



A health study for oil spill clean-up workers and volunteers

Development of an Integrated Data System for the Gulf Long-Term Follow-up STUDY (GuLF STUDY)

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Presentation Overview

Presentation Goals:

- GuLF STUDY Introduction
- Clinic Exams Components and Challenges
- Build or Buy
- System Features/Demonstration

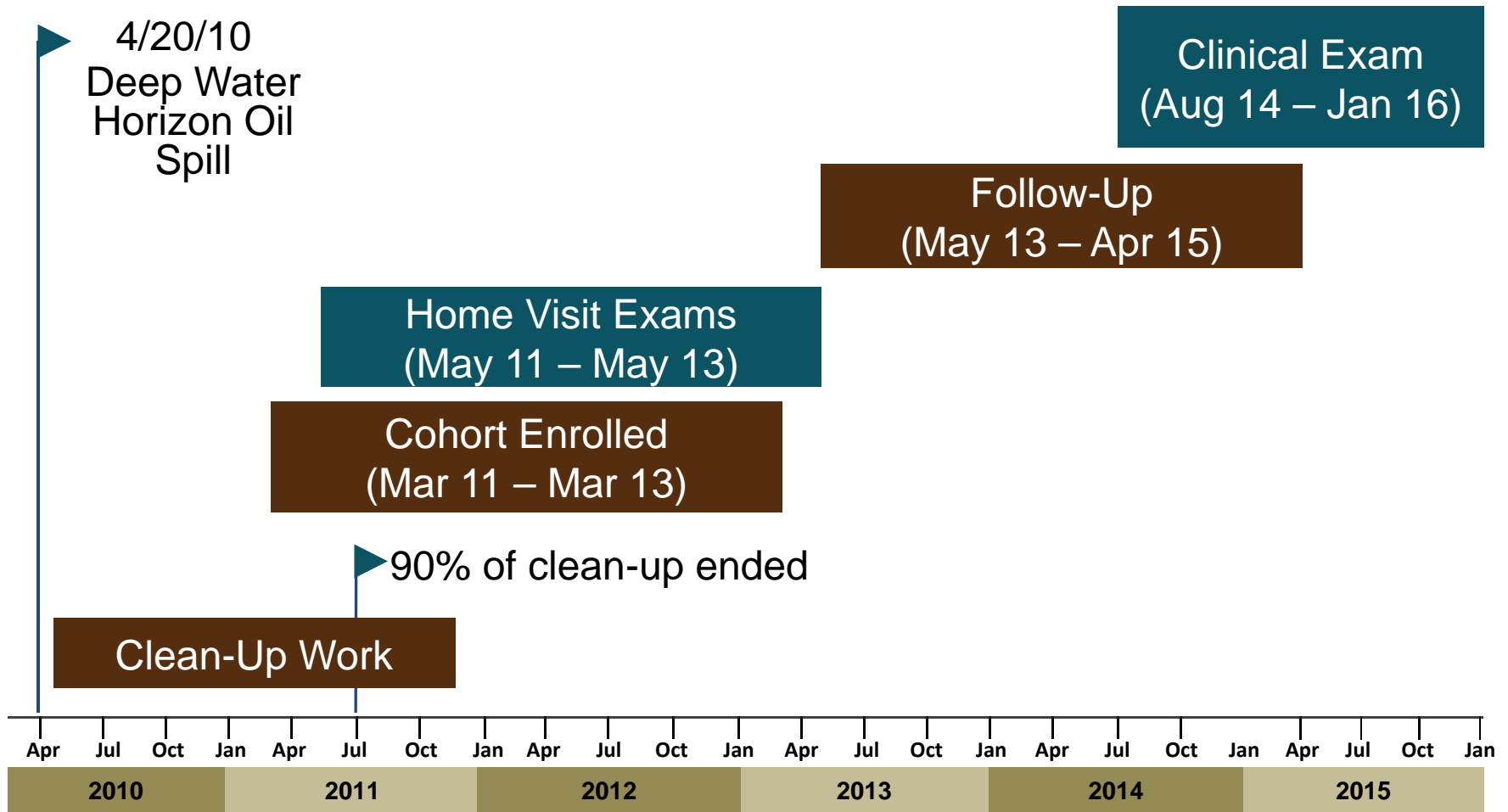
Study Objective

Assess health effects associated with oil spill clean-up





Study Timeline





Clinical Exam Overview

~6,200 eligible participants

4 - hour exam

Two clinical sites

- University of South Alabama
- Louisiana State University

Coordinating Center & Central Lab

- SSS, Durham, NC





Clinical Exam Procedures

Health Questionnaires

- *Physical health, mental health, substance abuse*

Clinical and anthropometric measurements

- *Height, weight, hip / waist circumference, blood pressure, heart rate*

Biological sample collections

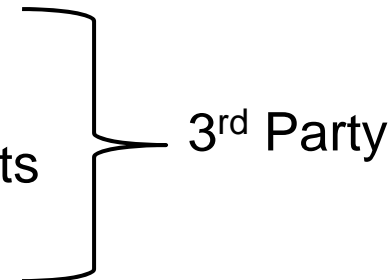
- *Hair, toenails, saliva, urine, blood,*

Peripheral nervous system testing

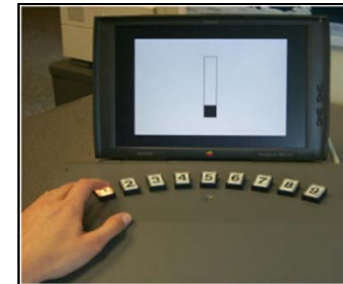
Computerized neurobehavioral assessments

