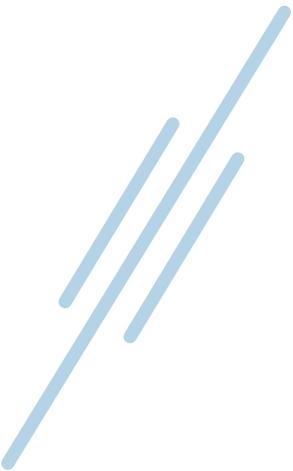




Office of the National Coordinator  
for Health Information Technology

# Optimizing Data Capture for Clinical Trials, An OSTP/ONC RFI Listening Session

January 11<sup>th</sup>, 2023



## Agenda at a Glance

Start Time	Agenda Item	Duration
[11:30am EST]	Opening remarks	(15 mins)
[11:45am EST]	Facilitated round table discussions	(65 mins)
<b><u>Topic #1</u></b> - Innovative approaches to designing and distributing emergency clinical trial (ECT) protocols		
<b><u>Topic #2</u></b> - Effective strategies to capture data during emergency clinical trials & feasible pilot demonstrations of data capture capabilities		
<b><u>Topic #3</u></b> - Aggregating data from multiple sites in a way that's easy to analyze		
<b><u>Topic #4</u></b> - Chat review / sharing key insights (time permitting)		
[12:50pm EST]	Closing remarks	(5 - 10 mins)
[1:00pm EST]	Event concludes	



# RFI Listening Session



## Our Vision

- ✓ We want to hear from YOU!
- ✓ Health Equity as a Guiding Principle



## Goal

- ✓ To garner additional feedback and industry insights as part of 2 open RFIs on advancing emergency clinical trials (ECTs) infrastructure

**For further background on the focus for today's listening session, please visit the following HealthIT Buzz Blog:**  
["OSTP, in Partnership with ONC, Seeks Input on Optimizing Data Capture for Clinical Trials"](#) (Oct2022)

# Opening Remarks

## Event Facilitator:

**Stephen Konya**, Senior Advisor and Innovation Portfolio Lead,  
Office of the National Coordinator for Health IT (HHS/ONC)

## Moderators:

**Grail Sipes**, Assistant Director for Biomedical Regulatory Policy,  
White House Office of Science and Technology Policy (OSTP)

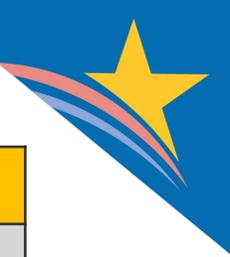
**Jennifer Roberts**, Assistant Director for Health Technologies,  
White House Office of Science and Technology Policy (OSTP)

## Other Federal Panelists:

**John Rancourt**, Director, Interoperability Division  
Office of Policy, Office of the National Coordinator for Health IT (ONC)  
U.S. Department of Health and Human Services (HHS)

**Brendan O'Leary**, Acting Director, Digital Health Center of Excellence (DHCoE),  
Center for Devices and Radiological Health (CDRH),  
U.S. Food and Drug Administration (HHS/FDA)





<b>Panelist</b>	<b>Title / Position</b>	<b>Affiliation</b>
<b>Derk Arts</b>	CEO and Founder	Castor
<b>Scott Chetham</b>	CEO and Co-Founder	Faro Health
<b>Tony Clapsis</b>	Senior Vice President, General Manager, Clinical Trial Services	CVS Health
<b>Michael Cohen-Wolkowicz, MD PhD</b>	Head, Pediatrics, Duke Clinical Research Institute and Kiser-Arena Distinguished Professor of Pediatrics	Duke University
<b>Amy Cramer</b>	Janssen Clinical Innovation Focus Area Leader, and Co-Chair Vulcan FHIR Accelerator	The Janssen Pharmaceutical Companies of Johnson & Johnson
<b>Manny Fombu</b>	Vice President, Digital Health Solutions	Alira Health
<b>Karen Hartman, M.S.</b>	Vice Chair, Research Administration	Mayo Clinic
<b>Melanie Ivarsson OBE, PhD, MBA</b>	Chief Development Officer	Moderna
<b>Craig H Lipset</b>	Co-Chair	Decentralized Trials & Research Alliance
<b>Michelle Longmire</b>	CEO & Co-founder	Medable
<b>Jane Myles</b>	Vice President of Clinical Trial Innovation	Curebase
<b>Ramita Tandon</b>	Chief Clinical Trials Officer	Walgreens Health
<b>Elena Viboch</b>	Partner, Life Sciences	General Catalyst
<b>Neil J. Weissman, MD</b>	Chief Scientific Officer, President, MedStar Health Research Institute	MedStar Health



