Update on CTR implementation, including new CTIS transparency rules

2 October 2024
Annual workshop of the European network of paediatric research at EMA (Enpr-EMA)

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Disclaimer

The presenter does not have any conflict of interests.

CTIS

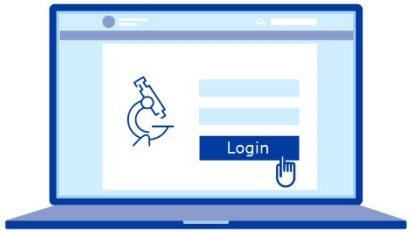
CTIS - backbone of the Clinical Trials Regulation, launched in 2022

- CTR aims to simplify the process for CTA submission, harmonise evaluation and increase transparency
- CTIS is the single entry point for clinical trial applications for up to 30 EU/EEA countries
- Used by sponsors and Member States during the clinical trial lifecycle
- Facilitates multinational trials to address key health issues
- Public, searchable database increases transparency & enables patient enrolment
- Improves access to clinical research data
- Supports the EU to remain a competitive clinical research hub globally

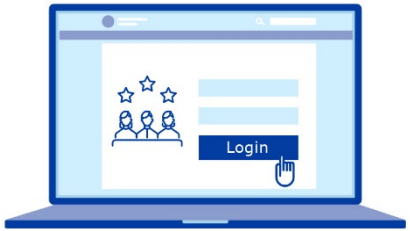
CTIS public website & secure domains

A **public website** where anyone can search for information on clinical trials https://euclinicaltrials.eu

Open access



A **Sponsor workspace** where clinical trial sponsors and the organisations that work with them can apply for and manage a clinical trial in up to 30 EU/EEA countries



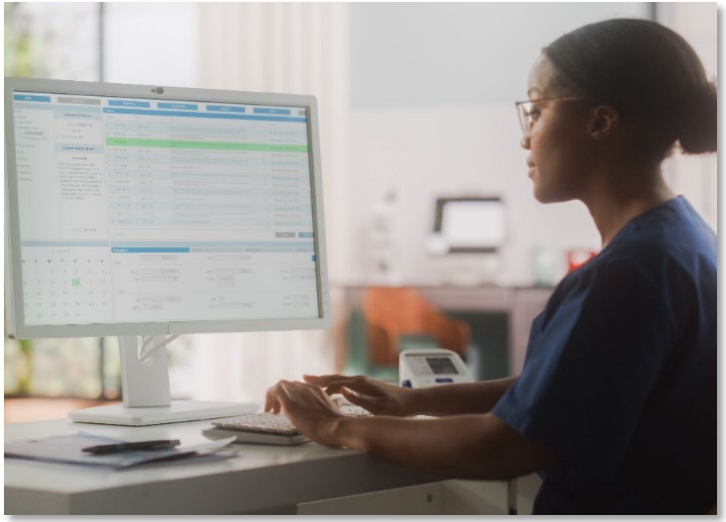
An **Authority workspace** for EU Member States, EEA countries and the European Commission to assess, authorise and oversee clinical trials

Secure access

Transparency in European clinical trials

Publication of clinical trials information is important:

- to enable trust
- to identify the right clinical development pathway
- to avoid unnecessary duplication of trials
- to inform on methods and results
- to ensure that patients have access to clinical trials information of their interest



Transparency is a legal requirement for trials conducted in EU/EEA under the Clinical Trial Directive 2001/20 and the Clinical Trials Regulation 536/2014

Launch of new CTIS Public Portal

- Clinical trial portal functionalities have improved since CTIS launch in January 2022
- Revised CTIS transparency rules became applicable on 18 June 2024 with the launch of a new version of CTIS public portal
- Additional functionalities on download and advanced search also available since 20 September 2024
- **Over 6,100 trials** have been published so far, of which over **1,560 with documents**
- Overall, more than 35,600 documents are now publicly available

Reference documents: Quick guide for users & all materials published on "Transparency in CTIS" - ACT EU website

What you can search for and how

Information you can view on each clinical trial includes:

- Trial identifiers (EU clinical trial number, protocol code, title, any other ID)
- Therapeutic intent and objectives
- Endpoints and trial design
- Participants inclusion and exclusion criteria
- Trial locations, Sponsor(s) and contact information
- Start and end dates and recruitment timelines

You can also view the following trial **documents**:

- Protocol and protocol synopsis
- Summary of the products characteristics, when applicable
- Recruitment arrangements, Subject information and informed consent form
- Summary of results, layperson summary and Clinical Study Report, when posted

Demo on CTIS public portal

ACT EU

ACT EU Priority actions 2023-2026

Delivering benefits to clinical trial stakeholders across key areas:

Mapping & governance

Implementation of the Clinical Trials Regulation

Support for non-commercial sponsors

Multi-stakeholder platform

Good clinical practice modernisation

Clinical trials analytics

Consolidated advice on clinical trials

Clinical Trials methodologies

Clinical trials safety

Clinical trials training curriculum

Clinical trials in public health emergencies

An overview: what is in scope

Governance: **CTR Collaborate** initiative to support optimisation of NCA and ethics collaboration on clinical trial authorisation and supervision (anchored to ACT EU).

