Clinical and Translational Science Awards Program
Coordination, Communication, & Operations Support

CTSA Program Webinar

June 28, 2023

National Center for Advancing Translational Sciences

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Agenda

TIME	TOPIC	PRESENTERS
2:00 pm ET	Welcome	Lauren Fitzharris, MPH, PMP *CCOS*
2:01– 2:10 pm	NCATS/CTSA Program	Michael Kurilla, MD, PhD *Director, Division of Clinical Innovation*
2:10 – 2:30 pm	CT Compliance Platform	Jesse Reynolds, MS *Yale University*
2:30 – 3:00 pm	CCOS Updates	Stephan Bour PhD *Digital Infuzion* Kerry James, MPH PMP *ICF*
3:00 pm ET	Adjourn	

NCATS

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NCATS/CTSA Program Updates

Michael Kurilla, MD, PhD

Director, Division of Clinical Innovation

NCATS

June 28, 2023

NIH National Center for Advancing Translational Sciences

Appropriations - FY 2023

- **Consolidated Appropriations Act, 2023** (P.L. 117-328)
  - Signed by President – 12/29/22

$ (in millions)	FY 2022	FY 2023	
NCATS	**Enacted**	**Enacted**	**Difference**
Total	**882.3**	**923.3**	**+41.0 (4.6%)**
CTSA	606.6	629.6	+23.0 (3.8%)
Non-CTSA	275.7	293.8	+18.1 (6.6%)

President's budget release March 28, 2023: **ZERO%** increase for NCATS

Steering Committee Pod Discussions

Through June 2023:

- Presentations to several pods by the ENACT and N3C and CCOS groups
- Need for emphasis on ensuring a robust workforce of physician-scientists / clinician scientists
- Suggested Crowd Sourced Topic for the Steering Committee was selected: To share ideas about how to construct EAB/EAC membership and what topics to discuss
- Interest expressed in revisiting consenting processes
- Challenges across NIH regarding AI (ChatGPT, ethics and equality of AI in Translational Science)
- Georgia CTSA Regional Conference, started in 2008; Attendees from Georgia, Florida, Alabama and S. Carolina. Next year: Feb 28-March 1, 2024 – registration open beyond these states

Note about NOT-TR-23-020

NOT-TR-23-020: Notice of Special Interest: Notice of Availability of Administrative Supplements for the NCATS Clinical and Translational Science Award (CTSA) Program (NOT-TR-23-020) National Center for Advancing Translational Sciences

NIH is back to pre-COVID rules

Now that COVID flexibilities have expired (NOT-OD-23-095), NIH is re-enforcing policies regarding administrative supplements:

- Administrative supplements must be within the originally approved scope of work and cannot be considered a change or expansion in scope.
- Administrative supplements should not be used to exceed the parent NOFO budget caps unless there is a clear indication that this is permissible in the NOSI and/or other extenuating circumstances. Furthermore, administrative supplements must comply with all parent grant NOFO requirements. For example – an administrative supplement cannot provide support for budget items that are unallowable on a parent award.

The parent NOFO for administrative supplements (PA-20-272) does not allow for the administrative supplement application plus the parent grant to exceed the parent NOFO budget caps.

NCATS issued the following NOSI (NOT-TR-23-020) to accommodate FY23 requests that meet the requirements for administrative supplement application requests.

Recipients experiencing unforeseen needs should discuss their concerns with their Program Official prior to submitting an administrative supplement application.

The publication of the NOSI is NOT an indication that funds are available.

If you have general questions contact: CTSAFOAQuestions@mail.nih.gov

National Center for Advancing Translational Sciences

NIH Notices

- NOT-TR-23-024: Notice of Early Termination of NOT-TR-21-022, Notice of Special Interest (NOSI): Availability of Emergency Competitive Revisions for the Clinical and Translational Science Award (CTSA) Program to Address COVID-19 Public Health Needs
- NOT-TR-23-023: Notice of Early Termination of NOT-TR-21-017, Notice of Special Interest (NOSI): Administrative Supplements for the Clinical and Translational Science Award (CTSA) Program to Address COVID-19 Public Health Needs

Notice of Change to PAR-21-293 Clinical and Translational Science Award (UM1 Clinical Trial Optional) in Award Information

NOT-TR-22-033 (FY24 Awards)

	Size Eligibility Budget Tiers for FOA Applicants *(FOA receipt dates January 13, 2023, May 12, 2023, September 15, 2023)*	Maximum Direct Cost Budget Requests for UM1
Hub Tier	*5-year average of the most current NIH Direct Cost (DC) Funding of the applicant institution, PLUS 5-year average of the most current NIH Direct Cost (DC) funding of any partner(s)** *(based on FY2017-FY2021 NIH Fund data)*	**UM1**
A	*>$320,000,000*	$6,500,000
C	*$235,000,000 - $320,000,000*	$5,000,000
T	*$145,000,000 - $234,999,999*	$3,600,000
G	*<$145,000,000*	$2,600,000

Institutional NIH Direct Cost (DC) Funding Table FY17-21
FY17-FY21_NIH_DC_Funding-all_Orgs-FINAL.xlsx

NOT-TR-23-022 (FY25 Awards)

	Size Eligibility Budget Tiers for FOA Applicants *(FOA receipt dates January 12, 2024, May 17, 2024, September 13, 2024)*	Maximum Direct Cost Budget Requests for UM1
Hub Tier	*5-year average of the most current NIH Direct Cost (DC) Funding of the applicant institution, PLUS 5-year average of the most current NIH Direct Cost (DC) funding of any partner(s)** *(based on FY2018-FY2022 NIH Fund data)*	**UM1**
A	*>$340,000,000*	$6,500,000
C	*$250,000,000 - $339,999,999*	$5,000,000
T	*$155,000,000 - $249,999,999*	$3,600,000
G	*<$155,000,0000*	$2,600,000

