

# ClinicalTrials.gov: Updates and Modernization

NIH Collaboratory Virtual Steering Committee Meeting April 23, 2020

Stacey Arnold, PhD

Results Team Project Specialist, ClinicalTrials.gov [Contractor, ICF]



U.S. National Library of Medicine  
National Center for Biotechnology Information

# Agenda

- ClinicalTrials.gov Basics
- Recent Updates to ClinicalTrials.gov
- Modernization Effort
- Collaboration with OBSSR to Develop Protocols and Support Materials





# ClinicalTrials.gov Basics

## Benefits of Comprehensive Registration and Results Reporting

*All contribute to  
increased public  
trust in clinical  
research*

- Honor commitment to participants that their contributions will advance science; support enrollment
- Mitigate publication bias
- Advance stewardship and accountability
  - Identify unmet research needs
  - Facilitate complete reporting
  - Avoid unnecessary study duplication
  - Evaluate research integrity
- Support evidence-based medicine

# Basics of Registration Information Submission

- Interactive data entry or automated upload
- Anyone can enter data, but “responsible party” must submit
- Content reflects:
  - Legal requirements
  - International standards
  - Good reporting practices
- NIH grant application aligns with subset of content

## *ClinicalTrials.gov PRS* *Protocol Registration and Results System*

[Help](#) [Definitions](#)

\* Organization's Unique Protocol ID:

\* Brief Title:

[Special Characters](#)

[\*] Acronym:   
(if any)  
If specified, will be included at end of Brief Title in parentheses.

\* Study Type:

- Interventional** (or clinical trial) — participants assigned to intervention(s) based on a protocol
- Observational** participants not assigned to intervention(s) based on a protocol; typically in context of routine care
- Expanded Access** availability of an experimental drug or device outside of a clinical trial protocol

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

# Basics of Results Information Submission

- Structure supports:
  - Complete reporting
  - Efficient quality review
  - Consistent data display
  - Detailed search and integration of other NLM resources
- Aligns with good reporting practices (CONSORT)

## ClinicalTrials.gov PRS Protocol Registration and Results System

### Edit Baseline Measure

[Help](#) [Definitions](#)

\* Study-Specific Baseline Measure Title:

Baseline Measure Description:

	Remuverol	Placebo	Total
Overall Number of Baseline Participants:	101	99	200
Baseline Analysis Population Description:			

\* Measure Type:

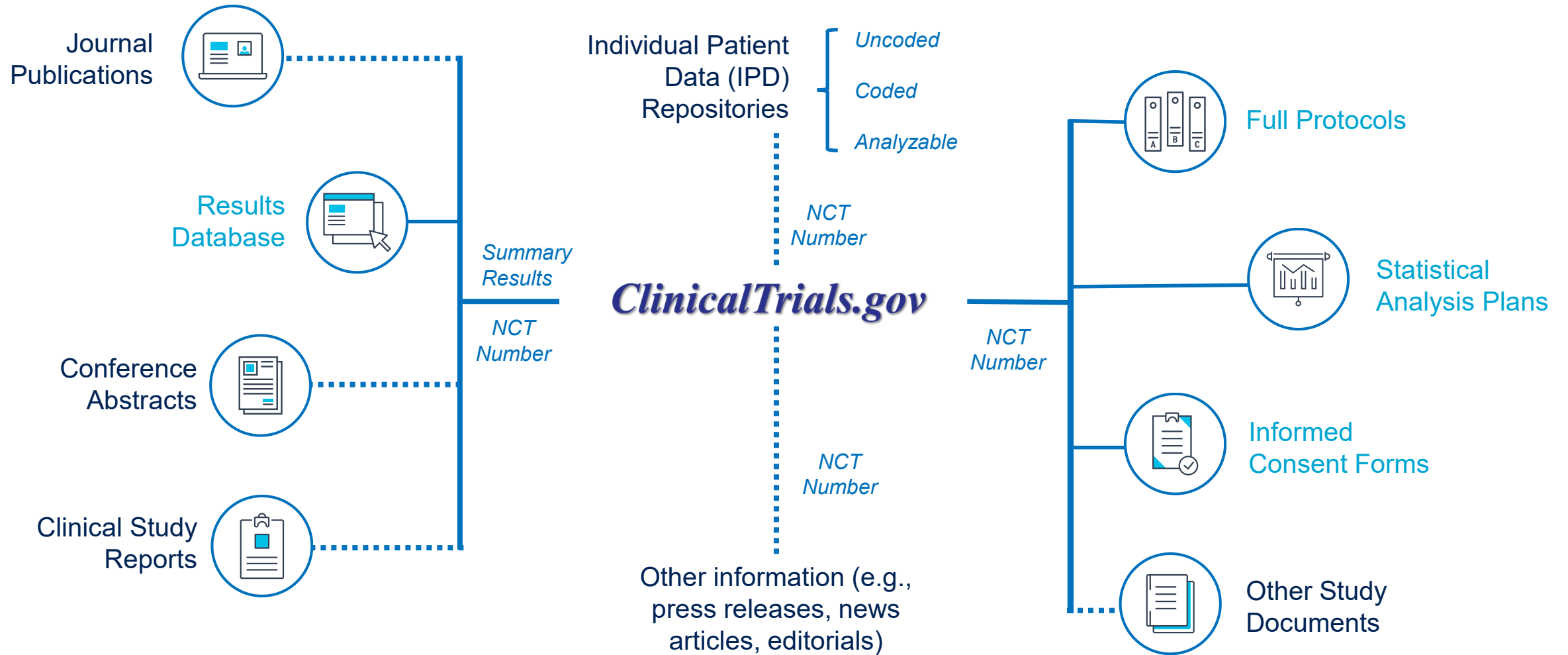
\* Measure of Dispersion:

