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Principal Investigator Impact Research in Medical Devices

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PREPARING SCIENTISTS FOR THE PRINCIPAL INVESTIGATOR ROLE AND IMPACT IN THE MEDICAL DEVICE SECTOR

WHITE PAPER

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FOREWORD

PROFESSOR ABHAY PANDIT

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Medical device research and development is driven by the scientists, engineers and clinicians who work in this innovative, multidisciplinary field, and none more so than the principal investigators (PIs) of publicly funded research projects. Individuals taking on the PI role are the linchpin for medical device invention and innovation and possess the potential to influence the impact of their work on the quality of life of patients.

However, there has been a lack of empirical focus on the role of the PI in translation and impact, and so this White Paper highlights essential research in this field.

At CÚRAM, our goal is to design the next generation of 'smart' medical devices. We want to provide our researchers with extensive pathways or routes to impact, through effective and focused collaboration with industry and clinicians and public engagement.

This White Paper has been developed based on the extensive work of the *Principal Investigator Impact: Research in Medical Devices* project team led by Professor Caroline McGregor, collaborating with Professor James Cunningham at Northumbria University UK, a leading international expert on PI impact, with Dr Brendan Dolan offering novel insights into the PI role in creating impactful research in the medical device field.

This White Paper provides much-needed insight into the PI role by providing some general findings on this role, alongside those more specific to medical device research. Importantly and uniquely this White Paper, based on original research, identifies the barriers and enablers of impact from a PI perspective as well as highlighting how scientists receive no formal training for becoming a PI.

Finally, this White Paper provides an understanding of this critical and complex role of the PI in the medical device research process and the need to support these scientists to become successful and impactful in their research activities. The key recommendations of this White Paper are focused on how to prepare scientists for the PI role that is relevant to all stakeholders seeking to support them in advancing their careers and research ambitions.

BACKGROUND AND OVERVIEW

The medical device sector is of significant strategic importance to the Irish economy. In the last two decades this sector has grown in scale and scope, leading to a growth in public research investment in scientific infrastructures and human capital. This has seen increased development of human research capital within the Irish third level sector and public research organisations. Such human capital provides the underpinning scientific infrastructure and support to enable the Irish medical device sector to grow and to enhance its international competitiveness.

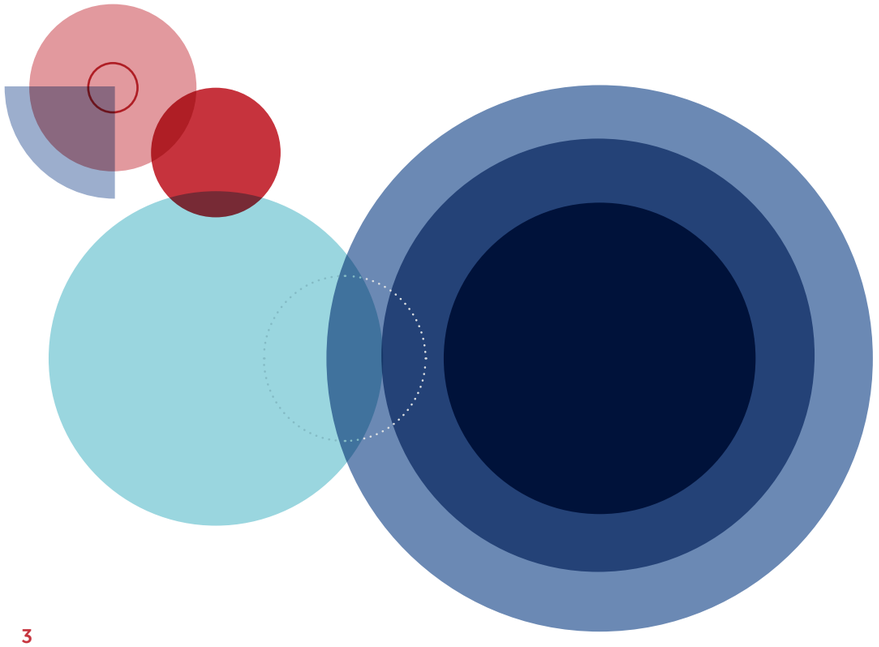
To continue to sustain this sector there is a need to prepare scientists for the principal investigator role so they have the capabilities necessary to lead large scale publicly funded research programmes that advance scientific knowledge and generate a range of economic and societal impacts and benefits. Since 2015, the Principal Investigator Impact Project Team at CÚRAM in NUI Galway have been examining different aspects of the PI role within and outside the medical device sector. Based on this research programme, this white paper provides an executive overview of the PI role, barriers, facilitators and challenges in relation to research impact, and concludes with a set of recommendations.

