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Designing and Prototyping

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By: Jeroen Keijser

October 8th, 2013

Technische Universiteit Eindhoven University of Technology

PHILIPS
sense and simplicity

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EXECUTIVE SUMMARY

EURECA is a platform to enable a stronger connection between the clinical care and clinical research settings through seamless, secure, scalable, and consistent information sharing between the currently disparate electronic health record (EHR) systems and clinical research information systems. This will allow both clinical care to more readily incorporate the latest research results and clinical research to access the wealth of real life clinical care data. Further, it will make the process simpler and create opportunities for patients to participate in clinical trials and potentially benefit from access to the latest treatments.

Philips, as leading partner of EURECA and a large player in the healthcare, continually expands its portfolio of services and products in the medical domain including those for clinical decision support. Yakobo, as a clinical trial recruitment tool, will flesh out the clinical decision support portfolio Philips is currently researching and developing for cancer care pathways.

Enrollment in clinical trials is thought to improve the standard of care for those participating in a clinical trial, as well as, and perhaps more importantly, it is thought to further research and impact and improve the quality of future standard treatment. However, enrollment in adult oncology clinical trials is generally quite low (3-5%) (National Cancer Institute, 2012). This is in sharp contrast to pediatric oncology where it is commonly standard practice to enroll patients in clinical trials (60% - nearly 100%). In pediatric oncology the 5 year survival rate has increased drastically in the last 20 years (from 30% to 80%) (Downs-Canner & Shaw, 2009) due in part to the effective enrollment of patients into clinical trials. In contrast, due to the low enrollment rate in adult oncology, research is slowed. The timeline for some clinical studies has to be extended to achieve enrollment rates (to get statistical significance). Other studies, in fact, simply do not get enough patients, and thus may have collected data and spent the significant amount of money to do so and cannot use the results for research.

Yakobo: a clinical trial recruitment tool is one of the first if not the first tool that allows you to quickly visually filter through patient data in an EHR (or any EURECA enabled database) based on the enrollment (eligibility) criteria for clinical trials and begin connecting with potential patient candidates through the appropriate channels.

Currently clinical trial recruitment is done with a minimal or adhoc usage of the information in EHRs. In fact there are several large companies that specialize in clinical trial recruitment that have elaborate recruitment strategies that work outside of the medical system (Clariness Patient Recruitment, 2013). However Yakobo through EURECA works with the medical system directly empowering the medical community to make clinical trial participation a natural part of clinical care.

Yakobo was created using an iterative design and adapted technology probe approach. Through the use of sketches, a problem space probe, site visits, metaphor exploration and the rapid creation of mockups, promising UI ideas were created. These were evaluated in an expert review, and the water cascading metaphor was chosen to develop further into conceptual prototype shown at the EURECA annual review. To further explore the potential of the water cascading metaphor, an interactive prototype was developed loosely following an iterative agile method and tested at the Computational Oncology Summer School. In the last stage the interactive prototype was connected to the EURECA platform and touch interaction was implemented. This was demonstrated and tested with various Philips employees, and EURECA partners.

The Yakobo prototypes were successful technology probes that helped facilitate discussion about the opportunities such a tool presents, and the central water cascading metaphor is a promising UI direction that easily generalizes to a clinical trial recruitment tool in other fields of medicine. Yakobo can be applied to any massive data that requires interactive visualization and filtering, and therefore presents a whole new paradigm for visual analytics that should be patented.

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ABSTRACT

Over the past 20 years in pediatric oncology the 5 year survival rate has increased drastically from 30% to 80%.This is due in part to the practice of enrolling the majority of patients in clinical trials which has resulted in steady research progress while giving patients high quality care. In stark contrast, the enrollment rates in adult oncology are generally low (3% -5%) and has slowed adult cancer research. In the hopes of having similar success and breakthroughs in adult oncology, there is a strong desire to increase the enrollment rates.

In the context of the EU project entitled *"Enabling information re-use by linking clinical Research and Care"* (EURECA), at Philips Research the goal of the current project was to design and create a clinical trial recruitment prototype. This report describes the result, Yakobo: a prototypical clinical trial recruitment tool, and its design process. Yakobo allows quick and efficient filtering of patients based on eligibility criteria for a clinical trial. Through the use of the visual metaphor of water cascading down through filtering layers Yakobo creates the basis for a distinct mental model, and allows clinicians and recruiters to readily explore and grasp the results of using an automated service that searches through patient data to determine whether a patient satisfies the trial criteria.

Yakobo was created using iterative design and an adapted technology probe approach. The project began with a period of sketching and conceptualization. Then, the design space and constraints were delineated to fit EURECA objectives through the use of sketches, a problem space probe and informal interviews with clinical partners and technical partners. After metaphor exploration and the creation of mockups, the most promising user interaction ideas were presented to a clinician and a technical partner in an expert review. The water cascading metaphor was chosen and the visual language was explored and developed into a medium fidelity mockup used to demonstrate the user interaction concept at the EURECA annual review. To further explore the potential of the water cascading metaphor, an interactive prototype was developed loosely following an iterative agile method and tested at the Computational Oncology Summer School. In the last stage the interactive prototype was connected to the EURECA platform and touch interaction was implemented. This was demonstrated and tested with various Philips employees, and EURECA partners.

The Yakobo prototypes were successful technology probes that helped facilitate discussion about the opportunities such a tool presents, and the central water cascading metaphor is a promising UI direction that easily generalizes to a clinical trial recruitment tool in other fields of medicine, and potentially to visually filter other types of data.

1 INTRODUCTION

Cancer is one of the most serious medical conditions in modern society. It impacts many people. So much so, that it has inspired many community initiatives to fundraise for cancer research. For research to progress, promising new treatments need to be tested in clinical trials. However, currently clinical trial enrollment rates in adult oncology are low: 3% -5%. This slows research progress. Currently, in clinical care settings, there is little or no support for clinical trial recruitment. It is mostly approached in an ad-hoc and word of mouth manner.

In this report the design and prototyping of a clinical trial recruitment tool entitled Yakobo is discussed. To ground the main discussion, in the next sections the broader medical context, the project context, the problem statement, and the approach are outlined.

1.1 BROADER MEDICAL PROBLEM CONTEXT

Several decades ago, the prognosis for a child diagnosed with cancer was dire and less than 30% survived to become adults. There simply was no effective standard treatment for these rare cancers. As a result it became standard practice in most pediatric hospitals to enroll the majority of patients, 60% to nearly 100%, in an appropriate clinical trial. Today, some of the rare cancers are now considered effectively cured, and overall the 5 year survival rate has increased from 30% to 80% (Downs-Canner & Shaw, 2009).

In contrast, there were some reasonably effective treatments for the more prevalent adult cancers and it did not become standard practice to enroll adult patients in clinical trials. Currently, enrollment rates in adult oncology are still low at around 3% – 5% (National Cancer Institute, 2012). This has slowed cancer research progress to the extent that the timeline for some clinical studies has to be extended in order to achieve sufficient enrollment for statistical significance. Other studies, in fact, simply do not get enough patients, and thus cannot use the results for research. Yet, the standard of care for a patient enrolled in a trial is consistently high due to the rigorous protocol of a clinical trial. In fact, the National Comprehensive Cancer Network guidelines state that "the best management of any cancer patient is in a clinical trial". Thus, there is a strong desire to increase the enrollment rates in the hopes of having similar success and breakthroughs as have occurred in pediatric oncology while giving patients access to high quality care.

1.1.1 Low Enrollment Rate

The causes behind the low enrollment rate are complex and involve many factors. There are a few worth discussing here. They are general public misperception of clinical trials; clinicians lack of awareness of all the relevant trials and their eligibility criteria; and the potential significant extra workload related to enrolling a patient in a trial.

Unlike the public perception of study participation, new treatments in clinical trials are rarely compared against a placebo. Rather, new treatments are compared against current best practices, making worries about non-treatment unfounded. Furthermore, before a completely new treatment is tested on sick patients, it has already gone through several rounds of testing for both potential and safety. Therefore, patients who are good candidates for a particular trial either receive the current best known treatment, or a treatment that shows potential to be better in some manner.

Currently, there is no systematic connection between clinical care and clinical research within the medical system. Clinicians in a top research hospital may be aware of most of the clinical trials being conducted in their hospital. Yet, clinicians in neighbouring hospitals may be completely unaware of the ongoing trials, and which ones are relevant to the patients they are treating. A lot of communication about clinical trials between the clinical care and research settings is currently *only* taking place outside of the medical system through the means of journals, and other traditional communication mediums. As a result there are several large companies that specialize in clinical trial recruitment that have elaborate recruitment strategies that similarly work outside of the medical system (Clariness Patient Recruitment, 2013).

At present, patient data stored in the Electronic Health Record (EHR) systems cannot be transferred electronically into the clinical research databases. This involves a lot of duplicate data entry and paperwork. Clinical trial protocols are substantial documents, and do not follow a particular standard. This entails that a clinician needs to spend a significant amount of time investigating and learning the protocol in order to enroll a patient in a new clinical trial, and treat the patient according to the protocol. Therefore clinicians, who have limited time, usually prescribe a standard treatment due to the lack of direct communication channels, extra paperwork, and learning time investment. Only if the treatment is ineffective, and the disease has progressed to a more severe stage do clinicians look at other possibilities.

1.1.2 Personalized Medicine

In medicine there is a trend and desire to use a more personalized approach to treating patients. Beyond giving patients more personal attention and increasing patient participation, the actual

treatment itself can be personalized. To personalize the actual given medical treatment, the treatment has to be based on what has been effective on patients who have similar genomic, demographic, and other relevant medical characteristics. Recently, in 2010, research uncovered that breast cancer is in fact a group of four different diseases that should be treated differently. In 2012, the number of distinct types of breast cancer is now dozens. This means clinical research has to be conducted that collects a larger amount of data and more specific data from patients. To benefit from this research, a clinician has to be able to match his patient to the conducted research somehow. This process is known as patient stratification. It also implies that the number of clinical trials will dramatically increase and each will have more restrictive eligibility criteria.

To make this personalized approach possible, clinicians and researchers alike need and want tools to interact with and make sense of the large wealth of data stored in EHR systems and clinical research databases. This is one area of research focus in Clinical Decision Support (CDS) at Philips Research.

1.2 DETAILED PROJECT BACKGROUND

In the research area of clinical decision support for oncology, Philips Research participates in several European Union projects, namely: "*Integrative Cancer Research through Innovative Biomedical Infrastructures*" (INTEGRATE), "*Enabling information re-Use by linking clinical REsearch and CAre*" (EURECA), and "*p-medicine - From data sharing and integration via VPH models to personalized medicine*" (p-Medicine). In this context, Philips Research is developing a number of things, including front-end tools for cancer treatment and research.

In the initial project brief (see Appendix F), the task was the development of a patient screening UI prototype. However, on actual arrival, a team had already been assigned to the task, and significant progress had been made; thus discussion began as to which of the other use cases should be tackled: trial feasibility or cohort selection. Later, after meeting with one of the project partners, Custodix, it was decided that the focus of the current project should be to tackle the development of a trial recruitment UI prototype, which would allow Custodix to focus on developing the underlying security framework, platform, and criteria matcher engine. They would in the meantime use a barebones technical UI for testing the engine.

1.1.3 EURECA

The clinical trial recruitment use case was conceived within the context of the larger EU project, EURECA (http://eurecaproject.eu/). In an iterative proposition cycle, the clinical partners came up with use cases and the technical partners would review them, consider their viability, and suggest possible changes. The clinical partners would then revise the use cases based on the feedback and repeat the process. The use cases were rated by both clinical and technical partners as to how useful and desirable each use case was, and the highest rated use cases were chosen for development. The clinical trial recruitment use case was one of the use cases chosen for development.

EURECA is specifically looking at connecting the disparate EHR data systems and clinical research systems and is developing a platform to support this. In addition, EURECA looks at what this platform enables. The opportunities are many, including addressing the issues mentioned earlier that are relevant to clinical trial recruitment: more direct access and communication between clinical care and research; reduction of duplicate data entry and the related paperwork; and support for understanding trial protocols and protocol adherence.

In particular, the closer connection also allows a system to be built that searches through patient data and determines whether a patient matches the eligibility criteria of a clinical trial. However, the system cannot always determine eligibility due to missing data, ambiguous data, or criteria that require a human judgement such as “the patient is capable of adhering to the treatment”. Thus, there is a need for a user interface that allows a clinician or other medical professional to see the results of the criteria matcher, inspect the evidence, decide which criteria are most relevant for eligibility, and then follow up with patients who seem good potential candidates.

1.3 PROBLEM STATEMENT

After an initial orientation and discussion phase, when it was decided that this project would focus on trial recruitment, the problem statement was agreed on, as can been seen in textbox 1, as a starting point for the exploration into the domain of supporting clinical trial recruitment.

Problem Description

For the EURECA project a large amount of development and time has been spent into constructing the backend and software infrastructure platform. To be able to use this platform frontend applications need to be developed to address several potential usage scenarios including trial recruitment.

> *Trial recruitment* is the task of finding patients who are good candidates to enroll in clinical trials. The person tasked with recruiting patients for particular trials will be actively scanning for current patients who match the protocol requirements for those trials. The recruiter will want to quickly screen out those who do not qualify, find potential trial participants, and begin the contact process with the treating physician to investigate participation of those potentials.

It is not clear what is the best way to incorporate the possible front-end solutions into the context of use and the workflow of recruiters. This project will investigate different possibilities, and use conceptual and interactive prototypes to garner feedback on usage scenario context and workflow. The overall project goal is thus to create a validated demonstrator. This will include the conceptual prototype and interactive prototype mentioned and will be validated by three external reviews.

Text Box 1:Original Problem Statement

The **main goals** from the problem statement were:

1. To develop a conceptual prototype
2. To develop an interactive prototype that worked upon the EURECA platform
3. Three external reviews

These goals were **achieved** by:

1. Conceptual mockup developed and shown at EURECA annual review
2. A UI prototype that can connect to the relevant webservices of the EURECA platform
3. Groenendael Expert Review (March 10-12, 2013, Groenendael, Netherlands), Computational Oncology Summer School Expert Review (June 23-28, 2013, Wadern, Germany), and Final Expert Review with Clinical partners (August 22, September 9, 2013, Philips Research, Eindhoven, Netherlands). These reviews were planned according to fit within the overall schedule of the EURECA project.

1.1.4 Technical Constraints and Deployment

There were several technical constraints and deployment constraints that had to be taken into consideration during the development of Yakobo. Firstly, due to privacy concerns and the current agreements within EURECA (which were uncovered during the problem space probe discussed below in section 2.1.1), Yakobo must be deployed onsite at each hospital separately. Researchers who run multi-site trials cannot search the data directly, but would have to contact someone at each site to run Yakobo locally so that data does not leave the site of the hospital. Secondly, the development of the underlying services was being done in parallel, and Yakobo would need to be demonstrable without access to those services, and be able to incorporate the services as they became available. Thirdly, Philips Research suggested that touch interaction on large displays is an area of interest, and that the design should incorporate this if possible.

1.4 APPROACH

The approach taken reflects the exploratory nature of the project.

