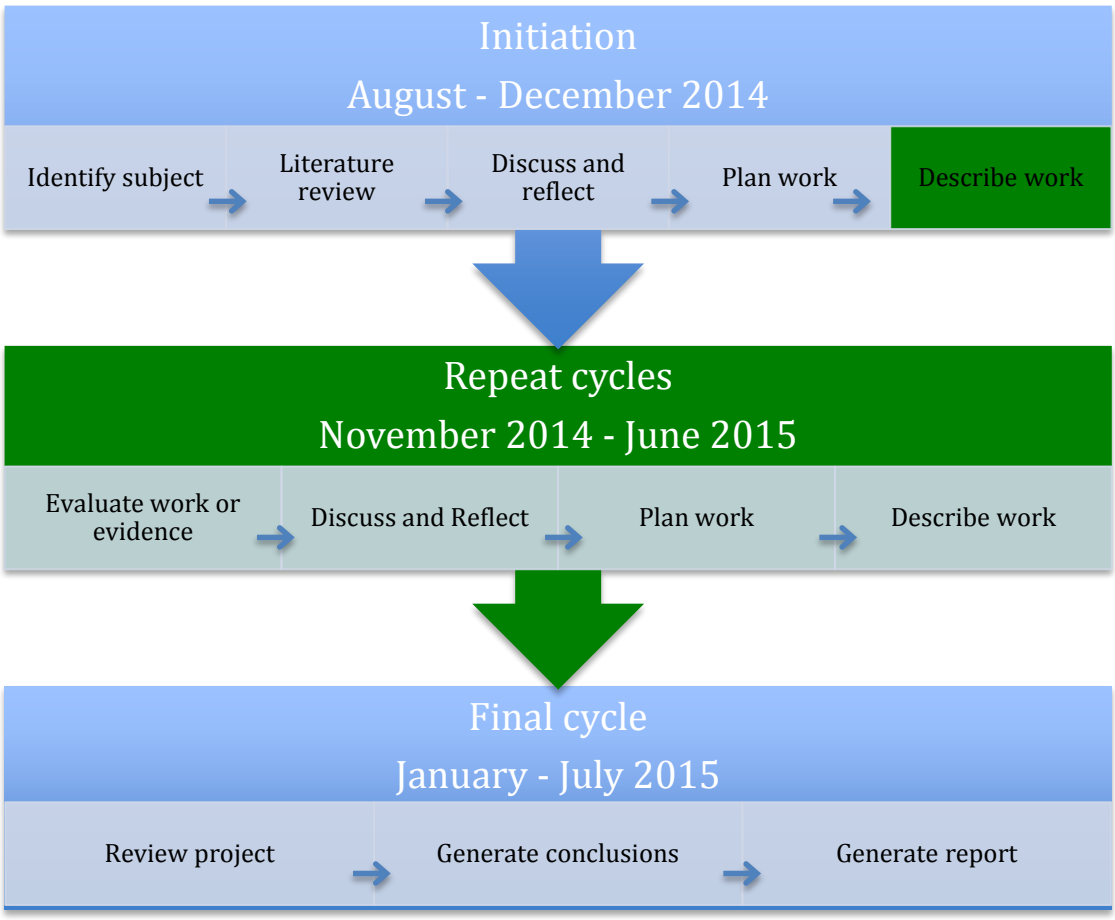
With a problem and context elaborated following a literature review and an overarching methodology identified, the next chapter identifies the sequence in which the author aimed to proceed with implementing the steps in the initial project plan (Figure 8).

CHAPTER 4. RESEARCH IMPLEMENTATION

Figure 11 reproduces the research methodology used for this project, with the research implementation component shaded in green. There is some overlap with the initiation phase, which was expected. The aim of the repeat cycles was to enable the author to gradually develop as a clinical modeler, while producing artifacts that could be validated, as a means to demonstrate that the author had successfully produced artifacts that contributed to the development of a patient registry. There is some overlap of themes as new understanding enables the author to revisit prior work with new insights.

It is worth noting to the reader that this chapter is long, as it describes 11 cycles of work undertaken by the author to progress the project to a point at which the appropriate quantity of work was performed.

Figure 11 Action research methodology used in this project

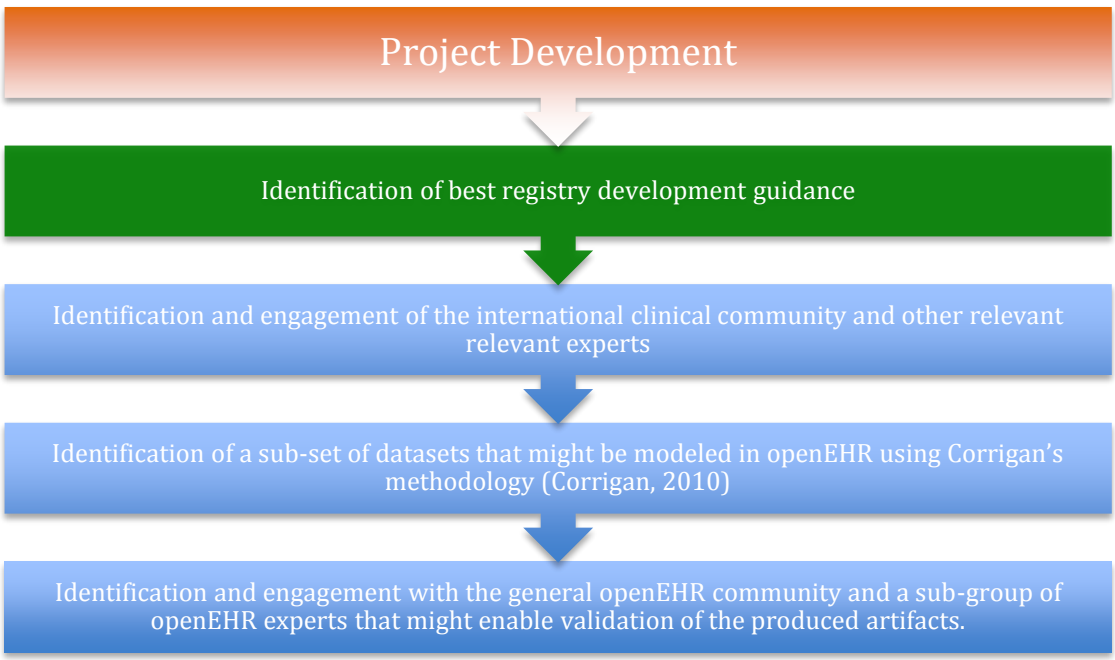


4.1. CYCLE 1 – DATA ELEMENTS FOR AN EB REGISTRY

4.1.1. CYCLE 1 – EVALUATION OF WORK AND EVIDENCE

Figure 12 reproduces the initial project plan, with the section relevant to this cycle shaded in green. This diagram is reproduced throughout this thesis, with additional components added where necessary to reflect adaptations required as new experience is gathered.

Figure 12 Project development plan cycle 1

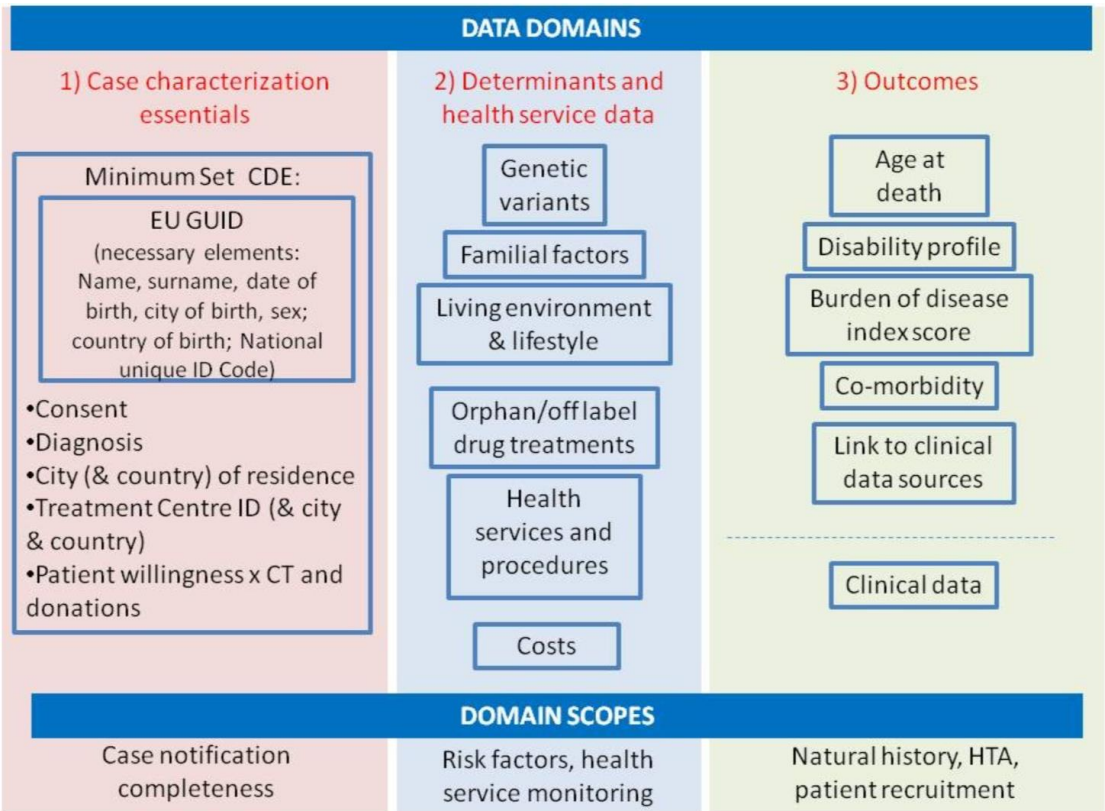


The literature review from the initiation phase of this project identified that the PARENT project supports an openEHR approach to registry development. Given that the chosen domain for development of openEHR artifacts is the rare disease EB, the EPIRARE project is assessed in more detail here to establish whether there are any obvious datasets to begin development of.

4.1.1.1. EPIRARE DATA ELEMENTS

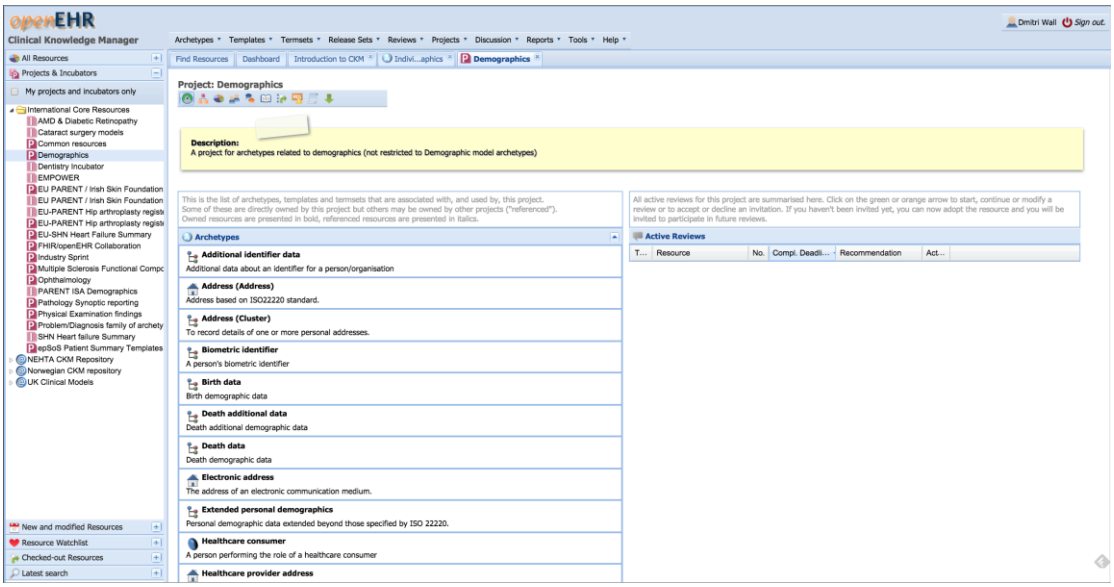
The EPIRARE project gathered a range of stakeholders' input and incorporated findings from previous projects to develop a list of indicators that would be required in the rare disease area to facilitate, for example, disease surveillance and health service monitoring (Taruscio et al., 2014). Data required to compute these variable were then identified and organised into "data elements common (CDE) to all rare diseases" (Taruscio et al., 2014). Figure 13 identifies these CDEs within the proposed EPIRARE data repository.

Figure 13 The organisation of the proposed EPIRARE platform data repository (Vitozzi et al.)



EPIRARE studies identified that a number of these elements should be considered mandatory to facilitate "best use of registry data" (Vitozzi et al.). Many of these are commonly captured data points and a search of the Clinical Knowledge Manager identified existing archetypes or projects aiming to define archetype them, such as in the case of Demographics (Figure 14).

Figure 14 Clinical Knowledge Manager Demographics project screenshot



4.1.2. CYCLE 1 DISCUSS AND REFLECT

As noted in the methodology, building all artifacts required to enable the development of a real-world patient registry was considered unfeasible in the context of this project and the author's inexperience. As such, a selection of artifacts would be required. On reflection, the generation of new artifacts was considered more beneficial to the author's development as a clinical modeler.

Of the EPIRARE CDEs, "Diagnosis" was identified as a useful area to model, in this case focused on EB, for a number of reasons:

- It would enable the author to examine how terminology and openEHR interact.
- The classification of EB is complicated and would require input from numerous experts throughout the world, which could facilitate the development of a network to support a patient registry.

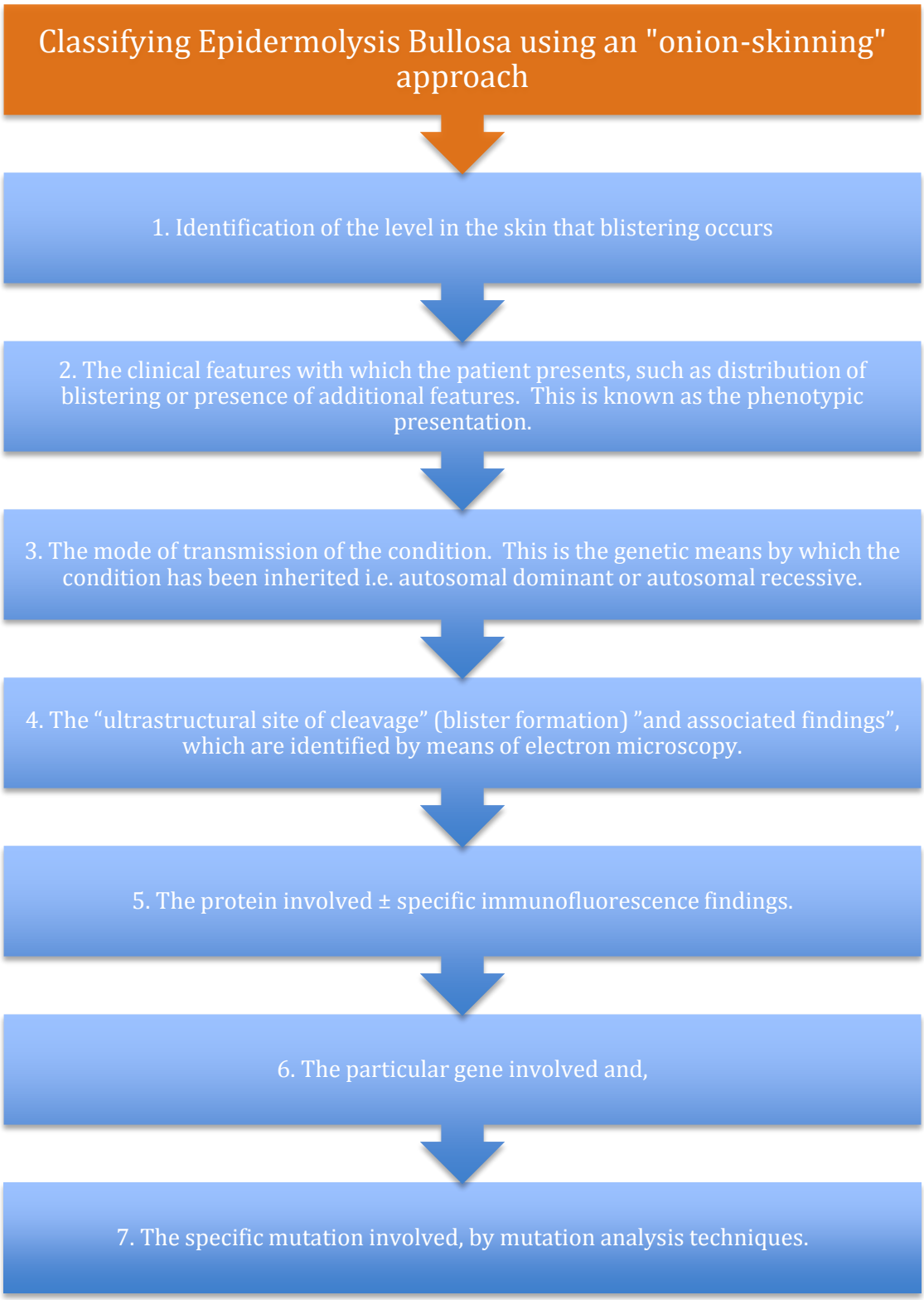
4.1.3. CYCLE 1 PLAN WORK

In view of the importance of diagnosis, further information regarding the classification of EB was deemed to be important. As such the author would identify an appropriate classification from the literature and from discussions with contacts within DEBRA Ireland.

4.1.4. CYCLE 1 DISCUSS WORK

Though there is extensive literature that classifies and discusses the classification of EB (Fine and Burge, 2010, Fine, 2010), the author was fortunate to discover a recently published consensus paper entitled "Inherited epidermolysis bullosa: Updated recommendations on diagnosis and classification" (Fine et al., 2014). This paper, a 24-page document, is the 4th consensus report of an international group, recognised as world leaders in the area of EB. It is a significant report as, in addition to being a mature reflection on the classification of EB, it introduces a new concept in how EB is classified termed "onion skinning". This approach utilises a number of sequential clinical observations and diagnostic tests to subclassify patients with EB. The sequential approach is outlined in Figure 15.

Figure 15 The Classification of Epidermolysis Bullosa, using the "onion skin" approach identified by Fine et al., 2014



With respect to each level – information is provided regarding each level via a number of detailed tables. These are not presented here given the quantity of data involved.

4.2. CYCLE 2 DEVELOPMENT OF OPENEHR ARTIFACTS BASED ON EPIDERMOLYSIS BULLOSA ONION-SKIN APPROACH

4.2.1. CYCLE 2 – EVALUATE EB CLASSIFICATION EVIDENCE

This literature provided an extremely useful source of information to provide a basis for a registry that aims to facilitate international interoperability.

4.2.2. CYCLE 2 – DISCUSSION AND REFLECTION

Discussion and reflection suggested that this phase might be considered an extension of aspects of Corrigan's (2010) archetype development methodology (steps relating to this phase are shaded in green) (Figure 16, Figure 17).

Figure 16 Summarised Archetype Design Methodology developed by Corrigan (2010)

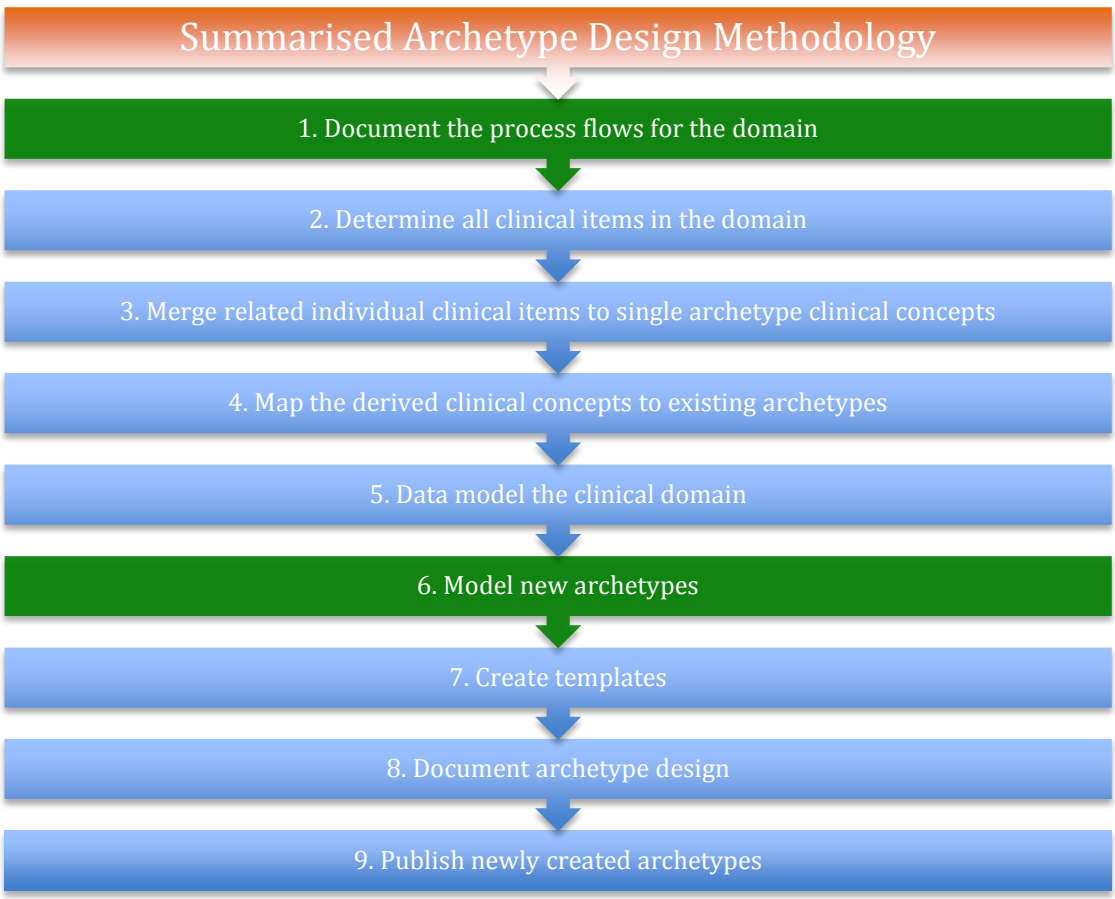
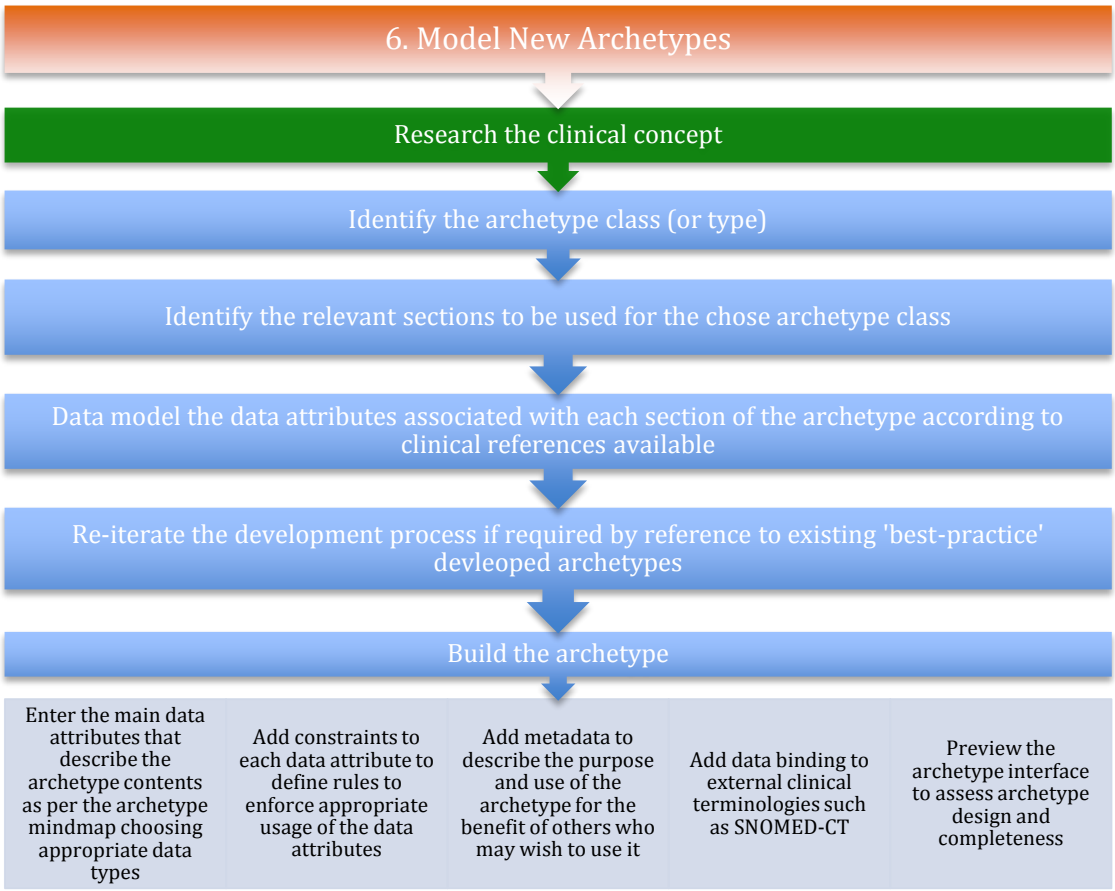


Figure 17 Detail of Step 6 in the summarised archetype design methodology proposed by Corrigan (2010)



Despite a comprehensive and well-considered methodology, the author encountered, difficulties applying it, many of which were technical. The author was then presented with an unexpected opportunity. Dr Ian McNicoll has a background in clinical medicine, having worked as a General Practitioner for a considerable number of years. Amongst other roles, he is currently the co-chair of the openEHR Management Board and a Clinical Knowledge Editor at the openEHR Foundation. The author had been introduced to Dr McNicoll during a common area of interest discussed within the PARENT project. On hearing of the author's project proposal, Dr McNicoll kindly offered to act as a mentor.

Though it would likely mean abandoning plans to use Corrigan's methodologies for developing openEHR artifacts, to have one of the foremost clinical openEHR modelers directly instruct the author and provide practical guidance and experience, was believed to be far too valuable an opportunity to decline.

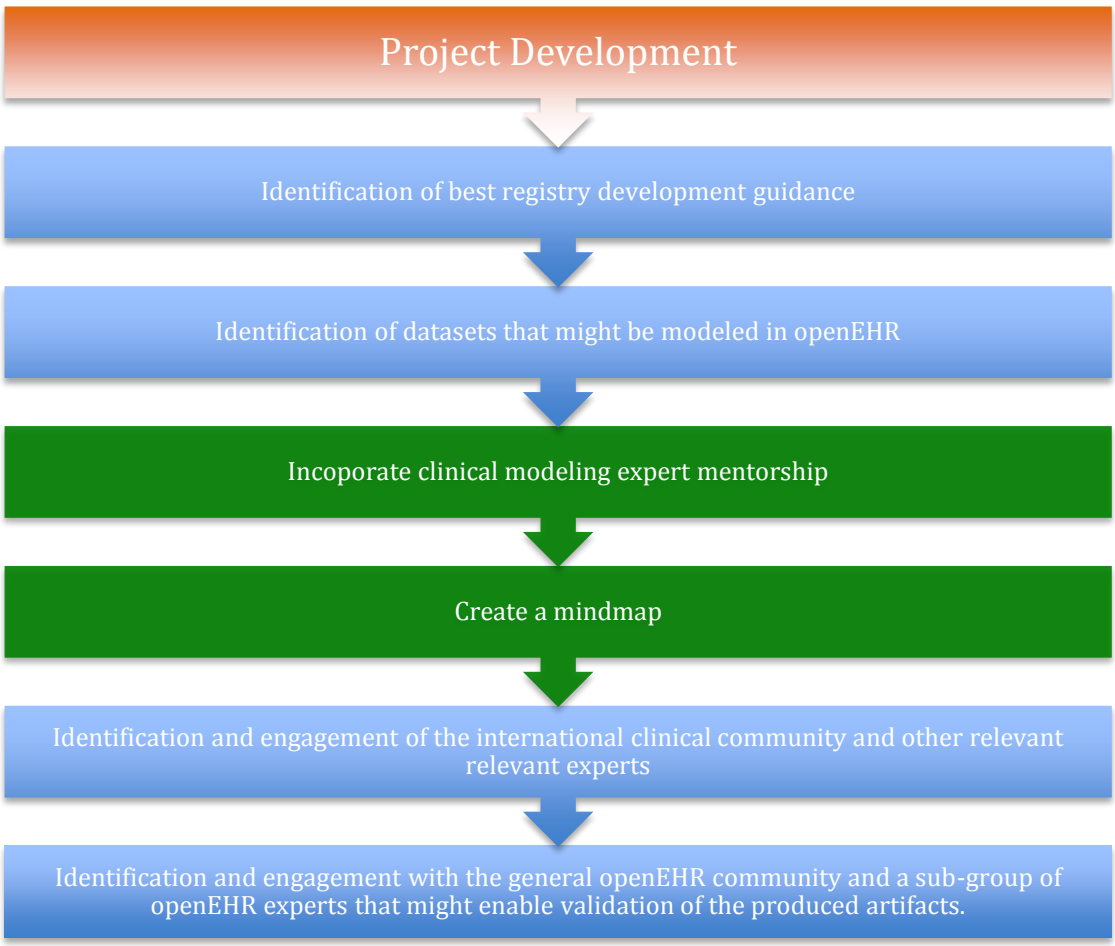
Dr McNicoll's discussed mindmaps, diagrams that organise information in a visual manner, as an appropriate means to prepare information for archetype development.

The author was aware of mindmaps previously, having viewed a small number that had been shared following interactions with Dr McNicoll in relation to the PARENT project. These are not presented in this thesis for privacy issues.

4.2.3. CYCLE 2 - PLAN WORK

The author would review a small number of mindmaps and then develop a mindmap of EB Classification. These are represented in the project development plan, shaded in green (Figure 18).

Figure 18 Cycle 2 project development plan



4.2.4. CYCLE 2 – EB MINDMAP

A difficulty with the onion-skin classification of EB is that the sheer volume of information that would be required to be represented on a mindmap would result in an artifact that would be extremely difficult to read and ultimately validate by a group of EB

experts. An example of the number of variations in phenotypic presentations alone is presented in an excerpt from the consensus document in a table reproduced from Fine et al (2014) Figure 19.

To overcome these difficulties, a simple overview of the "onion-skin" classification was created in mindmap form using XMind pro software (Figure 20). This omitted details regarding components 3-7 of the classification and focused on a high level description of the clinical phenotype a patient could present with, in addition to the level of blistering. Feedback from Dr McNicoll was received and a further mindmap was then produced to improve readability (Figure 21).

Figure 19 Clinical summary of a selection of epidermolysis bullosa subtypes, reproduced from Fine et al. (2014) classification paper

Table XI. Clinical summary of junctional epidermolysis bullosa generalized severe, generalized intermediate, and localized subtypes[20-23]

	JEB, generalized severe	JEB, generalized intermediate	JEB, localized
Eponyms or previous names	JEB, Herlitz	JEB, generalized non-Herlitz; JEB, generalized other; GABEB	None
Mode of transmission	AR	AR	AR
Onset (usual)	Birth	Birth	Birth
Skin distribution (predominant)	Generalized	Generalized	Localized
Skin findings (frequency*)			
Blisters	4+	3-4+	2+
Milia	2+	1-2+	1+
Atrophic scarring	3+	2-3+	Absent
Dystrophic or absent nails	4+	2-4+	4+
Granulation tissue	4+	Absent to rare	Absent
Scalp abnormalities	2+	Diffuse nonscarring or scarring alopecia	Absent
Keratoderma	Absent	Absent to focal +	Absent
Other	None	EB nevi	None
Relative inducibility of blisters	4+	2-4+	2+
Extracutaneous involvement*			
Anemia	4+	Absent −2+	Absent
Growth retardation	4+	Absent −2+	Absent
Oral cavity			
Soft-tissue abnormalities	4+	1-3+	1+
Enamel hypoplasia	4+†	4+	4+
Caries	Excessive	Excessive	Excessive
Gastrointestinal tract	3+	Absent −2+§	Absent
Genitourinary tract	2+	Absent −2+	Absent
Ocular	3+	Absent −2+	Absent
Pseudosyndactyly	1+	Absent§	Absent
Respiratory tract	3+	Absent −2+	Absent
Other	Delayed puberty	None§	None
Risk* by age 30 y of			
Squamous cell carcinoma	Uncommon	2+‖	None
Malignant melanoma	None	None	None
Basal cell carcinoma	None	None	None
Death related to EB	4+‡	1+‡	None

AR, Autosomal recessive; *EB*, epidermolysis bullosa; *GABEB*, generalized atrophic benign epidermolysis bullosa; *JEB*, junctional epidermolysis bullosa.

*Relative frequencies: absent or none; rare; 1+; 2+; 3+; 4+.

†Carriers with *LAMA3* null mutations have enamel defects.[22] Similarly, a mouse model for JEB has demonstrated that *COL17A1* plays a key role in enamel formation.[23]

‡Death occurs in about half of those with generalized severe JEB and generalized intermediate JEB within the first 2 y of life, with a further increase in the cumulative risk of death in the former JEB subtype with increasing age. Although there are a variety of causes of death in both JEB subtypes during infancy and early childhood, the most common ones are sepsis, upper airway occlusion, and failure-to-thrive, the latter primarily arising in generalized severe JEB.

§Rare patients have had pseudosyndactyly, protein losing enteropathy, profound failure to thrive, low birth weight, and/or early death.

‖The cumulative lifetime risk of squamous cell carcinoma has been estimated to be 18% in JEB generalized severe (per National EB Registry data[20]), whereas cross-sectional analysis of the Groningen, The Netherlands, JEB cohort has revealed the presence of these tumors in approximately 25% of those with generalized intermediate JEB.[21]

Figure 20 Initial simplified epidermolysis bullosa onion-skin classification mindmap

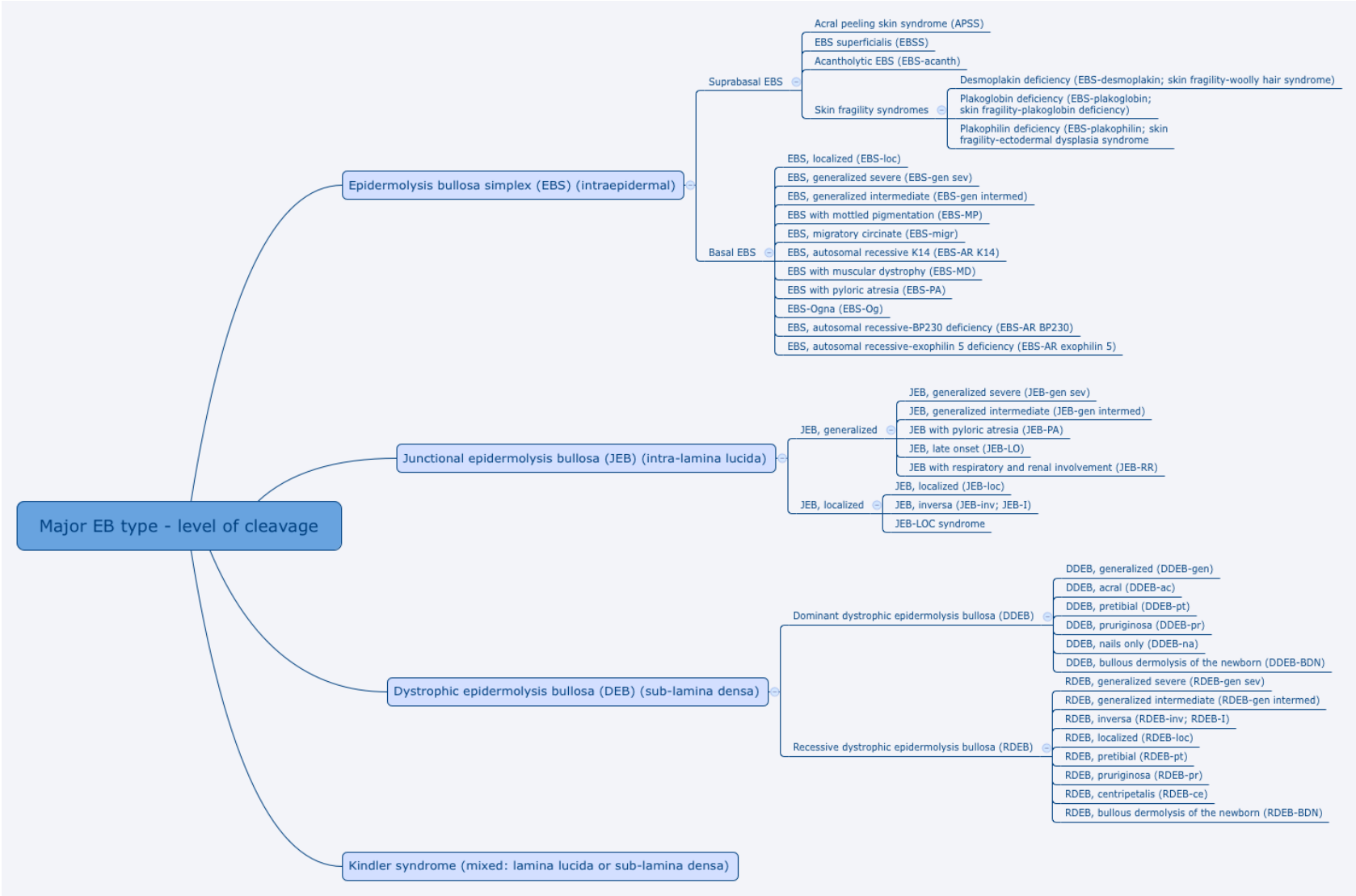


Figure 21 Amended simplified epidermolysis bullosa onion skin classification mindmap

4.3. CYCLE 3 GAINING INSIGHTS INTO THE EB MINDMAP

4.3.1. EVALUATION

While this was felt to be an appropriate representation of the "onion-skin" classification, given the complexity of the classification and the omission of vital aspects of the classification, the author believed that validation with the expert group who had authored the paper was appropriate before further artifacts were developed.

4.3.1.1. OPPORTUNITY

At the time of creating the mindmap, an opportunistic meeting occurred with one of the authors of the 'onion-skin' classification. This author was presented with an Excel spreadsheet that described the clinical subtypes identified in the classification described in the Fine et al (2014) classification paper, along with mapping to ICD-10 and to classification codes developed by British Association of Dermatologists (BAD). A mutual colleague, who was the Co-Chair: Dermatology Topic Advisory Group for ICD-11 was contacted, resulting in this author being encouraged to extend his classification work to update the ICD-11 classification of EB. From a clinical perspective, the value of this was seen as significant.

4.3.1.2. EPIRARE GUIDANCE

Review of the EPIRARE guidance revealed a table of International Coding systems and terminologies relevant to diagnosis (Vitozzi et al.) (Table 2). Significantly this also noted that "ORPHA-codes are being integrated in SNOMED and will be the basis for the codification of rare diseases in the next ICD-11". Further investigation revealed that the 1st 5 mentioned systems were of particular relevance to the author's work (shaded in green on **Error! Reference source not found.**). Preliminary searching of these systems revealed significant variations in the classification of EB when compared to the Fine et al (2014) classification.

4.3.2. DISCUSSION AND REFLECTION

While the mindmap was developed to facilitate the development of openEHR artifacts, it had also revealed a significant quantity of core work that would need to be undertaken to ensure that the archetype could meet the demands of best practice rare disease registry development.

The process of engaging with the clinical community also suggested that considerable, but extremely valuable changes might be required of the mindmap. For this to happen, the author believed that it was necessary to engage more formally with the publication's authors to validate the EB mindmap.

4.3.3. WORK PLAN

1) The author will develop a mapping of the EB mindmap to SNOMED, ICD-10, ICD 11, Orpha codes, Online Mendelian inheritance in Man (OMIM) and UMLS using mindmaps and a spreadsheet. Though ICD-9-CM was mentioned in EPIRARE, ICD-10 was felt to be sufficient, particularly in the context of also mapping to ICD-11. For continuity, the author has also attempted to identify changes that have occurred between the 3rd and 4th classification by the EB expert group given the introduction of the new "onion-skin" classification.
2) The author would develop a survey that would enable feedback from the authors of the Fine et al EB Classification paper, to facilitate further openEHR artifact development and the mapping process.

Ultimately it was an aim of the author to submit the mappings to a number of the relevant classification and terminology bodies for consideration.

4.3.4. DISCUSS WORK

As a number of significant processes occurred before the planned work was conducted, they are discussed at a later stage in this thesis.

Table 2 International coding systems and terminologies relevant to diagnosis, identified by the EPIRARE project (Vitozzi et al.)

International Coding systems and terminologies noted by EPIRARE project				
Area	**System**	**Author**	**Web-site**	**Remarks**
Medical Nomenclature	SNOMED	International Health Terminology Standards Development Organization	www.ihtsdo.org/snomed-ct	ORPHA-codes are being integrated in SNOMED.
Diseases	ICD-10-CM ICD-9-CM	WHO	www.who.int/classifications/icd/en	Billing-related. The coding of rare diseases in the next ICD-11 will be based on the ORPHA- codes
Rare Diseases	Orpha-codes	ORPHANET	www.orpha.net	ORPHA-codes are being integrated in SNOMED and will be the basis for the codification of rare diseases in the next ICD-11.
	UMLS	NIH ORDR	https://grdr.ncats.nih.gov/index.php?option=com_content&view=article&id=91&Itemid=160	This is the system used by the US GRDR and may be useful for interoperability with this platform.
Genes, genetic disorders and traits	Online Mendelian Inheritance in Man (OMIM)	McKusick-Nathans Institute of Genetic Medicine, Johns Hopkins University (Baltimore, MD)	http://omim.org/	
Genes	HGNC	Human Genome Organization (HUGO)	www.genenames.org/aboutHGNC. Html	
Genomic variations	-	Human Genome Variation Society	www.hgvs.org/mutnomen/	
Laboratory tests and results	LOINC	Regenstrief Institute for Health Care	www.regenstrief.org/loinc/	
Procedures	ICD-10-PCS ICD-9-CM Vol. 3	WHO	www.who.int/classifications/icd/en	Billing-related
Devices	Global Medical Device Nomenclature (GMDN)	GMDN Maintenance Agency	http://www.gmdnagency.com/	Supports the European Databank for medical devices foreseen by the EU Medical Device Directive. It includes 20 EU languages.
	Universal Medical Device Nomenclature System (UMDNS)	WHO Collaborating Centre ECRI	https://www.ecri.org/Products/Pages/UMDNS.aspx	The National Library of Medicine has included UMDNS in the Unified Medical Language System.
Drugs and Orphan Drugs	ATC/DDD index	WHO Collaborating Centre for Drug Statistics Methodology	http://www.whocc.no/atc_ddd_index/	
	MedDRA (Medical Dictionary for Regulatory Activities)	International Conference on Harmonization (ICH)	http://www.meddra.org/	
Adverse Reactions	WHO-ART	WHO, maintained by the Uppsala Monitoring Centre	http://www.umc-products.com/DynPage.aspx?id=73589&mn1=1107&mn2=1664	
	EU SPC ADR database	EMA	http://www.imi-protect.eu/methodsRep.shtml	Database of all adverse drug reactions (ADRs) listed in section 4.8 of the Summary of Product Characteristics (SPC) of medicinal products authorised in the EU according to the centralised procedure. It is based exclusively on MedDRA terminology.
	MedDRA (Medical Dictionary for Regulatory Activities)	International Conference on Harmonization (ICH)	http://www.meddra.org/	
Disability	ICF	WHO	http://apps.who.int/classifications/icfbrowser/	Billing-related. Available in English, French and Spanish. A Children and Youth version is also available in English only

4.4. CYCLE 4 FURTHER VALIDATION

4.4.1. EVALUATE WORK

Interaction with Drs Berry and McNicoll had guided the author towards a significant number of relevant resources that had not been evident to the author when searching the published literature. Examples included blogs and PowerPoint presentations from conferences. This prompted the author to consider whether further guidance might be made known to the author by conducting a survey of the wider openEHR clinical modeling community.

The considerable value of engaging with Dr McNicoll, and planned validation survey with the EB expert community, also spurred the author to consider how more formal evaluation of the author's work by openEHR expert modelers might be conducted.

4.4.2. PLAN WORK

It was decided that the author would work to create two further surveys in addition to the EB expert survey. All three surveys would require questionnaire development in addition to ethical approval. This was progressed over the following months by the author and as such, is detailed later in the thesis at a point where feedback from the relevant group was received and analysed.

4.5. CYCLE 5 FURTHER EB DATASETS

4.5.1. EVALUATE

While this mindmap was believed to be an extremely useful start, it was noted that further datasets would be required, both to create a useful patient registry and also for the purpose of the author learning to model.

4.5.2. DISCUSS AND REFLECT

Discussion and reflection with DEBRA Ireland suggested that incorporating the requirements described by EB patients themselves would form the basis of an extremely useful dataset.

4.5.3. PLAN WORK

In view of this, the author worked with DEBRA Ireland to prepare and submit a grant application to the Irish Research Council.

4.5.4. DISCUSS WORK

A study, entitled "RESpective: Registering the Patient's Perspective" was prepared in conjunction with DEBRA Ireland, my professional work supervisor, Professor Alan Irvine and a qualitative group based in University College Dublin: The UCD·RTI Applied Research Centre (ARC). ARC is described as "a centre of excellence combining advanced applied methodologies with world-leading academic expertise to research studies and innovations in social and behavioural research" (UCD•RTI Applied Research Centre, 2015).

The study proposed to assess what domains a registry for EB might need to include from the patient's perspective. It was envisaged that this qualitative research would lead to a better understanding of patient requirements that could ultimately be translated into openEHR archetypes and templates.

Irish Research Council

Government of Ireland 'New Foundations' Scheme 2014

Application Form

Informative text has been included throughout this application form: please delete this informative text when completing the Form.

1. SUMMARY PROPOSAL DETAILS:	
Name of applicant (including title):	Professor Alan Irvine, Consultant Dermatologist Our Lady's Children's Hospital & St James's Hospital; Professor of Dermatology, Trinity College Dublin.
Former award held: (name, awarding body, year & date of award)	
Title of proposed proposal:	Registering the EB Patient's Perspective
Abbreviation of proposal title	RESpective
Proposal abstract (100 words):	This project proposes to establish a multidisciplinary network, to support the development of an epidermolysis bullosa (EB) patient registry. The first stage of this process includes the design and implementation of a qualitative research project, to capture the views of patients. The information gathered from this study will enable those involved to represent the patient's perspective in designing the registry. It is expected that this will inform the creation of a registry that is inclusive and representative of patient's needs, while also involving patients in defining research strategies and enhancing researchers understanding of patient engagement.
Discipline/subject area(s):	Dermatology, patient registry, epidermolysis bullosa, patient engagement

2. Please indicate which Strand you are applying for under the Scheme	
	Please tick
Strand 1: Engaging Civic Society	✓
Strand 2: Marking the National Decade of Centenaries	
Strand 3: Enhancing Knowledge Exchange	

4.5.5. EVALUATE WORK

Unfortunately, the work that was conducted revealed that the time required to conclude this research would not have made information available for the purpose of creating openEHR artifacts in the timeline given to conduct the author's project. Ultimately, the grant application was also unsuccessful which is why it is not described in more detail in this thesis.

4.5.6. DISCUSSION AND REFLECTION

The author believes that this component is worth including in this thesis as it delivers an important lesson regarding the considerable burden required to obtain the appropriate information to facilitate the development of openEHR artifacts where it does not already exist. While information from patients to support the development of archetypes is undoubtedly required to meet the demands of what have been termed the "empowered" "patient-consumer" (Frist, 2014), the practical development of such openEHR artifacts where existing datasets are unavailable, will take considerable time, particularly when they are intended to support the development of an international patient registry that will include patients from different countries and backgrounds.

It is also worth establishing that this proposal was conducted as it was acknowledged that an expert's opinion is simply not sufficient to generate datasets on behalf of patients. In the same manner that openEHR is based on giving those with domain expertise the tools to directly influence the information that they know best, the creation of patient informed datasets should directly include patients as domain experts. I believe it also describes the considerable burden that can be involved in identifying the appropriate components of a high-quality archetype.

4.5.7. PLAN FURTHER WORK

This setback posed significant difficulty for the author. The process of establishing a network to provide the information required to develop an EB registry and even identify appropriate novel datasets to model was requiring significantly greater time than was available for this project.

At this point, however, it was becoming evident that a number of the risks associated with choosing Atopic dermatitis as a means to learn to model, were dissipating, instead replaced with significant opportunity. As such the author attempted to establish how this area might be utilised to develop more artifacts.

4.6. CYCLE 6 EVALUATE ATOPIC DERMATITIS PATIENT REGISTRY

During the period that the author had been developing EB artifacts the ISF had developed links with a European group called TREAT (The international TREatment of severe Atopic dermatitis Registry Taskforce) with a view to establishing an international atopic dermatitis registry that incorporated the openEHR approach. This collaboration involved an international group of experts, similar to that proposed for the EB registry, but at a more advanced stage of development. To facilitate this, a meeting had been arranged. This would involve clinical and industrial partners from Ireland and Europe, in addition to a representative from PARENT and Dr Ian McNicoll meeting in Dublin for a one-day conference.