	101 participants <input type="text" value="Edit"/>	99 participants <input type="text" value="Edit"/>	200
Number Analyzed: Participants			
Mean	<input type="text" value="77.03"/>	<input type="text" value="78.53"/>	<input type="text" value="77.77"/>
Standard Deviation	<input type="text" value="14.38"/>	<input type="text" value="13.56"/>	<input type="text" value="14.00"/>

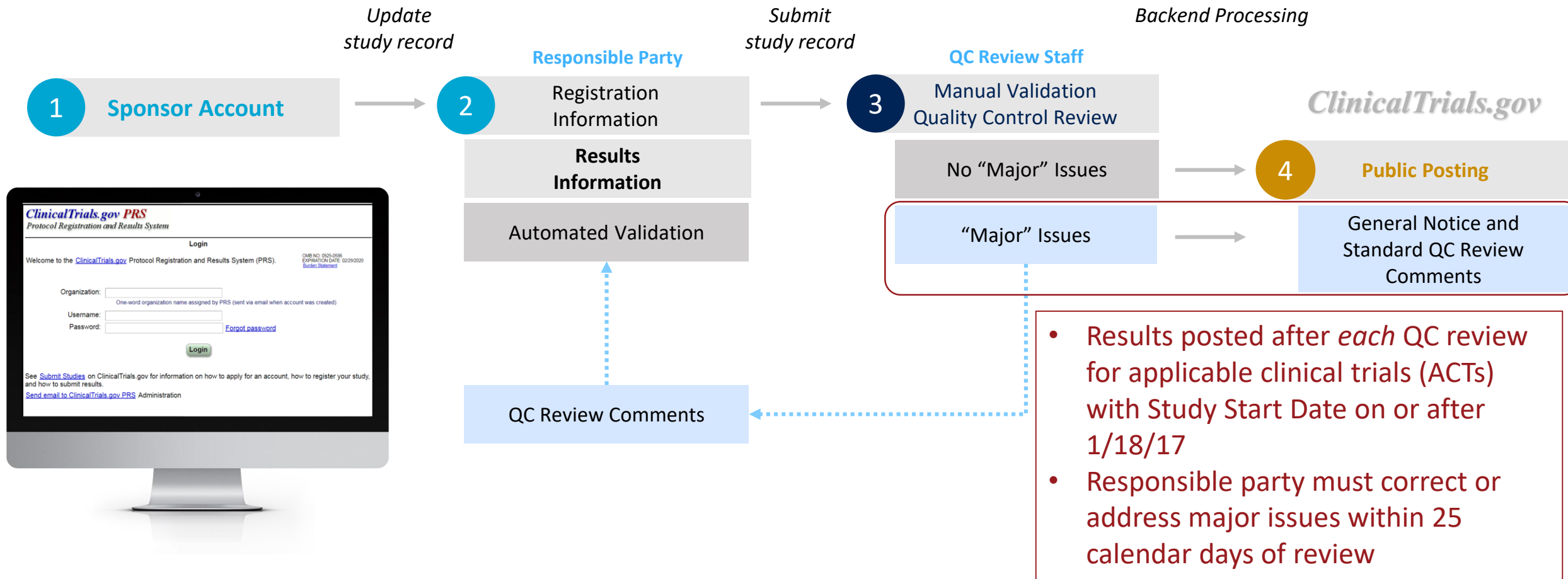
\* Unit of Measure:

