**Proof of Concept of Model-based Cardiovascular Prediction**

**Call identifier:** FP7-ICT-2013-10 - **Grant agreement no**: 611232

**Thematic Priority**: ICT-2013.5.2: Virtual Physiological Human

# Deliverable 3.4

# Prioritized functional specification, Personas, Wireframes, Usability test results

Due date of delivery: 30th September 2014

Actual submission date: 6th October 2014

**Start of the project:** 1st October 2013
**Ending Date**: 30th September 2016

Partner responsible for this deliverable: Fraunhofer MEVIS

Version: Final

**Dissemination Level: Restricted to a group specified by the consortium (including the Commission Services)**

**Document Classification**

| | |
|---|---|
| Title | Computational tool for computing the pressure-difference field from 4D Flow data |
| Deliverable | D3.4 |
| Reporting Period | 1 |
| Authors | Felix Ritter, Ashley Waring |
| Work Package | WP3 |
| Security | Restricted to a group specified by the consortium (including the Commission Services) |
| Nature | Report |
| Keyword(s) | Workflow Integration, Usability Optimization, Personas, Workflow Diagrams, User Research |

**Document History**

| Name | Remark | Version | Date |
|---|---|---|---|
| | | | |

**List of Contributors**

| Name | Affiliation |
|---|---|
| Felix Ritter | Fraunhofer MEVIS |
| Ashley Waring | Fraunhofer MEVIS |
| Jumana Al Issawi | Fraunhofer MEVIS |

**List of reviewers**

| Name | Affiliation |
|---|---|
| Edwin Morley-Fletcher | LYN |
| David Manset | Gnubilà |

**Abbreviations**

| | |
|---|---|
| 2D | Two-Dimensional |
| 3D | Three-Dimensional |
| 4D | Four-Dimensional |
| AVD | Aortic Valve Disease |
| CoA | Coarctation |
| US | Ultrasound |
| XA | X-Ray Angiographie |
| MRI | Magnetic Resonance Imaging |
| WP | Work Package |

# Contents

# Executive Summary

Fraunhofer MEVIS, together with collaboration from clinical partners conducted an analysis of the current status of therapy planning, decision workflow, and usage patterns in clinical practice. Patient journeys as well as clinical workflows and requirements were investigated in order to facilitate the maximum level of understanding of clinical needs and context. As part of this research, a variety of techniques were used to analyse the software currently used by clinicians, map out specified workflows, create personas, and develop wireframes for some of the software tool. In order to optimise the tool development and create universal understanding of all partners regarding the workflow, collaboration with other CardioProof work packages was instrumental in creating a cohesive result.

# Introduction

As part of the CardioProof project, visits were made to three clinical sights including ULC, OPBG, and DHZB. As part of these visits, workflows of surgical staff and procedures that occur prior to the interventions (CoA, AVD) were observed including MRI's and Echo's. Post intervention and surgical procedure workflows were also discussed and documented with help from medical staff. These observations allowed us to review the similarities and differences in workflow and develop personas for the three locations including medical staff (and specialties) present for each procedure, procedure length, post-op care and length of care, the journey patients must make for care in each of the three locations, and also opportunities for software integration.

## Work Package Connections

In addition to making the current workflow and patient journey for CoA and AVD available to all project partners, they are specifically targeted at the platform and software tool developments used by the end users, the clinical partners. As such, the partners providing the data management (WP3) and simulation tools (WP6, WP7) will use this information to optimize the clinical integration of the prototypes. Furthermore, the simulation of the comparative effectiveness (WP9) will use the workflow diagrams to refine the simulation model. As part of the usability optimization of the simulation tools, wireframes and detailed interface descriptions have been designed for the virtual stenting and hemodynamic simulation of WP6.

## Discussion on Workflow

Graphic workflows were developed after visits to the three clinical locations (ULC, OPBG, and DHZB). Mapping out the workflows of each of the individual sites allowed for in depth comparisons between the locations, identifying trends in procedures as well as differences in workflows and clinical requirements. Mapping out the workflow of the locations not only gives a deeper procedural understanding to those contributing to WP3, but also to each of the work packages allowing for in depth discussions. These collaborative meetings have enabled discussions on opportunities and timing of where developed web tools and simulation software could be most useful and appropriate and which features would be used when (and how). The workflow mapping and analysis contributes to developing unified and predictive modelling and simulation tools and helps to identify opportunities increased clinical usability and efficiency.

## Contextual Research

The contextual research carried out as part of WP3 involves immersion within the hospital environment to fully grasp the procedures and timelines that patients and families of patients with aortic coarctation and aortic valve disease experience. By performing contextual research, including the procedures preceding interventions and surgeries and post-treatment follow-ups, both the patient-family unit and the entire team of medical experts contributing the patient’s care are understood on a deeper and more insightful level. Timing of and leading up to procedures, simulations, segmentation, and other key components were all observed documented in order to understand the role that each medical expert plays in the treatment and care of a patient. By performing this type of research, a greater sense of the process of patient treatment is understood. This in-depth knowledge enables an understanding of the experience of the various users involved in the treatment and the individual responsibilities and requirements of each.

# Workflow

Three descriptive workflows were developed based on the observations at UCL, DHZB, and OPBG. These detailed and descriptive graphics can be found in Appendices 1-4. In addition to these three workflows, a third workflow was developed to sync the three into a more general workflow showcasing a unified workflow structure along with opportunities for software integration.

## Workflow Similarities

The vast majority of the workflow details between the three locations are quite similar. Pre-surgery and intervention imaging methodologies in order to determine the severity of the case are consistent with one another. All three locations also schedule routine weekly clinical conferences to dedicate time to each patient and determine the best course of treatment. All three hospitals have protocols enforcing an official decision to be made for each patient. This official decision typically results in choosing an intervention or surgery, but can also include a decision to conduct more tests/imaging to make a more informed decision about a patient's treatment.

Decisions made at clinical conferences for CardioProof patients can include to perform an intervention or valve replacement surgery or to conduct more tests. These tests can include Magnetic Resonance Imaging (MRI's), Ultrasounds (US), Electrocardiograms (ECG), or catheter exams. In the event that a catheter exam in conducted, this procedure can be combined with valve or stent replacements, blood tests, measurements of flow velocity or blood pressure, MRI's, Trans Oesophageal Echo (TEE), or surgery. These options were consistent with all three hospitals workflows. Additionally, post-surgical and intervention recovery times in hospital and follow up care with doctors were in sync with each other. Intervention patients were instructed to return to the hospital one year post intervention and valve replacement patients were instructed to return for a doctor's visit after six months and then again one year post surgery.

Software opportunities to potentially increase workflow efficiency and or accuracy were identified at the point where patients visit the cardiologist for an initial US, for additional, post clinical conference imaging of MRI and US imaging data, for post clinical conference simulation results, and during pre-surgery briefing sessions to review simulation results just before the surgery takes place.

## Workflow Differences

Although the vast majority of the workflows were in sync with one another a few minor differences were apparent when reviewing the data from each of the site visits. Patient entry into the hospital environment varies slightly between DHZB (refer to Appendix 1) and the other two hospitals. At all three hospitals patient can enter the system via the emergency room (ER) or through a private practice physician or paediatrician. At DHZB, patients can also enter the system via a visit to private cardiologist or in some instances by going directly to the hospital's cardiology department. The initial testing can also vary slightly, as DHZB performs stress tests and often MRI's on patients, unlike the other two facilities.