Institutional NIH Direct Cost (DC) Funding Table FY18-22
PENDING RELEASE

N3C Public Health Answers to Speed Tractable Results (PHASTR)

- **NEW questions released!! Application Deadline 7.31.2023!!**
  - Does metformin show a reduction of severe outcomes of COVID-19 or of Long COVID in the N3C Data Enclave?
  - Does molnupiravir show a reduction of severe outcomes of COVID-19 in the N3C Data Enclave?
- https://covid.cd2h.org/phastr
- Purpose
  - NCATS launched N3C PHASTR to address high-impact questions that are not being investigated by the research community. The effort also is funded by the NIH National Institute of General Medical Sciences.
- Goals
  - Provide fast, actionable analysis of high-impact, public health research questions. Engage the community capable of working with N3C “big data” to answer public health-related research questions of interest.
- Support Mechanism
  - The N3C Public Health Answers to Speed Tractable Results, or PHASTR, works through a subcontract mechanism ($50,000). Proposals to address questions will be submitted to NCATS’ primary contractor, Axle Informatics, from the N3C platform. Teams with successful proposals will work through Axle (as a subcontractor) to complete the work.

CTSA Program Research Supplements to Promote Diversity, Re-entry and Re-integration

NEW RECEIPT DATE: SEPTEMBER 15, 2023

- CTSA Program-Specific Guidance for Diversity, Re-entry and Reintegration Research Supplements: https://ncats.nih.gov/ctsa/funding/diversity-reentry-reintegration
  - Please ensure that packages are complete by adhering to this guidance

- Prospective applicants and their mentors are **strongly encouraged to contact their respective NCATS program officer and/or the scientific contact listed below during the initial preparation of a supplement application and prior to its submission** to discuss the goals and objectives of the supplement application.
  - **Scientific Contact:** Andrew Louden, Ph.D. @ andrew.louden@nih.gov
  - **Grants Management Contact:** Leslie Le @ leleslie@mail.nih.gov

NIH
National Center for Advancing Translational Sciences

STrengthening Research Opportunities for NIH Grants (STRONG): Structured Institutional Needs Assessment and Action Plan Development for Resource Limited Institutions (RLIs) (UC2 - Clinical Trial Not Allowed) PAR-23-144**

Purpose: The STRONG-RLI program is to support research capacity needs assessments by eligible Resource Limited Institutions (RLIs). The program will also support the grantee institutions to use the results of the assessments to develop action plans for how to meet the identified needs.

Goal: To support research active RLIs to conduct rigorous research capacity needs assessments and create action plans based on the results.

- Conducting objective needs assessments creating/using/adapting/existing instruments for research capacity at RLIs
- Developing action plans, including metrics and methods for assessing progress

Budget: $250,000 direct costs/year for a maximum of 3 years
Due Date: September 18, 2023

Technical Assistance Webinar: For prospective applicants on July 21st from 2-3.30pm EST. Webinar Link

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Questions: Erica.Rosemond@nih.gov (**Part of the trans-NIH UNITE initiative managed by NIMHD)

NIH National Institutes of Health
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NCATS 2024 Strategic Plan

Current NCATS Strategic Plan (Fall 2016): https://ncats.nih.gov/strategicplan

If you have feedback for the NCATS 2024 strategic plan, please send comments to:

NCATS2024StrategicPlan@nih.gov

Upcoming Dates to Remember

Next CTSA Program Webinar

July 26, 2023; 2-3 PM ET. Register here.

NEW REGISTRATION FROM CCOS!!

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National Center for Advancing Translational Sciences

The ClinicalTrials.gov Dashboard

Jesse S Reynolds, MS

The Yale Center for Analytical Sciences (YCAS)

June 28, 2023

Yale SCHOOL OF MEDICINE

Goals and Expectations

Goals

1. To provide the inspiration and background for the development of the ClinicalTrials.gov Dashboard
2. Discuss the development process of the tool
3. Give an overview of the tool and its features
4. Provide examples of how (and when) the tool is used in practice

Expectations

1. Attendees will:
    a. Have an understanding of how and why the ClinicalTrials.gov Dashboard was created
    b. Have an understanding of how and when the ClinicalTrials.gov Dashboard can be used

Acknowledgements

The Yale ClinicalTrials.gov Team

- Kaitlin Maciejewski, MS
  - Biostatistician, YCAS
  - *R* programmer
- Christina Barone, MS
  - Research Assistant, YCAS
  - PRS registration expert
- Lisa Calvocoressi, PhD
  - Research Scientist, YCAS
  - PRS results expert
- Sarah Andrychowski, MSHS
  - Project Manager, CTRP-CT.GOV
  - Yale Cancer Center Liaison
- Paula Maher-Rivera
  - Project Coordinator, YCAS
  - PRS accounts and communication
- Yasemin Kavak, MPH
  - Data Manager, YCAS
  - **Former team member*

Clinical Trials Registration and Results Reporting Taskforce

Work supported by Yale Clinical and Translational Science Award CTSA UL1TR001863

Inspiration and Background

Inspiration and Background

The Yale ClinicalTrials.gov Team was established in 2012

- 2 full time biostatisticians were hired by the Yale Center for Clinical Information (YCCI) to address results reporting needs at Yale University
- Clinical Translational Science Award (CTSA) funds were used
- The roles of the team members were expanded to address the ClinicalTrials.gov system across all required actions…
    - Accounts
    - Error Notifications
    - Review and Release of Submitted Records
    - Protocol Registration

Inspiration and Background

ClinicalTrials.gov PRS
Protocol Registration and Results System

The Ctgov PRS provides information (downloads), but it can be overwhelming…

- How do I determine the activity in my institution's PRS?
- How do I plan for and communicate with study teams about future required actions?

