

Up Next . . .

2–3 p.m.

Breakout Room 2: PRS Beta

Carrie Dykes, University of Rochester

Nachiket Dharker, PRS Beta Product Owner

Moderators:

Stacey Arnold, ClinicalTrials.gov Results SME

*Amanda Burton, ClinicalTrials.gov Lead
Information Research Specialist*

*Qiao Chang, ClinicalTrials.gov Registration
SME*

Summary

Anna Fine, Acting Director of ClinicalTrials.gov

We are currently
on a break and will
resume at 2 p.m.



PRS Beta Breakout Room



Carrie Dykes

University of Rochester



Nachiket Dharker

PRS Beta Product Owner



User Comments on PRS Beta

Carrie Dykes, PhD
PRS Administrator
University of Rochester


Homepage: Allows Users to Save a View

The screenshot displays a user interface for saving and managing views. At the top, there are two blue buttons: 'Saved Views' (with a checkmark icon) and 'Export' (with a download icon). Below these, a 'Customize Columns' button is visible. A search bar is present with a magnifying glass icon. A dropdown menu is open, listing several view options: 'Save Current View As...', 'Default View', 'Planning View', 'Public Site View', 'Carries view', and 'Problem Records'. The background shows a table with the following structure:

Primary IDs	Brief Title	Problem Records	Record Status
	<input type="text" value="Search this column"/>	Select...	Select...
	Myotonic Dystrophy and Facioscapulohumeral Muscular Dystrophy Registry	• Missing FDA... Information	Public
	Genotoxicity Assessment	• Missing FDA...	Public

PRS Beta allows users to save a particular view where the columns are customized for a particular purpose.

Homepage: Each Column Is Searchable

10 per page ▾ Viewing 1 - 10 | 250 records [Clear Filters](#) [Customize Columns](#) 

View Record	Group ▾	Unique Protocol ID ▾	Tags ▾	NCT Number ▾	Secondary IDs ▲	Brief Title ▾	Problems ▾	Records
	<input type="text" value="Search this column"/>	<input type="text" value="Search this column"/>	<input type="checkbox"/> No longer public <input type="checkbox"/> Results	<input type="text" value="Search this column"/>		<input type="text" value="Search this column"/>	<input type="checkbox"/> No Problems <input type="checkbox"/> Any # of Problems <input type="checkbox"/> Pending PRS Review Comments <input type="checkbox"/> Entry Not Completed <input type="checkbox"/> Not Recently Updated <input type="checkbox"/> Record Has Errors <input type="checkbox"/> Missing FDAAA Information <input type="checkbox"/> Late Results - per FDAAA <input type="checkbox"/> Incomplete Results—per FDAAA <input type="checkbox"/> Ready for Review and Approval <input type="checkbox"/> Never Released <input type="checkbox"/> Update Not Released	<input type="checkbox"/> Ir <input type="checkbox"/> E <input type="checkbox"/> A <input type="checkbox"/> R <input type="checkbox"/> P <input type="checkbox"/> P <input type="checkbox"/> N

Protocol Registration: Easier Navigation within a Record

Users can now click from module to module without having to click out of the modules.

UNIQUE PROTOCOL ID
STUDY234567

BRIEF TITLE
A test of the PRS Beta site

NCT NUMBER
NCT ID not yet assigned

Study Identification

Study Status

Sponsor / Collaborators

Oversight

Study Description

Conditions

Study Design

Arms and Interventions

Outcome Measures


Eligibility


Contacts / Locations

Study Identification

* Required

*  Required if Study Start Date is on or after January 18, 2017

 Conditionally required

Organization's Unique Protocol ID * 

STUDY234567


19 characters left

Brief Title * 

Write a short, easy-to-understand version of the official study title using title case.

This is a test protocol.


276 characters left

Acronym 

Required if one exists. It will be included in parentheses at the end of the Brief Title.

Test

10 characters left

Study Type * 

UNIQUE PROTOCOL ID

STUDY234567

BRIEF TITLE

A test of the PRS Beta site

NCT NUMBER

NCT ID not yet assigned

Study Identification

Study Status

Sponsor / Collaborators

Oversight

Study Description

Conditions

Study Design

Arms and Interventions

Outcome Measures

Eligibility

Protocol Registration: Information Buttons

Study Status

Information buttons for each field bring up additional information and definitions.



- * Required
- * § Required if Study Start Date is on or after January 18, 2017
- [i] Conditionally required

Record Verification Date * **i**



Month

Year

Overall Recruitment Status * **i**

If you select "Suspended," "Terminated," or "Withdrawn," an explanation of why the study was stopped is required.

