Facilitating the Translation of Academic Research into Clinical Practice – How to Move Forward

The EU CTR and academic research

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STARS Global Conference

Excellence in Regulatory Science

Clinical Trial Regulation 536/2014 (CTR)

- The CTR was **published in May 2014.** Its aim was to correct the shortcomings of the existing clinical trials directive (CTD) and to foster research in the EU while maintaining a high level of protection for participants
- It became **applicable on 31/1/2022** but is **optional** for one year
- After 31/1/2023, **every new clinical trial** will need to be submitted and authorised under the CTR
- The CTR allows that **trials authorised under the CTD continue until 31/1/2025**, after which they need to be transitioned to the CTR **if still ongoing**.

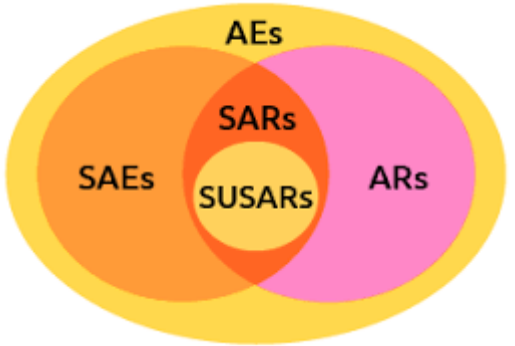
Objective: competitive research

1. Streamlining of the Clinical Trial Authorisation process :
   - **One submission** to all Member States concerned by a given trial of a **harmonised application** through a **single online interface (clinical trial information system – CTIS)** with maximum timelines
   - **Joint assessment** lead by a Reporting Member State between **Member States** of the "scientific" part of the application, and **coordination within a Member State** on assessment and decision making (roles in scientifical and ethical assessment to be defined by each Member State)
   - **Single decision** per Member State
2. New concepts and risk-based approaches

Objective: participants rights and safety

1. Coordinated safety assessment through work-sharing and streamlined safety reporting (no more national reporting of SUSARs)

2. Strengthened rules on the protection of patients and informed consent, specific modalities on cluster trials



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Objective : transparency

1. Transparency as a baseline – everything in CTIS is publicly available, provided exceptions (CCI, personal data, internal MS processes).

2. Additional information on the status of a trial in a given MS

3. Obligations for result reporting within set timelines, and specific reporting for laymen.

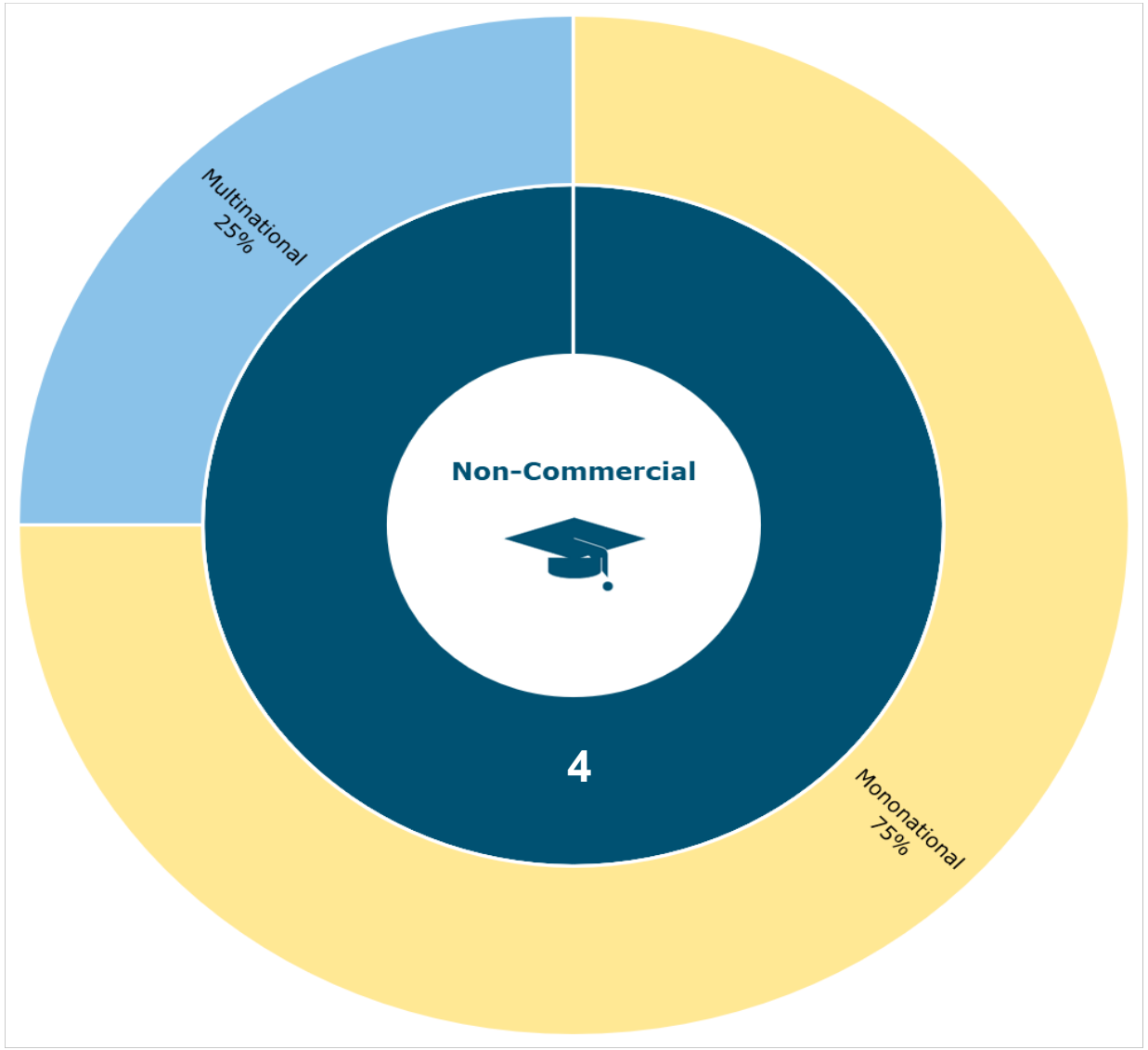
What is in it for academic research ?

1. Harmonisation of processes
2. Facilitation of multinational research in the EU

3. One stop shop to submit (CTIS) – includes training
4. Specific concepts (e.g. low-intervention trials, damage compensation, safety reporting)

5. Fee reductions for submissions and inspections – up to MS

Authorised trials in CTR (cut-off 01/05/2022)



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The bigger picture…

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Pharmaceutical Strategy for Europe

{SWD(2020) 286 final}

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