



OLLSCOIL NA
GAILLIMHÉ
UNIVERSITY
OF GALWAY

An Institiúid do Thrialacha Cliniciúla
Institute for Clinical Trials

The Hypercare *Initiative*

*Accelerating Medical Device
Clinical Investigations in Ireland*

A White Paper on the First
Three Hypercare Case Studies



Executive Summary

Objective

The Hypercare pilot initiative, led by the Institute for Clinical Trials at University of Galway and in partnership with HSE West North West, was established to support Ireland's capability, predictability, and competitiveness in MedTech clinical investigations.

The primary goal of the pilot is to support a small number of sponsors in navigating the complexities of the clinical investigation pathway to assess what material improvements to the clinical trial experience can be achieved by providing greater support to sponsors, ultimately aiming to improve Ireland's capability, predictability, and competitiveness in MedTech clinical investigations.

Interventions

Three cases were selected, which encompass a diverse range of sponsors—including a multinational corporation, an international small and medium enterprise (SME), and a local SME—and a variety of medical devices and clinical investigation strategies.

The Hypercare team provided structured support through early engagement, process visibility, and coordination. A single point of contact model was employed to manage interactions across multiple institutional stakeholders, reducing fragmentation and duplication. The team also facilitated preliminary and pre-submission engagements with the Health Products Regulatory Authority¹ and the National Office for Research Ethics Committees.²

Key Findings

The pilot demonstrated that material improvements to the clinical trial experience can be achieved by providing greater targeted supports to sponsors.

- All three cases achieved HPRA authorisation significantly faster than the current national median of 73 days, completing the formal end-to-end review process in an accelerated range of 36 to 59 days.
- Sponsors cited the single point of contact as a key driver of efficiency, removing administrative fragmentation and allowing their teams to focus on clinical execution rather than logistics.
- The HPRA reported that Hypercare significantly improved sponsor readiness and application quality. They noted that proactive early engagement helped streamline the process without compromising the rigor required for safety and performance.
- The National Office reported a very positive experience, observing that early engagement in pre-submission meetings resulted in more efficient validation and an overall higher quality of application dossiers submitted to the National Research Ethics Committee for medical devices (NREC-MD) for ethics opinion. Furthermore, logistical coordination by the Hypercare team reduced the administrative work of the NREC office.

Recommendations

The initial results of the Hypercare pilot are promising, and scaling this model presents a real opportunity to support the clinical research ecosystem for medical devices.

The continuation and potential expansion of the Hypercare pilot carry significant strategic importance for the country. Retaining and attracting clinical investigation activity yields substantial regional economic benefits, firmly positioning Ireland as a globally competitive hub for medical technology. Furthermore, increasing the volume of research activity within Irish hospitals directly benefits the broader health service by introducing novel technologies designed to address unmet medical needs. Ultimately, streamlining these clinical pathways ensures that patients gain earlier access to investigational and potentially life-enhancing medical innovations, offering an important societal benefit. To realise this potential, identifying a long-term, sustainable support and funding model will be key.



¹ See www.hpra.ie

² See www.nrec.ie



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Acronyms

CRDO	Clinical Research and Development Office
CRF/C	Clinical Research Facility/Centre
CTA	Clinical Trial Agreement
CTU	Clinical Trials Unit
DPIA	Data Protection Impact Assessment
DPO	Data Protection Officer
EU	European Union
FPFV	First Patient First Visit
GDPR	General Data Protection Regulation
GUH	Galway University Hospitals
HSE	Health Service Executive
HPRA	Health Products Regulatory Authority
ICT	Institute for Clinical Trials
MDR	Medical Device Regulation (EU) 2017/745
NCTOG	National Clinical Trials Oversight Group
NREC-MD	National Research Ethics Committee for medical devices
REC	Research Ethics Committee
SME	Small and Medium-Sized Enterprise



Introduction to the Institute for Clinical Trials





One of the key objectives of the Institute for Clinical Trials at University of Galway, in partnership with HSE West North West, is to accelerate the translation of novel therapeutics, medical technologies, and scientific discoveries into enhanced patient care. By leading collaborative initiatives, the Institute provides comprehensive support to streamline clinical investigations and establish Ireland as a premier global hub for clinical research.

