University of Bergen

Department of Information Science and Media Studies

Postmarket Surveillance of Orthopaedic Implants using Web-technologies

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Author:

Ørjan Ertkjern

Supervisor:

Ankica Babic

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Abstract

In the European Union (EU) between 8-12 % of patients admitted to hospitals, suffer harm from the healthcare they receive every year. There are many reasons for this, e.g. surgical error, error in diagnostics and medical device failures etc. (European Commission, 1994).

Currently there is no publicly available central system to log/archive failures of medical devices inside of Europe. Under the EU's medical device directive, surgeons are requested to report failures to the nation's relevant government department. In Norway, they have *Helsedirektoratet*, which covers this role. The Ministry of Health and Care Service administrate Helsedirektoratet (Helsedirektoratet, 2014). In the U.S., the **F**ood and **D**rug **A**dministration (**FDA**) has implemented such a system called **MAUDE** (**M**anufacturer **A**nd **U**ser **F**acility **D**evice **E**xperience) (FDA, 2014). In this Open Data search engine, surgeons and even the public can search data and information regarding all the failures collected in the system.

At *Haukeland University Hospital* in Bergen, the Biomaterial Research Group are implementing a retrieval centre where the goal of the centre is to promote surgeons to send failed knee and hip prosthesis to Bergen, so that they can be reported directly to Helsedirektoratet. The goal of the retrieval centre is to discover bad prosthesis, cements or bad surgery techniques as early as possible to avoid complications and to improve the treatment of patients. They would like to have a system similar to MAUDE, so that both surgeons and potentially the public could view all the failures collected in a reduced format. In addition to this, they want to be able to gather relevant data from several external sources (Helse Bergen, 2014).

A high-level prototype has been created in this project. The prototype gathers relevant medical data from the retrieval centre's local database containing failed hip- and knee-prosthesis records, as well as data from three different external sources. The external sources are MAUDE, Clinical Trials and PubMed which are publicly available web-based databases. The system is generating summaries and statistics based on user searches towards the different sources. The prototype is a web application that presents the functionalities and a design alternative for such a system, as well as to promoting Open Data for health research. The system will be a proof of concept as a proposition to generate further funding, with the goal of reaching the entire European Union.

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1) Introduction

Medical devices have an important role in the health care today, since they can be used to diagnose, prevent and treat diseases. Medical devices can offer great opportunities for a patient but they also carry risks (Kramer, Tan, Sato, & Kesselheim, 2013). The fact that medical devices fail and have to be removed surgically from the patient's body is well known. The reasons for this can be many: manufacturing flaws, surgical mistakes, physical and chemical deterioration with time and many more (U.S Food and Drug Adminsistration, 2015). The ***P**oly **I**mplant **P**rothèse* (**PIP**) which had been implanted in 300,000 women in 65 countries (Willsher, 2013), and the *Metal-on-metal hip replacement* which 65,000 patients in the United Kingdom have received since 2003 (Bates & Hope, 2012; MHRA, 2012), are two major events that have happened in the recent past. They both are dealing with medical devices failing and create problems for the patient, like pain and inflammation. Cases like this show the importance of having post market surveillance. The term post market surveillance covers all types of monitoring activities of medical devices in use (World Health Organization, 2003).

Currently there is no publicly available central system to log/archive failures of medical devices inside Europe. The competent authorities in each European state have the responsibility for post market surveillance and surgeons are requested to report failures to the relevant nation competent authorities. In Norway, it is Helsedirektoratet which covers this role. The Ministry of Health and Care Service administrate Helsedirektoratet. In the U.S. on the other hand, the **F**ood and **D**rug **A**dministration (FDA) have implemented such an open system called **MAUDE** (**M**anufacturer **A**nd **U**ser **F**acility **D**evice **E**xperience). MAUDE is a dataset and an Open Data search engine containing information about adverse events involving medical devices (FDA, 2014). Here everyone, surgeons, scientist and even the public can search data and information regarding all the failures collected in MAUDE.

At Haukeland University Hospital the Biomaterials Research Group collects knee and hip prosthesis that had failed and been removed from a patient's body to find the reason for the failure of the component. One of the aims of this retrieval centre in Bergen is to promote surgeons to send failed devices so that they can report then directly to Helsedirektoratet and analyse the device for research purposes. Last year (2014) a former master student from the

University of Bergen developed a prototype of a database system and desktop application for the same user group. The database system is integrating both data about hip- and knee-implants that they analyse at the Laboratory and the patient themselves (Berntsen, 2014). Much of this data is used by The Norwegian Arthroplasty Register, which publishes annual reports with descriptive statistical information regarding national data on operating volumes, use of different types of prostheses, cement, and other characteristics of the procedure (Department of Orhopedic Surgery & Haukeland University Hospital, 2015). Much of the data published here and stored at the local databases could and probably should be available as Open Data. To give transparency, create efficiency and innovation and to encourage surgeon to report incidents, as they now can follow up the matter they have reported.

Some of the researchers at Haukeland tend to use external sources when doing the analysis. Three of those external databases are the already introduced MAUDE database, ClinicalTrials.gov and PubMed web library. Clinical Trial is a search engine that provides an easy access to clinical studies on a wide range of diseases, conditions and of course medical devices. Everyone who might find the data stored here interesting can search through the records (U.S. National Institutes of Health, 2014). PubMed is the other external sources and is very much used by the employees at the Biomaterials Research Group. It is also a search engine and in this search engine biomedical literature can be retrieved from highly refereed and credible web sites (U.S. National Library of Medicine & U.S. National Institutes of Health, 2014). Open Data like this creates efficiency, innovation, provides transparency and gives broader insight for the public (Direktoratet for forvaltning og IKT, 2014a).

In the following thesis, a high-level prototype of a web application has been created. The prototype has been designed to have search functionalities to browse the local data stored at Haukeland University hospital about failed hip- and knee-implants collected and analyzed. The other goal was to merge these local records together with three external relevant sources; MAUDE, Clinical Trial and PubMed. This has been done to create one single search engine for all the available and credible data sources, both externally and internally. The thesis is a Design Research thesis on how to present Big Data in an appropriate and informative way for the relevant user groups, and to promote Open Data in health research. The web application also contains functionalities for a surgeon to submit records, to be able to monitor the records submitted and watch statistics based on the collected data. This feasibility of a web-based system could prove motivational and could encourage surgeons to contribute even more to the research field. The system is a proof of concept as a proposition to generate further funding, with the goal of reaching the entire European Union.

1.1 Research Questions

Four research questions have been made for this thesis:

- *Could an artefact be created to support data management, information retrieval of biomedical data and be of service to the research?*
- *How could Open Data strengthen the research field of orthopaedic implants?*
- *How could big data from multiple sources be presented in a relevant, informative and user friendly way for the user group?*
- *How could a web-based system be of service for the important user groups?*

1.2 Structure of the Thesis

The thesis is divided into seven main chapters and a short summary of the content in each chapter will be given in this section. Different methods and methodologies have been used during the thesis and it can be hard to assimilating them all. An overview model of the structure of the thesis is therefore presented in *Figure 1.1*.

The model starts with the creation of the research questions (*Chapter 1*) which was defined based on literature review and theories (*Chapter 2*). Personal motivation as well as experiences also affected the research question. Once the research questions were decided the hunt for requirements could start. The requirements could then facilitate creating a conceptual design of a prototype (*Chapter 4*). The requirements were found using qualitative methods (*Chapter 3*) and when a design has been outlined and clarified the system development process could start (*Chapter 4.5*). Having a working prototype could then be evaluated toward both end-users and expert users (*Chapter 5*). The evaluation was conducted using both qualitative and quantitative methods (*Chapter 3*). After the evaluation process a lot of data can be analyzed from the results and answers to the research questions can be provided (*Chapter 6 & 7*). The whole model being discussed is wrapped inside Kanban. This is because Kanban has been applied to all tasks during the whole thesis and not only the developing process (*Chapter 3*).

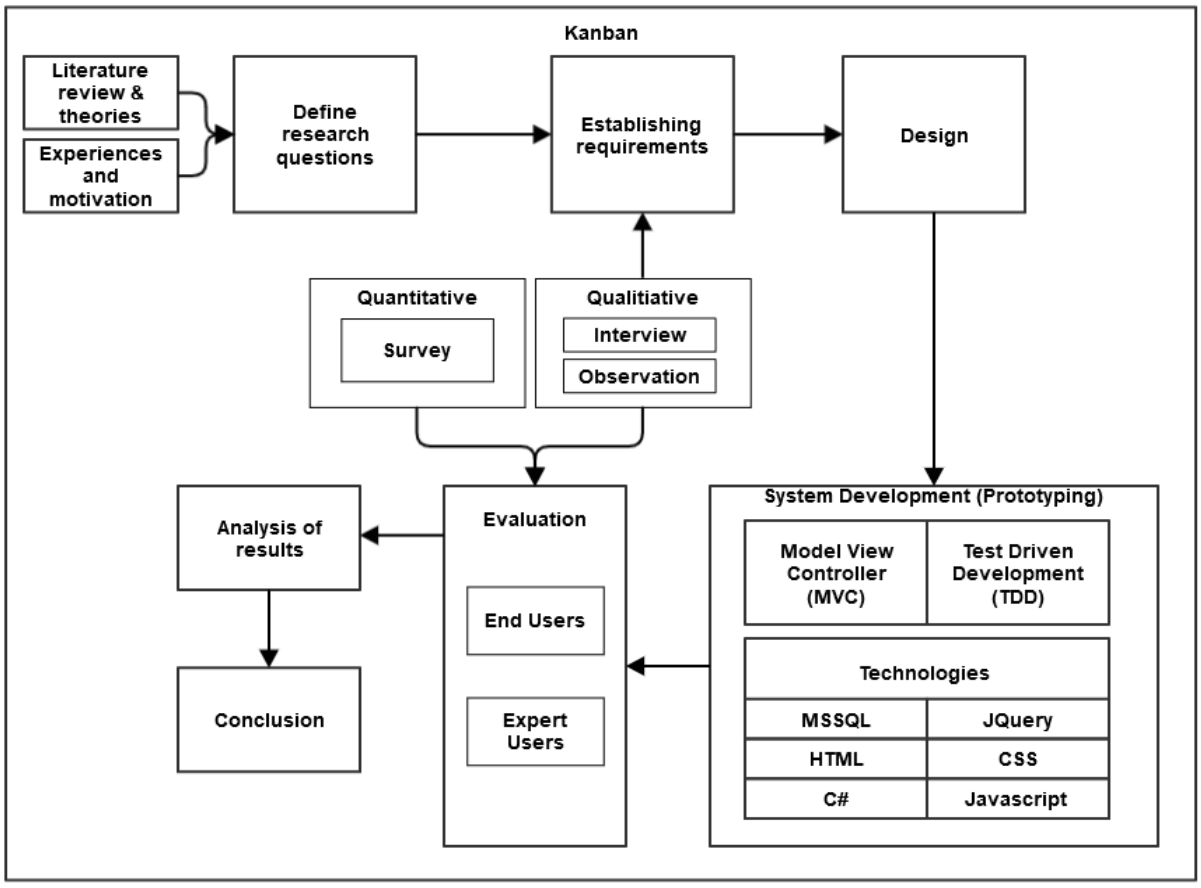


Figure 1-1: Model of the structure of the thesis

Chapter 1: In this chapter an introduction to the thesis, the problem domain and the research questions for the project is presented. An overview of all the chapters is also provided.

Chapter 2: Different theories and relevant literature for the thesis is presented in this chapter. This includes medical devices, postmarket surveillance, human computer interaction, Open Data, relevant applications and other relevant theories.

Chapter 3: In this chapter methods and methodologies are discussed. This includes how the seven guidelines by Hevner, Salvatore T, Jinsoo, & Sudha (2004) are used in the project and how Kanban has been applied as a methodology for structuring the project and system development. A discussion about what to use between quantitative and qualitative methods and what they are will also be provided.

Chapter 4: The whole development process is covered in this chapter. This includes everything from gathering user requirements, creating the design of the application to a complete high-level prototype using technologies like C#, HTML, JQuery, etc. The chapter is

following the framework of Nunamaker & Chen (1990), on how to apply system development in a research.

Chapter 5: How the end-user and expert user evaluation of the system was performed using both qualitative and quantitative methods is presented in this chapter. The results and a discussion of the results from the evaluation can also be read in the end of this chapter.

Chapter 6: In this chapter we will discuss the different research questions and try to answer each of them based on the evaluation results and the artefact created for this thesis.

Chapter 7: The final chapter of this thesis contains an overall conclusion of the work done as well as to a section about the future work.

2) Literature Review and Theories

This part of the thesis will review relevant literature and theories. These are theories about medical devices, both in general and with the focus on hip- and knee-prosthesis. Big Data and Open Data, as well as to related work for the thesis is literature that is covered in the following chapter.

2.1 Medical Informatics

This master thesis is a part of the field of M*edical Informatics*. This field of study incorporates a broad list of subjects, everything from building health care systems, electronic patient journals and to gathering knowledge from medical data by using information, technologies and other types of relevant science. The study of Medical Informatics is built upon close cooperation between experts from medicine and different health care vendors, and of course the most important user groups, the patients themselves (University of Bergen, 2014).

2.2 Medical Devices and Postmarket Surveillance

The directives of the European Commission as well as to a publication regarding regulation of medical devices by the World Health Organization (WHO) has been studied, in order to provide a clear explanation of what a medical device is, and how they are used by health care providers in numerous therapies. The definition of a medical device, as defined by the European Commission, is an article intended to be used for a medical purpose only (European Commission, 1994). Medical purposes might for instance be for diagnosis and/or treatment of a disease, monitoring patients or as assistance technology. General-purpose laboratory equipment and other general equipment tools are not defined as medical devices (MHRA, 2014). This thesis is focused on the implantable medical devices which are according to the ISO 23485:2003 standard partly or totally inserted into the human body or a natural orifice and are expected to stay there for 30 day or more (ISO 13485:2003, 2003). Surgical procedures are used to insert or apply implantable medical devices and surgical or medical

procedures must be used to remove them. Contemporary guidelines for reporting serious adverse events are stated as following:

> *"All serious adverse events must be fully recorded and immediately notified to all competent authorities of the Member States in which the clinical investigation is being performed"*
>
> *(European Commission, 2007).*

The European Commission defines an adverse event as an event in which unexpected or unwanted effects involving the safety of the user or patient of the medical device occur. For instance, if a patient's health gets worse due to medical device failure or maybe a patient's treatment is being interrupted by a medical device failure (European Commission, 2007).

The fact that medical devices can fail is well known, and the failure rate varies in a predictable manner relative to the life of the product. A medical device has a lifecycle of three defined periods illustrated in *Figure 2-1*: *infant mortality, useful life* and *wear out stage*. This graph is called the "bathtub curve", because of its shape. The graph tells us that medical devices tend to fail in the beginning of its lifetime, and the reason of failure might be weak components, manufacturing flaws etc. After the *infant mortality* period, the failure rate stabilizes and stays somewhat consistent. While at the last stage, the *wear out stage*, the failure rate will start climbing again and the cause can be the physical and chemical deterioration that happens over time (U.S Food and Drug Administration, 2015). In a paper published by the ***W**orld **H**ealth **O**rganization* (**WHO**) they state the importance of continuous monitoring of the medical devices when they are in use, as their characteristics can only be proven if one measures how a device stands up in certain conditions and find the reasons for failure. Post-market surveillance is a term that covers monitoring activities of medical devices in use, and the curve presented here shows us that there is a necessity to monitor medical devices tendency to fail, and try to find the cause of the failure (World Health Organization, 2003).

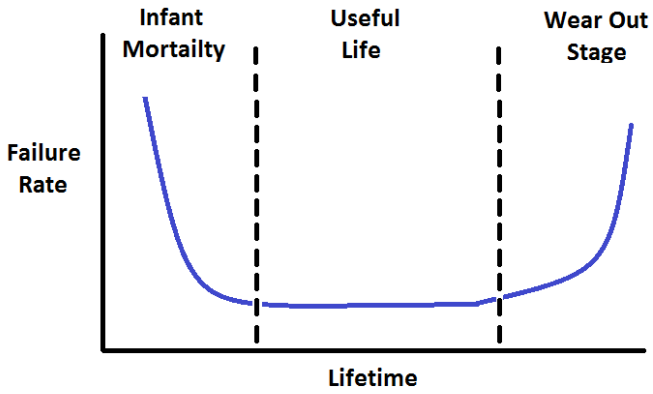


Figure 2-1: Variation in the failure rate of a manufactured product through its life (U.S Food and Drug Administration, 2015)

There are several incidents in Europe that show the importance of postmarket surveillance of medical devices; The ***P**oly **I**mplant **P**rothèse* (**PIP**) and *Metal-on-metal hip replacement*. On the 10th of December 2013 the boss of the PIP-company, Jean-Claude MAS was sentenced to four years in jail because of fraud. The company used cheap industrial silicon, not fit for humans, in the breast implants they were producing. It was estimated that around 300,000 women in 65,000 countries got them implanted (Willsher, 2013). The problem with the implants was that they had a double rate of rapture than other breast implants, which could be irritant, causing pain and inflammation, and the implants are more difficult for surgeons to remove once they had ruptured. Reports of rapture started in 2003, and the product was banned after seven years in 2010 (BBC, 2013).

65,000 patients in the United Kingdom have received the metal-on-metal hip implant since 2003. Early in the year 2012 the Medicines and Healthcare Products Regulatory Agency (MHRA) alerted the National Health Service about "small risks" for complications in patients using hip replacement where the replacement have a femoral head with a diameter of 36 millimetres more. The alert considers the friction between the two metal pates in the body, which will produce chemical byproducts that leak into the patient blood and trigger inflammation and swelling which could cause pain and lack of mobility. MHRA suggested that all patients with such a medical device implant should perform a MRI scan as soon as possible. Neither the hip implants or the breast implants did not have to pass any form of clinical trials before being inserted into patients (Bates & Hope, 2012; MHRA, 2012).

2.2.1 Device Safety Reporting in Norway

In Norway, clinicians report adverse events to the regulatory department of the national health authority, *Helsedirektoratetet*. On their web page, they state that error on equipment, damages, accidents or failures where medical equipment is, or may be, involved have to be reported to Helsedirektoratetets department of medical equipment. The obligation to notify is stated in the Norwegian law 12 January 1995 number six about medical equipment § 11 (Helsedirektoratet, 2014; Lov om medisinsk utstyr, 1995, § 11).

2.3 Biomaterial Research Group

Every year 4400-knee replacements are performed in Norway, and over 50 hospitals in Norway perform this procedure. This routine surgical treatment is very successful and results in improved patient mobility and consequently a better quality of life. In some case there are complications leading to reoperations and removing implants. The Biomaterial Research Group at Haukeland University Hospital studies the reasons for the failures, mainly for hip- and knee-prosthesis (Furnes, 2014). Biomaterials are materials that are intended to be used with biological systems. This can for instance be a replacement of a tissue, organ or maybe a function of the body like the knee- and hip-prosthesis (University of Bergen, 2015). The **goal** is to discover bad prosthesis, cements or bad surgery techniques as early as possible to avoid unnecessary complications and to improve the treatment of patients. It is done by systematically analysing the explanted prostheses, providing feedback to the surgeons and generating annular reports which should provide a constant, reliable and long term follow up of the safety and outcomes in the various patient groups. The research is done in a close cooperation with surgeons, who fill out a form with detailed information about the prosthesis, that has been removed surgically, and send it to the retrieval centre for further analysis (Helse Bergen, 2014). Based on this information calculations can give information about a prosthesis life span and one can be more prepared for the *wear out stage*, presented in the bathtub curve above (Furnes, 2014; Helse Bergen, 2014).

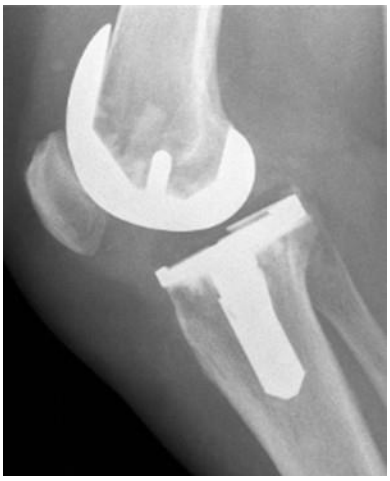


Figure 2-2: Knee-prosthesis from side (Furnes, 2014)

2.4 Human-Computer Interaction (HCI)

Human-computer interaction (HCI) is the study of interaction between humans and computers (Booth, 2014). HCI is an important research science because it provides methods that could make a system that works functionally and can be easily accessible and manageable by a wide range of users. A capable user interface can improve a perception of the system and make it eligible. That poor interface can lead to lower work rates and decreased motivation for the user of the system has shown the importance of HCI research (Booth, 2014). Every item used in the daily life is unconsciously reviewed for their interaction design features. How the item feels in the hand of the user, how easy it is to accomplish the desired task and how it looks is all about interaction design. Interaction design focuses on how to design user experiences. A good definition is that the meaning of interaction design is *designing interactive products to support the way people communicate and interact in their everyday and working lives* (Rogers, Sharp, & Preece, 2011, p. 9).

The evaluation part of the thesis can be seen as the most important part of interaction design that was undertaken to make sure that the developed product covers the desired needs of the various user groups. Identifying usability requirements is a way to ensure that the built product is efficient, effective, engaging, error tolerant and easy to learn from the users perspective (Quesenbery, 2003). For this thesis, those five usability requirements defined by Quesenbery (2003) has been used to assure a successful system will be appealing to the user (Rogers et al., 2011). A more detailed look on the evaluation part and the usability requirements can be found in *Chapter 5*.

The 10 usability heuristics for user interface design by Nielsen (1995) will also be evaluated by expert users which can be read more about during *Chapter 5.1.2 & 5.2.2*. The 10 heuristics are general principles for interaction design and is a good way of detecting usability problems in the user interface design. The 10 usability heuristics is as following (Nielsen, 1995):

- **Visibility of system status**

  This heuristics says that the user should always be informed by the system about what is going on by providing the user feedback within reasonable time. This can be as simple as having a progress bar which tells the user how much is left of the loading when the system has to perform a more complex task like loading a video.

- **Match between system and the real world**

  Use words that the user is familiar with and makes information appear in natural and logical orders. Do not use fancy system-oriented terms. Use “search” instead of “query”.

- **User control and freedom**

  Users make mistakes and an “emergency exit” is needed so that the user can get away from unwanted states. If the user navigates to a wrong place it should be easy to get back to the beginning point, by having “home”, “undo” or “back” buttons.

- **Consistency and standards**

  The system should follow platform conventions. The user should not have to wonder whether different words, situations or actions mean the same thing.

- **Error prevention**

  The system should have good design to prevent the user from doing mistakes. This might be as simple as check if all the forms are correctly filled in before passing them to the server-side of the system.

- **Recognition rather than recall**

  Minimize the user’s memory load by making object, actions and options visible. The user should not have to remember information from one part of the dialogue to another.

- **Flexibility and efficiency of use**

  Having tools that can speed the process for the expert users and allow users to tailor frequent actions, for example hotkeys on the keyboard. A user does not need them, but if the user learns how to use the shortcuts, the work will be done quicker.

- **Aesthetic and minimalist design**

  Avoid irrelevant or rarely needed information. For each extra information unit the relevant unit loses its visibility.

- **Help users recognize, diagnose, and recover from errors**

  The system should have error messages in plain language to indicate a problem when it occurs and suggest a solution to the transpired problem. The error message that follows should not contain any code and should be in a plain language.

- **Help and documentation**

  Any help and documentation provided should be easy to search, focused on the user's task, list concrete steps to be carried out and should not be overwhelmingly large for the user to use.

Likewise, the design principles presented by Rogers et al., (2011) have been kept in mind during the whole development process. They are used to aid interaction developers while designing the user experience. The different design principles presented are *visibility*, *feedback*, *constraints*, *consistency* and *affordance*. To give a brief introduction to each of them the *visibility* principles states that by having the functions more visible, the users will be able to more likely know what to do next, while those items outside our sight is difficult to find and know how to use. *Feedback* is a principle about informing the user what has been done and what has been accomplished. The design principle *constraints* is about restricting interactions that can take place at a given time guiding the user from doing errors. The principle about *consistency* makes it easier to learn and use a system by having similar object and operations for archiving similar tasks. *Affordance* is referring to an attribute of an object that makes the user understand how to use it, like the handle on a tea cup, you know you are supposed to lift the tea cup using the handle (Rogers et al., 2011).

2.5 Data Visualization

It can be easy to deal with low dimensional worlds. The human instinct and senses can help us deal with three to maybe five dimensions, perhaps a few more for someone adept, but what should be done when the data grows to a thousand in dimension? One answer is the data mining process, but again once the process has detected patterns, structured and filtered the data, the amount of data can still be overwhelming (Fayyad, Grinstein, & Andreas, 2002). Visualization can then be a great tool for data presentation and storytelling to the end user. Its two main purposes are: *sense making* and *communication* (Few, 2014).

Here is an example of how visualization can make the data easier to understand for everyone. A fake dataset containing the number of ice cream sold every month in year 2014 has been created in *Figure 2-3.*

Ice cream sold 2014

Month	Number
January	55
February	122
March	212
April	522
May	853
June	1872
July	2863
August	1220
September	503
October	101
November	82
December	32

Figure 2-3: Fake dataset of ice creams sold in 2014

It's not a very complicated data set, but the viewer still has to study it closely and go through all the numbers to find the month with the highest ice cream sales. Visualising the data will give the user a faster overview. When viewing the visualization, the end user will instantly discover that July it the top selling month for ice cream as illustrated in *Figure 2-4*.

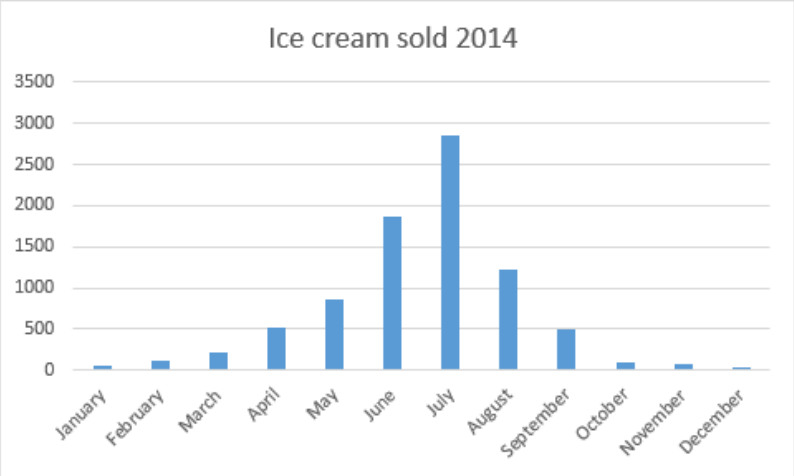


Figure 2-4: Visualisation of the fake ice cream dataset

Even though this was an easy dataset to analyse, it has to be viewed in the big picture. User can only imagine enormous datasets and what visualisation can do to them. A google search for *The Internet map*, which is a bi-dimensional presentation of links between websites on the internet, gives an idea of a good presentation. Every website is represented by a circle, and its size tells the amount of website traffic. It is also possible to search for a specific country to see the most popular websites and see how they are linked together (Enikeev, 2014).

There are a lot of presentation styles to use, for instance map-, bar- and pie-chart, when visualizing. There are also many things to consider when choosing what visualisation technique to use. In this project, visualization was used so that users of the system can easily get an overview of the results of their search query. Visualisation brings life to the data.

> *"There is a magic in graphs. The profile of a curve reveals in a flash a whole situation – the life history of an epidemic, a panic, or an era of prosperity. The curve informs the mind, awakens the imagination, convinces"*
>
> *Henry D. Hubbard (Brinton, 1939)*

2.6 Open Data

Open Data is structured data available in a way that is readable for both human and computers. It has an open license which makes it possible for whomever to reuse the data and use it in a different context if they wish so. The data can be everything from simple lists and tables to descriptive documents. A principle states that all *publicly funded research data should be openly available to the maximum extent as possible*. The reason for this principle is that research data publicly funded is produced in the interests of the public and therefore the public should also have access to the data. The data can also have benefits for public scientific research by promoting new research. Of course privacy and protection of confidentiality should be of importance and can restrict the availability of the data (Arzberger et al., 2004; Direktoratet for forvaltning og IKT, 2014b)

Data.norge.no, a register of Open Data available in Norway, states that Open Data would create **efficiency and innovation**, by sharing knowledge across both public and private sector and facilitates creativity. Creativity would then contribute to **business development** when people can use the Open Data to create applications. In the public sector it would mean more **democratization** when decisions and priorities are opened to the public, and by giving better insight into how things are done and therefore provide **transparency** (Direktoratet for forvaltning og IKT, 2014a).

The researchers at Haukeland are using external sources for their work, like the Clinical Trials and the MAUDE web-site. If this data had not been open and available, it could not

have been used as easily as it is today. The researchers usually meet at regular meetings and seminars where they share information and share their research results. They also publish annular reports about their findings (*Appendix B3*). This is good, but by having the data open it is possible to get data more efficiently and accurately regardless of the institutional boundaries.

As some surgeons think they get too little information about what is done to their reports (*Appendix B4*), Open Data in the combination with the real live data could encourage them to be more open when it comes to sharing their own data. They could witness what is done to their reports, and this could be encouraging for them to publish more reports. As the question about use of Open Data in the field of Medical Informatics is one of the main research questions in this thesis, there will be a more detailed look at this later on.

2.7 Big Data, Data Mining and Information Retrieval

Even though this thesis is not including a very advanced information retrieval and data mining algorithms there are done some data mining and information retrieval operations that should be mentioned in the relation to big amounts of data. Those three topics are very broad topics and a short introduction to each of them will be given in this part of the chapter.

2.7.1 Information Retrieval (IR)

Information **R**etrieval (IR) is a very broad term and can be nearly everything from finding a receipt in a cook book to searching through unstructured text. In computer science IR often includes web search, text classification, user interfaces, visualization of data, filtering and much more. In computer science research, IR is studied from two quite different but complementary points: *computer-centred* and *human-centred* IR. While the computer-centred focuses on creating indexes, process queries with high performance and ranking algorithms, the human-centred focus on the behaviour of the user and their needs, and how this affects the organization and operation of a retrieval system (Baeza-Yates & Ribeiro-Neto, 2011; Manning, Raghavan, & Schütze, 2008).

The prototype developed during this thesis will not contain too advanced computer-centred algorithms. Of course, some IR, in the form of *information look-up*, is used to get the data

from the different external sources, to generate some graphs and have some results to display for the user, even though it might be defined as information look-up processes instead of IR. The reason for this is that the data that the gathered data is well structured, and IR usually deals with natural language text which is not well structured. The main focus of this thesis has anyways been mainly about the human-centred part of IR, and the *search user interface*. Baeza-Yates & Ribeiro-Neto (2011) explain the role of the search user interface as a tool to aid in the searcher's understanding and expression of their information needs, formulating their queries, getting information from different information sources and making the user understand the search results returned by the computer system.

2.7.2 Big Data

Big data can be described as datasets and analytical techniques in applications that are so large and complex, or having such increasing amount of data, that they need advanced data storage, analysis and visualization technologies to be able to handle the data (Chen, Chiang, & Storey, 2012). Big data is not only the amount (*volume*) of data stored, there are more important attributes as well as *variety* and data *velocity*. *Volume*, *velocity* and *variety* is known as the three Vs in Big data and is visualized in *Figure 2-5* (Russom, 2011).

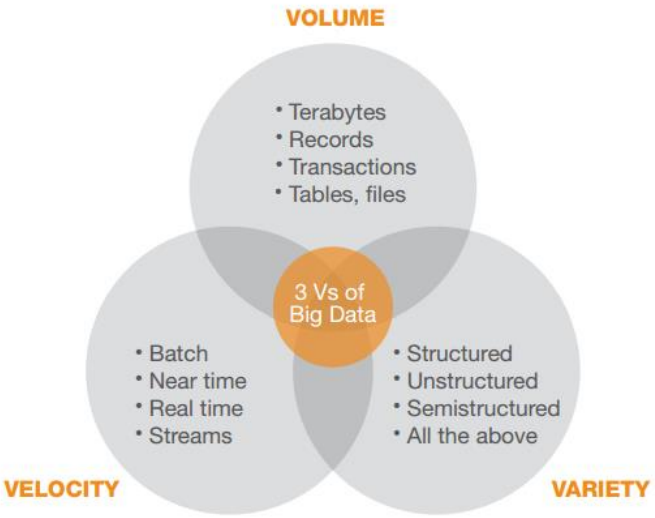


Figure 2-5: The three Vs (Russom, 2011, p. 6)

Regarding the Volume, this master project anticipated a lot of data due to evolving research activities which is documented by various kinds of biomedical data. Even though the

local data collected at the present time is not that vast, it will definitely keep growing as hip- and knee-prostheses will be performed more often to treat patients. On the other hand, when it comes to the external data that has been integrated into this project, the amount of data is pretty large. By the date 10/02-2015, a count was made of all records reported to the Open FDA MAUDE site, giving a result of 3,867,173 records. While refining the search results specifically for records on LCS knees, which is one of the main components they are studying at Haukeland, had given the result of 2,917 records. The other external data source, Clinical Trials, has a total of 183,813 related clinical studies, while narrowing the search to LCS knees related studies, the total studies has been narrowed down to 10 relevant studies.