SECTOR CONTEXT

The medical device sector in Ireland has grown substantially over the past 25 years with Ireland's medical device sector now recognised as one of the five global emerging hubs.[1] The number of medical technology companies has increased from 50 to over 450 in the past 25 years.[2] Nine of the top ten medical device companies globally have bases in Ireland, and alongside this growth, medical device related research has become a key national research priority. [3]

Of the most recent available data, Ireland has the highest proportion (74 per 10,000 inhabitants; i.e. 29,000) of people employed in medical technology industry in European countries.[4] It was estimated in 2016 that Ireland's medical technology sector had exports of €12.6 billion, quadrupling in the past ten years[2] with exports of medical devices and diagnostic products representing 8% of the country's total merchandise exports.[5] Alongside trade, there has been significant public government investment in medical device research through the Programme for Research in Third Level Institutions (PTRLI) and Science Foundation Ireland (SFI), including establishing Ireland's first stem cell manufacturing centre in 2015 and CÚRAM, the SFI Irish Centre for Research in Medical Devices, both based in NUI Galway, Ireland.

Galway's medical device industry cluster, primarily focusing on specialised surgical and medical equipment,[6] expanded first through FDI-focused industrial policy, with increased numbers of indigenous companies established in the past twenty years in line with industry policy trends.[7] This medical device cluster in the west of Ireland, in Galway city and county more specifically, currently has over 100 medical technology companies in the region, with the sector dominating local industrial employment, representing 56% of total industrial employment in Galway city alone in 2016, which is the highest share for any region in the state in this sector.[8] Alongside a strong ICT sector in the region, this cluster of medical device companies in Galway includes multinational corporations (MNCs) Medtronic and Boston Scientific, and a number of indigenous and foreign-owned SMEs, adding to the vibrancy of the regional cluster.[9]



GENERAL INSIGHTS INTO THE PRINCIPAL INVESTIGATOR ROLE

Amongst scientific communities, third level institutions, public research organisations and funders there is a commonly held understanding of the PI role. For scientists, becoming a PI is a significant career milestone and a signal as to their research standing among their peers. Being a PI is seen as prestigious and having scientists holding PI roles is essential to the advancement of science and scientific knowledge.

While different institutions and funding agencies have their own interpretations and definitions of the PI role, a PI can be defined as 'the person charged with direct responsibility for completion of a funded project, directing the research and reporting directly to the funding agency.'[10] A scientist taking on the position of PI undertakes additional roles and responsibilities in addition to being the scientific leader. These include knowledge broker, stakeholder manager, project manager, resource manager, research strategist, team leader and administrator. The formation of scientists is focused on developing their research capabilities in order to become a competent and excellent scientist. The formation experiences of scientists do not necessarily prepare them adequately to take on the complexities and demands of the PI role. Scientists learn how to be a PI on the job[11] and they can encounter a range of managerial challenges in relation to project adaptability and project management.[12] Research knowledge, open-minded research ability, research performability, stoic research skill, innovation and critical skills were identified as important human capital factors of the PI role.[13] The PI role can further be understood as consisting of threshold responsibilities (see Figure 1).