Inspiration and Background

ClinicalTrials.gov PRS
Protocol Registration and Results System

Other tasks, lead to more questions…

- Where can I get all the information needed to do administrative tasks?
  - Mail merges?
- How can I determine how many NIH studies are in the system?
  - When will results be due?

The Development of the Dashboard

The Development of the Dashboard

Ideas for a *PRS Tool* have been accumulating for since 2012…

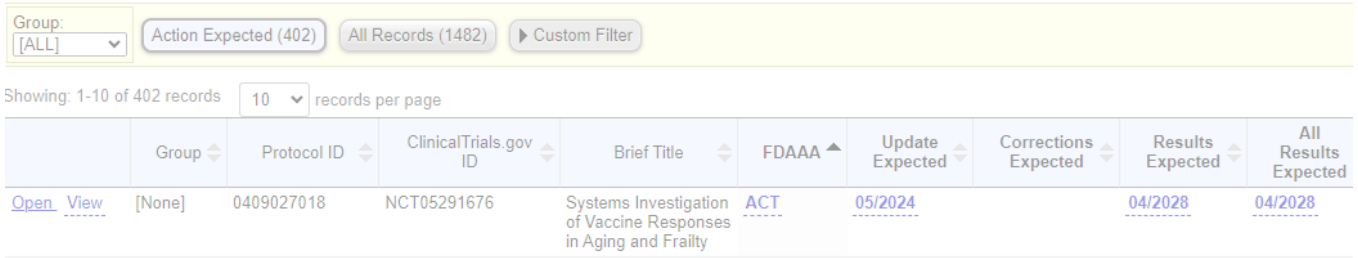
- Pursuits of a proprietary tool (cost) were not fruitful…
- In-house development of a tool were not possible with earlier versions of PRS reports…

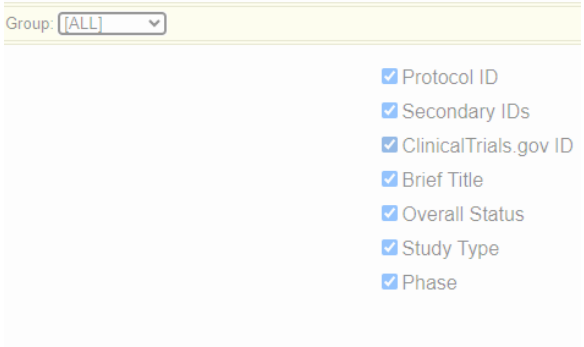
https://dribbble.com/shots/6994266-Data-Visualization-Dashboard

The Development of the Dashboard

Changes in the available PRS reports provided additional <u>needed</u> information…

- PRS Planning Report
  - Due dates in the future
- PRS Record Information Download
  - Information regarding study contacts
  - NIH funding field
  - Due dates in the future for updates, results (primary and all)
- PRS Review History Download
  - Information regarding updates to records
    - New registrations
    - Updated records
    - New results records





The Development of the Dashboard

The improved reporting in the PRS provided information but…

- Using multiple spreadsheets is ineffective
  - Updates to records happen in real time
    - Not always reflected in downloads
  - Changes to study information can lead to duplicative work
    - Contacting study teams after required updates have been made
- Excel (.csv, .xslx) files do not provide summary statistics
  - Difficult to quantify ‘work’
  - Filtering can lead to errors
    - Can be problematic for tracking results due dates

The Development of the Dashboard

So what were the *questions* that we needed answered but the system did not readily provide…?

- **How many studies were submitted for registration in a given time period?**
  - What kinds of studies?
    - NIH funded and/or ACT?
  - How many submissions did it take to get a protocol registered?
- **How many study records were updated, verified, and/or reviewed by the Yale PRS administrators?**
- **How many studies were results submitted for in a given time period?**
  - How many ACT?
  - How many NIH funded?
  - Were the results submitted on time?

The Development of the Dashboard

A *true* collaboration…

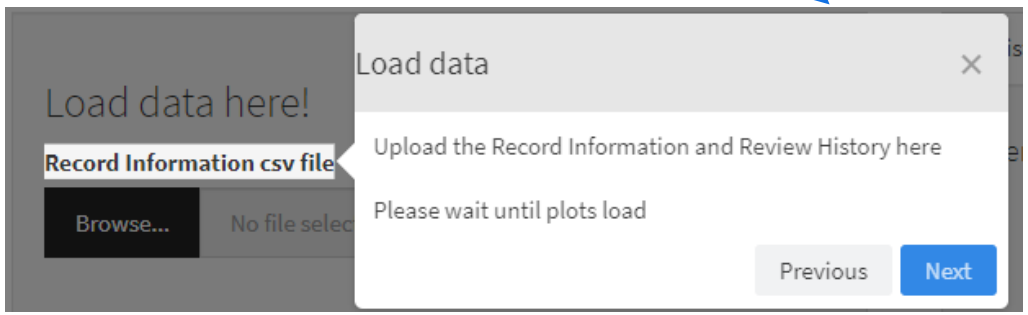
- YCAS biostatisticians and data managers were consulted
  - Yale Medical Informatics experts were consulted
- Discussions with members of the Taskforce regarding tools available at other institutions
- R software was chosen because it is *Open Source*
  - R Shiny can require a paid account for use
    - Provides the infrastructure for the interface and data visualizations
- The finished product designed for lay users
  - Instructions and a virtual tour available as part of the Dashboard
- The Yale CTgov Team provided iterative feedback and continuously uses the tool over to provide real time feedback on changes and updates

