Increasing the Speed and Efficiency of Clinical Research: An MHRA-HRA Coordinated Approach

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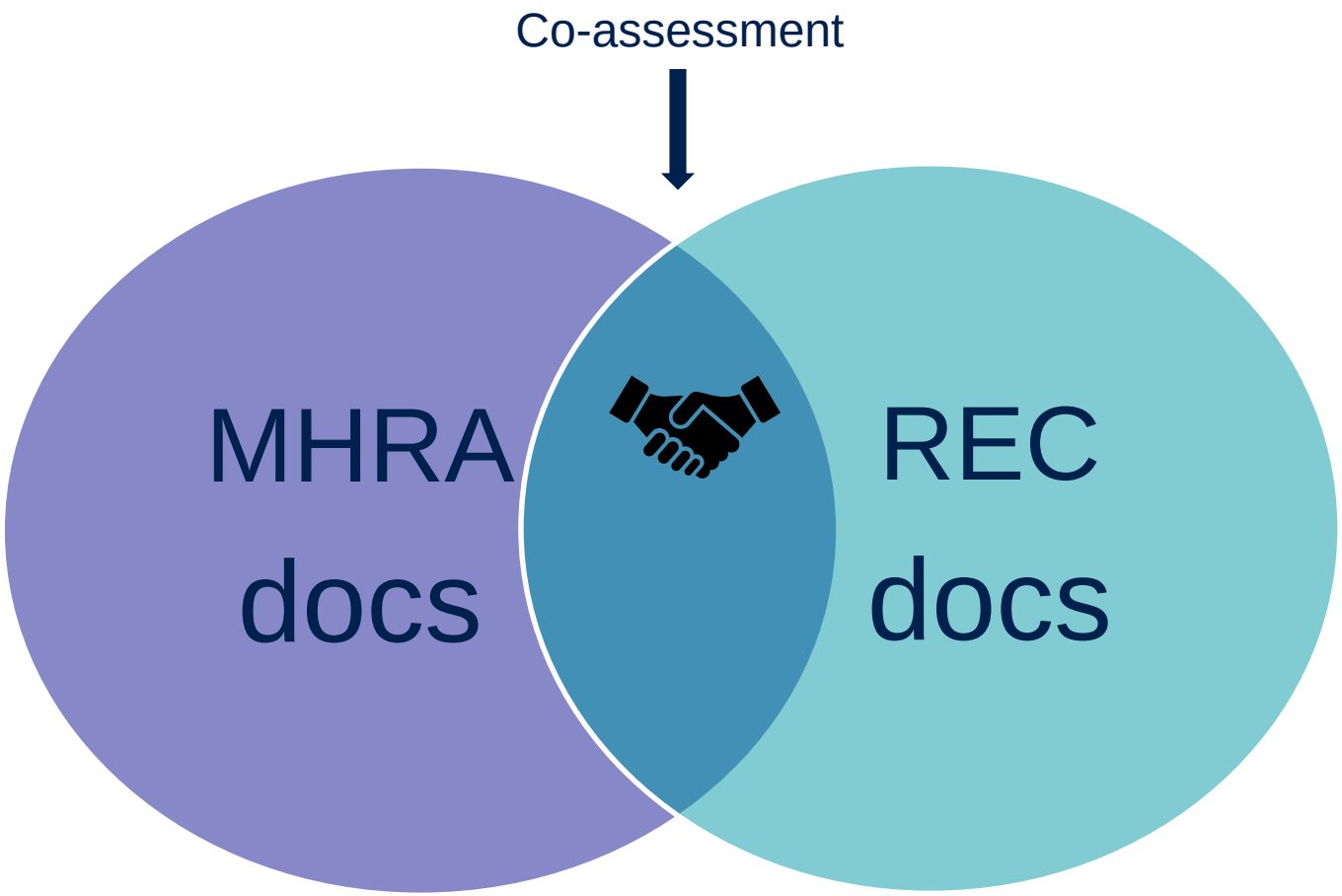
Combined Ways of Working (cWOW)

No matter what the outcome of negotiations, the UK is committed to offering a competitive service for clinical trial assessment.

https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal

Promoting increased collaboration between MHRA and the Health Research Authority to ensure balanced and risk-based regulation of clinical trials.