Record Verification Date

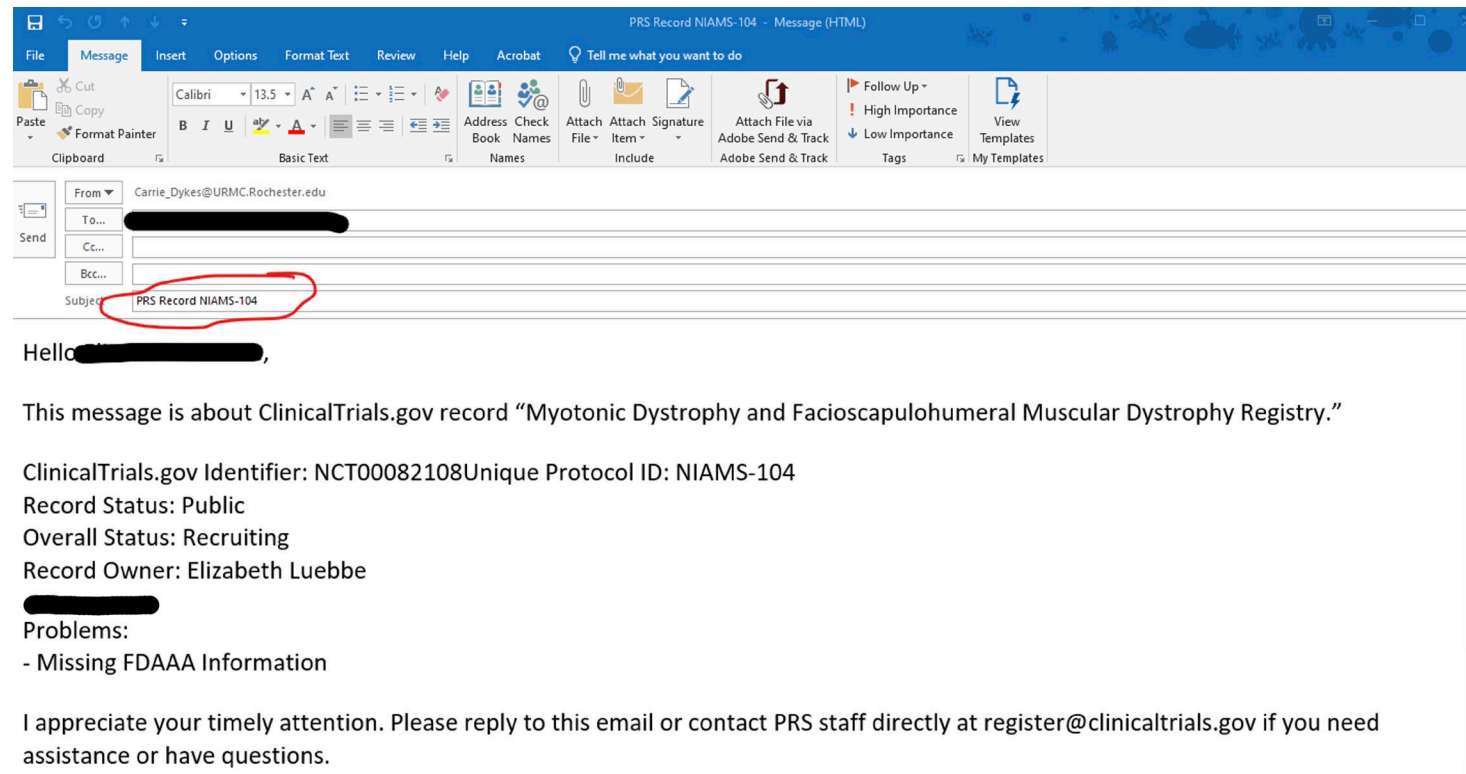
Enter the date that the study record information was last reviewed and confirmed by the responsible party.

Additional Information +

Data Element Definition +

Homepage: Messages to PRS Record Owners

- The NCT Number is a unique identifier used in all my email communications.
- It allows me to search messages using this unique number.
- It would be helpful to include it in the subject line of the beta system's email template.



Problem Records: Email Message Template

- It would be helpful in the future if the template language could be customized by each institution.
- My institution emails the responsible party and record owner.
 - It would be helpful to email them together rather than separately.

Email Notifications and Templates

Request: Include the NCT Number in the subject line.

Response: We can explore adding this information, but we would maintain the Unique Protocol ID in the subject line in all cases (for records without an assigned NCT Number).