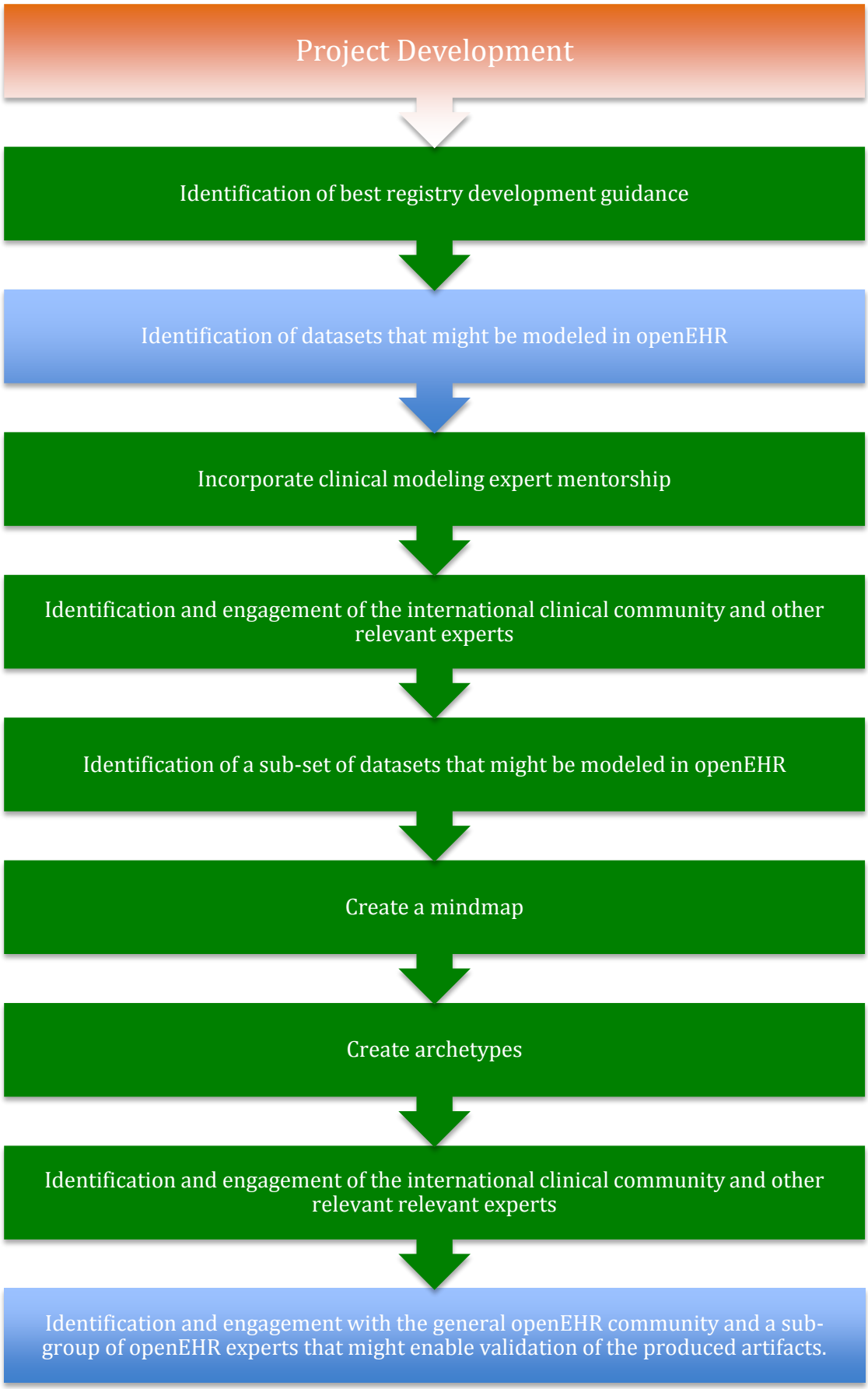
The TREAT group had prepared an extensive dataset and a number of documents that they felt described the information requirements to support the development of an international AD registry. Dr McNicoll would use these to develop a mindmap, archetypes and templates for the meeting.

4.6.1. DISCUSSION AND REFLECTION

Though only 6 days were available to the author prior to the meeting, discussion suggested that this would be an invaluable opportunity for the author to develop a small number of artifacts that could, if successful, be incorporated in a registry build, alongside a professional modeler.

This plan was seen to meet most of the requirements of the author's project plan requirements, in addition to adding further relevant artifact development steps (shaded in green in Figure 22).

Figure 22 Cycle 6 Project development plan



4.6.2. PLAN WORK - ATOPIC DERMATITIS ARTIFACTS

4.6.2.1. AIM

To utilise TREAT documentation to develop a small number of openEHR artefacts, under the supervision of a recognised expert clinical modeler.

4.6.2.2. METHOD

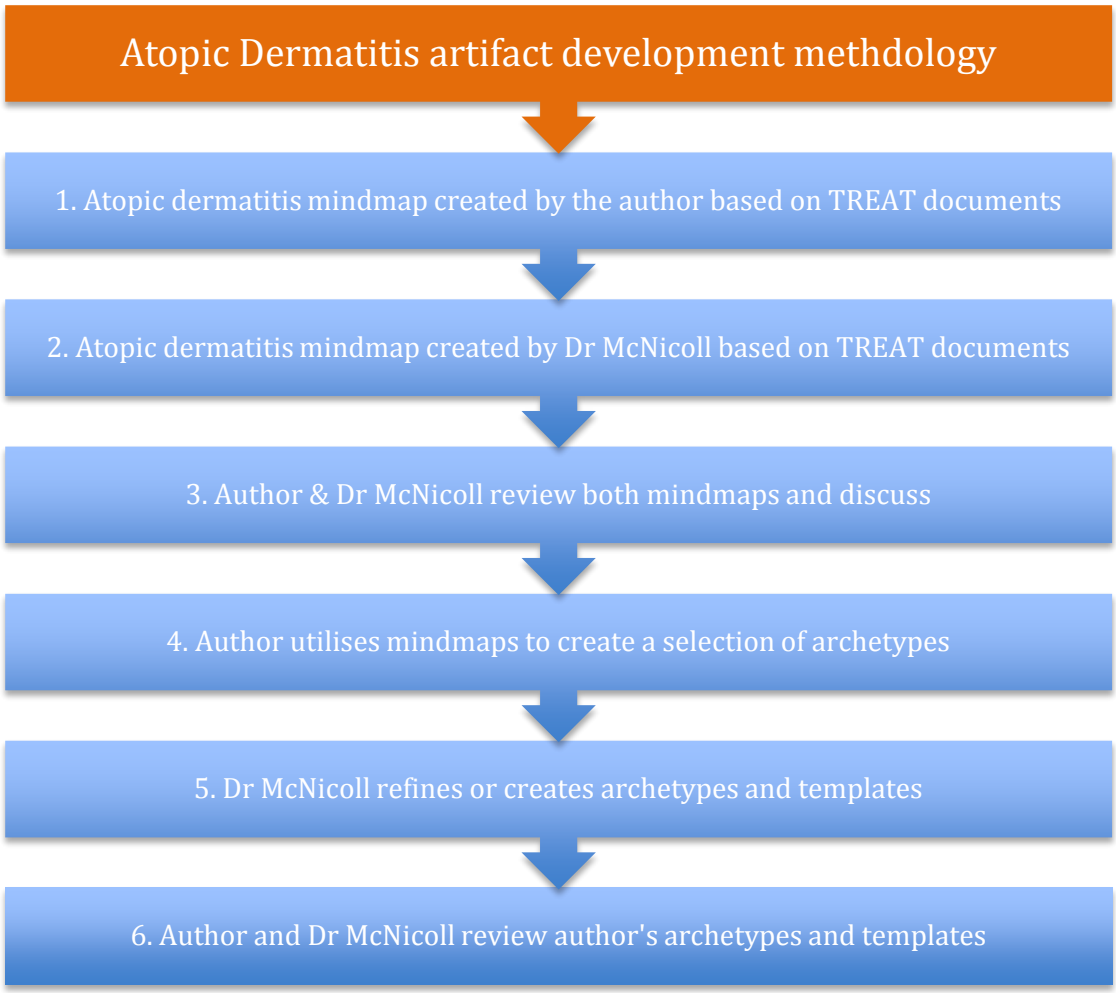
Further mentorship was provided to the author from Dr McNicoll. This consisted of discussions regarding openEHR and clinical modeling, in addition to help with familiarisation and setting up the freely available Ocean Informatics archetype designer software required to create artifacts in addition to XMind mindmapping software:

Two TREAT documents (neither are reproduced in this thesis as they form the basis of publications and proposals that the TREAT group are involved with) were used to facilitate the development of artifacts:

- A registry proposal document
    - This was a 46-page document that consisted of a proposal to develop an international atopic dermatitis registry. This detailed multiple aspects of the proposed registry project, including introduction and rationale, objectives, design, population, treatment methods, safety reporting, statistical methods and determination, ethical considerations, administrative aspects, monitoring, publication and references.
- A registry dataset document
    - This was a 14-page document containing specific data fields that the TREAT group considered that the registry might need to capture, such as patient details, medications and laboratory tests.

The proposed methodology of development is described in Figure 23.

Figure 23 Proposed atopic dermatitis artifact development methodology



4.6.3. ATOPIC DERMATITIS MINDMAP WORK

The author's mindmap (Figure 25) and Dr McNicoll's (Figure 26) are presented in a reduced size to demonstrate the obvious high-level structural differences. Full size versions, too large to print, are included in the CD accompanying this thesis. This work corresponds to the first three steps in the proposed AD artifact development methodology Figure 24.

Figure 24 Mindmap work within proposed atopic dermatitis artifact development methodology

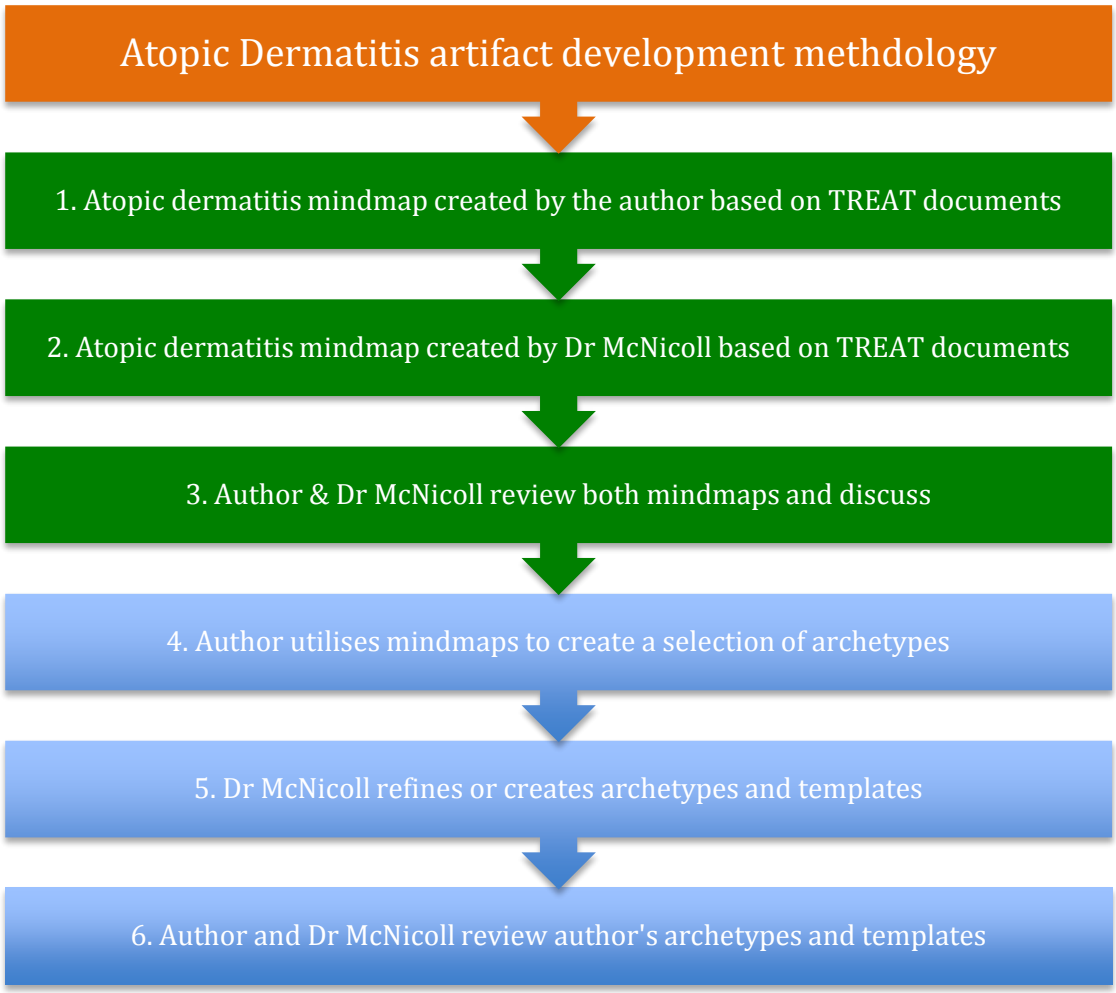


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Figure 25 Author's atopic dermatitis mindmap

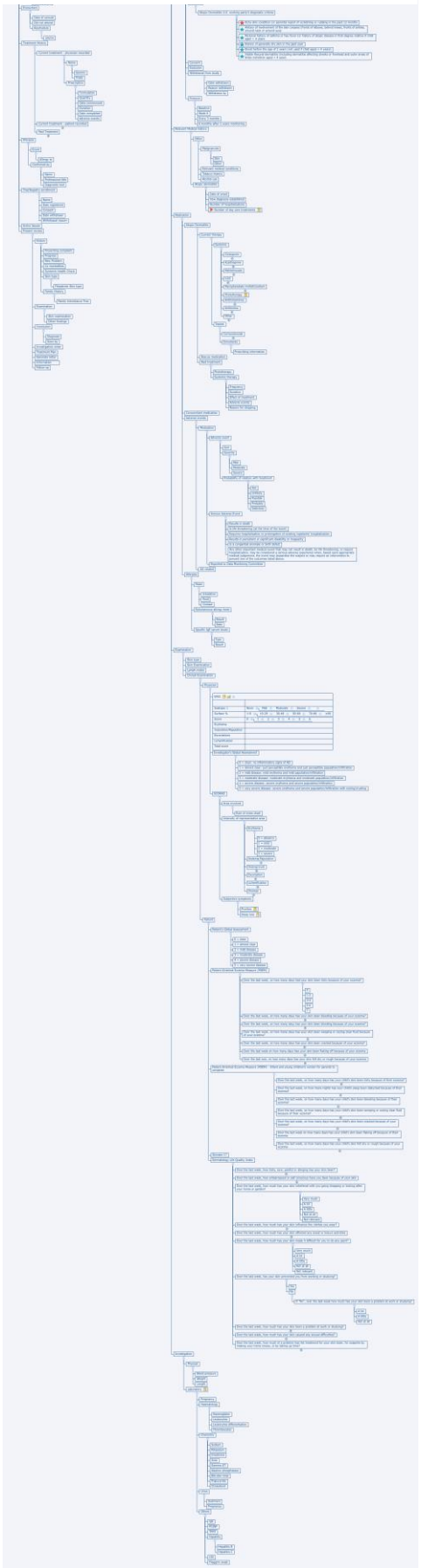
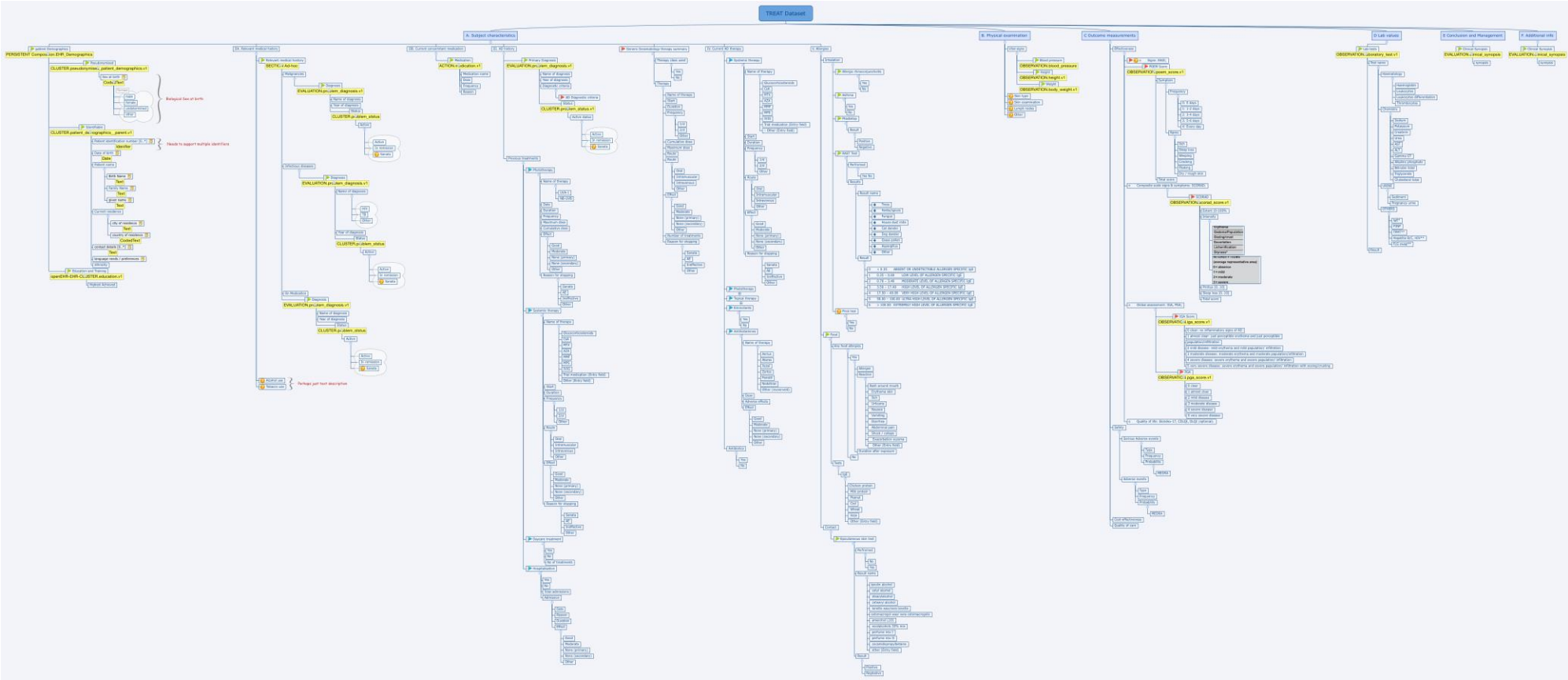


Figure 26 Dr McNicoll's atopic dermatitis mindmap



4.6.3.1. MINDMAP DISCUSSION AND EVALUATION

The author's mindmap, while containing a large number of similar data points, shows significant differences with respect to structure and organisation. What the author found particularly interesting is the addition of a number of components that reflect Dr McNicoll's experience with organising such large collections of data. Dr McNicoll has included references to existing archetypes in addition to signalling where new archetypes might need to be created and how these archetypes might be combined. The author also noted the use of tags and symbols by Dr McNicoll to represent either his understanding of the area or other information that helps in clarifying how the information is structured and what further work is required.

While the author's mindmap was significantly less developed, less aware of context and less clear, it was interesting that there were components of the author's mindmap that facilitated further additions to be made to the mindmap that was utilised to create archetypes and templates for the TREAT group. These were typically areas where Dr McNicoll required further understanding of the clinical area. The author feels that this is worth highlighting as it emphasizes the means by which 2-level modeling can add value, by enabling domain specialists to contribute in a meaningful way, that might not occur in the absence of their direct involvement.

4.6.3.2. DEVELOPMENT PROCESS DISCUSSION AND EVALUATION

Prior to attempting to use the archetype developer, the author had reviewed a number of publications, such as Derek Corrigan's thesis (2010), in addition to reviewing a small number of publically posted presentations. While a number of the components required to model were, to some extent, familiar to the author, faced with having to model in real-time, the author found himself stumped.

4.6.3.3. OVERALL MINDMAPS DISCUSSION AND EVALUATION

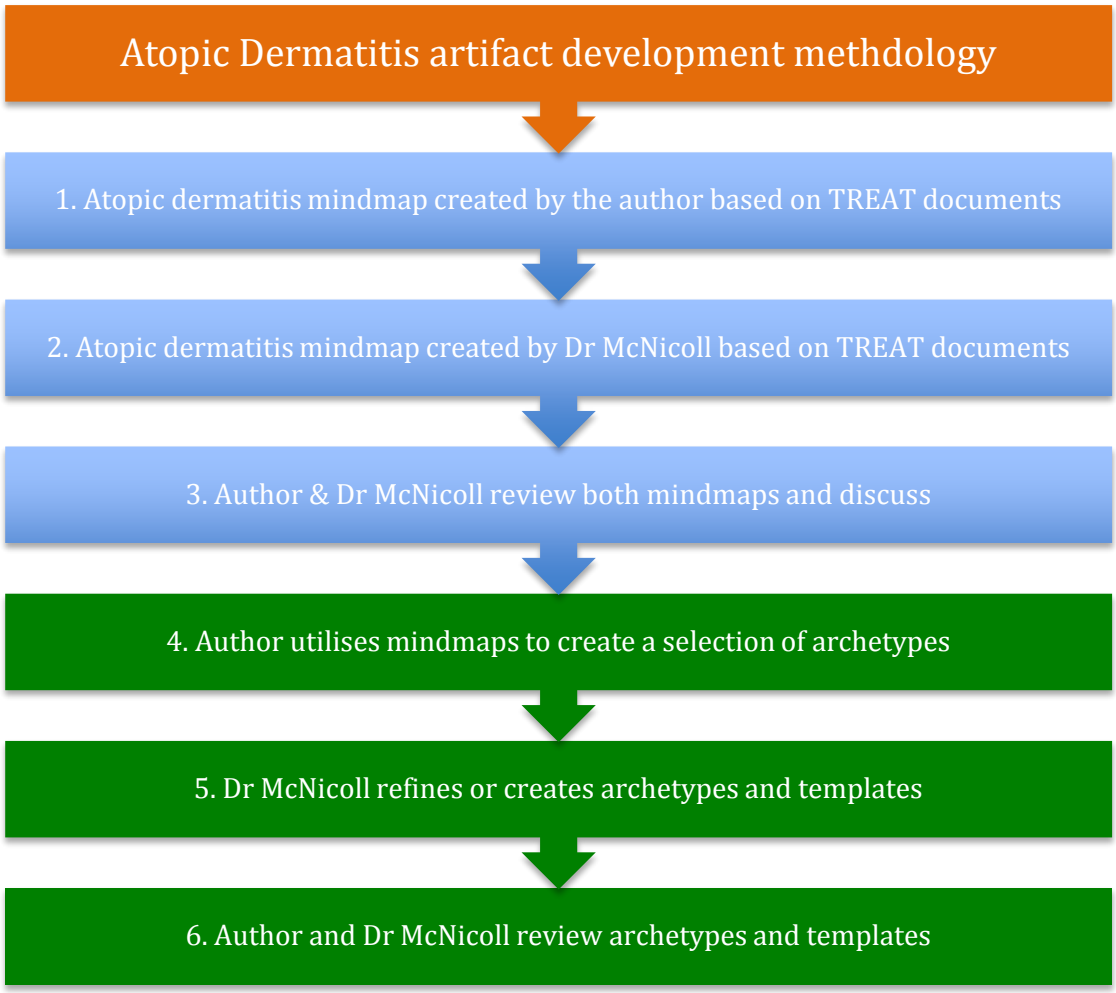
The author has now had experience with two sets of mindmaps. The development of an EB classification was quite intuitive and, as such, appeared to be a useful means of enabling a clinician to easily represent information models.

Experience of mindmap development for combinations of datasets as in AD was more difficult. At the larger scale, organisation was challenging and deeper understanding of existing archetypes, templates were critical factors that the author had not yet acquired.

Dr McNicoll's use of symbols and formatting to enrich the mindmap that facilitated archetype and template creation was interesting. The author proposes that much of this knowledge could be utilised to develop a rules-based wizard to facilitate novel clinicians as they learn to engage with mindmaps.

4.6.4. ATOPIC DERMATITIS ARTIFACT WORK

Figure 27 Remaining atopic dermatitis artifact work



Discussion with Dr McNicoll and review of the mindmaps enabled identification of six components for the author to archetype (this work correlated with steps 4-6 in the AD artifact development methodology, shaded in green in Figure 27):

- Dermatology Life Quality Index
- Eczema Area and Severity Index
- Fitzpatrick Skin Type
- Investigator Global Assessment
- Patient Global Assessment
- Patient Orientated Eczema Measure

The following sections provide information regarding each archetype and a screenshot captured from the archetype designer tool in each case. Each archetype developed was

an Entry type Observation archetype. Advice regarding choice of archetype class was given by Dr McNicoll and further understanding was obtained from reading Derek Corrigan's thesis (Corrigan, 2010) and sections of a comprehensive, but, to the author, technically complex openEHR Architecture overview (Beale and Heard, 2008).

4.6.4.1.1. DERMATOLOGY LIFE QUALITY INDEX (DLQI)

Name: openEHR-EHR-OBSERVATION.dlqi.v1 (Figure 28, Figure 29).

Figure 28 Dermatology Life Quality Index explanation

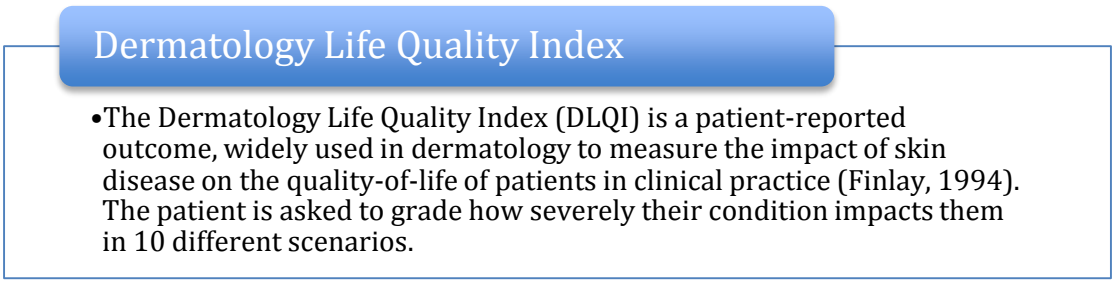
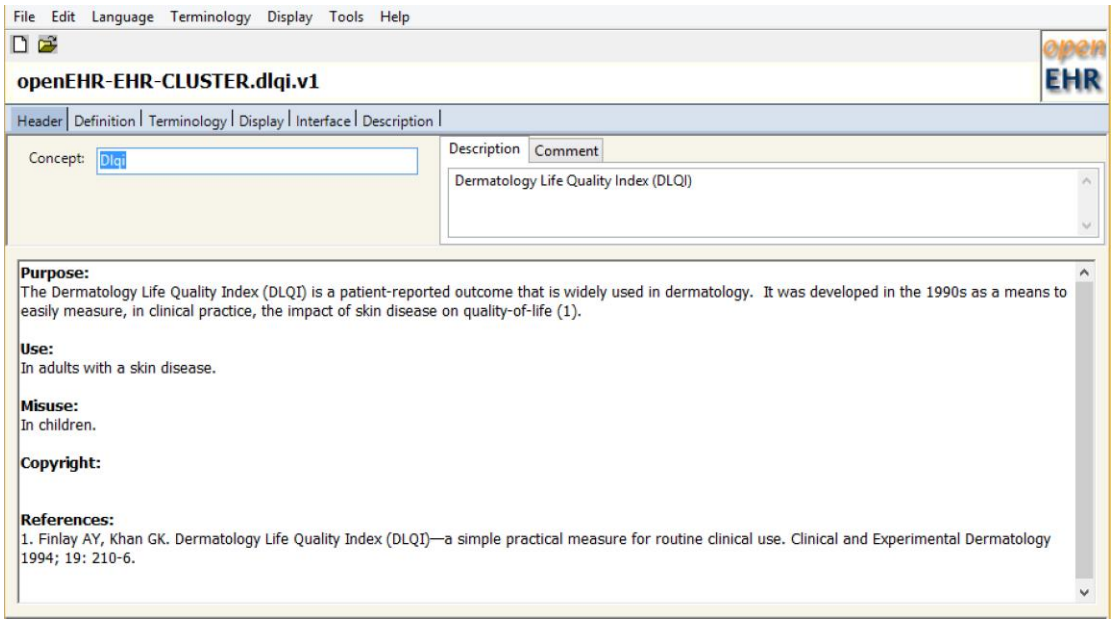


Figure 29 Screenshot from dlqi.v1 archetype development



4.6.4.1.2. ECZEMA AREA AND SEVERITY INDEX (EASI)

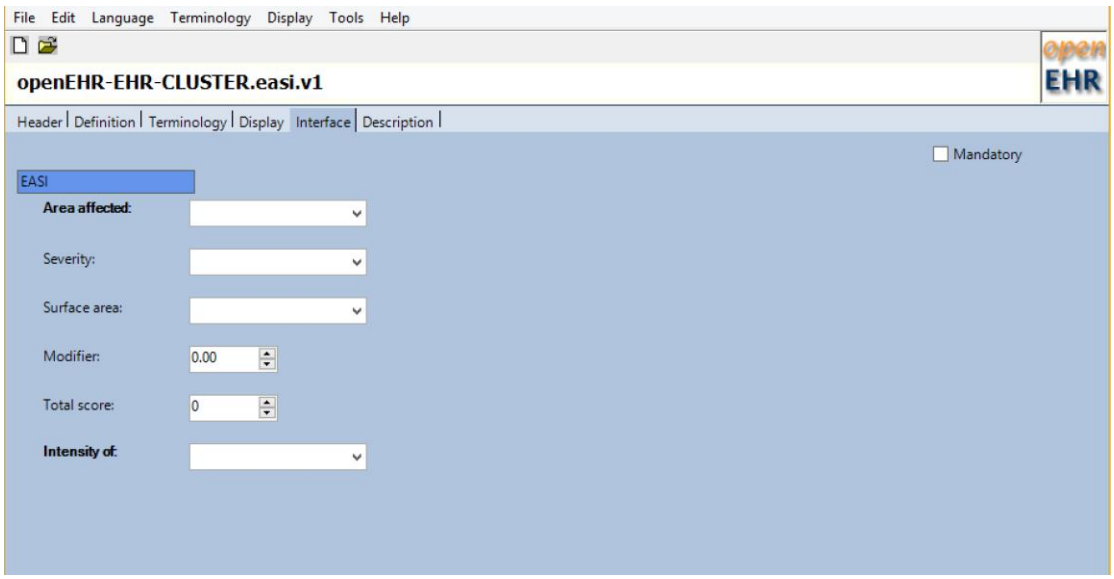
Name: openEHR-EHR-OBSERVATION.easi.v1 (Figure 30, Figure 31).

Figure 30 Eczema Area and Severity Index explanation

Eczema Area and Severity Index

- The Eczema Area and Severity Index is an instrument that enables standardized scoring of eczema/atopic dermatitis (Hanifin, 2001). 4 areas; the head/neck, trunk, upper and lower extremities are assessed and graded with respect to the area involved in case and the severity (0 = none; 1 = mild; 2 = moderate and 3 = severe) of 4 clinical signs of eczema/atopic dermatitis (erythema, oedema/papulation, excoriation and lichenification) in each area. This generates a score between 0 (no eczema) and 72.

Figure 31 Screenshot from EASI archetype development



4.6.4.1.3. FITZPATRICK SKIN TYPE

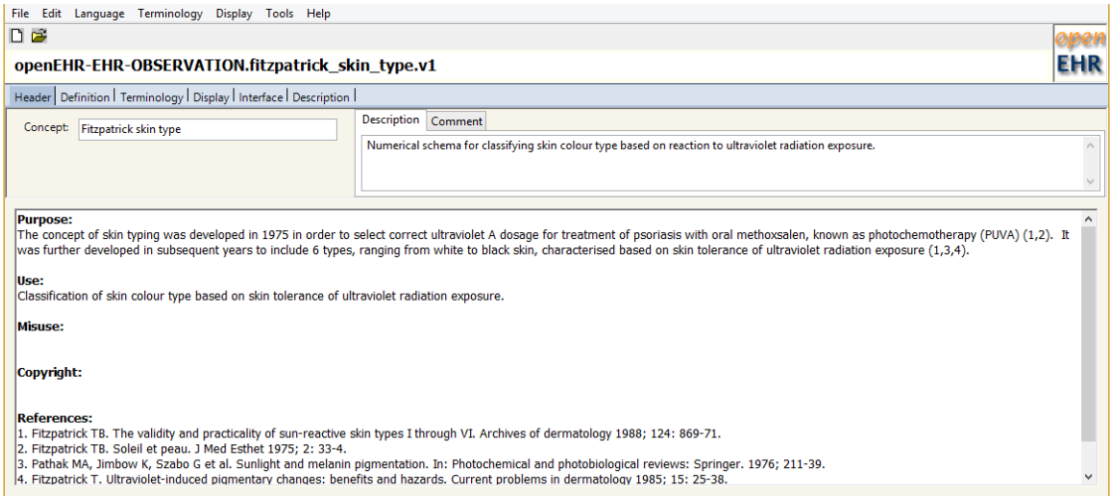
Name: openEHR-EHR-OBSERVATION.fitzpatrick_skin_type.v1 (Figure 32, Figure 33).

Figure 32 Fitzpatrick Skin Type explanation

Fitzpatrick Skin Type

- The concept of skin typing was originally developed to select correct ultraviolet A dosage for treatment of psoriasis with an oral compound, called methoxsalen, in a process known as photochemotherapy (PUVA) (Fitzpatrick, 1988; Fitzpatrick, 1975). It is used to describe different types of skin. It was further developed in subsequent years to include 6 types, ranging from white to black skin, characterised based on skin tolerance of ultraviolet radiation exposure (Fitzpatrick, 1988;Pathak, 1976;Fitzpatrick, 1985).

Figure 33 Screenshot from Fitzpatrick Skin Type archetype development



4.6.4.1.4. INVESTIGATOR GLOBAL ASSESSMENT

Name: openEHR-EHR-OBSERVATION.iga.v1 (Figure 34, Figure 35).

Figure 34 Investigator Global Assessment explanation

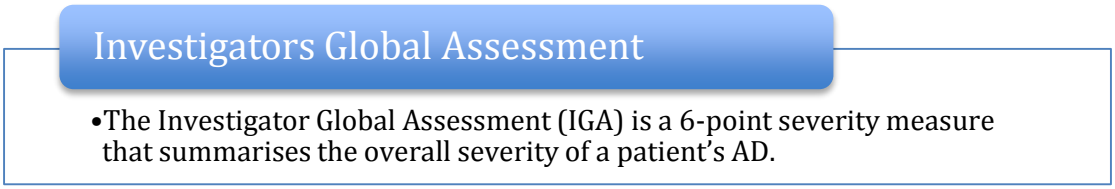
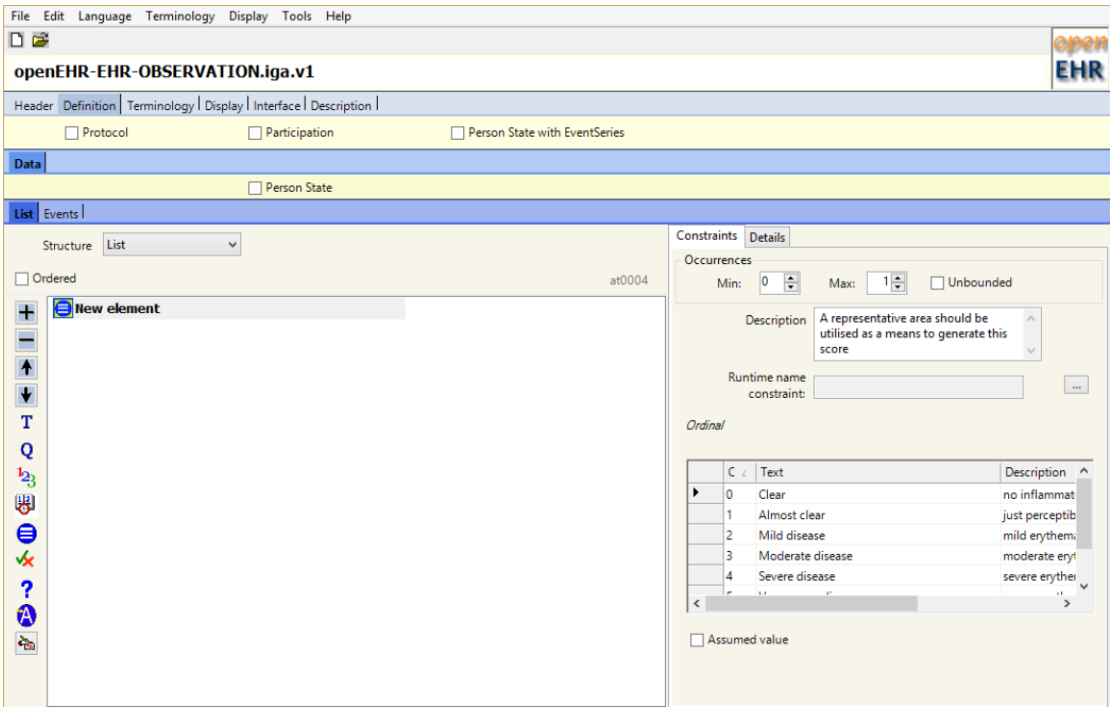


Figure 35 Screenshot from Investigator Global Assessment archetype development



4.6.4.1.5. PATIENT GLOBAL ASSESSMENT

Name: openEHR-EHR-OBSERVATION.patients_global_assessment.v1 (Figure 36, Figure 37).

Figure 36 Patient Global Assessment explanation

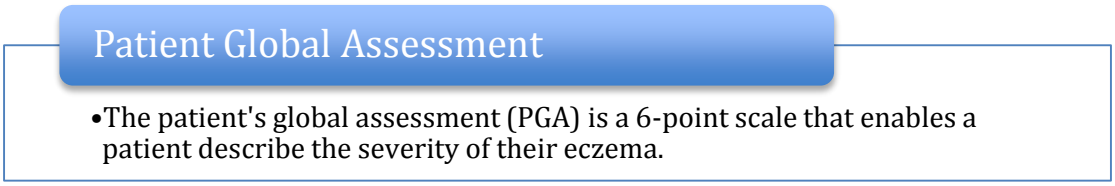
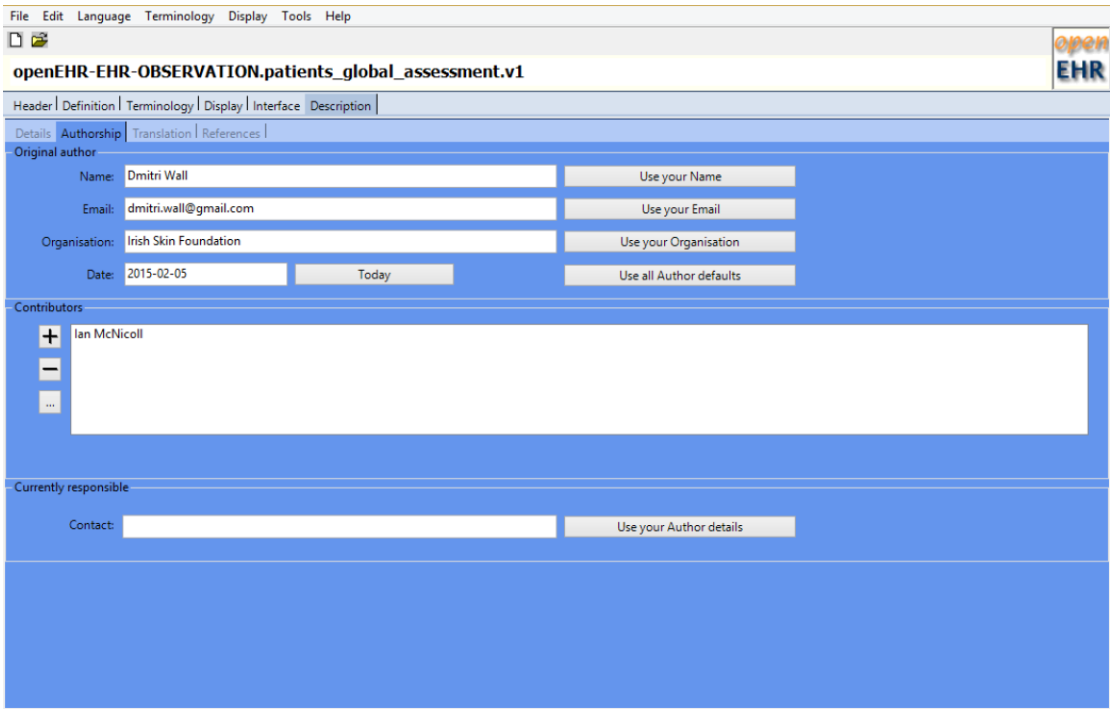


Figure 37 Screenshot from Patient Global Assessment archetype development



4.6.4.1.6. PATIENT ORIENTATED ECZEMA MEASURE

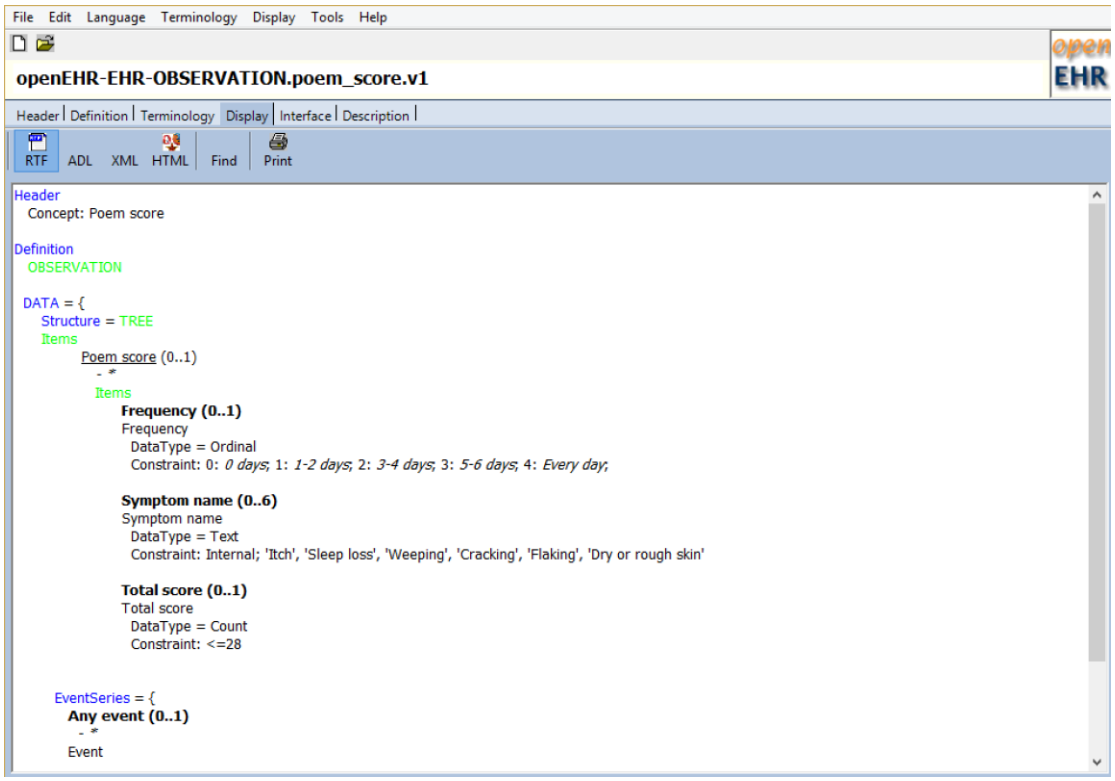
Name: openEHR-EHR-OBSERVATION.poem_score.v1 (Figure 38, Figure 39).

Figure 38 Patient Orientated Eczema Measure explanation

Patient Orientated Eczema Measure

- The Patient-Priented Eczema Measure (POEM), is a measure, developed "for research purposes, and to assist health care professionals such as general practitioners, dermatologists, pediatricians, and specialist nurses caring for patients in routine clinical practice" {Charman, 2004 #2270}. It is a tool that enables measurement of "atopic eczema severity from the patients' perspective" {Charman, 2004 #2270;Schram, 2012 #2269}.

Figure 39 Screenshot from Patient Orientated Eczema Measure archetype development



4.6.4.2. ARCHETYPE EVALUATION AND REFINEMENT

Each of the archetypes developed by the author was reviewed by Dr McNicoll and refined. HTML versions of the archetypes are printed in Appendix C. Given the short period of time available, not all the TREAT dataset was modeled, however a comprehensive selection was developed to form a large template. Within this, 5 of the author's archetypes were included following refinement by Dr McNicoll. These archetypes, which are available within an incubator on the CKM website, are presented in a printable format alongside the author's original archetypes for comparison in Appendix C.

The template, which is 31 pages long in printed format, is currently accessible to authorised members of the CKM, but is not printed here in view of its size and because it is currently undergoing further review and validation.

4.6.4.3. ARCHETYPE DISCUSSION AND REFLECTION

The development of archetypes by the author was a difficult process that required regular communication with Dr McNicoll for guidance. Many problems, however, related to a small number of technical queries and difficulties that required work-arounds that might possibly reflect shortcomings on the part of the archetype designer tool. Much of the data that was entered appeared to be quite intuitive on the part of the author. The author believes that work conducted by Atalağ (Atalağ, 2007) is extremely relevant in this regard. While he described the graphical user interface as "quite user friendly" for non-technical users, he described the importance of including bibliographic information and storage of multiple bindings (UMLS CUI and term UI) (Atalağ, 2007), which were developed as part of his work. The author firmly agrees with this. It is certainly in this regard that the author felt most familiar, as it is reflective of the publications that are familiar to the author from his medical research. It is an area that the author suggests domain experts could contribute to significantly, with ease.

While there were clear errors in the author's work, most became evident on review of Dr McNicoll's work. The author's practical understanding of archetype development increased dramatically as a result during this short period of time. It is suggested that this opportunity, is a valuable means for potential modelers to learn, should the opportunity arise or be created.

The meeting that produced this opportunity is worth noting. The opportunity to enable expert clinical and technical groups to meet was an exceptional opportunity, not only to promote the value of openEHR, but also to improve understanding across groups that can find considerable difficulties with respect to communication of their respective domains of expertise.

A particularly interesting development that arose from the meeting is that the information points developed are being prepared for a global, multi-stakeholder review, which will be conducted using a Delphi consensus methodology. This study is in progress at the time of writing this thesis and its methodology and findings will be described in a separate document that the author will contribute to. As such, it will not be discussed further in this thesis, except to comment on the suitability of the Delphi

process in the context of openEHR. The eDelphi process enables multiple groups to rate the value of data points over the course of a number of rounds of questionnaires, progressively developing consensus. The value of this with respect to the development of an internationally supported dataset has clear value with respect to developing semantic interoperability, but also with respect to developing an involved network that will support it. This process, while potentially lengthy and resource intensive, is one that the author suggests could be of significant value with respect to engaging a clinical community, to facilitate the development of highly interoperable openEHR artifacts.

Finally, with respect to the template produced by Dr McNicoll, this represented an interesting perspective from the point of view of seeing how different datasets can be constrained and merged to create a collection that begins to resemble the forms that clinicians are used to seeing in clinical practice. From the perspective of clinical modeling, it represented a further skill that would be of great value to the author, once further experience and mentoring had been obtained.

4.6.5. PLAN FURTHER WORK

The work creating archetypes demonstrated not only the practical and technical requirements of modeling, but also the wealth of experience that is required to understand the subtleties of health information structuring and how important experience is in that regard. The experience of working with multiple groups began to identify how an archetype must be aware of multiple perspectives, which are not possible to obtain without the input of those perspectives.

To gain a further insight into how archetypes are collaboratively reviewed to incorporate these perspectives and mature them to a point where they can be published on the CKM, it was suggested that the author take part in the archetype review process.

4.7. CYCLE 7 ARCHETYPE REVIEW PROCESS

4.7.1. REVIEWING OTHER MODELERS' ARCHETYPES

4.7.1.1. WORK DESCRIPTION

The CKM tool facilitates the archetype review process. The archetype in presented in a manner that enables a reviewer to comment on each component (Figure 40), before declaring whether the archetype requires major revisions, minor revisions or should be accepted for publication.

The author was invited to take part in a review of two archetypes:

- Relative anatomical location
- Anatomical location

Between March 3rd and May 10th 2015, the author participated in three rounds of reviews (Figure 41). Both were published (Appendix D).

There is a comprehensive overview of how the archetype revision process works which is conveniently presented for review when an invitation to review an archetype is sent. As such, the author will not describe the process of archetype review, but on the impact it had on the author's understanding of the review process and the way in which it affected the author's ability to model.