The next V in the model presented above is *Variety*. The big data that is analysed during this project is all structured but in different formats. The data retrieved from Clinical Trials is in the form of XML documents, Open FDA MAUDE is in the JSON format, while the local data registered at Haukeland is published to a Microsoft SQL database. So they are all structured, but in different formats.

When it comes to *Velocity*, all the data is processed in batch time. The Clinical Trial website is being updated once a day, while the MAUDE is being updated once a month. The local data is collected nearly in real time, but there are not that many records being reported monthly.

2.7.3 Data Mining

Data Mining is all about *knowledge discovery in* databases, which means finding new and useful information such as patterns, clusters, groups and trends from the data in the databases. This way of processing information from large databases has been viewed by many research communities as a key research topic in database systems and machine learning. For example, the discoveries made in the data can then be applied to decision making for a business (Yu, 1996, p. 866). Just think of the information that can be found in large data sets that a human alone could never discover! An incredible example of the power of Data Mining is the *Flue Trends* project by Google where influenza epidemics can be detected in areas with many web search users by analysing the search queries performed in these areas. This could be done because people have tendency to search online for information when they are showing symptoms of illness. Therefore, when large amounts of web queries for symptoms related to a typical flue are sent from the same area, a pretty safe prediction could be made that this is

now an epidemic. The Google experts say they can estimate the current level of weekly influenza activity in each region of the US, with a reporting latency of one day, whilst the traditional systems used by U.S. Centre for Disease Control and Prevention and European Influenza Surveillance Schemas typically have a 1-2 week reporting lag (Ginsberg et al., 2009, p. 1-2).

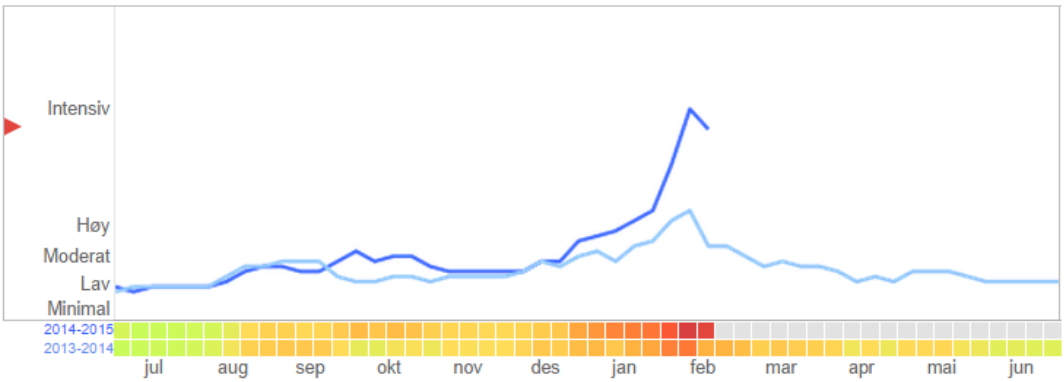


Figure 2-6: Google flu statistics - Norway (Google Inc., 2015a)

There are many different techniques for analysing big data that can be used to analyse the larger datasets. Some of them are *classification, cluster analysis, trend analysis, time series analysis, natural language processing (NLP)* etc. In this thesis, the focus will be on how to communicate with the end user, issues relating to the data collection and how the massive amount of data can be presented for the end user in a user friendly way. Presenting the large amount of information in such a way that people can consume it effectively is a key challenge when analysing big data (Manyika et al., 2011)

2.8 Related Work and Related Applications

There has been done a lot of projects and work of relevance for research presented in this thesis that will be listed and discussed. The discussion will include information about the topics and organisations driving them, why they are important for the thesis and how they can be incorporated in the research if relevant.

Name	Created by	Purpose
Information system for postmarket surveillance of total joint prostheses	Eirik Berntsen – University of Bergen	Database and desktop application for Biomaterials Research Group for knee implant analysis.
Clinical Trials	U.S National Institutes of Health	Database of clinical studies.
Manufacturer and User Facility Device Experience (MAUDE)	U.S Food and Drug Administration	Medical device reports (MDRs)
Open FDA	U.S Food and Drug Administration	API with datasets on adverse events, recalls & labelling
Re-motion Database	SBI (Small Bone Innovations, Inc.) & ISCC at the Technical University of Denmark	Database to collect, analyse and report data on wrist replacement, internationally.
PubMed	U.S National Library of Medicine & National Institute of Health	Consist of citations for biomedical literature.
ResearchAE	Social Health Insights LLC	Research application that combine datasets about adverse events, product recall etc. in one place

Figure 2-7: Related work of the interest for the research presented in the thesis

2.8.1 Information System for postmarket surveillance of total joint prostheses

The most relevant related work for this thesis is the master thesis of Eirik Berntsen (Berntsen, 2014). The goal of his thesis was to develop a prototype of a database system and desktop application for the same user group as in this thesis, the Biomaterials Research Group at Haukeland (University of Bergen, 2015). The database system is integrating both data about the explanted implants they had analysed at the laboratory and about the patients. Berntsen's desktop application could be used for the researchers to enter new data and get a visual presentation of the data already integrated into the database. The data in the database developed by Berntsen (2014) will be integrated into the web application prototype, since it will contribute as a data resource even in the future and it will help keep both the application concise. Much of the data in his thesis contains valuable information for this this thesis. This

is for instance the interviews he has done with the users, and therefore the same questions had not been needed when performing interviews regarding this thesis, because they are already answered (Berntsen, 2014).

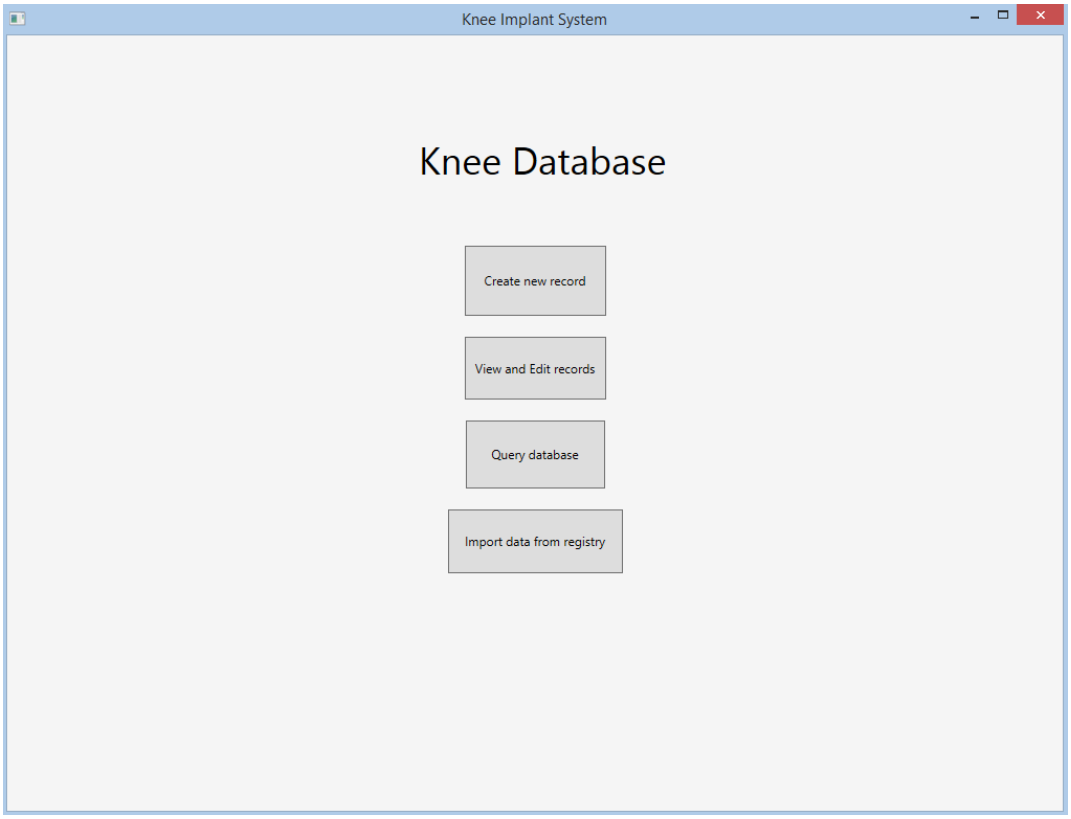


Figure 2-8: Desktop application made by Berntsen (2014)

2.8.2 Clinical Trials

Clinical Trials is a website, created by the U.S. National Institutes of Health, containing Open Data about interventional studies where volunteers are assigned for instance a medical device and are evaluated for their effect on biomedical or health outcomes. On the web site one can search through clinical trials based on different attributes like country, study topics, age, patient demographics and diagnosis, as well as outcome (U.S. National Institutes of Health, 2014).

ClinicalTrials.gov is used regularly by the researchers at Haukeland University Hospital to find relevant clinical studies for their own research or cases they are working on. Clinical Trials provides them with Open Data in a machine readable language in XML-forms, which

makes it possible to integrate the data from Clinical Trials into their already existing desktop application or at least on a web application.

2.8.3 Manufacturer and User Facility Device Experience (MAUDE)

MAUDE is a database for reporting adverse events involving different medical devices (FDA, 2014). The database provides a "search-engine" which lets the user search information in the database on medical devices that may have contained deficiencies, caused unwanted effects, death or serious injury on a patient. This data is Open Data and is searchable on their homepage and it is also available for download. This means that anyone can use this search engine to look up for information on various devices. If a search for one of the main devices at Haukeland University Hospital is operating with is performed, LCS-knees, for the year 2013, the search engine returned 387 records meeting our search criteria. Opening one of the retrieved results enables access to information like *Event Date, Event Type, Patient outcome, description, manufacturer narrative* and *information* about the device the report was about (FDA, 2014).

The data here is very interesting and useful for the researchers at Haukeland. The data is large, and contains a lot of information of different kind, and it would therefore be hard to store and use it with the current IT infrastructure and economic resources available. Coincidentally, following the initial project the FDA launched a new website (June 2th, 2014) called the Open FDA that solved this problem, which will be discussed in the next paragraph (U.S Food and Drug Administration, 2014a).

2.8.4 Open FDA

OpenFDA is a website released by the U.S Food and Drug Administration on June 2th, 2014, just in time for this thesis work (U.S Food and Drug Administration, 2014b). It is currently in beta version, so it should be used with care, but for a proof of concept project it works brilliantly. OpenFDA provides APIs for raw download access of high-value structured datasets. These datasets includes adverse events, product labelling and recalls. All the data from the MAUDE-site mentioned in the paragraph above is included in this API in the format of JSON. The data provided by the OpenFDA is updated each quarter (U.S Food and Drug Administration, 2014a).

This Open API is a great tool to retrieve relevant data for the researchers at Haukeland University Hospital directly into the web application and to perform statistical analysis. It is important to notice however that even private citizens can report incidents to the FDA, and therefore all the data is not necessarily fully reliable, but still interesting for the researchers.

2.8.5 Re-motion Database

This project is very exciting and supports a very important part of the thesis project, but it considers another implant type that was introduced by one of the orthopaedic surgeons at the Haukeland University Hospital during the interviews of this thesis. The database is supported by **SBI** (**S**mall **B**one **I**nnovations, Inc.) and ISCC at the Technical University of Denmark (Re-motion Database, 2015). The purpose of the system is to collect, analyse and report data on wrist replacement with the Re-motion total wrist. A presentation of the program was done by a surgeon at Haukeland, where the surgeon, after a surgery, can report data directly to this system through a web form, watch calculated statistics and data presentation (Re-motion Database, 2015). The surgeons gave the impression that they at the Haukeland department would really like this kind of functionality in hip- and knee-prostheses research to keep them up to date, instead of having them to wait for an annual report to be published.

2.8.6 PubMed Database

The PubMed database created by *National Center for Biotechnology Information* (NCBI) at the *National Institutes of Health* is a search engine to search citations for biomedical literature from MEDLINE, life science journals and online books from around the world. They might even include navigation to the full text (US Natinoal Library of Medicine & U.S. National Institutes of Health, 2014).

The website is often used by the researchers at Haukeland to find relevant literature to the current medical product they are working with. By having the program search for relevant literature regarding the relevant case would save them a lot of time. In addition, the NCBI provides functionality to query their data and retrieve it as XML called the *The Entrez Programming Utilities* (E-utilities). The E-utilities includes by now 37 databases to query, including PubMed (National Center for Biotechnology Information (US), 2010).

2.8.7 ResearchAE

This is a tool that was published a few months after the OpenFDA was published 2th June 2014, during the writing of this thesis. What it does is basically one of the main objectives in the following thesis, as it can search through Open Data sets like the OpenFDA, DailyMed, ClinicalTrials.gov and many more. It also lets you fill in specific information or just keywords to find the relevant reports according to your criteria and generates a summary and some statistics based on the keywords you have given. Even though it felt a bit disappointing that someone had done the same as the goal of the following project during the writing of this thesis it also further proofs the need of integrating all the sources into one system. However, they still lack a lot of the functionality that is needed for the specific user group defined in this thesis, like functions for reporting incidents and to look at the data collected at Haukeland (Social Health Insights LLC, 2015).

The website belongs to a company called *Social Health Insight*, which seems to be a consulting firm that mainly work with health data and software development. They also work with visualization of client data and a lot of other stuff (Social Health Insights, 2014).

3) Methods and Methodologies

The following chapter presents the methodologies used in this thesis research, what quantitative or qualitative methods that have been applied and how the seven guidelines by Hevner et al. (2004) have been integrated in the project work.

3.1 Design Science

Design Science and *Behavioural Science* are two paradigms in the art of information system research. While the Behavioural Science is based on development and verification theories on human or organizational behaviour, the Design Science paradigm is concerned with creating new and innovative artefacts that serve human or organizational purposes. The Design Science paradigm is the one that has been applied to this master thesis. In the research essay from the *Mis Quarterly* paper, seven *design-science research guidelines* have been established to assist researchers, editors and readers to understand the requirements for effective design science research (Hevner, Salvatore T, Jinsoo, & Sudha, 2004; March & Smith, 1995, p. 253). How the seven guidelines are applied to this project will be presented here, and an overview of the different guidelines is given the *table 3-1*.

Design as an Artefact

The first guideline presented is the "design as an artefact". As stated in *table 3-1* "*the design-science research must produce a viable artefact in the form of a construct, a model, a method, or an instantiation"*. The artefact created during the research is created to state an important organizational problem. Even though normally an artefact is not fully implemented or used in practice after the research is complete, they still define the ideas, practices and technical capabilities the information system can accomplish if developed further (Hevner et al., 2004, p. 83).

The artefact created in this thesis will be a web-based search engine prototype, where the user can search local data stored in the local database created by Berntsen (2015), which can be explored in *Chapter 2.8.1*. In addition, the artefact will allow searching for relevant external Open Data. The artefact was also expected to show different options on how to present massive amounts of data in a user friendly way and show the power and possibilities

of having Open Data accessible for everyone to use. This artefact will save its users a lot of arbitrary man hours and can be used as a motivational factor for the surgeons to report medical device related problems and failures to the Biomaterials Research Group (University of Bergen, 2015). Another artefact created for this thesis would be a copy of the local database in a machine-readable language. This will be done in the JSON format, so it can be used as Open Data in the future and maybe as an **A**pplication **P**rogramming **I**nterface (**API**) for others to utilize. As stated before, the artefact will not be a fully functional information system after the thesis. It will however be a good prototype for further development and as means to secure research funding.

Guideline	Description
Design as an artefact	Design-science research must produce a viable artefact in the form of a construct, a model, a method, or an instantiation.
Problem relevance	The objective of design-science research is to develop technology-based solutions to important and relevant business problems.
Design evaluation	The utility, quality, and efficacy of a design artefact must be rigorously demonstrated via well-executed evaluation methods.
Research contributions	Effective design-science research must provide clear and verifiable contributions in the areas of the design artefact, design foundations, and/or design methodologies.
Research rigor	Design-science research relies upon the application of rigorous methods in both the construction and evaluation of the design artefact.
Design as a search process	The search for an effective artefact requires utilizing available means to reach desired ends while satisfying laws in the problem environment.
Communication of research	Design-science research must be presented effectively both to technology-oriented as well as management-oriented audiences.

Figure 3-1: Design Science Research Guidelines (Hevner et al., 2004, p. 83)

Problem Relevance

The second guideline presented in *table 3-1* is *problem relevance: "The objective of design-science research is to develop technology-based solutions to important and relevant business problems"*. The difference between the current state of the system and the new state of the system can be defined as the problem (Hevner et al., 2004, p. 83-85).

The researchers at the Biomaterials Research Group are currently manually searching for data from several different resources manually and some of them do not have enough information about open resources that are readily available on the World Wide Web. The new system will gather relevant data based on a single case or search terms as defined by the user faster and easier, all within the same system. These functionalities will narrow down the search process and give the user an overview of all the relevant data quick and simple. To attain a quick overview, the system will provide a simple, visualized, statistics based on the search terms that the user provides to the system. More specific details can be found by opening a record. This will save the amount of workload for the given user as well as to promoting Open Data and its capabilities in the medical device domain in Europe today. It will also provide the surgeons a way of keeping track of their own reported records on device failures, as a motivational factor to keep reporting problems with medical devices.

Design Evaluation

Design evaluation, *"The utility, quality, and efficacy of a design artifact must be rigorously demonstrated via well-executed evaluation methods* is the third guideline presented in *table 3-1*. It shows the importance of evaluating the artefact being developed for the given research. There are several ways of evaluating the artefact, for instance by its functionality, performance, reliability, usability, efficiency and much more. When the artefact satisfies the requirements it was meant to solve, it is considered complete (Hevner et al., 2004, p. 85-86).

During this project both an end-user evaluation and an expert user evaluation was performed. A more detailed description of the evaluation is provided in *Chapter 5.1*, while a detailed description of how the evaluation actually was performed and the result of the evaluation will be presented in *Chapter 5.2*. Test-Driven-Development, which will be presented in *Chapter 3.2.2,* has also been applied as an evaluation method in this project to ensure quality code for the artefact being developed.

Research Contributions

The fourth guideline, research contributions, states that; *"Effective design-science research must provide clear and verifiable contributions in the areas of the design artifact, design foundations, and/or design methodologies"* (Hevner et al., 2004, s. 83). The main questions to ask yourself considering this guideline is what is new and interesting about this contribution?

In this thesis the main research contribution will be the design artefact developed for the targeted user group. The artefact contributes to the field of research by having all the external sources, used during research on biomaterials, gathered in one place together with their local data regarding explanted hip- and knee-prosthesis. This is to provide efficiency to the research and the work routines at the Biomaterial Research Group and to present the massive amount of data from different sources in a user friendly and clear way. The artefact is also designed to encourage surgeons to report to the Biomaterials Research Group and in that way promote and enhance research on biomaterials using information technology as well as Open Data itself.

Research Rigor

"Design-science research relies upon the application of rigorous methods in both the construction and evaluation of the design artifact" is the next guideline presented in the paper (Hevner et al., 2004, p. 83). It gives an overview of how the rigor methods are conducted both in the process of constructing the artefact and during evaluation of the artefact.

To keep the developing process going, the methodology Personal Kanban (Benson & Barry, 2011) has been adopted to manage the workflow and to plan the work progress. The development process has also been iterative by dividing the project in four iterations following the process of system development from a methodological viewpoint by Nunamaker & Chen, (1990).

The user interface of the system has been evaluated according to the *heuristic evaluation* presented by Nielsen (1995) which is a way to find usability problems in a user interface design. This is accomplished by having a couple of evaluators "judge" the system according to the 10 usability heuristics (Nielsen, 1994, 1995). ***S**ystem **U**sability **S**core* (SUS) has also been used towards the end-users to find the usability of a given product or service (Brooke, 1996). A closer look on how this is accomplished will be done in *Chapter 5.1* while the results of the evaluation can be found in *Chapter 5.2*.

Design as a Search Process

The second last guideline presented in the paper is as follows; "*the search for an effective artifact requires utilizing available means to reach desired ends while satisfying laws in the problem environment"*. For the sake of simplicity, let's break this sentence down: *mean*s are

the actions and resources, the *end* represents the goal and constraints and *laws* are uncontrollable forces in the environment (Hevner et al., 2004 s. 89).

The *Generate/Test* cycle presented in the journal has been followed during the whole developing process (*Figure 3-2).* For each iteration of the development phases, the design solution proposed has been presented for to a "super user" from the Biomaterials Research Group at Haukeland, to see if it fits their need and requirements. The requirements were created in the beginning of the development process. By following this model, each step would get the information system that's being developed a step closer to the desired design as the intended user wants.

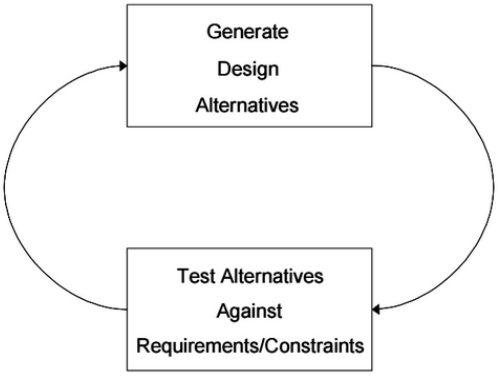


Figure 3-2: The generate/Test cycle (Hevner et al., 2004 s. 89)

Communication of Research

The final guideline presented by Hevner et al. (2004) is "*Design-science research must be presented effectively both to technology-oriented as well as management-oriented audiences"*. It is important to present the thesis to a management audience, as well as the technical audience, so that the management audience can get enough details to determine if it is worth funding, constructing or purchasing within their organizational context. The technical audience needs sufficient details to be able to implement the artefact created and to take advantage of the benefits offered by the artefact, and how it enables for further extensions and evaluation. It is therefore important to give a clear understanding for the audience how the artefact was constructed and evaluated (Hevner et al., 2004, s. 90).

This master thesis will be presented to both the target audiences. As this project will be used to secure further funding, it is very important that it can be of use to a non-technical reader. While information about how the system was implemented, what system development methodology and architecture was chosen might be of interest for the technical users. The evaluation results, conclusions made and the description of the need for the system might be more interesting for the management.

3.2 Methodologies

Methodologies are used in software development to structure, plan and control the process of developing an information system. There is lot of methodologies to choose from, like the well-known waterfall method or Agile methods, like Scrum (Schwaber, 2009) and *Extreme Programming* (XP) (Highsmith & Cockburn, 2001). Under the duration of this master project, the combination of two methodologies has been utilized to ensure a good quality and planning during the master thesis period: *Kanban* and ***T**est **D**riven **D**evelopment* (**TDD**).

3.2.1 Personal Kanban

Personal Kanban belongs to the *lean* family of methodologies. *Lean* is all about finding ways to eliminate "waste" and to increase efficiency. It was conceived in a manufacturing environment, but fits well for all types of projects (Klipp, 2013, p. 3). Personal Kanban was selected as methodology ahead of the similar methods, namely Scrum and XP, since they focus on teamwork. Scrum has roles like product owner, the team and the scrum master. For a single developer on a project like this, it would be impossible to assign all the different roles to one person. Even though the focus is largely on team work, a lot of the elements presented in Scrum are useful and can be adopted to the Personal Kanban methodology, like the practice of following a product backlog and sprints (Schwaber, 2009, p. 6-7). An introduction to the most important parts of Personal Kanban will be given in the following section.

There are only two main rules to follow when using Kanban

- Visualize your work
- Limit your work-in-progress (WIP)

"Visualize your work*"* means creating an actual visual representation of your tasks. One way to achieve this is by creating a *Kanban Board* with different statuses for the project tasks. The complexity of a Kanban Board can range from something as small and simple as a piece of paper to a whiteboard. In this thesis the web tool Kanbanize.com has been used to visualize the workflow (BusinessMap, 2015). The board can be kept as straight forward as having three main states "to do", "doing" and "done" like illustrated in *Figure 3-3*. "To do" will act as *product backlog* with all tasks that have yet to be complete. "Doing" contains the currently

ongoing tasks, while "Done" will here be all the tasks that are completed. The board for this master thesis employs a couple more states: *requested, in progress, approving* and *done*.

WIP (Work-In-Progress) is a way to set a limit on a number of ongoing tasks and to avoid overextending the amount of work. By setting a WIP-limit to a task, it can only be assigned that number of tasks in its current state, the limit cannot be exceeded. The philosophy behind this is that one gets more done by doing smaller jobs at a constant basis within a set time-frame, rather than having sporadic periods of down time and crunch time that you cannot predict. It is all about staying consistent and sticking to the project timeframe. There is a limited amount of jobs one can be working with at the same time and still make the most of the effort. By having a WIP-limit the project will have manageable chunks and the people working on the project will have a good chance to finish jobs that have been started. In *figure 3-2* a [5] has been placed behind the "doing" state, which was the WIP limit. No more than five post-it-notes, or tasks, is allowed on this state (Benson & Barry, 2011; Klipp, 2013).

To create the Kanban board for this thesis, User Stories (Cohn, 2004) have been thoroughly planned and conceived in collaboration with the super user, they have been based on interviews with the main user group of the project. The main user group are the employees at Biomaterial Research Group at Haukeland University Hospital. A view on the Kanban board created for this thesis will be done in *Chapter 4.2*.

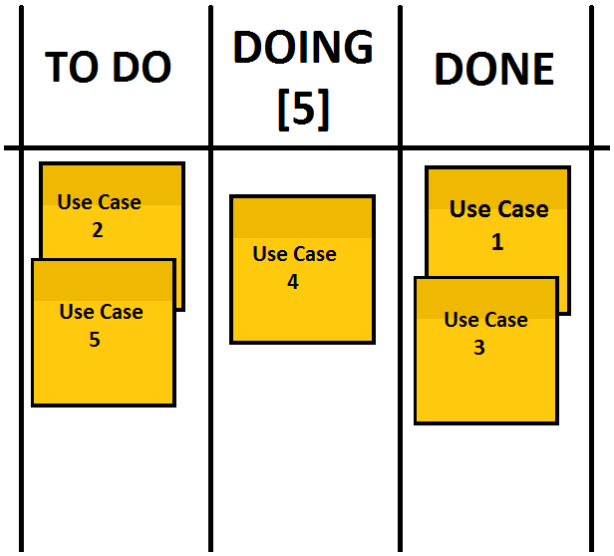


Figure 3-3: Kanban board with tasks, steps and WIP

3.2.2 Test Driven Development (TDD)

In addition to Kanban, **T**est **D**riven **D**evelopment (**TDD**) (Johnson, 2013) has also been used during the development phase. TDD lets the developer perform tests without having to create a user interface and it is a good way to create a prototype. It is an efficient way to write a bit of code and see if it had worked as expected (Johnson, 2013). It works the way that some new code is written only if the automated test has failed. How does this work one may ask? Briefly explained the developer has to write the tests before writing the code. The developer starts with a small test, that probably does not even compile at first, then has to make the test work by code before moving on to another task (Beck, 2003). In *Figure 3-4*, a simple example has been made to explain the logic of TDD. The first thing that is done (1) is to write a test method that describes what you want the program to do. The test of course fails when running it the first time, because there is no code to do the operations the test is told to do. By writing the test method the developer will have a good understanding of what the "real" code should be doing. In the second frame (2) the actual method for the test is written. If the test then is tested again, the test is complete (3), meaning that the goal of the methods is made. By using this methodology during the project, good quality code will be produced and errors occurring can quickly be found in the code.

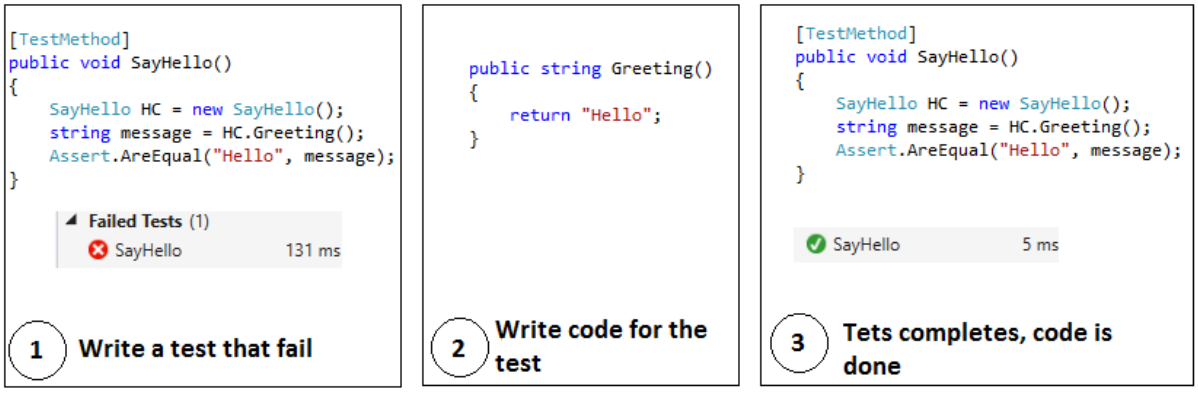


Figure 3-4: TDD explained in practice

3.3 Research Methods

What methodology to choose is an important question in the master thesis. There are two main form of research methods; *qualitative* and *quantitative*. An introduction to both of the methods will be given in the next section. Both the methods are quite different, but they have one important thing in common, which is that they both focus on how to gather, process and analyse data (Hellevik, 2011).

3.3.1 Quantitative Methods

Hellevik (2011) describes *quantitative* as a method where the scientist gathers comparable information on multiple investigation objects and represents the data as numbers, and then try to analyse patterns found in these statistics. Normally there are large numbers of data present in quantitative methods with many entities. An "entity" usually represents a single person responding to a survey. The quantitative data can be used to generalize and summarize as the quantitative research identifies that something happens (a lot of entities but a few number of variables). This, of course, differs from qualitative data where the number of entities usually is fewer and the researcher wants to go in depth of the topic. This will be discussed in the next section. Surveys are good examples of quantitative methods, where a large number of surveys are sent to a lot of people responding to them (Hellevik, 2011; Hoffmann, 2013).

3.3.2 Qualitative Methods

As mentioned in the section about quantitative methods, the *qualitative* methods differ from the quantity of examined entities by having a small number of entities that are explored in a less structured way. This means that instead of doing a broad and generalist research, the researcher can narrow down the number of entities to a few, which would give the opportunity to going in depth with each subject on the topic being researched. In qualitative methods, the scientist collects data based on his or her ability to empathize with and understand a pattern of sensations the researcher receives from interacting with the research subject. Observation and interviews are good examples of qualitative methods (Hellevik, 2011). There is a tendency within the scientific community to be sceptical towards the qualitative methods. The main criticism being that it is believed that serious research cannot

be archived on such a low number of participants, because the data gathered is not plentiful enough to be considered useful information itself. Another topic of discussion is the possibility of misinterpretation. What if the researcher misinterprets the participant? Then the research will surely loose validity. This thesis will not delve into the contentious debate between qualitative and quantitative research methods, but it is important to have this in mind when doing research (Hoffmann, 2013).

3.3.3 Method Usage: Mixed Methods

For this research both the methods, qualitative and quantitative, would be of great relevance and will therefore be mixed/combined. Relevant methods from both qualitative and quantitative methods (Hellevik, 2011) will be used and selectively applied to the project. In the next sections the methods that will be used during the research and a short description of each of them will be given.

Quantitative Survey

A structured survey is a quantitative method and it usually has predetermined response options to the questions asked of the participant. This is without a doubt the most used method to gather data by scientists today. An important thing to keep in mind while creating surveys is to have clear and meaningful questions which are not leading those responding to the survey to answer what the researcher wants them to answer (Hellevik, 2011).

Two surveys have been created for this thesis, one for the "normal" users (*Appendix D*) and one for the "expert" users (*Appendix E*). Both the surveys will be given after a user has evaluated the artefact created during this thesis, by performing some pre-defined tasks (*Appendix C*) to cover the main defined functionalities in the system. More about the content of the two surveys and why they were selected can be read in *Chapter 5.1.* In this chapter the results will be presented as well.

Qualitative Interview

An interview is usually conducted by having one person, the "interviewer", ask the subject questions orally while recording and then writing a transcript of what is being said. An interview could be face to face, by telephone or through the Internet. One advantage with interview is that the interview can follow up an answer with another question if the interviewer thinks that he is starting to get into something interesting (Hellevik, 2011).

