NCATS

COLLABORATE. INNOVATE. ACCELERATE.

CTSA Program Steering Committee

January 22, 2024

2:30 – 3:30pm ET

CTSA Clinical & Translational Science Awards Program

NIH National Center for Advancing Translational Sciences

Agenda January 22, 2024

Time	Topic	Speaker(s)
2:30 – 2:35pm ET	Welcome and Announcements	Michael Kurilla Ruth O'Hara
2:35 – 2:40pm ET	Introduction of New Steering Committee Members	Jennifer Kraschnewski Vesna Garovic
2:40 – 2:55pm ET	Working Group Report Out: CTSA Pharmacies & Compounding for Translational Research	Robert MacArthur, PharmD, MS Rockefeller University
2:55 – 3:05pm ET	Revision for Guidance of CTSA Program Groups	Cindy Mark, CCOS
3:05 – 3:25pm ET	TIN Survey	Daniel Ford Lindsay Eyzaguirre
3:25 – 3:30pm ET	Request for Volunteers	Michael Kurilla Ted Wun
3:30pm ET	Adjourn	

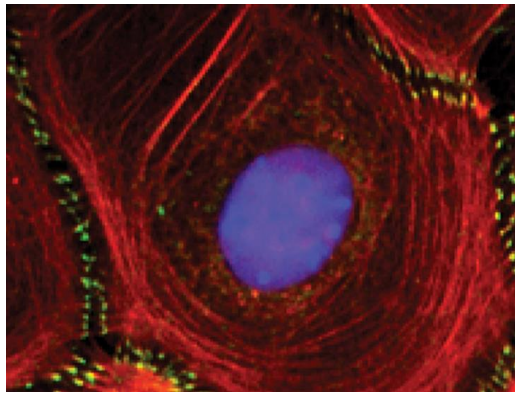
Incoming Steering Committee Members

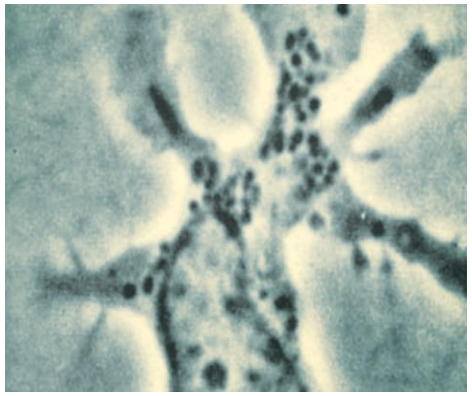
Vesna Garovic, MD, PhD
Mayo Clinic

Jennifer Kraschnewski, MD, MPH
Penn State College of Medicine

The Rockefeller University

SCIENCE FOR THE BENEFIT OF HUMANITY



CTSA Pharmacies & Compounding for Translational Research

THE ROCKEFELLER UNIVERSITY HOSPITAL

CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

SCIENCE FOR THE BENEFIT OF HUMANITY

Presentation Goals

- Overview of the CTSA Research Pharmacy Working Group
- Present initial data findings
  - Connect to FDA approved drugs to CTSA sites
  - Connect to FDA approved orphan drugs to CTSA sites
  - Describe drug products compounded for Ph1 and 2 studies
  - Update on survey
  - Update on SOPs
- Summarize next steps and deliverables

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Background

- CTSA hospital pharmacies have long provided compounding services as part of routine patient care.
- Compounding is also used to support clinical trials, especially early phase studies.
- Research pharmacists and compounded products are occasionally cited in clinical trial publications and in clinicaltrials.gov
- This project brings together Research Pharmacists from multiple CTSAs, to document their contributions to institutional research

Project Goals

- Identify FDA approved products, including orphan drug products, that utilized CTSA research pharmacy compounding services.
- Provide examples of compounded research products that have supported clinical and translational studies.
- Develop and administer a survey to CTSA Research Pharmacists to capture scope of practice.
- Develop a unified Research Pharmacy SOP list for sharing among sites, training, and publication,

The CTSA-RPWG

Research Pharmacist Collaborators

Data Collaborations

January 22, 2024

SCIENCE FOR THE BENEFIT OF HUMANITY

Phase 1 or 2 Studies at the 10 CTSA Sites

	Study Phase		Totals
	1	2	
Study Site			
Columbia	61	81	142
Duke Univ	181	124	305
Hopkins	207	181	388
Mayo	322	223	545
RW Johnson	2	3	5
Rockefeller	23	3	26
Univ Alabama	51	50	101
Univ Cal Davis	11	7	18
Univ Penn	192	141	333
Total	1050	813	1863