Figure 40 Screenshot from the CKM of an archetype review screen

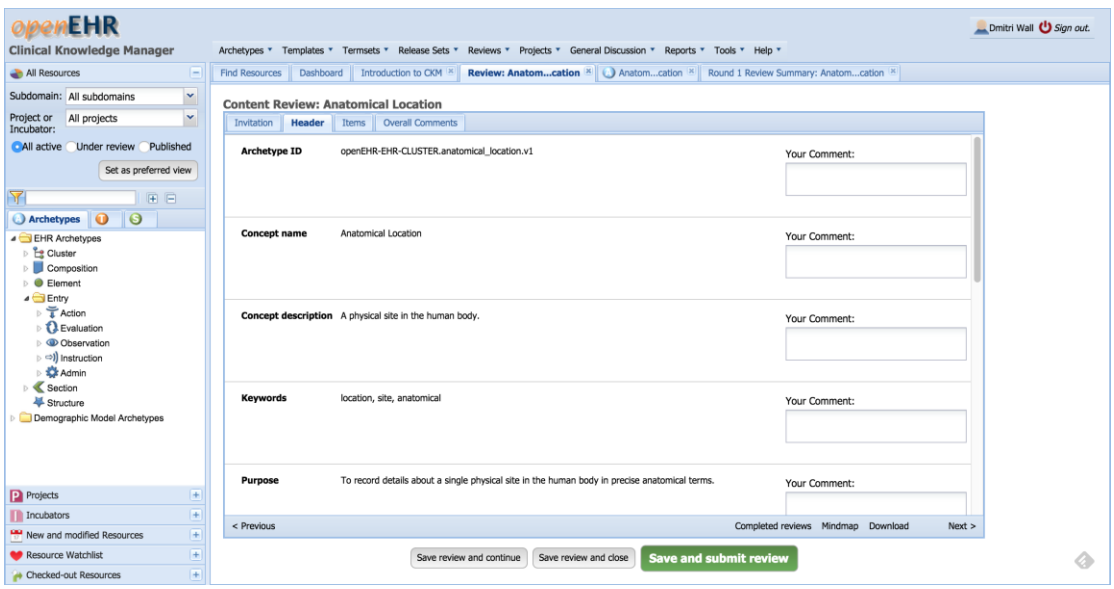
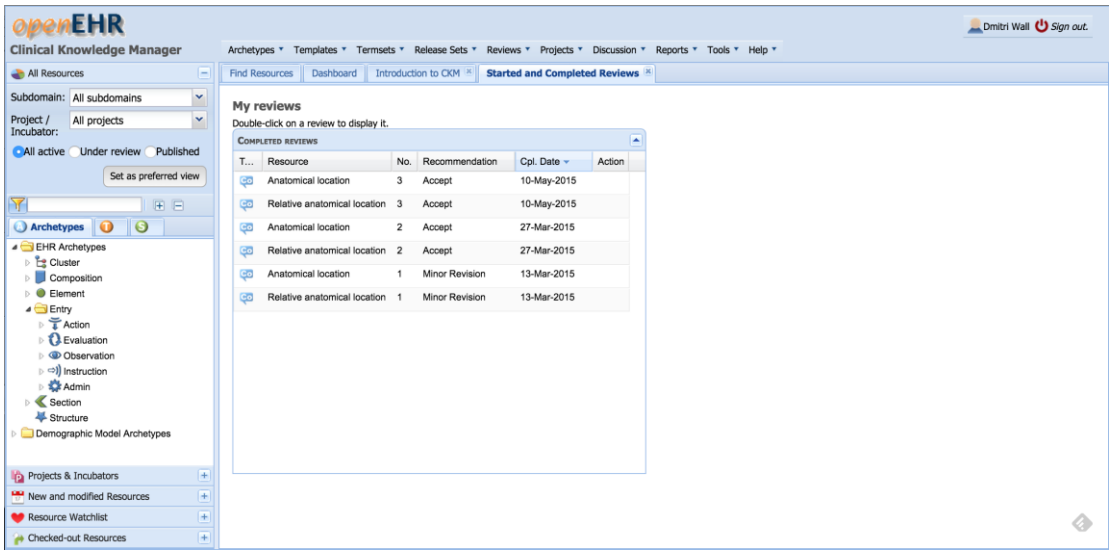


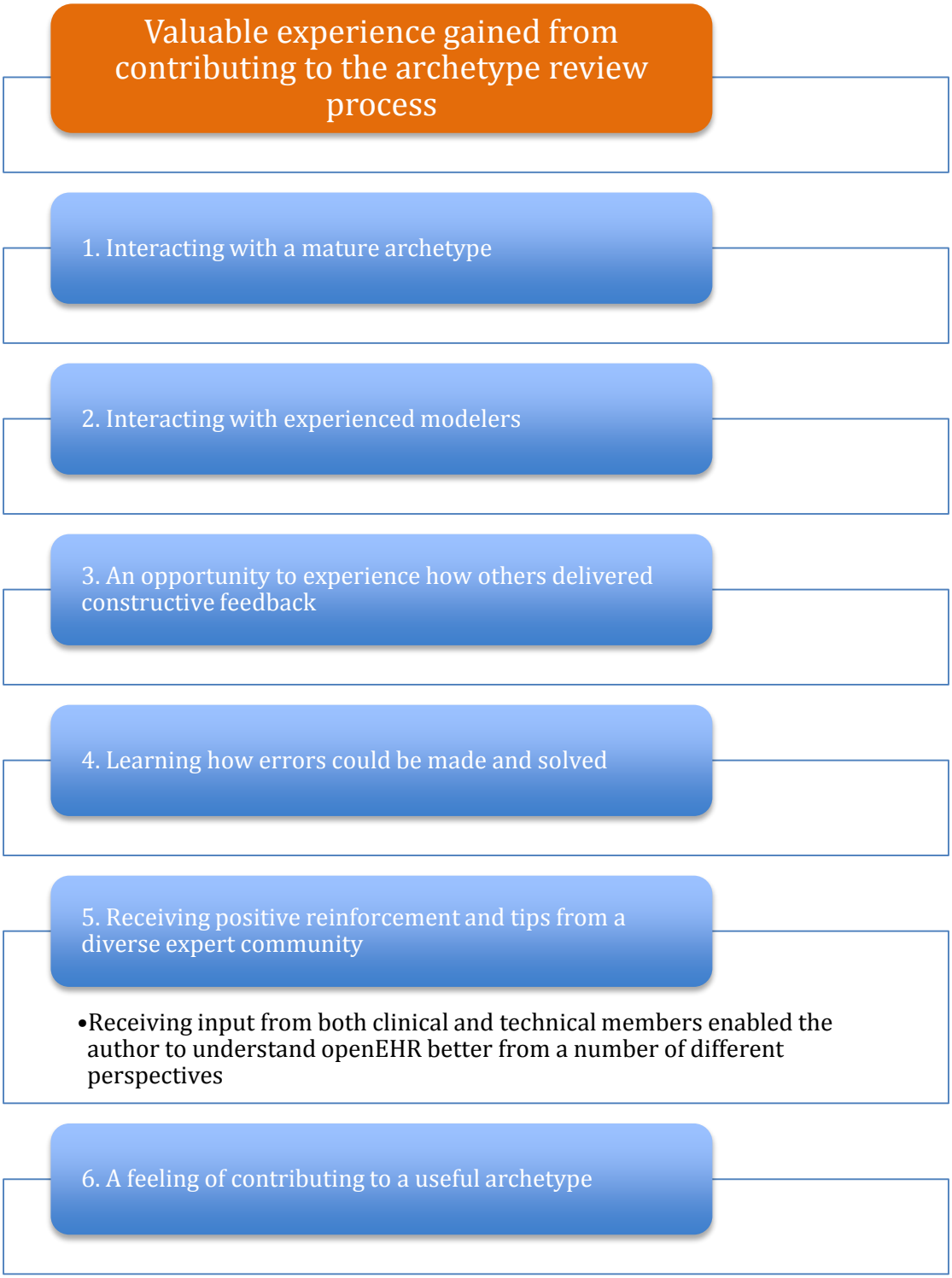
Figure 41 Screenshot of screen acknowledging the author's contribution to the archetype review process



4.7.1.2. DISCUSSION AND REFLECTION

The archetype review process provided the author with a number of valuable experiences, outlined in Figure 42.

Figure 42 Experience gained from the archetype review process



One example of the value of this experience is demonstrated in relation to a comment made by the author (Figure 43Figure 44Figure 45). From the perspective of a novice modeler or domain expert, the author believes that this type of feedback is particularly encouraging.

Figure 43 Screenshot showing the author's comment during a CKM archetype review

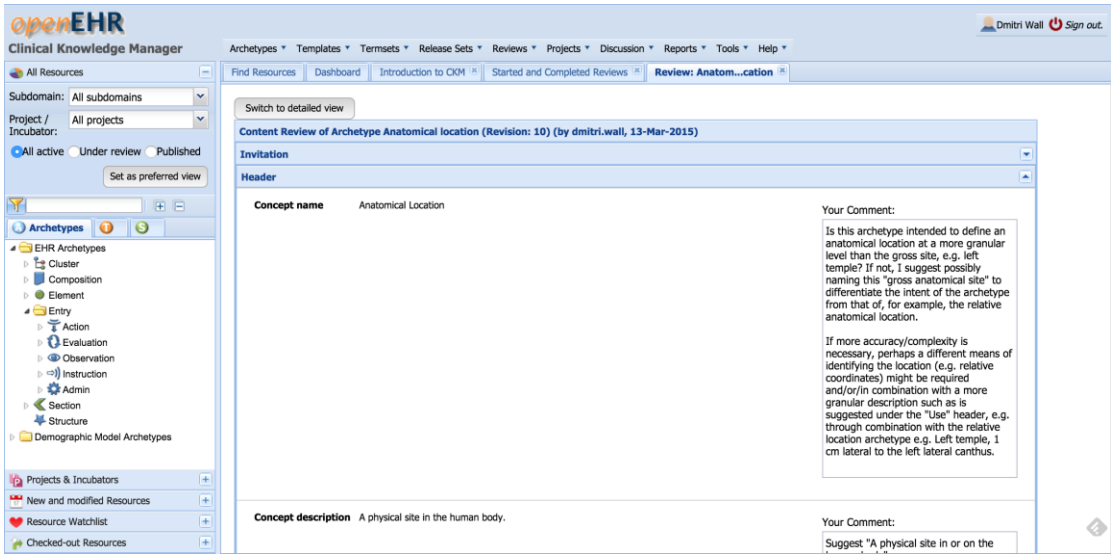


Figure 44 Author's comment during a CKM archetype review

> *"Dmitri Wall (13-Mar-2015)*
> Is this archetype intended to define an anatomical location at a more granular level than the gross site, e.g. left temple? If not, I suggest possibly naming this "gross anatomical site" to differentiate the intent of the archetype from that of, for example, the relative anatomical location. If more accuracy/complexity is necessary, perhaps a different means of identifying the location (e.g. relative coordinates) might be required and/or/in combination with a more granular description such as is suggested under the "Use" header, e.g. through combination with the relative location archetype e.g. Left temple, 1 cm lateral to the left lateral canthus."

Figure 45 Response to the author's comment during a CKM archetype review

> "@Dmitri - Thought provoking comment, thankyou. The scope it intended to be at the macroscopic level, but not just surface or topographic, ie it could be sites that imply internal locations such as right upper quadrant pain etc."

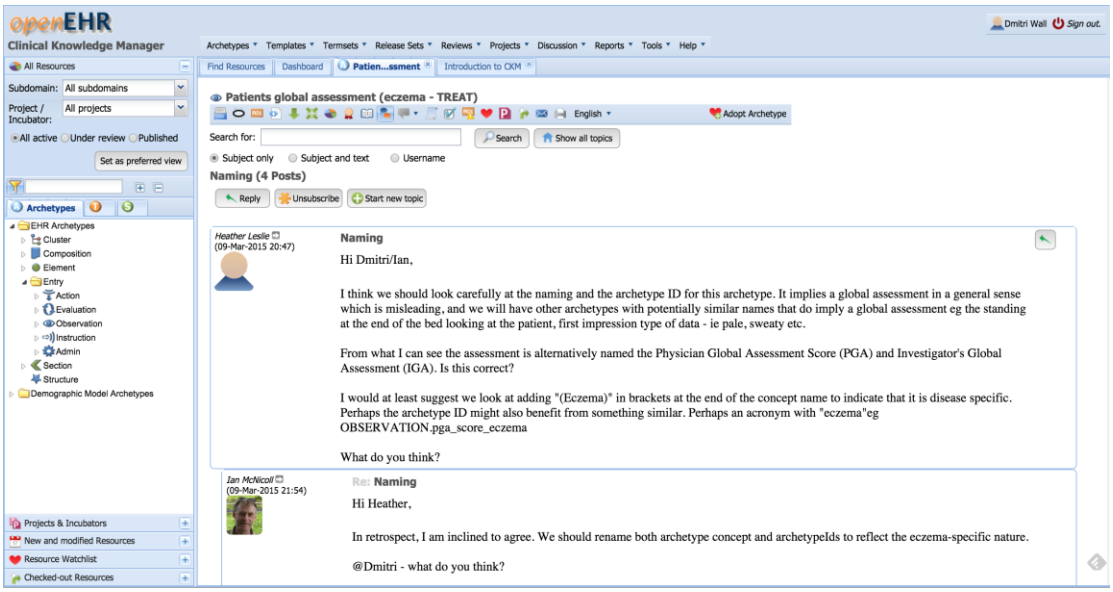
The author found the archetype review process to be a quick and extremely useful process that significantly improved understanding and developed a sense of comfort with the openEHR process and community.

4.7.2. AUTHOR'S ARCHETYPE

4.7.2.1. WORK DESCRIPTION

As noted previously, a number of archetypes developed by the author were uploaded to a sectioned area of the openEHR CKM, known as an incubator, by Dr McNicoll. One of these, openEHR-EHR-OBSERVATION.patients_global_assessment.v1.adl, received feedback from another editor, Dr Heather Leslie (Figure 46).

Figure 46 Feedback relating to the author's PGA archetype



4.7.2.2. DISCUSSION AND REFLECTION

It was particularly reassuring to be included in a debate on aspects of the archetype, where differences of opinion were shared by experienced editors, highlighting that clinical modeling is not a black and white process, but more a means to facilitate conceptual interoperability between clinicians.

It is worth noting that the process of uploading an archetype and subsequently reviewing and versioning it, was particularly complex and required significant guidance from Dr McNicoll. Three screenshots from this process are presented in Figure 47Figure 48Figure 49. While this process is expected to be carried out by experienced modelers,

it is suggested the complexity might create a significant burden of work from the relatively small group of CKM editors who have the experience to do this, creating a potential backlog as the user group of openEHR increases in number.

Figure 47 Managing archetype versions part 1/3

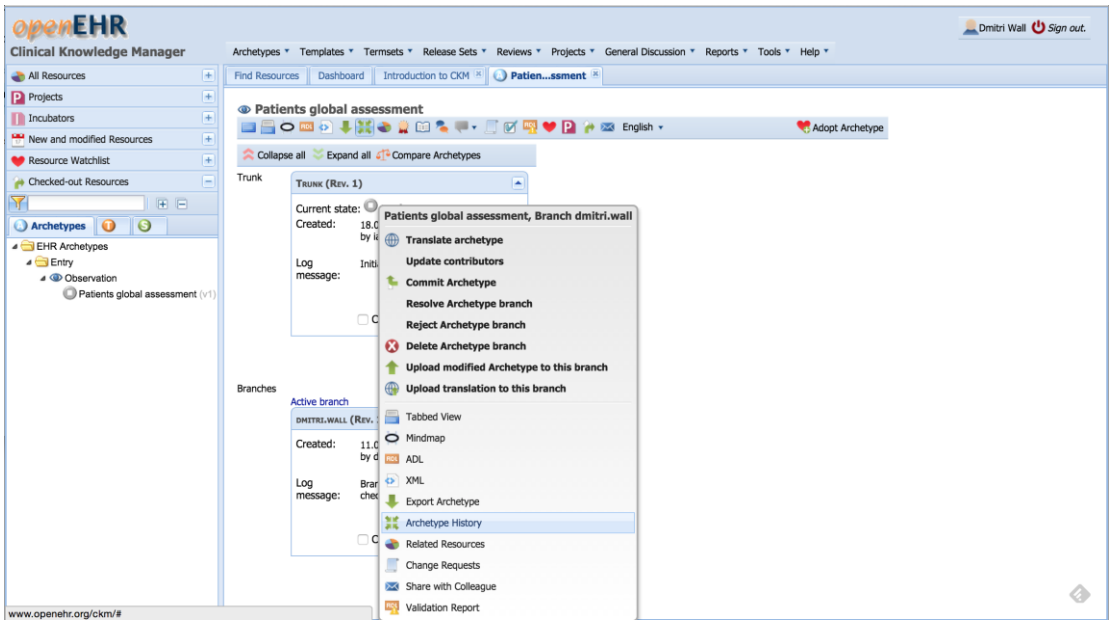


Figure 48 Managing archetype versions part 2/3

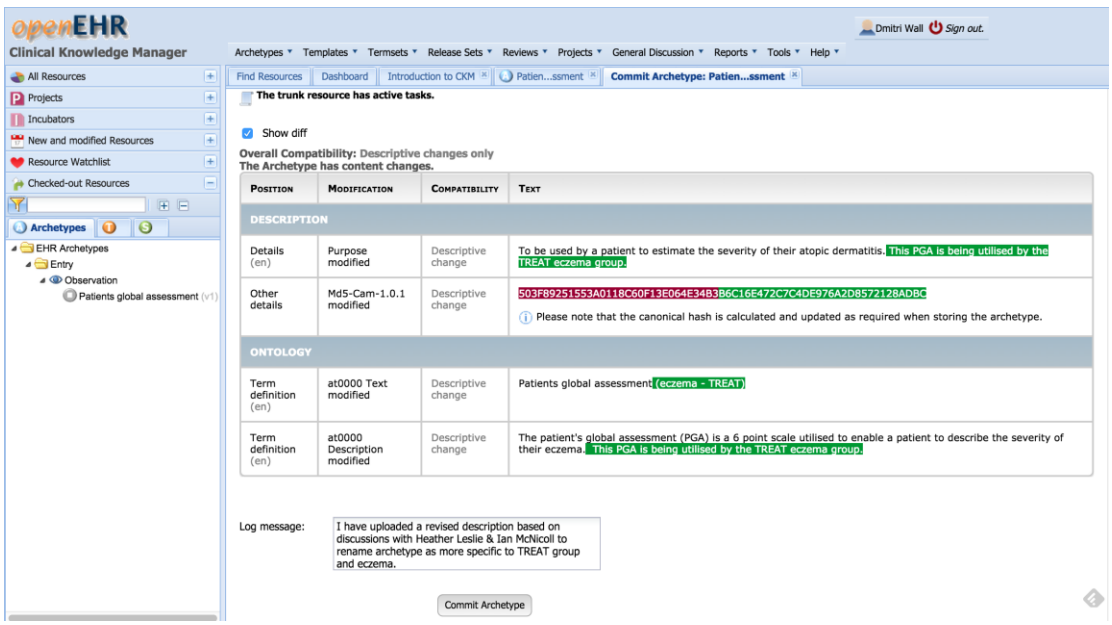
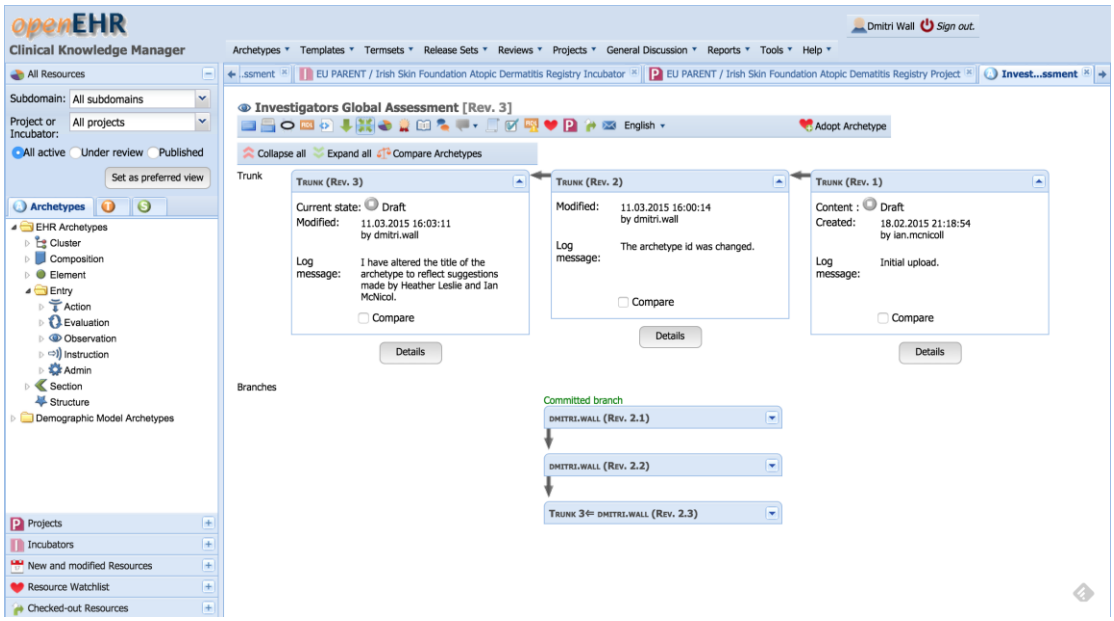


Figure 49 Managing archetype versions part 3/3

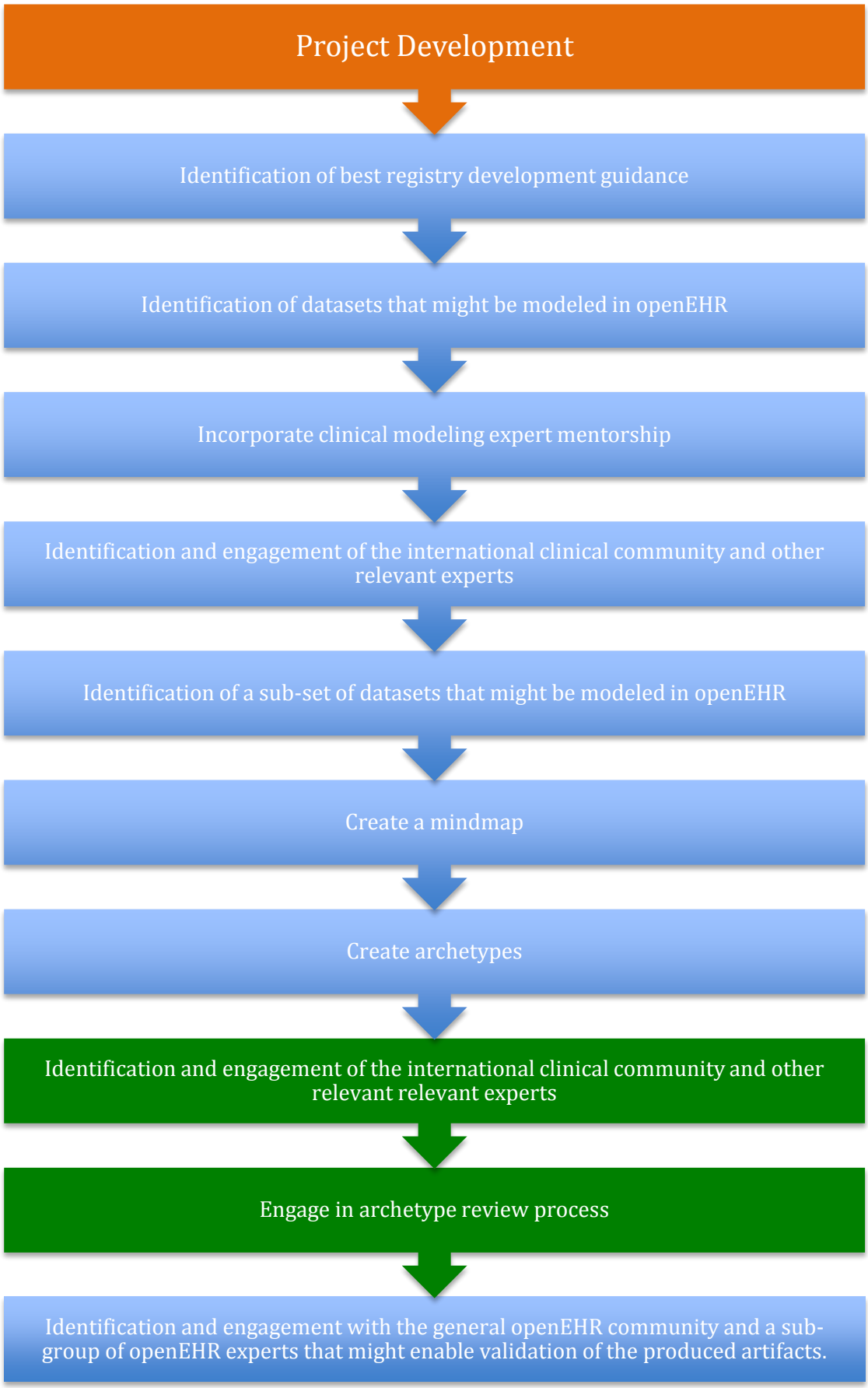


4.7.3. PLANNING FURTHER WORK

The archetype review process added a further useful piece of work to the author's development (Figure 50).

At this point in the thesis, previously planned surveys had yielded results that added to the author's understanding. These are discussed in the following sections.

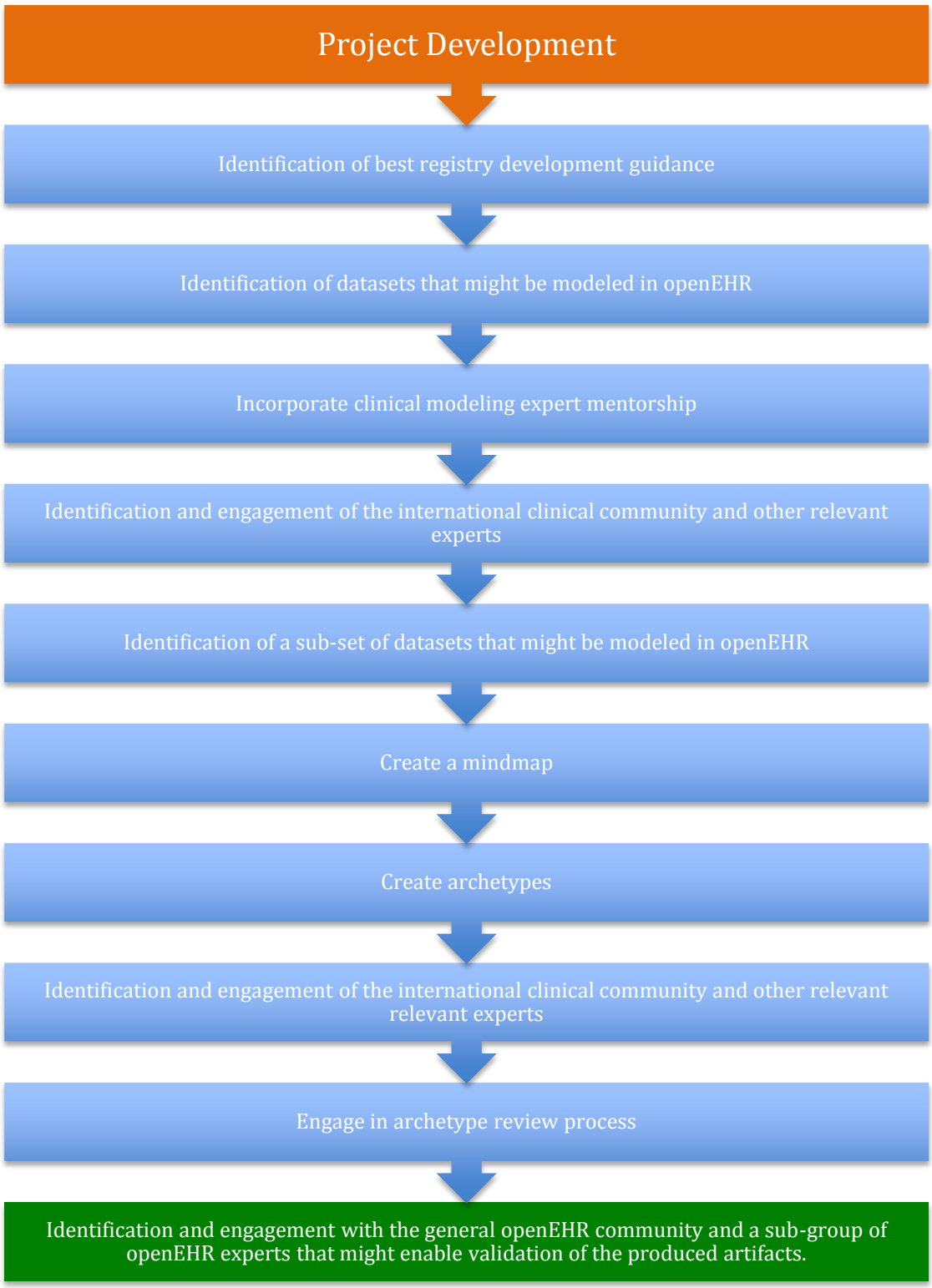
Figure 50 Cycle 7 project development plan



4.8. CYCLE 8 OBTAINING FEEDBACK

This section describes the validation surveys planned in Cycle 3 (EB expert engagement) and Cycle 4 (openEHR clinical modeling community) (Figure 51).

Figure 51 Cycle 8 Project development plan



4.8.1. SURVEY NAME: INVESTIGATING THE VALUE OF CONSULTATION WITH EXPERT CLINICIANS IN CLINICAL MODELING

This subsection describes the first of the two surveys covered in cycle 8.

4.8.1.1. STUDY PLAN

4.8.1.1.1. STUDY AIM

The aim of this survey was to investigate the value of clinical experts reviewing models which have been based on their published opinion; in this case, the previously described mindmap (Figure 21; reproduced again here for convenience) relating to the classification of Epidermolysis Bullosa (EB) (Fine et al., 2014) from chapter 4.2.4.

Figure 52 Amended simplified epidermolysis bullosa onion skin classification mindmap (repeat of Figure 21)

4.8.1.1.2. METHODS & MEASUREMENTS

Ethical approval was received from the Trinity College Dublin Research Ethics Committee. Prior to sending formal invites via Survey Monkey, an introduction to the primary author of the publication was kindly made possible by DEBRA Ireland. The other authors were then contacted by email to inform them of the planned survey, 3 by the author, and the remaining 16, unfamiliar to the author, by DEBRA Ireland. One further author's contact details were unknown. Though it was originally planned to post the mindmap for review and annotation, a pdf version was emailed to each author as a backup, and this was deemed to be more convenient for participants. Survey invitation emails were sent from Survey Monkey on the 22/03/2015 and again on the 28/03/2015. A further email was sent to one participant who had misplaced the link, on request, on the 30/05/2015.

The Survey Monkey questionnaire (Appendix E) explained the context of this thesis and study. 5 questions were posed. The first related to consent. The remaining questions asked the participant to consider the mindmap that they had received in the context of their publication.

Participants were then asked three questions:

- How easy it is to read and understand the mindmap on a 5-point Likert scale (1-very difficult, difficult, average, easy and 5-very easy)
- How accurate a representation of the classification of epidermolysis bullosa (with respect to the referenced publication) is the mindmap on a 5-point Likert scale (1- very inaccurate, moderately inaccurate, neither inaccurate nor accurate, accurate and 5-very accurate)
- How useful a representation of the classification of epidermolysis bullosa is the mindmap on a 5-point Likert scale (1-very useless, moderately useless, neither useless nor useful, useful, 5-very useful)

Comment boxes were available for each question, in addition to a "further comments" box, which formed the fifth question.

All survey questions were optional, except for the first question, which confirmed that the information literature had been reviewed and that consent was given. The final question regarding whether the participant wished to submit or "not submit, exit

without submitting" was also mandatory to ensure that participants had a means to withdraw consent, if desired.

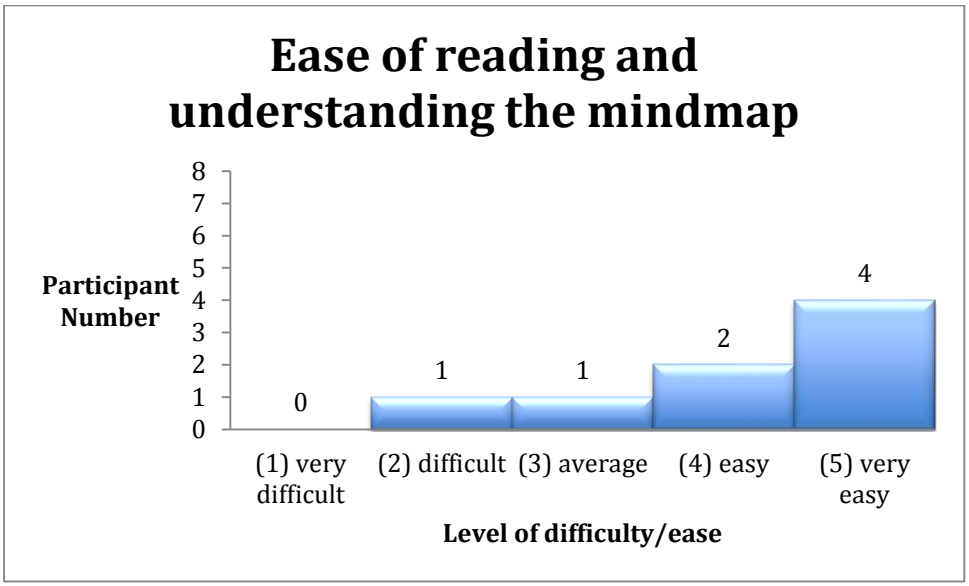
4.8.1.2. STUDY RESULTS

8 authors completed the Survey Monkey questionnaire. In addition, one author provided feedback by means of email. Though the participant noted that the mindmap was "easy to understand, is accurate and useful", this was not included in the analysis as it was not possible to determine the magnitude of ease, accuracy or usefulness implied. Comments from this participant, in addition to 2 other participants who completed the survey, but sent additional content by email, are discussed later in this section.

4.8.1.2.1. HOW EASY WAS THE MINDMAP TO READ AND UNDERSTAND?

The average score of the 8 participants was 4.125 demonstrating considerable ease in interpreting the mindmap (Figure 53). There were comments from 4 of the participants. One comment suggested that ease in understanding the mindmap was due to familiarity with the publication content, while another, in a similar vein, suggested that the mindmap may be more difficult to understand for those unfamiliar with epidermolysis bullosa. One author, who rated the mindmap difficult to understand, noted that the structure was understandable, but the lettering too small. A further author, who rated the mindmap easy to understand, similarly noted that the text was quite small, but that the concept was straightforward and easy to understand.

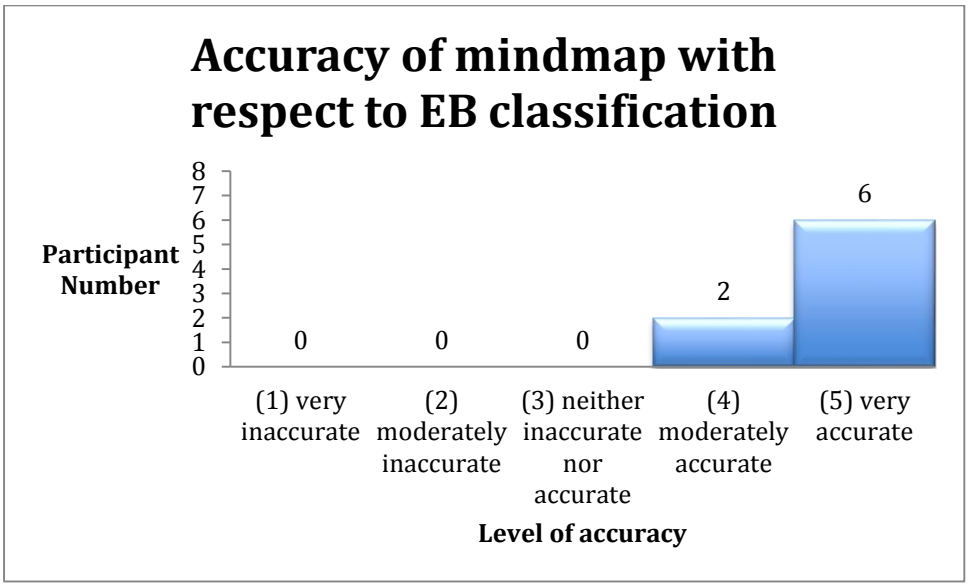
Figure 53 Experts ease of reading and understanding the EB mindmap



4.8.1.2.2. HOW ACCURATE WAS THE MINDMAP WITH RESPECT TO THE CLASSIFICATION OF EPIDERMOLYSIS BULLOSA?

The average score of the 8 participants was 4.75 suggesting that the mindmap was moderately to very accurate (Figure 54). There were comments from 3 of the participants. A comment, from a participant who rated the mindmap 4/5 (moderately accurate) suggested that there should be more detail captured by the mindmap with respect to one particular subgroup to represent further ways that EB can be subtyped. The same participant also noted a new subtype had been identified since publication of the document. A further participant who rated the mindmap 4/5 suggested that it was "quite reasonable", while a participant who rated it 5/5 commented, "it accurately lists the groups and subgroups".

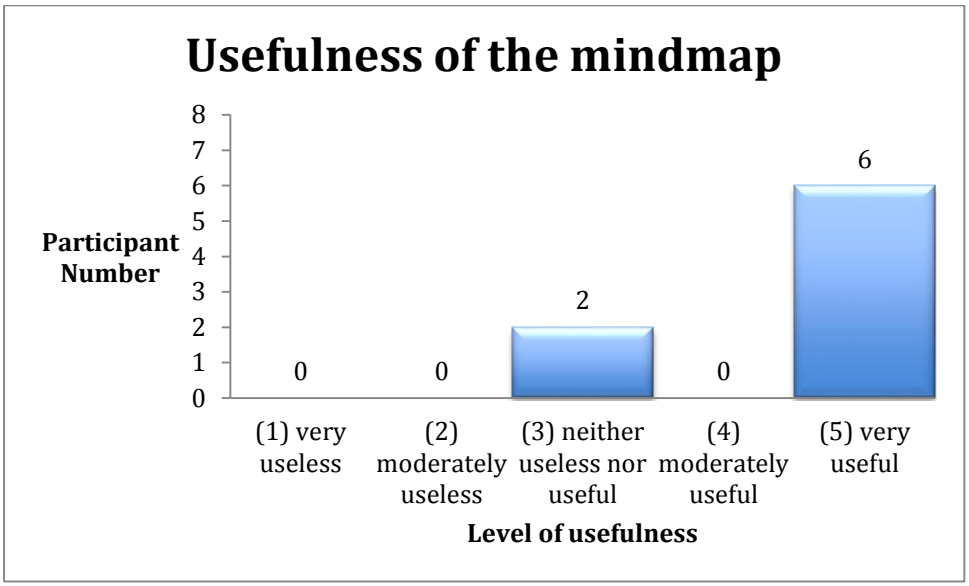
Figure 54 Experts rating of the accuracy of the EB mindmap with respect to Fine et al. (2014) classification of EB



4.8.1.2.3. HOW USEFUL A REPRESENTATION OF THE CLASSIFICATION OF EPIDERMOLYSIS BULLOSA IS THE MINDMAP

The average score of the 8 participants was 4.5, suggesting that the mindmap was moderately to very useful at representing the classification of EB (Figure 55). There were comments from 3 of the participants. One participant, who rated the mindmap 3/5, commented that it "accurately lists the groups and subgroups". A further author, who rated the mindmap 3/5, noted some concern related to weaknesses in the way EB was classified in the published document. They also noted that there were inconsistencies in the manner in which subtypes were named, some entities containing gene names and others not. It was also suggested that for the benefit of clinicians, it would be useful to stack the classifications in the order of how prevalent each subtype is. A final comment, by a participant who rated the mindmap 5/5, commented that the mindmap was "easy and quick to use, elegantly and clearly summarising different subtypes".

Figure 55 EB experts rating of the usefulness of the EB mindmap



4.8.1.2.4. FURTHER COMMENTS

4 participants made further comments. One comment noted that the mindmap was a limited representation of the classification of epidermolysis bullosa, restricted to clinical subtypes and therefore the term "onion skin classification" did not really apply to this representation. A further comment was similar to this, requesting further detail to represent the depth of classification inferred by the term onion. A comment suggested that one of the classifications might be altered, but acknowledged that that opinion would be not be consistent with the recommendations in the consensus publication. One participant suggested that the author should "keep up the good work".

4.8.1.2.5. EMAIL CORRESPONDENCE

One author suggested the addition of "other" fields for as yet undiagnosed subtypes of Epidermolysis Bullosa.

Another correspondence suggested, that the order of some of the classifications might be adapted to reflect "incrementation in severity".

4.8.1.3. STUDY DISCUSSION

The author accepts that it would not be appropriate to draw far-reaching conclusions about the value of mindmaps based on this study. The mindmap represents one author's attempt to represent, at a simple and constrained level, a complex publication

and validate its understandability, accuracy and usefulness within a small group. While this small group represents a significant collection of the world's foremost EB experts, they only represent a small collection of the population of expert clinicians in the world and so conclusions drawn from the sample can only be considered indicative with respect to the value of consultation with expert clinicians in clinical modeling. These concerns were considered and expected prior to performing the study. The survey was proceeded with, as value was expected regarding a number of points:

1. The study was a valuable and reasonable means of engaging with the type of group that could ultimately facilitate the development of an internationally interoperable patient registry.

2. The difficulty in arranging a group of clinical world experts to participate in the evaluation of mindmaps as a means to facilitate information modeling was believed to be relatively difficult and unlikely, so this opportunity was believed to be a fortuitous and worthwhile one.

3. In the context of archetype development it provided an opportunity to investigate 2 suspicions:

    a. That one clinician's interpretation of a clinical document may not be sufficient to produce a highly interoperable mindmap, and ultimately, archetype.

    b. That even highly relevant clinical documents may not be sufficient to be utilised, in isolation, to develop highly interoperable archetypes that could facilitate the development of a cross-border registry.

4.8.1.3.1. ONE CLINICIAN'S INTERPRETATION

The study results suggest that, while the mindmap was considered accurate, that further revision, with respect to structure and content, would be required in order to ensure that it is clearer and more faithful to the expert group's publication. This would undoubtedly require further input from the expert group given the complexity of the data required to more faithfully represent the extra layers of the "onion skin" classification.

This demonstrates that even a clinician with considerable domain knowledge, such as the author, requires significant guidance to ensure that their understanding of a domain

area is faithful to the beliefs of the domain's wider clinical group. This is particularly relevant at the level of generating archetypes intended to be used in the context of international registries.

4.8.1.3.2. CLINICAL DOCUMENTATION

While the publication chosen was an undoubtedly high value document with respect to characterising the domain, given the authors involved and that it is the 4th iteration of the classification, the study demonstrates that when engaged, there were differences of opinion.

Although this is expected in any consensus process, it is of particular relevance in the context of 2-level modeling, which supports a maximum dataset approach, rather than the minimum dataset that a consensus document aims to achieve. This richness in opinion is hidden from view in the consensus documentation and is only made obvious by engagement with the community who developed it. The author suggests that this extra information, which 2-level modeling can cater for, could be significant in increasing acceptance of a registry or EHR, potentially resulting in better implementation of a system. Again, this is of further relevance with respect to the development of an archetype that is due to facilitate cross-border interoperability, where broader consensus needs to be catered for.

4.8.1.3.3. ENGAGING WITH EXPERTS

The author therefore suggests that this study supports the suspicions raised in point 3, above, that neither high quality clinical documentation nor generic "clinician" opinion may be sufficient to develop information models of outstanding quality and that there is considerable value in engaging with an expert group to validate information models.

At present, openEHR does support clinician input at the archetype review stage, however, this may be at a stage well beyond that which an expert group, such as the one identified in this study, would participate in. The author suggests that broad, early expert clinical engagement could add considerable value to archetype development methodologies such as outlined in Corrigan's thesis (Corrigan, 2010).

In this study, 9 out of 21 (43.9%) of the targeted group participated. The author believes that this is not an insignificant engagement, particularly given the difficulty of accessing such a group. It is suggested that international patient registries may

generate the type of clinical engagement that could help realise the richness of clinical information that archetypes aspire to capture.

Related to this point, the author believes that it is worth noting that the clinical modeler's role is more valuable than simply the artefacts that they can produce. As identified in this study, the modeler can also be a significant means of increasing valuable input into openEHR models, by creating opportunities to involve wider networks of clinicians, although the author's strategy for doing so could be improved. For example, it was unfortunate that it was not possible to facilitate a situation that would have easily enabled annotation of the mindmaps, which might have increased the contribution that the expert group could have made.

This study also suggests that, though some improvements in presentation could be made, the mindmap could be a relatively easily understood, and useful means of engaging with an expert clinical group, particularly where simple concepts are being represented.

Finally the author believes that there are interoperability gains to be achieved beyond the creation of an openEHR archetype by engaging with clinical expert groups. Involving these groups, for example, can increase awareness of health informatics approaches such as openEHR, potentially reducing the number of silos that exist. Involvement can also unearth existing databases that can be mapped to openEHR or instances where terminologies and classification systems do not necessarily map to consensus expert opinion or might require updating as demonstrated earlier in this thesis. In the context of the development of a highly interoperable, international rare disease patient registry, this is of paramount importance.

4.8.2. SURVEY NAME: INVESTIGATING THE RESOURCES AVAILABLE FOR NOVICE OPENEHR CLINICIAN MODELERS

This subsection describes the second of the two surveys covered in cycle 8.

4.8.2.1. STUDY PLAN

4.8.2.1.1. INTRODUCTION

In section 4.4.1 it was described how interaction with experienced modelers guided the author towards particularly useful resources that may not be immediately obvious to the clinician, who's world is typically dominated by the peer review process of journal and textbook publication. Even if evident, the author suggests that resources outside traditionally trusted sources might not be as easily trusted or accepted by the clinical group they aim to serve. While clinicians can use a lifetime of training to assess the validity of medical text, entering a conceptual world, with little experience and without a frame of reference, might be a significant obstacle to the novice clinician modeler, in the absence of peer review.

This is a potentially significant concern, as, with the breadth of clinical information openEHR aims to capture and the rate of change of medical information, it would seem as though openEHR's success is dependent on the engagement of an active pool of connected clinical modelers.

Rather than ignore extensive and potential resources, this study was developed to facilitate identification and validation of useful resources for the novice clinical modeler, with the intention of supplementing the author's knowledge and providing a useful resource for future novice openEHR clinical modelers.

4.8.2.1.2. STUDY AIM

The aim of this survey was to identify the resources available for novice openEHR clinician modelers based on the knowledge of the openEHR clinical modelling community.

4.8.2.1.3. METHODS & MEASUREMENTS

Drs Berry and McNicoll had made the author aware of a Clinical Digest email list, which was believed to be the best means of accessing the international clinical modeling

community. This mailing list is delivered to all those who have signed up following their involvement with the openEHR modeling community and provides a means for the community to share experiences, information and ask questions. Statistics taken from the openEHR Clinical Knowledge Manager (openEHR Foundation, 2014) in January 2015 suggested that the number of registered modelers with a clinical background is 136 people. While there are likely clinician modelers who are not connected to this network, this study aimed to involve those who are actively involved with the modeling community and as such, are of most relevance to the novice clinician modeler from the perspective of availability and support.

Due to the international geographic distribution of the clinical modelers registered on CKM an online survey was considered to be the most appropriate means of engagement. An email was sent on the 16/03/2015 and a repeat request was sent on the 30/03/2015.

These short emails explained the context of this thesis and study, with a link to a SurveyMonkey® survey (Appendix E) which was approved by the Trinity College Dublin Research Ethics Committee.

In the survey, participants were asked to note their background (clinical, technical or other) and to provide up to 10 resources that the felt would be useful to novice clinical modelers. The participant was asked to describe the type of resource in each case. Options included:

- Publication
- Blog
- Websites
- Training event
- Tool
- Other - please elaborate

Participants were then asked to rate each resource's importance on a 5-point Likert scale (1-little importance, somewhat important, important, very important, 5-critically important) and to provide a link where possible or relevant.

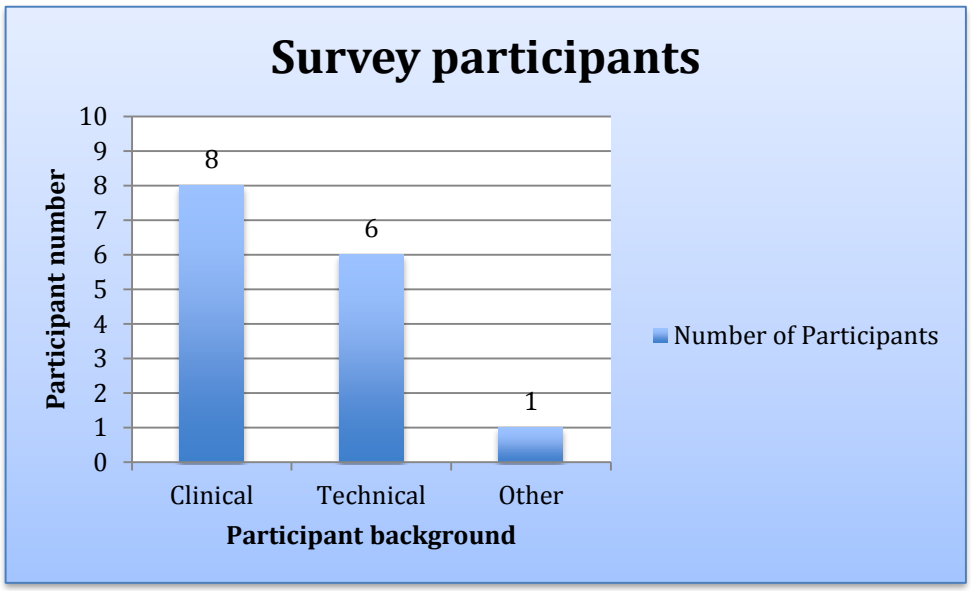
All survey questions were optional, except for confirmation that the information literature had been reviewed and that consent was given. The final question regarding whether the participant wishes to submit or "not submit, exit without submitting" was also mandatory to ensure that participants had a means to withdraw consent, if desired.

4.8.2.2. STUDY RESULTS

4.8.2.2.1. PARTICIPATION AND BACKGROUND

16 participants answered the survey, with one participant withdrawing consent before submitting their answers; their data was removed from the study in keeping with the study methodology. The background of the participants is described in Figure 56.

Figure 56 Background of the openEHR community survey participants



In the case of the 1 participant who described their background as "other", this was noted to be a combined clinical and technical background.

4.8.2.2.2. RESOURCES

Of the 15 participants, 7 provided the name of resources (Clinical, Technical, Other; n= 4, 2, 1), ranging in number from 1 to 10. In total 34 resources were noted. Each resource was accessed using participant links, where provided, or through a search if not. The author reviewed the contents of each resource, to identify duplication. Table 3 is a summary of all the resources, which are discussed further in the following subsections.

