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Combined Ways of Working: How UK Regulators are working together to streamline clinical trial approvals

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Reflections on day 1…

- Fast, flexible and integrated into frontline services

- Pragmatic, Preparedness, Pre-positioned

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Reflections on day 1…

- Fast, flexible and integrated into frontline services
- Pragmatic, Preparedness, Pre-positioned
- Ethics committees as barriers/challenges

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Scope of presentation

- Existing UK framework
  - Fast, flexible and integrated into frontline services
  - Advanced preparation
- Working together in the UK
- Future of clinical trial regulation in EU

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Advanced Preparation

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Advanced preparation – REC

- SOPs set out process for expedited review
- Established or ad hoc REC meeting
  - Have issued FO the same day
  - Important to be robust
    - The risk/benefit ratio may be different to standard clinical trials but still needs to be acceptable
    - Patients/participants still need to be protected
    - Methodology and statistics needs to be sound

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Advanced preparation - NHS

- NIHR – Clinical Research Network funded staff – aware of procedure
- Management teams – allocation of service support resources
- Expedited Research Lead – established role

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Advanced preparation - NHS

- Early CI and site identification
- Sleeper protocols
- Milestones for action and sign off measured in hours

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Working together

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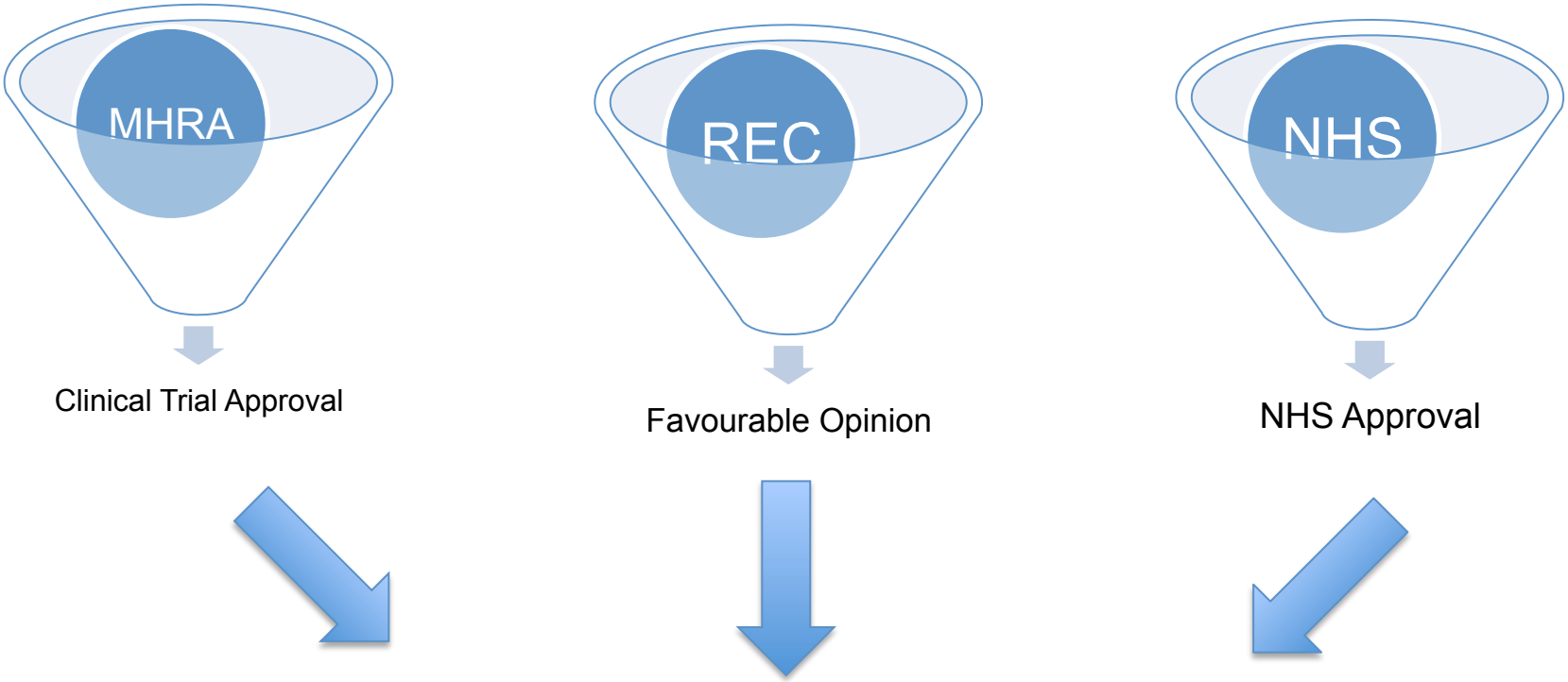
UK regulation of clinical trials

Getting the approvals in place!