CTR implementation: KPI reports; CTR sponsor survey; Support to transitioning CTs; New CTIS Transparency rules; **Support to non-commercial sponsors** with regulatory helpdesk.

Multi-stakeholder platform: Establishment of the MSP Advisory Group in March, regulatory & stakeholder co-chairs appointed, an advisory group to prioritise clinical trials related matters.

GCP modernisation: ACT EU PA04 - Multi-stakeholder Workshop on ICH E6 R3 in July 2023, a second workshop planned in Q1 2025

Data analytics: Definition of research agenda, Clinical Trials Analytics Workshop on 25-26 January 2024

An overview: what is in scope

Communications: Launch of the ACT EU website https://accelerating-clinical-trials.europa.eu/index_en; communications around end of CTR transition

Consolidated advice: Launch of consolidated pilots on clinical trials; support to SNSA pilot

Methodologies: Guidance for complex, decentralised, single-arm CTs; Multi-stakeholder methodology workshop held on 23 November 2023

Safety monitoring: Annual safety event (JA EU4Health Safe-CT) held on 15-16 January 2024

CT training curriculum: Developing training needs, now focussed on academia and SMEs

Public Health Emergency: Fast and efficient process in place to address PHE

Support to non-commercial sponsors

Objectives

- More non-commercial multinational clinical trials
- Non-commercial clinical trials generating **high quality scientific evidence**
- **Benefit for EU citizen's health** through optimized therapies and access to innovative medicines

Action plan in progress

- NEW - Interactive map of national initiatives on the ACT EU website (*signposting*), with input from NCAs
- Optimisation of regulatory helpdesk, including dedicated CTIS support, to support non-commercial sponsors in conducting more (multinational) clinical trials
- Involvement of academia in the MSP Advisory Group

MSP Advisory Group

- 1 **Regulator Co-chair** rotated within ACT EU
- 1 **Stakeholder Co-chair** selected amongst MSP AG non-commercial representatives and agreed by ACT EU Steering Group (SG)

20 permanent stakeholder representatives
appointed via public call from organisations of:

- industry EU trade
- patients/consumers
- healthcare professionals
- academia and funders

- First MSP AG meeting with both chairs on 4 July
- MSP annual meeting planned 22 October, broadcasted
- Input collected considered in revision of ACT EU workplan

- ACT EU regulatory partners
- 2 Ethics Committee representatives
- Ad hoc participation of other experts (HTA, ACT EU Priority Actions, payers, international authorities)

More information on the ACT EU website:
Multi-stakeholder platform

Consolidated advice pilots

1. SAWP/CTCG scientific advice pilot
2. Pre-CTA regulatory/ administrative pilot

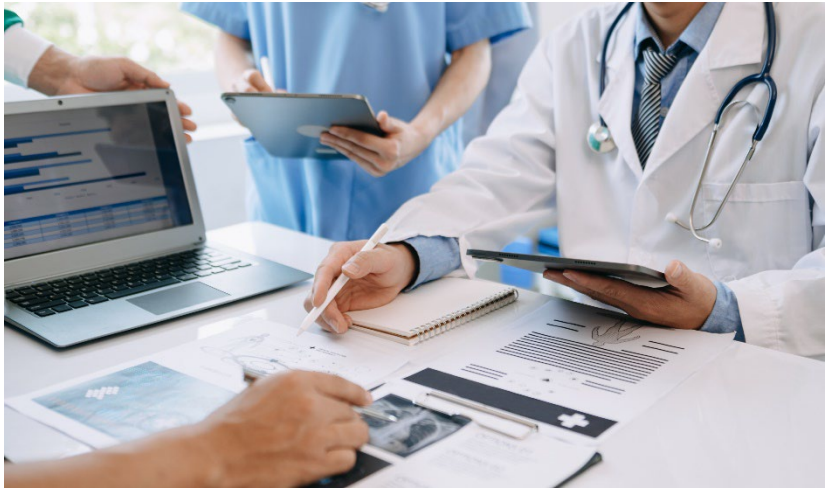
Improved quality of applications; improved EU environment for clinical trials

Consolidated advice for sponsors clarifying the landscape

Increased network coordination & efficiency

Launched in June 2024

8 applications already received



In line with ACT EU's vision, aiming to benefit patients and healthcare in the region.

Learn how to apply:
Consolidated advice on clinical trials

Thank you
for your
attention!