Pulmonary function testing

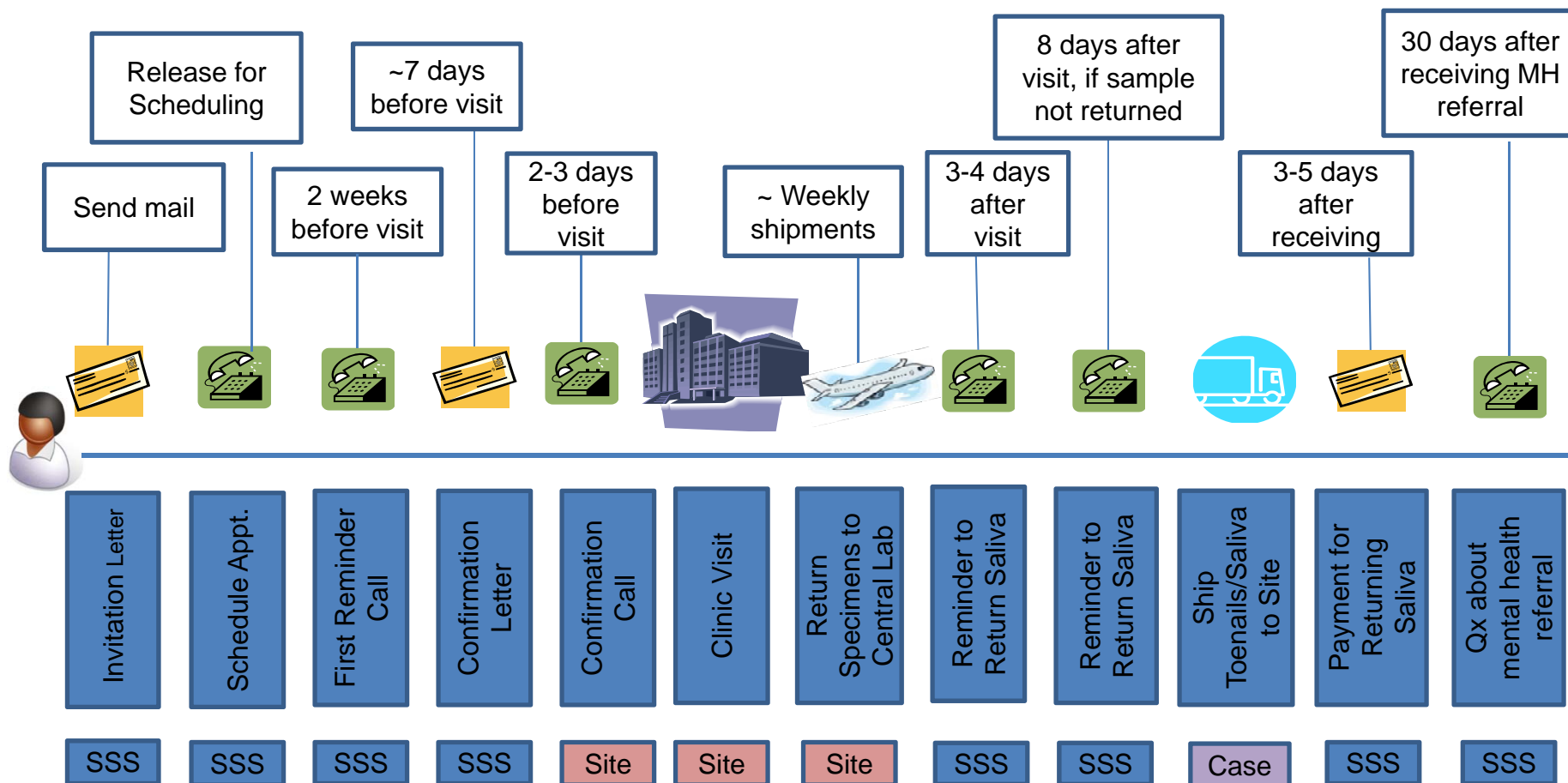
Mental health referral follow-up



Clinical Exam Procedures



Activities Controlled in Data System





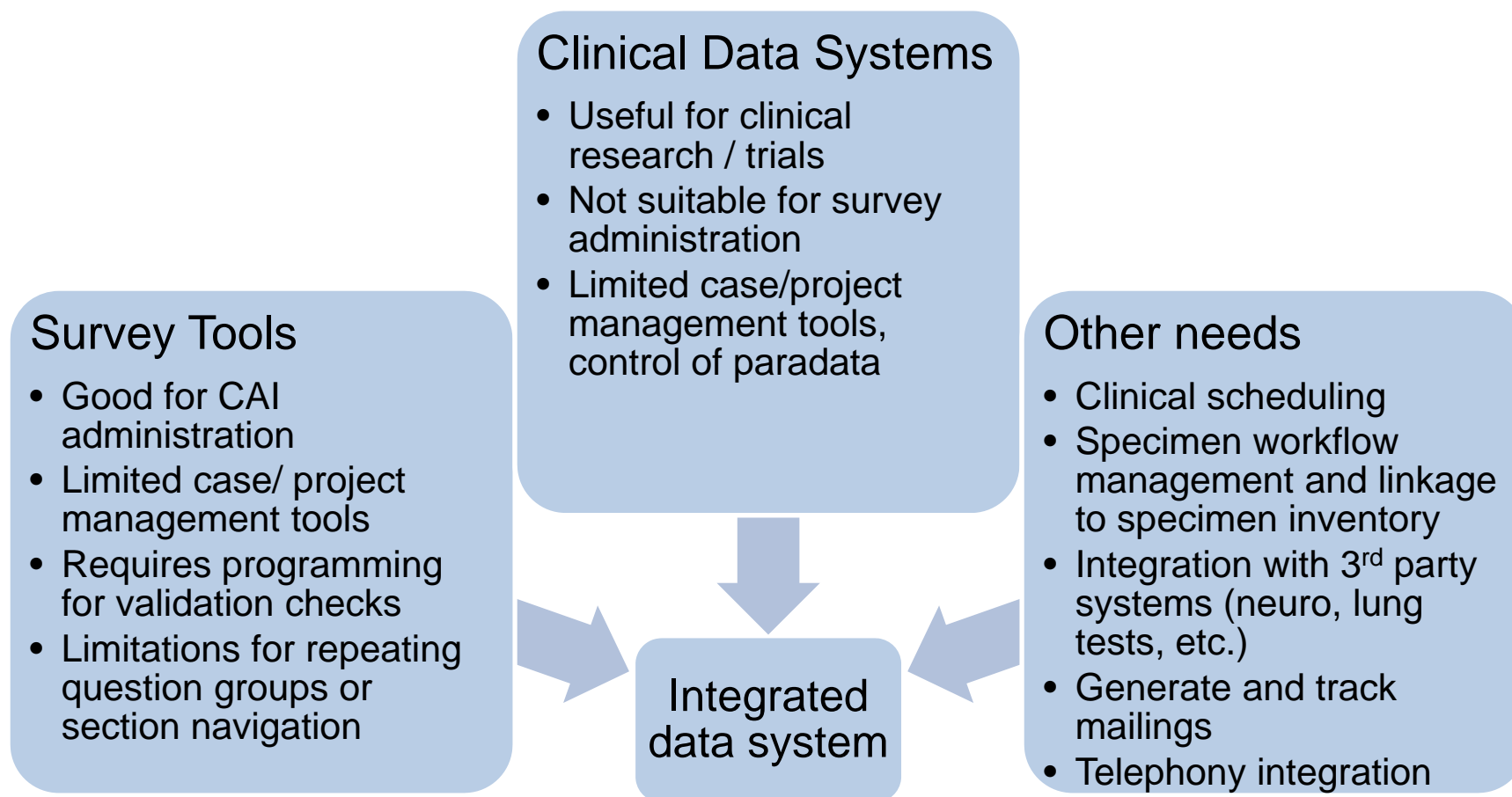
System Requirements

- Standardize data collection across sites
- Manage overall clinic workflow
- Support scheduling
- Allow for computer-assisted interviews
- Provide a means for real-time capture of clinical findings
- Print bar codes for samples and storage containers
- Generate report of clinical findings
- Link to external medical referral sources
- Track lab sample collection, processing, storage
- Upload data from medical devices
- Provide real-timed data QC checks

Additional Nuances

- Some procedures are done at one sight but not the other
- Data in one module can drive workflow in another (e.g. exam outcomes can influence scheduling, reminders and follow-up calls)
- Software had to be developed in the absence of a pilot study to fully assess workflow and user interactions with the system

Build or Buy?



Decided to build – no software currently available meets all requirements



Data System Modules

Launcher

- Grant and control user access

Mailing Applications

- Prepare lists for three letter types
- Send securely to fulfillment center

Scheduler

- Control call center and site tasks
- Scheduling, reminder calls, exam check-in, reminder and follow-up calls

Barcode Generator

- Prepare customized form, sample and box storage labels

Data Collection and Reporting