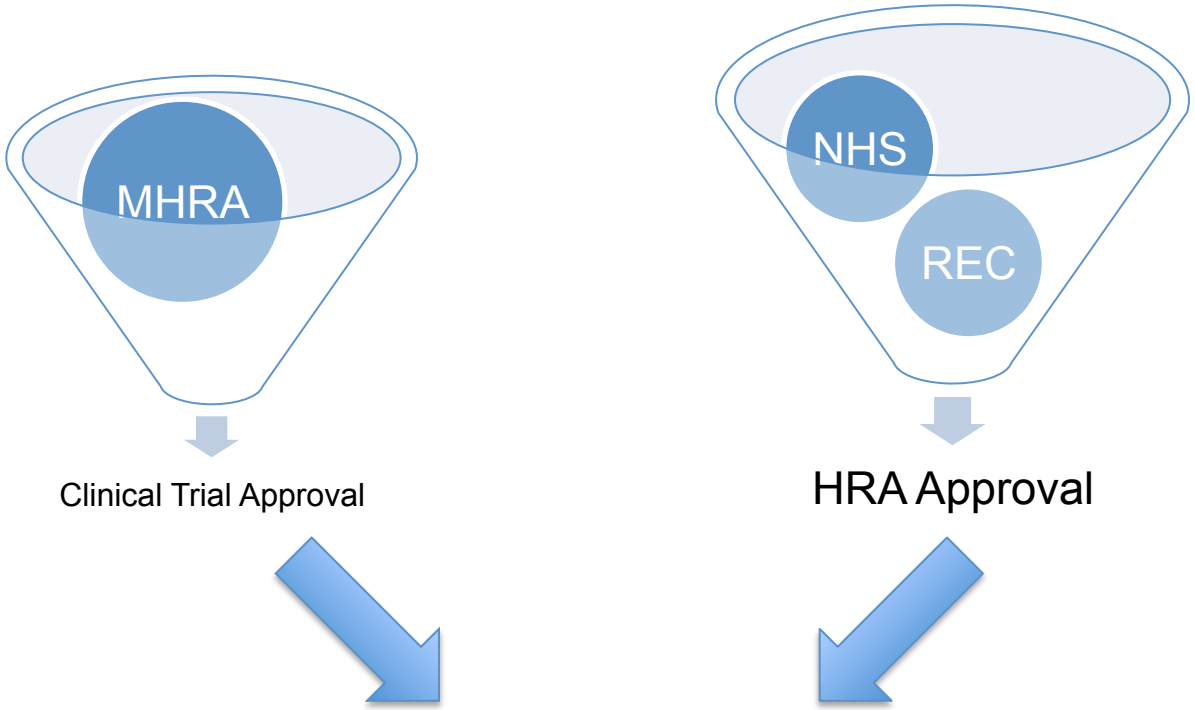
"Need to be fast and flexible"

- Competent Authority – MHRA
- Research Ethics Committee
- Governance approval (NHS)