In the thesis a few intended users of the system were interviewed before the development started, to establish a prediction of their needs and wants for the system being developed. The interview can be found in *Appendix B1-B4*, while the results gathered from the interview can be found in *Chapter 4.2*. The interview was semi-structured. When an interview is semi structured it uses both features from structured and unstructured interviews, by having both open and closed questions (Rogers et al., 2011, p. 229). The interviewer will therefore have a script for guidance so that the same topics are discussed in every interview. The interviewer can use the script in the beginning of the interview and then he probes to get the interviewee to tell more, if some interesting is coming forward. The reasoning as to why qualitative methods were chosen for this instance instead of quantitative, is because of the possibility to discuss in depth with the intended users and more easily understand their feedback (Rogers et al., 2011).

Qualitative Observation

Observation is another qualitative method put to use in this project. The method is in system development a useful data gathering technique both early in the design to help the designers understand the users and later in development for the evaluation to see how well the developed prototype support tasks and goals (Rogers et al., 2011, p. 247). *Field studies* and *controlled environments* are two ways of performing an observational study (Hellevik, 2011; Rogers et al., 2011).

In this project the controlled environment observational study have been adopted in the end-user evaluation. This study is when the participants are performing specific tasks within a controlled environment (Rogers et al., 2011). While the participants of the evaluation is performing some specific tasks that covers the most essential functionalities of the system (*Appendix C*), the leader of the evaluation will observe them performing the tasks to find usability flaws the user might not notice during the evaluation or they might forget writing it down in the survey. More details about the evaluation location, the participants and the execution of the evaluation can be studied in *Chapter 5.1.1*.

4) Development of the Prototype

Nunamaker & Chen (1990) have published an article where they critically review system development in information system research. In their article they propose a framework of research to describe how information system research can be adequate as a research method. The building process of an information system consists of the five stages presented in *Figure 4-1*. The entire project and the development of the system of this thesis has been following this process of system development.

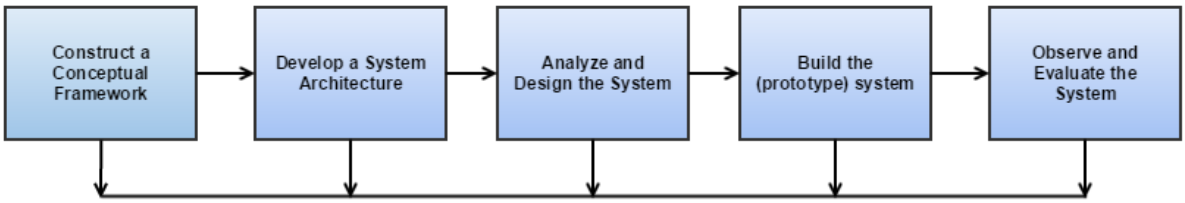


Figure 4-1: Process of system development from a methodological viewpoint (Nunamaker & Chen, 1990, p. 98)

The development of the prototype was mainly divided into four iterations, following the stages in *Figure 4-1*. *Construct a conceptual framework* was the first iteration carried out, followed by *develop a system architecture* and *analyse and design the system*, which has been merged together into the second iteration. In the third iteration, *build the (prototype) system* is the stage carried out, followed by the important *observe and evaluate the system* stage.

This chapter will follow the whole process of system development stage for stage, iteration for iteration. The main goal for this system development process is to create a user friendly prototype of a system (artefact) where the employees at the Biomaterial Research Group, and potentially the general public, can search the local data stored at Haukeland University Hospital. It will have functionalities as grabbing data and providing statistics from three different external sources, with relevant or similar data.

4.1 Project Start-up: Pre-iteration

The idea of the project was introduced by a *super user* working at the Biomaterial Research Group at Haukeland University Hospital, who saw the need of such a system being developed and funded for their business environment. During the entire developing the super user would be notified of what has been done, what tasks is in progress and the plan ahead. Together with the super user the main requirements and the involved user groups were outlined and discussed. The initial, temporary requirements outlined helped to get an understanding of what was desired. After some preliminary work was done, the main set of requirements could be set based on interviews with the remaining employees in the lab, as well as surgeon working with hip- and knee- prostheses.

In the beginning of this project the most important thing was to get an understanding of the work done at the Biomaterial Research Group, located at Haukeland University Hospital, as well as getting some basic knowledge about medical devices and how they are dealt with in Europe, the U.S. and especially in Norway today. A summary of the most relevant literature and findings can be read in *Chapter 2.2* and *2.3*. By having basic knowledge of the field it was easier to understand what the user group wanted and what they were talking about during interviews, discussion and developing.

4.2 Establishing Requirements: 1. Iteration

When knowledge and the basic ideas were obtained, the search for the real requirements could start. The requirements were acquired by interviewing the main users of the system. The interview was, as described in *Chapter 3.3.3*, semi-structured. The transcription of the interview can be found in A*ppendix B1-B4*. In the next section we will discuss the user groups created for the system and the use cases created based on the interviews.

4.2.1 User Groups and User Stories

Based on the data obtained from the interviews and by having frequent discussions with the *super user*, four main user groups and what functionality each of them should have in the

system were set. Who the different user groups are and what kind of functionality they should have in the web application is here presented:

- **Administrator:**
  This is the user group responsible for the security off the system, how much access the different users should have; this is the user responsible operating the system. The administrator could be an employee at the IT-department or a super user from the Biomaterial Research Group. The administrator has also the same functionalities as the remaining users presented.

- **Researcher user:**
  This is a researcher at the Biomaterials Research Group. This user is the one doing the analysis of the failed medical devices and is creating the records. The user will therefore have full access to all the functionalities in the system, except those presented in the administrator user. This user group will be able to create records, edit records and see all the information in the records available. The researcher also has all the functionalities as the remaining users presented.

- **Surgeon user:**
  A surgeon user contributes to the Biomaterials Research Group by sending samples and submitting data. A surgeon user does not have the same access as the *researcher user*. The user would be able to see all the information available in the case the surgeon has reported and other finished processed records, but not what other users have reported. The surgeon also has all the functionalities as the remaining users presented.

- **Public user:**
  The public user could be anyone, anywhere in the world. The public user could be anything from a student with interests in the research field of medical devices, maybe an analyst who wants to perform analyses on the data or maybe a curious person like a patient or the relative. The public user will have restricted access and can only see a small amount of information, just like the data presented in MAUDE (FDA, 2014), where no sensitive information is presented. This user, including all the other users,

will of course have access to the main functionality of the system, which is doing searches across all the open databases supported in the system.

After the main users had been identified, more specific use stories were made based on the interviews and by having continuous discussion with the *super user*. A user story has a standard form of writing, and it goes like this: *As a <type of user>, I want <some goal> so that <some reason>* (Cohn, 2004). A user story like this simply explains the needs in the system and the user requirements in an everyday language. The user stories created for the following project can be found in *Figure 4.2.*

U1	As a researcher user, I would like to only input a simple keyword, to easily find the record that I am looking for in the database.
U2	As a researcher user, I would like to input more detailed information, to easily obtain a list of relevant records according to the input given.
U3	As a surgeon user, I would like to be able to see the records I have submitted, so that I can see the progress of my case.
U4	As a public user and surgeon user, I would like to only input a simple keyword or more detailed information, to easily obtain a list of relevant records, with limited information, to the input given.
U5	As a general user, I would like to find similar cases or relevant cases from external sources like MAUDE, Clinical Trials and PubMed, to see experiences done by other or in other countries.
U6	As a general user, I would like both the meta data- and the keyword- search to be efficient, so that I can get the meta data as quickly as possible.
U7	As a surgeon and research user, I would like the system to follow medical query standards, to avoid confusion.
U8	As an administrator, general users must not have access to patient information or surgeon information, to prevent sensitive personal information is being misused.
U9	As a general user, I would like a simple graphical interface, so that I can easily navigate through the system and find the relevant data quickly.
U10	As a surgeon, I want to be able to report incidents using a simple web form,
U11	As a general user, I would like to be able to select some attributes I find interesting from local data and compare them to the external meta data search, so that I could get as best matching data as possible.

U12	As a general user, I would like to be able to give the system some attributes I find interesting and compare them to the external meta data search, so that I could get as best matching data as possible.
U13	As a system, I would like to index articles and records from the different external pages, to ensure efficiency and relevant search results for the user.
U14	As a general user, I would like to have some statistics/summary of the meta data result, so it's not getting to overwhelming.
U15	As a general user, I would like to be able to filter the result data, so I can simply find the record I am looking for.

Figure 4-2: User stories for the thesis

The user stories created were then ranged of importance in a **M**o**SC**o**W**-table (**M**ust have, **S**hould have, **C**ould have, **W**ant to have) (Stapleton, 1997, p. 28-29). A **M**o**SC**o**W** table is a good way to prioritize the different user stories, and to find out what should be implemented first and last. The requirements that ends up under the "**must have**" would be the most fundamental functionalities in the system, and the system would be rather useless without them. "**Should have**" is important and needed, even classified as mandatory, but the system will work fine without them and is therefore not crucial to implement. "**Could have**" is basically requirements that is nice to have but can easily be left out at this development stage. The final one, "**Want to have**" is really not important, but could be implement if time or at a later time (Stapleton, 1997, p. 28-29). The MoSCoW table for the following project can be viewed in *Figure 4-3*.

Must have	Should have	Could have	Want to have
1, 2, 5	3, 7, 8, 9, 10, 14	4, 6, 11, 12, 13	15

Figure 4-3: MoSCoW-table for the user stories presented in figure 4-2.

As well as being prioritized, the user stories were now added to the Kanban Board, and based on the prioritizing done in the MoSCoW table, it was decided which of the user stories that should be moved to "in progress" on the Kanban board and in what order. As for instance the *user story 1* was one of the first user stories to be moved. Because, without this functionality there would not be much of a system to use.

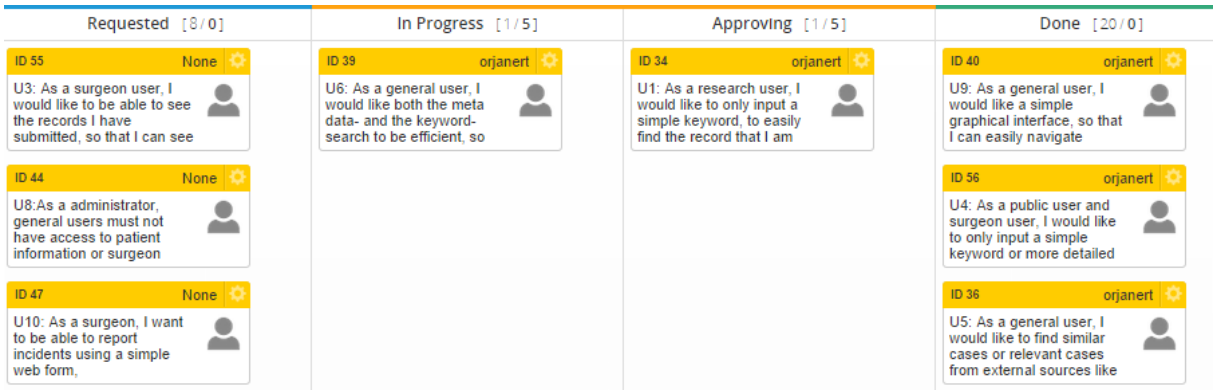


Figure 4-4: Kanban board from kanbanize.com

During the entire development process Kanban has visualized the workflow of the project and the different use cases will be moved around on the Kanban board according to its current state. The WIP-limit is set to 5 tasks. As described in *Chapter 3.2.1*, this is a good way to avoid taking on too much work and actually get the work done, by avoiding having a large amount of work halfway done (Benson & Barry, 2011).

4.3 Design Alternatives: 2. Iteration

4.3.1 Conceptual Design

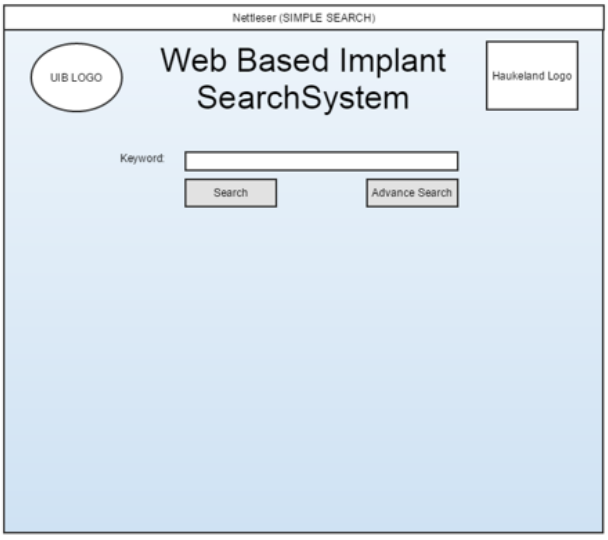
Before starting the development of the prototype, some suggestions for the design needed to be made and approved by the main user group which the system is being developed for. The previous steps in this chapter have given a lot of data to work with. It is now time to create some sketches on how the system should look and work. The mock-ups were drawn using the Gliffy tool presented in *Chapter 4.4.6.* In this section, each of the design mock-ups will be presented, and next to each of the mock-ups a content diagram is attached. A content diagram describes the organization and structure of the user interface. It describes the system by containers and links, where each of the containers have described functions and tasks for the given user interface (Stone, Jarrett, Woodroffe, & Minocha, 2005, p. 144). *Figure 4-5* gives an explanation of each of the symbols that can occur in the containers. Most of the symbols should be rather clear, but what

•	{ performed by user }
■	{ performed by computer }
▶	{ single link }
▶▶	{ double link }

Figure 4-5: Explanation of symbols that can occur in a container (Stone et al., 2005, p. 155)

is meant by single link is when the user moves to another container, the new container will be the main focus of the user work from then on. Double link means that the user might need to go back and forth between the two containers to get the "work done". When all the mock-ups of the system have been presented, an overview of all the content diagrams together, with links between them, displaying the relationship between different containers, that will describe the system architecture of the program (Stone et al., 2005). An explanation of the design choices taken will be provided for each of the content diagrams.

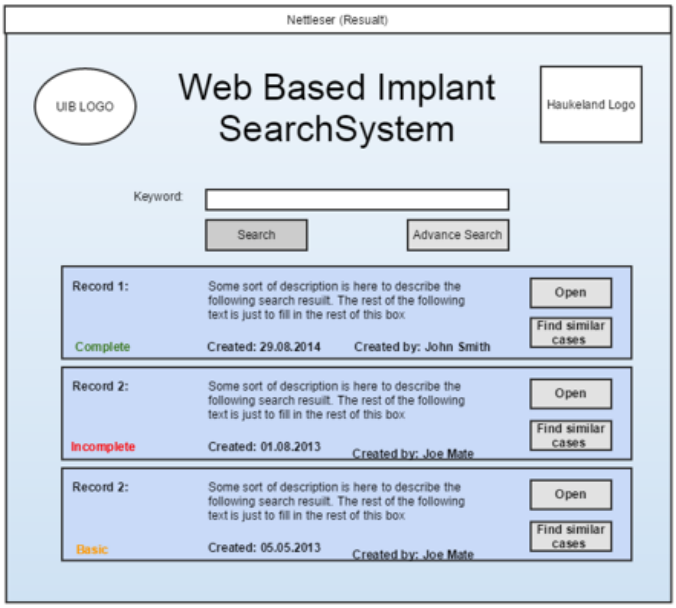
The first container presented is of course the main page (*Figure 4-6*). The main page is kept as simple as possible for an aesthetic and minimalist design, as it should be according to the ten heuristics by Nielsen, 1995. It contains only a single search bar, where the user can enter a keyword to search the local database, as well as a button to navigate to a more "advanced" search. This is expected to be the most frequent task performed by the user of the system and is therefore the only functionality available on the main page. Also known as use case 1: *As a researcher user, I would like to only input a simple keyword, to easily find the record that I am looking for in the database.* By having just a few functionalities on the main page can prevent the user from making errors while using the system (*error prevention*). By having visible elements that the user can make use off to complete the tasks also complies with the *visibility* design principle. The main page also *follows consistency and standards* by using words like "Search" and "Advanced search". Those are common words when working with search engines on the World Wide Web today. Both those design principles will be followed through the whole user interface. The colours of the application are mild and do not take much attention.



Name:	Main Page
Purpose:	Supports most frequent tasks
Functions:	• Search local data by keyword ▪ Check search criteria
Links:	▸ Search ▸ Advanced search

Figure 4-6: Main page with associated content diagram container

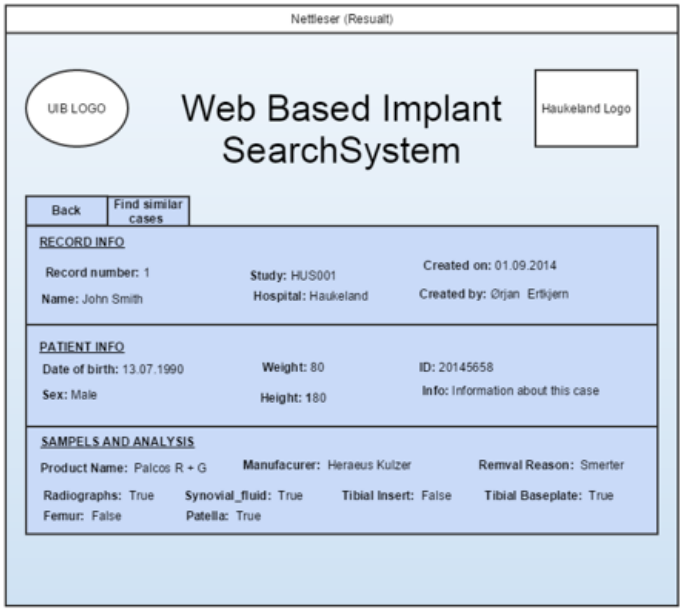
If the user enters a keyword into the search field, the search result will be presented like illustrated in *Figure 4-7*. The user is presented with a simple overview of the relevant records. The results contains a short abstract to describe the records and some other relevant information for the user, like if the data is complete or not complete with colours matching the status. Functionalities supported in this view is to open a specific record or to do a "find similar cases" search, which will search through all the external sources based on variables in the relevant record. To keep the system consistent the web application it will use the same terms and format as the Windows application the Biomaterial Research Group had developed last year (Berntsen, 2014).



Name:	Search Result
Purpose:	Display the relevant records based on the keyword given
Functions:	■ Show search result • Find similar cases • Open a spesific record • Search local data ■ Find relevant keywords for the similar cases search
Links:	▸ Main Page ▸ Advanced search ▸ Open Record ▸ Find similar cases

Figure 4-7: Search result

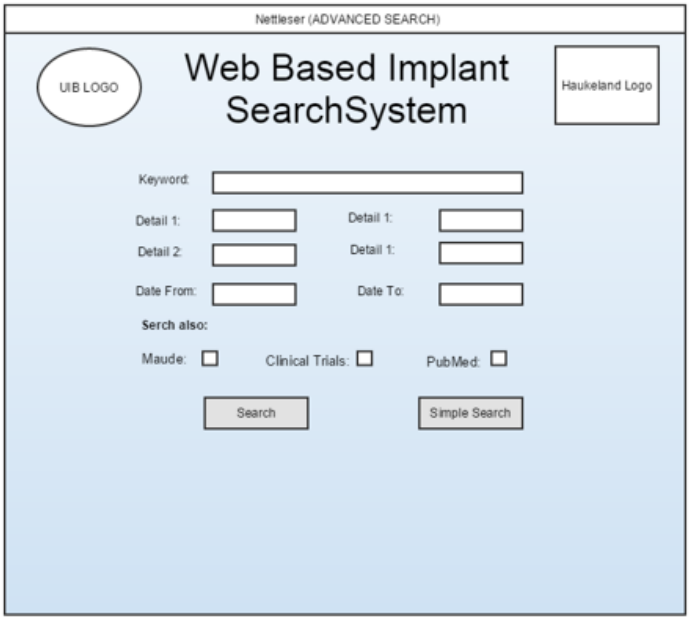
By opening a specific record the system will provide the user with a screen with more detailed information about a single record displayed in *Figure 4-8*. The page for a specific record will have the same user interface design as the Windows application. From this page the user can use the time studying the record, perform a "find similar cases" or go back to the search result page.



Name:	Record Details
Purpose:	Show detailed information about a selected record
Functions:	■ Show details for a record • Find similar cases ■ Find relevant keywords for the similar cases search
Links:	▸ Find similar cases

Figure 4-8: Record details

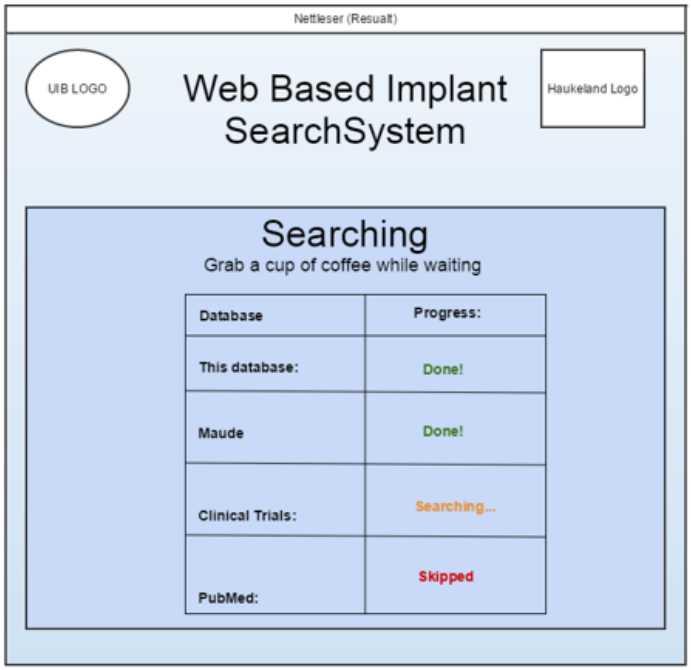
The advanced search, presented in *Figure 4-9*, will have the same design and functionalities as the "normal search". The difference here is more input possibilities, so that the user can narrow down the search results, which can be very large, and find more specific search results. In the advanced search the user also have the possibility of selecting what external databases to include in the search, by clicking on the corresponding checkboxes. External sources supported by the system prototype are as previously mentioned ClinicalTrials, MAUDE and PubMed which can be read more about in *Chapter 2.8.*



Name:	Advanced Search
Purpose:	Enter more spesific keywords and search multiple databases
Functions:	• Enter multiple keywords • Select different databases to search ■ Check search criteria
Links:	▸ Main Page ▸ Search

Figure 4-9: Advanced search

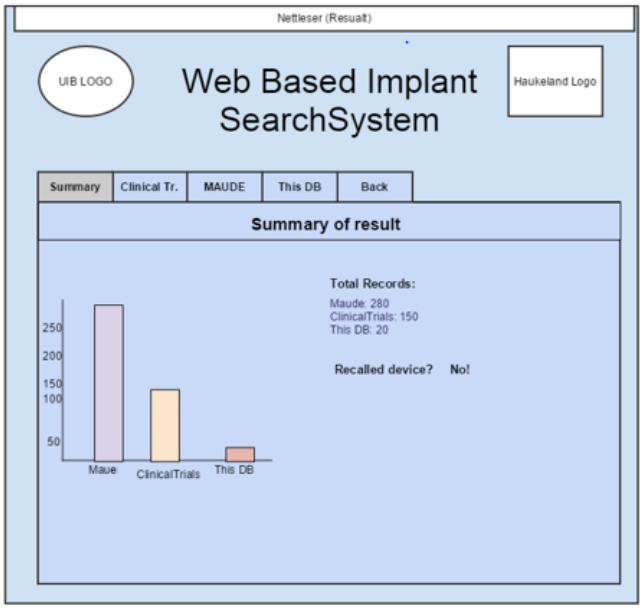
After performing an advanced search from several external sources, a lot of data needs to be gathered, processed and presented. Depending on how specific the user has been filling out the advanced form, it might take a few minutes processing inaccurate searches. To satisfy the visibility of system usability heuristic by Nielsen (1995) a loading page has been created, to tell the user that something is going on. This is a page where the user cannot do anything at all to the web application, just wait, as described in the container next to *Figure 4-10*. This page is mainly for the program to grab the relevant data from the different sources and to calculate relevant statistics that can be made.



Name:	Advanced Search (Loading)
Purpose:	To tell the user that something is happening. Just wait
Functions:	■ Searching for similar records ■ Calculating statistics
Links:	▸ Search results

Figure 4-10: Loading page

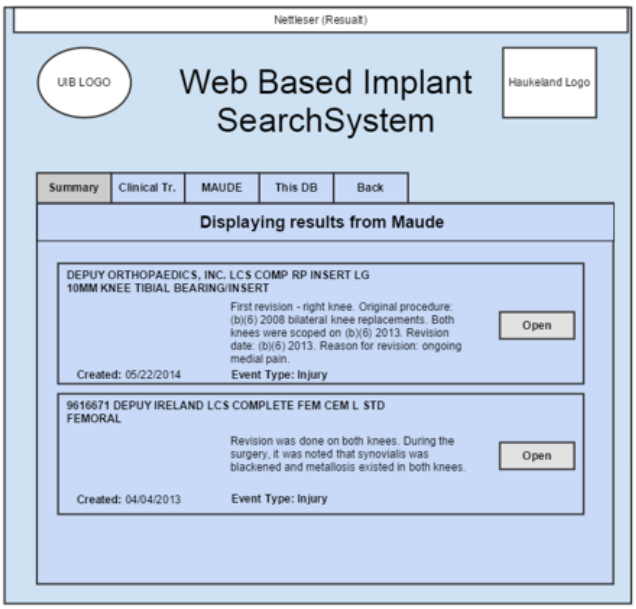
When the loading is finished, a summary page of all the results is presented for the user. This page contains some summary statistics based on the data retrieved from the different sources as well as a tab for each of the databases selected to retrieve data from. The user can click on each of the tabs to find the relevant records from them based on the search performed. A suggestion on how this page could look is presented in *Figure 4-11*.



Name:	Advanced Search Result (summary)
Purpose:	Give the user a short summary of what was found
Functions:	■ Display statistics ■ Display relevant data/records • Open tabs with relevant data from the different relevant databases
Links:	

Figure 4-11: Advanced search result

As mentioned in the previous section the user can select a specific tab to get the relevant data from that specific source. If the user for instance press the MAUDE tab, the user will be presented with relevant data retrieved from the MAUDE source. This could look like presented in *Figure 4-12*. The data presented in each tab is presented as they are on their own website to ensure consistency and to follow medical standards. This also ensure *match between system and the real world* for those that are going to use the system.



Name:	Search Result (Advanced search)
Purpose:	Display the relevant records from a spesific external resource based on the keyword given
Functions:	■ Show search result • Open a spesific record similar cases search
Links:	▸ Main Page ▸ Open Record

Figure 4-12: Search result for MAUDE tab

Based on the containers and the mock-ups created in this part a content diagram for all the pages together were created, to illustrate the workflow and architecture of the system. Only the titles from the containers are included (*Figure 4-13*).

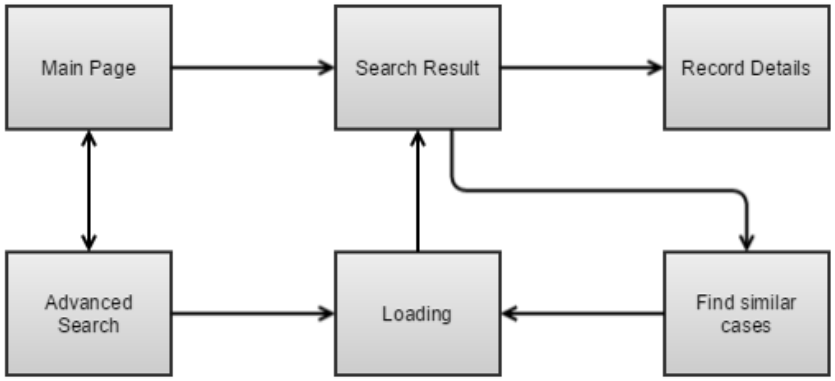


Figure 4-13: Content diagram of the system

By creating this content diagram and mock-ups a nice overview of what has to be done is provided. How the actual user interface looks like and what differences had been made will be presented in *Chapter 4.5*. The mock-ups of the system were presented for the user group so that they could give feedback, suggestions or identify needs that were missing in the mock-ups, like an informal focus group. All the sketches were approved before going to the next step of the project. Before moving on to the development part, a closer look on what development tools and programming languages used during this master thesis will be presented.

4.4 Development Tools and Programming Language

During the entire master thesis different tools have been used to complete the work. In this part of the chapter the most important tools used and the programming languages selected to complete this thesis will be presented.

4.4.1 Programming Languages

An earlier master student at the department of Information Science and Media Studies had already developed a Windows desktop application for the Biomaterial Research Group

written in the language of C#. The choice was therefore already taken. There was no need to develop a new prototype in any other language than this, to keep both the projects concise. The programming language choice therefore fell on C#. C# is based on the object-oriented programming principles, it is language independent for all the other .NET languages and much more (Nagel, Evjen, Glynn, Skinner, & Watson, 2011). The most important part is the good support for dynamic web pages using the ASP.NET technology, as this is going to be a web based application (Nagel et al., 2011). It will also follow the MVC standards as described in the next section.

As the project is a web project, HTML, CSS and JavaScript were used to develop the front-end part of the web application. Shortly introduced, HTML (Hypertext Markup Language) is a mark-up language used since the beginning of the web, and is using tags to provide formatting features. JavaScript is used in the project to create more behaviour and interactive pages, while CSS (Cascading Style Sheet) is used to design and provide a nice presentation for the user interface (Johnson, 2013).

4.4.2 Model View Controller (MVC)

Projects can grow exponentially and become enormous, containing millions of lines of code and hundreds of classes. A project of such magnitude might be difficult for other programmers to acquire. By using an architectural pattern, it will be easier to acquire the project for other developers and to understand the thought process of the previous developer. When it comes to architectural pattern, the project follows the **M**odel **V**iew **C**ontroller (**MVC**) pattern, The MVC architectural pattern is divided into three main components: *model, controller* and *view* (Freeman, 2012)

The *model* is the business logic of the application data, and represents the data being transferred between the views and the controller, or it can do some operations and manipulation of the data. An example of a model in an application can be a *Student* model, which holds on to information about a student signed up for a class. The *view* is the user interface that the users of the system are using to interact with the application logic. It can for instance be a dropdown list returned from the server with all courses available for a student to sign up for. The *controller* is the last component of the MVC architecture, and it is the component that process requests and cooperate with the model and selects what view should be displayed for the correct user. The controller might for instance be handling the selection

of the dropdown list, checking if the student has not registered too many courses and pass it over to the model. It can then update the database table which contains information about the students who have registered for the course. By having a clear definition of each of the component parts in MVC it will be easier to maintain the project in the long run, since one has a clear definition of each component's role in the project (Freeman, 2012; Microsoft, 2015; MSDN, 2014). *Figure 4.14* describes the logic of the MVC pattern and how the different models interact with each other.

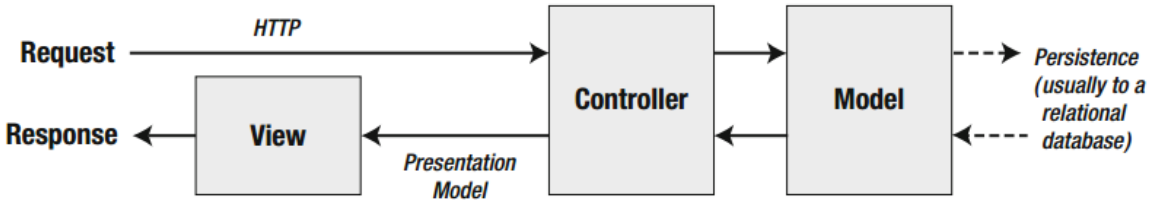


Figure 4-14: The interactions in a MVC-application and its components (Freeman, 2012, p. 49)

Since the project will be developed using .NET, Visual Studio as the integrated development environment (IDE) and C# as a programming language, the ASP.NET MVC 4 framework will be adopted. The ASP.NET framework is following the MVC conventions but is integrated with all the existing ASP.NET features. This might for instance be the master page and the membership based authentication (Microsoft, 2015).

4.4.3 Visual Studio 2013 Professional

The *Visual Studio 2013 Professional IDE* has been used during the developing of the project. It is said to be the ideal Visual Studio edition for a single developer or small teams who will develop for a wide range of web, Windows, phone and cloud applications. As earlier mentioned in this thesis, a previous master student developed a Windows application for the Biomaterial Research Group, while this project will be a web based solution. It was therefore nice to have an IDE supporting most of what Microsoft can offer. Visual Studio also has great support for HTML, CSS and JavaScript (Johnson, 2013). The Visual Studio add-on *Resharper* was med available during the master thesis for students to use for free, and is used for code inspection. It enables to analyse code quality, comply with coding standards, eliminate errors and nasty code and much more (JetBrains, 2015).

