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# Health Care Informatics Support of a Simulated Study

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**HEALTH CARE INFORMATICS SUPPORT OF A SIMULATED STUDY**

by

Zeinab Salari Far

A Thesis Submitted in  
Partial Fulfillment of the  
Requirements for the Degree of  
Master of Science  
in Health Care Informatics

at

The University of Wisconsin-Milwaukee

December 2012

## **ABSTRACT**

### **HEALTH CARE INFORMATICS SUPPORT OF A SIMULATED STUDY**

by

Zeinab Salari Far

The University of Wisconsin-Milwaukee, 2012  
Under the Supervision of Professor Peter J Tonellato  
and  
Professor Timothy B Patrick

The objective of this project is to assess the value of REDCap (Harris, 2009) by conducting a simulated breast cancer clinical trial and demonstration. REDCap is a free, secure, web-based application designed to support data capture for research studies. To assess REDCap's value, we conducted a simulation of a clinical trial study designed to compare the use of two new technologies for breast cancer diagnosis and treatment with current best practice breast cancer diagnosis and treatment. We call the trial, "Real-Time Operating Room BC Diagnostic Treatment (RORBCDT)". The RORBCDT clinical trial is designed to assess the value of a new breast cancer operating room diagnostic technology "Intra-operative diagnosis of Sentinel Lymph Node (Sentimag)"( Keshtgar, n.d) and real-time treatment option "Intra-operative Radiotherapy (IORT)"( Williams, 2011.) A Sentimag is used to "stage" certain cancers to determine their degree of spread to lymph nodes. If the diagnose is positive, then the new treatment device (IORT) is used to treat the remaining cancerous tissue.

This Clinical Trial simulation consists of several steps:

1. Design the clinical trial
2. Create the REDCap project environment to conduct the trial
3. Recruit and train fictitious patients, providers and project team.
4. Execute the simulated trial
5. Assess the value of REDCap in conducting the simulation.

Note: This entire exercise is a **SIMULATION** – no actual patients, physicians or devices were used. Rather, a simulated clinical trial was performed with trained volunteers pretending to be patients, physicians and research staff. Consequently, the assessment of REDCap and all results, conclusions and observations are based on a **SIMULATION**. The simulated clinical trial - RORBCDT - is a two arm clinical trial designed to test the efficacy of the real-time diagnostic (Sentimag) and treatment (IORT) devices. In one arm of the trial, breast cancer surgery patients (volunteers not real patients) will experience a simulated best practice operation and therapy. In the other arm, breast cancer surgery patients (volunteers not real patients) will experience a simulated real-time diagnosis and treatment using the intra-operative devices. This research seeks to execute a fictitious clinical trial to assess the value of REDCap.

We anticipate that this simulation and those similar to it, will help health care researchers become familiar with REDCap and assess REDCap's value and use in conducting health research.



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I lovingly dedicate this thesis to my husband, who supported me each step of the way.  
Also, my unreserved gratitude goes to my parents who always encouraged and support all  
of my scholarly endeavors.

# TABLE OF CONTENTS

Chapter 1 .....	I
Introduction To Health Care Informatics.....	2
Chapter 2.....	5
Needs For Clinical Trial Management System .....	6
Assessment Of Options.....	7
Why Redcap For This Project.....	8
Research Objective .....	9
Clinical Trial Preparation.....	10
Chapter 3 .....	12
Introduction.....	13
Real-Time Operating Room Breast Cancer Diagnostic Treatment .....	13
Real-Time Operating Room Breast Cancer Diagnostic Treatment Rorbcdt Clinical Trial .....	17
Rorbcdt Site .....	17
Public Health Informatics Tools Supporting Rorbcdt .....	18
Participants.....	26
Rorbcdt Implementation And Results.....	28
Chapter 4.....	32
Discussion .....	33
Conclusion .....	34
Limitation.....	35
Bibliography.....	37
Appendices.....	42
Appendix A : Redcap.....	43
Appendix B : Installing Redcap V4.5.1 On Local Windows Machine.....	46
Appendix C : Installing Redcap V4.5.1 On Local Synology Dsm 3.2 .....	54
Appendix D : Breast Cancer Clinical Trial Assesment Surveys.....	59
Appendix E : Breast Cancer Clinical Trial Completion Survey .....	68
Appendix F : Informed Consent Form.....	71
Appendix G : Data Analysis .....	80
Appendix H : Figures.....	110

## LIST OF FIGURES

Figure 1 : Breast Cancer Clinical Trial Project.....	111
Figure 2: Breast Cancer Clinical Trial Steps .....	112
Figure 3: REDCap Login Page .....	113
Figure 4: REDCap Projects.....	113
Figure 5: How to Create Project .....	114
Figure 6: REDCap Training Resources .....	114
Figure 7: REDCap Project Home .....	115
Figure 8: REDCap Project Online Designer .....	115
Figure 9: Basic User Rights .....	116
Figure 10: Comprehensive User Rights .....	117
Figure 11: Data Export Tool .....	118
Figure 12: Data Import Tool .....	119
Figure 13: Data Comparison Tool .....	120
Figure 14: Logging .....	120
Figure 15: Designate Instruments for the Events.....	121
Figure 16: Scheduling .....	122
Figure 17: Calendar.....	123
Figure 18: File Repository .....	123
Figure 19: Report Builder .....	124
Figure 20 : Eligibility Report.....	125
Figure 21: Define Events .....	126
Figure 22: Create Multiple Arms .....	127
Figure 23: Data Entry.....	127

## LIST OF TABLES

Table 1: Assesment survey-Patients- Race .....	81
Table 2: Assesment survey-Patients- Smoker.....	81
Table 3: Assesment survey-Patients- Marital status .....	82
Table 4: Assesment survey-Patients- Breast cancer diagnosis .....	82
Table 5: Assesment survey-Patients- Clinical trial knowledge .....	83
Table 6: Assesment survey-Patients- Clinical trial participation.....	83
Table 7: Assesment survey-Patients- Type of participated clinical trial .....	84
Table 8: Assesment survey-Patients- Willingness to participate in BC clinical trial .....	84
Table 9: Assesment survey-Patients- Willingness to participate in RORBCDT .....	85
Table 10: Assesment survey-Patients- Menopause age .....	85
Table 11: Assesment survey-Patients- Menopause status .....	86
Table 12: Assesment survey-Patients- First Menstoral cycle .....	86
Table 13: Assesment survey-Patients- Having Children .....	87
Table 14: Assesment survey-Patients- Age having first child .....	87
Table 15: Assesment survey-Patients- Number of children .....	88
Table 16: Assesment survey-Patients- Biopsy.....	88
Table 17: Assesment survey-Patients- Closed relatives with breast cancer .....	89
Table 18: Assesment survey-Patients- Breast cancer surgery .....	89
Table 19: Assesment survey-Patients- Type of breast cancer surgery .....	90
Table 20: Assesment survey-Patients- Medication.....	90
Table 21: Assesment survey-Patients- Radiotherapy .....	91
Table 22: Assesment survey-Patients- Intra-operative radiotherapy .....	91
Table 23: Assesment survey-Patients-Radiotherapy after surgery .....	92
Table 24: Assesment survey-Physicians- Specialty.....	93
Table 25: Assesment survey-Physicians- Breast cancer diagnostic tests .....	93
Table 26: Assesment survey-Physicians- Breast cancer exprience .....	94
Table 27: Assesment survey-Physicians- Biopsy result .....	94
Table 28: Assesment survey-Physicians- Frequent biopsy.....	95
Table 29: Assesment survey-Physicians- Breast cancer treatment .....	95

Table 30: Assesment survey-Physicians- Type of breast cancer surgery .....	96
Table 31: Assesment survey-Physicians- Type of Radiotherapy .....	96
Table 32: Assesment survey-Physicians- Experience in sponsered clinical trial .....	97
Table 33: Assesment survey-Physicians- Type of previously attended clinial trial .....	97
Table 34: Assesment survey-Physicians- Experience using sentimag .....	98
Table 35: Assesment survey-Physicians- Experience using sentimag .....	98
Table 36: Assesment survey-Physicians- Intrest in clinical trial using sentimag .....	99
Table 37: Assesment survey-Physiciansce- Sentimag impact on breast cancer treatment	99
Table 38: Assesment survey-Physicians- Experience using IORT.....	100
Table 39: Assesment survey-Physicians- Intrest in clinical trial using IORT .....	100
Table 40: Assesment survey-Physicians- IORT impact on breast cancer treatment .....	101
Table 41: Completion survey-Patients- Clinical trial justification .....	102
Table 42: Completion survey-Patients- Side effects.....	102
Table 43: Completion survey-Patients- Consent form.....	103
Table 44: Completion survey-Patients- Trial cost .....	103
Table 45: Completion survey-Patients- Investigators' manner .....	104
Table 46: Completion survey-Patients- Overall satisfaction .....	104
Table 47: Completion survey-Patients- Clinical trial recommendation .....	105
Table 48: Completion survey-Patients- Opinion on clinical trial .....	106
Table 49: Completion survey-Physicians- Clinical trial justification.....	106
Table 50: Completion survey-Physicians- Preferred method .....	107
Table 51: Completion survey-Physicians- Clinical trial overall satisfaction.....	107
Table 52: Completion survey-Physicians- Patients participation overall satisfaction....	108
Table 53: Completion survey-Physicians- Impact of trial outcomes.....	108
Table 54: Completion survey-Physicians- Imapct on future treatement .....	109

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# **Chapter1**

## Introduction to Health Care Informatics



## **Introduction to Health Care Informatics**

In 2009, William Hersh defined “Health Information Technology (HIT) as the term used to describe the application of computers and technology in health care settings” (Hersh, 2009). Hersh also defined “informatics” as “the discipline focused on the acquisition, storage, and use of information in a specific setting or domain” (Hersh, 2009). Informatics is more about information than technology, but information has its roots in a domain and it distinguishes that from information and information science. The former School of Informatics at the State University of New York Buffalo defined informatics as the intersection of the people, information, and technology. Charles Friedman has defined his "fundamental theorem" of informatics, Three corollaries illustrate that informatics is more about people than technology and states that informatics is more about using technology to help people do cognitive tasks better than about building systems to mimic or replace human expertise (Friedman, 2009).

Reinold Haux (Haux, 1997) defined “Medical Informatics” as the discipline concerned with systematic processing of data, information and knowledge in medicine and health care. The domain of medical informatics covers computational and informational aspects of processes and structures in medicine and health care. The aims of medical informatics are: To provide solutions for problems related to data, information and knowledge processing and to study general principles of processing data, information and knowledge in medicine and health care. The ultimate goal of medical informatics should always be to improve quality of health care, and to improve research education in medicine and in the health sciences (Haux, 1997).

In 2009, President Barack Obama stated that "We have the most inefficient health care system imaginable. We're still using paper. Nurses can't read the prescriptions that doctors have written out. Why wouldn't we want to put that on an electronic medical record that will reduce error rates, reduce our long term costs of health care, and create jobs right now?" (Bernie Monegain, 2009). Since, HIT was elevated to new prominence in the US by inclusion in the *American Recovery and Reinvestment Act (ARRA) of 2009*, the federal economic stimulus package signed into law by President Barack Obama on February 17, 2009 (Hersh, 2009).

When health records were first computerized, the term electronic medical record (EMR) was most commonly used. However, this has mostly been supplanted by the term electronic health record (EHR), which implies a broader and more longitudinal collection of information about the patient (Detmer, 2008).

Clinical informaticians are playing an important role in transition from paper records to electronic ones. Recently, the number of electronic solutions and applications to manage electronic health record have been increasing.

In the 1990s Electronic Data Capture (EDC) was referred to "remote data capture" (RDC). They were essentially data "silos" that had no easily ability to interchange their data with other systems. Today, the integration of EDC software with other types of software in the eClinical spectrum (randomization, supply management, adverse event reporting, coding, submissions, etc.) systems is increasingly feasible and beneficial. The ability to quickly and reliably import electronic data from other sources (such as lab reports, imaging data sources, and electronic health records) is also becoming commonplace. The rise of open source EDC software and independent

standards for characterizing and sharing data are key enablers towards accelerating the productivity and decreasing the cost and burden associated with clinical trials (OpenClinica, n.d).

Therefore, clinical informaticians who bring expertise at the intersection of health care and IT to assure successful adoption and use of HIT and the information within it are responsible to assess the values of different applications prior to adopting them in their health facilities. These individuals also optimize the use of information through leadership of clinical staff, organizing and structuring information for its direct and secondary use, and serving as a bridge between IT and clinical personnel (Hersh, 2009).

In the past ten years, Medical Informatics has evolved from a more conceptual approach to improving healthcare to a funded, well documented science that has achieved a number of substantial outcomes and is funded through ARRA to help change the practical approach and use of HIT in best care practice. One important role of Medical Informaticians, is to provide insight and value of the tools, methods and approaches that medical informatics produces. The objective of this thesis is to conduct a low cost, highly efficient, yet representative clinical trial simulation to demonstrate the value on one of the most promising medical informatics systems – REDCap.

# **Chapter 2**

## **Clinical Trial Management System**

### **Needs for Clinical Trial Management System**

A clinical trial is a research study in which a treatment or therapy is tested in people to observe whether it is safe and effective. The information obtained from clinical trials helps to improve health care and to keep people healthier. It is also conducted by researchers to find out which treatments are more effective than others. The results of clinical studies give better knowledge about diseases and its conditions (Shweta, 2007). A Clinical Trial Management System (CTMS) is software to manage the large amount of data in clinical trial studies. The software is customizable to maintain and manage the planning, preparation, performance, and reporting of clinical trials. In addition, it can track deadlines and milestones in targeted clinical trial. According to Thomson CenterWatch, in 2004, pharmaceutical sponsors used Electronic Data Capture EDC and/or interactive voice response systems (IVRS) in 44 percent of Phases I - IV clinical trials (Korieth, 2005).

The number of clinical trials and their complexity is growing accompanied by longer trial duration. The costs for conducting clinical trials are rapidly increasing and manual and paper based methods are no longer useful to manage clinical trials. Therefore, there is a need for a better method to help investigators reduce trial length and manage huge amount of data and reduce expenditure. Clinical trials are increasingly global in nature and conducted across multiple geographies. Making trial information accessible to the right people at the right time with the right level of detail becomes ever more critical.

### **Assessment of options**

The cost of purchasing and supporting major vendor solutions for clinical data management systems can be prohibitive (Value of Hosted Clinical Data Environments, n.d). Although costs can be justified in large organizations running multiple sponsored clinical trials, the academic research environment is typically home to many preclinical investigator-initiated research studies requiring a fraction of the subjects needed for larger trials. In these cases, traditional EDC setup time for CRFs and software expense may outweigh benefits for the study (Weber, 2005).

An Electronic Data Capture (EDC) system is a computerized system designed for the collection of clinical data in electronic format for use mainly in human clinical trials. Modern electronic data capture software is typically web-based, which means that the software runs entirely on a web server and utilizes a thin client which means that the only tool you need is an ordinary web browser connected to the internet in order to access and utilize the EDC software. Clinical trial data may be captured electronically or in paper form and later transcribed into the EDC system (OpenClinica, n.d).

The REDCap (Research Electronic Data Capture) is a free, secure, web-based application designed to support data capture for translational and clinical research studies and provides a rapid-development and flexible informatics systems-based approach to supporting studies (Harris, 2009). The system was developed by a multi-institutional consortium initiated at Vanderbilt University.

REDCap enables global clinical organizations to maintain a centralized trial management database while providing users with the most relevant and appropriate information based on their specific roles and responsibilities. Data collection is

customized for each study or clinical trial by the research team. REDCap is useful for collecting and tracking information and data from research studies, scheduling study events (e.g., patient visits) and conducting surveys (Appendix A).

### **Why REDCap for this Project?**

REDCap offers the following features which are very useful to collect data for research studies and conduct different kind of projects (e.g. longitudinal projects). REDCap has been developed over two years by a wide collection of investigators and developers (Harris, 2009). Many validation projects have been conducted and after this effort REDCap is:

- Fast and has Quick project start-up. Clinical report forms can be implemented without the need for a programmer.
- Easy. It has intuitive user interface and work flow, online training materials which is readily available.
- Fully customizable. You are in control of shaping your database.
- Secure. It has backed up offsite nightly and hosted in a secure environment.
- Web-based. You are able to enter data or build your database from anywhere in the world over a secure web connection with authentication and data logging. This feature will help to conduct collaborative studies.
- A data export tool. You can export data to common data analysis packages, data export function for Excel, SAS, Stata, R, and SPSS.

- A data import tool. It has data import capability through Microsoft Excel.
- A multi-site utility. It can be used by researchers from multiple sites and institutions.
- An autonomous user management tool. Research groups have complete autonomy and control to add new users and set several levels of specific user rights.

REDCap has some advanced features including mid-study modifications, auto-validation, branching logic, and calculated fields.

### **Research Objective**

According to Haux's statement, the essential aims of medical informatics are diagnostic, therapy, therapy simulation, early recognition and prevention, compensating physical handicaps, health consulting, health reporting, health care information systems, medical documentation, comprehensive documentation of medical knowledge and knowledge-based decision support.

As Haux stated, in some cases, simulation of the intervention will result in considerably improved therapy quality, but we have to ask ourselves in what extent we can simulate a therapeutical intervention close to reality (Haux, 1997).

The objective of this project is to demonstrate the value of REDCap (Harris, 2009) by conducting a simulated breast cancer clinical trial process.

Simulation is the imitation of the operation of a real-world process or system over time (Banks, 1984). The breast cancer clinical trial simulation is called, Real-Time Operating Room Breast Cancer Diagnostic Treatment (RORBCDT). The RORBCDT



clinical trial is designed to assess the value of a new breast cancer operating room diagnostic technology “Intra-operative Diagnosis of Sentinel Lymph Node (Sentimag)” (Keshtgar, n.d) and real-time treatment option “Intra-operative Radiotherapy (IORT)” (Williams, 2011). Sentimag can detect for staging of certain types of cancer to see if they have spread to any lymph nodes. If the diagnose is positive, then the surgery will apply and then a new treatment device (IORT) can be used to treat the remaining cancerous tissues.

The outcome of this simulation will be an executed clinical trial process in REDCap environment. The entire project will be conducted using fictitious patients, physicians and clinical trial team who will be trained to participate in the simulation as real patients, physicians and clinical trial staff.

### **Clinical Trial Preparation**

This Project will include several steps:

1. Install REDCap on a local system.

Laboratory for Public Health Informatics and Genomics (LPHIG) at university of Wisconsin-Milwaukee, Ziber School of Public Health should become REDCap Partner. Then REDCap will install on both local Windows and Linux system by research coordinator. (Appendices B, C).

2. Design the clinical trial.

The research coordinator will design a clinical trial simulation to implement in REDCap Environment.

3. Create REDCap project environment to conduct trial.

REDCap environment will be created in order to conduct the simulation. Then the simulated trial will be implemented in REDCap environment.

4. Recruit and train fictitious patients, physicians and project team.

The required fictitious participants (Patients, Physicians, Research team, etc) will be hired and trained to participate and execute the trial.

5. Execute the trial.

The simulated Trial will be executed in REDCap environment by research team.

6. Assess the Value of REDCap.

The fictitious results will analyzed and used to show the Value of REDCap in health domain especially in clinical studies (Appendix G.)

# **Chapter 3**

## **Clinical Trial Simulation**

## **Simulation of Real-Time Operating Room Breast Cancer Diagnostic Treatment Clinical Trial**

The objective of this project is to demonstrate the value of REDCap (Harris, 2009) by conducting a simulated breast cancer clinical trial and demonstration. The breast cancer clinical trial is called, Real-Time Operating Room Breast Cancer Diagnostic Treatment (RORBCDT).

The entire project will be conducted using fictitious patients, physicians and clinical trial team who will be trained to participate in the simulation as real patients, physicians and clinical trial staff.

### **Introduction**

Breast cancer (malignant breast neoplasm) is a cancer originating from breast tissue, most commonly from the inner lining of milk ducts or the lobules that supply the ducts with milk (Sariego, 2010). Cancers originating from ducts are known as ductal carcinomas; those originating from lobules are known as lobular carcinomas. Breast cancer is a disease of humans and other mammals; the overwhelming majority of cases in humans are women (US NIH).

### **Real-Time Operating Room Breast Cancer Diagnostic Treatment**

The RORBCDT clinical trial is designed to assess the value of a new breast cancer operating room diagnosis technology “Intra-operative Diagnosis of Sentinel Lymph Node (Sentimag)” and real-time treatment option “Intra-operative Radiotherapy (IORT)”. Generally, when breast cancer surgery is performed, patients recover for a week

before chemo or radiotherapy protocols can begin. However, under certain circumstances, radiotherapy can begin immediately in the operating room using a new technology. First, Sentimag can detect for staging of certain types of cancer to see if they have spread to any lymph nodes. If the diagnose is positive, then the surgery will apply and then a new treatment device (IORT) can be used to treat the remaining cancerous tissues.

### **Intra-operative Diagnosis of SLN- Sentimag**

A “sentinel” lymph node is defined to be the hypothetical first lymph node or group of nodes reached by metastasizing cancer cells from a primary tumor. The concept of the sentinel lymph node is important because of the advent of the Sentinel Lymph Node Biopsy (SLNB) technique, also known as a sentinel node procedure. This technique is used in the staging of certain types of cancer to see if they have spread to any lymph nodes, since lymph node metastasis is one of the most important prognostic signs. It can also guide the surgeon to the appropriate therapy. SLNB has been validated as an accurate predictor of the status of the lymph node basins. This technique introduces a new concept of selective lymphadenectomy based on the histological status of the sentinel lymph node. This enables the surgeon to stratify patients for appropriate surgery without submitting the majority of those without sentinel lymph node metastases to unnecessary regional lymph node dissection with its associated morbidity and cost. This concept creates a major new opportunity for real-time stratification of patients for immediate surgery. However, until now, no real-time operating room diagnostic

technology exists to detect sentinel nodes in real time. Recently, an intra-operative diagnosis of SLN- Sentimag was created (Keshtgar, n.d.)

Usually, during surgery, a lymph gland called “the sentinel node” is taken from the armpit and tested for spread – if the test is positive, the patient will have to undergo a second operation. This new device, however, is an optical scanner which can be used in operating rooms during surgery. It allows for an instant assessment, and if needed, be an immediate further surgical procedure – which obviates the need for the patient to undergo a separate, second operation at a later date. Its technology relies on light and elastic scattering spectroscopy which displays a different optical signature for cancerous and non-cancerous cells, and leaves the sentinel node intact for any other tests which may be required (Keshtgar, n.d.)

### **Intra-operative Treatment Radiotherapy- IORT**

Once a real-time diagnostic is available, then the treatment team needs a real-time therapy option to take advantage of the rapid diagnosis. The new Intra-operative Radiotherapy (IORT) provides an option to immediately treat the cancerous tissue while the patient is still in the surgery.

Post-operative radiotherapy, which forms part of breast conserving therapy, may not need to encompass the whole breast. Apart from the consumption of huge resources and patients' time, post-operative radiotherapy deters many women from receiving the benefits of breast-conserving surgery, forcing them to choose a mastectomy instead. If radiotherapy could be given in the operating theatre immediately after surgery, many of these disadvantages could be overcome. IORT is an intensive radiation treatment that's

administered during surgery. IORT is used to treat cancers that are difficult to remove during surgery and there is a concern that microscopic amounts of cancer may remain. IORT allows direct radiation to the target area while sparing normal surrounding tissue. IORT will use radiotherapy during a surgical procedure, usually in the treatment of diffused neoplasia that cannot be completely removed by surgical methods alone.

During IORT, women undergoing breast conserving surgery (lumpectomy) may receive their radiotherapy at the time of their breast cancer operation while still under anesthesia, completely replacing the need for a 6-7 week course of radiotherapy normally given after surgery ( Williams, 2011.)

IORT takes just 20-35 minutes to administer and replaces 6-7 weeks of daily visits to the hospital for post-operative radiotherapy. IORT permits women to complete their cancer treatments sooner, allowing them a quicker return to their normal lives. In this new approach the patient has just one dose of radiation, during the operation. It is done using a mobile radiotherapy machine. The probe is inserted into the breast so that it can target the exact site of the cancer. Then the surgeons leave the theatre while specialists deliver the radiation for about 30 minutes (Williams, 2011.)

The objective of RORBCDT is to conduct a clinical trial to test the value of two new operating room breast cancer diagnostic and treatment devices. The trial will include assessment surveys to collect data from breast cancer physicians and patients to assess their interest in participating in the clinical trials and completion surveys to assess impressions and possible problems during clinical trials.

The entire assessment and completion surveys and clinical trial will be conducted using fictitious patients, physicians and clinical trial team who will be trained to participate in the simulation as real patients, physicians and clinical trial staff.

### **Real-Time Operating Room Breast Cancer Diagnostic Treatment RORBCDT Clinical Trial**

The RORBCDT is a two-arm clinical trial designed to test the efficacy of these real-time diagnosis and treatment devices. In one arm of the trial, breast cancer surgery patients will be diagnosed but no real-time therapy will be given. In the other arm, breast cancer patients will be both diagnosed and treated by the intra-operative devices (Figure1).

