Health Research Board
NCTO
National Clinical Trials Office

# Advancing Ireland's Medtech Clinical Research Ecosystem: Insights, Comparisons, and Actionable Recommendations

Enterprise Ireland

Irish Medtech
Ibec

IDA Ireland

# ABBREVIATIONS

- AI: Artificial Intelligence
- CNS: Central Nervous System
- CRF/C: Clinical Research Facility/Centre
- CRO: Clinical Research Organisation
- CTA: Clinical Trial Agreement
- DPIA: Data Protection Impact Assessment
- DPO: Data Protection Officer
- EFS: Early Feasibility Study
- EI: Enterprise Ireland
- EU: European Union
- FDA: Food and Drug Administration (US)
- GDPR: General Data Protection Regulation
- HSE: Health Service Executive
- HPRA: Health Products Regulatory Authority
- IDA IRELAND: Industry Development Agency Ireland
- IDE: Investigational Device Exemption
- IPHA: Irish Pharmaceutical Healthcare Association
- KOL: Key Opinion Leader
- mCTA: Model Clinical Trial Agreement
- MDR: Medical Device Regulation
- MNC: Multinational Corporation
- NCTO: National Clinical Trials Office
- NO-REC: National Office for Research Ethics Committees
- PI: Principal Investigator
- PM: Project Manager
- R&D: Research and Development
- SME: Small and Medium-sized Enterprise
- US: United States
- WG: Working Group

# Advancing Ireland's Medtech Clinical Research Ecosystem: Insights, Comparisons, and Actionable Recommendations

## Executive Summary

This report summarises a survey conducted to assess medtech industry stakeholders' experiences and perspectives regarding the conduct of clinical investigations both in Ireland and internationally. Respondents included companies and organisations actively engaged in clinical medtech research, providing insights into regulatory processes, workforce challenges, patient recruitment, and compliance with the EU Medical Device Regulation (MDR). Key findings highlight widespread recognition of Ireland's strengths—particularly its infrastructure and regulatory clarity—tempered by challenges related to skill gaps and lengthy approval timelines. Recommendations emphasise improving regulatory efficiency, addressing skills shortages, and fostering EU-wide harmonisation to bolster Ireland's competitiveness.

### Acknowledgement

I would like to thank Dr. Tom Melvin, Associate Professor in Medical Device Regulatory Science, Institute for Clinical Trials, University of Galway, and Ms. Alison McDonnell, PhD student at the University of Galway, for their academic support.

I am also grateful to my colleagues in the NCTO MedTech Working Group and at NCTO - Niall, Eoghan, Michèle, Ruben, and Evelyn - led by our Director, Dr Robert O'Connor, for their ongoing collaboration and encouragement.

I would like to sincerely thank our national stakeholders - Enterprise Ireland, IDA Ireland, and Irish Medtech - for their continued support and engagement throughout this work.

Finally, I would like to express my appreciation to all participants who took the time to complete the survey. Their input has been invaluable in providing meaningful insights and shaping the results presented in this report. The feedback gathered has allowed for a more informed analysis and will contribute significantly to guiding future decisions and strategies.

*Fiona Ryan*

*Clinical Industry Liaison Officer*

# 1. Introduction

This survey was conducted to evaluate industry stakeholders' perceptions and experiences regarding the landscape, challenges, and opportunities associated with conducting clinical medtech research in Ireland. This report summarises a survey conducted to assess industry stakeholders' experiences and perspectives regarding the conduct of clinical investigations both in Ireland and internationally (See Appendix 1). It aimed to gather insights from MedTech companies about their experiences in regulatory processes, workforce challenges, patient recruitment, and compliance with EU MDR regulations, as well as Ireland's comparative standing internationally. In this report, findings from the clinical investigations survey were presented and analysed. The profile of all respondent companies and organisations is published in Appendix 2 – Table of Figures, figures 9 to 12, providing additional context regarding the participants included in the study.

Specifically, the survey assessed:

- Stakeholder interest in selecting Ireland for clinical investigations and their motivations.
- Satisfaction levels with Ireland's clinical research environment, including perceptions of Ireland's attractiveness for clinical studies.
- Experiences and challenges faced by respondents conducting clinical investigations in Ireland, covering regulatory approval, ethics, funding, patient recruitment, and clinical partnerships.
- Comparisons drawn by respondents based on their experiences conducting clinical research in other countries, emphasising regulatory timelines, patient recruitment, and beneficial practices that could be adopted in Ireland.
- Engagement with Clinical Research Organisations (CROs), including reasons for or against their use.
- Detailed profiles of participating companies, capturing organisation type, size, industry affiliations, and targeted health sectors.
- Information about the stage of product development, financial support received, and skill-related challenges faced in Ireland.
- Recommendations for improvements in Ireland's clinical research ecosystem, addressing identified gaps in expertise, regulatory challenges, and participants' views on ideal research ecosystems.

Additionally, the survey sought feedback on compliance with EU MDR regulations and invited interested participants to engage in further discussions.

# 2. Method

## 2.1. Development of an on-line anonymised survey

The survey questionnaire was developed collaboratively with Irish MedTech, Enterprise Ireland, IDA Ireland, University of Galway academic group and supported by the NCTO MedTech WG and industry representatives. It was promoted broadly through industry bodies and the social media channel - LinkedIn, to ensure comprehensive participation. The survey launched in October 2024 and closed in February 2025, gathering 31 complete responses from key industry stakeholders.

# 3. Results

A total of 31 participants responded to this survey questionnaire. Respondents were not required to answer all questions; thus, the number of responses varies per question. All data presented below reflect the number of respondents who answered each specific question.

## 3.1. Perceptions of:

### *3.1.1 Ireland*

Respondents generally recognised Ireland's established clinical research framework, highlighting strengths such as well-trained clinicians, presence of MedTech companies, and infrastructure like Clinical Research Facilities/Centres (CRF/Cs). Nonetheless, concerns were expressed regarding specific challenges unique to Ireland, including perceptions of slow approval processes exacerbated by local regulatory requirements and General Data Protection Regulation (GDPR) compliance. Recruitment difficulties due to limited patient pools, heavy clinician workloads, and administrative burdens also featured significantly as negative perceptions. Moreover, some respondents indicated a perception of inadequate preparation for early-stage or non-CE-marked device studies. The recent improvements in regulatory frameworks were noted positively, though respondents emphasised that clearer roles between local and national ethics committees and more efficient approval processes remain essential.

### *3.1.2 International Experiences*

Respondents generally perceived international clinical research experiences positively, highlighting streamlined processes, clear regulatory frameworks, effective recruitment, and engaged clinicians, notably in the US and Australia. However, some also encountered challenges, such as high costs, lengthy ethical and regulatory pathways, administrative complexities, and occasional slower-than-expected site activation and recruitment. Overall, initial expectations varied, with many respondents experiencing better standards and efficiency abroad than anticipated.

## 3.2 Company experiences of conducting clinical investigations in:

### *3.2.1 Ireland:*

65% (20) of respondents have conducted clinical investigations in Ireland of which 70% (14) have conducted more than one clinical investigation in Ireland. Respondents identified several significant strengths of the Irish clinical research ecosystem. These include the presence of established CRF/Cs, well-trained and qualified staff, engaged investigators, and strong networking opportunities facilitated by Ireland's relatively small geographic scale. Other notable strengths include:

- Local healthcare industry partnerships and effective communication among stakeholders.
- Familiarity and ease of access, particularly beneficial for early-stage and established medical device companies.
- Skilled personnel, robust infrastructure, and a clear regulatory and ethics framework, recently enhanced through MDR and the establishment of a central ethics committee office – National Office for Research Ethics Committees (NO-REC).
- Rapid patient enrolment in certain studies and highly engaged clinicians, often with international training and experience.
- Availability of academic sites and CROs that support research activities, along with attractive government funding and R&D tax incentives.
- Positive relationships and efficient processes with regulatory authorities - HPRA and NO-REC.