Currently there is no software support to search through EHR data based on clinical trial eligibility criteria. Current practice for trial recruitment is thus ad-hoc. If a senior member of the medical staff takes a particular interest in a study, he may assign a younger member of the staff to keep an eye out for good candidates. If a pharmaceutical recruitment representative comes and visits a site, the contacted medical practitioner may have a look through the patients currently being treated, and look for obvious candidates, but due to the effort involved would look no further. It appears there is no real current practice and there is no supporting workflow to set the project within. This implies that the clinical trial recruitment tool that is developed in

this project, would introduce a new workflow, and possibly even a new medical position at a hospital.

This lack of appropriate current work practice implies that the traditional User Centered Design (UCD) approach is less suitable as it is most effective when applied to a concrete problem in a particular work setting. An exploratory approach was taken. Through a series of design iterations, adapted technology probes were created. Technology probes (Hutchinson, et al., 2003) facilitate discussion by allowing people to try out new interactions themselves. Elements in the probes could highlight process, possible issues, and design directions to get insight into how clinicians respond to the possibilities of such a new tool. Further, as this new tool introduces a new way of working for clinicians, the importance of a cohesive metaphor is substantial. Determining the suitability of a promising metaphor is best done by creating a working prototype. Thus, the focus is on creating a working touch enabled interactive prototype.

1.5 TARGET AUDIENCE

This report is written to document the process of creating the Yakobo prototype developed as partial fulfillment of the USI program. As such, part of the target audience is those at the TU/e namely, Mia Jelsma, Panos, Jun Hu, who will be evaluating it. However it is also intended for those at Philips, particularly Njin-zu Chen and Anca Bucur who have a vested interest in the project. Further, it can also be used as a reference document for interested parties in the EURECA project.

1.6 DOCUMENT SETUP

The rest of the report is organized and presented in the order that project was developed. In the original project plan there were many phases (See Figure 2). The concept phase, definition phase, and design phase are grouped into the Design section of the report. The preparation

phase and realization phase are discussed in the Realization section of the report.

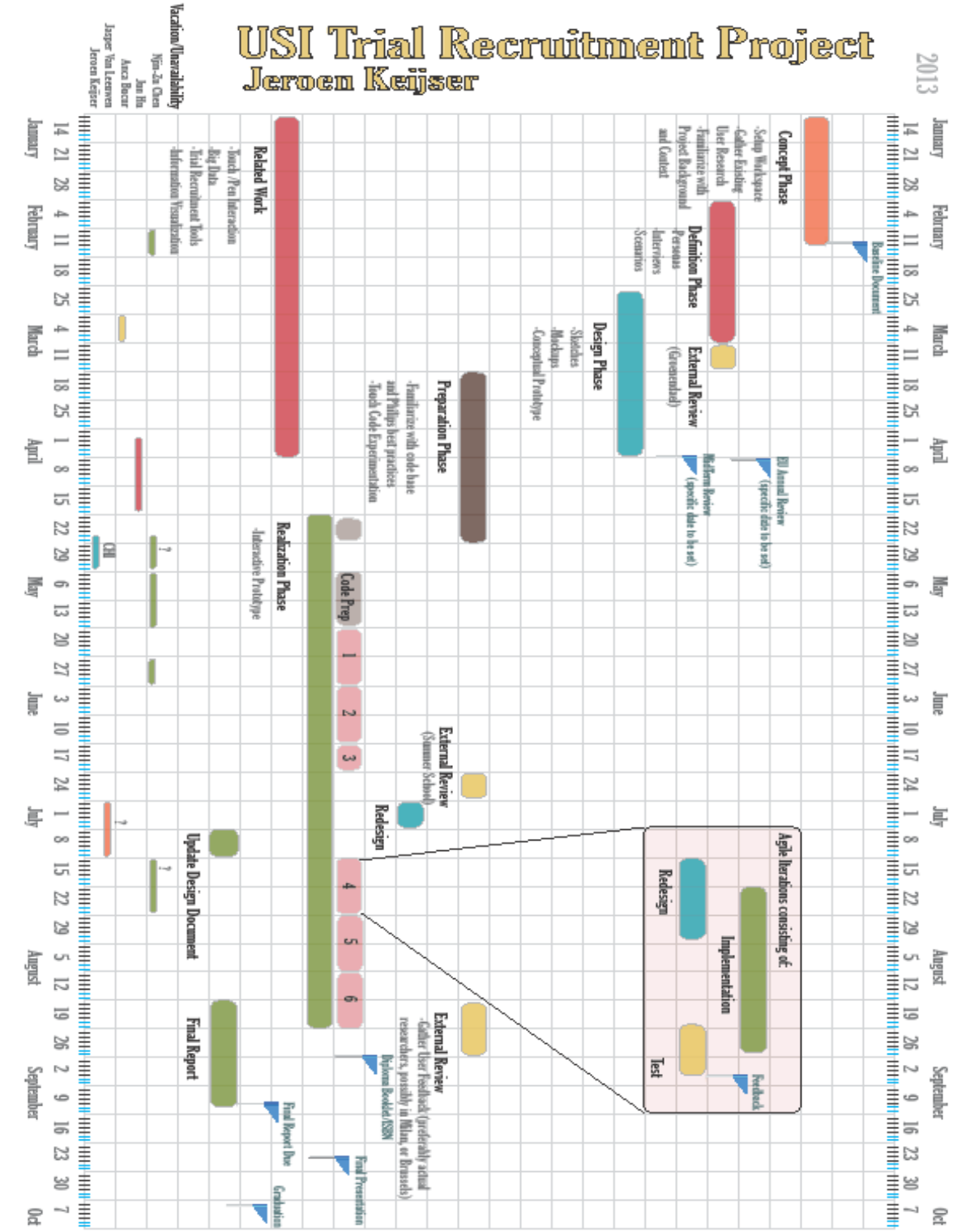

Figure 2: Project Plan from Baseline document

2 DESIGN

This section discusses the design process up until the development and creation of the conceptual prototype that cemented the core interaction metaphor. The objectives of this phase of the project included: defining project scope and constraints, revealing underlying assumptions, understanding possible context of use, exploring the design space, and finding a cohesive core metaphor. These objectives were achieved through various methods. Sketches, a problem space probe, and the related discussion allowed project scope, project constraints, and some underlying assumptions to be brought forward. Through informal interviews with clinicians and site visits an understanding of the possible context of use was gained. Through sketches, creation of rapid throwaway mockups, and metaphor exploration, the design space was explored. Lastly, through the evaluation of the most promising UI directions and underlying metaphors in an expert review, and the development of the conceptual prototype, the cohesive core metaphor was decided upon.

2.1 SKETCHING AND CONCEPTUALIZATION

To begin understanding the problem domain, quick sketches were made, the web was scanned for related projects, and informal talks with project members were conducted.

It became clear from those initial web searches that currently clinical trial software solutions work mostly outside of the medical system. Similarly, clinical trial recruitment consultant agencies reach potential candidates for trials through advertising and marketing directly to the general public, and through magazines, websites, and other traditional marketing methods targeted at doctors. Thus there is an opportunity to build tools that work within the medical system.

Sketching out possibilities for the five W's (who, what, where, why and how) allowed for very quick exploration of the breadth of possible scope, and illustrated the initial understanding of the problem space (See Figure 3 for example sketches). This was then used to discuss and get further details about the project and directions within Philips.

Figure 3: Who and Where sketches

In those discussions it became clear that there are some strong underlying assumptions for the various UI use cases. For example, it is assumed that clinical trial recruitment would occur only at a single hospital or site. In the associated use case documentation from EURECA a usage scenario is outlined that also occurs at a single site. However, the motivation for this was unclear. Particularly, within the context of EURECA's overarching goals of connecting the clinical care and research settings and allowing useful information to flow, it would seem beneficial to support multi-site trial recruitment and support patients participating in clinical trials at neighbouring hospitals.

A problem space probe was constructed to uncover the motivation behind these assumptions, to determine the scope of the design space, and to have a better understanding of how trial recruitment fit within EURECA.

2.1.1 Problem Space Probe

The EURECA working meeting (February 18, 2013, Ghent, Belgium) served multiple purposes for this project. The goals of attendance were to meet the EURECA partners, to get a better understanding of the EURECA platform, and to get a better understanding of what was desired for the trial recruitment demonstrator. The meeting also provided the opportunity to use and present a problem space probe. For this meeting, the problem space probe took the form of a presentation that outlined the basic idea of clinical trial recruitment, a set of examples that showed the possible breadth of scope, and the trial recruitment use case as it was written in the EURECA documents. It soon became clear that many of the partners were not familiar with the details of the use case. The use case, as it is written, focuses on supporting pharmaceutical companies with trial recruitment. The clinical partners did not want the focus to be on supporting pharmaceutical companies. Rather, they wanted to focus on supporting clinical

research and care. The problem space probe further uncovered and reinforced some undocumented decisions, assumptions, and underlying motivations related to trial recruitment.

Local deployment is presently a firm constraint in EURECA due the legal agreements made regarding privacy. Luckily this is in-line with current thinking within EURECA. There is a strong assumption that in a multi-site trial, that each site will be responsible for recruitment at that site. At present in Germany, within pediatric oncology a principal investigator is designated for a clinical trial at each participating site. This principal investigator is responsible for recruitment at their site. Even though the EURECA platform would easily allow for multi-site recruitment and coordination, the clinical partners didn't see any immediate benefit to doing so. There is also a pragmatic motivation as well. As recruitment inherently means some eventual identification of the patients in order to recruit them, there are potential privacy issues. If EURECA is only deployed locally at a specific site, then issues of privacy are less of a concern as the information does not leave the site, and each site is more easily able to enforce whatever privacy measures necessary to meet the local requirements.

The probe further uncovered that clinicians were uncertain about supporting a dedicated recruiter workflow. Thus concerns about addressing dropouts from studies, and related issues, they deemed irrelevant. However it is still unclear exactly where in the workflow this new clinical trial recruitment tool would best fit. As such, future probes would hint at possible connection points, and workflows.

2.1.2 Site Visits and informal interviews

Site visits were incorporated when possible for several purposes: to more quickly come up to speed on the overall EURECA project; to get a feel for what those partners were working on within EURECA; but more importantly to have a feel for the environment in which the tools developed would actually be deployed. During the visits, casual interviews were conducted to understand how clinical trial recruitment could be incorporated at the site (See Appendix B for details).

2.1.2.1 MAASTRO Site Visit (February 25, 2013)

MAASTRO is a radiation therapy clinic in Maastricht, Netherlands. As such patients are referred to the clinic when radiation therapy is considered the best treatment for the patient. In an effort to increase trial enrollment, MAASTRO has assigned a trial nurse who looks at the patients coming in the next day, and if they are possibly good candidates the trial nurse adds a

physical blue folder with the trial information to the stack of information given to the intake physician. This is still a very manual process, and is only possible as there are a limited number of trials being conducted at any one time at the MAASTRO clinic, and thus it is possible for the trial nurse to become familiar with the eligibility criteria and where within the EHR system to look for the relevant data.

2.1.2.2 Homburg Site Visit (February 27, 2013)

The Homburg clinic is in Germany. It is the home of the pediatric oncology clinical partner in EURECA. At this clinic, unless parents object, all patients are enrolled in clinical trials. If there is no relevant trial for a particular patient being run at the center, the head oncologist will spend significant effort finding a possible trial elsewhere in the country, or if necessary the world. As such, the clinic is more of an inspiration or gold standard for recruitment.

2.2 CONCEPTUAL PROTOTYPE

The conceptual prototype was developed through metaphor exploration, rapid UI mockup creation, expert evaluation, and visual language exploration. The resulting conceptual prototype is first described. This is followed by the details of the process leading up to its creation.

2.2.1 Conceptual Prototype in Detail

The conceptual prototype took the form of a clickable mockup constructed in the mockup tool Balsamiq (Balsamiq, 2013) which was exported as a clickable pdf. The prototype consisted of three core screens, and all other pages were added to describe interaction with those three screens. Those screens are a login screen, a trial selection screen, and the main interaction screen.

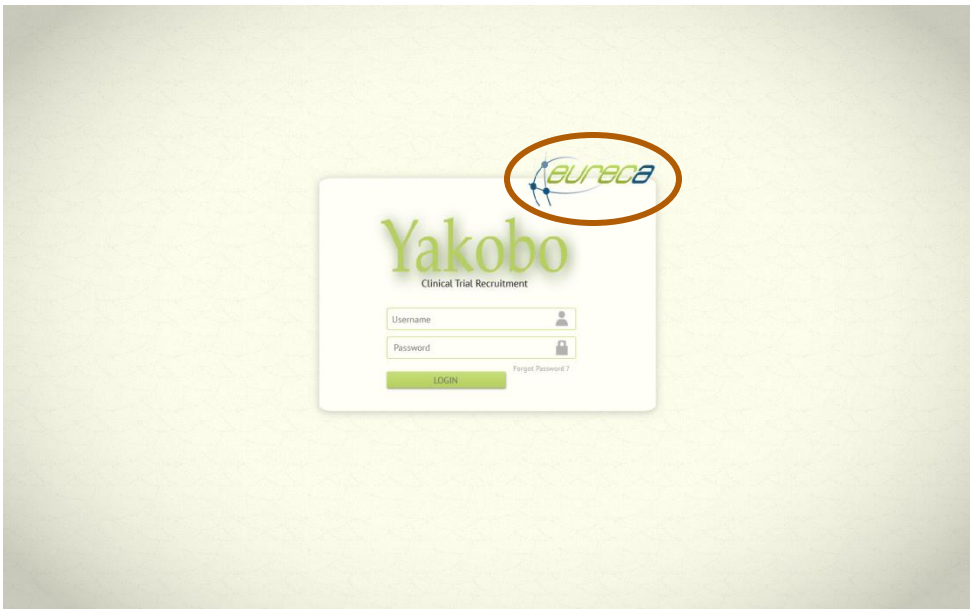

Figure 4: Login Screen emphasizes Yakobo is part of eureca (circled in orange) and for authorized users only

The login screen (See Figure 4) is used simply to give the feel of a real system, to state that only authorized users should use the system, and to indicate that Yakobo is part of EURECA. The trial selection screen (See Figure 5) emphasizes that Yakobo is run locally at a particular hospital, in this case, it is St. Joseph's hospital. It also indicates the possibility of continuing to recruit for a trial already running on location, or grabbing the information about the trial from the EURECA metadata trial repository.

