NHS
Health Research Authority

# EU CT Regulation: UK Research Ethics Service Preparation Work

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# Scope of presentation

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- Key information about the initial application and decision process
- Key impact for RECs
- Preparation and testing plan for next 18 months
- Next steps

# Background

- Expected to apply from 2019
  - Implementation date dependent on completion of EU Portal
  - Likely to be post Brexit
  - Consider ‘Deal’ and ‘No Deal’ scenarios

    Regardless of outcome – expect to align

# EU CT Regulation

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- Single Member State decision comprised of:
  - Part 1 (applies across all MS') - REC & MHRA (Article 6)
  - Part 2 ( MS specific) – REC & desk assessment (Article 7)

# EU CT Regulation

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- Part 1 (applies across all MS') - REC & MHRA (Article 6)

  - Anticipated benefits / risks / burdens
  - Suitability of population
  - Robustness of data (stats / design etc.)
  - Safety / risk minimisation
  - Compliance with Good Manufacturing Practice
  - Compliance with labelling requirements

# EU CT Regulation

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- Part 1 (applies across all MS') - REC & MHRA (Article 6)

  - Anticipated benefits / risks / burdens (REC)
  - Suitability of population (REC)
  - Robustness of data (stats / design etc.) (REC & MHRA)
  - Safety / risk minimisation (REC & MHRA)
  - Compliance with Good Manufacturing Practice (MHRA)
  - Compliance with labelling requirements (MHRA)

# EU CT Regulation

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- Part 2 ( MS specific) – REC & desk assessment (Article 7)
  - Informed consent
  - Payment
  - Recruitment
  - Compliance with data legislation
  - Suitability of investigator and site
  - Insurance and indemnity
  - Compliance with tissue legislation

# Key Impacts for RECs

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- No IRAS form for CTIMPs – ‘application dossier’
- Consolidation with MHRA of Part 1 assessment
  - single UK request for further information and output
- Completion of structure assessment forms
  - Forms agreed EU wide
- Timelines
  - Less flexibility as always require consolidation with MHRA and may require consolidation with other MS’

## 1) ADMINISTRATIVE INFORMATION

| | |
|---|---|
| EudraCT number | |
| Title of the study | |
| Name of sponsors | |
| IMPs (repeat for PR1, PR2.....) | **Substance (name/ code):**<br>**Marketing authorisation status (MA number, MS where authorised etc):**<br>**Modified in relation to MA:** |

| | |
|---|---|
| Has Part I been submitted prior to the submission of Part II? | Yes ☐ No ☐ |
| *IF Yes* | |
| Is there already a conclusion on part I? | Yes ☐ No ☐ |
| Is the CT already approved in any member state ? | Yes ☐ No ☐ |

## 2) GENERAL INFORMATION

| | |
|---|---|
| Is the CT a low-interventional trial?[1] | Yes ☐ No ☐ |
| First in man ☐, Phase I ☐, II ☐, III ☐, IV☐ NA☐ | |
| Is the CT a cluster trial[2] | Yes ☐ No ☐ |
| Is the CT intended to be performed in more than one member states? | Yes ☐ No ☐ |
| Does the CT involve more than one site in the concerned member states? | Yes ☐ No ☐ |
| Does the CT include healthy volunteers? | Yes ☐ No ☐ |
| Does the CT include female ? | Yes ☐ No ☐ |
| male? | Yes ☐ No ☐ |
| Age group | |
| Adults (18-64 years) | Yes ☐ No ☐ |
| Elderly (>= 65 years) | Yes ☐ No ☐ |

| | |
|---|---|
| Preterm Newborn Infants (up to gestational age < 37 weeks) | Yes ☐ No ☐ |
| Newborns (0-27 days) | Yes ☐ No ☐ |
| Infants and toddlers (28 days - 23 months) | Yes ☐ No ☐ |
| Children (2-11 years) | Yes ☐ No ☐ |
| Adolescents (12-17 years) | Yes ☐ No ☐ |

| | |
|---|---|
| Does the CT include vulnerable persons ? | Yes ☐ No ☐ |
| *If yes* | |
| Minors | Yes ☐ No ☐ |
| Incapacitated subjects | Yes ☐ No ☐ |
| Pregnant women | Yes ☐ No ☐ |
| Breastfeeding women | Yes ☐ No ☐ |
| Subjects in emergency situations | Yes ☐ No ☐ |
| Other groups<br>If yes, specify: ..... | Yes ☐ No ☐ |

| | |
|---|---|
| Are there study-specific procedures and/or interventions beyond the drug application? | Yes ☐ No ☐ |
| *If yes* | |
| Specify: ..... | |

## 3) INFORMED CONSENT FORM
*(repeat for ICF1, ICF2 ....)*

| | |
|---|---|
| Date/version of Informed Consent Form | |
| Does the of Informed Consent Form contain the correct title of the CT? | Yes ☐ No ☐ |
| Does the Informed Consent Form contain placeholder for the dated signature of the person performing the interview? | Yes ☐ No ☐ |
| Does this placeholder indicate the qualification of the person | |

# Timelines

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- No ‘clock stop’ for not accepting the first available
  - Impact on ability to offer choice
- Need to consolidate with MHRA & potentially other MS’
  - Need to factor in time to share output of the REC review plus consolidation period
    - Both initial review and review of response to request for further information

# Timelines (based on multi state)

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- Will likely apply Part 1 multi state timelines across the board to avoid complication
- Issue decision in total 45 days
- Can extend by 31 days where a request for further information is made
  - 12 days for Sponsor to respond
  - 12 days to review the response
  - 7 days to  issue decision

# Next 18 months

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- Raising awareness!
  - Update at Regional Chairs meetings
  - Written communications
  - Member training events
  - Attending REC meetings
- Working with individual RECs
  - Attending meetings
  - Written communications

# Next 18 months

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- Testing work
  - How to review an ‘application dossier’
    - Feedback on challenges etc.
  - How to record the outcome of the REC discussion
    - What are the challenges?
    - What can we put in place to support?
  - How to consolidate a response with the MHRA
    - What happens when have different perspective?

# Next 18 months

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- ‘Dummy’ application dossier reviews
  - One application per meeting for 4 – 6 months
  - Consider impact on workload etc.

- Voluntary Live Testing Pilot
  - Applications received going through the new process
  - Continue to issue output in accordance with current law

# What next?

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| | |
|---|---|
| **Work with Sponsors** | - Protocol and cover sheet templates<br>- Encourage submission for voluntary live testing |
| **Voluntary live testing** | - To commence April 2018 – start with 5 - 7 RECs. |
| **RECs confirmed to review** | - 20 RECs by January 2019<br>- Have reviewed application dossier and completed assessment report forms for 6 months<br>- Deemed to meet set standards |
| **Training** | - REC Members & Staff |

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# Thank you

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