When asked if they had any issues with patient enrolment with their investigations in Ireland, 11 respondents (79% of those who replied) said No (see Figure 1).

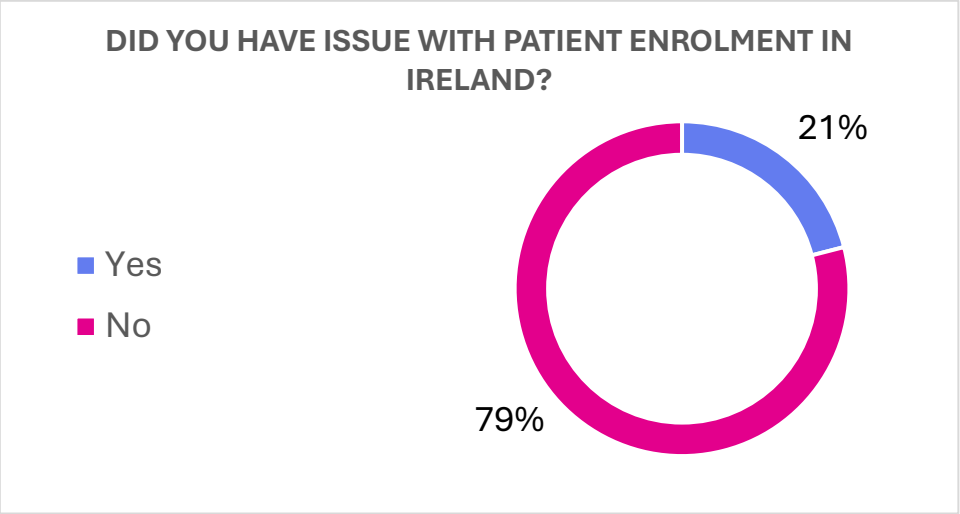


*Figure 1 - Did You Have Issue with Patient Enrolment?*

Figure 2 shows the results when the 20 respondents were asked if they experienced any additional burdens in the clinical development pathway in Ireland compared to other countries:

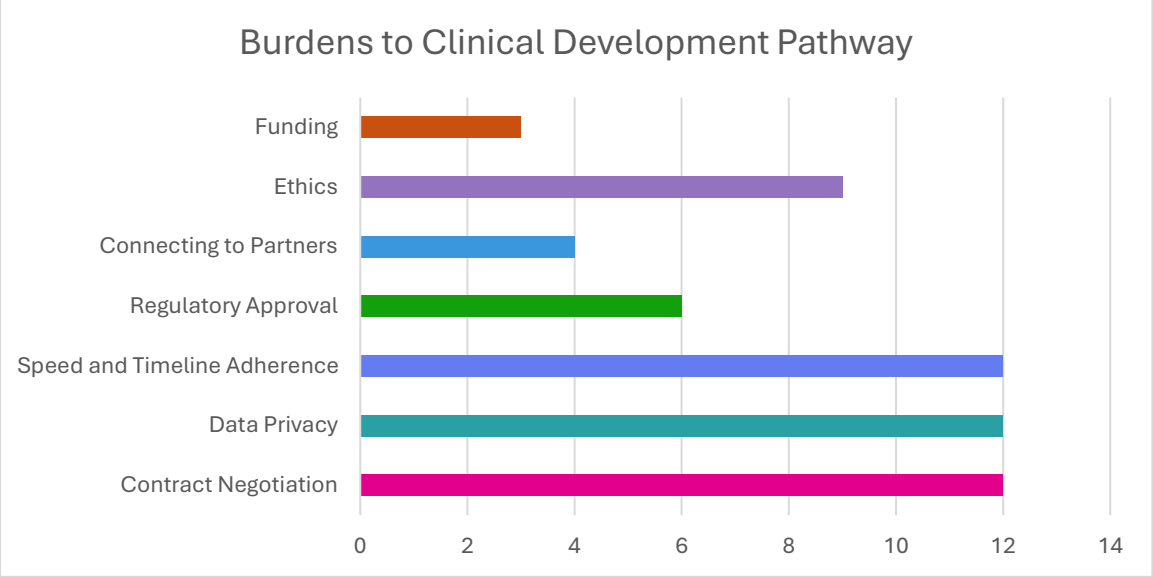


*Figure 2 - Burdens to Clinical Development Pathway*

### *3.2.1.2 Perception v Reality:*

Initial perceptions of Ireland as a clinical trial location were not uniformly positive. One company, for example, expected Ireland to be a "slow" country with "low enrolment." However, their actual experience revealed "fast enrolling sites for the studies we have running in Ireland," demonstrating a notable shift from initial expectations to positive real-world outcomes.

Another stakeholder noted that "all parties in the ecosystem communicate with each other and have demonstrated a willingness to do better," reflecting the collaborative nature of the clinical research environment. A further comment suggested that "once you get past the regulation, recruitment, retention and data quality is excellent," which appears to summarise the overall sentiment among stakeholders engaging with the Irish clinical research landscape.

Additionally, another respondent stated, "In our current communication with both HPRA and NO-REC, there is great willingness to review timelines critically and review increasing efficiencies, so I am hopeful for a good reduction in start-up times, leading to positive examples and, as a consequence, putting Ireland higher up on the preferred countries list when we have new studies coming."

Figure 3 shows that when asked if they would conduct another clinical investigation in Ireland, 12 of the 14 respondents said yes.

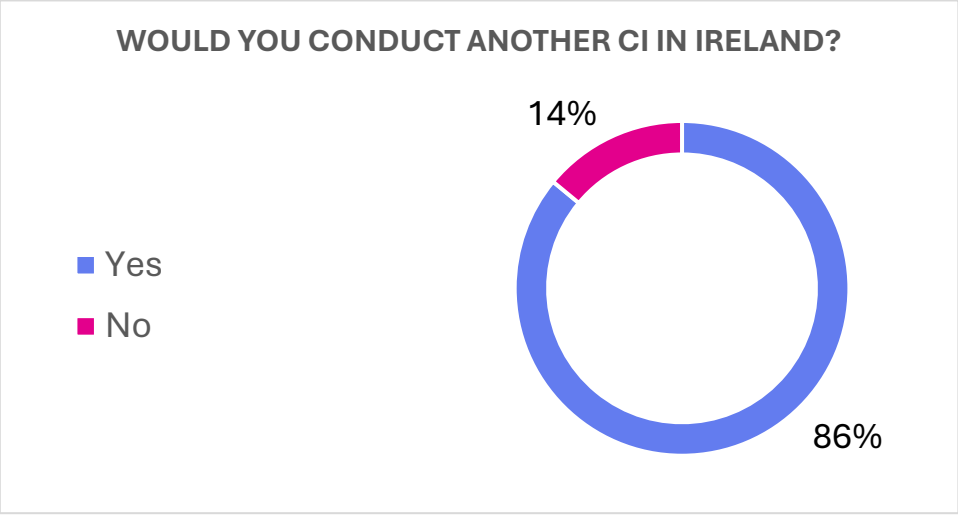


*Figure 3 - Would You Conduct Another CI in Ireland?*

### 3.2.2 *Overseas territory:*

71% of respondents (22) have conducted clinical investigations in an overseas jurisdiction. Figure 4 outlines the number of investigations per country:

