

# SDSU HealthLINK Center Career Enhancement Workshop series

## Introduction to the RealTime Clinical Trial Management System (CTMS)

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**Dr. Claudia Carrizosa**  
Bio-Behavioral & Human  
Performance Coordinator



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Center Research Manager

SDSU HealthLINK Center for Transdisciplinary Health Disparities Research

*Funder: National Institute on Minority Health and Health Disparities (U54MD012397 & S21MD010690);*

*MPIs: Guadalupe X. Ayala, PhD, MPH, MA, and Kristen J. Wells, PhD, MPH*

# Agenda

**SDSU**

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- 1. SDSU HealthLINK Center Mission**
- 2. Introduction to main features of the RealTime Clinical Trial Management System (CTMS) for human subject studies**
- 3. Available to SDSU, SDSU IV, SDSURF, and partner organizations at a discounted rate!**

# About the Center

**SDSU**

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- Established in September 2018
- Funding: National Institute on Minority Health and Health Disparities (U54MD012397) & the SDSU HealthLINK Endowment (S21MD010690)



**Dr. Guadalupe X. "Suchi"  
Ayala,  
Co-Director  
Professor of Public Health**



**Dr. Kristen J. Wells,  
Co-Director  
Professor of Psychology**

- Mission
  1. Support development of research capacity, collaborations, and innovative investigations and solutions
  2. Foster meaningful, high quality, transdisciplinary research that advances health equity

## **Zoom poll:**

- 1. Does your study involve human subjects?**
- 2. Does your study involve protected health information (PHI)?**
- 3. How are you managing your current study?**

# Electronic Data Capture Systems for Research

protected health  
information (PHI)  
involved?

No



Google Form  
Qualtrics Survey

Yes

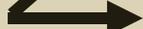


International behavioral/survey



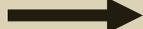
REDCap Cloud

Domestic behavioral/survey



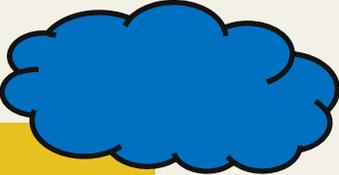
REDCap Academic & mEMA/Illumivu

On-site visit scheduling  
(e.g. physical exam, clinical test etc)  
Accounting to track payments \$\$  
Auditor access ready  
Web Integration  
Mobile Communication



Clinical Trial Management (CTMS)

# WHAT CAN CTMS DO FOR YOU?



## SECURE HOSTING

- World-class application hosting provides excellent performance and robust data protections.
- HIPAA-compliant architecture and application rules ensure data privacy and regulatory compliance.



## COMPLIANCE ASSURANCE

- eDOCS is Part-11 and HIPAA Compliant.
- Provides a platform to facilitate inspections, audits and study record requests.
- Complete remote monitoring and query discussion board for sponsors, CROs, and IRBs.
- Ability to request unlimited eSignatures in our system that are FDA-compliant.

# WHAT CAN CTMS DO FOR YOU?



## TRACK FINANCIALS

- Track revenue, costs and profitability.
- Build your budget templates according to the study event schedule.
- Create and send invoices to sponsors for completed/monitored visits or for other study revenue items as needed.



## STORE eREGULATORY DOCUMENTS

- Standardize eRegulatory binders while maintaining flexibility in one secure location for quick and easy access.
- Unlimited users and unlimited storage.
- Provide proficiency in your regulatory workflow for studies.



## ACCESS REPORTS

- Instant access to study financials brings your site's financial health into focus in real-time.
- Ensure subject recruitment is on time and within budget with multiple reports specifically for recruitment.
- Track advertising budgets and effectiveness of your campaigns.
- Assess productivity of recruiters, coordinators, and providers.



## INTEGRATION CAPABILITIES

- MailChimp integration allows for database re-marketing and robust engagement with study applicants.
- Facebook campaigns can be linked within RealTime-CTMS allowing leads to drop directly into study recruitment rosters.
- Build landing pages seamlessly for each study with website integration.
- Integration with other leading vendors for subject recruitment and business development.

WHAT CAN CTMS DO FOR YOU?