4.4.4 Microsoft SQL

A Microsoft SQL database was installed within the University intranet by the IT-department for the previous master student. This server has been adopted for this thesis so that both his Windows application and the project develop during this thesis is integrated against the same database. The database also contains a lot of test data from the previous project which can be very useful to use within this project. As Berntsen (2014) describes in his thesis, the databases has only 10 gigabyte size limit and in the future it will most likely needed to be upgraded. Microsoft SQL is a RDBMS (Relational Database Management System) created by Microsoft. It also support full text search which means that you can search for text within columns that have full-text-search enabled by mapping the data and speeding the search (Atkinson & Vieira, 2012).

4.4.5 GitHub, Kanbanize and Gliffy

GitHub has been used as repository for the following project. GitHub is a repository for hosting code and is based on the Git version control system. Both private and public repositories can be made, and for this project a private repository was made (GitHub, 2015).

To manage and visualize the workflow for the project, the Kanban tool Kanbanize has been used. Using this makes it simple to share you Kanban board with the team members, like the super user, so that he can also have a look at what is being done and what is planned to be done. This give the super user the opportunity to interrupt if he see something that is wrong or should be done in a different way (BusinessMap, 2015). Gliffy also deserve a short note in this section as it is used during this project to create the necessary models and sketches (Gliffy, 2015).

4.5 Prototyping: 3. Iteration

Now as the system requirements have been set as well as the design has been created and approved, the time for developing a prototype has arrived. In this part of the chapter we will walk through the implementation of a few of the functionalities, how the data is retrieved from the different sources as well as a look on the “final” user interface.

4.5.1 Searching Data

As mentioned several times during this thesis, the web application is going to grab data from several sources. One internal source, which is the knee implant database created by Berntsen (2014), as well as three external sources; *ClinicalTrials.gov, MAUDE* and *Pubmed.* Both the web application, now given the name **W**eb**BISS** (**Web B**ased **I**mplant **S**earch **S**ystem), can currently only be used if connected to the University of Bergen (UiB) network or by VPN (to the left in *figure 4-15*). Even though the web application easily could be placed online there is no need for this right now as the system is too dependent on the local data, which currently is only accessible through the UiB-network. In the future, the goal would be to have parts of the local data available as Open Data. This will give others, like scientist or developers, the opportunity to use the data as can be done to the external sources used in this system. At the time of writing, the user group of the system is not sure what elements of the data that should be public or how much, and is something that will be discussed in the future. A suggestion on how this could look is illustrated to the right in *Figure 4-15*, and a small prototype on how the data can be presented as Open Data will be discussed later in this chapter.

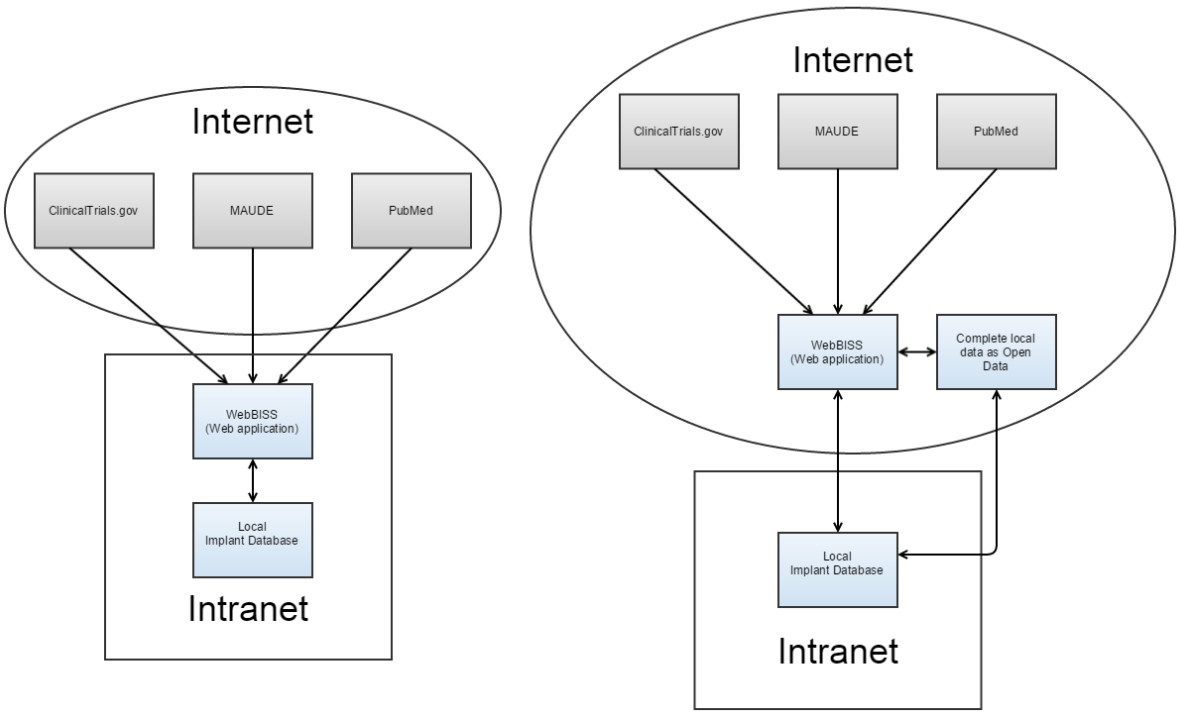


Figure 4-15: The system model today (left) and in the future (right)

Retrieving Local Data

The local data was simply retrieved from the already existing database created by Berntsen, 2014 using LINQ queries. Doing more efficient search would require a restructuring of the database. As this is not the focus of the thesis it was decided to put this on hold.

To search the local data using the *search user interface*, a concept presented in *Chapter 2.7.1*, can simply be done using the main page of the web application. The design of the main page (*Figure 4-16*) is pretty equal as the sketch created in *Chapter 4.3.1*. Some help and information has been added to the bottom of the page to fit the tenth usability heuristics, *help and documentation*. Here the user of the system can find some simple descriptions on how to use the system as well as some simple tutorial videos. The tutorials show how to use the most frequent system functionalities. The main page also has a navigation link to the local database in XML-format for others to use, but this will be covered later. Instead of "Advanced search", it has been given the name "Search multiple databases. The reason for this is that the functionality is not what the user normally would expect as an advanced search, but more like a different search functionality. The "show all records" button, beneath the search bar, will display all the records stored in the local database. This functionality has been added as this is a frequent used functionality in the Windows desktop application. A "home" button has also been added to the top of the web site as an "emergency button" for the user to provide *user control and freedom*. Pressing the Haukeland logo will provide the same functionality as the "home" button. This is a very common way of navigating back to the home page in most web pages, as not all users are familiar to this functionality, this button was added. The observant reader might also notice that a "Login" opportunity has appeared in the top right corner, but this will be covered later. Otherwise, the usability heuristics for interface design are the same as presented in *Chapter 4.3.1*.

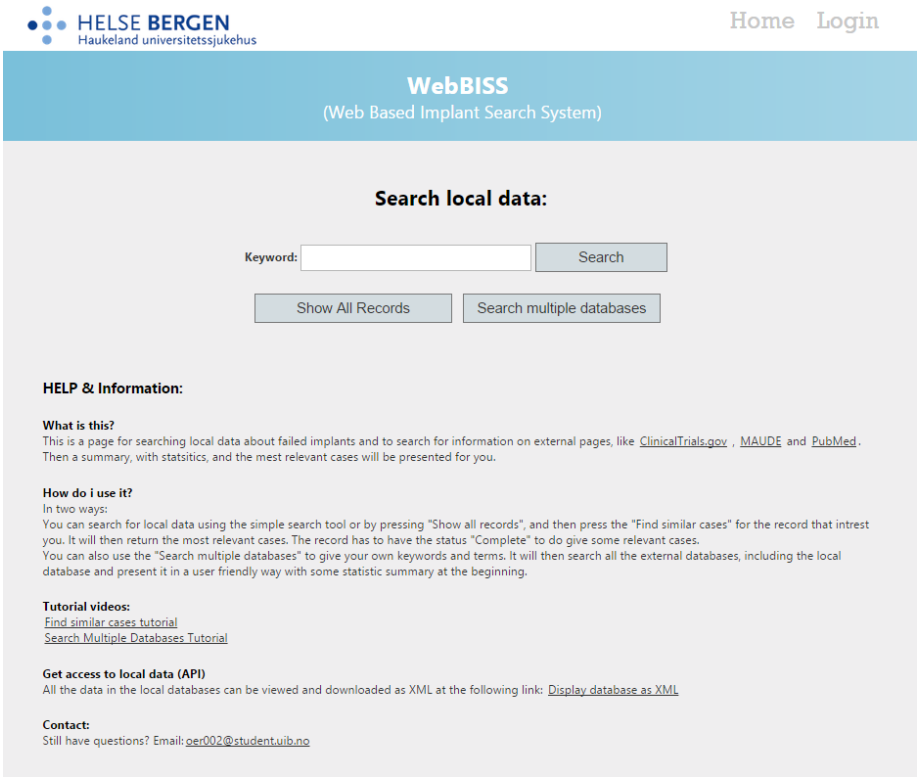


Figure 4-16: Prototype main page

When a term has been written into the input field on the main page and the search button is pressed, the results from the local database will be presented in a vertical list, as displayed in *Figure 4-17*, to the left. If no data is found an error message will be displayed to the users telling what went wrong to help the user *recognize, diagnose and recover* from the error. An abstract from each of the records is here presented, as well some other useful meta-data information. A status for each of the records has also been added to tell the user about the completeness of the record. Lack of basic information gives a red "incomplete" status, the yellow "basic" status is missing registry data while the "complete" status is given the color green. If the user find an interesting record, more detailed information about the record can be found by pressing the "details" button The detail page layout is based on the design layout of the desktop application when looking at a single record to keep both the applications concise (Berntsen, 2014).

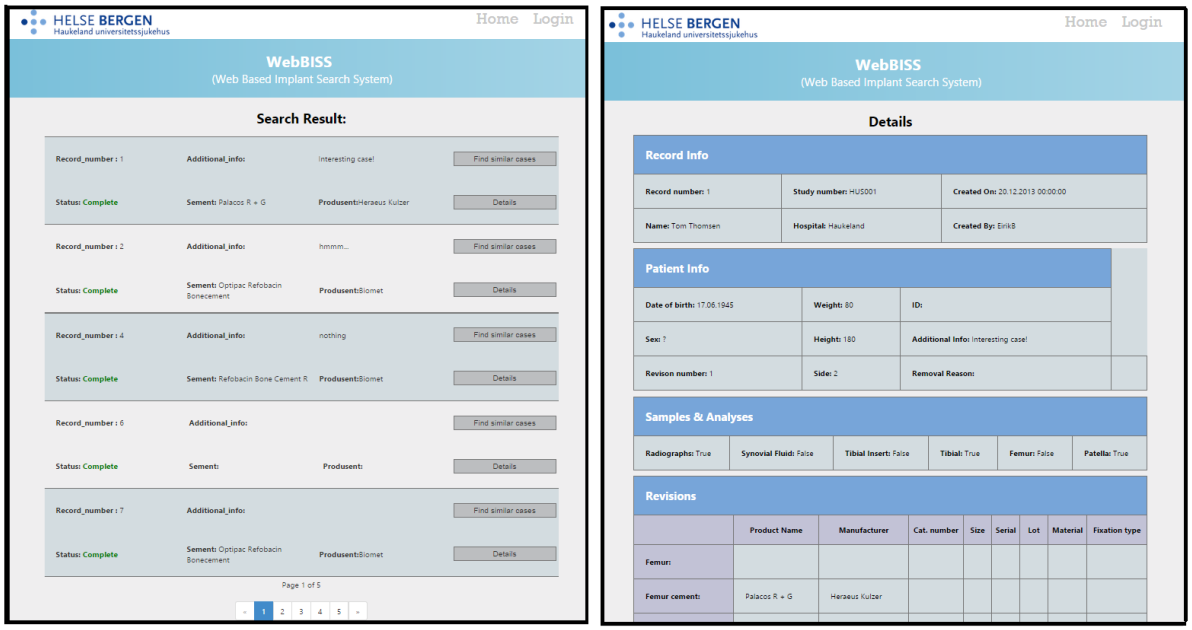


Figure 4-17: Result view for a local search to the left, and the record details to the right

Retrieving Data from MAUDE

The original plan, before the release of the OpenFDA website June 2th, 2014, presented in C*hapter 2.8.4*, was to download all the data stored in MAUDE to a local storage. The number of data was large and the scare for lack of space disappeared as soon as this website was published, just in time for the master thesis. The website has several endpoints that serve unique data which are returned in the JSON format (U.S Food and Drug Administration, 2014a). If you perform the same search at the MAUDE website and in the OpenFDA API, you will not find the exact same data. The reason for this is that the OpenFDA website only updates the data each quarter. Therefore the results provided by the MAUDE search engine will contain the newest data first.

Because this website was recently released, there is lack of developed tools for parsing and using their Open Data. A library (.dll) for C# was therefore developed, both for this project but also for other developers to make use of. The C# library created can take a single keyword and retrieve the relevant data based on this keyword using the API provided by OpenFDA. The data is then parsed and deserialized to C# objects which make it easier to work with the data. It also handles other functionalities, like counting the number of events by year or performing more advanced search with more specific variables.

Performing queries towards the OpenFDA API is of course resource intensive. They therefore have some demands for the developers using their API. It is only allowed to do 40 request per minute and 1,000 requests per day. For this project there has been applied for an

API-key which increase this amount to 240 requests per minute and 120,000 requests per day. This should be more than sufficient for the intended user group in this thesis (U.S Food and Drug Administration, 2014a).

Retrieving Data from Clinical Trials

ClinicalTrials.gov was the next website to retrieve relevant data from. As mentioned in *Chapter 2.8.2* their data is open and available in the format of XML. Also this dataset is enormous, and the lack of local storage space also here brought the decision of doing queries directly towards their page. After all this is just a proof of concept, and downloading their data locally is something that needs to be done in the future. Another reason why it was decided to do the search directly on their site, was the user group wish for the program to rank the relevant records the same way Clinical Trials does it. This wish is covered in Use Case 7: *As a surgeon and researcher user, I would like the system to follow medical query standards, to avoid confusion* (*Chapter 4.2.1*). Since Clinical Trials have already done the ranking there was no need to perform any new ranking on the data.

For Clinical Trials there was also a lack of tools when working with their data using the C# language. It was therefore decided to create a simple API for this site as well. The API is accessible for download at the authors of this thesis GitHub account. The library created for parsing Clinical Trials is a well-documented library with the possibilities to search a single record by its ID, search several records by a keyword, perform a more advanced search with several parameters, counting studies, filtering studies and much more.

Retrieving Data from PubMed

The final place to retrieve data from was the PubMed website (Us National Library of Medicine & U.S. National Institutes of Health, 2014). The same way of grabbing the data is similar to the two other external sources. It was not much information in this external data source that needed to be handled, so no advanced API was created for this. It only takes a single keyword and returns the most relevant publication as XML and parses the XML. More information about PubMed can be read in *Chapter 2.8.6*.

Searching Multiple Databases

Now as the libraries and search functionalities for all the sources that should be supported in the system is created, they can be merged together into the search multiple databases

functionality. The "search multiple databases" button will bring the user to the screen presented in *Figure 4-18*. In this screen the user can select the different databases for the search. For each database selected more details can be included to the search field for a more specific result. As you can see in the *Figure 4-18*, clinical trials has been selected, and some search fields customized for this database has appeared, so that the results can be more specific. *Recognition rather than recall* has been provided here by reminding the user what keywords that might be relevant for the given source. The page contains the same elements as the *main page*, but a "go back" button has been added to provide *user control and freedom*, so that the user can simply get back to the "simple search" page when needed too.

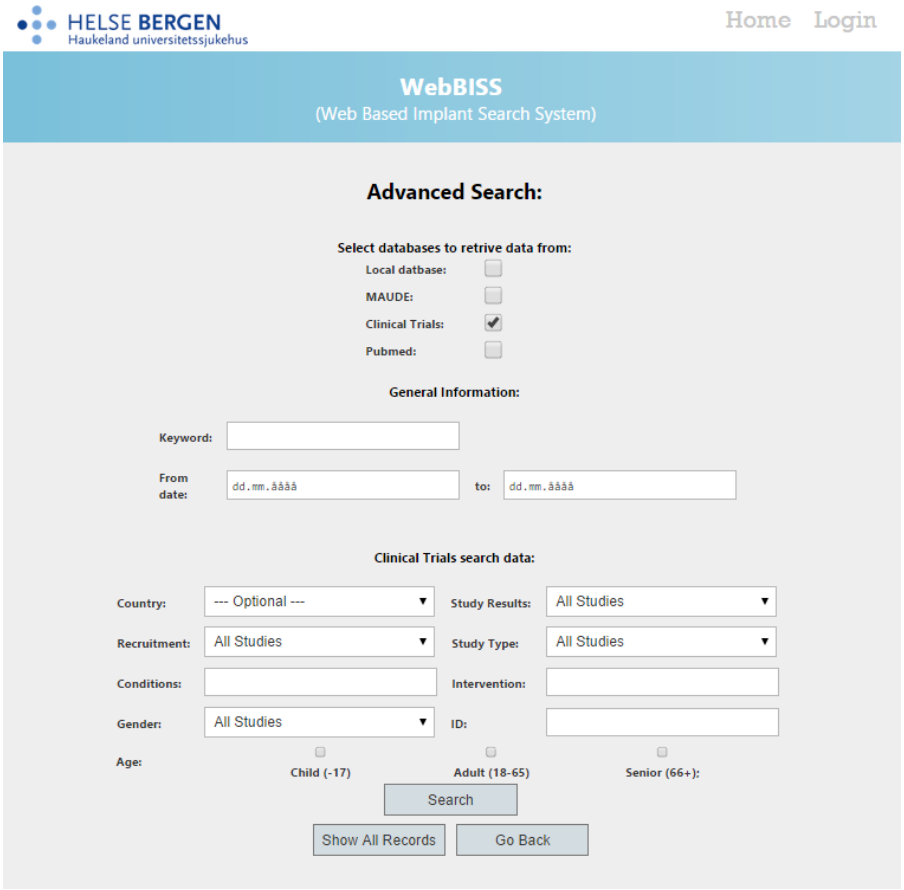


Figure 4-18: Functionality to search mutiple databases

When terms have been added and the user presses the search button the user will be navigated to a loading page (*Figure 4-19*). As described in the conceptual design part, the loading screen is there mainly to give the user some information that something is going on (visibility of system status). During the loading screen the system is gathering relevant data, according to the user's search criteria, from all the sources selected by the user. The only

action the user is able to perform at this page is to press to “home” button, which will cancel the search process.

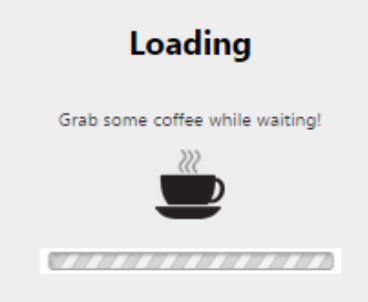


Figure 4-19: Loading page

When the loading is done, the user will be sent to a summary page (*Figure 4-20*). On this page the user can view different diagrams created based on the search criteria results. The diagrams is for example containing information about how many different cases was found from the different sources, how many reports/records that has been reported for each year in MAUDE and more. The opportunities and the benefits of visualization and diagrams can be read more about in *Chapter 2.5*.

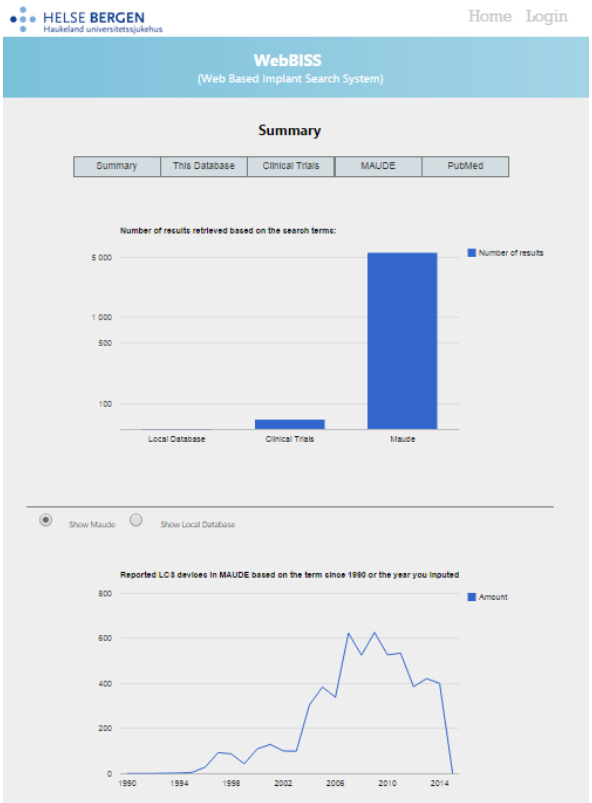


Figure 4-20: Summary page of the results when searching multiple database search

The user is also provided with five tabs, one for the summary page, one for the local database and one for each of the external sources. By pressing one of the tabs, the user is presented with relevant data from the different external sources. The data presented in each of the tabs have the same ranking as the official pages of the external sources. By physically navigating to one of the external sources official web page, performing the same search, will give the exact same result in the same order, with a small exception when it comes to MAUDE which updates their database each quarter, as previously mentioned. This has been done to support the wish of *use case 7.* Even though the abstracts and meta-data presented in each of the result tabs differ, the design layout is very similar and therefore only the screenshot of the Clinical Trials results will be presented in this thesis (*Figure 4-21*). The selected tab gets a blue box around it to tell the user which results is currently being viewed. The statuses in *Figure 4-21* have the same colours as at the official Clinical Trials page. It is possible to navigate directly to their web page by pressing the "Go official site", button or find more information about the relevant case by pressing details.

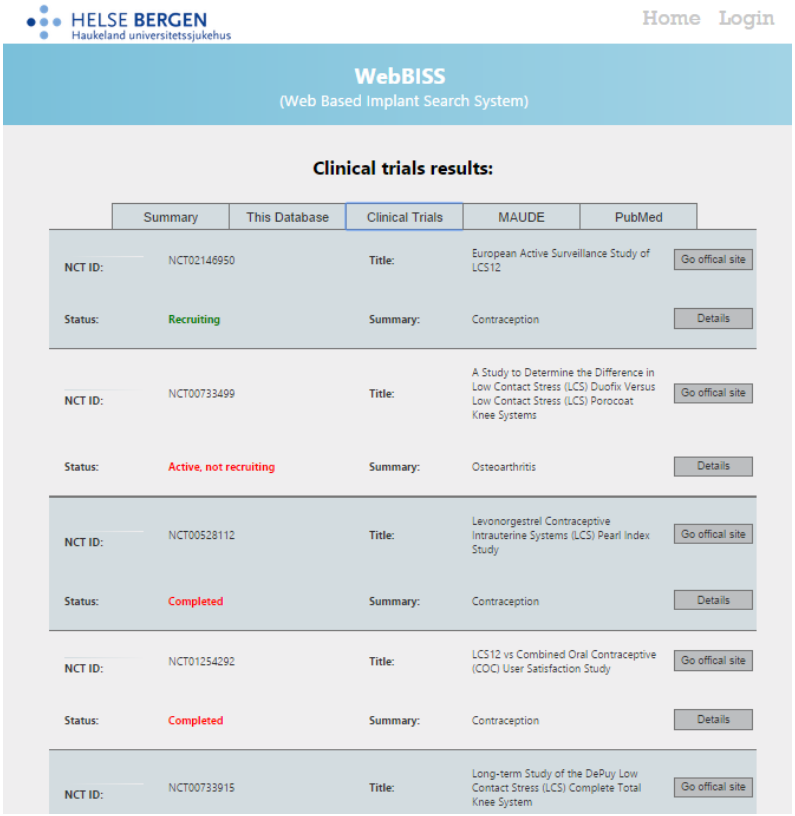


Figure 4-21: Clinical Trials result

By hovering a single trail, case or record, it will mark it green to tell the user what record is currently being viewed. A short abstract is presented for the user for each of the relevant cases. As mentioned above, each of the tabs have the same design layout, but different data according to what the user might find interesting for each of the external sources.

There are very few steps leading from the search page to the results, the users also have possibilities to tailor their search to find the best matching results. This has been kept in mind to ensure *flexibility and efficiency of use.*

Meta Search Functionality

By searching local data the user is provided with a button with the text "find similar cases" which can be pressed to initiate the meta-search functionality (*Figure 4-17*, to the left). The meta-search functionality is at the current state grabbing a relevant keyword from the preferred record and then performs a search on all the external sources, giving the same result page as presented in *Figure 4-20*. For future development more advanced search functionality could be added to this system functionality. At the current state this functionality is more a proof of concept of what can be done in the future.

4.5.2 Other System Functionalities

Information Visualization

The researchers at the Biomaterial Research Group requested some basic statistics, based on the data gathered from the different external sources as well as the local data. By generating visualized statistics based on the data from the system helps the user detect patterns, trends and anomalies (Rogers et al., 2011, p. 181). Different tools for creating statistics on the web were thought off, but in the end, the choice fell on Google Charts. Google have a large gallery of different ways to visualize data: bar chart, geo chart, column chart, pie chart, org chart etc. The Google chart technology use JavaScript and is very easy to use, and most importantly, it supports older versions of Internet Explorer. This is very important since Haukeland at the time of writing was using IE7 on a regular basis (Google Inc., 2015). In *Figure 4-22* a Google Chart graph has been generated based on the number of records that has been reported during the years, based on the keyword "LCS". This gives the users of the system a quick overview instead of analysing each of the data items by themselves, as discussed in *Chapter 2.5* that speaks about the visualisation.

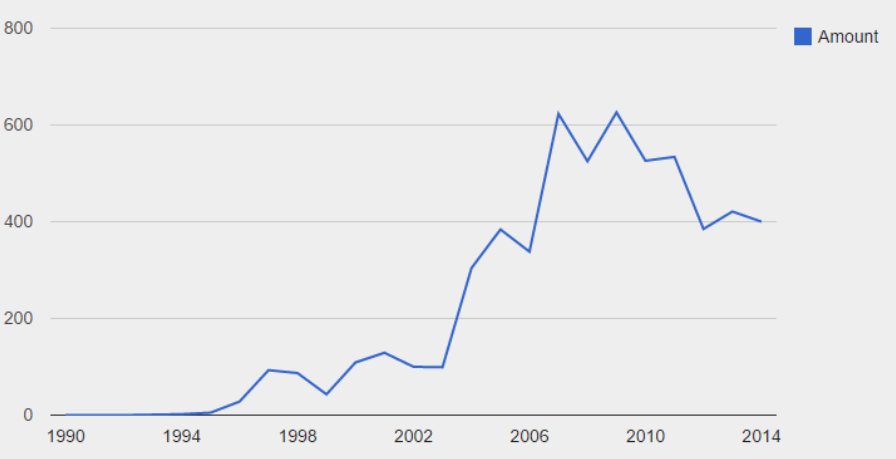


Figure 4-22: Number of reported LCS-devices from MAUDE generated by the system

Login Functionality

An important functionality in the system is that surgeon and other employees can log into the system and keep track on the records they have been submitted/reported. After the interview with one of the orthopaedic implant surgeons (*Appendix B4*), there was requested for more feedback, much like the system called *Re-motion database* which was presented in *Chapter 2.8.5.* A proof of concept on how this should be done was therefore made. The surgeons will have a profile where they can view at the reports they have created as well as reporting new records. The surgeon can also look at relevant statistics based on what has been reported. The different roles in a system can be set by an admin user, which tells the system what privileges each of the users should have. No other than the system administrator can give roles and create users in this version of the system.

By taking a look at most of the screenshots provided earlier in this chapter, a "login" button on the top right can be detected, next to the "home" button. By pressing this button the user will be navigated to a login form. The user enters his credentials and can then access records reported by the logged in user as well as the possibility of reporting new records. The administrator can add new users to already existing records so that surgeons don not "lose" any of their earlier reported records. If the user enters wrong login information, he will be provided with an error message that you can see in *Figure 4-23*. The *error message help users recognize, diagnose and recover from errors*.

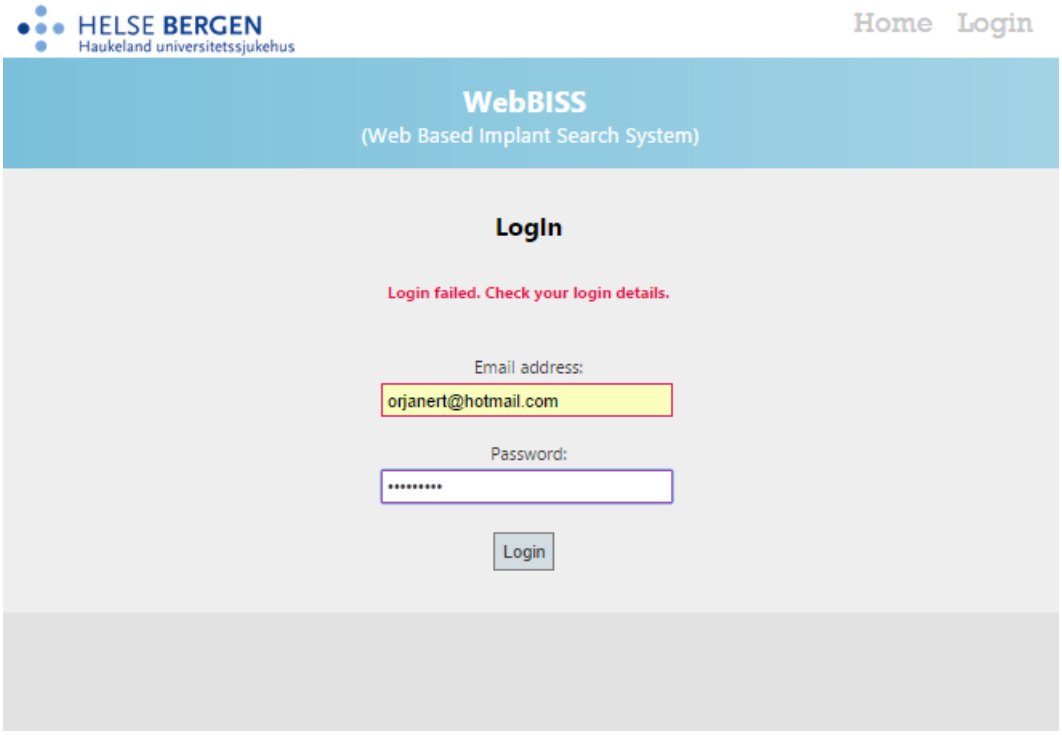


Figure 4-23: Login screen

If the user presses “My records”, which has appeared next to the home button, as well as the email of the logged in user, the user can look through earlier reported records (*Figure 4-24*), some statistics and report new incidents.

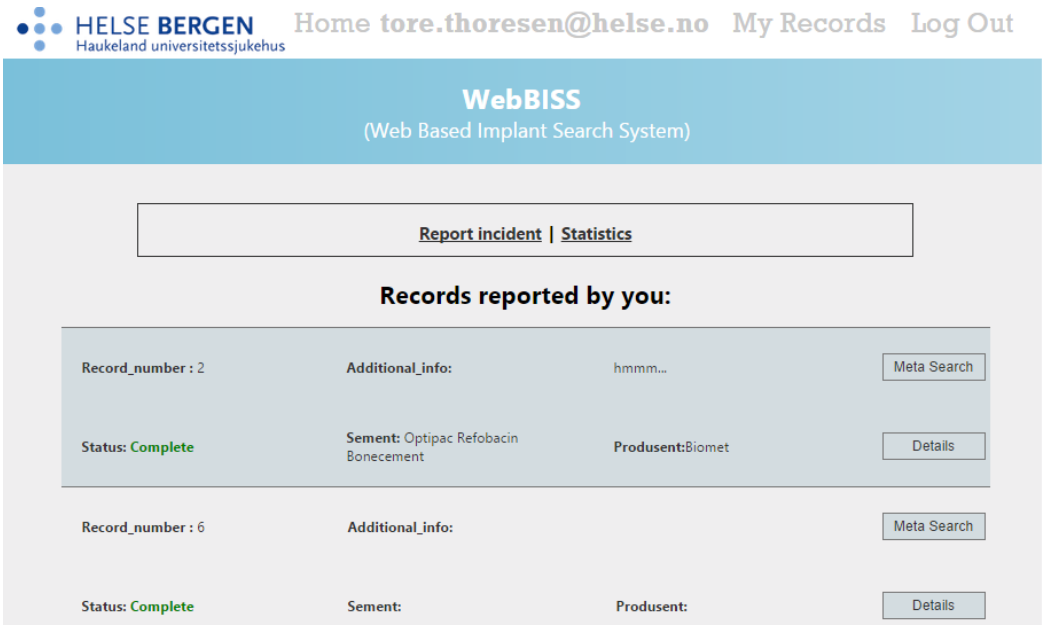


Figure 4-24: User profile

By reporting a new incident, the user will see the following form (*Figure 4-25*) which has the same design layout as the desktop application (Berntsen, 2014). The user who creates the record needs to fill the input fields marked red as a minimum. Some of the data is already filled in by the system, like who is creating the record, record date and record number to minimize the work load for the user.