Importance

The initiation of a medical device clinical investigation relies on the coordinated contribution of multiple organisations. Sponsors, regulatory bodies, ethics committees, clinical sites, and university research and governance teams must work together to progress a study from pre-submission to first patient enrolled.

Ireland is a global leader in MedTech manufacturing and innovation and is the highest *per capita* employer in MedTech in the European Union.³ At the same time, Ireland has historically not been perceived as a viable location of choice for medical device clinical investigations. Feedback from both small and medium enterprises (SMEs) and multinational organisations has highlighted concerns regarding predictability of timelines, fragmentation of responsibilities, complex application of legislative requirements, and limited visibility of the end-to-end approval process for regulatory, ethics and contracting processes.⁴

Different inter-institutional approaches can also raise complexity for study sponsors, and a number of these were also noted in the recent National Clinical Trial Oversight Group (NCTOG) report (2025).⁵ Examples of this include:

-  **Lack of standardised contracts:** Unlike the pathways for Investigational Medicinal Products (IMPs), there is currently no standard Medical Device Clinical Trial Agreement (CTA) template universally adopted across Irish sites.⁶
-  **Variable data privacy assessments across sites:** Data Protection Officer (DPO) assessments can vary significantly and may be subject to individual institutional interpretation.⁷
-  **Inconsistent activation procedures:** Sites possess varying and sometimes complex internal processes to complete final 'greenlight' approvals.⁸
-  **Absence of dedicated research infrastructure:** In hospitals without a dedicated clinical research support office or similar structure, sponsors may be forced to route contract and operational reviews through general administrative or finance departments, leading to administrative bottlenecks.



Hypercare was established following a meeting convened by the Institute for Clinical Trials with multi-agency and stakeholder support in April 2024. Challenges with data protection requirements, contracts and coordination were noted at this time. Supporting clinical trials and resolving administrative barriers is a key national policy priority. During the Hypercare pilot, recommendations from the NCTOG were issued to streamline the data protection impact assessment (DPIA) process for multi-site studies in Ireland.

³ MedTech Europe. (2025). The European medical technology industry in figures. MedTech Europe. <https://www.medtecheurope.org/wp-content/uploads/2025/09/medtech-europe-facts-and-figures-2025-digital-1.pdf>

⁴ Health Research Board – National Clinical Trials Office. (2025). Advancing Ireland's medtech clinical research ecosystem. https://ncto.ie/wp-content/uploads/2025/04/NCTO_Advancing-Ireland's-Medtech-Clinical-Research-Ecosystem_April2025-2.pdf

⁵ Department of Health. (2025). National Clinical Trials Oversight Group: Final Report. Government of Ireland. https://assets.gov.ie/static/documents/9ba19a09/DOH_National_Clinical_Trials_Oversight_Group_Final_Report_V4.pdf

⁶ NCTOG recommendation Priority area 2, recommendation 3, Page 40

⁷ NCTOG recommendation Priority area 2, recommendation 4, Pg 40

⁸ NCTOG recommendation, priority area 2, recommendation 5, Pg 40

Objective

Hypercare was established by the Institute for Clinical Trials to support Ireland's capability, predictability, and competitiveness in MedTech clinical investigations.

The Hypercare initiative was established to:

- Select a small number of clinical investigations at the pre-submission stage
- Support sponsors as they progress through existing regulatory, ethical, and site start up processes
- Engage directly with all stakeholders to facilitate progress, whilst maintaining the overall responsibility of the study sponsor
- Closely monitor timelines, interactions, and decision points across all stakeholders
- Capture data-driven insights on what works well and where bottlenecks arise

Hypercare does not seek derogation from legislation or preferential treatment. All studies follow standard national and institutional requirements. The added value lies in coordination, early engagement, visibility, and structured support throughout the submission process for approval.



