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
<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td>Apr 2014:</td>
<td>EU Parliament and EU Council approve</td>
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<td>May 2014:</td>
<td>Published in Official Journal by Commission</td>
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<td>Jun 2014:</td>
<td>Entered into force</td>
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<td>May 2016:</td>
<td>Will apply “no earlier than…”</td>
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<td>Dec 2017:</td>
<td>Revised application date</td>
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<td>Oct 2018:</td>
<td>Revised application date</td>
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<td>??? 2019:</td>
<td>Revised application date</td>
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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

CTR

EU

IT (portal and database)
Legislation and Guidance
Training
National IT
Policy and Legislation
REC interaction
Comms and Training (inc pilot)

UK

CTR

EU
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**
- Any CTA submitted at this time, is still governed by the old Directive until 3 years after go live

**Period 1: First 12 months**
- 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

**Period 2: Next 24 months**
- All initial CTAs *must* be submitted in the new EU portal and be governed by the new Regulation

**Period 3: From 3 years after go live**
- 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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