

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

FDA Background on DCTs Draft Guidance: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FDA DCTs Draft Guidance :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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