Future Resourcing of Clinical Research in Ireland

Steering Committee Mandate and Terms of Reference

Background

A well-resourced and functioning clinical research capability is an essential part of any National infrastructure. It benefits patients, the healthcare delivery system and academia, and is a unique selling point for the very large life-sciences sector operating in Ireland.

With a view to exploring the mid and long-term needs for clinical research infrastructure in Ireland, following a series of bilateral meetings, Clinical Research Development Ireland (CRDI) convened a discussion with a number of key stakeholders in March 2018. These stakeholders included the funding and enterprise agencies (HRB, EI, SFI and IDA Ireland), industry representative bodies (IPHA, IMSTA, BioPharmachem Ireland and Irish MedTech Association), the Directors of the Clinical Research Facilities/Centres, and Board and staff colleagues from CRDI.

Following an interesting and wide-ranging discussion, and with due regard to the valuable efforts and funding investments already made by stakeholders, it was agreed by all present that significant opportunity exists to enhance the level of clinical research in Ireland and that the issue of resourcing to enable this opportunity to be realised needs to be reviewed. A range of key issues were highlighted including, but not limited to: investment in core infrastructures, both facilities and staff; need for career structure for research staff; protected time for investigators; electronic health records; and the approach to biobanking and patient registries.

It was agreed to establish a **Future Resourcing of Clinical Research Steering Committee (FRCR SC)** with a mandate to strategically examine and define the optimal future clinical research infrastructure, support, capacity and capability. The report developed will inform a plan that clearly outlines the evidence to support the need identified and will provide a draft high-level coordination road-map on how best to achieve the desired outcome.

All stakeholders identified above have agreed to participate in and support the work of the FRCR SC. It is foreseen that additional stakeholders will be invited to join the initiative and to participate in the Steering Committee as appropriate.

Mandate and Terms of Reference

The Steering Committee's mandate comes from its constituent stakeholders, all of whom agree that there is a need for the plan to be developed. The Steering Committee is responsible for:

1. Establishing the baseline of Ireland's current clinical research infrastructure and performance.
2. Formulating a plan for clinical research in Ireland that examines and defines in broad terms:
    - The required physical and human capital infrastructure to sustain all forms of clinical research in Ireland.

- The estimated capital and revenue costs of providing and maintaining this infrastructure for clinical research based in both hospital and CRF settings.
- Any legislative or policy change that enables the development of clinical research in Ireland.

3. Ensuring that the development of the plan is resourced with the personnel who have the relevant knowledge and expertise, along with appropriate contributions from the individual Committee members and the stakeholders they represent.
4. Ensuring the scope of the plan addresses the needs of all stakeholder groups, including; patients, industry, academia, healthcare service, government, development agencies, research charities and clinicians.
5. Ensuring that the plan outlines a system for economic sustainability of the proposed infrastructure over the long term.
6. Endorsing the plan and promoting it internally to the stakeholder each member represents and externally to representatives of the Government and the general public.
7. Making themselves available for the work of the Committee and the various meetings that may be scheduled.

Steering Committee Membership

The Steering Committee shall comprise senior representatives from the following:

- IPHA
- IMSTA
- BioPharmachem Ireland
- Irish MedTech Association
- Cancer Trials Ireland
- Health Research Board
- Health Services Executive
- Enterprise Ireland
- Science Foundation Ireland
- IDA Ireland
- Directors, Irish Clinical Research Facilities and Centres (RCSI, UL, UCD, HRB-CRF-G, HRB CRF-C, Wellcome HRB CRF at St. James's Hospital)
- HRB – CRCI
- CEO, Clinical Research Development Ireland
- Hospital Groups, CEOs and Chief Academic Officers
- Other stakeholder representatives as required.

The Steering Committee will be chaired by the CEO of CRDI. In addition, the Steering Committee will be supported by a Working Group consisting of:

- Dr. Pat O'Mahony, CEO, CRDI
- Dr. Fionnuala Keane, COO, HRB-CRCI
- Dr. Áine Murphy, Translational Research Manager, CRDI
- Dr. Fiona Killard, Head of Strategic Research Development, TCD

- Mr. Jeremy Towns, Programme Manager, Wellcome - HRB Clinical Research Facility
- Ms. Alex Sumner, CRDI
- Other members as may be required.

Meetings

The Steering Committee shall meet to review the progress and development of the plan on the following dates:

- 26 June 2018
- 12 November 2018
- 15 January 2019
- 12 March 2019
- 16 April 2019
- 14 May 2019

Further meetings may be scheduled by general agreement, or at the call of the Chair. Meetings will be held at in the Dublin area and longer meetings may be held at an offsite location. All agenda packages will be issued at least five working days in advance of meetings.

Decision Making

Steering Committee decisions and approvals of the clinical research plan will be made by consensus of those present at the meetings, facilitated by the Chair of the Steering Committee.

Members are expected to be in physical attendance at meetings. In circumstances where a member cannot attend in person, members will nominate an alternate representative to attend on their behalf. Alternates are invited to participate in the discussion and decision-making process.

In a circumstance where a Steering Committee member is not a party to the final consensus, he/she may opt not to be represented in the final report.