Table 3 Resources for novice clinical modelers identified by the openEHR community

Resource type	Resource Name	Average importance	No of times noted	Participant background
Blog	Archetypical blog (Heather Leslie)	4	3	2 Clinical 1 Combined
Blog	Wolandscat.net	3	1	Clinical
Other - conference paper	Building Archetypes	4	1	Technical
Other - document	Archetype Definition Language (ADL)	3	1	Technical
Other - document	Archetype Definitions and Principles	4.5	2	1 Technical 1 Clinical
Other - document	Introducing openEHR	3	1	Technical
Other - document	The openEHR Modelling Guide	1	1	Technical
Other - document	Architecture Overview	3	1	Technical
Publication	Archetypes 101	4	1	Technical
Publication	Archetypes: Constraint-based Domain Models for Future-proof Information Systems	4	1	Technical
Tool	Archetype Editor	4	1	Combined
Tool	Template Designer	4	1	Combined
Tool	EhrScape	4	1	Clinical
Training event	openEHR Clinical Modelling Course	4.5	4	3 Clinical 1 Combined
Website	Code4Health website	2	1	Clinical
Website	openEHR.org website	3	2	2 Clinical
Website/ Tool	Clinical Knowledge Manager	4.67	7	3 Clinical, 3 Technical, 1 Combined
Website/ Wiki	Archetype review checklist	5	1	Technical
Website/ Wiki	Introduction to Archetypes and Archetype classes	5	1	Clinical
Website/ Wiki	openEHR Wiki	3.5	2	2 Clinical

4.8.2.2.2.1. BLOGS

Two blogs were noted (Table 4Table 5).

Table 4 Summary of Dr Heather Leslie's blog "Archetypical"

Archetypical	
Link	https://omowizard.wordpress.com/
Number of times noted	3
Participant background	2 Clinical, 1 Combined
Average score	4 (very important)
Comment This is the blog of Dr Heather Leslie, a clinician by training and currently the Director of Clinical Modeling for an openEHR vendor called Ocean Informatics. Dr Leslie is also an editor for the openEHR Clinical Knowledge Manager. Dr Leslie's blog contains extremely useful insights into the world of openEHR and provides numerous resources that this author believes would be of significant interest and utility to the novice clinician modeler, particular in view of Dr Leslie's clinical background.	

Table 5 Summary of Thomas Beale's blog "Woland's cat"

Woland's cat	
Link	http://www.wolandscat.net
Number of times noted	1
Participant background	Clinical
Average score	3 (important)
Comment This is the blog of Thomas Beale, one of the architects of openEHR. As with Dr Leslie's, this blog provides extremely useful insights into openEHR and the world of health informatics, from the perspective of an acknowledged world expert. There may be elements that the novice clinician modeler will struggle with, given Thomas Beale's more technical background.	

4.8.2.2.2.2. PUBLICATIONS

Two publications were noted (Table 6Table 7).

Table 6 Summary of the publication "Archetypes 101" (Leslie and Heard, 2006)

Archetypes 101 (Leslie and Heard, 2006)	
Reference	LESLIE, H. & HEARD, S. Archetypes 101. *In:* WESTBROOK, J. & CALLEN, J., eds. Health Informatics Conference 2006 Bridging the Digital Divide: Clinician, consumer and computer, 2006. Health Informatics Society of Australia Ltd (HISA).
Number of times noted	1
Participant background	Technical
Average score	4 (very important)
Comment	This paper, authored by Heather Leslie and Sam Heard (Leslie and Heard, 2006), provides an overview of the concepts and potential of the openEHR methodology, with clinicians in mind, in a manner that this author feels would be relatively accessible to the novice clinician modeler. It does not describe the requirements that a clinician would need to become a clinical modeler, nor a guide to archetype and template development, however, it does note that the "few available practical guides for grass-roots clinicians to create archetypes encapsulate only the most basic principles (Conrick et al., Garde). This reflects relative infancy of the 'art' of creating archetypes, and emphasises the need to develop non-technical documentation and guidelines to support clinician experts to participate in creating and maintaining archetypes." It notes that as "the technical and design aspects of openEHR have largely been determined, the next phase is to get clinicians involved in archetype development". Of note, neither referenced texts were accessible to this author.

Table 7 Summary of the publication "Archetype: Constraint based Domain Models for Future-proof Information Systems (Beale, 2002)

Archetypes: Constraint based Domain Models for Future-proof Information Systems (Beale, 2002)	
Reference	BEALE, T. Archetypes: Constraint-based domain models for future-proof information systems. OOPSLA 2002 workshop on behavioural semantics, 2002.
Number of times noted	1
Participant background	Technical
Average score	4 (very important)
Comment This paper, authored by Thomas Beale (Beale, 2002), gives an in-depth perspective on the need for 2-level modeling and how this is achieved. While providing exceptional insights into this area, there is considerable technical detail that may be difficult for the novice clinician modeler.	

4.8.2.2.2.3. TOOLS

The tools required to create archetypes, templates and an open health data platform that can utilise archetypes and templates, were noted (Table 8Table 9Table 10).

Table 8 Summary of the Ocean Informatics Archetype Editor tool

Archetype editor	
Link	http://openehr.org/downloads/archetypeeditor/home
Number of times noted	1
Participant background	Combined
Average score	4 (very important)
Comment A link (http://openehr.org/downloads/archetypeeditor/home) was provided to a webpage (**Figure 57**) that enables downloading of software that enables creation of archetypes. It also contains links to a tutorial that can help provide guidance through the archetype creation process, including illustrated, step-by-step guides, which were particularly helpful.	

Because the tutorial takes the form of a number of webpages that are linked, however, this author found that progression through the tutorials could become disorientating at times and difficult to appreciate whether all relevant information had been viewed. It is suggested that it would be extremely helpful to have a better-defined path that constantly relates to the bigger picture for the novice clinician modeler. This author also noted that a number of images and links within the tutorial were broken at the time of writing this thesis (29/05/2015 access). Furthermore, there are a number of occasions where examples would be extremely helpful, to facilitate understanding for those who are not used to the terminology associated with archetype creation. In addition, there were aspects of the tutorial that appeared quite technical and somewhat confusing to this author.

The archetype designer tool (**Figure 58**) has been noted earlier in this thesis. It is a tool that utilises a graphical user interface to facilitate the construction of archetypes. As such, it is essential software for the novice clinician modeler to become familiar with. This author utilised the Ocean Informatics archetype designer during the course of this thesis.

Figure 57 Screenshot of the webpage that has links to download artifact development tools

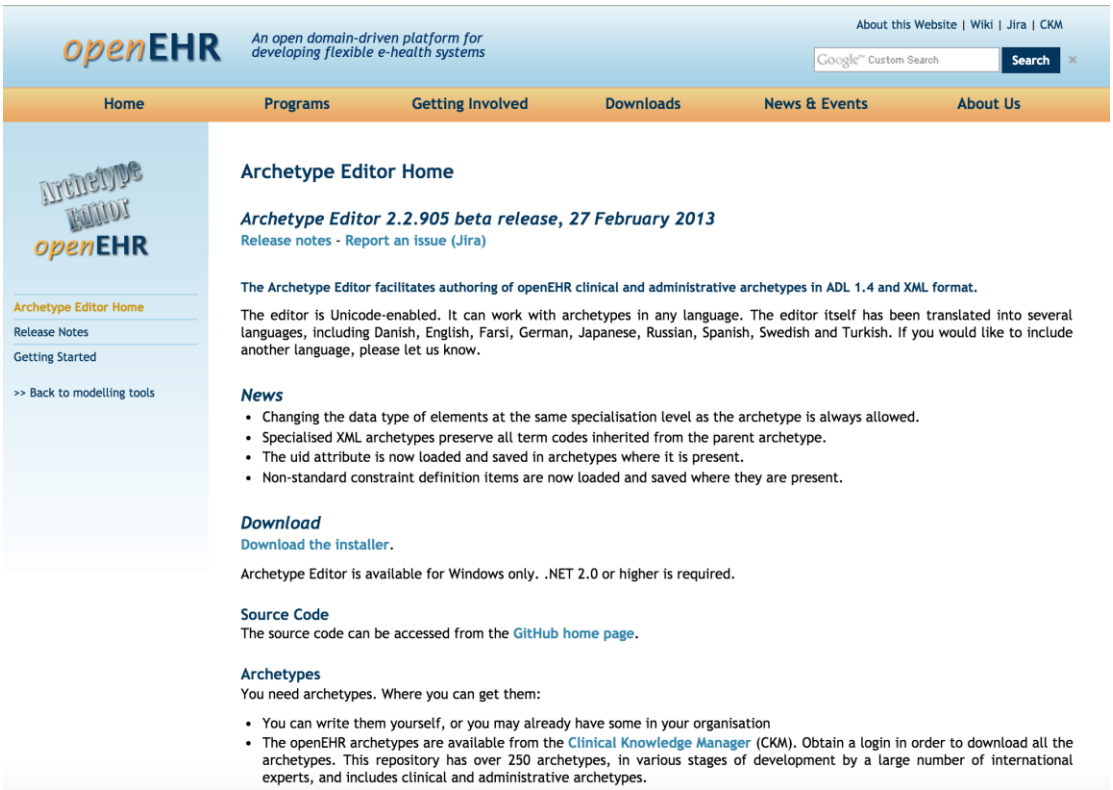


Figure 58 Screenshot of the Ocean Informatics Archetype designer tool

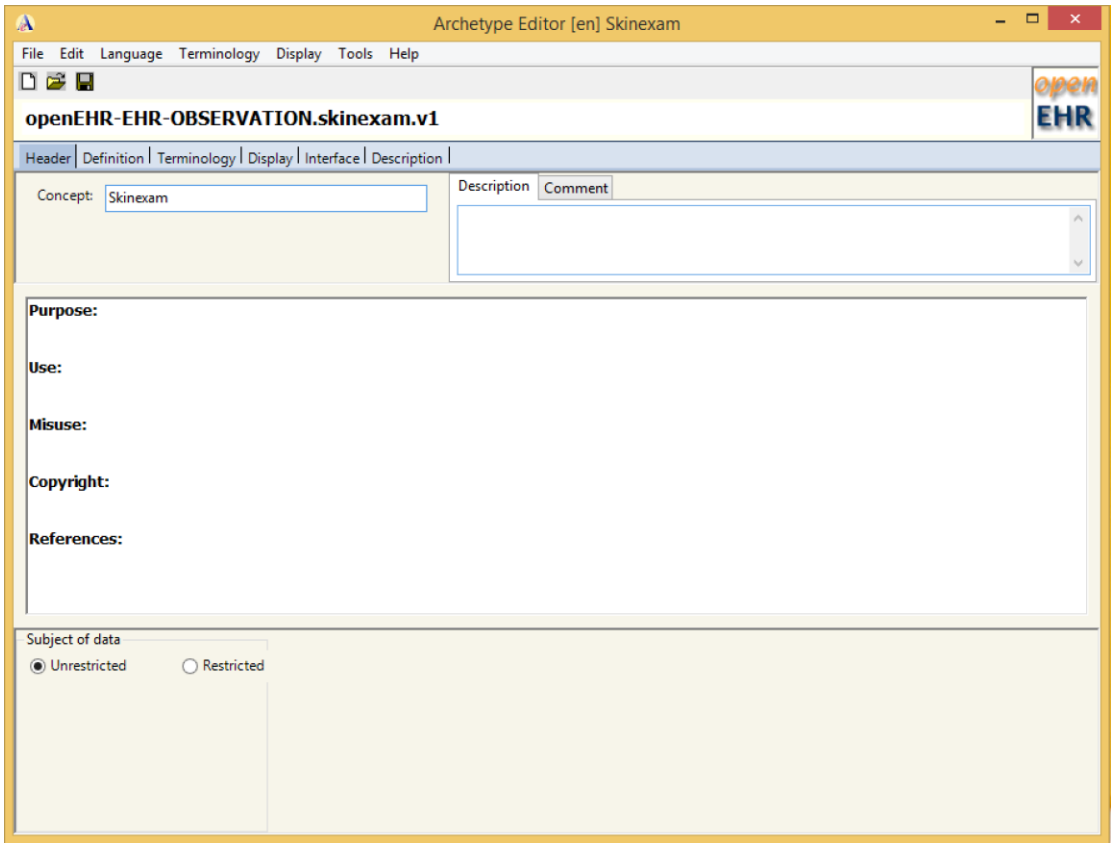


Table 9 Summary of the Ocean Informatics Template Designer Tool

Template Designer	
Link	http://www.openehr.org/downloads/modellingtools (Ocean Informatics Template designer)
Number of times noted	1
Participant background	Combined
Average score	4 (very important)
Comment	
The template designer (**Figure 59**) is a tool that, through the use of a Graphical User Interface, enables a modeler to select and constrain an archetype or archetypes with a view to capturing information within a particular clinical context. An example might be a template that captures information relating to adverse events in the context of a prescribed medication. While this might include a blood pressure archetype, it is unlikely that all possible features of a blood pressure archetype will be required in this context. Constraining the archetype refers to the process of removing the	

unnecessary features of the blood pressure archetype to facilitate this context. This might be combined with other constrained archetypes until all the information required for this context are contained in the template. The template might be considered as the equivalent of a paper form that can be filled with the relevant information, in this case, with respect to adverse events associated with the prescribed medication.

While the user interface is quite intuitive, considerable help was required on the part of the author to set-up the template designer in a manner that enabled linking in with archetypes downloaded from the Clinical Knowledge Manager and archetypes developed by the author.

Figure 59 Screenshot of the Ocean Informatics Template designer tool

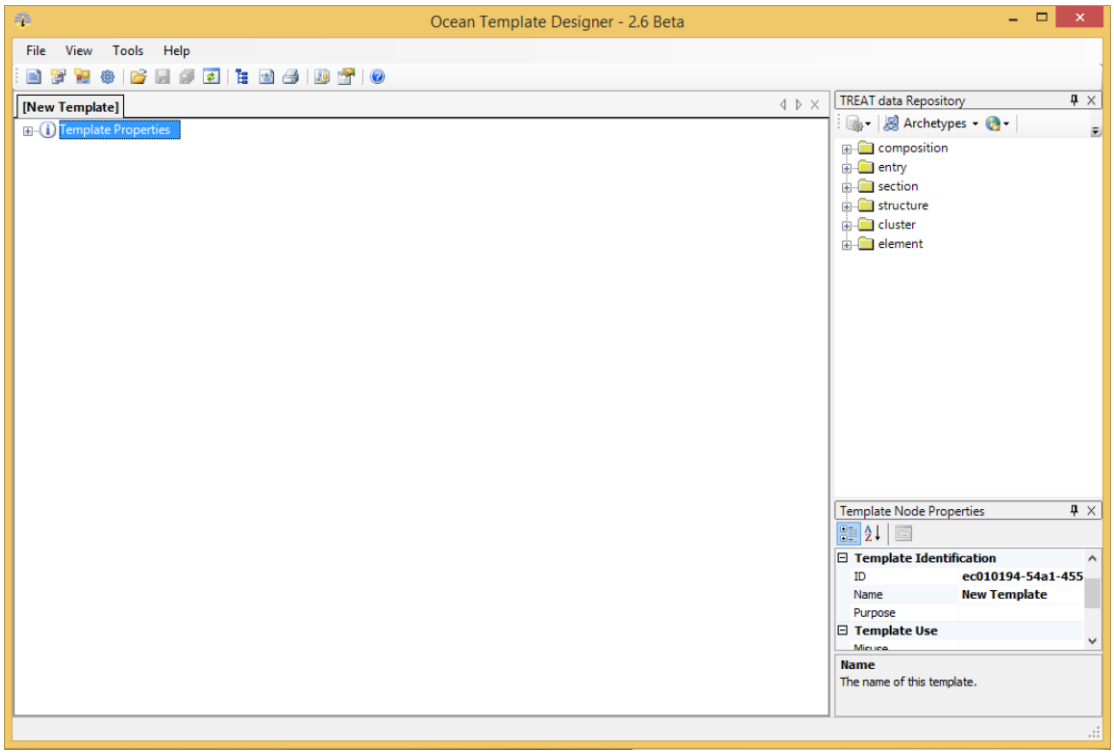
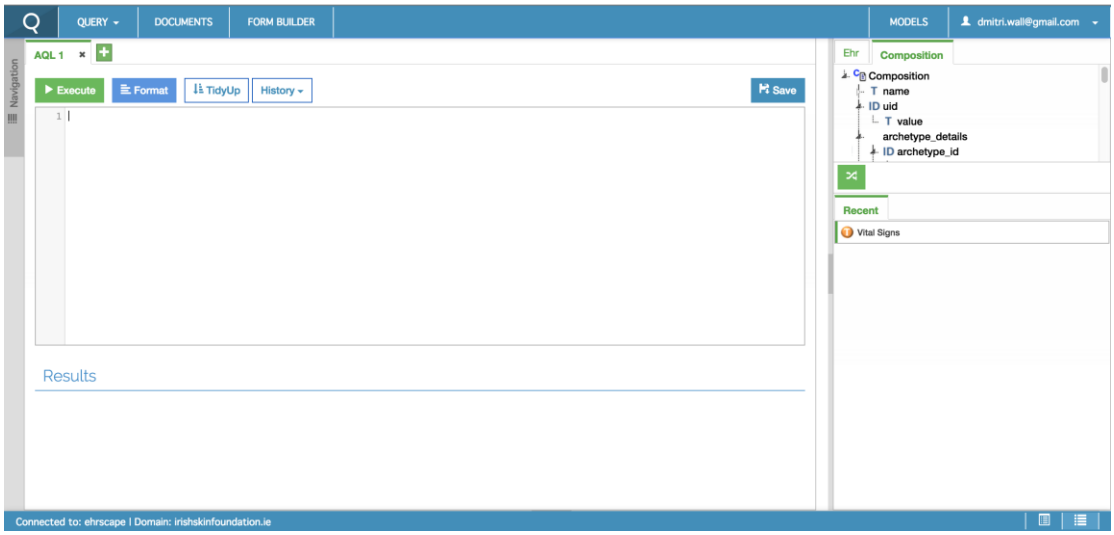


Table 10 Summary of the Marand EhrScape tool

EhrScape	
Link	https://www.ehrscape.com/explorer/
Number of times noted	1
Participant background	Combined
Average score	4 (very important)
Comment This is an industry (Marand) tool, accessed via a web browser (**Figure 60**), for developing an open Health Data Platform, based on openEHR archetypes and templates. Its use requires registration, which this author requested and received, however, its use was beyond the scope of this author's skills at the time of writing this thesis.	

Figure 60 Screenshot from the Marand EhrScape tool



4.8.2.2.2.4. TRAINING COURSE

Multiple participants noted the value of training courses (Table 11).

Table 11 Summary of Clinical modeling training courses

Clinical Modeling Course	
Link	https://www.ehrscape.com/explorer/
Number of times noted	4
Participant background	3 Clinical, 1 Combined
Average score	4.5 (very important – critically important)
Comment Training events were mentioned on 4 occasions, rating between very important and critical. One industry group, Ocean, were noted to provide courses. A link to a site noting available training courses was provided, but was unfortunately broken on testing.	

4.8.2.2.2.5. WEBSITES

A number of website-based resources were noted ().

Table 12 Summary of the openEHR.org website

openEHR.org website	
Link	http://www.openehr.org/
Number of times noted	2
Participant background	2 Clinical
Average score	3 (important)
Comment This is the openEHR website (**Figure 61**) that contains a large quantity of current material relating to all aspects of openEHR, in addition to links to numerous relevant sites and resources, such as modeling tools which are essential to the novice clinician modeler. While containing a vast quantity of useful material, it caters for all groups within openEHR. As such, as a portal for novice clinician modelers, the website might be difficult to navigate in a manner that captivates and easily orientates those who are interesting in becoming part of the modeling community.	

Figure 61 Screenshot of the home page of the openEHR.org website

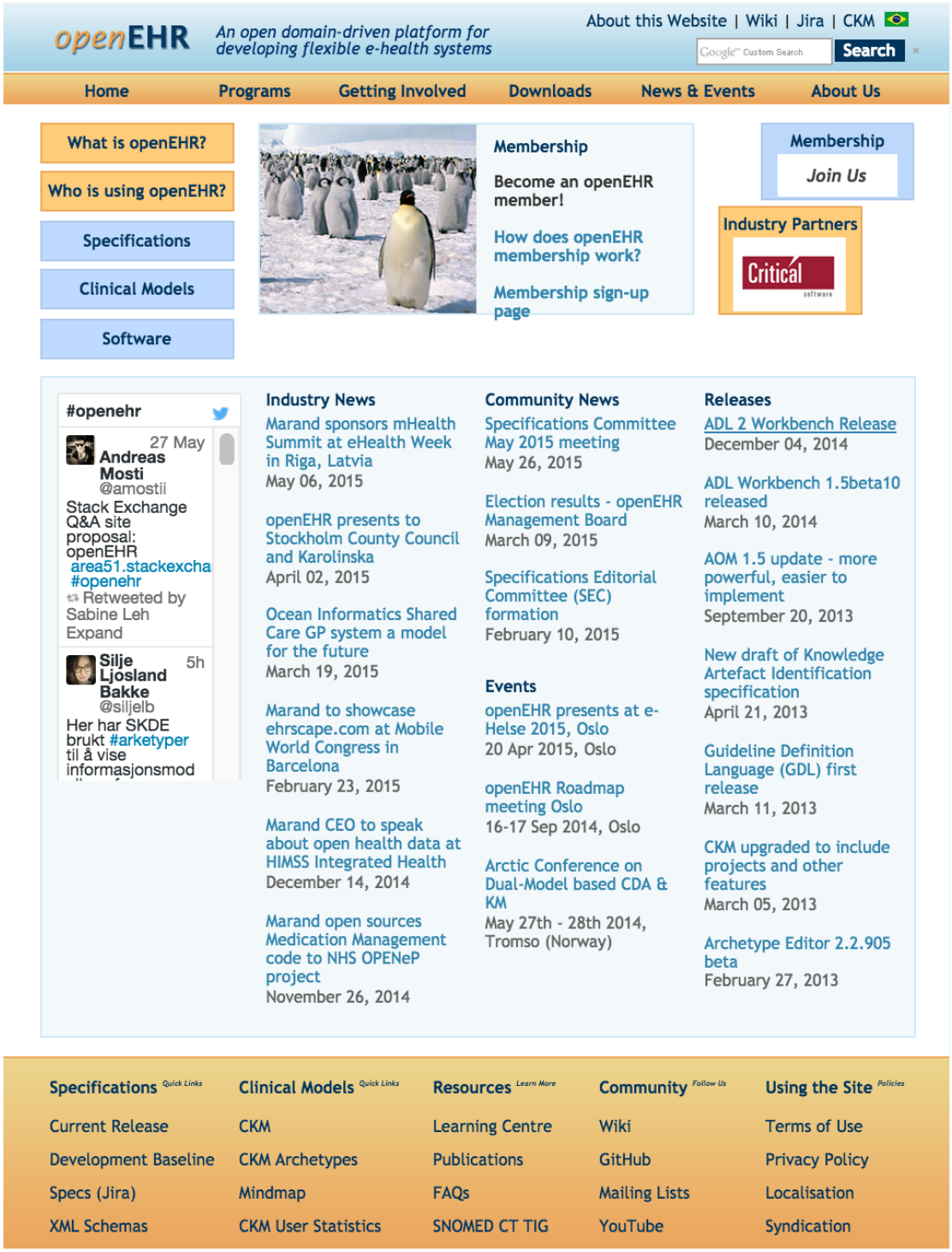


Table 13 Summary of the Code4Health website

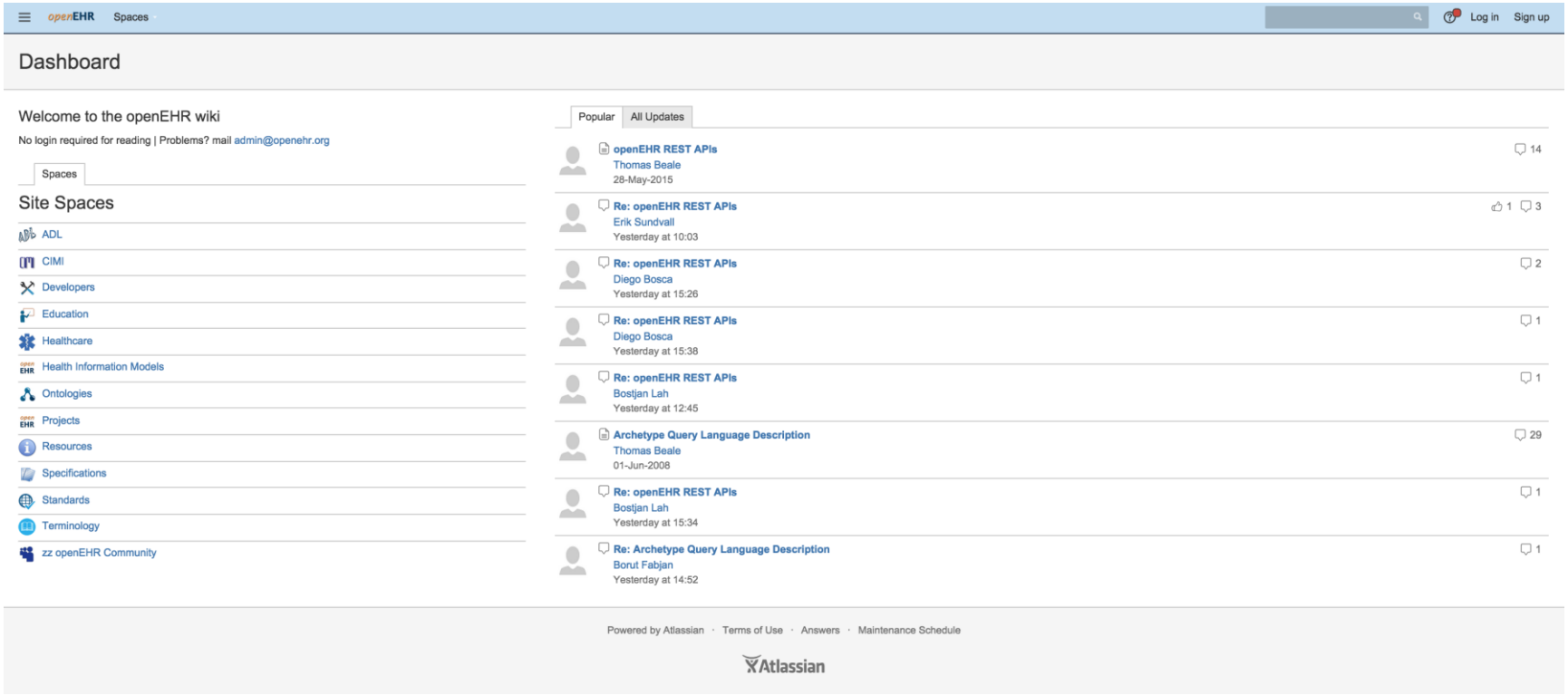
Code4Health website	
Link	"not yet available"
Number of times noted	1
Participant background	Clinical
Average score	2 (somewhat important)
Comment Unfortunately this was unavailable to the author at the time of writing this thesis. Code4Health is a "collaborative workspace for all involved to find digital solutions for the NHS" (NHS England, 2015). It is a platform that emerged from the HANDI HOPD (Health Open Platform Demonstrator), which was developed to "provide a platform to enable clinician to learn to code and to provide a testing and development environment to build apps" (Handi, 2015). This would appear to be a group, at least within the UK, who will be able to support clinicians who are interested in learning to, amongst other things, become experienced clinical modelers. This author discovered an extremely helpful PowerPoint presentation created by Dr Ian McNicoll, which was available at the time of writing this thesis from Slide Share (McNicoll, 2015). In addition to describing the role of HANDI-HOPD and Code4Health, it provides an exceptionally useful insight into the world of electronic health records and the role that openEHR and HL7 FHIR can play in that world. From the perspective of a novice clinician modeler, the author found this presentation to be very helpful.	

Table 14 Summary of the openEHR wiki

openEHR wiki	
Link	https://openehr.atlassian.net/wiki/dashboard.action
Number of times noted	2
Participant background	2 Clinical
Average score	3.5 (important – very important)
Comment The openEHR wiki (**Figure 62**) provides a considerable collection of webpages that aim to explain concepts regarding openEHR. While this is extremely useful, this	

author found the numerous subsections, at times, difficult to navigate. There were also a number of areas that the author found difficult to understand, particularly during the early stages of learning to model. Similar to the tutorial linked to the archetype editor noted earlier, it is suggested that, particularly from the perspective of introducing the novice modeler, an approach that provides a sense of being on a journey may be beneficial. It would be extremely useful to note how much of the information had been accessed at any given point and how much remains to be accessed. It would also be useful to note the complexity of information being presented at any given stage. Having a feedback and rating mechanism might be useful in this regard and also to facilitate the organisation of the valuable educational material by complexity, which it is also suggested would be useful.

Figure 62 Screenshot of the openEHR wiki dashboard



Participants noted two further resources within the openEHR wiki (Table 15, Table 16).

Table 15 Summary of the Archetype review checklist

Archetype review checklist	
Link	https://openehr.atlassian.net/wiki/display/healthmod/Archetype+review+checklist
Number of times noted	1
Participant background	Technical
Average score	5 (critically important)
Comment	
This table has already been presented by the author in chapter 2.2.1.3 (**Table 1**). While this author feels that this article is extremely useful, it might be difficult for the novice modeler to utilise as a number of the recommendations are at a conceptual level or require a good knowledge of the archetype modeling process. It is suggested that the advice contained within this document might inform the creation of software that sits within the modeling tools, acting as a wizard or development support tool. This might support both education and best practice with respect to clinical modeling.	

Table 16 Summary of the webpage "Introduction to Archetypes and Archetype classes"

Introduction to Archetypes and Archetype classes	
Link	https://openehr.atlassian.net/wiki/display/healthmod/Introduction+to+Archetypes+and+Archetype+classes
Number of times noted	1
Participant background	Clinical
Average score	5 (critically important)
Comment	
This is a very useful webpage with some overlap with the Archetypes 101 article, the first author of which was also Dr Heather Leslie. Though some of the information is difficult to conceptualise without direct experience of archetype authoring, it has an associated example of an observation archetype that is very useful for explaining archetypes with a visual representation of content an author would expect to produce.	

4.8.2.2.2.6. OTHER

Seven further resources, mostly available through the openEHR website were noted by survey participants.

Table 17 Summary of the document Archetype Definition Language (ADL)

Archetype Definition Language (ADL)	
Link	http://www.openehr.org/releases/trunk/architecture/am/adl1.4.pdf
Number of times noted	1
Participant background	Technical
Average score	3 (important)
Comment This document, dating from 2008, is primarily focused on the technical aspect of the formal language that underlies openEHR, called archetype definition language. As such, this may be difficult to understand for the novice clinical modeler.	

Table 18 Summary of the document "Archetype Definitions and Principles"

Archetype Definitions and Principles	
Link	http://www.openehr.org/releases/trunk/architecture/am/archetype_principles.pdf
Number of times noted	2
Participant background	1 Clinical, 1 Technical
Average score	4.5 (important – very important)
Comment This document describes the principles of archetypes and templates. While providing vital information, the document might be considered by a clinician who is openEHR naïve, to be written in technical language that assumes significant knowledge on the part of the reader.	

Table 19 Summary of the "Architecture Overview" document

Architecture Overview	
Link	http://www.openehr.org/releases/trunk/architecture/overview.pdf
Number of times noted	1
Participant background	Technical
Average score	3 (important)
Comment	
This document, dating from 2007, is described as “the key technical overview of openEHR, and should be read before all other technical documents". As such, it may be seen as difficult from the perspective of the novice clinician modeler.	

Table 20 Summary of the "Introducing openEHR" document

Introducing openEHR	
Link	http://www.openehr.org/releases/1.0.2/openEHR/introducing_openEHR.pdf
Number of times noted	1
Participant background	Technical
Average score	3 (important)
Comment	
Though a fantastic overview of openEHR at a high level, this document, dating from 2007, contains a considerable amount of information. Unfortunately, a number of links regarding participating in openEHR at the end of the document are broken.	

Table 21 Summary of "The openEHR Modeling Guide"

The openEHR Modeling Guide	
Link	http://www.openehr.org/releases/1.0.2/architecture/modelling_guide.pdf
Number of times noted	1
Participant background	Technical
Average score	1 (little importance)
Comment	
This document, dating from 2007, is a technically orientated document, and as such, might be difficult to fully comprehend by novice clinician modelers.	

Table 22 Summary of the Clinical Knowledge Manager

Clinical Knowledge Manager	
Link	http://www.openehr.org/ckm/
Number of times noted	7
Participant background	3 Clinical, 3 Technical, 1 Combined
Average score	4.67* (very important - critically important) * one participant, with a technical background, did not rate this; therefore this is the average of the 6 participants who did score the resource.
Comment This is mentioned within the other category because, while it is a website, it is also a powerful tool. The Clinical Knowledge Manager is the hub of openEHR from an authoring perspective. It contains numerous features, including an archive of existing archetypes and a tool to manage the archetype review process. The graphical user interface is very helpful, however, for more complicated actions is likely to require assistance from an experienced clinical modeler.	

Table 23 Summary of the conference paper "Building Archetypes"

Building Archetypes	
Link	
Number of times noted	1
Participant background	Technical
Average score	4 (very important)
Comment This is a conference paper which the author was unfortunately unable to access at the time of writing this thesis	

4.8.2.3. STUDY CONCLUSION

4.8.2.3.1. METHODOLOGY

The methodological approach adopted in this study was not designed to reach significance with respect to validating the utility of the resources available. It was designed to discover a number of resources that might be available, particularly to the channels available to the novice clinician modeler. It was hoped that by adopting this strategy, this thesis might be able to contribute to bridging some of the gaps that prevent potential novice clinician modelers from engaging with openEHR.

Although there are 136 clinical modelers registered on Clinical Knowledge Manager, it cannot be assumed that all are members of the Clinical Digest mailing list. 8 participants with a clinical background, of which 4 contributed resources, is likely to suggest a very low rate of engagement, however. A more proactive recruitment policy may have increased this number, however, the author felt that adopting such a strategy, particularly as a new member of the community, might not have been constructive

4.8.2.3.2. RESOURCES

Despite a low rate of engagement, the quantity and quality of information and advice supplied was exceptional and the author is indebted to the participants who provided such rich information, which has certainly resulted in a much-increased level of understanding on the part of the author.

The difficulty faced by the novice clinical modeler, is the vast quantity of information across a number of different media. Without guidance, this might quickly become demoralising and, in this author's experience, generate a sense that clinical modeling is for the elite. Though it quickly becomes apparent that modeling is less of a tightly regulated process, and more of an art form, during the course of this thesis, this author has found considerable contributions have been made and are possible with guidance. The concern is that much of that feeling of optimism comes more with engagement with the modeling community, and mentors in particular, rather than the manner in which interested clinicians might discover openEHR in an incidental manner.

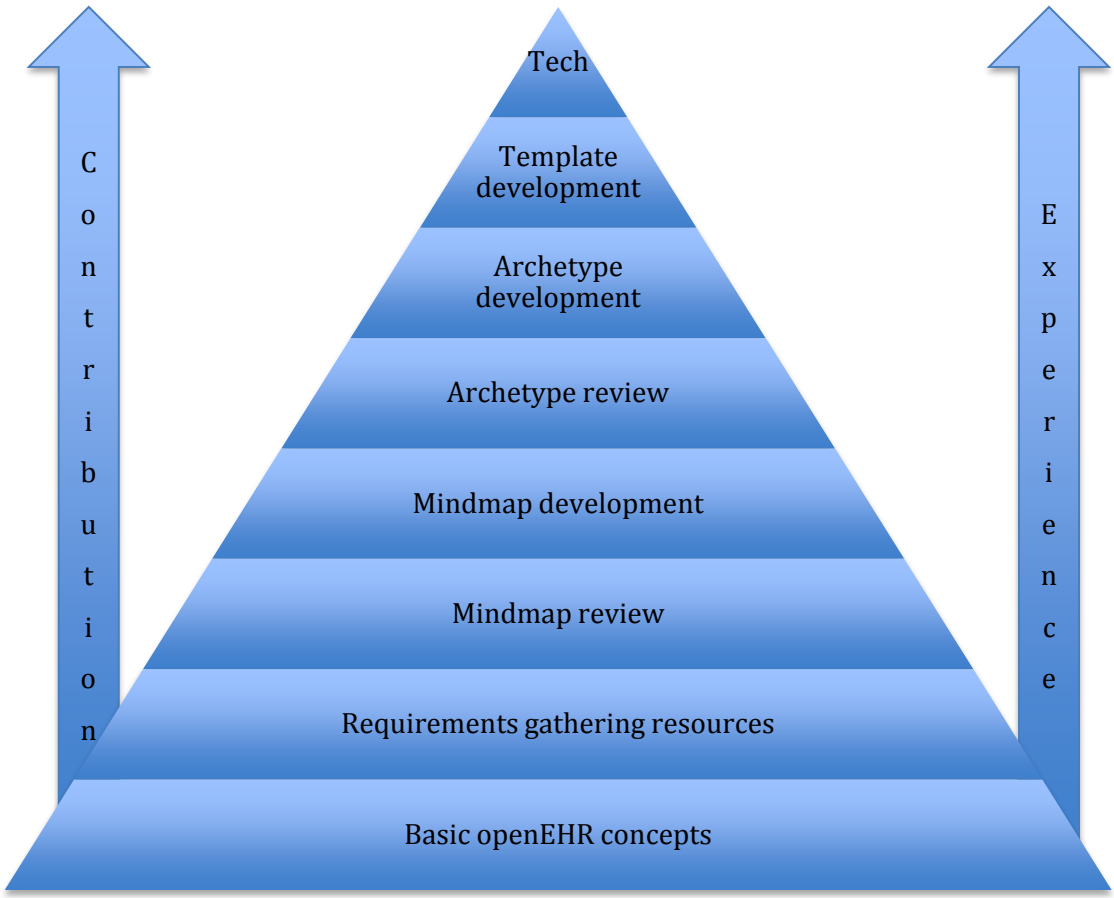
There were a number of resources that were not mentioned during this study that were surprising to the author. One of the most accessible means of introducing clinicians to modeling, mindmaps, did not feature significantly. Although these were mentioned

within some of the resources, it would appear to be an area that could be focused on to generate confidence and a sense of practical achievement on the part of the novice clinician modeler, based on the experience of the author during this thesis.

The most significant absence, was, in this author's opinion, one of the strongest features of openEHR; the community that has emerged within it. There is an active discourse that occurs globally as a result of the openEHR Clinical Digest mailing list, which was utilised by the author to recruit participants for this study. This community is also to be found on social media such as Twitter (@openehr - https://twitter.com/openehr) as are a number of openEHR's most senior figures. It has been extremely uplifting to discover how engaging and accessible this group is and has resulted in active direction towards extremely useful resources, advice and other interested clinician modelers. All of this interaction has rapidly increased this author's understanding of openEHR and clinical modeling.

There appeared to be a significant range in the level of knowledge, both clinical and technical, required to fully appreciate all the resources discovered during the course of this study. A point that this warrants discussing is, what is enough knowledge to become a clinical modeler? The author believes that there is a spectrum of competence and that it would be worth making this much clearer to potential novice clinician modelers. This concept is represented in Figure. Although this does borrow from work described later in this thesis, in reality in occurred in parallel with the analysis of this study, and the author believes that it is best described at this point.

Figure 63 Proposed spectrum of clinical modeling competence



This graphic attempts to display concepts that a clinical modeler might understand and contribute to. As the complexity of understanding and contribution increases, the narrowing of the pyramid is intended to display that less modelers are expected to develop the experience to reach these levels. At the top of the pyramid, "Tech" describes the clinical modeler who is also capable of understanding and working with the technical components of openEHR. While greater contributions are expected to be obtained from these more experienced clinical modelers, the figure intends to display that significant contributions can be achieved by modelers at all levels of experience. It suggests that even by being aware of openEHR, existing, relevant resources could be identified that could be developed by more experienced modelers. These resources may include, for example, datasets and forms.

In reality, it is accepted by the author that learning to model is not a linear process and that this graphic is an over-simplification of the manner in which openEHR develops clinically useable patient records. It is hoped, however, that this graphic is criticised, as

this author suggests that this criticism is likely to increase the focus on making openEHR, at any level, more accessible to the vast number of clinicians, which its success depends on.

4.8.2.3.3. SUGGESTIONS

A number of suggestions are proposed in this section. The author is, however, aware of the significant burden of work that faces the openEHR community that may make many of these impractical. Suggestions beyond the control of openEHR groups, such as targeting professional development or research strategies are not discussed.

4.8.2.3.3.1. TOOLING

4.8.2.3.3.1.1. ARCHETYPES

The incorporation of guidance within an archetype designer would be exceptionally helpful, both from the perspective of guiding new users through the archetype development process, but also to incorporate best practice suggestions.

4.8.2.3.3.1.2. MINDMAPS

At present there is no tooling that the author is aware of that incorporates best practice mindmapping, from an openEHR perspective, although experience with development of mindmaps and review with experienced modelers suggests that there are accepted norms and practices. In the absence of tooling, a guidance document would be extremely helpful.

4.8.2.3.3.1.3. TEMPLATES

While documentation that explains the installation of both the archetype and template designer has been included in the resources discovered by this study, the author still required guidance for a number of processes for which the tools were to be used. It is accepted that the complexity of software required to facilitate the development of a wizard might be significant.

4.8.2.3.3.1.4. INTERACTIVE ENVIRONMENT

While significant background reading was required on the part of this author, the greatest lessons learned were as a result of face-to-face and online real-time interactions

with experienced clinical modelers and members of the openEHR technical community. As a result of this thesis, this author has forged relationships with members of the community which have been exceptionally helpful, but this author has also joined, utilising online collaborative tools, a small group of similarly experienced clinical modelers to share ideas, resources and work. This may be facilitated by the Code4Health initiative noted previously.

A number of the interactions the have resulted in significant learning have been facilitated by videoconferencing solutions. It is suggested that this would be an ideal means to develop practical skills within the clinical modeling community. Screen sharing could facilitate demonstration of artifact building in a real-time environment that enables specific questions and problems to be addressed. In a similar manner to an online book club or journal club, the author suggests that this concept could be used to both increase practical and conceptual competence, while simultaneously developing a supportive and active network.

4.8.2.3.3.1.5. NOVICE MODELER PORTAL

It is suggested that a sub-site on the openEHR.org website that specifically targets potential clinical modelers might be established. The aim of this site would be to rapidly orientate potential modelers by:

- Listing available resources such as those noted in this study. It is also suggested that it might be possible for novice clinicians to rate these resources to facilitate building a map of the most relevant and most accessible resources.
- Directing towards communities and groups who are actively engaged in openEHR, such as those noted above.
- Hosting an interactive environment, such as that suggested above.

4.8.2.3.4. STUDY SUMMARY

While the methods used in this study could be criticised and the number of participants recruited is quite low, the author suggests that the primary purpose of revealing useful resources has been met. It is also suggested that the commentary, while extremely subjective, might provide relevant insights about clinical modelers, a group seen as critical to the success of openEHR. Combined with the author's experience in developing clinical modeling skills, it is also suggested that there are a number of

solutions that might increase awareness and involvement with openEHR in that group. Finally, the author has suggested the concept of levels of knowledge as a means of identifying to clinicians interested in openEHR, potentially overwhelmed with information, how significant contributions can be made, even in the early stages of the development as clinical modelers.

4.8.3. PLAN FURTHER WORK

Based on advice from the "Investigating the resources available for novice openEHR clinician modelers" study and from feedback from the clinical modeling network, attendance at a training course was noted as an excellent means to facilitate the development of further modeling skills.

4.9. CYCLE 9: TRAINING COURSE

4.9.1. DESCRIPTION OF WORK

The author attended at a short, 2-day training course delivered by Dr McNicoll and hosted by an industry group, Code24 in Alkmaar, The Netherlands. The first day was a clinical modeling course and the second day, a technical support course.

4.9.2. DISCUSSION AND REFLECTION

Both days proved to be exceptionally valuable to the author's understanding of openEHR and the value of 2-level modeling.

The first day included a very valuable review of the concepts underpinning openEHR and a practical session involving mainly mindmapping and archetype creation. There were participants from both a clinical and a technical background. This provided a unique perspective to see the value of the manner in which openEHR enables clinicians to directly contribute clinical understanding to an information model that a person without a clinical background might find more difficult to understand and articulate.

The principle of 2-level modeling was known to the author, but witnessing clinical and technical groups working independently, but still have the products of their work integrate seamlessly, in a real-world scenario, was enlightening.

It was also illuminating to physically experience the flexibility of openEHR as template alterations were smoothly integrated within an openEHR based electronic patient record. Despite significant reading and experience, it was these events that enabled realisation, at a practical rather than conceptual level, the promise of openEHR and the implications for its use. This certainly seems to correlate with a previously noted abstract paper from (Sundvall et al., 2013) (Figure 64).

Figure 64 Quote from Sundvall et al. (2013) regarding the need to experience archetype-based systems in action

> "It can be hard to imagine what an archetype-based clinical system combined with modern terminology systems will look like and what consequences different modeling choices have, without seeing and experimenting with an operational system"

Finally, this course, for the first time, enabled the author to experience a "cradle to the grave" modeling process. This involved identification of a clinical event that was mindmapped, archetyped, templated and finally embedded within an electronic patient record. Much of the difficulty this author has experienced has been with respect to dealing with information at a conceptual level and understanding how openEHR becomes a reality. The ability to witness an openEHR development process become a tangible system capable of facilitating work in a clinical environment delivered a much more holistic understanding of how clinical modeling can translate into real-world products that can capture the essence of a clinician's information requirements.

4.9.3. PLAN WORK

In the next section, the author returns to the EB mindmap with a view to incorporate findings from the "Investigating the value of consultation with expert clinicians in clinical modeling" study.

4.10. CYCLE 10 EB MINDMAP FOLLOW UP

4.10.1. EB MINDMAP FOLLOW UP WORK

It was the author's initial intention to create a high level mindmap of the classification of EB and to use this to create an EB archetype. Mapping the Fine et al (2014) classification system was intended to facilitate the author learning to bind terms within this archetype.

The complexity of this plan increased when evidence from the EPIRARE (Vitozzi et al.) project in section 4.3, (The table from section 4.3.3, noting these systems and terminologies, is repeated here for convenience (Table 24)), in addition to colleagues suggestions identified that numerous terminologies and classifications would need to be mapped to the simple classification created by the author in section 4.2.4. Further complexity still would be required to incorporate feedback from the EB expert study in section 4.8.1, which highlighted that a more detailed representation of the onion-skin classification was required.

The artifacts developed to meet these needs include a series of mindmaps and a spreadsheet mapping each terminology or classification system to the Fine et al (2014) classification. One of the mindmaps (Figure 65) and the spreadsheet (Figure 66) are presented here, despite being too large to print legibly within a thesis, to give an idea of the complexity involved in each artifact. Higher resolution versions are included in the compact disc that is attached to this thesis. The text required to explain these artifacts would be significant and extend well beyond the scope of this thesis.

The reason for including these artifacts, which are well beyond the scope required to support openEHR, is to demonstrate the considerable effort that can be required to undertake tasks, identified during the process of modeling, as important by expert clinicians.

