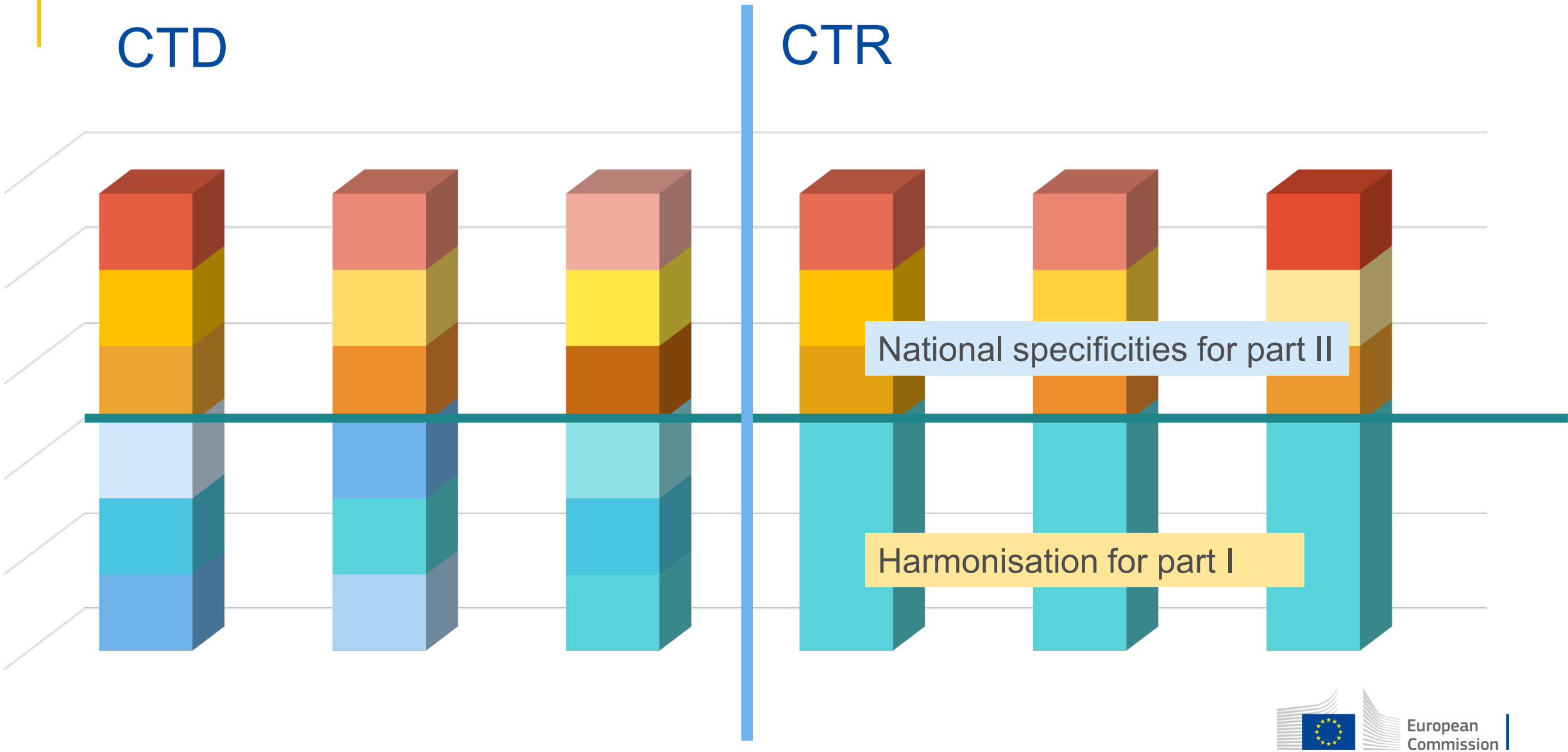
Clinical Trial Regulation:
Implementation tasks for the European Commission

ACT EU Multistakeholder platform

EMA workshop 22 – 23 June 2023

CTR: a new legal framework



European Commission

Delegated and implementing acts

- Implementing Regulation (EU) 2017/556 of 24 March 2017 on detailed arrangements for the good clinical practice inspection procedure
- Commission Delegated Regulation (EU) 2017/1569 specifies principles and guidelines for good manufacturing practice for investigational medicinal products and arrangements for inspections
- Commission Implementing Regulation (EU) 2022/20 setting up the rules and procedures for the cooperation of the Member States in safety assessment of clinical trials, became applicable on 31/1/2022.
- Commission Delegated Regulation (EU) 2022/2239 as regards labelling requirements for unauthorised investigational medicinal products