Scientists take on the PI role because it gives them control of their research direction and their career ambition, advancement and direction. Some scientists take on the role due to push factors such as having a unique set of skills and experiences, pressure in their current role to become a PI or contractually they have no other option but to apply for public funding in order to sustain their own employment.[14]

The nature of the PI role requires collaborating with an array of stakeholders including other scientists in related or unrelated domain areas, industry (SMEs and multinational firms), regulators, policy makers and civil society organisations. Given the extent of collaboration and engagement required by the PI, they must perform as boundary spanners and are 'linchpin' actors within public science, thereby advancing science and shaping markets.[15]

FIGURE 1: PI THRESHOLD ROLES AND RESPONSIBILITIES

Role	Focus	Core Responsibilities
Research Leader	*Research excellence*	*Deliver stated scientific research objectives*
Resource Allocator and Controller	*Determine resource requirement*	*Acquire and deploy resources*
Innovation Enabler	*Innovation excellence*	*Envision and maintain scientific and innovation alignment*
Project Co-ordinator and Manager	*Proactively manage all facets of the project*	*Deliver project objectives on time*
Boundary Spanner	*Bridge gap between science and industry*	*Manage and coordinate internal and external boundaries (discipline, international, intersectoral, institutional)*

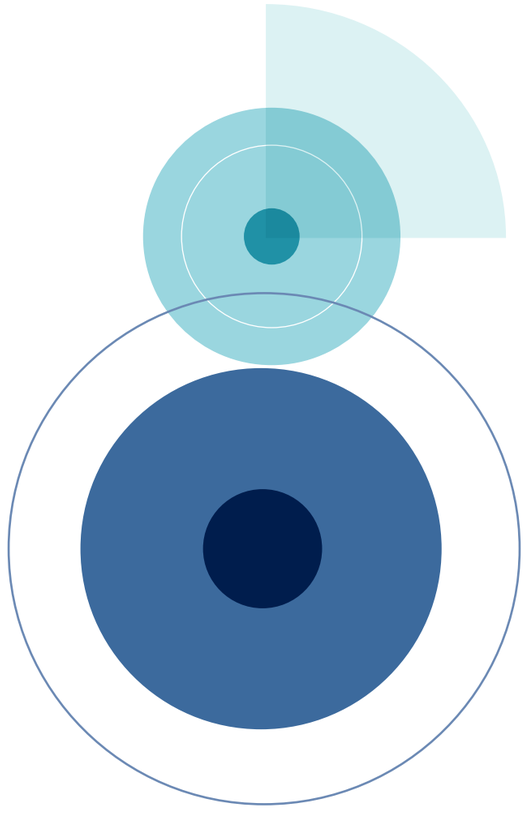
Adapted from Cunningham J.A. & O'Reilly (2019) Roles and Responsibilities of Project Coordinators: A Contingency Model for Project Coordinator Effectiveness EUR 29869 EN, Publications Office of the European Union, Luxembourg, ISBN 978-92-76-11711-7, doi: 10.2760/55062, JRC117576.

The emerging studies of PIs have unearthed key insights about scientists in the PI role including:[16]

- Clear vision of scientific contribution
- Proactive strategic posture meaning PIs shape new scientific avenues
- Focused and highly selective in relation to research funding
- Open to all forms of collaboration in order to realize their scientific vision
- Constantly strategising about achieving their scientific vision
- Motivated by the prioritization of new knowledge
- Accumulate role practices but don't shed older practices
- Allocate more time to technology transfer, industry collaboration and end user engagement based on the value they attach to each of these activities.
- Manage complex governance arrangements between different stakeholders
- Create and deliver value for all stakeholders

Some gender differences exist in relation to external orientation, commercial experiences, international projects and project organization experiences along with the underrepresentation of female PIs.[17]

PIs experience barriers in their role at the project, institutional and broader political and external environment levels. In particular, the lack of technology transfer supports and dedicated support in general for the PI role are significant barriers experienced by PIs. For technology transfer between SMEs and PIs, personal relationships, proximity and asset scarcity can be either barriers or enablers.[18] PIs are reluctant to incorporate technology transfer and commercialization activities into their research programmes where there is a deficit in appropriate support and resources within their institution.[20]