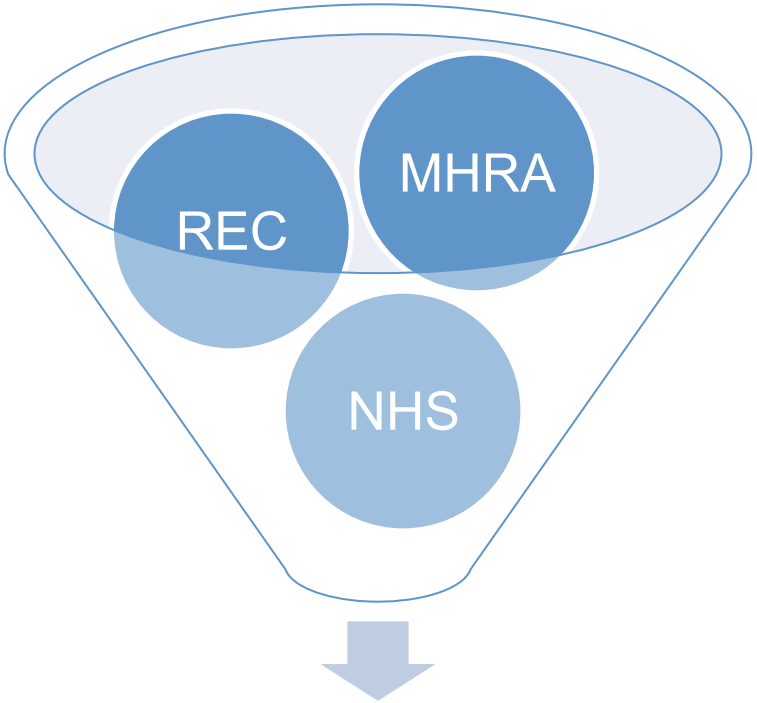
Previous Process



Current Process



Future process



Clinical Trial Approved

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Combined Ways of Working

- Single point of submission
  - IRAS
- Single validation
- Co-ordinated review
- Co-ordinated request for further information
- Single authorisation communication

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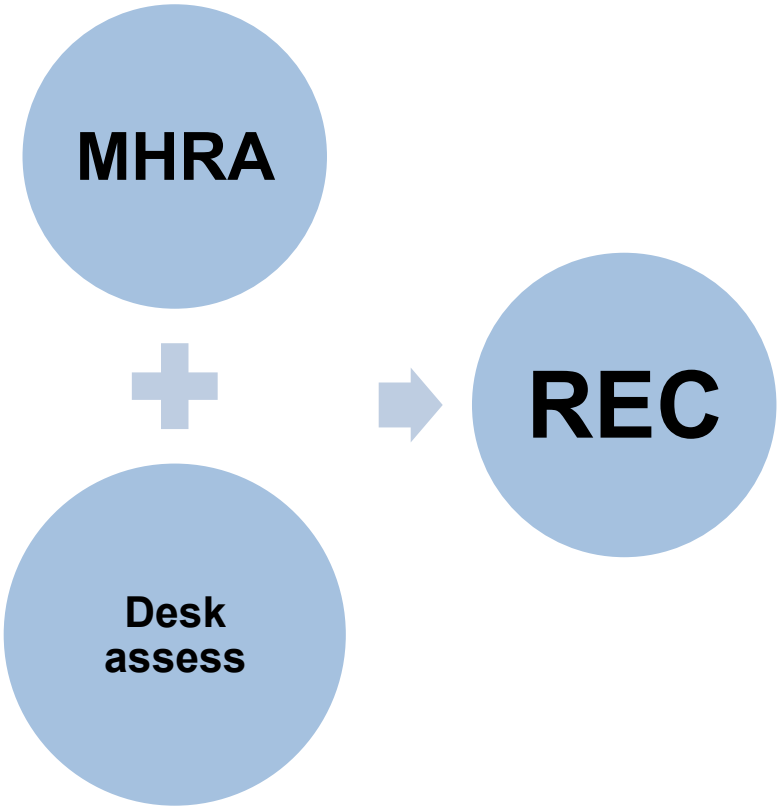
CWoW – Co-ordinated review

Desk assessment (NHS) =
HRA Approval (England)
HCRW Approval (Wales)
Study Wide Review (NI & Scotland)



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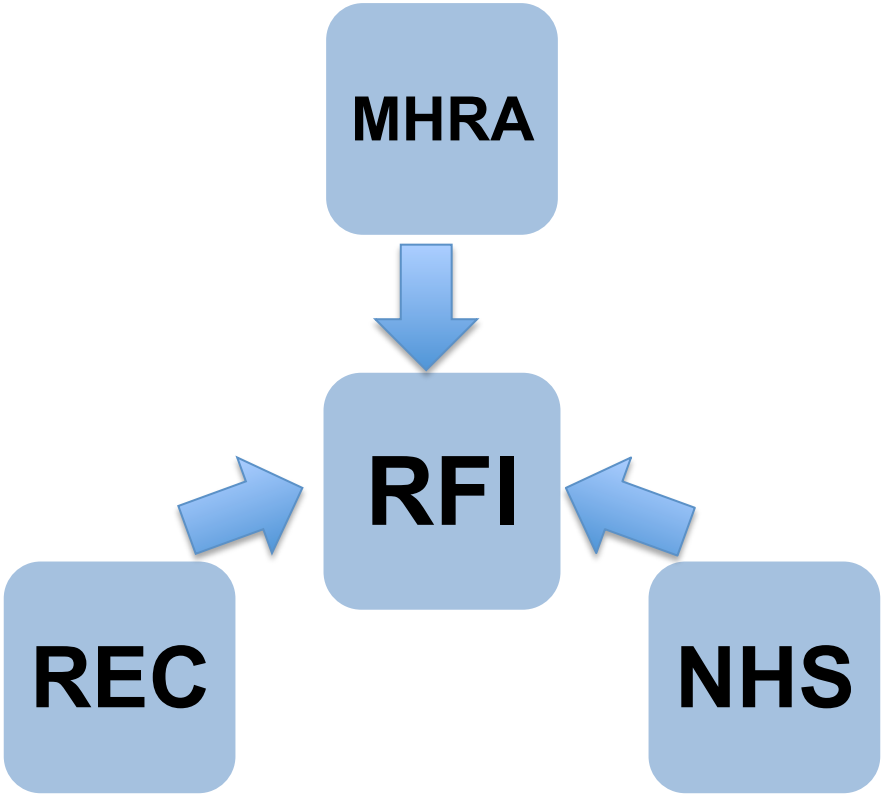
CWoW – Co-ordinated review



