

# Introduction to the CTSI Software Toolbox

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# CTSI Resources

- The BU CTSI is now providing software to BUMC investigators
- Charges vary (free to cost per participant)
- CTSI will offer consulting on which package is appropriate for your study (free of charge) through CTSI BERD (Biostatistics, Epidemiology, Research Design) Core
- CTSI will run package-specific user-groups, drop-in Q&A sessions and on-line forums



# Software Currently Available

Software	Purpose	Cost to BUMC Investigators
<b>REDCap</b>	Web-based data collection software	No cost
<b>OpenClinica</b>	Web-based clinical trial data management software (21CFR part 11 compliant)	No cost
<b>StudyTRAX</b>	Web-based study management software (21CFR part 11 compliant)	Fee per participant (\$5-\$35 depending on study design)
<b>FreezerPro</b>	Web-based freezer inventory and management software	\$199 per user license charge
<b>i2b2</b>	See CTSI website for more info	




# See CTSI Website: <http://ctsi.bu.edu/>



*Advancing Translational Research*

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FUNDING

- PILOT GRANT PROGRAMS
- OTHER FUNDING OPPORTUNITIES

CLINICAL RESEARCH RESOURCES OFFICE (CRRO)

CONSULTING

- BIostatISTICS AND DATA MANAGEMENT
- BIOMEDICAL INFORMATICS

TOOLS

PROFILES

GENERAL CLINICAL RESEARCH UNIT (GCRU)

- GCRU APPLICATION AND SCHEDULING

CORES

HELPFUL LINKS

## Welcome to the BU CTSI

The Boston University Clinical and Translational Science Institute is dedicated to improving public health by providing BU researchers with the resources, training, and support they need to succeed. Our institute brings faculty, trainees, and university resources together to strengthen and facilitate the translational process and innovation.

- CTSI Toolbox Intro Session
- BU Clinical and Translational Institute Supports Transition from Early Career toward Independent



*Advancing Translational Research*

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## Resources

- Funding
  - Pilot Grant Programs
  - Other Funding Opportunities
- Clinical Research Resources Office (CRRO)
- Consulting

## Tools

**Software available at no cost to BU Investigators:**

- OpenClinica
- REDCap
- BU-i2b2

**OpenClinica** is open source clinical trials software. The software is available in both free and paid editions. The freely available OpenClinica Community Edition is now available to BU investigators through the CTSI.

OpenClinica (community version) is software designed to collect, manage, and store data on clinical trials in an electronic database. While it provides the means to manage clinical research, OpenClinica also includes tools to aid protocol design, create and manage electronic Case Report Forms (eCRFs), monitor studies, and obtain real-time transparency across multiple studies and sites. The software accepts user created "CRF" forms (made in Excel) and transforms them into dynamic electronic CRFs in the OpenClinica interface. Note that there is also an OpenClinica Enterprise version which is not currently available to BU investigators. For more information on OpenClinica Community Version please see OpenClinica Community.

**REDCap (Research Electronic Data Capture)** is a secure web application for building and managing online surveys and databases. Using REDCap's streamlined 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



# REDCap

- **REDCap (Research Electronic Data Capture)** is a secure web application for building and managing online surveys and questionnaires
- No cost for CTSI consortium members (of which BU is one)
- Applications for emailed surveys or traditional data entry
- Can manage longitudinal data and follow up visits
- Developed at and supported by Vanderbilt University

# REDCap (continued)

- Easy set up can be done by study coordinators and other “non-programmers”
- Can program in required fields, skip patterns and simple logic checks
- System maintains audit trails to document changes to data
- Easy to export data for analysis and reporting
- Available through CTSI and BUMC IT partnership

## 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)





For quick access, place your bookmarks here on the bookmarks bar. [Import bookmarks now...](#)



Logged in as **site\_admin**

- My Projects
- Project Home
- Project Setup

Project status: **Production**

### Data Collection

- Demographics
- Baseline Data
- Month 1 Data
- Month 2 Data
- Month 3 Data
- Completion Data

### Applications

- Calendar
- Data Export Tool
- Data Import Tool
- Data Comparison Tool
- Logging
- File Repository
- Graphical Data View & Stats
- Report Builder

### Help & Information

- Help & FAQ
- Video Tutorials
- Suggest a New Feature

If you are experiencing problems, please contact your [REDCap administrator](#).



## Example Database

- Project Home
- Project Setup**

Project status: **Production**



### Modify project settings or make customizations

You have created your project and are ready to begin building on it. If you would like to modify the general project settings that you set when creating the project or if you wish to make some customizations to the project (e.g. enable auto-numbering for new records), use the buttons below.