MEDICAL DEVICE PRINCIPAL INVESTIGATORS

In relation to medical device research, PIs engaged in this important field of health research are required to meet **multiple scientific, educational, economic and societal objectives** in their work, in a complex and disparate research environment.[21] Disciplinary backgrounds in the field of medical device research vary widely across the translational research continuum, from basic to applied, translational and clinical science.[22] As such, med-tech PIs are required to engage in **cross-, inter-, and multidisciplinary collaboration** with other academics in order to successfully translate their research from bench to bedside. Similarly, medical device PIs need to develop **strong relationships with clinicians and end-user or patient groups**, to develop relevant research questions and to address vital unmet clinical needs. PIs of medical device research are required to meet commercialization objectives, and as such require a strong technology transfer skill set to prosper in their field.[23] Specifically in relation to medical device PIs, there is increasing pressure for PIs to engage with industry, form partnerships and collaborations with SMEs and MNCs, in order to bring their research to market. **PIs require dedicated supports** in this regard, which can come in the form of cooperative research centres such as CÚRAM SFI Irish Centre for Research in Medical Devices, to enhance opportunities for effective industry collaborations and partnerships, and the translation of research from bench to bedside.[21]

Therefore, med-tech PIs need to understand impact in the context of their own discipline domain.

PRINCIPAL INVESTIGATOR IMPACT AND TRANSLATION CHALLENGES

Impact has grown in prominence in the last decade, with funding bodies and national reviews of research excellence, such as the REF in the UK, requiring individual researchers to demonstrate the impact of their research beyond academia and research communities. This in turn has influenced public funding schemes, and PIs are increasingly required in preparing project proposals to demonstrate how they will achieve different types of impact from their research, and who and how different project stakeholders will benefit. There are different interpretations and definitions of impact among funding agencies and different scientific communities. As an example, Science Foundation Ireland (SFI) defines impact as 'the demonstrable contribution that excellence research makes to society and the economy'. A common representation of impact uses a logic model conceptualization, with impact as the end goal of research (Figure 2). However, this representation is often criticized as too linear in approach[24] and thus hides the complexities of impact that are faced by PIs.

FIGURE 2: LOGIC MODEL OF IMPACT

There are ongoing debates in relation to impact measurement, assessment and evaluation. These include attribution of impact and the claims made in terms of their legitimacy, what categories of impact are more or less valued and whether scientific impact is included or not. Moreover, a central component in debates around impact is in how to measure, assess, evaluate and monitor societal impact and how researchers and PIs should engage with stakeholders in planning for impact.

Core drivers of the research impact agenda include:[22]

- Changing science-society relationship
- Mission-orientated research – societal and economic needs linked to growth – addressing the 'grand challenges'
- Commercialisation of research
- Return or payback on investment
- Expectations relating to translational research

Against this backdrop, PIs are expected to deliver above and beyond traditional metrics of scientific impact (e.g. publications, citations) and must demonstrate this capability and track record for broader, non-scientific or socio-economic impact to secure further public funding. Med-tech PIs need to be able to demonstrate the ability, capacity and competence to diffuse and translate their knowledge, beyond the scientific community and academia, to other beneficiaries such as industry and society. Factors that influence this capacity include contextual influences in their research environment, researcher competency, experience levels, motivation and prior knowledge of technology transfer.[25]

Med-tech PIs' perspective on societal impact influences what societal impact is actually achieved by these experienced scientists.[26] However, the main focus of experienced PIs is to preserve and extend group vitality, with the acquisition of funding the highest priority. In comparison, the younger generation spend more time on group management and research activities, but less time than the more experienced PIs on education. Also, it was found that the younger generation of PIs have a higher dependence on external funds for their research, which the authors suggest may give the younger PIs less freedom to explore their own individual research interests.[27]

For the med-tech PI, the main impact challenge relates to translational research - *from bench to bedside*. The impact agenda exists essentially to bridge the translation gap, or what is sometimes termed the 'valley of death',[28] and to reduce research redundancy and waste. Medical device-related basic scientific discovery is high risk and takes time to develop and mature (see Figure 3). As such, the translational research continuum from bench to bedside presents many dangers and risks, or gaps and chasms. An ongoing challenge for medical device PIs is how to approach and address the various categories of impact (See Figure 4) and overcome translation gaps.