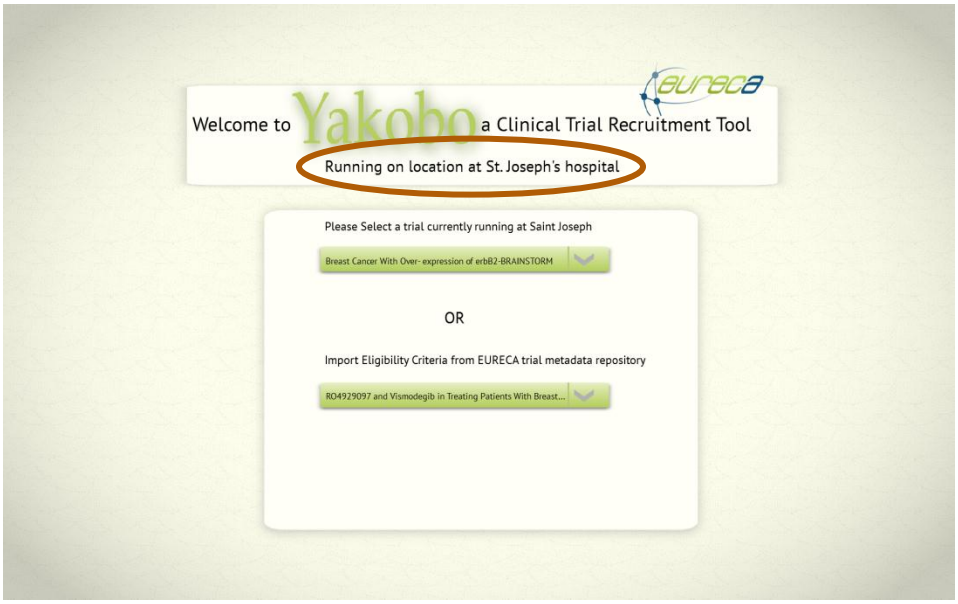

Figure 5: Trial Selection Screen emphasizes running on location (circled in orange) and choice between a current trial and importing from the EURECA trial metadata repository

The main interaction screen (See Figure 6) is where the heart of the work is done, and where the core concept is shown. The core concept is applying a water cascading metaphor to the filtering of patient data to match inclusion and exclusion criteria of a clinical trial. The original patient dataset from the EHR can be represented as a stream of water pouring down from the top of the screen. Each criterion can be thought of as a physical filter that then blocks those candidates that do not satisfy that criterion. Those candidates who satisfy the criterion and those candidates the system cannot determine whether they satisfy the criterion pass through the filter and cascade down to the next filter. The process then repeats until all the criteria for the clinical trial have been applied. The resulting set of patients is displayed at the bottom of the screen (See Figure 6).

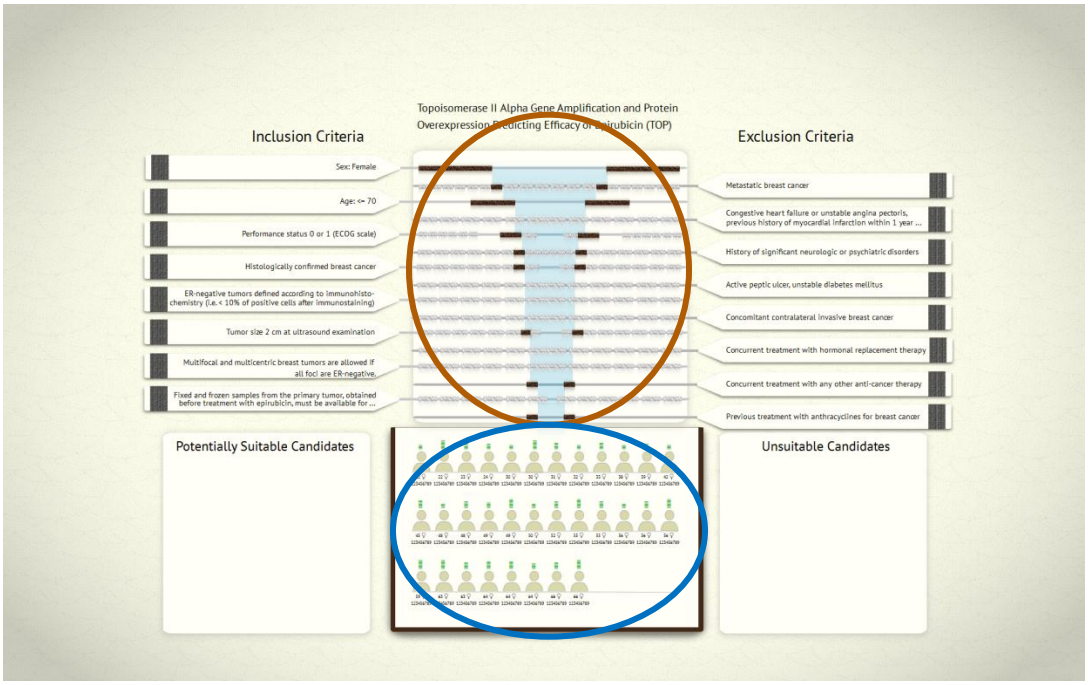

Figure 6: Main Concept as shown in the conceptual prototype. The water cascades down through the filters (circled in orange), and the results are shown at the bottom (circled in blue)

This visual way of filtering data allows several types of information about the filtration process to be presented. First, the visual representation of the water filter can display the *discernment power* of a criterion. All the filters applied together then give insight into the patient dataset as a whole. Lastly, selection of a patient allows a *detail in context* view, where one can see how that particular patient satisfies the criteria in the context of the whole filtration process.

The *discernment power* is shown using a horizontal percentage scale. The width of the container (circled in orange in Figure 6) is the total number of patients in the dataset under consideration. If one considers a criterion filter in isolation, then the total width of the dark blocking bars, relative to the container's width, is equal to the percentage of patients that do not satisfy that criterion. Similarly, the total width of the grey sponge like bar is equal to the percentage of patients where the system cannot determine satisfaction. The remaining width then represents

those who do satisfy the criterion. These bar lengths show the absolute *discernment power*, or in other words, they show the effect of filtering based only on that one criterion (See Figure 7).

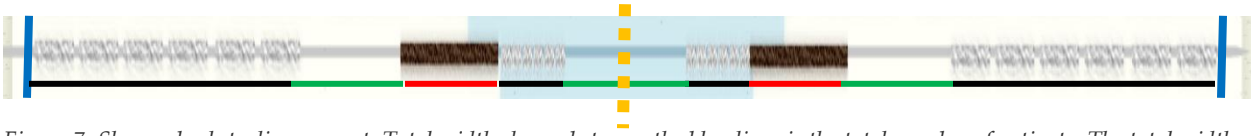

Figure 7: Shows absolute discernment. Total width shown between the blue lines is the total number of patients. The total width of the dark blocking bars underlined in red is the total percentage that does not satisfy. The total width of grey sponge like bars underlined in black is the total percentage of undetermined satisfaction. The total width of the rest underlined in green is the total percentage that satisfies. Note to allow water to cascade through the center the results are duplicated and equivalent on both sides of the middle.

The relative *discernment power* is also shown. If one looks at the area under the water flow (See Figure 8), the percentage of not satisfied, undetermined, and satisfied relative to the previous results are shown. They are respectively shown by the width of the dark blocking bar, grey speckled bar, and the remainder of the width under the water flow. The area outside the water flow represents candidates previously filtered out and the bar widths represent the relative percentages of the remainder.

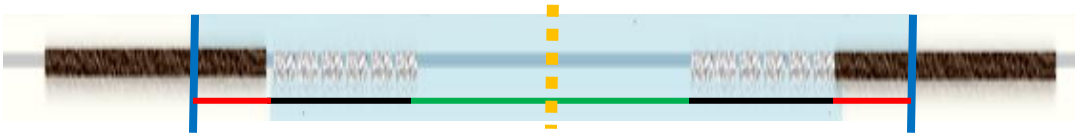

Figure 8: Shows relative discernment. The water flow from above, between the blue lines, represents the total number of candidates that are the results of previously applied criteria. Similar to in Figure 5, the width underlined in red is not satisfied, the width underlined in black is undetermined, and the width underlined in green is satisfied. In this case, the percentages are relative to the previous results. Again, the results are split in half and symmetric over the center.

The central part of the screen thus gives the overview of the data filtration. An individual patient can be selected, and compared in the context of the overall filtration. When a patient is selected, the respective criteria tabs will change colour to reflect whether the patient satisfies (green), does not satisfy (red), or is undetermined (grey). This is then the *detail in context* view (See Figure 9).

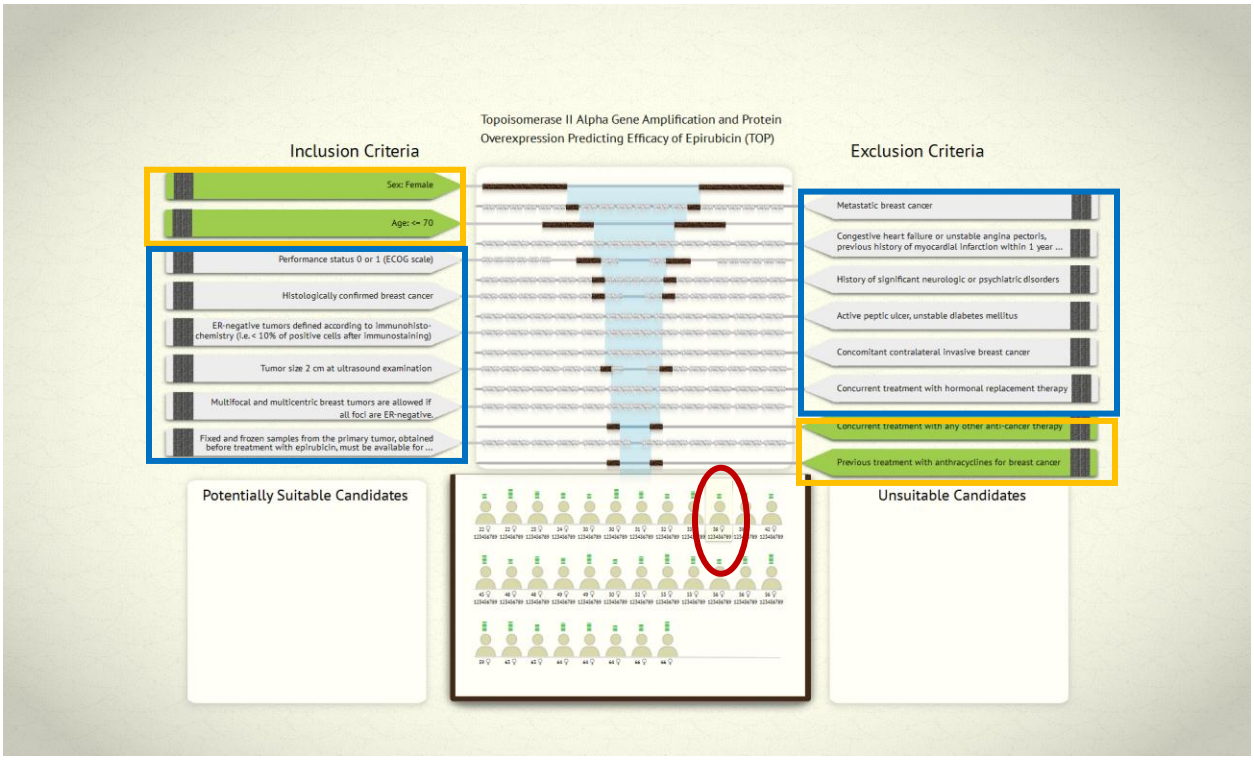

Figure 9: Detail in Context. The overall filtering results can be seen while the results for the selected patient (circled in red) are shown. In this case, 4 criteria are satisfied and the respective tabs are green (highlighted by orange boxes), and the rest are undetermined and colored grey (highlighted by blue boxes)

Once a patient is selected, each criterion can be clicked upon to reveal the evidence that supports the satisfaction status (See Figure 10). In this way, a medical practitioner can make an informed decision, as to whether the patient is a good potential candidate or unsuitable for the particular trial. To emphasize this process, there is space to place "potentially suitable candidates", and "unsuitable candidates". The idea is that the medical practitioner would place candidates in each area to sort through the results (dragging with a mouse and swiping by touch). Then when they have enough potential candidates, they can export the details for these candidates, or contact the treating physicians by email, or whatever process is decided upon to follow up with candidates to consider trial enrollment. This follow up process was determined out of scope for this project.

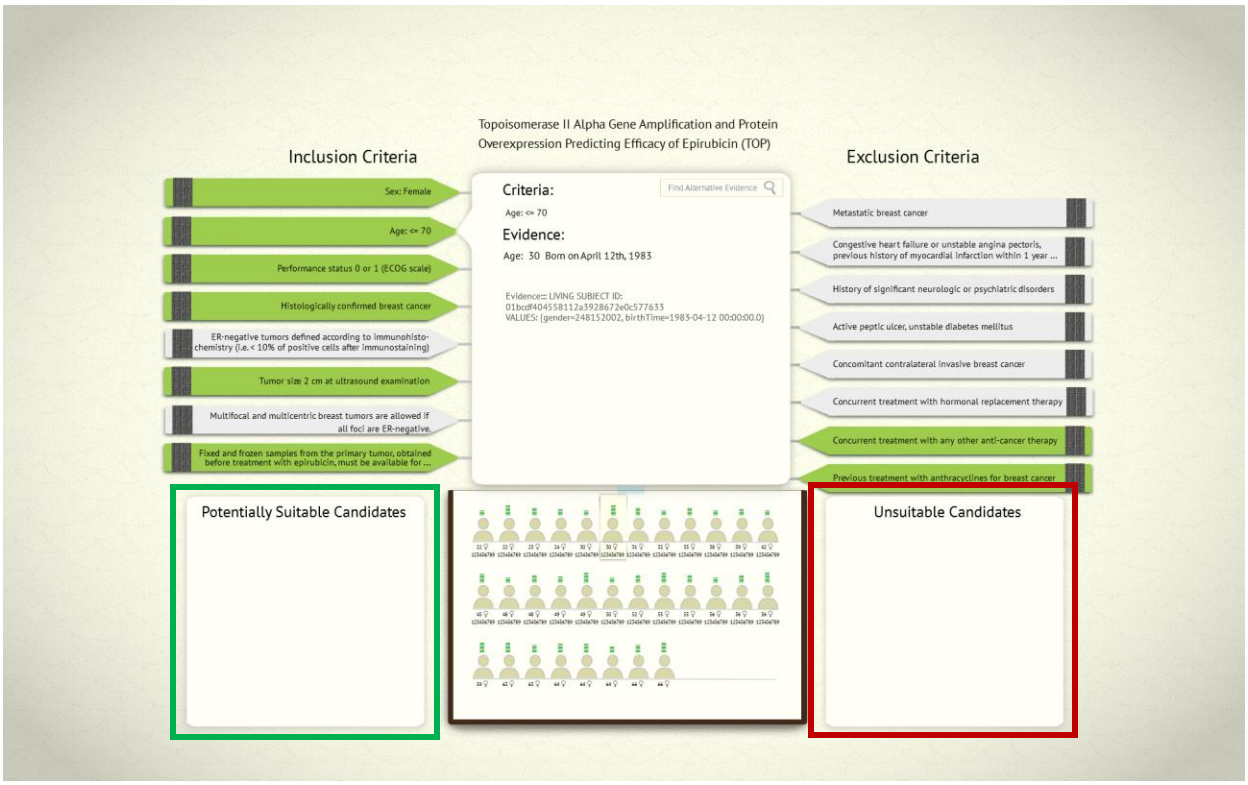

Figure 10: Evidence shown for one criterion. Explicit potential bucket on the left (highlighted with green box), Explicit unsuitable bucket on right (highlighted with red box)

Another interaction was also considered and added. To have more insight into the data, and in the case of no results, criteria filters can be enabled and disabled by clicking on the handles on the criteria tabs. The handles allow interaction with a mouse, but as a touch interface the interaction is envisioned as swiping the criteria in and out (See Figure 11).