## Summary: RealTime CTMS is a secure & cloud-based solution for managing your human subjects study

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- Secure HIPAA-compliant hosting
- **Manage regulatory records electronically**
- Collect electronic source data
- **Calendar, scheduling, and track study participant visits**
- **Appointment reminders & retention**
- Customize procedures
- Delegate project staff roles
- Protocol compliance checks to ensure subject safety and eligibility

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  - a. DEMO 1: Tracking study regulatory compliance documents
  - b. DEMO 2: Study homepage & scheduling participant visits
  - c. DEMO 3: Web integration for recruitment
3. Available to SDSU, SDSU IV, SDSURF, and partner organizations at a discounted rate!

REALTIME

Eliminate paper-based  
logs to **improve**  
**compliance**



# Stay audit ready with RealTime eDOCS

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## What's in it for you?

- Centralize regulatory binders securely in one secure location.
- Easily track personnel curriculum vitae, professional licenses, and certifications.
- Informed consent tracking for all subjects in a study.
- Convenience and flexibility with electronic signatures.

## Benefits for Sponsors/CROs

- Sites can grant remote access to monitors and sponsor contacts, in turn reducing travel costs for sponsors.
- Accelerate the process of updating trial master files.

# Folder template for storing regulatory documents

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The image shows a screenshot of a digital folder template for regulatory documents. On the left is a vertical sidebar with icons for home, calendar, folder, CTMS, and other functions. The main area contains several folders, each with a title and a list of documents. The 'Protocol/Amendments' folder is highlighted with a gold border.

- Monitoring**
  - Contact List
  - Monitor Visit Letters
  - Site Visit Log
- Delegation Log and Staff Training**
  - Site Delegation Log
  - Study-Specific Training Records
- Protocol/Amendments**
  - Protocol Clarification Letters
  - Protocol Signature Pages
  - Protocol/Amendments
- Study Materials**
  - Non-Drug Shipment Receipts/Records
  - Reference Materials
  - Inclusion/Exclusion Criteria
  - CRF
  - Source Documents
  - Study Logs
  - Study Manuals
  - Subject Materials
- Drug Accountability**
  - Drug Accountability Log
  - Drug/Device Receipts
  - Non-Drug Supply Receipts/Records
  - Supply Destruction Records
- Institutional Review Board (IRB)**
  - FWA and IRB Registration Number
  - Informed Consent Forms
  - Notice of Approval/Reapproval
  - IRB Submissions
  - IRB Approvals
  - IRB Recruitment Materials
  - IRB Rosters
  - IRB Correspondence
- SAEs/Deviations**
  - Deviations
  - SAE Reporting Forms
- Form FDA 1572/Statement of Investigator**
  - FDA 1572/Investigator Statement
- Financial Disclosure Forms**
  - Financial Disclosure Forms

# Storing staff/site certificates with version control!

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Huang W. CITI Certifications + Add Documents ↓

**Huang W. HSR Biomedical Researchers** + Add Version

Seq	Version	File	Comments	Status	Expires	
1		W.Huang-HSR_Biome...		CURRENT	Expires 10/JUL/2026	  

**Huang W. HSR Soc-Beh** + Add Version

Seq	Version	File	Comments	Status	Expires	
1		W.Huang-HSR_Socia...		CURRENT	Expires 10/JUL/2026	  

**Huang W. IPS** + Add Version

Seq	Version	File	Comments	Status	Expires	
1		W.Huang-IPS_citiC...		CURRENT	Expires 07/JUL/2026	  

# Automatic notifications of upcoming regulatory document expiration

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## Expiring Document Notification - SDSU External



**RealTime-CTMS eDOCS** <eDOCS-Notifications-NoReply@realtime-host01.com>  
to Whuang5 ▾

Hi Wendy Jia Men,

You have a document expiring on 13/MAR/2024

- Site ID: SDSU
- Document ID: 36
- Document: test\_expiring
- Document Type: Site Document

Login to Realtime to [review and update this document here](#)

**REALTIME**  
CLINICAL TRIAL MANAGEMENT SYSTEMS

*Notice: Please Do Not Reply to this email. This email was sent from a notification-only email address and*

# Generate reports on your study documents

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REALTIME  
CLINICAL TRIAL MANAGEMENT SYSTEMS

Welcome Wendy Jia Men Huang (PDT)  
SDSU HealthLINK Center CTMS  
LOG OUT

SDSU HealthLINK Center

## Reports

Current Subject: Test 3, Test 3

Quick search...