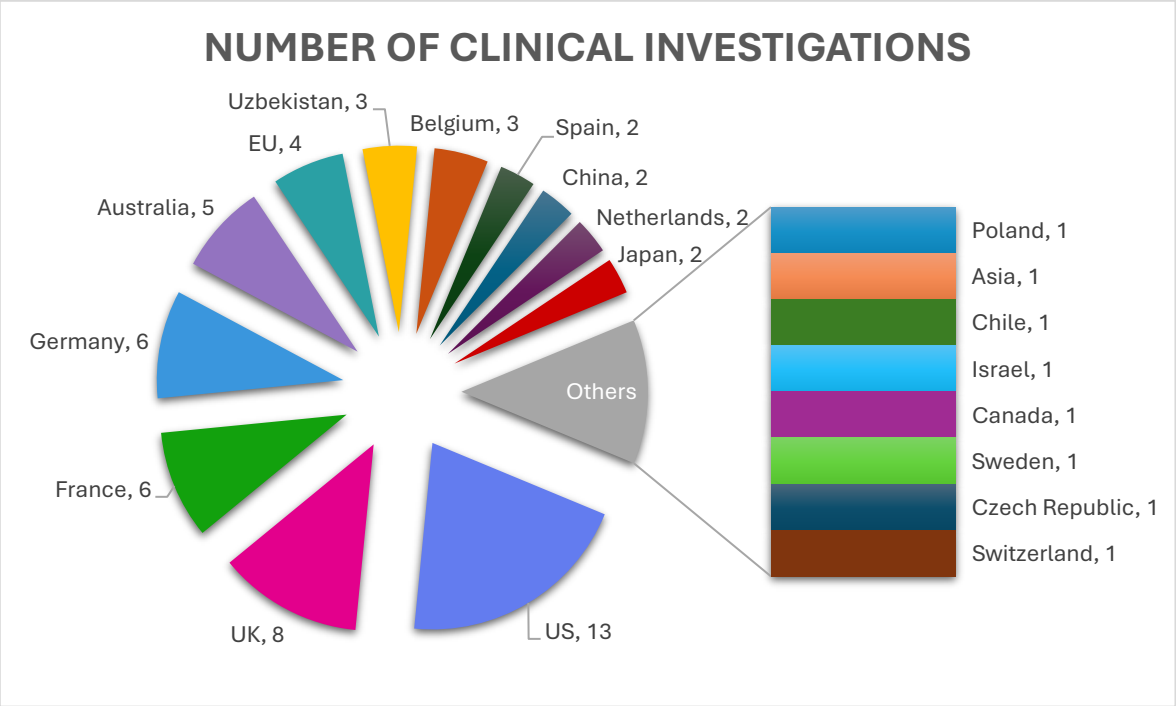


*Figure 4 - Number of Clinical Investigations*

Respondents identified several useful approaches observed in other territories that could enhance the Irish clinical research ecosystem. Key suggestions include:

- Adoption of an Early Feasibility Study (EFS) model initiated by the FDA in the US.
- Simplification of GDPR processes to reduce delays.
- Centralisation and simplification of ethics approval processes.
- Clear contract templates and streamlined administrative pathways, minimizing Data Protection Officer (DPO) reviews.
- Provision of dedicated administrative departments and supportive staff at clinical sites for managing trials.
- Strategic initiatives similar to FDA's Q-Submission (Q-Sub) process, increased early engagement, and centralised patient databases.
- UK-style local R&D approval processes ensuring resource availability and recruitment targets.

- Risk mitigation strategies for non-CE marked medical devices, exemplified by the practices of France's Institute of Health and Medical Research (IHU) network in medical and research training (IHU France - Network of University Hospital Institutes).

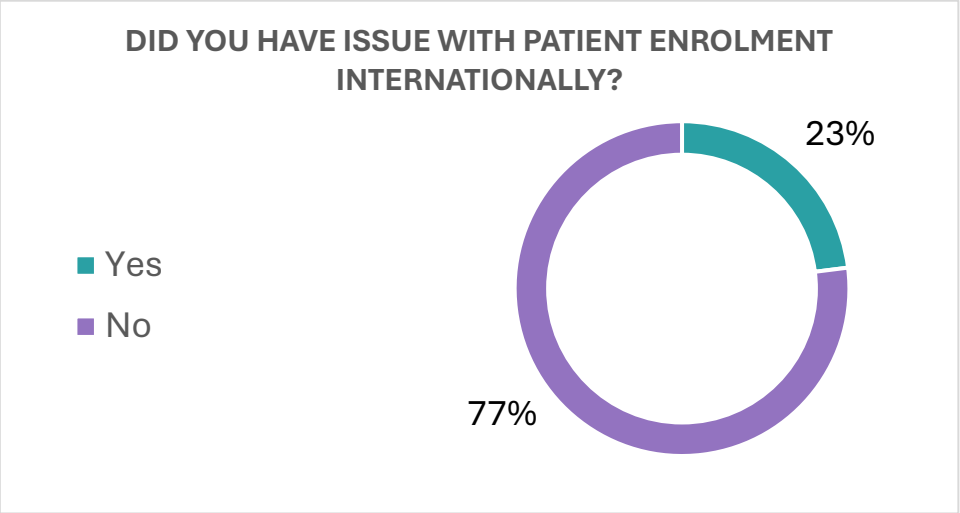


*Figure 5 - Did You Have Issue with Patient Enrolment?*

Figure 5 shows that 77% of respondents (17) did not encounter any issues with patient enrolment. Those 5 respondents reported several common challenges related to patient enrolment in clinical investigations abroad, including slower-than-expected recruitment rates, seasonal fluctuations impacting participant availability, and variability in site performance based on Principal Investigator (PI) engagement. Additional challenges involved logistical issues such as limited access to specialised assessments (e.g., radiology), misalignment with commercial partners, and the perception among senior leadership that slower enrolment overseas could make domestic options, such as Early Feasibility Studies (EFS) in the US, more attractive. Despite these issues, utilising multiple independent sites often helped achieve overall recruitment targets.

All respondents (22) expressed interest in conducting additional clinical investigations in the overseas territory primarily due to clear and efficient regulatory pathways, the availability of supportive clinical networks, and the need for broader adoption and data supporting new medical devices or technologies. Other significant reasons included efficient approval processes, effective collaboration opportunities with key clinical sites, minimal bureaucratic obstacles, and the establishment of successful previous experiences or networks in those territories. Respondents particularly valued predictable timelines, strong engagement from clinical sites, and simplified administrative procedures that support timely and successful clinical investigation execution.

Based on the responses provided, there is no clear consensus on which country is the best place to conduct clinical investigations. However, several countries were frequently mentioned positively:

- **United States (US)**: Frequently identified for streamlined regulatory processes, clear expectations, robust infrastructure, efficient review times, and supportive frameworks such as Early Feasibility Studies (EFS).
- **Germany, Belgium, and the Netherlands**: Highlighted for their efficient approval processes, strong institutional support, and favourable regulatory and ethical review frameworks.
- **Australia**: Valued for effectiveness in early feasibility studies despite geographical distance.
- **Denmark and Sweden**: Praised for their healthcare systems, registries, and clinical trial efficiency.
- **Israel**: Noted for innovation support, active medical research centres, and strong venture capital availability.

Several respondents indicated uncertainty or lack of sufficient experience to provide a definitive judgment, suggesting no single country universally meets all requirements but rather that each has distinct advantages and challenges depending on the specific clinical investigation needs.