- Questionnaire and clinical data
- Produce report of findings
- Control checkout activities

Upload Utility

- Transfer exam test files from site laptops to SSS servers
- Check file names and contents
- User at site resolves problems

Lab Tracker

- Receipt and control
- Sample batching, processing, shipping



Launcher

- Provides access to all other applications
- Displays subsystems currently in use
- Admin features control user access and privileges

The screenshot shows the 'GuLFSTUDY Application Launcher' window. The main interface is split into a green left pane with the GuLFSTUDY logo and a dark blue right pane with application buttons: Bar Code, Lab Tracker, Mail List, Return Mail, Scheduler Running, and Survey. An 'Admin' dialog box is overlaid on top, containing user selection and security settings.

Select Operator: Lab Tech USA [Load]

Full Name: Lab Tech USA
Username: mem_it_usa
Operator Id: 403
Email: []
Site: USA Clinic []

Active?
 Change Password?

Application Level Security

Classification: Select a Classification []
Application: Lab Tracker []
Role: User []

[Add] [Clear]

#	Application	Role
1	Lab Tracker	User



Scheduling

Daily Tasks | Current Participant | Search

Clinic Check-in for [redacted]
Due Date: 02/18/2015 01:21 PM EST

Participant: 0676328 *Black or African American male* [redacted] Edit Follow-up survey: 10/04/2015

Notes:

Date	Time	Phone	Task Type	Caller	Outcome	Notes
02/18/2015	01:25 ...	[redacted]	Clinic Check-in	Carley Pryn	Complete	Checkin completed