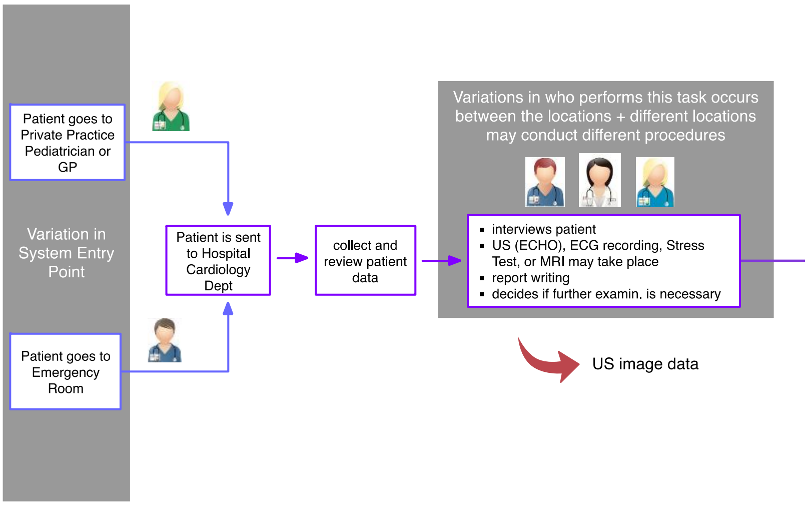



Figure 1 Workflow of Entryway into hospital system and variation in task responsibility

Other differences between the locations include the general number of people present for procedures. UCL (Appendix 3) is the largest paediatric hospital in Europe and also a teaching hospital, so the number of individuals within the OR tended to be higher than in the other locations. UCL also employs a number of fellows or trainees, so these individuals are often doing work that technicians or radiologists in the other locations are doing.

The age of patients receiving anaesthesia also varies between locations. Patients in Berlin (DHZB) and in London (UCL) typically receive anaesthesia if they are under the age of six, while patients in Rome (OPBG, Appendix 2) receive anaesthesia if they are under age eight. The variation in this age may be due to ULC's ability to have a video playing for children in the MRI machine, which can lengthen the amount of time they are willing to stay still in the machine. This reasoning however, does not work for Berlin (DHZB) where no video capabilities are currently present. The age for all three locations may become similar in the future though, as Rome (OPBG) recently installed a new MRI machine and have plans to install video capabilities in the near future. A follow-up post installation would provide more conclusive results regarding this difference in anaesthesia usage.

Similarly, the length of the MRI procedures in the locations varies. UCL has the shortest MRI collection times due to their use of self-developed, proprietary sequences. This means their MRI procedures lasts 30 minutes as opposed to DHZB and OPBG where the procedure lengths are roughly one hour. All three locations do have longer procedure times when anaesthesia is used however, due to additional procedures and individuals involved for its administration.

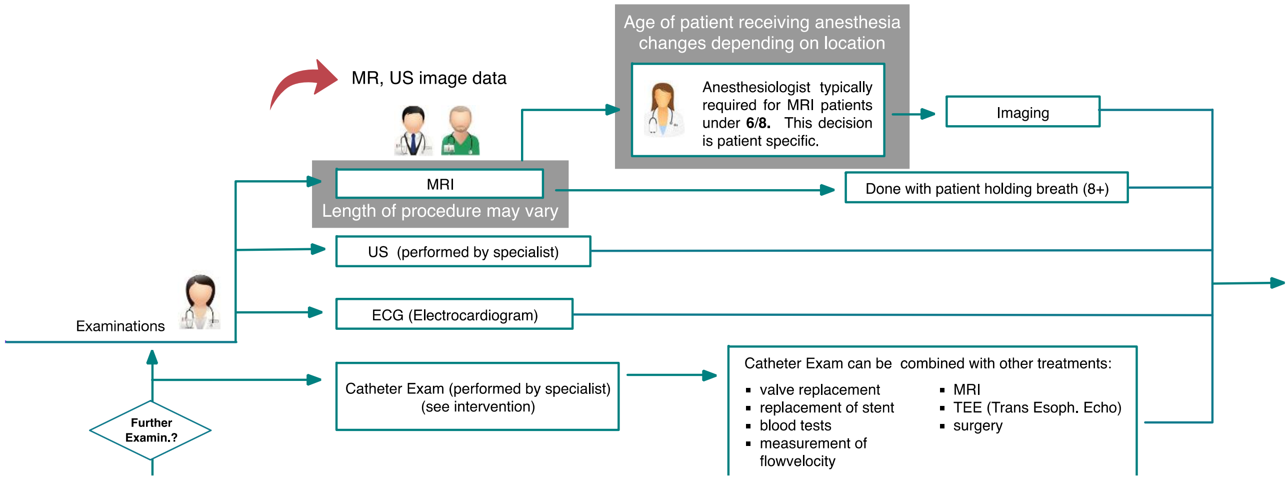



**Figure 2 Workflow of MRI procedural differences**

Another noted difference is with the post surgical and intervention paperwork provided by UCL. When the patient is released in this location, they are given the same letter sent to the patient's GP and one for him/herself so that parents and older children can legally read all results. This detailed information is not provided at OPBG or DHZB.

Although there are some differences in the workflow between the locations, the majority of the workflow for each of the locations is very similar. This constancy makes it easier to pinpoint opportunities in each of the workflows where additional software can be integrated while the differences in workflows help to visualize potential locations for improvements and increased efficiency.

## Description of Workflow Diagrams

The diagrams can be read from left to right with the patient entry into the system at the top left of the diagram. Following the arrows from left to right allows the reader to proceed through the imaging and treatment processes. Key points where decisions must be made are identified with a diamond shaped. The key on the bottom right hand side of the diagram also shows the key stakeholders involved in the workflow. These individuals can be seen throughout the patient's journey with the step they are typically involved in or responsible for. Appendix 4 displays the diagrams for the three locations in addition to the fourth diagram, which displays the generalized workflow along with simulation opportunities for new software, which is not currently being implemented.

## Personas and Stakeholders

Within the group of stakeholders involved in the processes of diagnosing, treating, and assessing CoA and AVD, we identified the ones acquiring and assessing images or the information derived from them (e.g. the simulation tools). You find a description of their participation in the workflow diagrams. To make these stakeholders more real for the software design process, we turned them into Personas (Appendix 5), sometimes also called user models. A Persona is a fictional character constructed to represent the needs of a whole category of real users (Garrett 2011). The following Personas have been extracted from the user research: Cardiac Radiologist, Cardiac Fellow / Trainee, Cardiac Interventionist, Radiographer, and

Anaesthesiologist. Figure 4 below is the persona of a Cardiac Intervention list while Figure 3 identifies each of the stakeholders.