#### **RORBCDT Site**

The breast care center, St. James hospital, UWM School of Public Health and Laboratory for Public Health Informatics and Genomics (LPHIG) will conduct a breast cancer clinical trial assessment surveys from patients and physicians in breast care center, St. James breast care center, which is located at 9210 W Ardmore Avenue, Milwaukee, WI 53226, and then based on the survey's results, conduct a longitudinal breast cancer clinical trial in this center. Breast care center provides education, research, and treatment for patients with diseases of the breast with a special emphasis on breast cancer, the most common form of cancer in women. Staffed by MCW physicians, the clinic provides convenient access to early detection screening, follow-up programs, and state-of-the-art techniques in cancer management. Patients receive specialized education about their



disease and its treatment, and emotional support for their change in body image and the threat of cancer.

## **Public Health Informatics Tools Supporting RORBCDT**

### **Breast cancer clinical trial assessment surveys.**

Our objective to conduct these surveys is to assess the willingness of patients and physicians and the potential participants of breast cancer clinical trial using REDCap, to show the value and effectiveness of two new diagnostic and treatment technologies.

#### ***Patients survey.***

We have created a survey containing 31 questions. Some questions have branching logic. It means that by choosing answers some more related questions to those answers will appear. This survey will ask patients about previous clinical trial experiences and their willingness to participate in clinical trials using the two new technologies. If they show their interest in participating in the clinical trial, they need to answer some more questions about their cancer and family history. Link to Assessment Survey-Patients: <http://lphig.sph.uwm.edu/redcap/surveys/?s=cmuRdD>

#### ***Physicians Survey.***

We have created a survey containing 26 questions. This Survey has Branching logics and will ask physicians about previous clinical trial experiences and their willingness to attend in our clinical trial. Link to Assessment Survey-Physicians: <http://lphig.sph.uwm.edu/redcap/surveys/?s=rFz45s>

### **Longitudinal breast cancer clinical trial.**

We will have a longitudinal clinical trial database containing information about our participants in the clinical trials, their cancer procedures and selected treatment.

### ***What is a clinical trial.***

The clinical trial is “the most definitive tool for evaluation of the applicability of clinical research. It represents a key research activity with the potential to improve the quality of health care and control costs through careful comparison of alternative treatments.”

(NIH) A clinical trial is a biomedical or health-related research study in human beings that follows a pre-defined protocol (Understanding Clinical Trials, n.d.) A clinical trial is a prospective study to compare the effect and value of interventions. In prospective study, participants must be followed forward in time. Each participant must be followed from a well defined point, which becomes time zero or baseline for the study. This contrasts them with a control arm study (Friedman, P2.) The two kinds of clinical trial studies are called interventional and observational. Interventional studies are those in which the research subjects are assigned by the investigator to a treatment or other intervention, and their outcomes are measured. Observational studies are those in which individuals are observed and their outcomes are measured by the investigators (Understanding Clinical Trials, n.d.) In addition, treatment trials test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy. In our clinical trial project we will conduct an interventional treatment study.

### ***Benefits and risks.***

Clinical trials that are well-designed and well-executed are the best approach for eligible participants to:

1. Play an active role in their own health care.
2. Gain access to new research treatments before they are widely available.
3. Obtain expert medical care at leading health care facilities during the trial.
4. Help others by contributing to medical research (Understanding Clinical Trials, n.d.)

However, there are possible risks in clinical trials.

1. There may be unpleasant, serious or even life-threatening side effects to experimental treatment.
2. The experimental treatment may not be effective for the participant.
3. The protocol may require more of their time and attention than would a non-protocol treatment, including trips to the study site, more treatments, hospital stays or complex dosage requirements (Understanding Clinical Trials, n.d.)

***Clinical trial phases.***

Clinical trials are conducted in phases with different purpose and objectives:

1. In phase I trials, researchers test an experimental drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
2. In phase II trials, the experimental study drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
3. In phase III trials, the experimental study drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.

4. In phase IV trials, post marketing studies delineate additional information including the drug's risks, benefits, and optimal use (Understanding Clinical Trials, n.d.)

RORBCDT is a phase III clinical trial. The objective of RORBCDT is to assess the effectiveness of two intra-operative diagnostic and treatment devices. Half of the participants will receive single-day intra-operative radiotherapy (IORT) given at the time of surgery. The other half will receive conventional post-operative radiotherapy given over a 6-7 week period beginning after surgery. The goal of the trial is determine if intra-operative diagnosis of SLN-Sentimag and single-day intra-operative radiotherapy-IORT is as effective as lymphoscintigraphy and 6-7 weeks conventional post-operative radiotherapy for the treatment of early stage invasive breast cancer.

A randomized controlled trial is a scientific study in which different treatments are compared in an organized and objective manner. “Randomized” means that a computer will assign one of the two treatments to each patient similar to tossing a coin. “Controlled” means that the study is being performed under well-defined conditions to ensure that other variables do not impact the results. The goal of a randomized controlled trial is to eliminate bias so that the results of the study will be truly believable (USC, Department of surgery, n.d.)

A randomized controlled trial is the best way to determine the safety and effectiveness of different treatments. In fact, it is because of randomized controlled trials that most women today can safely receive breast conservation therapy (lumpectomy + radiotherapy) instead of mastectomy, without fear of reducing the chances of surviving

breast cancer. Prior to these trials, mastectomy was the only treatment offered to women with breast cancer (USC, Department of surgery, n.d.)

*Clinical trial steps. (Figure2)*

*Determination of subject eligibility.*

Prior to joining the study, a patient must meet with the LPHIG Research Team Representative at St.James to determine if she qualifies for this trial. This evaluation will include a physical examination, review of her mammograms and ultrasounds, and review of her pathology results. Additional radiology studies (mammograms, ultrasounds, and/or breast MRI) may also be requested prior to determining her eligibility for the study (Targit, n.d), (USC, Department of surgery, n.d.)

Subject inclusion criteria:

- Invasive (also called infiltrating) breast cancer
- Breast cancer treatable with lumpectomy
- Capable of receiving breast radiotherapy (not pregnant, no history of previous radiotherapy to the same breast, no connective tissue disorder)
- None breastfeeding

Subject exclusion criteria:

- Multiple areas of breast cancer
- Cancer in both breasts
- Extensive non-invasive cancer (DCIS or Ductal Carcinoma in Situ).
- Lymph nodes contain cancer metastasis.

*Informed Consent.*

Informed consent is the process of teaching the key facts about a clinical trial to a patient before they decide whether or not to participate. It is also a continuing process throughout the study to provide information for participants. If a patient qualifies for the trial, she will be given an informed consent statement that clearly describes important aspects of the trial, including the benefits and risks of the different treatments. To help someone decide whether or not to participate, the trial investigators will review the informed consent statement with patient, answer any questions that she has, and request that she sign the informed consent statement to confirm willingness to participate in the Trial. If the participant's native language is not English, translation assistance can be provided. Then the research team provides an informed consent document that includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. By signing of the informed consent statement, the patient indicates that she is interested in participating in the Trial and that she is willing to receive whichever treatment assigned to her. Informed consent is not a contract, and the participant may withdraw from the trial at any time. (Understanding Clinical Trials, n.d.)

#### *Randomization.*

Randomization is the preferred way of assigning participants to control and intervention groups (Friedman, 2010, p.42.) Randomized control studies are comparative studies with an intervention group and a control group; the assignment of the participants to a group is determined by the formal procedure of randomization. Randomization, in the simplest case, is a process by which all participants are equally likely to be assigned

to either the intervention or control group. (Friedman, 2010, p.43.) Green and Byar in their scheme confirmed that the randomized clinical trial is the strongest clinical trial design (Green, 1984.)

There are three advantages of the randomized design over other methods for selecting controls (Byar, 1976.) Randomization tends to produce study groups comparable with respect to the measured and unknown prognostic factors, removes investigator bias in the allocation of participants, and guarantees that statistical tests will have valid significance levels (Byar, 1976.)

After the informed consent statement is signed, a computer will randomly assign two treatments to the patient. Half of the participants will receive intra-operative diagnosis of SLN-Sentimag and single-day intra-operative radiotherapy-IORT and the other half will receive no real time lymphoscintigraphy and conventional post-operative radiotherapy.

In any clinical trial, bias is one of the main concerns. Bias can be caused by conscious factors, unconscious factors or both. The general solution to the bias is to keep the patients and investigator blinded to the identity of the assigned intervention. In double blind studies, neither the patients nor the investigators know which patients are in each group. In studies where double-blind is impossible, single blind or open study is favored. In an unblinded study or open trial, both the patient and investigator know to which intervention the patient has been assigned. In single blind studies, patients do not know whether they are in the control or study group, but the investigator does. Some kinds of trials can be conducted only in open trial. Such studies include those involving most

surgical procedures, comparisons of devices and medical treatment, and changes in lifestyle or learning technique (Friedman, 2010, p.82.)

*Scheduling.*

After treatment has been determined, the patient, the surgeon, and the radiation oncologist will schedule the date of her operation. If she has been assigned to receive Sentimag and IORT, she will receive them at the time of her breast cancer surgery while she is still under anesthesia. The radiotherapy treatment will take approximately 30-35 and will add approximately 45 minutes to the length of the operation. On the other hand, if she had been assigned to receive lymphoscintigraphy, she will receive it in the same day or a day before surgery. If she had been assigned to receive conventional post-operative radiotherapy, she will receive conventional post-operative radiotherapy over a 6-7 week period after she has recovered from breast surgery.

**Breast cancer clinical trial completion surveys.**

*Clinical trial completion survey- physicians.*

We have created a survey containing 16 questions. This survey is designed to collect data about possible problems which may occur during project and to assess the pros and cons of those two intra-operative technologies. In addition, it will measure the physicians' overall satisfactions with the clinical trial. This survey will collect the physician's point of view regarding the clinical trial and their suggestions for improving future related studies. Link to completion survey- physicians:

<http://lphig.sph.uwm.edu/redcap/surveys/?s=X7CGwm>



***Clinical trial completion survey-patients.***

We have created a survey containing 8 questions. This survey is designed to collect data from patients participating in clinical trial in order to measure their overall satisfactions and to assess the quality of clinical trial design. This survey will also collect the patients suggestions for future trial improvement. Link to completion survey-

Patients: <http://lphig.sph.uwm.edu/redcap/surveys/?s=kFvVx9>

These surveys will be conducted using REDCap. In assessment surveys researchers will store and analyze data collected from women with breast cancer admitted in the breast care center, St. James hospital during 2010-2011. In addition, breast cancer physicians (Surgeons, Radiotherapists and Pathologists) will be asked to complete a survey designed for them. In completion surveys, researchers will collect information from patients and physicians who were participating in a clinical trial. REDCap will help us to design a longitudinal clinical trial database to do the designed project. Our research participants are LPHIG research team, St. James breast care center physicians and staff, patients and a project coordinator.

**Participants**

**Breast cancer physicians.**

In this project we will ask St. James breast care center physicians (surgeons, radiotherapists and pathologists) to participate in our project by filling out the assessment and completion physician's surveys. We will provide a link to the Survey. So they can fill out the survey through any computer. We do not ask identifying question, so the collected information are anonymous.

### **Breast Cancer patients or study population.**

The study population is the subset of the population with the condition or characteristics of interest defined by the eligibility criteria. (Friedman, 2010, p30.)

Patients are our population in a large and playing an important role in our project. We have designed a separate survey for women with breast admitted in the breast care center, St. James hospital during 2010-2011 to access the potential participant in our clinical trial project. For patient's convenience, the survey will be available both in print and online. There will be an option for patients who have a disability to fill out the form with the help of our researchers in the Cancer Center. We do not ask identifying questions, so the collected information is anonymous.

As we discussed in "Determine Subject Eligibility" in "Clinical Trial Steps", In order to participate in the Trial, some inclusion criteria must be met. To see the Relationship of study sample to study population and population at large see the "Fig1" in the appendices.

### **LPHIG researchers.**

LPHIG researchers are responsible for collecting, storing, analyzing data using REDCap. They have designed surveys and made it available to patients and physicians. They will modify the Survey and retake it if necessary. In addition, some LPHIG researchers should be in the Cancer center in case a patient need help to fill out the survey. They are also responsible to train physicians how to work with REDcap. LPHIG researchers are responsible to analyze the data and propose it to the Cancer center to help them decide about starting clinical trial by using those new technologies in their center. If the center decides to have clinical trial, LPHIG researchers are responsible to create a

longitudinal project and help the cancer center to schedule events for patients and conduct the clinical trial project using REDCap. After finishing the project, LPHIG members are responsible to conduct a Clinical Trial Completion Surveys to collect the feedback from conducted project.

**Breast care center staff.**

If the center decides to conduct a clinical trial, staff is responsible to do the project in the center by using Longitudinal Clinical Trial Database designed by LPHIG Researchers.

They are responsible to collect data from patients and schedule appointments for them and follow up their treatments.

**Research coordinator.**

The research coordinator is responsible for coordinating all participants in the project to perform a high quality research study and get the proper results. To do so, the coordinator is responsible to train all LPHIG researchers how to work with REDCap. In addition he/she is responsible for any software problems or administrative issues.

### **RORBCDT Implementation and Results**

The clinical trial simulation was executed using the REDCap environment (Appendix A.) The surveys were conducted and false data was collected for participating fictitious patients.

We assumed that we have conducted assessment surveys a year before starting clinical trial. The objective of conducting assessment surveys was to assess the potential participants for the future clinical trial studies. As we aimed to show the REDCap value,

we assumed there are enough potential participants to start clinical trial, so we have generated false data to show the patients and physicians interest in participating in clinical trial. (Appendix D). The fictitious assessment survey results show that 80% of patients have heard about clinical trial (Table 5) and 40 % of patients participated in other clinical trials before (Table 6) 60% of participants indicate their interest to participate in breast cancer clinical trial (Table 8) and 87% of those who were interested specifically would like to attend RORBCDT clinical trial (Table 9).

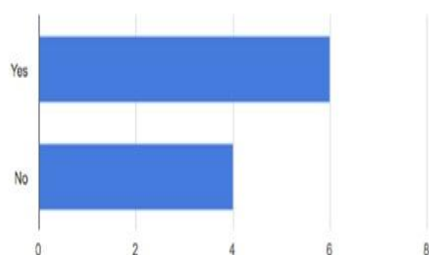


Table 8

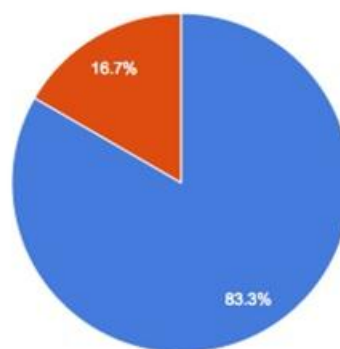


Table 9

The results also show that 47.4 % of physicians have experience participating in clinical trials as investigator (Table 32) and 26.3% of them have already attended in similar intra-operative diagnosis of SLN using Sentimag (Table 34) and 36.8 % have experience of IORT (Table 38) and 88.9 % would like to attend RORBCDT clinical trial (Table 36), (Table 39).

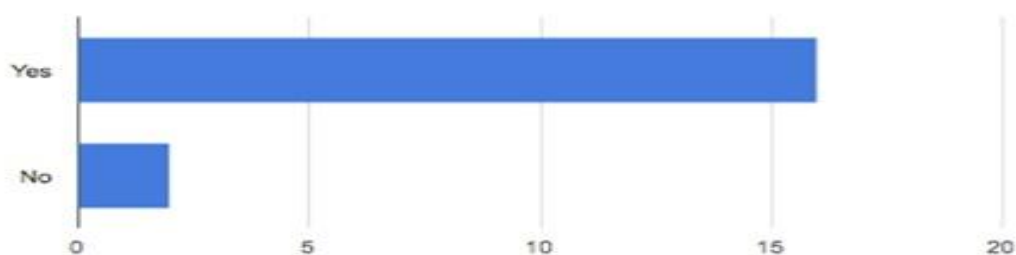


Table 36

By conducting the assessment surveys we assessed that if we start the clinical trial there will be at least 5 physicians and 50 patients interested and eligible to participate. We also assumed that we have 8 fictitious physicians who are interested in participating in clinical trials. After designing the clinical trial, we asked the physicians to start recruiting fictitious patients and inform them about the RORBCDT clinical trial.

After assessing potential participants, the clinical trial was executed in REDCap environment (Appendix A). The eligibility determination was completed (Figure 20) and 50 eligible patients signed the informed consent form (Appendix F). By randomization, we assigned 25 patients in each arm and scheduled them for following visits, surgery and radiotherapy depending on the arm they were assigned to (Figure 16), (Figure 17).

After clinical trial completion, we have conducted completion patients and physicians surveys (Appendix E). The aim of conducting patients survey was to assess the quality of the clinical trial design and measure the overall satisfaction of patients participated in the trial and get their feedback for future improvements. Based on the results we have gained, 88.4% of patients indicated that they received required information in order to participate in clinical trial (Table 41) and 90% indicated that they have been informed about possible side effects (Table 42). And most of the patients were satisfied about participating in breast cancer clinical trial (table 46) and 90.7 % recommend other patients to attend such clinical trials (Table 47).

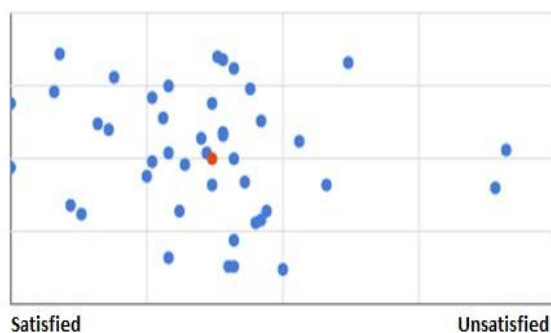


Table 46

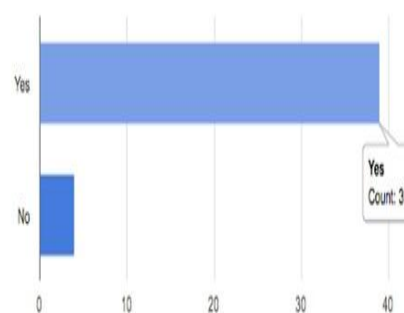


Table 47

The physicians' survey shows that 50% of physicians have a positive opinion about the executed clinical trial and 37.5 % indicated that the clinical trial could be better (Table 48). 100% of physicians prefer using intra-operative diagnostic devices rather than standard technology (Table 50). All physicians were satisfied with this clinical trial (Table 51) and thought these technologies will have an impact on breast cancer treatment (Table 53).

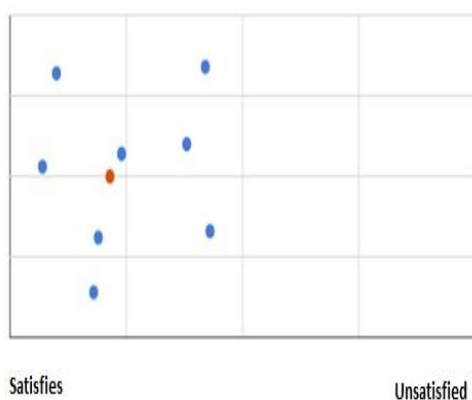


Table 51

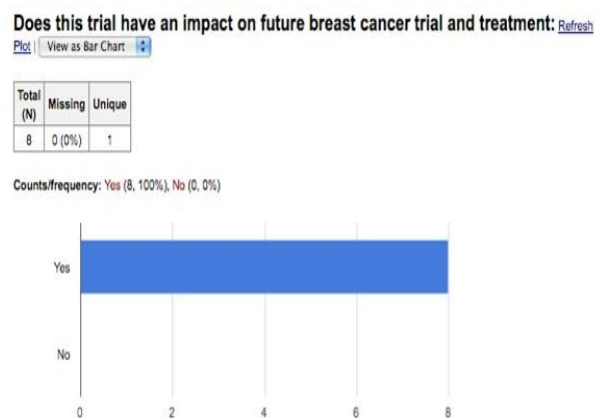


Table 54

# **Chapter4**

## **Discussion, Conclusion and Limitation**

## **Discussion**

To prepare for this trial we conducted Physicians and Patients Assessment Surveys. We gathered false data from fictitious physicians and patients. Based on the generated result (Tables 5, 6, 8, 9, 32, 34, 36, 38, 39) we recruited the clinical trial participants and executed Real Time Operating Room Breast Cancer Diagnostic Treatment (RORBCDT) clinical trial in the REDCap environment. The objective of executing RORBCDT was to assess the value of REDCap.

REDCap has provided a free environment to conduct Clinical and Translational studies. We took benefit of using REDCap in designing and executing RORBCDT. REDCap has features which are very useful in these studies. The web based access to data across academic departments and institutions helps researchers to conduct collaborative study, which we have done in RORBCDT. The REDCap installed on LPHIG local machines and researchers no matter where they are can access to the REDCap through this link: [www.lphig.sph.uwm.edu/redcap](http://www.lphig.sph.uwm.edu/redcap) (Figure 3). The user authentication and role-based security helps researchers to conduct studies in a secure environment and grant access to the participants based on their roles in the study. In our study we took benefit of this role-based feature and granted access to the LPHIG researchers based on their roles in conducting project (Figure 9),(Figure10). REDCap survey is a very useful feature of REDCap. This will allow researchers to collect data from participants by simply sending a survey link or manually entering survey result in a system or giving a PDF version of the survey to participants. In our Project we have conducted four surveys before and after executing RORBCDT in REDCap (Appendix D), (AppendixE). We sent the survey links to our participants and analyzed the data using



Graphical data view and stats which is another good feature of REDCap (AppendixG). Intuitive electronic case report forms help researchers to get the customizable report based on their needs (Figure 19). File repository helps researchers to keep track of all documents stored in different projects and events. In our clinical trial project we could keep track of patients' informed consent forms which were uploaded for each patient in informed consent event (Figure 18). Data export functions for common statistical packages let researchers easily export data to some statistical package format for further analyzing (Figure 11) Data import function is very useful in clinical studies which facilitates bulk import of data from other systems (Figure 12). REDCap will let research coordinators to create different kind of projects such as longitudinal projects and Surveys (Figure 7). The longitudinal project provides scheduling module which lets investigators to schedule patients' visits and track them in a calendar (Figure 16), (Figure17). In the longitudinal project it is possible to assign patients in different arms (Figure 21), (Figure22) and compare them using data comparison tools (Figure 13). Therefore, REDCap provides a good environment to conduct longitudinal projects such as clinical trial as we have done it.

### **Conclusion**

The Electronic Health Record (EHR) Systems emerged to facilitate some of the essential aims of medical informatics which are diagnostic, therapy, therapy simulation, health care information systems and medical documentation (Haux, 1997). Clinical informaticians are playing an important role in transition from paper records to electronic ones. Recently, the number of electronic solutions and applications to manage electronic health record is increasing. Therefore, clinical informaticians who bring expertise at the

intersection of health care and IT to assure successful adoption and use of HIT and the information within it are responsible to assess the values of different applications prior to adopting them in their health facilities. By conducting RORBCDT, a simulated breast cancer clinical trial, we, as informaticians aimed to show the value of REDCap as a tool supporting health informatics. REDCap installed on both Windows (Appendix B) and Unix systems (Appendix C) and is easy to learn. The executed assessment and completion surveys and clinical trial in REDCap environment show that REDCap provides cleaner data which is particularly good at enforcing certain aspects of data quality. REDCap also provides more efficient processes which help guide the site through the series of study events, requesting only the data needed for the particular patient's circumstance at a particular time. It facilitates the process of clarifying data discrepancies with tools for identifying and resolving data issues with sites, and can help reduce the number of in-person site visits required during a trial. In addition REDCap provides faster access to data; web-based system can provide near real-time access to data in a clinical trial. This insight enables faster decision making, and can support adaptive trial designs. Therefore, REDCap is a valuable tool which provides a free and secure environment to support health care informatics and conduct translational and clinical studies.

### **Limitations**

Beside the value of REDCap, it has some limitations. Multiple surveys in a single project were always needed when we were designing this project. REDCap has an option to create single survey projects which is not enough sometimes. In addition, to conduct

clinical trials, there is a need of financial management which is available in other Clinical Trial Management Systems. Therefore, it is not the best environment to conduct the clinical trial. However, by considering its cost in comparing to other solutions it is still a good choice to conduct simple clinical trials in health facilities such as universities.

