ACT EU and CTIS update

Industry Standing Group (ISG) meeting, 26 June 2023

Presented by Peter Arlett, Data Analytics and Methods Task Force

ACT EU 2023 focus

- Reinforced focus on successful **implementation of the Clinical Trials Regulation**, including use of Clinical Trials Information System (CTIS): change management including stakeholder engagement, surveys, training, communication
- Launch a scheme to **support academic sponsors** conducting large multi-national clinical trials
- **Creation of the Multi-stakeholder platform**
  - A sustainable platform that enables all stakeholders to collaborate for better clinical trials
  - Kick-off meeting: **22-23 June 2023**
- **Revise workplan** informed by learnings and Network needs and priorities (CTR)
  - Incorporate actions to enable CTs in public health emergencies

ACT EU Key updates

Successful implementation CTR

KPI report revamp – work in progress

Survey for sponsors – September 2023

Transparency rules and Transition Trials

ICH E6 (R3) public consultation

13-14 July

ACT EU PA04 - Multi-stakeholder Workshop on ICH E6 R3 - Public Consultation

ACT EU website

Q3 2023

Clinical trials data analytics

Multi-stakeholder workshop

October 2023

Methodologies

Multi-stakeholder workshop

November 2023

Successful launch of MSP

Recoding to be made available

The kick-off meeting on 22-23 June offered participants the opportunity to:

- **understand different stakeholder perspectives** on how to transform the EU environment for clinical trials,
- take stock of **ACT EU activities**,
- shape the **plans and priorities** for the multi-stakeholder platform,
- **discuss** those topics which are most relevant to stakeholders at present such as:
  - the implementation of the **Clinical Trials Regulation**, including transparency aspects;
  - the coordination between **scientific advice and clinical trial approval**.

ICH E6 (R3) 13-14 July

Hybrid Event

Multi-stakeholder workshop on ICH E6 R3 public consultation

13 July (live broadcast)

- Rapporteur and Regulatory Chair of the ICH E6 R3 Expert Working Group (EWG), in-depth presentations
- principles of ICH E6 R3 and Annex I, panel discussions with relevant stakeholders and multiple Q&A sessions.

14 July

- Breakout sessions l not publicly broadcast l pre-registration required.

Clinical trials data analytics

Problem statement

- Need to understand which trial designs are successful in terms of:
  - Generating good evidence
  - Support of down-stream decision-makers
- Planning of trials currently not fully informed by historical experience.

Opportunities

- Provide access to and support analysis of clinical trials data
- Capitalise on technological developments in *advanced analytics* (i.e., machine learning, AI, NLP)
- Publish a research agenda to stimulate collaborative research

Potential impact

CT analytics workshop to identify research priorities

For our stakeholders:

- Increase R&D efficiency in the EU: inform public funding and private investment
- Inform decision-making on new and authorized medicines

For the EMRN:

- Track the impact of guidelines or scientific advice (PA7 and PA8)
- Create a common understanding around the impact of the CTR (PA2)

Get better medicines to patients faster

Methodologies Workshop November 2023

Hybrid Event

Deliver on the vision of Priority Action 8:

"To facilitate aligned clinical trial guidance development across our European network resulting in high impact guidance documents implemented in practice"

Multi-stakeholder focus:

- Discussion of key topics
- Identification of guidance needs and scopes

EMRN focus:

- Creating mutual awareness of guidance activities
- Alignment and consolidation of guidance development processes