# 4. Other Findings

## 4.1 Contract Research Organisations (CROs)

Figure 6 shows that nearly half of respondents have used the services of a CRO:

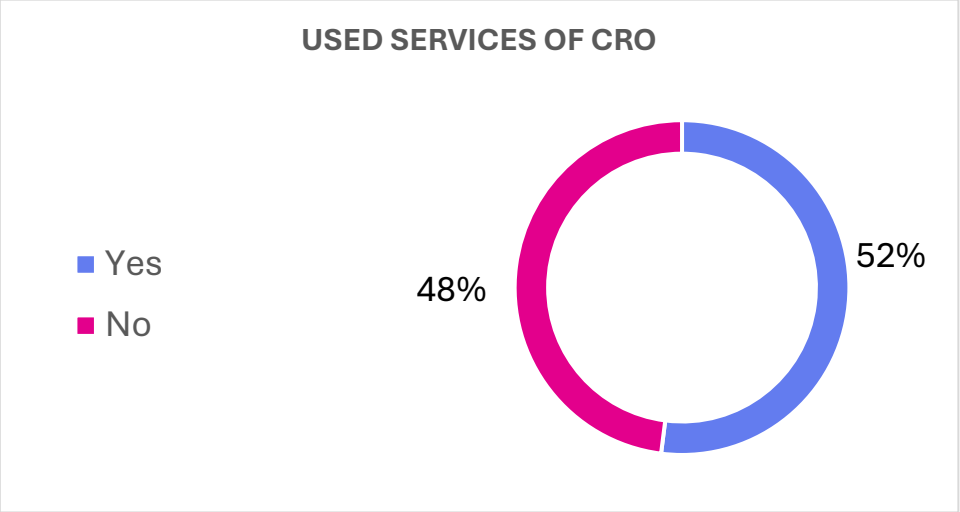


*Figure 6 - Used Services of CRO*

**Use of Contract Research Organisations (CROs)**

Companies chose to use CROs (see Figure 7 & 8) primarily due to:

- Lack of internal expertise.
- Insufficient internal resources or time to manage documentation and processes.
- Access to trained, experienced personnel without the need for ongoing recruitment or retraining due to short-term contract structures.
- Cost-effectiveness.

Reasons for not engaging CROs included dedicated internal resources, high perceived costs, specialisation of the research area, lack of awareness, or being at a very early stage of research (preclinical).

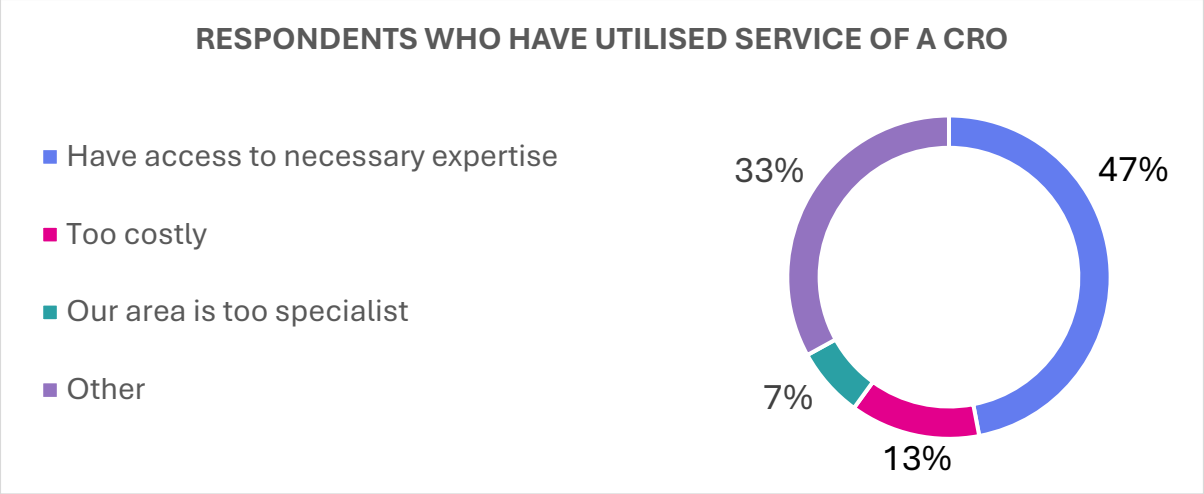


*Figure 7 - Respondents Who Have Utilised Services of a CRO*

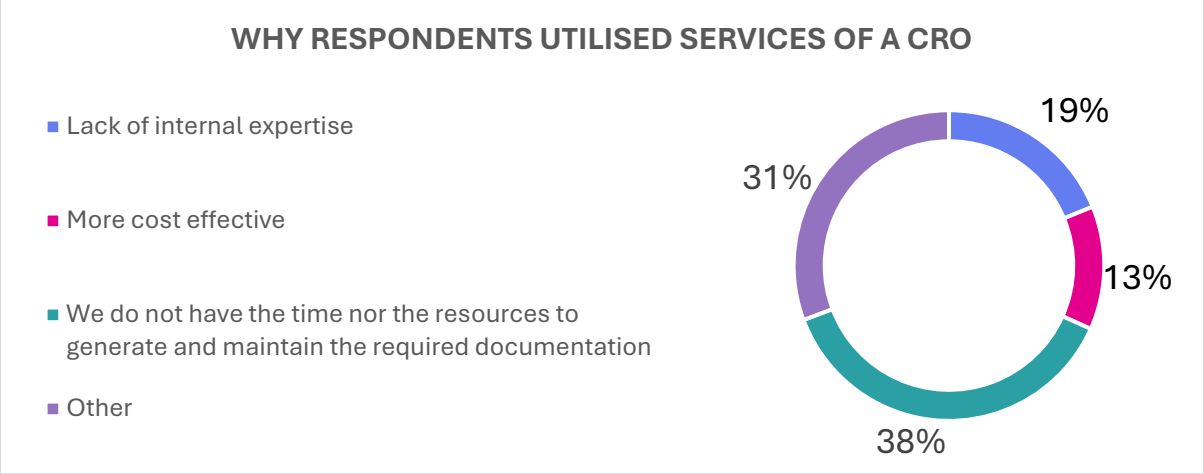


*Figure 8 - Why Respondents Utilised Services of a CRO*

## 4.2 Addressing Perceived Skills Gaps and Training Needs

### *4.2.1 Perceived Skills Gaps*

Respondents identified several critical skills gaps affecting clinical research in Ireland, including:

- Project management skills, significantly impacted by short-term funding cycles causing frequent retraining.
- Insufficient stable infrastructure and dedicated research personnel to effectively attract and manage industry trials.

- Shortage of experienced staff in clinical trial management, patient enrolment, and specialised statistical analysis.
- Limited expertise in pre-clinical and first-in-human studies.
- Deficiencies in data management, clinical reporting, and statistical design capabilities.
- Awareness of Good Clinical Practice (GCP) varies across healthcare settings, highlighting the potential value of continued professional development in this area.
- Inadequate follow-on funding, hindering the growth and scalability of research projects.
- Limited access to facilities suitable for advanced preclinical research, particularly involving large animal models.

### *4.2.2 Training and Skill Development Recommendations*

In response to these perceived skills gaps, respondents recommended:

- Enhancing Ireland's marketing and communication to highlight recent improvements, increased transparency from regulatory agencies, and openness to industry collaboration.
- Advanced training in AI integration with medical devices.
- Clinical trial management, patient recruitment strategies, and operational management.
- Regulatory and ethical framework courses specific to clinical research.
- Practical workshops on technical dossier preparation, clinical protocols, and clinical report writing.
- Comprehensive GDPR compliance, data management, and analytics training.
- Specialised courses in Good Clinical Practices (GCP) and clinical assay management.
- Leadership and project management training tailored specifically for clinical research roles.
- Enhanced clinical experience through direct participation and mentoring schemes.
- Statistical analysis, clinical trial design, and regulatory strategy training.
- Facilitation of structured forums to encourage investigator and industry collaboration.

- Clarification and standardisation of Data Protection Impact Assessment (DPIA) processes across institutions to avoid redundancy.
- Training in preclinical laboratory methods, software engineering, and specialised healthcare sectors such as CNS health.
- Regulatory affairs training to navigate complex compliance requirements and mitigate litigation risks.
- Development of preclinical facilities to support advanced research and innovation.

## 5. Challenges and Recommendations

The results of the survey have been thoroughly analysed and cross-referenced, with key insights summarised in this section. Challenges and corresponding recommendations have been categorised into short-term and long-term perspectives, further divided into those identified at both Irish and European levels.

**Short-Term Challenges**

**Irish Level**

- Prolonged approval timelines and fragmented regulatory and ethical approval processes.
- Limited protected research time for clinicians, reducing their ability to participate effectively in clinical investigations.
- Repetitive and redundant DPIA reviews across hospitals, universities, and commercial entities.
- Insufficient skills and expertise in clinical trial management, regulatory compliance, and GDPR among research staff.