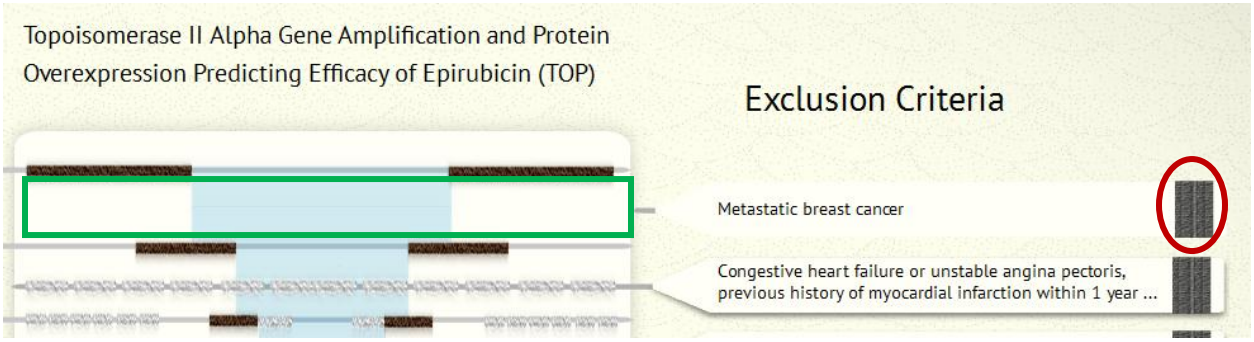

Figure 11: Exclusion Criterion for metastatic breast cancer disabled. The filter bar is not present in the central filtration area (highlighted with green box), and the tab is flattened and pushed into the background. The disable/enable handle is circled in red.

2.2.2 Metaphor Exploration

After a better understanding of clinical trial recruitment, how it fits within EURECA, and the type of medical locations it may be deployed at, it was time to begin roughing out the interface and explore metaphors that could become the basis for the interaction mental model.

The main task in clinical trial recruitment is the *filtering* through the large set of information in EHRs based on inclusion and exclusion criteria to find patients who are potential candidates for that particular trial. What metaphors could support visual *filtering*? A number of filtering metaphors were considered including:

- *Panning for Gold* Using a set of sieves to get rid of the dirt and finding the nuggets.
- *Light Lenses* Using a set of focal lenses like in a microscope, or colour filters in a photo camera to get precisely what you want in focus
- *Jenga Blocks* The order that filters are applied may matter and like a Jenga block, the stability of the Jenga tower, resembles the interdependency of layers of filter criteria
- *Prisms* Light filtering through a set of prisms
- *Blackhole* Candidates with the most amount of satisfied criteria would have the largest density and gravitate to the center the quickest.
- *Coffee Filtration* Layers of coffee filters to arrive at the fine coffee flavour.

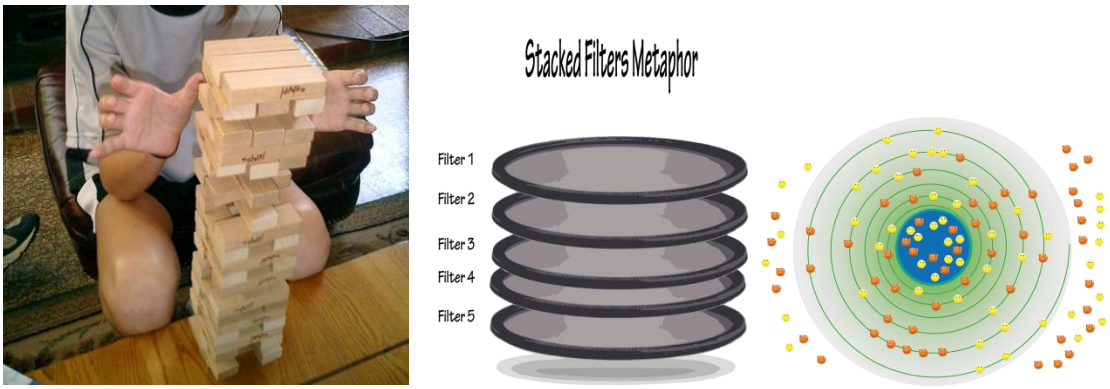

Figure 12: Jenga blocks as shown on Wikipedia[1], stacked lenses, and blackhole metaphors

These metaphors were then taken and sketched out using the Balsamiq mockup tool (Balsamiq, 2013). This allowed for rapidly creating and testing out UI options inspired by these metaphors, as well as testing out issues related to screen real estate, initial iconography, and ideas related to the possibility of using a large touch display as the input. Several of the more promising interface mockups were taken to Groenendael for the first expert review (See Figures 13 & 14 for two examples).

[1] http://en.wikipedia.org/wiki/File:Jenga.JPG

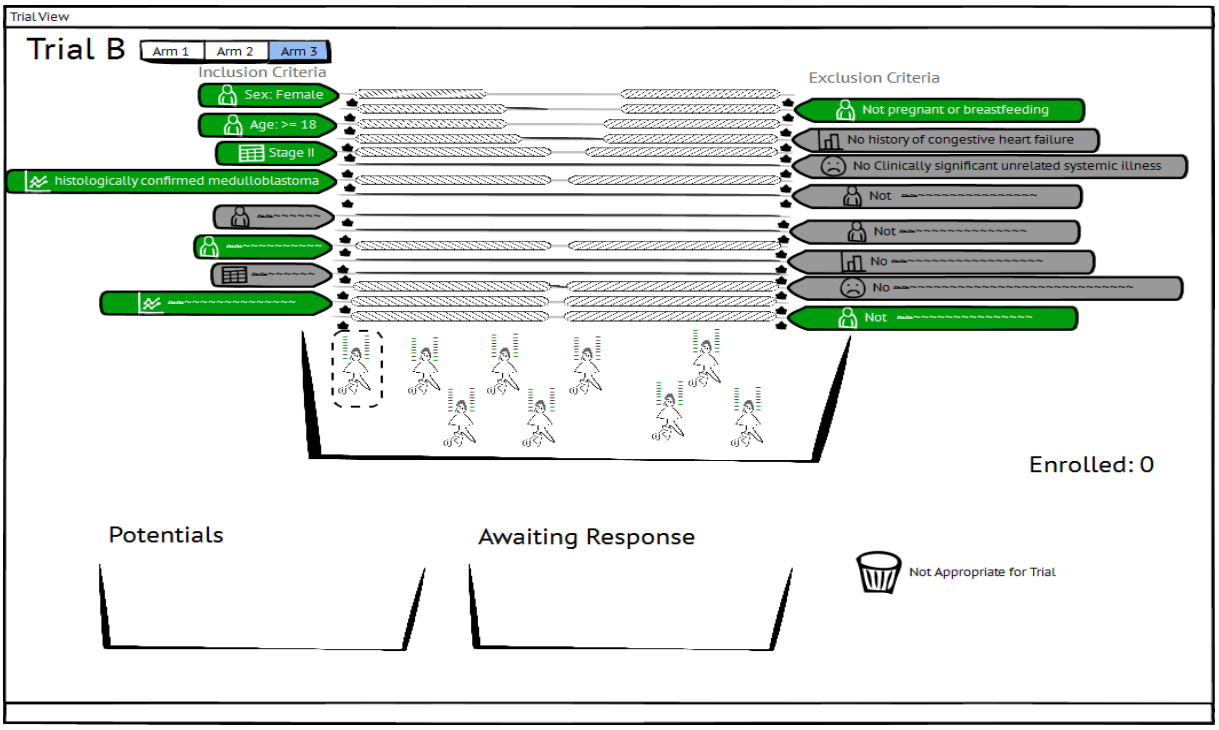

Figure 13: the basis for the eventual water cascading metaphor interface

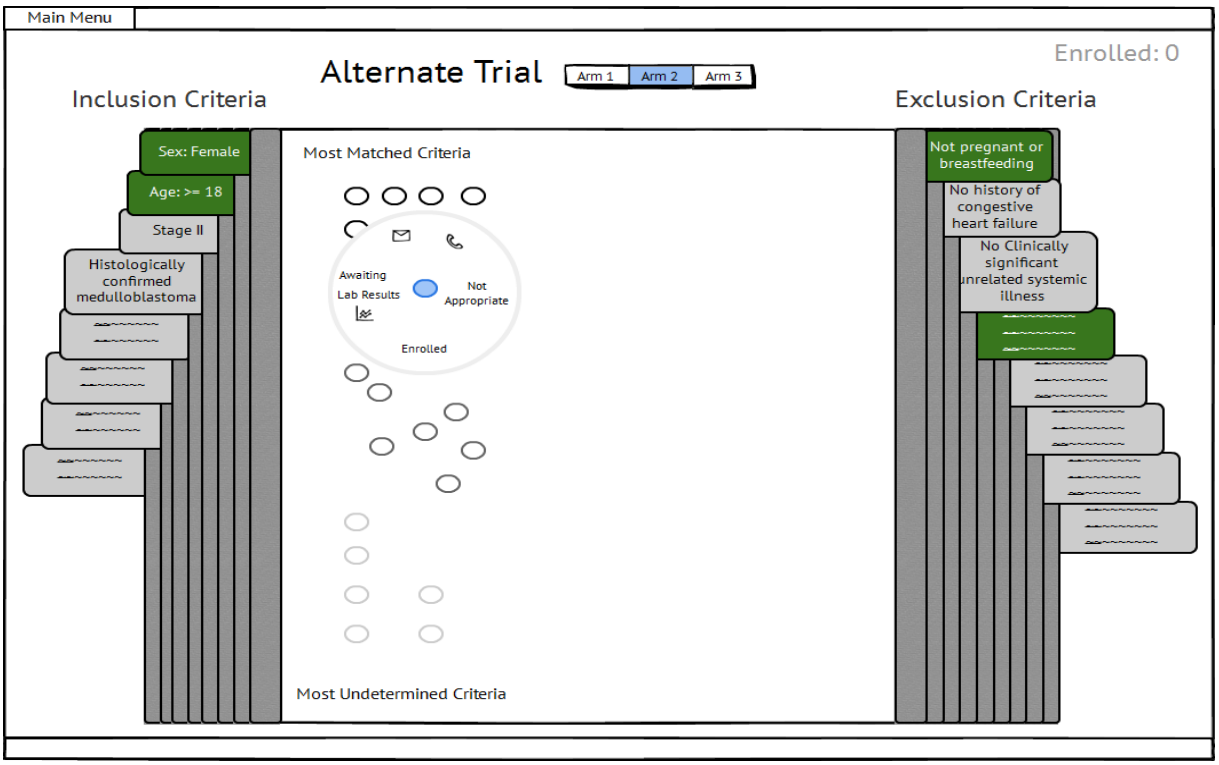

Figure 14: One of the alternative interfaces shown based on photo lens filters.

2.2.3 Groenendael Expert Review

A meeting for Integrate, a related project, in the Groenendael conference centre provided the opportunity to conduct an expert review, March 10-12, 2013, in Groenendael, Netherlands. One of the main technical partners from Custodix and an oncologist were in attendance. Each was taken aside for one-on-one sessions. Both sessions were videotaped to allow possible further analysis. The interface mockups were presented, and the experts could click through the interface to have a feel for the potential interaction. Along with the interface mockups, a step-by-step task breakdown and personas were also presented and discussed to get a more well-rounded picture of the problem space.

In the interview with the technical partner, the step-by-step task breakdown was confirmed as correct, although he considered the follow up with treating physicians out of scope. The mockups provided a different way of looking at the problem, and resulted in much discussion about the current mental model for the development of the underlying criteria matching engine. The UI mockup (See Figure 4) derived from the coffee filtration and jenga blocks metaphor particularly sparked conversation about possibilities, and how the engine could be used to support it.

Figure 15: Groenendeal expert review, interview with oncologist

The interview with the oncologist (See Figure 15) focused more on uncovering clinical domain knowledge, and consideration of use within the clinical setting. The oncologist, who has worked both in clinical care, and clinical research revealed that in the institutions that he worked at there was no similar support of clinical trial recruitment as is proposed. Rather, if a senior oncologist took a particular interest in a clinical, he or she would assign a junior oncologist to "keep an eye out" and as such, recruitment is done in a sort of ad-hoc manner. In observing the usage of the mockups, it was noticeable that the preferred mockup of the technical partner (shown in Figure 4), was also the one that was resonating with the clinician

the most. After describing the main interaction as a cascading water metaphor, the clinician understood how to interact with the system and allowed discussion of the possibilities this type of interface enables. Discussion about the iconography, and other visual clarity issues also occurred. For details see Appendix C.

It became clear that the water cascading mockup derived from the coffee filtration and jenga blocks metaphors appealed to both parties more than the alternatives, was more readily understood, and had the most potential for further development.

2.2.4 Medium Fidelity Conceptual Prototype & Annual Review

To meet a goal for the EURECA project it was decided to further develop the water cascading metaphor based interface into a more refined visual mockup (i.e. a medium fidelity mockup) to be presented at the EURECA annual review (April 17, 2013, Brussels, Belgium). Because of this goal this then became the form for the conceptual prototype.

This goal allowed time to focus on exploring the visual language, aesthetics, and the impact of adding colour, texture, and depth. As a starting point, a few colours were extracted from the EURECA logo to be the basis for the colour palette. Visual assets were created in Adobe Illustrator. They were imported into Balsamiq, and the medium fidelity interaction mockup took shape.

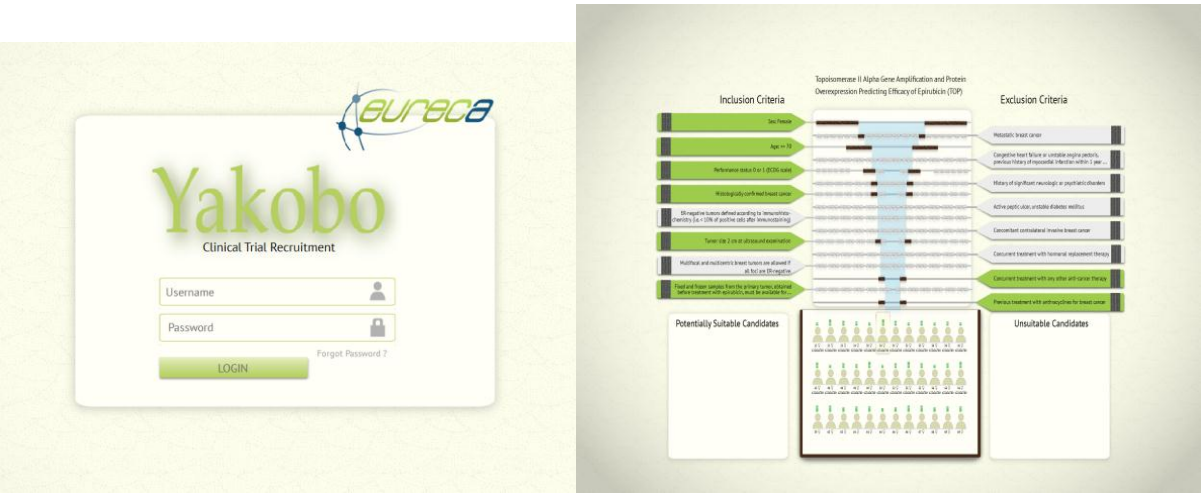

Figure 16: Screenshots from the Conceptual Prototype shown at the EURECA Annual Review

For the EURECA annual review, a presentation was created to give the context of the development of this conceptual prototype, and go along with the presentation of the conceptual prototype (See Figure 16 for a reminder). At the annual review, the reviewers gave minimal comments, and thus deemed the concept acceptable, as anything not up to standard was

immediately pointed out and discussed at the review. Other partners within EURECA responded very favourably to the concept, and one party thought it would be very effective for trial feasibility as well. After the EURECA annual review milestone, it was time to move onto realizing an interactive prototype.

