A brighter future for clinical trials in the EU: continuing the journey

Current CTR challenges

National Requirements

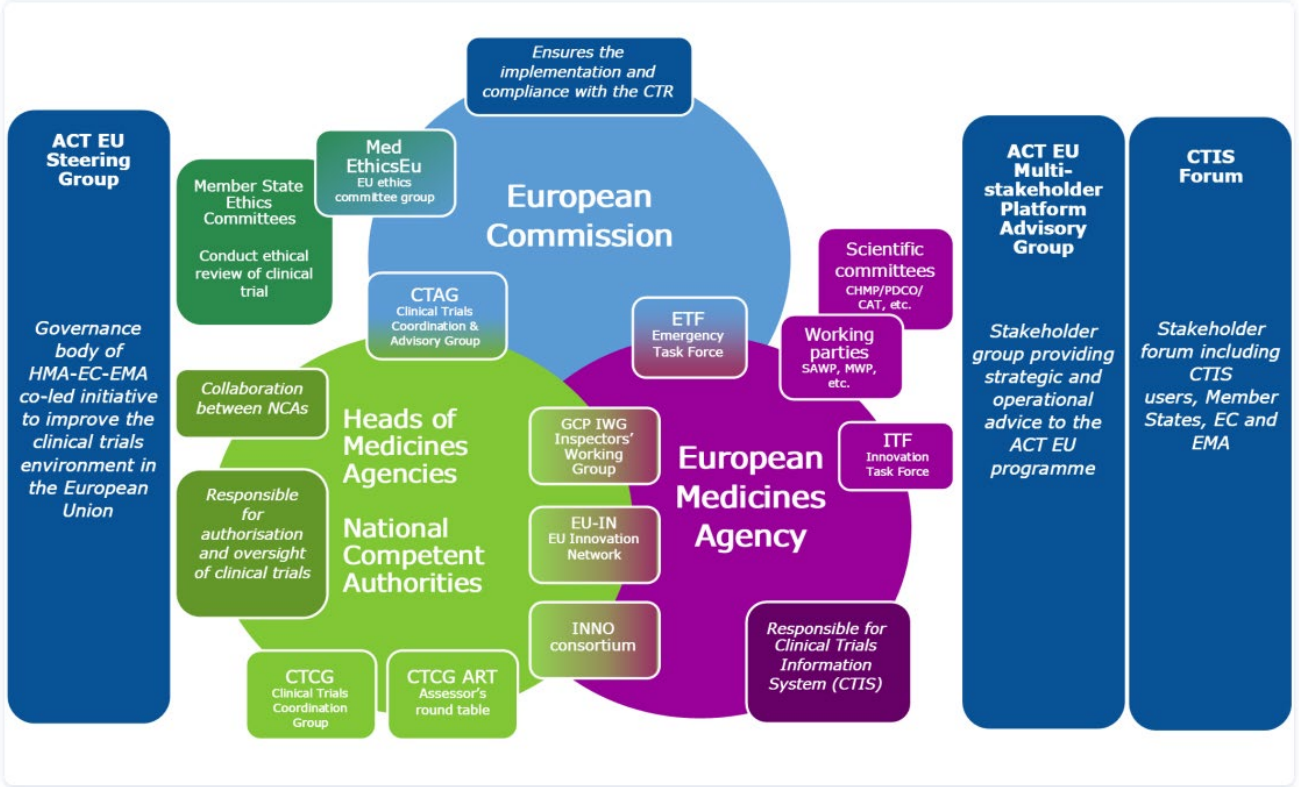
- Current variation in national requirements across member states complicates the process.
- This results in bespoke applications for each member state (MS), increasing administrative burden.

Lack of Harmonisation

- Multiple RFIs (requests for information) and approval conditions create unpredictable outcomes.
- Inconsistent use of RMS and reliance on previous assessments slow down trial approval.

Inflexibility of the Process and CTR

- Difficulties in running innovative trials due to no flexibility for minor changes or parallel reviews.
- CTIS workarounds and rigid communication channels impede efficient trial management.



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CTR (harmonised) implementation

- Role of the RMS
- Improved integration of CTIS
- Amendments
- Ethics committee integration

Scientific Advice & Training

- Sustained access to SA
- Specialised/coordinated training for industry and within the network (assessors, sites etc.)

Increased CT awareness

- Lack of public information on ongoing trials available for recruitment is an issue
- Integrate CTs into standard healthcare across Europe

Regulatory interface CTR-MDR-IVDR

- Harmonised submission processes and better coordination between various EU regulations including CTR, MDR, IVDR, GDPR and national laws