Tool Overview and Features

Tool Overview and Features

- A “how to use” landing page…
- An “application tour” button to press once the dashboard has started…

- A step-by-step, *guided* tour…



Clinical Trials Reporting Dashboard

An interactive dashboard for investigating site reporting

How to use:

To use this dashboard first **download** the Record Information Download and Review History Download csv files from ClinicalTrials.gov PRS.

Under the "Records" dropdown tab select the following:

Record Information Download
ensure all fields are selected, and group selected is *[All]*

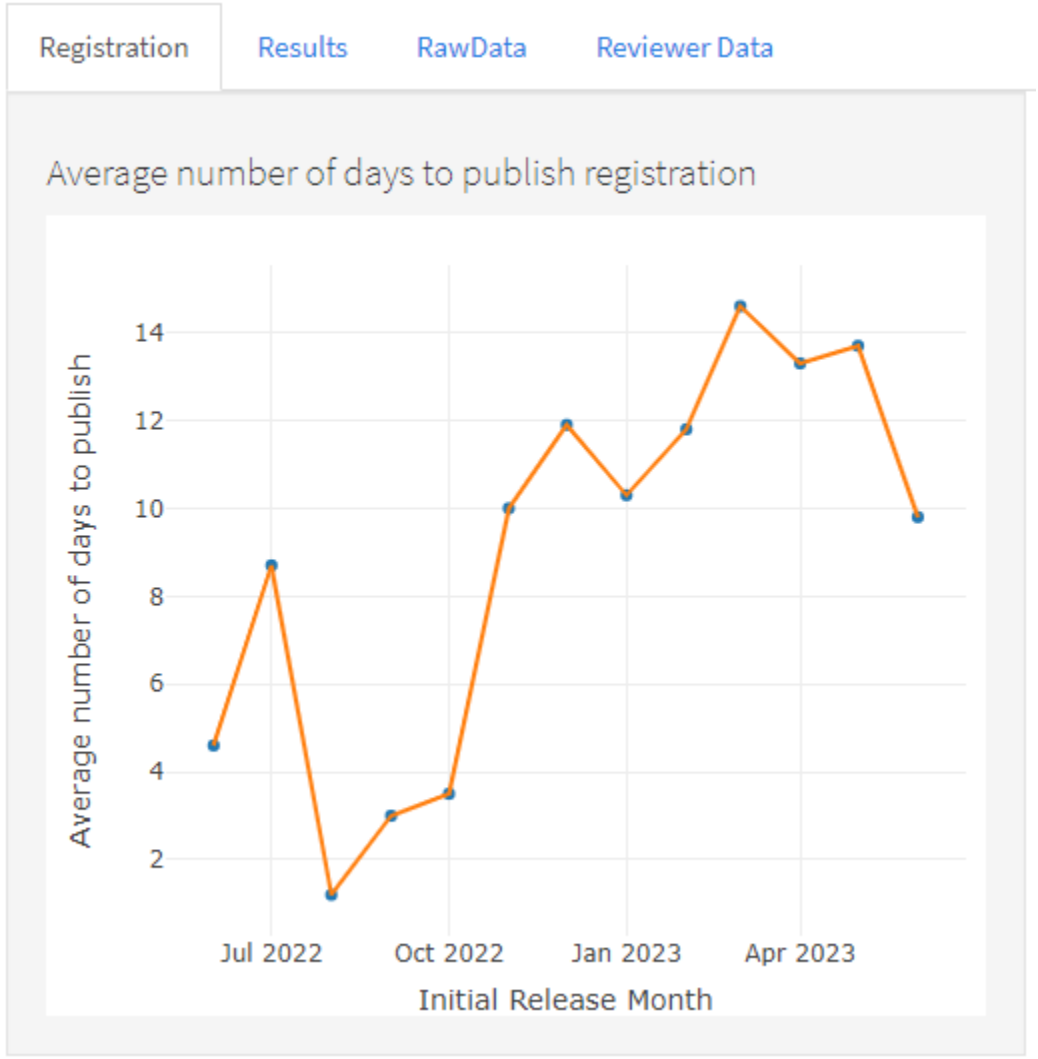
Review History Download
ensure group selected is *[All]*

Next, **upload** the Record Information and Review History csv files; this is on the top left sidebar

Important: after uploading, wait until the top loading bar dissapears and you see plots before interacting with dashboard functions

Click the **"Application Tour"** button at the top right to read more about the dashboard functions