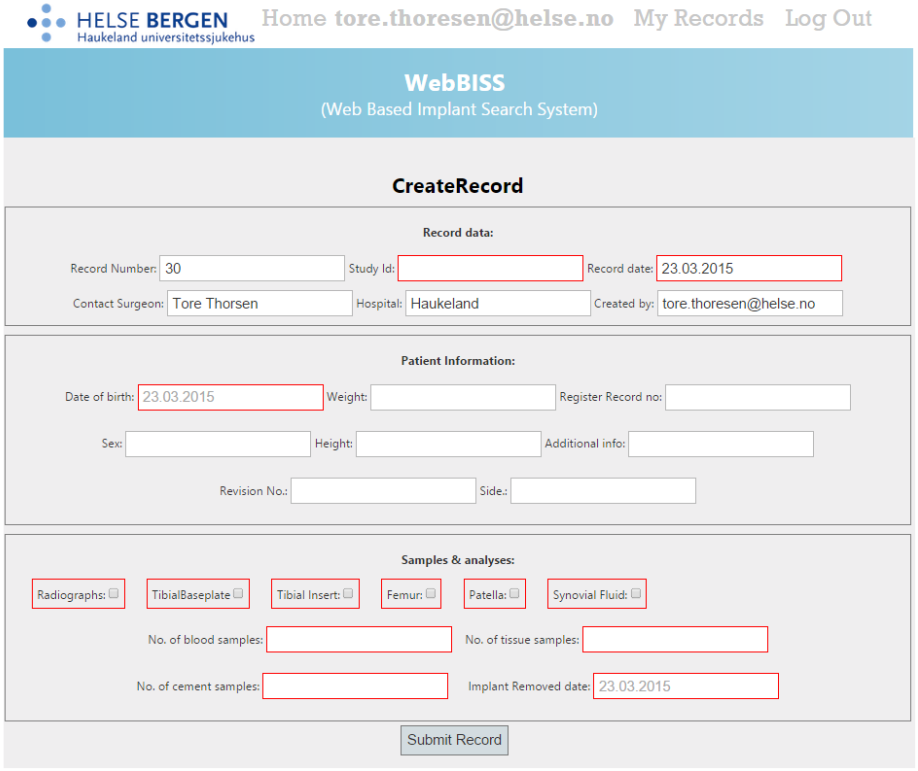


Figure 4-25: Form for reporting an incident

Simple API

Some of the users of the prototype didn't really see the point of making the reported data available and usable for the public, as it can be read in the interviews (*Appendix B1 & Appendix B2*). The reason for this, among others, is that they do not see how the public can benefit from having the data accessible to everyone. As mentioned in *Chapter 2.6*, this is really the point of having Open Data, that the data can be used in new ways never though off before (Direktoratet for forvaltning og IKT, 2014b). This prototype could never been made if there were no Open Data about medical devices accessible online. A simple example of how the data could be made open and available for the general public has been developed and integrated into the prototype. This is done using the ASP.NET web API which is a framework for building web APIs on top of the .NET framework (Wasson, 2014).

On the main page of the prototype, the user can beneath “Help & Information” find a link that navigates to the following URL: “…/API/records”. Here all the local data is made available, as Open Data, for other developers to make use of it (*Figure 4-26*). If the data is going to be actually published in the future, this has to be made nicer and easier to use, by having search functionality and sorting functionalities. It is important to notice that not all the data from the database is discoverable in the API. This is to show the possibility of hiding elements you do not want the public to see or have access to.

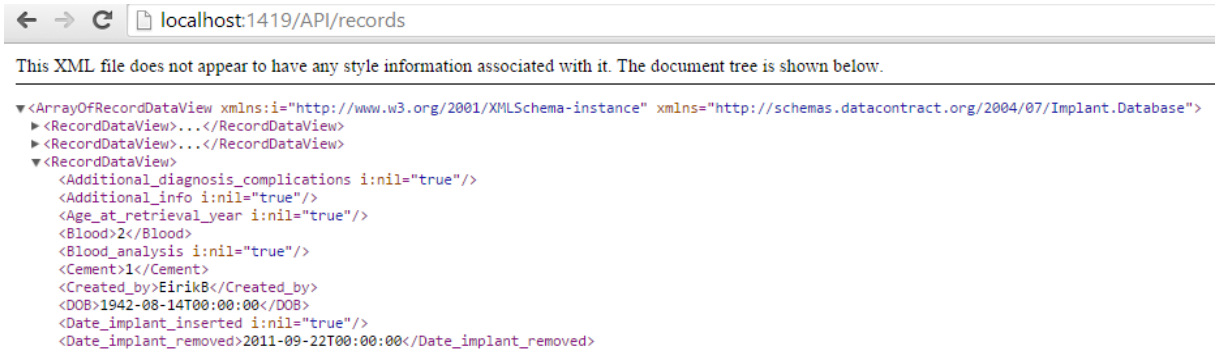


Figure 4-26: Navigating to the API - database in XML-format

4.6 Evaluation: 4. Iteration

Now as a functional prototype of the intended system has been created based on the initial sketches, the time has come to evaluate the resulting system. As earlier described in the project, both an expert evaluation as well as a “normal user” evaluation will be performed. The expression “normal user” stands for the intended user who is not necessarily an expert on system development. As this activity can be viewed as one of the most important part of the thesis it will have its own chapter, following this one.

5) Evaluation and Results

How the evaluation was performed, as well as the results of the evaluation will be presented in this chapter. The chapter start off with an introduction to evaluation and why and how it should be done, followed by how the evaluation was performed and who the participants of the evaluation were. After the evaluation methods have been discussed, the results of the evaluation will be presented and the findings are discussed.

5.1 Introduction to Evaluation

An evaluation of the system has many benefits. It gives a better understanding of the user experience, gives insight into where the difficulties are and what needs to be improved within the system. The evaluation is a way to check if the system meets the usability requirements (Stone et al., 2005). The usability requirements is concerned with five bullet points created by Quesenbery (2003) as ways to arrive at a successful system at the end of the developing phase. The five E's are listed below this section (*Figure 5-1*).

Effective	The completeness and accuracy with which users archive their goals
Efficient	The speed (with accuracy) with which users can complete their tasks.
Engaging	The degree to which the tone and style of the interface makes the product pleasant or satisfying to use.
Error tolerant	How well the design prevents errors or helps with recovery from those that do occur
Easy to learn	How well the product supports both initial orientation and depending understanding of its capabilities

Figure 5-1: The five E's by Quesenbery (Stone et al., 2005, p. 108)

Stone et al., (2005) has a great guide and descriptions on how an evaluation of an information system should be performed. This doctrine will be followed during the evaluation of this thesis. The process of usability evaluation by Stone et al., (2005) is described with four main steps:

1. **Evaluation strategy:** Formulate what you want to archive with the evaluation.
2. **Evaluation plan:** How and when the evaluation will be conducted.
3. **Data analysis:** Gather/collect and summarize data from the testing. This can be notes from when a user has tested the system or the responses collected in a survey.
4. **Data interpretation:** Try to find the causes of the usability problems, try to find ways to solve those problems and document the results of the evaluation testing.

There are mainly two groups of participants that will evaluate the system and two main evaluation methods that have been used. The two participant groups are the end-users and the "expert" users. The end-user group consists of people that will use the system once the development has been finished. Their evaluation has been done according to the *System Usability Scale (SUS)* (Brooke, 1996). The "expert" users on the other hand are users with knowledge and formal education in computer science, system developing and human-computer interaction (HCI). They have performed a *heuristics evaluation* (Nielsen & Molich, 1990). Both the user groups have been asked to perform the same tasks to test the most fundamental functionalities of the system. The tasks were based on the use cases created in the development chapter (*Chapter 4.2*). The different tasks the evaluators had to perform can be found in *Appendix C*. After those tasks had been performed, the evaluators were asked to answer a survey. The survey was adjusted to suit the two groups and both the versions of the survey had indirectly answered whether the five E's has been fulfilled in the system, as several of the questions and heuristics are geared towards answering this question. The two different surveys are explained in depth in the next sections together with a discussion about the two user groups. It is of interest to know who the participants are, what evaluation survey has been used for the current group, and finally how the evaluation was executed.

5.1.1 End-User Evaluation

The Participants

The end-users are the employees at the Biomaterial Research Group. From whom only four could perform the evaluation. One of them also had to be excluded because of his already large impact on the project, leaving us with three evaluators. This excluded end-user is the *super user* of this project, the person who came up with the need for such a system being developed. The super user has been following the whole developing process step by step and collaborated closely during the entire project. This could therefore cause an evaluation bias.

Since different evaluators tend to find different problems, it is good to have several evaluators, as a single evaluator only tend to find 35 % of the usability problems in a system being evaluated (Nielsen, 1994). Nielsen (1994) has made a graph illustrating the proportion of usability problems found in the percentage based on the number of evaluators' participating (*Figure 5-2*). It is a good payoff to have more than one evaluator. From a business perspective, the number of evaluators chosen for the evaluation will depend on a cost-benefit analysis. As there is no money involved in this thesis project, as many evaluators as possible were engaged, which summed up a total of three in the end-user evaluation group. Even though the number of participants is very low, a group of three participants was actually expected to find approximately 60 % of the usability problems, as seen in *Figure 5-2* (Nielsen, 1994).

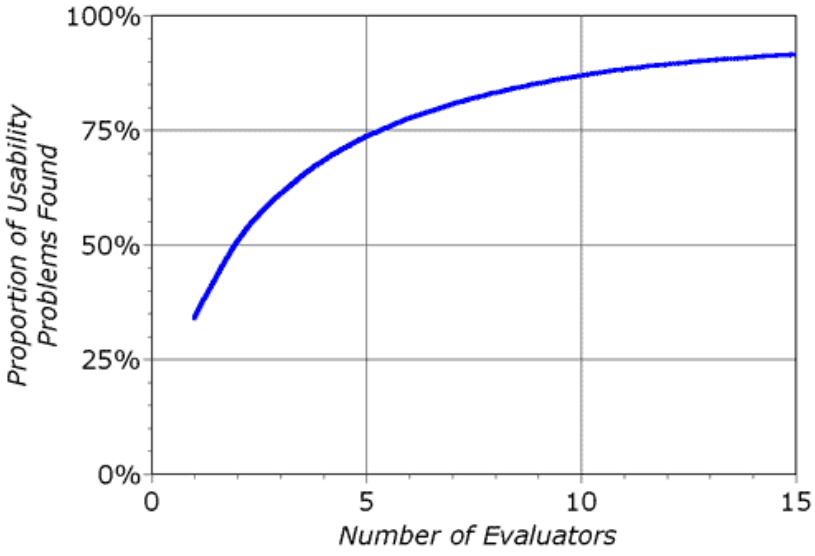


Figure 5-2: Proportion of usability problems found based on number of evaluators (Nielsen, 1994)

Methods

In this end-user evaluation both quantitative and qualitative methods, presented in *Chapter 3.3*, have been adapted. The qualitative method used is by observation of the participants when using the system, to observe what they struggle with and to find other usability flaws. A survey that the participants filled out, after they have tested the system, was the quantitative method used during this evaluation.

When choosing what survey to use for the end-user group a lot of different alternatives were considered. One particular alternative that emerged during research was *The System Usability Scale (SUS).* A comparison of five questionnaire for assessing usability of a website, concluded that the SUS survey gave the most reliable results (Tullis & Stetson, 2004). *The System Usability Scale (SUS)* was therefore selected as the end-user survey. It is defined as a "quick and dirty" survey to find usability of a given product or a service (Brooke, 1996). The survey contains 10 questions on a 5-point scale, and the participant is told to rank each of the questions after they have tested and evaluated the system. The survey can be found in *Appendix D.* To help the user evaluate the system, they have to complete 10 tasks that cover the most fundamental functionalities of the system, as discussed in the previous section. Those tasks can be found in *Appendix C*. The final scores calculated from the SUS-survey can range from the number 0-100. Higher scores indicate better usability for the system (Bangor, Kortum, & Miller, 2008).

Execution of the Evaluation

The evaluation was performed at the participants workplace, i.e. at the Biomaterial Research Group at Haukeland University Hospital. It was done on a laptop where the screen of the laptop and the voice of the subject was being recorded, to gather as much data as possible to analyse. The evaluation was done with one person at the time, while the leader of the evaluation (the author of this thesis) was sitting next to the subject performing the tasks, taking notes and answering questions raised during the sessions. After the participants had performed all the tasks on the paper they should had a good overview of the systems main functionalities and the design of the system, and based on that they could answer the SUS-questionnaire which could be found in *Appendix D*.

5.1.2 "Expert" User Evaluation

The Participants

The "expert" users that had evaluated the system are users with knowledge and formal education in computer science, system development and Human-Computer Interaction (HCI), presented in *Chapter 2.4*. The expert users were asked to inspect and examine the user interface while performing the given tasks (*Appendix C*). Whilst the end-users had their screen sessions recorded, to identify cumbersome tasks, this was not necessary for the expert users. The expert users were supposed to stop and look for usability flaws, and therefore a recording of the screen would not give any valuable data to analyse. The leader of the evaluation will of course take notes during the execution based on what he observes (Stone et al., 2005, p. 525-537).

A drawback in this evaluation could have been that the expert participants had limited knowledge on the domain of medical devices or prosthesis, so their evaluation could have been restricted to the information science issues. Some words and terms might therefore had limited if any meaning for this user group. The system is not target towards this user group, so they had to ignore this aspect.

The participants selected for the expert user evaluation are Information Science students from the Department of Information Science and Media Studies at the University of Bergen. They all have had courses with HCI and they all have a very good knowledge of information systems which made them well suited for the expert group evaluation.

The total number of participants chosen for this evaluation is 15. This is a much larger number of evaluators than the end-user evaluation. By taking a look at *Figure 5-2* we can see that the graph stabilize at this point and most of the usability flaws are found (Nielsen, 1994).

Methods

In this evaluation only quantitative methods were adopted. After the users had performed the tasks, they were asked to rate each of the Nielsen (1995) 10 heuristics on a scale from 1 (very poor) to 10 (very good) on how well each of the heuristics were applied to the system. Each of the heuristics has been presented in *Chapter 2.4*, and the survey can be found in *Appendix E*. A heuristic evaluation is a good way to find usability problems in the user interface (Nielsen, 1994). The reason why it was decided to give the expert users their own survey was because of their knowledge in the field. There is no point hiding the heuristics behind easily

formulated words. The expert evaluators know what they mean, and that they are supposed to keep them in mind during the whole evaluation progress.

Execution of the Evaluation

The execution of the evaluation is performed in two sessions. The first evaluation was performed in a classroom with 8 master students at once. A short presentation was held about the project and then the students connected to a server that was set up temporary for this project. This made it possible to "stress test" the application, by having 8 students use it at once from different computers. When connected to the server they were performing the set of given tasks, and once they were done with the tasks they responded to the survey. This evaluation gave a lot of respondents in a short amount of time, and a lot of data to work with. One of the respondents did not answer the questionnaire, and some of them did not answer all the questions. Despite this, there was a lot of data to analyse.

The next 7 expert evaluators were volunteers, and the evaluation was performed at one of the study halls at the university. They were performing the same tasks as the 8 first students, all by themselves, and upon the completion of the tasks, they responded to the same survey has the previous master students.

5.1.3 Other Evaluation Methods

It is not only the interface of the system that was important to evaluate, but also the code behind the system, as well.

There are mainly two ways of testing a system, *black-* and *white-boxing*. *Black-boxing* is when the software or application is tested by examining the functionality of it, without digging into the code. This is how the system could be tested with the help of the intended users as well as the expert users, who were described in the previous sections. They will be performing defined tasks to test the functionality while having no idea what is going on behind the scenes in the system. To the contrary of this approach, *white-boxing* is a more transparent form of testing where the quality of the code is being examined and tested (Srivastav, Bansal, & Sharma, 2014).

When it comes to white box testing, the *Test Driven Development* method was used to ensure good quality of the code by writing unit-tests (Beck, 2003). By covering both white box and black box testing the system was very well evaluated.

5.2 Evaluation Results

5.2.1 End-user Evaluation Results

System Usability Scale (SUS) Results

After the participants had tested the information system developed, by completing the given tasks, they were asked to complete a survey. The results from the survey can be used to calculate a SUS score, presented in *Chapter 5.1*. The *odd* numbered questions in the survey are positive questions, while the *even* numbered questions are negative. To calculate the SUS-score one has to subtract one point from the *odd* questions, and five points from the *even* numbered questions. This gives each question a score between 0-4. Then all the scores, for each participant are summed up and multiplied by 2.5 (Brooke, 1996). The SUS-score calculated for each of the participants can be found in *Figure 5-3* and *Figure 5-4.*

Participant	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	SUS Score
P1	5	1	5	1	4	1	5	1	5	1	97,5
P2	5	2	4	1	4	3	5	2	4	2	80,0
P3	4	2	4	1	5	3	2	3	4	1	72,5

Figure 5-3: SUS-Score calculated

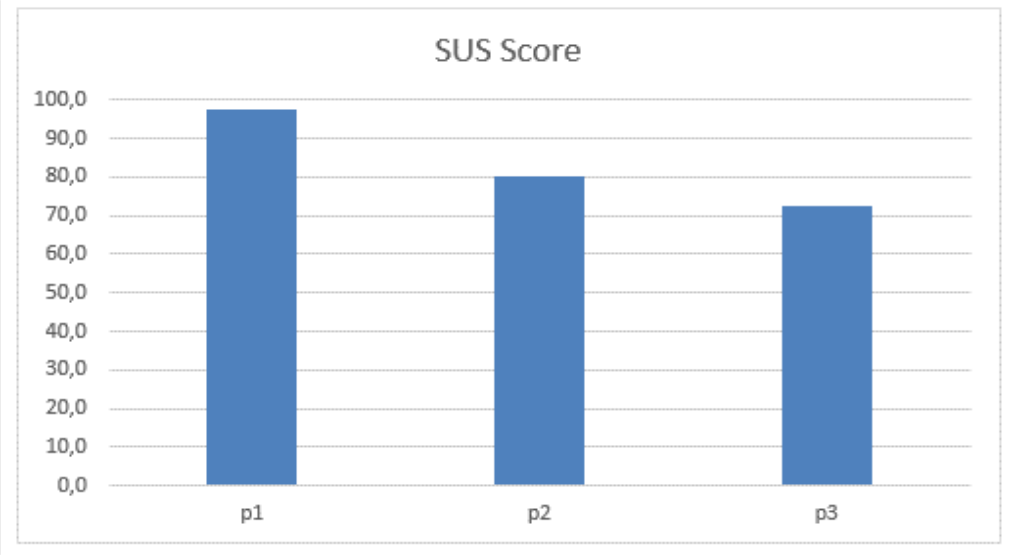


Figure 5-4: SUS score visualized

When it comes to what is an acceptable SUS-score, it can be said that systems that gives a SUS-score above 70 is at least passable. A very good system will provide a score of 90 or higher. Systems that gives a SUS-score below 70 should be considered for improvements and change (Bangor et al., 2008). All the evaluators gave the developed information system a SUS-score greater than 70. The lowest score given was 72.5, while the maximum score given was at 97.5. The median of all the scores was 80.0. The average SUS score for the information system that has been developed during this thesis is 83.3 (*Figure 5-5*). The SUS-score given by all the evaluators for this system can therefore be seen as acceptable.

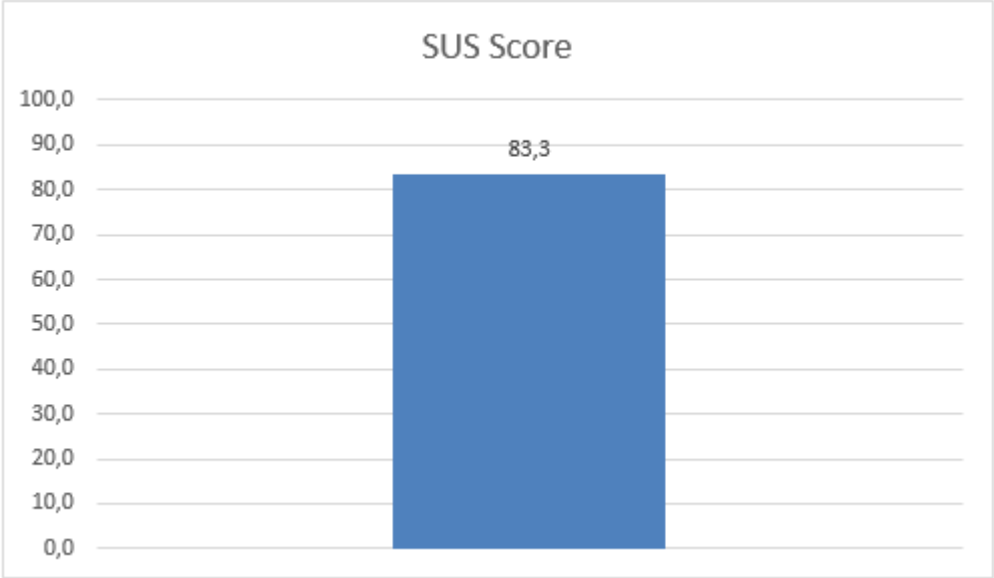


Figure 5-5: The average of SUS score for each of the participants

It would be nice to know how much time each of the participants spent on each task. Unfortunately this data was not of much use as the participants tend to stop talking, discussing the user interface or other things. Some of the participants also started exploring the user interface, going away from the intended tasks. The time will therefore not tell anything valuable and was therefore not included into this thesis.

Observational Findings

In the survey the user could point out errors and propose amendments, but none of the evaluators opted to do so. However, during the observation some problems with the user interface were discovered. It was for instance discovered that the button “show all records” could be replaced saying “show all local records” instead, as most of the users did not

understand that this was a function to retrieve all the **local** records. Most of them though they would get all records from every database integrated into the project, so some of the participants were therefore afraid pressing the button. Another usability problem was noticed when the users wanted to create a new record for the local database; they all seemed to struggle finding the button for this, the naming convention "report incident" did not seem to make any sense for most of the users and they were all looking for a "create record" button. This might also be a mistake in the list of tasks where the user where told to "create a new record", and not "report an incident" (*Appendix C*).

It was also very interesting to see the learning curve of each of the participants. After finishing one of the tasks, the next tasks were completed much quicker than the first one. It would be nice to have some time tables to show this, but unfortunately this data did not give a clear picture of the time they actually used. Nevertheless, there is some compensation for a precise assessment of time via the SUS questions 3: *I thought the system was easy to use* and 7: *I would imagine that most people would learn to use this system very quickly*, both showing tendencies to that the participants think using the system would not be time consuming.

5.2.2 "Expert" Evaluation Results

In this section the results of the heuristic evaluation given by the expert users, presented in *Chapter 5.1.2*, will be given in more detail. The results for each of the heuristics presented in *Chapter 2.4* will be discussed here. The average score for each of the heuristic is presented in *Figure 5-6*, and a more descriptive table for each of the scores for each expert user can be found in *Appendix F1*.

Based on the results in *Figure 5-6* the average score for each of the questions is good. There is no score below 6 and the average score of all the scores is 7,7. As the max score is 10 it can therefore be concluded that this was a satisfying score. The number of evaluators was 15.

The average score can still be misleading, and the whole truth is not revealed by looking at this one figure. A closer look at each of the heuristics will therefore follow. For each of the heuristics the most interesting and relevant comments made by the evaluators will be discussed. All the comments can be found in *Appendix F2*.

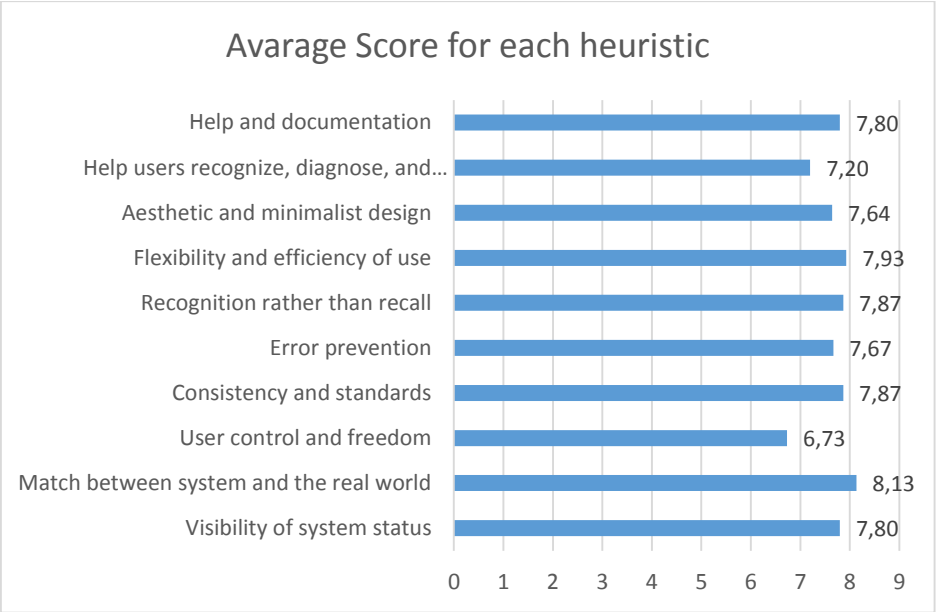


Figure 5-6: Average score for each of the heuristic

Visibility of System Status

This is the first heuristic presented by Nielsen (1995). As we can see in *Figure 5-7*, the lowest score given for this heuristic is by *user 7*, who gave this heuristic a score of 3. The average score is 8, while the median is 8. The score for this heuristics is pretty satisfying despite one low score, as 93,33 % of the evaluators gave a higher score than 5. But one should not underestimate the one giving a low score, even though the majority is positive.

The evaluator who gave the lowest score gave the following comment to the current heuristics: *"Load bar is present, but does not move. "Has it frozen?". Also, the search leaves no time for coffee. When presented results from a search, the graphs are confusing. We expect to find a list or a number of hits first. Results do not tell you why the results are relevant (e.g. bolded keywords)"*. When it comes to the comment about the load bar not moving, this might be a problem with the user's browser turning off animations. A progress bar telling how much is left of the process in percentage could be added to strengthen the heuristic in the system. The evaluator also complains about the presented results and the graphs being confusing. It is hard to know what was found confusing about the graphs, as the user later states that the visualization is nice. It might be that the user did not understand the data, as this is meant for a specific user domain. Number of hits might be added to the summary page as well as the top relevant records. Bolded keywords to tell why a result is relevant could definitely be added. Another user stated that a *breadcumb* would be nice to have. A *breadcumb* is a way of telling the user about the site structure, where the user is at a given time, what path the user has

chosen and as a way to navigate back by pressing one of the previous pages (Instone, 2002). An example of a *breadcumb* for the following project might be: **Home** > **Search Summary** > **MAUDE** placed somewhere logically on the page. The final negative comment was when a user searched for something that gave zero results no error message was provided for the user, just a blank page. This is really another heuristic but should anyways be included and is already included in the local database search. Unfortunately, it has not yet been implemented to the multiple database search.

User	Score
U1	7
U2	8
U3	8
U4	9
U5	8
U6	7
U7	3
U8	6
U9	10
U10	6
U11	8
U12	10
U13	7
U14	10
U15	10
Average	7,8
Median	8
Standard dev	1,9346465

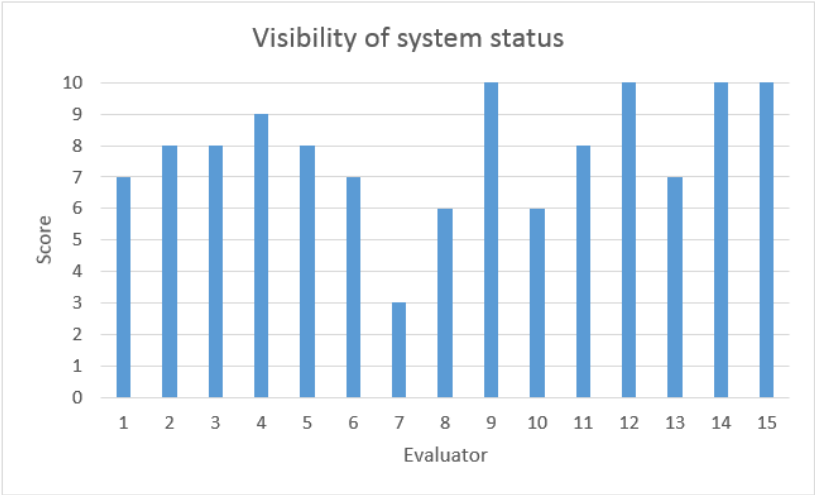


Figure 5-7: Visibility of system status score

Match between System and the Real World

This heuristics has been given an average score of 8,13, the median is 8 (*Figure 5-8*). Most of the comments given by the evaluators here state their problem understanding the medical terms and the data presented. This is understandable as none of the evaluators have any experience with failed implants, medical devices or any other medical background. Someone stated the problem with the "show all record" button, as they did not understand that this was all the **local** data. This is something that was observed during the end-user testing as well. A simple solution would just be to call it "show all local data" instead. Another comment was that the "search multiple databases" should maybe just be called "advanced search" as done in the conceptual designs. It name was changed because it really was not an advanced search. It is more another search functionality for other databases. What could be done is to let the user

have the possibility to search different databases in the "simple search" as well, and then called the "search multiple databases" for more "advanced search", if the user would like to add more variables to the search. Also here, as mentioned in the end-user evaluation, some had problems with the "report incident" which they were supposed to press when creating a new record. This might be because of not clearly formulated tasks where the evaluators were asked to "create a new record".

User	Score
U1	8
U2	9
U3	9
U4	9
U5	6
U6	7
U7	7
U8	9
U9	9
U10	8
U11	7
U12	9
U13	8
U14	8
U15	9
Average	8,1333333
Median	8
Standard dev	0,9904304

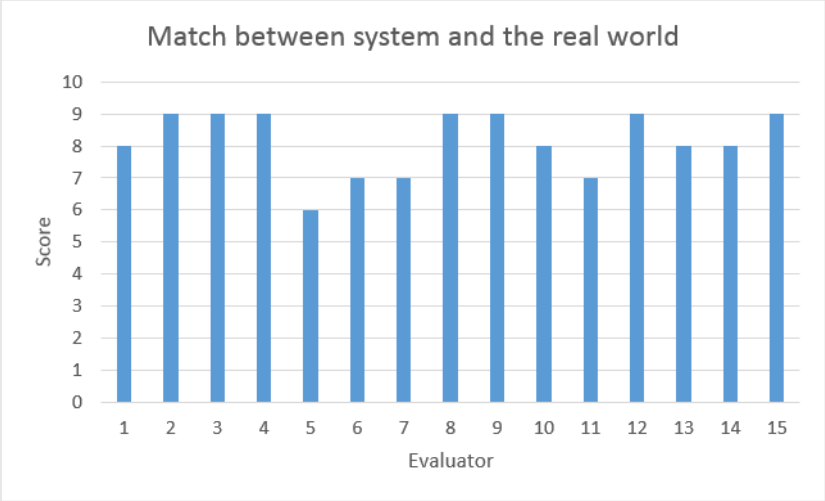


Figure 5-8: Match between system and the real world score

User Control and Freedom

The following heuristic is the one getting the lowest average score of them all, with an average score of 6,73, while the median is 7 (*Figure 5-9*). Most of the users states that there is no back button available and that they had to use the browsers own "back" button, which works but sometimes not, depending on the browser and the browser settings. The only back button included in the system is the "home", button which takes the user back to the main page. A *breadcumb* presented in one of the earlier heuristic could solved this problem. Otherwise, having a search bar everywhere, on every page, would be preferred by some users.