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# Appendices

# **Appendix A**

## **REDCap**

## **REDCap**

“REDCap” (Harris, P. A., et al, 2009) is a free, secure, web-based application designed to support data capture for translational and clinical research studies. The system was developed by a multi-institutional consortium initiated at Vanderbilt University. Data collection is customized for each study or clinical trial by the research team. REDCap is useful for Collecting and tracking information and data from research studies, scheduling study events (e.g., patient visits), conducting surveys

### **REDCap Features**

REDCap provides user-friendly web-based case report forms, real-time data entry validation (e.g. for data types and range checks) and the ability to set up a calendar to schedule and track critical study events (Figure 16), (Figure17). Also, designated users can assign different levels of access for each member of the research team (Figure 9), (Figure10). REDCap Survey provides a powerful tool for creating and managing surveys in the web browser. Collect responses from survey participants by:

- Sending a link to survey participants via email
- Entering data manually, and/or
- Posting a link on survey participants’ website

REDCap Survey gives survey participants the option to keep their participant responses anonymous, or track and identify responses by building an email contact list.

REDCap offers the following features which are very useful to collect data for research studies and conduct different kind of projects (e.g. longitudinal projects).

REDCap is

- Fast and has Quick project start-up. Clinical report forms can be implemented without the need for a programmer (Figure 19).
- Easy. It has intuitive user interface and work flow, online training materials which is readily available. (Figure 4), (Figure 6).
- Fully customizable. You are in control of shaping your database. (Figure 8)
- Secure. It has backed up offsite nightly and hosted in a secure environment.
- Web-based. You are able to enter data or build your database from anywhere in the world over a secure web connection with authentication and data logging. (Figure 3), (Figure 9), (Figure14).
- A data export tool. You can export data to common data analysis packages, data export function for Excel, SAS, Stata, R, and SPSS. (Figure 11)
- A data import tool. It has data import capability through Microsoft Excel.(Figure 12)
- A multi-site utility. It can be used by researchers from multiple sites and institutions.
- An autonomous user management tool. Research groups have complete autonomy and control to add new users and set several levels of specific user rights.(Figure 9).

# **Appendix B**

## **Installing REDCap v4.5.1 on a Local Windows Machine**

### **Apache HTTPD Installation**

Download the Apache Win32 Binary including OpenSSL 0.9.8o (MSI Installer): [httpd-2.2.17-win32-x86-openssl-0.9.8o.msi](http://httpd-2.2.17-win32-x86-openssl-0.9.8o.msi)

Run the installation package. Choose a typical installation.

The default installation directory is C:\Program Files (x86)\Apache Software Foundation\Apache2.2

After installation open a web browser and enter <http://localhost/>

### **PHP Installation**

Download the VC6 x86 Thread Safe PHP binaries (MSI installer): [php-5.3.4-Win32-VC6-x86.msi](http://php-5.3.4-Win32-VC6-x86.msi)

Run the installation package. Choose Apache 2.2.x Module. Choose a typical installation.

When asked for Apache's location enter C:\Program Files (x86)\Apache Software Foundation\Apache2.2\conf

The default installation directory is C:\Program Files (x86)\PHP

Run windows cmd prompt.

Copy "C:\Program Files (x86)\PHP\php5ts.dll" "C:\Program Files (x86)\Apache Software Foundation\Apache2.2\bin"

cd "\Program Files (x86)\Apache Software Foundation\Apache2.2\conf"

notepad httpd.conf

Find "PHPIniDir"

Change to:

PHPIniDir "C:\Program Files (x86)\PHP\"

Find “LoadModule php5\_module”

Change to: LoadModule php5\_module "C:\Program Files

(x86)\PHP\php5apache2\_2.dll"

Save and exit notepad.

cd "\Program Files (x86)\PHP\"

notepad php.ini

Find “doc\_root”

Change to:

doc\_root =

Save and exit notepad.

cd "\Program Files (x86)\Apache Software Foundation\Apache2.2\htdocs"

notepad phpinfo.php

Insert:

<?php

phpinfo();

?>

Save and exit notepad.

Completely stop and then start Apache services by using the tool icon to open the Apache control panel.

After configuration open a web browser and enter <http://localhost/phpinfo.php>

### **MySQL Installation**

Open the Windows security center firewall control panel, and add an exception for port 3306 using TCP.

(An advanced setting, choose new rule, and port)

Download the MySQL Community Server Windows (x86, 32-bit), (MSI Installer):

mysql-5.5.8-win32.msi

Run the installation package. Choose a complete installation.

When asked to run configuration, choose a) detailed, b) developer machine, c) multifunctional database, d) decision support, e) TCP/IP & strict mode, f) standard character set, g) windows service & include Bin directory

Enter a root password: fengshui

The default installation directory is C:\Program Files (x86)\MySQL\MySQL Server 5.5

Run windows cmd prompt.

Copy "C:\Program Files (x86)\MySQL\MySQL Server 5.5\lib\libmysql.dll" "C:\Program Files (x86)\Apache Software Foundation\Apache2.2\bin"

After configuration, in the command prompt type: mysqlshow -uroot -pfengshui

### **PEAR Installation**

Download the PEAR package (TGZ File): PEAR-1.9.1.tgz

Unzip file contents (PEAR-1.9.1.tgz) into C:\temp

Run windows cmd prompt.

Move "C:\temp\PEAR-1.9.1\PEAR.php" "C:\temp\PEAR-1.9.1\PEAR\"

Move "C:\temp\PEAR-1.9.1\PEAR5.php" "C:\temp\PEAR-1.9.1\PEAR\"

Run windows file explorer.

Move the folder "PEAR" to the directory "C:\Program Files (x86)\PHP\"

notepad php.ini

Find "include\_path =" for Windows



Delete the semicolon before “include\_path =”

Change “include\_path =” to:

```
include_path = ".;C:\Program Files (x86)\PHP\PEAR"
```

Save and exit notepad.

Completely stop and then start Apache services by using the tool icon to open the Apache control panel.

### **PEAR Auth Installation**

Download the PEAR Auth package (TGZ File): Auth-1.6.4.tgz

Unzip file contents (Auth-1.6.4.tgz) into C:\temp

Run windows file explorer.

Move the folder “Auth” to the directory “C:\Program Files (x86)\PHP\PEAR\”

Move the file “Auth.php” to the directory “C:\Program Files (x86)\PHP\PEAR\”

Completely stop and then start Apache services by using the tool icon to open the Apache control panel.

### **PEAR DB Installation**

Download the PEAR DB package (TGZ File): DB-1.7.14RC2.tgz

Unzip file contents (DB-1.7.14RC2.tgz) into C:\temp

Run windows file explorer.

Move the folder “DB” to the directory “C:\Program Files (x86)\PHP\PEAR\”

Move the folder “doc” to the directory “C:\Program Files (x86)\PHP\PEAR\”

Move the folder “tests” to the directory “C:\Program Files (x86)\PHP\PEAR\”

Move the file “DB.php” to the directory “C:\Program Files (x86)\PHP\PEAR\”

Completely stop and then start Apache services by using the tool icon to open the Apache control panel.

### **phpMyAdmin Installation**

Download the phpMyAdmin all languages (ZIP file): phpMyAdmin-3.3.8.1-all-languages.zip

Unzip file contents (phpMyAdmin-3.3.8.1-all-languages.zip) into C:\Program Files (x86)\Apache Software Foundation\Apache2.2\htdocs

Rename the folder from “phpMyAdmin-3.3.8.1-all-languages” to “phpMyAdmin”

Run windows cmd prompt.

Mkdir "C:\Program Files (x86)\Apache Software

Foundation\Apache2.2\htdocs\phpMyAdmin\config"

After creating the config folder open a web browser and enter

<http://localhost/phpMyAdmin/setup/index.php>

The phpMyAdmin setup script will run.

In the configuration file section, select “save”.

Run windows cmd prompt.

Cd "\Program Files (x86)\Apache Software

Foundation\Apache2.2\htdocs\phpMyAdmin\config"

Move config.inc.php ..

Open a web browser and enter <http://localhost/phpMyAdmin>

### **REDCap Source Code Installation**

Unzip file contents (redcap4.5.1.zip)into C:\temp

Run windows file explorer.

Move the folder “redcap” to the directory “C:\Program Files (x86)\Apache Software Foundation\Apache2.2\htdocs”

Open a web browser and enter <http://localhost/redcap/install.php>

Open a second window in your web browser and enter

<http://localhost/phpMyAdmin/index.php>

Run windows cmd prompt.

Cd "\Program Files (x86)\Apache Software Foundation\Apache2.2\htdocs\phpMyAdmin"  
notepad config.inc.php

Add the following lines following other \$cfg lines:

```
$i=0;

$i++;

$cfg['Servers'][$i]['user']      = '###';

$cfg['Servers'][$i]['password']  = '###';

$cfg['Servers'][$i]['auth_type'] = '###'
```

Save and exit notepad.

Login to phpMyAdmin with the user/password.

In the field under the heading 'Create new database' type in the name “redcap”, and click “create”.

On the main page of phpMyAdmin click the 'Privileges' link, and then near the middle of the page click the 'Add a new User' link.

Enter the username: “LPM”, host: “localhost”, and password “fengshui”, and click “Go”.

Run windows cmd prompt.

Cd "\Program Files (x86)\Apache Software Foundation\Apache2.2\htdocs\redcap"

notepad database.php

Change to:

```
$hostname    = '###';  
$db          = '###';  
$username    = '###';  
$password    = '###';  
$salt = '###';
```

Save and exit notepad.

Reload webpage <http://localhost/redcap/install.php>

Accept all default options in Step 3 and click on “Save Changes”.

In the phpMyAdmin webpage, click the redcap link on the left panel to choose the redcap database, click on the ‘SQL’ link, and then copy and paste the SQL code from Step 4 into the text box in phpMyAdmin, and click “Go”.

Open web browser and enter [http://localhost/redcap/redcap\\_v4.5.1/test.php](http://localhost/redcap/redcap_v4.5.1/test.php) (or click on the link in Step 5)

Initial and 1-5 tests should be successful. It is ok if some additional tests fail.

Open web browser and enter <http://localhost/redcap/index.php>

# **Appendix C**

**Install REDCap v4.5.1 on local**

**Synology DSM 3.2**

This page describes how to install and test the following 3rd party Unix software packages required by REDCap:

### **PHP**

If PHP is not installed, it is available through the PHP Group

(<http://www.php.net/downloads.php>).

In Synology DSM 3.2, PHP is located in Control panel/Network services/ web services/ PHP settings.

/etc.defaults:/usr/bin/php:/usr/syno/synoman:/etc:/var/run:/tmp:/var/spool/php:/volume1/  
@tmp/php:/var/services/web:/var/services/photo:/var/services/blog:/var/services/homes:/  
volume1/web/redcap/Include/pear

### **MySQL**

If MySQL is not installed, it is available through MySQL AB

(<http://www.mysql.com/downloads>).

### **phpMyAdmin**

If phpMyAdmin is not installed, it is available through the phpMyAdmin Project

([http://www.phpmyadmin.net/home\\_page/index.php](http://www.phpmyadmin.net/home_page/index.php)). Or

<http://www.synology.com/support/download.php?lang=enu&b=4%20bays&m=DS411j>

### **PEAR Installation**

Download the PEAR package (TGZ File): PEAR-1.9.1.tgz

Unzip file contents (PEAR-1.9.1.tgz) into Lphig/web/redcap/Include

Find “include\_path =” for Linux

Delete the semicolon before “include\_path =”

Open php.ini in notepad Change “include\_path =” to:

```
include_path = "./volume1/web/redcap/Include/pear"
```

Save and exit notepad.

Create a notepad file in home/web/redcap/pear and name it “.pearrc” and put this content in to the file:

```
#PEAR_Config 0.9
```

```
php_value include_path "./home/your_cpanel_username/your_include_path"
```

save file and close it.

Completely stop and then restart Synology.

### **PEAR Auth Installation**

Download the PEAR Auth package (TGZ File): Auth-1.6.4.tgz

Unzip file contents (Auth-1.6.4.tgz) into C:\temp

And move the file to home/web/redcap/include/pear

Completely stop and then start Synology.

### **PEAR DB Installation**

Download the PEAR DB package (TGZ File): DB-1.7.14RC2.tgz

Unzip file contents (DB-1.7.14RC2.tgz) into C:\temp

And move the file to home/web/redcap/include/pear

Move the folder “DB” to the directory “home/web/redcap/include/pear”

Move the folder “doc” to the directory “home/web/redcap/include/pear”

Move the folder “tests” to the directory “home/web/redcap/include/pear”

Move the file “DB.php” to the directory “home/web/redcap/include/pear”

Completely stop and then start Synology.

## REDCap Source Code Installation

Unzip file contents (redcap4.5.3.zip) into C:\temp

Move the folder “redcap” to the directory “ home/web/redcap”

Open a web browser and enter <http://lphig.sph.uwm.edu/redcap/install.php>

Open a second window in your web browser and enter <http://lphig.sph.uwm.edu/index.php>

Run windows cmd prompt.

Open phpMyAdmin in sinology menu

notepad config.inc.php

Add the following lines following other \$cfg lines:

```
$i=0;

$i++;

$cfg['Servers'][$i]['user']      = '###';

$cfg['Servers'][$i]['password']  = '###';

$cfg['Servers'][$i]['auth_type'] = '###'
```

Save and exit notepad.

Login to phpMyAdmin with the user/password.

In the field under the heading 'Create new database' type in the name “redcap”, and click “create”.

On the main page of phpMyAdmin click the 'Privileges' link, and then near the middle of the page click the 'Add a new User' link.

Enter the username: “###”, host: “####”, and password “####”, and click “Go”.

Cd "home\web\redcap"



notepad database.php

Change to:

```
$hostname    = '###';  
$db          = '###';  
$username    = '###';  
$password    = '###';  
$salt = '###';
```

Save and exit notepad.

Reload webpage <http://lphig.sph.uwm.edu/redcap/install.php>

Accept all default options in Step 3 and click on “Save Changes”.

In the phpMyAdmin webpage, click the redcap link on the left panel to choose the redcap database, click on the ‘SQL’ link, and then copy and paste the SQL code from Step 4 into the text box in phpMyAdmin, and click “Go”.

Open web browser and enter [http://lphig.sph.uwm.edu/redcap/redcap\\_v4.5.1/test.php](http://lphig.sph.uwm.edu/redcap/redcap_v4.5.1/test.php) (or click on the link in Step 5)

Initial and 1-5 tests should be successful. It is ok if some additional tests fail.

Open web browser and enter <http://lphig.sph.uwm.edu/redcap/index.php>

# **Appendix D**

## **Breast Cancer Clinical Trial**

### **Assessment Surveys**

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Page 1 of 4

## Breast Cancer Clinical Trial Assessment Survey- Patients

Please complete the survey below.

Thank you!

---

### Basic Information

1. What is your date of birth?

---

Age

---

2. What is your Race?

- ☐ African American
- ☐ White
- ☐ Asian
- ☐ Hispanic
- ☐ Other

3. Are you a smoker?

- ☐ Yes
- ☐ No

4. What is your marital status?

- ☐ 1. Never married
- ☐ 2. Married

5. Have you been diagnosed with breast cancer?

- ☐ Yes
- ☐ No

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Page 2 of 4

**Clinical Trial**

6. Have you ever heard about clinical trial?

- ☐ Yes  
☐ No

7. Clinical trials are research studies that involve people. These studies test new ways to prevent, detect, diagnose, or treat diseases. People who take part in cancer clinical trials have an opportunity to contribute to scientists' knowledge about cancer and to help in the development of improved cancer treatments. They also receive state-of-the-art care from cancer experts. Different kinds of cancer clinical trials are: Treatment, Prevention, Screening, Diagnostic, Quality of Life or Supportive care. Some possible Benefits: 1. Trial participants have access to promising new interventions that are generally not available outside of a clinical trial. 2. The intervention being studied may be more effective than standard therapy. If it is more effective, trial participants may be the first to benefit from it. 3. Trial participants receive regular and careful medical attention from a research team that includes doctors, nurses, and other health professionals. 4. The results of the trial may help other people who need cancer treatment in the future. 5. Trial participants are helping scientists learn more about cancer (e.g., how it grows, how it acts, and what influences its growth and spread). Some possible harms: 1. The new intervention being studied may not be better than standard therapy, or it may have harmful side effects that doctors do not expect or that are worse than those associated with standard therapy. 2. Trial participants may be required to make more visits to the doctor than they would if they were not in a clinical trial and/or may need to travel farther for those visits. 3. Health insurance may not cover all patient care costs in a trial.

8. Have you ever participated in a clinical trial?

- ☐ Yes  
☐ No

9. What kind of clinical trial have you been engaged before? (Check All That Apply)

- ☐ Treatment  
☐ Prevention  
☐ Screening  
☐ Diagnostic  
☐ Quality of Life or Supportive care.

10. Would you like to participate in breast cancer clinical trial?

- ☐ Yes  
☐ No

11. Our center is adopting two real time technologies which are used in operating room, called "Intraoperative diagnosis of SLN and Intraoperative Radiotherapy." Intraoperative diagnosis of SLN: Usually, during surgery, a lymph gland called 'the sentinel node' is taken from the armpit and tested for spread - if the test is positive, the patient will have to undergo a second operation. This new device, however, is an optical scanner which can be used in operating theatres during surgery. It allows for an instant assessment and, if need, be an immediate further surgical procedure - which obviates the need for the patient to undergo a separate, second operation at a later date. Its technology relies on light and elastic scattering spectroscopy which displays a different optical signature for cancerous and non-cancerous cells, and leaves the sentinel node intact for any other tests which may be required. Intraoperative Radiotherapy: The new Intraoperative Radiotherapy (IORT) provides an option to immediately treat the cancerous tissue while the patient is still in the surgery. Postoperative radiotherapy, which forms part of breast conserving therapy, may not need to encompass the whole breast. Apart from the consumption of huge resources and patients' time, postoperative radiotherapy deters many women from receiving the benefits of breast-conserving surgery, forcing them to choose a mastectomy instead. If radiotherapy could be given in the operating theatre immediately after surgery, many of these disadvantages could be overcome. Intraoperative radiotherapy is to use radiotherapy during a surgical procedure, usually in the treatment of diffuse neoplasia that cannot be totally removed by surgical methods alone. With Intraoperative Radiotherapy, women undergoing breast conserving surgery (lumpectomy) may receive their radiotherapy at the time of their breast cancer operation while still under anesthesia, completely replacing the need for a 6-7 week course of radiotherapy normally given after surgery. Intraoperative Radiotherapy takes just 20-35 minutes to administer and replaces 6-7 weeks of daily visits to the hospital for post-operative radiotherapy. Intraoperative Radiotherapy permits women to complete their cancer treatments sooner, allowing them a quicker return to their normal lives. In this new approach the patient has just one dose of radiation, during the operation. It is done using a mobile radiotherapy machine. The probe is inserted into the breast so that it can target the exact site of the cancer. Then the surgeons leave theatre while specialists deliver the radiation which lasts about 30 minutes.

14. Would you like to attend Intraoperative Radiotherapy and Intraoperative diagnosis of SLN clinical trial?

- ☐ Yes  
☐ No

Confidential

Page 3 of 4

---

**History**

---

16. What is your menopause age?
- ☐ 40 to 44  
☐ 45 to 49  
☐ 50 to 54  
☐ 55 to 59  
☐ 60 to 64  
☐ 64 to 69  
☐ 70 to 74  
☐ 75 to 79  
☐ NA
17. What is your Menopause Status?
- ☐ Natural, (Natural menopause is the permanent ending of menstruation that is not brought on by any type of medical treatment)  
☐ Premenopausal ( For women undergoing natural menopause, the process is described in three stages: perimenopause, menopause, and post menopause)  
☐ Surgical ( Surgical menopause occurs when a premenopausal woman has her ovaries surgically removed in a procedure called a bilateral oophorectomy.)
18. What age did you have your first period?
- ☐ <=11  
☐ 11.to 12  
☐ 12 to 13  
☐ 13 to 14  
☐ >=14
19. Have you ever had children?
- ☐ Yes ☐ No
20. When (what age) did you have your first child?
- ☐ <=19  
☐ 20 to 24  
☐ 25 to 29  
☐ 30 to 34  
☐ 35 to 39  
☐ >=40
21. How many children do you have?
- ☐ 1  
☐ 2  
☐ 3  
☐ 4  
☐ 5  
☐ 6  
☐ 7  
☐ >=8
22. How many times have you had biopsy?
- ☐ 0  
☐ 1  
☐ >=2
23. How many close relatives with breast cancer do you have?( Mother, Sister, Daughter, Aunt, Grand mother).
- ☐ 0  
☐ 1  
☐ >=2
24. Have you ever had breast cancer surgery?
- ☐ Yes ☐ No
25. What kind of breast cancer surgery did you have?
- ☐ Lumpectomy  
☐ Mastectomy  
☐ Sentinel node biopsy  
☐ Axillary Lymph node dissection  
☐ Other

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Page 4 of 4

26..Are you under medication?

- ☐ Yes  
☐ No

27. Please specify the name of the medication you are taking.

---

28. Have you ever had radiotherapy?

- ☐ Yes  
☐ No

29. Have you had radiotherapy in the operation room?

- ☐ Yes  
☐ No

30. How long after your surgery did you start radiotherapy?

- ☐ Less than 3 days  
☐ 3 to 7 days  
☐ 1 - 2 weeks  
☐ 2- 4 weeks  
☐ More than a month

31. Please specify other breast cancer surgery you have had?

---

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Page 1 of 4

## Breast Cancer Clinical Trial Assessment Survey- Physicians

Please complete the survey below.

Thank you!

1.What is your specialty?

- ☐ Surgeon  
☐ Radiotherapist  
☐ Pathologist

2.What kind of test do you do to diagnose breast cancer? (Check All That Apply)

- ☐ Breast MRI  
☐ Breast CT Scan  
☐ Breast ultrasound  
☐ Mammography  
☐ Pet Scan  
☐ SLNB  
☐ Ductal Lavage  
☐ Breast exam  
☐ Chest X ray  
☐ Breast Biopsy  
☐ Other

3.Please specify other tests you use to diagnose breast cancer.

---

4.How long have you been dealing with breast cancer patients?

- ☐ 1. =< 2  
☐ 2. 2 to 5 years  
☐ 3. =>5

5.How long does it take to get the biopsy results?

- ☐ Less than a day  
☐ 1 to 3 days  
☐ 3 to 6 days  
☐ 7 to 30 days  
☐ More than one month

6.How many times do you take biopsy from patient?

- ☐ 1  
☐ >=2

7.What kind of Breast Cancer treatment have you been using? (Check All That Apply)

- ☐ Surgery  
☐ Chemotherapy  
☐ Radiation therapy  
☐ Hormonal Therapy  
☐ Targeted Therapy  
☐ Complementary and Holistic Medicine  
☐ Drugs for treatment and risk reduction  
☐ Treatments for pain  
☐ Surgical menopause  
☐ Other

8.Please specify the other treatments you use

---

9.What kind of surgery do you do? (Check All That Apply)

- ☐ Lumpectomy  
☐ Mastectomy  
☐ Sentinel node biopsy  
☐ Axillary lymph node dissection  
☐ Other

10.Please specify the other kinds of surgeries you do

---

11.What kind of radiotherapy do you use? (Check All That Apply)

- ☐ External beam radiotherapy  
☐ Brachytherapy  
☐ X ray  
☐ Gamma ray  
☐ Other

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Page 2 of 4

12. Please indicate the other kind of radiotherapy you use.

---

13. Do you have experience as an investigator in sponsored clinical research trial (e.g. research funded by device, pharmaceutical, or biotech companies)?

- ☐ Yes  
☐ No

14. Approximately how many years of experience do you have in clinical research trial?

---

15. What kind of clinical trial have you had experience in before? (Check All That Apply)

- ☐ New combinations of existing drugs.  
☐ Bone-building drugs to prevent breast cancer recurrence.  
☐ Using higher doses of radiation over a shorter period of time on a smaller portion of the breast.  
☐ Other

16. Please specify the other clinical trials you use

---



Confidential

Page 3 of 4

**17. Intraoperative diagnosis of SLN:**

Usually, during surgery, a lymph gland called 'the sentinel node' is taken from the armpit and tested for spread - if the test is positive, the patient will have to undergo a second operation. This new device, however, is an optical scanner which can be used in operating theatres during surgery. It allows for an instant assessment and, if need, be an immediate further surgical procedure - which obviates the need for the patient to undergo a separate, second operation at a later date. Its technology relies on light and elastic scattering spectroscopy which displays a different optical signature for cancerous and non-cancerous cells, and leaves the sentinel node intact for any other tests which may be required.

18. Have you had experience using "Intraoperative diagnosis of SLN" before?

- ☐ Yes  
☐ No

19. Would you like to participate in the clinical trial using "Intraoperative diagnosis of SLN Technology" for the first time in our center?

- ☐ Yes  
☐ No

20. Please specify the reasons why you do not want to participate.

\_\_\_\_\_

21. What do you think about the impact of "Intraoperative diagnosis of SLN Technology" on cure progress?

Very helpful                      No Impact                      Vary bad

=====

(Place a mark on the scale above)

**22."Intraoperative Radiotherapy":**

The new Intraoperative Radiotherapy (IORT) provides an option to immediately treat the cancerous tissue while the patient is still in the surgery.