Done

European Commission

Guidance on the CTR application: the Q&A document

- Under EUDRALEX Volume 10 - The rules governing medicinal products in the European Union
- Version 6.4, CTEG consulted, CTAG endorsed.
  - Annex II: Language requirements for part I documents
  - Annex III: Part II documentation - where sponsors can find national requirements
- Size:
  - 127 pages, 162 with annexes
  - 527 paragraphs
  - 12 chapters

European Commission

National competent authorities, ethics committee
EMA (CTIS helpdesk, Product Ownner Expert Group, ACT EU)

Escalate if horizontal issue

CTCG
Best practices
Roundtable of assessors

Escale if not solved by best practices

CTAG / CTEG

Amend Q&A

From the CTR provision to CTIS functionality

REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 April 2014

on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

(Text with EEA relevance)

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

This Regulation applies to all clinical trials conducted in the Union.

It does not apply to non-interventional studies.

Article 2

Definitions

13) 'Substantial modification' means any change to any aspect of the clinical trial which is made after notification of a decision referred to in Articles 8, 14, 19, 20 or 23 and which is likely to have a substantial impact on the safety or rights of the subjects or on the reliability and robustness of the ~~data generated~~ in the clinical trial;

Example:

CTR – Article 2

Definition of substantial modification

European Commission

Q&A – procedures and conditions

February 2023

The rules governing medicinal products in the European Union
VOLUME 10 - Guidance documents applying to clinical trials

CLINICAL TRIALS REGULATION (EU) NO 536/201

QUESTIONS & ANSWERS

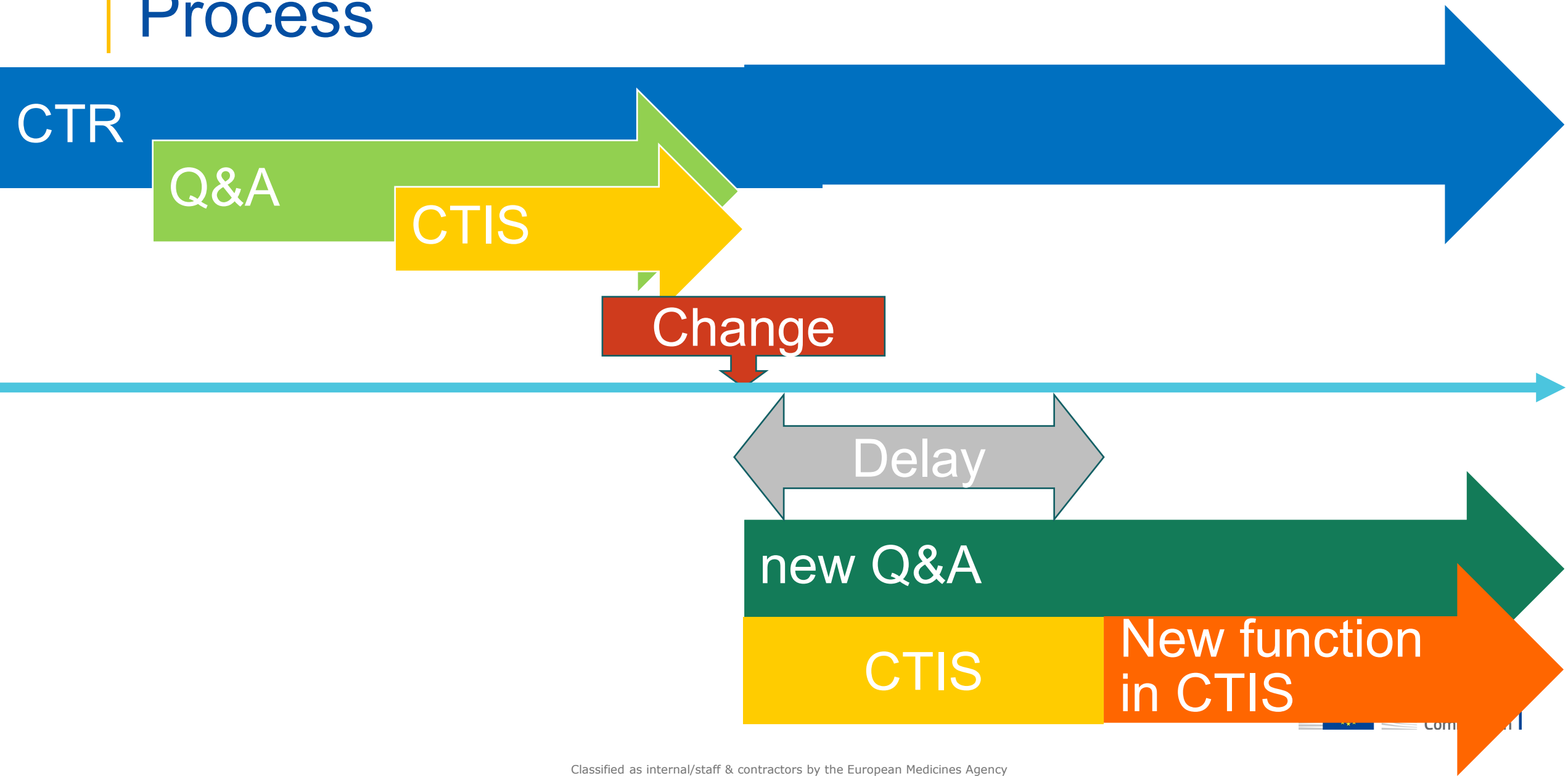
VERSION 6.