Phone: [redacted] Dial Add New Number Edit Phone

Address: [redacted] Update

Clinic: LSU Clinic Distance From Home: 5 miles Hotel Is Needed

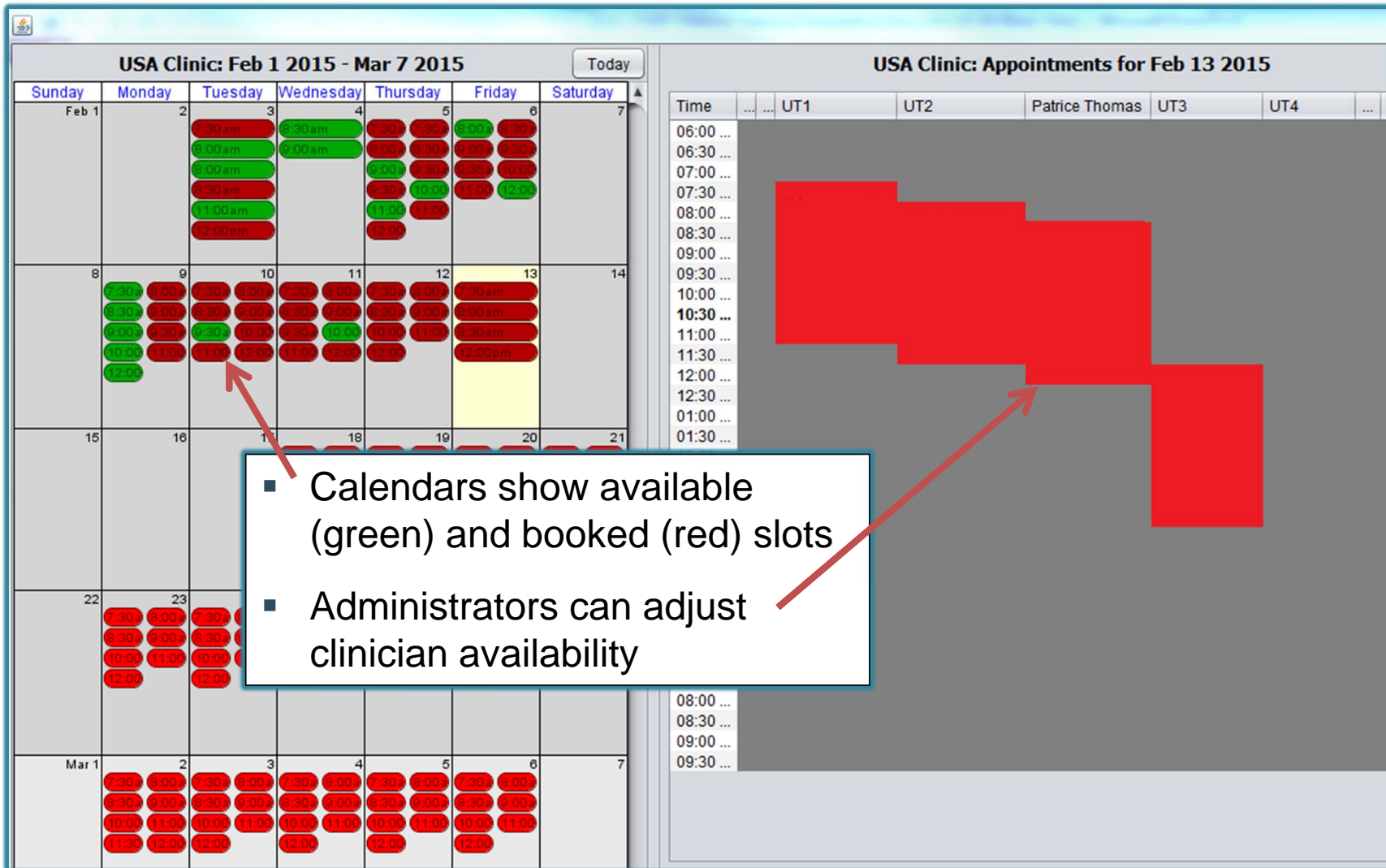
Appt: 02/18/2015 01:30 PM EST Clinician: [redacted] Requests 2-hour Visit

Action: Check In Information Agrees to QA testing

Outcome: Reached Participant Complete

- Displays participant information (name and demographics)
- Displays contact history
- User confirms or updates contact information
- Set appointment or enter other status information

Scheduling – Clinic Calendar View



The screenshot displays two views of a clinic's scheduling system. The left view, titled "USA Clinic: Feb 1 2015 - Mar 7 2015", is a weekly calendar grid. It shows appointment slots for each day, with green circles indicating available slots and red circles indicating booked slots. The right view, titled "USA Clinic: Appointments for Feb 13 2015", is a detailed hourly view for a specific day. It shows a list of time slots on the left and columns for different clinicians: UT1, UT2, Patrice Thomas, UT3, and UT4. A large red rectangular area is overlaid on the right view, and a red arrow points from a text box to this area.

USA Clinic: Feb 1 2015 - Mar 7 2015

USA Clinic: Appointments for Feb 13 2015

Time	UT1	UT2	Patrice Thomas	UT3	UT4
06:00 ...					
06:30 ...					
07:00 ...					
07:30 ...					
08:00 ...					
08:30 ...					
09:00 ...					
09:30 ...					
10:00 ...					
10:30 ...					
11:00 ...					
11:30 ...					
12:00 ...					
12:30 ...					
01:00 ...					
01:30 ...					