User	Score
U1	4
U2	7
U3	5
U4	6
U5	2
U6	4
U7	8
U8	4
U9	7
U10	8
U11	9
U12	10
U13	7
U14	10
U15	10
Average	6,7333333
Median	7
Standard dev	2,520393

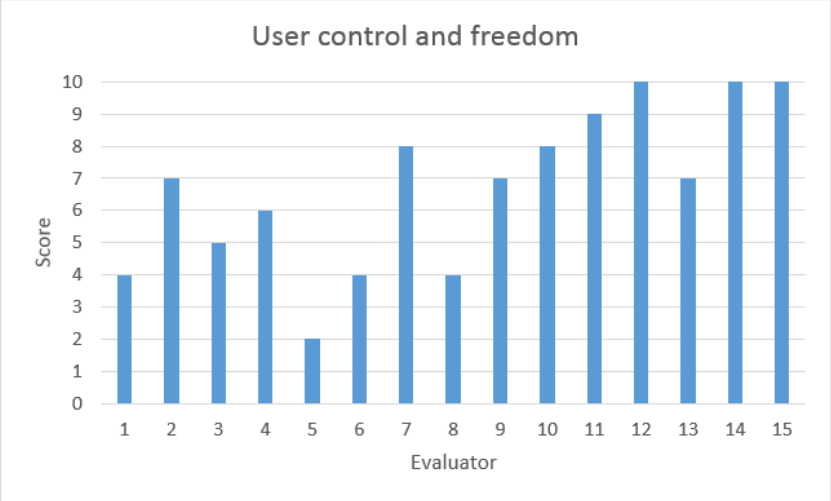


Figure 5-9: User control and freedom score

Consistency and Standards

In the following heuristic the average score was 7,87 while the median was 8 (*Figure 5-10*). Even though the score is pretty satisfying there was still one evaluator that had given a lower score than the rest of the evaluators. The evaluator gave this score the following comment: "Ambiguous words / phrases". Another consistency problem is that the "home" button change position if one logs in to the application.

User	Score
U1	8
U2	8
U3	6
U4	9
U5	8
U6	8
U7	6
U8	8
U9	10
U10	4
U11	10
U12	9
U13	6
U14	9
U15	9
Average	7,8666667
Median	8
Standard dev	1,6846647

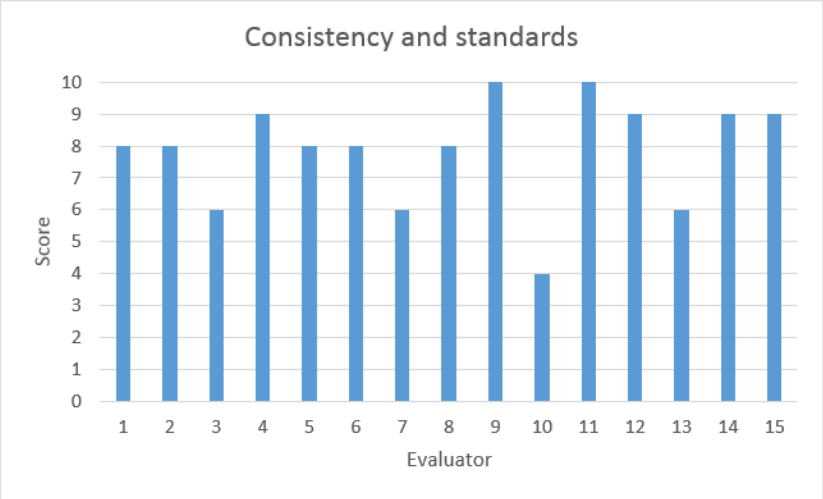


Figure 5-10: Consistency and standards

Error Prevention

The score for the error prevention has an average on 7,7 while the median is 8 (*Figure 5-11)*. Once again it can be seen as a good score as only one evaluator gave a lower score than five. Some feedback from the heuristic is that a lot of people did not come across any errors, which is a good thing in itself. A big issue is that, if one does not enter any keywords it still performs a search, which takes forever. The reason for this is that the system then finds all records at Clinical Trials, a current total of 188,173 studies. This could easily be prevented by forcing the user to enter at least one valid variable. Otherwise, the rest were mostly positive comments and can be read in *Appendix F2*.

User	Score
U1	7
U2	9
U3	9
U4	7
U5	5
U6	8
U7	4
U8	7
U9	7
U10	8
U11	7
U12	10
U13	9
U14	10
U15	8
Average	7,6666667
Median	8
Standard dev	1,6761634

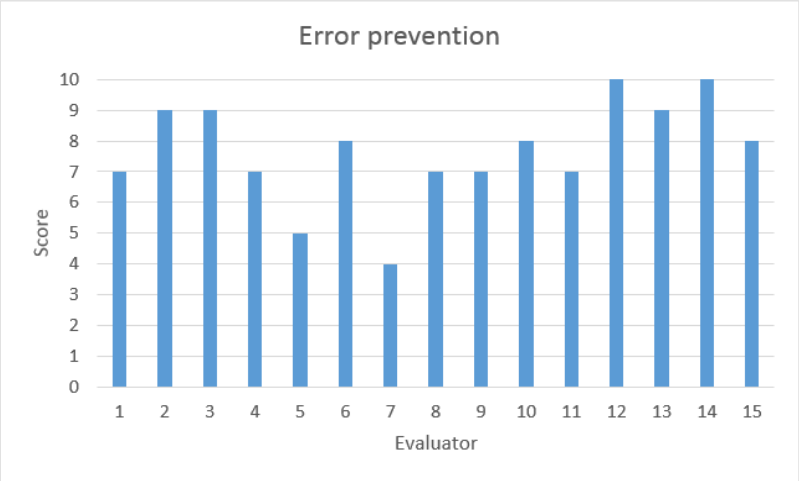


Figure 5-11: Error prevention score

Recognition rather than Recall

Most of the evaluators told they got a nice flow using the system after "warming up". As it can be noticed, only one person gave this heuristic a score below 5. The average score was 7,9 whilst the median was 8 (*Figure 5-12*). Many evaluators thought that when a keyword was inserted in the local database search and they decide to move to "search multiple databases", the keyword should be automatically passed over to this search. Some other comments regarding this heuristic was about the log-in details being a bit too invisible and that it might be a bit too much information on the result page.

User	Score
U1	8
U2	10
U3	9
U4	7
U5	6
U6	8
U7	3
U8	8
U9	10
U10	6
U11	8
U12	10
U13	8
U14	7
U15	10
Average	7,8666667
Median	8
Standard dev	1,9223002

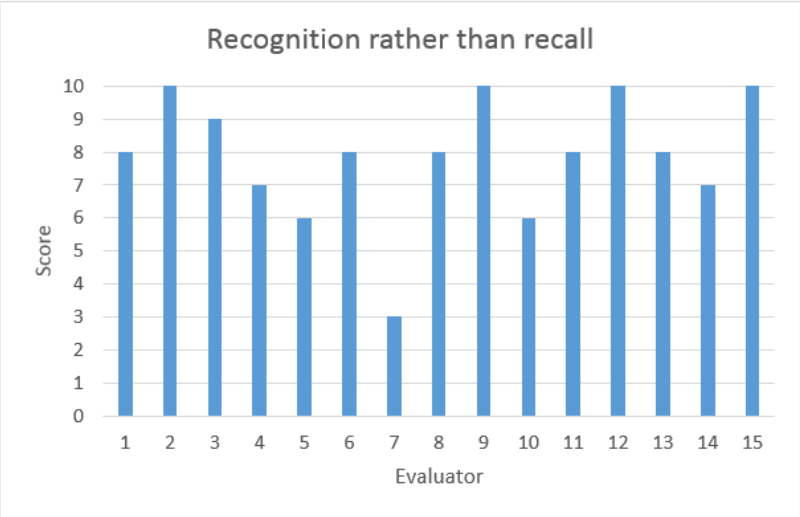


Figure 5-12: Recognition rather than recall score

Flexibility and Efficiency of use

Here there is no score below 5 (*Figure 5-13*). One of the participants has not answerd the question for unkown reasons, prehaps due to the lack of time for testing. The avarage score was 7,93 while the median was 8. Most of the respondents answered here tought it worked well, but to find a more accurate score they would need to test the system more. Regradless of this, most of the evaluators found the system efficent.

User	Score
U1	6
U2	8
U3	8
U4	10
U5	8
U6	7
U7	5
U8	
U9	9
U10	7
U11	8
U12	8
U13	7
U14	10
U15	10
Average	7,9285714
Median	8
Standard dev	1,4917355

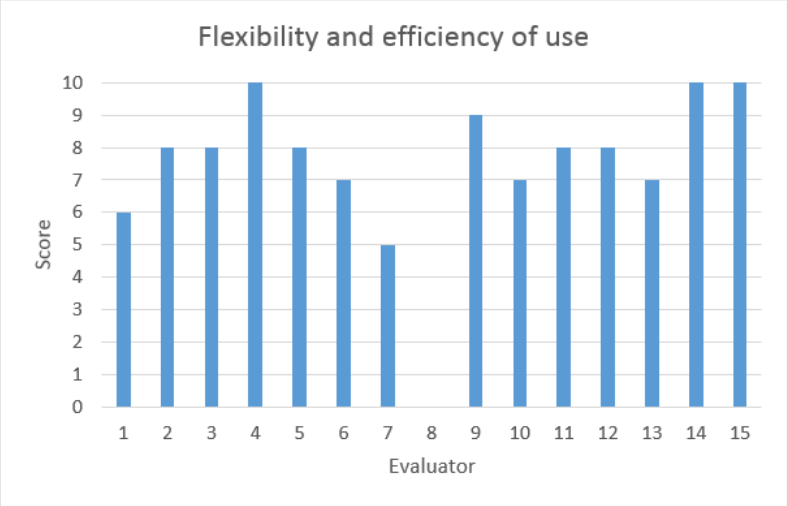


Figure 5-13: Flexibility and efficiency of use

Aesthetic and Minimalist Design

In this heuristic one evaluator has not answered for unknown reasons, no comment has been given. The average score is 7,65 whilst the median is 8,5 (*Figure 5-14*). In this result set there are also some extreme values as U7 have given the score of 1. This give a standard deviation on 2,5. The commenter has given the following comment: "*Too much…. Stuff.*". There is a very large amount of data that has to be presented in an aesthetic way and this can be very hard. The comment will be kept in mind for future development. Giving the score of 1, means that there is NO aesthetic and minimalistic design, but it might as well be a lot of text floating randomly around. Two evaluators thought there was a bit too much text which will be kept in mind for future development and maybe the search result data could be minimized somewhat. Otherwise the majority of the evaluators had a positive attitude toward this heuristic dimension.

User	Score
U1	8
U2	10
U3	8
U4	9
U5	5
U6	
U7	1
U8	7
U9	10
U10	5
U11	9
U12	9
U13	9
U14	7
U15	10
Average	7,6428571
Median	8,5
Standard dev	2,5300393

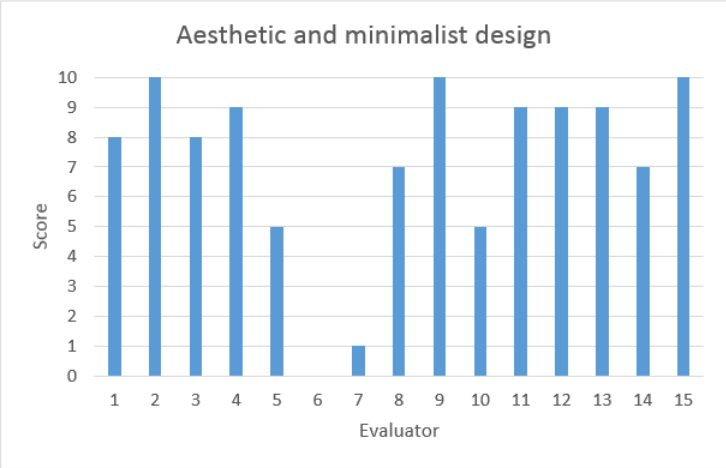


Figure 5-14: Aesthetic and minimalist design score

Help users Recognize, Diagnose, and Recover from Errors

In the following heuristic the average score was 7,2, the median 7 (*Figure 5-15*). Here again there are some large differences. Even though most people have scored the design principle above 5 there still are three evaluators who have given a score of 5 or less. The majority of the evaluators did not discover any errors. Those who gave low scores gave the following comments: *"When the page was outdated I had to go forward again and then go to the main page to do the search again."* and *"The same return error".*

User	Score
U1	5
U2	9
U3	9
U4	9
U5	7
U6	4
U7	5
U8	7
U9	3
U10	7
U11	8
U12	10
U13	6
U14	10
U15	9
Average	7,2
Median	7
Standard dev	2,2103652

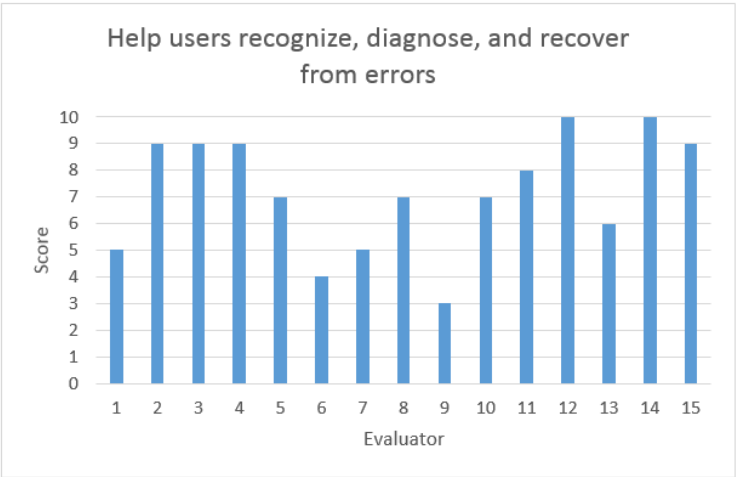


Figure 5-15: Help users recognize, diagnose, and recover from errors

Help and Documentation

The average score for this is 7,8 and the median is 8 (*Figure 5-16*). Here once more there is some variations on the score giving a standard deviation of 2,2. Those giving low score did not seem to find the tutorial videos or the instructions on the main page whilst other felt the documentation was a bit too much as the web page was self-explanatory.

User	Score
U1	4
U2	8
U3	9
U4	10
U5	7
U6	8
U7	8
U8	10
U9	10
U10	6
U11	5
U12	10
U13	4
U14	8
U15	10
Average	7,8
Median	8
Standard dev	2,1778102

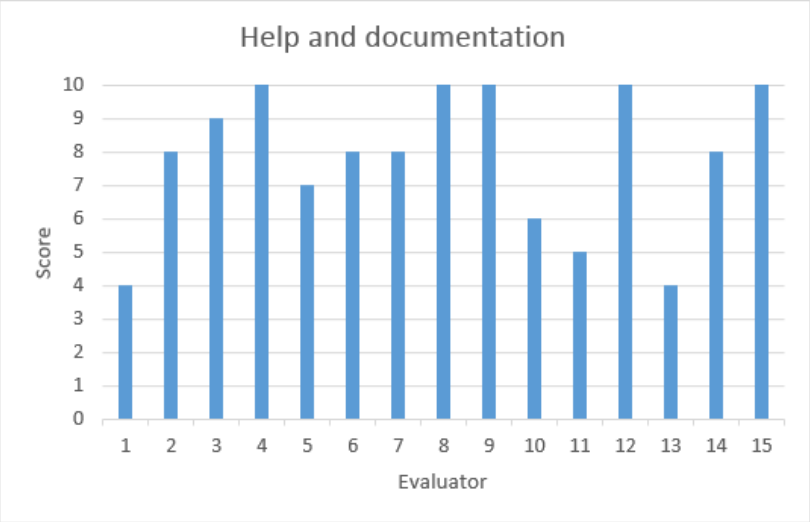


Figure 5-16: Help and documentation

Other Evaluation Comments

It seems like people did not find the tasks very hard to complete. Most of the troubles they had using the system seemed to be because of an unfamiliar domain and that they misunderstood some of the tasks. Some of the evaluators though it might be a good idea to have only one search functionality and not two as it has been implemented in the current system. This solution might make more sense as a lot of users seemed to always start searching in the "local database" search field before moving on the "search multiple databases" search bar.

6) Discussion

In the upcoming chapter a discussion of the different research questions will be done. In *Chapter 1* the different research questions have been outlined to keep the research focused and set the direction of the research. In this chapter it will be discussed how the different research questions have been dealt with using information science and clinical research applications.

6.1 Research Question 1: *Could an artefact be created to support data management, information retrieval of biomedical data and be of service to the research?*

The design science paradigm in information system research is about creating new and innovative artefacts that serve human or organizational purposes (Hevner et al., 2004). Hevner et al. (2004) have also created seven guidelines on how to understand the requirements for effective design science research. The seven guidelines can be found in *Chapter 3.1* where they have been discussed in detail. For system development to be viewed as a valid piece of research the system developed need to contribute to something new, like new functions not previously automated using information technology, adopt new algorithms or theories (Oates, 2006). In this thesis an artefact of a web-based prototype has been developed to answer both the research questions designed as well as serving the Biomaterial Research Group organizational and data management purpose. That means to organise their local data about failed hip- and knee-prosthesis and clinical data of their patients, as well as a massive amount of relevant external data from several remote sources. The data should be delivered to the end-users in a structured and user-friendly way. The functionalities of the prototype are not very innovative, but how the functionalities have been added to a problem domain makes it unique, as very few systems support these functionalities towards the relevant data. By collecting all the data within the same framework it was possible to provide operational efficiency to the user group as well as to simplify the data by visualising the returned results (Fayyad et al., 2002). The user friendliness and efficiency have been evaluated by the end-users according to the System Usability Scale (Bangor et al., 2008), while a group of expert users have evaluated the system according to the 10 usability heuristics for user interface

design (Nielsen, 1995). The results and findings of this evaluation can be found in *Chapter 5.2*. In the introduction to *Chapter 4* a process of system development was presented from a methodological viewpoint (Nunamaker & Chen, 1990). It is divided into five processes and the different processes have been followed iteratively during the entire thesis.

Creating this artefact following both the seven guidelines (Hevner et al., 2004) and the process of system development from a methodological viewpoint (Nunamaker & Chen, 1990) has provided this thesis an artefact that can help answering the next three research questions as well as providing a physical prototype that can be tested against relevant evaluators. The artefact has also been created for organizational purposes as well as contributing to the research by answering the research questions.

6.2 Research Question 2: *How could Open Data strengthen the research field of orthopaedic implants?*

During the qualitative interviews with the *researcher user* group, it could be observed that there were mixed feelings about making their own records available as Open Data. The majority did not see the need for everyone having access to the local records, only some groups like surgeon or employees at Haukeland University Hospital would need or should have this access. Others were more positive about the idea (*Appendix B1, B2 & B3*). Based on the data gathered from the SUS-survey, which can be explored in *Chapter 5.2.1*, it emerges that most of the end-users would like to use the prototype created for this project in the future and think it is good and implementable artefact. The positive feedback on the prototype might tell that their attitude to Open Data is changed and more favourable when they see the benefits of it in use as the prototype adopt Open Data and covers many Open Data principles.

As described in Chapter 2.6 and several other times in this thesis, Open Data would create efficiency and innovation (Direktoratet for forvaltning og IKT, 2014b). This principle has been covered in this project as Open Data has made it possible to create a prototype that facilitates research by Biomaterial Research Group to be more efficient, by collecting data from all remote and local data in the framework of one program. It also enables statistics based on some of the data retrieved from the external sources to meet the needs of the intended user groups of the prototype. Currently there seems to be only a few complex systems that deliver solid quality data based on the Open Data adopted during the writing of this thesis, as the OpenFDA was just released on June 2th, 2014 (U.S Food and Drug

Administration, 2014a). One application delivering such data is ResearchAE which can be read more about in C*hapter 2.8.7* (Social Health Insights LLC, 2015).

Other principles of Open Data is that it contributes to **business development** and to more **democratization** and **transparency** (Direktoratet for forvaltning og IKT, 2014b). The principle of business development has been covered by creating this prototype for the Biomaterial Research Group. When it comes to democratization and transparency, it could be said it is done by publishing annual reports as described in *Chapter 2.3*, but more could be done by providing their complete data as Open Data. A suggestion on how it could be done is presented in *Chapter 4.5.2*, where a basic API has been created to help answering this research question. This makes it possible for everyone to use the data submitted at the Biomaterial Research Group in new ways never thought off before. Maybe a much better version of the prototype developed is only to come. The API needs more twerking before it can be fully used, but it is a good start of development and a proof of concept (Direktoratet for forvaltning og IKT, 2014a)**.**

As stated in *Chapter 2.6* all *publicly funded research data should be openly available to the maximum extent as possible* (Arzberger et al., 2004). Making the local data available as Open Data can have substantial benefits for the research field of orthopaedic implants by providing transparency for everyone finding the data interesting, innovation to the field of study and promotion of new research. By having data open, and by having postmarket surveillance systems, could provide patients with information on the newest medical devices but still protect them from new devices that turn out to be unsafe or ineffective (Kramer et al., 2013). If every country in the European Union made their data open and accessible, trends could be discovered earlier and incidents like the The ***P**oly **I**mplant **P**rothèse* (**PIP**) and *Metal-on-metal hip replacement*, presented in *Chapter 2.2*, could maybe have been avoided.

6.3 Research Question 3: *How could big data from multiple sources be presented in a relevant, informative and user-friendly way for the user groups?*

Presenting such a massive amount of data from different sources on a single web page is not an easy task and it will bear risks of becoming unstructured and messy. To answer this research question different design principles, heuristics and visualization techniques were used and followed to create and develop a design alternative. The user interface was evaluated

according to two different evaluation methods; *end-user evaluation* (*Chapter 5.1.1*) and *expert user evaluation* (*Chapter 5.1.2*). In the end-user evaluation there was three participants, while the expert user evaluation had fifteen. Both the number of evaluators is acceptable as three evaluators tend to find approximately 60 % of the usability problems in a system (Nielsen, 1994). The results of both the evaluations can be explored in detail in *Chapter 5.2*. In the end-user evaluation the average SUS-score given by the participants was 83 of 100. This is a very good score as SUS scores above 70 can be seen as acceptable (Bangor et al., 2008). In theory this means that the user interface is good and that the system could be finalized and put in use. As expected and described in the evaluation results, some usability flaws were discovered and need to be changed before the finalization. Keeping the 10 heuristics (Nielsen, 1995) in mind during the whole development and design process the expert evaluators were told to evaluate the system according to them. This evaluation too got a satisfying average score. Usability issues were also here found and will be considered revised during the finalization process. As described in *Chapter 5.1.2* about 95 % of all usability problems should be found with the number of participants used in this test and an idea of what remains to be done before the initialization is clarified (Nielsen, 1994). The results of the both the evaluations give us a picture that the design alternative created is satisfying.

6.4 Research Question 4: *How could a web-based system be of service for the important user groups?*

As described in *Chapter 4.2*, there are several user groups for the system developed; *researcher user*, *surgeon user* and *public user*. The user group *administrator* is not included in this research question as this group has not participated in the development, but becomes actual once the system is created and put into use. The research question was answered using qualitative methods by interviewing the main user group of the system, the *researcher users*. Based on the qualitative data gathered, user stories could be created and ranked based on importance in cooperation with a *super user*. Their needs were identified and a prototype could be developed based on the user stories and priorities created in *Chapter 4.2.1*. The system developed could be of service in different ways for the different groups. This section is therefore divided into the three different user groups and the question will then be discussed against each of the user groups individually.

By using this system, the *researcher user*s will have an efficient way off searching their local data and to find more specific records, more efficiently than by using the desktop application developed. The desktop application was created by a previous master student, and could only query some predefined specific terms (Berntsen, 2014). External sources of interest can also easily be searched using the same web application, integrating all the data into one single web application. Generated statistics based on the data retrieved locally and externally show the possibilities of doing analyses on the web application. Local data can be compared towards external data and causalities might be discovered. Not only could the workload of a single user be reduced but also findings could be made.

When it comes to the *surgeon user* the system can be seen more as a motivational factor. The surgeon user can more easily report incidents using the system and keep track on the reported records. As can be read in the transcription (*Appendix B4*) with an orthopaedic surgeon is that the surgeons are not very satisfied with the feedback they receive. Based on the interviews it seems like the surgeons would like the possibility to see what they have reported and the progress of their reports. Having this functionality would let them know that it actually helps reporting and they would be able to see the progress of their own reports. This prototype shows the possibilities of doing so by providing such appropriate functionalities. When logging into the system the user can also see statistics based on the records submitted by the user. The statistics can be of motivation for the surgeons to keep reporting incidents as they occur. Statistics like this can also show the surgeon that he/she is not the only one reporting, and that the surgeons have to keep reporting to avoid being the one reporting the least.

The final user group this system can be a service for is the *public user group*. The public user group can, as explained in *Chapter 4.2.1*, be anyone who might find the data interesting, such as patients, relatives, students or someone working in the health care sector. They can look at reported data, which has been made public, as well as search the external sources and take use of the statistical functionalities. The advantages of Open Data have already been covered in the second research question.

By looking at *Figure 6-1* we can see the different user stories created in *Chapter 4.2.1* and how well they are implemented in the project. Looking at this table shows that most of the user stories have been implemented. 9/15 is fully implemented, 3/15 partially implemented and 3/15 not implemented. By comparing the MoSCoW-table (Stapleton, 1997, p. 28-29) presented in the same chapter as the user stories, we can see that the most important user stories have been implemented. Since the end-user participants scored the “I think that I

would like to use this system frequently" in the SUS-survey highly (Brooke, 1996), gives also an indication that they felt the needed functionalities were well integrated. More detailed information about the SUS-survey can be found in *Chapter 5.1.1* while a more details about the results can be explored in *Chapter 5.2.1*.

U1	U2	U3	U4	U5	U6	U7	U8	U9	U10	U11	U12	U13	U14	U15
I	I	I	I	I	PI	I	PI	I	I	PI	NI	NI	I	NI

Figure 6-1: The degree the various user stories have been implemented. I = Implemented, P = Partially Implemented and NI = Not Implemented

7) Conclusion and Future Work

In this thesis project a prototype of a web application has been developed. This web application has been created to state an important organizational problem as described in *Chapter 3.1* (Hevner et al., 2004). The lack of a joint postmarket surveillance system for orthopaedic implants, in general all types of medical devices, in the European Union (Kramer et al., 2013) and the different user groups business needs (*Chapter 4.2*) is this organizational problem. During this thesis different methods and methodologies have been used to create the desired artefact. The artefact implemented is a search engine similar to MAUDE (FDA, 2014) for the local data stored at the Biomaterial Research Group at Haukeland University Hospital about failed hip and knee-prosthesis. It also has the possibility of gathering data from MAUDE and several other remote sources relevant for the user groups in one application framework. This could be done thanks to Open Data, as it makes it possible to use the collected data by the United States together with the data gathered in Norway. The web application also supports other important functionalities like analysing data by visualization and for surgeon to monitor their own records. The artefact has been created not only to state the organizational problem but also to be able to answer the different research questions presented in *Chapter 1*. A detailed discussion of the research questions can be found in C*hapter 6*.

To develop the artefact, as well as to answer the research questions, several methods were used. To get a knowledge base on the domain the artefact was being developed for, relevant literature was carefully studied. It has included articles defining medical devices and how the reporting and pharmacovigilance work today, in both Europe and the United States. The literature review also included relevant theories about Human Computer Interaction, Data Visualization, Open Data and other relevant research fields. The seven guidelines by Hevner et al. (2004) were followed during the entire project development to ensure that the project can be seen as a valid system development research. How the project fulfils those guidelines can be read in detail in *Chapter 3.1*. The thesis has developed iteratively, following the structure presented by Nunamaker & Chen (1990) together with Personal Kanban (Benson & Barry, 2011).

The prototype developed can be of service for the different user groups in various ways depending on their needs as defined by the use cases, which were created based on qualitative interviews in *Chapter 4.2*. The researcher user group can see the system as a tool for

improving efficiency of their research, whilst the surgeons might find it interesting to keep track of their own records. Open Data can strengthen the research field of orthopaedic implants by providing democratization and transparency for the public by giving them insight to the records and data reported. As the data is provided in machine-readable language the data can be used to create new exiting systems, never though off before. If all countries reported their data about failed medical devices to an open central database a worldwide database could be created, providing high-level information about failed devices and their reason for failure. Information retrieval algorithms could also be used on the data gathered to detect anomalies or trends protecting the patients from unsafe or ineffective medical devices (Kramer et al., 2013).

A large focus during the writing of this thesis was on how to represent the large amount of data in a user friendly way. The needs of the users were as earlier mentioned carefully created by the help of qualitative interviews, which has enabled design alternatives for a prototype. Different design principles, heuristics and visualization techniques were also used and followed to create and develop a design alternative. The prototype was evaluated both trough end-user evaluation and expert evaluation. The results and how the evaluation was conducted are presented in detail in *Chapter 5*. By having performed an end-user evaluation of the system using the SUS-survey and an expert user evaluation according to the 10 heuristics (Nielsen, 1995), there was a good understanding of what was good with the user interface and which usability issues in the system needed to be dealt with before finalization of the system. The high scores provided in both the evaluations indicate that the system is nearly ready for finalization.

7.1 Future Work

The next step for this project would be to implement a working prototype accessible on a server for the researcher user group. With appropriate funding it might even be further developed to meet the needs of the other user groups. Even though both the evaluations have provided high scores for the system it still is a lot of work left to do before finalization. More effort should go into fixing some of the usability issues found during the evaluation in *Chapter 5.2.1* and *5.2.2*. Further work could also include program development by implementing more advanced algorithms to do data analysis across the different databases, better login security and authentication and alerts for adverse events. The data for the external

sources should also be downloaded to a local server to avoid request limits. The Open Data API should be further developed to ensure that the availability of Open Data is done properly and can be adapted by other developers according to their specific needs.

In the long term future, with financial support the system can be designed to support multiple countries and not only the data retrieved at Haukeland University Hospital. The rest of the Scandinavian countries could be a part of the system and maybe in the future even the whole European Union. This is of course far beyond this master thesis goal, but perhaps this project can help starting a small ripple effect by showing the importance of having such systems available.

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9) Appendices

Appendix A1: User testing Consent form

Forespørsel om deltakelse i forskningsprosjektet

Postmarket Surveillance of Orthopedic Implants using Web-technologies

Bakgrunn og formål

Jeg heter Ørjan Ertkjern (oer002@student.uib.no) og jobber med et masterprosjekt ved Institutt for Informasjons og Medievitenskap ved Universitetet i Bergen, som også er et samarbeidsprosjekt med avdeling for biomaterial forskning ved Haukeland Universitetssykehus. Veileder for dette masterprosjektet er Ankica Babic (Ankica.Babic@infomedia.uib.no).

Målet med studien er å utvikle et offentlig tilgjengelig sentralt system for å loggføre og rapportere medisinsk utstyr som har feilet innenfor Europa. The US **F**ood and **D**rug **A**dministration (FDA) benytter seg av en slik database i dag for både rapportering og hente ut slik informasjon. I løpet av dette masterprosjektet vil en prototype av et slikt system bli utviklet. Systemet vil støtte funksjoner som integrering av data samlet ved Haukeland Universitetssykehus, og utvikle en søkemotor som FDA's MAUDE system med funksjonaliteter for dataintegrering og data-mining over landegrensene.

Utvalget er basert på relevante brukergrupper av systemet som vil bli utviklet gjennom dette masterprosjektet, og er derfor ikke tilfeldig trukket.

Hva innebærer deltakelse i studien?

Studiet vil bli gjennomført i form av et ustrukturert personlig intervju. Intervjuet vil ta rundt 1 time og spørsmålene vil omhandle dagens rutiner, fordeler og ulemper ved et slikt system og holdninger til åpne medisinske data. Intervjuet vil bli gjennomført på deltakerens arbeidsplass ved Haukeland Universitetssykehus. Ettersom det er vanskelig å få skrevet ned alt som blir sagt under et intervju vil det også bli gjennomført lydopptak dersom dette er greit for deg som deltaker.

Hva skjer med informasjonen om deg?

Alle personopplysninger vil bli behandlet konfidensielt og som forsker har jeg **taushetsplikt**. Intervjuet vil som tidligere beskrevet bli tatt opp som lydopptak og skrevet ned. Lydopptaket vil bli slettet så fort dette er gjort. Det er kun jeg og min veileder som vil ha tilgang til dataene og alt som samles inn vil bli anonymisert. Ved publisering og presentasjon av prosjektet vil personlig informasjon som for eksempel navn bli anonymisert. Ettersom brukergruppen ikke er veldig stor, vil trolig kollegaer kjenne igjen personene i intervjuet, til tross for

anonymisering, basert på andre spørsmål som daglige gjøremål på arbeidsplassen. Studien er meldt til Personvernombudet for forskning, Norsk Samfunnsvitenskapelig Datatjeneste AS.

Prosjektet skal etter planen avsluttes 1. juni 2015 og alle opptak og innsamlet data som ikke er anonymisert vil da være slettet.

Frivillig deltakelse.

Det er frivillig å delta i studien, og du kan når som helst trekke ditt samtykke uten å oppgi noen grunn. Dersom du trekker deg, vil alle opplysninger om deg bli anonymisert. Det er også helt valgfritt å svare på spørsmålene som blir gitt.

Dersom du har spørsmål til studien, ta kontakt med Ørjan Ertkjern (**Epost**: oer002@student.uib.no **Tlf**: 994 22 364) eller veileder Ankica Babic (Ankica.Babic@infomedia.uib.no).

Studien er meldt til Personvernombudet for forskning, Norsk samfunnsvitenskapelig datatjeneste AS.