Figure 65 Mindmap Classification and mapping of epidermolysis bullosa

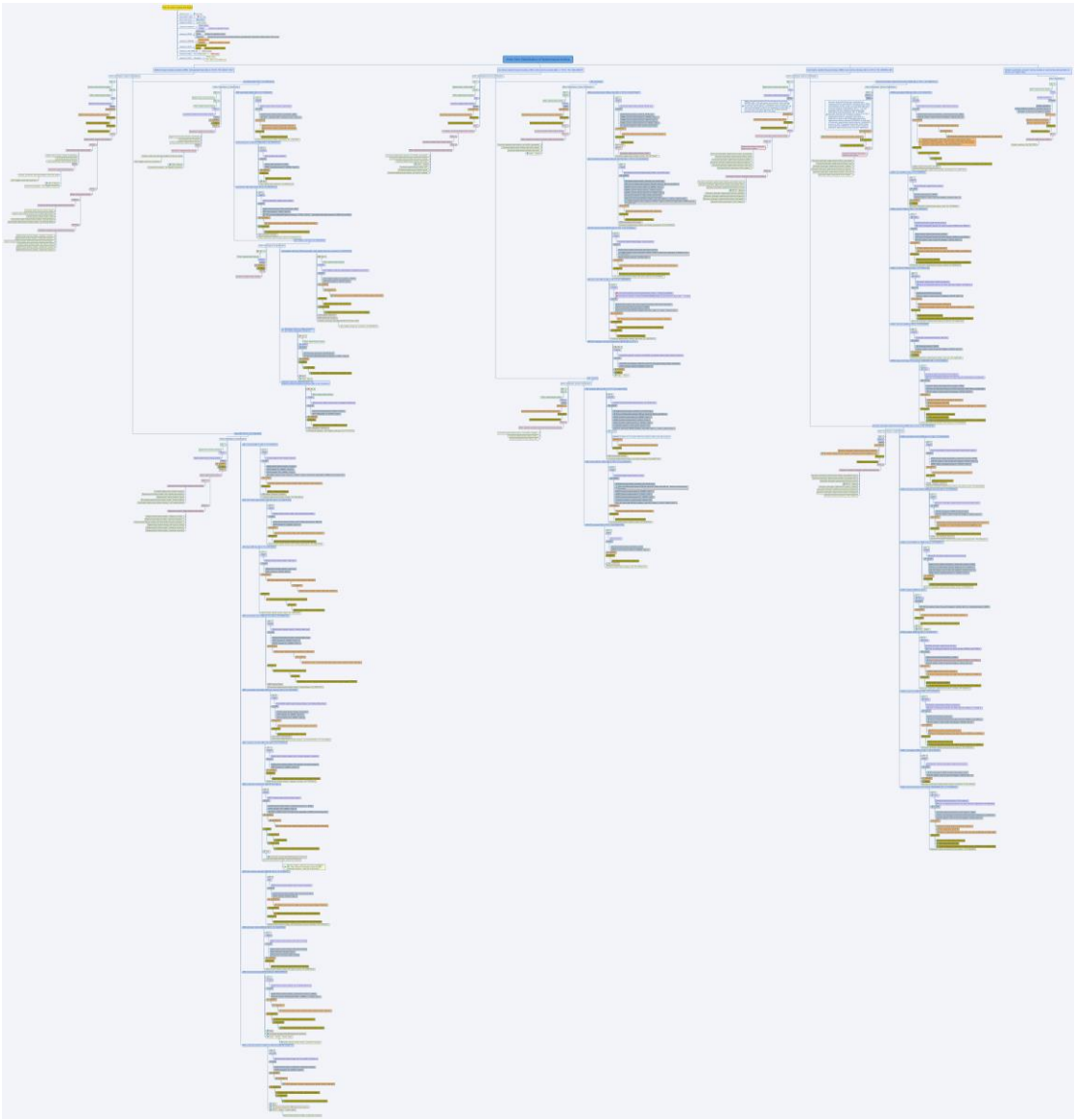
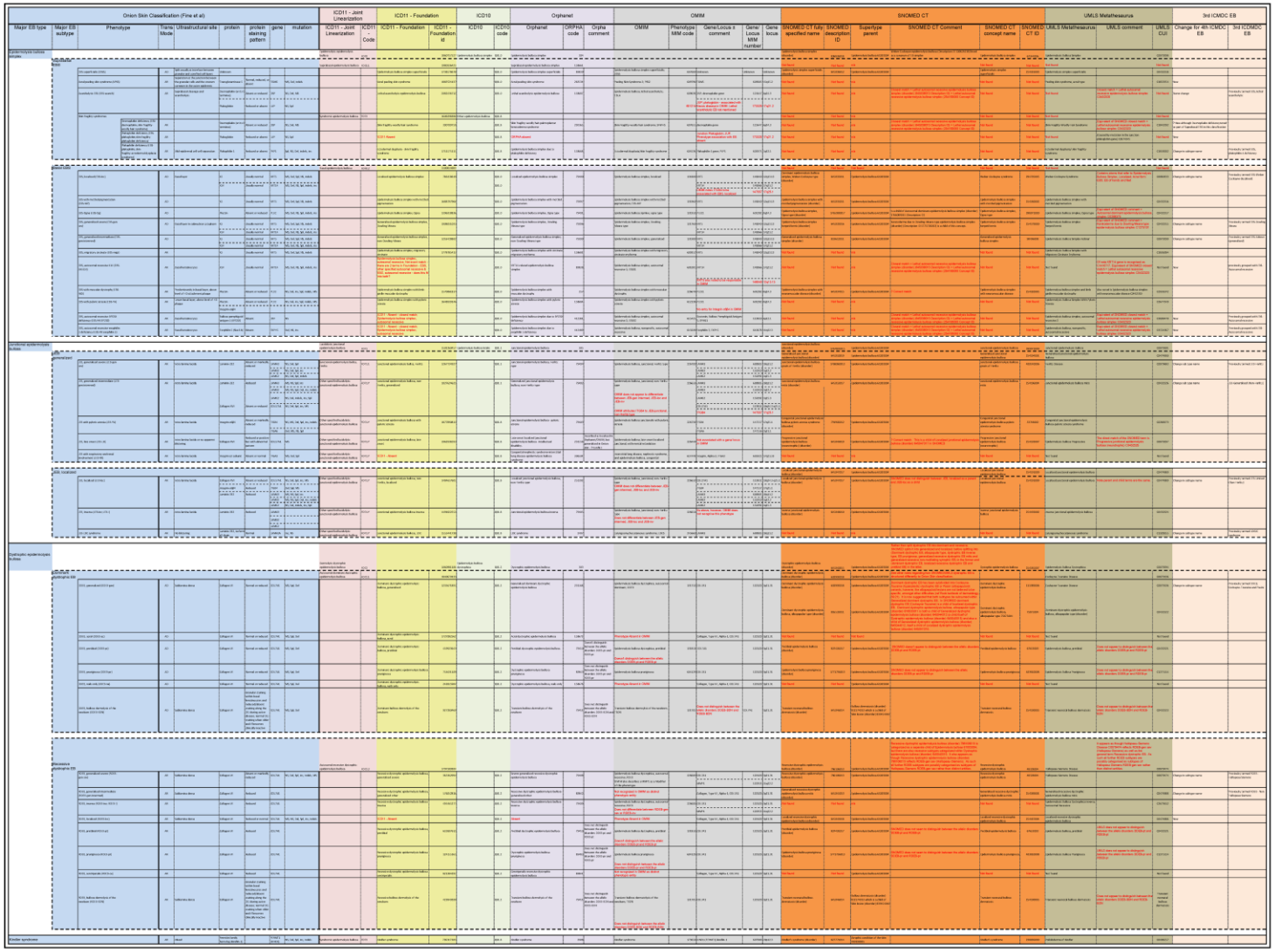


Table 24 International coding systems and terminologies relevant to diagnosis, identified by the EPIRARE project (Vitozzi et al.)

International Coding systems and terminologies noted by EPIRARE project				
Area	**System**	**Author**	**Web-site**	**Remarks**
Medical Nomenclature	SNOMED	International Health Terminology Standards Development Organization	www.ihtsdo.org/snomed-ct	ORPHA-codes are being integrated in SNOMED.
Diseases	ICD-10-CM	WHO	www.who.int/classifications/icd/en	Billing-related. The coding of rare diseases in the next ICD-11 will be based on the ORPHA- codes
	ICD-9-CM			
Rare Diseases	Orpha-codes	ORPHANET	www.orpha.net	ORPHA-codes are being integrated in SNOMED and will be the basis for the codification of rare diseases in the next ICD-11.
	UMLS	NIH ORDR	https://grdr.ncats.nih.gov/index.php?option=com_content&view=article&id=91&Itemid=160	This is the system used by the US GRDR and may be useful for interoperability with this platform.
Genes, genetic disorders and traits	Online Mendelian Inheritance in Man (OMIM)	McKusick-Nathans Institute of Genetic Medicine, Johns Hopkins University (Baltimore, MD)	http://omim.org/	
Genes	HGNC	Human Genome Organization (HUGO)	www.genenames.org/aboutHGNC.Html	
Genomic variations	-	Human Genome Variation Society	www.hgvs.org/mutnomen/	
Laboratory tests and results	LOINC	Regenstrief Institute for Health Care	www.regenstrief.org/loinc/	
Procedures	ICD-10-PCS	WHO	www.who.int/classifications/icd/en	Billing-related
	ICD-9-CM Vol. 3			
Devices	Global Medical Device Nomenclature (GMDN)	GMDN Maintenance Agency	http://www.gmdnagency.com/	Supports the European Databank for medical devices foreseen by the EU Medical Device Directive. It includes 20 EU languages.
	Universal Medical Device Nomenclature System (UMDNS)	WHO Collaborating Centre ECRI	https://www.ecri.org/Products/Pages/UMDNS.aspx	The National Library of Medicine has included UMDNS in the Unified Medical Language System.
Drugs and Orphan Drugs	ATC/DDD index	WHO Collaborating Centre for Drug Statistics Methodology	http://www.whocc.no/atc_ddd_index/	
	MedDRA (Medical Dictionary for Regulatory Activities)	International Conference on Harmonization (ICH)	http://www.meddra.org/	
Adverse Reactions	WHO-ART	WHO, maintained by the Uppsala Monitoring Centre	http://www.umc-products.com/DynPage.aspx?id=73589&mn1=1107&mn2=1664	
	EU SPC ADR database	EMA	http://www.imi-protect.eu/methodsRep.shtml	Database of all adverse drug reactions (ADRs) listed in section 4.8 of the Summary of Product Characteristics (SPC) of medicinal products authorised in the EU according to the centralised procedure. It is based exclusively on MedDRA terminology.
	MedDRA (Medical Dictionary for Regulatory Activities)	International Conference on Harmonization (ICH)	http://www.meddra.org/	
Disability	ICF	WHO	http://apps.who.int/classifications/icfbrowser/	Billing-related. Available in English, French and Spanish. A Children and Youth version is also available in English only

Figure 66 Image of spreadsheet required to map the Fine et al. (2014) classification to a sample of terminologies and classifications noted in the EPIRARE project (Vitozzi et al.)



4.10.2. CREATING EB ARCHETYPES

Following the completion of the author's mapping exercises, two archetypes were constructed with a view to exploring how terminology could be bound to an archetype. The full versions of these archetypes are included in the compact disc that is attached to this thesis.

4.10.2.1. EB DIAGNOSIS

Name: openEHR-EHR-CLUSTER.eb_diagnosis_detail.v1.adl (Figure 67, Figure 68, Figure 69).

Figure 67 EB Diagnosis archetype explanation

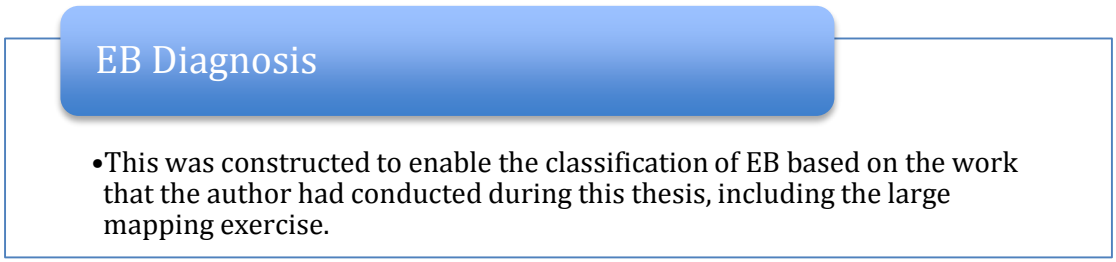


Figure 68 Screenshot of the Archetype designer while creating the EB Diagnosis archetype

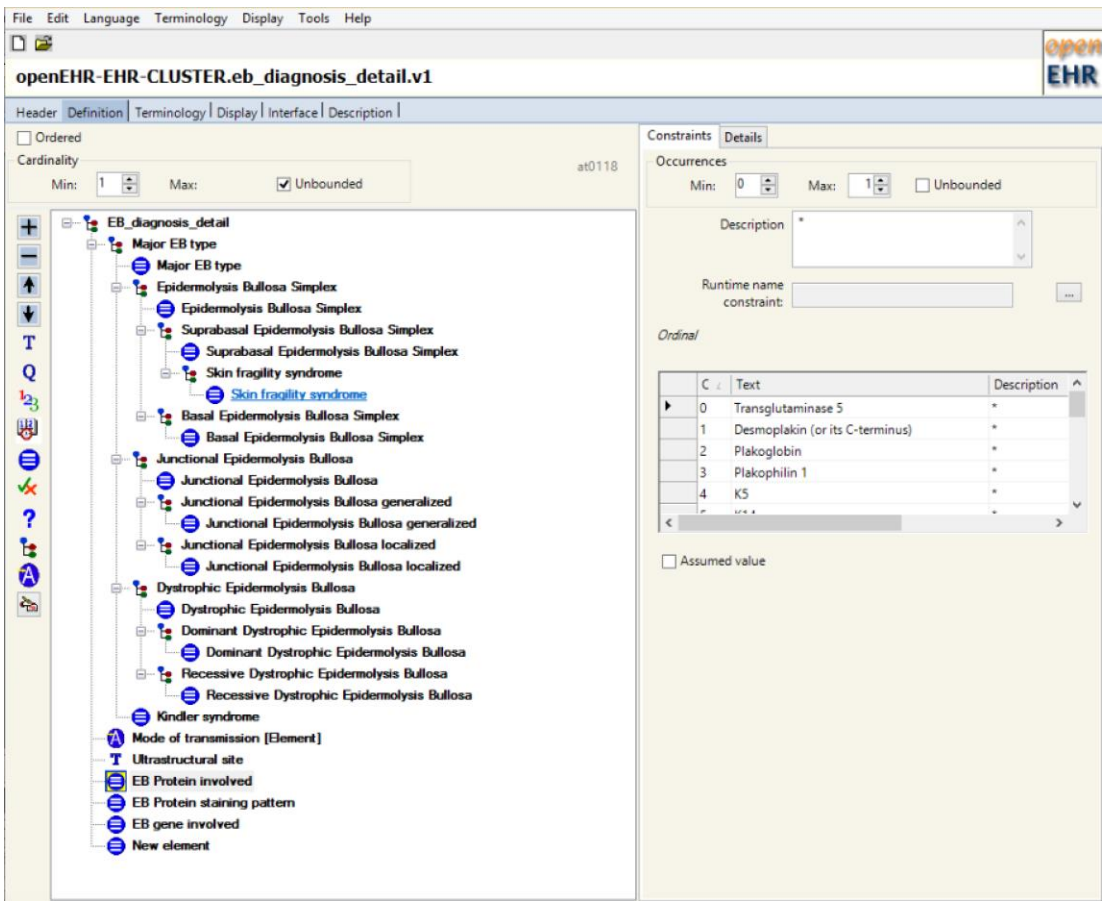
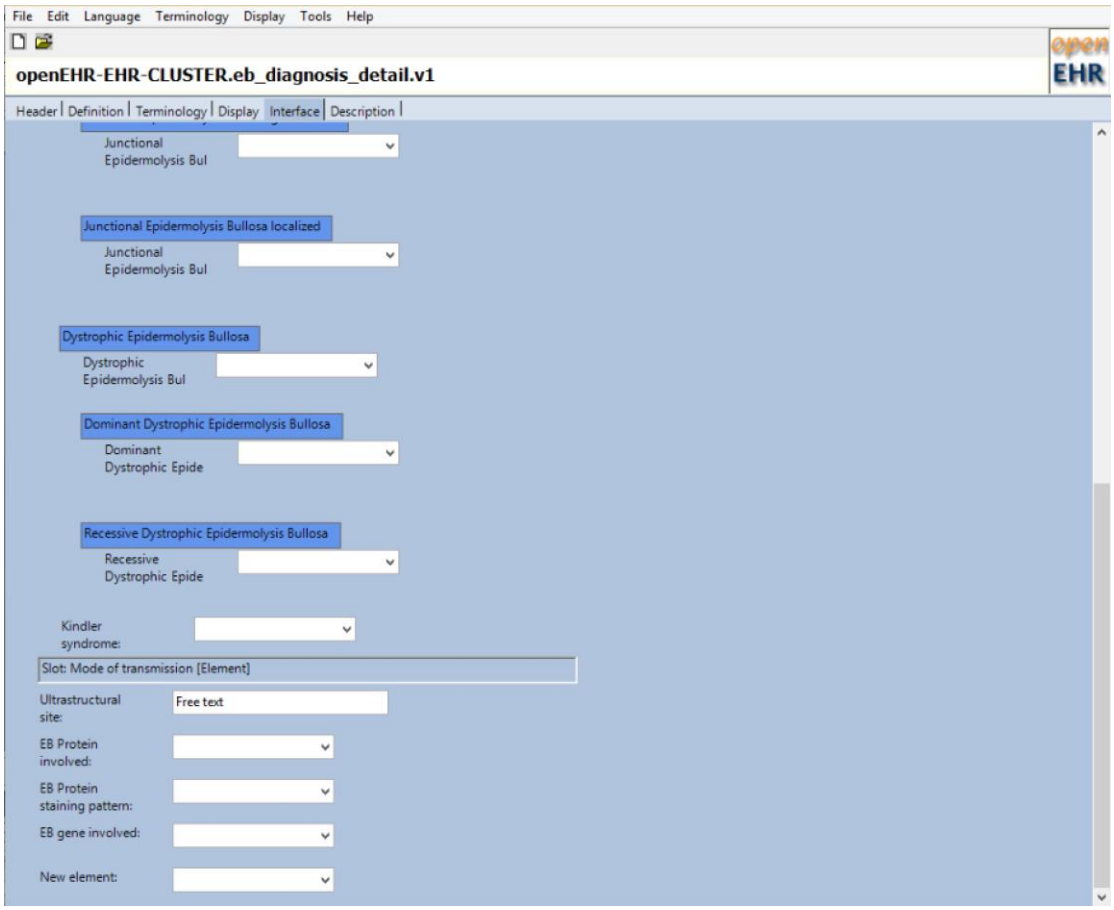


Figure 69 Screenshot from the archetype developer during the creation of the EB diagnosis archetype



4.10.2.2. MODE OF TRANSMISSION

Name: openEHR-EHR-ELEMENT.mode_of_transmission.v1.adl (Figure 70).

Figure 70 Mode of transmission archetype explanation

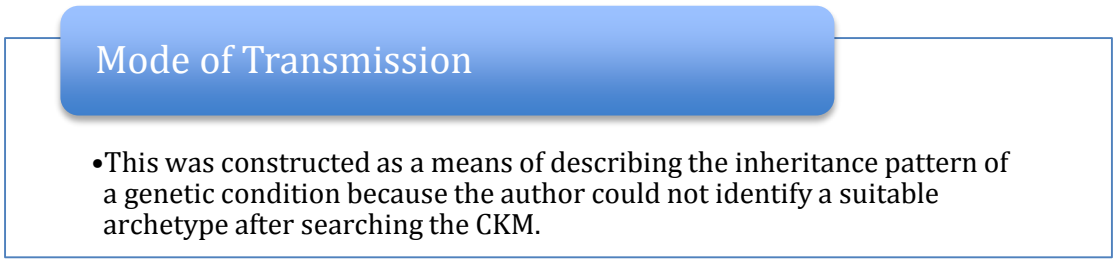
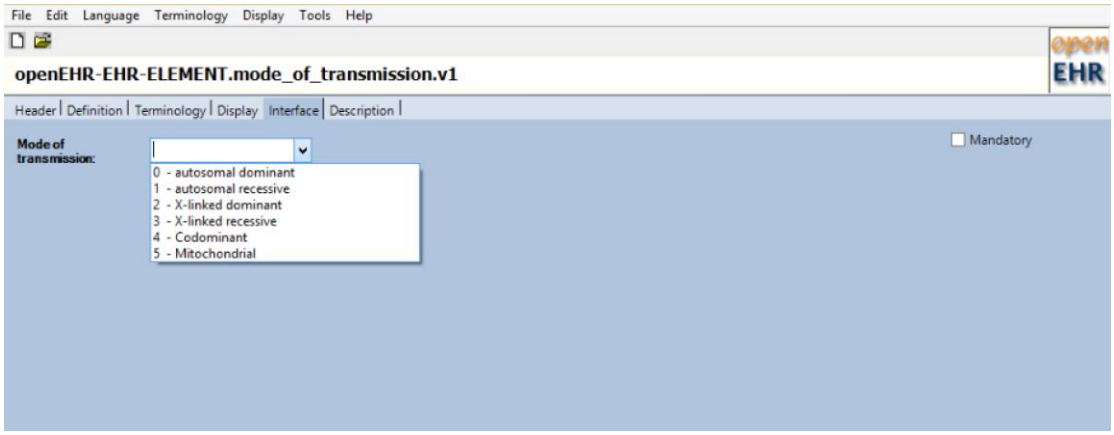


Figure 71 Screenshot from the archetype designer during the creation of the Mode of Transmission archetype



4.10.3. WORK OUTCOME

Unfortunately, terminology binding was beyond the author's expertise at the time of completion of this thesis.

4.10.4. DISCUSSION

The author believes that this chapter is significant, because it demonstrates:

- The limits of the author's modeling ability.
- How clinical requests can introduce unexpected complexity and value. The process of mapping was resource intensive and somewhat at a tangent to the process of learning to model, however, it contributed significantly to the author's understanding of classifications systems and terminologies, which are essential for interoperability. In addition, this is a process that would appear to be extremely significant to clinicians, researchers and patient registries. As such, it might be considered to be an area that could add further value to openEHR, particularly as a means of attracting these groups. Finally, it has also created valuable opportunities for the author to have work recognised, as though the mapping needs further validation with EB experts, the author has been invited to submit the mappings for review by individuals working with ICD-11 and Orphanet. The author suggests that this type of validation is an important means of encouraging a developing modeler and of acknowledging the worthwhile nature of their work.
- An interesting topic that the author was unaware of, termed "the boundary problem" or the "gray-area" (Braun et al., 2014, Markwell et al., 2008). While this project and thesis focuses on openEHR and information models as a means to describe how information should be organised for the purpose of information

systems, there is another school of thought that suggests that ontologies; “a formal representation of our understanding of the meaning in terms of our understanding of the world” (Rector et al., 2009), could achieve a similar purpose. Markwell notes that each approach might be more suitable for describing different areas, however, there are domains where both approaches are equally reasonable. Difficulties, however, arise in joining both approaches, as identified in this section of the thesis.

4.10.5. PLAN FURTHER WORK

The final artifact left to be developed by the author was a template. In the following section, this is discussed.

4.11. CYCLE 11 CREATING A TEMPLATE

4.11.1. EVALUATE PROGRESS, DISCUSS AND REFLECT

While the author felt that significant progress had been made with respect to learning to model, no template had yet been produced. As the mindmaps created for the TREAT registry suggested that a number of complex templates, beyond the ability of the author would be required, a realistic, but more simple scenario was constructed that would enable the author to utilise a small number of the author's archetypes and a small number of pre-existing archetypes noted in Dr McNicoll's mindmap.

4.11.2. PLAN WORK

The author would create a template enabling the capture of data from atopic eczema patients prior to being assessed by a physician in a clinic, including:

- Blood Pressure (existing archetype)
- Body weight (existing archetype)
- Height (existing archetype)
- POEM score (author designed archetype)
- DLQI (author designed archetype)

4.11.3. DESCRIBE WORK

To facilitate this, the author created 3 further archetypes. These are included in full in the compact disc that is attached to this thesis

4.11.3.1. PRE CLINIC ASSESSMENT ARCHETYPE

Name: openEHR-EHR-COMPOSITION.pre_clinic_assessment.v1 (Figure 72, Figure 73).

Figure 72 Pre Clinic Assessment archetype explanation

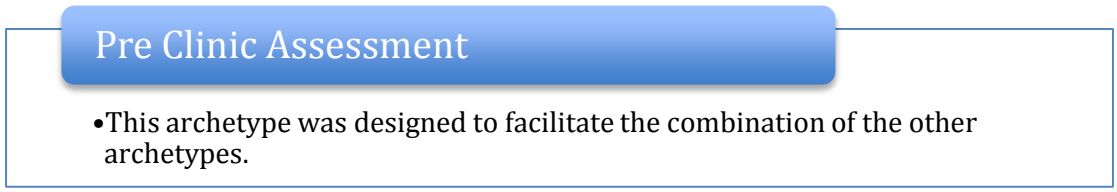
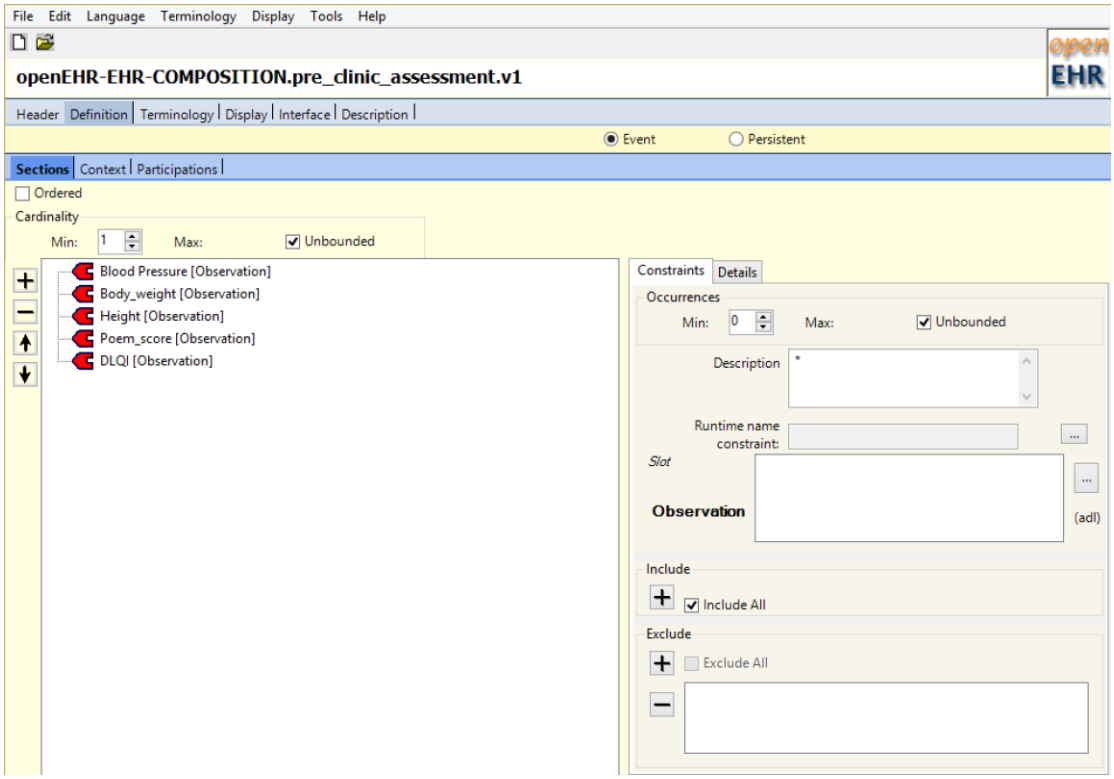


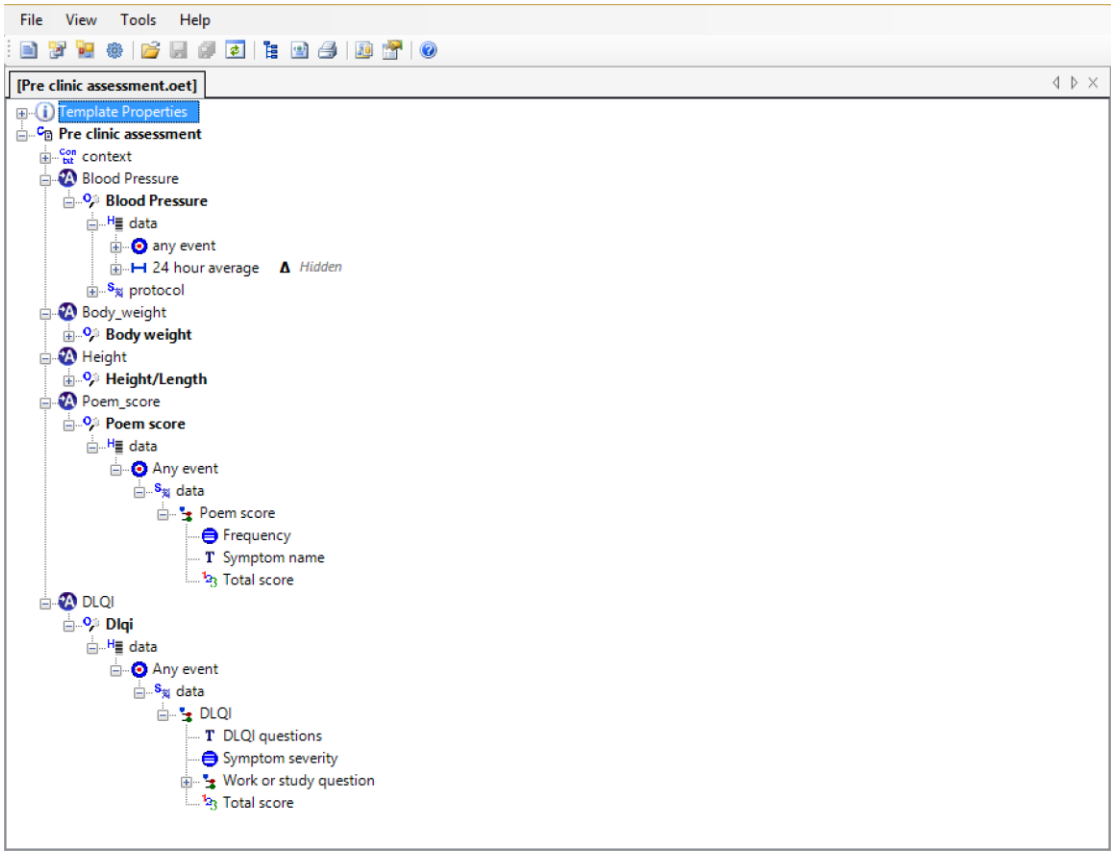
Figure 73 Screenshot from the archetype designed during the development of the Pre Clinic Assessment archetype



Finally, the Ocean Informatics Template editor was utilised to combine the noted archetypes and attempted to constrain them appropriately.

Name: Pre clinic assessment.oet (Figure 74).

Figure 74 Screenshot from the template designer tool during the development of the Pre Clinic Assessment template



4.11.4. DISCUSSION

As with the EB archetypes, template development pushed the limits of the author's ability. A considerable number of attempts were required to construct a technically valid template. This, however, enabled further understanding regarding, how good design of all individual openEHR components is required to ensure their seamless integration.

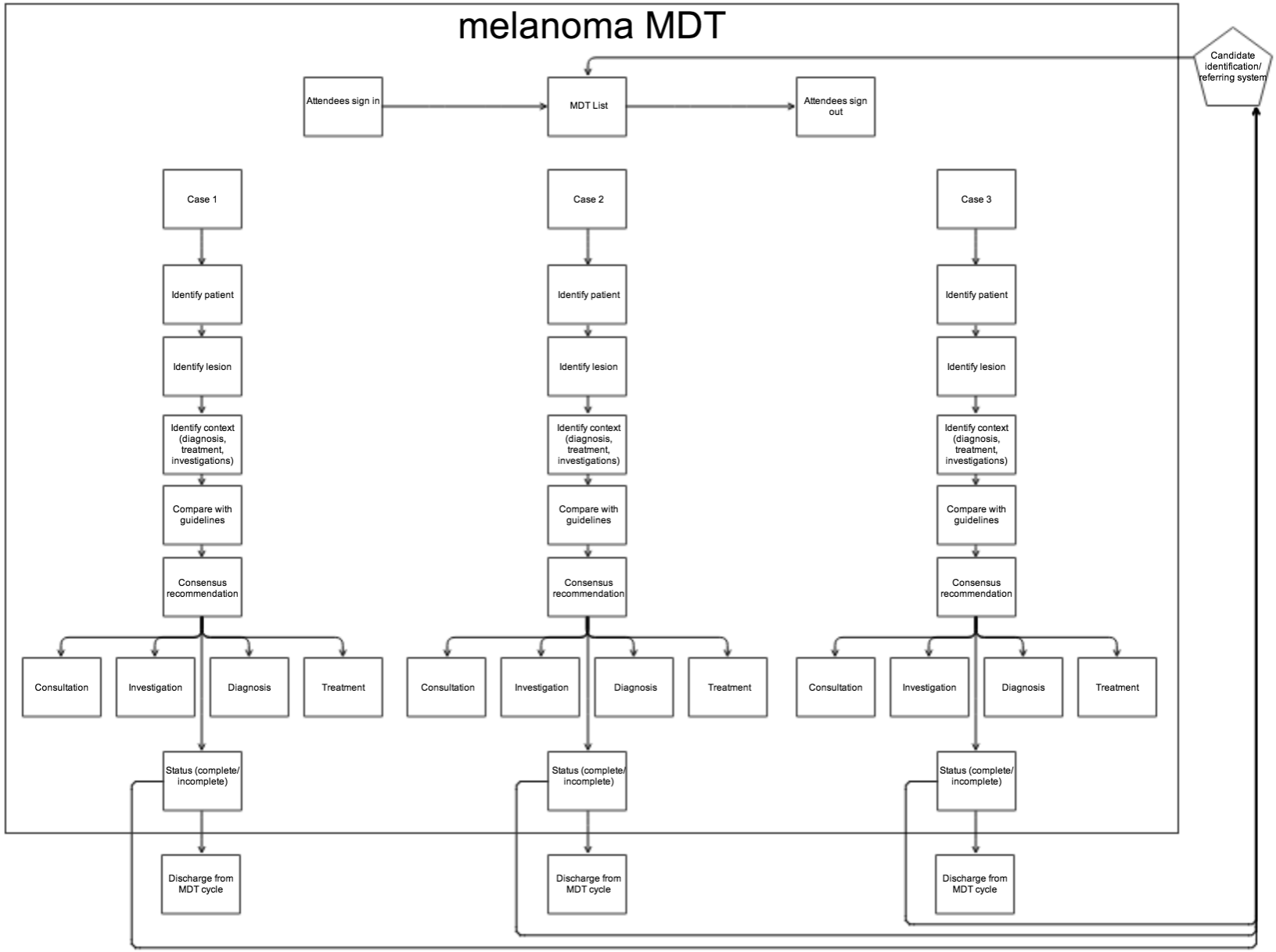
Seeing "the big picture" emerge helped the author to understand the promise that openEHR holds and the potential of multi-level modeling with respect to capturing the domain expert's knowledge. While the skill set required to adequately model all elements required to create a template is challenging, the author believes that template demonstration is an important component in gaining buy-in from clinicians. At this level, which was particularly notable at the training course in Alkmaar, the struggle that this clinician's brain appears to have dealing with abstract concepts, begins to find more

familiar territory as templates begin to move information back into the practical world that can easily be appreciated by any clinician.

Throughout the thesis, the author struggled with the way in which the preparation of mindmaps and archetypes required abstraction of information, which contrasts with the manner in which the author understands information flow as a clinician. While the author has not studied whether this is representative of all, or most, clinicians, experience suggests that this may be the case. The author has learned to appreciates information in respect to process flow as a result of medical training. A diagram (Figure 72) from an abstract publication [in press] is included for reference. The author and colleagues aimed to understand the process involved in a multidisciplinary team meeting for the management of melanoma, a form of skin cancer. A simple diagram was constructed to identify the events that occurred in that care pathway. By developing and using this map with a number of clinicians, it was possible to generate an extensive list of the information content and functionality required to support this process. While Unified Medical Language (UML) and Business Process Model and Notation (BPMN) are known to the author and have been suggested, the author's experience is that a significant skill set is required to utilise these adequately. The author suggests a very simple process that can create a frame of reference for a clinician to use, which may make development of mindmaps and ultimately archetypes significantly easier by embedding them in familiar clinical processes. It is suggested that this could orientate the clinician by, not only identifying information required, but also, by representing the multiple occasions that the same information is utilised at different points in a clinical care pathway, aiding information organisation for the purpose of mindmap and archetype development. It is also believed that this would be able to identify how these information points might be best targeted by clinical decision support systems or utilised with knowledge management systems. While this is not the ultimate aim of openEHR, it is suggested that this high level overview of the practical flow of information within a system identify how information can be more efficiently captured and used, leading to a situation where systems can be designed to significantly improve process.

Ideally, such a map would be developed with an ability to connect relevant mindmaps or archetypes to nodes in the process flow. The author is aware of the potential complexity this might entail, possibly requiring 3 dimensional maps. Nonetheless, it is suggested that the ability of such a system to bridge the abstraction gap that exists for clinicians when entering the information world may be significant.

Figure 75 Process flow for a melanoma multidisciplinary team meeting



4.11.5. REFLECTION

This marks the completion of work performed by the author during the thesis. In the final cycle of the author's action research methodology (Figure 76, Figure 77 – active sections highlighted in green), 2 leading members of the openEHR clinical modeling community have been involved to gain some external perspective on the artifacts produced by the author to facilitate in an evaluation of the project.

Figure 76 Final cycle of research project

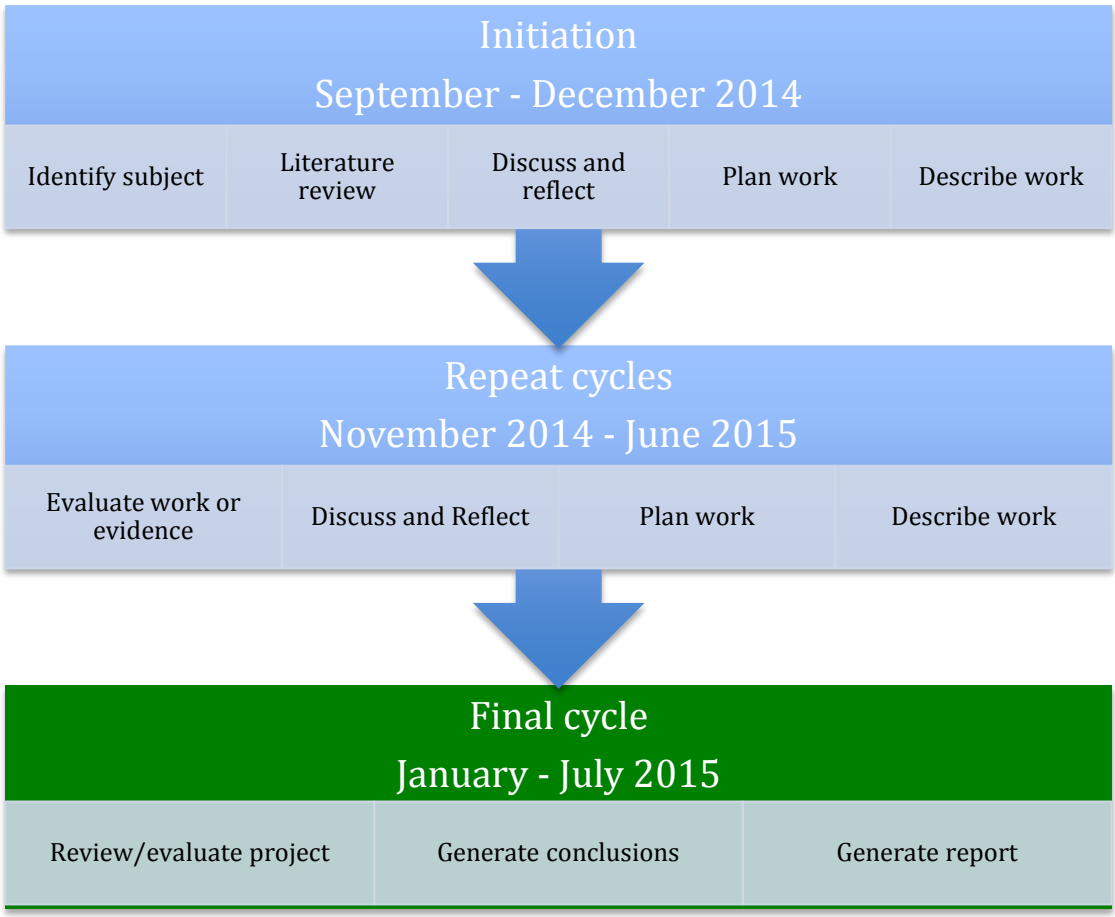
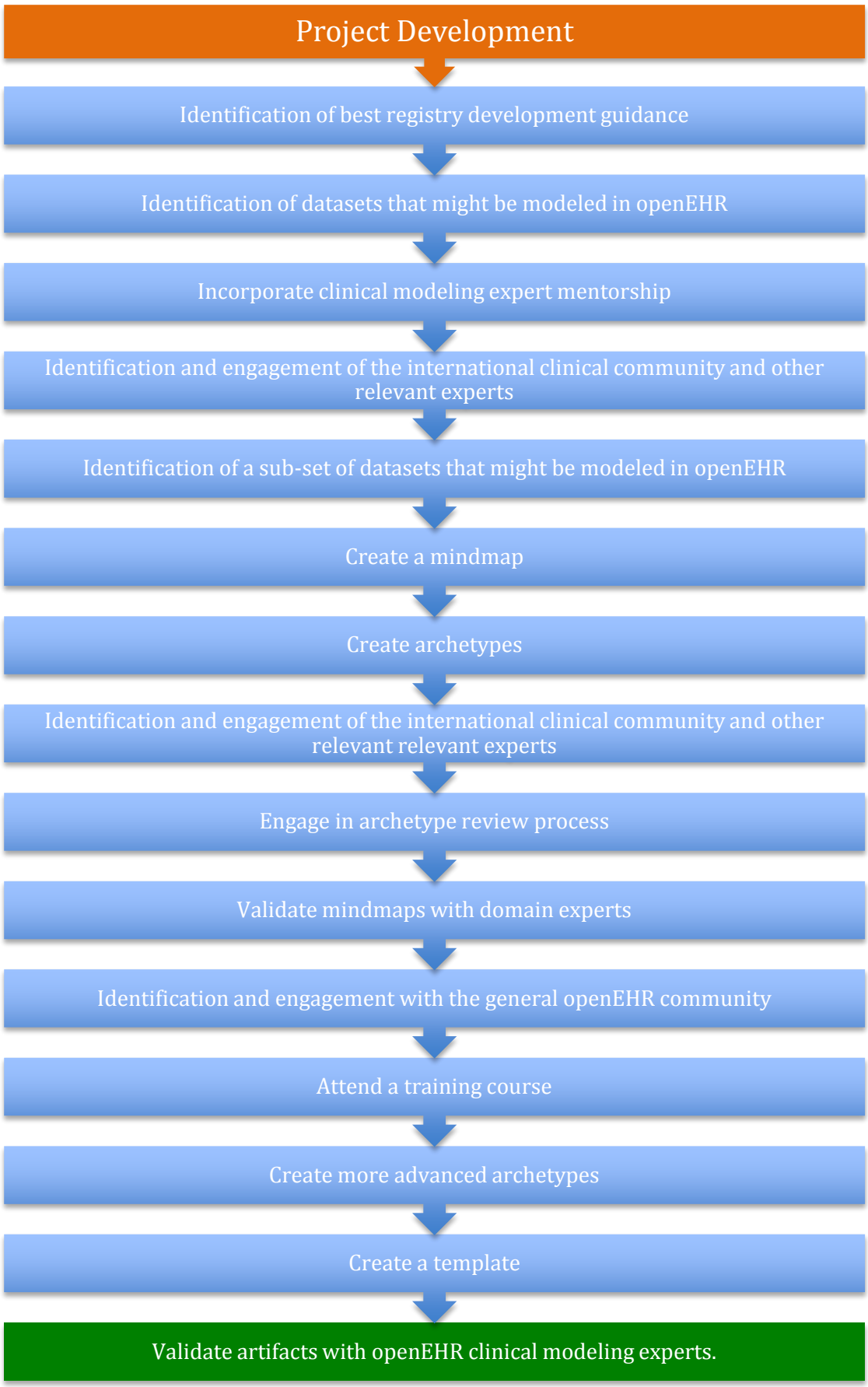


Figure 77 Final cycle project development plan



CHAPTER 5. CYCLE 12 – PROJECT AND THESIS EVALUATION

5.1. DISCUSSION AND PLANNING

There are three major focuses with respect to evaluation of the author's project and thesis.

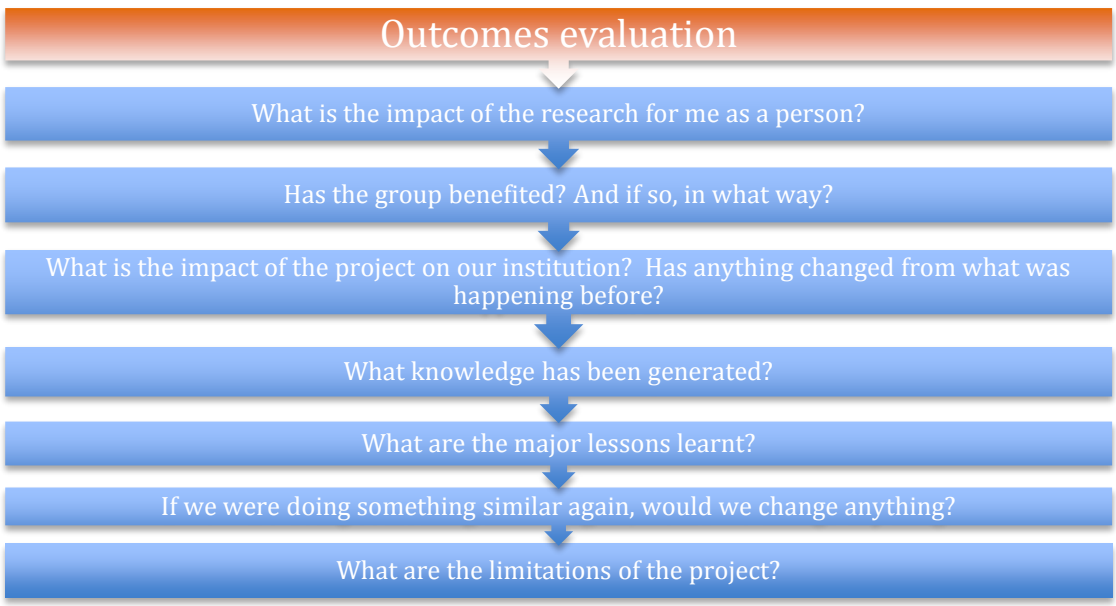
1. Has the project and thesis aim been met?

- Is it feasible to expect a clinician to learn to use the openEHR approach to successfully model artifacts in a manner that can make a meaningful contribution to the development of a real-world system; in this case, the development of a patient registry?

2. Evaluation of outcomes using an action research reflective discussion.

- This is facilitated by the use of an outcomes evaluation form suggested by (Koshy et al., 2010) which was outlined in the methodology section of this thesis (Figure 78).

Figure 78 Outcomes evaluation plan



3. Questions posed at the project outset:

- What would it take to understand openEHR?
- How difficult would it be for a clinician to learn to model?
- Are resources available to answer these questions?

Has the work undertaken by the author enabled these questions to be adequately answered?

5.1.1. HAS THE PROJECT THESIS AIM BEEN MET?

It is suggested that the practical indicator of whether a useful contribution has been made by the author is whether the artifacts produced in this thesis have been utilised to facilitate the development of a real-world registry. While the author is pleased to write that this is the case, it is suggested that a more useful evaluation involves external validation. The survey developed to meet this purpose, previously discussed in section 4.4 of the thesis, is described in the following sub-sections.

5.1.1.1. STUDY TITLE:

Investigating the resources available for novice openEHR clinician modelers.

5.1.1.2. AIM

To identify the resources available for novice openEHR clinician modelers based on the knowledge of the openEHR clinical modelling community.

5.1.1.3. METHODS & MEASUREMENTS

Ethical approval was received from the Trinity College Dublin Research Ethics Committee. During the course of this project the author interacted with recognised experts in the area of clinical modeling via a number of media, including email, telephone, face-to-face, tele- and video-conferencing. Two of these experts, Dr Ian McNicoll and Dr Heather Leslie, are Clinical Knowledge Manager editors. They kindly agreed to provide feedback via a Survey Monkey questionnaire in relation to artefacts produced by the author.

The Survey Monkey questionnaire (Appendix E) explained the context of this thesis and study. 6 questions were posed. The first two related to consent. The remaining questions asked the participant to consider 13 artefacts produced by the author (Figure 79)

Figure 79 Artifacts evaluated by openEHR expert clinical modelers

Dr McNicoll's mindmap was also shared with Dr Leslie to facilitate orientation in view of the large dataset involved.

Participants were then asked to rate:

- "How useful was each artifact produced by the author" on a 5-point Likert scale (1-not at all useful, slightly useful, useful, very useful and 5-extremely useful).
- "How complex was each artifact produced by the author" on a 5-point Likert scale (1-not at all complex, slightly complex, complex, very complex, 5-extremely complex).

With respect to both questions, a further option was given (no answer; N/A) to enable the participant to skip a question if desired. In analysis, an absent answer or answering N/A were given a score of 0 to indicate no score.

Comment boxes were available for each rated item. Question five provided a general comments box, asking participants to "please feel free to add further comments you feel are appropriate with respect to facilitating the author as a novice clinician learning to model utilising an openEHR methodology".

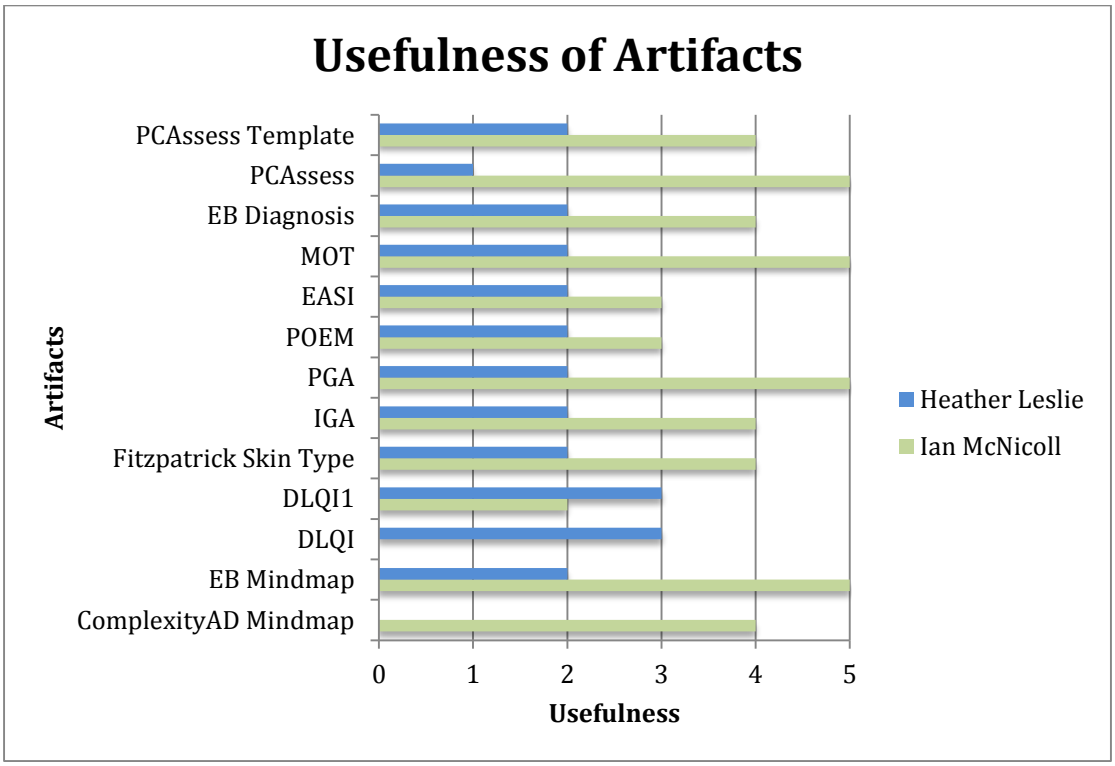
All survey questions were optional, except for the first two questions, which confirmed that the information literature had been reviewed and that consent was given, and the final question, regarding whether the participant wished to submit or "not submit, exit without submitting" to ensure that participants had a means to withdraw consent, if desired.