Submitted for discussion to the Expert C… al Trials and through written procedure to the Clinical T… ion and Advisory Group

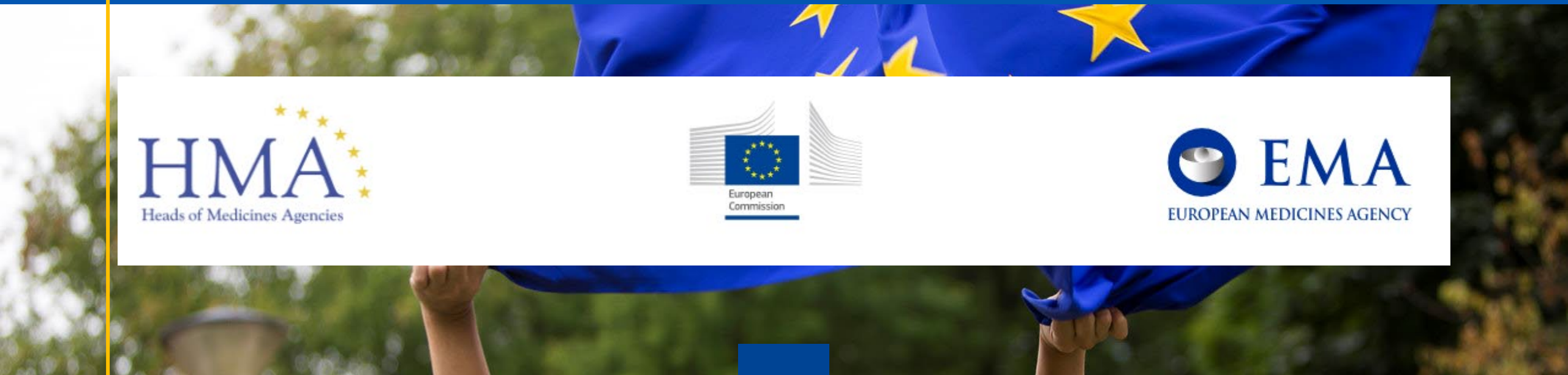
Regularly updated

CTIS

Process



EU Survey on the implementation of the Clinical Trials Regulation



Survey on the implementation of the Clinical Trials Regulation – round 1

Survey run between 18 July and 9 September 2022 from commercial and non-commercial sponsors