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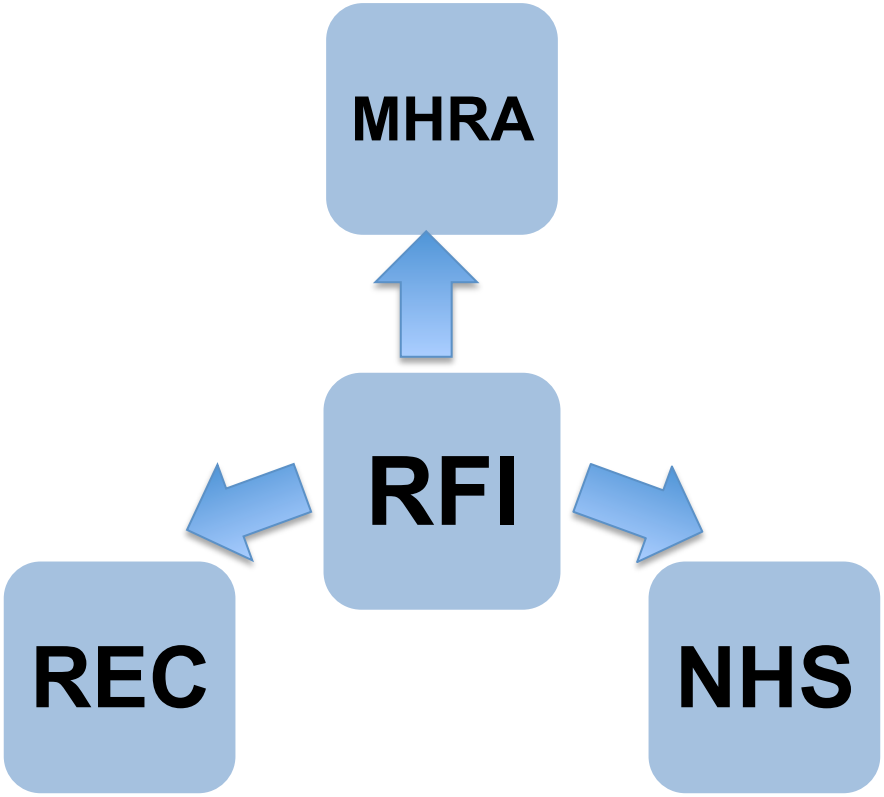
CWoW – Co-ordinated review



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Approvals quick but….

"Needs to be integrated into frontline services"

- Clinical Research Network
  - Research staff – right people, right place, right time
  - Resources
    - Radiology
    - Pharmacy

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Future of clinical trials in the EU

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EU Clinical Trial Regulation

- 2020+
- Harmonise clinical trial approvals and data transparency across EU
- Single EU protocol
- Single point of application
- Single application management portal

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EU Clinical Trials Regulation … Context

- Part 1
  - Single EU approval
  - Reporting MS leads review
  - Consolidation by Concerned MS
  - Safety / Risk / Benefit / Burden / IMP
- NCA & REC

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EU Clinical Trials Regulation … Context

- Part 2
  - Informed consent / recruitment / compensation / insurance / data / tissue / site & investigator suitability
  - MS specific approval
- REC & NHS governance

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EU Clinical Trial Regulation

"In the event of a public health crisis, Member States should have the possibility to assess and authorise a clinical trial application swiftly. No minimal timelines for approval should therefore be established."

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EU Clinical Trial Regulation

However……

- Dependent on national policy
  - Which will vary
- EU consolidation may limit overall timeframe?
- Still tbc…….

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