Clinical Trial Regulations
EU *VS.* UK

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Clinical Trial Regulations EU versus UK

EUCTR

- Directly effective in all EU member states and the EEA
- Transition period of 3 years
- Objective to make the EU an attractive destination for drug R&D
- Clear focus on transparency and accessibility of trial data
- Trials of medical devices and other types of treatment such as surgical techniques are not within its scope
- Observational trials do not require EUCTR authorization
- Summary of trial results in a lay person language
- Clinical Trials Information System (CTIS) acts as a single portal for trial authorisation and management

MHRA

- Provides proposals and consultation to update the UK Clinical Trial's legislation
- Several years until any proposed law changes may be implemented
- Objective to ensure that UK retains its reputation as a world leading base for life sciences
- Clear focus on transparency, innovation, efficiency of approvals
- MHRA consults the extension of the term 'non-investigational medicinal product' and is differentiated from the EUCTR investigational medicinal product labelling requirements
- Aims to increase diversity in clinical trials and promote and encourage the inclusion of underserved populations
- IRAS to act as a system that would enable sponsors to make a combined MHRA / research ethics application

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- Introduces the 'low-level' clinical trial, where the experimental drug has already been authorised for use
- Presents special care for informed consent in cluster trials, clinical trials in vulnerable populations and emergency situations
- Additional burdens for the sponsor/investigator (i.e. trial notifications, deadlines, amendments, recruitment, SUSARs etc.)
- EUCTR prioritises transparency and public accessibility

MHRA
Regulating Medicines and Medical Devices

- For low intervention trials MHRA proposes that sponsors should notify them so the clinical trial can be approved without the need for regulatory review
- Simplified/low-burden informed consent process for patients
- Reduce certain reporting requirements that do not contribute to patient safety
- Registry of trials to a WHO compliant public database

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