- Calendars show available (green) and booked (red) slots
- Administrators can adjust clinician availability

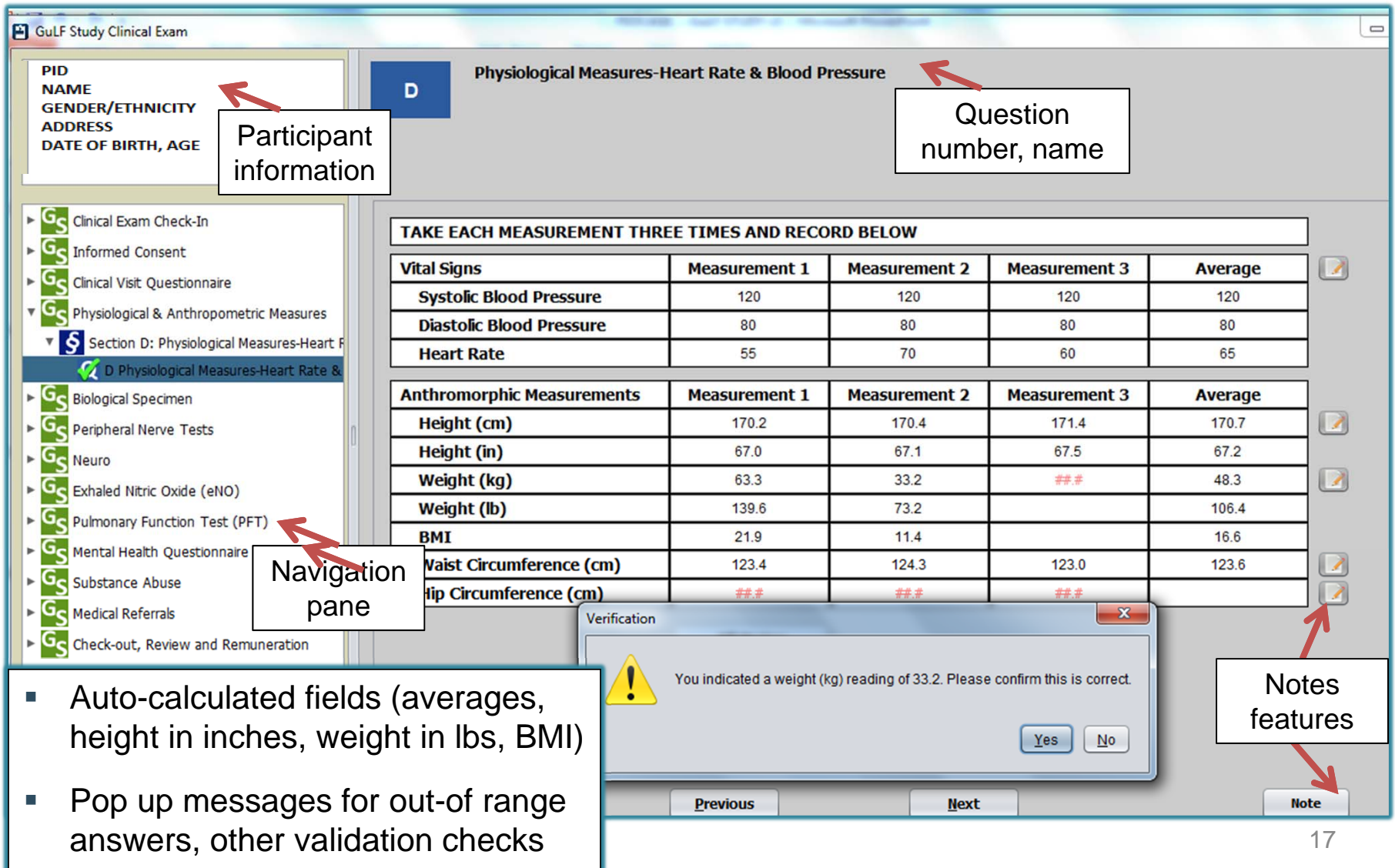


Barcode Generator

- Customized labels generated for each participant
- Barcodes and human-readable text
- Controls all exam-related documents and samples, including parent and child aliquots
- Participant receives lanyard and card with barcode
- Used at each step in exam to ensure match between participant and data entry

0043793 RFD105	0043793 SER101	0043793 SER102	0043793 SER103	0043793 SER104	0043793 CLT101	0043793 DOC	
0043793 RED205	0043793 SER201	0043793 SER202	0043793 SER203	0043793 SER204	0043793 CLT201	0043793 DOC	
0043793 LAV100	0043793 PLA101	0043793 PLA102	0043793 PLA103	0043793 PLA104	0043793 PLA105	0043793 DOC	
0043793 PCV101	0043793 PCV102	0043793 PCV103	0043793 PCV104	0043793 PCV105		0043793 DOC	
0043793 LAV200	0043793 PLA201	0043793 PLA202	0043793 PLA203	0043793 PLA204	0043793 PLA205	0043793 DOC	
	0043793 PCV201	0043793 PCV202	0043793 PCV203	0043793 PCV204	0043793 PCV205	0043793 DOC	
0043793 ACD100	0043793 ACD15M	0043793 WBL101	0043793 WBL102	0043793 WBL103		0043793 DOC	
0043793 BLU101	0043793 TOE101	0043793 WBL104	0043793 WBL105	0043793 WBL106		0043793 DOC	
0043793 PAX101	0043793 HAR101						
0043793 URN100	0043793 URN101	0043793 URN102	0043793 URN103	0043793 URN104	0043793 URN105	0043793 URN106	0043793 URN107
	0043793 URN108	0043793 URN109	0043793 URN110	0043793 URN111	0043793 URN112	0043793 URN113	0043793 URN114
0043793 SLV100		DAY 1 0043793 SLV101	DAY 1 0043793 SLV102	DAY 1 0043793 SLV103	DAY 1 0043793 SLV104	DAY 1 0043793 SLV105	SLV BOX 0043793
PID 0043793		DAY 2 0043793 SLV201	DAY 2 0043793 SLV202	DAY 2 0043793 SLV203	DAY 2 0043793 SLV204	DAY 2 0043793 SLV205	0043793 SLV QX

Clinical Exam Application



The screenshot shows the 'GuLF Study Clinical Exam' application. On the left is a navigation pane with a tree view of sections. The main area displays 'Section D: Physiological Measures-Heart Rate & Blood Pressure' with two tables for data entry. A 'Verification' pop-up message is shown for an out-of-range weight value. Annotations with red arrows point to various UI elements.