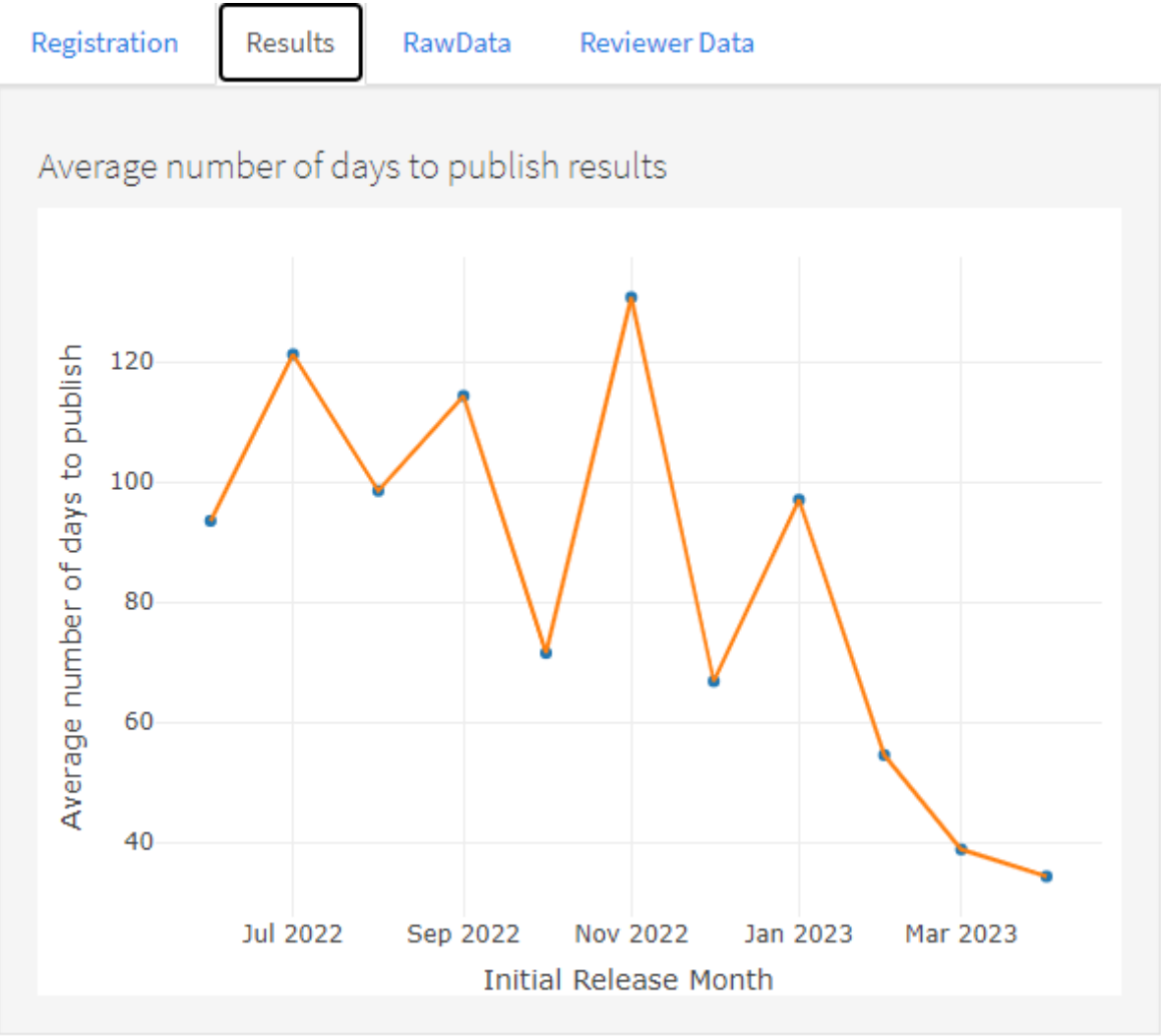
Tool Overview and Features



Registration

- Visualizations for:
  - Average Days to Publish
  - Average Number of Tries to Publish
  - Percent Success on First Try (<= 2)
  - Average Response by Ctgov Reviewers
- Filters Include:
  - Study Type (e.g. Interventional)
  - Study Phase
  - FDAAA Status
  - NIH Status
- Can be customized by: date range and aggregation (e.g. month)

Tool Overview and Features



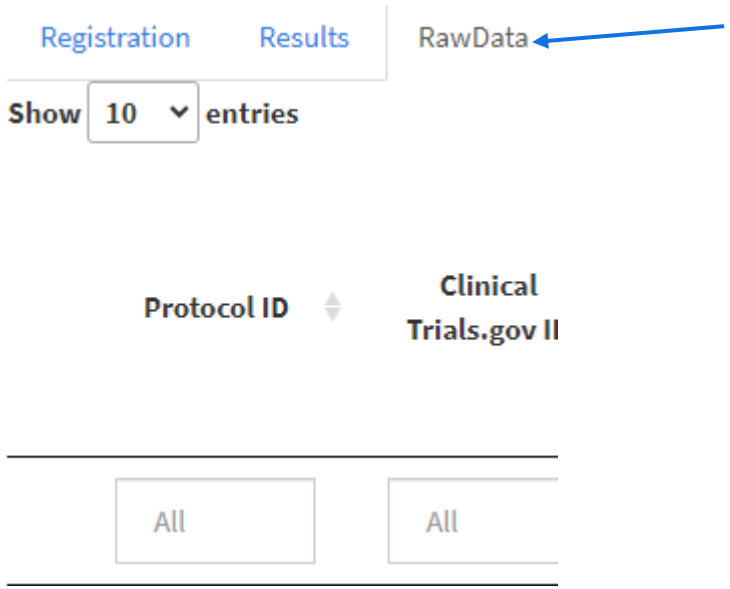
Results

- Visualizations for:
  - Average Days to Publish
  - Average Number of Tries to Publish
  - Percent Success on First Try (<= 2)
  - Average Response by Ctgov Reviewers
  - Results Published <= 12Months
  - Average Days to Publish Results
- The filters and aggregation are the same as the Registration tab