Current Study: SDSU HealthLINK Center - NIH - HLINK CRC Service and Space Use

Clinical Studies » Reports

SELECT REPORT

SELECT REPORT CRITERIA FOR GENERAL SITE DOCUMENTS REPORT - MS

inSITES

Quick search...

Creates an Excel or HTML report, based on a selected date range and document search criteria, that shows the following document information: Category, Folder, Document Title, File Name, Status, Expiration Date, Document Version, and Date Uploaded. The HTML report allows you to click on the document and the report will take you directly to that document to view.

### eDOCS Document Tracking

- General Site Documents Report - MS
- Monitor Query Report (eDOCS) - MS
- Signature Status Report - MS
- Study Documents Report - MS
- User Document Report - MS

### eSOURCE

- Alert Tracking Report - MS
- Monitor Query Report (eSOURCE) - MS
- Subject Source Data - MS
- Subject Source Data - Single Page - MS
- Variable Mapping Report - MS

### Managerial

- Central Campaign Results Overview - MS
- Recruiter Status - MS
- Subject Birthday Locator - MS
- Trial Master Log - MS

### Select Uploaded Date Range

Start Date 01 / JAN / 2024 End Date 26 / MAR / 2024  No Date Filter

### Select Site

Site

All Sites

### Select Report Criteria

Show Me:

All Current Site Documents

Output to Excel

- STUDIES
- SUBJECTS
- CONTACTS
- REPORTS
- MY DOCS AND ALERTS
- MY TASKS
- CALENDAR
- UNIVERSITY
- ACCOUNTING
- ADMINISTRATION

# Generate reports on your study documents

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General Site Documents Report - MS  
26/MAR/2024 10:28:38 (America/Chicago)

All Current Site Documents  
Report Run: 26/MAR/2024 10:28:38 (America/Chicago) by Wendy Jia Men Huang

CATEGORY ↕	FOLDER ↕	DOCUMENT TITLE ↕	FILE NAME ↕	STATUS ↕	EXPIRATION DATE ^	DATE UPLOADED ↕
Site Calibrations	Equipment Maintenance and Calibrations	DXA PM Report_6.30.2021	DXA PM report 6.30.21.pdf			12/JAN/2024 00:58
Site Calibrations	Equipment Maintenance and Calibrations	DXA PM Report 6.30.2022	DXA PM Report 6.30.22.pdf			12/JAN/2024 00:59
Personnel	██████████ CITI Certifications	██████████ Biosafety IBC Members	IBC Members.pdf	Current		19/FEB/2024 23:15
Site Calibrations	Equipment Maintenance and Calibrations	DXA PM 6.24.2023	DXA PM Report_6.24.23_PO30141.pdf			12/JAN/2024 01:00
Standard Operating Procedures	Phlebotomy Suite SOPs	Blood Sample Process Procedure	HLINK_Phlebotomy Blood Sample Processing Procedure_V1_5-10-22 CH.pdf			14/FEB/2024 22:10
Personnel	██████████ CITI Certifications	test_expiring	test.pdf	Current	13/MAR/2024	12/MAR/2024 20:47
Personnel	██████████ Licenses	██████████ - Xray Lics	██████████_Cal Dept of Public Health Permit_valid until 8-24-2024 (2).pdf	Current	24/AUG/2024	14/FEB/2024 22:08

# eSignature tracking

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The screenshot displays a web application interface for clinical studies administration. The breadcrumb trail at the top reads "Clinical Studies » Administration » Documents". The main navigation area includes tabs for "MANAGE STUDIES", "MANAGE ENTITIES", and "QC VISITS". Below these, there are sub-sections for "General Site Documents" and "Study Regu". A filter dropdown is set to "All Site Locations". A search bar is labeled "Search documents for this sectic" with a magnifying glass icon. A blue button labeled "+ Add Category" is visible. Below the search bar, there are two yellow buttons: "+ Site Calibrations" and a partially visible "+ Temperature Log".