3 REALIZATION

This section discusses the realization of the interactive prototype. An interactive prototype that works on the EURECA platform was one of the main goals of this project and a substantial amount of time and effort was expended to construct it. The main implementation details are discussed first. This is followed by a discussion divided into the two main development cycles. Each ended in an expert review. One took place at the Computational Oncology Summer School (June 23-28, 2013, Wadern, Germany) and the other final review at Philips Research (August 22, September 9, 2013, Eindhoven, Netherlands).

The development up until the conceptual prototype showed that there was enough potential in the central metaphor, the basic navigation, and the visual language to continue further and create an interactive prototype. There were many goals associated with developing an interactive prototype, these included:

- To test out the viability of the conceptual prototype as an actual working prototype.
- To allow people to actually interact with a working system.
- To connect to the EURECA platform, and discover what still needs to be developed.
- To test the impact of using the underlying platform on the user experience.
- To use "real" data.
- To allow touch interaction.

3.1 INTERACTIVE PROTOTYPE IMPLEMENTATION

As the clinical trial recruitment tool Yakobo is eventually intended to be used on location at hospitals and other medical sites and likely in an office setting, it could developed as a desktop application. At Philips, for other use cases, front-end tools, like Decima, were already being developed with the Microsoft .Net framework. To be able to take advantage of that expertise, and make future development of Yakobo by Philips simpler, it was decided to also develop Yakobo with the Microsoft .Net framework. Consequently, the interactive prototype was developed in C# using the following tools and frameworks: Windows Presentation Framework (WPF), Microsoft Blend, Microsoft Visual Studio 2012, Resharper, Caliburn Micro and Adobe Illustrator.

To be able to quickly develop the core features, an agile approach to development was considered useful. As such, the creation of the interactive prototype included several agile

iterations of development ending in review sessions where a number of colleagues, Anca Bucur, Jasper van Leeuwen, Njin-Zu Chen, and/or David Perez del Rey were present.

In .Net, the Windows Presentation Framework (WPF) is a powerful modern framework to support the development of rich user interfaces. It has a recommended design pattern that goes along with it, Model-View-ViewModel (MVVM). It, like the more commonly known Model-View-Controller (MVC), enables a powerful programming concept, namely, separation of concerns (See Figure 17). The development of the graphical user interface and its code is kept clearly separate from the business or back end logic and code. This modular development means that the connection to the EURECA platform and services as they change and develop can be kept separate from the development of the user interface. This also allows more flexibility to later change elements in the user interface as well. In MVVM, the view defines the UI look and layout. The model, or data model, defines the business logic and data access. The viewmodel keeps the state of the UI, handles a lot of the display logic and converts data from the model into a format the view can understand and use. In WPF the view is declared in XAML, an XML language. The viewmodel and model are written in C# code.

Figure 17: Model View Viewmodel (MVVM) separation of concerns. View only communicates with the Viewmodel, the Viewmodel communicates with both the View and Model, and the Model communicates only with the Viewmodel

Similar, to the conceptual prototype, the interactive prototype has three main screens: the login screen, the trial selection screen, and the main interaction screen. With MS Blend the visual assets created in Adobe Illustrator for the conceptual prototype could be easily imported or replicated and inserted into the appropriate views. The login screen and trial selection screen are fairly simple and were represented as a single view and viewmodel each. The main interaction screen is more complex and was decomposed into several views and related viewmodels. They are: the main view, to layout and place the other views on; a patient avatar, a view to represent a selectable patient; a criteria tab view, a view to represent the tab and where interactions to enable a criterion, disable a criterion, and display evidence occur; and a criteria percentages view, a view to contain the criteria tab view and the related display of the percentages (See Figure 18).

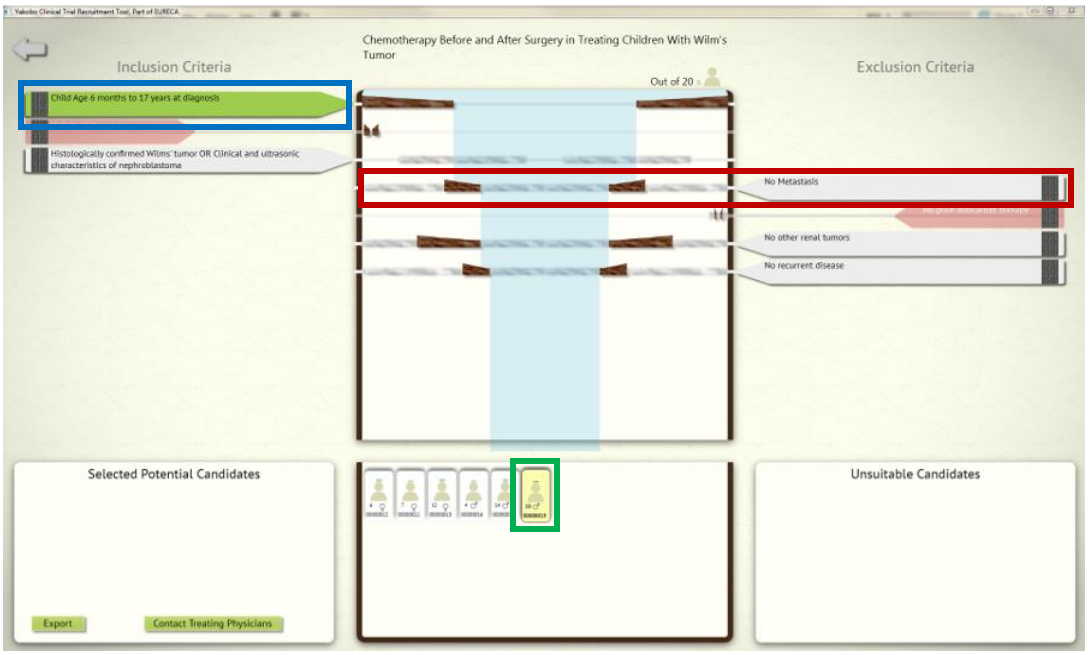

Figure 18: Views in the main interaction screen. a patient avatar view (highlighted in the green box), a criteria tab view (highlighted in the blue box), a criteria percentages view (highlighted in a red box), all contained in the main view.

After several agile iterations, a criteria satisfaction matrix data model was created to encapsulate all the calculations and the data underlying the central water cascading visualization. Also a Yakobo service was created to keep all the connections to the EURECA services, or placeholder dummy services in one place. In this way, separation of concerns was maintained[2].

3.2 Development of the Interactive Prototype for the Computational Oncology Summer School

The next opportunity to evaluate the concept and the first opportunity to evaluate the interactive prototype was at the Computational Oncology Summer School during June 23-28, 2013 in Wadern Germany. To be able to evaluate the main concept and interaction with the interactive prototype, development was focused on creating as much of the UI as possible, and mocking up features that would not be supported by the platform in the near future. The EURECA platform exposes its functionality with a set of web services. It became clear at this point that the dedicated recruitment web service, that would expose all the necessary

[2] A host of other classes were created to support these main classes. However, discussion of those classes is considered too much detail. Interested readers should contact the author.

functionality in one single service, would not be completed on time for the summer school. To allow further UI development a set of placeholder dummy data services, used previously in Decima, were adapted to give similar functionality with appropriate dummy data. These services were eventually wrapped into the Yakobo service, as the one touch point in the code that would need to be changed as services from EURECA became available. To make the usage of the prototype more clinically relevant, the created dummy data was based on anonymized clinical trial data from our clinical partner in pediatric oncology.

To be able to focus on creating a working prototype, development of the visual language was halted. The visual language from the conceptual prototype was simply taken and incorporated into the interactive prototype. As mentioned in the implementation section, visual assets created in Adobe Illustrator for the conceptual prototype could be imported or duplicated in MS Blend to incorporate the visual language into the views. The related viewmodels were also constructed at this point. To add more realism to the cascading water metaphor, an animation of the water filtering down through the filters was added. Font readability issues were also considered, and slight adjustments made. To enable the central visualization to work with actual data (dummy data in this case), the criteria satisfaction matrix was also implemented at this point.

To allow testing on a regular laptop, interaction was focused for this cycle on enabling mouse interaction. Thus, the implementation of drag and drop to move patients into the appropriate buckets, criteria handles to disable and enable criteria, clicking on patients to display the patient's criteria satisfaction, and clicking on criteria tabs to display the related evidence.

3.2.1 Computation Oncology Summer School Expert Review

To prepare for the summer school session, a planning session with some fellow USIs was held to discuss the prototype and possible ways to take the most advantage of the unusual situation for conducting the study at the summer school. Initially, the situation was such that the only opportunity to obtain feedback would be through a half hour presentation and possibly a question session much later in the day. Luckily later, permission was received to pull people aside and have one-on-one interviews and user interface evaluations (See Figure 19 for an example session). This enabled participants to actually use the UI, and hence be able to observe participant's interaction with the system, as well as get feedback on the metaphor and overall UI. The expert review thus involved the one-on-one sessions, the presentation, and feedback after the presentation.

Figure 19: Research Oncologist interacting with the interactive prototype

A few highlights from the expert review are summarized here (see Appendix D for more details). For one, during the design, discoverability and some readability had been sacrificed for visual appeal. It was evident that without any explanation of the main interaction screen or core metaphor, participants were unclear about the possible interaction possibilities. Although, to compensate, participants employed random search strategies and were reasonably successful. However, if given a short explanation of the metaphor behind the interface and the main related interaction, participants had an immediate clear understanding. The cohesive metaphor was memorable, and as such learnability appeared high. Second, the prototype was effective as a probe, as it brought to light several reasons why the criteria for clinical trials become more specific (such as enabling comparison of results with other studies, and more personalized and specific targeting of treatment), interest in applying this tool with in silico (simulated) clinical trials, and a desire to be able to specify time restrictions on the dataset.

3.3 Interactive Prototype Connecting To The EURECA Platform

The final implementation iteration was focused on connecting Yakobo to the EURECA platform, implementing touch interaction, and incorporating some of the results from the Computational Oncology Summer School expert review.

Integration with the EURECA platform would allow possible technical issues for implementing the full clinical trial recruitment tool to come to the surface. One fairly obvious issue was the resulting delay of using a real service to search through patient data. As such, this resulted in implementing a loading data indicator.

It should be noted at this stage in the development of EURECA, that the EURECA project is still busy gathering and incorporating more actual patient data, and that the metadata trial repository only contains one trial with the appropriate format. Therefore, any serious testing of the system with real data on the user experience could not be conducted at this stage.

3.3.1 Connecting to the EURECA platform

Yakobo is not developed in isolation. Indeed, the interactive prototype is intended to fit within the development of the EURECA framework and be able to interact and use the services of the platform. Figure 20 illustrates how the clinical trial recruitment use case, and thus Yakobo will be able to use services in EURECA. The diagram hides many details, and only shows the portion of EURECA that is directly relevant to the use case. As development of the platform was occurring in parallel with the development of Yakobo, not everything was complete. In fact, neither the trial recruitment service, nor the free text service were implemented yet. However, the query engine, and the services within the semantic layer to support patient data access, and the trial metadata repository were sufficiently developed at this point. As the trial recruitment service had not been developed yet, Yakobo could directly inform what the trial recruitment service should support.

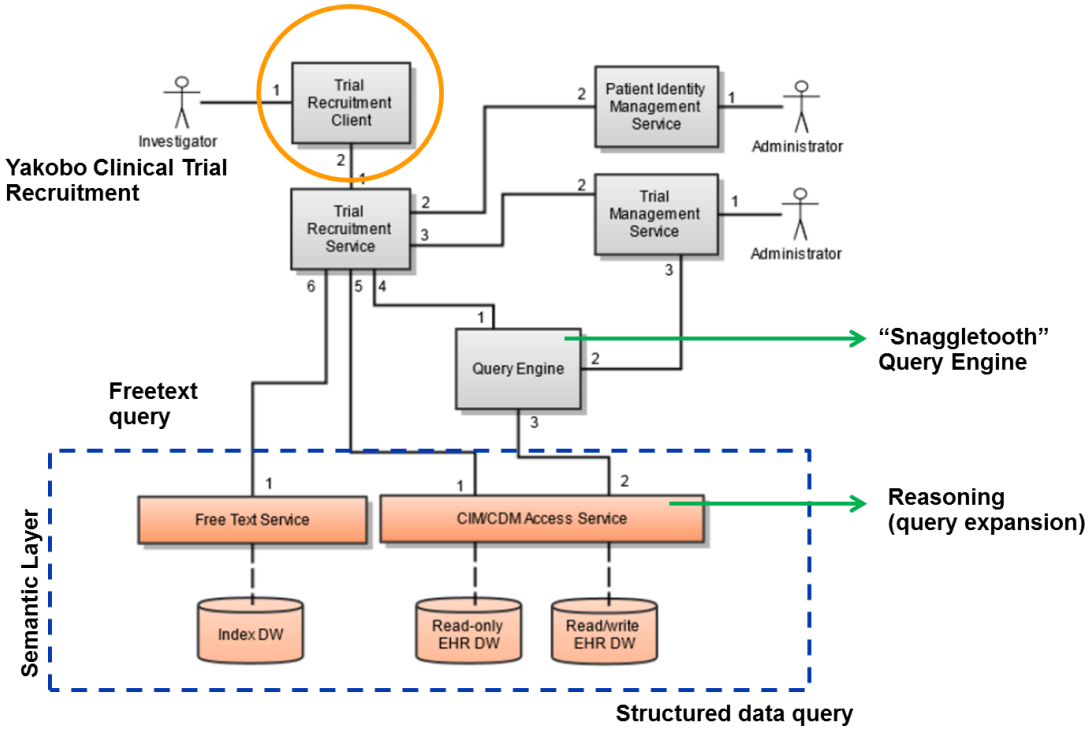

Figure 20: A partial schematic showing how Yakobo is supported within the EURECA platform. The orange circle highlights where Yakobo fits. Image is courtesy of Custodix

As neither the dedicated recruitment service has been implemented yet, nor is the EURECA platform ready for local deployment, to be able to use the EURECA platform for trial recruitment immediately, there are a set of web services that need to be connected:

- a web service to connect to the metadata repository to retrieve trial inclusion and exclusion criteria
- a web service to access the structured patient data
- a web service to match patient data to inclusion and exclusion criteria using the query engine
- a web service to access the actual evidence to support the query engine's decisions

The web service for the metadata trial repository was made available by Philips Research. The web service to access to structured patient data was provided by the Polytechnical University of Madrid (UPM) as a data source for the query engine. To access the query engine, it was decided that the connection would be done through directly exposing the "Snaggletooth" query engine (a Custodix built engine) on the Custodix VPN, as directly exposing the engine on the public web would create a security risk.