Among the 10 CTSA sites there are 1863 phase 1 or 2 clinical trials listed in clinicaltrials.gov

Some sites perform more phase 1 and 2 studies than others, so the project may expand to include phase 3 and 4 research pharmacy services to capture those efforts

*Clinicaltrials.gov

Example: CTSA Ph 1/2 Studies That Preceded FDA Product Approval

NCT Number	Study Phase	FDA Approved Drug	Study Start Date	FDA Approval Date	Years Ph1 to Approval
NCT00000189	2	GEPIRONE	01JAN1990	22SEP2023	33.75
NCT00002239	2	EFAVIRENZ	01MAY1999	17FEB2016	16.81
NCT01236638	2	MOMELOTINIB	01NOV2010	15SEP2023	12.88
NCT00002239	2	ENFUVIRTIDE	01MAY1999	13MAR2003	3.87
NCT02052791	1	NUSINERSEN	01JAN2014	23DEC2016	2.98

Example: Orphan Products Approved After CTSA Phase 1/2 Studies

Study Phase	Drug	CTSA Location(s)	Approved Orphan Indication
2	MOMELOTINIB	Mayo and Multisite	Treatment of myelofibrosis
1	NUSINERSEN	Columbia and Multisite	Treatment of spinal muscular atrophy

Example: Approved High Profile Product that followed CTSA Phase 1/2 Studies

A Study of Tirzepatide in Overweight and Very Overweight Participants

Study Phase	Drug	CTSA Location(s)	Approved Indication
1	TIRZEPATIDE (Mounjaro)	Hopkins and Multisite	GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Early Phase Dosage Forms

Type	Dosage Form
Oral, Non-Sterile	API powder in capsule or bottle API liquid in capsule Aqueous solutions and suspensions Formulated capsules
Injection or Other, Sterile	Prefilled syringes Vials + syringes Small volume infusions
Inhaled, Sterile	Vial + nebulizer (Mesh or Jet) Sterile powder + powder inhaler

Dosage forms commonly compounded for early phase studies, a time when the final marketed dosage form is not yet available

Via survey and literature review, pharmacists will describe research drug compounding performed at their site to support clinical trials

No. of Journal Articles Connected to CTSA Phase 1 and 2 Studies

Site	No. Full Text References
Columbia	73
Duke	77
Emory	44
Howard	24
Mayo	84
Penn	52
Rockefeller	53
RW Johnson	3
Univ Alabama	13
Total	423

423 publications identified which are connected to the 10 CTSA sites and their combined 1863 phase 1 and 2 studies

Where possible, articles will be used to document the pharmacy compounded products administered during the study

If pharmacy not mentioned that will also be noted

Survey and SOP Lists

Survey was reviewed and edited by all collaborating pharmacists and has been submitted to CCOS for finalization

Survey will be used to describe Research Pharmacy services provided by each CTSA site, in detail

CCOS has developed submission portal for SOP list upload from each collaborating pharmacist and site

Deliverables

A publication that includes the survey results and documented connections between compounded products, early phase CTSA site studies, and, where possible, FDA approved and orphan drug products

A publication that combines the SOP lists from all CTSA Research Pharmacies

A webinar, "Investigational Drug Compounding for Translational Research”

Revision of Report Out Processes to Steering Committee

Cindy Mark, CCOS

National Center for Advancing Translational Sciences

Revision of EC Report Outs to Steering Committee

Annual presentation to the SC: The purpose of this **10-minute, pre-recorded presentation** is to provide updates to the SC about annual EC goals and highlights of EC activities. This presentation will be followed by 5-10 minutes of discussion to solicit constructive feedback from the SC regarding EC activities. ***Each presentation should follow the structure below***:

1. Intro slide: List EC Lead team members, Chair(s) and # EC members (by hub) who participated in EC this year (CCOS coordinator will provide)
2. Highlights of what the EC has accomplished in the past year
    - What specifically have you achieved related to EC goals?
    - Work product (e.g., publication, guidance document, etc) (if any)
    - Sponsorship of WGs (if any)
    - Cross EC initiatives or other CTSA collaborations (if any)
3. Upcoming goals for the next year
    - What will the EC work towards in the next year?
4. Discussion / constructive feedback from SC members (directed questions) (**NEW**)
    - EC Chairs should develop a set of questions for the SC to provide feedback on and to serve as a primer for the discussion. Examples below:
        - Is the EC's progress satisfactory to date?
        - Are there short-term goals that this EC should prioritize in the next year?
        - Are there any additional suggestions as to how to enhance the work of this EC?

Revision of EC Report Outs to Steering Committee (Con't)

SC members (at least 2) will review content and lead discussion. (*The SC members will be assigned by CCOS*).