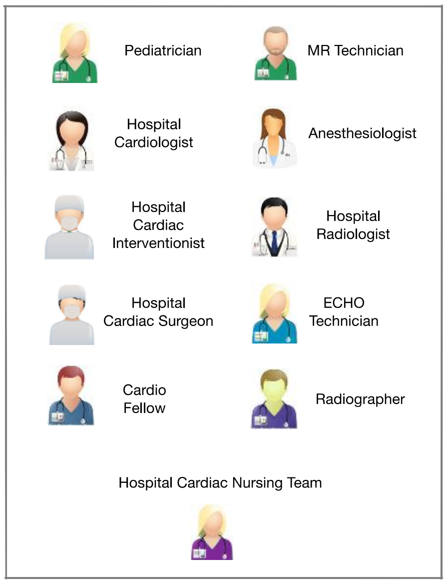



Figure 3 Stakeholder Identification

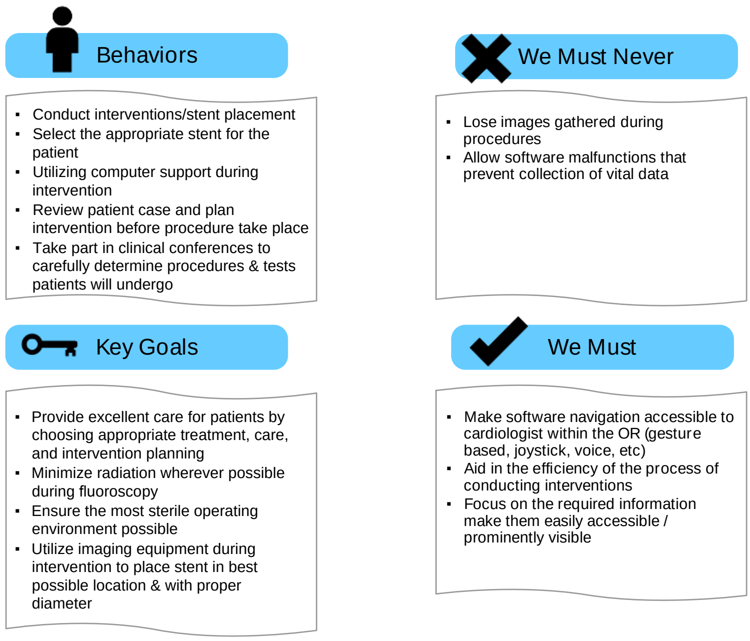



Figure 4 Persona of Interventional Cardiologist

# Wireframing and Information Design of Web Based Tool

The wireframe is a bare-bone description of all the components of a screen and how they fit together. It combines information design, interface design, and navigation design and can be used by almost anybody involved in the development process of software at some point. They serve as documentation and by itself are the result of an analysis of the required information and interaction requirements. The process of having to work out the details of the wireframes together enables each side (e.g. mathematicians, developers, clinicians) to see the requirements from the others point of view and help to uncover issues early.

We produced wireframes for the virtual stenting and Hemodynamic (CFD) modelling tool developed in WP6. This software tool will provide web-based, direct access to the study data for the cardiologists (Cardiac Fellow / Trainee, Cardiac Interventionist), which of course will benefit from usability optimization and good workflow integration.

After analysis of the required functionality (Appendices 7A-D) six workflow steps have been identified, namely:

1. Patient Selection (also querying the database for patients with certain attributes)
2. Segmentation of the Image data
3. Exploration of Hemodynamic from the image data
4. Virtual Stenting
5. Simulation of Hemodynamic based on the Virtual Stenting
6. Presentation of the Results

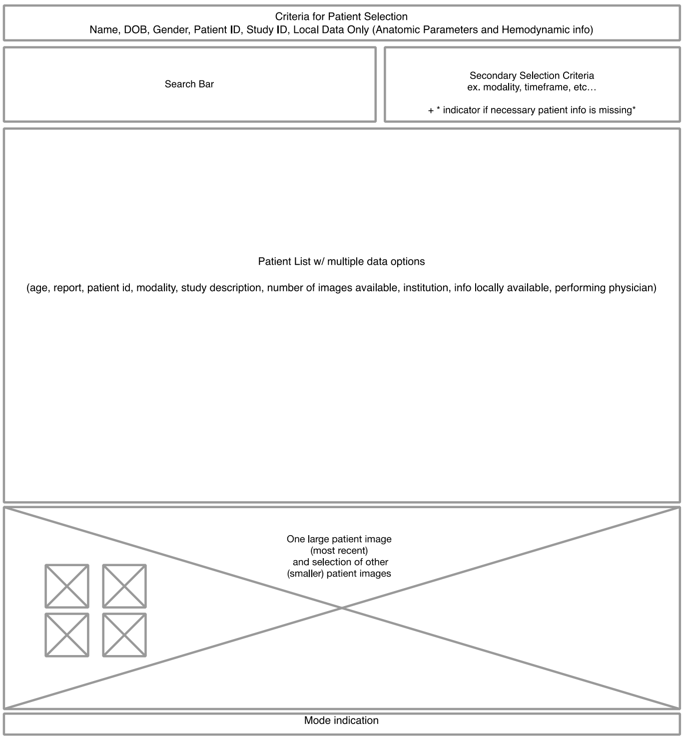



Figure 3 Wireframe of Patient Selection

Since fewer workflow steps means also less interaction modes or different screens, we combined steps with similar information design. For example, the initial exploration of the hemodynamics is based on the current shape of the aorta. The information views that are presented are the same required in order to present the results of the simulation after virtual stenting. Hence combining them not only facilitates the comparison but also reduces the number of presentation screens. Since the parameterization of the simulation can be reduced mostly to the virtual stenting, an integration of these two steps is possible as well. The final wireframes represent these four workflow steps:

1. Patient Selection (also querying the database for patients with certain attributes)

2. Segmentation of the Image data
3. Exploration of Hemodynamics from the image data & simulation
4. Virtual Stenting and Simulation of Hemodynamics

The content of the wireframes is based on the functional requirements and on the familiarity of the target users with the screen design of medical imaging workstations. We tried to optimize the interaction requirements and also analysed the required parameters, e.g. for the virtual stent placement and how small adjustments can be best carried out to an already placed stent. The wireframes are included in the appendix and a prototype based on the wireframe can be seen in Figure 6 (Refer to Appendices 6-8).