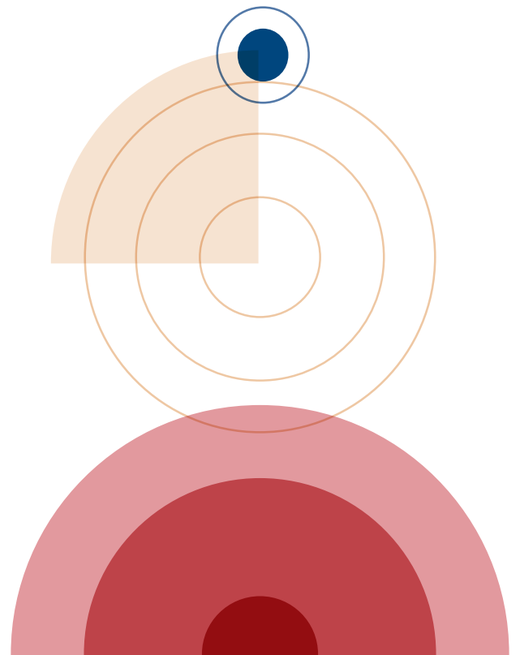
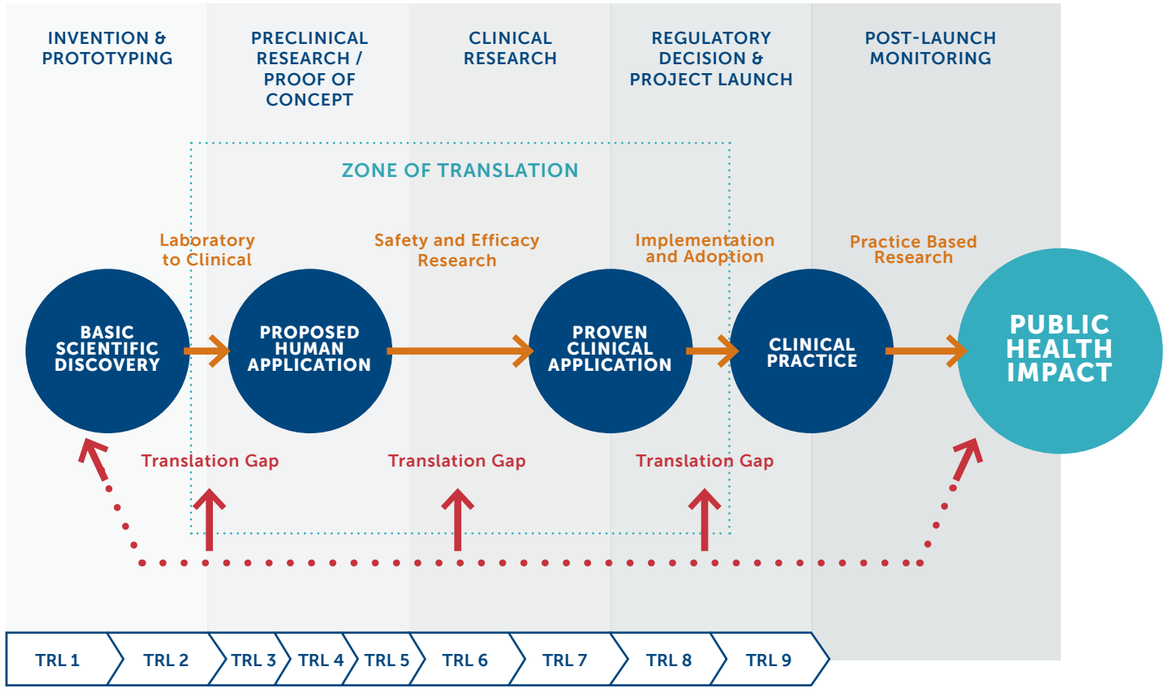


FIGURE 3: MED-TECH TRANSLATIONAL RESEARCH PROCESS[29]



Adapted from Drolet and Lorenzi (2011)

FIGURE 4: EXAMPLES OF CATEGORIES OF IMPACT IN MEDICAL DEVICE RESEARCH

Adapted from SFI Types of Impact[30]

INSIGHTS ON IMPACT FROM MED-TECH PIs

Based on an in-depth study of Irish-based med-tech PIs, PIs working within the broad field of medical device research understand research impact along two distinct tracks, scientific excellence or impact, and broader impacts (i.e. economic, human capital, health and societal). PIs have a primary focus on the established scientific and economic impact metrics such as publications, citations, journal impact factors (JIFs), patents and licensing. In general, broader, societal impact is understood by med-tech PIs in macro-level terms, and as a hybrid or resultant impact of other factors (e.g. economic, human capital impacts).