Commonly reported units:

# ClinicalTrials.gov: Information Scaffold



# Results Posted Within 30 Days







# Recent Updates to ClinicalTrials.gov

# ClinicalTrials.gov Home Page Update: COVID-19

## 1. New links added:

- CDC – latest public health information
- NIH – latest research information

## 2. Targeted ClinicalTrials.gov search results – studies related to COVID-19

1

COVID-19 is an emerging, rapidly evolving situation.  
Get the latest public health information from CDC: <https://www.coronavirus.gov>.  
Get the latest research information from NIH: <https://www.nih.gov/coronavirus>.

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

2

Explore 336,139 research studies in all 50 states and in 210 countries.

See [listed clinical studies](#) related to the coronavirus disease (COVID-19)

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

**IMPORTANT:** Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).

### Find a study (all fields optional)

**Status** ⓘ

Recruiting and not yet recruiting studies

All studies

**Condition or disease** ⓘ (For example: breast cancer)

X

**Other terms** ⓘ (For example: NCT number, drug name, investigator name)

X

**Country** ⓘ

United States ▾ X

**State** ⓘ **City** ⓘ **Distance** ⓘ

▾ X  X  ▾

[Search](#) [Advanced Search](#)

# Targeted Search Results: COVID-19

- Search results include those for related identifiers (e.g., SARS-CoV-2, 2019-nCoV)

COVID-19 is an emerging, rapidly evolving situation.  
Get the latest public health information from CDC: <https://www.coronavirus.gov>.  
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NIH U.S. National Library of Medicine  
**ClinicalTrials.gov** Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About Site ▾

Home > Search Results

Modify Search Start Over

585 Studies found for: COVID-19  
Also searched for SARS-CoV-2 and 2019-nCoV. [See Search Details](#)

Your search included: COVID-19  
Learn more about clinical studies related to COVID-19:

- **ClinicalTrials.gov:** [Federally-funded clinical studies related to COVID-19](#)
- **WHO Trial Registry Network:** [COVID-19 studies from the ICTRP database](#)
- **CDC:** [Information for Clinicians on Therapeutic Options for COVID-19 Patients](#)

List By Topic On Map Search Details

Hide Filters Download Subscribe to RSS

Showing: 1-100 of 585 studies 100 studies per page Show/Hide Columns

Filters

Apply Clear

Status

Recruitment ⓘ :

Not yet recruiting

Row	Saved	Status	Study Title	Conditions	Interventions	Phase	Sponsor/Collaborators	Study Design
1	<input type="checkbox"/>	Recruiting NEW	<a href="#">Application of Desferal to Treat COVID-19</a>	• COVID-19	• Drug: Deferoxamine	Phase 1 Phase 2	• Kermanshah University of Medical Sciences	• Allocation: Randomized • Intervention Model: Parallel Assignment

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List By Topic On Map Search Details

Hide Filters

Filters

Apply Clear

Status

Recruitment ⓘ :

Not yet recruiting

Showing: 1-100 of 585 studies

Row	Saved	Status	
1	<input type="checkbox"/>	Recruiting	<a href="#">Apply to Treatment</a>

Terms and Synonyms Searched:

Terms	Search Results*	Entire Database**
Synonyms		
<b>COVID-19</b>	585 studies	585 studies
SARS-CoV-2	187 studies	187 studies
2019-nCoV	32 studies	32 studies
2019 novel coronavirus	18 studies	18 studies
severe acute respiratory syndrome coronavirus 2	11 studies	11 studies

-- No studies found

\* Number of studies in the search results containing the term or synonym

\*\* Number of studies in the entire database containing the term or synonym

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Study Design  
Location:  
Randomized  
Intervention  
Model:  
Parallel  
Assignment

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# Targeted Search Results: COVID-19

- Search results include those for related identifiers (e.g., SARS-CoV-2, 2019-nCoV)
- Links to additional resources:
  - ClinicalTrials.gov – subset of federally-funded studies
  - WHO Trial Registry Network
  - CDC – information for clinicians