Design, Setting, and Participants

The Hypercare pilot recruited studies meeting the following criteria:

- Pre-market medical device clinical investigations under the Medical Device Regulation (EU) 2017/745 (MDR)
- Advanced stage of readiness for clinical investigation submission
- Single-site or multi-site studies conducted in Ireland, at Galway University Hospital, or any other public hospital in Ireland
- Sponsors willing to engage with the pilot with respect to their study start-up activities from early engagement through site activation

The key principles underpinning Hypercare are:

- Sponsor accountability is retained at all times
- Hypercare acts as a partner, guide, and coordinating liaison
- Engagement in the Hypercare process was pre-agreed with the applicable agencies
- Existing regulatory and ethics pathways are followed
- Data are collected to enable objective evaluation of timelines and outcomes

Intervention

The three Hypercare cases were selected to include diversity of sponsors, devices and regulatory strategies.

The cases included:

- **Case 1: Multinational sponsor undertaking an early feasibility study**
- **Case 2: International SME undertaking a first-in-human study**
- **Case 3: Local SME undertaking a randomised controlled trial**

The Institute for Clinical Trials (ICT):

- Assessed and selected appropriate clinical investigations to qualify for the Hypercare pilot
- Facilitated early engagement with the Health Products Regulatory Authority (HPRA) and the National Office for Research Ethics Committees (National Office).
- Supported sponsors in understanding the Irish regulatory and ethics landscape
- Supported sponsors in navigating the requirements of the Health Service Executive (HSE) in the conduct of an investigation at a clinical site
- Coordinated engagement with site-level operational and governing stakeholders
- Acted as a single point of contact to reduce fragmentation and duplication
- Identified and intervened to resolve bottlenecks arising during the process
- Tracked progress and milestones using structured metrics and dashboards
- Captured lessons learned and engaged with all stakeholders to inform continuous improvement

The Hypercare pilot did not include trial design, protocol writing,⁹ delegated Clinical Trial Unit (CTU) operational activities or site-level operational delivery subsequent to first patient first visit (FPFV), which were outside scope.



⁹ Supports for this activity are available from the Trials Accelerator at University of Galway, University of Galway, Trials Accelerator, Institute for Clinical Trials, University of Galway. Retrieved December 14, 2025, from https://www.universityofgalway.ie/trials_accelerator/



Case Study 1: Multinational Sponsor

Sponsor Type: Multinational MedTech company
Device Category: Renal denervation system
Study Type: Early feasibility study
Site: Galway University Hospital

This case represents a multinational sponsor with prior experience, engaging with Ireland as a location for device clinical investigations.

Key Hypercare supports included:

- Early alignment meetings to clarify Irish regulatory and ethics expectations
- Facilitation of pre-submission engagement with HPRA and NREC
- Coordination with the Clinical Research and Development Office (CRDO), with respect to legal and governance aspects) and site (clinical) teams to support parallel processing
- Ongoing liaison with site, radiation safety and data protection representatives to support responses to queries received by the sponsor from HPRA and National Office
- Structured tracking of milestones and review feedback

The sponsor reported that project management and parallel processing significantly improved activation speed. Furthermore, pre-consultation meetings with regulators, along with pre-approved contract and DPIA templates, streamlined the process and reduced delays.



Case Study 2: International SME

Sponsor Type: International SME
Device Category: Venous thrombectomy catheter
Study Type: First-in-human
Site: Galway University Hospital

This case reflects an SME sponsor with no prior experience of the Irish clinical investigation landscape. Initial sponsor concerns included regulatory complexity, response timelines, and clarity of roles.