The need for a separate evidence web service was surprising. In the previously built web service for the patient screening tool, Decima, the matching service also returned the evidence. However, due to privacy and security concerns, access to the evidence, which may be raw patient data and contain private information, is planned to be provided in a distinct "providence information" service, so that separate authorization for access can be clearly enforced. The "providence information" web service has not been implemented yet, and as such Yakobo cannot display evidence beyond the act id (the unique identifier pointing to the evidence in the common data model of EURECA).

A considered alternative approach to have access to evidence was to use a web service already available for patient screening and Decima. However, this service is setup to compare a single patient against a trial or set of trials, and as such would mean querying the engine patient by patient (p x c queries) instead of querying all the patients at the same time for each criterion (c queries). This would significantly increase the response time and would potentially make the system unusable due to significant extra delay. Furthermore, it also meant implementing the authentication scheme which added no value to evaluating Yakobo at this time. To get the best of both worlds (evidence and efficiency) it was thought that it is perhaps possible to use both services concurrently. However, the Decima service could not run on the VPN due to the authentication and as such, the two services could not be used in parallel. Thus, for pragmatic reasons the engine behind the VPN was used.

3.3.2 Incorporating Results from the Computational Oncology Summer School Expert Review

From the Computational Oncology Summer School, it was clear that there was potential to improve the visual language for the central visualization. Tilted surfaces were added to the blocking non-satisfied bars to increase the water filtering down effect (See Figure 21 in which red boxes highlight examples). The undetermined nature of the grey filter bars was encoded further by making the speckled grey bars blurred (See Figure 21 in which blue boxes highlight examples).

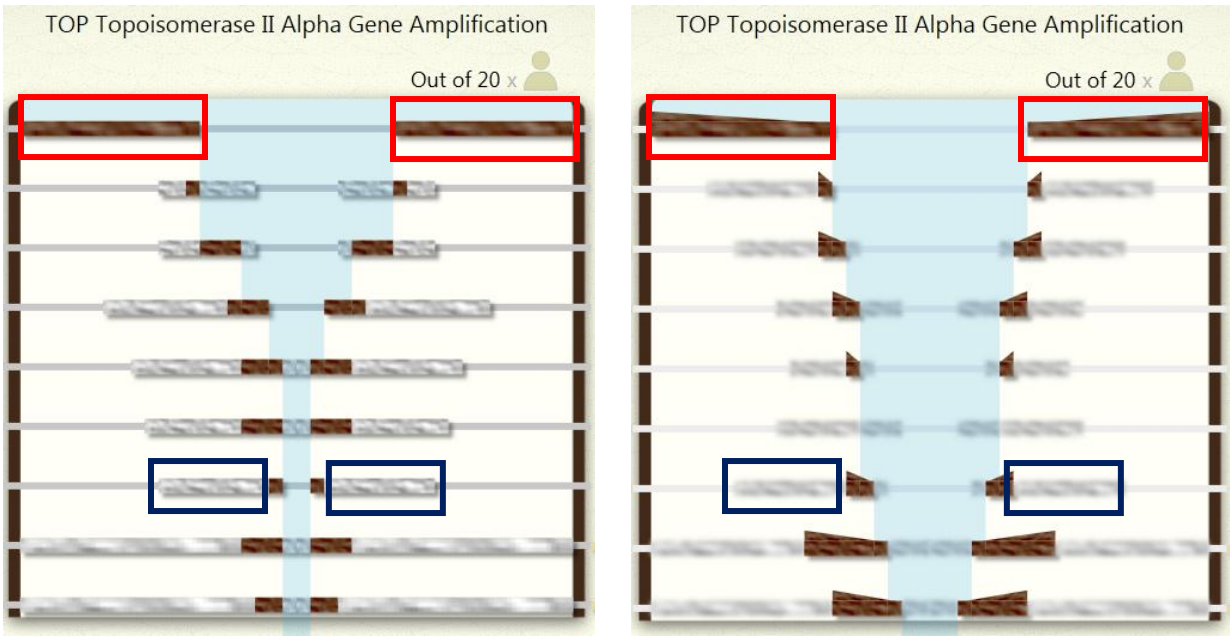

Figure 21: Before and After adjusting visuals based on Summer School feedback

Visual consistency was enhanced by adding depth to all clickable areas and removing it from some of the other areas which are not clickable. Furthermore, a hover popout effect over all clickable areas was added to improve discoverability for usage of the tool with a mouse.

3.3.3 Touch Interaction

An initial part of the design space included the idea that touch interaction is likely to be common practice in many instances (note the current pervasiveness of iphones and tablets), and how would this system be envisioned in a touch environment. As such, thinking about incorporating touch interaction has affected the design ideas. In particular, in the final water cascading metaphor based design, the criteria tabs were envisioned as physical handles to be

able push in or pull out the filters from the center container. Further to allow patients to be quickly sorted, the patient is represented in a graspable icon that can be tossed into the appropriate bucket. Consequently, it made sense to integrate and develop touch at this point, as Yakobo's design was conceived with touch in mind.

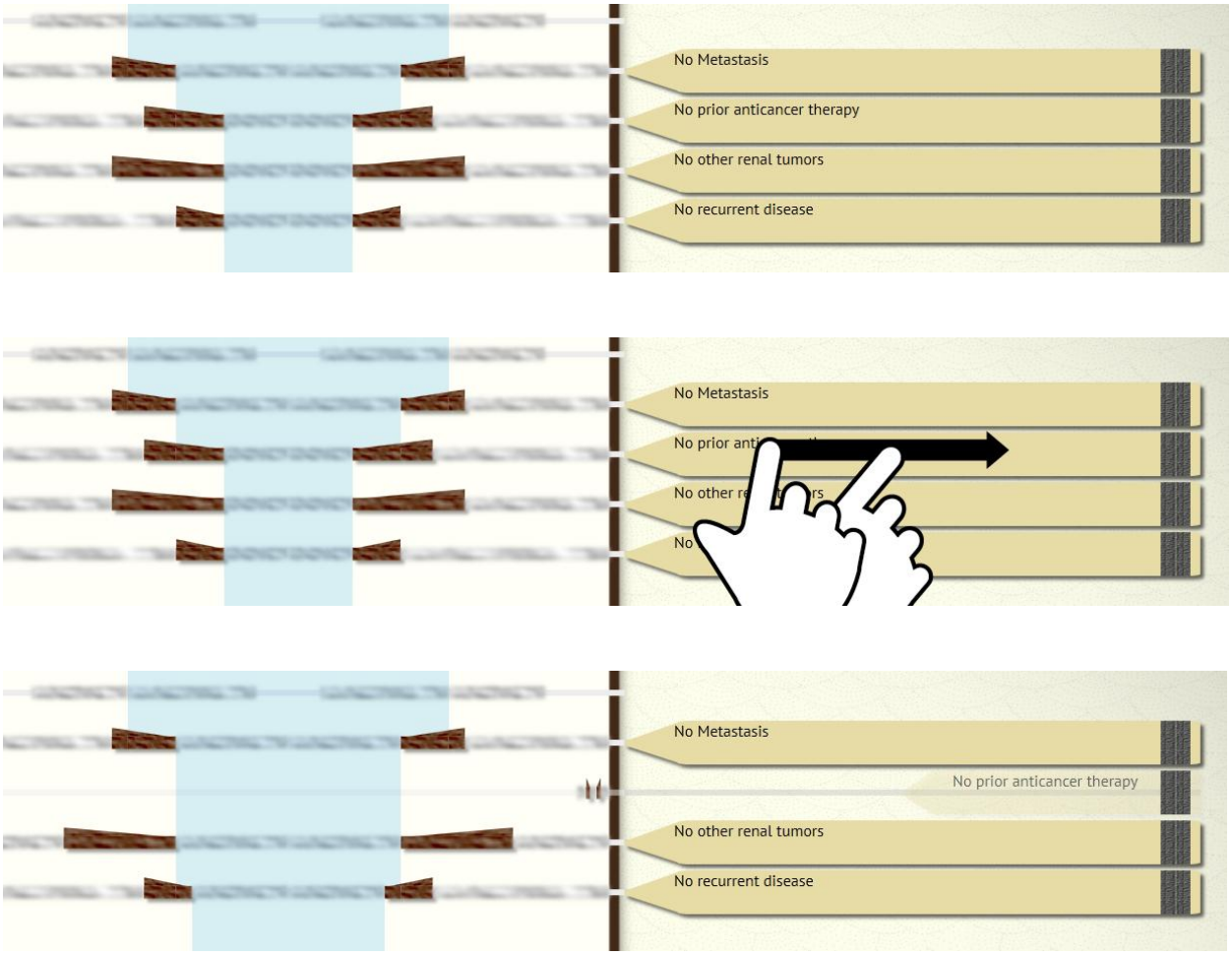

Figure 22: Disabling a criterion with a swipe action. Top- before interaction, middle- swipe the no prior anticancer therapy out, and thus disable it, bottom- the criterion is disabled, and no longer is applied to the central filtration

Minor things such as target sizes were increased to facilitate touch interaction. The main implementation for touch was the implementation of the "swipe a criteria filter" in and out interaction (See Figure 22), and the "swipe a candidate" into the potential bucket or not suitable bucket (See Figure 23). The latter was implemented as a tap and swipe due to implementation constraints that could not be dealt with within the time constraints.

Figure 23: Deciding a patient is not a good candidate and putting them in the unsuitable bin with a swipe action. The selected candidate (thus already tapped) at the top, is swiped (middle) into the unsuitable candidates bucket (bottom)

3.3.4 Final Expert Review

This review was considered as an opportunity to test the effect of having "real" data, and to test out the touch interaction. However, without any real evidence, the impact of real data is limited to a loading delay, and an increase to the number of patients under consideration. With the current datasets of 80 or 120 patients the delay was merely a few seconds and implemented to only occur on initial load of the main interaction screen. Participants considered the central visualization still completely useful and understandable. The impact of investigating a dataset of thousands of patients is left to future work.

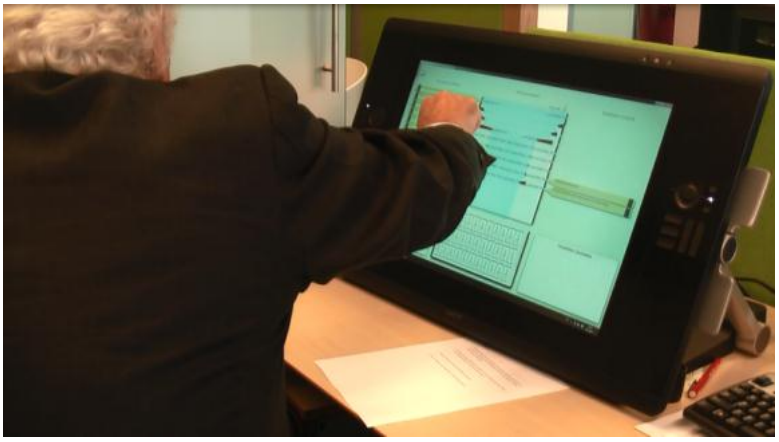

Figure 24: Oncologist interacting with Yakobo on the large touch screen

The touch interaction was tested out on a large touch screen (See Figure 24) with two Philips employees, and a two EURECA partners (See Appendix E for complete details). There were a few minor issues due to touch registration of the touchscreen itself. A participant had a bit of difficulty acquiring some touch targets, and it might be advisable to increase the target size slightly more to compensate. As expected, the discoverability of the swipe touch interactions were low. However, after a quick demonstration, participants could readily interact with the system. Particularly, the swiping in and out of the criteria filters was considered intuitive. One participant remarked "that is elegant". The tap and swipe interaction was a bit problematic, in that occasionally participants would try to directly swipe a previously unselected candidate, and were surprised when the selected candidate would move. Thus a more finessed implementation of a direct swipe is recommended instead of the tap and swipe. Addition of touch had an overall impact on the interaction experience. The interaction and design was more cohesive, and this was reflected by participants commenting that it is user friendly, or easy to use, and one even called it "fantastic".

4 CONCLUSION

The project goals were met by the conceptual prototype, the touch enabled working interactive prototype, and the three expert reviews. Yakobo and its central cascading water metaphor appealed to both researchers and clinicians alike. With some minimal explanation of the central metaphor and interactions, all participants could effectively use the tool. This allowed ready discussion of how to extend the tool, and in which other areas it could be potentially used. Several areas were suggested, for example, in trial feasibility, and for in silico (simulated) clinical trials. Though Yakobo was developed specifically for clinical trial recruitment in oncology, the central filtration through patient data process, based on inclusion and exclusion criteria, remains the same in other medical domains. Yakobo could readily generalize to clinical trial recruitment in other medical domains. Furthermore the interactive filtering approach in Yakobo can be applied to any massive data that requires interactive visualization and filtering, and therefore presents a whole new paradigm for visual analytics that should be patented.

4.1 FUTURE WORK

As Yakobo was not designed as a walkup and use system, there are a few interactions that are not immediately discoverable. However, after one demonstration, these interactions are easily remembered, namely: swiping criteria filters in and out, and swiping candidates into potential and unsuitable buckets. Thus those two interactions, and the overall water filtering metaphor should be introduced to new users. Once the interaction and metaphor were shown, they were memorable and easily understood and used. Possible avenues to explore for introduction are an intro video tutorial, a UI walkthrough, coach marks or progressive disclosure. The colour coding, green for satisfied, grey for undetermined, and red for unsatisfied, should likely be introduced in a similar manner, as it was not self-evident that the colour change reflected the satisfaction status.

There is possible further work on how the satisfied, undetermined, and not satisfied statuses are represented in the criteria filters (currently, thin line, fuzzy grey area, and brown solid bar) This mapping was less clear to participants, and likely should be described in hover or tap hints. (e.g. Undetermined: There are 5 out of the 20 patients left after filtering by the above criteria that the system cannot determine whether those 5 patients match this criteria.)

It should be investigated what the impact of truly large data sets is on the visualization and how much exploration of the relative impacts of criteria is desired. If the visualization no longer gives valuable information with the use of a large dataset, then ideas like locking criteria to reduce the visualized data set could be explored. If there is a strong desire to explore the

relative impacts of the criteria then allowing the reordering of criteria could be a fruitful interaction idea.
At this point in time, Yakobo does not explicitly address the actual contact and follow up with treating physicians. To be truly useful for a recruiter, Yakobo should create a smooth transition from its results to the actual contact and recruitment process. As such, investigation should be undertaken to see the best way to tie Yakobo into the local practices of various hospitals, and whether explicit support of the recruiting process is desired, or whether a simple export of the contact info is sufficient.

