

***HRB's new funding model to
support cancer clinical trials in
Ireland***

DSSG - 23 October 2020

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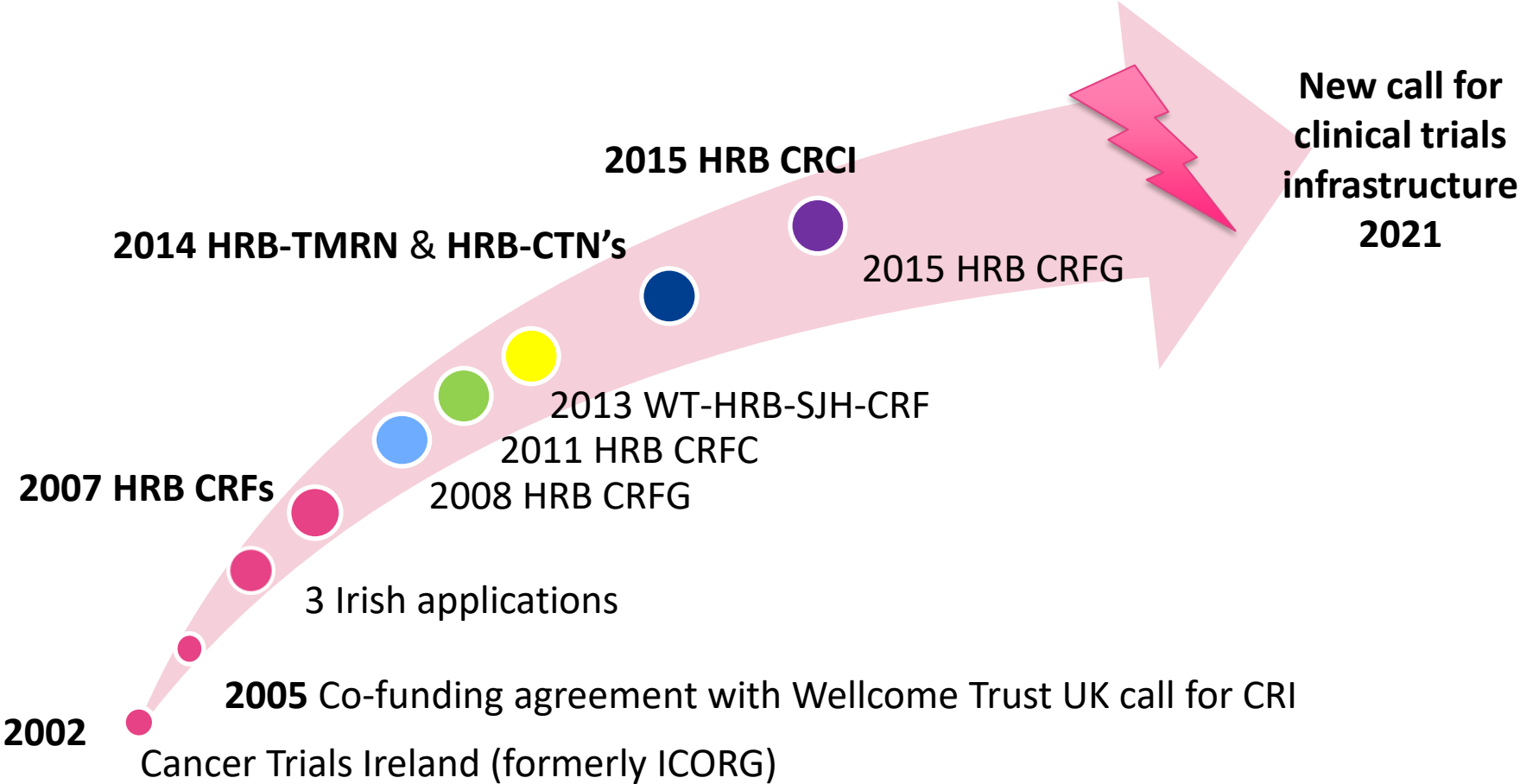
Agenda

- Background to new funding model
- Purpose of the call
- Overview of the requirements/expectations
- Key dates
- Q&A (FAQ)

Background....