Participant information (points to the top-left form fields):

PID
NAME
GENDER/ETHNICITY
ADDRESS
DATE OF BIRTH, AGE

Question number, name (points to the section header):

D Physiological Measures-Heart Rate & Blood Pressure

Navigation pane (points to the left sidebar):

- Clinical Exam Check-In
- Informed Consent
- Clinical Visit Questionnaire
- Physiological & Anthropometric Measures
 - Section D: Physiological Measures-Heart Rate & Blood Pressure
 - D Physiological Measures-Heart Rate & Blood Pressure**
- Biological Specimen
- Peripheral Nerve Tests
- Neuro
- Exhaled Nitric Oxide (eNO)
- Pulmonary Function Test (PFT)
- Mental Health Questionnaire
- Substance Abuse
- Medical Referrals
- Check-out, Review and Remuneration

Table 1: Vital Signs

Vital Signs	Measurement 1	Measurement 2	Measurement 3	Average
Systolic Blood Pressure	120	120	120	120
Diastolic Blood Pressure	80	80	80	80
Heart Rate	55	70	60	65

Table 2: Anthropomorphic Measurements

Anthromorphic Measurements	Measurement 1	Measurement 2	Measurement 3	Average
Height (cm)	170.2	170.4	171.4	170.7
Height (in)	67.0	67.1	67.5	67.2
Weight (kg)	63.3	33.2	###	48.3
Weight (lb)	139.6	73.2		106.4
BMI	21.9	11.4		16.6
Waist Circumference (cm)	123.4	124.3	123.0	123.6
Hip Circumference (cm)	###	###	###	

Verification (pop-up message):

You indicated a weight (kg) reading of 33.2. Please confirm this is correct.

Buttons: Yes, No

Notes features (points to the 'Note' button at the bottom right).

Annotations:

- Participant information:** Points to the top-left form fields.
- Question number, name:** Points to the section header 'D Physiological Measures-Heart Rate & Blood Pressure'.
- Navigation pane:** Points to the left sidebar.
- Notes features:** Points to the 'Note' button at the bottom right.



Clinical Exam Application – Walk Test

GuLF Study Clinical Exam

PID
NAME
GENDER/ETHNICITY
ADDRESS
DATE OF BIRTH, AGE

U5. RECORD LAP TIMES FOR LONG DISTANCE CORRIDOR WALK (400M)

Lap		U5a. Lap Start Time	U5b. Lap Time	U5c. Total Time Elapsed
Start	Click Here	13:44:22.002	00:00:000	00:00:000
1	Click Here	13:44:23.505	00:01:503	00:01:503
2	Click Here	13:44:28.081	00:04:576	00:06:079
3	Click Here	13:44:30.977	00:02:896	00:08:975
4	Click Here	13:44:34.320	00:03:343	00:12:318
5	Click Here	13:44:38.568	00:04:248	00:16:566
6	Click Here	13:44:44.312	00:05:744	00:22:310
7	Click Here			
8	Click Here			
9	Click Here			
End	Click Here			
Quit*	Click Here			
Reset**	Click Here			

*Quit - TEST ENDED PREMATURELY
**Reset - False Start / Misclick

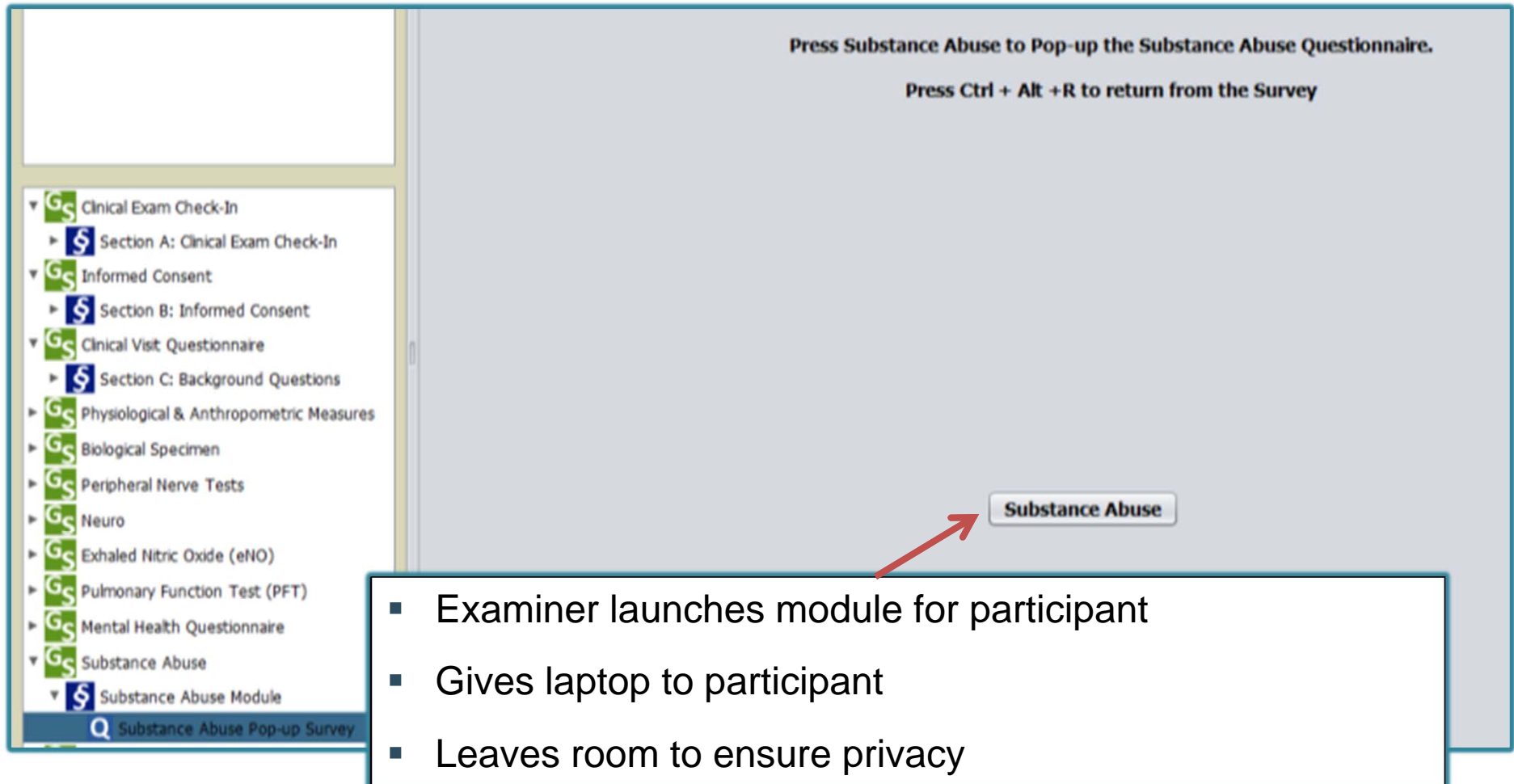
U5. RECORD LAP TIMES FOR LONG DISTANCE CORRIDOR WALK (400M)