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Appendix A: Terminology List

Balsamiq	Balsamiq is prototyping tool that allows someone to quickly mockup screens with a sketchy like appearance and the interaction clickable (www.balsamiq.com)
Caliburn Micro	Caliburn Micro is a framework that supports a variety of good programming design principles including the use of the Model-View-ViewModel design pattern.
CDS	Clinical Decision Support systems are software tools developed to assist clinicians in effectively making treatment and care decisions.
Cohort	A group of patients that share an attribute(statistic factor) or set of attributes such as age, gender, and/or a specific diagnosis
Cohort Selection	Selecting cohorts out of a large dataset to see whether they exist within the data set, either for further analysis, or to test viability for clinical trial design
Decima	Patient screening tool developed at Philips Research
EHR	Electronic Health Record systems are the software systems running at hospitals that continue the medical files of patients and the related administration to help treat patients
Model-View-ViewModel	A software development design pattern to keep separation of concerns between UI development, and the backend services that works well with WPF
Multi-Site	Refers to a clinical trial that is run in multiple locations in order to reach the numbers necessary for a trial to complete successfully.
Patient Screening	Looking at clinical trial participation from the

	perspective of a physician treating a particular patient and looking for relevant trials for that particular patient.
Snaqltooth Engine	The underlying engine being developed by Custodix to allow criteria matching to be executed on the various data sources
Site	A hospital or other medical treatment location where a clinical trial is being conducted.
Technology Probe	A technique where a prototype is built focused on a particular interaction to be able to generate discussion and allow feedback through usage
Trial Metadata Repository	The repository contains all the relevant information related to a clinical trial, its protocol and inclusion and exclusion criteria
Trial Feasibility	Designing and exploring the possibility of conducting a new trial
VPN	Virtual Private Network is a technology that allows one to remotely access and use software as if you were located on site and directly accessing a network
WPF	Windows Presentation Framework is the user interface framework within .Net

Appendix B: Site Visits

YAKOBO : Trial Recruitment Project Data Sources Site Visits

Visit To MAASTRO clinic in Maastricht and Pediatric Oncology Clinic (Klinik für pädiatrische Onkologie und Hämatologie) in Homburg Germany

By: Jeroen Keijser

March 4, 2013

TU/e Technische Universiteit Eindhoven University of Technology

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2 INTRODUCTION

A number of meetings were setup with EURECA project partners to discuss the data sources, data models, and setting up the mapping from these data sources to what will be provided to EURECA. I attended two of the meetings. One at the MAASTRO clinic in Maastricht and the other meeting in Homburg Germany at the pediatric oncology clinic, in order to personally visit both sites and to get a better understanding of what data and in what form will be available for trial recruitment. . Both sites conduct clinical trials and thus how trial data will be represented in the EURECA trial metadata will reflect their input.

> ***NOTE:*** What was clear was from both sites was that neither site would directly conduct trial recruitment. In pediatric oncology in Germany every patient is enrolled in a clinical trial unless specifically stating they do not want to participate, and thus trial recruitment is irrelevant. MAASTRO clinic specializes in radiology and thus the decision on treatment type has been made (namely radiology) and thus a patient screening process is applied for the relevant trials running at MAASTRO and no further trial recruitment is necessary.

3 MAASTRO RADIOLOGY CLINIC

3.1 DETAILS OF VISIT

The MAASTRO clinic is situated at the Maastricht University. It is a clinic that specializes in radiology for the Limburg province and serves six regional hospitals and treats approximately 4,000 patients per year. The focus of the MAASTRO meeting was on what data the clinic would provide to EURECA and where that comes from within the clinic. MAASTRO is one of the partners who will be supplying data (and already is?) early in the EURECA project life cycle for use cases related to trials. In the meeting how data related to a patient is created and added into the MAASTRO clinic was discussed. It was formalized and you can see how a patient goes through the system and data created in Figure 1. Further, we looked at the type of data needed to match trial eligibility and how data in MAASTRO is mapped to the HL7 messages sent to EURECA (See Table 1). Lastly we had a brief tour of the MAASTRO clinic.

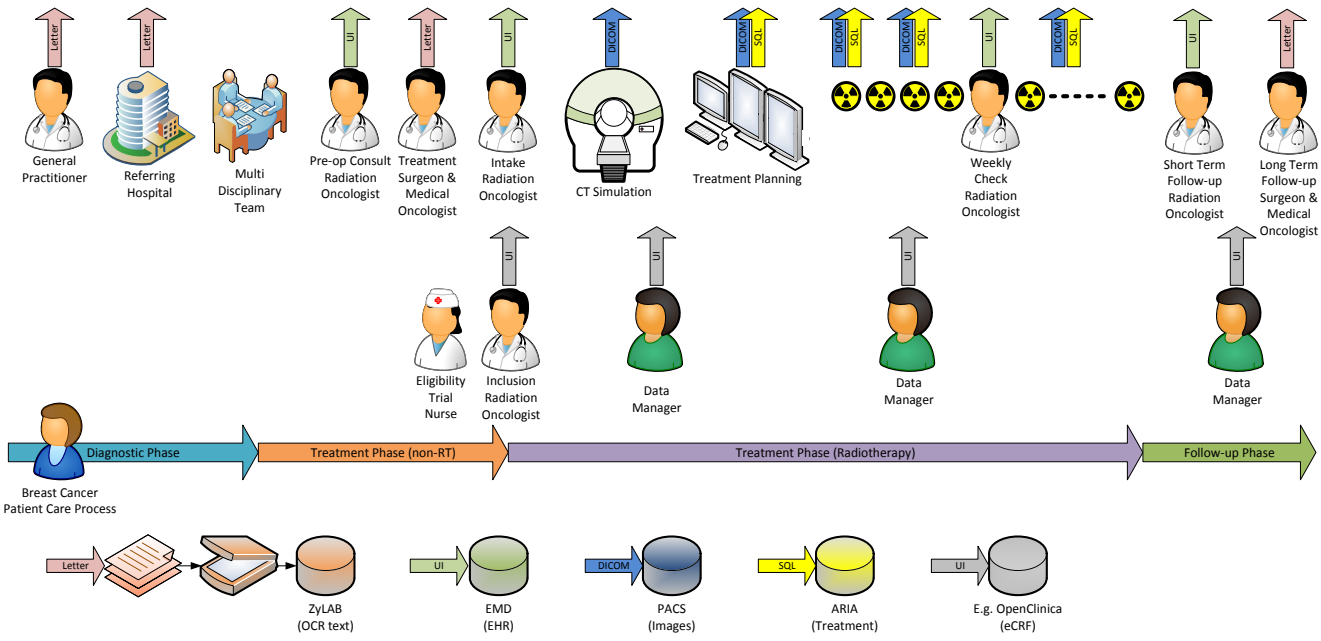

Figure 1: MAASTRO care process and data sources. Top: Radiotherapy care process including data generation (arrows). Top-Middle: Additional data generation if patient is included in a clinical trial. Bottom-Middle: Chronological treatment phases (not to scale). Bottom: Clinical data sources to be used in EURECA. (*courtesy of MAASTRO partners*)

3.2 INTERESTING POINTS

- What was interesting to me was that many of the radiation oncologists are 50% of their time on the road visiting the regional hospitals and attending the multidisciplinary boards
- The trial nurse suggests a potentially relevant clinical trial by putting the large blue folder related to the trial with the patient's charts. (He looks at patients the day before intake and suggests trials based on what he sees then)
- Some data will simply not be recorded as it will be per guidelines of the clinic (i.e. they do not treat pregnant women)
- They needed to add the concept of fractional part (radiation is given in repetitive small doses i.e. fractions) and other radiology specific terminology to the ontology
- Currently use openClinica for electronic CRFs (Case Report Forms)
- Data may be missing, may not be consistently entered in the same location or format
- There is a special shorthand notes section in the Electronic health record (EHR) which includes such things as "triple positive" (referring to HER2, ER, and PR)
- Some eligibility criteria are simply a judgement call (e.g. ability to tolerate treatment)
- Administration has read access to regional hospital databases which they use manually to supplement data received by post and OCR.

Eligibility	**Source DB**	**Description**	**Unstr/str/n.a./per guideline**
Menopausal Status			n.a.
Currently Pregnant			per guideline
Currently Nursing			n.a.
Hispathology	EMD	Pathology lookup table	str
HER2	EMD	Oncological history	unstr
ER	EMD	Oncological history	unstr
PR	EMD	Oncological history	unstr
Stage	EMD	TNM Lookup table	str
Tumor Size	Zylab	Surgical PA report	unstr
Lymph Nodes	EMD	Pre-op N-stage	str
Distant Metastases	EMD	M-stage	str
Informed consent	EMD	Lookup table	str

EMD	Electronic Medical Dossier (EHR)
ZyLAB	OCR-ed scanned paper letters from referring hospitals

Table 1: Eligibility Criteria, Data sources and format (*courtesy of MAASTRO partners*)

3.3 CLINIC TOUR

4 PEDIATRIC ONCOLOGY CLINIC IN HOMBURG

4.1 DETAILS OF VISIT

The pediatric clinic is situated at the University of Saarland medical campus. The campus has many historical buildings and each department appears to be in a different building. The pediatric clinic is a more recent addition to the campus and has mechanical playground out front and the internal decorations reflect the younger audience. In the pediatric clinic in Homburg the focus of the meetings was more on other EURECA use cases, particularly to those related to adverse event prediction. At the meeting, I learnt more about Case Report Forms (CRFs) and was given an example and paper copy of a protocol (within which are CRFs) for a study that ran at the pediatric oncology clinic and across germany.

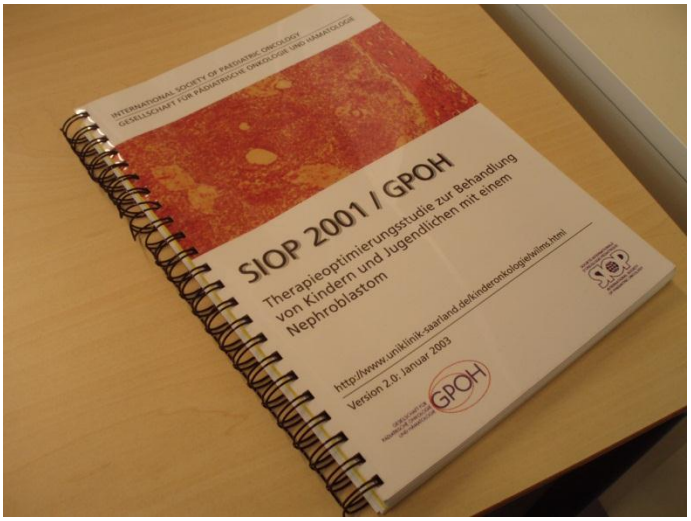

Figure 2: Example protocol

At the meeting I was able to talk with Dr. Norbert Graf one of EURECA's clinical partners and discuss a few things more relevant to trial recruitment. Particularly, when I asked to describe how trial recruitment is done locally, he clearly stated that trial recruitment is not done and not necessary in pediatric oncology. However he mentioned he would contact a colleague in adult oncology and see if he could setup a meeting to discuss how trial recruitment is done in Homburg. When asked how good candidates for multiple trials are shared between trials, he said that in pediatric oncology a patient is rarely a good candidate for multiple trials as how specific and rare the different conditions are in pediatric oncology. However, he did discuss that in adult breast cancer there are a large number of cases and that it would be possible to get

highly significant study results if there was more cooperation(multi-site) and enrollment in clinical trials (enrollment in trials is low in adult oncology). When I asked whether referrals to other sites were done for clinical trials, he indicated that yes it does happen. He recently referred a patient to a clinical trial running in the United States. However, in general it is rare as it takes several days of work to research relevant trials and make all the contacts, and thus an additional strain on oncologist's time when a conventional treatment or possibly local trial option are available.

Appendix C: Groenendael Expert Review

YAKOBO : Trial Recruitment Project
Groenendael Expert Review

By: Jeroen Keijser

March 13, 2013

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2 INTRODUCTION

The meeting in Groenendael was deemed a good opportunity to get feedback and input from both technical partners and clinical partners. For the discussion, I brought along the personas, the step by step breakdown of trial recruitment and a set of three initial interface mockups.

3 INTERVIEW WITH ONCOLOGIST

The oncologist was working at a clinical research hospital in Zurich, Switzerland and now is a research fellow in Brussels with minimal or no clinical duties.

We discussed the current situation as it surrounds clinical trial recruitment, and he said he mostly draws from his knowledge and time in Zurich. Later in the interview we used the personas, and the mockups as basis for further discussion.

3.1 ZURICH CURRENT SITUATION

The current situation at the Zurich hospital as described by him is as follows:

As a research hospital there are ongoing clinical trials on site. There exists a type of database that can be thought of as a folder of ongoing clinical trials. It is up to individual treating physicians to keep up to date. When a new clinical trial was going to occur on site a short informational meeting is setup. The people in charge of the trial would present to the medical team to discuss the trial itself, the eligibility, the purpose, and profile of suitable patients. It would rarely be the principal investigator who runs the information session (he may even be at a different location). Rather it would be a physician who has been assigned the task of spreading the information related to the trial. This physician isn't necessarily related to the trial in any other way.

The idea is that during the first consult with a patient a treating physician is supposed to have the mentality to consider clinical trials. However, in reality, given that there are already reasonable standard practices, this doesn't always happen. Later however, if a patient becomes metastatic, when as a treating physician you are out of options, is when you start to really think about alternatives as standard treatment is not working. To consider a patient for a clinical trial you think if he is matches the profile of a good candidate for any particular trial. Then you do a manual check. You open up the electronic file of a patient which has a broad general categorization such as radiological, pathology reports, the treatments received etc. However, within each particular categorization there is free text, and you have to dig through and read to see if there any applicable exclusion criteria etc.

3.2 PERSONAS REVIEW

Looking at the personas of trial recruiters, he said currently there isn't anyone who formally recruits candidates for a trial. Rather this is quite loose and fluffy. If a senior doctor had an interest in a particular trial he would give the task to a junior clinician to keep his eyes and ears open for potential candidates. (He deemed investigator probably a better term than principal

investigator). Currently instead really individual treating physicians are the main feeders to clinical trials. Looking at the second persona he discussed that clinicaltrials.gov is not particularly helpful for trial info. The information there may not be updated recently. For example, information about which centers are in fact recruiting may not be accurate nor exhaustive. Further to find relevant trials on there can be difficult as you can mostly just do loose broad searches such as HER2 for breast cancer. Another way that information is currently spread for recruitment is online. Websites relevant to a particular field will have advertisements of clinical trials relevant to that field.

3.3 MOCKUPS

During the discussion of the mockups, I brought up the idea of categories of criteria, such as judgement calls that need to be made by the treating physician, and not be a recruiter. His response to this was that there are many criteria that can be objectively assessed such as: diagnosis, setting, prior treatment history, and baseline organ functions. However, there always other factors that may make a candidate unsuitable for a trial that may not be captured formally. For example, the personality or character of a candidate may make him/her unreliable as a participant and lead to inconsistent data. There are logistical reasons such as a patient where transportation is an issue, then weekly visits to a hospital would be extremely difficult for them and make them less suitable for a trial that requires that.

The oncologist qualified that this was a tool for oncological trials only or not. I am uncertain, but I think he was concerned with some sort of information overload if it was for all clinical trials occurring at a hospital. He also mentioned he hasn't seen trial recruitment in this sense being done in practice currently, but rather always from the treating physician and patient screening side. Later he suggested that broad categorizations of inclusion and exclusion could be useful. He suggested: demographics, clinical pathological data, history of previous treatment, and biological background.

