An Roinn Sláinte
Department of Health

EU Clinical Trials Regulation – national legislation

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EU Clinical Trials Regulation (No. 536/2014)

- Adopted April 2014 and originally scheduled to apply from May 2016
- Long-running problems with development of CT Information System (CTIS) – the EU portal & database
- Following successful audit of CTIS, implementation confirmed for 31 January 2022

Key elements of new Regulation

- Single submission by sponsor via CTIS
- Coordinated assessment process led by Reporting Member State
- Shorter timelines; tacit approval & withdrawal
- Single national decision per Member State
- Enhanced transparency

EU laws – Regulations v. Directives

- Directives set out objectives that all EU countries must achieve, but individual countries can determine how to achieve in legislation
- Regulations: binding legislative acts applicable across all Member States, and have primacy over national laws.

BUT – some inherent flexibility

- In recent years, many EU Regulations have tended to give greater discretion to Member States as to how they transpose certain elements
- This is the case with CTR. For example, Member States can decide how to organise the involvement of ethics committees

National Research Ethics Committee Bill

- July 2019 - Government approval for General Scheme of the NREC bill
- Intended to reform the REC framework across all health research in Ireland
- National legislation on CTR to provide template for approach in other research areas
- General Scheme of NREC bill available on DoH website

National legislation transposing CTR

- Two Statutory Instruments (SIs) to be made under the European Communities Act 1972 – Minister for Health can sign into law
- One SI is focused on NREC Office and NRECs, the other focused on role of HPRA, with some overlapping provisions (EG, re authorisation)
- Both at advanced stages of drafting

Sponsors & Investigators

- For the most part, roles and responsibilities are clearly set out in CTR and Commission Q&A – no need to transpose into national legislation
- Sponsor's legal representative. Some flexibility in Article 74, but we are retaining current requirement for legal rep. established in the EU (where sponsor is not established in EU).

NREC for clinical trials

- Established May 2021, current legal basis is SI 190 of 2004, members appointed by Minister for Health
- Will have new legal basis under national legislation transposing Clinical Trials Regulation
- As of 31 January, will be only RECs entitled to provide opinions on CTIMP applications in IE

Informed consent

- Issues relating to informed consent are under consideration within the Department
- CTR gives us some flexibility within national law
- We are aware of need for clarity, and will provide as soon as possible

Clinical Trial Master File and Archiving

- Article 57 - Clinical Trial Master File (CTMF) to contain all essential documents relating to the clinical trial being conducted
- Art. 58 - Sponsor and investigator to retain CTMF for at least 25 years after the completion of the trial
- Medical files of subjects to be retained in line with institutional guidelines

Manufacture & import of IMPs

- Provisions of CTR Chapter IX apply
- HPRA responsible for conducting inspections to ensure compliance with Articles 61 and 63
- Article 61(5) offers exemptions for some processes, such as re-labelling or re-packaging
- National legislation will provide for framework to enable HPRA to inspect these processes

Language

- Articles 26 and 69 of CTR
- Application dossier and documentation addressed to subjects to be in English
- Information on IMP and AMP labels to be in English
- Other languages may appear on labels, in addition to English

Other considerations

- Fees: HPRA to collect single national fee - info on websites of HPRA and NREC Office
- Article 92: IMPs, and other products and procedures, to be free of charge to subjects
- Article 49: Investigator to be registered medical practitioner or a registered dentist

And some more….

- Legislation to address appeals procedure, as required under CTR
- At present, not envisaged that we will introduce additional national measures under Article 34
- Transitional arrangements

Article 98 of CTR

- For CT applications submitted before 31 January, trial continues to be governed by Clinical Trials Directive until January 2025
- Up to 31 January 2023, applications may be submitted under Directive, and remain under Directive until Jan. 2025
- Applications submitted under Directive during this one-year period will go to NREC-CTs for ethical review.

Thank you for listening!