Tool Overview and Features

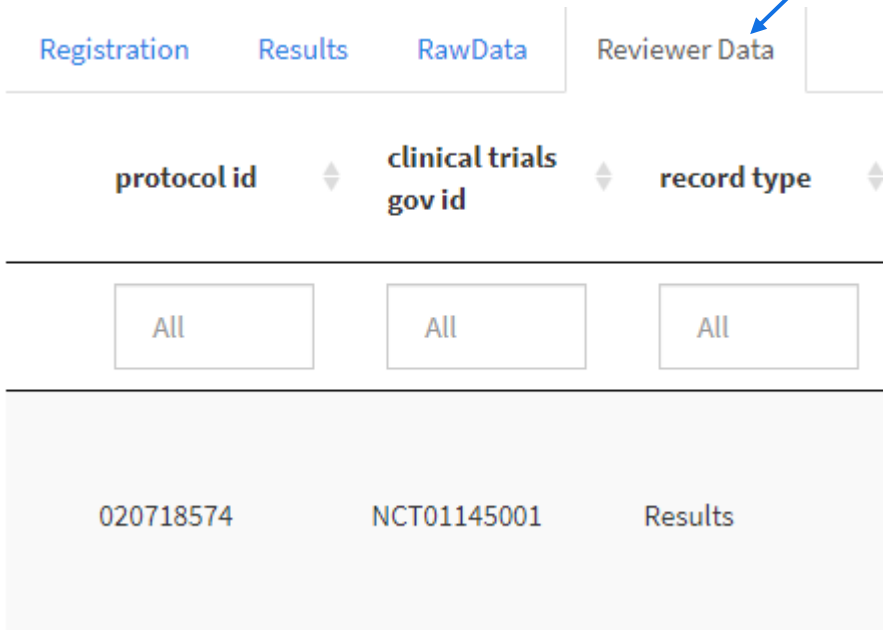
Raw Data

- The raw data for all data visualizations can be filtered and downloaded



Reviewer Data

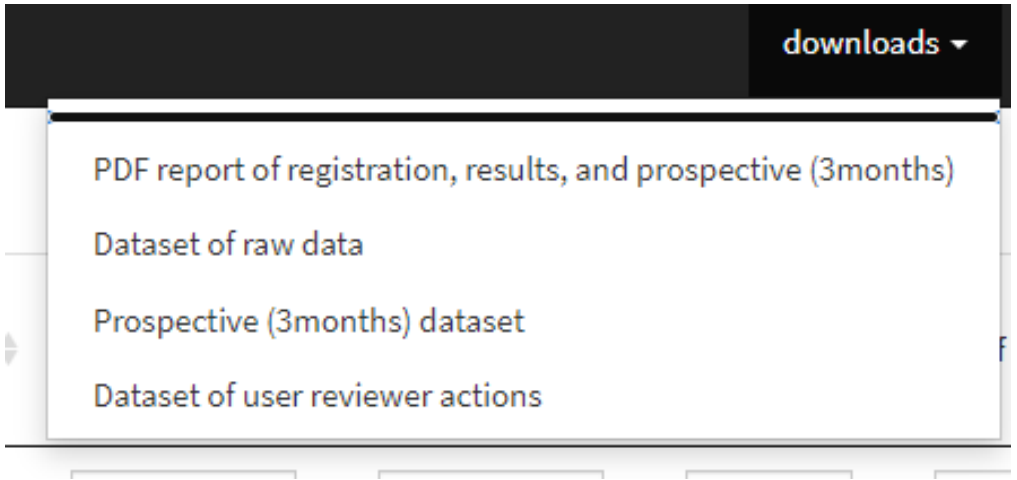
- The reviewer data can be filtered and downloaded
  - Useful for tracking activity by Admins at the institution



Tool Overview and Features

Downloads

- There are data downloads available for various tasks…



- The PDF report provides a summary of all upcoming activity for the next 3 months
- The full raw dataset (.csv) can be downloaded from here in its entirety
- The prospective 3-month dataset (.csv) provides information formatted to be used to contact study teams
- The full dataset of user reviewer actions (.csv) can also be downloaded in its entirety

Tool Overview and Features

Data selected

Study Type	Intervention Types	U S Fda Regulated Device	Record Status
Interventional	Behavioral	Missing	Approved
Observational	Biological/Vaccine	No FDA regulated device	In Progress
missing	Combination Product	FDA regulated device	No Longer Public
	Device		PRS Review
	Diagnostic Test		Public
	Dietary Supplement		Released
	Drug		missing
	missing		
	Other		
	Procedure/Surgery		
	Radiation		

Results Status	Fdaaa Status	Responsible Party	Nih Grants
Created	Yes	Sponsor	Yes
Missing	No	PI	No
Posted		missing	
Released			

Registration report between Dec 2020 and Dec 2021

	Number of records	Average time (days)	Avg CT.gov response time (days) for first try	Average tries	% Success first try	N Success first try	Avg CT.gov response time (days)
Dec 2020	8	8	2.6	1.5	100	8	2.4

Report

- Provides information in a downloadable pdf that includes:
  - Summary of Data Selections
  - Tabled Stats for Registration and Results
  - Prospective List of Studies with Expected Updates and Results due
    - NIH included

Prospective

Expected updates and results in next quarter, between Jun 2023 and Sep 2023

Record Type	Update Type	Number of Records
Registration	All Results Expected	16
Registration	Results Expected	2
Registration	Update Expected	38
Results	All Results Expected	1

Note: **NIH** signifies an NIH-defined clinical trial

All results or **Results** expected are colored red, **Updates** expected are not colored