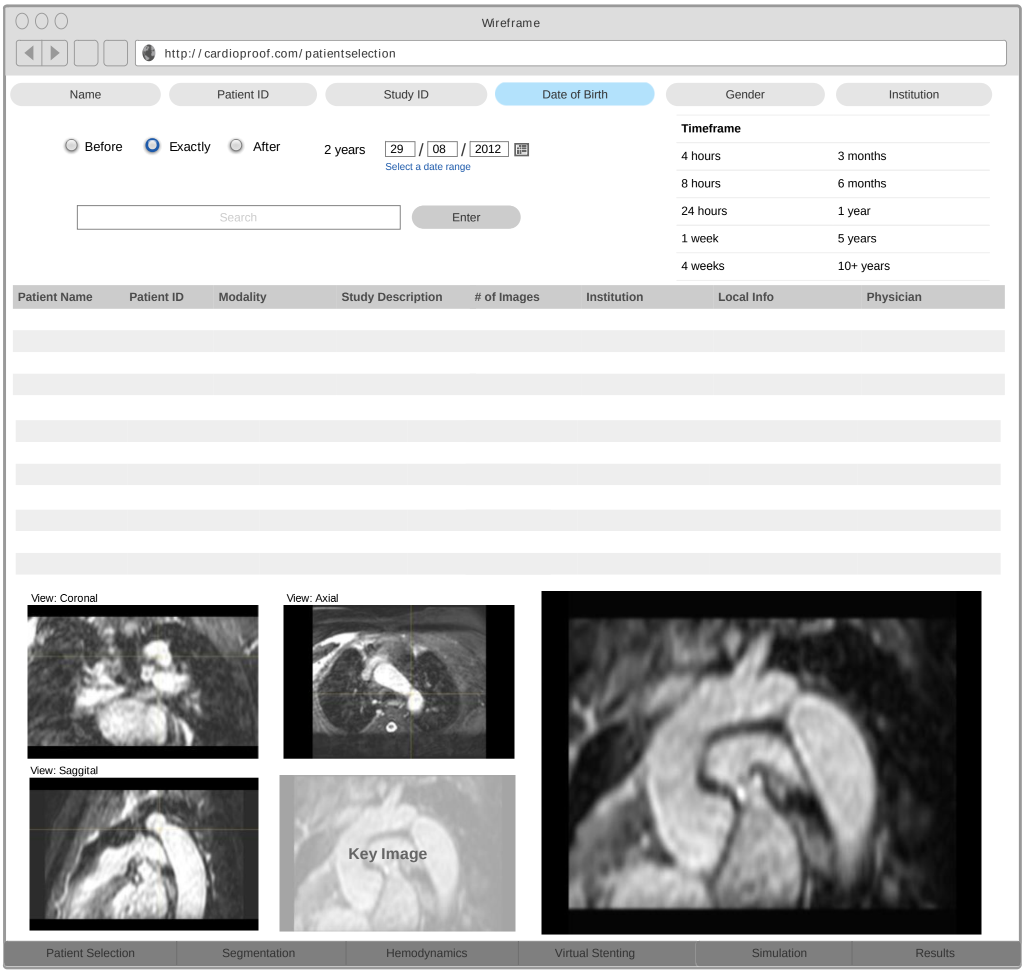



Figure 6 Prototype of Patient Selection based on wireframing

# Conclusions and Outlook

We presented the results of Task 3.3 aimed at the workflow integration and usability optimization of the software tools. Besides the work already done, we will support the on-going development of the software tools and platforms, which are directly operated by the clinical user with expert reviews and usability testing where applicable.

Next steps for the WP involve conducting usability testing and analysis on stenting simulation software. Assisting in the creation of a uniform and efficient workflow as well as thought interface design will enable the clinicians to have a better experience with the software and help to reduce both errors and time spent on completing the task.

# Bibliography

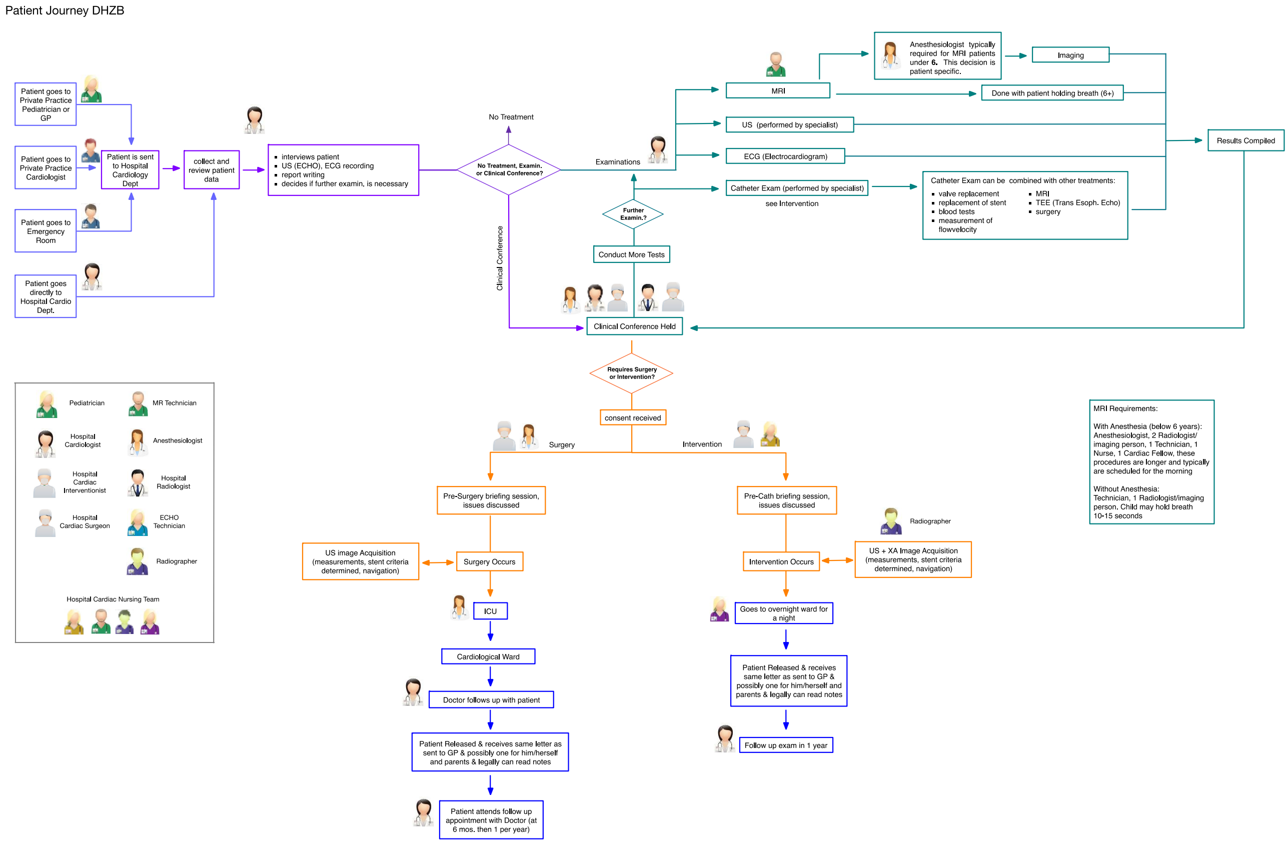
Garrett, Jesse James. “The Elements of User Experience: User-Centered Design for the Web and Beyond.” New Riders. 2011

Caddick, Richard and Cable, Steve. “Communicating the User Experience: A Practical Guide for Creating Useful UX Documentation.” Wiley. 2011

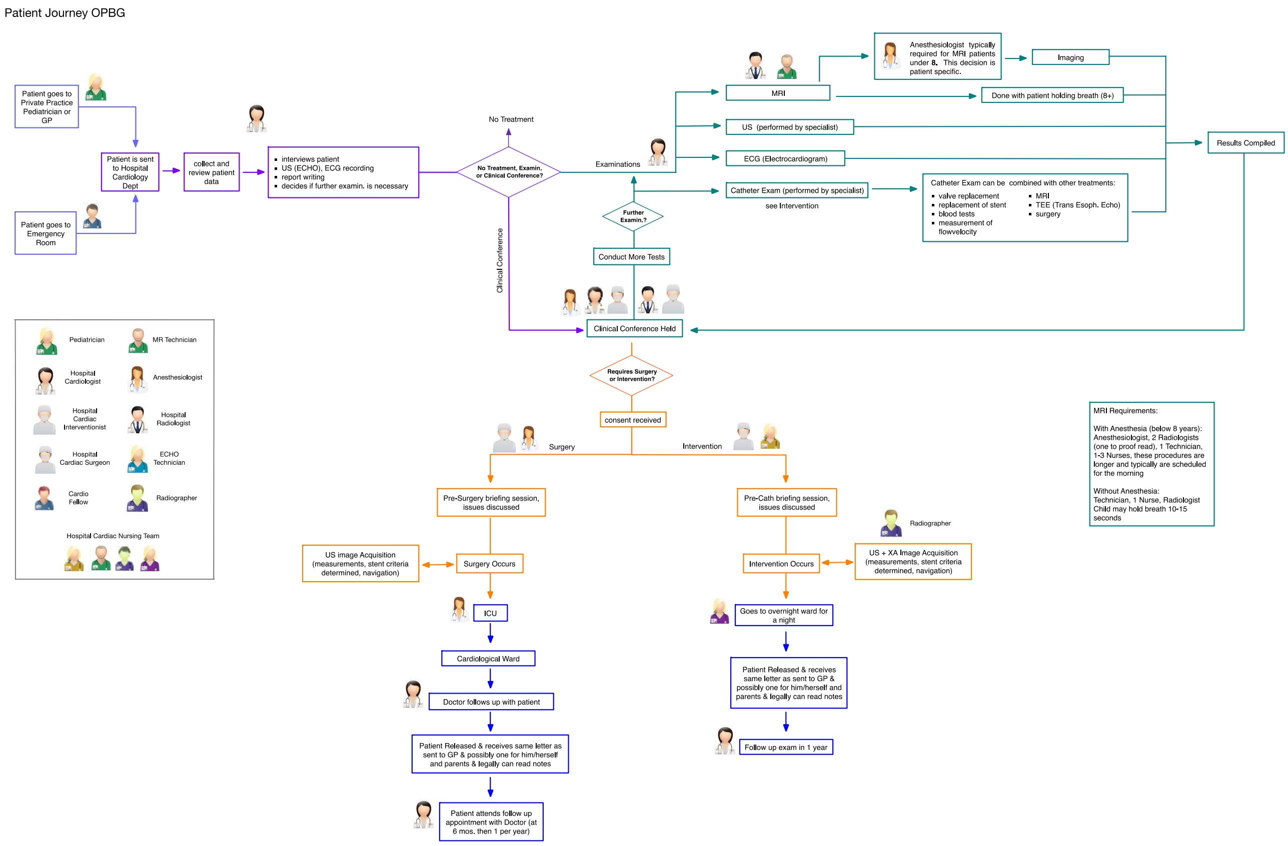
Saffer, Dan. “Designing for Interaction: Creating Innovative Applications and Devices.” New Riders. 2010