Samtykke til deltakelse i studien

Jeg har mottatt informasjon om studien, og er villig til å delta

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(Signert av prosjektdeltaker, dato)

(Signert av intervjuer, dato)

☐ ***Jeg har lest og forstått hva det innebærer å delta i studiet «Postmarket Surveillance of Oprthopedic Implants using Web-technologies» og samtykker til å delta i intervju***

Appendix A2: User testing Consent form

Forespørsel om deltakelse i forskningsprosjektet

Postmarket Surveillance of Orthopedic Implants using Web-technologies

Bakgrunn og formål

Jeg heter Ørjan Ertkjern (oer002@student.uib.no) og jobber med et masterprosjekt ved Institutt for Informasjons og Medievitenskap ved Universitetet i Bergen, som også er et samarbeidsprosjekt med avdeling for biomaterial forskning ved Haukeland Universitetssykehus. Veileder for dette masterprosjektet er Ankica Babic (Ankica.Babic@infomedia.uib.no).

Målet med studien er å utvikle et offentlig tilgjengelig sentralt system for å loggføre og rapportere medisinsk utstyr som har feilet innenfor Europa. The US **F**ood and **D**rug **A**dministration (FDA) benytter seg av en slik database i dag for både rapportering og hente ut slik informasjon. I løpet av dette masterprosjektet vil en prototype av et slikt system bli utviklet. Systemet vil støtte funksjoner som integrering av data samlet ved Haukeland Universitetssykehus, og utvikle en søkemotor som FDA's MAUDE system med funksjonaliteter for dataintegrering og data-mining over landegrensene.

Utvalget er basert på relevante brukergrupper av systemet som vil bli utviklet gjennom dette masterprosjektet, og er derfor ikke tilfeldig trukket.

Hva innebærer deltakelse i studien?

Studiet vil bli gjennomført i form av en brukertest, hvor brukeren vil få utdelt 10 oppgaver som dekker de mest sentrale funksjonalitetene i systemet som har blitt utviklet. Under gjennomføring vil skjerm og lyd bli tatt opp. Lydfilen vil bli slettet og er i hovedsak for forskeren sin del. Etter at oppgavene har blitt gjennomført vil deltakeren få tildelt et spørreskjema med noen spørsmål som omhandler systemet som har blitt testet. Dette blir gjort for å finne ut hvilke oppgaver brukeren sliter mest med, for å finne interaksjonsfeil eller behov som ikke dekkes av systemet.

Hva skjer med informasjonen om deg?

Alle personopplysninger vil bli behandlet konfidensielt og som forsker har jeg **taushetsplikt**. Det er kun jeg og min veileder som vil ha tilgang til dataen og alt som samles inn vil bli anonymisert. Studien er meldt til Personvernombudet for forskning, Norsk samfunnsvitenskapelig datatjeneste AS.

Prosjektet skal etter planen avsluttes 1. juni 2015 og alle opptak og innsamlet data som ikke er anonymisert vil da være slettet.

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Samtykke til deltakelse i studien

Jeg har mottatt informasjon om studien, og er villig til å delta

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(Signert av prosjektdeltaker, dato)

(Signert av intervjuer, dato)

☐ ***Jeg har lest og forstått hva det innebærer å delta i studiet «Postmarket Surveillance of Oprthopedic Implants using Web-technologies» og samtykker til å delta i intervju***

Appendix B1: Interview transcript – lab user 1

R = *researcher*

U = *User*

R: What is your role here?

U: Research engineer. So I am applying for a PHD position and doing research on this.

R: How are you using the access databases today? And how are you using it?

U: Eh.. I use it often to find patient, just recently, with certain hip

R: Ok?

U: So I want all the patient with a spectrum, and then I want to know if there is radiograph available, and if it isn't I search for radiograph.

R: Radiographs? I'm sorry but I am not familiar with what this is?

U: Just pictures

R: Ok just pictures of the**…**

U: *nodding*

R: When you are getting data from the surgeons are you filling it into the database.

U: Just a little bit**.**

R: But you are mainly looking at the data available in the database?

U: Yes.

R: Do you tend to try to find similarities between different records.

U: You mean like the same surgeons?

R: Well the same types of devices, if two having an infection, to compare them.

U: Well yeah, if data is in there.

R: Okay, so there is no data?

U: eeh yeah I search if there is or not, for the rest … I just find as much detail I got, so I have to measure it. I will if it is in there. So in the future we will put it in there.

R: Are you often using external resources like clinical trials… I'm not sure if you heard about it?

U: oh yeah.

R: and MAUDE? Those two?

U: Not that website. But I just search for.. um.. not meta search, I just find articles myself.

R: Ok. What are you looking for when you are searching, and when are you using those pages?

U: When I want to know what a problem is.

R: Do you know about the procedures the surgeons are doing today, when a surgeon has removed a prosthesis.

U: Not really.

R: Okay, then we skip that part. Do you think the surgeon's that report, think they get any feedback and are happy with the feedback they get? Or are they getting any feedback?

U: At least the surgeons outside the hospital don't get it from here, but for the rest, I think they have to find it for themselves, on the internet.

R: aah, ok. So the data that is collected here is only for Haukeland or is it sent to another places?

U: uum… we only make scientifically articles, that's the only thing. And for the work I do, I tell it to some surgeons, but I can't tell them to everything before its published.

R: So you are mainly making articles?

U: "Nodding"

R: When the article is published, do you still keep the data in the database.

U: Yes, but I haven't published yet, but it will be done.

R: What do you think about the way data on knee and hip prostheses, and medical devices in general are treated today? Both from authorities and research side?

U: um….. Yeah, I See they are taking them from the market

R: yeah?

U: But yeah, it could be done more to find the reason why it goes wrong. So that surgeons and manufactures know what they should do so it won't go wrong.

R: Just to move back a bit to the clinical trials part. What do you think about pages like that has articles open and available for everyone, or like MAUDE that has records about failed data available.

U: um…

R: Do you think open data like this is a good thing?

U: uuum? Yees?

R: but do you…

U: Is it complete data?

R: In MAUDE they have not patient data, only about device. But what do you think about the data at Haukeland? Could those be publicly available. Of course anonymous?

U: ??? or the summary?

R: Just create a summary, like Eirik Berntsens (the previous master student (Berntsen, 2014)) system, where he had a summary page of the data and take some of this data publicly? Data that don't contain personal sensitive data. Is that something data that could be done or would you like that to happen?

U: For everyone or only those who has access?

R: If we first say everyone?

U: For surgeons its good, but for patients… when I look around people just want to… yeah.. find trouble owner.

R: I see

U: I don't know how to explain.

R: So you don't see the need of everyone to have access to the data.

U: … no…. um… yeah… not for everyone to see single records.

R: For instance if you could, I'm not very familiar with different hip prostheses. If they could search for a single device, and see what has failed and so one.

U: Ooh, yeah, maybe that could be interesting,

R: If you could compare data in the records, and find relevant articles and cases in different. Is that something that would be used?

U: Yes, because that's what I do by hand now, go to the internet and type keywords.

R: What keywords are you mainly search on?

U: Well for example component name, brand, spectrum, titan or sometimes just semantic cup.

R: And it works? You find it quickly?

U: Yeah, well sometimes I find it quickly, sometimes not.

R: But you are using the variables that are already in record?

U: No, I find articles and read it from there

R: Oh, yeah but the search terms. Like titan and brand name etc. it's all in the records?

U: Yes.

R: Based on the records in the database, could it be interesting to have some statistics of simple automatic analysis on the data there, if there is even something to make statistics of?

U: Um yes.

R: is there something you are thinking about then?

U: Maybe some statistics about how long it was? We have for instance date inserted and date removed. Some statics about the timing there?

R: ok.

U: For instance survival time? Histogram would be nice

R: Yeah.

U: I don't know if the others, eh.. I noticed, the clinicians is not standards, so usually they have this survival curve.

R: ok, eh.. Is there data about this in the record?

U: No, but you know how long it has been in a patient

R: Aah, for the medical device, not a patient**.**

U: Yeah, not of the patient

R: Ah okay. Just in general, if you should have a web interface for searching. Is there something you felt that you need? Or maybe you feel you are missing that could do the work easier for you?

U: Uuh, well, what we have now in the system we can only search for a keyword and all the relevant records show up. But yeah indeed some statistics?

R: But when you say keyword, do you think about more a detailed search? So that you can search for more than one keyword?

U: Oh no, just searching or, stem type and cup type. Yeah usually one, sometime two. I want to know this stem and cup term.

R: Thank you for your time. If you don't have anything to add then I think we are done here!

U: One thing that could be handy for me, would be to be able to convert the data I found on the internet to EXCEL or maybe CSV.

Appendix B2: Interview transcript – lab user 2

R: *Researcher*
U: *User*

R: Du kan jo begynne med å forklare hva rollen din er her?
U: Jeg er den som, når vi får, tilsendt proteser. Pakker opp, registrer, vasker og da sørger for at vev blir levert der det skal for innstøpning, tar imot tilbake og registrerer det. Ja. Blodprøver, de tar jeg å behandler for at [redacted] kan bruke de i hans analyser av metallioner/partikler.
R: Den databasen dere har, Access databasen, bruker du den ofte?
U: Eh… Når vi får inn proster går jeg inn i databasen og registrerer, så målet er jo at alt skal bli lagt inn der. Om pasientene, og at det er der vi finner det tilbake igjen. Også har jeg en papirutgave med sjekkliste.
R: Hvor mange rapporter blir rapportert, sånn ca. i måneden.
U: Det er rundt en til to i måneden. Men målet nå er jo at vi skal samle inn det meste av proteser.
R: Noe annet enn hofte og kne tenker du på?
U: Ja i hovedsak hofte og kne.
R: Dataen i systemet, har du noe mer å gjøre med det etter at det er registrert.
U: Nei, da er det mer de som forsker videre på det.
R: Litt om prosedyrene kirurgene har. Når de har fjernet en protese, hva gjør de da?
U: Da, har det vært litt frem og tilbake, om de skal vaske eller ikke vaske protesen. Ideelt skal de egentlig ikke vaskes, for når jeg da legger den i formalinbad så stivner blodrester og sånt, og da får du jo ikke vasket de ren, og det kan jo virke litt forstyrrende når du ser på slitasje at det ligger hinner og blod i veien som skjuler det. Nå er de skylt av når de kommer fra sykehuset.
R: Når de fjerner det, er det sånn at de pakker ned? Fyller ut spørreskjemaet, pakker ned og sender protesen?
U: Ja, og på forhånd sender jeg en sånn *retrieval* pakke med samtykkeskjema til pasient, med prosedyrer over hva som skal gjøres, og så de kan merke av på hvor vevsprøver er tatt, jeg kan gjerne vise
R: Ja, jeg tror jeg har sett spørreskjemaet

U: Ja, men jeg kan vise deg, for jeg skal sende avgårde en pakke som nesten er klar. Så da sender jeg med rør med ??? og formalin og putter vevsprøvene opp i det. Som gjør at vevet ikke råtner.
R: Ja! Og pasientene og må samtykke?
U: Ja!
R: For det er jo litt data om de?
U: Ja det er litt data om de. Også mottar vi og blodprøve, så vi sender med en sånn kateter, venekateter. For en tidligere studie som [redacted] har gjort, har vist at katetret var en sånn liten metallring i som gjorde at metallverdiene i blodet ble veldig høye, og det var på grunn av utstyret som ble brukt. Så vi sender med en venekateter og, for å unngå at blodprøvene blir forurenset. Om det da er lege eller sykepleier som tar blodprøven det vet jeg ikke.
R: Det er vel ikke så viktig om hvem som tar de så lenge dere får de? Hehe.
U: Hehe nei! Vi har sett at de ofte ikke er like flink. Ved at de tror at vevsprøve og blodprøve ikke er så nøye og kun sender protesen. Men det gir et tydeligere bilde. Så fotoavdelingen skal kanskje lage en liten videosnutt med bilde for bilde for å få det inn med teskje.
R: Ja det må jo til, men fungerer prosedyrene fungerer bra.
U: Ja de fungerer bra i dag, men unntak av noe mangelfull data. Vi vil ha både blod, vev og protese.
R: Skjemaet de fyller ut, pleier det å være mangler der?
U: Nei de pleier som oftest å være greie. De har gjort som det står at de skal gjøre. Men det har hendt at de noen ganger har tatt vevsprøve og merket påtegningen men glemt å merke glassene. For de må selv skrive en to tre og fire, men jeg burde kanskje ha nummerert dem på forhånd.
R: Dataen som kommer fra spørreskjemaet, det plotter du inn manuelt?
U: Ja, men så er målet at mye av de dataene skal komme rett fra leddregisteret så man skal slippe å registrere to ganger, så type protese som har blitt brukt og litt sånt
R: Ja, så det blir litt mer automatisk
U: Ja!
R: Ja, skjønner, tror jeg leste litt om det i Eirik (Berntsen, 2014) sitt intervju og.
U: Ja det er vel målet.
R: Kirurgene da? Er de positive til å sende inn ting?
U: Ja, vi har et par ivrige sjeler heldigvis. Hehe.. også er det, de synes det er viktig, men de måtte få en liten oppmuntring ved at de hadde sendt mye, men lurte på hvor enden var?
R: Ja, skjønner. Får de noen tilbakemelding?

U: Ja, så da ble det sendt tilbakemelding på ting som var på gang, og presentasjoner.

R: Ja så de får rapporter?

U: Ja, for å holde de interessert i å sende mer, for det er jo merarbeid for de.

R: Ja, de har blitt mer positive etter tilbakemelding?

U: Ja, eller de har iallfall fortsatt å sende inn!

R: Hehe, det er jo positivt.

U: Det var vel en som trakk seg, for det ble litt for mye og omfattende, skjema, blod og vev som måtte gjøres

R: Er det tidkrevende prosesser?

U: Mmm.. ja det er iallefall merarbeid for ortopeden. Men samtidig er det jo viktig

R: Om dette skulle bli gjort elektronisk, tror du det ville vært nødvendig å ha det elektronisk? De må jo allikevel sende protesen i post, men om skjemaene for eksempel hadde blitt sendt på nett? Om det kunne gjort jobben lettere? Ved å slippe å plotte inn.

U: Ja jo, kanskje det hadde vært noe. Ja nå i disse tider. Også er det jo litt å sende ting via sykehus og sykehus.

R: Ja sikkerheten kommer til å gjøre at det kommer til å ta lang tid, men leker litt med tanken. Meg og «super user» har diskutert litt og lekt litt med tanken på at kanskje om kirurgene rapporterte på nettet, at de da kunne følge med på det de registrerte. Og kunne se på sine egne *records*.

U: Ja, så de ser at det skjer noe? Ja jo, jeg tror at om de er interessert i forskning så tror jeg at, for de som sender inn er jo interessert i forskning. Så ja det tror jeg kunne vært en ide.

R: Har du noen erfaring med Clinical Trials og MAUDE?

U: *rister på hodet*

R: <*Forklarer om konseptet*>

U: Står det noe om hvor mange som fungerer? Ellers blir jo det skjevt bilde?

R: Nei her er det bare rapporter om de som har feilet.

U: Ja jeg skjønner. Men om det står at 100 har feilet, mens 1,000,000 stykker har godt bra så gir jo det et veldig skjevt bilde.

R: Ja, det kan du jo kanskje søke videre på, men de har bare feilete ja. De blir publisert offentlig. Hva synes du om det? Du snakket jo om det skjeve bilde

U: Ja det var jo min første tanke. Nei, jeg tror ikke det hadde vært noe.

R: Det går jo kanskje an, bare tenker nå, om man ser et utstyr, at man kan finne økninger av feilete.

U: Ja, ja om man oppdager sånne ting. Men i leddregisteret får jo du ut i fra helheten hvor mye som feiler. I forhold til det som er sendt inn vet man hva som feiler. Jeg tror jo ingenting er feilfritt.
R: Nei ikke sant.
U: Så i mitt hode vil jo alt feile, men om man ser i forhold til hvor mye det blir brukt så sier det jo ingenting
R: Enig. «Forklarer om Clinical trials». Men ja, når var du jo litt kritisk til MAUDE. Men om vi tenker på Haukeland dataene, tror du det samme kunne gjort med de?
U: Ja være publisert? Ja årsrapporten til leddregisteret er offentliggjort. Så den går an å finne på nett.
R: Klarer du å forklare hva den inneholder?
U: Ja den inneholder statistikk, over kneproteser. Så mange er satt inn, den typen sånn, den typen sånn osv. De har mange statistikker der nede.
Men ja, akkurat med Haukeland vet jeg ikke hvor informasjon om hvor mye som er vellykket og sånt. Så om man ikke har forhåndstallene, sier det ikke så mye.
R: Du sammenligner ikke så mye data.
U: Nei
R: Generelt sett, om det skulle kommet en slik nettportal. Er det noe du føler du mangler**.**
U: I begynnelsen, når jeg hadde en buke og vi begynte med databasen og dette skulle inn, når man rettet på noe som var gjort med en feiltakelse. Skrev inn et annet tall på rec 10, men skulle vært rec. 11, så får man ikke spørsmål om man vil endre.
R: Heller ingen mulighet for å angre fort?
U: Nei… uten at det skal bli for tungvint. Man vil jo ikke bli spurt om endringer hele tiden. VI har en maskin som spør hele tiden om du vil lagre endringene. Men nei, jeg har jo ikke gjort noen endringer.
U: Ja jeg kom også de SPSS filene fra registeret, for de har jeg vært nede å hentet fra leddregisteret, og de har jo et annet skjema som gir informasjon, men så vil de ikke at vi skal kunne koble rec. nummer og personnummer. Men det har vært litt tungvint system. Dette må en spesifikk person gjøre, men prioriteringene er litt forskjellig. Men kanskje internett kan løse det?
R: Ja, det får sikkert ikke internett lov til heller siden dere ikke har lov

Appendix B3: Interview transcript – lab user 3

***R**: Researcher*

***U**: User*

R: Hva er din rolle her på Haukeland?

U: [*Store deler av dette svaret har blitt fjernet for å opprettholde anonymiteten best mulig*] Jeg er da forsker, fortiden. Jeg forsker da på disse ortopediske problemstillingene som handler om hvorfor proteser svikter og havarerer, hvor jeg da i hovedsak fokuserer på kjemiske og biologiske årsaker, mens [redacted] og [redacted] ser mer på mekaniske grunner på hvorfor proteser løsner. Og forså vidt andre implantater, som ble brukt ved bruddbehandling, men vi fokuserer mest på leddplantater som kne og hofte. Det var en innledning, det var jeg som begynte dette arbeidet med min postdoktorgrad i 2007, var det vel, hvor jeg etablerte en *biobank* for vev og blod fra da disse pasientene som skiftet ut leddprotesen sin. Eller skiftet ut eller fjerner bruddimplantater, hvis man har et brudd som er forbundet til et en plate eller skrue. Når bruddet har grodd tar man ut. Men, vi har bare noen få bruddpasienter i banken, det er for det meste protesepasienter, ca. 150 stk. siden den tid. Senere startet vi da å samle inn selve materiale, revisjon, tok ut protesen og analyserte den. Når [redacted] kom ble det enda mer fokus på den analysen, hadde erfaring fra industri og bioengineer som [redacted], og kunne en del materialtekniske analysemetoder. Også fokuserer jeg mest på å påvise slitasje på artikler og ioner i vev, som du ser på bildet her. Så svaret på min rolle er å analysere eksponeringen til kroppen fra de protesene, og den biologiske reaksjonen på det.

R: At kroppen prøve å bryte det ned tenker du på?

U: Nei, bruke disse vevsprøvene til å måle hvor mye som har blitt frigjort fra protesen, og det er det som er årsaken til den biologiske årsaken som bidrar til havari.

R: Det var veldig interessant, sånn som det er i dag. Den databasen dere har, bruker du den ofte?

U: Ja, bruker den i alle fall ukentlig, og i perioder hvor vi jobber med en studie bruker vi jo den hver dag.

R: Hvordan bruker du den da? Se på dataen, hente ut data?

U: Veldig ofte for å legge inn nye data, hver gang vi får en retrieval, med alt materialet, så må vi legge inn data, så analyserer vi den, så legger vi inn analysedata. Først er det bare en demografi, hvor gammel pasienten osv.
R: Det dere mottar fra kirurgen?
U: Ja, de skjemaene der. Så begynner du å gjøre vevsanalyse og blodanalyse som må legges inn i andre skjemaer. Så det gjøre jeg. Så senere når man har samlet nok data til å gjøre en studie, bruker man databasen til å høste ut pasienter med samme type proteser, for å få listet opp.
R: Er det lett å gjøre nå?
U: Ja det er ganske greit.
R: Så da får du de ulike pasientene, på en enkel måte.
U: Ja, men parallelt må jeg jo innrømme at jeg har statistikkprogrammer, der jeg legger inn data i tillegg, jeg har i alle fall ikke benyttet meg til å eksportere data fra databasen til statistikkprogrammene. Så jeg gjør nok litt dobbelt arbeid der. Først legge til Excel, så til to eller tre program. Noen er god til grafisk, mens andre er gode til å teste signifikans mellom grupper eller variabler.
R: SPSS for eksempel?
U: Ja den brukes mye, og Graph Analysis.
R: Den til å tegne å lage modeller?
U: Ja, presentere det grafisk. Så den bruker jeg til å lage figurer i publikasjoner, men den har også innebygde statestikkpakke som gir de nødvendige og mest å bruke tester som T-test. Og gjøre korrelasjon osv. Det er vel mest det jeg gjør,
R: Pleier du ofte å gå tilbake å se på enkle rapporter eller pleier du oftest å sammenligne de med like tilfeller.
U: Jeg er veldig for å identifisere alle de rec-numrene slik at jeg kan gå inn i biobanken, hvor jeg har alle vevsnittene med samme kode, plukke de ut og analysere de. Det er mer et sorteringsverktøy, og liste ut hvor mye har vi og hva var spesielt med vært case. Hvorfor løsnet det? Var det bare fem-delen eller også kopp-delen? Også mer detaljer om løsningsmekanisme, var det, mye, ja der ligger røntgenbildene, de forteller ofte veldig mye, var det osteolyse, altså beinoppløsning, hvor var det, hvor tok vi vevsprøvene og vevsprøvene i forhold til biologiske reaksjoner, hvor store var komponentene, stammene kan jo ha mange forskjellige størrelser, hva overflate har de. Alle opplysningene vil ligge i databasen. Der får vi også informasjon fra leddregisteret. Og de har detaljert om de forskjellige produktene som blir brukt, så slipper å legge det inn manuelt. Det henter vi fra SPSS filer og vi importerer til

Access. De har det vel i Oracle, så om til SPSS til Access. Mye data transformasjon med andre ord. Og det var vel det din forgjenger jobbet litt med.

U: Ja, prøvde å forenkle det en del?

R: Ja.

U: Han ville jo ikke operer med Access-databaser, men programmerte sine egne ut i fra vårt behov. Kun for kneproteser, men kunne jo egentlig blitt gjort for hofte og.

R: Ja, han sa så. Pleier du å sammenligne dataen dere lokalt med eksterne data fra andre steder i Europa eller verden. USA? Andre land? Eller er fokuset på Skandinavia?

U: Man gjør jo det ved å se på andre sine publikasjoner. Men ikke andre registre, har vel ikke tilgang heller. I alle fall ikke direkte tilgang. Det har jo nasjonale leddregistre som samarbeider med andre land. Og utveksler data der. Spesielt i Norden. Danmark, Finland osv. Så de avtaler litt og forbedrer dataen litt. De vil jo ikke dele alt. Men du har jo nevnt at det finnes noe online data, som FDA.

R: Ja jeg tenkte å diskutere dette. <*forklarer hva MAUDE er*>

U: Jeg skal innrømme at jeg ikke har brukt kildene. Det var jo bruker [redacted] som delte denne siden med meg, for han synes de var spennende. Så det burde jo vi vært flinkere til.

R: Om vi går rett til dette emnet da, hva synes du om å dele slik informasjon til offentligheten slik?

U: Jo, jeg er veldig positiv til det. Det er vel mest industrien som kanskje har mest å «skjule». Men ja, de har vel et behov for å være åpen de og. Dersom de lager et produkt som viser seg å fungere dårlig på markedet er jo det viktig for dem å korrigere så tidlig som overhode mulig. Det som har skjedd nå, er at det har gått for lang tid, mange misfornøyde kunder, de må trekke tilbake et produkt og kanskje betale store erstatningssummer til pasientene. Spesielt i USA med gode advokater.

R: Hehe.

U: Så vi har hatt noen sånne «recalls» på en del produkt. Det er jo bedre å være føre var. Om alle gjør det er det veldig balansert og demokratisk, om bare noen deler, får kanskje noen konkurransefortrinn

R: Dersom det viser seg at et medisinsk utstyr begynner å feile. Hvordan foregår da datautvekslingen til resten av verden?

U: Den skjer jo gjennom jevnlige internasjonalekonferanser og møter. Hvor da data blir delt. Det er jo ikke direkte *retrieval* data, ja, jo, de samarbeider jo også med oss, så det blir vel delt det og. På forskningsplan finnes det en god del store multinasjonale arenaer, du har en europeisk, en amerikansk, og de deler på hverandres store internasjonale møter, og da deler de

de siste dataen, analyse dataen om *survival* av protese for eksempel. Så det er jo ganske stor åpenhet. Men det er jo ikke direkte *retrieval* data som registeret her i Bergen deler, jo ja, de samarbeider jo også med oss, så da går jeg ut i fra de deler det vi og har publisert i samarbeid med registrene. Så… Vi synes jo at registeret bør ha stor interesse av å ha oss med på laget, så vi påviser jo ikke bare at en protese begynner å feile men hvorfor det begynner å skje.
R: Den andre siden er ClinicalTrials <*Forklarer hva dette er*>
U: Jeg har ikke vært så veldig mye borti den nei. Men om man gjør en klinisk utprøving av en protesetype, så anbefales det at det gjøres etter ClinicalTrials malen, i forbindelse med kvalitetskriterier og følge og metodologiske prinsipp og at du registeret studie her.
R: Gjør dere det?
U: Vi har ikke hatt noen klinisk utprøving. Men vi samarbeider med kirurger som gjør det.
R: Dersom vi ser på MAUDE. Tror du de dataen kan være nyttig og samarbeide med dataen dere har
U: Det tror jeg, men jeg har ikke sett nok på hva det inneholder. Så vanskelig å gi et svar
R: Vi kan se på det nå! <*Viser MAUDE på en datamaskin*>
U: Hvorfor har jeg ikke brukt dette før? Dette er via FDA?
R: Ja, det er den offisielle siden. Slik jeg har forstått det er alt som er rapportert kommer rett inn dit, og det kan jo virke som at det pasienter og kan rapporterer. Men man kan jo si at du kun vil ha de rapportene som er registrert av helsepersonell.
U: mhm.
U: Så du kan lage en søkemotor som kan søke gjennom denne dataen?
R: Ja, det bør gå an. Men da regner jeg med rapporterer rapportert av pasienter ikke er så spennende, ettersom dette går an?
U: Nei det bør kanskje vektes litt lavere. Men og kanskje relevant. Kanskje de rapporterer mer ærlig.
R: Ja det kan vel være interessant og se hva de har å si og?
U: Ja, de har jo kanskje selv identifisert hvile del av protesen som har gått galt, men kanskje beskrivelsen av det ikke er så faglig og korrekt.
R: Ja ikke sant, har blant annet også sett andre nettsider som lager statistikk basert på dataen til FDA. For eksempel se voksende kurver!
U: Ja
R: Jeg så forresten at de rapportert av pasienter inneholdt en del mindre enn de som er rapportert av andre…..<*mye mumling om MAUDE*>
U: Dette er bare for det amerikanske markedet regner jeg med?

R: Ja, jeg snakket med [redacted], og det virker som andre land rapporterer og. På grunn av mangel på rapporteringssystemer på sine sider. Og det kunne jo være dumt siden vi da ikke bare får det amerikanske markedet, men blandet.
U: Det hadde vært fint om du kunne sjekke? Om det er en aktuell problemstilling
R: Ja det kan jeg!
U: For hvert land har ofte hver sin versjon av protesen. Det er ikke alltid at protesen er lik i alle land.
R: Ja, du mener det er samme leverandør men ikke samme produsent.
U: Ja, ikke alltid leverer fult spekter av en protese i alle land, kan være små forskjeller. Så det må jo alltid undersøke hva slags LOT-nummer som er registrert. For produktet er stadig i endring.
R: Ja, for LOT-nummer vil alltid være unik for en protese. Så om en blir oppdatert eller endret så vil LOT-nummeret endre seg også. Og det er unikt for hele verden?
U: Ja, det er et stempel som fabrikken setter på og skal være internasjonalt. Finner du samme LOT her som i USA er det samme produkt og lagd på samme tidspunkt og har like spesifikasjoner og betingelser. Så da vet du at du sammenligner eple mot eple.
R: Har du mye med prosedyrene med kirurgene gjør etter at de har fjernet en protese? Hva er rett og slett kirurgens oppgave?
U: Da har vi lagd et system, en protokoll, for hvordan protesen skal pakkes ned og oversendes. Hvordan vevsprøven skal ta ut og hvordan man skal føre på info på skjema, legge oppi de rette prøveglassene, pakke i trygg beholder/pose.
R: Er det noen ganger feil med de rutinene eller gjøres det ofte korrekt?
U: Ja det blir gjort en del feil feil…
R: Er det da selve rapportutfyllingen det går galt eller behandlingen av protesen?
U: Noen sender protesene i en vaskemaskin, andre putter den rett i posen så vi kan vaske det her. Så her er det litt forskjell. Noen glemmer for eksempel vevsprøvene og blodprøvene. Noen glemmer å fylle ut ting på skjemaet. Men stort sett er de veldig flinke. Her lokalt, pleier man av og til å glemme at denne retrievalpakken eksisterer og improviserer ved å ta noen rør her og noen rør der.
R: Skjønner
U: Men ja, av og til avvik, men flinke
R: Føler du at de ser nytten av å rapportere og ser nytten?

U: Ja, vi har utvalgte samarbeidspartnere som er nok mer motiverte enn andre. Var en gang vi sendte ut forespørsmål til flere sykehus, og var da rundt 60 %, som sa seg villig til å være med, dette er bare basert røfflig på hukommelse, som svarte og ville være med.
Vi har også presentert arbeidet vårt på det årlige, møte for ortopedkirurger, for å få flere til å sende *retrieval* til oss. Vi hadde forventet en kraftig økning etter det, men vi så ikke helt den store økningen vi håpet på. Så vi er avhengig at kirurgene lokalt her driver litt rekruttering for oss, da de snakker litt bedre sammen med hverandre for å forstå viktigheten. Men det tar jo litt ekstra tid for arbeidet
R: Får de noen tilbakemelding på arbeidet de gjør?
U: Ja der har vi lurt på om vi burde være litt flinkere. Hvis vårt mål er å produsere vitenskapelige artikler, tar det jo litt tid. Kanskje flere år.
R: Ja om det tar 5 år så er det kanskje ikke så gøy å drive å rapportere.
U: Ja det har vi tenkt på kanskje lage litt delrapporter med status nå. Mye gjort via epost ved å sende tilbakemelding til den spesifikke kirurgen. Men vi burde kanskje lage rapporter, kanskje en årsrapport for virksomheten total sett, som leddregisteret gjør. Det er de jo pålagt å gjøre, av helsedirektoratet, fordi de har den statusen som nasjonal kompetanse, den statusen har vi ikke nå. Da måtte vi vært flinkere. Riktig det du sier, ofte rapportering vil motivere kirurgene.
R: En tanke vi har hatt, at de kan se recordene de har rapportert, og da kun sine, og følge med på sine og se hva analysen er.
U: Vi har jo tenkt på muligheten å gi kirurger tilgang til deler av databasen, ikke hele, men se på noen enkle data.
R: Ja, hele har de nok ikke behov for.
U: Ikke har de behov for det, kanskje heller ikke forstå alt heller. Så ja, et eller annet grensesnitt, web-basert kanskje. Litt sånn som det her (MAUDE). Liste opp dataen, og kanskje litt mer om hva vi har funnet så langt. Fra case til case.
R: Den dataen dere har lokalt, hva synes du om å ha det offentlig som MAUDE
U: Det er nok litt for uferdig for å legges ut offentlig, i og med at vi av og til jobber litt her og litt der, mye blir stående litt tomt.
R: Men når det er komplett?
U: Men kanskje når det er komplett. La oss si vi hadde en knapp som het «ferdigstill» eller noe som bekreftet at den var ferdig. En status som gjør at det kan offentliggjøres. Men ofte er det ikke nok å bare legge ut et case. Men heller statistisk grunnlag for det vi fant, et gjennomsnitt av det vi fant. For eksempel det jeg ofte ser på er metallnivået i blod, det vil

ofte svinge fra pasient til pasient, om jeg for eksempel kunne lagd boxplot med min og max gjennomsnitt, så kunne vært enkeltcasene vært plottet inn i dette. Dette ville nok vært mer informativt. Et enkelt verdi sier kirurgen ikke så mye.