Go to [Modify project settings](#) or [Make customizations](#)



### Move your project to production status

Move the project to production status so that real data may be collected. Once in production, you will not be able to edit the project fields in real time anymore. However, you can make edits in Draft Mode, which will then need to be approved by a REDCap administrator before taking effect.



### Set up project bookmarks (optional)

You may create custom bookmarks to webpages that exist inside or outside of REDCap. These bookmarks will be seen as links on the left-hand project menu and can be accessed at any time by users who are given privileges to do so. Every project bookmark has custom settings that allow one to control its appearance and behavior.

Go to [Add or edit bookmarks](#)



### User Rights and Permissions

You may grant other users access to this project or edit the user privileges of current users on this project by navigating to the User Rights page. Additionally, if you wish to limit user access to certain records/responses for this project, you may want to use Data Access Groups, in which only users within a given Data Access Group can access records created by users within that group.

Go to [User Rights](#) or [Data Access Groups](#)

### Modify your data collection instruments in Draft Mode

For quick access, place your bookmarks here on the bookmarks bar. [Import bookmarks now...](#)



Logged in as **site\_admin**

- My Projects
- Project Home
- Project Setup

Project status: **Production**

### Data Collection

Add or View Survey Responses

- Open survey
- Email survey link

### Applications

- Data Export Tool
- Data Comparison Tool
- Logging
- File Repository
- Graphical Data View & Stats
- Report Builder

### Help & Information

- Help & FAQ
- Video Tutorials
- Suggest a New Feature

If you are experiencing problems, please contact your [REDCap administrator](#).

## Example Survey

- Project Home
- Project Setup

### Quick Tasks

- 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.

### Project Dashboard

The tables below provide general dashboard information, such as a list of all users with access to this project, general project statistics, and upcoming calendar events (if any).

Current Users	
User	Expires
site_admin (Joe User)	never

Survey Response Summary	
Total Responses	0
- Partial	0
- Complete	0
Total Invitations Sent (using Participant List)	0
- Responded	0
- Unresponded	0


Project Statistics	
Records in project	0
Most recent activity	
Space usage for docs	0 MB
Project status	Production



DATE questions are also an option: if you click the calendar icon on the right, a pop-up calendar will appear, thus allowing the respondent to easily select a date. Or it can be simply typed in.

Today Y-M-D

The FILE UPLOAD question type allows respondents to upload any type of document to the survey that you may afterward download and open when viewing your survey results.

 [Upload document](#)

A SLIDER is a question type that allows the respondent to choose an answer along a continuum. The respondent's answer is saved as an integer between 0 (far left) and 100 (far right) with a step of 1.

You can provide labels above the slider: Middle label, Right-hand label



Click bar above and then drag to set response

reset value

You may also use DESCRIPTIVE TEXT to provide informational text within a survey section.

**ADVANCED FEATURES: The questions below will illustrate how some advanced survey features are used.**

**BRANCHING LOGIC:** The question immediately following this one is using branching logic, which means that the question will stay hidden until defined criteria are specified.

- This option does nothing.
- Clicking this option will trigger the branching logic to reveal the next question.
- This option also does nothing.

For example, the following question has been set NOT to appear until the respondent selects the second option to the right.

reset value

**STOP ACTIONS** may be used with any multiple choice question. Stop actions can be applied to any (or all) answer choices. When that answer choice is selected by a respondent, their survey responses are then saved, and the survey is immediately ended.

- This option does nothing.
- This option also does nothing.
- Click here to trigger the stop action and end the survey.

The third option to the right has a stop action.

If you need the respondent to enter a large amount of text, you may use a NOTES BOX.

This question has also been set as a **REQUIRED QUESTION**, so the respondent cannot fully submit the survey until this question has been answered. ANY question type can be set to be required.

