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Regulatory initiatives: national and European aspects

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Transition to CTR 536/2014



NCA support: national level

- CT safety assessor + backups
- New Ethics committee
 - Administrative support
 - Regular joint meetings
- Trainings for commercial and non-commercial sponsors
 - Webinars
 - SAM web page
- Medical devices
 - Collaboration
 - Merging into SAM from 2025

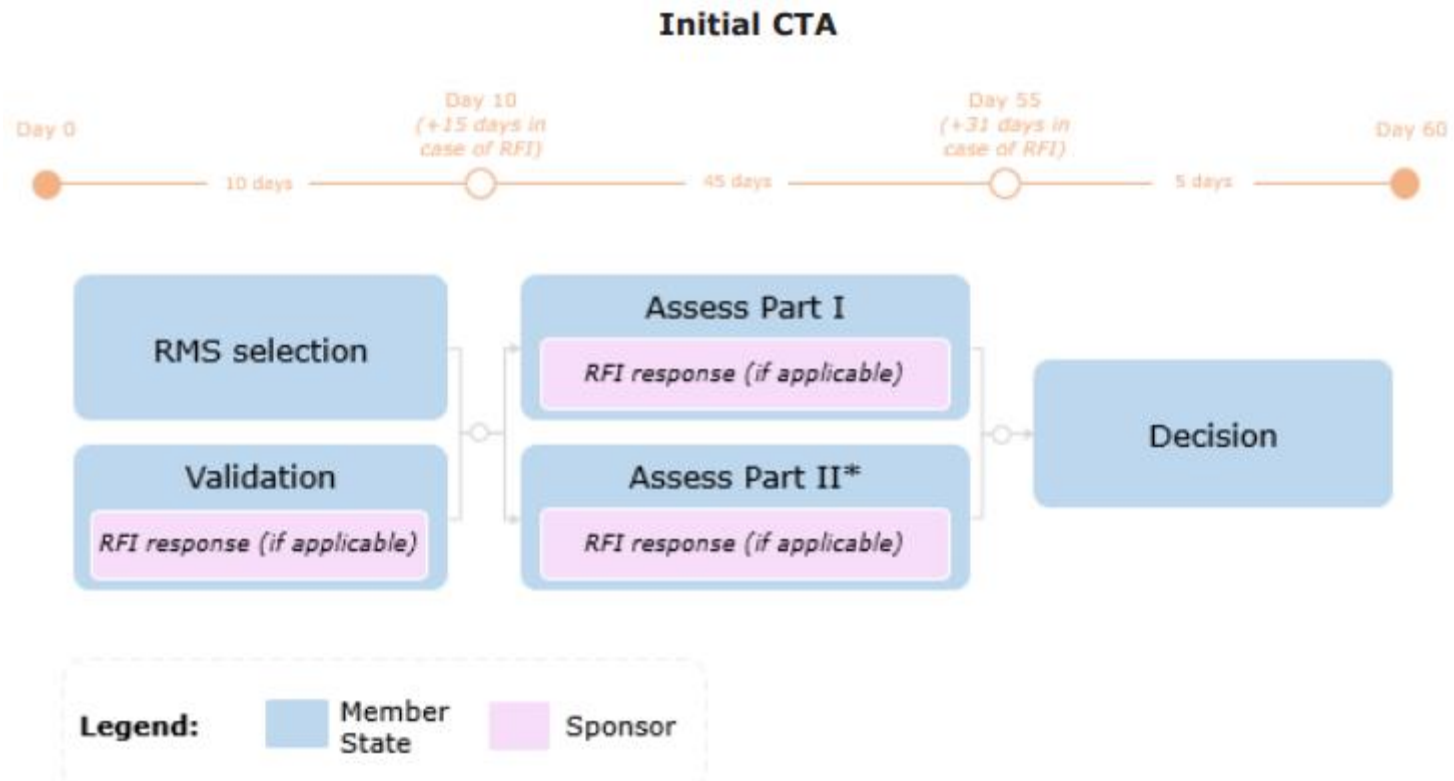
Estonian law

- Medicinal Products Act
- Health Insurance Act
- Academic clinical trials:
 - (7) The Health Insurance Fund has the right of recourse against the sponsor of the scientific research where the insured person's need for the health insurance benefit stems from participation in scientific research, unless it is a clinical trial or a performance study of a medicinal product or device and the sponsor is exempt from the professional assessment remuneration under subsection 3 of § 997 of the Medicinal Products Act.
 - (3) The State Agency of Medicines exempts the sponsor from the obligation to pay the specialised assessment fee where all of the following criteria are met:
 - 1) the sponsor has submitted a respective application;
 - 2) the sponsor of the clinical trial of the medicinal product is a health service provider holding a valid activity licence, an independent research institution or a professional organisation of doctors;
 - 3) a person or institution specified in clause 2 of this subsection does not receive any financial or other remuneration from the manufacturer of the medicinal product or from a representative thereof.

National scientific advice

- Launch March 2024
- Chemical/biological/pharmaceutical, preclinical and/or clinical development
- Selected therapeutic areas (anaesthesiology, immunology, blood products, cardiology/cardiovascular, diabetes, haematology, oncology)

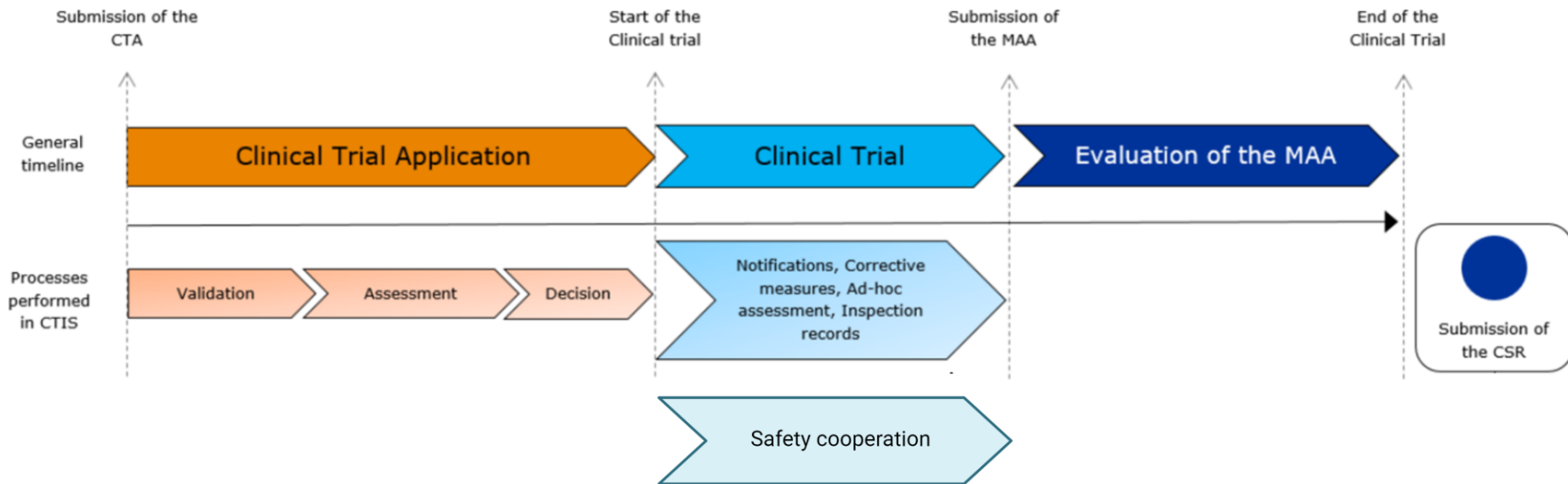
New principles in CT assessment



NCA support: EU level

- ACT EU
 - 10 priority actions
- SAFE-CT
 - Safety assessment cooperation between NCAs (new requirement set out by the regulation)
- CT-CURE
- CTCG, CTAG
- Pre-CTA SA, SNSA
- MedEthicsEU
 - 15 Feb 2024
- Best practice guideline development

CTR → harmonized approach in assessing CTs





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