R: Sånn, med tanke på dataen dere har. Kunne det vært gjort noe enkel analyse eller statistikk? For eksempel basert på tidsperioder.

U: Eh, ja... Om jeg tenker på de dataene som ligger der inne i dag. For eksempel nivået på krom i blod, som blir målt på nesten alle pasientene. Da må du kanskje sortere på samme protesetype, også lage en statistikk for krom på blod for alle casene. Gjennomsnitt, spredningsmål eller kanskje hver rekke bortover en tidsakse med alle rec.ene også nivå av krom i blod. Så plotter du bortover, kan trekke en linje og lage gjennomsnitt, spredningsmål osv. Ta alle protesene kanskje, og gjøre sortering. Kanskje en frekvensfordeling av type proteser over tid. Altså kor mange som har blitt rapportert på en tid, det gjør jo ofte registeret. At en øker og øker i havari, mens en går ned. Trendkurver med andre ord over det vi får inn. Det hadde vært enda mer aktuelt dersom vi fikk gjennomført å få *retrievals* over hele Norge, for da hadde du fått komplett utvalg og ikke selektert utvalg. Nå samler vi bare 3-4 typer som registeret har sagt vi bør fokusere på, og ikke samle alt. Problemet med å bare plukke de som har vist seg å være et problem etter 15 år er at de er på vei ut av markedet, og bruken går ned. Men dersom vi hadde tatt en protese som nettopp har kommet på markedet vil havariene starte og til slutt nå en toppkurve at havari. Det er ikke så spennende å ta en som holder på å dø på markedet. For vi vet alt om denne protesene, den brukes ikke allikevel så hvorfor publisere det? Det har sikkert vitenskapelig interesse men ikke markedsinteresse. Det er gøyere å være med på oppturen, på de nye.

R: Ja!

U: Da kan kanskje en sånn statistikk, som du kan hente fra andre sider, ikke på retrieval siden men hva som brukes på markedet i dag. Det kunne jo du hentet fra andre sider?

R: Sånn som?

U: Da kan du bruke for eksempel leddregisteret. For de rapporterer jo årlig. Har du sett?

R: Ja, jeg har sett litt på det

U: Men ja, om du kunne krysse *failures*, som vi samler med de trendene for status på markedet i dag. Jeg vet ikke. .

R: Ja, verdt å titte på i alle fall

U: Ja, så kunne du laget en eller annen link der. Men, ellers har du jo dette systemet (MAUDE) der du får en tydelig indikasjon på når noe begynner å se på et produkt. Og det kan kanskje gi en retning på oss, hva bør vi gå inn på og begynne å samle og begynne å

etterspørre, istedenfor at vi sitter å venter på at de kontakter oss og være litt proaktiv: Ja vi har hørt at i USA begynner den og den protesen og havarere. Og den er kanskje ikke fullt introdusert på det norske markedet, og vi bør begynne å følge med på den når den kommer til Norge.

R: Ja

U: Registeret i Norge sier at det må være 10 års klinisk utprøving, som må skje i et annet land. Så vi bruker på en måte USA som prøvekanin, og om det går bra der prøver vi i Norge. Så være litt mer, innovativt, og tidlig ute, på *retrieval* siden. Så der kan du jo bruke dataverktøy og se på trender.

R: Er det noe ander nyttige funksjoner du føler du mangler som kunne vært kjekt å ha?

U: Kanskje muligheten til å eksportere bloddataene fra en tabell, overføres i et sammenstilt regneark

R: Excel?

U: Ja, det er jo et greit startpunkt og ta det over i et annet etterpå, SPSS osv. Kan være Access allerede muliggjør dette,

R: Jeg har ikke prøv Access så mye.

U: Jo, ganske sikker på det. Så skjer jo det en del med tegnsetting på veien. Plutselig blir tall om til data og sånt. Jeg sender en epost om jeg kommer på noe!

Appendix B4: Interview transcript – Surgeon

***R**: Researcher*

***U**: User*

R: Hva er rollen din her?

U: Jeg er [redacted] for seksjon for leddprotesekirurgi og revmakirurgi, så jeg driver nå å operer på disse folkene og har litt med personalet på den seksjonen å gjøre da.

R: Så da jobber du vel ofte med kneproteser?

U: Ja, det er det som fyller det meste av arbeidstiden vår egentlig?

R: Er det mange operasjoner som blir gjennomført i måneden eller?

U: Nja, vi har vel sånn i snitt 8 eller 9 i uken, og da vil en eller to av de være revisjonen, altså annen, tredje eller fjerdegangs operasjoner. Hvor man da skifter hele eller deler av protesen.

R: Det er de dere rapporterer?

U: Så det er de vi rapporterer til labben, til [redacted] og [redacted]

R: Når dere får en revisjon, den prosedyren med å pakke ned og vaske...

U: Ja, den er jo, det er jo stort sett jeg som har gjort det her, det er vel 10 år siden vi har begynt med det.

R: Ja ok.

U: Ja det er litt sånn at jeg må huske på det, og spørre pasientene, selv om dette aldri har vært noe problem selvfølgelig. Det er jo bare snakk om vevsprøver eller vev som vi ellers hiver i bosset. Så det er jo ikke noe risiko forbundet med dette for pasienten. Så jeg har enda ikke fått nei av noen da, men man må huske å spørre og få påskrift og ha med seg ned i operasjonsstuen og ha med prøveglass og vevsprøver.

R: Dette får du av de (labben)?

U: Ja, det er litt sånn, man må passe litt på, hvis vi skal prøve å få det til å gjøres til litt mer rutine må vi få til å lage noen «kit» som kan ligge der nede, så om vi kommer på det underveis så kan vi ta prøvene og spørre pasientene etterpå.

R: Ja, så selve prosedyren, spørreundersøkelsen hvor man markerer.

U: Ja, det er sånn samtykkeskjema, som det viste meg her nå. Som forklarer hva vi holder på med som du skriver på her, også er det vel egentlig to skjema hvor man fyller ut med informasjon om den forrige operasjonen, og hvorfor den forrige operasjonen har sviktet da,

diagnosen da, indikasjonen på det siste inngrepet og det første. Også legge ved røntgenbilde. Så det er jo litt arbeid forbundet med hver enkelt sak.

R: Ja det tar litt ekstra tid

U: Ja det tar jo en del ekstra tid. Og hittil er jo det bare en andel av operasjonene, for det er jo ikke sånn at hver gang jeg gjør en revisjon så tar jeg prøver. Vi/de har vært på jakt etter spesielle implantater eller problemstillinger som vi har siktet oss inn på. Du kan jo se oppi den der boksen der ligger jo noen kilo med (proteser). Det meste går i den boksen der

R: Ja, se der ja. Det er slike du sender inn?

U: Nei, ja, det er tilsvarende ting jeg sender inn. Men om det har vært en infeksjon, at vi fjerner en protese på grunn av en bakteriell infeksjon så har vi ikke sett det på den labben enda.

R: Nei ok.

U: Men om jeg skrifter noe på grunn av det er løst eller det har løsnet fra beinet, eller det er sånne osteolyser, altså sånne blemmer hvor beinet har blitt spist opp rundt protesen. Så pleier vi å huske å få sendt det til «retrieval senteret».

R: Ja, men når det løsner er det?

U: Neida, løsning er den vanligste årsaken har det i alle fall vært inntil nylig. Den vanligste årsaken til at man re-opererer hofteproteser særlig. Det er jo sånn at de kan begynne å løsne etter åtte til ti år. De fleste vi reviderer på grunn av løsning har ofte stått i pasienten i et par år tidligere før de løsner. Sementerte protester løsner oftere enn usementerte proteser.

R: Du viste meg et system i sted (Re motion databasen)

U: Ja det som vi prøvde å åpne?

R: Ja det til hånledd. Hva slags informasjon er det du fyller inn her?

U: Der fyller vi inn, der gjør vi enn sånn undersøkelse av pasienten på forhånd. Hvor vi måler leddutslagene, kraften, med et sånt instrument vi måler kraften med, før operasjon og etter operasjon, så fyller vi eller når de er på poliklinikken. Også fyller vi det i et skjema, og når vi kommer på kontoret på tampen av dagen så legger vi det inn i databasen her. Det er bare det. Og det skal alle gjøre i prinsippet da, som bruker den protesen da. Og det er firmaet som selger protesen som har tatt initiativ til å få laget denne databasen. Så det er jo ganske lurt, særlig siden det er så sjelden kirurgi, for da kan man holde på i årevis før man finner ut om det er en god metode eller ikke.

R: Ja, det tar jo en god stund før man får resultater da.

U: Når man sitter på hver sin topp i hele verden er det umulig å ha en oversikt over hvordan det egentlig funger før man samler alt materialet.

R: Men er for eksempel det spørreskjemaet om hvor vevsprøver er tatt. Er det noe sånt du kunne tenkt deg å ha elektronisk?

U: Ja, det er noe jeg gjerne kunne hatt elektronisk. Slik at jeg nede på operasjonsstuen bare har ferdig merkede prøveglass hvor det står 1, 2, 3 og 4, også skriver vi enten på en lapp eller noe sånt jeg kan ta opp her etterpå hvor prøvene er tatt. Også bare legge det rett inn, og bare legge inn alle de dataene jeg skriver ned på det arket, det kunne jeg godt tenk meg å legge rett inn. Men det er ikke gitt at alle mener det samme, det har vært en diskusjon lenge det om proteseregisteret vårt det om man skal gå over til online registrering.

R: Kanskje begge deler?

U: For det er jo ikke alle, særlig de over 40 er ikke alltid så positive til det. Så det er jo ikke gitt at det er noen kjempefordel akkurat det.

R: Ja jeg så jo for meg at det kanskje var like greit.

U: Særlig det at jeg er her, og [redacted] er der, det er jo ikke langt, men så er jo det sjeldent jeg ser de. Så hver gang jeg har tatt ut sånne, sender jeg en mail så kommer noen å henter griseriet da. Og da må jeg ta kopi av skjemaene jeg fyller ut, så får de med seg kopien også må jeg sørge for at vi har kontakt med registeret, en slags mellommann for å unngå at vi har for mye personnumre og sånt på labben.

R: Når det gjelder å følge med på rapporter, er dette noe kunne vært fint?

U: Mhm... det hadde vært veldig interessant ja!

R: Jeg føler kanskje dere får litt mangelfull informasjon.

U: Ja, det er vanskelig for oss å gjøre sånn som det er nå

R: Hvor mye får dere av tilbakemelding?

U: Nei jeg, får ingen tilbakemelding om jeg ikke spør. Men jeg har en slags oversikt i permen min der.

R: Men du får vel publikasjoner og sånt?

U: Ja det er jeg jo med på. Så der, det er ofte først da jeg begynner å se hva vi har av materiale når man begynner å skrive om det og det komme ut sånne manuskriptsforslag. Så det hadde vært veldig greit for meg ha en tilgang til en oversiktlig greie over den der banken. Kunne sortere i hofte og knær osv.

R: Ja er det også å se i forhold til andre land, og kunne sammenligne.

U: Ja absolutt, veldig.

R: Når det kommer til rapportering, er det interessant å se på andre sine kirurger sine data, eller er det kun ditt som er interessant å se på. Det er kanskje litt dårlig gjort å se på andre kirurger om de rapporterer mye.

U: Neeei, jeg tror ikke det er noe dårlig gjort. Vi er vant med at det er veldig åpent og at alle revisjoner meldes til register uansett, selv om det ikke der er noe personlig, det blir jo ikke registrert navnet til kirurgen, nei det gjør det jo ikke, men sykehusavdelingen får jo det på rullebladet. Så det tror jeg ikke er noe problem altså, men det kunne jo kanskje vært at en kjernegruppe, altså de som er involvert i manuskriptet og fortolking av data må nesten ha full tilgang. Men ellers kunne man jo organisert det slik at de som bare leverte data kunne hatt tilgang til sine egne, og få statistikk og sånn. Slik som det er i re-motion databasen.

R: [redacted] snakket jo om denne åpne dataen fra FDA. Hva synes du om sånn offentlighet? At data er så åpnet?

U: Jaa jo…

R: Det er ikke noe pasientinformasjon. Mer slik at for eksempel, en protese har feilet. Årsaken til det, dette skjedde og dette var gjort.

U: Altså om det hadde vært snakk en generell helseovervåkningstypetanke der, hvor man har en svær co-hort som man følger. Men her er det bare stikkprøver egentlig, så man kan ikke regne med at dersom 80 % av protesene som ligger der har allerede har blitt reoperert fordi den ene delen er løs, betyr ikke det sikkert at 80 % av alle revisjonene skyldes det samme. For det, er ikke et tilfeldig utvalg, om du skjønner. Jeg vet ikke hvor, man risikerer jo at det kan komme ut, om det ikke ligger noen profesjonell fortolkning av det som presenteres, tror jeg det bør forbeholdes fagfolk.

R: Du kan jo få se dataene, om du skrive MAUDE på Google.

<Finner frem siden>

Du tror ikke noe av denne dataen kunne vært nyttig å sammenligne med for eksempel dataen dere rapporterer?

U: Ja, jo, kanskje, nå har jeg ikke fått sett så nøye på dataen her da.

R: Er det noe funksjonalitet du ser for deg at du ønsker i et slikt system?

U: God tilgang på dataen, så man ikke føler man leverer data uten å se noe til de. Om man kan få noe veldig greie lister over hvem du har, og de og de implantatene.

R: Ja, skjønner. Kanskje det kan hjelpe til å motivere og flere blir lysten på å motivere.

U: ja for per i dag, for de ivrige kirurgene som vi har klart å lokke med på dette her de levere jo jevnt og trutt, men det å få med nye er ikke så lett om det blir mye arbeid for de. Om man har sånn kit, en bøtte med alt oppi, prøveglass, beskrivelse hva som skal gjøres, returkonvolutt, slik at det går av seg selv. Og har et system hvor man kan føle seg litt inkludert da!

R: Men da var det alt tror jeg. Takk for hjelpen!

Appendix C: User testing tasks

Thank you for participating in this usability test. After each tasks you can return to the home page to restart. Good luck!

Task 1:
Search for local records where the hospital is "*Haukeland"* and find the study number of the first relevant record.

Task 2:
Search for local records with the term "*Heraeus Kulzer"*, and find similar cases for the first relevant record.

Task 3:
Go to the start page, and find data about "*Heraeus Kulzer"* from all the supported databases, between the dates 01.01.2000 to 31.12.2014 and have a look at the results from each of the databases.

Task 4:
Find the number of records from *MAUDE* and *Clinical Trials* when searching for "*LCS"*.

Task 5:
What year had the highest number of reports in *MAUDE* and the *local database* when searching for "*Heraeus Kulzer*"?

Task 6:
Find all relevant records from *clinical trials* about "*knee*" where the country is "*Sweden"* and "*has results"*, recruitment is "*completed*" and study type is "*interventional"* and find the purpose of the first relevant trial.

Task 7:
Navigate to the official clinical trials site for the first trial about "*Heraeus Kulzer"* by using the program.

Task 8:

Get the first relevant literature in PubMed about "*LCS knees*".

Task 9:

Log in by using the username: "*tom.thomsen@helse.no"* and the password: "t*estbruker"* and find all records reported by this user (Do not log off when finished).

Task 10:

Create a new record to this user.

Data:

Study id: HU2525

Date of birth: 12.02.1983

RadioGraphs: true, Tibial Insert: true

No. of blood samples: 2, No of tissue samples: 0, No. of cement samples: 0,

Implant removal date: 18.02.2015

DONE!

Appendix D: System Usability Scale Survey (Bangor et al., 2008)

	Strongly disagree				Strongly agree
1. I think that I would like to use this system frequently	1	2	3	4	5
2. I found the system unnecessarily complex	1	2	3	4	5
3. I thought the system was easy to use	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
5. I found the various functions in this system were well integrated	1	2	3	4	5
6. I thought there was too much inconsistency in this system	1	2	3	4	5
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
8. I found the system very cumbersome to use	1	2	3	4	5
9. I felt very confident using the system	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system	1	2	3	4	5

Appendix E: Heuristic evaluation survey

Expert Evaluation

Thank you for participating in this evaluation!

Now that you have tried out the system by performing some tasks, you will be asked to rank each of Jakob Nielsen 10 Usability Heuristics for User Interface Design for the system. If you are not familiar with the Heuristics, a description will be presented below each of them or you can view the following YouTube video describing each of them:

https://www.youtube.com/watch?v=hWc0Fd2AS3s .

Each of the Heuristics can be ranged in a scale from 1 to 10, were "1" = "Very Poor" and "10" = "Very good!". If you have anything to add to the heuristics, please leave a comment below.

Please ask if you have any questions.
Thank you again and good luck!

Visibility of system status

The system should always keep users informed about what is going on, through appropriate feedback within reasonable time.

	1	2	3	4	5	6	7	8	9	10	
Very poor	○	○	○	○	○	○	○	○	○	○	Very good

Comment:

Match between system and the real world

The system should speak the users' language, with words, phrases and concepts familiar to the user, rather than system-oriented terms. Follow real-world conventions, making information appear in a natural and logical order.

	1	2	3	4	5	6	7	8	9	10	
Very poor	○	○	○	○	○	○	○	○	○	○	Very good

Comment:

User control and freedom

Users often choose system functions by mistake and will need a clearly marked "emergency exit" to leave the unwanted state without having to go through an extended dialogue. Support undo and redo.

	1	2	3	4	5	6	7	8	9	10	
Very poor	○	○	○	○	○	○	○	○	○	○	Very good

Comment:

Consistency and standards

Users should not have to wonder whether different words, situations, or actions mean the same thing. Follow platform conventions.

	1	2	3	4	5	6	7	8	9	10	
Very poor	○	○	○	○	○	○	○	○	○	○	Very good

Comment:

Error prevention

Even better than good error messages is a careful design which prevents a problem from occurring in the first place. Either eliminate error-prone conditions or check for them and present users with a confirmation option before they commit to the action.

	1	2	3	4	5	6	7	8	9	10	
Very poor	○	○	○	○	○	○	○	○	○	○	Very good

Comment:

Flexibility and efficiency of use

Accelerators -- unseen by the novice user -- may often speed up the interaction for the expert user such that the system can cater to both inexperienced and experienced users. Allow users to tailor frequent actions.

	1	2	3	4	5	6	7	8	9	10	
Very poor	○	○	○	○	○	○	○	○	○	○	Very good

Comment:

Aesthetic and minimalist design

Dialogues should not contain information which is irrelevant or rarely needed. Every extra unit of information in a dialogue competes with the relevant units of information and diminishes their relative visibility.

	1	2	3	4	5	6	7	8	9	10	
Very poor	○	○	○	○	○	○	○	○	○	○	Very good

Comment:

Help users recognize, diagnose, and recover from errors

Help users recognize, diagnose, and recover from errors

	1	2	3	4	5	6	7	8	9	10	
Very poor	○	○	○	○	○	○	○	○	○	○	Very good

Comment:

Help and documentation

Even though it is better if the system can be used without documentation, it may be necessary to provide help and documentation. Any such information should be easy to search, focused on the user's task, list concrete steps to be carried out, and not be too large.

	1	2	3	4	5	6	7	8	9	10	
Very poor	○	○	○	○	○	○	○	○	○	○	Very good

Comment:

Do you think some of the tasks were difficult? Which and why?

Appendix F1: Expert evaluation result

Heuristic	Visibility of system status	Match between system and the real world	User control and freedom	Consistency and standards	Error prevention	Recognition rather than recall	Flexibility and efficiency of use	Aesthetic and minimalist design	Help users recognize, diagnose, and recover from errors	Help and documentation
Score	7	8	4	8	7	8	6	8	5	4
	8	9	7	8	9	10	8	10	9	8
	8	9	5	6	9	9	8	8	9	9
	9	9	6	9	7	7	10	9	9	10
	8	6	2	8	5	6	8	5	7	7
	7	7	4	8	8	8	7		4	8
	3	7	8	6	4	3	5	1	5	8
	6	9	4	8	7	8		7	7	10
	10	9	7	10	7	10	9	10	3	10
	6	8	8	4	8	6	7	5	7	6
	8	7	9	10	7	8	8	9	8	5
	10	9	10	9	10	10	8	9	10	10
	7	8	7	6	9	8	7	9	6	4
	10	8	10	9	10	7	10	7	10	8
	10	9	10	9	8	10	10	10	9	10
Average Score	7,8	8,1333333	6,7333333	7,8666667	7,6666667	7,8666667	7,9285714	7,6428571	7,2	7,8
Median	8	8	7	8	8	8	8	8,5	7	8
Modus	8	9	4	8	7	8	8	9	9	10

Appendix F2: Expert User Comments

Visibility of system status
include search query in results display
Navigeringen var god, visste hvor jeg var til enhver tid.
No results give blank page rather than telling you that it found nothing
Load bar is present, but does not move. "Has it frozen?". Also, the search leaves no time for coffee. When presented results from a search, the graphs are confusing. We expect to find a list or a number of hits first. Results do not tell you why the results are relevant (e.g. bolded keywords)
Animasjonen fungerte ikke. Hadde likt at systemet vist hvilken database den jobber med.
Veldig bra med progress-bar for å vise at systemet jobber. Ellers er det oversiktlig og greit å vite hvor man befinner seg i systemet til enhver tid.
Match between system and the real world
Works well, but im not an expert on searching on medical records.
Litt usikker på hvilke termer/faguttykk som brukes i ekte prosedyrer i medisin, men mitt synspunkt ser det konsistent ut.
Some buttons have confusing names, "search multiple databases" is what I'd usually call "Advanced search".
Relevant for doctors and such users. not as much casual ones
Good visualization
Trakk for brudd med My Profile. Brukes vanligvis om personlig informasjon.
Incident report on a button was a bit odd
Litt misvisende syntaks i forhold til testoppgaven gitt, men ikke noen faktisk diss-assosiasjon med det man faktisk forventer.
It is hard to evaluate the language when one is not familiar with the terms associated with the domain that the database covers
Et par ganger var ikke informasjonen helt der jeg hadde forventet å finne den. Litt vanskelig å si noe om brukernes språk for meg, men det ser bra ut.
Veldig bra bortsett fra litt forvirring rundt "Show all records" (? - tror det var det den het) og "Search", det kom ikke tydelig nok frem at det var de lokale dataene som vises ved den første knappen.
User control and freedom
missing obvious back button.
Veldig bra, men skulle ønsket at tilbakeknappen i nettleseren tok deg til forrige steg. Eg havnet tilbake på startsiden når eg gjorde dette valget.
Would love to be able to have a search-bar everywhere. Feels awkward to navigate backwards or press home.
Når man trykker "tilbake" knappen, så kommer man ikke tilbake der man var, men til hjemmesiden. Blir litt forvirret når dette skjer, og må gå inn igjen for å komme tilbake til der man var.
Very inconsistent "back functon", in some cases lackign entirely. Having to navigate back to a previous page manually is not good design. The only way to go back is by using the browsers back function, and the address bar doesn't update for every action making it impossible to undo to a certain stage in some scenarios.
When i want to return to the previous page, for example the advanced search, it changes the result page instead of returning.
Back sometimes takes you someplace you don't want to be
Mangler gå-tilbakeknapp
Fikk data utdatert når jeg forsøkte å gå tilbake en rute.
Ingen problematikk i bruk av systemet eller misforståelser over hva knapper gjør.
I did not test if back/forward button works without losing data, but I did get stuck at some point having to resort to keyboard back shortcut.
De gangene jeg gjorde noe feil fungerte det å trykke back knappen til web browseren

Opplevde ingen vansker i forhold til dette.
Consistency and standards
Veldig bra, men reagerte litt på at valget for å opprette record heter report incident. Kan kanskje oppstå litt forvirring med blanding av begrepene record/incident?
When you log in, "home"-button is place a totally different place.
Lett å forstå.
Easy to navigate
Some confusing terms: Difference between 'Search' and 'Show all results', especially when using the 'Search multiple databases'-functionality. Is the "hint"-date doing something, or does actually no input mean no input? (Oh, and you should totally add JQuery PopupDate Widget!)
Var konsistent nok
Records så ut til å være konsistente.
Tvetydige ord/uttrykk
Samme merknad som tidligere.
The two search buttons on home page should be organized differently. One searches and the other takes you to a different search interface, but they both give the impression of starting the search when they are clicked.
New record vs new incident?
Litt uklarheter rundt de to knappene nevnt tidligere (under "Match between system and the real world"), ellers tydelig og intuitivt.
Error prevention
did not see any, but also did nt make any errors
Good, doesn't allow me to write incomplete dates.
Når man ikke angir noen data i søket, får man likevel resultater, etter en lang lastetid. Burde kanskje vært en sjekk om at man har angitt data, eller gitt informasjon om hvilke data som vises når man ikke har tastet inn noen keywords.
Did not encounter
Login errors are a bit overkill.
Vanskelig å si om error prevention, men antar at systemet ikke lar deg registrere feil informasjon osv.
Fikk ikke feedback om hvilke servere den jobbet mot. Vet ikke hvilken server som feiler hvis ett problem oppstår.
Ta jeg ikke opplevde noen feil, kan jeg bare anta at disse var unngått på fornuftig vis.
Fikk ikke prøvd så mye her, men det så bra ut
Opplevde ikke å komme utenfor store feil, utenom da jeg glemte å ta med "keyword" i et søk. Keyword burde kanskje være obligatorisk å fylle inn - men kun hvis det er slik at brukeren ikke skal kunne gjøre søk uten keyword (finnes det tilfeller der de vil søke uten keyword?). Hvis det skal kunne gjøres søk uten keyword vil jeg i det miste anbefale å ha med en form for påminner rundt feltet som viser at det er viktig å fylle inn.
Recognition rather than recall
Got a nice flow after only a couple of searches.
Oversiktlig. Eneste var at hvis man trykker inn søkeordet, og deretter trykker "Search in multiple databases", må man taste inn keyword på nytt. Litt unødvendig kanskje?
Parameters searched do not carry over to result, you have to go back to see what you searched for.
Veldig bra i følge oppgavene vi fikk.
How about using search completion/suggestion for text fields?
Noen ganger ble det veldig mye informasjon på en gang, det var ikke alltid at ting var der jeg hadde forventet at de skulle være og noe av informasjonen var ikke så veldig tydelig (for eksempel var pålogget brukerinfo litt for lite iøynefallende/grå(?))
++for instruksjonsvideo
Flexibility and efficiency of use
Would like to have a collection of all results.
Lett å navigere.

Keyboard shortcuts in advanced search work very well. Backspace does not.
Easy to learn.
No idea.
Både enkelt og avansert søk er fleksibelt. Ingen forskjell i hastighet mellom metodene.
Jeg vet ikke om jeg tested systemet nok til å kunne gi en faktisk score her, men med tanke på at jeg ikke følte at noen av oppgavene gikk tregt så vil jeg score dette høyt allikevel.
Hard to tell if it tailors to both groups as I consider myself an inexperienced user in the medical domain.
Det virket bra, men burde sikkert ha testet systemet bedre for å kunne si noe bastant om dette.
Aesthetic and minimalist design
Godt og minimalistisk grensesnitt.
Not an expert in medicine, I do not know what is and isnt relevant or needed.
Aesthetically pleasing.
Too much... Stuff.
Store og fine knapper.
breadcrumb, antall saker
Enkelt og greit, lett å lese.
Noen ganger ble det litt for mye tekst på en gang.
Synes designet var veldig elegant. Fint med visualisering i grafer. Informasjonen generalt var minimalistisk, rein og ryddig - flott presentert.
Help users recognize, diagnose, and recover from errors
made no errors
Appriciate the dialog box that prevents users to insert an invalid date
Fikk ingen systemfeil, så det er bra! :)
Wrong login gave appropriate feedback to recover
The same return error.
No idea.
Når siden var utdatert måtte jeg gå frem igjen for så å gå til hovedsiden for å gjøre søket på nytt.
Opplevde ingen feil, så vanskelig å kommentere
Back knappen fungerte når jeg gjorde feil.
Litt problemer rundt "keyword", om man glemmer det i søk - hadde kanskje vært greit å få opp litt informasjon om at søket muligens vil ta litt lenger tid siden det søkes uten keyword.
Help and documentation
did not see any
Spennende prosjekt og flott program :)
Guess the tutorials are helpful(frontpage). Maybe it should be a own page and link at the top (where home and login are placed.) Cant find this documentation when you enter a search and are lost.
Var tutorial videoer, så det er til god hjelp for brukeren.
Information at the intro screen was informative but a little TL;DR.
Helpful tutorials
OK.
Leste ikke dokumentasjonen, men tydelig i seg selv.
Var i hovedsak unødvending
Didn't see, nor need much documentation!
Dette vet jeg egentlig ikke så mye om, bortsett fra at søk. Søket fungerte greit, men det var litt utydelig hvilke knapper som fungerte på hvilken måte (f.eks. search multiple records).
Fin forklaring på forsiden, og bra med instruksjonsvideoer. Ellers synes jeg systemet var ganske selvforklarende.

Do you think some of the tasks were difficult? Which and why?
no difficult tasks , very clear instructions
Fikk til alle, men stusset litt på incident vs records. Gjettet på at det var riktig valg.
task 5 was hard since i didnt care to look at the graphs, so i tried to count.
Task 6 var litt vanskelig siden jeg ikke fant muligheten for avansert søk før jeg faktisk hadde valgt en database og søke fra.
most of them were easy. Task 3 gave some confusing results.
5. Assumed the graph showed cumulative data, but proved to be only from MAUDE
Trodde jeg skulle finne informasjon når jeg bare skulle teste funksjonalitet. Kan være fordi jeg er profesjonell skolegjenger.
Ingen oppgaver, men kunne fjernet normalt søk og kun hatt avansert søk.
A bit difficult, but mainly because of unfamiliarity with the domain.
Den siste!
Det var et par oppgaver hvor ordene man skulle se etter ikke samsvarte med det i systemet, men det ble påpekt under testen, slik at det gikk fint. Utenom det var alle oppgavene lett forståelig.

Appendix G: Relevant publication (Ertkjern & Babic, 2014)

Postmarket Surveillance of Otrhopedic Implants using Web-technologies

Ørjan Ertkjern[1]
[1] *Department of Information Science and media Studies, University of Bergen, Bergen, Norway*

1. Introduction

In the European Union (EU) between 8-12 % of patients admitted to hospitals suffer harm from the healthcare they receive every year. There are many reasons for this, among others surgical errors, errors in diagnostics and medical device failures [1].

Currently there is no central system to log/archive failures of medical devices inside of Europe. Under the EU's medical device directive, surgeons are requested to report failures to the nation's relevant government department. In Norway the *Helsedirektoratet* has the responsibility for safety reporting under the *Ministry of Health and Care Service* [2]. In the US the Food and Drug Administration (FDA) has implemented such a web-based system called **MAUDE** (**M**anufacturer **A**nd **U**ser **F**acility **D**evice **E**xperience)[3]. The system has a search engine through which surgeons and even the general public can search information regarding all the failures collected within the system.

At *Haukeland University Hospital* in Bergen, they are implementing an information system as a part of the failure retrieval centre where the goal is to support surgeons in the safety reporting which is done as a part of collecting explanted devices which are analysed by the Biomaterials laboratory in Bergen, so that they can be reported directly to the Helsedirektoratet. As the part of the effort to make reporting user friendly, the project has been launched together with the Department of Information Science and Media Studies to develop a system which is in the functionality and purpose similar to the MAUDE system. Ideally, this new system will be developed in the ways that will assist surgeons and potentially the general public to view all the failures collected and retrievable in a simple manner.

Here presented project will therefore support integration of the data and creating a search engine like the MAUDE system. The work will be of national interest as the part of safety reporting, but integration into European systems and exchanges is already considered.

2. Introduction

A web-based system is being developed as a proof of concept, with the goal of integrated resources in Bergen and beyond with the ultimate goal to enable the European Union framework for gathering and exchange of the information.

During the research both qualitative and quantitative methods are simultaneously used. Elements that will be used from quantitative methods are surveys and quality interviews which will be used to acquire knowledge from the intended users of the system, which are mainly surgeons and to some extend representatives of the non-clinical users such as patients and their relatives. The aim of the survey in Norway is to understand the important user group's needs and get their feedback during the system development. The prototype will also be tested by using qualitative methods, as observation and interview, on some intended users to ensure that the system meets the *usability requirements* defined by Quesenbery [4], [5].

3. Expected Results and Discussion

The main goal of this research is to create a search engine and reporting system for medical device failure that should serve needs and interests of the main user groups as well as being complaint with the safety reporting regulations. For that purpose a couple of research questions that will be answered throughout this thesis: *"How could a web based-System be of service to the important user groups?"*, *"In what way, can reports about failed medical devices, be distributed as Open Linked Data in a secure way, without sharing any sensitive information"* and *"How database integration and systematic development of a web based system can have functionalities such as data integration and information extraction"*.
The prototype will be tested and evaluated at the Haukeland University Hospital and taking into the consideration the Norwegian Arthroplasty Registry [6].

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