Postoperative radiotherapy, which forms part of breast conserving therapy, may not need to encompass the whole breast. Apart from the consumption of huge resources and patients' time, postoperative radiotherapy deters many women from receiving the benefits of breast-conserving surgery, forcing them to choose a mastectomy instead. If radiotherapy could be given in the operating theatre immediately after surgery, many of these disadvantages could be overcome. Intraoperative radiotherapy is to use radiotherapy during a surgical procedure, usually in the treatment of diffuse neoplasia that cannot be totally removed by surgical methods alone.

With Intraoperative Radiotherapy, women undergoing breast conserving surgery (lumpectomy) may receive their radiotherapy at the time of their breast cancer operation while still under anesthesia, completely replacing the need for a 6-7 week course of radiotherapy normally given after surgery.

Intraoperative Radiotherapy takes just 20-35 minutes to administer and replaces 6-7 weeks of daily visits to the hospital for post-operative radiotherapy. Intraoperative Radiotherapy permits women to complete their cancer treatments sooner, allowing them a quicker return to their normal lives.

In this new approach the patient has just one dose of radiation, during the operation. It is done using a mobile radiotherapy machine. The probe is inserted into the breast so that it can target the exact site of the cancer. Then the surgeons leave theatre while specialists deliver the radiation which lasts about 30 minutes.

23. Have you had experience using "Intraoperative Radiotherapy Technology" before?

☐ Yes  
☐ No

24. Would you like to participate in the clinical trial using "Intraoperative Radiotherapy Technology" in our center?

☐ Yes  
☐ No

25. Please specify the reasons why you do not want to participate in this clinical trial?

\_\_\_\_\_

26. What do you think about the impact of "Intraoperative Radiotherapy Technology" on cure progress?

Very helpful                      No Impact                      Vary bad

=====

(Place a mark on the scale above)

# **Appendix E**

## **Breast Cancer Clinical Trial Completion Surveys**

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Page 1 of 1


## Breast Cancer Clinical Trial Completion Survey- Patients

Please complete the survey below.

Thank you!

- 1) Did you receive required information from researchers in order to attend in the breast cancer clinical trial? ☐ Yes ☐ No
- 2) Have you been informed about possible side effects of using those new technologies in the trial? ☐ Yes ☐ No
- 3) Did you understand each part of consent form? ☐ Yes ☐ No
- 4) Did you pay out of your pocket for participating in this trial? ☐ Yes ☐ No
- 5) Did you find investigators well-mannered during clinical trial? ☐ Yes ☐ No
- 6) Please choose your overall satisfaction with this clinical trial  

Satisfied
Neutral
Unsatisfied



(Place a mark on the scale above)
- 7) What are your suggestions for future trials?
- 8) Would you recommend this procedure to some other patients with breast cancer? ☐ Yes ☐ No

Page 1

# Breast Cancer Clinical Trial Completion Survey- Physicians

Please complete the survey below.

Thank you!

What is your opinion about breast cancer clinical trial?

- ☐ 1. Good  
☐ 2. Bad  
☐ 3. Could be better  
☐ 4. No opinion

Please specify cons of the breast cancer clinical trial design

---

Please specify pros of the breast cancer clinical trial design

Please specify pros & cons of two intraoperative technologies

What kind of difficulties have you had during clinical trial?

What kind of difficulties have you had while working with two intraoperative technologies?

What do you suggest to improve clinical trial for future?

Have you seen any problems in clinical trial justification for participants?

- ☐ Yes  
☐ No

Please specify problems you have seen in justifying the clinical trial for participants

How intraoperative radiotherapy device is better/worse than standard radiotherapy technologies

How Intraoperative SLN Diagnostic treatment device is better/worse than standard SLN technologies?

Which method do you prefer to use?

- ☐ Intraoperative radiotherapy and SLN Biopsy  
☐ Standard Radiotherapy and SLN Biopsy

Please rate your overall satisfaction of this trial

Satisfied                      Neutral                      Unsatisfied

\_\_\_\_\_

(Place a mark on the scale above)

Please rate your overall satisfaction of patients participation in this trial

Good Fair Bad

(Place a mark on the scale above)

How did you find the impact of trial outcomes on breast cancer treatment

Useful Not useful



(Place a mark on the scale above)

Does this trial have an impact on future breast cancer trial and treatment

- ☐ Yes  
☐ No

Please specify the possible impacts

# **Appendix F**

## **Informed Consent Form**

MEDICAL COLLEGE OF WISCONSIN- FROEDERT HOSPITAL- BREAST CARE CENTER  
9200 W Wisconsin Avenue Milwaukee, WI 53226. Phone: (414) 805-4950, Fax: (414) 805-4955

#### INFORMED CONSENT

**TITLE:** Real-Time Operating Room Breast Cancer Diagnostic-Treatment Randomized Controlled Trial to Compare Intra-operative Radiotherapy with Conventional Post-operative Radiotherapy and compare Intraoperative diagnosis of SLN with Lymphocinigraphy in Conservative Breast Surgery for Women with Early Stage Breast Cancer.

**PRINCIPAL INVESTIGATOR:** Zeinab Salari Far

---

You have been asked to participate as a subject in a medical experiment. Before you decide whether you want to participate in the experimental procedure, you have a right to the following information:

***WISCONSIN LAW REQUIRES THAT YOU MUST BE INFORMED ABOUT:***

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks to be expected from the study.
4. Benefits to be expected from the study.
5. Alternative procedures, drugs or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The opportunity to ask questions about the study or the procedure.
8. The opportunity to withdraw at any time without affecting your future care at this institution.
9. A copy of the written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.
11. Statement regarding liability for research-related injury, if applicable.

I have carefully read the information contained above and I understand fully my rights as a potential subject in a medical experimentation involving people as subjects.

Date: \_\_\_\_\_ Time \_\_\_\_\_

Signature: \_\_\_\_\_  
(patient)

Signature: \_\_\_\_\_  
(parent/legally authorized representative)

If signed by other than patient, indicate relationship: \_\_\_\_\_



MEDICAL COLLEGE OF WISCONSIN- FROERTHER HOSPITAL- BREAST CARE CENTER  
9200 W Wisconsin Avenue Milwaukee, WI 53226. Phone: (414) 805-4950, Fax: (414) 805-4955

#### INFORMED CONSENT

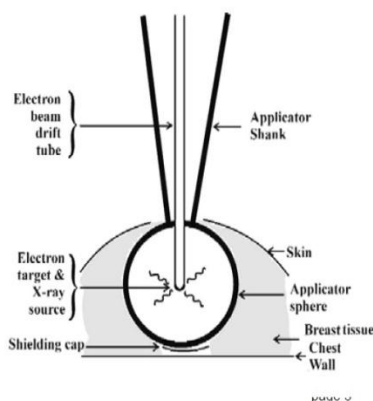
**TITLE:** Real-Time Operating Room Breast Cancer Diagnostic-Treatment Randomized Controlled Trial to Compare Intra-operative Radiotherapy with Conventional Post-operative Radiotherapy and compare Intraoperative diagnosis of SLN with Lymphocinigraphy in Conservative Breast Surgery for Women with Early Stage Breast Cancer.

**PRINCIPAL INVESTIGATOR:** Zeinab Salari Far

#### WHY IS THIS STUDY BEING DONE?

You are invited to take part in a research study. Treatment for the type of breast cancer you have has traditionally been mastectomy (removal of the whole breast). However, it has now been clearly shown that removal of only the lump and the lymph nodes under the armpit, followed by radiotherapy after surgery, is equally effective, and has the benefit of preserving the breast. Conventional radiotherapy is given to the whole breast. This can take up to 6 weeks of daily (Monday through Friday) visits to hospital. Although this is known to considerably reduce the risk of breast cancer recurrence, over a Ten -year period, a few patients in every hundred will have a recurrence of the tumor in the treated breast. Over the last few years, a new device has been developed that delivers the radiotherapy accurately targeted to the tumor bed immediately after the tumor is removed in the operating room. It has been tested in a pilot study with 25 subjects.

This device, the Intrabeam Photon Radiosurgery System, will provide a means to position a radioactive source within the cavity created by the lumpectomy (See Figure 1). This radioactive source will deliver the radiation therapy to the breast tissue over a 30-35 minute period.



**Figure 1.**

Drawing showing the Intrabeam Photon-Radiosurgery System positioned within the breast at the time of surgery. Applicator containing X-ray source is inserted into biopsy cavity. X-rays are released to treat the surrounding breast tissue. Shielding cap used to minimize exposure of underlying chest to X-rays.



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The purpose of this study is to assess whether Targeted Intraoperative Radiotherapy is as effective as the standard 6-week course of radiotherapy after surgery (which we will now call Conventional Radiotherapy). If you agree to participate, you will have an equal chance of receiving either Conventional Radiotherapy (up to six weeks of treatment) or Targeted Intraoperative Radiotherapy (done only at the time of surgery). This study is designed to enroll 2400 patients internationally. Half of the patients will receive Targeted Intraoperative Radiotherapy and half will receive Conventional Radiotherapy. About 100 patients from USC will participate.

The study is being done to find out whether there is any difference between the treatments in reducing the risk of the cancer returning in the affected breast and in the long-term changes to the breast tissue.

#### **WHAT IS INVOLVED IN THE STUDY?**

If you are willing to join the study, your doctor will contact the research center where the study computer will assign one of the two treatments to you by a process similar to tossing a coin. This is the best scientific way to obtain results that are not biased in any way. Your doctor will then let you know whether you will receive the Conventional Radiotherapy or the Targeted Intraoperative Radiotherapy. If you are going to receive Conventional Radiotherapy, you will have your operation and be discharged from the hospital. The radiation oncologist will then arrange for you to receive Conventional Radiotherapy at USC or at a treatment center near your home. After Conventional Radiotherapy is completed, you will be asked to attend the clinic at USC for routine checkup visits.

If you are going to receive Targeted Intraoperative Radiotherapy you will be given treatment while still under anesthesia in the operating room. This treatment will last 30-45 minutes. This means that you will complete your radiotherapy during surgery, and then be discharged from the hospital when you are well enough. You will be asked to return for routine checkup visits.

Prior to your surgery, a series of tests will be performed to determine if you qualify for participation in the clinical study, including additional imaging studies (mammograms, ultrasounds or breast MRI) to fully understand the extent of cancer within your breast. Your physician will ask you a series of questions regarding your medical history. Your temperature, blood pressure and pulse will be taken. Standard physical exams will be performed. If you are a woman of childbearing age, you will be asked to give a urine specimen so that a pregnancy test can be performed.

After seeing the pathology report (the detailed examination of the removed tissue) there is a small chance that your surgeon will want to re-operate because he is not completely sure that he has removed all the affected tissue or because it is an unusual type of breast cancer. All breast cancers are reviewed in this way-it is not just because you are in the study. If further surgery is necessary, he will talk to you about it. If you are in the group treated with Targeted Intraoperative Radiotherapy, you will receive radiotherapy at the time of surgery. If a second surgery is needed, but you have already received Targeted Intraoperative Radiotherapy at the time of your first operation, your doctor will recommend that you undergo Conventional Radiotherapy after the second operation, since re-treatment with Targeted Intraoperative Radiotherapy may cause increased wound complications. If you receive Targeted Intraoperative Radiotherapy, but are found to have extensive cancer affecting your lymph nodes, your doctor will recommend that you undergo Conventional Radiotherapy because patients with extensive cancer affecting the lymph nodes respond better to Conventional Radiotherapy.

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If you are in the Conventional Radiotherapy group, then the radiotherapy will be given after you have completed all surgery. If your doctors recommend chemotherapy to treat your breast cancer, then the chemotherapy will be given after surgery, followed by Conventional Radiotherapy given after chemotherapy.

If you have undergone surgery at another hospital for breast cancer, you may still participate in this study. To determine if you qualify for this study, your doctors might request that you undergo additional studies (for example, mammogram, ultrasound or breast MRI) to ensure that your original surgery was adequate. If the doctors decide that your original surgery was inadequate, you will be advised to have additional biopsies or surgery to remove affected breast tissue. If you are placed in the group receiving Targeted Intraoperative Radiotherapy, the radiotherapy will be given at the time of this second operation. Even if your first surgery was successful, you will still need to undergo a second operation in order for the Targeted Intraoperative Radiotherapy to be given. Also, at the time you receive Targeted Intraoperative Radiotherapy, the surgeon might need to remove additional breast tissue or re-shape your breast tissue so that the radiotherapy may be given properly. The surgeon will discuss this with you prior to surgery.

If you have undergone surgery at another hospital for breast cancer and have been placed in the Conventional Radiotherapy group, your doctors might request that you undergo additional studies (for example, mammogram, ultrasound or breast MRI) to ensure that your original operation was successful. If your doctors decide that your original surgery was inadequate, you will be advised to have additional biopsies or surgery before being allowed to remain in this study. Once you have received permission to remain in this study, the radiation oncologist will arrange for you to receive Conventional Radiotherapy at USC or at a treatment center near your home. After Conventional Radiotherapy is completed, you will be asked to return to USC for routine checkup visits.

Most patients with breast cancer are recommended to take additional treatment (adjuvant therapy) to try to stop the cancer from coming back. This may be chemotherapy or hormone therapy. These treatments are not part of the study. If you are in the Targeted Intraoperative Radiotherapy group and have been advised to receive chemotherapy, your radiotherapy will be given at the time of surgery and chemotherapy will be given after surgery. If you are in the Conventional Radiotherapy group and have been advised to receive chemotherapy, you will be given chemotherapy after surgery followed by Conventional Radiotherapy after completing chemotherapy. If hormone therapy is recommended, it is usually started after the completion of surgery, chemotherapy, and radiotherapy.

In order for the international research center to analyze the results of this study, data on you, your treatment and how you do afterwards will be sent from USC. This will be done in a secure way and all data referring to you will be kept private.

The data may not be analyzed for several years, following strict scientific guidelines as to when this should be done. During this period, the data from the study will be regularly reviewed by a small group of international experts not directly involved in the study (called the Data Monitoring and Safety Committee). They will advise and make recommendations on the safety and conduct of the study. They are independent and ensure that the study is run to the highest ethical and scientific standards.



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When the results have been analyzed, your doctor will be informed so that he can pass on the information to you. A paper will also be published in a scientific journal so that doctors all over the world can read the results. Individual patients will not be identifiable from the information in any publication.

In order to produce reliable results, the research center would like to receive information on you for at least ten years following completion of your treatment. Therefore, if you move and will no longer be able to attend your original treating hospital, please let your doctor know.

If you agree, we would like to collect a small piece of the tissue removed at operation but currently stored in your local hospital. There are now a number of ways we could use this tissue to learn more about breast cancer. There will be no results from this that will affect you or your treatment in any way but we hope that we might be able to learn more about the disease. If you are willing to donate your tissue as a gift to be used in this way please check the appropriate box below:

My tissue samples stored after surgery may be used in future research as described above.

Yes \_\_\_\_\_ No \_\_\_\_\_ Initials \_\_\_\_\_

#### WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

You may experience no side effects, some of them or most of them. Although you will be closely monitored, not all side effects can be predicted and unforeseen problems can arise. There may be some unknown or unanticipated risks or discomforts in addition to those specified here. If you experience any discomfort or side effects following your study participation, please report these to your doctor.

**Surgery:** Complications associated with the surgery are similar to any tumor removal surgery. These possible complications include, but are not limited to: infection, bleeding, loss or reduced nerve function, swelling (edema), blood clotting, fluid accumulation, wound breakdown, bruising, skin ulceration, scarring, and allergic reactions.

**Conventional Radiotherapy:** Just as with patients not in the study, Conventional Radiotherapy may cause side effects such as reddening and soreness of the skin, feeling sick (nausea) and tiredness. These side effects gradually disappear once your course of treatment has finished, though the tiredness may continue for some months. Complications arising from Conventional Radiotherapy include, but are not limited to infection, loss or impairment of nerve function, swelling (edema), scarring, rib fracture, chest wall pain, skin ulceration and radiation induced tissue death. Scarring may be a longterm complication of radiation treatment and some firmness, tenderness, pain or deformity in the treated area of the breast may develop in the future.

**Targeted Intraoperative Radiotherapy:** Complications arising from Targeted Intraoperative Radiotherapy include, but are not limited to infection, loss or impairment of nerve function, swelling (edema), scarring, rib fracture, chest wall pain, skin ulceration and radiation induced tissue death. Scarring may be a long-term complication of radiation treatment and some firmness, tenderness, pain or deformity in the treated area of the breast may develop in the future. Since Targeted Intraoperative

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Radiotherapy gives radiotherapy to only a portion of the breast, there is a risk that the untreated portions of the breast will be at greater risk of a breast cancer recurrence. This is the main question that this study is trying to answer. For your protection, your doctors will make every reasonable effort to ensure that you are a good candidate for Targeted Intraoperative Radiotherapy. One possible problem with the new treatment may be delayed wound healing.

Chemotherapy: If chemotherapy is needed to treat your cancer, some patients undergoing chemotherapy after radiation therapy may experience a radiation recall reaction that may cause redness, blistering, or peeling of the skin of the breast.

Pathology: If you have received Targeted Intraoperative Radiotherapy at the time of surgery, but are found after surgery to have a tumor greater than 3 centimeters (1 inches), extensive non-invasive cancer, or cancer involving four (4) or more lymph nodes, you will be advised to undergo Conventional Radiotherapy, and possibly more surgery.

#### **WHAT ABOUT PREGNANCY?**

Radiotherapy is harmful to an unborn child. If you are pregnant, you may not take part in this study. If you are a woman who could become pregnant, you must have a pregnancy test to make sure you are not pregnant prior to receiving either Targeted Intraoperative Radiotherapy or Conventional Radiotherapy. You must use birth control while receiving radiotherapy.

If you are breastfeeding and do not want to stop, you may not join this study. The only way you can take part in this study is to stop breastfeeding and not use your breast milk to feed your child until your doctor tells you it is safe.

#### **WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?**

Patients receiving Targeted Intraoperative Radiotherapy will avoid up to 30 visits to the radiotherapy department for post-operative radiotherapy. The entire breast treatment, including radiotherapy, will have been completed at the time of surgery. Also, because of the way the intraoperative radiotherapy is given, the tissues at greatest risk receive the maximum dose.

Except for shortening the duration of your radiation therapy, you will not receive additional benefit if you are in the group treated with Targeted Intraoperative Radiotherapy.

The potential benefit to society is the development of a new way of getting radiation to the tumor cells in the area where the tumor was and kill those tumor cells. This new method is designed to spare normal tissue from radiation effects and to reduce the total duration of therapy. The information obtained from this study may be used scientifically and may possibly be helpful to others in the future.

Other treatment options include mastectomy, Conventional Radiotherapy, chemotherapy or other methods of partial breast irradiation or experimental agents to make you feel better. Another option is no further therapy. Your doctor can provide information about your disease and the benefits of the different treatments for you. You should feel free to talk with your doctor about your disease and expected outcomes. The doctor involved in your care will be available to answer any questions you have about this program. You are free to ask your doctor any question concerning this program now or in the future.



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**WILL YOUR INFORMATION BE KEPT PRIVATE?**

Every effort will be made to maintain the confidentiality of your medical records for this study by the investigators and the Institutional Review Board (IRB). However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Specific study-related information will be made available to Zeiss, Inc., the manufacturer of the IntraBeam Photon Radiosurgery System. The Food and Drug Administration (FDA) will be allowed access to your medical records. Unless required by law, the FDA will maintain the confidentiality of your medical records. If results of this study are published in medical literature, you will not be identified by name.

**WHAT ARE THE COSTS?**

If you take part in this study, your insurance company may not pay for some or all of the procedures, treatments and tests. If that happens, you need to pay for these procedures, treatments and tests yourself.

**ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?**

You will not be paid for taking part in this study.

**WHAT HAPPENS IF YOU GET INJURED OR NEED EMERGENCY CARE?**

If you require medical treatment as a result of injury arising from your participation in this study, emergency medical care required to treat the injury will be provided. However, the financial responsibility for such care will be yours. No compensation will be provided for any injury you may suffer as a direct consequence of non-negligent performance of the procedures described above.

**WILL YOU RECEIVE NEW INFORMATION ABOUT THIS STUDY?**

During the study, we may learn new things about the risks or benefits of being in the study. If we do, we will share this with you. You might change your mind about being in the study based on this information. If new information is provided to you, we will ask for your agreement to continue taking part in this study.

**UNDER WHAT CIRCUMSTANCES CAN YOUR PARTICIPATION BE TERMINATED?**

If you do not follow your doctor's instructions, if your disease gets worse, or if the sponsor closes the study, you may be removed from this study. If this happens, your doctor will discuss other options with you.

**WHAT ARE YOUR RIGHTS AS A PARTICIPANT AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?**

Your participation in this study is voluntary. Your decision whether or not to take part will not affect your current or future care at this institution. You are not waiving any legal claims or rights. If you do decide to take part in this study, you are free to change your mind and stop being in the study at any time.

**WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?**

Your participation will be under the care of \_\_\_\_\_, MD at \_\_\_\_\_. You may contact your doctor with any questions about your care. If you have any questions about problems related to this study, you should contact the Principal Investigator, Zeinab Salari Far at Zeinab@uwm.edu.

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**AGREEMENT:** I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions were answered. I have decided to sign this form in order to take part in this study.

\_\_\_\_\_  
Name of Subject Signature    Date Signed Time *(if consented on same day as treatment)*

\_\_\_\_\_  
Name of Witness Signature    Date Signed Time *(if consented on same day as treatment)*

If applicable:

I have verbally translated this informed consent document to the study subject.

\_\_\_\_\_  
Name of Translator Signature    Date Signed Time *(if consented on same day as treatment)*

I have personally explained the research to the subject and answered all questions. I believe that he/she understands the information described in this informed consent and freely consents to participate.