1.0.0181 20150211-001327

Previous Next Note

- Participant completes 10 laps while examiner coaches and records data
- Clicks button at each lap
- System records start time of each lap
- Auto-calculates elapsed lap, total time

Clinical Exam Application – Substance Abuse Module



The screenshot shows a software interface for the Substance Abuse Module. On the left is a navigation tree with the following items: Clinical Exam Check-In (with a sub-item Section A: Clinical Exam Check-In), Informed Consent (with a sub-item Section B: Informed Consent), Clinical Visit Questionnaire (with a sub-item Section C: Background Questions), Physiological & Anthropometric Measures, Biological Specimen, Peripheral Nerve Tests, Neuro, Exhaled Nitric Oxide (eNO), Pulmonary Function Test (PFT), Mental Health Questionnaire, Substance Abuse (with a sub-item Substance Abuse Module), and Substance Abuse Pop-up Survey. The main area displays the text: "Press Substance Abuse to Pop-up the Substance Abuse Questionnaire." and "Press Ctrl + Alt +R to return from the Survey". A button labeled "Substance Abuse" is visible, with a red arrow pointing to it from a callout box. The callout box contains the following instructions:

- Examiner launches module for participant
- Gives laptop to participant
- Leaves room to ensure privacy



Clinical Exam Application – Substance Abuse Module

The following questions are about recreational drug use. We know this information is personal, but please remember that your answers will be kept confidential. You do not have to answer any questions that you do not want to answer. However, the information you provide will help us to understand your health and how oil spills affect health, including mental health. After you finish answering these questions, clinic staff WILL NOT be able to see your answers.

- Module is launched
- Participant completes questions about recreational drug use in privacy
- Module cannot be closed or minimized without hotkey

Previous

Next



Lab Tracker – Receiving Samples

GuLF Lab Tracking Application

File About

Lab Technician : Polly Armsby

Receiving Batching Processing Boxing Shipping Tracking Reporting

Scanning

Scan Barcode:

PID: 0999670

Specimen Type :

Disposition:

Collected By:

Scheduled Visits					
	PID	Scheduled	Date	Status	Status Time
✓	0292214	8:31 AM	18-Feb-15	Completed	9:38 AM
✓	0660655	8:55 AM	18-Feb-15	Completed	10:24 AM
✓	0711630	9:34 AM	18-Feb-15	Completed	10:36 AM
✓	1179675	10:16 AM	18-Feb-15	Completed	11:13 AM
✓	0561860	11:15 AM	18-Feb-15	Completed	12:14 PM
✗	0999670	11:54 AM	18-Feb-15	Arrived	11:54 AM
✗	0370455	2:48 PM	18-Feb-15	Arrived	2:48 PM

Participant's Specimens				
Specimen Type	Collection Time	Received Time	Disposition	Received By
URN100	To Be Collected			
RED100	1:07 PM	2:36 PM	Intact	Ar'Keya Mitchell
RED200	1:07 PM	2:36 PM		
LAV100	1:07 PM	2:37 PM		
LAV200	1:07 PM	2:37 PM		
ACD100	1:07 PM	2:37 PM		
BLU101	1:07 PM	2:38 PM		
PAX101	1:07 PM	2:37 PM		
HAR101	1:00 PM	2:38 PM		
QSLV	1:04 PM	2:38 PM		
TOE101	Collection Failure			

- Displays participants expected today and overall collection status (arrived, completed, etc.)
- Samples scanned in lab and receipt status updated
- Uncollected samples cannot be received, unreceived samples cannot be processed, etc.