MacKenzie, I. Scott. “Human-Computer Interaction: An Empirical Research Perspective.” Morgan Kaufmann. 2013

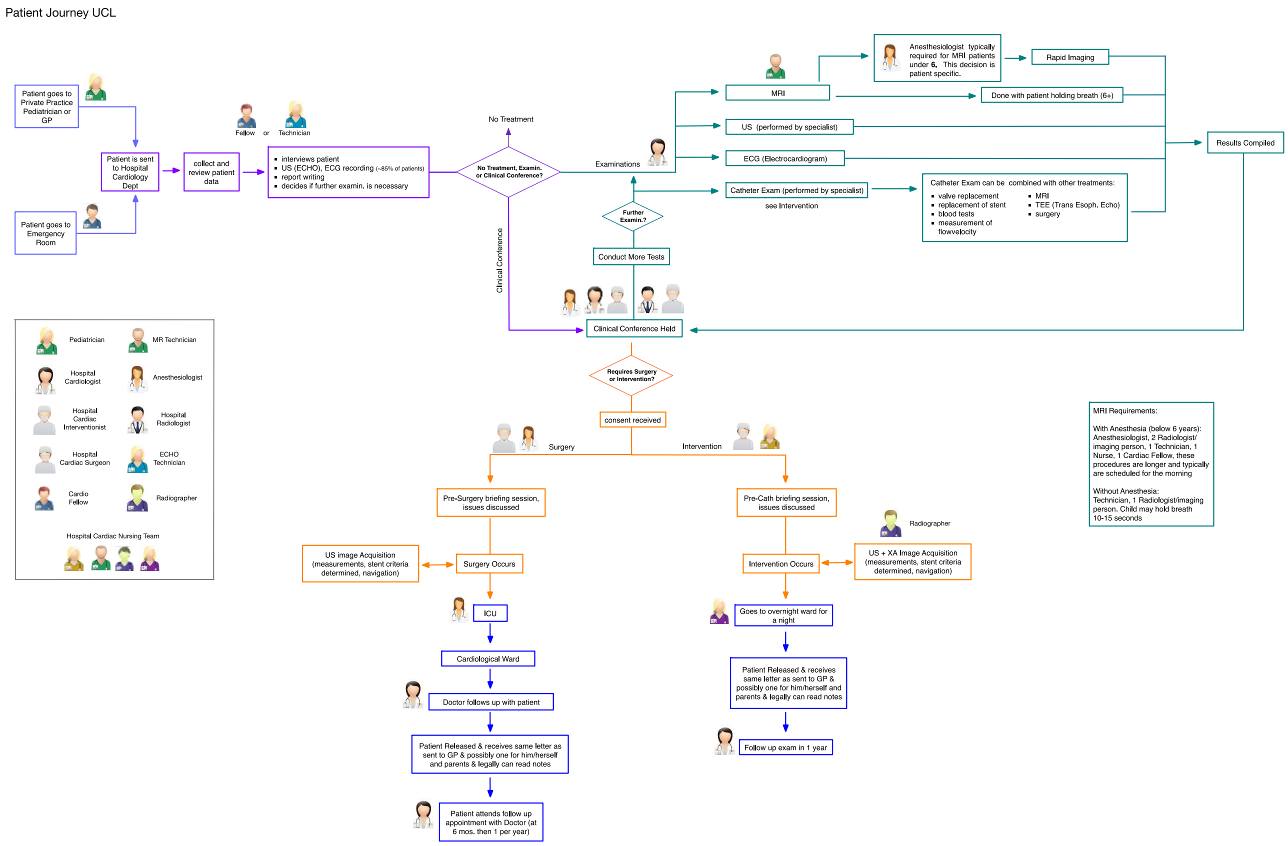
# Appendix 1 – Workflow of DHXB/Berlin



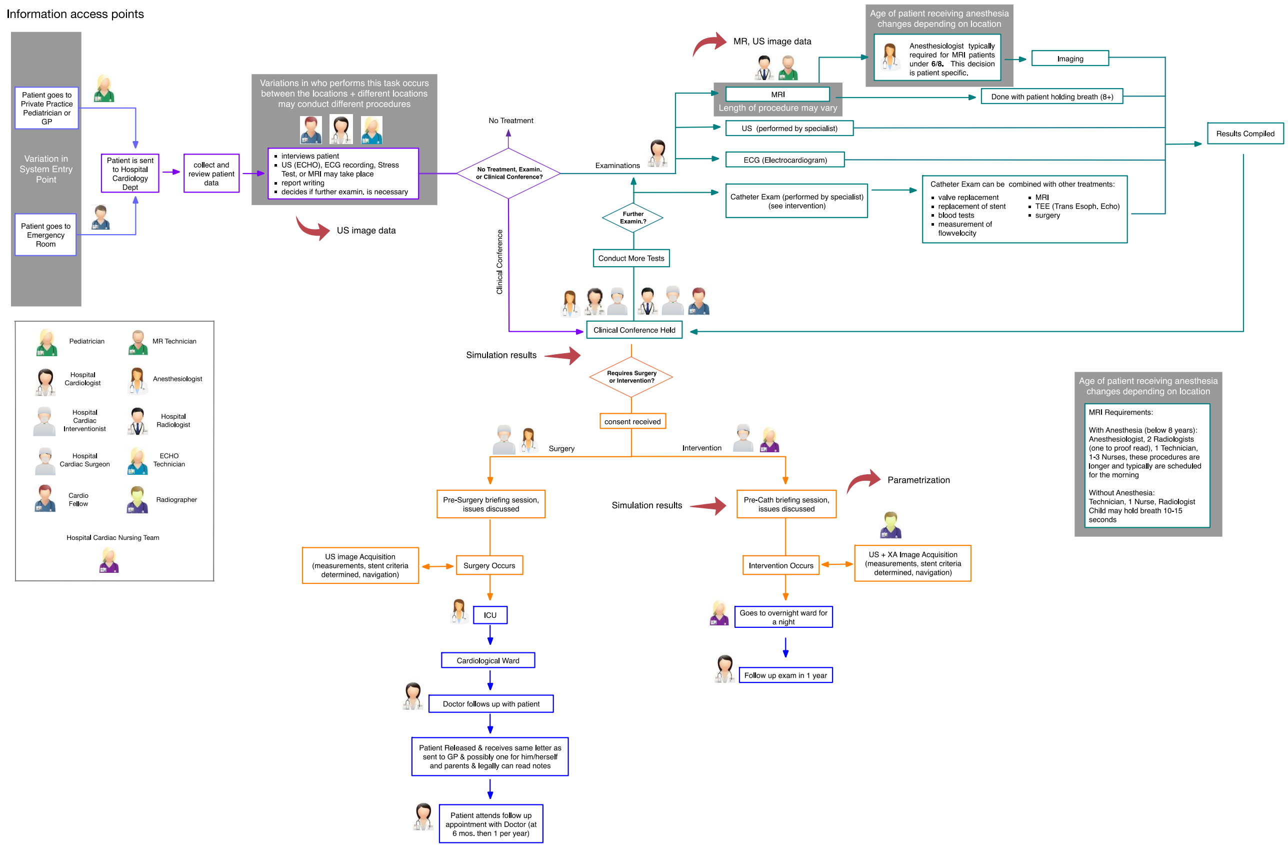

# Appendix 2 – Workflow of OPBG/Rome



# Appendix 3 – Workflow of ULC / London




# Appendix 4 – General Workflow With Access Points



# Appendix 5 – Personas

## Anesthesiologist MRI

Meredith

### Behaviors

- Monitoring patient and vital signs on monitors
- Expertise required for MRI's for (most) children under 6
- Must be present for surgeries and post surgery ICU care

### We Must Never

- Lengthen the time of the procedure due to imaging so that more anesthesia is needed

### Key Goals

- Provide patient with medication for pain management while not giving more medication than necessary

### We Must

- Reduce intervention & surgery time whenever possible with efficient imaging and pre-surgery/intervention simulations

## Cardiac Fellow | Trainee (UCL)

Dr. Dan

### Behaviors

- Frequently provide treatment (ECHOs)
- Attends clinical conferences for experiential learning
- Writes initial reports which senior cardiologist checks
- Does image analysis (e.g. segmentation)

### We Must Never

- prevent fellow from learning necessary skills/learn from senior cardiologist

### Key Goals

- Works as a fellow for 3 years, getting more responsibilities each year
- Gain professional experience to work independently in the future

### We Must

- Encourage information sharing so fellow gets the best possible training experience
- Provide state of the art/new image analysis functionality
- Leverage on the willingness to learn new procedures and tools

## Cardiac Radiologist

Dr. Marina

### Behaviors

- Guides technician through MRI describing which images are needed
- Prefers collecting imaging data / guiding tech because she knows she will collect all the necessary data this way
- Only interacts with patients at the time when imaging is taking place

### We Must Never

- Lose images gathered during procedures
- Allow software malfunctions that prevent collection of vital data

### Key Goals

- Collect all of the necessary images to make informed decisions about patient treatments and care
- Aid the in decision making at clinical conferences for the best possible path of treatment for the individual patient's needs taking many factors into account (history, anatomy, age, gender, etc…)

### We Must

- Provide easy upload of images for CardioProof study (e.g. DICOM node accessible by MRI workstation)

## Cardiac Interventionist

Dr. Graham

### Behaviors

- Conduct interventions/stent placement
- Select the appropriate stent for the patient
- Utilizing computer support during intervention
- Review patient case and plan intervention before procedure take place
- Take part in clinical conferences to carefully determine procedures & tests patients will undergo

### We Must Never

- Lose images gathered during procedures
- Allow software malfunctions that prevent collection of vital data