5.1.1.4. SURVEY RESULTS

5.1.1.4.1. HOW USEFUL WAS EACH ARTIFACT PRODUCED BY THE AUTHOR?

Figure 80 describes the rating given to each artifact by each expert with respect to usefulness.

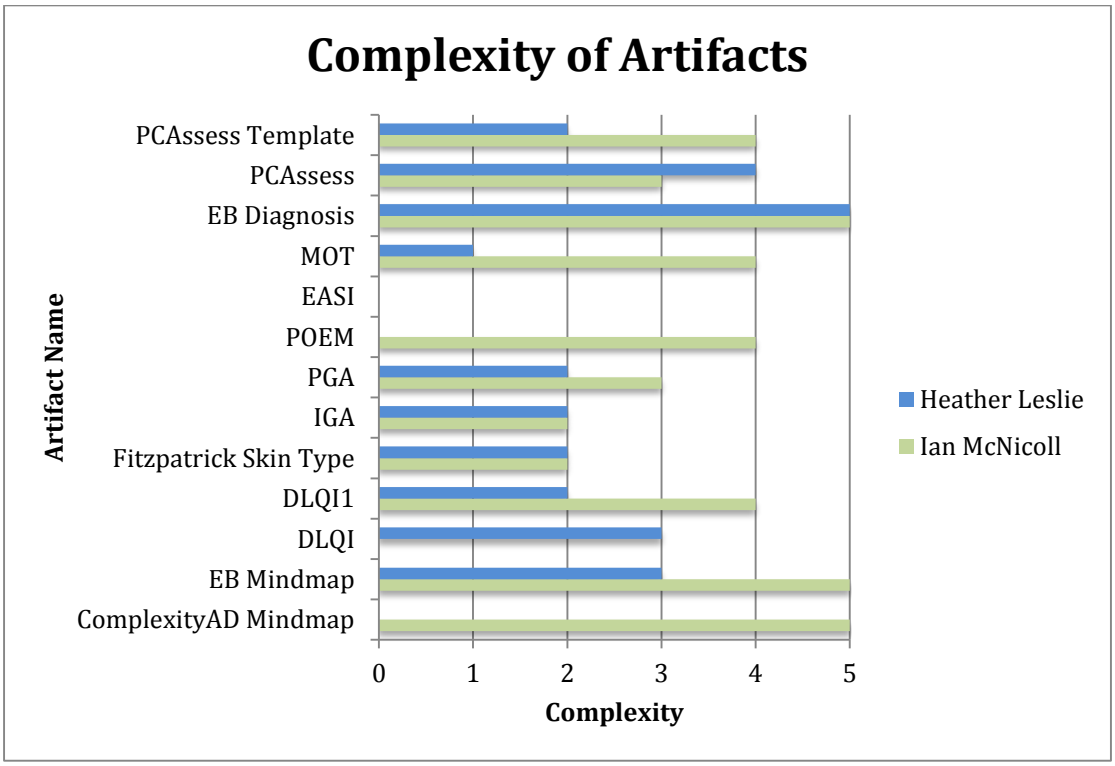
Figure 80 Experts' ratings with respect to usefulness of each artifact produced by the author.



5.1.1.4.2. HOW COMPLEX WAS EACH ARTIFACT PRODUCED BY THE AUTHOR?

Figure 81 describes the rating given to each artifact produced by the author with respect to complexity.

Figure 81 Expert's ratings with respect to complexity of each artifact produced by the author.



5.1.1.4.3. COMMENTS ASSOCIATED WITH RATINGS

A substantial quantity of information was shared with the author as a result of this survey. The author found this to be extremely helpful and as such has reproduced it, with the consent of the survey participants, in the following tables, accompanied with comments from the author regarding each point.

Table 25 Atopic Dermatitis (AD) mindmap evaluation by expert clinical modelers.

Name of Reviewer	Ian McNicoll	Heather Leslie

Atopic Dermatitis Mindmap		
Utility	Very useful	N/A
Complexity	Extremely complex	N/A
Comment re utility	Good coverage of the topic area. Optimising the tree structure to maximise legibility is always tricky. This mindmap is very long and quite difficult to understand. I would probably have tried to re-factor some of the structures to give it more width and less length. Alternatively just break the whole thing down into multiple mindmaps.	There is no mindmap labelled with this name. Is this the 'Dmitri 1st attempt mindmap?'.
Comment re complexity	No answer	Not sure which mind map you are referring to.
Author's response	This was quite a detailed dataset to model. It was an early attempt at modeling and as such, the author had very little experience with respect to what was expected.	The mindmap was misleadingly labelled 'Dmitri 1st attempt mindmap'.

Table 26 Epidermolysis Bullosa (EB) mindmap evaluation by expert clinical modelers.

Epidermolysis Bullosa Mindmap		
Utility	Extremely useful	Slightly useful
Complexity	Extremely complex	Complex
Comment re utility	Nice layout. Easy to understand the classification	Utility in what respect? I have no idea of the background of this. For example, I'm not sure if this is amalgamating data from disparate sources or using a mind map to represent a single list. If this is a classification from a single list, then a word document or table might have been clearer. It is hard to comment. The .png file is hard to navigate and the source mind map file might have been easier for me to use. It seems that there is additional content under each condition that is not revealed and not sure of its relevance.
Comment re complexity	No answer	No answer
Author's response	The author required a significant quantity of time to review a complex publication and understand the authors' perspectives. Significant input was received from both EB experts and researchers, in addition to significant external literature review to produce the mindmap.	The author believes that this highlights some of the difficulties with mindmaps. While the classification is easy to understand for someone with clinical domain expertise, or, as in the case of Dr McNicoll, where extra information regarding the background of the information has been given as a result of interaction with Dr McNicoll, it is easy to see how a mindmap can become difficult to read. Criticism regarding the format in which the mindmap was presented is acknowledged. As with the EB experts who reviewed this image, the author aimed to provide the mindmap in a widely readable format.

Table 27 Dermatology Life Quality Index (DLQI) archetype, version 1, evaluation by expert clinical modelers

openEHR-EHR-CLUSTER.dlqi.v1.adl		
Utility	N/A	Useful
Complexity	N/A	Complex
Comment re utility	This is not actually a CLUSTER archetype, just an internal cluster inside an archetype.	Not sure if this is intended as an alternative to the OBSERVATION.dlqi? The archetype has a CLUSTER appears to be intended to be repeatable, but that only has occurrences of 0..1 - it will need to be modified to 0..* for this to work as intended. Questionnaires are difficult to model sensibly and clearly. This is a very reasonable attempt and there are a number of other ways to try to represent it. My preference, after much trial and error just like yourself, is to represent each data element succinctly and add the question in its entirety as the data element description, then add the values directly - so there is one data element per question, more like the Barthel Index or your EASI score. Otherwise the pattern itself seems to overtake the content and clarity is lost. It is not clear how this is intended to be used in the clinical context, e.g. within which ENTRY archetype.
Comment re complexity	No answer	No answer
Author's response	The author produced this as an early exercise. Considerable advice was received from Dr McNicoll as the author struggled with understanding a number of the basics of utilising the archetype editor appropriately at the time. From a clinical perspective, the author felt significant responsibility to ensure that the description of the archetype used was supported with appropriately referenced literature. Atalağ (Atalağ, 2007) has noted the significance of this previously. Particularly from the perspective of ensuring broad clinical acceptance of the archetype, the author strongly feels the importance of ensuring accuracy in this area, which, in some cases, will require significant input from very experienced clinicians. A number of areas in the description were left unfilled as the author was not aware fully aware of them at the time of creating the archetype.	Occurrences was a concept that the author was not aware fully aware of them at the time of creating the archetype. It is reassuring to see that a proficient modeler recognises the difficulty in modeling a questionnaire and to get an insight into how Dr Leslie has identified as the best way to do so.

Table 28 Dermatology Life Quality Index (DLQI) archetype, version 2, evaluation by expert clinical modelers.

openEHR-EHR-OBSERVATION.dlqi1.v1.adl		
Utility	Slightly useful	Useful
Complexity	Very complex	Slightly complex
Comment re utility	Correct archetype class – OBSERVATION. This is actually quite a tricky score to model because of a number of repeating structures, some with identical values and you have not got the construct quite right. The basic questions are well modelled with appropriate data types but the nesting and use of multiple occurrences is not quite right to model the score correctly. Descriptions of terms are missing. Having said that, this is not an easy exercise for a beginner.	As above, the pattern is more complex, but the intent appears to be the same. Occurrences are still 0..1. I'd still suggest the same modelling pattern and approach as for CLUSTER.dlqi. At least here we can see that this is a standalone assessment. For most questionnaires, this is the best archetype class to use.
Comment re complexity	No answer	No answer
Author's response	This is almost a repeat of openEHR-EHR-CLUSTER.dlqi.v1.adl. It was redesigned as the author, at the time of creating the Pre Clinic Assessment template discovered that the archetype Class was incorrect and, as a result, could not be incorporated within the template. There is also a variation in the structure of the archetype as the author recognised that the original structure did not account for a variation in the scoring of the patient reported outcome measure. The author was unaware that descriptions of the terms could be performed. Multiple occurrences were believed to be a means of enabling the score to be repeated on multiple occasions.	

Table 29 Fitzpatrick Skin Type archetype evaluation by expert clinical modelers.

openEHR-EHR-OBSERVATION.fitzpatrick_skin_type.v1.adl		
Utility	Very useful	Slightly useful
Complexity	Slightly complex	Slightly complex
Comment re utility	Not in the template. Correct archetype class – OBSERVATION. The values for the Skin type are appropriate but you should give the element a meaningful name, not just leave it as 'New Element'. It also needs a description. I am not clear what the element slot is for – no name or description.	The intent of this archetype is not clear. The background is explained to a simple degree in the metadata, but the purpose/use is not clear. There is a single unnamed data element containing the scale and the explanation of each component. Choice of data type as ordinal is good, as it means it can potentially be tracked and graphed over time. There is no indication of the purpose of the unnamed SLOT.
Comment re complexity	No answer	No answer
Author's response	From a clinical perspective, this was a difficult archetype to develop. Although the author had a functional understanding of Fitzpatrick skin type, when the author investigated the origin and development of the score for the purpose of describing it, significant difficulties arose. Many versions of the score became apparent and identifying what version should be used was difficult. It was assumed that further specialist clinical input would be required to definitively solve this problem. In the interim a basic score was proposed. An element slot was included based on a misunderstanding by the author at the time, that to enable the archetype to be included within a template, it would require an empty element slot.	It is particularly interesting to receive Dr Leslie's feedback as the author spent considerable time ensuring that the metadata for this archetype was well researched and considered. The author suggests that this is another example of the value of having domain experts and informaticians contribute to archetype development, as what can be clear to one, may not be to another. It is also interesting to see that the author's difficulty in conceptualising how an archetype might ultimately be used in clinical practice can be a difficulty for experienced modelers when the context is not appropriately explained or familiar.

Table 30 Investigator Global Assessment (IGA) archetype evaluation by expert clinical modelers.

openEHR-EHR-OBSERVATION.iga.v1.adl		
Utility	Very useful	Slightly useful
Complexity	Slightly complex	Slightly complex
Comment	Correct archetype class – OBSERVATION. Correct data type for the IGA score but it needs 'New element' to be given a meaningful name, e.g. IGA Score. The data structure selected 'List' is technically correct but as a routine now we always choose 'Tree' which gives us more flexibility in the future. No references.	This observation archetype has limited explanation – it appears this is a standardised assessment, so the class of archetype is likely correct. The single data element is unnamed and the ordinal values are clearly described; the ordinal will allow for these values to be tracked and graphed over time. The representative skin area which has been used for the assessment does not appear to be identified. Is this an issue?
Comment re complexity	No answer	No answer
Author's response	This was an early attempt at archetyping by the author. The author was unaware at the time of the variations in structure that could be chosen e.g. 'list' rather than 'tree'. Due to time pressure to develop the basic outline of archetypes for the TREAT project, the author did not have sufficient time to complete a literature review to support the archetype. It was intended to rectify this with further iterations of the archetype.	The author believes that this is another example of the value of having domain experts and informaticians contribute to archetype development to facilitate clarity, as what can be clear to one, may not be to another. In this case a 'representative' area is an area of skin chosen by an investigator because they feel that it is 'representative' of the patient's atopic dermatitis for the purpose of grading the overall severity of their atopic dermatitis.

Table 31 Patient Global Assessment (PGA) archetype evaluation by expert clinical modelers

openEHR-EHR-OBSERVATION.patients_global_assessment.v1.adl		
Utility	Extremely useful	Slightly useful
Complexity	Complex	Slightly complex
Comment re utility	Correct archetype class. Appropriate Ordinal datatype and element name 'PGA' but missing description. Also ordinal term descriptions missing. Absent references and purpose. Technically useable but would not pass muster on CKM!!	As above for OBSERVATION.iga, however each of the ordinal values are not described. The name of the archetype is potentially problematic in the context of a national or international pool of archetypes as it is clearly a skin-specific archetype but the name implies a more general intent.
Comment re complexity	No answer	No answer
Author's response	Similar to openEHR-EHR-OBSERVATION.iga.v1.adl, this was meant as an initial guide and as an exercise to help the author understand basic organisation of an archetype. Due to time pressure to develop the basic outline of archetypes for the TREAT project, the author did not have sufficient time to complete a literature review to support the archetype description.	The topic of naming stimulated an interested conversation between the author, Dr McNicoll and Dr Leslie when it was uploaded to the CKM. The author had named it patient's global assessment as that is what the score is officially known as in dermatology. The author believes that this is an interesting example of how specialties can often see their own domain area in isolation, and can gain significant input from informaticians who may see the "bigger picture" and interoperability difficulties that might arise.

Table 32 Patient Orientated Eczema Measure (POEM) archetype evaluation by expert clinical modelers.

openEHR-EHR-OBSERVATION.poem_score.v1.adl		
Utility	Useful	Slightly useful
Complexity	Very complex	No answer
Comment re utility	Correct archetype class. Good references and other general meta data. The data types are correct but as for dlq1 the use of clusters and multiple occurrences is not correct and would not allow multiple symptoms to be recorded each with a frequency score. However, as above, this is not easy to model	As for the DLQI, my preference, after much trial and error just like yourself, is to represent each data element succinctly and add the question in its entirety as the data element description, then add the values directly – so there is one data element per question, more like the Barthel Index or the EASI score on CKM – http://www.openehr.org/ckm/#showArchetype_1013.1.1871. The descriptions are missing etc. – but are really important to a non-domain expert like myself trying to understand the intent of the archetype. They are time-consuming and drive modellers nuts, but are worth it in the longer term.
Comment re complexity	No answer	One data element
Author's response	While the concept of how this score would work in clinical practice was clear to the author, it was difficult to understand how this would be structured as an archetype to enable multiple symptoms to be recorded and scored resulting in a cumulative score.	The guidance from Dr Leslie is particularly well received. The author's experience of providing descriptions is that this can be time-consuming, but it can also be extremely difficult as delivering a suitably comprehensive and knowledgeable description can require significant investigation and expertise beyond the functional level of knowledge that is required to simply utilise these scores.

Table 33 Eczema Area and Severity Index (EASI) archetype evaluation by expert clinical modelers.

openEHR-EHR-CLUSTER.easi.v1.adl		
Utility	Useful	Slightly useful
Complexity	No answer	No answer
Comment re utility	It is not clear why this was a CLUSTER archetype. I would have expected it to be an OBSERVATION. As with some other scores, the basic modelling of datatypes is correct but the nesting and use of multiple occurrences is wrong and would not allow the model to work as intended. Could do with more descriptions of terms and elements but references and general metadata is good	This CLUSTER archetype appears to need to be represented as an OBSERVATION, as a repeatable questionnaire. I'm don't understand if there is a specific reason why it is a CLUSTER. Like the others above, the cluster heading appears to be intended to be repeated but occurrences are 0..1 rather than 0..*. It is not clear what the Qualifier is intended to be used for, especially with the quantity data type. The 'intensity of' data element has occurrences 4..4 – is this to try to represent a multichoice?
Comment re complexity	No answer	No answer
Author's response	This eczema severity-scoring tool was difficult to model due to the manner in which it utilises algorithms to create a total score. A cluster was utilised to try and accommodate the elements required to facilitate this, due to a lack of experience and understanding of how this might best be achieved.	Again, Dr Leslie's advice is well received, as the issue of occurrences is an area that the author had difficulty with. In relation to the qualifier, this is simply part of an algorithm used to calculate a score. The author found that with complex scores that it was difficult to model and often explain these within the confines of the archetype designer. It is suggested that uploading an example of a paper form and a case example might be useful in these cases; perhaps with images in the case of dermatology where scores are often utilised to describe visual appearance.

Table 34 Mode of transmission archetype evaluation by expert clinical modelers.

openEHR-EHR-ELEMENT.mode_of_transmission.v1.adl		
Utility	Extremely useful	Slightly useful
Complexity	Very complex	Not at all complex
Comment re utility	This is an interesting use of an ELEMENT archetype which technically could slot into an ENTRY archetype such as an OBSERVATION and fulfil the intended role. In practice we would probably use an external terminology and termset to fulfil the same purpose but this a legitimate, if unusual, use of an ELEMENT archetype.	"Describes the manner in which a train is inherited" – not sure what this means. For an archetype to be names so generically, consideration will need to be made about the other uses of this same phrase. The archetypes that this ELEMENT is intended to be used within should be identified to provide context
Comment re complexity	Not complex but sophisticated thinking!	One data element
Author's response	This archetype was a late attempt by the author to describe the inheritance of a particular EB subtype as it was unclear to the author how this might otherwise be achieved. As with a number of archetypes developed, the author intended this archetype to serve as a means of expressing relevant concepts in a manner that could be discussed and improved with more experienced modelers.	The word 'train' was a typographical error and should have read trait. While this is a mistake on the author's part, the author believes that it nicely demonstrates how human error can contribute to significant semantic errors.

Table 35 Epidermolysis Bullosa (EB) diagnosis detail archetype evaluation by expert clinical modelers.

openEHR-EHR-CLUSTER.eb_diagnosis_detail.v1.adl		
Utility	Very useful	Slightly useful
Complexity	Extremely complex	Extremely complex
Comment re utility	This is good use of a CLUSTER archetype that could for example slot into a parent Problem/diagnosis archetype to carry the extra detail. The general structure is correct with good use of the internal clusters to achieve the correct tree structure. The use of the Ordinals to carry the various sub-categories is not really necessary. The numeric values have no meaning here and a Text/CodedText element with an internal list would have worked just as well, and been more semantically correct. There are a few missing descriptions and the top-level EB_diagnosis_detail cluster node is not really required since the whole archetype structure is already a Cluster. If you were to pull this into a Diagnosis archetype slot at template time it would be apparent that the top-level has some duplication.	This archetype appears to have two components: - it is trying to indicate a relational structure between diagnosis, effectively supporting a decision tree that is best kept out of the EHR and the archetype inside a knowledgebase, rather than allowing for recording of the selected diagnosis; and also - providing additional detail about the diagnosis protein/genome etc. The diagnosis for this patient should be recorded in the archetype, not the whole knowledgebase that supports clinicians to make the decision as this could change as knowledge changes as each diagnosis would be one of a picklist stored/managed elsewhere, but the pattern in the archetype should be able to withstand that. In the second part, I would anticipate that there could be a standardised pattern that could be identified for any diagnosis with a genomic component and we should utilise this generic pattern here and apply it to all of the variations of EB.
Comment re complexity	No answer	No answer
Author's response	This was one of the last archetypes developed by the author. To develop the level of clinical understanding required significant time and was certainly facilitated by the responses received in relation to a high level mindmap reviewed by the Epidermolysis Bullosa expert community and by the further work undertaken by the author in relation to mapping the classification of EB to other classifications and terminologies. The author felt that, while there is significant clinical detail in the various elements that have been extracted from the publication, they might not have been appropriately arranged. The author felt that there was still a significant experience	The concept of a standardised pattern is interesting. The author suggests that with such a complex means of classifying a disease, this solution would not have been suggested were it not for expert explanation of a particular condition. The author accepts Dr Leslie's point regarding keeping a knowledgebase out of archetypes: it is clear from the point made regarding Dr McNicoll's comments that the concept of a clinical decision support to facilitate diagnosis was prominent in the author's mind. This does, however, reflect a particularly complex classification scheme whereby multiple information points need to be identified to give a complete diagnostic description, however, it is not always the case that each of these points will

	gap on his part with respect to understanding how the archetype should be constructed to best facilitate a clinical decision support tool that could be utilised in a clinic. Much of the design of the structure was influenced by the "Interface" display of the data points, which the author utilised to help understand how the data might appear in such a tool. The use of ordinals as a means to list the various options within elements is an example of this incomplete understanding and experience. The author had conducted significant further work in an effort to match the EB classification as detailed in this archetype, with a number of terminologies and classifications. Unfortunately, the author was unable to progress to a level whereby an accurate mapping of the archetype was conducted. The author believes that this would have significantly increased the value of the archetype from an interoperability perspective.	be available for every patient. In addition, it is worth noting that the true value of a clinical decision support would come with matching this diagnosis with signs and symptoms of the patients, which was not included in the author's work.

Table 36 Pre clinic assessment archetype evaluation by expert clinical modelers.

openEHR-EHR-COMPOSITION.pre_clinic_assessment.v1.adl		
Utility	Extremely useful	Not at all useful
Complexity	Complex	Very complex
Comment re utility	I would probably have renamed a generic Encounter or Report composition archetype, rather than created a specific Pre-clinical assessment composition but this is a matter of debate.	I would prefer to see a generic COMPOSITION archetype used here – perhaps a COMPOSITION.self_assessment (not yet developed) which will provide appropriate semantics for your purpose but not require its own archetype. The specifics of the dermatology pre-clinic assessment will then be specified in the template.
Comment re complexity	No answer	No answer
Author's response	This archetype was created towards the end of this thesis to facilitate the development of a template. The author found a significant practical knowledge deficit with respect to how archetypes should be created or altered to best facilitate incorporation within templates. A significant number of attempts were made to make this archetype work in a manner that would enable generation of a template. It was unclear in many respects as to what the author was doing incorrectly. Ultimately, trial and error resulted in the ability to utilise this as the basis for a template.	The concept of the not yet available COMPOSITION.self-assessment is of particular interest. The author did feel that significant time was required to generate what should be a standard variation of a generic template.

Table 37 Pre clinic assessment template evaluation by expert clinical modelers.

Pre clinic assessment.oet		
Utility	Very useful	Slightly useful
Complexity	Very complex	Slightly complex
Comment re utility	You generally have the correct idea about how templates are put together but have mistakenly tried to use 'Hide on Form' to constrain out the un-needed data points, rather than Zero I.	The intent is not clear as no purpose has been described. I assume it is for patient self-assessment prior to attending the clinic and so only has relevant archetypes included. The maximal data sets need to be constrained so only relevant data elements are made available. Otherwise OK.
Comment re complexity		Just right amount of complexity?
Author's response	As described in openEHR-EHR-COMPOSITION.pre_clinic_assessment.v1.adl, the author had particularly difficulty in preparing archetypes that could be utilised to generate a template. It was also difficult to conceptualise how a number of the outcome measures would function within this setting. While it was, at this point, understood, that much of this would be facilitated by the group who would ultimately produce a clinically usable artifact, the author's experience in a clinical setting is that it is as important to understand how information will be captured, presented and utilised as it is to understand what information is to be collected. Though the author was aware of a form generator, he did not progress to a level where this was utilised.	The author acknowledges the lack of appropriate direction given regarding the use of the template. The purpose is as Dr Leslie has outlined.

5.1.1.4.4. GENERAL COMMENTS

Both Dr McNicoll and Dr Leslie left very helpful comments regarding their assessment of the artifacts produced by the author in Figure 82 and Figure 83.

Figure 82 General comments regarding evaluation of the author's artifacts made by Dr Ian McNicoll

Dr Ian McNicoll:

"Given the lack of any formal training I think this demonstrates that an untrained clinician can use the openEHR tools with a high level of success.

There were some significant omissions and errors but these could be easily corrected by a little feedback. A particular problem is how to nest repeating structures, using clusters and multiple occurences but this is a common difficulty for new modellers, unused to technical data structures.

Some of the scores are actually quite tricky to model even for expert modellers.

The tooling can always be improved but the main challenge in developing good modelling skills as actually around developing a good informatics understanding not how to build an archetype.

This is definitely an art not a science"

Figure 83 General comments regarding evaluation of the author's archetypes by Dr Heather Leslie

Dr Heather Leslie:

"I'd suggest that the complexity of the artefacts is not such a useful question - every archetype should be complex enough to represent the data it needs to, and no more! And that level of complexity varies per clinical concept.

The COMPOSITION and the eb diagnosis archetypes are problematic in my opinion, for reasons stated in the usefulness questions.

All other archetypes are useful but could do with some refining to improve clarity and ease of implementation.

Consultation with the CKAs could be useful when naming some of the concepts or deciding upon the right classes to use, but that is something that can be tweaked when submitting the archetypes to a repository for broader use.

All in all, a great effort. Working with experienced editors to refine the archetypes and bring into a formally governed CKM project will further improve a novice modeller's understanding, ready for the next project and should be seen by all as a valuable component of upskilling modellers and ongoing mentoring.

Thanks for asking me to participate. I hope you feel encouraged to continue building archetypes and not put off by these comments."

5.1.1.5. DISCUSSION

It is worth noting that while only two experts participated in this evaluation, they are both globally recognised experts. As such their comments are considered highly significant by the author.

5.1.1.5.1. USEFULNESS

The concept underlying multi-level modeling and openEHR is to draw domain experts' knowledge into information systems by empowering them to become architects of

information models. If the author was unable to produce useful artifacts, it could be legitimately questioned whether the process of learning to become a clinical modeler was achievable, and, as such, whether this process was likely to be a reasonable one for other clinicians to undertake and a good use of their time. Although the scores vary from both experts, the author believes that these are encouraging given the experience that both experts possess.

It is suggested that Dr McNicoll's generally higher scores may reflect the relationship that emerged between him and the author, not necessarily from politeness, but because Dr McNicoll also had significantly more information regarding the artifacts that were produced, obtained both from the author and as a result of his professional modeling work in the area of atopic dermatitis. This is a significant point that the author feels is worth noting: it seems to the author that the greatest leaps in his understanding came from interaction with experienced modelers, rather than reading good information sources. (O)penEHR demands not just knowledge adoption, but also that physicians develop practical skills. It requires mastery, culminating in an ability to be able to sufficiently teach others the acquired skills. To enable clinician modeling requires far more than the presentation of static information. I believe that it requires an interactive environment that engages clinicians when they can engage and provides them with feedback as required. Utilising texts to achieve this process ultimately leads to frustration and vast quantities of time searching for answers that can even be difficult to articulate as questions. Texts don't typically answer the question "what am I doing wrong?" By getting formal feedback from the expert clinical modelers enabled the author to discover multiple errors he was unaware of and provided practical clarity on concepts that he was struggling with. It was also an opportunity to assess the thought process of the expert clinical modeler with respect to test cases the author had attempted to solve.

Although it is not explored in the implementation component of this thesis as ethical approval was not available to study it, the author also found particular support from a novice modeling community that evolved as a result of interactions with Ian McNicoll. Sharing experiences, questions, theories and practical examples assisted the process of learning to model. Often other novice modelers were able to identify solutions to shared conceptual roadblocks that the experienced clinical modeler might not have realised was a difficulty.

This journey finds strong resonance in contemporary perspectives on professional development and expertise. Traditionally, professional training in medicine has relied heavily on experiential learning on the part of the student or practitioner, situated,

especially in the case of the former, in an apprenticeship context. As the seminal work of Schön (Schön, 1983) has cogently argued, experiential learning for professionals is potentiated by adopting a reflective practitioner approach. Recent approaches to professional formation and ongoing professional development emphasise the complementary role of evidence-informed practice in enhancing professional effectiveness, especially where professionals act as "critical consumers" of scientific research and its applications. Of significant relevance in the context of the current research is the concept of communities of professional practice (Lave and Wenger, 1991, Boulos et al., 2006, Parboosingh, 2002), which create meaningful opportunities for professionals both to share knowledge and expertise and also to engage in shared problem-solving. As Dr McNicoll notes, “this is definitely an art not a science”.

5.1.1.5.2. COMPLEXITY

The author fully acknowledges Dr Leslie’s insightful remark that an archetype should be “complex enough to represent the data it needs to, and no more!” In medicine, the problems that cause the most concern are not the problems that we know and understand, it is the ones we don’t recognise and don’t understand: “what have I missed?” Medicine is a complicated area and without an ability to describe those complexities, we will have a difficult task of creating information systems that help us avoid those situations where we neither recognise nor understand. As such, the author was seeking to establish whether he was capable of representing complex models. It is hoped that, with time, the author will have the experience to make these complex models appear straightforward.

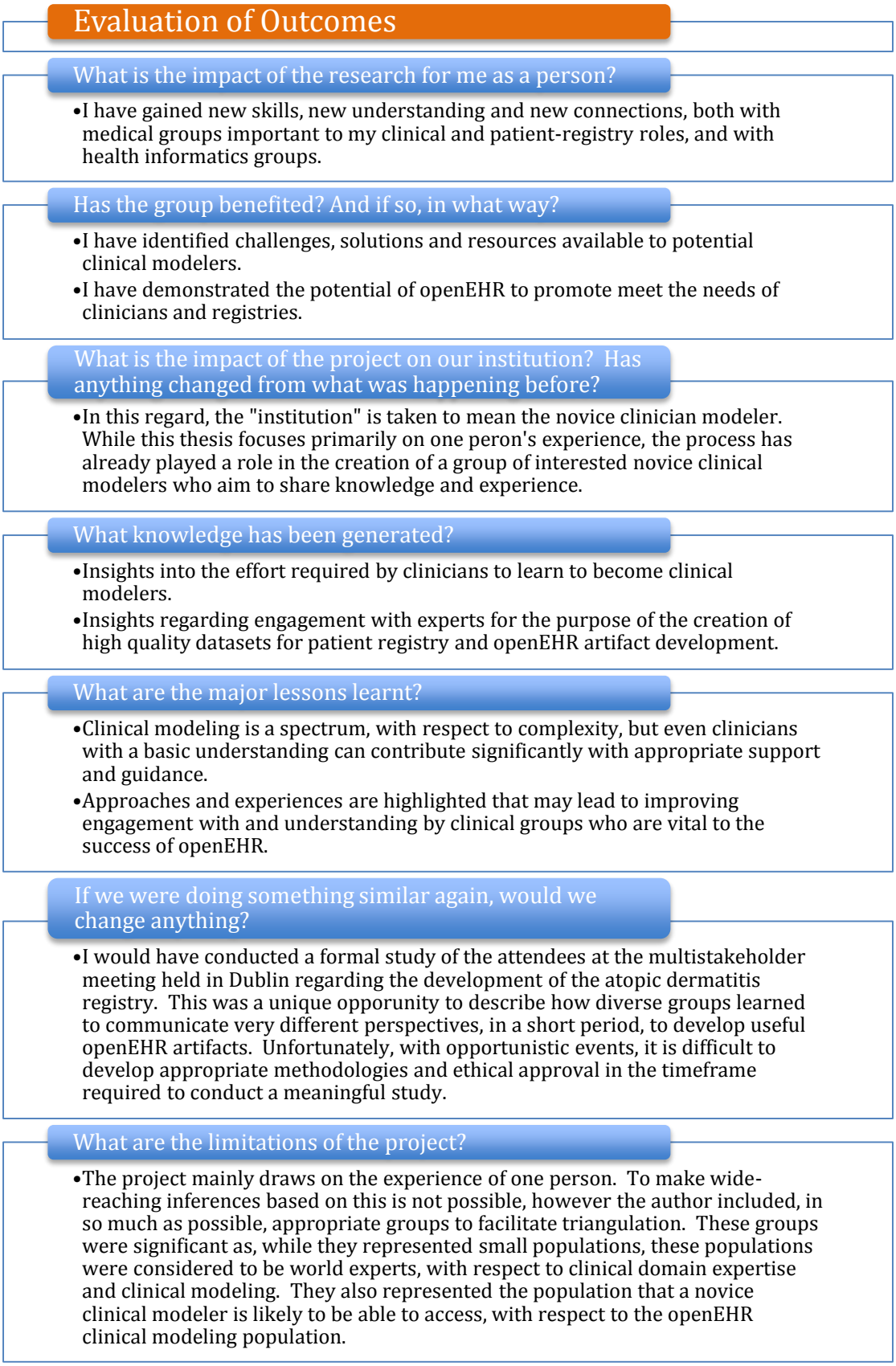
5.1.1.6. CONCLUSION

While the author lacks considerable experience and continues to make a number of significant errors, it is exceptionally reassuring to see that it is possible to make worthwhile contributions to openEHR after a short period of time learning to model. More work, it is imagined, will be required to gain a sense of comfort that the author can create rugged archetypes. This is likely to be facilitated by further interaction with the clinical modeling community. It is suggested that a demonstrator would be extremely useful to enable authors to see how their archetypes might ultimately result in artifacts that could be utilised in a clinical setting, particularly from the perspective of understanding how subtleties in modeling result in significant difference in functionality.

5.2. EVALUATION OF OUTCOMES USING AN ACTION RESEARCH REFLECTIVE DISCUSSION

The work conducted during this thesis has enabled completion of an Action Research evaluation form identified in the methodology section of this thesis (Figure 84).

Figure 84 Evaluation of Outcomes using an Action Research Reflective Discussion



5.3. ANSWERS TO QUESTIONS POSED AT THE PROEJCT AND THESIS OUTSET

5.3.1. UNDERSTANDING OPENEHR AND LEARNING TO MODEL

This thesis suggests that it is possible for clinicians to learn to model, and that there are multiple levels of proficiency and understanding that can be achieved. It is suggested that the concept of a clinician capable of developing all artifacts required, at the appropriate standard to be incorporated within a real-world system, is overly ambitious, at least for the vast majority of clinicians with limited time and resources. It is reassuring, however, that even at an early level, a valuable contribution can be made.

5.3.2. RESOURCES TO FACILITATE CLINICIANS' UNDERSTANDING OF OPENEHR AND TO LEARN TO MODEL

While the author has discovered a number of resources through a literature review and a survey of experienced modelers, it is suggested that the most critical resource that a novice clinical modeler needs to access, is the openEHR community. The engagement and support that has been afforded the author throughout this process has been exceptional and the author believes it is this interaction that has been most significant with respect to the new understanding and skills he has acquired. The author suggests that, while 2-level, or, multi-level modeling, receives appropriate attention as the key to unlocking the difficulty posed by *(Norman, 1998),* that *"We are analog beings trapped in a digital world… We are compliant, flexible, tolerant. Yet we have constructed a world of machines that requires us to be rigid, fixed, intolerant"*, it is the openEHR community, and the systems, such as the CKM, that have been developed to enable them to collaborate, that enables the key to be turned and the problem unlocked.

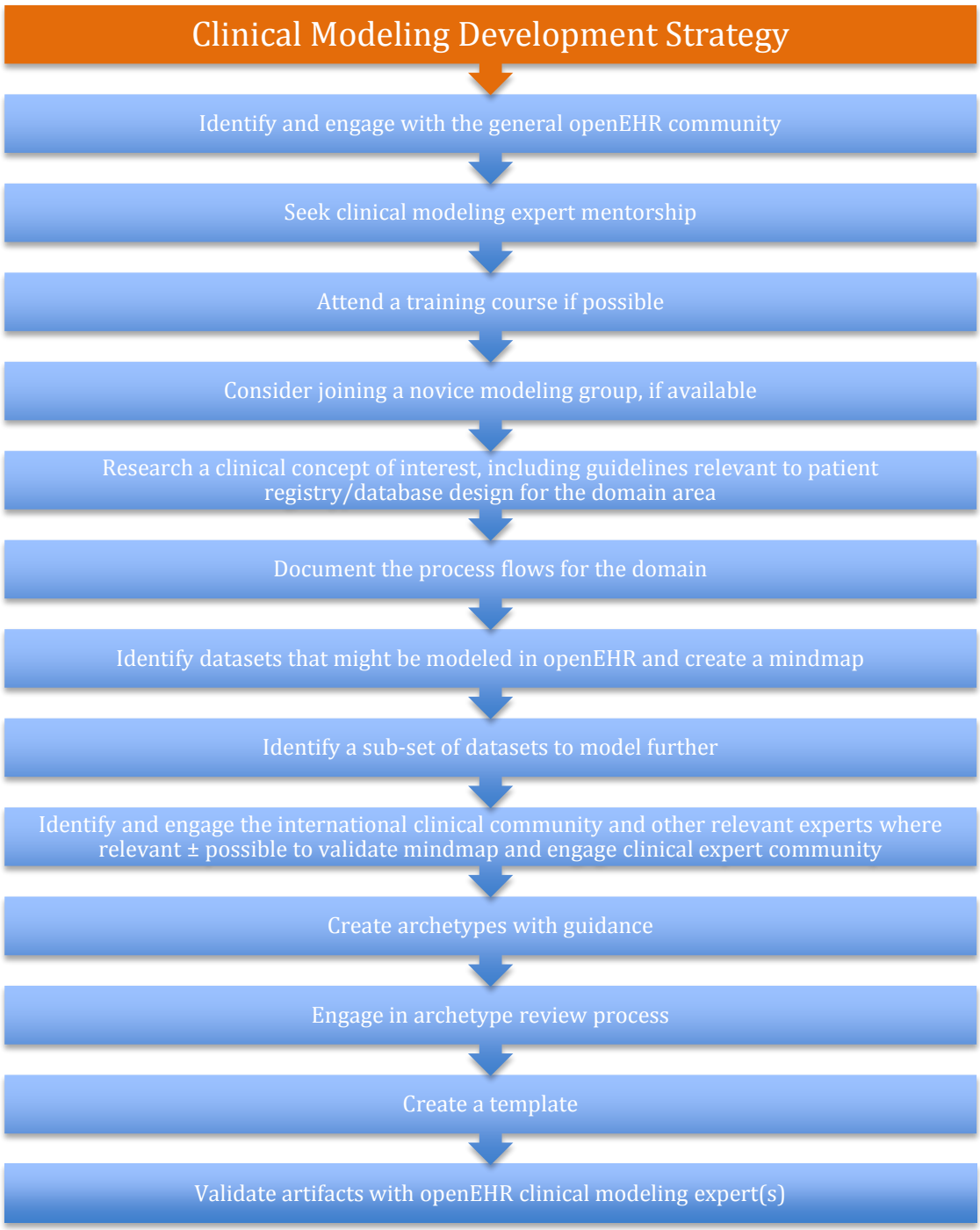
Derek Corrigan (Corrigan, 2010) questioned whether clinicians would have the time and interest to become clinical modelers. It is this author's perspective, after completing this project, that with appropriate engagement with the openEHR community, that clinicians would be likely to engage, in keeping with Dr McNicoll and Dr Leslie's published opinion (Leslie et al., 2009). This project and thesis does provide a number of suggestions that the author feels could facilitate easier engagement, such as an interactive environment to learn to model in and tooling improvement, but ultimately, Dr McNicoll's point is well taken "this is definitely an art not a science" and that the "tooling can always be improved but the main challenge in developing good modelling skills as actually around developing a good informatics understanding not how to build an archetype". As such,

the author suggests that, there is also a very significant role for the health informatician in facilitating clinician modeling as Corrigan (Corrigan, 2010) highlighted when referencing (Bernstein et al., 2005).

An action research methodology was implemented by the author to enable an honest, prospective presentation of the process of learning to model. The author believes that this approach enabled the learning process to be conducted within a context that is more likely to be representative of the one that prospective modelers are likely to face in reality. The real-world projects that provide an impetus for the busy clinician to justify the time spent producing openEHR artifacts are all likely to have associated challenges of deadlines, network building, stakeholder engagement and access to resources and guidance.

Though an excellent methodology for archetype and template development was identified, the author has not strictly adhered to this. This was not through design, but because the author required assistance to navigate the complexity. It is hoped that with time, the author will have the necessary skillset to engage more with this methodology. For the novice clinical modeler, an approach similar to the one the author adopted is proposed (Figure 85).

Figure 85 Proposed Clinical Modeling Development Strategy for novice clinical modelers



It is suggested that, in addition to providing perspective on the process of openEHR clinical modeling, that this thesis has a number of suggestions that could add to best modeling advice. The author's limited experience is accepted, however, an altered version of Corrigan's Summarised Archetype Design Methodology (Corrigan, 2010) is proposed (Figure 86 and Figure 87).

Figure 86 Proposed Summarised Archetype Design Methodology

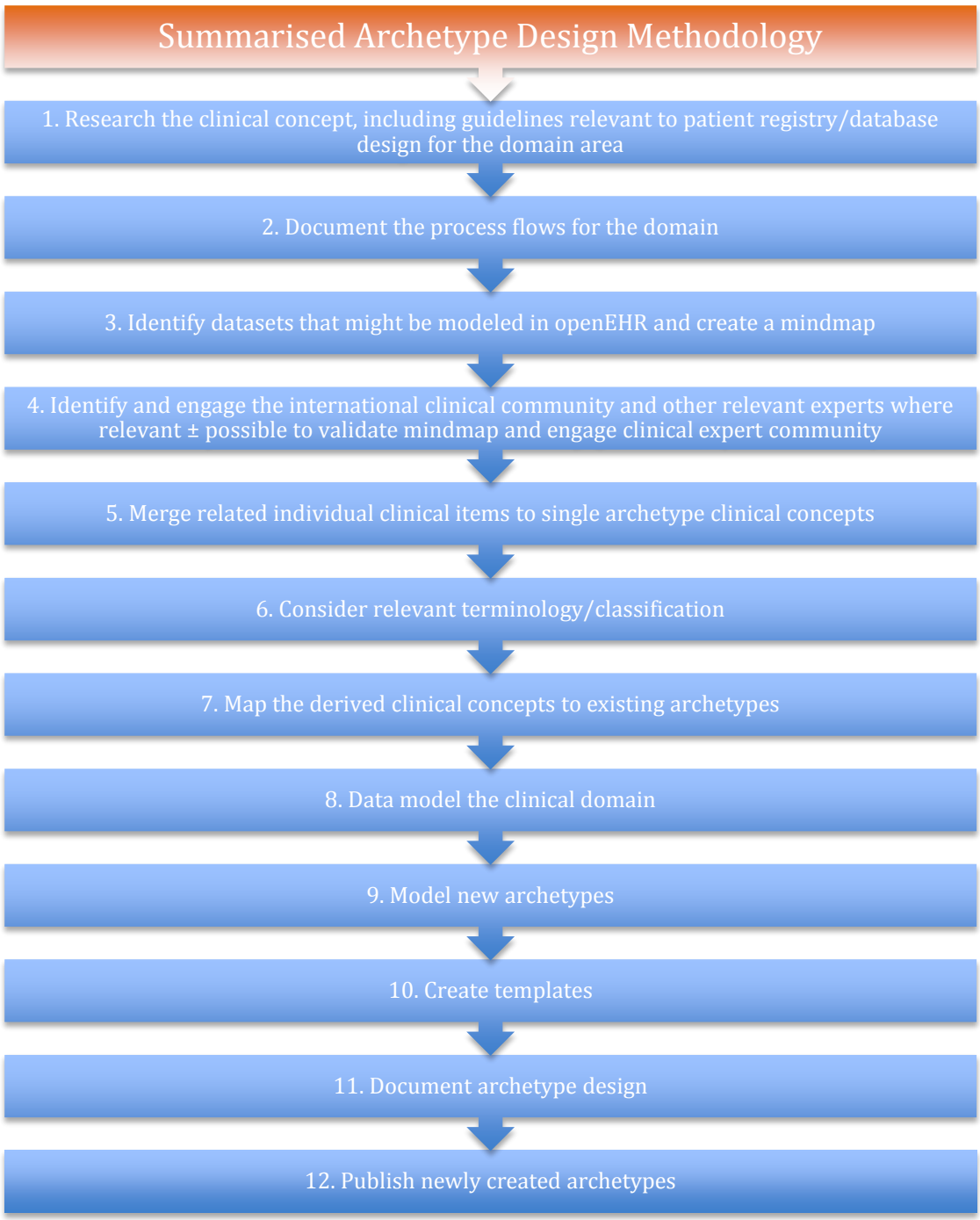
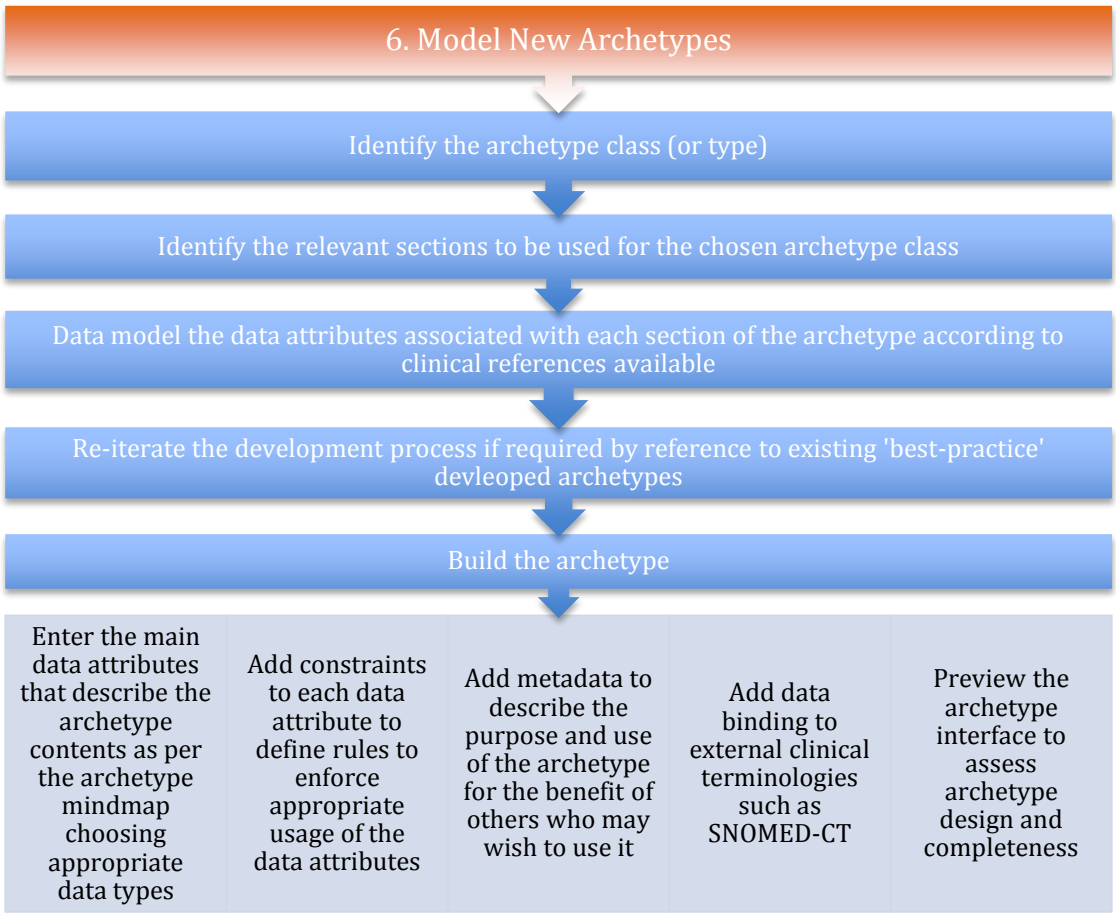
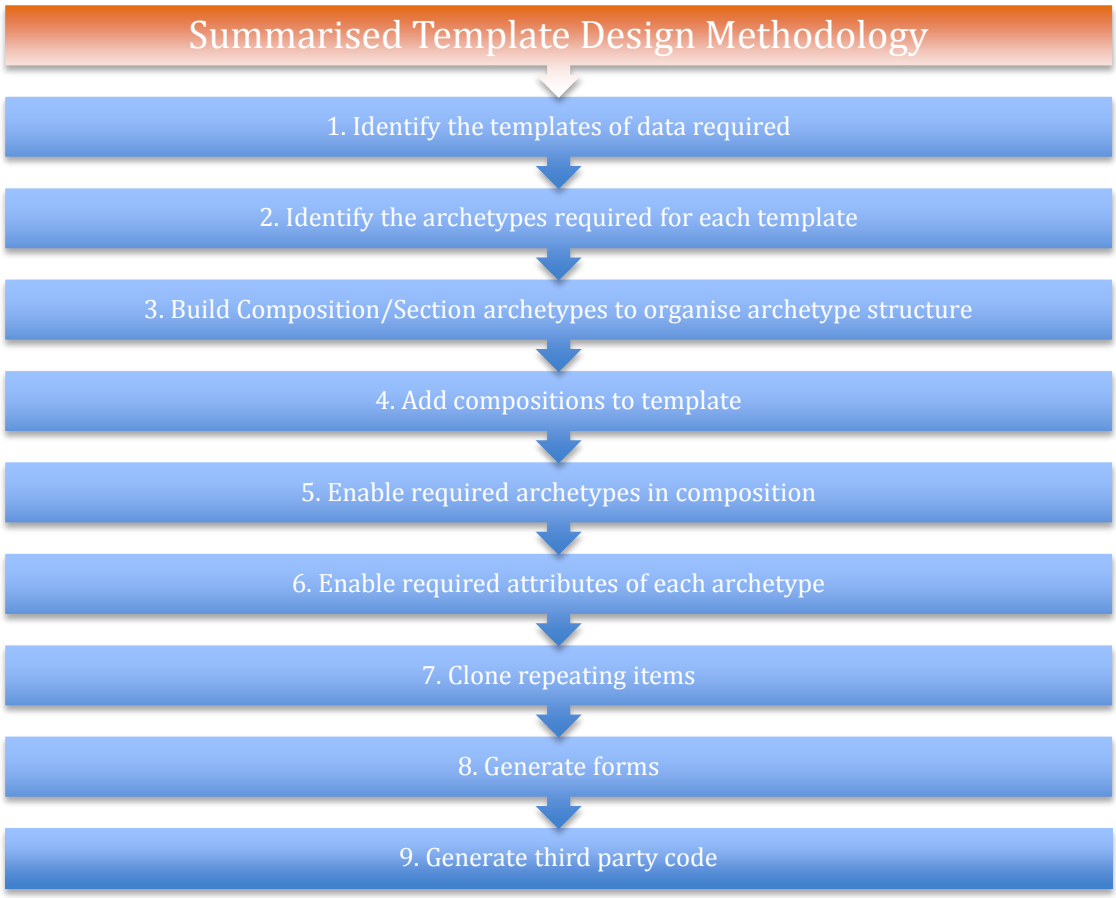


Figure 87 Proposed Archetype Modeling Methodology



There are very little changes suggested with respect to step 6 "Model New Archetypes" except that the "Research the clinical concept" step has been moved to an earlier point in the Summarised Archetype Design Methodology. No changes are suggested with respect to the Summarised Template Design Methodology proposed by Corrigan, which is reproduced again for completeness (Figure 88).