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Home > Search Results

[Modify Search](#) [Start Over](#) +

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List By Topic On Map Search Details

Hide Filters Download Subscribe to RSS Show/Hide Columns

Showing: 1-100 of 585 studies 100 studies per page

Row	Saved	Status	Study Title	Conditions	Interventions	Phase	Sponsor/Collaborators	Study Design
1	<input type="checkbox"/>	Recruiting NEW	<a href="#">Application of Desferal to Treat COVID-19</a>	• COVID-19	• Drug: Deferoxamine	Phase 1 Phase 2	• Kermanshah University of Medical Sciences	• Allocation: Randomized • Intervention Model: Parallel Assignment

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Home > Search Results

[Modify Search](#) [Start Over](#)

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**ClinicalTrials.gov**  
 Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About Site ▾

Home > WHO COVID-19 Studies

**COVID-19 Studies from the World Health Organization Database**

The following are ongoing and completed COVID-19 studies listed on the World Health Organization's International Clinical Trials Registry Platform (WHO ICTRP). Information in the WHO ICTRP comes from clinical trial databases maintained by other countries or regions of the world. COVID-19 studies listed on ClinicalTrials.gov are not included in the list below, but can be found using our [search for COVID-19](#).

To give researchers and the public rapid access to studies on COVID-19 in other countries, ClinicalTrials.gov will update this list weekly. You can also access the information directly from the [WHO ICTRP](#).

Showing: 1-10 of 590 studies  studies per page Find in Table:  Show/Hide Columns

TrialID	Public title	Date registration	Source Register	web address	Recruitment Status
ACTRN12620000421932	ExtraCorporeal Membrane Oxygenation for 2019 novel Coronavirus Acute Respiratory Disease (COVID-19)	3/30/20	ANZCTR	<a href="https://anzctr.org.au/ACTRN12620000421932.aspx">https://anzctr.org.au/ACTRN12620000421932.aspx</a>	Recruiting
ACTRN12620000417987	Chloroquine Chemorophylaxis Countermeasure against COVID-19	3/30/20	ANZCTR	<a href="https://anzctr.org.au/ACTRN12620000417987.aspx">https://anzctr.org.au/ACTRN12620000417987.aspx</a>	Not Recruiting
ChiCTR2000031376	A medical records based study for safety and effectiveness analysis of data from novel coronavirus pneumonia (COVID-19) patients with conventional therapy	3/29/20	ChiCTR	<a href="http://www.chictr.org.cn/showproj.aspx?proj=51724">http://www.chictr.org.cn/showproj.aspx?proj=51724</a>	Recruiting

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Phase	Sponsor/Collaborators	Study Design
Phase 1	• Kermanshah University of Medical Sciences	• Allocation: Randomized • Intervention Model: Parallel Assignment
Phase 2		

# Answers to Top Questions: COVID-19

- Links to responses available on What's New and Support Materials pages
- Updated as needed

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Get the latest research information from NIH: <https://www.nih.gov/coronavirus>.

 U.S. National Library of Medicine  
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## What's New

2020

April 2, 2020

- **Answers to Questions from Responsible Parties on Submitting Information to ClinicalTrials.gov Related to Coronavirus (COVID-19) Available:** Questions about submitting information to the ClinicalTrials.gov Protocol Registration and Results System (PRS) have been addressed in [Responses to Top Questions from Responsible Parties Related to Coronavirus \(COVID-19\)](#) (PDF). COVID-19 is an emerging, rapidly evolving situation. These responses will be updated as needed. Document is available on the [Support Materials](#) page.
- **Train-the-Trainer Workshop Postponed:** The [Results Database Train-the-Trainer Workshop](#) scheduled for May 18-19, 2020 is canceled and will be rescheduled at a later date. Updates will be provided when they are available.
- **PRS Guided Tutorials Registration Content Available:** The [PRS Guided Tutorials](#) now include registration content providing step-by-step instructions for submitting registration and results information in the ClinicalTrials.gov Protocol Registration and Results System (PRS).
- **ClinicalTrials.gov Modernization Public Meeting:** The public meeting scheduled for April 30, 2020 will be entirely virtual. For more details and to register, visit the public meeting [website](#).