Examples of how (and when) the tool is used in practice…

Examples of how (and when) the tool is used *in practice…*

Dataset of Review Actions

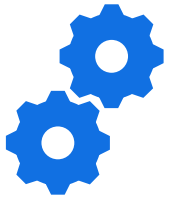
- Allows us to…
  - Capture all Ctgov Team record approvals
  - Determine how many studies registered
    - *Initial Release*
  - Determine how many results were submitted
    - *Initial Results Release*

Examples of how (and when) the tool is used *in practice…*

Track the successful submission of records

- Registration
  - Accepted and made public with 2 or fewer *tries* (first try)
- Results
  - Accepted and made public with 2 or fewer *tries* (first try)

Examples of how (and when) the tool is used *in practice…*



Graphic displays can be customized to ‘sub-groups’

Study type

Study phase

Intervention type

ACT (y/n)

NIH (y/n)

All ‘toggles’ can be used in different combinations

E.g. NIH Interventional studies w behavioral interventions

Graphic displays can be customized by date range and shown in different aggregations (e.g. 1, 3 or 6 months)

Contact Information and Next Steps

Contact Information

Personal Work Email: jesse.reynolds@yale.edu

Yale ClinicalTrials.gov Team Email: Yale.Ctgov@yale.edu

Next Steps

1. Continue to use and refine the tool (in house: Yale)
2. Begin the process of making the tool available to other organizations
    a. GitHub materials
    b. Discussion of ITS policies at institutions

Thanks!

Clinical and Translational Science Awards Program
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CCOS Updates

June 28, 2023

National Center for Advancing Translational Sciences

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2023 Fall Program Meeting

- **Date:** November 6-8, 2023
- **Location:** Double Tree (Crystal City) Washington, DC
  - Room Block (400 sleeping rooms for 6th and 7th)
- **Schedule:** 2.5 Days
  - **Day 1 - November 6th**
    - CTSA Administrators (8:00am-12noon ET)
    - Steering Committee Meeting (1:00pm-6:00pm ET)
  - **Day 2-3 - November 7th– 8th**
    - CTSA Program Meeting (8:30am-4:30pm ET)
    - CTSA Program Meeting (8:00am-12:30pm ET)

2023 Fall Planning Committee

VOLUNTEERS
Nicolas Abreu, KL2 Scholar - New York University
Alexander Brunfeldt, TL1 Trainee - Georgetown University
Mike Holinstat, TL1 PI - University of Michigan
Natalia Marone, KL2 PI - Boston University
Don McClain, UL1 Director- Wake Forest
Cindy Morris, UL1 Director- Oregon Health & Science University
Maureen Murtaugh, KL2 PI - University of Utah
Ruth O'Hara, UL1 Director- Stanford, Co-Chair
Dominic Reeds, KL2 PI - Washington University of St. Louis
Muredach Reilly, UL1 Director- Columbia
Patricia Rodriguez-Lozano, KL2 Scholar - University of Virginia
Michelle Romanick, Rockefeller University- Administrator
Julian Solway, UL1 Director- University of Chicago
Robert Toto, UL1 Director- UT Southwestern
Rosalind Wright, UL1 Director- Mt Sinai

NCATS
Michael Kurilla, Co-Chair
Erica Rosemond
Heather Baker
Jennie Conroy

CCOS
Kerry James
Lauren Fitzharris
Kate Fetherston
Beck Lazelle
Cindy Mark

Planning Committee Collaboration with New Steering Committee Task Force

- Dr. Rutter has called for a new Steering Committee Task Force

Implementing a Vision for Data-Driven Clinical Research:

A CTSA Enterprise

- The Fall Planning Committee is collaborating with the Task Force to develop the session on RWD/RWE for the Fall meeting
  - Muredach Reilly and Ruth O'Hara will serve on this Task Force and liaison between the two groups

2023 Fall Program Meeting

Meeting Theme: Leveraging RWD and AI to Advance Translation

Meeting Goals: To provide Hub leadership with an opportunity to:

- Network with their peers
- Share best practices for practical applications
- Gain knowledge through resource updates

Keynote Speaker: Dr. Renee Wegrzyn, Director, ARPA-H, accepted invitation to be keynote on November 7th.

2023 CTSA Program Annual Meeting Draft Agenda

Tue, Nov 7th – General Session	
Session	**Timing (ET)**
Session 1 – Welcome	**8:30am**–10:00am
Welcome	8:30am–9:00am
Keynote / Q&A	9:00am–9:45am
Break	9:45am-10:15am
Session 2 – Clinical Trial Design	10:15am-11:45am
Lunch	11:45am-1:00pm
Session 3 – AI in Clinical Research	1:00pm-2:30pm
Break	2:30pm-3:00pm
Session 4 – Training in the Science of Translation	3:00pm-**4:30pm**
Poster Session	6:00pm-8:00pm