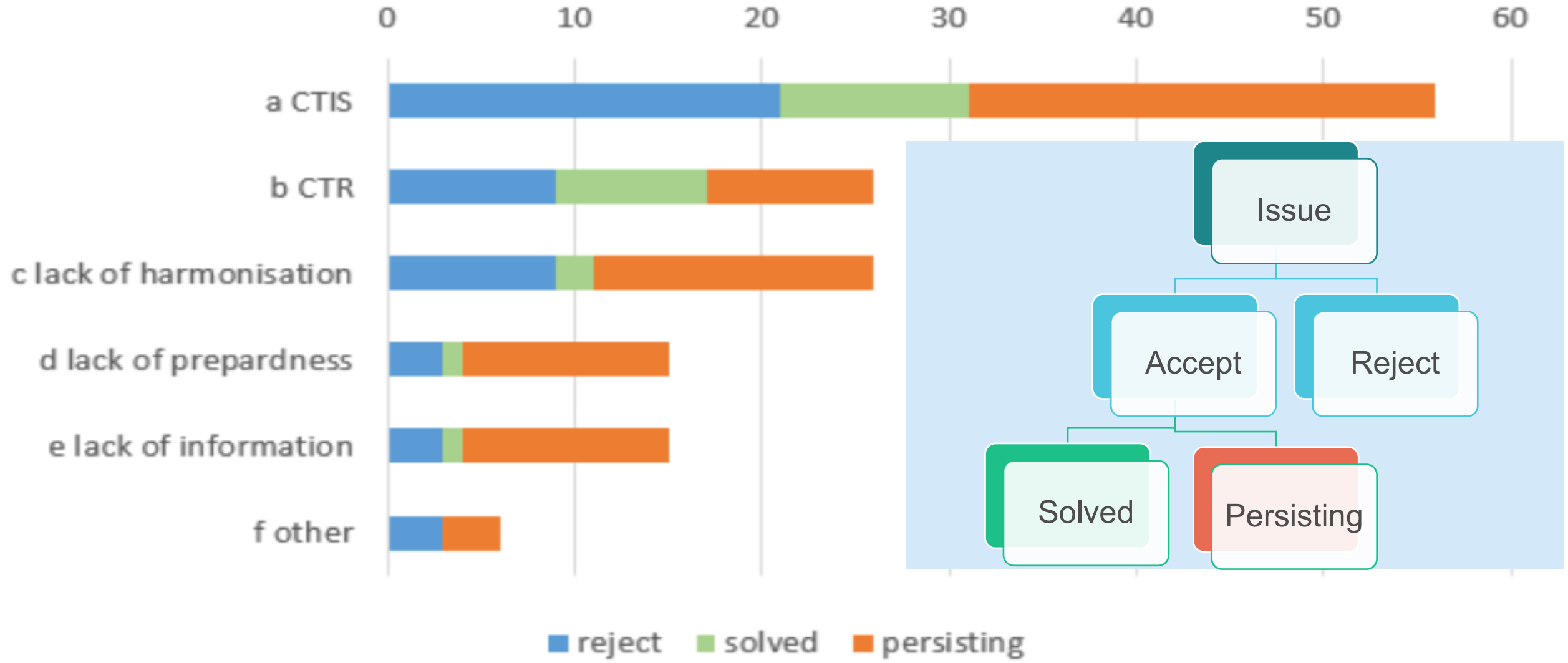
CTIS: difficult to use, bugs, lack of functionalities

CTR: difficult to cope with the deadlines for RFIs, with new provisions on transparency

Lack of preparedness of certain MS: (use of CTIS, national legislation not yet aligned

Lack of harmonization: additional requirements out of the scope of the CTR, guidelines not followed

Survey on the implementation of the CTR - Identification and screening of comments



Solutions provided by:

EMA - CTIS

- CTIS releases
- Guidance revision and production (Q&A on transparency)
- Revision of the rules on transparency

CTAG and CTEG

- Guidance revision and production (Q&A)
- List of web link to national contact for specific requirements
- Clarification of language requirements

CTCG

- Enhanced Member States coordination and cooperation
- Assessor roundtable, Ethics Committee forum
- Guidance revision and production (Best practices documents)

Commission / Member States

- Commission structured dialogue with Member States to ensure full alignment of national rules with the CTR

