Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Stakeholder Engagement Meeting 16th Nov 2017

Overview of the Regulation

New simplified approval procedure

- Single EU Portal & Database
- Single dossier and single submission
- Sponsor nominated Reporting MS
- Coordinated assessment for multi-state clinical trials
  - Part I – joint assessment by all concerned MS
  - Part II – National assessment only (R&D offices and Ethics Committee)
- Clear timelines, concept of tacit approval

Overview of the Regulation

- Risk-based approach to trial authorisation and management.
- Simplified safety reporting, new EU safety databases
- Introduction of rules for emergency clinical trials, co-sponsorship and serious breaches.
- Increased transparency (registry, results; dbase publically accessible)
- Commission inspection powers

CTD→CTR

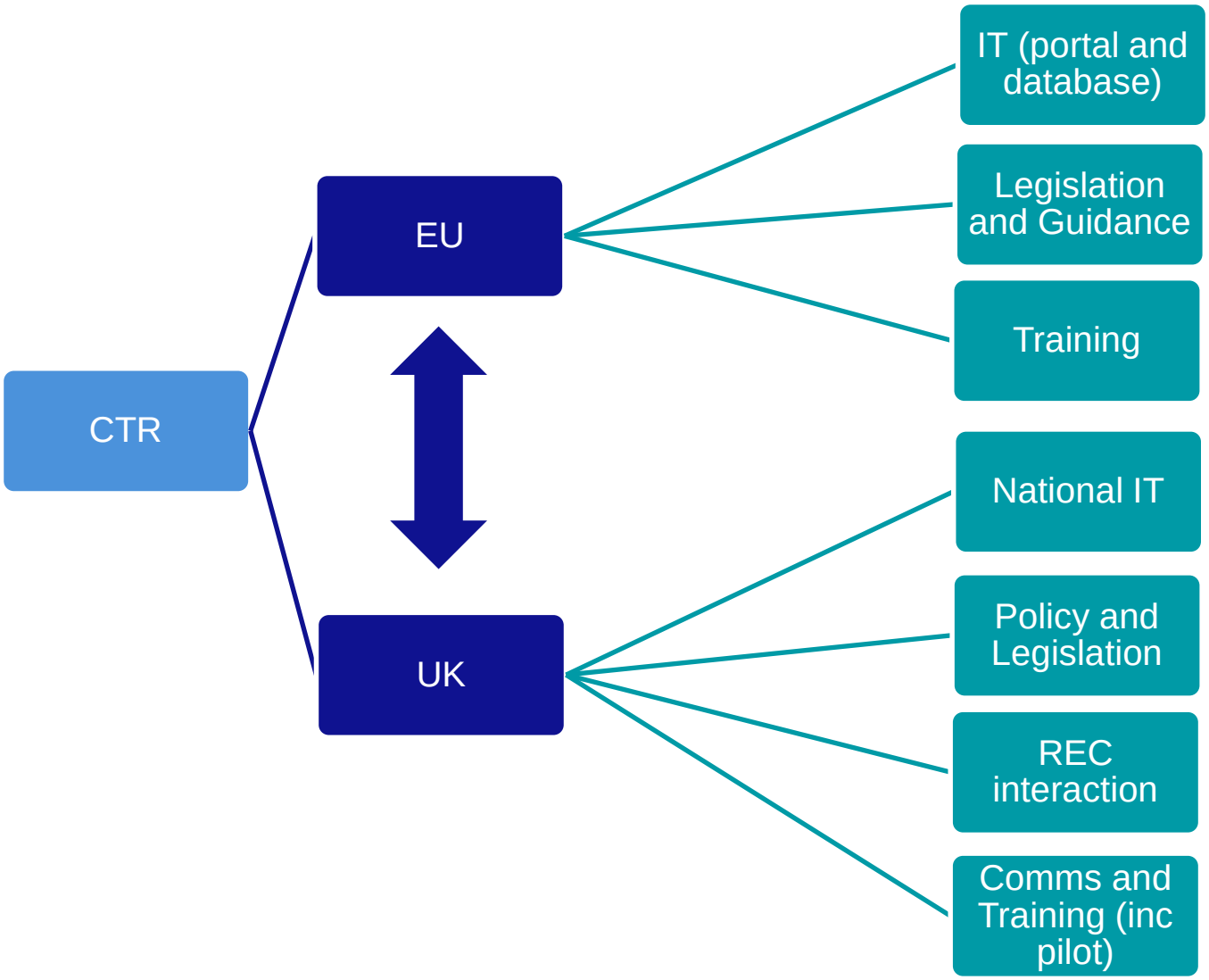
Apr 2014: EU Parliament and EU Council approve
May 2014: Published in Official Journal by Commission
Jun 2014: Entered into force
May 2016: Will apply “no earlier than…”
Dec 2017: Revised application date
Oct 2018: Revised application date
??? 2019: Revised application date