Key Hypercare supports included:

- Early alignment meetings to clarify Irish regulatory and ethics expectations
- Hands-on preparation for HPRA and National Office pre-consultation meetings
- Critical review of submission readiness to anticipate regulator questions
- Brokering collaborative interactions with national authorities
- Acting as a single point of contact across multiple institutional stakeholders
- Providing clarity on data protection, contracts, and site processes
- Structured tracking of milestones and review feedback

The sponsor reported that without Hypercare, Ireland would not have been on their radar for clinical trials. They praised the collaborative approach and critical review process, which helped in understanding the regulatory body better and alleviated initial apprehensions.



Case Study 3: Local SME

Sponsor Type: Irish SME
Device Category: Compression therapy to reduce peripheral neuropathy during chemotherapy
Study Type: Randomised Controlled Trial
Site: St. James's Hospital, Dublin (Trinity College Dublin)

This case involves a local SME developing a novel interventional device and seeking to complete initial high-quality clinical research in a rigorous, compliant, and timely manner.

Key Hypercare supports included:

- Early strategic engagement with HPRA to clarify expectations
- Structured preparation for regulatory and ethics interactions
- Close monitoring of dependencies and sequencing of approvals
- Facilitating efficient communication between sponsor, investigator, and site
- Supporting external site readiness through sharing of lessons learned
- Structured tracking of milestones and review feedback

The sponsor reported that the engagement gave them a structured platform to navigate the Irish ethics and regulatory system. They found the support invaluable and noted that the time spent in preliminary and pre-submission meetings helped reduce the back-and-forth process post-submission.



Results

Predictability and Timelines

As part of the implementation of MDR, ethics approvals changed from local institutional assessments to a single national ethical assessment conducted by the NREC-MD. This allows a single opinion to cover the entire country when multi-site studies are planned. A strategic benefit of the Irish ecosystem when compared to some EU Member States, is that submissions may be made to both HPRA and NREC in parallel, rather than sequentially.

The NREC-MD reviews submissions at scheduled monthly meetings. For the three Hypercare pilot cases, two studies required a single round of questions and one study had two rounds. As all queries were addressed promptly, they were successfully resolved by the subsequent monthly meeting. As a result of this structured cadence, all three sponsor companies reported the ethics review process to be highly transparent, predictable, and efficient.

The HPRA validate submissions prior to assessment. This typically takes 10 days, but may be extended if deficiencies are identified. The HPRA timeline for assessment is typically 45 days post-validation (with a possible 20-day extension). 'Stop-clocks' may be utilised when queries are issued to the sponsor. As shown in Figure 1, all three Hypercare cases achieved HPRA authorization significantly faster than the current national median of 73 days. Both the sponsors and the HPRA welcomed the robust preliminary and pre-submission interactions. These early preparations were instrumental in keeping the formal end-to-end review times within an accelerated range of 36 to 59 days.