**European Level**

- Fragmented and inefficient regulatory submissions across EU member states, causing delays and duplication.
- Complex and inconsistent interpretations of GDPR regulations.
- Lack of clear, practical guidance for SMEs regarding EU MDR compliance.

**Short-Term Recommendations**

**Irish Level**

- Streamline Contract Approvals and Timelines: Establish predictable and transparent timelines for contract approvals. Introduce a standardised template for clinical investigations similar to the Clinical Trial Agreement (CTA) templates agreed by the HSE and the Irish Pharmaceutical Healthcare Association (IPHA): Clinical Trials - HSE | Research & Development
- Protected Clinician Time: Ensure protected research time for clinicians to facilitate increased participation in clinical studies.
- Mutual Recognition of DPIAs: Implement mutual recognition agreements among DPOs to eliminate repetitive DPIA reviews.
- Skills and Training Development: The creation of a MDR Support Hub for Medtech companies to offer targeted training in regulatory compliance, GDPR, clinical trial

operations, and patient recruitment, supported by structured forums for clinician-industry collaboration.

- Data Protection Templates: Develop standardised GDPR-compliant documentation templates to accelerate approvals.

**European Level**

- Unified Regulatory Submission Process: Advocate for a single regulatory and ethical approval submission across the EU, similar to the system in place for medicinal products.
- Clear EU MDR Guidance: Provide explicit, SME-focused guidance on MDR compliance, reducing complexity and improving accessibility.
- Simplified GDPR Framework: Harmonise GDPR regulations across the EU using a streamlined, risk-based approach to simplify compliance.

**Long-Term Challenges**

**Irish Level**

- Unstable and short-term funding structures, causing high staff turnover and expertise gaps.
- Limited preclinical and clinical research facilities, restricting capacity for advanced research.
- Inadequate innovation support and limited financial incentives for early-stage MedTech research.

**European Level**

- Lack of mutual recognition and inconsistent regulatory and ethical decisions across EU member states.
- Variability in clinical investigation standards and processes, leading to inefficiencies.
- Insufficient EU-wide support frameworks for early feasibility and first-in-human clinical studies.

## Long-Term Recommendations

### Irish Level

- Permanent Research Funding: Establish sustainable, long-term funding models to retain skilled research staff and reduce turnover.
- Expand Research Infrastructure: Develop advanced preclinical (ex-vivo and in-vivo) facilities to enhance Ireland's capability in early-stage clinical research.
- Financial and Innovation Support: Increase financial incentives and provide better access to venture capital funding for early-stage MedTech projects.
- Dedicated Innovation Units: Set up specialised innovation departments within healthcare services (e.g., HSE) to streamline research processes and support medical innovation.
- Career Pathways: Create permanent career paths with incentives to attract and retain experts in clinical research management and biostatistics.

### European Level

- Mutual Recognition of Approvals: Foster mutual recognition and harmonisation of regulatory and ethical approvals across EU member states.
- Harmonise Clinical Research Standards: Standardise clinical trial procedures across Europe to ensure consistency, efficiency, and quicker initiation.
- Early Feasibility Support Framework: Develop EU-wide regulatory frameworks and dedicated funding schemes specifically aimed at facilitating early feasibility and first-in-human studies to boost European competitiveness.
- Increased Access to Regulatory Expertise: Enhance access to notified bodies and regulatory expertise, particularly for SMEs, to simplify navigation through complex EU MDR compliance processes.

## 6. Next Steps

The survey results provided valuable insights into current challenges and highlighted areas requiring immediate attention. Drawing upon these insights, an extensive analysis was conducted, resulting in tailored recommendations - some directly informed by respondents' feedback and others derived from a critical evaluation of the concerns identified. To ensure the successful implementation of these recommendations, the following steps are proposed as priority actions:

- Stakeholder Consultation: Conduct workshops and consultation sessions with key stakeholders, including regulators, healthcare professionals, industry representatives, and research institutions, to refine strategies for short-term and long-term improvements.
- Action Plan Development: Develop a detailed action plan with clearly defined roles, responsibilities, and timelines for implementing the recommendations at both Irish and European levels.
- Funding and Resource Allocation: Identify and secure appropriate funding and resources to support the implementation of recommended actions, particularly infrastructure enhancements and training initiatives.
- Monitoring and Reporting Framework: Establish a robust framework to regularly monitor progress, measure outcomes, and report on implementation status to ensure transparency and accountability.
- Pilot Initiatives: Launch pilot projects to test and demonstrate the effectiveness of proposed changes, particularly around streamlined regulatory processes and new infrastructure.
- Contracting Efficiency: Establish predictable and transparent timelines for contract approvals. Consider the adoption of a standardised template for clinical investigations, similar to the model Clinical Trial Agreement (mCTA) currently agreed by the HSE and the Irish Pharmaceutical Healthcare Association (IPHA) for clinical trials involving medicinal products.
- Enhanced Marketing and Communication: Develop and implement effective strategies to communicate Ireland's regulatory improvements, transparency, and openness to collaboration with industry stakeholders.

## 7. Conclusion

This survey highlights significant opportunities as well as critical challenges facing the medtech clinical research environment in Ireland and across Europe. Addressing these challenges through structured, practical, and collaborative actions will greatly enhance Ireland’s position as a leading destination for medtech clinical research. Improved contracting efficiency, supported by clear timelines and wider use of a standardised template like the HSE-IPHA CTA, will strengthen industry engagement and expedite clinical study start-up. Clear and effective communication of Ireland's improved regulatory transparency, efficiency, and openness to collaboration will further reinforce its attractiveness for international clinical investigations, benefiting medtech industry stakeholders, healthcare professionals, and ultimately, patients.

# References

## HSE-approved Clinical Trial Agreement Templates

Clinical Trials - HSE | Research & Development

## Network of University Hospital Institutes, France

IHU France - Network of University Hospital Institutes

# APPENDIX 1 Survey Questions

## SURVEY ON IRISH MEDTECH COMPANIES' EXPERIENCES WITH CLINICAL INVESTIGATIONS & STUDIES

This survey, supported by Enterprise Ireland and conducted by the National Clinical Trials Office (NCTO) in collaboration with IDA Ireland and Irish Medtech, aims to gather crucial insights from organisations involved in clinical investigations and performance studies both in Ireland and internationally. It seeks to identify key challenges and opportunities faced by commercial and research organisations, ranging from small start-ups to multinational companies. The data collected is of utmost importance and will be used anonymously to inform and drive significant improvements across the sector. We appreciate your participation and value your contribution to this vital initiative. Thank you for your support. Any queries can be directed to Fiona Ryan, Clinical Industry Liaison Officer at NCTO - FionaRyan@ucc.ie

*required

### IRELAND

**1. Would you choose Ireland as a location to conduct a clinical investigation?***

- Yes

- No

**2. If Yes, briefly explain your answer ***

**3. If No, briefly explain your answer ***

**4. How do you rate your satisfaction as to how Ireland compares internationally with attracting clinical investigations/studies?***

▪ Very Satisfied ▪ Satisfied ▪ Neutral

▪ Somewhat Satisfied ▪ Very Dissatisfied

**5. Have you ever undertaken clinical investigations/performance studies in Ireland?***

- Yes

- No

**6. What perceptions did you have before conducting clinical investigations/performance studies in Ireland?***

**7. In your experience, what are the strengths of the Irish clinical research ecosystem?***

**8. Have you found any additional burdens in the clinical development pathway in Ireland compared to other countries that you have experience with? Select all that apply. ***

☐ Speed and timeline adherence ☐ Data privacy

☐ Ethics ☐ Regulatory approval

| | | | |
|---|---|---|---|
| ☐ | Connecting to relevant clinical partners | ☐ | Funding |
| ☐ | No burdens | ☐ | Other |