The right-hand side of the interface shows an "Audit Trail: eSign Test: Confidentiality agreement" window. It features two dropdown menus for "Action Type" and "User". The audit trail contains the following entries:

- Signed by [redacted] on 15/JAN/2024 8:32:00 AM PST / 99.132.72.193
- Updated by system on 15/JAN/2024 8:32:00 AM PST / 99.132.72.193
- Updated by [redacted] on 15/JAN/2024 8:31:00 AM PST / 99.132.72.193
- Viewed by [redacted] on 15/JAN/2024 8:30:00 AM PST / 99.132.72.193
- Viewed by [redacted] on 15/JAN/2024 8:29:00 AM PST / 99.132.72.193
- Viewed by [redacted] on 15/JAN/2024 8:28:00 AM PST / 99.132.72.193

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# Example homepage with multiple studies

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**Clinical Studies**

Welcome Chuck as Admin  
Dynamisch CTMS  
LOG OUT

S.O.M.S.  
Site Operations Management System

Current Subject: Test1004, Test 1543

Current Study: Abbott - Print Encounter - 8.20 - CAH

Clinical Studies Status Filter: All Active Studies

SPONSOR	CLINICAL DESCRIPTION	PROTOCOL	CUSTOM ID	STATUS	OPTIONS	GOAL	SCHED	SCRN	FAIL	RAND	COMP	% GOAL
★ AMAG	CAH - Test - 9.28.2021	CAH - Testing - Region - Euro		Enrolling	    	0	0	2	1	1	0	--%
★ Novartis	lorem, luctus ut, pellentesque eget, dictum placerat, augue. Sed molestie.	C7E4E2		Enrolling	     	0	0	0	0	0	0	--%
☆ Intarcia	Type 2 Diabetes - Adults	22589-INT-300		Enrolling	     	3	1	8	2	5	0	167%
☆ Abbott	Profile Communications Control Testing	Profile Communication Control Testing		Enrolling	    	0	1	0	0	0	0	--%

# Study-specific homepage: Recruitment Roster

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The screenshot displays the 'Recruit Roster (Enrolling)' page in a web browser. The browser address bar shows the URL: `realtime-host01.com/rtdemo/index.php?StudyID=33&action=list_patient`. The page header includes a welcome message for 'Natalie Melisano' and a 'LOG OUT' button. The current study is identified as 'DO NOT USE - Admin and User Training-DO NOT USE (LISA STUDY FOR TRAINING)'. A 'Batch Update' button is visible in the top right corner.

The main content area features a navigation bar with tabs: RECRUIT ROSTER, ENROLLED ROSTER, VISIT TRACKING, ReSOURCE, eDOCS, STUDY PROGRESS, GENERAL INFO, and ADD SUBJECT. Below this is a table of patient statuses:

Status	Count	Scheduled	Overdue
Not Contacted	25	0	0
Contact Attempt 02	4	0	0
Contact Attempt 03	16	0	0
Follow-up Required	7	2	2
Follow-up by CRC	9	2	2
Scheduled For PRE-SCREEN	1	1	1
Qualified for Screening	2	0	0
Scheduled For SCREEN	18	8	8
Enrolled	93	0	0
DNQ (Other)	1	0	0
Imported	493	0	0

# Study-specific homepage: Visit Tracking

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RECRUIT ROSTER	ENROLLED ROSTER	VISIT TRACKING	ReSOURCE	ReDOCS	STUDY PROGRESS	GENERAL INFO	ADD SUBJECT	⚙️		
Study Arm	Visits	Status	All	Excel Output	Refresh Display	Manage Study Template	<<	<	>	>>
Ini.	DOB	Status	Screen/Rand	Visit 1 - Screening (Line1...)	Visit 2 - Baseline (Line1...)	Visit 3 - (Fixed Amt)	Visit 4 - EOS			
CB		In Screening	123 /	02/MAR/2020	09/MAR/2020	23/MAR/2020	23/MAR/2020			
TT		In Screening		30/JUL/2020	06/AUG/2020	13/AUG/2020	20/AUG/2020			
CV	04/APR/2019	Randomized	1104-08 / 1104-...	11/SEP/2019	12/SEP/2019	19/SEP/2019	26/SEP/2019			
CT		Completed	123456 /	01/AUG/2019	08/AUG/2019	22/AUG/2019	29/AUG/2019			
NV	01/JAN/1998	Completed	12345 / 12345	08/NOV/2019	08/NOV/2019	08/NOV/2019	08/NOV/2019			
LR	01/JAN/2000	Completed		01/JUN/2020	08/JUN/2020	15/JUN/2020	22/JUN/2020			
BW		Completed	240-7.29 /	15/JUL/2020	22/JUL/2020	.	.			
SW		Completed	123-456 / 654-3...	01/MAR/2020	08/MAR/2020	15/MAR/2020	16/MAR/2020			
TU		Screen Fail	01 /	02/SEP/2019	.	.	.			