\* must provide value



	A	B	C	D	E	F	
1	Variable / Field Name	Form Name	Section Header	Field Type	Field Label	Choices, Calculation	Field I
2	study_id	demographics		text	Study ID		
3	date_enrolled	demographics	Demographic Characteristics	text	Date subject signed consent		YYYY-M
4	first_name	demographics		text	First Name		
5	last_name	demographics		text	Last Name		
6	address	demographics	Contact Information	notes	Street, City, State, ZIP		
7	telephone_1	demographics		text	Phone number		Includ
8	telephone_2	demographics		text	Second phone number		Includ
9	email	demographics		text	E-mail		
10	sex	demographics		dropdown	Gender	0, Female   1, Male	
11	given_birth	demographics		dropdown	Has the subject given b	0, No   1, Yes	
12	num_children	demographics		text	How many times has the subject given birth?		
13	ethnicity	demographics		radio	Ethnicity	0, Hispanic or Latino   1, N	
14	race	demographics		checkbox	Race	0, American Indian/Alaska	
15	dob	demographics		text	Date of birth		
16	age	demographics		calc	Age (years)	round(datediff([dob],'toda	
17	height	demographics		text	Height (cm)		
18	weight	demographics		text	Weight (kilograms)		
19	bmi	demographics		calc	BMI	round(((weight]*10000)/((	
20	patient_document	demographics		file	Patient document		
21	comorbidities	demographics		text	Any comorbid condition		
22	diabetes	demographics		dropdown	Patient has a diagnosis	0, No   1, Yes	
23	diabetes_type	demographics		dropdown	Type of Diabetes Mellit	0, Type 1 insulin-dependen	
24	dialysis_initiation	demographics	Dialysis Information	text	Date of first outpatient dialysis treatment		
25	access_type	demographics		dropdown	Type of vascular access	0, Graft   1, Fistula   2, Cath	
26	access_location	demographics		dropdown	Location of currently us	0, Forearm   1, Upper arm	
27	dialysis_unit_name	demographics		text	Name of dialysis unit		
28	dialysis_unit_phone	demographics		text	Phone number		Includ
29	dialysis_schedule_days	demographics		radio	Days of the week patie	0, Monday-Wednesday-Fri	
30	dialysis_schedule_time	demographics		dropdown	Shift patient is dialyze	0, First shift   1, Second shi	
31	etiology_esrd	demographics		dropdown	Etiology of ESRD	0, Diabetes   1, Hypertensi	
32	subject_comments	demographics	General Comments	notes	Comments		
33	date_visit_b	baseline_data	Baseline Measurements	text	Date of baseline visit		
34	date_blood_b	baseline_data		text	Date blood was drawn		
35	alb_b	baseline_data		text	Serum Albumin (g/dL)		

# OpenClinica

- Open source clinical trials software for electronic data capture and clinical data management
- No cost for BUMC investigators
- Web-based application designed to collect, manage, and store data
- Includes tools to aid protocol design and create and manage electronic Case Report Forms, monitor studies, and obtain real-time transparency across multiple studies and sites.

# OpenClinic (continued)

- Software is 21 CFR, part 11 compliant
- Excellent data management and querying package for randomized clinical trials
- Has features for:
  - Data collection/submission
  - Monitoring and data management
  - Data extraction
  - Study build for configuring to your protocol
  - User roles to designate appropriate access to data
  - Administration tool for system oversight, auditing and configuration

Alerts & Messages

Instructions

Please see the instructions to the right on the main page.

Other Info

Study: DCC Test Study

Start Date: N/A





End Date: N/A

PI: Tasha Watson

Protocol Verification/IRB Approval Date:

### DCC Test Study

Welcome to the Build Study page of OpenClinica! This page is designed to help you build and configure your study by following a task based approach. The list of tasks below need to be completed in order to start using your study. Once you have finished each step, please check "Mark Complete" then click the "Save" button.

- To start a step, select the  icon. You can always select the  icon to add a new component to your study.
- Select the  icon to see a list of existing pieces in each task of building a study.
- Select the  to view all of the pieces for that task.

To add users to different sites, you must first change your study/site to the appropriate site. Then select Users in the Study Setup Section under the Tasks link.

When you are ready to start adding subjects to your study, please select Available from the Set Study Status drop down box and click the "Save" button. If the study status is Design, subjects can not be added.

Set Study Status Design Save Status

	Task	Status	Count	Mark Complete	Actions
1	Create Study	In Progress	NA	<input type="checkbox"/>	 
2	Create CRF	Not Started	0	<input type="checkbox"/>	
3	Create Event Definitions	Not Started	0	<input type="checkbox"/>	
4	Create Subject Group Classes	Not Started	0	<input type="checkbox"/>	
5	Create Rules	Not Started	0	<input type="checkbox"/>	 

	Task	Status	Count	Mark Complete	Actions
--	------	--------	-------	---------------	---------









For quick access, place your bookmarks here on the bookmarks bar. [Import bookmarks now...](#)

**Alerts & Messages** ▾**Instructions** ▾**Other Info** -**Study:** Docetaxel in Patients With Completely Resected NSCLC**Site:** Cambridge Center for Surgical Oncology**Start Date:** N/A**End Date:** N/A**PI:** Thomas Katz MD, PhD**Protocol Verification/IRB Approval Date:**

## Cambridge Center for Surgical Oncology: Add Subject

\* indicates required field.