## Background on OSTP Requests for Information (RFIs)

- **OSTP issued two RFIs related to clinical trials in October 2022**
  1. RFI on “Clinical Research Infrastructure and Emergency Clinical Trials” (October 26, 2022); Key topics include
    - US-level governance/coordination
    - Building a more diverse, comprehensive network of sites
    - Developing a “warm base” of clinical research
    - International coordination
  2. RFI on “Data Collection for Emergency Clinical Trials and Interoperability Pilot” (October 28, 2022); Key topics include
    - Technical strategies for distributing protocols and capturing trial data using common APIs
    - Designing a pilot or demonstration project to operationalize data capture
- **Comment period for both RFIs has been extended to January 27, 2023**



# Overview of Today's Session

- **Scenarios**

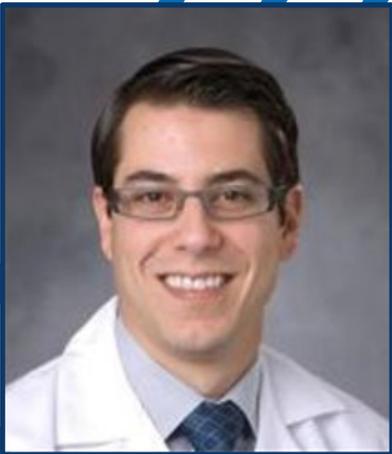
- A variety of clinical sites all need to carry out the same clinical trial protocol in an emergency setting
- The sites may not have all previously worked together
- Sites may include hospitals, clinics, community centers
- A representative sample of patients may need to be recruited in real time or they could be drawn from an existing pool of volunteers

- **Technical themes**

- Topic 1 – Design and distribution of clinical trial protocols for emergency settings
- Topic 2 – The execution phase: strategies for data capture and ideas for pilot programs
- Topic 3 – Aggregating and analyzing clinical trial data



**Topic #1:**  
Innovative approaches to designing and distributing  
emergency clinical trial (ECT) protocols  
(approx. 20 mins)



**Michael Cohen-Wolkowicz,  
MD PhD**  
Head, Pediatrics,  
Duke Clinical Research  
Institute



**Melanie Ivarsson**  
Chief Development Officer,  
Moderna



**Neil Weissman, MD**  
Chief Scientific Officer,  
MedStar Health  
  
President,  
MedStar Health Research Institute



**Scott Chetham**  
CEO and Co-Founder,  
Faro Health



**Craig Lipset**  
Co-Chair, Decentralized Trials &  
Research Alliance  
Adjunct Assistant Professor,  
Rutgers University  
Managing Partner, Clinical  
Innovation Partners



## Topic #2:

Effective strategies to capture data during emergency clinical trials  
& feasible pilot demonstrations of data capture capabilities  
(approx. 20 mins)



**Ramita Tandon**  
Chief Clinical Trials Officer,  
Walgreens Health



**Elena Viboch**  
Partner, Life Sciences,  
General Catalyst



**Manny Fombu**  
Vice President,  
Digital Health Solutions



**Michelle Longmire**  
CEO & Co-founder,  
Medable



**Karen Hartman, M.S.**  
Vice Chair,  
Research Administration,  
Mayo Clinic



## Topic #3:

Aggregating data from multiple sites in a way that's easy to analyze  
(approx. 20 mins)



**Tony Clapsis**  
Senior Vice President,  
General Manager,  
Clinical Trial Services,  
CVS Health



**Jane Myles**  
Vice President,  
Clinical Trial Innovation,  
Curebase



**Derk Arts**  
CEO and Founder,  
Castor



**Amy Cramer**  
Janssen Clinical Innovation  
Focus Area Leader,  
Johnson and Johnson  
Co-Chair,  
Vulcan FHIR Accelerator



**Chat Review (time permitting)**

# Next Steps

## 1) Please review and consider responding to the following 2 RFIs;

**RFI #1:** Request for Information (RFI) on Data Collection for Emergency Clinical Trials and Interoperability Pilot;

**Extension of Comment Period (now due 1/27/23)**

<https://www.federalregister.gov/documents/2022/11/18/2022-25166/request-for-information-rfi-on-data-collection-for-emergency-clinical-trials-and-interoperability>

**RFI #2:** Request for Information; Clinical Research Infrastructure and Emergency Clinical Trials **(also now due 1/27/23)**

<https://www.federalregister.gov/documents/2022/11/22/2022-25163/request-for-information-clinical-research-infrastructure-and-emergency-clinical-trials>

## 2) Still time to register for tomorrow's listening session\* (focused on RFI #2 above)!

**Date:** January 12<sup>th</sup>, 2023

**Time:** 1:00pm – 2:30pm EST

**Registration:** <https://ida-org.zoomgov.com/meeting/register/vJIsduqsrijkPH1Ns9cHQVVO7Nd-nYuLEMDM>

\*For further background, please visit the following White House OSTP blog post:

["Preparing U.S. Clinical Trials Infrastructure for Emergencies: A White House Virtual Roundtable Discussion"](#) (Jan2023)



Office of the National Coordinator  
for Health Information Technology

# Contact ONC

Stephen Konya [stephen.konya@hhs.gov](mailto:stephen.konya@hhs.gov)



Phone: 202-690-7151



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