\_\_\_\_\_  
Name of Investigator/Person Signature    Date Signed Time *(if consented on*  
Obtaining Informed Consent    *same day as treatment)*

# **Appendix G**

## **Data Analysis**

## Breast Cancer Clinical Trial Assessment Survey- Patients

### 2. What is your Race?: [Refresh Plot](#) [View as Pie Chart](#)

Total (N)	Missing	Unique
48	0 (0%)	4

Counts/frequency: African American (11, 22.9%), White (20, 41.7%), Asian (11, 22.9%), Hispanic (6, 12.5%), Other (0, 0%)

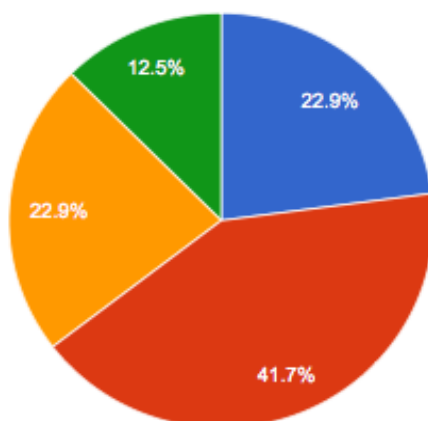


Table 1

### 3. Are you a smoker?: [Refresh Plot](#) [View as Bar Chart](#)

Total (N)	Missing	Unique
41	7 (14.6%)	2

Counts/frequency: Yes (19, 46.3%), No (22, 53.7%)



Table 2



#### 4. What is your marital status?: [Refresh Plot](#) [View as Pie Chart](#)

Total (N)	Missing	Unique
48	0 (0%)	3

Counts/frequency: 1. Never married (21, 44.7%), 2. Married (26, 55.3%)

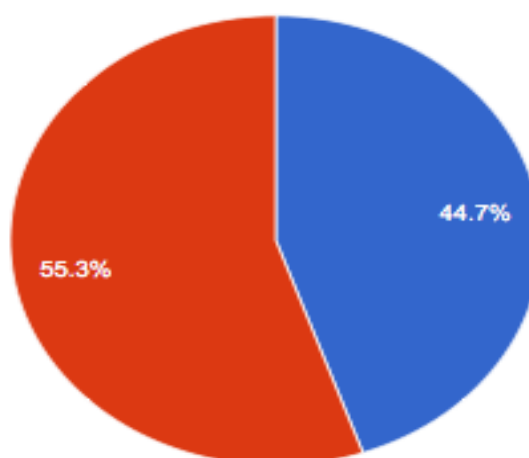


Table 3

#### 5. Have you been diagnosed with breast cancer?: [Refresh Plot](#) [View as Bar Chart](#)

Total (N)	Missing	Unique
13	35 (72.9%)	2

Counts/frequency: Yes (10, 76.9%), No (3, 23.1%)

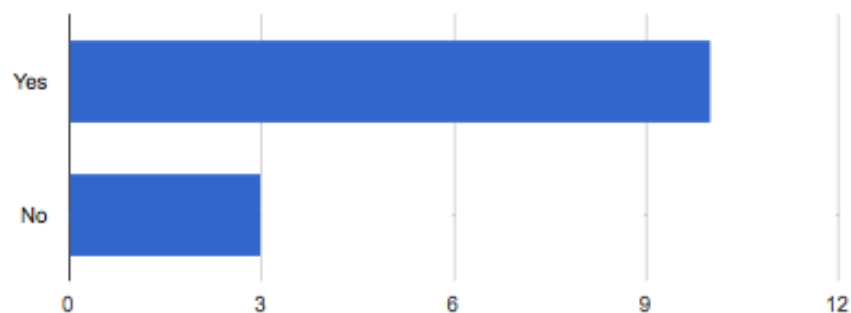


Table 4

**6. Have you ever heard about clinical trial?:** [Refresh Plot](#) [View as Pie Chart](#)

Total (N)	Missing	Unique
10	<a href="#">38 (79.2%)</a>	2

Counts/frequency: Yes (8, 80%), No (2, 20%)

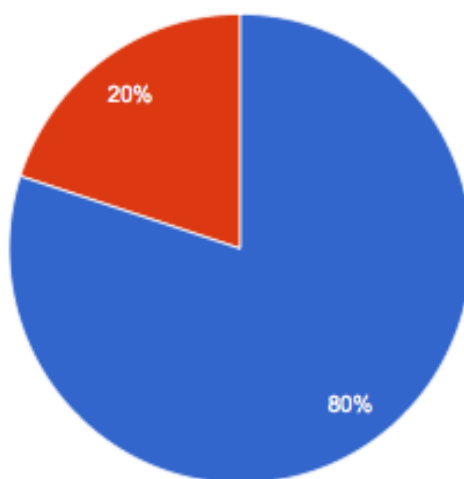


Table 5

**8. Have you ever participated in a clinical trial?:** [Refresh Plot](#) [View as Bar Chart](#)

Total (N)	Missing	Unique
10	<a href="#">38 (79.2%)</a>	2

Counts/frequency: Yes (4, 40%), No (6, 60%)



Table 6

**9.What kind of clinical trial have you been engaged before? (Check All That Apply) :** [Refresh Plot](#) [View as Pie Chart](#)

Total (N)	Missing	Unique
4	44 (91.7%)	1

Counts/frequency: Treatment (4, 30.8%), Prevention (4, 30.8%), Screening (2, 15.4%), Diagnostic (3, 23.1%), Quality of Life or Supportive care. (0, 0%)

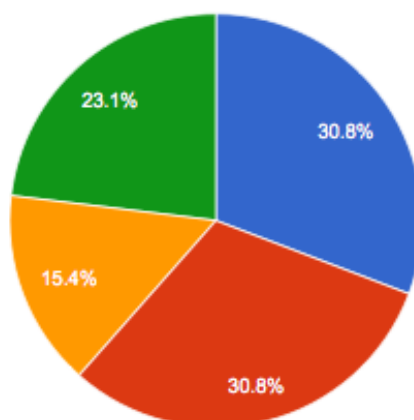


Table 7

**10.Would you like to participate in breast cancer clinical trial?:** [Refresh Plot](#)

[View as Bar Chart](#)

Total (N)	Missing	Unique
10	38 (79.2%)	2

Counts/frequency: Yes (6, 60%), No (4, 40%)



Table 8

**14. Would you like to attend Intraoperative Radiotherapy and Intraoperative diagnosis of SLN clinical trial?:** [Refresh Plot](#) [View as Pie Chart](#)

Total (N)	Missing	Unique
6	<a href="#">42 (87.5%)</a>	2

Counts/frequency: Yes (5, 83.3%), No (1, 16.7%)

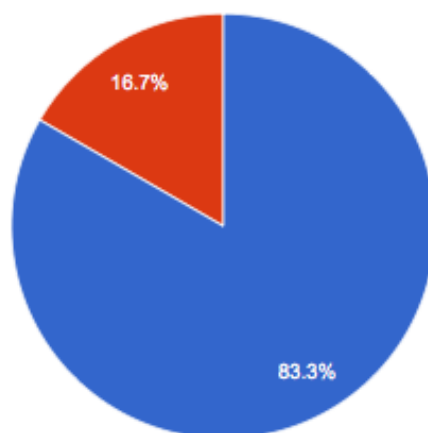


Table 9

**16. What is your menopause age?:** [Refresh Plot](#) [View as Pie Chart](#)

Total (N)	Missing	Unique
33	<a href="#">15 (31.3%)</a>	8

Counts/frequency: 40 to 44 (4, 12.1%), 45 to 49 (4, 12.1%), 50 to 54 (5, 15.2%), 55 to 59 (3, 9.1%), 60 to 64 (1, 3%), 64 to 69 (2, 6.1%), 70 to 74 (1, 3%), 75 to 79 (0, 0%), NA (13, 39.4%)

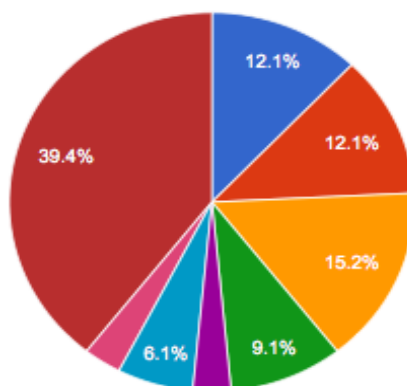


Table 10

### 17. What is your Menopause Status?: [Refresh Plot](#) [View as Bar Chart](#)

Total (N)	Missing	Unique
18	30 (62.5%)	3

**Counts/frequency:** Natural, (Natural menopause is the permanent ending of menstruation that is not brought on by any type of medical treatment) (5, 27.8%), Premenopausal ( For women undergoing natural menopause, the process is described in three stages: perimenopause, menopause, and post menopause) (8, 44.4%), Surgical ( Surgical menopause occurs when a premenopausal woman has her ovaries surgically removed in a procedure called a bilateral oophorectomy.) (5, 27.8%)

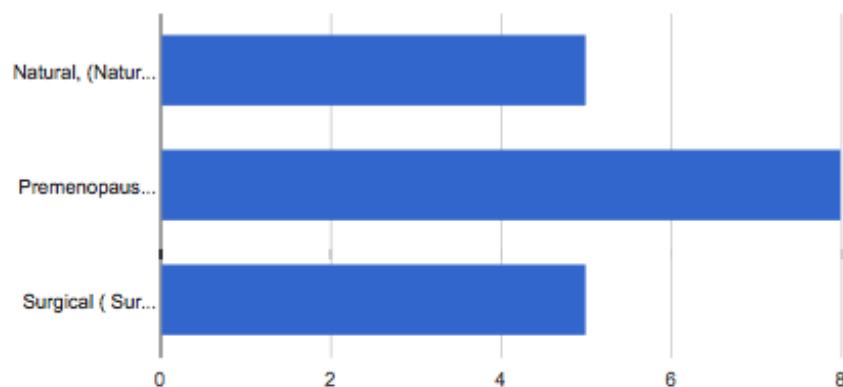


Table 11

### 18. What age did you have your first period? : [Refresh Plot](#) [View as Pie Chart](#)

Total (N)	Missing	Unique
38	10 (20.8%)	5

**Counts/frequency:** <=11 (5, 13.2%), 11.to 12 (11, 28.9%), 12 to 13 (10, 26.3%), 13 to 14 (7, 18.4%), >=14 (5, 13.2%)

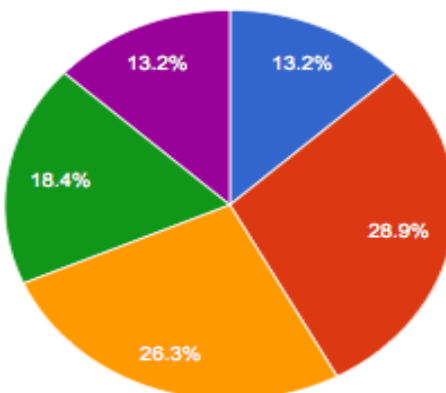


Table 12

### 19. Have you ever had children?: [Refresh Plot](#) [View as Bar Chart](#)

Total (N)	Missing	Unique
20	<a href="#">28 (58.3%)</a>	2

Counts/frequency: Yes (13, 65%), No (7, 35%)

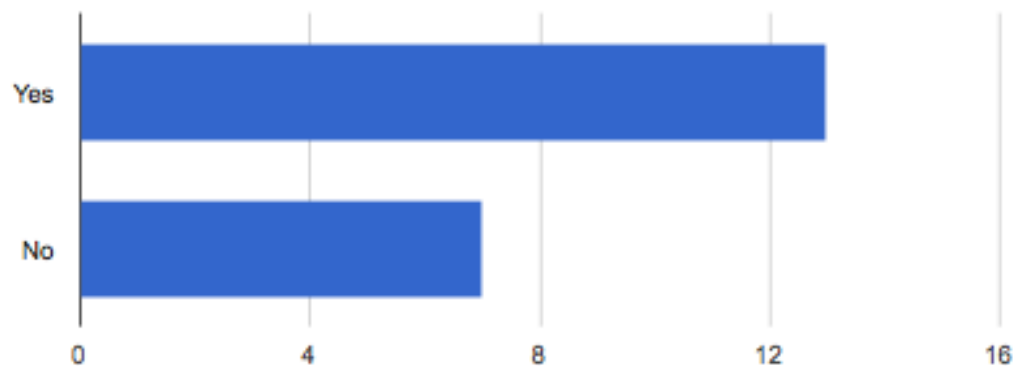


Table 13

### 20. When (what age) did you have your first child?: [Refresh Plot](#) [View as Pie Chart](#)

Total (N)	Missing	Unique
14	<a href="#">34 (70.8%)</a>	5

Counts/frequency: <=19 (1, 7.1%), 20 to 24 (5, 35.7%), 25 to 29 (5, 35.7%), 30 to 34 (2, 14.3%), 35 to 39 (0, 0%), >=40 (1, 7.1%)

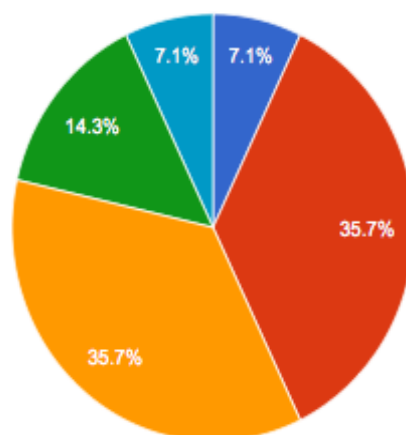


Table 14

## 21. How many children do you have?: [Refresh Plot](#) [View as Pie Chart](#)

Total (N)	Missing	Unique
14	<a href="#">34 (70.8%)</a>	6

Counts/frequency: 1 (2, 14.3%), 2 (6, 42.9%), 3 (3, 21.4%), 4 (1, 7.1%), 5 (0, 0%), 6 (0, 0%), 7 (1, 7.1%), >=8 (1, 7.1%)

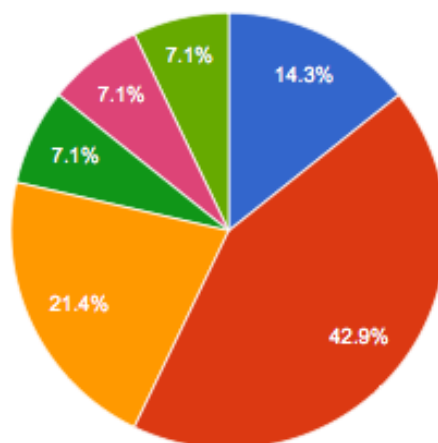


Table 15

## 22. How many times have you had biopsy?: [Refresh Plot](#) [View as Bar Chart](#)

Total (N)	Missing	Unique
41	<a href="#">7 (14.6%)</a>	3

Counts/frequency: 0 (12, 29.3%), 1 (19, 46.3%), >=2 (10, 24.4%)

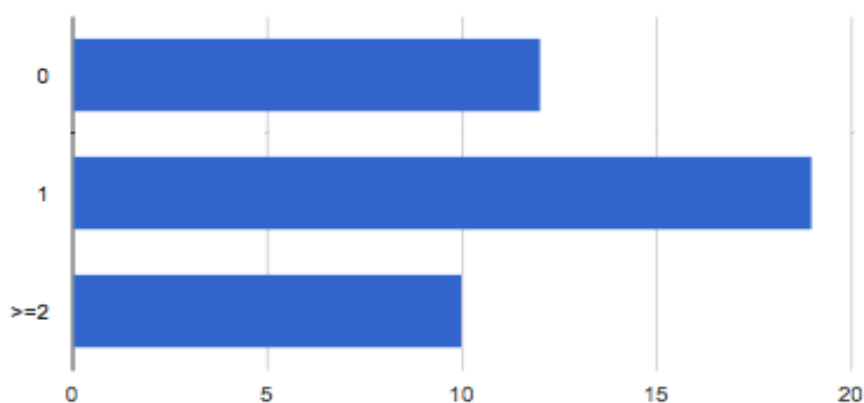


Table 16

**23. How many close relatives with breast cancer do you have?( Mother, Sister, Daughter, Aunt, Grand mother):** [Refresh Plot](#) [View as Pie Chart](#)

Total (N)	Missing	Unique
41	7 (14.6%)	3

Counts/frequency: 0 (11, 26.8%), 1 (15, 36.6%), >=2 (15, 36.6%)

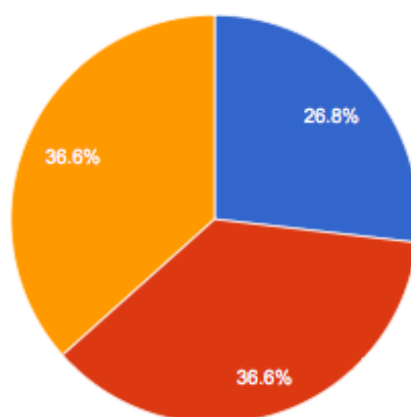


Table 17

**24. Have you ever had breast cancer surgery?:** [Refresh Plot](#) [View as Bar Chart](#)

Total (N)	Missing	Unique
39	9 (18.8%)	2

Counts/frequency: Yes (14, 35.9%), No (25, 64.1%)



Table 18



### 25. What kind of breast cancer surgery did you have?: [Refresh Plot](#) [View as Pie Chart](#)

Total (N)	Missing	Unique
14	34 (70.8%)	1

Counts/frequency: Lumpectomy (4, 18.2%), Mastectomy (8, 36.4%), Sentinal node biopsy (3, 13.6%), Axillary Lymph node dissection (7, 31.8%), Other (0, 0%)

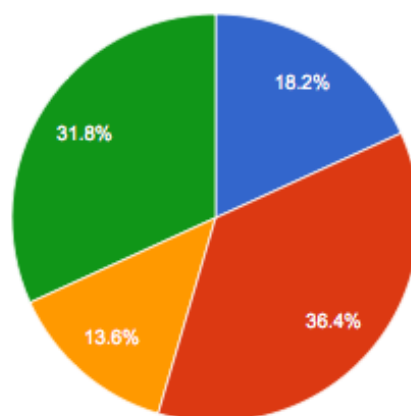


Table 19

### 26..Are you under medication?: [Refresh Plot](#) [View as Bar Chart](#)

Total (N)	Missing	Unique
8	40 (83.3%)	2

Counts/frequency: Yes (1, 12.5%), No (7, 87.5%)

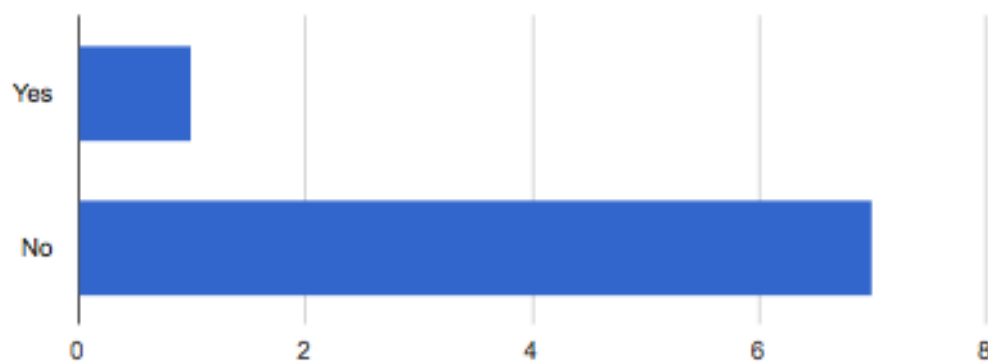


Table 20

## 28. Have you ever had radiotherapy?:

Total (N)	Missing	Unique
7	<a href="#">41 (85.4%)</a>	2

Counts/frequency: Yes (4, 57.1%), No (3, 42.9%)



Table 21

## 29. Have you had radiotherapy in the operation room?: [Refresh Plot](#) [View as Bar Chart](#)

Total (N)	Missing	Unique
6	<a href="#">42 (87.5%)</a>	2

Counts/frequency: Yes (2, 33.3%), No (4, 66.7%)

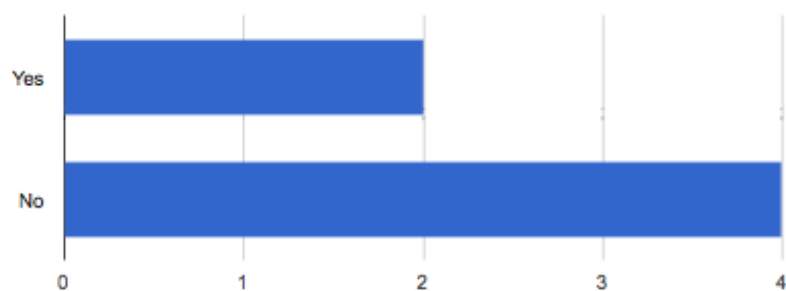


Table 22

**30. How long after your surgery did you start radiotherapy?:** [Refresh Plot |](#)

View as Pie Chart

Total (N)	Missing	Unique
2	<a href="#">46 (95.8%)</a>	2

Counts/frequency: Less than 3 days (0, 0%), 3 to 7 days (0, 0%), 1 - 2 weeks (0, 0%), 2- 4 weeks (1, 50%), More than a month (1, 50%)

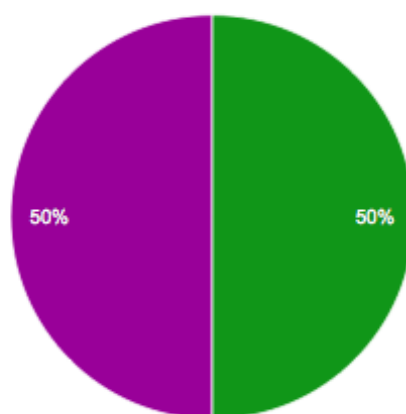


Table 23

## Breast Cancer Clinical Trial Assessment Surveys-Physicians

### 1.What is your specialty?: [Refresh Plot](#) | [View as Pie Chart](#)

Total (N)	Missing	Unique
60	<a href="#">2 (3.2%)</a>	5

Counts/frequency: Surgeon (20, 41.7%), Radiotherapist (17, 35.4%), Pathologist (11, 22.9%)

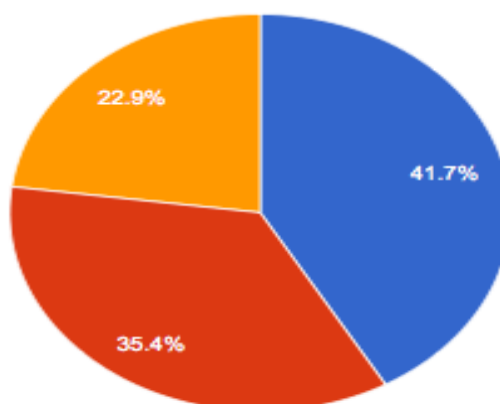


Table 24

### 2.What kind of test do you do to diagnose breast cancer? (Check All That Apply): [Refresh Plot](#) | [View as Pie Chart](#)

Total (N)	Missing	Unique
40	<a href="#">22 (35.5%)</a>	1

Counts/frequency: Breast MRI (19, 12.4%), Breast CT Scan (17, 11.1%), Breast ultrasound (16, 10.5%), Mammography (18, 11.8%), Pet Scan (14, 9.2%), SLNB (7, 4.6%), Ductal Lavage (13, 8.5%), Breast exam (19, 12.4%), Chest X ray (14, 9.2%), Breast Biopsy (16, 10.5%), Other (0, 0%)

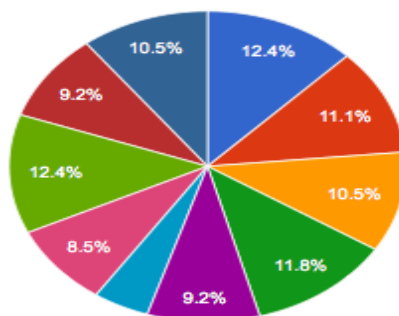


Table 25

#### 4. How long have you been dealing with breast cancer patients?: [Refresh Plot](#)

View as Pie Chart

Total (N)	Missing	Unique
60	<a href="#">2 (3.2%)</a>	3

Counts/frequency: 1. =<2 (13, 21.7%), 2. 2 to 5 years (26, 43.3%), 3. =>5 (21, 35%)

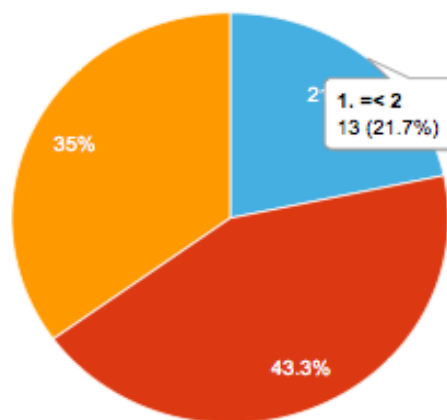


Table 26

#### 5. How long does it take to get the biopsy results?: [Refresh Plot](#)

View as Pie Chart

Total (N)	Missing	Unique
17	<a href="#">45 (72.6%)</a>	4

Counts/frequency: Less than a day (0, 0%), 1 to 3 days (3, 17.6%), 3 to 6 days (9, 52.9%), 7 to 30 days (4, 23.5%), More than one month (1, 5.9%)

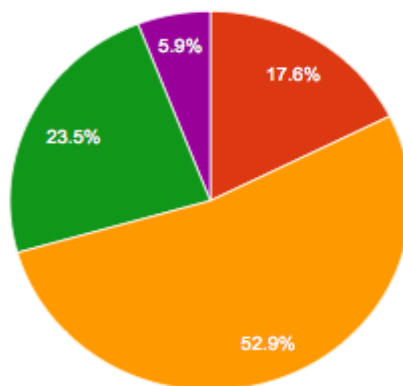


Table 27

### 6. How many times do you take biopsy from patient? : [Refresh Plot](#) [View as Pie Chart](#)

Total (N)	Missing	Unique
17	45 (72.6%)	2

Counts/frequency: 1 (3, 17.6%), >=2 (14, 82.4%)

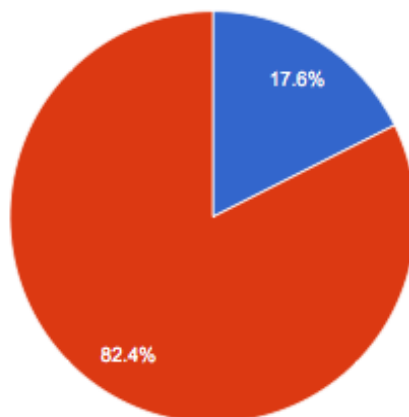


Table 28

### 7. What kind of Breast Cancer treatment have you been using? (Check All That Apply): [Refresh Plot](#) [View as Pie Chart](#)

Total (N)	Missing	Unique
50	12 (19.4%)	1

Counts/frequency: Surgery (21, 14.6%), Chemotherapy (22, 15.3%), Radiation therapy (21, 14.6%), Hormonal Therapy (15, 10.4%), Targeted Therapy (18, 12.5%), Complementary and Holistic Medicine (6, 4.2%), Drugs for treatment and risk reduction (11, 7.6%), Treatments for pain (12, 8.3%), Surgical menopause (15, 10.4%), Other (3, 2.1%)

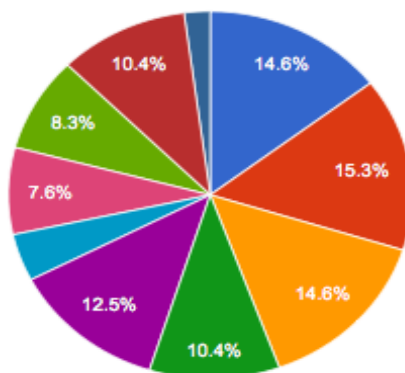


Table 29

### 9.What kind of surgery do you do? (Check All That Apply): [Refresh Plot](#)

View as Pie Chart

Total (N)	Missing	Unique
21	41 (66.1%)	1

Counts/frequency: Lumpectomy (19, 35.8%), Mastectomy (13, 24.5%), Sentinel node biopsy (10, 18.9%), Axillary lymph node dissection (9, 17%), Other (2, 3.8%)