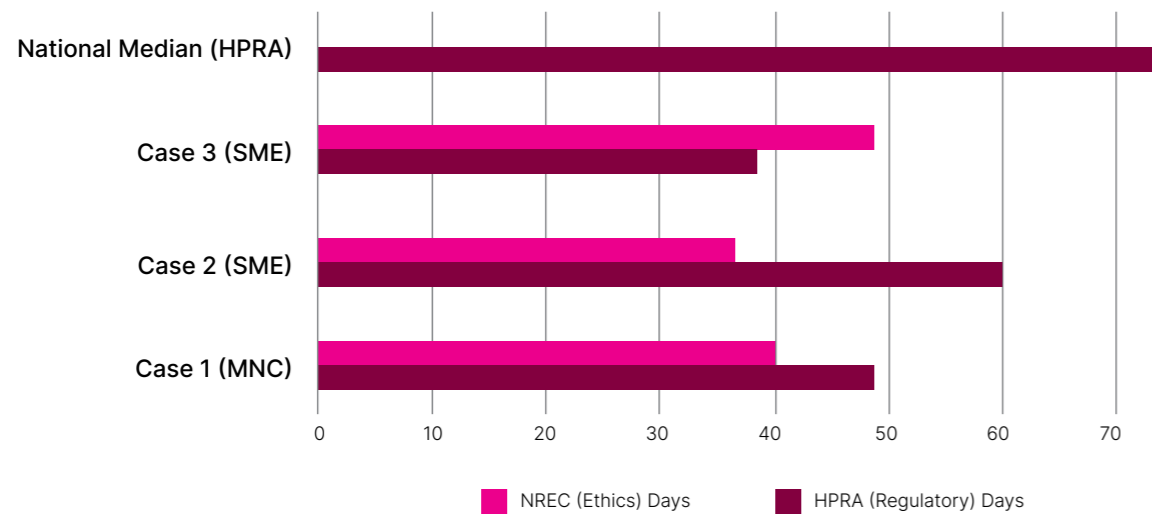


Figure 1. HPRA and NREC timelines from submission to decision presented in calendar days



Study Sponsors

Feedback from the participating sponsors identified a shift in their perspective compared to historical perceptions of the Irish clinical research environment. The following themes emerge from feedback:

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Operational Efficiency: The “Single Point of Contact” model was cited as a key efficiency driver. Sponsors noted that having a dedicated liaison to coordinate between the local Clinical Research Facility (CRF), Clinical Research Development Office (CRDO) and national offices removed administrative fragmentation, allowing their internal teams to focus on clinical execution rather than logistics.
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Reduction of Uncertainty: Sponsors explicitly reported that the Hypercare supports—specifically the “hands-on” preparation for pre-submission meetings—“significantly reduced uncertainty and avoided re-work.” By anticipating regulator questions and clarifying requirements (e.g., for data protection and contracts) before submission, the pilot removed the “trial and error” sometimes associated with study implementation.
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Strategic Confidence: Perhaps most critically, the pilot successfully altered the perception of approval processes in Ireland. Sponsors indicated that the “collaborative and responsive” nature of the Hypercare model provided the assurance needed to place high-priority development milestones—such as early clinical research and pivotal studies—in Ireland, confirming that the ecosystem is capable of supporting the approval process for complex clinical studies when coordinated effectively.



Health Products Regulatory Authority

Feedback from the HPRA highlighted that the Hypercare initiative has significantly improved sponsor readiness and application quality. The Authority noted that companies engaged in the pilot demonstrated a clearer understanding of the expectations for clinical investigation applications, largely due to the Hypercare team proactively encouraging early utilization of HPRA's consultation and pre-submission meeting offerings.

The HPRA highlighted the value of the "learning by doing" model, where real-time, tailored support helped to align stakeholders and ensure sponsors were fully aware of their regulatory obligations. Crucially, the Authority appreciated that this facilitation helped to streamline the process without compromising any of the rigour required for safety and performance.

Looking forward, the HPRA sees this pilot as a potential model for academic-industry collaboration, noting that it demonstrates that independent stakeholders can perform their distinct roles effectively while still supporting a collaborative engagement that advances innovation and serves patient priorities.

Quotes from HPRA

We believe that the Hypercare initiative has helped companies have a much greater understanding of the expectations for clinical investigation applications as the Hypercare team proactively encouraged companies to engage early with the preliminary and pre-submission meetings service which are part of the HPRA support offering.

This is a good example of how Ireland can deliver high-quality, early-phase Medtech trials that meets industry needs, regulator expectations and standards and patient priorities.



National Office for Research Ethics Committees

Feedback from the National Office that supports the NREC-MD, highlighted that their experience of the Hypercare initiative was very positive. Engagement of study teams with the National Office in pre-submission meetings led to more efficient validation of applications and an overall higher quality of the application dossier. Dedicated meetings with the National Office to clarify Committee queries were particularly effective in supporting the Committee in completing assessments.

By acting as a single point of coordination for logistics—managing meeting dates, locations, and formats—the Hypercare team reduced the administrative work associated with Hypercare from the National Office, allowing them to focus on their core mandate of supporting the NREC-MD to deliver a robust single national ethics opinion, with efficiency. Although the National Office does not judge ethical merit directly, pre-submission meetings allowed them to highlight key components relating to the protection of study subjects early in the process, ensuring sponsors addressed them before formal submission for review by the NREC-MD.