Study Subject ID:	<input type="text"/>	*
Person ID:	<input type="text"/>	* 
Secondary ID	<input type="text"/>	
Date of Enrollment for Study 'Docetaxel in Patients With Completely Resected NSCLC':	<input type="text" value="04-Sep-2012"/>	*  
Sex:	<input type="text" value="-Select-"/>	
Date of Birth:	<input type="text"/>	 * 

Subject Group Class:	<b>Treatment Group</b> <input type="text" value="--"/>
Notes:	<input type="text"/>

[Save and Assign Study Event](#)[Save and Add Next Subject](#)[Save and Finish](#)[Cancel](#)



For quick access, place your bookmarks here on the bookmarks bar. [Import bookmarks now...](#)

**Alerts & Messages**
**Instructions**
**Other Info**

**Study:** Docetaxel in Patients With Completely Resected NSCLC

**Site:** Cambridge Center for Surgical Oncology







**Start Date:** N/A

**End Date:** N/A

**PI:** Thomas Katz MD, PhD

**Protocol Verification/IRB Approval Date:**

**Icon Key**
**Statuses**

-  Not Started
-  Scheduled
-  Data Entry Started
-  Stopped
-  Skipped
-  Completed

## View Subject: CAM104

[Study Subject Record](#)

[Events](#)

Page 1 of 1

 **Find**
[Schedule New Event](#)

Event (Occurrence Number)	Start Date	Location	Status	Actions	CRFs (Name, Version, Status, Updated, Actions)
Follow-up Treatment (1)	20-Jun-2011		scheduled	 	Agent Administration v1.0    
					Concomitant Medications v1.0    
					Physical Exam English    
Initial Treatment	13-Jun-2011		scheduled	 	Concomitant Medications v1.0    
					Physical Exam English    
					Agent Administration v1.0    
Registration Visit	06-Jun-2011		scheduled	 	Verification of Informed Consent v2.0    
					Eligibility v1.0    
					Physical Exam English    

[Group](#)

[Global Subject Record](#)

[Go Back to Subject List](#)

P25

	A	B	C	D	E	
1	<b>ITEM_NAME</b>	<b>DESCRIPTION LABEL</b>	<b>LEFT_ITEM_TEXT</b>	<b>UNITS</b>	<b>RIGHT_ITEM_TEXT</b>	<b>SE</b>
2	PEDAT	Date of Physical Exam	Date of Physical Examination:			I B
3	PETIM	Time of Physical Exam	Time of Physical Examination:	HH:MM		I B
4	HEIGHT	Height	Height:	in		I B
5	WEIGHT	Weight	Weight:	lb		I B
6	TEMPERATURE	Temperature	Temperature:	F		I B
7	PULSE	Pulse Rate	Pulse Rate:	per min		I B
8	RESPIRATION	Respiration Rate	Respiration Rate:	per min		I B
9	SYSTOLIC	Systolic	Systolic:	mm		I B
10	DIASTOLIC	Diastolic	Diastolic:	Hg		I B
11	BMI	Body Mass Index	Body Mass Index:			II B
12	APPEARANCE	Appearance	Appearance			II B
13	APPEARANCE_COMMENTS	Appearance Comments	Comments:(Required if Abnormal)			II B
14	SKIN	Skin	Skin			II B
15	SKIN_COMMENTS	Skin Comments	Comments:(Required if Abnormal)			II B
16	HEENT	H/E/E/N/T	H/E/E/N/T			II B
17	HEENT_COMMENTS	H/E/E/N/T Comments	Comments:(Required if Abnormal)			II B
18	THYROID	Thyroid	Thyroid			II B
19	THYROID_COMMENTS	Thyroid Comments	Comments:(Required if Abnormal)			II B
20	CHEST	Chest	Chest			II B
21	CHEST_COMMENTS	Chest Comments	Comments:(Required if Abnormal)			II B
22	LUNGS	Lungs	Lungs			II B
23	LUNGS_COMMENTS	Lungs Comments	Comments:(Required if Abnormal)			II B
24	BREAST	Breasts	Breasts			II B
25	BREASTS_COMMENTS	Breasts Comments	Comments:(Required if Abnormal)			II B
26	HEART	Heart	Heart			II B
27	HEART_COMMENTS	Heart Comments	Comments:(Required if Abnormal)			II B
28	ABDOMEN	Abdomen	Abdomen			II B
29	ABDOMEN_COMMENTS	Abdomen Comments	Comments:(Required if Abnormal)			II B
30	MUSCULOSKELETAL	Musculoskeletal	Musculoskeletal			II B
31	MUSCULOSKELETAL_COMM	Musculoskeletal Comments	Comments:(Required if Abnormal)			II B
32	GENITALIA	Genitalia	Genitalia			II B
33	GENITALIA_COMMENTS	Genitalia Comments	Comments:(Required if Abnormal)			II B
34	PELVIS	Pelvis	Pelvis			II B
35	PELVIS_COMMENTS	Pelvis Comments	Comments:(Required if Abnormal)			II B