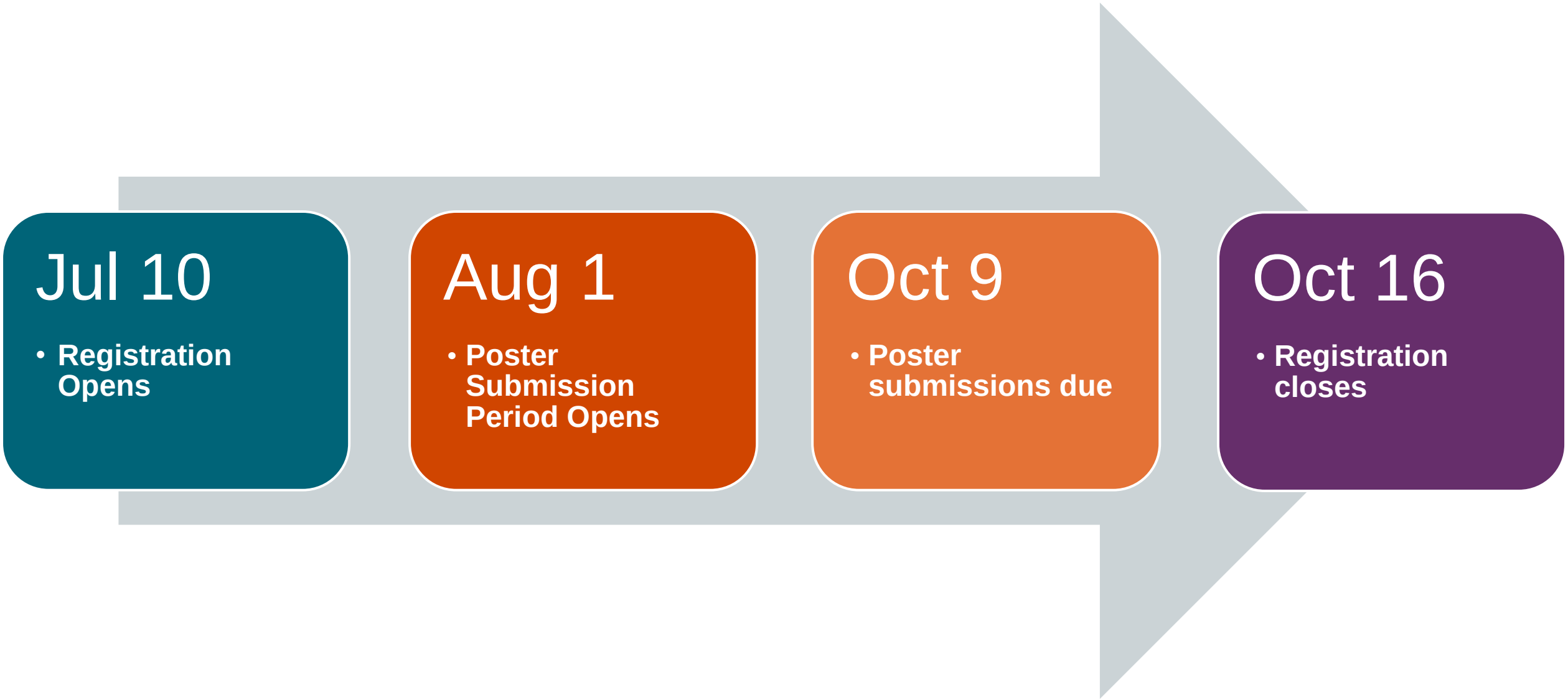
Wed, Nov 8th – General Session	
Session	**Timing (ET)**
Session 5 – Real World Data / Real World Evidence (RWD/RWE)	**8:00am**-9:00am
Breakout 1 - Clinical Data / eCRF	9:00am-10:00am
Breakout 2 - Patient Generated Data	
Breakout 3 - Cost and Utilization Data	
Breakout 4 - Public Health Data	
Break	10:00am-10:30am
Session 6 – NCATS Session	10:30am – 12:00pm
Closing Session / Top 10 Takeaways / Adjourn	12:00pm – **12:30pm**

Fall Planning – Session Leaders

Tue, Nov 7th – General Session	
Session	**Session Leaders**
Session 1 – Welcome	NCATS
Session 2 – Clinical Trial Design	Julian Soloway Patricia Rodriquez-Lozano
Session 3 – AI in Clinical Research	Rosalind Wright Josh Fessel
Session 4 – Training in the Science of Translation	Maureen Murtaugh Cindy Morris
Poster Session	Ruth O'Hara

Wed, Nov 8th – General Session	
Session	**Session Leaders**
Session 5 – Real World Data / Real World Evidence (RWD/RWE)	Muredach Reilly David Rehkopf
Session 6 – NCATS Session	NCATS

Important Dates for Fall Meeting



2023 CTSA Program Poster Session

Scheduled for November 7 at 6-8pm

- One poster per hub
- Posters to be submitted by Trainees selected at hubs
- Same overall theme as Fall meeting, *Leveraging RWD and AI to Advance Translation*
- Posters to be viewable on CCOS website in advance of meeting (Within 7-10 days of meeting)
- Poster submission period: August 1st – October 9th
- ***More details to come regarding submission process***

Other Details

- **Meeting will be hybrid (in person + virtual option)**
  - Virtual participation to be enhanced to enable interaction / Q&A
- **Networking and opportunities for discussion / interaction**
  - Breaks / lunch time
  - Group discussions at table (integrated into session agendas)
  - Poster session
  - Breakout sessions
  - Wellness Activities (Running / walking groups, Yoga / meditation)

More details to come at ***CCOS-CC.CTSA.io***

Meeting Logistics - Status

- CTSA Virtual Group Meetings – Completed
  - Office 365 Mailboxes set up for each group from ***ccos.ctsa.io*** accounts
    - Examples: Steering@ccos.ctsa.io; DEIA@ccos.ctsa.io
  - Meeting invitations have been sent out for all CTSA groups.

- Trial Innovation Network (TIN) Meetings - In Progress
  - The 2016 TIN “1.0” awards expire at the end of June 2023
  - CCOS will coordinate online meetings for TIN “2.0” awards starting July 2023
  - CCOS team working closely with NCATS and Duke to manage transition