Lab Tracker – Processing Samples

GuLF Lab Tracking Application

File About

Lab Technician : Polly Armsby

Receiving Batching Processing Boxing Shipping Tracking Reporting

Choose Batch Red / Lavender Yellow - Lymphocytes Yellow - Whole Blood Urine

Processed By : Polly Armsby

Enter start time for first centrifugation 03:15 AM PM

Enter end time for first centrifugation 03:30 AM PM

Warning :

⚠ Clotted time less than the required 30 minutes, youngest collected time :: 2:55 PM

Spinner Malfunction

Processing Protocol Deviation

Other

Please explain :

- Validations ensure adherence to standards like adequate clotting, centrifugation times, etc.
- Explanations required for exceptions to standards



Lab Tracker – Processing Samples

Enter start time for first centrifugation

Enter end time for first centrifugation

Scan aliquot

PID	Type	Lipemia	Hemolysis	Serum / Plasma			Clot / PCV	Status
0676328	RED100	Not Lipemic	None	<input checked="" type="checkbox"/> SER101 <input checked="" type="checkbox"/> SER104	<input checked="" type="checkbox"/> SER102	<input checked="" type="checkbox"/> SER103	<input checked="" type="checkbox"/> CLT101	Closed - Complete
0676328	RED200	Not Lipemic	None	<input checked="" type="checkbox"/> SER201 <input checked="" type="checkbox"/> X SER204	<input checked="" type="checkbox"/> SER202	<input checked="" type="checkbox"/> SER203	<input checked="" type="checkbox"/> CLT201	<input type="button" value="Open"/> Closed - Lost / Destroyed Open Closed - Complete Closed - Insufficient Sample

Next Step

- Each tube is processed according to unique needs of sample type
- Individual aliquots are created, scanned and tracked
- Sample conditions are documented to inform future analyses



Lab Tracker – Boxing Specimens

Receiving Batching Processing **Boxing** Shipping Tracking Reporting

Boxing performed by : Polly Armsby

Scan Box : Lid : Box #: 5019 Type: 7 mL
 Bottom : Box #: 5019 Type: 7 mL

Scan Sample :

Samples Not Boxed			Samples		
Type	Count				
7 mL ODD	7	⊕⊕	4347637-CLT101		
7 mL EVEN	35	⊕⊕	0574501-CLT101		
2 mL ODD	110	⊕⊕	0203340-QURN14		
2 mL EVEN	170	⊕⊕	0203340-QURN13		
Blue top & PAXgene	39	⊕⊕	0203340-QURN12		
Toenail	3	⊕⊕	0203340-QURN11		
Hair	5	⊕⊕	0166300-CLT101		
Saliva	4	⊕⊕			
Total	373	⊕⊕			

>>>

Boxes Available			
Box #	Type	Slots	
5030	7 mL EVEN	2	⊕⊕ ▲
5019	7 mL ODD	1	⊕⊕
6539	Hair	1974	⊕⊕
6733	Saliva	42	⊕⊕
5585	2 mL ODD	1	⊕⊕
5130	7 mL EVEN	9	⊕⊕
6609	Blue top & PAXgene	3	⊕⊕
6604	Blue top & PAXgene	36	⊕⊕ ▼
Total		2205	⊕⊕

Box #: 5019 Type: 7 mL ODD
 4285359-CLT101
 0091329-CLT101

Enter time placed in -80 storage area. 05:00 AM PM

- Samples are boxed and shipped by type
- Ensures materials are placed in appropriate containers and storage areas (fridge, -20°C freezer, -80°C freezer, etc.)





Report of Findings

Participant Data

Name: John Doe Participant ID Number: 123456
Gender: Male Date of Clinic Visit: 04/01/2014
Date of Birth: 01/02/1958

This report summarizes results recorded during your GuLF STUDY Clinical Examination on April 1, 2014. We encourage you to follow the advice provided for following up on any abnormal results. If you have any questions about your results or need assistance with a referral for health care, please let the clinic staff know.

Body Measurements and Body Mass Index

Body Mass Index (BMI) is a number calculated from a person's weight and height. BMI does not measure body fat directly, but research has shown that BMI is a fairly reliable indicator of body fatness as a screening tool to identify possible weight problems.

Height: 73.5 inches Weight: 231.2 pounds

Interpretation and Advice¹

Your BMI indicates that your weight is in the obese range (30.0 or above). People who are obese are at higher risk for chronic conditions such as high blood pressure, heart disease, and type 2 diabetes.

¹ NHLBI Obesity Education Initiative Expert Panel on the Identification, Evaluation, and Treatment of High Blood Pressure (US). Clinical Guidelines on the Identification, Evaluation, and Treatment of High Blood Pressure: Evidence Report. Bethesda (MD): National Heart, Lung, and Blood Institute; 2003.

Blood Pressure

Blood pressure (BP) is written as two numbers. Systolic BP, usually written as the first number, represents the pressure while your heart is beating. Diastolic BP, usually written as the second number, represents the pressure when your heart is resting between beats. A systolic pressure of 120 mm of mercury (also known as Hg) or lower is considered normal. Blood pressure that is extremely high could indicate a serious condition and should be reported to a health professional immediately. Lowering blood pressure is important to prevent heart disease and stroke.

Your blood pressure reading

160 mm Hg

105 mm Hg

Interpretation and Advice²

Your blood pressure is very high. See a health care provider **within the next month** to have your blood pressure rechecked and managed.

² The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. JNC 7 Report, 2003.

Report generated includes:

- Body measurements and body mass index
- Blood pressure
- Heart rate
- Hemoglobin A1C
- Cholesterol and triglyceride levels
- Lung function results

Referrals for affordable healthcare offered, as needed

Summary

- No single commercial product could cover all of our needs.
- Integrating disparate commercial products had major drawbacks that would –
 - Force us to compromise on some key requirements.
 - Limit our ability to change in response to real world implementation challenges.
 - Potentially box us in for future exams, which could include new requirements.
- For all these reasons, we decided to build, and so far, so good.



Acknowledgements

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For questions, email David Johndrow: djohndrow@s-3.com