# StudyTRAX

- Electronic data capture software system which integrates data collection, study management and academic output
- Charge for use is per-participant enrolled and ranges from ~\$5 for simple one-time survey to ~\$35 for entry into a randomized clinical trial.
- Accommodates various methodological designs (clinical trials, epidemiological studies, patient registries, multi-site trials)
- Includes applications designed to maximize research productivity (e.g., automated manuscript ready table generator, streamlined analytical process, re-usable data definition and case report form libraries)

# StudyTrax (continued)

- Includes features for randomization (stratified and blocked)
- Can set email notifications
- Can set User roles to designate appropriate access to data
- Designed with academic researcher in mind – auto export of tables (e.g., “Table 1”)
- Easy export of data into analytic packages

## 2. List of Features for each study

### Project Overview

The design of the project, which includes the project configuration, users, sites, reports, encounter variables, project subject variables, universal subject variables, intervals, and medications

Back Edit Project Data Management Import Data Edit Expression Print Forms

## Advanced Study

- Attributes
- Custom Attributes
- Identifying Subjects
- Randomization**
- Features
- Variable Groups
- Intervals
- Medications**
- Report Templates
- Users

### Features

The features enabled in the project (marked with a green check), use "Edit Project" to update

- Adverse Events
- Change Reason
- Double Data Entry
- Electronic Signatures
- Medications
- Show Screening And Enrollment Date
- Randomization
- Screening
- Subject Login
  - Allow View History
  - Allow Edit Past Forms
  - Allow Disable Notifications
- Project Name For Subjects **Advanced Study Name That Subjects See**
- Versioning