Figure 88 Summarised Template Design Methodology (Corrigan, 2010)



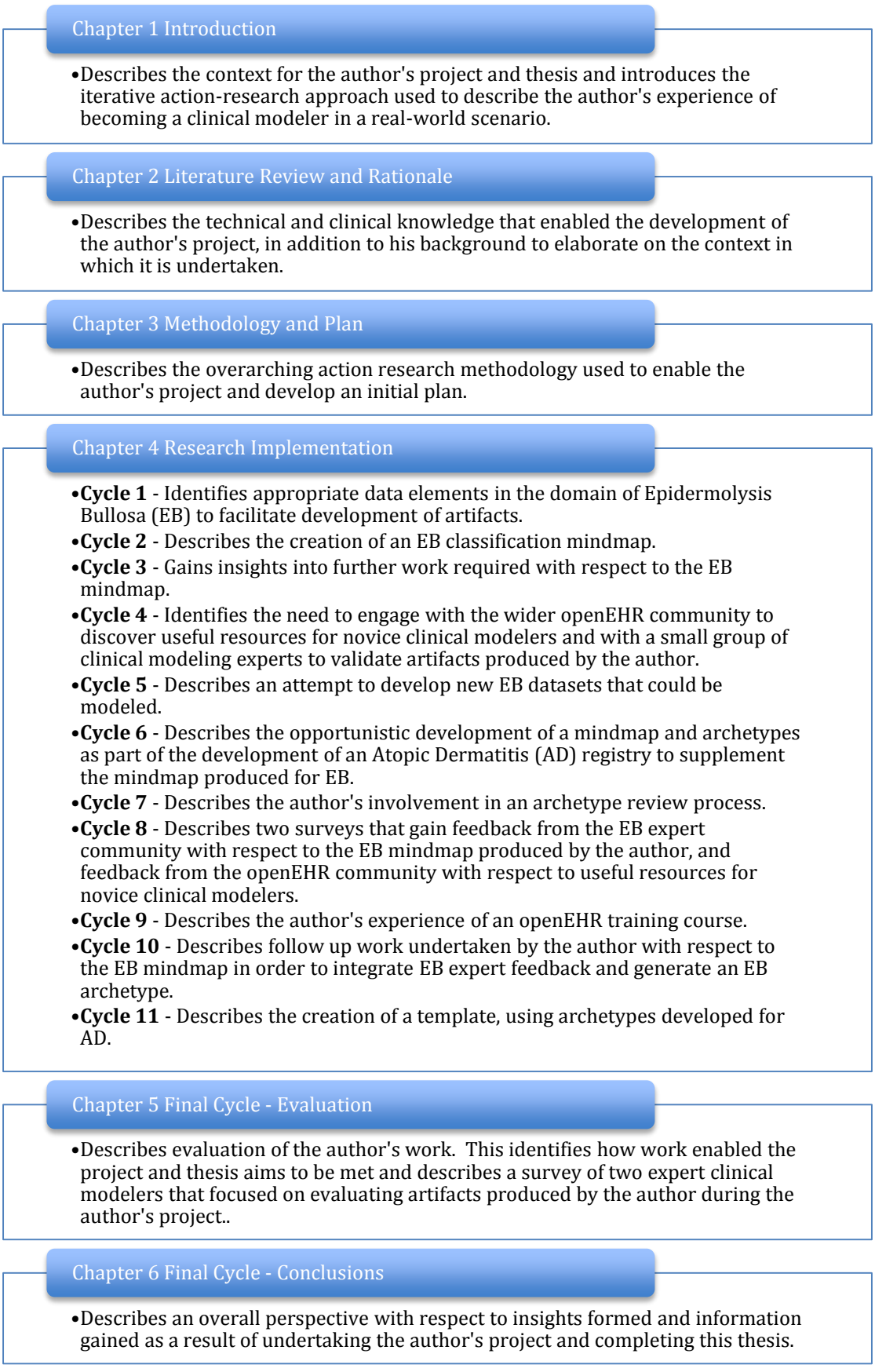
5.4. SUMMARY

It is hoped that the multiple strategies adopted to evaluate the author's project that and thesis are supportive of the methodology adopted. In the next chapter, observations and conclusions are discussed.

CHAPTER 6. FINAL CYCLE – PROJECT CONCLUSIONS

In the final section of this thesis, key conclusions that have resulted from undertaking this project are discussed. For convenience and to facilitate this section, an overview of the author's thesis is contained in Figure 89.

Figure 89 Thesis development summary



6.1. KEY THEMES

6.1.1. INTEROPERABILITY

"Interoperability is a fundamental requirement for the health care system to derive the societal benefits promised by the adoption of electronic medical records" (Brailer, 2005). By engaging with openEHR, clinicians have an opportunity to make valuable contributions that can facilitate interoperability, not only by creating information models, but also by forming networks to support these and link with useful projects such as patient registries. This thesis suggests that, while resource intensive and difficult, linking terminology and information models is of value to clinicians.

6.1.2. TOOLING AND ARTIFACT DEVELOPMENT

Many documents relating to openEHR call on improved tooling. The author's experience during his project is that the available tooling is highly developed and complex. In many cases, the author's difficulties were related to frustration and difficulty with not having the required understanding to utilise the available tools to their full potential. The addition of a wizard or support and education tool could be extremely helpful for many of the known mistakes that are often made by novice modelers.

The author suggests that improving the manner in which tools interact would be particularly helpful. The difficulty in creating such complex tools is acknowledged, however, the ability to utilise one tool to create mindmaps, process flow diagrams, archetypes and templates in an integrated fashion, could have a considerable impact on users' experience, productivity and the quality and on the consistency of artifacts produced. It is also suggested that it would be exceedingly helpful to have a facility within CKM that archives mindmaps created to inform the development of archetypes.

The author's work suggests that early engagement with expert networks, facilitated by clinical modelers, offers a useful opportunity to incorporate groups, of particular relevance to the domain being developed, who may not necessarily be likely to participate in the CKM archetype review process. The relevance of these insights may identify vital components that could be missed by clinicians unfamiliar with the domain in question at the time of CKM review. A mindmap is suggested as a useful means of facilitating this process, though the process of doing so in the author's project could be improved. The author suggests that the Delphi methodology is an attractive model to engage the clinical community, enabling the generation of high quality information sets that could be utilised to create archetypes that can be accepted internationally.

6.1.3. CONCEPTUAL DIFFICULTIES

(O)penEHR represents an ongoing challenge for the author, despite considerable advances in understanding during the course of this project. The spectrum of understanding described during this thesis, was not clear prior to undertaking this project, when the volume of difficult concepts acted as a deterrent to engagement. It is suggested that highlighting that there is a spectrum of understanding and practical ability that clinicians can reasonably expect to achieve, but that all levels contribute value is preferable to promoting a message that clinical modeling is accessible to all. It is suggested that this approach might reduce the risk of appealing only to the most technically adept individuals, rather than connecting with the large community of clinicians who could drive the success of openEHR.

The author proposes that this is a vital message to deliver to clinicians when they first encounter openEHR in the form of an "elevator pitch". With such complexity, it is difficult to imagine how this can be achieved. The author has unsatisfactorily attempted throughout his project to imagine what such an openEHR synopsis might be. One such attempt is contained in Appendix F. The focus, to date, seems to have been on getting clinicians into a technical way of thinking, rather than applying information to a physician's frame of reference. It is also suggested that an example of the practical clinical benefits openEHR adoption might deliver could be useful. An example of this, developed during the course of the author's project is also presented in Appendix F.

6.1.4. RESOURCES FOR NOVICE CLINICAL MODELERS

There are numerous resources available for the novice clinical modeler, which this thesis has attempted to highlight, many of which may not be obvious to clinicians. The author discovered that the most valuable resource during his project, however, were communities of professional practice involving experienced modelers and informaticians who can orientate and guide them, in addition to fellow novice modelers. It is suggested that a means of more quickly facilitating these connections could significantly facilitate novice clinical modeler development.

Diversity in these communities is suggested to be an important means of developing a novice clinician's appreciation of the importance of considering other perspectives. It was the author's experience that, even though more experienced modelers could provide technically proficient artifacts, valuable elements, which would otherwise have been omitted, were consistently contributed when additional perspectives were considered.

6.1.5. THE VALUE OF PATIENT REGISTRIES TO OPENEHR

The author suggests that patient registries might be of considerable benefit to the success of openEHR. This thesis suggests that they could be conducive to the development of highly interoperable information models, an ideal environment in which to train future clinician modelers, and a means to increase the penetration of openEHR for a number of reasons:

- Patient registries focus on identifying information that can be gathered to address specific research questions, resulting in:
    - Well-defined datasets, which will be easier to model than more abstract concepts.
    - The generation of networks of clinicians who can provide expert knowledge and generate valuable consensus datasets.
    - Information systems that gather outcomes focused data that are intended to be reported. This is of value to physicians, both with respect to gaining insights into their patients and the disease processes that have interested them, but also from the perspective of professional development.
- As patient registries continue to increase in importance, gaining funding and traction from their ability to drive outcomes-based medicine, they are drawing funding and favour, for example as a means of fulfilling post-marketing drug safety requirements. The integration of openEHR in their development could identify clinical modeling as an essential skill set.
- Projects such as PARENT emphasise the importance with which international governments now attach to the ability to generate high-quality information networks that are interoperable across international borders. For an organisation, such as openEHR, that aims to improve the semantic interoperability of health information, this seems like a good opportunity to become further embedded in international policy.

6.2. BENEFITS TO THE AUTHOR DURING THIS THESIS

The author believes that a number of benefits associated with learning to model in the manner outlined in this thesis were encountered, including:

- The development of information models relevant to my specialty.
- The development of collaboration between my specialty and the health informatics community.
- The development of clinical expert networks
- The facilitation of the increasing the potential of patient registries to be interoperable
- The opportunity to implement recommendations made by two European projects; EPIRARE and PARENT
- The opportunity to contribute to the 11th revision of the International Classification of Diseases and the work of Orphanet, which it is hoped will facilitate the alignment of terminology with EB archetypes
- An improved understanding about how information can be better identified, captured and used successfully, as a result of learning about how openEHR information models are constructed.

6.3. WHAT THIS THESIS ADDS

While providing further use cases relating to openEHR artifact development, in particular ones that aim to fuse electronic health records and patient registries, the author believes the main contribution made by this thesis is the description of a novice clinician's prospective perspective on learning to model using the openEHR approach. The author hopes that observations made, can facilitate the engagement of further clinical modelers. These observations are summarised, chapter-by-chapter in Figure 90, Figure 91 and Figure 92.

Figure 90 Insights developed during the course of the author's project (Chapter 1-3)

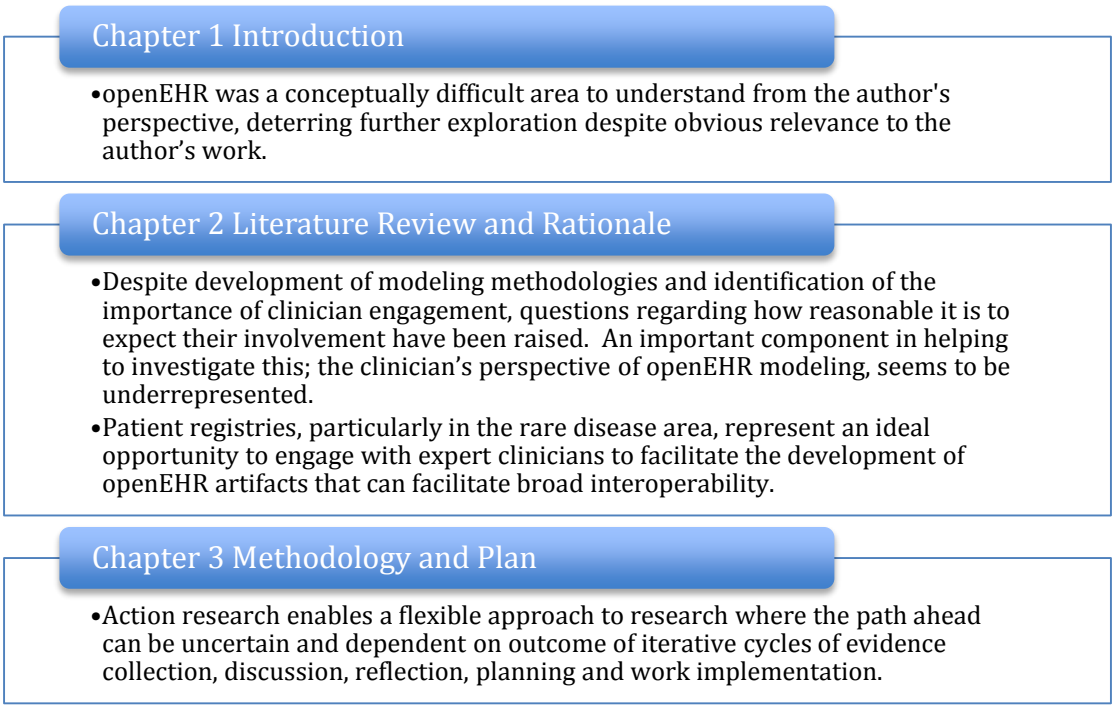


Figure 91 Insights developed during the course of the author's project (Chapter 4)

Chapter 4 Research Implementation

- **Cycle 1** - Excellent guidance is available with respect to the identification and creation of core datasets for the development of rare disease registries.
- **Cycle 2** - Mentorship from an expert clinical modeler provides enormous assistance facilitating practical modeling work. This can deviate from theoretical modeling methodology.
- **Cycle 3** - Experts and rare disease registry guidance values the mapping of datasets to coding systems and terminologies that could increase the value of an archetype for the clinician.
- **Cycle 4** - There are valuable resources for the novice clinician modeller beyond the published literature, such as in blogs.
- **Cycle 5** - The development of new datasets can be challenging, time-consuming and demand significant resources that may be difficult to obtain.
- **Cycle 6** - Registries can take a considerable time to mature to the stage where they can be comprehensively modeled.
- With modeling it is important to avail of opportunities to involve clinicians and learn from expert modelers.
- The skill required to develop mindmaps can increase significantly as datasets become more complex, but it is possible even for a novice to contribute meaningfully to their development.
- The author found archetype development to be challenging and required significant mentorship. Aspects that drew on clinical knowledge were confidence building, but sub-specialist input may be required to supplement a clinical modeler's clinical understanding.
- The Delphi methodology can facilitate achieving consensus amongst clinicians for the purpose of developing interoperable datasets.
- **Cycle 7** - Participating in the archetype review process is an extremely useful means of gaining confidence for the novice clinician and developing links with the openEHR community.
- **Cycle 8** - Even highly developed datasets may benefit significantly from review by expert clinicians before being utilised to develop openEHR artifacts both to validate the information model using a mindmap and to reveal useful insights lost during a consensus process. It is also a means of engaging with influential groups likely to use systems that can make use of the artifacts.
- There are levels of proficiency with respect to clinical modeling, but significant contributions can be made at all levels.
- Enabling direct interaction between novice and expert clinical modelers appears to this author to be essential in the engagement and development of clinical modelers.
- **Cycle 9** - An openEHR training course was immensely helpful, giving the author a tangible, rather than conceptual, sense of the potential of openEHR.
- **Cycle 10** - Supporting the linkage of terminology/classification/ontology and information models is difficult and resource intensive.
- **Cycle 11** - The skill and understanding required to develop templates is significant, but it is a powerful means of enabling the novice clinician to see "the big picture" by creating an artifact reminiscent of real-world forms that clinicians can associate with.
- A means to enable clinicians to more easily associate process flow with information model development could be of significant value.

Figure 92 Insights developed during the course of the author's project (Chapter 5)

Chapter 5 Final Cycle - Evaluation

- Even though there are significant errors within the author's modeling work, their usefullness is recognised.
- Clinical modeling is "an art not a science".
- The value of the openEHR community in supporting interoperability, facilitated by "multi-level" modeling cannot be overstated.
- Patient registries provide an excellent opportunity to build networks that can support the development of highly interoperable openEHR artifacts.
- The author's development might serve as a useful guide for would-be clinician modelers.
- Mentorship is a critical means of engaging clinicians given their time constraints.

6.4. LIMITATIONS

The author acknowledges again the difficulty in making conclusions based on one person's perspective and experience. It is hoped that the manner in which the author has involved members of the clinical and openEHR community in his project, has to some extent helped to reduce bias. It is also hoped that the extent with which the author has engaged with the openEHR community over an 11-month period has helped the author to experience a number of perspectives with respect to openEHR.

A significant question posed by Derek Corrigan is whether clinician's have the time to engage with openEHR. He also suggested that we "*need to distinguish between clinicians working in the research arena and clinicians working in the field*" (Corrigan, 2010). While the author acknowledges that his work and research were more closely aligned than would be expected of a typical clinician, thereby generating more interest in, and affording more time to, the process of learning to model, the author again notes that significant contributions can be made without investing the time that the author invested.

A further relevant point is made in Corrigan's thesis regarding limited data modeling skills. It is acknowledged that although there is a spectrum of technical capability amongst clinicians, right up to physicians who are competent programmers, the author's technical expertise and health informatics knowledge entering this thesis would be considered better than average. Again, the point is made that artifacts in this thesis have been shown to be accessible to expert clinicians in a manner that enabled valuable contributions to be made.

6.5. REFLECTIONS AND FURTHER WORK

The author hopes that this thesis has shown the journey that a clinician made to become a contributing member to the openEHR community. It is hoped that this will serve as a guide to those who wish to do similarly, or a means for other clinicians to establish whether openEHR is a methodology that can meet their needs. While the journey undertaken by the author has been a difficult and demanding one, requiring far more than he expected, the author believes it is a necessary one for other clinicians to make if we are to make the best use of patient data and deliver health information systems that meets our needs. As such the author's advice to interested clinicians will be that the author's openEHR journey has been a vastly rewarding and interesting one that is highly recommended.

This recommendation could be strengthened by further work that gathers the opinions and experience of a number of novice clinician modelers.

Furthermore, the author would welcome opinion or research regarding all opinions, suggestions and artifacts presented by the author, including:

- The Clinical Modelling Development Strategy
- The Adaptation of Corrigan's Summarised Archetype Design Methodology from more experienced modelers
- Relevant resources for novice clinician modelers identified and discussed as a result of the survey of the openEHR community
- The role and value of mindmaps for consulting with expert clinicians in clinical modeling

6.6. FINAL CONCLUSION

Ultimately, the author believes that error is the unifying concept that ran through his project and this thesis. The systems that will enable us to navigate our way through the complexities of medicine need to be designed with an understanding that, as humans, we are prone to error, even in the design of those systems and especially the clinicians who will attempt to contribute to and use those systems. The author believes that appreciating and admitting error forms a crucial part of learning and it is this belief that has motivated him to present a thesis that is candid about the errors he has made in an attempt to become a clinical modeler.

The beauty of openEHR is that it recognises that a successful medical information system will need to recognise not only the complexity and chaos of medical information,

but also the characteristics of its users: that “to err is human” (Kohn et al., 2000), as is diversity of behaviour. While the depth and flexibility of the openEHR model caters for the former, it is the collaborative communities of professional practice, ‘professionals learning from other professionals’, that have emerged that cater for the latter, designing a broad range of perspectives into clinical information models, while iteratively removing error. The guidance and understanding of these communities can enable all those who will engage to make a valuable contribution, regardless of their level of development as clinical modelers. This creates a sense that clinical modeling, though challenging and error laden, is attainable and rewarding. As such, the author claims that, to openEHR is human.

CHAPTER 7. BIBLIOGRAPHY

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CHAPTER 8. APPENDIX A – EB REGISTRIES AND DATABASES

In Chapter 2.3.5 a number of Epidermolysis Bullosa registries and databases were noted to have been identified by a literature review. These were:

- International dystrophic eb Patient Registry (2014)
- ebCare Registry (DEBRA International, 2014)
- National Epidermolysis Bullosa Registry (US) (Fine, 1999, Fine, 2010)
- EB-CLINET
- Orphanet is a "reference portal for information on rare diseases and orphan drugs" "led by a consortium of around 40 countries" (Orphanet, 2014). It lists a further 14 registries/database which contain information regarding EB.
    - Epidermolysis bullosa network (EB): the EB-SCC tissue and cell bank (Germany)
    - ROMSE: German patient registry of orofacial manifestations in rare diseases
    - LOVD-EDS VD: PLOD3 gene (procollagen-lysine, 2-oxoglutarate 4-> dioexygenase 3) variant database (United Kingdom)
    - KINDLERNET: Central patient registry Kindler syndrome (Germany)
    - International Dystrophic Epidermolysis Bullosa Patient Registry (Netherlands)
    - COL7A1 Mutation Registry - part of the International Dystrophic Epidermolysis Bullosa Patient Registry (Netherlands)
    - Human Intermediate Filament Database (United Kingdom)
    - Austrian Country Node of the Human Variome Project (HVP) (Austria)
    - Mendelian cytogenetics network online database (Denmark)

- Biobank of the Estonian genome centre (Estonia)
- Galliera Genetic Bank (Italy)
- Korean Mutation Database for Rare Diseases (Republic of Korea)
- MoHuMuDa: Moroccan Human Mutation Database
- LOVD-LMD: PLEC gene (Plectin) variant database

CHAPTER 9. APPENDIX B – ACTION RESEARCH PLANNING TOOLS

As described in Chapter 3.2.3.1, a number of tools were to facilitate planning the author's project. This included an adapted version of an Action Research Planning Sheet (Koshy et al., 2010). Two entries are demonstrated in Table 38 and Table 39.

A reflective journal was used by the author to assist in the process of reflective learning. An excerpt from the reflective log, kept using an Excel spreadsheet, is demonstrated in Table 40.

Table 38 Action Research Planning Sheet adapted from Koshy et al., 2010

Action Research Planning Sheet		
Date	11/01/15	Interim Actions: The developments in this area occurred as a result of interactions with my supervisor, reviewing the literature and presenting my thesis proposal/ literature review to my Masters Class.
Our topic of inquiry is about?	Clinicians' roles in openEHR	
Why do we wish to research this topic?	The literature and research suggests that openEHR is a promising methodology to improve data sharing. Its success is premised on the central involvement of clinicians, however debate exists regarding how feasible this is. My circumstances have placed me in an unusual position that will enable me to straddle a number of fields that will allow me to test these ideas in practice. I am hopeful that through an action research approach I can understand how a plan might be developed that maximises the capacity of physicians to engage with the openEHR model, based on my experience.	
What is the working title	To openEHR is human	
What is the research question or aspect that is the study's focus?	How accessible is openEHR to the openEHR novice clinician? Might gaps be identified that could be informed by a practical exploration of this? Are there other factors that this process can identify as important to maximising the quality of openEHR artefacts from a clinical perspective?	
What is known about this?	Mainly opinion.	
Where will the search for literature be focused?	On the research methodology, openEHR and the clinical domain which will be utilised to conduct a practical use case (registries and epidermolysis bullosa).	
Who will be involved in the research?	The international epidermolysis bullosa community and the international openEHR community and the author.	
What ethical procedures should be put in place?	Ethical approval will be required for specific data acquisition methods; 2 (general survey & specific feedback) from the openEHR community and 2 from the EB community (general feedback & specific feedback).	
What is the time-line?	Data collection complete by April 2015.	
What kind of data should be collected? Why are these needed?	General EB - to examine components of a registry & to expand on a publically available dataset, which will be modeled. Specific EB to assess whether the artefact represents the data appropriately. General openEHR to assess suitable tools and know-how from experienced clinical modelers. Specific to assess the quality of the artefacts and templates produced.	
Are the plans workable?	Possibly.	
Having completed the grid so far, does anything need to change in the plan?	There may need to be reconsideration of the number of interactions with the 2 communities. There may also need to be consideration given to how the concept of "cycles", with respect to action research, is framed.	
What are the possible outcomes of the research?	A methodology for clinicians that expands on existing openEHR modeling guidance. A resource repository of relevant information for would-be clinician modelers. Identification of further means of improving the quality/relevance of archetypes from a clinical perspective. Identification of resource needs.	
What is the final choice of topic or research question?		
Primary	Can a clinician develop an openEHR modeled epidermolysis bullosa patient registry?	
Secondary		

Table 39 Action Research Planning Sheet adapted from Koshy et al., 2010

Action Research Planning Sheet	
Date	20/01/15
Our topic of inquiry is about?	Clinicians roles in modeling utilising openEHR to develop a rare disease registry
Why do we wish to research this topic?	The literature suggests that openEHR is a promising methodology to develop interoperable health information systems. This success is premised on the central involvement of clinicians, however debate exists regarding how feasible this is. My experience with dermatology, rare diseases and registries have given me a unique opportunity to utilise an action research approach to test whether openEHR can be utilised by a physician to develop the basis of an interoperable Epidermolysis Bullosa registry and to understand how the capacity of physicians to engage with the openEHR model might be maximised, based on my experience.
What is the working title	To openEHR is human
What is the research question or aspect that is the study's focus?	How accessible is openEHR to the openEHR novice clinician? Are there gaps that could be informed by a practical exploration of this? Are there other factors that this process, or the registry development process could identify as important to maximising the quality of openEHR artefacts from a clinical perspective?
What is known about this?	There is much described in the literature regarding rare disease, registries and openEHR, however, there is little information regarding openEHR development, particularly specific to enabling the clinician to become a successful modeler. It is chiefly opinion that has been expressed with respect to the latter.
Where will the search for literature be focused?	On the research methodology, openEHR and the clinical domain which will be utilised to conduct a practical use case (registries and epidermolysis bullosa).
Who will be involved in the research?	The international epidermolysis bullosa community and the international openEHR community and the author.
What ethical procedures should be put in place?	Ethical approval will be required for specific data acquisition methods; general and specific feedback from the openEHR community and specific feedback from the EB community.
What is the time-line?	Data collection and artefact generation will need to be complete by April 2015.
What kind of data should be collected? Why are these needed?	Specific feedback from the EB community will assess whether mindmaps I generate represent EB concepts appropriately. General openEHR community feedback will assess suitable tools and know-how from experienced clinical modelers. Specific openEHR community feedback will assess the quality of the artefacts and templates produced and engage with me as I learn to model.
Are the plans workable?	Significant background work has been required to develop this project to the stage it is currently at. I believe that it is now in a position to be completed within the required timeframe.
Having completed the grid so far, does anything need to change in the plan?	This will be guided by the results of continued implementation of the plan to date.
What are the possible outcomes of the research?	A methodology for clinicians that expands on existing openEHR modeling guidance. A resource repository of relevant information for would be clinician modelers. Identification of further means of improving the quality/relevance of archetypes from a clinical perspective. Identification of resource needs.
What is the final choice of topic or research question?	
Primary	Can a clinician develop an openEHR modeled epidermolysis bullosa patient registry?
Secondary	Demonstrate what effort is involved for the clinician and identify mechanisms to ease that process. Assess whether openEHR is enough or are there other components required to improve interoperability? Assess whether there are other benefits to the rare disease and registry domain by utilising openEHR and vice versa.

Table 40 Example of the reflective log kept by the author using an Excel spreadsheet.

Reflective journal					
Date	Action	Content	Reflection	Plan	Coding
29/01/15	Email from xxxxx	Opportunity emerged to model archetypes outside EB, but related to project. Change in direction of project.	Action research approach designed to follow unplanned changes. This opportunity is reflective of real-world practice and should be embraced.	Proceed with opportunity.	
	Conversation with xxxxx	Review of greater work project. The role of openEHR in enabling it essential.	Validation of the need to utilise openEHR to ensure interoperability. Difficulty in enabling this in the context of multiple partners required to deliver success.	Proceed with understanding of difficulties involved in embracing interoperability in context of multiple partners.	
	Conversation with xxxxx	Role of the CMIO - recognised in other countries as central to success.	Interoperability is not as simple as introducing a framework - it's also about ensuring that the appropriate people are present to enable them.	Recognise as a significant concept in thesis.	
	Reading Action Research - data gathering and data analysis	Data collection and analysis - methods & considerations	Reminded me of the need and means to ensure data quality.	Review overview of reflective journal. Create this template.	Thesis genesis - operational

CHAPTER 10. APPENDIX C – ATOPIC DERMATITIS ARCHETYPES

This appendix contains the atopic dermatitis archetypes developed by the author in html format, in addition to the printable versions of 5 of the archetypes which were refined and are available within an incubator on the CKM website. These archetypes are also available on the compact disc accompanying this thesis, along with other artifacts produced during the course of the author's project.

10.1. AUTHOR DERMATOLOGY LIFE QUALITY INDEX - OPENEHR-EHR-OBSERVATION.DLQI.V1

Figure 93 Author's dlqi archetype in html format

Dlqi

Entity: Cluster

Concept description:		**Identification:**			
Dermatology Life Quality Index (DLQI)		*Id*: openEHR-EHR-CLUSTER.dlqi.v1 *Reference model*: openEHR_EHR			
Purpose	**Use**	**Misuse**	**Copyright**	**References**	**Contact**
The Dermatology Life Quality Index (DLQI) is a patient-reported outcome that is widely used in dermatology. It was developed in the 1990s as a means to easily measure, in clinical practice, the impact of skin disease on quality-of-life (1).	In adults with a skin disease.	In children.		1. Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI)—a simple practical measure for routine clinical use. Clinical and Experimental Dermatology 1994; 19: 210-6.	

Concept	**Description**	**Constraints**	**Values**
DLQI	*	*Cluster* 0..1	
DLQI symptoms	*	*Text* 10..10	Internal; 'Over the last week, how itchy, sore, painful or stinging has your skin been?', 'Over the last week, how embarrassed or self-conscious have you been because of your skin?', 'Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden?', 'Over the last week, how much has your skin influence the clothes you wear?', 'Over the last week, how much has your skin affected any social or leisure activities', 'Over the last week, how much has your skin made it difficult for you to do any sport?', 'Over the last week, has your skin prevented you from working or studying?', 'Over the last week, how much has your skin been a problem at work or studying?', 'Over the last week, how much has your skin caused any sexual difficulties?', 'Over the last week, how much of a problem has the treatment for your skin been, for exapmle by making your home messy, or by taking up time?'
Symptom severity	*	*Ordinal* 0..1	0: *Not at all/not relevant* *1: A little* *2: A lot* *3: Very much*
Total score	*	*Count* 0..1	<=30

10.2. AUTHOR ECZEMA AREA AND SEVERITY INDEX - OPENEHR-EHR-OBSERVATION.EASI.V1

Figure 94 Author's easi archetype in html format

Easi

Entity: Cluster

Concept description:	**Identification:**
unknown	*Id*: openEHR-EHR-CLUSTER.easi.v1 *Reference model*: openEHR_EHR

Purpose	**Use**	**Misuse**	**Copyright**	**References**	**Contact**
The Eczema Area and Severity Index is an instrument that was developed to enable standardized scoring of eczema/atopic dermatitis (1). 4 areas; the head/neck, trunk, upper and lower extremities are assessed and graded with respect to the area involved in case and the severity (0 = none; 1 = mild; 2 = moderate and 3 = severe) of 4 clinical signs of eczema/atopic dermatitis (erythema, oedema/papulation, excoriation and lichenification) in each area. This generates a score between 0 (no eczema) and 72.	To be used by healthcare professionals for the assessment of adults with atopic dermatitis/eczema.	In children aged 8 or less. The algorithm is similar, but multiplication factors are different, due to difference in proportional body surface area in this age group.		1. Hanifin JM, Thurston M, Omoto M, et al. The eczema area and severity index (EASI): assessment of reliability in atopic dermatitis. Experimental Dermatology 2001;10(1):11-18.	

Concept	**Description**	**Constraints**	**Values**
EASI	*	*Cluster* 0..1	
Area affected	*	*Text* 4..4	Internal; 'Head', 'Arms', 'Trunk', 'Legs'
Severity	*	*Ordinal* 0..1	0: *None* *1: Mild* *2: Moderate* *3: Severe*
Surface area	*	*Ordinal* 0..1	0: *0%* *1: 1-9%* *2: 10-29%* *3: 30-49%* *4: 50-69%* *5: 70-89%* *6: 90-100%*
Modifier	*	*Quantity* 0..1	Property =
Total score	*	*Count* 0..1	<=72
Intensity of	*	*Text* 4..4	Internal; 'Redness', 'Thickness', 'Scratching', 'Lichenification'

10.3. CKM PROVISIONAL EASI - OPENEHR-EHR-OBSERVATION.EASI.V1

Figure 95 CKM Provisional easi archetype in printable format

EASI SCORE

HEADER

Concept name	EASI score
Concept description	Atopic dermatitis EASI score.
Purpose	To record details of the Atopic dermatitis EASI score.

ATTRIBUTION

Archetype ID	openEHR-EHR-OBSERVATION.easi_score.v1
Other Identification	Canonical MD5 Hash: 1A70BBE81ECA8D50B44CDD7C95E429EF
Original Author/Publisher	Author name: Ian McNicoll Organisation: HANDIHealth,UK Email: ian@handihealth.org Date originally authored: 2015-02-18
Other Contributors	Dmitri Wall, Irish Skin Foundation
Licencing	Copyright: © openEHR Foundation

DATA

(Body area) Cluster Optional, repeating Cardinality: Mandatory, repeating	The part of the body being assessed.	Runtime name constraint: • Head and neck [Head and neck skin area.] • Upper limbs [Upper limb skin area.] • Trunk [The trunk skin area.] • Lower limbs [Lower limbs skin area.]
(Severity index) Ordinal Optional, repeating	The level of severity of the symptom for a representative part of the body area.	0: Absent [The symptom is absent.] 1: Mild [The symptom is mild.] 2: Moderate [The symptom is moderate] 3: Severe [The symptom is severe.] Runtime name constraint: • Redness [The extent of redness.] • Thickness [The thickness of the lesion.] • Crusting [The extent of crusting.] • Lichenification [The extent of lichenification.]
Affected area Ordinal Optional	The extent of the area affected.	0: 1% to 9% [1% to 9% of the body area is affected.] 1: 10% to 29% [10% to 29% of the body area is affected.] 2: 30% to 49% [30% to 49% of the body area is affected.] 3: 50% to 69% [50% to 69% of the body area is affected.] 4: 70% to 89% [70% to 89% of the body area is affected.] 5: 90% to 100% [90% to 100% of the body area is affected.]
Total EASI score Count Optional	The total EASI score.	min: >=0; max: <=72

EVENTS

Any event Event Optional	Any event.	

10.4. AUTHOR FITZPATRICK SKIN TYPE - OPENEHR-EHR-OBSERVATION.FITZPATRICK_SKIN_TYPE.V1

Figure 96 Author's Fitzpatrick skin type archetype in html format

Fitzpatrick skin type

Entity: OBSERVATION

Concept description:		**Identification:**			
Numerical schema for classifying skin colour type based on reaction to ultraviolet radiation exposure.		*Id*: openEHR-EHR-OBSERVATION.fitzpatrick_skin_type.v1 *Reference model*: openEHR_EHR			
Purpose	**Use**	**Misuse**	**Copyright**	**References**	**Contact**
The concept of skin typing was developed in 1975 in order to select correct ultraviolet A dosage for treatment of psoriasis with oral methoxsalen, known as photochemotherapy (PUVA) (1,2). It was further developed in subsequent years to include 6 types, ranging from white to black skin, characterised based on skin tolerance of ultraviolet radiation exposure (1,3,4).	Classification of skin colour type based on skin tolerance of ultraviolet radiation exposure.			1. Fitzpatrick TB. The validity and practicality of sun-reactive skin types I through VI. Archives of dermatology 1988; 124: 869-71. 2. Fitzpatrick TB. Soleil et peau. J Med Esthet 1975; 2: 33-4. 3. Pathak MA, Jimbow K, Szabo G et al. Sunlight and melanin pigmentation. In: Photochemical and photobiological reviews: Springer. 1976; 211-39. 4. Fitzpatrick T. Ultraviolet-induced pigmentary changes: benefits and hazards. Current problems in dermatology 1985; 15: 25-38.		

Data

Structure: Tree

Concept	**Description**	**Constraints**	**Values**
New element	*	*Ordinal* 0..1	1: *I* 2: *II* 3: *III* 4: *IV* 5: *V* 6: *VI*
	Slot	Include : Element	Exclude : Element

Event Series

Events	**Description**	**Constraints**
Any event	*	Event

10.5. CKM PROVISIONAL FITZPATRICK SKIN TYPE - OPENEHR-EHR-OBSERVATION.FITZPATRICK_SKIN_TYPE.V1

Figure 97 CKM provisional Fitzpatrick Skin Type archetype in printable format

FITZPATRICK SKIN TYPE

HEADER

Concept name	Fitzpatrick skin type
Concept description	Numerical schema for classifying skin colour type based on reaction to ultraviolet radiation exposure.
Keywords	Dermatology, Skin colour
Purpose	The concept of skin typing was developed in 1975 in order to select correct ultraviolet A dosage for treatment of psoriasis with oral methoxsalen, known as photochemotherapy (PUVA) (1,2). It was further developed in subsequent years to include 6 types, ranging from white to black skin, characterised based on skin tolerance of ultraviolet radiation exposure (1,3,4).
Use	Classification of skin colour type based on skin tolerance of ultraviolet radiation exposure.
References	1. Fitzpatrick TB. The validity and practicality of sun-reactive skin types I through VI. Archives of dermatology 1988; 124: 869-71. 2. Fitzpatrick TB. Soleil et peau. J Med Esthet 1975; 2: 33-4. 3. Pathak MA, Jimbow K, Szabo G et al. Sunlight and melanin pigmentation. In: Photochemical and photobiological reviews: Springer. 1976; 211-39. 4. Fitzpatrick T. Ultraviolet-induced pigmentary changes: benefits and hazards. Current problems in dermatology 1985; 15: 25-38.

ATTRIBUTION

Archetype ID	openEHR-EHR-OBSERVATION.fitzpatrick_skin_type.v1
Other Identification	Canonical MD5 Hash: F29A2B9C493C05498471AA0D7E48423E
Original Author/Publisher	Author name: Dmitri Wall Email: dmitri.wall@gmail.com Date originally authored: 2015-02-18
Other Contributors	Ian McNicoll, freshEHR, UK
Licencing	Copyright: © openEHR Foundation

DATA

Skin type Ordinal Optional	The Fitzpatrick Skin type.	1: I [Always burn, never tan] 2: II [Usually burn, tan less than average (with difficulty)] 3: III [Sometimes mild burn, tan about average] 4: IV [Rarely burn, tan more than average (with ease)] 5: V [Brown skin, rarely burns, tans profusely] 6: VI [Black skin, never burns]

EVENTS

Any event Event Optional	*	

10.6. AUTHOR INVESTIGATORS GLOBAL ASSESSMENT - OPENEHR-EHR-OBSERVATION.IGA.V1

Figure 98 Author's Investigator Global Assessment archetype in html format

Investigators Global Assessment

Entity: OBSERVATION

Concept description:	**Identification:**
The Investigators Global Assessment (IGA) is a 6 point scale. It is a severity measure intended to provide a clinically meaningful snapshot of atopic dermatitis severity that can be understood by both patients and physicians.	*Id*: openEHR-EHR-OBSERVATION.iga.v1 *Reference model*: openEHR_EHR

Purpose	**Use**	**Misuse**	**Copyright**	**References**	**Contact**
	A representative area should be chosen as a means to determine a patient's IGA.				Dmitri Wall

Data

Structure: Table

Concept	**Description**	**Constraints**	**Values**
New element	A representative area should be utilised as a means to generate this score	***Ordinal*** 0..1	0: *Clear* *1: Almost clear* *2: Mild disease* *3: Moderate disease* *4: Severe disease* *5: Very severe disease*

Event Series

Events	**Description**	**Constraints**
Any event	*	Event

10.7. CKM PROVISIONAL INVESTIGATORS GLOBAL ASSESSMENT - OPENEHR-EHR-OBSERVATION.IGA.V1

Figure 99 CKM Provisional Investigator Global Assessment archetype in printable format

INVESTIGATORS GLOBAL ASSESSMENT (ECZEMA - TREAT)

HEADER

Concept name	Investigators Global Assessment (eczema - TREAT)
Concept description	The Investigators Global Assessment (IGA) is a 6 point scale. It is a severity measure intended to provide a clinically meaningful snapshot of atopic dermatitis severity that can be understood by both patients and physicians. This version is being used by the TREAT eczema group.
Keywords	Atopic Dermatitis, Dermatology, Effectiveness outcome parameter, Severity scale
Purpose	To record a clinical assessment of the severity of atopic dermatitis. This version is being used by the TREAT eczema group.
Use	A representative area should be chosen as a means to determine a patient's IGA.

ATTRIBUTION

Archetype ID	openEHR-EHR-OBSERVATION.iga_eczema_treat.v1
Other Identification	Canonical MD5 Hash: 6075EB7C7B9C1F267D10F6932AA702F7
Original Author/Publisher	Author name: Dmitri Wall Organisation: Irish Skin Foundation Email: dmitri.wall@gmail.com Date originally authored: 2015-02-05
Current Custodian	Current contact: Dmitri Wall
Other Contributors	Ian McNicoll, freshEHR Ltd, UK
Licencing	Copyright: © openEHR Foundation

DATA

Investigator Global Assessment score Ordinal Optional	The total IGA score. Comment: A representative area should be utilised as a means to generate this score.	0: Clear [No inflammatory signs of atopic dermatitis.] 1: Almost clear [Just perceptible erythema and just perceptible papulation/infiltration.] 2: Mild disease [Mild erythema and mild papulation/infiltration.] 3: Moderate disease [Moderate erythema and moderate papulation/infiltration.] 4: Severe disease [Severe erythema and severe papulation/infiltration.] 5: Very severe disease [Severe erythema and severe papulation/infiltration with oozing/crusting.]

EVENTS

Any event Event Optional	Any event.	

10.8. AUTHOR PATIENT GLOBAL ASSESSMENT - OPENEHR-EHR-OBSERVATION.PATIENTS_GLOBAL_ASSESSMENT.V1

Figure 100 Author's Patient Global Assessment archetype in html format

Patients global assessment

Entity: OBSERVATION

Concept description:	**Identification:**
The patient's global assessment (PGA) is a 6 point scale utilised to enable a patient to describe the severity of their eczema.	*Id*: openEHR-EHR-OBSERVATION.patients_global_assessment.v1 *Reference model*: openEHR_EHR

Purpose	**Use**	**Misuse**	**Copyright**	**References**	**Contact**
	Should be used by a patient to estimate the severity of their atopic dermatitis				

Data

Structure: Tree

Concept	**Description**	**Constraints**	**Values**
PGA	*	***Ordinal*** 0..1	0: *Clear* *1: Almost clear* *2: Mild disease* *3: Moderate disease* *4: Severe disease* *5: Very severe disease*

Event Series

Events	**Description**	**Constraints**
Any event	*	Event

10.9. CKM PATIENT GLOBAL ASSESSMENT - OPENEHR-EHR-OBSERVATION.PATIENTS_GLOBAL_ASSESSMENT.V1

Figure 101 CKM provisional Patient Global Assessment in printable format

PATIENTS GLOBAL ASSESSMENT (ECZEMA - TREAT)

HEADER

Concept name	Patients global assessment (eczema - TREAT)
Concept description	The patient's global assessment (PGA) is a 6 point scale utilised to enable a patient to describe the severity of their eczema. This PGA is being utilised by the TREAT eczema group.
Keywords	Atopic Dermatitis, Dermatology, Disease severity score, Effectiveness outcome parameter, Severity scale
Purpose	To be used by a patient to estimate the severity of their atopic dermatitis. This PGA is being utilised by the TREAT eczema group.

ATTRIBUTION

Archetype ID	openEHR-EHR-OBSERVATION.patients_global_assessment_eczema_treat.v1
Other Identification	Canonical MD5 Hash: B6C16E472C7C4DE976A2D8572128ADBC
Original Author/Publisher	Author name: Dmitri Wall Organisation: Irish Skin Foundation Email: dmitri.wall@gmail.com Date originally authored: 2015-02-05
Other Contributors	Ian McNicoll
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DATA

Patient Global Assessment score Ordinal Optional	The total score.	0: Clear [Clear.] 1: Almost clear [Almost clear.] 2: Mild disease [Mild disease.] 3: Moderate disease [Moderate disease.] 4: Severe disease [Severe disease.] 5: Very severe disease [Very severe disease.]

EVENTS

Any event Event Optional	Any event.	

10.10. AUTHOR PATIENT ORIENTATED ECZEMA MEASURE - OPENEHR-EHR-OBSERVATION.POEM_SCORE.V1

Figure 102 Author's Patient Orientated Eczema Measure archetype in html format

Poem score

Entity: OBSERVATION

Concept description:		**Identification:**			
POEM (Patient-Oriented Eczema Measure)		*Id*: openEHR-EHR-OBSERVATION.poem_score.v1 *Reference model*: openEHR_EHR			
Purpose	**Use**	**Misuse**	**Copyright**	**References**	**Contact**
The Patient-Priented Eczema Measure (POEM), is a simple measure, developed "for research purposes, and to assist health care professionals such as general practitioners, dermatologists, pediatricians, and specialist nurses caring for patients in routine clinical practice"(1). It is a tool that enables		Should not be utilised in children.		1. Charman CR, Venn AJ, Williams HC. The patient-oriented eczema measure: development and initial validation of a new tool for measuring atopic eczema severity from the patients' perspective. Archives of dermatology 2004; 140: 1513-9. 2. Schram M,	
measurement of "atopic eczema severity from the patients' perspective"(1,2).				Spuls PI, Leeflang M et al. EASI, (objective) SCORAD and POEM for atopic eczema: responsiveness and minimal clinically important difference. Allergy 2012; 67: 99-106.	

Data

Structure: Tree

Concept	**Description**	**Constraints**	**Values**
Poem score	*	*Cluster* 0..1	
Frequency	*Frequency	*Ordinal* 0..1	0: *0 days* *1: 1-2 days* *2: 3-4 days* *3: 5-6 days* *4: Every day*
Symptom name	*Symptom experienced by the patient in the past week	*Text* 0..6	Internal; 'Itch', 'Sleep loss', 'Weeping', 'Cracking', 'Flaking', 'Dry or rough skin'
Total score	*	*Count* 0..1	<=28

Event Series

Events	**Description**	**Constraints**
Any event	*	Event

10.11. CKM PROVISIONAL POEM - OPENEHR-EHR-OBSERVATION.POEM_SCORE.V1

Figure 103 CKM provisional Patient Orientated Eczema Score archetype in printable format part 1

POEM SCORE

HEADER

Concept name	Poem score
Concept description	POEM (Patient-Oriented Eczema Measure).
Keywords	Atopic dermatitis, Eczema, PROM (patient-reported outcome measure)
Purpose	The Patient-Oriented Eczema Measure (POEM), is a simple measure, developed "for research purposes, and to assist health care professionals such as general practitioners, dermatologists, pediatricians, and specialist nurses caring for patients in routine clinical practice"(1). It is a tool that enables measurement of "atopic eczema severity from the patients' perspective"(1,2).
Misuse	Should not be utilised in children.
References	1. Charman CR, Venn AJ, Williams HC. The patient-oriented eczema measure: development and initial validation of a new tool for measuring atopic eczema severity from the patients' perspective. Archives of dermatology 2004; 140: 1513-9. 2. Schram M, Spuls PI, Leeflang M et al. EASI,(objective) SCORAD and POEM for atopic eczema: responsiveness and minimal clinically important difference. Allergy 2012; 67: 99-106.

ATTRIBUTION

Archetype ID	openEHR-EHR-OBSERVATION.poem_score.v1
Other Identification	Canonical MD5 Hash: 7C13C7CDA39863508C8EA92B34C35E99
Original Author/Publisher	Author name: Dmitri Wall Organisation: Irish Skin Foundation Email: dmitri.wall@gmail.com Date originally authored: 2015-02-07
Other Contributors	Ian McNicoll
Licencing	Copyright: © openEHR Foundation

DATA

Symptom score Cluster Optional, repeating Cardinality: Mandatory, repeating	The symptom score.	
Symptom name Coded Text Optional (0..6)	Symptom experienced by the patient in the past week.	• Itch [The patient experienced itch.] • Sleep loss [The patient experienced sleep loss.]