# CTMS is used for scheduling a visit to the SDSU HealthLINK Clinical Research Center

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The SDSU HealthLINK Center offers SDSU, SDSU IV, community partners, space to host Study Participant Visits for behavior-clinical research trials

&

Dual X-ray Absorptiometry (DXA scan) services for bone health assessments

We use CTMS to manage compliance and human subjects enrolled in these studies.

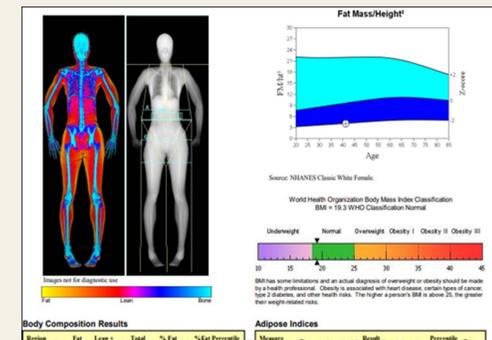
CTMS: lobby check in



CTMS: recording medical history



CTMS: secure storage of visit documentations



# Study-specific homepage: Scheduling a Visit

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San Diego State University Research Foundation on behalf of SDSU HealthLINK CTMS : RealTime-CTMS - Google Chrome

realtime-host01.com/sdsu/index.php?action=calendar&target=editevent&studyid=1&patientid=2&trackingid=2&category=4

**Event Information**

**Your Participation**  Display on My Calendar **Event Status** Scheduled

**Assigned Calendar** San Diego State University Rese DXA scanner **Color Code** Blue

**Subject** Test - Test2 Test2 - Future Candidates - 510-213-3161 undefined **Location** 5250 Campanile Drive , San Diego, CA 92182

**Start Date : Time** 16 / JAN / 2024 1200  All Day **End Date : Time** 16 / JAN / 2024 1230

**Visit Window** 16/JAN/2024 -0 +0 Days

There are no ICF Documents Uploaded for this Study. 

[+ View All Available Informed Consents](#)

**Comments**

Save Event & Close Save Event & Return Cancel/Close

**Manage Assigned Staff and Resources**

San Diego State University Research Foundation on behalf of SDSU

Inform Consent Form (ICF) & eSignature

# Study-specific homepage: Scheduling a Visit

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The screenshot displays the REALTIME Clinical Trial Management Systems interface. On the left is a navigation sidebar with options: STUDIES, SUBJECTS, CONTACTS, REPORTS, MY DOCS AND ALERTS, MY TASKS, CALENDAR (highlighted), UNIVERSITY, ACCOUNTING, and ADMINISTRATION. The main content area shows a calendar for 'DXA scanner' visits. At the top, there are navigation links (Home, Daily, Weekly, Monthly, Chronological, Multi-View), an 'Add New Event' button, and dropdown menus for 'Calendar' (set to 'SDSU Research Foundati...') and 'DXA scanner'. Below this is a sub-header for 'DXA SCANNER' with a 'Study: All Studies' dropdown. The calendar view shows the week of March 13, 2024, with columns for Sun-10 Mar, Mon-11 Mar, Tue-12 Mar, Wed-13 Mar, Thu-14 Mar, and Fri-15 Mar. The time slots range from 07 to 13. A blue event box is visible on the Wednesday, March 13, 2024, at the 12:00 slot, labeled 'Visit 1 - Test5 Test5 - LaunchReady DXA\_CRC - 510\_212\_2153\_110000'.