# 6. Flexible eCRF Layout

**Encounter Update**
?

Save and Return Cancel Save Refresh Re-calculate Completion Status

<b>100</b> <b>John Q Public</b> <hr/> Date: <input type="text" value="4/9/2011"/> <input type="checkbox"/> Show Actions Menu <b>Table Of Contents</b> <ul style="list-style-type: none"> <li><input checked="" type="radio"/> All Variable Types 1</li> <li><input checked="" type="radio"/> Matrix Example 1</li> <li><input checked="" type="radio"/> Variable Dependency Example 1</li> <li><input checked="" type="radio"/> Hide Form Example 1</li> <li><input checked="" type="radio"/> Web-based Forms: Some Examples 1</li> <li><input checked="" type="radio"/> Images in Selection (iPad) 1</li> <li><input checked="" type="radio"/> Frontal Cephalometric Radiograph 1</li> <li><input checked="" type="radio"/> Ultrasound 1</li> <li><input checked="" type="radio"/> Cornea Fluorescein Green Staining 1</li> </ul>	<div style="border: 1px solid black; padding: 5px;"> <p><b>Project</b> Basic Study <b>Interval</b> Baseline</p> <hr/> <p><b>Images in Selection (iPad)</b></p> <p>What is your sex?</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"><input type="radio"/>  Male</div> <div style="text-align: center;"><input type="radio"/>  Female</div> <div style="text-align: center;"><input type="radio"/>  Unknown</div> </div> <hr/> <p><b>Frontal Cephalometric Radiograph</b></p> <div style="display: flex; align-items: flex-start;"> <div style="flex: 1;"> </div> <div style="flex: 1; padding-left: 10px;"> <p>Lateronasal (Ln) <input type="text"/></p> <p>Upper central incisor root apex (Uia) <input type="text"/></p> <p>Maxillary (Mx) <input type="text"/></p> <p>Upper Molar (Um) <input type="text"/></p> <p>Upper Incisor edges (Uei) <input type="text"/></p> <p>Palatal plane (PaL) <input type="text"/></p> <p>Sphenoid plane (Spl) <input type="text"/></p> </div> </div> <hr/> <p><b>Ultrasound</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: #ADD8E6;">RIGHT HIP:</th> <th style="background-color: #FFFF00;">LEFT HIP:</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;"> <p><b>Ultrasound:</b> <input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>% coverage: <input type="text"/></p> <p><b>I. Bony Acetabular Morphology:</b></p> <p><input type="radio"/> A = Good <input type="radio"/> B = Deficient/Rounded <input type="radio"/> C = Dysplastic</p> <div style="border: 1px solid black; padding: 2px; text-align: center;"> </div> <p><b>II. Cartilage Roof Triangle:</b></p> <p><input type="radio"/> A = Narrow <input type="radio"/> B = Broad/undisplaced</p> </td> <td style="padding: 5px;"> <p><b>Ultrasound:</b> <input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>% coverage: <input type="text"/></p> <p><b>I. Bony Acetabular Morphology:</b></p> <p><input type="radio"/> A = Good <input type="radio"/> B = Deficient/Rounded <input type="radio"/> C = Dysplastic</p> <div style="border: 1px solid black; padding: 2px; text-align: center;"> </div> <p><b>II. Cartilage Roof Triangle:</b></p> <p><input type="radio"/> A = Narrow <input type="radio"/> B = Broad/undisplaced</p> </td> </tr> </tbody> </table> </div>	RIGHT HIP:	LEFT HIP:	<p><b>Ultrasound:</b> <input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>% coverage: <input type="text"/></p> <p><b>I. Bony Acetabular Morphology:</b></p> <p><input type="radio"/> A = Good <input type="radio"/> B = Deficient/Rounded <input type="radio"/> C = Dysplastic</p> <div style="border: 1px solid black; padding: 2px; text-align: center;"> </div> <p><b>II. Cartilage Roof Triangle:</b></p> <p><input type="radio"/> A = Narrow <input type="radio"/> B = Broad/undisplaced</p>	<p><b>Ultrasound:</b> <input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>% coverage: <input type="text"/></p> <p><b>I. Bony Acetabular Morphology:</b></p> <p><input type="radio"/> A = Good <input type="radio"/> B = Deficient/Rounded <input type="radio"/> C = Dysplastic</p> <div style="border: 1px solid black; padding: 2px; text-align: center;"> </div> <p><b>II. Cartilage Roof Triangle:</b></p> <p><input type="radio"/> A = Narrow <input type="radio"/> B = Broad/undisplaced</p>
RIGHT HIP:	LEFT HIP:				
<p><b>Ultrasound:</b> <input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>% coverage: <input type="text"/></p> <p><b>I. Bony Acetabular Morphology:</b></p> <p><input type="radio"/> A = Good <input type="radio"/> B = Deficient/Rounded <input type="radio"/> C = Dysplastic</p> <div style="border: 1px solid black; padding: 2px; text-align: center;"> </div> <p><b>II. Cartilage Roof Triangle:</b></p> <p><input type="radio"/> A = Narrow <input type="radio"/> B = Broad/undisplaced</p>	<p><b>Ultrasound:</b> <input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>% coverage: <input type="text"/></p> <p><b>I. Bony Acetabular Morphology:</b></p> <p><input type="radio"/> A = Good <input type="radio"/> B = Deficient/Rounded <input type="radio"/> C = Dysplastic</p> <div style="border: 1px solid black; padding: 2px; text-align: center;"> </div> <p><b>II. Cartilage Roof Triangle:</b></p> <p><input type="radio"/> A = Narrow <input type="radio"/> B = Broad/undisplaced</p>				