Barriers to impact experienced by med-tech PIs relate to complexities and misunderstandings of impact, including:

- Lack of universal definitions and categories of impact
- Incompatible or conflicting goals of academic publishing and commercialization activities
- Issues of attribution and causality in relation to impact from specific research activities
- Temporal issues associated with impact measurement, assessment and evaluation (e.g. time lag between research and impact)

Facilitators of and approaches to impact for med-tech PIs include the following:

- Commercialisation as the most effective route to health or societal impact
- Collaboration as a crucial activity for increasing the broader impact potential of research, with academic, industry and clinician partners
- Deliberate project formation strategies to enhance impact potential
- Planning for and consideration of impact throughout the project lifecycle and beyond
- Long term career planning and strategising for impact
- Collaborative research centres (CRCs) (e.g. CÚRAM) as supports in enhancing the broader, non-scientific impact potential of medical device research[21]

As med-tech PIs receive no formal PI role preparation, being a member of a designated research institute can provide support at the micro level in dealing with the multiple demands that they face, particularly with respect to enhancing research quality, networks and collaboration.[21] Moreover, med-tech PIs adopt different strategies to enhance their research's impact potential through a variety of deliberate collaboration and networking strategies, with PIs displaying both proactive and reactive strategic postures to boost the impact potential of their work. Developing strong, reciprocal relationships with project partners can provide greater opportunity for identifying prescient unmet clinical needs, gaining valuable and novel expertise, increased access to resources (e.g. financial, material), and thus enhancing broader impact potential, both in specific projects and across the PI's academic career.

Medical device PIs must deal with a complicated translational path from discovery to application, and therefore, strategic planning is of paramount importance to the successful translation of their research. Elements of this planning process, as identified through our study, include the hiring of project team members that will bolster the impact potential of the project, deciding on the collaborations and 'productive interactions'[31] that can add to the societal relevance of the project outputs, outcomes and impact, and long-term planning and strategising for impact. Due to the serendipitous and often unpredictable nature of impact, as evidenced throughout the study findings, PIs, and the plans they put in place, must be flexible, adaptable and receptive to the ever-changing medical device research environment in which they work. There is, of course, a need for further research that specifically examines scientists in med-tech research, and extends this pioneering research.

KEY POLICY RECOMMENDATIONS

PI Role Recognition

The PI role is a pivotal role in med-tech research in advancing all forms of impact that ultimately benefits society. The PI role is invisible and hence there needs to be a wider recognition of the position of PI amongst med-tech ecosystem stakeholders. Concurrently, there is a need for administrative and financial support for PIs in their wider management roles, including responsibility to demonstrate impact through their research practices.

PI Role Preparation

There is a need to better prepare medical device scientists, particularly early career researchers (ECRs), to take on the PI role so they are fully equipped with the necessary skills and capabilities to plan and realize impact, as well as the additional roles and responsibilities beyond scientific leadership. This should include training in strategic planning that incorporates planning for impact as part of the development of the PI role and supports around this.

Project Structures & Resources

Public funding of medical device research is at a significant level per project funded which is a domain norm. However, if impact is to be sustained within and beyond funded projects, individual project structures and the associated project resources need to be configured to reflect this agenda. In practice this may require having a dedicated full-time project resource manager that manages and supports the PI in planning, monitoring and realizing various forms of impact during the project, and beyond, such as technology transfer and commercialization supports.

PI Mentoring

Medical device PIs learn the role on the job. In addition to more formal role preparation there is a need for ongoing mentoring of PIs to support them to cope with multiple demands that they face in leading large-scale public research programmes. Moreover, in turn these med-tech PIs should be enabled to provide and contribute more formally to mentoring of early career researchers.

Enhancing Institutional Support

Dedicated supports that research institutes provide to med-tech researchers are critical and necessary to aid them in pursing their research programme objectives. Funding provides PIs with additional capacity and should be sustained to provide the optimal environment to allow experienced and nascent med-tech PIs to grow and flourish. Attention to the barriers and facilitators identified in the research findings outlined above could inform the development of appropriate supports in this regard.

Increasing Female PIs Participation

There is an evident underrepresentation of female PIs within the medical device landscape and there is a need for proactive action and specific interventions among all med-tech ecosystem stakeholders to close this participation gap.