# Answers to Top Questions: COVID-19

- Links to responses available on What's New and Support Materials pages
- Will be updated as needed

COVID-19 is a  
Get the latest public health  
Get the latest research inf

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**ClinicalTrials.gov**

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### What's New

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## What's New

2020

April 2, 2020

- **Answers to Questions from Responsible Parties Available:** Questions about submitting information are addressed in [Responses to Top Questions from Responsible Parties](#) for this evolving situation. These responses will be updated as needed.
- **Train-the-Trainer Workshop Postponed:** The workshop will be rescheduled at a later date. Updates will be posted as soon as a date is confirmed.
- **PRS Guided Tutorials Registration Content:** Updated instructions for submitting registration and results information are available on the [PRS Guided Tutorials](#) page.
- **ClinicalTrials.gov Modernization Public Meeting:** To register, visit the public meeting [website](#).

**ClinicalTrials.gov**

*ClinicalTrials.gov is a service of the  
National Institutes of Health.*

### Responses to Top Questions from Responsible Parties Related to Coronavirus (COVID-19)

NOTE: COVID-19 is an emerging, rapidly evolving situation. These responses will be updated as needed.

NIH recognizes that the COVID-19 public health emergency may impact ongoing research and the availability of organizations and staff for research-related activities, including submission of clinical trial information to ClinicalTrials.gov. These responses aim to address situations that Responsible Parties may face with managing clinical trial information in the ClinicalTrials.gov Protocol Registration and Results System (PRS).

Responsible Parties have asked about updating and correcting clinical trial information during this evolving situation. We reinforce the importance of making accurate and up-to-date clinical trial information available to the public on ClinicalTrials.gov, particularly for COVID-19 related research. However, due to the potential exceptional impact of this public health emergency on research-related staff availability, NIH acknowledges that delayed updates and corrections may be unavoidable. We expect clinical trial information to be updated or corrected as soon as any organization or staff-related delays are resolved and recommend that sponsors and investigators retain documentation that would allow for determination of the appropriateness of the delay.

#### 1) How do Responsible Parties update the overall recruitment status of their study records and/or recruitment status of individual sites that close temporarily due to COVID-19?

Responsible Parties should update the [Overall Recruitment Status](#) or [Individual Site Status in their study records](#). For more information, see the FAQ, [When must I update clinical trial registration information?](#)

To help ensure that accurate up-to-date clinical trial information is available, it is important to make any necessary changes to recruitment status on the Study Status page of the Protocol Section in the PRS. Refer to [the list of recruitment status options and their definitions](#) to determine the best answer based on the specific situation for your study. When the Overall Recruitment Status is a status other than Recruiting, the Individual Site Status data element no longer needs to be updated because the Overall Recruitment Status applies to each individual site. Note: If you select Suspended, Terminated, or Withdrawn as Overall Recruitment Status, you must provide a brief explanation for the reason why this study was stopped as part of the [Why Study Stopped](#) data element.

You may also provide additional information about the study status in the [Detailed Description](#) data element. When doing so, please include the date on which you added the information.

#### 2) How does the Sponsor update a study record when a principal investigator designated as the Responsible Party is not available?

If the Principal Investigator designated by the Sponsor as the Responsible Party for the study is not able to update the record, then the Sponsor can change the [Responsible Party](#). Select Sponsor in the Responsible Party data element on the Edit Sponsor/Collaborators page of the Protocol section. The PRS Administrator for your organization can then approve and release the record to ClinicalTrials.gov.

Coronavirus (COVID-19): Top Questions

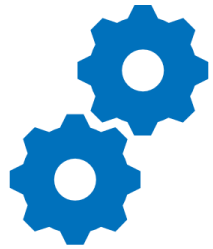
02 April 2020



# PRS Guided Tutorials

The screenshot shows the 'Introduction' page of the PRS Guided Tutorials. The header includes the ClinicalTrials.gov PRS logo and the title 'Introduction'. A left-hand navigation menu lists various tutorial topics, including 'REGISTRATION TUTORIALS', 'UPLOADING STUDY DOCUMENTS', and 'RESULTS TUTORIALS'. The main content area contains three paragraphs of introductory text. The first paragraph explains the purpose of the tutorials. The second paragraph describes the navigation menu. The third paragraph details the focus of the tutorials and the order of modules. At the bottom, there is a call to action: 'Select Registration to continue to the Registration tutorials.' with a blue 'REGISTRATION' button.