### Key Goals

- Provide excellent care for patients by choosing appropriate treatment, care, and intervention planning
- Minimize radiation wherever possible during fluoroscopy
- Ensure the most sterile operating environment possible
- Utilize imaging equipment during intervention to place stent in best possible location & with proper diameter

### We Must

- Make software navigation accessible to cardiologist within the OR (gesture based, joystick, voice, etc)
- Aid in the efficiency of the process of conducting interventions
- Focus on the required information make them easily accessible / prominently visible

## Radiographer Intervention

Dr. Joy

### Behaviors

- Junior Level Radiographer moves the C-arms and fills up the dye injectors
- Senior level does MRI's
- Makes x-rays for Radiologist to interpret
- Directed by Radiologist or Imaging Cardiologist which images to capture
- Operates software as instructed by the cardiologist during the intervention

### We Must Never

- Delay or prevent the capture of necessary images

### Key Goals

- Collect clear and usable images for the radiologist to interpret
- Provide the images and quantitative information (e.g. measurements) required for effective and efficient procedures

### We Must

- Optimize image capturing procedure via efficient and easy to use software
- Efficient interaction with image data

# Appendix 6 – Wireframes Development

Virtual stenting and hemodynamics simulation (interaction / information)

**Patient Selection** ▶ PACS access ▶

Criteria for patient selection:
- name/ID/study ID
- age
- gender
- anatomic parameters / geometric description (ex. ratio between aortic and stenosis diameter)
- hemodynamic info / pressure gradient (before and after stenosis)
- feedback on currently available data for patient (icons showing what info is already available)

**Segmentation** ▶ positioning of **include** (2D interaction for placing markers in 3D) & **exclude** markers (in 3D) ▶ 2D images giving 3D info & also real 3D interaction ▶ add tool to cut off parts of the segmentation ▶ annotate structures e.g. carotid arteries

**Exploration of Hemodynamics**

**Data reviewed** (- used to decide if stent is placed? - confirm this)

These two steps are used decide initial stent placement/ location

**Quantitative**
pressure curve along center line
(pressure value for each part of the line)

**Qualitative**
ray casting / MIP (maximum intensity pressure)
(usually at location of stenosis) ▶ this info used for virtual stenting planning

**Virtual Stenting**

Adjustable values **VESSEL**
(user will not be able to change)
- Rigidity

User adjusts certain values **STENT:**
- stiffness of stent (effects how straight vessel is)
- radial force
- balloon diameter

These are adjusted/edited using 3D model to assume potential outcome

**Simulation**
(additional hemodynamics results)

**Minimal user interaction ideal** (easy)
- BP adjustment

**Other physiodynamic parameters may be necessary**
- selection of the 3 branches
- boundary selection and/or define end of aortic arch to place cut/boundary