Request: Create emails from user-defined templates.

Response: This would require storage in the PRS. We will need to explore our capacity for this storage.

Request: Allow multiple addressees to be emailed at once (e.g., responsible party and PRS Record Owner).

Response: We can explore the potential to select multiple names in the To, Cc, and Bcc fields from the study record's Access List.

Protocol Registration: Entering Contact Information

- There are several places in the record where red asterisks are not appropriate.
- Red asterisks indicate the field is mandatory to complete.
- For example, the Middle Initial and Extension are mandatory when entering the Central Contact information.

The screenshot displays a web form for entering contact information. On the left is a vertical navigation menu with the following items: Sponsor / Collaborators, Oversight, Study Description, Conditions, Study Design, Arms and Interventions, Outcome Measures, Eligibility, **Contacts / Locations** (highlighted in blue), IPD Sharing Statement, and References. The main content area is titled "Central Contact * i" and contains a placeholder text: "Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua." Below this are several input fields:

- First Name ***: A text input field with a red asterisk and a red circle around it. Below the field is the text "62 characters allowed".
- Middle Initial ***: A text input field with a red asterisk and a red circle around it. Below the field is the text "30 characters allowed".
- Last Name/Official Title ***: A text input field with a red asterisk. Below the field is the text "62 characters allowed".
- Degree ***: A text input field with a red asterisk. Below the field is the text "30 characters allowed".
- Phone Number ***: A text input field with a red asterisk and a red circle around it. Below the field is the text "30 characters allowed".
- Extension ***: A text input field with a red asterisk and a red circle around it. Below the field is the text "14 characters allowed".
- Email ***: A text input field with a red asterisk. Below the field is the text "254 characters allowed".

At the bottom of the form is a section titled "Central Contact Backup * i" with a red asterisk and an information icon. It contains a placeholder text: "Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna" and a partially visible input field below it.

Protocol Registration: How Errors Are Shown

- Having a list of Errors at the top of the record as you complete it is not helpful.
- Just like how most forms on the web are completed, the system should highlight the fields that have Errors, so they are easier to find.
- Errors appear about downstream sections of the record before the record is completed.

! Errors Found (9)

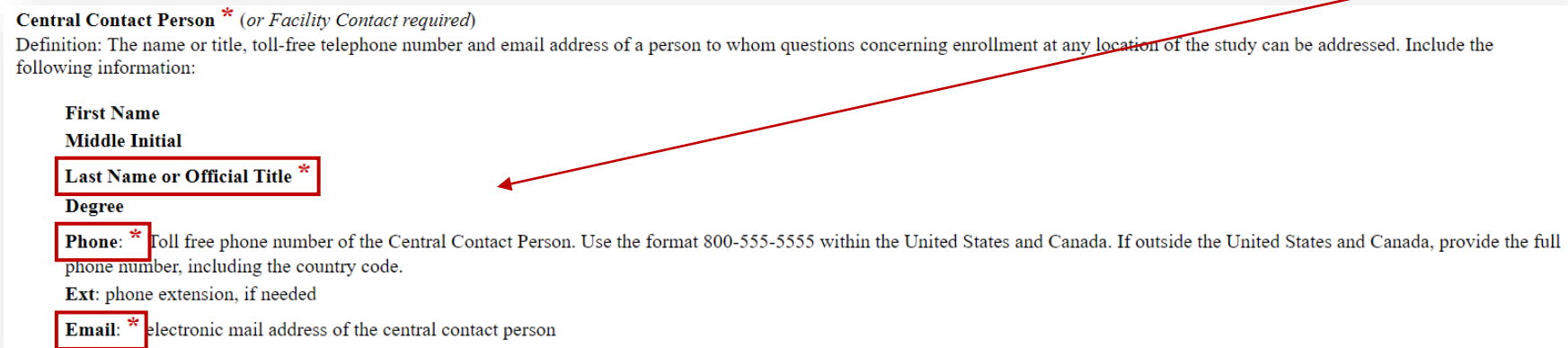
- Overall Recruitment of the study is 'Recruiting', but no Locations have Recruitment Status set to Recruiting.
- gov.nih.nlm.prs.service.validation.MessageConstants@3bc13947.STUDY_COMPLETION_DATE_HEAD 2021-02-28 gov.nih.nlm.prs.service.validation.MessageConstants@3bc13947.STUDY_COMPLETION_DATE_2_6_1_2
- gov.nih.nlm.prs.service.validation.MessageConstants@3bc13947.STUDY_COMPLETION_DATE_HEAD 2021-02-28 gov.nih.nlm.prs.service.validation.MessageConstants@3bc13947.STUDY_COMPLETION_DATE_2_6_1_3
- Study Completion Date must be in the future for a study that is Recruiting.
- Study Completion Date Type cannot be Actual for a study that has not been completed.
- Actual and Overall Recruitment Status not COMPLETED or TERMINATED
- The 'Start Date' should not be in the future for studies that are Recruiting
- Study Start Date Type cannot be Actual for a study that has not yet started
- Actual Start Date cannot be in the future.