EU Portal & Database

Key Time points:

- Release 0.6 – UAT dates: 6 Nov - 27 Nov 2017
- Release 0.7 – UAT dates: end of Q1 2018
- Audit of the EU Portal and Database: Q2 2018
  - **The purpose of the audit is to confirm that the EU Portal and Database have achieved full functionality and the system meets the functional specifications which are defined**
- Release 0.8 – UAT dates: Q3 2018
- EMA MB to endorse the results of the audit
- EU Portal and database launch: 2019 (actual date to be six months after the notice referred to in Article 82(3) of the CT Regulation No.536/2014 is published)

Implementation



UK IT systems development

- Scope dependent on clarification on functionality of the system being developed by EMA, the extent to which we can interface with the EMA system and Brexit implications.

  - At minimum will manage national workflows and timelines at assessor level, performance metrics, co-assessment with ethics and communication to the applicant (eg upload to portal)

Interaction with ethics

- Ongoing meetings with HRA/DAs on developing policy, processes and responsibilities.
- High level agreement on which organisation assesses which aspects of Part 1 assessment.
- High level agreement on which organisation interacts with EU portal.
- Engagement of IT teams to explore solutions for UK part 1 co-assessment.
- Further discussions on detailed process mapping required.
- Developing a pilot co-assessment using Part 1 template.
- Recognise stakeholder value of MHRA expedited review for phase 1 studies. Aim is to maintain competitive timelines.

Coordinated assessment

- Major change will be movement from national only assessment to coordinated assessment of multi-state trials.

- Actively involved in Voluntary Harmonisation Procedure (VHP) for past few years to prepare for coordinated working
  - MHRA acts as RMS in about 35% of the VHP we take part in

- Trials will still be approved on a national basis (decision based on part 1 and part 2 assessment reports).

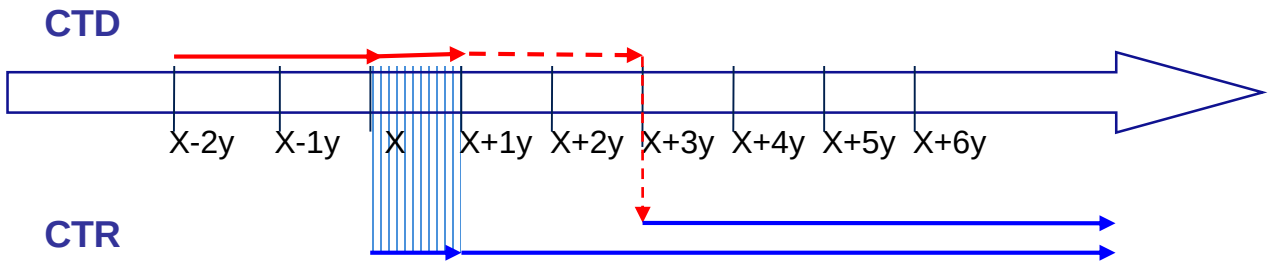
UK Policy and Legislation

- CTR text refers to: *Member States shall*… *Member States may*… …. *in accordance with national law*..

- Good progress being made on national legislation development – complicated by Brexit!
- Instructions sent to lawyers on a number of issues with input from MHRA, HRA, DAs, DH and other HMG Departments
- Still under discussion:
  - Who can take consent
  - Who can be an investigator
  - MIA(IMP) / GMP exemptions
  - Appeals process
  - Sanctions
  - Fees

Transition to the new CT System

Period 0: Before go live	Period 1: First 12 months	Period 2: Next 24 months	Period 3: From 3 years after go live
• Any CTA submitted at this time, is still governed by the old Directive until 3 years after go live	• A CTA ***may*** still be submitted in EudraCT and governed by the old Directive • A CTA ***may*** be submitted in the new EU portal and be governed by the new Regulation	• All initial CTAs ***must*** be submitted in the new EU portal and be governed by the new Regulation	• **All CT's are governed by the new Regulation,** regardless of their date of submission



Summary

Achievements

- EC delegated/implementing acts complete and published
- Guidance progressing well (4 published)
- Good interactions with ethics services
- Pilot of co-assessment with ethics progressing – hope for ‘live’ pilot by end of Q1 2018
- Communication plan established (UK wide)

Concerns

- Evident timelines are a challenge for EMA
- No end-to-end testing yet (Nov 2017)
- Some key functionalities planned for post-audit
- Total scope of national IT project therefore unclear
- Brexit uncertainty

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