▶ Simulation tool should handle the rest

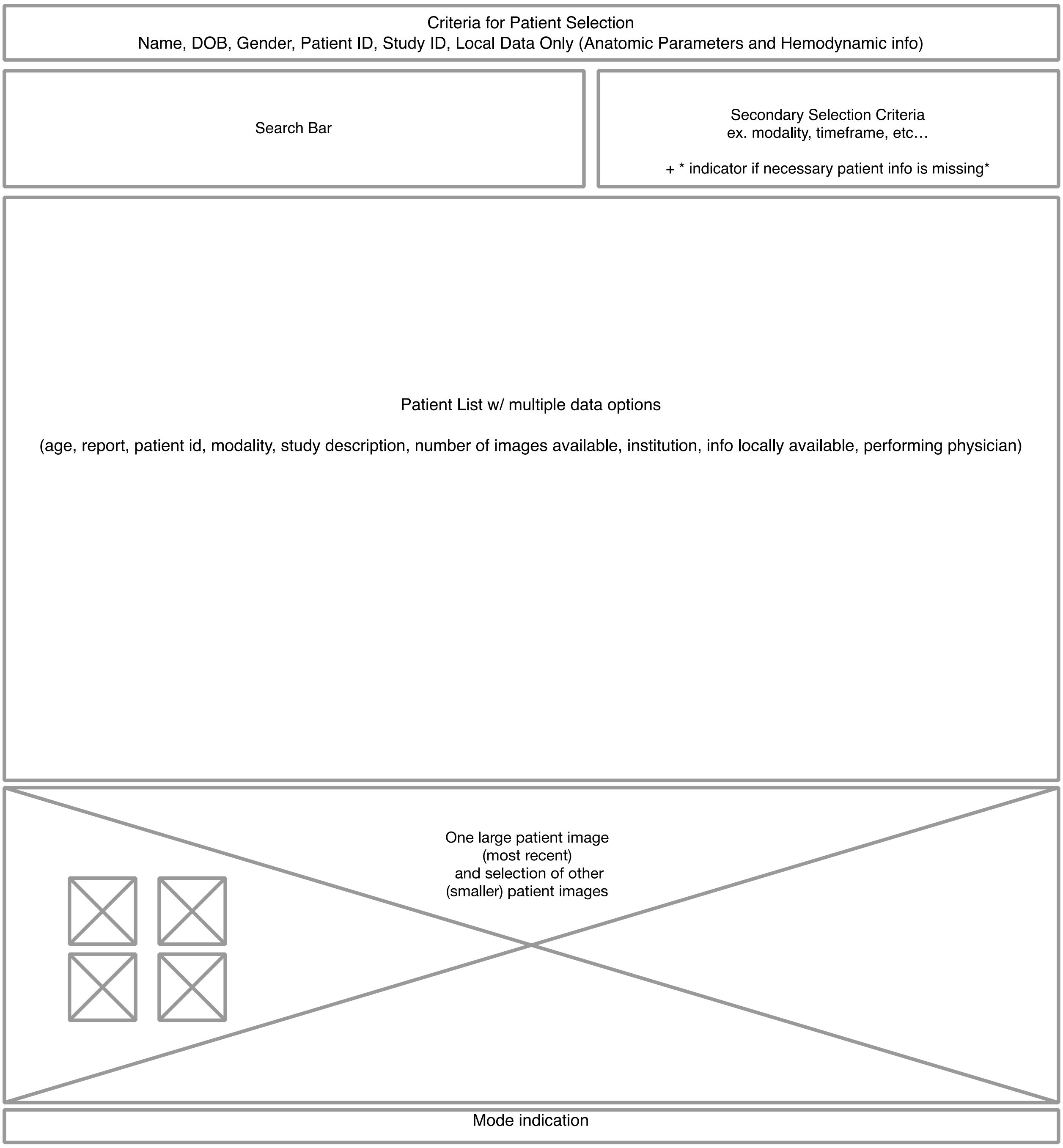
**Result / Presentation**

- linked side by side view to visualize data sets
- overlay

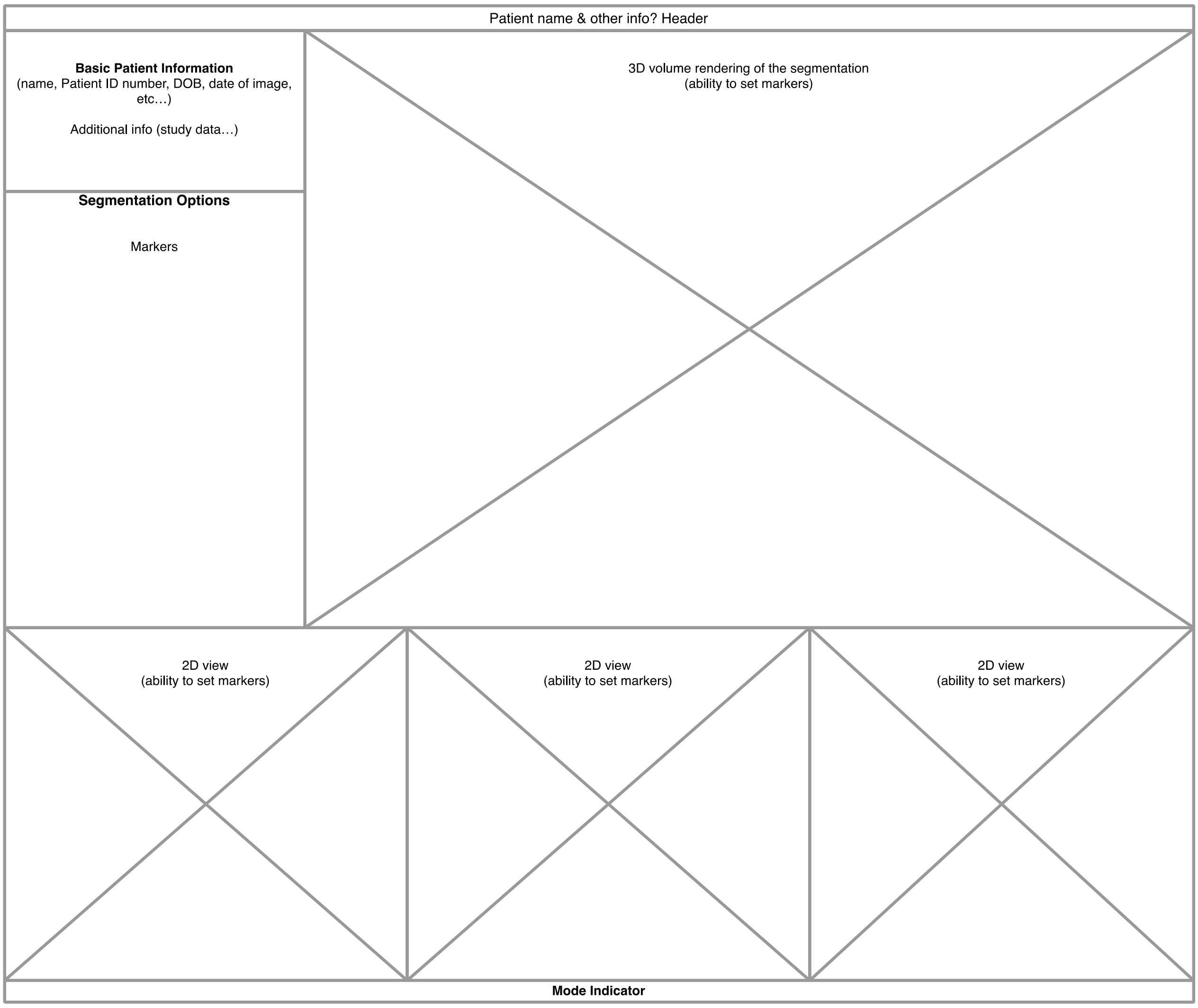
**Future**: deal with data schemes
Persistency handling possible:
- new data branches created
- result comparison between different simulations