Calculation time: 36 milliseconds

# 3. Data Sets

**Data Set Export**

Back

**Example Data Set**

Options  
Preview  
Download

**Preview** Preview the data before exporting.


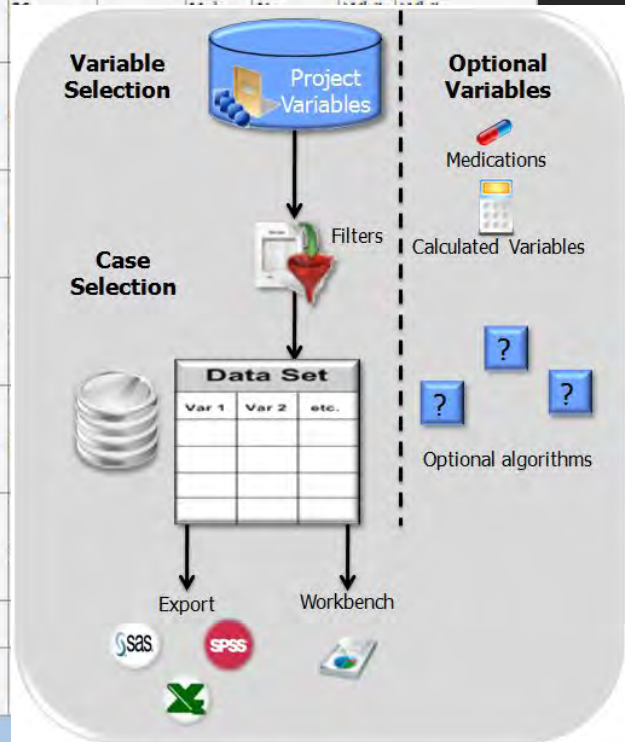
Preview Max Rows: 8 Filter: Baseline Systolic BP > 155 Submit

Reference Id	Systolic BP_Baseline	Systolic BP_1 Year	Systolic BP_2 Year	Systolic BP_3 Year	Diastolic BP_Baseline	Diastolic BP_1 Year	Diastolic BP_2 Year	Diastolic BP_3 Year	Sex	Hispanic	Race	Self Percieved race/ethnicity
101	157	197	90		72	90						
				87	84	102						
				107	65	106						
				101	81	106						
				125	89	66						
				113	83	77						
					68							
					80							

**Collapsible Intervals**

## Data Sets

- Seamless Export to Statistical Packages
- Data sets may contain...
  - Any variable on a form
  - System Variables automatically generated (dose equivalence scale)
  - Recoded Variables
  - Calculated Variables
  - Filters

## 5. Subject Reports (Summary Across Visits) (2)

Report: ALS Patient Data Summary								
<a href="#">Back</a> <a href="#">PDF</a> <a href="#">Word</a> <a href="#">Excel</a>								
Motor Exam (LMN)	Right				Left			
	4/8/2010	6/6/2010	7/11/2011	10/18/2011	4/8/2010	6/6/2010	7/11/2011	10/18/2011
Neck Flexion	2.000	4.000	5.000	2.000	2.000	4.000	5.000	2.000
Neck Extension	1.000	4.000	5.000	2.000	1.000	4.000	5.000	2.000
Arm Abduction	2.000	5.000	3.000	2.000	2.000	5.000	5.000	4.000
Elbow Flexion	1.000	4.000	5.000	2.000	2.000	5.000	2.000	3.000
Elbow Extension	3.000	3.000	3.000	3.000	3.000	1.000	5.000	5.000
Wrist Extension	1.000	5.000	5.000	1.000	3.000	5.000	5.000	3.000
Wrist Flexion	1.000	1.000	2.000	2.000	1.000	5.000	5.000	5.000
Thumb Extension	1.000	5.000	5.000	5.000	2.000	5.000	2.000	2.000
Thumb Adductor	2.000	5.000	3.000	2.000	4.000	5.000	3.000	3.000
Finger II Extension	1.000	5.000	5.000	5.000	3.000	5.000	5.000	5.000
Finger III Extension	4.000	5.000	2.000	1.000	1.000	5.000	5.000	1.000
Finger IV Extension	3.000	5.000	5.000	1.000	5.000	5.000	5.000	1.000
Finger V Extension	2.000	5.000	5.000	1.000	1.000	5.000	5.000	2.000
F1 Digitorum Longus	3.000	5.000	5.000	1.000	5.000	5.000	5.000	3.000
Flex Pol Longus	3.000	5.000	5.000	1.000	4.000	5.000	5.000	3.000
1st Dorsal Interos	5.000	5.000	5.000	2.000	5.000	5.000	5.000	3.000
Hypothenar	3.000	5.000	5.000	2.000	4.000	5.000	5.000	1.000
Opponens	1.000	5.000	5.000	3.000	2.000	5.000	5.000	3.000
Abductor Poll Brevis	3.000	5.000	5.000	1.000	2.000	5.000	5.000	3.000
PAD Interossei	2.000	5.000	5.000	1.000	3.000	5.000	5.000	2.000
Hip Flexor	5.000	5.000	2.000	3.000	5.000	3.000	5.000	3.000
Hip Extensor	5.000	4.000	5.000	1.000	5.000	5.000	2.000	3.000
Hip Abductor	5.000	5.000	3.000	1.000	5.000	3.000	5.000	3.000
Hip Adductor	5.000	5.000	3.000	1.000	5.000	5.000	5.000	3.000
Knee Flexor	5.000	3.000	3.000	2.000	5.000	5.000	3.000	3.000
Knee Extensor	5.000	5.000	5.000	1.000	5.000	3.000	5.000	3.000
Ankle Dorsiflexion	5.000	3.000	1.000	2.000	5.000	5.000	3.000	3.000
Ankle Plantarflexion	5.000	3.000	5.000	2.000	5.000	4.000	5.000	1.000
Ankle Inversion	5.000	2.000	2.000	2.000	5.000	5.000	2.000	2.000
Ankle Eversion	5.000	5.000	5.000	2.000	5.000	5.000	5.000	1.000
Great Toe Extension	5.000	3.000	1.000	3.000	5.000	3.000	3.000	3.000
Great Toe Flexion	5.000	5.000	5.000	2.000	5.000	5.000	5.000	3.000
Toe Dorsiflexion	5.000	3.000	2.000	1.000	5.000	4.000	3.000	3.000
Toe Plantarflexion	5.000	5.000	2.000	2.000	5.000	5.000	2.000	3.000