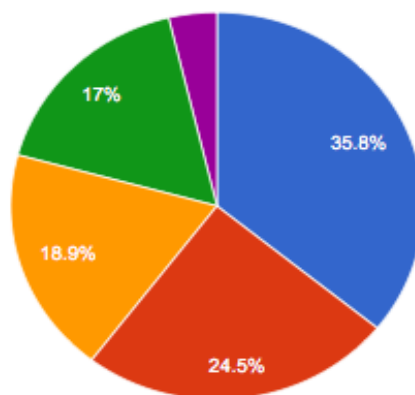


Table 30

### 11.What kind of radiotherapy do you use? (Check All That Apply): [Refresh Plot](#)

View as Pie Chart

Total (N)	Missing	Unique
21	41 (66.1%)	1

Counts/frequency: External beam radiotherapy (11, 24.4%), Brachytherapy (8, 17.8%), X ray (15, 33.3%), Gamma ray (11, 24.4%), Other (0, 0%)

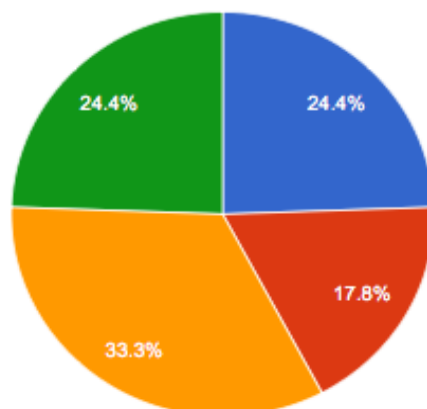


Table 31

**13. Do you have experience as an investigator in sponsored clinical research trial (e.g. research funded by device, pharmaceutical, or biotech companies)? :**

Total (N)	Missing	Unique
19	43 (69.4%)	2

Counts/frequency: Yes (9, 47.4%), No (10, 52.6%)

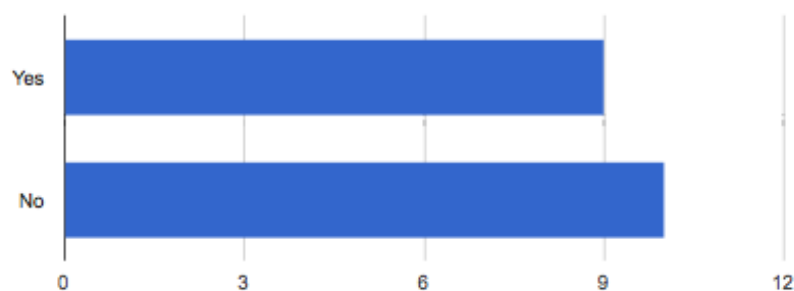


Table 32

**15. What kind of clinical trial have you had experience in before? (Check All That Apply):** [Refresh Plot](#) | [View as Bar Chart](#)

Total (N)	Missing	Unique
26	36 (58.1%)	1

Counts/frequency: New combinations of existing drugs. (12, 31.6%), Bone-building drugs to prevent breast cancer recurrence. (10, 26.3%), Using higher doses of radiation over a shorter period of time on a smaller portion of the breast. (15, 39.5%), Other (1, 2.6%)

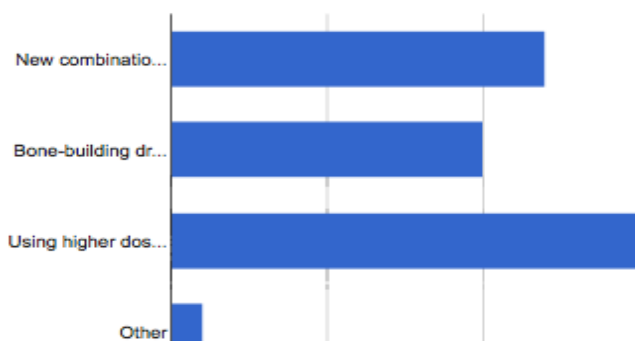


Table 33



### 18. Have you had experience using "Intraoperative diagnosis of SLN" before?:

Total (N)	Missing	Unique
19	43 (69.4%)	2

Counts/frequency: Yes (5, 26.3%), No (14, 73.7%)

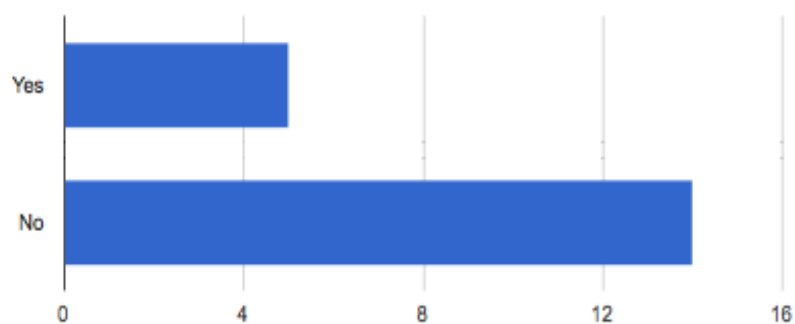


Table 34

### 18. Have you had experience using "Intraoperative diagnosis of SLN" before?:

Total (N)	Missing	Unique
19	43 (69.4%)	2

Counts/frequency: Yes (5, 26.3%), No (14, 73.7%)

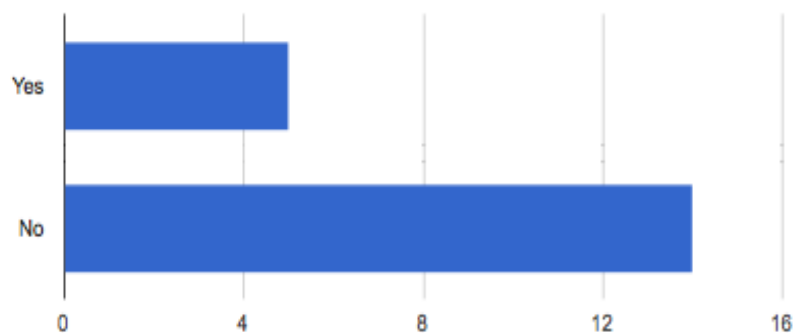


Table 35

### 19. Would you like to participate in the clinical trial using "Intraoperative diagnosis of SLN Technology" for the first time in our center?: [Refresh Plot](#)

View as Bar Chart

Total (N)	Missing	Unique
18	<a href="#">44 (71%)</a>	2

Counts/frequency: Yes (16, 88.9%), No (2, 11.1%)

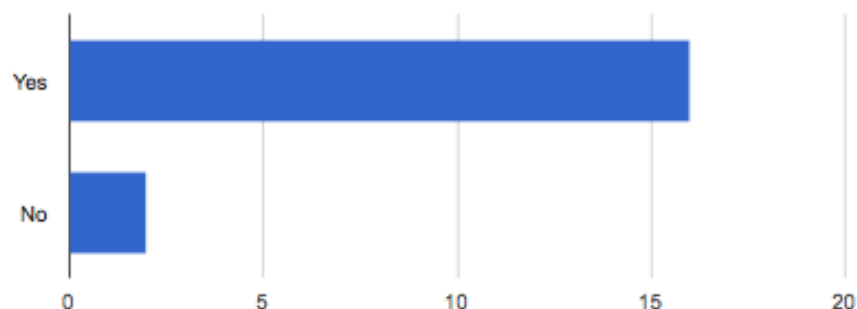


Table 36

### 21. What do you think about the impact of "Intraoperative diagnosis of SLN Technology" on cure progress?: [Refresh Plot](#)

Total (N)	Missing	Unique	Min	Max	Mean	StDev	Percentile						
							.05	.10	.25	.50 Median	.75	.90	.95
58	<a href="#">4 (6.5%)</a>	34	0.00	82.00	31.64	25.65	0.00	0.00	8.00	27.50	49.00	73.50	77.50

Lowest values: 0, 0, 0, 0, 0

Highest values: 75, 77, 77, 78, 82

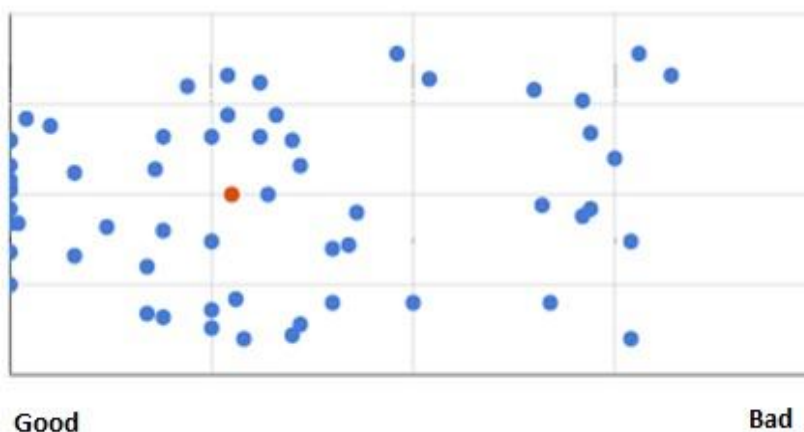


Table 37

**23. Have you had experience using "Intraoperative Radiotherapy Technology" before?:** [Refresh Plot](#) [View as Bar Chart](#)

Total (N)	Missing	Unique
19	43 (69.4%)	2

Counts/frequency: Yes (7, 36.8%), No (12, 63.2%)

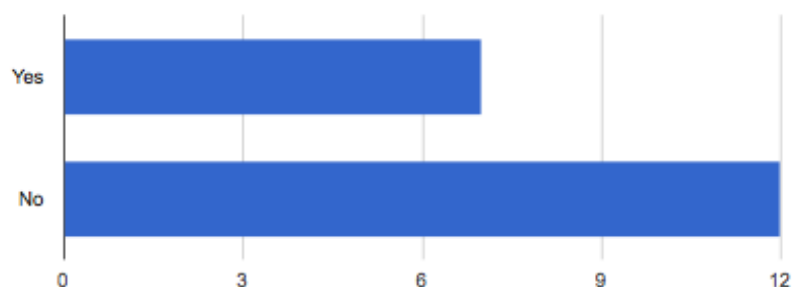


Table 38

**24. Would you like to participate in the clinical trial using "Intraoperative Radiotherapy Technology" in our center?:** [Refresh Plot](#) [View as Bar Chart](#)

Total (N)	Missing	Unique
18	44 (71%)	2

Counts/frequency: Yes (16, 88.9%), No (2, 11.1%)

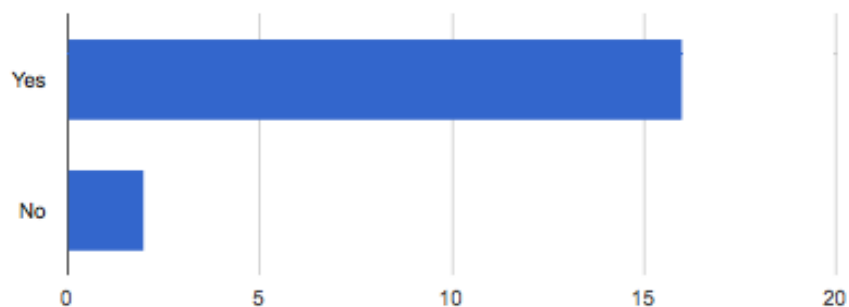


Table 39

26.What do you think about the impact of "Intraoperative Radiotherapy Technology" on cure progress?: [Refresh Plot](#)

Total (N)	Missing	Unique	Min	Max	Mean	StDev	Percentile						
							.05	.10	.25	.50 Median	.75	.90	.95
18	44 (71%)	13	0.00	74.00	29.94	23.68	0.00	0.00	15.00	27.00	47.00	73.00	74.00

Lowest values: 0, 0, 0, 14, 16  
Highest values: 40, 54, 68, 72, 74

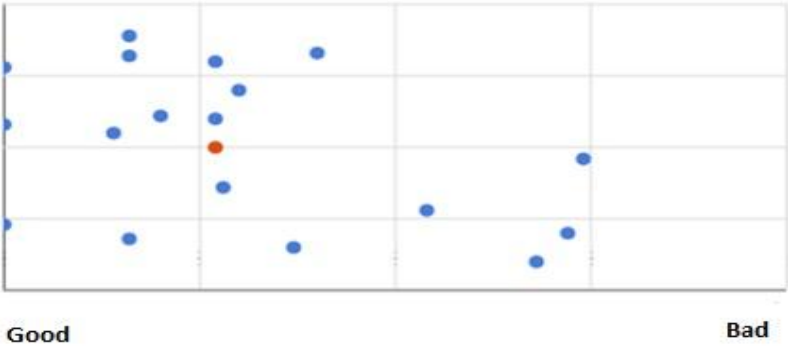


Table 40

### Breast Cancer Clinical Trial Completion Survey-Patients

**Did you receive required information from researchers in order to attend in the breast cancer clinical trial?:** [Refresh Plot](#) | [View as Pie Chart](#)

Total (N)	Missing	Unique
43	0 (0%)	2

Counts/frequency: Yes (38, 88.4%), No (5, 11.6%)

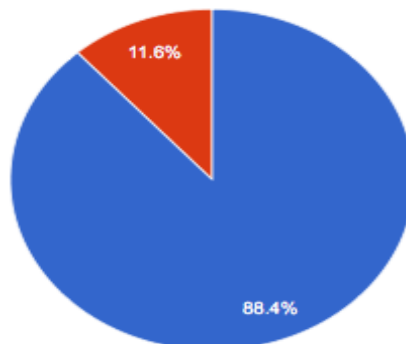


Table 41

**Have you been informed about possible side effects of using those new technologies in the trial?:** [Refresh Plot](#) | [View as Pie Chart](#)

Total (N)	Missing	Unique
43	0 (0%)	2

Counts/frequency: Yes (39, 90.7%), No (4, 9.3%)

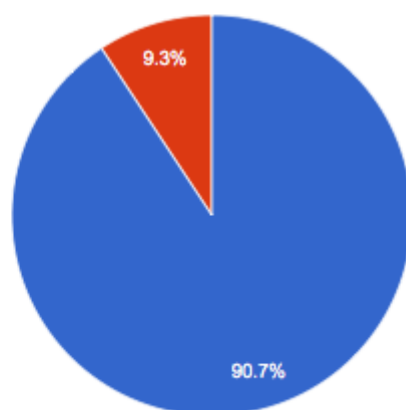


Table 42

**Did you understand each part of consent form?:** [Refresh Plot](#) [View as Pie Chart](#)

Total (N)	Missing	Unique
43	0 (0%)	2

Counts/frequency: Yes (35, 81.4%), No (8, 18.6%)

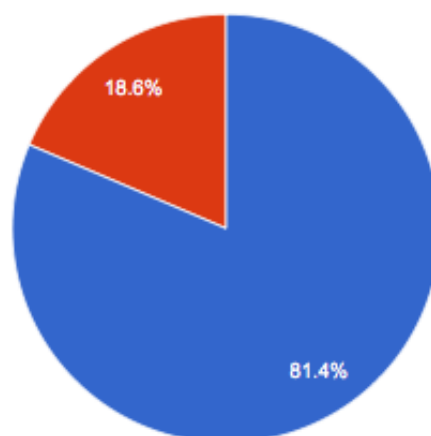


Table 43

**Did you pay out of your pocket for participating in this trial?:** [Refresh Plot](#) |

[View as Pie Chart](#)

Total (N)	Missing	Unique
43	0 (0%)	2

Counts/frequency: Yes (14, 32.6%), No (29, 67.4%)

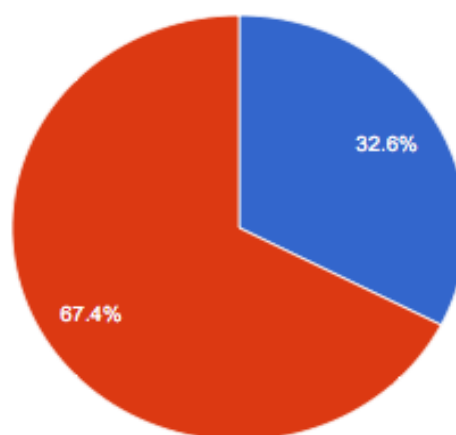


Table 44

Did you find investigators well-mannered during clinical trial?: [Refresh Plot](#)

View as Pie Chart

Total (N)	Missing	Unique
43	0 (0%)	2

Counts/frequency: Yes (37, 86%), No (6, 14%)

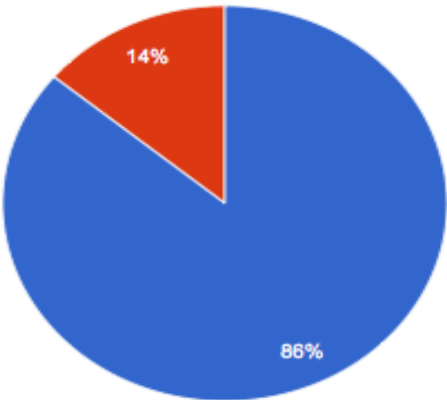


Table 45

Please choose your overall satisfaction with this clinical trial: [Refresh Plot](#)

Total (N)	Missing	Unique	Min	Max	Mean	StDev	Percentile						
							.05	.10	.25	.50 Median	.75	.90	.95
43	0 (0%)	32	0.00	91.00	35.51	18.88	4.00	10.00	26.00	37.00	44.00	55.50	75.50

Lowest values: 0, 0, 8, 9, 11

Highest values: 53, 58, 62, 89, 91

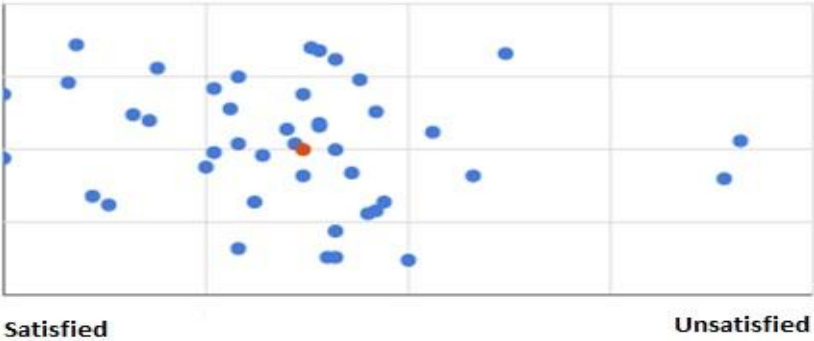


Table 46

**Would you recommend this procedure to some other patients with breast cancer?:**

Total (N)	Missing	Unique
43	0 (0%)	2

Counts/frequency: Yes (39, 90.7%), No (4, 9.3%)

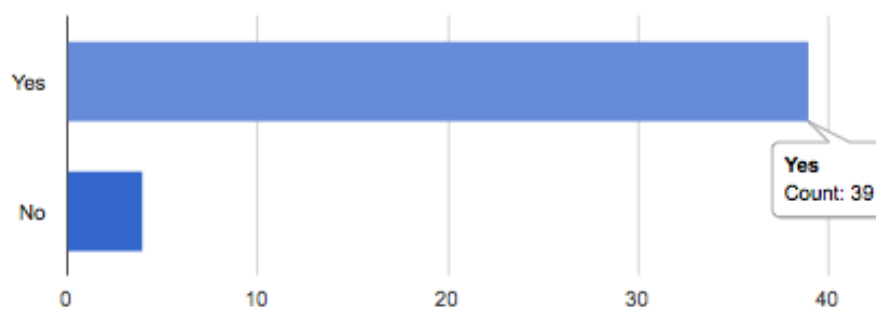


Table 47



### Breast Cancer Clinical Trial Completion Survey-Physicians

**What is your opinion about breast cancer clinical trial?:** [Refresh Plot](#)

View as Pie Chart

Total (N)	Missing	Unique
8	0 (0%)	3

Counts/frequency: 1. Good (4, 50%), 2. Bad (0, 0%), 3. Could be better (3, 37.5%), 4. No opinion (1, 12.5%)

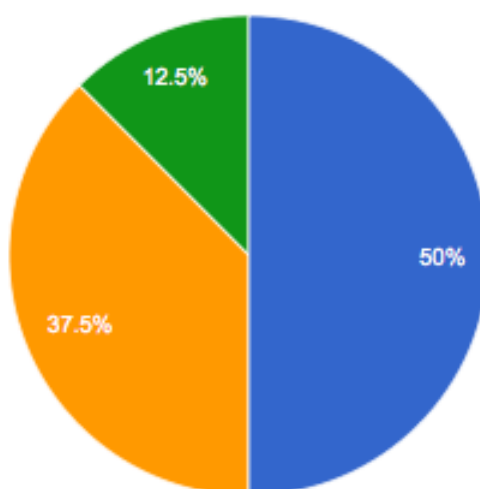


Table 48

**Have you seen any problems in clinical trial justification for participants? :**

Total (N)	Missing	Unique
8	0 (0%)	2

Counts/frequency: Yes (1, 12.5%), No (7, 87.5%)

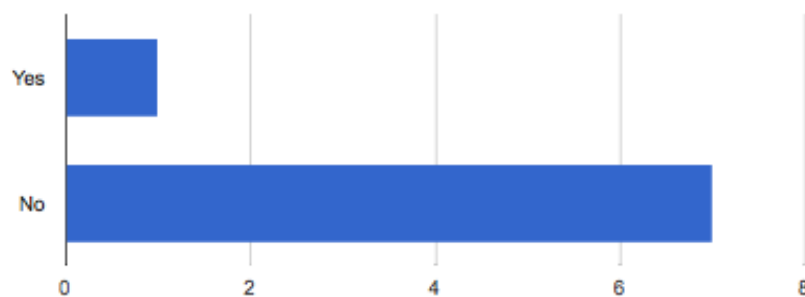


Table 49

Which method do you prefer to use?:

Total (N)	Missing	Unique
8	0 (0%)	1

Counts/frequency: Intraoperative radiotherapy and SLN Biopsy (8, 100%), Standard Radiortherapy and SLN Biopsy (0, 0%)

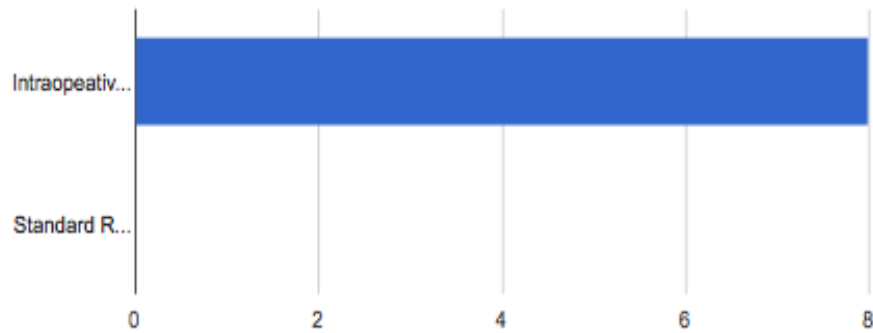


Table 50

Please rate your overall satisfaction of this trial: [Refresh Plot](#)

Total (N)	Missing	Unique	Min	Max	Mean	StDev	Percentile						
							.05	.10	.25	.50 Median	.75	.90	.95
8	0 (0%)	8	7.00	43.00	25.13	14.23	7.00	7.00	14.00	21.50	40.00	43.00	43.00

Lowest values: 7, 10, 18, 19, 24  
Highest values: 19, 24, 38, 42, 43



Table 51

Please rate your overall satisfaction of patients participation in this trial: [Refresh Plot](#)

Total (N)	Missing	Unique	Min	Max	Mean	StDev	Percentile						
							.05	.10	.25	.50 Median	.75	.90	.95
8	0 (0%)	8	1.00	41.00	20.00	14.97	1.00	1.00	6.50	20.50	32.00	41.00	41.00

Lowest values: 1, 6, 7, 16, 25  
Highest values: 16, 25, 26, 38, 41



SatisfiedUnsatisfied

Table 52

How did you find the impact of trial outcomes on breast cancer treatment: [Refresh Plot](#)

Total (N)	Missing	Unique	Min	Max	Mean	StDev	Percentile						
							.05	.10	.25	.50 Median	.75	.90	.95
8	0 (0%)	8	4.00	41.00	20.50	12.58	4.00	4.00	10.00	20.50	29.00	41.00	41.00

Lowest values: 4, 6, 14, 20, 21  
Highest values: 20, 21, 26, 32, 41



GoodBad

Table 53

Does this trial have an impact on future breast cancer trial and treatment: [Refresh](#)

Plot | [View as Bar Chart](#)

Total (N)	Missing	Unique
8	0 (0%)	1

Counts/frequency: Yes (8, 100%), No (0, 0%)

