# ACT EU Training for non-commercial sponsors: Transitioning trials to CTIS

**9 February 2024**
Virtual event

The virtual event aims to support non-commercial sponsors of clinical trials in preparing and completing the transition of trials expected to continue after 30 January 2025 from the Clinical Trials Directive to the Clinical Trials Regulation (CTR).

From 31 January 2025 onwards only the CTR and its Delegated Acts will apply. Sponsors, therefore, need to transition any trials that will continue after 30 January 2025 from the Clinical Trials Directive to the legal framework of the CTR.

During the event, representatives from the European Commission, Member States and EMA will provide guidance and resources to support non-commercial sponsors in transitioning their trials to the Clinical Trials Information System (CTIS), the IT tool of the CTR.

# ACT EU Training on transition trials for non-Commercial sponsors

*9 February 2024, 10:00 – 13:00 CET*

## 09:50 Joining and technical checks

## 10:00 Welcome and opening speech

**Opening remarks from EMA** **5'**

*Laura Pioppo (EMA)*

## 10:05 Session 1

*Moderator: Giacomo Capone (EMA)*

**Useful links and info when creating/transitioning trials in CTIS** **15'**
*Ornela Ademi (EMA)*

**Preparing and proceeding with transition of clinical trials**

*Lene Birgitte Grejs Petersen (Danish Medicines Agency)* **20'**

*Elena García Méndez (Ethics Committee, Spain)* **20'**

**CTIS Demo on new/transitional trials** **30'**
*Charalampos Drosos (EMA)*

**Basic knowledge on Organization Management Service (OMS)** **15'**
*Debora Martins Braga (EMA)*

**Introduction and basic requirements in xEVMPD** **15'**
*Veronika Baker (EMA)*

## 12:00 Coffee break

## 12:15 Session 2: Q&A

*Moderator: Giacomo Capone (EMA), Ornela Ademi (EMA)*

**Q&A with the experts** **45'**
*Ornela Ademi (EMA), Charalampos Drosos (EMA), Francesca Scotti (EMA), Debora Martins Braga (EMA), Veronika Baker (EMA), Lene Birgitte Grejs Petersen (Danish Medicines Agency), Elena García Méndez (Ethics Committee, Spain), Monique Al (Central Committee on Research Involving Human Subjects (CCMO), The Netherlands) and Marianne Lunzer (CTCG, Austrian Agency for Health and Food Safety)*