Survey on the implementation of the Clinical Trials Regulation - second round

Objectives

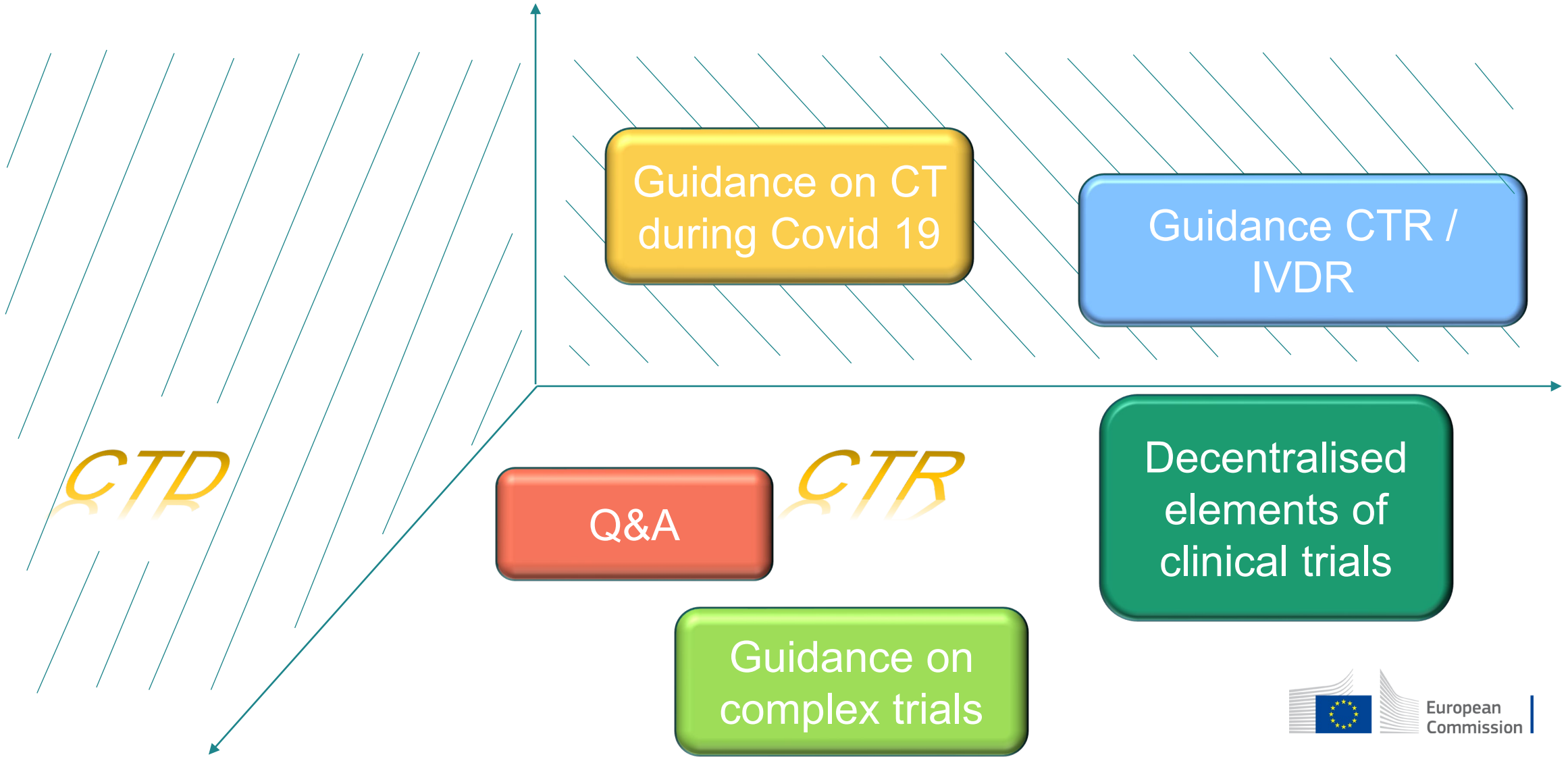
- To understand the remaining hurdles that hamper:
  - a smooth **implementation** of the CTR
  - a smooth **transition** of the clinical trials from EudraCT to CTIS
  - **CTIS** user friendliness
- To measure the **progress** achieved since the last survey

Deadline for responses: 30 September 2023

Duration: 3 weeks

European Commission

CTR framework



European Commission

THE LANCET

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Decentralised elements in clinical trials: recommendations from the European Medicines Regulatory Network

Monique Al • Solange Levison • Wolfgang E Berdel ✉ • Ditte Zerlang Andersen •

for the Decentralised Clinical Trials Task Force

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European Commission

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