4 INTERVIEW WITH TECHNICAL PARTNER

During the interview with the technical partner, Brecht Claerhout from Custodix (with Anca Bucur from Philips in attendance), we discussed his experience and knowledge about trial recruitment in clinical settings, walked through the mockups and related questions, and discussed the step by step breakdown of trial recruitment. The main points that came up are listed below:

- Secondhand knowledge through talking to a doctor who built a tool for trial recruitment. That a clinician is motivated to build a tool himself is part of the motivation of creating the EURECA use case which is the basis for Yakobo
- Envisioning usage of this tool by a role not currently common in hospitals.
- Categories suggested by oncologist shouldn't be a binding categorization and should look at clinicaltrials.gov for broad categories
- Discussion of whether contact and follow-up workflow data should be part of the system.
- Enrolled/Not Enrolled should and is part of the Common Data Model
- Actual contact etc. may be supported by trial management tool (export so can use there?)
- When adding a trial to the list of locally running trials only import from EURECA trial metadata
- A simple list view was suggested for viewing the patients
- Data specific to trial recruitment and workflow will be stored locally
- The sand filter metaphor mockup was preferred over the sieve metaphor mockup

Step by Step breakdown was verified (though follow up is

Appendix D: Computation Oncology Summer School Expert Review

YAKOBO: Trial Recruitment Project Computational Oncology Summer School Expert Review

By: Jeroen Keijser

July 8, 2013

TU/e Technische Universiteit Eindhoven University of Technology

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2 INTRODUCTION

The Computational Oncology Summer School (http://computationaloncology.org/) was considered for this project as an opportunity to conduct the second official expert review session. This year's summer school was attended by a few oncologists, biologists, and many people with a technical background working in the biomedical/bioinformatics domain. I both demonstrated the current prototype in one-on-one sessions, and had some participants try out the system. Further I presented the prototype on Thursday, and had some feedback from the group, as well as a few follow-up discussions.

3 ONE-ON-ONE SESSIONS

Please note that this section is written in essence in raw note format. Drawing conclusions is left to the reader

3.1 BIOMEDICAL ENGINEERING STUDENT

- Wasn't immediately sure about what the visualization meant. Though realized that the tool selected the patients at the bottom (3 individuals).
- Wasn't sure what was clickable. Once clicking on a patient could see how the patient matched particular criteria. (Colour coding needed to be explained).
- Accidently clicked the grip, but understood immediately that it was disabling a criteria.

3.2 MEDICAL DOCTOR/ONCOLOGIST

This research oncologist had recruited patients for his own clinical trials. In recruitment for those trials, which were regional studies, they called by phone. They called different hospitals, or contacted the most important centres. He would ask the director, or other important urologists, and also ask which urologists are good to contact and who are able to actually conduct a trial. Thus recruitment was done through telephone or through people we have already met (word of mouth). The urology study recruitment took 2 and a half months to recruit participants. Collecting in radiotherapy took less time as had a network. Knew which centers actually treated prostate cancer (through family network).

- Immediately recognized the back button, immediately recognized inclusion and exclusion criteria
- wasn't sure what "out of" meant, consistently doubleclicked grips to disable.
- Thought he could click on the patient) . Wanted to be able to see more detailed info about patient directly. Again vis wasn't immediately clear.

He started wondering about using the tool on large blastoma trials. Thought might want a filter directly by cancer type/diagnosis.

Thought the tool much more important for common cancers (prostate or breast), and might be much more important to filter. Every year 500 patients are treated at his centre, so in five years might be useful. (Medical note: fixed sample usually available not frozen)

Some studies he's familiar with they are looking at little molecules gephotemene erotimine. Sensitivity to drug, you need to check) genetic sensitivity. Only 5% of the total actually respond. The rest 95% dirty your results if you do not make this a criteria for inclusion in the trial.

Sometimes it can be difficult to not include a patient due to statistical issues. In Torino, chemotherapy, colon cancer, surgery are the common treatment. Said breast and prostrate the most common, but lung cancer has the highest mortality (out of the most common cancers). Breast, prostate, colon, and lung.

Electronic record needed first for a tool like Yakobo to work. Currently, in Italy an urologist will check all the data history, clinical cases, and look if may be eligible (In Italy SOD has the principle diagnosis. So if there is an electronic record can search using this). If you go through urology department as first filter … you get all kinds of procedures not only for cancer.

In Italy, the hospitals are obligated to fill the SOD, and get reimbursed, thus will eventually have this data as a first row filter. Case history… (document inconsistencies can be an issue) He was concerned about how the platform will deal with current data, and in free text

He says the filter practically already makes the decision (would like more data about patient to check about other issues) He doesn't see why you would ever need to say they are not suitable. (Indicates that the inclusion/exclusion criteria may change over time)

Stratification is a problem in cancer studies. Classification of tumor size is 0-2, 2-5. Etc. 38min approx. is stages not maybe rational, but is practical for external validation. Stages do change occasionally.

Pathologist sees their own sample, they love it.

Wanted more information on the actual patient

3.3 BIOLOGIST

Described the desire for good data by researchers, and why there is a push for more and more criteria in clinical trials. That is they want more data so that they can compare their results to

other studies. Mentioned that some questions are simply asked from the patient (no previous history …). This may or may not be noted somewhere in the system. The biologist thought that users of the system would definitely like to see the imagery. But more importantly want to know the resolution of the imagery tool used. (i.e. For tumour size) which instrument was used and the resolution is important. Thought that it may be more useful in small institutions that may not have as organized understanding /communication of clinical trials (I.e. Possibly seeing trials running nearby etc.). Suggested an alternative visualization instead of percentages actually show the range and show the filter more literally e.g. for adult less than 70 show the filter letting patients through from 18-70 and blocking on both sides out of it. (similarly divide categories equally to show splits per category)

3.4 IN SILICO MODELLER

- Excited about the prospects and sees the potential of using such a tool as Yakobo in In Silico trials as well.
- Also used TOP trial data for their modelling.
- Immediately read, and didn't quite notice the criteria were separated into inclusion and exclusion) explicitedly asked what the viz was.
- Said it looks user friendly and pleasant. Likes the filtering water metaphor.

For modeling, it would be nice to have more than just the largest dimension but to have the 3 mutually perpendicular dimensions or estimate of volume tomographic imaging. Would be great to collect this detailed information from this point (recruitment point) Why lose such valuable information, by the simplification (down to the single dimension)

He was interested in the Spatial Temporal response to treatment.

Thinks this tool be useful for virtual in silico trial, which can match the branches in the in silico trials. Thinks it's important for real trials and virtual trials. Very much enthused, and inspired by this nice interface.

Wanted Diacon representation (if tomographical data is available) and more advanced imaging, histological differentiation of types of cells, microphotos of slides

3.5 UX STUDENT

New to the field and commented that she thought doctors/medical people preferred large data tables and entering and displaying information in a tabular way, and was excited to see that

visual approaches such as Yakobo and another visualization work shown at the summer oncology school were so well received and liked. Didn't realize you could click on an actual patient. Immediately clicked on grips

4 PRESENTATION, FEEDBACK, AND FOLLOW UP SESSIONS

During a half hour session in the morning on Thursday I presented Yakobo, the context within the EURECA project, defined clinical trial recruitment, and the design process that lead up to the development of the current prototype. It was all presented as an invitation to participate and discuss the problem domain and the current implementation of Yakobo.

4.1 FEEDBACK

- Disliked double negative with exclusion criteria. Background contrast for legibility (from a UX person).
- Suggested the possibility of hiding the criteria filtering, to just show the results (i.e. ready to be used) and then only show the visualization on demand.
- Some discussion on where this would be used, (not likely in small trials where the researchers have ready access to patients who are good candidates for participation).
- Fuzzy presentation of patient data was discussed as was wondering of privacy issues and usage outside of the local site.
- time frame filters desired (or at least explicit indication of is it the whole EHR, those currently in the hospital, or due for treatment, or what kind of subset?

4.2 FOLLOW UP SESSIONS

There was reiteration by several people that having a time frame filter would extremely informative and useful.

In a cardiology setting, a researcher indicated that they look exclusively at those arriving at the clinic in the next week or so, to chose as candidates for a clinical trial. This was possible as was working on medical devices in cardiology in smaller trials. He said they never ask people to come back for a trial if they are not already coming in for treatment. (he thinks this is different than for large pharmaceteucal trials) The only reason they ask someone to come back for a trial is if that's part of the followup protocol. Thought there might be more potential for diabetic trials.

Appendix E: Final Expert Review

YAKOBO : Trial Recruitment Project
Final Expert Review

By: Jeroen Keijser

September 10, 2013

TU/e Technische Universiteit Eindhoven University of Technology

eureca

SEVENTH FRAMEWORK PROGRAMME

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2 INTRODUCTION

The final expert review was originally intended to evaluate the impact of using "real" data on the EURECA platform, and the addition of the touch interaction. The current underlying platform does not yet allow the display of actual evidence for criteria, and currently the metadata repository only contained one useful trial in the correct format. As such, testing the impact of "real" data on the user experience wasn't feasible. However the touch interaction could be tested, and issues of general understandability could be looked at once more.

There were three main things to test in terms of the touch interaction:

- Whether the enlargement of target sizes (buttons, comboboxes, and other elements) was sufficient
- The swipe interaction to disable and enable criteria filters
- The tap and swipe gesture to move candidates into the potential and unsuitable boxes

3 SESSIONS

A number of evaluation sessions were run with Philips Employees, a Technical Partner, and one Clinical Partner. A short intro was given, and they were asked to do several tasks. (See section 4 and 5)

3.1 PHILIPS EMPLOYEES & TECHNICAL PARTNER

To test the touch interaction itself it was not explicitly necessary to have potential end users test it. Thus, it was possible to test with some internal Philips employees, as well as those who stopped by and were interested in a demo of the system (4 in total).

Once introduced to the possibility of swiping the criteria filters in and out, all participants were able to easily enable and disable criteria (a minor note: one participant tried to swipe across the disable handle, and thus support for swipe across this should be included).

There were some issues with touch registration of the actual touch screen, particularly for one participant. However, otherwise it appeared that the target sizes were sufficiently large enough to allow interaction to readily occur. Though, it is possible a slight increase in size might help overcome a bit of the touch registration issue.

The swiping of candidates into the potential and unsuitable buckets was intended to be just a simple swipe gesture. The implementation as a tap and swipe gesture was done due to some technical issues that made just a swipe difficult to implement in the given time. When participants interacted using the tap and swipe, they were able to successfully move the candidates into the appropriate buckets. However, it was noticeable that they were trying to do just a swipe, and that this resulted in them occasionally moving another candidate (i.e. the previously tapped and selected one) and some confusion as to why this was happening. Thus implementing the direct swipe would be desirable.

As expected discoverability is similarly low as it was in the mouse interaction. Perhaps due to the setting, participants did only very minimal tapping to figure out what things did. No random search strategies were used. Thus the quick intro or demonstration of interaction possibilities and the central metaphor is confirmed to be necessary. However, once shown, all participants could readily grasp, and interact with the system.

3.2 CLINICAL PARTNER

The clinical partner's visit was concerned a key opportunity to test out the developed prototype.

Discussed some of the background related to where clinical trial information would come from. He suggested that you could follow up with the patient, with patient friendly information, and allow them to be involved in choice of the trial. Also should follow up with both treating physician and the patient. In his initial interaction with the system, he thought you had to choose which filters to apply and tapped them in a series. That the filters were already applied

wasn't immediately apparent. This again reflects the necessity of having a proper intro. However, when shown how to take out one of the criteria filters, he immediate understood the results at the bottom were the patients who made it through the filtration process. (Side note it may have been possible that as there were no results when first loaded, he thought nothing had occurred yet, and thus he needed to apply the filters). When shown the possibility of directly seeing the evidence, he commented "that's elegant". He commented this could all be done by a data manager or research nurse. This is a possible way that Yakobo could be integrated into current medical practices. He mentioned that there needs to be flexibility for inclusion criteria. That is there will be criteria where a patient is a candidate if he has A or B or C, but doesn't need to have them all. He mentioned the tension between personalized medicine which needs more and more specific criteria for a trial, and the desire to have more generic trials.

He suggested potential validation possibilities to test with clinicians in Italy. He also suggested the central metaphor could be used to apply Saint Gallen guideline criteria to patients. When an observer asked whether he could see that the system was easy to use, he said "ah it's fantastic". Later he mentioned, in a rather self-deprecating remark "Even I understand it."

4 INTRODUCTION GIVEN TO PARTICIPANTS

When recruiting patients for a clinical trial, a patient has to meet a certain number of inclusion and exclusion criteria. In Yakobo each criteria is applied as a filter. Using the visual metaphor of water pouring through filters, each criteria filters the results of the previously applied criteria.

The central visualization indicates this filtration process by blocking(with a brown solid bar) the appropriate percentage out of the total number of patients. It allows the leftover percentage flow through. A fuzzy grey bar show the system cannot determine and a thin line indicates when the criteria is satisfied. Thus for undetermined and satisfied the water flows down to the next criteria and the process is repeated.

Similarly, when a patient is selected, each criteria filter changes color to indicate whether that particular patient satisfies (green), doesn't satisfy (red), or it's unknown either way (grey) whether the patient satisfies each criteria.

Notes:

- Each criteria filter can be enabled/disabled by swiping them in or out.
- Inspecting evidence can be done by selecting a patient and tapping on a criteria
- A candidate can be swiped into the potential bin

5 TASKS GIVEN TO PARTICIPANTS

1. Determine whether there are any patients being treated at Saint Joseph's hospital who are potential candidates for the "Chemotherapy before and after surgery in treating Wilm's Tumor" clinical trial.

2. Determine how many children ages 6 months to 17 years at diagnosis are being treated at Saint Joseph's hospital. (i.e. the first inclusion criteria)

3. Inspect the evidence for the criteria matching for a patient

4. Choose a candidate you like and put him or her in the potential bin.

Appendix F: Initial Project Brief

DEVELOPMENT OF UI PROTOTYPES FOR ONCOLOGY TREATMENT

Context

Within the healthcare architectures group in Philips Research, work is done on UIs for accessing oncology treatment data. This is part of a European project (Integrate: Integrative Cancer Research through Innovative Biomedical Infrastructures). Treating physicians and cancer researchers use large databases of patient information in order to personalize cancer treatment. The type of targeted tasks:

- Investigating the efficacy of treatments
- Checking how to customize a treatment for a patient
- Checking how to set up clinical trials

For this assignment, we are looking at the patient screening process. Patients in a clinic may or may not be eligible to take part in a clinical trial. A physician needs to screen the patient and check whether the patient satisfies the requirements for the trial. Usually, this is not immediately clear and additional testing needs to be done to get to an answer. A big part of the question is how to visualize the medical data in an effective way.

There will be extensive contact with the European partners in the project for design and integration. Contacts with end users will be possible for evaluation of prototypes.

Assignment

Analysis, design, creation and evaluation of a UI to perform these tasks. There are already live systems that can provide the actual data.

Deliverables

- Detailed design of the interface and workflows
- Working prototype for evaluation and user testing purposes