Known Issues

Issue: Inappropriate requirement labeling for data element fields

Response: We are aware of this issue and have been working on a solution.

The goal is to label fields according to individual requirements (as is done in the DED).



Central Contact Person * (or Facility Contact required)
Definition: The name or title, toll-free telephone number and email address of a person to whom questions concerning enrollment at any location of the study can be addressed. Include the following information:

First Name
Middle Initial
Last Name or Official Title *
Degree
Phone: * Toll free phone number of the Central Contact Person. Use the format 800-555-5555 within the United States and Canada. If outside the United States and Canada, provide the full phone number, including the country code.
Ext: phone extension, if needed
Email: * electronic mail address of the central contact person

A red arrow points from the top right of the form area towards the 'Last Name or Official Title' field label.

Issue: Errors appear at the top of the page, instead of near the problem areas, and are sometimes inappropriate.

Response: We are aware of these issues and have been working on solutions.

The goal is to identify errors closer to the relevant fields and to avoid inappropriate errors.

Study Status

Sponsor / Collaborators

Oversight

Study Description

Conditions

Study Design

Arms and Interventions

Outcome Measures

Eligibility

Contacts / Locations

IPD Sharing Statement

References

Month

Day

Year

Type

Anticipated

Actual

Study Completion Date * § i

Final data collection date for the primary outcome measures, secondary outcome measures, and adverse event information.

The Day field is optional for anticipated dates.

Month *

Day *

Year *

Type

Anticipated

Actual

Save Edits

[Cancel](#)

Protocol Registration: Creating a New Record

- “Save Edits” is not an intuitive action button when creating a record for the first time and all the fields are blank.
- “Next,” “Save,” or “Continue” are more intuitive.

User Accounts

- User lists that populate fields like Investigator Name should be alphabetized by last name, not by username or first name.
- Lists should be searchable.

Sponsor / Collaborators
Oversight
Study Description
Conditions
Study Design
Arms and Interventions
Outcome Measures
Eligibility
Contacts / Locations
IPD Sharing Statement
References

Principal Investigator

Sponsor-Investigator

Investigator Information i

Investigator Name i

(Username)

- Select -

- Select -

Annamarie Bailey (abailey6)

Adrienne Bonham (ABonham)

April Buttaccio (AButtaccio)

Alison Carletta (ACarletta)

Ann Colasurdo (acolasurdo)

Ann Falsey (afalsey)

Autumn Gallegos (AGALLEG2)

Andrew Goodman (AGoodman)

Aram Hezel (ahezel)

Audrey Impellizzeri (Almpellizzeri)

Ashokkumar Jain (AJain)

Alan Katz (akatz)

Amy-Lee Bredlau (albredlau)

Ann Leonhardt (aleonhardt)

Allison W McIntyre (amcintyre)

Addisu Mesfin (amesfin)

Arthur J. Moss (AMoss)

Ann Muhs (AMuhs)

Avice O'Connell (aoconnell)

University of Rochester

Additional Suggestions

Request: Change the name of the **Save Edits** button to something more intuitive when entering information for the first time.

Response: This makes sense, and we think “Save” might work for both first-time entries and revisions.

Request: Alphabetize user lists by last name, and make them searchable.

Response: We will explore making lists of names searchable. Alphabetization by last name is trickier because full names are entered in a single field when accounts are created.