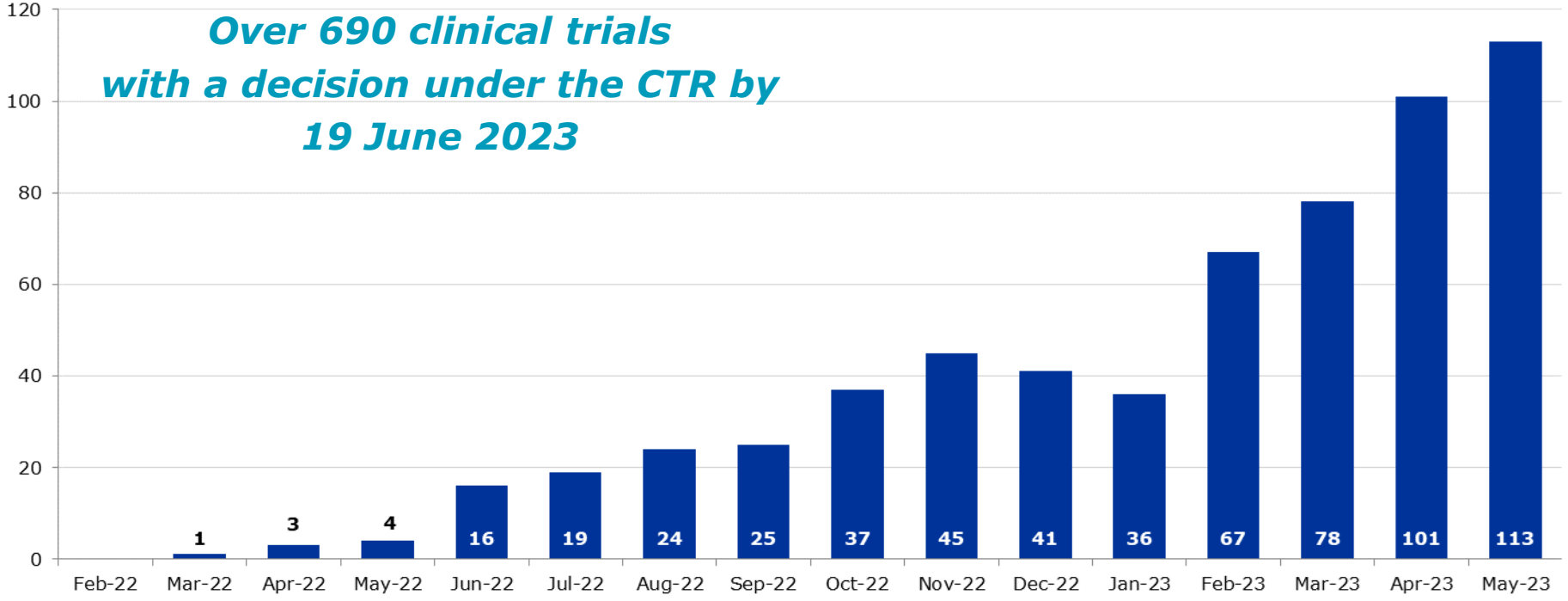
CTIS update

- Since 31 January 2023, **CTIS mandatory for all CT applications**
- Over 890 initial clinical trial applications submitted since 31 January 2023: submissions increasing
- Ongoing collaboration to support users and improve CTIS
- CTIS is now a registered data provider for WHO's International Clinical Trials Registry Platform

For more information on recent CTIS improvements, see Release Notes and Known Issues:
Website outages and system releases - EMA (euclinicaltrials.eu)

Clinical Trials with a decision* in CTIS per month

(*authorised and not-authorised)



Reinforced transparency and stakeholder engagement

Regular Communications

- CTIS Newsflash *to 10.000+ CTIS users* - link
- Clinical Trials Highlights Newsletter - *next in July 2023* – link

Regular Events

- CTIS Walk-in Clinics - link
- Bitesize talks - link
- Quarterly CTIS Forum with Stakeholders
- CTIS Info event on 4 July 2023 - link

Trainings & related materials

- Sponsor end user trainings - *next in June 2023* – link
- Interim guidance document & annex on current transparency rules - link
- *Revised* Q&A on protection of personal data & CCI in CTIS version 1.2 – link
- CTIS Training environment – survey link to request access

Open consultation on CTIS transparency rules launched, concluding on 28 June 2023.

Transitioning trials from CTD to CTR/CTIS

- **By 30 January 2025**, any ongoing trials under the Clinical Trials Directive will need to be transferred to CTIS and approved
- Sponsors have already submitted over 180 transitional trials in CTIS
- CTIS webinar on 4 July 2023 on 2nd year of transition, focusing on transitional trials
- More information on transitional trials:
  - Module 23 of the CTIS online training programme
  - CTCG's best practice guide for multinational sponsors of transitional trials

CTIS Service Desk move to ServiceNow from 31 July 2023

- CTIS User Support Service to move from Jira to ServiceNow:
  - Industry best practice
  - More user-oriented service
- ServiceNow will be accessible via a link (starting 31 July) and via a mobile app
- Training material and information for end-users available here
- More details in upcoming communications in CTIS Newsflash, CT Highlights Newsletter, CTIS website support page

Key messages

- ACT EU Focus in 2023: supporting CTR, academic CTs and the multi-stakeholder platform (MSP)
- Over 500 stakeholders participated in the kick-off meeting of the MSP
- Over 890 initial CTs submitted in CTIS since 31 January 2023: submissions increasing
- CTIS now a data provider for WHO
- Intensified communication and stakeholder engagement via publications, open consultations and public events/workshops

Any questions?

Further information

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