Exploring Combined Ways of Working

Aim to run a scheme that will test:

- a new process that will result in a single UK decision on a clinical trial (consisting of the current ethics opinion and MHRA clinical trial authorisation).
- a single clinical trial application route that incorporates both the Research Ethics Service and the MHRA regulatory centre
- The pilot is currently open to applications by prior agreement only, with the expectation that it will be opened up to all CTIMP applications as it develops.

Ultimately, we hope to discover, evidence and refine a combined way of working and the processes needed to enable this.

1. Submission and validation

- Submission package is submitted by the Sponsor via IRAS
- The package is retrieved by the CTU Support team and confirmation of receipt is sent
- Package is extracted to CTU SharePoint Team Site
- Submission is validated by the CTU support team and Ethics documents are updated to the HRA Hub

1. Submission

1. Cover letter
2. EudraCT form PDF and XML file
3. Protocol
4. Investigator’s Brochure (IB)
5. Documents relating to compliance with Good Manufacturing Practice (GMP) for the IMP
6. Investigational Medicinal Product Dossier (IMPD)
7. Auxiliary (I,e non-IMP) Medicinal Product Dossier
8. Scientific Advice and Paediatric Investigation Plan
9. Content of the labelling of the Investigational Medicinal Product
10. Recruitment arrangements
11. Subject information, informed consent form and informed consent procedure
12. Suitability of the investigator
13. Suitability of the facilities (For non NHS sites the SSI form to be submitted via IRAS)
14. Proof of insurance cover or indemnification
15. Financial and other arrangements
16. Proof that data will be processed in compliance with current data protection legislation.

2. Allocation & Assessment

- Allocation to assessors with a 30 day initial assessment timeline (but CTU assessment team have 14 days to assess)
- By Day 14, medical assessor uploads DAR to the Hub
- By Day 21, DAR will include REC input
- DAR consolidated by assessor
- By Day 28 – HRA will upload the Part 2 assessment and ethics opinion letter (approval/RFI) to the Hub

3. Request for Information (RFI)

By Day 30

- If no RFI 2x approval letters sent to sponsor. If RFI, CTU Support team will combine the RFI from MHRA and HRA for Part 1 assessment into a common letter.
- Email Part 1 and Part 2 RFI letters to named contact

- Sponsor has 14 days to respond to the list of RFI

- By Day 58, MHRA medic and REC agree position
- MHRA Medic to upload FAR to case folder
- HRA upload Part 2 decision to the Hub

4. Finalisation

- By Day 60 – CTU support team will email 2 decision letters (MHRA + HRA) to named contact

cWOW tracking spreadsheet updated throughout process to monitor performance.

MHRA/HRA Interaction in UK: Status

- Ongoing meetings with HRA/DAs on developing policy, processes and responsibilities.
- Agreement on which organisation assesses which aspects of joint assessment.
- Agreed process maps for new process.
- Building new IT including electronic workflow.
- Recognise stakeholder value of expedited review for phase 1 studies. Aim is to maintain competitive timelines.

Status of pilot

- Pilot launched in April 2018; First application 29th May 2018

51 Initials consisting of:

15 Phase 1 HVTs

36 Phase 2-4

37 Amendments consisting of:

11 Phase 1 HVTs

26 Phase 2-4

4 End of Trials

Timelines for Approved Applications – Initials

Validation:	0-3 days
Initial applications:	quickest 20 days
	average 51 days
Amendments:	quickest 2 days
	average 10 days

Some reflections

- At this stage a resource-heavy process! Need to develop national IT further to support scale-up

- Very good relationship with ethics coordinator body (HRA)
- “Journey” required for EC to move from ‘conversation’ with sponsors to GNA. Clear concise questions, review of responses with decision.
- Delay in receiving EC considerations after the meeting (writing minutes, sign-off etc)

- Mix of phases and sponsors (many CROs)
- Seeing value-added already; good sponsor feedback so far
- Fortnightly support call with stakeholders

Next steps

- Development of ‘new IRAS’ to support scale-up of the pilot
  - Will remain ‘by invitation’ until scale-up possible
- Implementation of new MHRA case management system
- Development of interface between MHRA and HRA case management systems to facilitate co-assessment
- ‘Live’ guidance document updated based on discussion in support calls
- Ongoing formal feedback gathering from applicants

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