The SC meeting coordinator will reach out to EC Chairs to schedule their presentation at least 2 months in advance of the presentation.

The presentation should be 10 minutes in length and pre-recorded prior to SC meeting. The pre-recorded presentation will be followed by 5-10 minutes of discussion between EC chair(s) and SC, as noted above.

Draft slides and SC questions should be provided to the SC **at least 1 month prior** to their presentation.

Revision to Annual Presentation from EC on Monthly Webinar

Annual Presentation on the CTSA Program Webinar: The EC presentation to the webinar will take place after the SC presentation – typically within 1-2 months. The purpose of this presentation is to provide a high-level status report to the CTSA consortium about EC goals and highlights of the EC activities. The presentation should be tailored for the larger CTSA-wide audience and include a ***summary*** of the SC constructive feedback.

A CCOS meeting coordinator will reach out to EC Chairs to schedule their webinar presentation at least 2 months in advance of the presentation.

The presentation should be 10 minutes in length and pre-recorded prior to webinar.

Draft slides should be provided to the CCOS coordinator **at least 1 month prior** to their presentation.

Revision to WG Report Outs to Steering Committee

Annual presentation to the SC: The purpose of this **10-minute, pre-recorded presentation** is to provide updates to the SC about annual WG goals and deliverables. This presentation will be followed by 5-10 minutes of discussion between WG chair(s) and SC to solicit constructive feedback regarding WG activities. ***Each presentation should follow the structure below***:

1. Introductory slide (WG title, chair(s) and membership)
2. WG goals and deliverables, along with a timeline
3. Progress towards goals and deliverables
4. Discussion/constructive feedback from SC members (directed questions) (**NEW**)

WG Chairs should develop a set of questions for the SC to provide feedback on and to serve as a primer for the discussion. Examples below:

- Is the progress satisfactory to date?
- In your opinion, are we on the right track to make an impact with this WG?
- Are we engaging the appropriate stakeholders/participants or are there others we are missing to date?
- Are there other goals or deliverables that we missed in the conception of this WG that you think we need to incorporate now to enhance the significance? (This could be future facing or as an additional follow-on WG)
- Are there any additional suggestions as to how to enhance implementation and dissemination of the deliverables of this WG?

Revision to WG Report Outs to Steering Committee (con't)

SC members (at least 2) will review content and lead discussion. (The SC members will be assigned by CCOS).

The SC meeting coordinator will reach out to WG Chairs to schedule their presentation at least 2 months in advance of the presentation.

The presentation should be 10 minutes in length and pre-recorded prior to SC meeting. The pre-recorded presentation will be followed by 5-10 minutes of discussion between WG chair(s) and SC, as noted above.

Draft slides and SC questions should be provided to the SC **at least 1 month prior** to their presentation

Revision to Annual Working Group Presentation on Monthly Webinar

Annual Presentation on the CTSA Program Webinar: The annual presentation to the webinar will be scheduled after the SC presentation – typically within 1-2 months. The purpose of this presentation is to provide a high-level status report to the CTSA consortium about WG goals and deliverables, with a focus on the value and impact of the WG. The presentation should be tailored for the larger CTSA-wide audience and include a summary of the SC constructive feedback.

A CCOS meeting coordinator will reach out to WG Chairs to schedule their webinar presentation at least 2 months in advance of the presentation.

The presentation should be 10 minutes in length and pre-recorded prior to webinar.

Draft slides should be provided to the CCOS coordinator **at least 1 month prior** to their presentation.

SC Assignments to ECs

Name of EC	Steering Committee Members Assigned	Scheduled Date of Report Out to SC
Diversity, Equity, Inclusion and Accessibility	Melissa Haendel Steven Reis	May 13, 2024
Collaboration & Engagement	Kathryn Sandberg Tesheia Johnson	June 10, 2024
Workforce Development	Jen Kraschnewski Dan Ford	July 8, 2024
Informatics	Doris Rubio Grace McComsey	September 9, 2024
Integration Across the Lifespan	Mimi Kim Arleen Brown	October 28, 2024

SC Assignments to Working Groups

Name of Working Group	Steering Committee Members Assigned	Scheduled Date of Report Out to SC
Advancing Dissemination and Implementation Sciences	Gerry Moeller Rosalind Wright	March 25, 2024
Engaging Individuals with Disability in the Research Process	Jessica Kahn Ted Wun	May 13, 2024
Translational Science Competency-Based Assessment (TS-CBA)	Doris Rubio Elizabeth Ofili	June 10, 2024
21 CFR Part 11 Compliance for REDCap	Mimi Kim Randall Urban	September 25, 2024
TL1 Visiting Scientist	Grace McComsey Tesheia Johnson	October 28, 2024