- Clinical trials have a key role in evaluating the safety and effectiveness of healthcare interventions and are an essential step in translating research discoveries into improvements in health and health services.
- Patients benefit from having access to high quality clinical trials and overall outcomes are better in health systems that support clinical trials.
- The economy also benefits from clinical trials by supporting enterprise development in areas such as pharma, medical devices and diagnostics; this in turn creates jobs and delivers significant benefits to the exchequer through direct and indirect savings.
- Irish government through the HRB have invested significantly in infrastructure in recent decades to ensure **a robust enabling environment exists to support clinical trials within our healthcare delivery settings.**

The journey so far.....



Clinical Research Facilities (CRFs)

Located on hospital sites, CRFs provide the physical space and specialist support staff, including research nurses, needed to support clinical trials and studies.

National Clinical Trials Coordination Programme

A national “hub” that coordinates multi-centre clinical trials by networking all CRFs to achieve a standardised approach and increase our capacity to successfully deliver multicentre trials led by Irish or international investigators.

Clinical Trial Networks

Brings together clinicians, health professionals and researchers working in a specific disease or health area. A network aims to develop a more strategic approach to the choice of trials, develops a community of trialists in that area and provides the critical mass needed to conduct trials.

HRB Trials Methodology Research Network

Develops national capacity in trial methodology and reporting of trials in Ireland by providing the research community with the appropriate support for complex methodology, training and education.

Funder expectations: informed by....

- HRB experience in funding and reviewing clinical trials infrastructures
- International panels – 2017, 2018
- Review of governance and financial arrangements (2019)
- HRB Review of Clinical Research Infrastructure in Ireland (2019)
- HRB Policy on Clinical Trials & Interventions and Governance (2019)
- Stakeholder consultations (DoH/HSE/CAOs/CEO HGs/VPR/Funders/Cancer Trials Ireland)
- HRB Board
 - *New Investments in Clinical Trials Infrastructures ~ €60M*

Purpose of the call

The overall goal of this investment is to support an appropriate **infrastructure**; enabling Irish patients to **access** a diverse portfolio of **high quality cancer clinical trials**.

- Efficient, coordinated and focused infrastructure
- Integrated and embedded system of cancer trial activity
- Strategic approach to the portfolio of clinical trials developed or adopted
- Embed PPI in all cancer clinical trials
- Greater transparency of all financial and governance matters
- Build on positive achievements of our investment
- Improve the performance of trials/infrastructures against key metrics

Cancer trials in Ireland - 2021

HRB investment will be **€21M over five years** (including of overheads)

- **Two strands** of an open competitive call to support;
 - Clusters of **cancer delivery units** aligned to existing clinical research infrastructures, Hospital groups and an academic institution, and
 - A national **Cancer Clinical Trials Network**.

Applications for both strands must be made in partnership with University Partner/recognised Host Institution.

HRB will contract directly with the recognized Host Institutions.

New HRB co-investment in clinical trials infrastructure 2021

HRB wants to build on national investments and adopt a co-investment model with the Health Service Executive (HSE), universities and other stakeholders to transform the quality, capacity and accessibility of clinical trial infrastructure across Ireland.

- CRF/C's – Co investment 1:1
- **Cancer Clusters – Co-Investment 2:1**

Co-investment is a key feature of the current competitive call, and is necessary to ensure a more sustained integration of research within the health system.

Out of scope

HRBs investment through this specific instrument will **not support**;

- **funding for individual cancer clinical trials**, as it is expected that trials should come with competitive funding from sources with effective independent international peer review.
- costs associated with **routine patient care or translational studies, biobanks, patient registries and questionnaires.**
- **Establishing new premises including building work, or fit out of buildings.**

To build capacity in Investigator led cancer clinical trials the HRB will ring fence funds within the main HRB Definitive Interventions and Feasibility Awards from 2021 to specifically support high quality Investigator led cancer clinical trials.