# Auto-appointment confirmation to the research team members

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The screenshot shows an email client interface. At the top, there is a search bar and navigation icons. The email subject is "DXA Scan 1 - Test2 Test2 - Future Candidates - 510-213-3161 undefined". The sender is "Wendy Jia Men Huang via realtime-host01.com" and the recipient is "to Whuang5". The email content includes a calendar widget for January 23rd, a "View on Google Calendar" link, and event details: "When: Tue Jan 23, 2024 2pm - 2:30pm (PST)", "Where: 5250 Campanile Drive, San Diego, CA 92182", and "Who: noreply@realtime-host01.com\*". There are response buttons for "Yes", "Maybe", and "No", along with "More options". To the right, an "Agenda" for Tuesday, January 23, 2024, lists several events: "HLINK Internal IT Meeting" at 2pm, "Test - Test Test - Future Candidates ..." at 2pm, "DXA Scan 1 - Test2 Test2 - Future Can..." at 2pm, and "User Group Training (Tue 6 PM CT)" at 4pm. At the bottom, it indicates "One attachment • Scanned by Gmail" and provides a "Download" link for the "invite.ics" file.

Search in mail

Active

SDSU

1 of 3

DXA Scan 1 - Test2 Test2 - Future Candidates - 510-213-3161 undefined

Wendy Jia Men Huang via realtime-host01.com to Whuang5

1:16 PM (9 minutes ago)

Jan 23 Tue

DXA Scan 1 - Test2 Test2 - Future Can...  
[View on Google Calendar](#)

When Tue Jan 23, 2024 2pm - 2:30pm (PST)  
Where 5250 Campanile Drive, San Diego, CA 92182  
Who noreply@realtime-host01.com\*

Yes Maybe No More options

Agenda  
Tue Jan 23, 2024

- 2pm [HLINK Internal IT Meeting](#)
- 2pm [Test - Test Test - Future Candidates ...](#)
- 2pm DXA Scan 1 - Test2 Test2 - Future Can...
- 4pm [User Group Training \(Tue 6 PM CT\)](#)

One attachment • Scanned by Gmail

[invite.ics](#) Download

# Texting study participants & automatic appointment reminders (advanced feature)

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Each site has its own phone number to text from!

### Communications Preferences

Do not include in future recruiting efforts

Marketing Emails: This subject does not have an email address saved.

**TEXT**  Appt. Reminders/Manual Text Text Opt-In/Out Log: SMS Mobile #: 510-213-3161

Opt-In/Out:  Marketing  RealTime-Pay Card Loads

Manual Opt-out

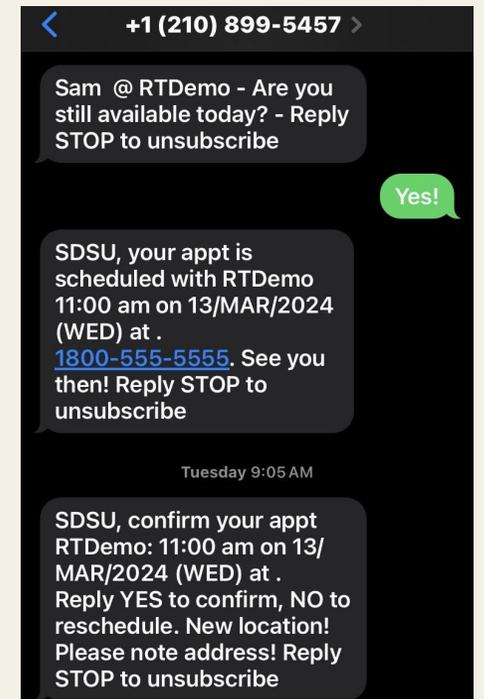
### Participant Portal Connection

Send Welcome Email

### Progress Notes

Study: All Studies

CONTACT DATE/TIME	RESULT / FOLLOW-UP
Study: DO NOT USE - RT-PAY and TEXT	Contact Outcome: No Outcome Selected
Sam Jones 05/MAR/2024 1608	
05/MAR/2024 2108 DO NOT USE - RT-PAY and TEXT Subject Text Message Received	No Outcome Selected Yes!
05/MAR/2024 2108 DO NOT USE - RT-PAY and TEXT Sam Jones - Sent as SMS Text to Subject	Text Message Are you still available today? - STOP=Unsub.





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