SC Assignments to Working Groups (Con't)

Name of Working Group	Steering Committee Members Assigned	Scheduled Date of Report Out to SC
CTSA Pharmacies and Compounding for TR	Arleen Brown Elizabeth Ofili	This group will report out again in 2025 – Date TBD
Integrating CTS into the CTSA Virtual Visiting Scholar Program	Vesna Garovic Steven Reis	This group will report out in February 2024, prior to initiating new process; they will report out in 2025; Date TBD
Harnessing CTSA innovation and engagement in the recruitment and retention of diverse populations in clinical and translational research	Kathryn Sandberg Dan Ford	This group started meeting in January 2024. Their report out will be scheduled in early 2025.
Learning About the Science of Translation	Melissa Haendel Jessica Kahn	This group started meeting in January 2024. Their report out will be scheduled in early 2025.

Working Group Cycle XII opens in March 2024; there are three open slots for new working groups. Those report outs will happen in 2025.

Needs Assessment Survey

Multisite Clinical Trial Science Training Academy

TRIAL INNOVATION NETWORK

CTSA Clinical & Translational Science Awards Program

Purpose of the Survey

- The survey is a training needs assessment that has been developed by our TIC to inform the development of our Training Academy.
- The purpose of bringing it here is to seek your approval for its distribution to the Clinical and Translational Science Awards (CTSA) Points of Contact (POCs) across our network.
- The survey has 8 questions.
- We estimate it will take 10 minutes to complete.
- The collection of identifiers is optional, participants have the option to provide their name and email.

Email to POCs

- Following approval of this committee, the survey will be sent to CTSA POCs, preferably Q1 2024.
- POCs will be encouraged to disseminate the survey to as many as possible **active clinical trial PIs** and their **respective project managers / research coordinators** within their institutions.
- We would also like to send it to all the PIs who went through the TIN consultation process during our first 7 years.

TRIAL **INNOVATION** NETWORK

Dear CTSA POCs,

The Trial Innovation Network, funded by NCATS, is committed to enhancing the skills and knowledge that inform multisite, randomized clinical trial (mRCT) quality and efficiencies, especially when investigators and clinical research managers transition from single center trials to managing mRCTs.

We are developing a new clinical trial training program. We seek feedback from you and from investigators and research project managers at your institution to help shape this new training program.

Please extend this request and the enclosed survey link to investigators and research project managers at your institution who manage single center clinical trials or have recently applied for or received a first multicenter clinical trial grant. We depend on you to help us reach our audience at your institution.

SURVEY LINK:

We aim to collect all responses by [DATE] to facilitate curriculum development.

For an optimal survey experience, we recommend completing this survey on a computer in a full screen window. In case of browser issues, please try using Safari, Chrome, or Microsoft Edge. We do not recommend using Firefox.

Your participation and insights are highly valued, and we appreciate your contribution to the enhancement of our training program.

Thank you for your time and collaboration.

Best,

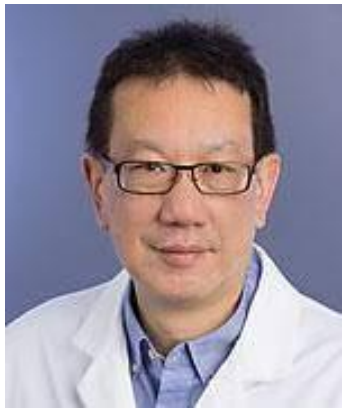
[NAME], on behalf of the Johns Hopkins Trial Innovation Center

TRIAL **INNOVATION** NETWORK

Using Survey Results

- The survey will assist us in pinpointing the most significant knowledge gaps and determining their priority.
- The survey will help us tailor the training academy curriculum to emphasize the most essential training requirements.
- The survey will play a crucial role in identifying the best approach for disseminating the curriculum, ensuring alignment with preferred learning modes.

Request for Volunteers



Ted Wun will be leading the planning committee for the In-Person Fall CTSA Meeting.

Are you interested in helping to plan this exciting, informative meeting?

We value your suggestions and hope you will become involved.

Please email Michael Kurilla at Michael.Kurilla@nih.gov or Ted Wun at twun@ucdavis.edu to express your interest.

Volunteers, to date:

Grace McComsey
Mimi Kim
Doris Rubio
Kathryn Sandberg
Tesheia Johnson
Gelise Thomas
Dan Ford
Jessica Kahn

February 12, 2024
2:30-3:30pm ET

National Center for Advancing Translational Sciences

Adjourn