Clusters (n=7) strategically aligned to HG

Partner with an **academic host institution** and local **Clinical Research Facility/Centre** based on hospital group delineation (Clinical Lead and CRF Director)

Demonstrate a **previous track record** and **level of co-investment** from the HSE/NCCP and/or Academic Partner or others (verifiable under accounting standards). Ratio 1:1

Deliver a portfolio of trials in conjunction with the centralised network with a focus on patient recruitment and data monitoring at sites.

Use a **Centralised data management system**, such as CRF manager, aligned with other clinical trials infrastructure. **Clear reporting of metrics** is a prerequisite for continued funding.

All clinical trial infrastructures receiving HRB funding will be expected to **support, and to contribute to, the national clinical coordination feasibility programme**, and resources should be assigned for that purpose.

National Cancer clinical trial network

- Partner with an academic host institution
- Provide **Governance support** as Sponsor for the conduct of **HRB funded multicentre** regulated cancer clinical trials
- Provide **Support services for HRB funded studies** including project management, database design and build, clinical trial data management, data analysis, statistical analysis plans and reports, monitoring, reporting and administration of trial activity at each approved cluster where required.
- Provide **Networking support for Clusters** to network and integrate at a national level, the critical mass of expertise and resources needed to provide Irish leadership in Investigator-led and commercial cancer clinical trials, including network support to all trial delivery teams at sites by providing a communication platform for all members e.g. **development of a community of practice.**

National Cancer clinical trial network

Policies:

- Study selection and prioritisation for the network as a whole
- Procedure and criteria for stopping trials
- Charging model/list of fees for commercial studies
- PPI

Collaboration with other infrastructures

- Details given in guidance notes, see e.g. pp 8 section 3.3 & 5.1.1
- Describe how you will work with the other infrastructures: what services/supports are on offer locally, and how this complements national infrastructure
- Clarify contribution to NCTCP Working Groups, and how outputs will be adopted in the Clusters/Network
- Discreet work packages with specific resources assigned to same
- Infrastructure Agreement forms

Assessment Criteria - Clusters

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- Strategic direction and business plan
- Operational model
- Governance structures and arrangements
- Expertise and fit of teams, including Leadership
- Expertise and track record of team in delivering trials
- Host Institution support, Co-Investment

Assessment Criteria - Network

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- Strategic direction and business plan
- Governance structures and arrangements
- Strength of the strategic partnerships
- Quality of the proposed network activities
- Relevance for the academic and healthcare practitioner community
- Team and environment

Important timelines

Stage	Indicative dates
Invitation to submit applications	August 2020
Closing date	15 Jan 2021
Review period	Jan 2021 – late March 2021
International Review Panel meeting (Virtual)	21,22,23 April 2021
HRB Board	June 2021
Pre-contract (including approving any conditions of funding) and contract negotiation	July - Nov 2021
Awards commence from	Jan 2022

Standing Advisory Group - 2021

- Post Award – a Standing Advisory Group of International Experts will work with the HRB to contribute strategic leadership and expertise while safeguarding our investment in Clinical trials infrastructures.
- Period of 5 years
- Metrics – Clinical Trial Activity and Infrastructures
- Benchmarking mechanism

Q & A

Work packages – modular budgets. It is possible that the Panel will recommend funding for some work packages/positions but not others.

Clusters will be paid on a claims made basis in arrears, annually. Manage action plans with this in mind

Each position requested should make sense in terms of the scope of the role, and when it will come on-stream.

Co-investment will be monitored closely per annum. Sources of co-investment need to be verifiable in accounting standards.