**9. Have you conducted more than one clinical investigation/performance study in Ireland? ***

- Yes

- No

**10. Please select how many clinical investigations/performance studies you have participated in. For the purposes of this survey, please answer the following questions in relation to your most recent completed clinical investigation/performance study.***

| | | | |
|---|---|---|---|
| Level 1 | Level 2 | Level 3 | Level 4 |
| Level 5 | Level 6 | Level 7 | Level 8 |

**11. How long has it taken your organisation to gain Health Product Regulatory Authority (HPRA) Approval for investigations/performance studies?***

| | | | |
|---|---|---|---|
| ☐ | 60 days or less | ☐ | 61 to 120 days |
| ☐ | 120 – 180 days | ☐ | > 180 days |

**12. How long has it taken your organisation to gain Research Ethics Committee/National Office for Research Committees Approval for investigations/performance studies? ***

| | | | |
|---|---|---|---|
| ☐ | 60 days or less | ☐ | 61 to 120 days |
| ☐ | 120 – 180 days | ☐ | > 180 days |

**13. Subsequent to HPRA & National Office for Research Committees approval, how long did it take for your first patient to be recruited?***

| | | | |
|---|---|---|---|
| ☐ | 60 days or less | ☐ | 61 to 120 days |
| ☐ | 120 – 180 days | ☐ | > 180 days |

**14. Have you found issues with patient enrolment in your investigation in Ireland? ***

- Yes

- No

**15. Please briefly outline the key issues.***

**16. Select as appropriate. Our patient recruitment was:***

| | | | |
|---|---|---|---|
| ☐ | Less than we had targeted | ☐ | similar to what we had targeted |
| ☐ | more than we had targeted | | |

**17. Please indicate how many patients you recruited from Ireland.***

**18. Would you consider conducting another clinical investigation/performance study in Ireland?***

- Yes

- No

**19. If Yes, Please explain your answer***

**20. If No, Please explain your answer***

**21. Have you conducted clinical investigations/performance studies in a territory outside of Ireland?**

- Yes

- No

**22. Please name the territories***

**23. For the purpose of this survey please name the territory in which you have most recently completed your clinical investigation/performance study and answer the following questions relating to this clinical investigation/performance study. ***

**24. What perceptions of this territory did you have before conducting clinical investigations/ performance study in this country? ***

**25. Is there any useful approach within the clinical research development pathway that you have seen in this or another territory that would be useful to incorporate into the Irish system?***

**26. How many calendar months did it take to gain National Regulator approval investigation/ performance study in this other jurisdiction? ***

| | | | |
|---|---|---|---|
| ☐ | 60 days or less | ☐ | 61 to 120 days |
| ☐ | 120 – 180 days | ☐ | > 180 days |

**27. How many calendar months has it taken your organisation to gain Ethics Approval for clinical investigations/performance studies? ***

| | | | |
|---|---|---|---|
| ☐ | 60 days or less | ☐ | 61 to 120 days |
| ☐ | 120 – 180 days | ☐ | > 180 days |

**28. Subsequent to National Regulator and Ethics approval, how many months did it take for your first patient to be recruited? ***

| | | | |
|---|---|---|---|
| ☐ | 60 days or less | ☐ | 61 to 120 days |
| ☐ | 120 – 180 days | ☐ | > 180 days |

**29. Did you encounter any issues with patient enrolment in your investigation in this other territory? ***

- Yes

- No

**30. Please explain your answer.***

**31. Select as appropriate. Our patient recruitment was: ***

☐ less than we had targeted ☐ similar to what we had targeted
☐ more than we had targeted

**32. Please indicate how many patients you recruited.***

**33. Would you consider conducting another Clinical Investigation/Performance Study in that territory? ***

- Yes

- No

**34. If Yes, Please explain your answer***

**35. If No, Please explain your answer ***

**36. Is there any useful approach within the clinical research development pathway that you have seen in another territory that would be useful to incorporate into the Irish system? ***

**37. Have you utilised the services of a Clinical Research Organisation (CRO)? ***

- Yes

- No

**38. If No, Please select why: ***

☐ Have access to necessary expertise ☐ Too costly
☐ Our area is too specialist ☐ Other

**39. If Yes, Please select why: ***

☐ Lack of internal expertise ☐ More cost effective
☐ We do not have the time nor resources to generate and maintain the required documentation

☐ Other

**40. Which of the following best describes your organisation?***

☐ Medical Technology company with less than 10 employees
☐ Medical Technology company with 10-20 employees
☐ Medical Technology company with 20-100 employees
☐ Medical Technology company with more than 100 employees
☐ University/Academic spinout
☐ Clinical Research Facility/Centre
☐ Hospital
☐ Other

### 41. Is your organisation a client of the following *

| | | | |
|---|---|---|---|
| ☐ | Enterprise Ireland HPSU | ☐ | IDA Ireland |
| ☐ | Enterprise Ireland Comms Fund participant | ☐ | Other |

### 42. Is your organisation a member of Irish Medtech? *

- Yes

- No

### 43. From the Health Research Classification System, what areas of health is your device targeting? *

| | | | | | |
|---|---|---|---|---|---|
| ☐ | Blood | ☐ | Cancer | ☐ | Cardiovascular/Cardiac |
| ☐ | Congenital Disorders | ☐ | Ear | ☐ | Eye |
| ☐ | Infection | ☐ | Inflammatory & Immune system | | |
| ☐ | Accidents & Injuries | ☐ | Mental Health | ☐ | Mental Health |
| ☐ | Musculoskeletal | ☐ | Neurological | ☐ | Oral & Gastrointestinal |
| ☐ | Renal & Urogenital | ☐ | Reproductive Health & Childbirth | | |
| ☐ | Respiratory | ☐ | Skin | ☐ | Stroke |
| ☐ | Generic Health Relevant | ☐ | In vitro diagnostics | ☐ | Other |

### 44. What stage of development would best describe the product you are currently working on?*

☐ Idea - no officially documented pre-clinical testing completed.
☐ Early Concept - Documented pre-clinical testing completed in animal models or similar. The final design selection needs to be completed.
☐ Under initial clinical evaluation for safety and performance testing.
☐ Design Selected - Safety and performance testing completed, and the final design is ready for Design Verification and Validation Testing.
☐ Ready for Clinical Testing - Sufficient testing completed to submit an application for clinical investigation.
☐ Completed First in-Man Clinical Investigation
☐ CE certified
☐ Completed multiple Clinical Investigations
☐ Other

### 45. Have you received state financial support for the research activity leading up to these clinical investigations/studies?

- Yes

- No

### 46. From which agency/ organisation?

| | | | |
|---|---|---|---|
| ☐ | Enterprise Ireland | ☐ | IDA Ireland |
| ☐ | Udaras na Gaeltachta | ☐ | HRB |
| ☐ | HRB Spark | ☐ | Other |

### 47. Do you perceive any critical skills needed/ skill gaps that need to be addressed in this country?*

### 48. What courses/training could benefit your own efforts? *

**49. Would you choose Ireland as a location to conduct a clinical investigation/performance study? ***

- Yes

- No

**50. Are there any areas of expertise within the MedTech sector that you have found Ireland is lacking in? ***

**51. What two improvements would you like to see better support clinical research for the MedTech sector? ***

**52. Have you or do you plan to discontinue certain medical devices due to challenges meeting the EU MDR clinical evaluation requirements? ***

**53. Which country has the most ideal research eco-system from your experience and why? ***

**54. We may invite some participants to further discuss their experiences in clinical investigations or performance studies. Please provide your email address if you are interested in joining us.**