**Key**

- no movement
- flicker
- moves with gravity eliminate
- moves against gravity, but not resistance
- moves against resistance, but weak
- normal



# FreezerPro

- Web-based software application that allows you to create an inventory of your laboratory freezers and track and ship contents.
- Web interface enables users to know precisely where a frozen sample is located before opening the freezer door.
- Features include automatic alerts of low number of sample aliquots, sample expiration date, sample volume or freeze-thaw count along with powerful reporting.

ID	Sample Name	Description	Type	Vials	Owner
----	-------------	-------------	------	-------	-------

All Samples In All Freezers

No Samples To Display.

- Bacteria
- Cell Line
- DNA
- DNA/RNA Probe
- Embryo
- Monoclonal Ab
- Mouse
- Nuclear Extract
- Oligo
- Organic Compound
- PCR Primer
- Peptide
- Plasmid
- Polyclonal Ab
- Primary Tumor
- Protein
- Protein Extract
- RNA
- Tissue
- Vial
- Viral DNA/RNA
- Virus
- siRNA

- Samples By Expiration Date
- All Expired
  - Expired Yesterday

# What to use...?

- To determine which package is best for your project see the CTSI website and individual software companies' websites for more information
- Request a consult through the CTSI

**WEB-BASED ELECTRONIC DATA CAPTURE AND DATA MANAGEMENT SOFTWARE AVAILABLE TO BUMC FACULTY/STAFF  
THROUGH THE CTSI**

**REDCap****OpenClinica (community edition)****StudyTRAX**

SIMPLE DESCRIPTION	Web-based EDC and data management software	Web-based open source EDC and data management software	Web-based EDC, data management, and project management software
BEST FOR...	Online surveys, emailed survey links, clinical trials; easiest set-up of these software options	Randomized clinical trials; more robust form design; studies requiring internal data logic checks during data capture	Complex clinical trials, but also epidemiological studies, patient registries, and multi-site trials; pre-programmed academic reporting
LIMITATIONS	No internal data logic checks; not 21 CFR Part 11 compliant	More complicated to set up	Not free; more complex
LONGITUDINAL DATA COLLECTION	✓	✓	✓
RANDOMIZATION	✗	✗	✓
MULTI-SITES SUPPORTED	✓	✓	✓
REPORTING	Simple reporting capability	Simple reporting capability	Manuscript-ready reporting possible (e.g., "Table 1")
USER BASED PRIVILEGES	✓	✓	✓
AUDIT TRAIL	✓	✓	✓
21 CRF Part 11 COMPLIANCE	✗	✓	✓
DATA STRUCTURE IMPORT	Excel	Excel	Excel
DATA SET EXPORT	Excel, PDF, and common statistical packages (SPSS, SAS, Stata, R).	HTML, tab-delimited, Excel, and SPSS	Excel, CSV, SAS, SPSS, Word
COST	Free to BUMC faculty/staff	Free to BUMC faculty/staff	Fee per enrolled subject (limited waivers available)
LINKS	<a href="http://project-redcap.org/">http://project-redcap.org/</a>	<a href="https://community.openclinica.com/">https://community.openclinica.com/</a>	<a href="http://www.sciencetrax.com/studytrax">http://www.sciencetrax.com/studytrax</a>

# For more information...

- See the CTSI website: <http://ctsi.bu.edu/>
- Attend a drop-in session
- Send an email: [ctsi@bu.edu](mailto:ctsi@bu.edu)