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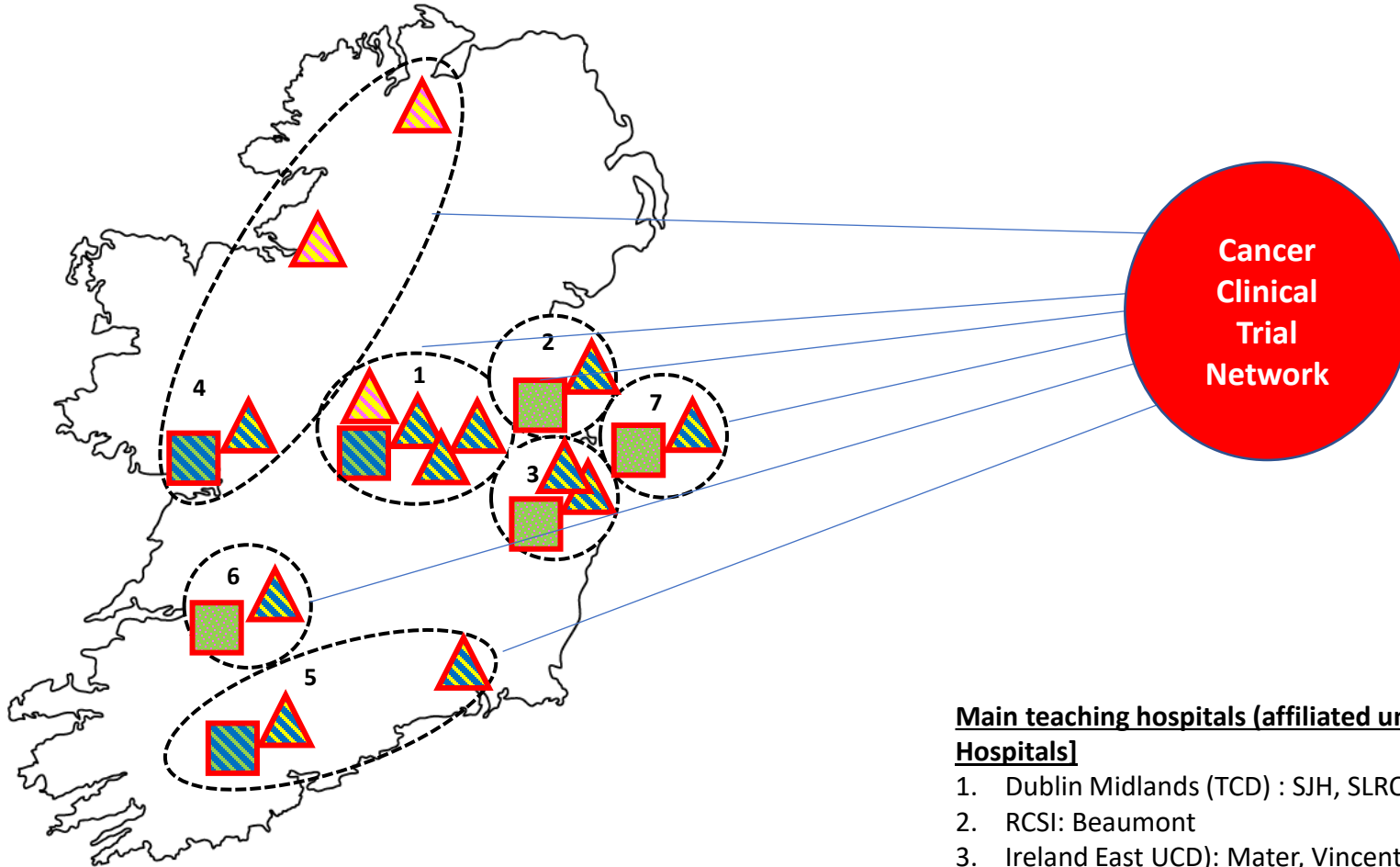


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about our work**



Cancer trials in Ireland

Based on current hospital group delineation



Main teaching hospitals (affiliated universities) [CTI Hospitals]

1. Dublin Midlands (TCD) : SJH, SLRON, Tallaght
2. RCSI: Beaumont
3. Ireland East (UCD): Mater, Vincent's
4. Saolta (NUIG): UHC
5. South-South West (UCC): UHC, Waterford
6. Midwestern (UL): UHL
7. Children's (Various) OLCHC

Infrastructure key



Clinical Research Facilities / Centres (CRFs)



Cancer Trials Units (under Cancer Trials Ireland)