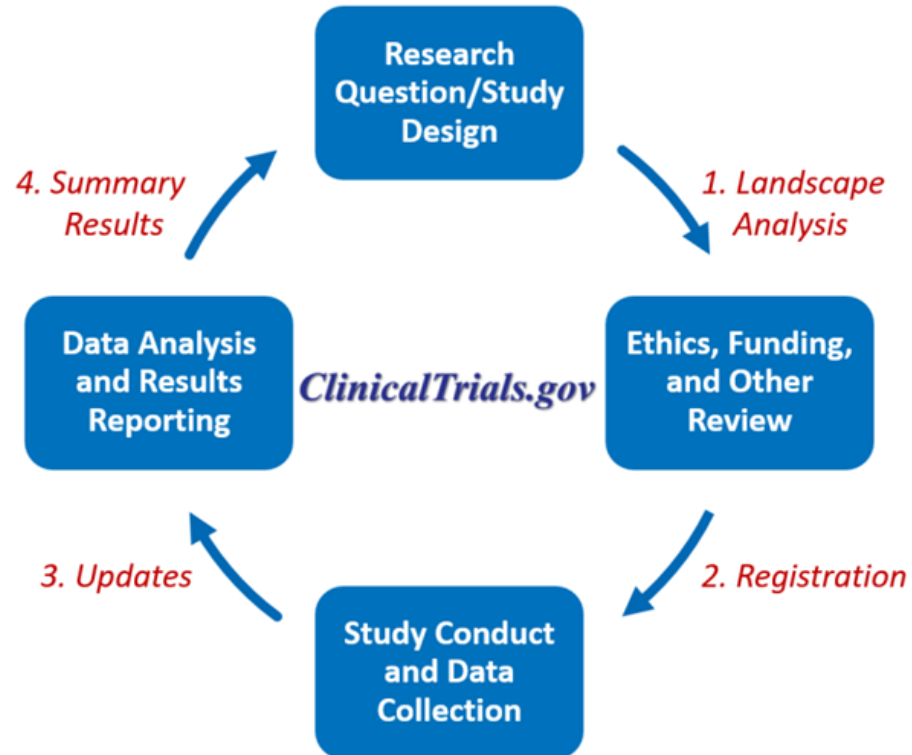
- Results tutorials launched in Beta in August 2019
- **Registration tutorials launched March 2020; tutorials taken out of Beta**
- Tutorials can be accessed on ClinicalTrials.gov or from within the PRS
- Feedback has been collected
  - User testing: further updates are planned
  - Survey (continuing): <https://bit.ly/2N1mMHV>
- Fictional manuscript and example ClinicalTrials.gov record for Units Other Than Participants Study Design now online



# Modernization Effort

# ClinicalTrials.gov Modernization Overview

## Clinical Research Life Cycle |



## Current year: Engagement

- Engage with stakeholders to determine and validate approach and specifications
  - Request for Information (RFI) and Public Meeting
  - NLM Board of Regents Working Group
- Develop modernization roadmap
- Enhance internal business processes

## Future (years 2 – 5):

### Implementation of Roadmap

- Conduct user evaluation and continue engagement
- Make improvements to support compatibility across trial lifecycle (seamless end-to-end process)
- Upgrade system infrastructure components

# Request for Information (RFI)

- Solicited input on key modernization-related topics to guide planning for infrastructural enhancements:
    1. Website functionality
    2. Information submission
    3. Data standards
  - Received over 260 Comments from a 75-day comment period (December 30, 2019 - March 14, 2020)
- NLM's modernization effort aims to deliver an improved user experience on an updated platform to accommodate growth and enhance efficiency
  - Note: RFI was not intended to modify existing legal and policy requirements for clinical trial registration and results submission

# Public Meeting

## Goals of the public meeting

- Share high-level summary of RFI comments and key themes
- Gather diverse stakeholders to collectively share synergistic and competing needs
- Obtain further information on certain themes/topic areas

April 30, 2020, Virtual Meeting  
9:30 am - 12:30 pm



To register, visit: <https://events-support.com/events/ClinicalTrials-gov Modernization Public Meeting>



# Collaboration with OBSSR to Develop Proto-papers and Support Materials



# OBSSR Materials Development

• Fictional manuscripts and example ClinicalTrials.gov records for 4 designs:

1. Cluster Randomized
2. Fractional Factorial
3. SMART
4. Micro-randomized

**Disclaimer:** The following information is fictional and is only intended for the purpose of illustrating key concepts for results data entry in the Protocol Registration and Results System (PRS).