The screenshot shows a 'User Information' form with the following fields:

- Group: [none] v
- Access Level: Administrator v
- Username: AdminStacey
- * Responsible Party Contact Information: Enter all information for investigators designated as Responsible Party per FDAAA 801. Contact information will not be made public -- for administrative purposes only.
- Name of Individual: Administrator Stacey (highlighted with a red box)

Example: John J Smith, MD

Question 1 (Record Summary)—Context

[Home](#) [Help](#)

Record Status

In Progress → Entry Completed → Approved →

Next Step: Finish Results section **Entry Complete**

Record Owner: AdminMichael

Last Update: 04/04/2023 16:55 by AdminStacey

Initial Release: [Not yet released]

[Spelling](#) [Preview](#) **Draft Receipt (PDF RTF)** [Download](#)

DownloadReceipt 1 / 4 95%

ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov PRS DRAFT Receipt (Working Version)
Last Update: 03/10/2022 14:02

ClinicalTrials.gov ID: [Not yet assigned]

Study Identification

Unique Protocol ID: TTTParallel
Brief Title: Parallel Study Design Example
NOTE : A title this short may not be sufficiently descriptive.
Official Title: A 24-Week Double-Blind Trial of Remuverol in Adults With Disc Herniation
Secondary IDs:

Study Status

Record Verification: March 2022
Overall Status: Completed
Study Start: March 1, 2017 [Actual]
Primary Completion: June 1, 2018 [Actual]
Study Completion: August 1, 2018 [Actual]

Question 1 (Record Summary)

Do you use the Draft Receipt option on the Record Summary page to download the PDF or RTF file?

- A. Yes, I use both the PDF and RTF file formats.
- B. Yes, I use only the PDF file format.
- C. Yes, I use only the RTF file format.
- D. No, I don't use this option.




Question 2 (Contacts and Locations)—Context 1

[Protocol Section](#) [Help](#) [Definitions](#)

[Edit](#) **Overall Contacts**

Central Contact Person:
Central Contact Backup:
Overall Study Officials:

 NOTE: Study Official is required by the WHO and ICMJE.

[Copy locations...](#) from a master list, extracted from this organization's records.
[Set multiple Locations' Site Recruitment Status...](#)

United States, Maryland

[Edit](#) **Location**

NIH
Bethesda, Maryland, United States, 20892

Canada, Quebec

[Edit](#) **Location**

McGill University
Montreal, Quebec, Canada

Mexico

[Edit](#) **Location**

University of Quintana Roo
Cozumel, Mexico

Question 2 (Contacts and Locations)—Context 2

Copy Locations

Check the Locations to copy into the current study from the following list using checkboxes on left and then click on Copy (at the bottom of the list).

	Facility/Location	Central Contact Person	Investigator(s)
<input type="checkbox"/>	Montreal, Quebec Canada		Showers, April
<input type="checkbox"/>	Brigham and Women's Hospital at Harvard Medical School Boston, MA United States		Bowe, Rain
<input type="checkbox"/>	Charleston University College of Arts and Sciences Charleston, South Carolina United States		
<input type="checkbox"/>	Children's Hospital Montefiore Bronx, NY United States		Bowe, Rain
<input type="checkbox"/>	City Hospital Montreal, Quebec Canada		Showers, April

Question 2 (Contacts and Locations)—Context 3

Site Recruiting Status

Update Site Recruitment Status for multiple Locations.

Tip: It is only necessary to maintain Site Recruitment Status when Overall Recruitment Status for the study is Recruiting.

1. Select the desired Recruitment Status.

* Recruitment Status:

2. Check the Locations for which Site Recruitment Status is to be changed.

	Facility	Location	Current Status
<input type="checkbox"/>	NIH	Bethesda, Maryland, United States, 20892	
<input type="checkbox"/>	McGill University	Montreal, Quebec, Canada	
<input type="checkbox"/>	University of Quintana Roo	Cozumel, Mexico	

CAUTION: This operation can only be undone by restoring Site Recruitment Status for each Location individually.

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Question 2 (Contacts and Locations)

Which of these features do you use?

- A. Both the Copy locations and Set multiple Locations' Site Recruitment Status features
- B. Only the Copy locations feature
- C. Only the Set multiple Locations' Site Recruitment Status feature
- D. Neither of these features

[Protocol Section](#) [Help](#) [Definitions](#)

[Edit](#) **Overall Contacts**

Central Contact Person:
Central Contact Backup:
Overall Study Officials:

NOTE: Study Official is required by the WHO and ICMJE.

[Copy locations...](#) from a master list, extracted from this organization's records.
[Set multiple Locations' Site Recruitment Status...](#)

United States, Maryland

[Edit](#) **Location**

NIH
Bethesda, Maryland, United States, 20892

Canada, Quebec

[Edit](#) **Location**

McGill University
Montreal, Quebec, Canada

Mexico

[Edit](#) **Location**

University of Quintana Roo
Cozumel, Mexico

[+ Add Location](#) [Sort Locations...](#)

Open Q&A

Please direct your questions in the chat to “Everyone in Meeting.”