Figure 104 CKM provisional Patient Orientated Eczema Score archetype in printable format part 2

		• Weeping [The patient experienced weeping skin.] • Cracking [The patient experienced cracking of skin.] • Flaking [The patient experienced flaking skin.] • Dry or rough skin [The patient experienced dry or rough skin.]
Frequency Ordinal Optional	Frequency of the symptom.	0: 0 days [The symptom was not experienced in the past week.] 1: 1-2 days [The symptom was experienced on 1 or 2 days of the last week.] 2: 3-4 days [The symptom was experienced on 3 or 4 days of the last week.] 3: 5-6 days [The symptom was experienced on 5 or 6 days of the last week.] 4: Every day [The symptom was experienced every day of the past week.]
Total Poem score Count Optional	The total Poem score. Comment: The score is the sum of the frequencies with which all of the symptoms are experienced in the past week.	max: <=28

EVENTS

Any event Event Optional	Any event.	

CHAPTER 11. APPENDIX D - PUBLISHED ARCHETYPES

The author was involved with an archetype review process for two archetypes regarding anatomical location and relative anatomical location. Printable versions of these archetypes are included here.

11.1. ANATOMICAL LOCATION ARCHETYPE

Figure 105 Anatomical location archetype part 1/5

ANATOMICAL LOCATION

HEADER

Concept name	Anatomical location
Concept description	A physical site on or within the human body.
Keywords	location, site, anatomical, anatomic region, topographic anatomy, macroscopic, anatomic, anatomy
Purpose	To identify and record structured details about a single physical site on, or within, the human body using macroscopic anatomical terms.
Use	Use to record structured and consistent details about a single identified physical site on, or within, the human body. This archetype is specifically designed to be used within the context of any appropriate ENTRY or CLUSTER archetypes which supply the context of the anatomical location. As a fundamental part of clinical practice, clinicians can describe anatomical locations in a myriad of complex and variable ways. In practice, some archetypes carry a single data element for carrying a simple description of body site - for example, OBSERVATION.blood_pressure and CLUSTER.symptom when describing ear pain. In this situation, where the value set is predictable and simple to define, this single data element is a very accurate and pragmatic way to record the site in the body and to query at a later date. However in the situation where the anatomical location is not well defined or needs to be determined at run-time, it may be more flexible to use this structured archetype. For example, in the situation where any symptom can be recorded without any predefined scope of the type of symptom, then allowing the use of this archetype to specifically define an anatomical location in the body may be useful. In this case the CLUSTER.symptom archetype also carries a SLOT for 'Detailed anatomical location' which can include this archetype to support maximal flexibility in recording anatomical location data. This archetype supports recording complex structured anatomical sites. For example, the apex beat of the heart is typically found at the fifth left intercostal space in the mid-clavicular line, tenderness at McBurney's point on the abdominal wall or a laceration on the palmar aspect of the proximal right thumb. A combination of the data elements in this archetype can be used to individually record each component of a postcoordinated terminology expression that represents the anatomical site. The 'Alternative structure' SLOT allows inclusion of additional archetypes that provide an alternative structure for describing the same body site, such as CLUSTER.anatomical_location_relative or CLUSTER.anatomical_location_clock, should this be required. In the situation where this archetype can only be used to name a large and/or non-specific body part, the additional use of the CLUSTER.anatomical_location_relative archetype will support recording of a more precise location - for example, 2 cm anterior to the cubital fossa of the left forearm or 4 cm below R costal margin on the chest wall in the mid-clavicular line. If this archetype is used within other archetypes where the specified subject of care is not the individual for whom the record is being created, for example a fetus in-utero, then the anatomical location will be identifying a body site on or within the fetus.
Misuse	Not to be used for specifiying unilateral/bilateral occurrences of an anatomical feature.

Figure 106 Anatomical location archetype part 2/5

References	Anatomy Mapper website [Internet]. Matt Molenda, [cited 2015 Apr 27]. Available from: http://www.anatomymapper.com/.

ATTRIBUTION

Archetype ID	openEHR-EHR-CLUSTER.anatomical_location.v1 Original namespace: org.openehr Original publisher: openEHR Foundation Revision: 1.0.1 (published)
Other Identification	Build Uid: 8703b7fa-f3cb-4c17-aaee-8d2bdd13ce31 Major Version ID: 2fe9e9f8-adfd-4406-878a-82b38ef498a9 Canonical MD5 Hash: 910D849C4514BA7DB4D5812F30AF63D6
Original Author/Publisher	Author name: Heather Leslie Organisation: Ocean Informatics Email: heather.leslie@oceaninformatics.com Date originally authored: 2008-11-10
Current Custodian	Custodian Organisation: openEHR Foundation Custodian Namespace: org.openehr Current contact: Heather Leslie, Ocean Informatics, heather.leslie@oceaninformatics.com
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Translators	*Slovenian:* Biljana Princic *Norwegian Bokmål:* Lars Bitsch-Larsen, Haukeland University Hospital of Bergen, Norway, MD, DEAA, MBA, spec in anesthesia, spec in tropical medicine. *Arabic (Syria):* Mona Saleh
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Figure 107 Anatomical location archetype part 3/5

	http://creativecommons.org/licenses/by-sa/3.0/.

ITEMS

Body site name T Text Mandatory	Identification of a single physical site either on, or within, the human body. Comment: This data element is the only mandated data point in this archetype and should be used as the primary data point to record an anatomical location with a commonly used name. It is strongly recommended that 'Body site name' be recorded as specifically as is anatomically possible. For example: record 'upper eyelid' rather than recording 'eyelid' with 'upper' as a qualifier; 'fifth rib' rather than 'rib' with a numeric qualifier. Use the other data elements for laterality, aspect, region and anatomical line to provide more detail. This data element should be coded with a terminology capable of triggering decision support, where possible - an appropriate termset for use here could comprise individual concepts or a list of precoordinated terms. Free text should be used only if there is no appropriate terminology available.	
Specific site T Text Optional	Additional detail using a specific region or a point on, or within, the identified body site. Comment: Use to increase precision of identification of the body site, if required. For example, the upper right quadrant or McBurney's point on the abdominal wall or interphalangeal joint of the great toe. If the 'Body site name' data element uses pre-coordinated terms that include the specific site, then this data element is redundant.	
Laterality T Coded Text Optional [**SNOMED-CT**::272741003] (Laterality (attribute))	The side of the body on which the identified body site is located. Comment: If the identified body site has no laterality, this data element should not have a value. If the 'Body site name' data element uses pre-coordinated terms that include laterality, then this data element is redundant.	• Left [Left side of the body.] [**SNOMED-CT**::419161000] (Unilateral left (qualifier value)) • Right [Right side of the body.] [**SNOMED-CT**::419465000] (Unilateral right (qualifier value))

Aspect
Choice
Optional (0..2)
	Qualifying detail about the specific aspect of the identified body site.
	Comment: Use to increase precision of identification of the body site, if required. Common aspects have been included as a value set, which can be extended over time, plus a free text option. Assumes that the body is being described while in the anatomical position. For example:
		Choice of:
		• T Coded Text
		  ◦ Medial [Towards the midline of the body site.]
		  ◦ Lateral [Towards the side, or edge, of the body site.]
		  ◦ Superior [Above the body site, often meaning towards the head.]

Figure 108 Anatomical location archetype part 4/5

	proximal urethra; plantar aspect of the left thumb. Multiple aspects can also be described, if required, by allowing for 0..2 occurrences. For example: a lesion may be on the left anterior/lateral (ie anterolateral) chest wall. If the 'Body site name' data element uses pre-coordinated terms that include the aspect, then this data element is redundant.	○ Inferior [Below the body site, often meaning towards the feet.] ○ Anterior [Towards the front, or ventral surface, of the body site.] ○ Posterior [Towards the back, or dorsal surface, of the body site.] ○ Proximal [More central or closer to the point of attachment, and usually describing part of a limb, digit or appendage.] ○ Distal [More peripheral, or further from the point of attachment, and usually describing part of a limb, digit or appendage.] ○ Palmar [Towards the palm of the hand.] ○ Plantar [Towards the sole of the foot.] ○ Mid [In the middle of the body site.] ○ Oral [Towards the mouth. Usually used to describe locations within the digestive system.] ○ Anal [Towards the anus. Usually used to describe locations within the digestive system.] • T Text
Anatomical Line Choice Optional	Additional detail using theoretical lines drawn through anatomical structures used to provide a consistent reference point on the human body. Comment: Common anatomical lines have been included as a value set, which can be extended over time, plus a free text option. The additional use of this data element allows for recording of the typical position of the heart's apex beat at 5th intercostal space, left side, and mid-clavicular line. If the 'Body site name' data element uses pre-coordinated terms that include anatomical line, then this data element is redundant.	*Choice of:* • T Coded Text ○ Midline [Line running vertically which divides the body into left and right portions, passing through the head, spinal cord, and umbilicus. Alternatively it can refer to a line dividing a body part into two equal portions, for example a digit.] ○ Midaxillary line [Line running vertically down the surface of the body, passing through the apex of the axilla.] ○ Anterior axillary line [Line running vertically down the surface of the body, passing through the anterior axillary skinfold.] ○ Posterior axillary line [Line running vertically down the surface of the body, passing through the posterior axillary skinfold.] ○ Mid-clavicular line [Line running vertically down

Figure 109 Anatomical location archetype part 5/5

		the surface of the body, parallel to the midline and passing through the midpoint of the clavicle.] ◦ Mid-pupillary line [Line running vertically down the face through the midpoint of the pupil when looking directly forward.] ◦ Mid-scapular line [Line running vertically down the posterior surface of the body, parallel to the midline and passing through the inferior point of the scapula.] • T Text
Description T Text Optional	Narrative description that can be used to further refine and support the 'Body site name'. Comment: For example: adjacent to the vermilion border; a tattoo covers the bottom half of this area.	
Alternative structure SLOT (Cluster) Optional, repeating	Additional detail about the anatomical site using alternative approaches to describe the same body site. Comment: For example, relative location or precise locations using coordinates.	**Include:** openEHR-EHR-CLUSTER.anatomical_location_relative.v1 and specialisations *Or* openEHR-EHR-CLUSTER.anatomical_location_clock.v1
Multimedia representation SLOT (Cluster) Optional, repeating	Image or other media used to support identification of the body site.	**Include:** openEHR-EHR-CLUSTER.multimedia.v1 and specialisations

11.2. RELATIVE ANATOMICAL LOCATION ARCHETYPE

Figure 110 Relative anatomical location archetype part 1/4

RELATIVE ANATOMICAL LOCATION

HEADER

Concept name	Relative anatomical location
Concept description	A physical site on or within the human body that is described in terms of its relationship to other body parts.
Keywords	location, site, anatomical, relative, approximate, anatomic region, topographic anatomy, macroscopic anatomy, macroscopic, anatomic, anatomy
Purpose	To identify and record structured details about a single physical site on, or within, the human body in terms of its relationship to other macroscopic anatomical landmarks.
Use	Use to record structured and consistent details about a single identified physical site on, or within, the human body by describing its location in relation to identified macroscopic anatomical landmarks. It may be necessary to describe the single physical location using more than one relative location - for example, 2 cm inferior to 'landmark A' AND 3 cm medial to 'landmark B'. In practice, some archetypes carry a single data element for carrying a simple description of body site - for example, OBSERVATION.blood_pressure and CLUSTER.symptom when describing ear pain. In this situation, where the value set is predictable and simple to define, this single data element is a very accurate and pragmatic way to record the site in the body and to query at a later date. However in the situation where the anatomical location is not well defined or needs to be determined at run-time, it may be more flexible to use this structured archetype. This archetype is specifically designed to be used within the context of any appropriate ENTRY or CLUSTER archetypes which supply the context of the identified body site, including insertion within the CLUSTER.anatomical_location if 'Body site name' or other data elements are also required. Clinical use cases: - 5 cm inferior to the left tibial tuberosity - 2 cm medial to the right nipple - medial aspect of R great toe nail. In the situation where the CLUSTER.anatomical_location can only be used to name a large and/or non-specific body part, the use of this archetype within the 'Alternative Structure' SLOT will support recording of a more precise location - for example, 2 cm anterior to the cubital fossa of the left forearm or 4 cm below R costal margin on the chest wall in the mid-clavicular line.
Misuse	Not to be used for specifying unilateral/bilateral occurrences of an anatomical feature. Not to be used to specify a simple location of a named physical site in the body, such as left femur or medial aspect of nose. Use the CLUSTER.anatomical_location archetype for this purpose.

ATTRIBUTION

Archetype ID	openEHR-EHR-CLUSTER.anatomical_location_relative.v1 Original namespace: org.openehr Original publisher: openEHR Foundation Revision: 1.0.0 (published)

Figure 111 Relative anatomical location archetype part 2/4

Other Identification	Build Uid: be02a9db-adaa-4b4d-97f5-daaf828f4b84 Major Version ID: cf6935cb-7093-41eb-ac6d-b0319ff7a3c4 Canonical MD5 Hash: E2EF0C2B197F39A65D7A5489BF587C2B
Original Author/Publisher	Author name: Heather Leslie Organisation: Ocean Informatics Email: heather.leslie@oceaninformatics.com Date originally authored: 2008-11-10
Current Custodian	Custodian Organisation: openEHR Foundation Custodian Namespace: org.openehr
Other Contributors	Tomas Alme, DIPS, Norway Vebjoern Arntzen, Oslo university hospital, Norway Koray Atalag, University of Auckland, New Zealand Gustavo Bacelar-Silva, Healthcare Designs, Brazil (openEHR Editor) Silje Ljosland Bakke, Bergen Hospital Trust, Norway Lars Bitsch-Larsen, Haukeland University hospital, Norway Aitor Eguzkitza, UPNA (Public University of Navarre) - CHN (Complejo Hospitalario de Navarra), Spain Shahla Foozonkhah, Ocean Informatics, Australia Einar Fosse, National Centre for Integrated Care and Telemedicine, Norway Sebastian Garde, Ocean Informatics, Germany Heather Grain, Llewelyn Grain Informatics, Australia Dunmail Hodkinson, Black Pear Software Ltd, UK Lars Karlsen, DIPS ASA, Norway Shinji Kobayashi, Kyoto University, Japan Sabine Leh, Haukeland University Hospital, Department of Pathology, Norway Heather Leslie, Ocean Informatics, Australia (openEHR Editor) Vesna Levasic, Orthopaedic Hospital Valdoltra, Slovenia Hallvard Lærum, Oslo University Hospital, Norway Luis Marco Ruiz, Norwegian Center for Integrated Care and Telemedicine, Norway Ian McNicoll, freshEHR Clinical Informatics, United Kingdom (openEHR Editor) Bjoern Naess, DIPS ASA, Norway Andrej Orel, Marand d.o.o., Slovenia Rowan Thomas, St. Vincent's Hospital Melbourne, Australia Richard Townley-O'Neill, NEHTA, Australia John Tore Valand, Helse Bergen, Norway Dmitri Wall, Irish Skin Foundation, Ireland
Translators	*Slovenian:* Biljana Princic *Norwegian Bokmål:* Lars Bitsch-Larsen, Haukeland University Hospital of Bergen, Norway, MD, DEAA, MBA, spec in anesthesia, spec in tropical medicine. *Arabic (Syria):* Mona Saleh
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ITEMS

Relative location Cluster Optional, repeating Cardinality: Mandatory, repeating	Detail to identify a single physical site either on, or within, the human body in terms of its relationship to other macroscopic anatomical landmarks. Comment: More than one relative location may be required to provide an accurate cross reference.	
Landmark name Text	Identified body site used as a reference point for the actual body site.	

Figure 112 Relative anatomical location archetype part 3/4

Mandatory	Comment: 'Landmark name' can identify an anatomical structure (such as the umbilicus), an anatomical line (such as the mid-clavicular line), a well defined anatomical point (such as McBurney's point). This data element should be coded with a terminology capable of triggering decision support, where possible - an appropriate termset for use here could comprise individual concepts or a list of precoordinated terms. Free text should be used only if there is no appropriate terminology available. It is strongly recommended that 'Landmark name' be recorded as specifically as is anatomically possible. For example: record 'upper eyelid' rather than recording 'eyelid' with 'upper' as a qualifier; 'fifth rib' rather than 'rib' with a numeric qualifier.	
Laterality T Text Optional	The side of the body on which the identified landmark is located. Comment: If the identified landmark has no laterality, this data element should not have a value. If the 'Landmark name' data element uses pre-coordinated terms that include laterality, then this data element is redundant.	
Distance from landmark Q Quantity Optional	Distance of location from the identified landmark.	Property: Length Units: • >=0.0 cm Limit decimal places: 1..1 • >=0.0 in Limit decimal places: 1..1 • >=0.0 mm Limit decimal places: 1..1
Direction Choice Optional (0..6)	Detail about the relative direction of the body site to the landmark. Comment: Common aspects have been included as a value set, which can be extended over time, plus a free text option. Assumes that the body is being described while in the anatomical position. Occurrences are set to allow for a maximum of six directions to be recorded. Within this value set, clinicians will recognise that there are six mutually exclusive directional pairs - for example, a body site cannot be simultaneously 'medial to' and 'lateral to' an identical landmark. Other mutually exclusive pairs are 'Superior to' and 'Inferior to'; 'Anterior to' and 'Posterior to'; 'Proximal to' and 'Distal to'; 'Superficial to' and 'Deep to'; and 'Within' and 'External to'. Combinations made from one selection from within each of the six pair sets is potentially valid, although	*Choice of:* • T Coded Text ◦ Medial to [Towards the middle, from the landmark.] ◦ Lateral to [Towards the side, from the landmark.] ◦ Superior to [Above the landmark, often referring towards the head.] ◦ Inferior to [Below the landmark, often referring towards the feet.] ◦ Anterior to [Towards the front, or ventral aspect, from the landmark.] ◦ Posterior to [Towards the back, or dorsal aspect, from the landmark.] ◦ Proximal to [Closer to the body, relative to the landmark.] ◦ Distal to [Further from

Figure 113 Relative anatomical location archetype part 4/4

	in clinical practice it will be very unlikely to need to simultaneously record more than two directions to describe a specified body site.	the body, relative to the landmark.] ○ Superficial to [Nearer the outer surface, relative to the landmark.] ○ Deep to [Further away from the outer surface, relative to the landmark.] ○ Within [Inside the landmark.] ○ External to [Outside the landmark.] ○ Oral to [Towards the mouth. Usually used to describe locations within the digestive system.] ○ Anal to [Towards the anus. Usually used to describe locations within the digestive system.] • T Text
Description T Text Optional	Narrative description that can be used to further refine and support the relative location structured data. Comment: For example: a tattoo covers the bottom half of this area.	
Multimedia representation SLOT (Cluster) Optional, repeating	Image or other media used to support identification of the location on the body.	**Include:** openEHR-EHR-CLUSTER.multimedia.v1 and specialisations

CHAPTER 12. APPENDIX E – SURVEY QUESTIONNAIRES

This appendix contains images of the printed version of the surveys undertaken in the author's project and described in this thesis. The information and consent forms given to participants are included within the questionnaires.

12.1. SURVEY 1 "INVESTIGATING THE VALUE OF CONSULTATION WITH EXPERT CLINICIANS IN CLINICAL MODELING"

Investigating the value of consultation with expert clinicians in clinical modeling

Informed consent

Many thanks for agreeing to take this survey. Before progressing, your consent to participate is required.

You will have received an information leaflet and consent form via the post. These are presented again below for your convenience. By confirming that you have read these and consent to participate in the question that follows them it will be possible to progress to the survey by pressing the "next" button at the bottom of the screen.

Trinity College Dublin
Information Sheet re: Investigating the value of consultation with expert clinicians in clinical modeling

Background of Research: Registries are recognized as an important means to collect patient data for scientific, clinical and policy purposes. Unfortunately, many registries have emerged which have been unable to share the useful data they contain. Best practice advice from European projects, such as PARENT JA (PAtient REgistries iNiTiative Joint Action), which have been established to improve the quality of registries and their ability to share information, has pointed towards strategies to overcome that limitation. The openEHR approach, which emerged in the electronic health record domain, is one such strategy. It was designed to enable clinicians to directly describe how information in their area of clinical specialisation should be organized without relying on technical experts to interpret them instead. This is achieved by creating archetypes and templates. An archetype is a means of representing a maximum dataset for a particular clinical concept, while templates are means to specify what components of multiple archetypes are required in potential clinical situations. In this manner, broad standardization of health information can occur, but an ability to tailor information capture for any particular setting is maintained. Archetypes and templates can be made visible, via a web-accessible portal (Clinical Knowledge Manager), to a global network of openEHR experts and users who ensure quality and standardization in a well-governed review process.

Though the openEHR approach has huge potential, the literature suggests that it requires the investment of considerable resources. There is also considerable debate regarding the feasibility of expecting busy clinicians to become successful openEHR modelers.

The author, a dermatology trainee, is currently employed by an Irish charity, the Irish Skin Foundation, to coordinate the development of a number of dermatology patient registries, of which one is an epidermolysis bullosa (EB) registry. It is aimed to develop these registries to be highly interoperable and as such have the potential to become international registries. The openEHR approach has been identified as a means to facilitate this. The author will use this opportunity to conduct a thesis, the primary aim of which is to ascertain whether a clinician such as this author, can, using the openEHR approach, develop information models of appropriate quality to contribute to the development of an international standard registry.

One component of the archetype development process can include the development of diagrammatic representations of clinical content in the form of a mindmap. As such, the author has created a mindmap of the classification of EB based on the published consensus document "Inherited epidermolysis bullosa: Updated recommendations on diagnosis and classification"(Fine et al., 2014). **The purpose of this study, which will form part of the author's thesis and for which your involvement is requested, is to investigate the value of clinical experts reviewing models which have been based on their published opinion and whether a mindmap is a useful means of doing this.**

1

It is proposed that, following this consultation with EB experts, the classification will be submitted for inclusion in ICD-11 (International Classification of Diseases) and SNOMED-CT (Systematized Nomenclature of Medicine-Clinical Terms) to update the current classification, in line with current international opinion. With respect to this thesis, this is a means of demonstrating the practical value of a clinician modeler's work. This will also be of value to the development of the EB patient registry noted above.

Relevant procedures: You have been invited to participate in this research in view of your involvement in the classification of epidermolysis bullosa (EB). As a clinical expert in this field, you will be asked to review the EB classification mindmap, which will be posted to you. You will be then be asked to complete a short SurveyMonkey® survey, which will be emailed to you, regarding:

1. How easy it is to read and understand the mind map (Likert scale + free text comment box).
2. If the mind map is an accurate representation of the classification of EB (Likert scale + free text comment box).
3. If the mind map is a useful representation of the classification of EB (Likert scale + free text comment box).
4. Further comment is possible in a final free text comment box.

In the event that you note any errors or opportunities for improvement, you are invited to amend these on the mindmap, which can be returned using the addressed envelope provided. These amendments will be analysed and considered for incorporation in the final representation of the classification.

Conflicts of Interest: The author is a research fellow with the Irish Skin Foundation and is coordinating the development of registries in a number of dermatology domains. This project has given the author access to expert clinicians in these domains.

Participation: Your participation is voluntary and you can withdraw your consent at any time or omit individual responses without penalty. In the event that you wish to withdraw from the study, your data will be manually deleted by the author.

Duration of involvement: It is expected that this study will take approximately 10-30 minutes of your time.

Anticipated risks/benefits of participation: It is anticipated that your participation will inform the development of a patient registry that aims to be of significant value to the EB population. It is also expected that participation will enable the author to submit work that will increase the visibility of the participants' work.

Debriefing after participation: I would be delighted to share the results of this study and thesis with you on request.

Preservation of participant and third-party anonymity: This is not applicable with respect to the collection of data in the context of this study; however, your specific responses will be anonymised with respect to reporting, subject to your approval.

Discovery of illicit activities: If you make illicit activities known, these will be reported to appropriate authorities

Reference: FINE, J.-D., BRUCKNER-TUDERMAN, L., EADY, R. A. J., BAUER, E. A., BAUER, J. W., HAS, C., HEAGERTY, A., HINTNER, H., HOVNANIAN, A., JONKMAN, M. F., LEIGH, I., MARINKOVICH, M. P., MARTINEZ, A. E., MCGRATH, J. A., MELLERIO, J. E., MOSS, C., MURRELL, D. F., SHIMIZU, H., UITTO, J., WOODLEY, D. & ZAMBRUNO, G. 2014. Inherited epidermolysis bullosa: Updated recommendations on diagnosis and classification. Journal of the American Academy of Dermatology, 70, 1103-1126.

TRINITY COLLEGE DUBLIN

Informed Consent Form re: Investigating the value of consultation with expert clinicians in clinical modeling

LEAD RESEARCHER: Dmitri Wall

BACKGROUND OF RESEARCH: The aim this study is to investigate the value of clinical experts reviewing models, which have been based on their published opinion, and whether a mindmap is a useful means of doing this. This study forms part of a thesis designed to understand the role of a clinician in developing openEHR information models in the context of the development of internationally interoperable registries. This is discussed in more detail in the associated information literature.

PROCEDURES OF THIS STUDY: As a clinical expert in the field of epidermolysis bullosa (EB), you will be asked to complete a short SurveyMonkey® survey regarding the mindmap noted above. This is explained in greater detail in the accompanying information literature. The survey is expected to take approximately 10-30 minutes. No risks are anticipated with respect to your participation.

PUBLICATION: The information provided and the process associated with obtaining this information will be incorporated within the author's thesis. The information will also be used to inform the development of a prototype, interoperable EB patient registry. The classification will be submitted for consideration for inclusion in ICD and SNOMED-CT as a revision of existing content.

DECLARATION:

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
- I understand that if I make illicit activities known, these will be reported to appropriate authorities.
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
- I understand that I may request that my participation is made fully anonymous and in such circumstances, that no personal details about me will be recorded.
- I understand that if I or anyone in my family has a history of epilepsy then I am proceeding at my own risk
- I have received a copy of this agreement.

PARTICIPANT'S NAME:_____

PARTICIPANT'S SIGNATURE: _____ **Date:**

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

RESEARCHERS CONTACT DETAILS:
Email: walldm@tcd.ie; **Phone:** 00 353 87 9932777

INVESTIGATOR'S SIGNATURE:_____ Date:

* 1. I have read the information leaflet and consent form and I consent to proceed with this survey.

○ Yes

3

Investigating the value of consultation with expert clinicians in clinical modeling

Mind map feedback

Each question in the survey is optional. Feel free to omit a response to any question; however the researcher would be grateful if all questions are responded to.

You will have received a diagrammatic (mind map) representation of the classification of epidermolysis bullosa based on the published consensus document "Inherited epidermolysis bullosa: Updated recommendations on diagnosis and classification" (Fine et al., 2014). With this in mind I would be extremely grateful if you could answer the following questions.

2. How easy it is to read and understand the mind map?

very difficult	difficult	average	easy	very easy
○	○	○	○	○

Please comment

3. How accurate a representation of the classification of epidermolysis bullosa (with respect to the referenced publication) is the mind map?

very inaccurate	moderately inaccurate	neither inaccurate nor accurate	moderately accurate	very accurate
○	○	○	○	○

Please comment

4. How useful a representation of the classification of epidermolysis bullosa is the mindmap?

very useless	moderately useless	neither useless nor useful	moderately useful	very useful
○	○	○	○	○

Please comment

5. Further comments.

4

Investigating the value of consultation with expert clinicians in clinical modeling

End of Survey

Many thanks for participating in this survey. Your participation is very much appreciated.

You may still withdraw from this study. If you select "not submit, exit without submitting", your answers to this point will be manually deleted by the author.

* 6. Finish survey

- ○ Submit
- ○ Not submit, exit without submitting

12.2. SURVEY 2 – "TO IDENTIFY THE RESOURCES AVAILABLE FOR NOVICE OPENEHR CLINICIAN MODELERS BASED ON THE KNOWLEDGE OF THE OPENEHR CLINICAL MODELLING COMMUNITY"

Investigating the resources available for novice openEHR clinician modelers

Informed consent

Before progressing, your consent to participate is required.

After reading the information and consent literature below regarding this survey, (which may be selected and copied for your records) please verify that you have done so and are happy to consent. By pressing the "next" button at the bottom of the screen you will then be able to progress to the survey.

Trinity College Dublin
Information Sheet re: Investigating the resources available for novice openEHR clinician modelers

Background of Research: Registries are recognized as important means to collect patient data for scientific, clinical and policy purposes. Unfortunately, many registries have emerged which have been unable to share the useful data they contain. Best practice advice from European projects, such as PARENT JA (PAtient REgistries iNiTiative Joint Action), which have been established to improve the quality of registries and their ability to share information, has pointed towards strategies to overcome that limitation. The openEHR approach is one such strategy.

While the potential of the openEHR approach to facilitate interoperability by directly involving clinicians in the modeling process is recognized, the literature suggests that this process requires the investment of considerable resources. There is also considerable debate regarding the feasibility of expecting busy clinicians to become successful openEHR modelers.

The author, a dermatology trainee physician, is currently employed by an Irish charity, the Irish Skin Foundation, to coordinate the development of a number of dermatology patient registries. It is aimed to develop these registries to be highly interoperable and as such have the potential to become international registries. The openEHR approach has been identified as a means to facilitate this. The author will use this opportunity to conduct a thesis, the primary aim of which is to describe the role of an openEHR naïve clinician, such as this author, in developing openEHR artifacts of appropriate quality to contribute to the development of international standard registries. By undertaking this process it is also intended to:

- Demonstrate what effort is involved for an openEHR-naive clinician to model using that approach.
- Identify mechanisms to ease that process for other clinicians.
- Assess whether other components, in addition to openEHR, are required to improve registry interoperability.
- Assess whether there is potentially useful cross-fertilisation of ideas between the registry establishment process and openEHR modeling.

The purpose of this aspect of this study, which will form part of the author's thesis and for which your involvement is requested, is to investigate the resources available for novice openEHR clinician modelers.

Relevant procedures: You are invited to participate in this research in view of your experience as a clinical openEHR modeler, you will be asked to complete a short SurveyMonkey® survey consisting of 2 questions:

1. What is your background (Option: Clinical, Technical, Other – (further comment is possible in an associated free text comment box))
2. What resources would you recommend to a novice clinician learning to model in openEHR. For each resource you will be asked to:
    - a. note the type of resource (publication, blog, website, training event, tool, other – please elaborate),
    - b. rate the utility of the resource (5 point Likert scale) and
    - c. provide a link (if relevant/possible)

Conflicts of Interest: The author is a research fellow with the Irish Skin Foundation and is coordinating the development of dermatology patient registries. This has facilitated access to members of the openEHR clinical community.

Participation: Your participation is voluntary and you can withdraw your consent at any time or omit individual responses without penalty. In the event that you wish to withdraw from the study, your data will be manually deleted by the author.

1

Duration of involvement: It is expected that this study will take approximately 5 to 15 minutes of your time.

Anticipated risks/benefits of participation: It is anticipated that your participation will be utilized to generate a resource to be published for the benefit of clinicians wishing to learn to model in openEHR.

Debriefing after participation: The author will aim to make the findings available to the openEHR community.

Preservation of participant and third-party anonymity: Your anonymity will be maintained in analysis, publication and presentation of resulting data and findings.

Discovery of illicit activities: If you make illicit activities known, these will be reported to appropriate authorities

TRINITY COLLEGE DUBLIN
Informed Consent Form re: Investigating the resources available for novice openEHR clinician modelers

LEAD RESEARCHER: Dmitri Wall

BACKGROUND OF RESEARCH: The aim this study is to investigate the resources available for novice openEHR clinician modelers. This study forms part of a thesis designed to understand the role of a clinician in developing openEHR information models in the context of the development of internationally interoperable registries. This is discussed in more detail in the associated information literature.

PROCEDURES OF THIS STUDY: As a clinical openEHR modeler, you will be asked to complete a short SurveyMonkey® survey regarding useful resources for a novice clinician modeler. This is explained in greater detail in the accompanying information literature. The survey, consisting of 2 questions, is expected to take approximately 5 – 15 minutes of your time. The survey will be available to complete for a 3-week period.

PUBLICATION: The information provided and the process associated with obtaining this information will be incorporated within the proposed thesis. It is expected that the information received from this study will be published for the benefit of clinicians wishing to learn to model in openEHR.

DECLARATION:

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
- I understand that if I make illicit activities known, these will be reported to appropriate authorities.
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
- I understand that my participation is fully anonymous and that no personal details about me will be recorded.
- I understand that if I or anyone in my family has a history of epilepsy then I am proceeding at my own risk.
- I have received a copy of this agreement.

PARTICIPANT'S NAME: _____

PARTICIPANT'S SIGNATURE: _____ **Date:**_____

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

RESEARCHERS CONTACT DETAILS:
Email: walldm@tcd.ie;

INVESTIGATOR'S SIGNATURE: _____ **Date:**_____

* 1. Information sheet

I have read the information sheet

* 2. Informed consent

I have read the consent literature and give my consent

Investigating the resources available for novice openEHR clinician modelers

Background

Each question in the survey is optional. Feel free to omit a response to any question; however the researcher would be grateful if all questions are responded to.

3. What is your background as a clinical openEHR modeler?

- ○ Clinical
- ○ Technical
- ○ Other (please specify)

4

Investigating the resources available for novice openEHR clinician modelers

Available resources

What resources would you recommend to a novice clinician learning to model in openEHR. For each resource named, in the following 3 pages, you will be asked to choose the type of resource from a dropdown menu (publication, blog, website, training event, tool, other – please elaborate), provide a link if possible/relevant and finally, rate the utility of the resource on a 5-point Likert scale.

4. Name of resource 1

5. Name of resource 2

6. Name of resource 3

7. Name of resource 4

8. Name of resource 5

9. Name of resource 6

10. Name of resource 7

11. Name of resource 8

12. Name of resource 9

13. Name of resource 10

5

Investigating the resources available for novice openEHR clinician modelers

Resource type

Please describe the type of resource you have mentioned in each case

14. Please choose a resource type for each resource you have mentioned (publication, blog, website, training event, tool, other)

	Resource type
[Q4]	
[Q5]	
[Q6]	
[Q7]	
[Q8]	
[Q9]	
[Q10]	
[Q11]	
[Q12]	
[Q13]	

6

Investigating the resources available for novice openEHR clinician modelers

Resource importance

15. Please rate the utility of each resource you have mentioned

	Little importance	Somewhat important	Important	Very important	Critically important
[Q4]	○	○	○	○	○
[Q5]	○	○	○	○	○
[Q6]	○	○	○	○	○
[Q7]	○	○	○	○	○
[Q8]	○	○	○	○	○
[Q9]	○	○	○	○	○
[Q10]	○	○	○	○	○
[Q11]	○	○	○	○	○
[Q12]	○	○	○	○	○
[Q13]	○	○	○	○	○

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Investigating the resources available for novice openEHR clinician modelers

Resource links

16. Please add a link to each resource where relevant/possible

[Q4]

[Q5]

[Q6]

[Q7]

[Q8]

[Q9]

[Q10]

[Q11]

[Q12]

[Q13]

8

Investigating the resources available for novice openEHR clinician modelers

End of survey

Thank you for taking the time to participate in this survey; it is greatly appreciated. You may still withdraw from this study. By selecting the "not submit, exit without submitting", you will exit the survey and your answers to this point will be manually deleted by the author.

* 17. Complete survey

- ○ Submit answers
- ○ not submit, exit without submitting

Investigating the resources available for novice openEHR clinician modelers

Opt out page

You have opted to exit the survey and have answers deleted.

* 18. Are you sure you wish to exit without recording your answers?

- ○ Yes - not submit, exit without submitting
- ○ No - I want to submit my answers

10

12.3. SURVEY 3 – "INVESTIGATING THE RESOURCES AVAILABLE FOR NOVICE OPENEHR CLINICIAN MODELERS"

Facilitating clinician modeling

Informed consent

Before progressing, your consent to participate is required.

After reading the information and consent literature below regarding this survey, (which may be selected and copied for your records) please verify that you have done so and are happy to consent. By pressing the "next" button at the bottom of the screen you will then be able to progress to the survey.

Trinity College Dublin
Information Sheet re: Facilitating clinician modeling

Background of Research: Registries are recognized as important means to collect patient data for scientific, clinical and policy purposes. Unfortunately, many registries have emerged which have been unable to share the useful data they contain. Best practice advice from European projects, such as PARENT JA (PAtient REgistries iNiTiative Joint Action), which have been established to improve the quality of registries and their ability to share information, has pointed towards strategies to overcome that limitation. The openEHR approach is one such strategy.

While the potential of the openEHR approach to facilitate interoperability by directly involving clinicians in the modeling process is recognized, the literature suggests that this process requires the investment of considerable resources. There is also considerable debate regarding the feasibility of expecting busy clinicians to become successful openEHR modelers.

The author, a dermatology trainee physician, is currently employed by an Irish charity, the Irish Skin Foundation, to coordinate the development of a number of dermatology patient registries. It is aimed to develop these registries to be highly interoperable and as such have the potential to become international registries. The openEHR approach has been identified as a means to facilitate this. The author will use this opportunity to conduct a thesis, the primary aim of which is to describe the role of an openEHR naïve clinician, such as this author, in developing openEHR artifacts of appropriate quality to contribute to the development of international standard registries. By undertaking this process it is also intended to:

- Demonstrate what effort is involved for an openEHR-naive clinician to model using that approach.
- Identify mechanisms to ease that process for other clinicians.
- Assess whether other components, in addition to openEHR, are required to improve registry interoperability.
- Assess whether there is potentially useful cross-fertilisation of ideas between the registry establishment process and openEHR modeling.

Your involvement is requested to provide guidance and feedback as the author learns to become a clinical modeler. Ethical consent is required as the author intends to incorporate these interactions and your opinions in a research thesis.

Relevant procedures: You have been invited to participate in this research by virtue of your role as an openEHR expert modeler and in view of your offer to interact with the author as he learns to model in openEHR. A report will be generated by the author for you to review before it is incorporated in this thesis, which will include aspects of your correspondence. In addition you will be asked to complete a brief survey using the SurveyMonkey® tool. You will be asked to rate and comment on:

1. The usefulness of artifacts produced by the author during your interactions (Likert scale and free text comment)
2. The complexity of artifacts produced by the author (Likert scale and free text comment)
3. Other comments (free text)

Conflicts of Interest: The author is a research fellow with the Irish Skin Foundation and is coordinating the development of dermatology patient registries. This has facilitated access to members of the openEHR clinical community.

1

Participation: Your participation is voluntary and you can withdraw your consent at any time or omit individual responses without penalty. In the event that you wish to withdraw from the study, your data will be manually deleted by the author.

Duration of involvement: It is expected that your involvement will be required between the months of February and June 2015.

Anticipated risks/benefits of participation: Risks include the incorporation of your opinions in a publically available thesis and that this process may be time-consuming. The former risk will be mitigated by ensuring that you are able to review the author's thesis and any relevant artifacts that are produced during the thesis, and by ensuring that these will only be published subject to your consent. The latter risk will be mitigated by the understanding that your involvement is completely voluntary and that you may withdraw from your role in this thesis at any stage. Anticipated benefits include the generation of a clinical modeler who aims to become proficient in the area of openEHR modeling and that your participation will be recognized as part of the author's thesis and relevant publications.

Debriefing after participation: The author's findings will be available to you as part of this research.

Preservation of participant and third-party anonymity: This is not applicable with respect to the design of this research in the context of to data collection and analysis. Provisions will be made for anonymity with respect to reporting, if you wish.

Discovery of illicit activities: If you make illicit activities known, these will be reported to appropriate authorities.

TRINITY COLLEGE DUBLIN
Informed Consent Form re: Facilitating clinician modeling

LEAD RESEARCHER: Dmitri Wall

BACKGROUND OF RESEARCH: The aim of your involvement is to provide guidance and feedback as the author learns to become a clinical modeler. A review of these interactions and your feedback will form part of the author's thesis, the overall aim of which is to understand the role of a clinician in developing openEHR information models in the context of the development of internationally interoperable registries. This is discussed in more detail in the associated information literature.

PROCEDURES OF THIS STUDY: As an openEHR expert modeler, you will be asked to interact with the author as he learns to model in openEHR between February and June 2015. You will be asked to complete a survey using the SurveyMonkey® tool and review components of the author's work and a reflection of your interactions, which will be incorporated in his thesis.

PUBLICATION: The author will incorporate a reflection of your interactions and the results of the survey you complete, following your approval, in a Masters thesis.

DECLARATION:

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
- I understand that if I make illicit activities known, these will be reported to appropriate authorities.
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
- I understand that my participation is fully anonymous and that no personal details about me will be recorded.
- I understand that if I or anyone in my family has a history of epilepsy then I am proceeding at my own risk.
- I have received a copy of this agreement.

PARTICIPANT'S NAME: _____

PARTICIPANT'S SIGNATURE: _____ **Date:**_____

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

RESEARCHERS CONTACT DETAILS:
Email: walldm@tcd.ie; **Phone:** 00 353 87 9932777

INVESTIGATOR'S SIGNATURE: _____ **Date:**_____

* 1. Information literature.

◯ I have read the information literature

* 2. Informed consent

◯ I have read the consent literature and give my consent

3

Facilitating clinician modeling

Artifact feedback - Usefulness

Each question in the survey is optional. Feel free to omit a response to any question; however the researcher would be grateful if all questions are responded to.

The author has produced a number of artifacts during the course of his Masters thesis. From the perspective of usefulness in developing a registry using openEHR, please rate each artifact and feel free to add comments.

3. How useful was each artifact produced by the author?

	Not at all useful	Slightly useful	Useful	Very useful	Extremely useful	N/A
Atopic Dermatitis Mindmap	○	○	○	○	○	○

Please comment in relation to the utility of this artifact.

	Not at all useful	Slightly useful	Useful	Very useful	Extremely useful	N/A
Epidermolysis Bullosa Mindmap	○	○	○	○	○	○

Please comment in relation to the utility of this artifact.

	Not at all useful	Slightly useful	Useful	Very useful	Extremely useful	N/A
openEHR-EHR-CLUSTER.dlqi.v1.adl	○	○	○	○	○	○

Please comment in relation to the utility of this artifact.

4

	Not at all useful	Slightly useful	Useful	Very useful	Extremely useful	N/A
openEHR-EHR-OBSERVATION.dlqi1.v1.adl	○	○	○	○	○	○

Please comment in relation to the utility of this artifact.

openEHR-EHR-OBSERVATION.fitzpatrick_skin_type.v1.adl	○	○	○	○	○	○

Please comment in relation to the utility of this artifact.

openEHR-EHR-OBSERVATION.iga.v1.adl	○	○	○	○	○	○

Please comment in relation to the utility of this artifact.

openEHR-EHR-OBSERVATION.patients_global_assessment.v1.adl	○	○	○	○	○	○

Please comment in relation to the utility of this artifact.

openEHR-EHR-OBSERVATION.poem_score.v1.adl	○	○	○	○	○	○

5

	Not at all useful	Slightly useful	Useful	Very useful	Extremely useful	N/A

Please comment in relation to the utility of this artifact.

openEHR-EHR-CLUSTER.easi.v1.adl

Please comment in relation to the utility of this artifact.

openEHR-EHR-ELEMENT.mode_of_transmission.v1.adl

Please comment in relation to the utility of this artifact.

openEHR-EHR-CLUSTER.eb_diagnosis_detail.v1.adl

Please comment in relation to the utility of this artifact.

openEHR-EHR-COMPOSITION.pre_clinic_assessment.v1.adl

6

	Not at all useful	Slightly useful	Useful	Very useful	Extremely useful	N/A

Please comment in relation to the utility of this artifact.

Pre clinic assessment.oet	○	○	○	○	○	○

Please comment in relation to the utility of this artifact.

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Facilitating clinician modeling

Artifact feedback - Complexity

Please rate the complexity of each artifact produced and feel free to add comments.

4. How complex was each artifact produced by the author?

	Not at all complex	Slightly complex	Complex	Very complex	Extremely complex	N/A
Atopic Dermatitis Mindmap	○	○	○	○	○	○

Please comment in relation to the utility of this artifact.

	Not at all complex	Slightly complex	Complex	Very complex	Extremely complex	N/A
Epidermolysis Bullosa Mindmap	○	○	○	○	○	○

Please comment in relation to the utility of this artifact.

	Not at all complex	Slightly complex	Complex	Very complex	Extremely complex	N/A
openEHR-EHR-CLUSTER.dlqi.v1.adl	○	○	○	○	○	○

Please comment in relation to the utility of this artifact.

	Not at all complex	Slightly complex	Complex	Very complex	Extremely complex	N/A
openEHR-EHR-OBSERVATION.dlqi1.v1.adl	○	○	○	○	○	○

Please comment in relation to the utility of this artifact.

8

	Not at all complex	Slightly complex	Complex	Very complex	Extremely complex	N/A
openEHR-EHR-OBSERVATION.fitzpatrick_skin_type.v1.adl	○	○	○	○	○	○

Please comment in relation to the utility of this artifact.

openEHR-EHR-OBSERVATION.iga.v1.adl	○	○	○	○	○	○

Please comment in relation to the utility of this artifact.

openEHR-EHR-OBSERVATION.patients_global_assessment.v1.adl	○	○	○	○	○	○

Please comment in relation to the utility of this artifact.

openEHR-EHR-OBSERVATION.poem_score.v1.adl	○	○	○	○	○	○

Please comment in relation to the utility of this artifact.

openEHR-EHR-CLUSTER.easi.v1.adl	○	○	○	○	○	○

9

	Not at all complex	Slightly complex	Complex	Very complex	Extremely complex	N/A
Please comment in relation to the utility of this artifact.						
openEHR-EHR-ELEMENT.mode_of_transmission.v1.adl	○	○	○	○	○	○
Please comment in relation to the utility of this artifact.						
openEHR-EHR-CLUSTER.eb_diagnosis_detail.v1.adl	○	○	○	○	○	○
Please comment in relation to the utility of this artifact.						
openEHR-EHR-COMPOSITION.pre_clinic_assessment.v1.adl	○	○	○	○	○	○
Please comment in relation to the utility of this artifact.						
Pre clinic assessment.oet	○	○	○	○	○	○

10

Not at all complex | Slightly complex | Complex | Very complex | Extremely complex | N/A

Please comment in relation to the utility of this artifact.

11

Facilitating clinician modeling

Other Comments

Please feel to add further comments you feel are appropriate with respect to facilitating the author as a novice clinician learning to model utilising an openEHR methodology.

5. Further comments.

12

Facilitating clinician modeling

End of Survey

Many thanks for participating in this survey. Your participation is very much appreciated.

You may still withdraw from this study. If you select "not submit, exit without submitting", your answers to this point will be manually deleted by the author.

* 6. Finish survey

- ○ Submit
- ○ Not submit, exit without submitting

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CHAPTER 13. APPENDIX F - OPENEHR EXPLANATION FOR CLINICIANS

13.1. AN INTRODUCTION TO OPENEHR FOR CLINICIANS

1. The ability to share information is essential in modern healthcare to prevent duplication.

2. The difficulty is that medicine is a rapidly evolving speciality that takes place at different rates in different places.

3. To create a system that is flexible enough to adapt, but sturdy enough to enable information sharing requires an approach referred to as 2-level modeling. (O)penEHR is the longest existing approach to this and over some 20 years has evolved from a primarily academic venture to a practical model that underlies the EHRs in cities such as Moscow and countries, such as Slovenia.

4. The building blocks of openEHR

    a. The Reference Model

        i. This establishes the housekeeping rules for a system and can be considered to be scaffolding on top of which we can build a structured EHR. “In general, only reasonably abstract classes will be defined in the reference model, rather than concrete business entity types.”(Beale, 2002)

    b. Mindmaps

        i. Mindmapping is not a formal part of the openEHR methodology, however, it is used by a number of successful clinical modelers as a means organise information, by using diagrams to organise information that can facilitate archetype development. The offer an advantage in that they can give form to the final vision of what information is required. This can identify what archetypes can be re-used, where new archetypes need to be created and how these might be combined in templates to meet a user’s needs.

ii. Because mindmaps refer to information at a very superficial level, typically without the detail that archetypes help to define, they can be accessed and created by many without technical understanding and without requiring the experience of using archetyping and templating software.

c. Archetypes

i. These are the building blocks of our EHR. An archetype is created for each clinical concept. To reflect the diversity that exists, archetypes can be created to contain as many information points that exist as is required, in the fashion of a maximal dataset. This helps to overcome the common political difficulties that exist when minimal datasets are created.

ii. From a practical perspective archetypes are built using software with a very accessible interface. The software enables the addition of multiple information points and enables the collection of information about these data points, which helps ensure that the data is collected in an appropriate way and respecting limitations. The Reference model helps to dictate how the archetype fits into the larger EHR picture.

iii. When an archetype is complete it can be uploaded to a central repository where it can begin a verification process where other modelers and clinicians can comment and adapt it collaboratively in an iterative peer-review and quality improvement process.

d. Templates

i. Templates enable the combination of archetypes and the constraint of unnecessary components to create the equivalent of a paper form for a particular situation.

ii. Templates are built using software with a very accessible interface.

5. Becoming a clinical modeler should not be seen as something everyone can do, but it is something that all clinicians can contribute to. It should be considered an art form that requires on-going training and networking. There is literature

available that describes, to varying levels of depth, how modeling can be practically performed, but, because it is a skill that is complex and requires subtlety, instruction, rather than textual descriptions of the processes required might be a more effective way developing expertise. It is, however, acknowledged that a broad understanding of health informatics will be required to understand the context in which this skill should be applied.

6. The practical relevance of this approach, utilising patient registries as an example, openEHR can support both core datasets and local variations through the use of templates. It is designed to be flexible enough to let clinicians develop solutions for local problems, while still meeting the needs of national or international datasets, allowing comparability of data across clinics, centres and even countries. This could reduce duplication and increase efficiency and meaning of the data that clinicians collect.

Figure 114 Potential example of the practical relevance of openEHR to clinicians. * denotes security and privacy issues apply.