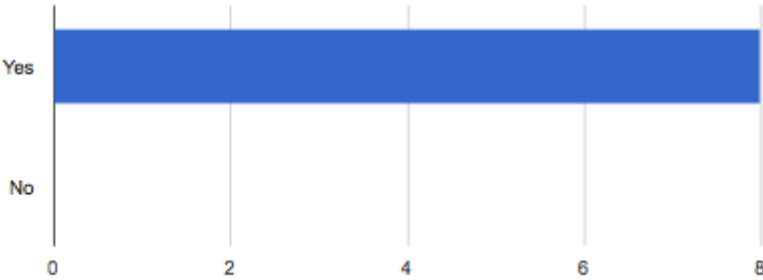
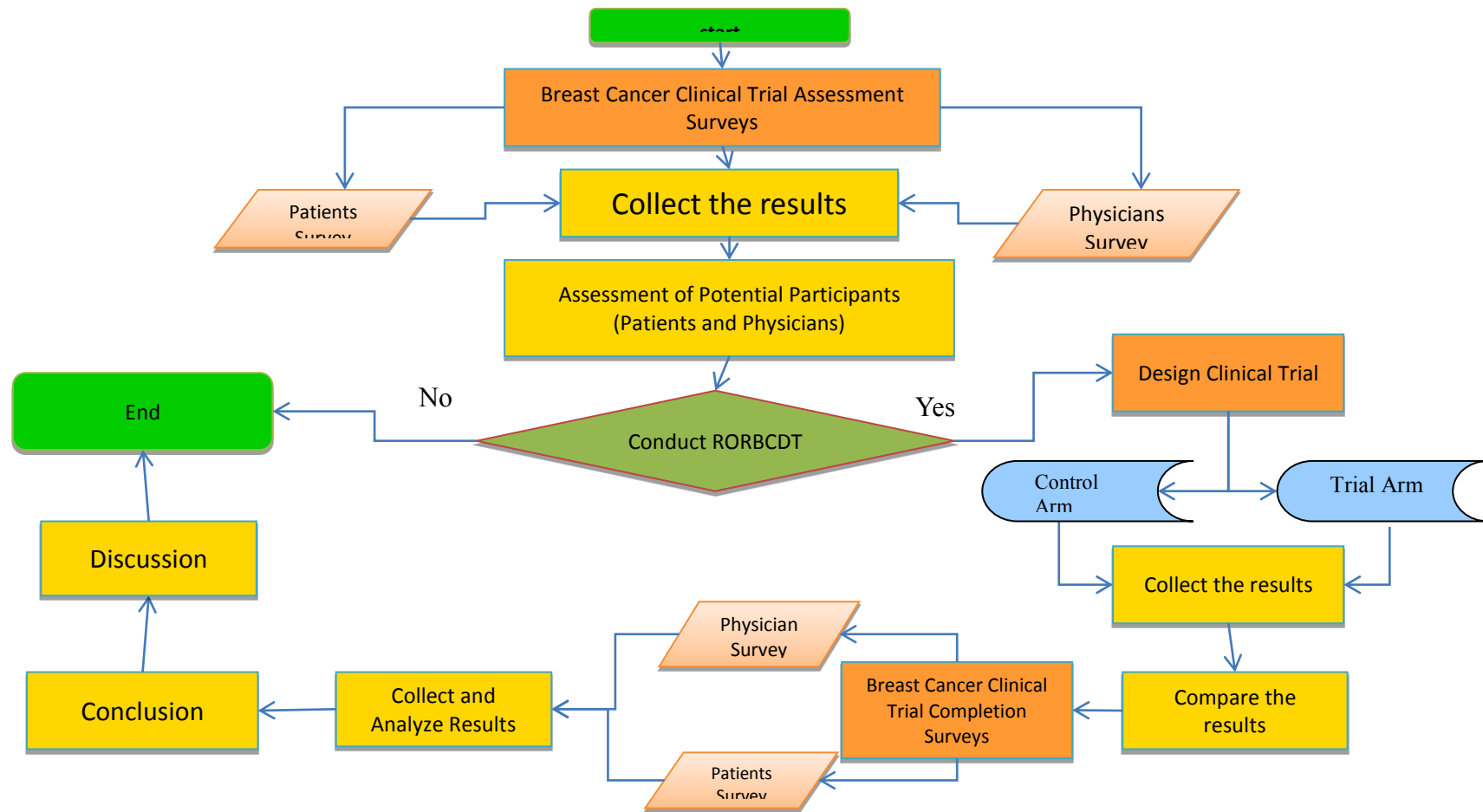


Table 54

# **Appendix H**

## **Figures**

**Figure 1 : Breast Cancer Clinical Trial Project**



**Figure 2: Breast Cancer Clinical Trial Steps**

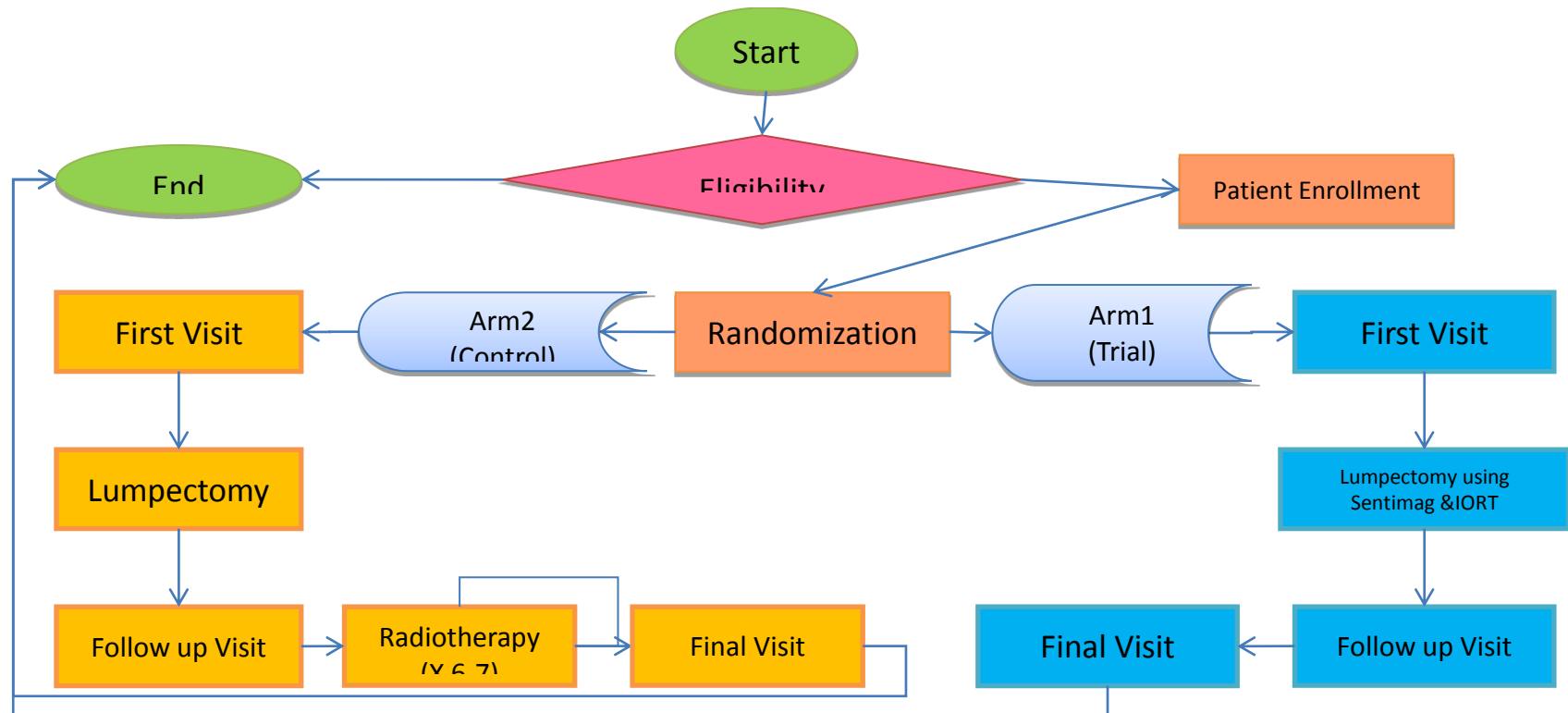
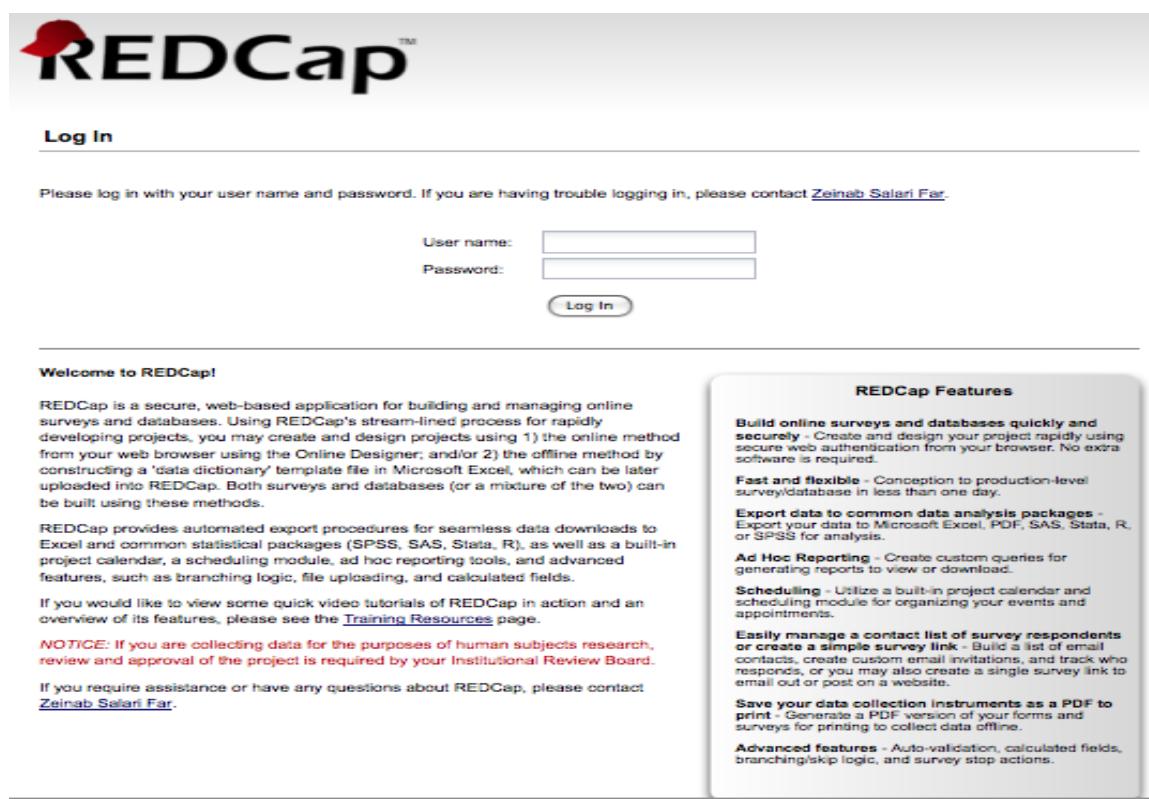


Figure 3: REDCap Login Page



**REDCap**<sup>TM</sup>

## Log In

Please log in with your user name and password. If you are having trouble logging in, please contact [Zeinab Salari Far](#).

User name:

Password:

---

**Welcome to REDCap!**

REDCap is a secure, web-based application for building and managing online surveys and databases. Using REDCap's stream-lined process for rapidly developing projects, you may create and design projects using 1) the online method from your web browser using the Online Designer; and/or 2) the offline method by constructing a 'data dictionary' template file in Microsoft Excel, which can be later uploaded into REDCap. Both surveys and databases (or a mixture of the two) can be built using these methods.

REDCap provides automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.

If you would like to view some quick video tutorials of REDCap in action and an overview of its features, please see the [Training Resources](#) page.

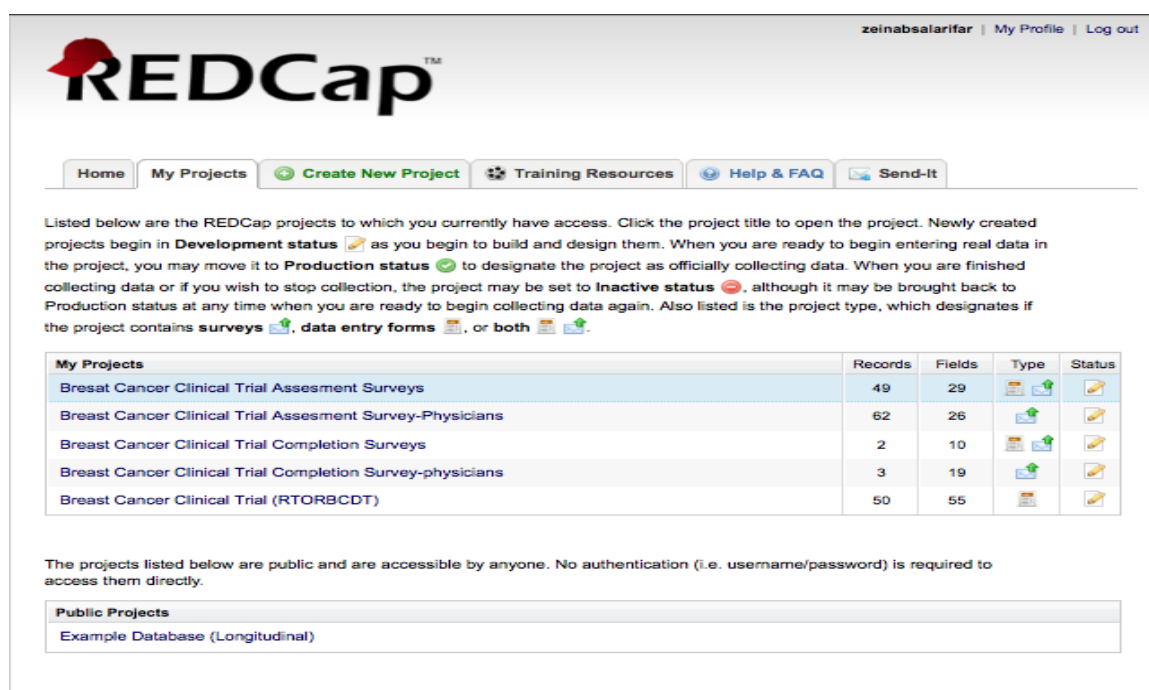
**NOTICE:** If you are collecting data for the purposes of human subjects research, review and approval of the project is required by your Institutional Review Board.

If you require assistance or have any questions about REDCap, please contact [Zeinab Salari Far](#).

**REDCap Features**

- Build online surveys and databases quickly and securely** - Create and design your project rapidly using secure web authentication from your browser. No extra software is required.
- Fast and flexible** - Conception to production-level survey/database in less than one day.
- Export data to common data analysis packages** - Export your data to Microsoft Excel, PDF, SAS, Stata, R, or SPSS for analysis.
- Ad Hoc Reporting** - Create custom queries for generating reports to view or download.
- Scheduling** - Utilize a built-in project calendar and scheduling module for organizing your events and appointments.
- Easily manage a contact list of survey respondents or create a simple survey link** - Build a list of email contacts, create custom email invitations, and track who responds, or you may also create a single survey link to email out or post on a website.
- Save your data collection instruments as a PDF to print** - Generate a PDF version of your forms and surveys for printing to collect data offline.
- Advanced features** - Auto-validation, calculated fields, branching/skip logic, and survey stop actions.

Figure 4: REDCap Projects



zeinabsalarifar | My Profile | Log out

**REDCap**<sup>TM</sup>

Home | My Projects | [Create New Project](#) | [Training Resources](#) | [Help & FAQ](#) | [Send-It](#)

Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. Newly created projects begin in **Development status** as you begin to build and design them. When you are ready to begin entering real data in the project, you may move it to **Production status** to designate the project as officially collecting data. When you are finished collecting data or if you wish to stop collection, the project may be set to **Inactive status**, although it may be brought back to Production status at any time when you are ready to begin collecting data again. Also listed is the project type, which designates if the project contains **surveys**, **data entry forms**, or **both**.

My Projects	Records	Fields	Type	Status
<a href="#">Bresat Cancer Clinical Trial Assesment Surveys</a>	49	29		
<a href="#">Breast Cancer Clinical Trial Assesment Survey-Physicians</a>	62	26		
<a href="#">Breast Cancer Clinical Trial Completion Surveys</a>	2	10		
<a href="#">Breast Cancer Clinical Trial Completion Survey-physicians</a>	3	19		
<a href="#">Breast Cancer Clinical Trial (RTORBCDT)</a>	50	55		

The projects listed below are public and are accessible by anyone. No authentication (i.e. username/password) is required to access them directly.

**Public Projects**

[Example Database \(Longitudinal\)](#)



Figure 5: How to Create Project

**REDCap**™

zeinabsalarifar | My Profile | Log out

Home | My Projects | **Create New Project** | Training Resources | Help & FAQ | Send-It

### Create a new REDCap Project

You may begin the creation of a new REDCap project on your own by completing the form below and clicking the Create Project button at the bottom.

**Project title:**

Title to be displayed on project webpage

**Purpose of this project:**  
(How will it be used?)

**Design your project:**

**STEP 1: Choose the type of project you want to build** [Tell me more](#)

- ☐ Single Survey
- ☐ Data Entry Forms (e.g. traditional database)
- ☒ Single Survey + Data Entry Forms (e.g. pre-screening survey with follow-up data capture)

**STEP 2: Choose collection format for data entry forms** [Tell me more](#)

- ☐ Classic (each form available for use once for each subject/record)
- ☐ Longitudinal / repeating forms (each form available for use one or more times for each subject/record)

☐ Enable the scheduling module? [Tell me more](#)

Figure 6: REDCap Training Resources

**REDCap**™

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Home | My Projects | Create New Project | **Training Resources** | Help & FAQ | Send-It

### REDCap Training Resources

**Just Getting Started?**

In you are new to REDCap, this first set of videos below can help you get started to learn the basics of REDCap and provide a general overview for some of REDCap's preliminary concepts and features.

Title	Description	Watch Video
<b>REDCap Overview</b>	This video provides an overview of basic functions and features within a REDCap project. It will serve as a starting point for learning about the basic concepts of REDCap, what REDCap projects are, how to create them, and how to use them.	50 minutes
<b>Building Your Data Collection Forms</b>	<b>The Online Designer</b> Use this online method for making modifications to project fields and data collection instruments very easily using only your web browser. Changes can be made quickly and viewed immediately as you build your data collection forms in real time.	5 minutes
	<b>The Data Dictionary</b> Use this offline method, called the 'Data Dictionary', which is a specifically formatted Microsoft Excel file within which you may construct your project fields and afterward upload the file into REDCap to commit the changes to your project. If you wish to view an example of how your Data Dictionary may be formatted, you may download the <a href="#">Data Dictionary demonstration file</a> .	14 minutes
<b>The Scheduling Module</b>	If you elect to utilize the Scheduling module in your REDCap project, you may then generate schedules based upon pre-defined events/time-points, after which the scheduled events get added to your project calendar. Scheduling may be done in conjunction with proper data collection, or scheduling may be performed on its own.	6 minutes

Figure 7: REDCap Project Home

**REDCap**

Logged in as: zelnabsalarifar  
Log out

My Projects  
Project Home  
Project Setup  
Project status: Development

**Data Collection**

Invite Participants  
- Get a public survey link or build a participant list for inviting respondents

Data Collection Instruments:

Survey @@  
Breast Cancer Clinical Trial Assessment Survey-Patients (survey)

**Applications**

- Calendar
- Data Export Tool
- Data Import Tool
- Data Comparison Tool
- Logging
- File Repository
- User Rights
- Record Looking Customization
- E-signature and Locking Mgmt
- Graphical Data View & Stats
- Report Builder

**Reports**

**LPHIG**  
Laboratory for Public Health Informatics and Genomics  
University of Wisconsin-Milwaukee  
School of Public Health-LPHIG

**Bresat Cancer Clinical Trial Assessment Surveys**

Project Home | Project Setup | Other Functionality

**Quick Tasks**

- Invite Participants**: Invite participants to complete your survey by emailing a public survey link or building a participant list for batch notification.
- Export data**: Export your data from REDCap to open or view in Excel or various stats packages.
- Create a report**: Build custom reports for quick views of your data, and export reports to Excel/CSV.
- User Rights**: Grant new users access to this project or modify user privileges for current users.
- Online Designer and Data Dictionary Upload**: Create new fields/questions on your data collection instruments or modify existing ones using the Online Designer or by uploading a Data Dictionary. Quick link: [Download the current Data Dictionary](#)
- Copy this project**: Create an exact duplicate of this project, which copies over all data collection instruments, any surveys that exist, as well as the option to copy all users and reports to the new project.
- Data Access Groups**: Create groups of users to limit user access to certain records/responses, in which only users within a given Data Access Group can access records created by users within that group.

**Project Dashboard**

The tables below provide general dashboard information, such as a list of all users with access to this project, general project

Figure 8: REDCap Project Online Designer

Project Setup | Online Designer | Upload Data Dictionary

[VIDEO: How to use this page](#)

The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. Below you have the options to select an existing form to edit, to delete a form, to create a new form, and to reorder your forms as they are displayed. **NOTE: While in development status, all field changes will take effect immediately in real time.**

**Data Collection Instruments**

Add new instrument: [Create](#) new instrument from scratch  
[Download](#) a new instrument from the REDCap Shared Library

Instrument name	Fields	Actions
Demographics	10	<a href="#">Rename</a> <a href="#">Delete</a>
Patient consent form	1	<a href="#">Rename</a> <a href="#">Delete</a>
Eligibility determination	12	<a href="#">Rename</a> <a href="#">Delete</a>
Doctor Visit Form	9	<a href="#">Rename</a> <a href="#">Delete</a>
Surgery Report	10	<a href="#">Rename</a> <a href="#">Delete</a>
Radiotherapy Report	11	<a href="#">Rename</a> <a href="#">Delete</a>

Figure 9: Basic User Rights

Basic User Rights

Invite Participants

☒

Calendar

☒

Data Export Tool

☐ No Access  
☐ De-identified  
☒ Full Data Set

Data Import Tool

☒

Data Comparison Tool

☒

Logging

☒

File Repository

☒

User Rights

☒

Data Access Groups

☒

Graphical Data View & Stats

☒

Reports & Report Builder

☒

Project Design and Setup

☒

Settings pertaining to record locking and E-signatures:

Record Locking Customization

☒

Lock/Unlock Records

☐ Disabled  
☐ Locking / Unlocking  
☒ Locking / Unlocking with E-signature authority  
[What is an E-signature?](#)

Users with locking privileges also have access to the E-signature and Locking Mgmt page on the left-hand Applications menu.

Watch video about locking

Allow locking of all forms at once for a given record?

☒

Settings pertaining to project records: [Explain these settings](#)

Create Records

☒

Rename Records

☒

Delete Records

☒

Expiration Date (if applicable)


Data Entry Rights

	None	Read	Edit
Breast Cancer Clinical Trial Assessment Survey-Patients	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>


**Figure 10: Comprehensive User Rights**

User name	Expiration	Invite Participants	Calendar	Data Export Tool	Data Import Tool	Data Comparison Tool	Logging	File Repository	User Rights	Data Access Groups	Graphical Data View & Stats	Reports & Report Builder	Record Locking Customization	Lock/Unlock Records	Project Design and Setup	Create Records	Rename Records	Delete Records
crawford.m	never	✓	✓	✗	✗	✓	✗	✓	✗	✗	✓	✓	✗	✗	✗	✗	✗	✗
Hmadkour	never	✓	✓	Full Data Set	✗	✓	✗	✓	✗	✗	✓	✓	✗	✗	✗	✗	✗	✗
huangc	never	✓	✓	Full Data Set	✗	✓	✗	✗	✗	✗	✓	✓	✗	✗	✗	✓	✗	✗
kravvaz	never	✓	✓	Full Data Set	✗	✓	✗	✗	✗	✗	✓	✓	✗	✗	✗	✓	✗	✗
Michiyo_Yamada	never	✓	✓	✗	✗	✓	✗	✗	✗	✗	✓	✓	✗	✗	✗	✗	✗	✗
murphycj	never	✓	✓	Full Data Set	✗	✓	✗	✗	✗	✗	✓	✓	✗	✗	✗	✓	✗	✗
omid.ghiasvand	never	✓	✓	Full Data Set	✗	✓	✗	✗	✗	✗	✓	✓	✗	✗	✗	✓	✗	✗
ptonellato	never	✓	✓	Full Data Set	✗	✓	✗	✗	✗	✗	✓	✓	✗	✗	✗	✓	✗	✗
ruidu	never	✓	✓	Full Data Set	✗	✓	✗	✗	✗	✗	✓	✓	✗	✗	✗	✓	✗	✗
zeinab	never	✓	✓	Full Data Set	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✓	✗	✗
zeinabsalarifar	never	✓	✓	Full Data Set	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Figure 11: Data Export Tool

 **Data Export Tool**


REDCap allows you to easily export your project data to Microsoft Excel, SAS, Stata, R, or SPSS for analysis. Exporting your data out of REDCap is as simple as you want it to be. To get a quick data dump of all records for your project, choose the Simple Export one-click option. However, if you prefer more granular control over the data you are exporting, you may choose the Advanced Export option. Whenever you perform a data export, REDCap will automatically place a back-up copy of all exported files in the File Repository, if you wish to view it later.

