13. Establishment of a Sponsor Capability Trial

Research

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Introduction

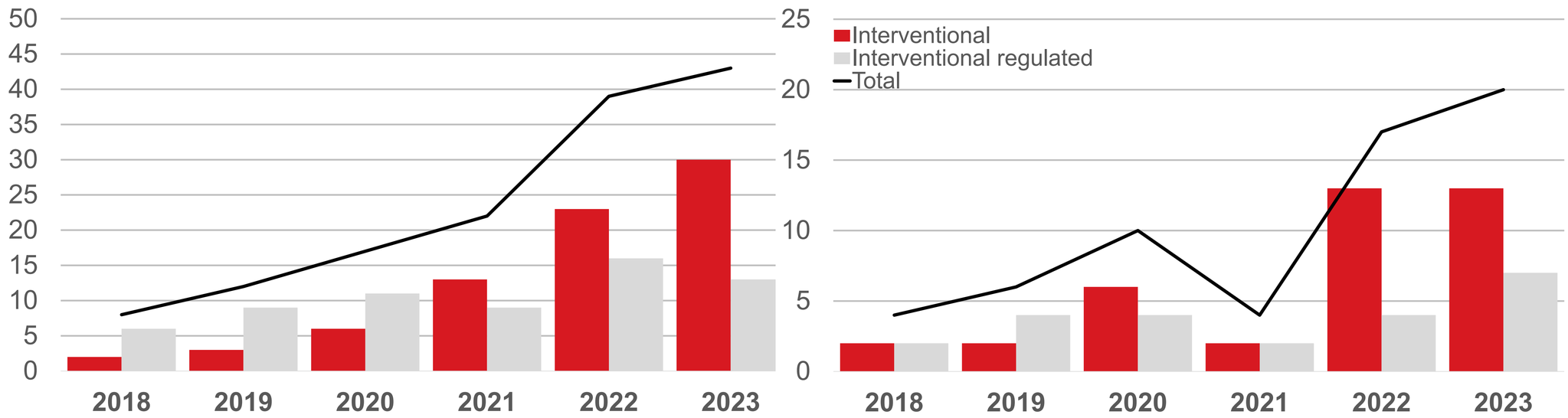
Following the launch of new Health Research Board (HRB) funding scheme to support investigator led clinical trials, RCSI received its first request to sponsor a clinical trial. In responding to this request, it became evident that RCSI had insufficient regulatory, operational, and legal experience to fulfil this role. As a result, the Office of Research Integrity (ORI) engaged with other Irish universities and research organisations, and found that across the Irish academic and, more broadly, the Irish health research sector, there were inconsistencies of approaches and understandings on how clinical research should be governed and how sponsorship responsibilities and risks should be managed. These inconsistencies were creating inefficiencies across the clinical research system, potential risks for patient safety, and legal, financial, and reputational exposure for the academic sponsors. A cross-sectoral approach to addressing these issues was needed.

Initiative

To address these challenges, in 2017, the RCSI Associate Director of Research, in collaboration with the Secretary of UCC, led the establishment and implementation of an inter-institutional initiative, the Corporate Enabling of Clinical Research (CECR) initiative. CECR aimed to identify and address the challenges of sponsoring clinical studies in the areas of governance, contracts, insurance, operations, financial resources, engagement with the health sector, training, and support. Several key organisations agreed to participate in the initiative including all Irish universities, HRB, Enterprise Ireland, voluntary hospitals, the HSE and Cancer Trials Ireland. CECR commenced by undertaking a gap analysis to identify the challenges of sponsoring and supporting clinical research. The outcome of the gap analysis was then used to develop an action plan.

The action plan was delivered by six working groups (WGs) and its implementation was overseen by the Governance and Leadership WG, whose membership included all WGs co-chairs and senior management representatives from the organisations involved in the initiative. Overall, 67 people participated in the development and implementation of the action plan, including 4 members of RCSI staff. Participants contributed to one or more WG activities and brought expertise ranging from financial, to quality and regulatory affairs, risk management, governance and legal affairs, research support and senior management.

To deliver on the initiative, CECR also engaged the Irish State Claims Agency (for clarifications on Clinical Indemnity Scheme), Imperial College London (for their extensive experience in sponsoring clinical trials), and other external legal and regulatory advisors, which delivered training and contributed to the development of sponsorship and contractual resources.



Note: **2023 DATA FOR TRIALS SUPPORTED** is based on thenumber of trials which, as of Feb 2023, are being supported and those which have been approved and will be supportedin 2023

2023 DATA FOR TRIALS GREEN LIGHTED based on a number of trials that, as of Feb 2023, are preparing for green light.

Figure 1. *Clinical Trials overseen and supported by RCSI Sponsorship Office*

Outcome

The extensive work conducted over two years was outlined in a report. The initiative delivered many cross-sectoral benefits:

- It enabled a dialogue on the institutional challenges of clinical studies and brought together the perspective of key stakeholders in the delivery of the action plan.
- It highlighted the importance of cooperation between academic institutions, funders, and the health sector to deliver a sustainable and safe clinical research system.
- It leveraged a critical mass of professionals with substantial and complementary experience and expertise across several areas.
- It demonstrated the complexity associated with the sponsorship of clinical trials and the absolute requirement for inter-sectoral cooperation to deliver a safe and efficient clinical research system for the safety and benefit of patients.
- It improved the working relationship between academic institutions and demonstrated the importance of cooperation to improve practices.

In 2018, RCSI leveraged the learnings and outputs of CECR at institutional level by developing an institutional governance plan for the sponsorship of clinical trials establishing the RCSI Sponsorship Office. The Sponsorship Office set institutional approval and oversight requirements, sponsorship procedures and quality standards, a plan for the coordination of its activities with pre-award, post-award, and legal teams, and created a clinical trial planning and costing model to ensure that clinical trials are sustainable. Since 2018, Sponsorship office activities have expanded significantly, as shown in the figure above.

In 2020, the Sponsorship Office, supported the establishment of a Sponsorship Office in RCSI Bahrain and underwent a benchmarking exercise with Oxford University to identify areas of improvements. It is currently engaging with RCSI's Clinical Research Centre to put in place consistent quality standards, quality support and oversight for all clinical trials, including those externally sponsored. It is also working with affiliated hospitals to put in place a joint approval process to achieve consistency of requirements and coordination of institutional review activities which precede the commencement of clinical trials.