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NREC-CT: Enabling Ireland's transition to harmonised assessment under the CTR

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Clinical Trial Regulation
Timeline

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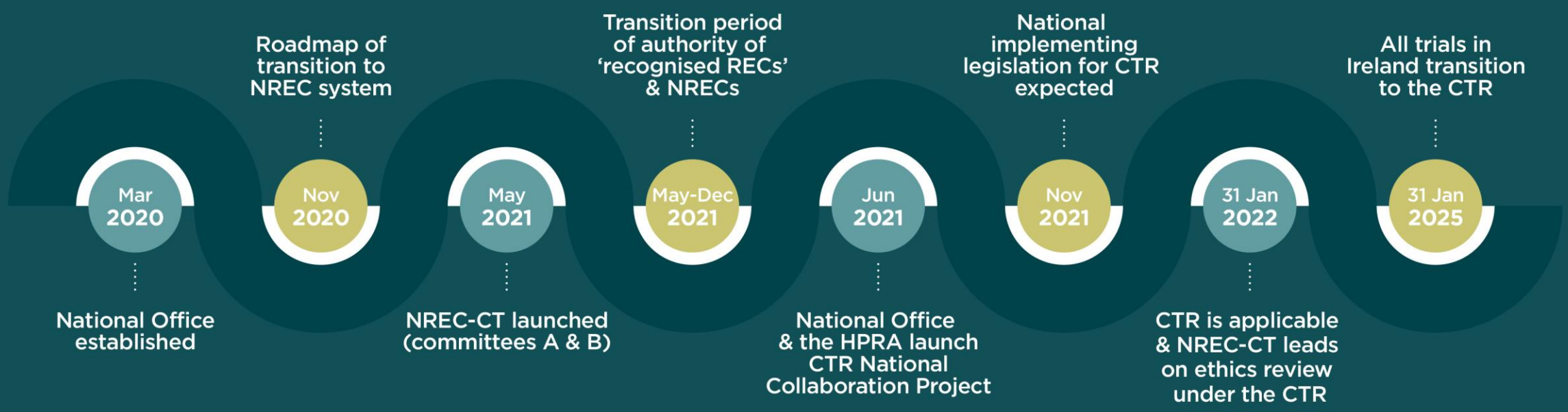

CTR Clinical Trial Regulation
HPRA Health Products Regulatory Authority
NREC(s) National Research Ethics Committee(s)
NREC-CT National Research Ethics Committee for Clinical Trials of Investigational Medicinal Products
REC(s) Research Ethics Committee(s)

nrecoffice.ie

NREC-CT Structure

	NREC-CT A	NREC-CT B
Scope	**Clinical Trials of Investigational Medicinal Products SI190 (CTD) & CTR**	
Membership	21 max. each for A & B	
Meeting Frequency	Two main meetings per month, up to two subcommittee meetings per month	
Reporting	Minister for Health	
Operational Support	National Office	
Remit	New clinical trial applications, substantial amendments, safety notifications, corrective measures	

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"Clinical trials are necessary to determine the most effective treatments for patients in Ireland. The establishment of a national research ethics committee will increase Irish patients' ability to participate in these practise-changing trials."

Professor Alistair Nichol, Chair of NREC-CT A

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"I look forward to leading the NREC-CT Committee B in our goal of ensuring that the interests of research participants are paramount, while maintaining momentum in the conduct of clinical trials in Ireland."

Dr Cliona McGovern, Chair of NREC-CT B

CTR-National Collaboration Project 2021

- Pressure-test coordination & efficiency of national system for EU CTR
- EU CTR dossier documentation (Parts I & II)
- Single submission to HPRA and NREC
- Work with select volunteer industry and academic sponsors over 6-month period
- Replicating ‘Single National Decision’ approach
- Learnings to feed into national CTR implementation

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CTR implementation

CTR National Implementation

Decision for Member State to delineate roles in Part I and Part II assessment (i.e. HPRA / NREC-CT) to reach single national decision;

NREC role and composition remains national decision, need to comply with CTR procedure and timelines.

Part I assessment

Validation 10d

Part I* – Coordinated Assessment (45 days / + 31 days)

- **Scope of Trial**
- **Benefits vs. Risks** – for subjects, including relevant of CT, reliability robustness of data
- **Manufacturing information**
- **Labelling requirements**
- **Investigator's brochure**

Acceptable/ Acceptable with conditions / Unacceptable

NREC-CT involvement:

RMS scenario

- HPRA lead on the assessment
- NREC-CT review relevant documents with ethics considerations e.g. protocol
- Compilation of ethics considerations from other MSCs

* Non-exhaustive list of Part I assessment requirements

Part II assessment

Validation 10d

Part II* – National Evaluation (45 days / + 31 days)

- **Informed consent, subject recruitment, data protection**
- **Reward/compensation** investigators/subjects
- **Suitability of investigators and of trial sites**
- **Damage compensation**
- Collection/storage/use of **biological samples**.

Decision 5 days

Notification of single decision by MSC sent to sponsor through the EU Portal

NREC-CT role

- NREC-CT to lead on the assessment of Part II
- HPRA no involvement
- Completion of assessment reports and conclusions

* Non-exhaustive list of Part II assessment requirements

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Part II documentation requirements

Part II requirements	NREC-CT documents required
Recruitment arrangement information per Member State concerned	Recruitment and informed consent procedure template; All other relevant materials
Subject information, informed consent form and informed consent procedure per Member State concerned	Recruitment and informed consent procedure template'; Consent / assent forms; Participant information leaflets
Suitability of the investigator per Member State concerned	Signed CV template
Suitability of facilities per Member State concerned	Signed site suitability template
Proof of insurance cover or indemnification per Member State concerned	Evidence of policy cover
Financial and other arrangement per Member State concerned	Statement confirming source of funding; Compensation for trial participants template; Signed 'Declaration of interest' template
Arrangements for the collection, storage and future use of biological samples	Compliance with use of human biological samples template
Proof that data will be processed in compliance with union law on data protection	DPIA or statement why DPIA is not required; statement outlining measures in place to comply with national and EU legislation

Safety notifications and corrective measures

SI190 (Transition period)

- Notify NREC-CT of SUSARS and DSURs
- Notify recognised RECs of SUSARs and DSURs where study has not transitioned to NREC system.
- No role in corrective measures.

Clinical Trial Regulation

- HPRA leads on the assessment of safety notifications
- NREC-CT involvement at the request of HPRA
- No notification required outside of CTIS
- NREC-CT to work with HPRA on corrective measures

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Challenges and opportunities

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Major change for ethics review across member states

Opportunities

- Harmonised submission
- Fostering collaboration
- Improved transparency
- Major benefits for Irish patients

Uncertainties

- Volume of submissions
- Delayed Part II submissions
- Strict deadlines
- Multinational coordination
- Sustainability of volunteer systems

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Thank You!

Questions welcome ☺

Enabling a trusted national ethics opinion