

## AGENDA

### Joint Meeting of CTTI/FDA Patient Engagement Collaborative (PEC) and EMA Patients' and Consumers' Working Party (PCWP)

**July 20, 2023**

**9:00 am – 11:00 am (EDT) / 15.00 – 17.00 (CEST)**

**8:45/14.45**      *Meeting open early for optional icebreaker and audio check*

#### **9:00 / 15.00**      **Welcome and Agenda**

- ▶ Lori Wiggins, Patient Affairs, U.S. Food and Drug Administration
- ▶ Juan García Burgos, European Medicines Agency

#### **9:10 / 15.10**      **Opening Session: Decentralized Clinical Trials Overview**

*Facilitator: Sabrena Mervin-Blake, CTTI*

- ▶ **CTTI:** Overview of Decentralized Clinical Trials  
Lindsay Kehoe, Senior Project Manager  
Clinical Trials Transformation Initiative (CTTI)  
Q & A

#### **9:30 / 15.30**      **Decentralized Clinical Trials: What's Happening in EU and US?**

*Facilitator: Wendy Slavit, Patient Affairs, U.S. Food and Drug Administration*

- ▶ **Speaker #1: DCTs and EMA**  
Mårten Wendt, MD, PhD, Clinical Assessor, Swedish Medical Products Agency
- ▶ **Speaker #2: DCTs and FDA**  
Leonard Sacks, MD, Associate Director, Clinical Methodologies  
Office of Medical Policy (OMP), CDER, FDA

**9:50 / 15.50**      **Break**

#### **10:05 / 16.05**      **Panel Discussion**

*Facilitator: Juan García Burgos, European Medicines Agency  
Head of Public and Stakeholder Engagement Department*

Panelist 1: PEC Member (Kim Hindery)  
Panelist 2: PCWP Member (Christine Dehn)  
Panelist 3: EMA (Mårten Wendt)  
Panelist 4: FDA (Leonard Sacks)

10:45 / 16.45

## Suggestions for Next Year

*Facilitator: Lori Wiggins, Patient Affairs, U.S. Food and Drug Administration*

10:55 / 16.55

## Final Comments and Adjourn

*Facilitator: Lori Wiggins, Patient Affairs, U.S. Food and Drug Administration*

### Background Information

About the EMA:

<https://www.ema.europa.eu/en>

About the PCWP:

<https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/patients-consumers-working-party>

About the FDA:

<https://www.fda.gov/>

About the PEC:

<https://www.fda.gov/patients/learn-about-fda-patient-engagement/patient-engagement-collaborative>

### Decentralized Clinical Trials (DCTs) Resources

EMA DCTs News

<https://www.ema.europa.eu/en/news/facilitating-decentralised-clinical-trials-eu>

EMA DCTs Recommendations:

[https://health.ec.europa.eu/system/files/2023-03/mp\\_decentralised-elements\\_clinical-trials\\_rec\\_en.pdf](https://health.ec.europa.eu/system/files/2023-03/mp_decentralised-elements_clinical-trials_rec_en.pdf)

FDA Background on DCTs Draft Guidance:

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/decentralized-clinical-trials-drugs-biological-products-and-devices>

FDA DCTs Draft Guidance :

<https://www.fda.gov/media/167696/download>

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