## Cluster Randomized Study Design Example

(A Phase 4, Cluster Randomized Trial Comparing Two Interventions with Standard Practice to Reduce *Poissonosis davrilorum* Infection in Intensive Care Units)

### Methods

#### Study Design

This was a pragmatic, three-group, cluster randomized trial designed to compare strategies for preventing *Poissonosis davrilorum* (PD) infections in adult intensive care units (ICUs) in the Southern Innovative Clinical Health System (SICHS). ICUs were randomly assigned to one of three groups. All ICUs located within a hospital and all adults in those ICUs were assigned to the same group. There was a 12-month baseline period from January 31, 2016, to January 30, 2017. The 12-month intervention period immediately followed, from January 31, 2017, to January 30, 2018.

During the intervention period, each of the three groups used a different intervention strategy. Group 1, standard care, consisted of screening for PD on ICU admission and following transmission-based precaution policies, based on guidance from the Centers for Disease Control and Prevention (CDC). Group 2, targeted decolonization, included PD screening and transmission-based precautions like those in Group 1; in addition, PD-positive patients received a 5-day decolonization regimen of twice-daily intranasal 2% No-Bug (mupirocin) cream and daily bathing with 4% No-Scrub (hydrogen peroxide) sanitizing cloths. In Group 3, enhanced room disinfection, patients were screened for PD and health care staff used transmission-based precautions, as in Groups 1 and 2; in addition, hospital staff disinfected rooms from which PD patients were discharged with a solution containing hypochlorite

(bleach) plus a disinfecting ultraviolet light (UV-C) device. Patient notices about group-specific protocols were posted in each ICU room.

The study protocol was reviewed and approved by the SICHS institutional review board. The requirement for written informed consent was waived; however, participants were required to be at least 18 years old at the time of ICU admission. All hospital record data were de-identified.

#### Eligibility Criteria

The inclusion criteria for participation in the study were: commitment by the hospital's administration to have all its ICUs randomized for the trial; less than 30% of patients in participating adult ICUs currently receiving either intranasal 2% No-Bug cream or 4% No-Scrub sanitizing cloths at baseline; and stable use of infection-prevention initiatives and products during the baseline period. The exclusion criterion was adoption of new infection-control initiatives that would conflict with the study protocol.

#### Data Sources

We obtained hospital-specific, individual patient data for ICUs from the SICHS data system for both the baseline and intervention periods. Participants with repeat visits to a hospital over the course of the study contributed data for only their first ICU visit; consequently, there were unique, nonoverlapping patients included in the analyses for these hospital ICUs during the baseline and intervention periods. We randomized the ICUs so that the three intervention groups included a similar

## Cluster Randomized Study Design Example (With Results)

**Disclaimer:** The following information is fictional and is only intended for the purpose of illustrating key concepts for results data entry in the Protocol Registration and Results System (PRS).

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT00055633

Recruitment Status: Completed  
First Posted: January 31, 2016  
Results First Posted: February 28, 2019  
Last Update Posted: February 28, 2019

### Sponsor:

PRS Results Training

### Information provided by (Responsible Party):

PRS Results Training

### Study Description

#### Brief Summary:

This is a pragmatic, three-group, cluster randomized trial designed to compare strategies for preventing *Poissonosis davrilorum* (PD) infections in adult intensive care units (ICUs). ICUs will be assigned to one of three intervention strategies: standard care, targeted decolonization, or enhanced room disinfection. After a 12-month baseline period, ICUs will implement the assigned strategy for a 12-month intervention period.

Condition or disease	Intervention/treatment	Phase
Poissonosis Davrilorum Infection	Drug: 2% mupirocin cream Drug: 4% hydrogen peroxide sanitizing cloth Diagnostic Test: PD screening Transmission-based precautions Room disinfection	Phase 4

# OBSSR Materials Development

- Fictional manuscripts and example ClinicalTrials.gov records for 4 designs:

- Cluster Randomized
- Fractional Factorial
- SMART
- Micro-randomized

- Supplementary Materials:

- Question and Answer documents
- **Annotated Participant Flow tables**
- Cross-walk of PRS data elements to OBSSR Protocol Template