For future applicants the necessity of adopting a "participant-focused lens" was a key theme in these meetings. The National Office feedback suggests that while technical and regulatory compliance is often strong, sponsors must ensure the ethical perspective is integrated from the outset, rather than treated as a retrospective checklist.

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Quotes from NREC

Early engagement with study teams through the Hypercare initiative has allowed us to discuss the ethics application and review process in-depth and address specific questions, without compromising the independence and rigour of the NREC-MD review.

The Hypercare initiative has the potential to strengthen Ireland's research infrastructure and benefit patients at the fore of research.

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Hypercare Team Observations

Several themes emerged across the first three cases:

- **Early regulator and ethics engagement matters:** Pre-consultation meetings are likely to have reduced downstream queries and rework and ensured key considerations were highlighted early to sponsors.
- **Coordination adds tangible value:** Parallel processing of regulatory and ethics submissions with contract preparation, and a single-point-of-contact model improved efficiency.
- **Understanding site requirements:** Planning for clinical site activation through mapping out process requirements supports efficient PPFV timelines.
- **Co-development with patients:** Patient and public involvement in study planning is valuable for ethics assessments.
- **Clarity of roles and decision making is critical:** Ambiguity around responsibilities can introduce avoidable delays.
- **Perception shift:** Sponsors reported a more collaborative and responsive experience.

The Hypercare team found engagements with both HPRA and National Office to be highly collaborative. Dedicated meetings of the Hypercare team with HPRA and National Office allowed for sharing of experience.



Recommendations

The initial results of the Hypercare pilot are promising, and scaling this model presents a real opportunity to support the clinical research ecosystem for medical devices. This has the potential to support national priorities identified by the NCTOG, such as developing agile and responsive systems, and supporting strategic workforce development.⁵ To realise this potential, identifying a long-term, sustainable support and funding model will be key. Building towards a unified national approach will require leveraging of national clinical trial networks and CRFs to streamline national rollouts and attract both local and global sponsors.

Conclusion

The first three Hypercare cases demonstrate that structured coordination, early engagement, and visibility can materially improve the efficiency, quality and experience of achieving approval for medical device clinical investigations in Ireland—without changing the underlying regulatory framework.

Beyond resolving administrative bottlenecks, the continuation and potential expansion of the Hypercare pilot carry significant strategic importance. Retaining and attracting clinical investigation activity yields substantial regional economic benefits, firmly positioning Ireland as a globally competitive hub for medical technology. Furthermore, increasing the volume of research activity within Irish hospitals directly benefits the broader health service by introducing novel technologies designed to address unmet medical need. This will require support beyond FPFV, to ensure that enrolment and trial completion is conducted efficiently. Ultimately, streamlining these pathways ensures that patients gain earlier access to investigational and potentially life-enhancing medical innovations, offering an important societal benefit.



Mitigations applied to Drive Efficiency

The use of a single point of contact by the Hypercare team, allowed streamlined interactions between sponsors and other organisations, which was highly valued by the sponsors.

In order to streamline the timeline between HPRA and NREC-MD approvals and contract finalisation, Hypercare engaged in proactive coordination and early engagement with the Clinical Research and Development Office (CRDO). By initiating contract preparation in parallel with HPRA and NREC submissions, the overall time to site initiation was likely significantly reduced.

Hypercare facilitated inter-organisational data collection to support coordination between the sponsor, university research and governance teams, and the hospital site. In one instance, the Hypercare team worked with the hospital in preparing a report with a 2-week turnaround to support an NREC-MD query, ensuring timely ethical approval.

The NCTOG policy recommendation regarding data protection impact assessments (DPIAs) was finalised during the pilot, which simplified and streamlined this process. Furthermore, the NREC-MD does not review DPIAs, but rather a 'statement of compliance' to demonstrate data protection requirements are met.