**55. Please share any feedback that you think was not addressed in this survey and why.**

# APPENDIX 2 Table of Figures

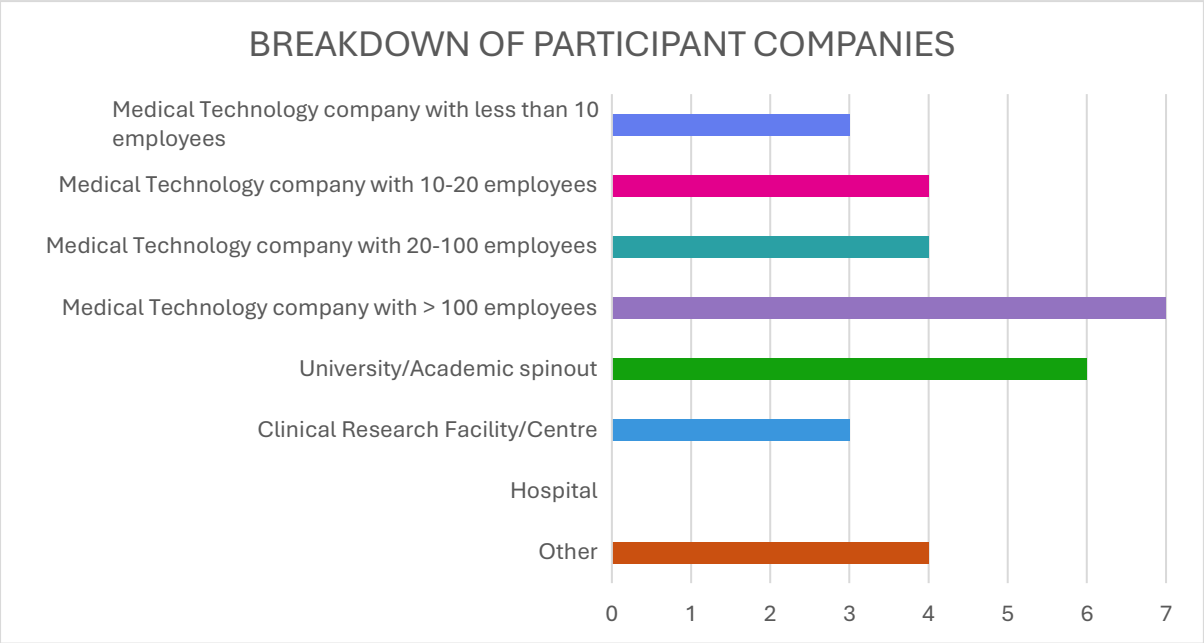


*Figure 9 - Breakdown of Participant Companies*

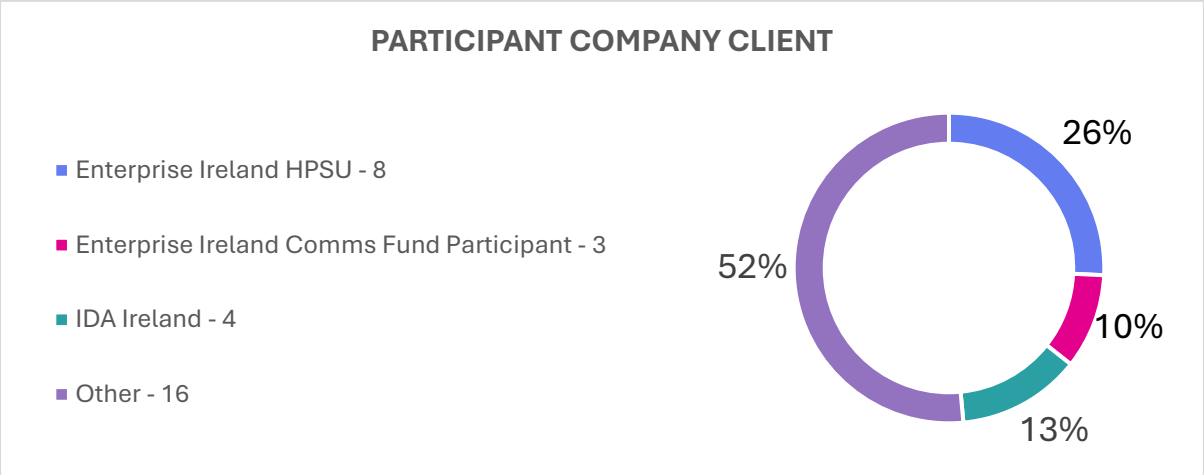


*Figure 10 - Participant Company Client*

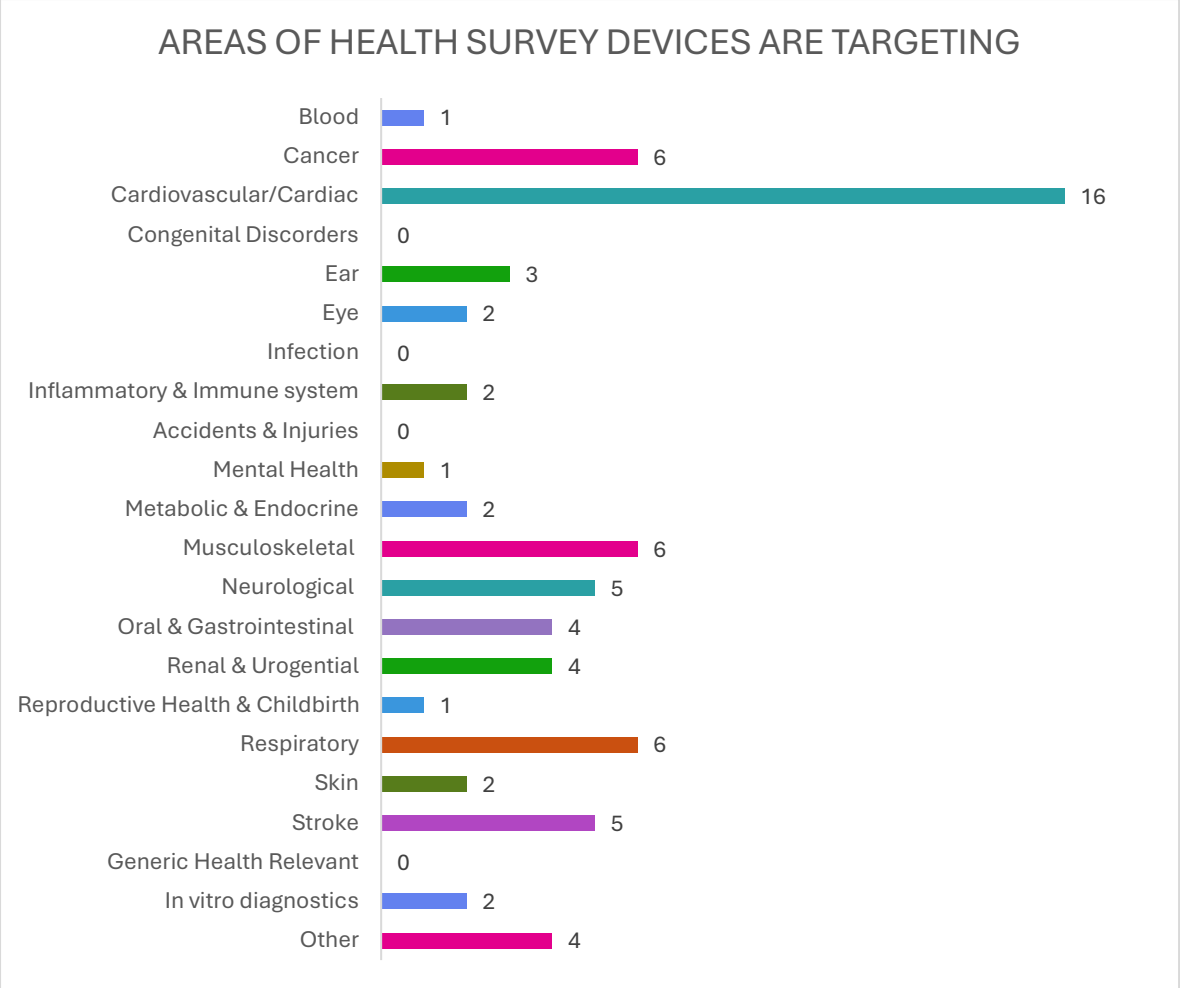