# Appendix 7 - Wireframes

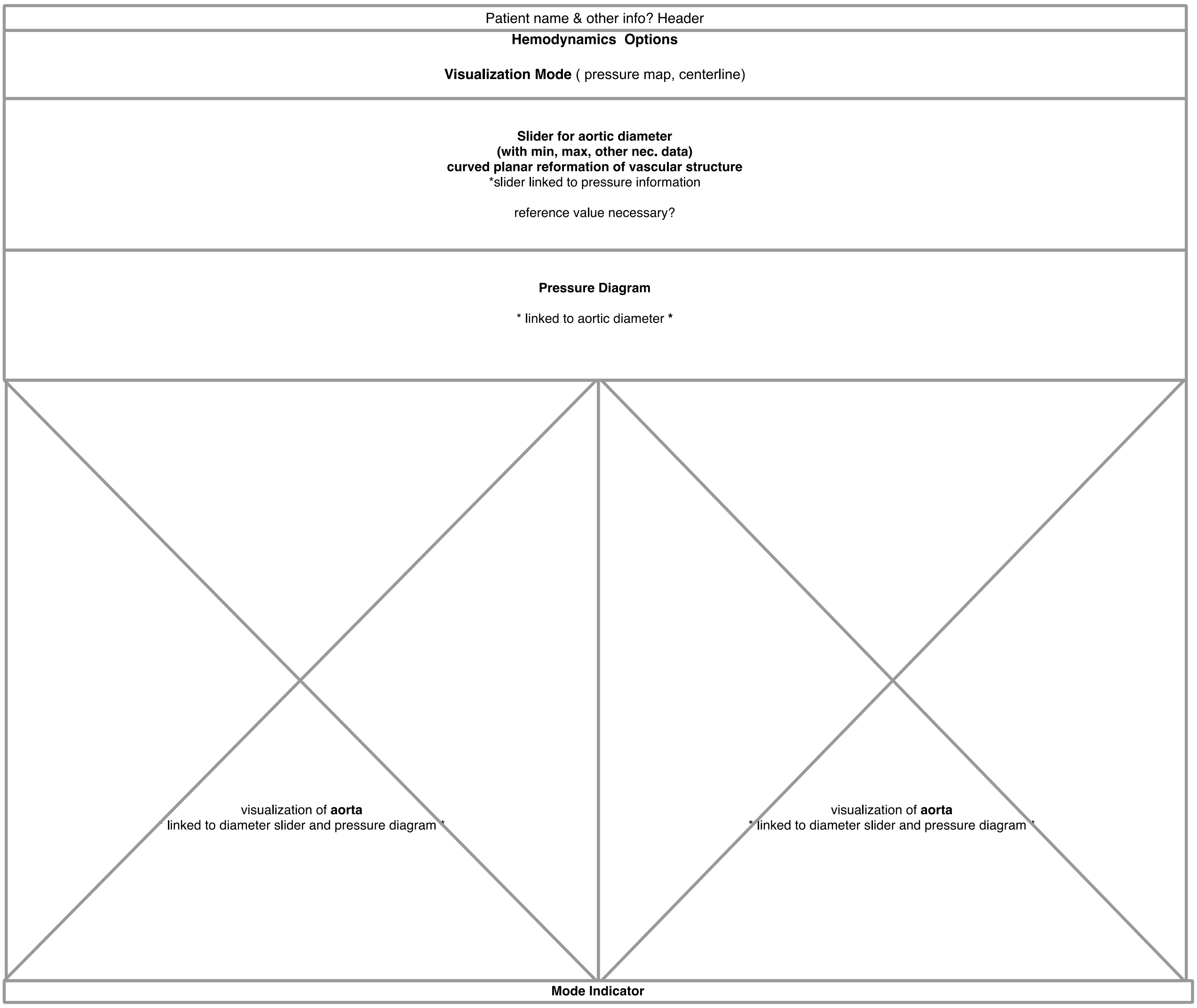
## A. Patient Selection



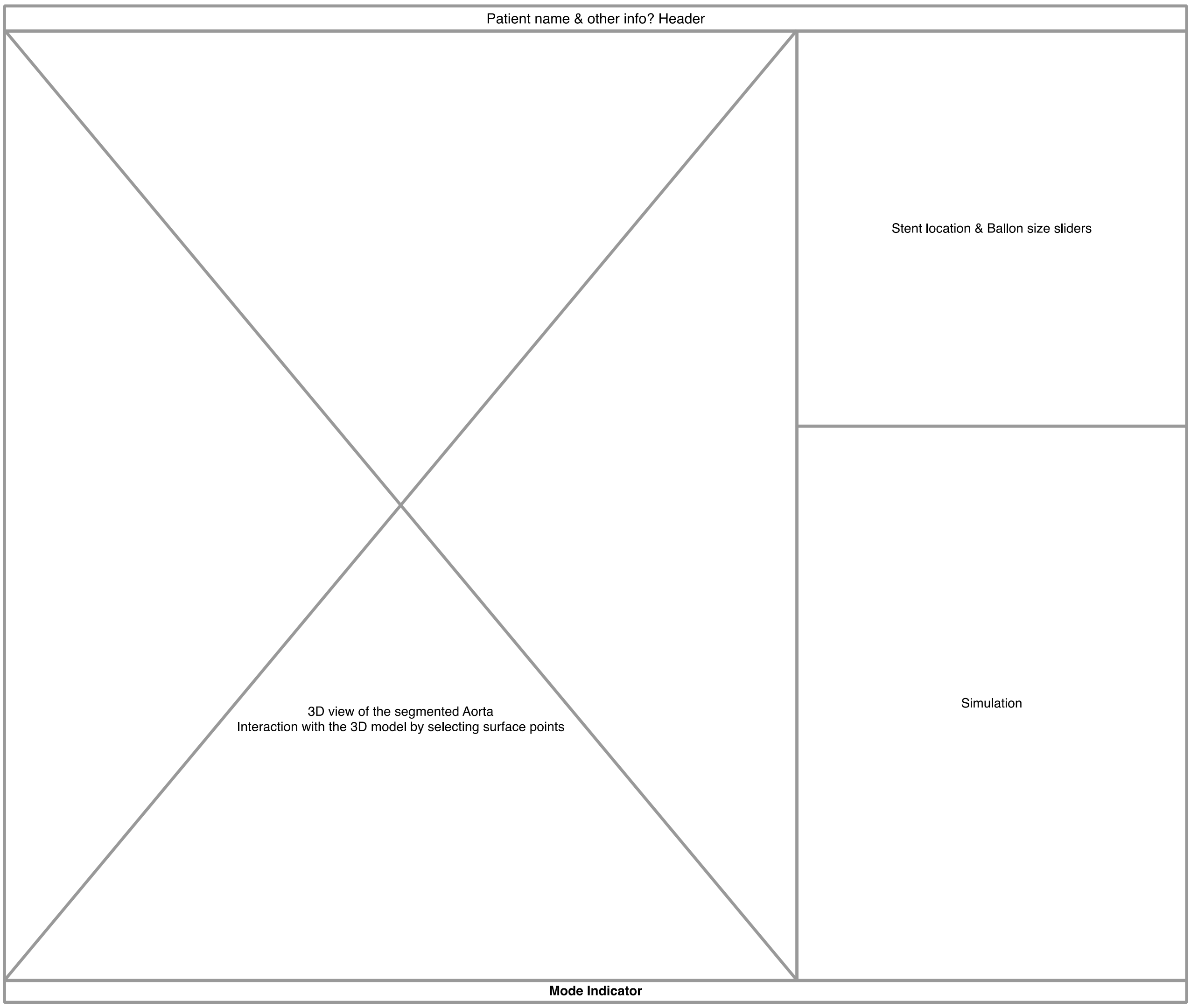
## B. Segmentation



## C. Exploration of Hemodynamics & Segmentation



## D. Virtual Stenting



# Appendix 8- Web Tool Prototype