Arm/Group Titles are brief, information labels; Arm/Group Descriptions specify details about the interventions administered to participants based on the cluster assignment

Type of Units Assigned is used to indicate that Intensive Care Units are the clusters assigned to each arm/group

Two periods document the two stages of the study (baseline, intervention)

Protocol Enrollment: 236931  
Total Started in Participant Flow: 119563

Recruitment Details		Pre-assignment Details						Total (Not public)	
		ICUs were randomized. All the ICUs in a hospital and all adults in those ICUs were assigned to the same group. Participants were counted only once during the study (first ICU visit); participants in the baseline and intervention periods did not overlap. 78 ICUs were randomized; 4 were excluded (met exclusion criterion) before the baseline period.							
Arm/Group Title	Group 1: Standard Care	Group 2: Targeted Decolonization Plus Standard Care	Group 3: Enhanced Room Disinfection Plus Standard Care						
Arm/Group Description	Patients were screened for <i>Poissonosis davilarum</i> (PD) infection on intensive care unit (ICU) admission. Each enrolled ICU took transmission-based precautions, based on guidance from the Centers for Disease Control and Prevention (CDC).	As in Group 1, patients were screened for PD infection on ICU admission and each enrolled ICU took transmission-based precautions, based on guidance from the CDC. In addition, PD-positive patients received a 5-day decolonization regimen of twice daily intranasal 2% No-Bug cream and daily bathing with 4% No-Scrub sanitizing cloths.	As in Groups 1 and 2, patients were screened for PD infection on ICU admission and each enrolled ICU took transmission-based precautions, based on guidance from the CDC. In addition, rooms from which PD patients were discharged were disinfected with solution containing hypochlorite (bleach) plus a disinfecting ultraviolet light (UV-C) device.						
Period Title: <b>Baseline Period: Months 1-12</b>									
Type Units Assigned: Intensive Care Units	Number of participants	Number of units (Intensive Care Units)	Number of participants	Number of units (Intensive Care Units)	Number of participants	Number of units (Intensive Care Units)			
Started	39530	23	41229	22	38804	29			119563 Participants Intensive Care Units
Completed	39530	23	41229	22	38804	29			119563 Participants Intensive Care Units
Not Completed	0	0	0	0	0	0			0 Participants Intensive Care Units
Period Title: <b>Intervention Period: Months 13-24</b>									
Type Units Assigned: Intensive Care Units	Number of participants	Number of units (Intensive Care Units)	Number of participants	Number of units (Intensive Care Units)	Number of participants	Number of units (Intensive Care Units)			
Started	39123 NOTE: The number of participants to start a Period is not equal to the number who completed previous Period.	23	41103 NOTE: The number of participants to start a Period is not equal to the number who completed previous Period.	22	38789 NOTE: The number of participants to start a Period is not equal to the number who completed previous Period.	29			119015 Participants Intensive Care Units
Completed	39123	23	39456	20	38789	29			117368 Participants Intensive Care Units
Not Completed	0	0	1647	2	0	0			1647 Participants Intensive Care Units
Reason Not Completed Withdrawal of ICUs (Not Public)	0		1647		0				1647
		Not Completed =0 Total from all reasons =0	Not Completed =1647 Total from all reasons =1647		Not Completed =0 Total from all reasons =0				

Total Started in Participant Flow only counts participants who started the first period; Protocol Enrollment includes all unique participants who started any period

Pre-Assignment Details clarify how participants were distributed between periods, how clusters were randomized, and how many clusters were excluded before assignment

System Notes have been addressed by information provided in the Pre-Assignment Details field, which clarifies why participant numbers are different between periods.



# OBSSR Materials Development

- Subject matter experts within and outside of OBSSR reviewed the proto-papers and provided invaluable feedback
- Goal is to share materials on the ClinicalTrials.gov website this summer
  - Content will be incorporated into the PRS Guided Tutorials
- Working with OBSSR to promote availability of tutorials via:
  - OBSSR Webinar
  - Clinical & Translational Science Awards Program (CTSA) Presentation

Thank You

**Questions? Submit to the ClinicalTrials.gov  
Information Team, National Library of Medicine**  
[register@clinicaltrials.gov](mailto:register@clinicaltrials.gov)

**ClinicalTrials.gov Modernization Information**  
[https://clinicaltrials.gov/ct2/about-  
site/modernization](https://clinicaltrials.gov/ct2/about-site/modernization)