*Figure 11 - Areas of Health Survey Devices Are Targeting*

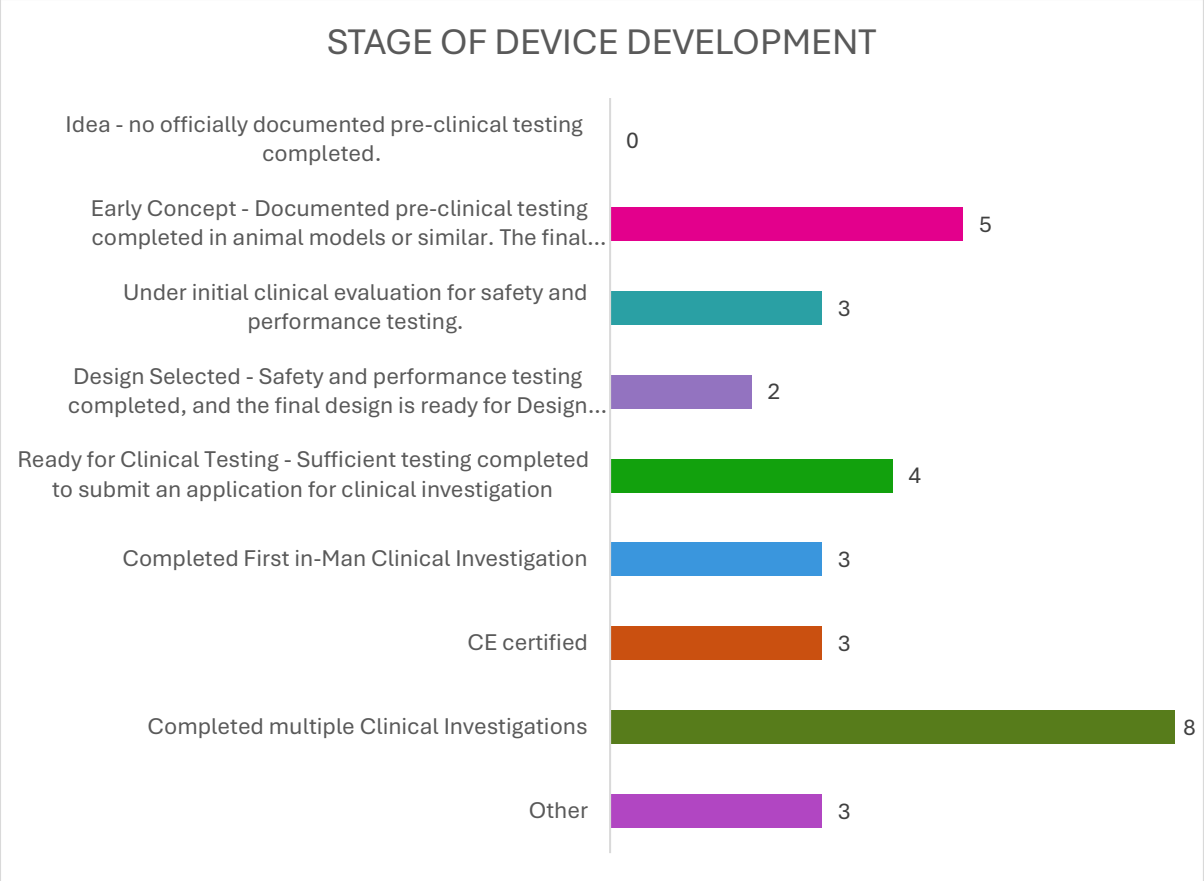


*Figure 12 - Stage of Device Development*

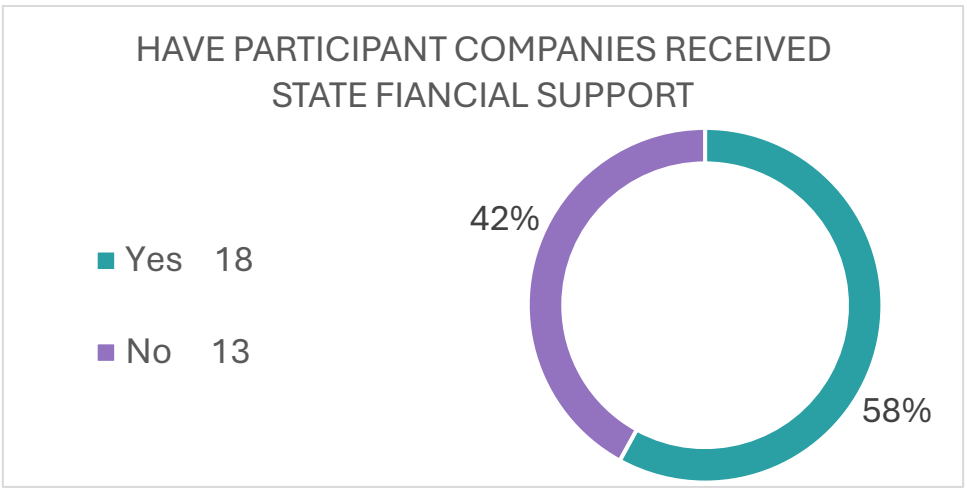


*Figure 13 - Have Participant Companies received State Financial Support*

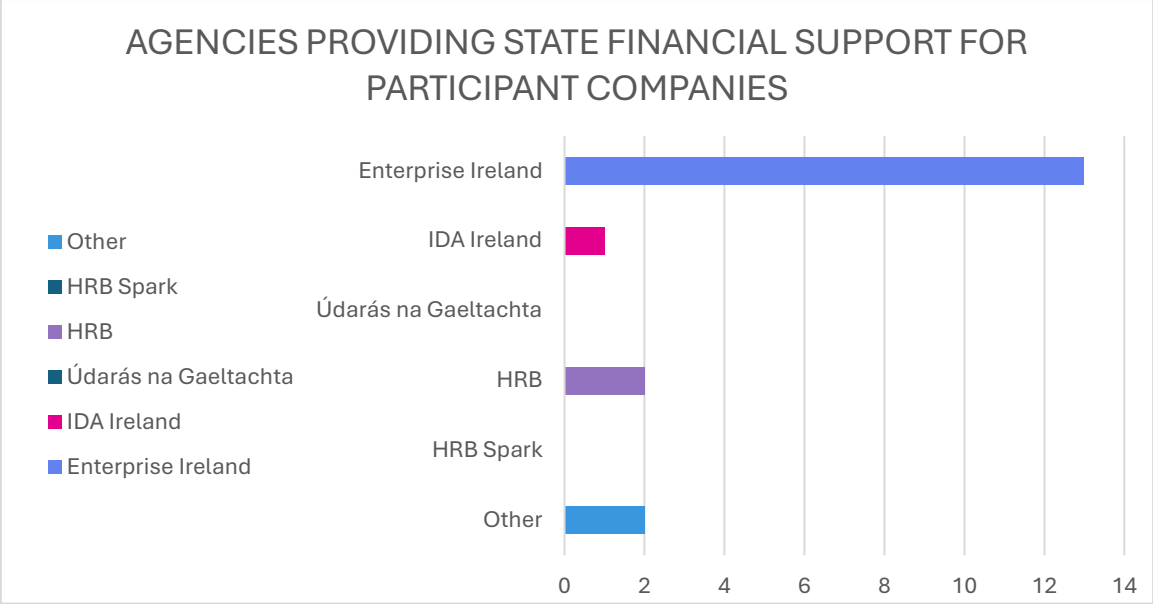


*Figure 14 - Agencies Providing State Financial Support for Participant Companies*