 **Simple Data Export (one-click)**

To perform a quick data dump of your entire data set, simply click the button below. When done, it will provide you with various format options for downloading your data.

Export all data now


— OR —

 **Advanced Data Export**

This option provides a variety of choices for customizing what data gets exported. You may select individual fields one at a time or entire data collection instruments to export. You may also utilize the data de-identification options (if your user privileges permit) that allow you to limit the amount of sensitive information that you are exporting, if you wish.


Display advanced options


**Other export options**

 **PDF (includes data for all records)**

The data for all records in this project may be downloaded in a single PDF file. This file contains the actual page format as you would see it on the data entry page or survey and includes all data for all records for all data collection instruments. Click the icon to the right to begin downloading the file.

*Note: If your project has a large amount of fields/questions or records/responses, the resulting PDF file may be very large both in file size and in page length. Please be patient if the file takes time to download.*



 **Data Export Tool**

Use the page below to select fields you wish to extract from the project. Each row contains language from the original data collection instrument, plus a parenthetical listing of the actual project field name.

You may use the buttons at the top of the form to select or deselect all fields for a given data collection instrument, duplicate your last data retrieval, or select all fields in the project for export. Once all fields are selected, go to the bottom of this page and click the Submit button. After submitting this page, wait for a page to appear allowing you to save the file to your computer. The files are comma-delimited and may be read into SPSS, Excel, R, SAS or other analysis packages. If any fields in the project have been tagged as Identifiers, those particular fields will be displayed below in **red**.

Use the buttons below to select fields by form - or click individual fields below. Click the SUBMIT button at bottom of page to finalize data export procedure.

Select All

Deselect All

**Every field in the project**

Select All

Deselect All

**Form: Demographics**

Select All

Deselect All

**Form: Patient consent form**

Select All

Deselect All

**Form: Eligibility determination**

Select All

Deselect All

**Form: Doctor Visit Form**

Select All

Deselect All

**Form: Surgery Report**

Select All

Deselect All

**Form: Radiotherapy Report**

Form: **Demographics**

Participant ID ( <i>participant_id</i> )	<input type="checkbox"/>
Study ID ( <i>study_id</i> )	<input type="checkbox"/>
<b>Demographics Information</b>	
First Name ( <i>first_name</i> )	<input type="checkbox"/>
Last Name ( <i>last_name</i> )	<input type="checkbox"/>
Date of Birth ( <i>dob</i> )	<input type="checkbox"/>
Street, City, State, ZIP ( <i>address</i> )	<input type="checkbox"/>
Phone number ( <i>phone_number</i> )	<input type="checkbox"/>
Patient's surgeon name ( <i>patient_s_doctor</i> )	<input type="checkbox"/>
Patient's radiotherapist name ( <i>patient_s_radiotherapist_n</i> )	<input type="checkbox"/>
Patient's Consent Form ( <i>patient_s_consent_form</i> )	<input type="checkbox"/>
<b>Form Status</b>	
Complete? ( <i>demographics_complete</i> )	<input type="checkbox"/>

Form: **Patient consent form**

<b>Form Status</b>	
Complete? ( <i>patient_consent_form_complete</i> )	<input type="checkbox"/>

Form: **Eligibility determination**

## Data Export Tool

✓ Data export was successful!

Your files have been created and automatically saved within the File Repository section of this project. You may click the icons below to retrieve the files necessary for importing data into your preferred data viewing or analysis package. After clicking the icon(s) on the right, choose SAVE and specify the desired location on your computer when prompted in order to download each file to your computer. Remember that the files may contain confidential information and should thus be protected.

◀ RETURN TO PREVIOUS PAGE


















		Download Syntax & Data
	<b>Microsoft Excel</b> You may download the survey results in CSV (comma-separated) format, which can be opened in Excel. You have the choice of downloading the data either with the full headers and answer labels or just with the answer codes (i.e. raw data).  <i>NOTE: If you are using a version of Microsoft Excel prior to Excel 2007, due to limitations the data will only be read to 255 columns when opened.</i>	<div>   </div> <p>Send file?</p>
	<b>SPSS Statistical Analysis Software</b> Instructions: Download and save all 3 files on the right to a common location. First, double-click on the Pathway Mapper (.bat) file, which will run quickly and invisibly. (If you are not using a Windows operating system, such as Mac or Linux, please see the <i>Additional Instructions</i> .) Now double-click on the *.sps file, which will open SPSS. When the file is loaded and displayed, choose Run-->All from the top menu options. This action will launch the script that will automatically read in all data and manipulate data fields with labels, option values, etc. <a href="#">Additional instructions</a>	<div>   </div> <p>Pathway Mapper</p> <p>Send file?</p>
	<b>SAS Statistical Software</b> Instructions: Download both files to common location and double-click on *.sas file. When the file is loaded and displayed, choose from the menu options: Run-->Submit. This action will launch the script that will automatically read in all data and manipulate data fields with labels, option values, etc. Before running the syntax file, be sure to change the SAS current working folder to the folder where both files were saved.	<div>   </div> <p>Send file?</p>
	<b>R Statistical Software</b> Instructions: Use command read.csv('filename') to read in data file.	<div>   </div> <p>Send file?</p>
	<b>STATA Analysis and Statistical Software</b> Instructions: Download both files to common location and double-click on *.do file. This action will launch the script that will automatically read in all data and manipulate data fields with labels, option values, etc.	<div>   </div> <p>Send file?</p>

Figure 12: Data Import Tool

### Instructions:

- Click the link below to download your data import template as a CSV (comma delimited) file. Save it locally to your computer and then open it to begin filling it with the data you wish to import.
 

 [Download your Data Import Template](#) (with records in rows)  
 OR  
 [Download your Data Import Template](#) (with records in columns)
- In each column of the Data Import Template file that you downloaded, place the data for each record that you wish to import. Once all your data has been added, save the file.
  - Be sure not to change the Variables/Field Names in the file or an error may occur.
  - Also, for all of the 'dropdown' or 'radio' fields in the project, you must make sure that the numerical value (rather than the text value) is entered in those cells, or else it cannot be processed.
  - Any empty rows or columns in the file can be safely deleted before importing the file. Doing this reduces the upload processing time, especially for large projects.
- Click the 'Browse' or 'Choose File' button below to select the file on your computer, and upload it by clicking the 'Upload File' button.
- Once your file has been uploaded, the data will NOT be immediately imported but will be displayed and checked for errors to ensure that all the data is in correct format before it is finally imported into the project.

**Record format:** The file to be uploaded has its records stored as separate Rows

 **Upload your CSV file:**

Browse...

Upload File

Data comparison tool



Figure 13: Data Comparison Tool

Label (field name)	Form Name	Participant ID	
		10	19
1.What is your data of birth? (age)	Breast Cancer Clinical Trial Assesment Survey-Patients	9	6
2. What is your Race? (race)	Breast Cancer Clinical Trial Assesment Survey-Patients	White (1)	African American (0)
3. Are you a smoker? (are_you_smoker)	Breast Cancer Clinical Trial Assesment Survey-Patients	1	0
16. What is your menopause age? (menopause_age)	Breast Cancer Clinical Trial Assesment Survey-Patients	50 to 54 (2)	NA (8)
18. What age did you have your first period? (age_at_menarch)	Breast Cancer Clinical Trial Assesment Survey-Patients	>=14 (4)	11.to 12 (1)
20.When (what age) did you have your first child? (age_at_birth)	Breast Cancer Clinical Trial Assesment Survey-Patients	30 to 34 (3)	20 to 24 (1)
21. How many children do you have? (parity)	Breast Cancer Clinical Trial Assesment Survey-Patients	3 (3)	2 (2)
22. How many times have you had biopsy? (biops)	Breast Cancer Clinical Trial Assesment Survey-Patients	>=2 (2)	1 (1)
24. Have you ever had breast cancer surgery? (have_you_ever_had_breast_c)	Breast Cancer Clinical Trial Assesment Survey-Patients	Yes (1)	No (2)
25. What kind of breast cancer surgery did you have? (Choice = <b>Mastectomy</b> ) (what_kind_of_breast » what_kind_of_breast__2)	Breast Cancer Clinical Trial Assesment Survey-Patients	Checked (1)	Unchecked (0)
25. What kind of breast cancer surgery did you have? (Choice = <b>Sentinal node biopsy</b> ) (what_kind_of_breast » what_kind_of_breast__3)	Breast Cancer Clinical Trial Assesment Survey-Patients	Checked (1)	Unchecked (0)
25. What kind of breast cancer surgery did you have? (Choice = <b>Axillary Lymph node dissection</b> ) (what_kind_of_breast » what_kind_of_breast__4)	Breast Cancer Clinical Trial Assesment Survey-Patients	Checked (1)	Unchecked (0)

Figure 14: Logging

### Logging

 [Download entire logging record to Microsoft Excel \(CSV\)](#)

This module lists all changes made to this project, including data exports, data changes, and the creation or deletion of users.

Filter by event:

Filter by user name:

Filter by record:

Displaying events (by most recent):

Time / Date	User name	Action	List of Data Changes OR Fields Exported
9:41pm 04/23/2012	zeinab	Created User zeinabsalarifar	user = 'zeinabsalarifar'
7:46pm 04/23/2012	zeinab	Manage/Design	Download data entry form as PDF
9:45am 04/23/2012	zeinab	Manage/Design	Checked off item in project checklist
9:45am 04/23/2012	zeinab	Manage/Design	Checked off item in project checklist
9:44am 04/23/2012	zeinab	Manage/Design	Enabled survey notification for user
9:44am 04/23/2012	zeinab	Manage/Design	Checked off item in project checklist
9:44am 04/23/2012	zeinab	Manage/Design	Checked off item in project checklist
9:44am 04/23/2012	zeinab	Manage/Design	Checked off item in project checklist
9:44am 04/23/2012	zeinab	Manage/Design	Checked off item in project checklist
9:35am 04/23/2012	zeinab	Manage/Design	Download data entry form as PDF

Figure 15: Designate Instruments for the Events

 [VIDEO: How to use this page \(2 min\)](#)

[Project Setup](#)
[Define My Events](#)
[Designate Instruments for My Events](#)

Since you have defined multiple events on the [Define My Events](#) page, you may now select which data collection instruments that you wish to utilize for each event by using the table below. This allows you to enter data on any data collection form multiple times for any given project record. Any and all data collection instruments can thus be used for any event defined.


Click the [Begin Editing](#) button to change the relationships below by designating which forms you wish to utilize for which events. When you are finished making changes, click the [Save](#) button to finalize your changes.

[Arm 1](#)
[Arm 2](#)

Arm name: **Trial**

[Begin Editing](#)
[Save](#)

Data Collection Instrument	Events						
	Eligibility determination (1)	Patient enrollment (2)	Randomization (3)	First visit (4)	Surgery (5)	Follow up Visit (6)	Final Visit (7)
Demographics		✓		✓		✓	✓
Patient consent form		✓					
Eligibility determination	✓						
Doctor Visit Form				✓		✓	✓
Surgery Report					✓		
Radiotherapy Report					✓		

 [VIDEO: How to use this page \(2 min\)](#)

[Project Setup](#)
[Define My Events](#)
[Designate Instruments for My Events](#)

Since you have defined multiple events on the [Define My Events](#) page, you may now select which data collection instruments that you wish to utilize for each event by using the table below. This allows you to enter data on any data collection form multiple times for any given project record. Any and all data collection instruments can thus be used for any event defined.

Click the [Begin Editing](#) button to change the relationships below by designating which forms you wish to utilize for which events. When you are finished making changes, click the [Save](#) button to finalize your changes.

[Arm 1](#)
[Arm 2](#)

Arm name: **Control**

[Begin Editing](#)
[Save](#)

Data Collection Instrument	Events													
	Eligibility determination (1)	Patient enrollment (2)	Randomization (3)	First visit (4)	Surgery (5)	Follow up visit (6)	Radiotherapy 1 (7)	Radiotherapy 2 (8)	Radiotherapy 3 (9)	Radiotherapy 4 (10)	Radiotherapy 5 (11)	Radiotherapy 6 (12)	Radiotherapy 7 (13)	Final visit (14)
Demographics		✓		✓		✓								✓
Patient consent form		✓												
Eligibility determination	✓													
Doctor Visit Form				✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
Surgery Report					✓									
Radiotherapy Report							✓	✓	✓	✓	✓	✓	✓	



Figure 16: Scheduling

**Scheduling**
[VIDEO: How to use this page \(6 min\)](#)

[Create Schedule](#)
[View or Edit Schedule](#)

The Schedule Generator will allow you to **generate a new schedule** based upon your Events and their Days Offset that have been defined on the [Define My Events](#) page. You may generate a schedule for a new or existing Participant ID below by selecting a Start Date, which will be used as the starting point for projecting schedule dates using your Days Offset. Once scheduled, you may then view it on the [Calendar](#), after which, if desired, you may also perform data entry for that calendar event. You may create a new project record here while performing scheduling or you may choose a currently existing one that has not yet been scheduled.

Add new Participant ID:  OR

Start Date:

Select Arm:

**Scheduling**
[VIDEO: How to use this page \(6 min\)](#)

[Create Schedule](#)
[View or Edit Schedule](#)

To view or edit the calendar events of a previously scheduled Participant ID, select it from the drop-down menu below.

Select a previously scheduled Participant ID:

### View/Edit Existing Schedule for "13"



Below are the calendar events for Participant ID "13". Dates that fall on weekends will be listed in **red**. You may edit any calendar event by clicking the Edit icon, remove an event by clicking the Delete icon, or view the full details of the event by clicking the View icon. You may also add a new unscheduled event at the bottom of the table by selecting a date and clicking the **Add** button.

Time	Date / Day of Week	Event Name	Status	Notes
	02/02/2012 Thursday	Eligibility determination	☆ Due Date	
	02/02/2012 Thursday Range max: 02/07/2012	Patient enrollment	☆ Due Date	
	02/02/2012 Thursday	Randomization	☆ Due Date	
	02/09/2012 Thursday Range: 02/04/2012 - 02/14/2012	First visit	☆ Due Date	
	03/02/2012 Friday Range: 02/27/2012 - 03/08/2012	Surgery	☆ Due Date	
	03/08/2012 Thursday Range: 03/05/2012 - 03/11/2012	Follow up Visit	☆ Due Date	
	05/10/2012 Thursday Range: 05/02/2012 - 05/15/2012	Final Visit	☆ Due Date	




Add new Ad Hoc calendar event on

[Print Schedule](#)

Figure 17: Calendar


 **Calendar**  [VIDEO: How to use this page \(5 min\)](#)

The Calendar application can be used as a project calendar within this project to help organize your schedule and keep track of any upcoming events. It will allow you to add or modify calendar events and then view them either in a daily, weekly, or monthly format below. To add a new note or calendar event to any day, click **+New** at the top of that day's box to begin entering the information. Since you have already defined multiple events for this project, you may additionally [generate a schedule](#) using your pre-defined Events, which will then be added to the calendar.


May
2012

 [Print Calendar](#)

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		+ New <b>1</b> <div> <div>☆ 43 (Radiotherapy 7)</div> <div>☆ 45 (Radiotherapy 7)</div> <div>☆ 47 (Radiotherapy 7)</div> <div>☆ 41 (Radiotherapy 7)</div> <div>☆ 42 (Radiotherapy 7)</div> </div>	+ New <b>2</b>	+ New <b>3</b>	+ New <b>4</b>	+ New <b>5</b>
+ New <b>6</b>	+ New <b>7</b>	+ New <b>8</b>	+ New <b>9</b> <div> <div>☆ 9 (Final visit)</div> <div>☆ 2 (Final Visit)</div> <div>☆ 3 (Final Visit)</div> <div>☆ 5 (Final Visit)</div> <div>☆ 11 (Final Visit)</div> </div> <a href="#">+5 more</a>	+ New <b>10</b> <div> <div>☆ 10 (Final visit)</div> <div>☆ 15 (Final visit)</div> <div>☆ 18 (Final visit)</div> <div>☆ 16 (Final visit)</div> <div>☆ 12 (Final Visit)</div> </div> <a href="#">+5 more</a>	+ New <b>11</b> <div> <div>☆ 22 (Final visit)</div> <div>☆ 23 (Final visit)</div> <div>☆ 21 (Final Visit)</div> <div>☆ 24 (Final Visit)</div> <div>☆ 28 (Final visit)</div> </div> <a href="#">+5 more</a>	+ New <b>12</b>
+ New <b>13</b>	+ New <b>14</b> <div> <div>☆ 30 (Final Visit)</div> <div>☆ 34 (Final Visit)</div> <div>☆ 35 (Final Visit)</div> <div>☆ 32 (Final Visit)</div> <div>☆ 37 (Final Visit)</div> </div> <a href="#">+5 more</a>	+ New <b>15</b> <div> <div>☆ 43 (Final visit)</div> <div>☆ 45 (Final visit)</div> <div>☆ 47 (Final visit)</div> <div>☆ 44 (Final Visit)</div> <div>☆ 46 (Final Visit)</div> </div> <a href="#">+5 more</a>	+ New <b>16</b>	+ New <b>17</b>	+ New <b>18</b>	+ New <b>19</b>
+ New <b>20</b>	+ New <b>21</b>	+ New <b>22</b>	+ New <b>23</b>	+ New <b>24</b>	+ New <b>25</b>	+ New <b>26</b>
+ New <b>27</b>	+ New <b>28</b>	+ New <b>29</b>	+ New <b>30</b>	+ New <b>31</b>		

Figure 18: File Repository

 **File Repository**

This page may be used for storing and retrieving files and documents used for this project. You may upload files here to save for retrieval later, or you may download previously uploaded files in the file list below. Whenever a data export is performed, the resulting data and syntax files are stored here also.





Filter by file type: <span>ALL</span>		Action
 <b>Patient Contest Form</b> File name: 12_02_09_ZS_BC_Project_Consent_Form.pdf Date uploaded: 02/09/2012 File size: 209.2 KB	  	

Figure 19: Report Builder

## Report Builder

You may use this page to build and save custom reports, which will query the project in real time and display the resulting data in a table format. Once created, you may view your reports at any time as well as modify or even delete them. Your saved reports be displayed on the right-hand menu as links, which can be clicked to display the report.

My Reports			
1.)	Eligibility Report	<a href="#">view</a>	<a href="#">edit</a> <a href="#">copy</a> <a href="#">delete</a>
2.)	Patient's list	<a href="#">view</a>	<a href="#">edit</a> <a href="#">copy</a> <a href="#">delete</a>

Create a New Report

You may create a new report by selecting the fields/variables below that you want to include in the report. You may add as many fields to your report as you wish. You will also need to provide a name for your report, which will then be displayed on the project's right-hand menu. When you are finished selecting the fields you wish to include in the report, click the Save Report button at the bottom. The new report will then be added to your list of reports above.

<b>Name of Report:</b>	<input type="text"/>		
	<b>Field Name / Label</b>	<b>Limiters (optional)</b> Operator / Value	
<b>Field 1</b>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<b>Order the Results</b> (optional)			
<b>First by</b>	<input type="text"/>	Ascending order <input type="text"/>	
<b>Then by</b>	<input type="text"/>	Ascending order <input type="text"/>	

**Figure 20 : Eligibility Report**

 Print page  Edit this report

Number of results returned: **50**

Total number of records queried: 100 (\*records\* = total available data across designated Events)

Eligibility Report									
First Name (first_name)	Last Name (last_name)	Does the patient have invasive (also called infiltrating) breast cancer? (does_the_patient_have_inva)	Is this treatable with lumpectomy? (is_this_treatable_with_lum)	Does she have cancer in both of her breasts? (does_she_have_cancer_in_bo)	Does she have a history of previous radiotherapy to the same breast? (does_she_have_a_history_of)	Is the patient pregnant? (is_the_patient_pregnant)	Does the patient diagnostic biopsy shows extensive non-invasive cancer? (does_the_patient_diagnosti)	Does the patient lymph nodes contain cancer metastasis? (does_the_patient_lymph_nod)	Does she have a connective tissue disorder? (does_she_have_connecti)
Alejandra	Brin	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Selena	Howson	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Nita	Durio	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Alejandra	Slevin	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Annabelle	Pulice	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Gay	Simeone	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Zelma	Barrio	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Alejandra	Jetton	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Ericka	Hargrow	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Esmeralda	Jacome	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Mallory	Rothermel	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Ericka	Bryd	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Pearlie	Holen	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Allie	Ezzell	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Althea	Pedretti	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Pearlie	Johnosn	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Tabatha	Sanderlin	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Pearlie	Gaymon	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Jami	Mccampbell	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Tia	Rhymes	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Annabelle	Lacefield	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)
Harriett	Loew	Yes (1)	Yes (1)	No (0)	No (0)	No (0)	No (0)	No (0)	No (0)

Figure 21: Define Events

Project Setup

Define My Events

Designate Instruments for My Events

This application allows you to define 'events' for your project that allow for the **utilization of data collection forms multiple times for any given project record** (often used when collecting longitudinal data), as well as for **generating new schedules** to display on the [Calendar](#). An 'event' may be a temporal event in the course of your project, such as a participant visit or a task to be performed. After events have been defined, you may use them and their Days Offset value to generate schedules. For data collection purposes, you will additionally need to designate the data collection instruments that you wish to utilize for any or all events, thus allowing you to use a form for multiple events for the same project record. You may **group your events into 'arms'**, in which you may have one or more arms/groups for your project. Each arm can have as many events as you wish. You may use the table below to create new events and/or arms, or modify existing ones. (One arm and one event will be initially defined as the default for all projects.)

**STEP #1:**  
To add new events below, provide an **Event Name** and the **Days Offset** for that event, and then click the **Add new event** button. If your events are temporal (e.g. visits, tasks), you may use the Days Offset to provide a timeframe of all your events relative to the time of the first event defined. If you will be using the [Scheduling module](#), the Days Offset will be used to generate a schedule based on a start date that you provide, and then that new schedule will be added to the Calendar. The Offset Range may be used to help you stay within a range of days, if needed, when scheduling is being done by changing it to a value other than 0. If your events are not temporal but are ordered, you may still use the Days Offset simply as a means of ordering your events.

**STEP #2:**  
If you will be performing formal data collection in this project, then once you have defined your events on this page, you may navigate to the [Designate Instruments for My Events](#) page, where you may select which data collection instruments that you wish to utilize for each event you defined.

Arm 1

Arm 2

Add New Arm

Arm name: **Trial** [Rename Arm 1](#) | [Delete Arm 1](#)

	Event #	Days Offset	Offset Range Min / Max	Event Name	Unique event name (auto-generated)
	1	0	-0/+0	Eligibility determination	eligibility_determ_arm_1
	2	0	-0/+5	Patient enrollment	patient_enrollment_arm_1
	3	0	-0/+0	Randomization	randomization_arm_1
	4	7	-5/+5	First visit	first_visit_arm_1
	5	30	-5/+5	Surgery	surgery_arm_1
	6	35	-3/+3	Follow up Visit	follow_up_visit_arm_1
	7	98	-8/+5	Final Visit	final_visit_arm_1

Add new event

Days
 

-0+0

[Convert from other units](#)

Descriptive name for this event

Figure 22: Create Multiple Arms

Arm 1
Arm 2
Add New Arm

Arm name: **Control** [Rename Arm 2](#) | [Delete Arm 2](#)

	Event #	Days Offset	Offset Range Min / Max	Event Name	Unique event name (auto-generated)
	1	0	-0/+0	Eligibility determination	eligibility_determ_arm_2
	2	0	-0/+5	Patient enrollment	patient_enrollment_arm_2
	3	0	-0/+0	Randomization	randomization_arm_2
	4	7	-5/+5	First visit	first_visit_arm_2
	5	30	-5/+5	Surgery	surgery_arm_2
	6	35	-3/+3	Follow up visit	follow_up_visit_arm_2
	7	42	-1/+1	Radiotherapy 1	radiotherapy_1_arm_2
	8	49	-1/+1	Radiotherapy 2	radiotherapy_2_arm_2
	9	56	-1/+1	Radiotherapy 3	radiotherapy_3_arm_2
	10	63	-1/+1	Radiotherapy 4	radiotherapy_4_arm_2
	11	70	-1/+1	Radiotherapy 5	radiotherapy_5_arm_2
	12	77	-1/+1	Radiotherapy 6	radiotherapy_6_arm_2
	13	84	-1/+1	Radiotherapy 7	radiotherapy_7_arm_2
	14	98	-8/+3	Final visit	final_visit_arm_2

Add new event
 Days  -  0  +  0 
  
[Convert from other units](#)
 Descriptive name for this event

Figure 23: Data Entry

**Data Entry**

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, type a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto-populate with existing record names as you begin to type in it, allowing you to select it.

**Total records: 50**

**Choose an existing Participant ID**

-- select record --
from
Arm 1: Trial

**Enter a new or existing Participant ID**

for
Arm 1: Trial

**Data Search**

**Choose a field to search**  
(excludes multiple choice fields)

-- select search field --

**Search query**  
Begin typing to search the project data, then click an item in the list to navigate to that record.