Planning for Impact Support

With the increasing role complexity of the PI position, PIs have a limited amount of time and resources in their day-to-day activities and in their career to plan for and achieve impact from their research. In particular, PIs of medical device research require a variety of supports in their journey towards impact, due to the long road of translational research, the complex nature of medical device research and impact, the heavy workload of PIs of public research and the various activities they need to engage in to maximise impact potential. As such, it is imperative that PIs plan for impact efficiently and effectively prior to project development, and throughout the lifecycle of the project. Impact preparation and planning supports could aid PIs to develop coherent and focused impact goals.

Evaluation of Impact

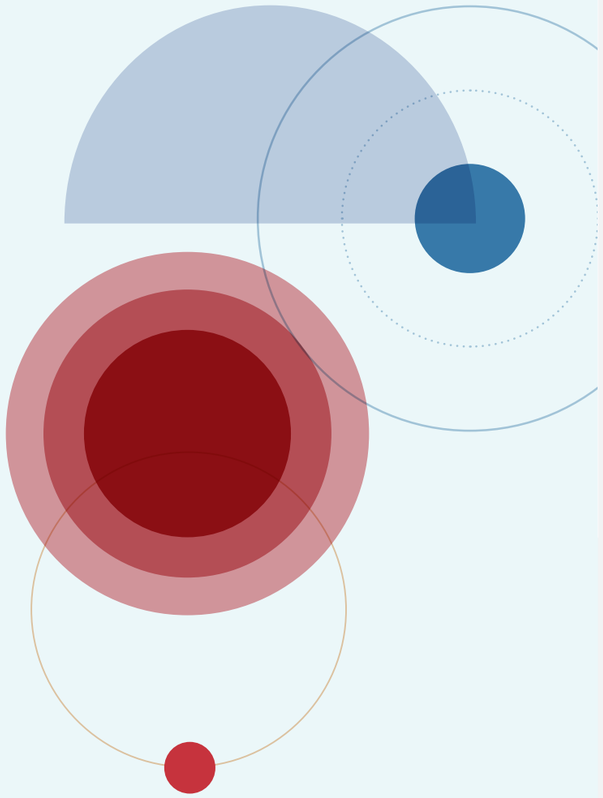
While traditional scientific impact has relatively clear measures for evaluation such as peer reviewed publication outputs and citations, it is more difficult to measure wider social and economic impact. Sometimes the 'bedside' impact of a medical device research project can happen long after the formal end of a funded project. The metrics for evaluating impact have improved in recent years, as reflected in exercises such as the UK's Research Excellence Framework (REF) and Australia's Engagement and Impact Assessment (EIA). However, as our findings show, principal investigators have broad and varied interpretations of impact which make it difficult to specify a shared programme of evaluation. Greater clarity and coherence amongst med-tech research stakeholders in how impact is defined, measured, assessed, evaluated and monitored is required to progress and improve impact evaluation frameworks. Specifically in relation to medical device research, due to the long road of translation from discovery to application, greater consideration must be given to temporal factors in relation to the potential and eventual impact of medical device research. Alongside this, current evaluation processes for impact must be reassessed to incorporate the key role of PIs in research impact.

Realistic Impact Evaluation

As PIs are most often the point of contact to research evaluation, it should be emphasised more that evaluation looks at intended impacts, not that PIs demonstrate the actual impact of their research, something that could be years away, perhaps even beyond their lifetimes. Intended impact can lead to real impact but PIs need to be encouraged to think more holistically and creatively about impact, not view it as an impossible task to prove the impact of their endeavours. For the broader impacts of research as identified by PIs, particularly human capital, health, and societal, there is a lack of tangible, graspable metrics for PIs to engage with that clearly connect to defined and distinct categories of impact. Achievable and tangible outputs with proven, transparent routes to impact could encourage PIs to engage more openly and fully with impact.

Career Progression – A Holistic Approach

At the core of the med-tech sector is research and scientific excellence. However, the impact demands being placed on med-tech PIs means that this creates tensions for them. Career progression remains very focused on traditional metrics over broader impact – for example, citation count is more valued than commercialization success. A more holistic approach to career progression is necessary.

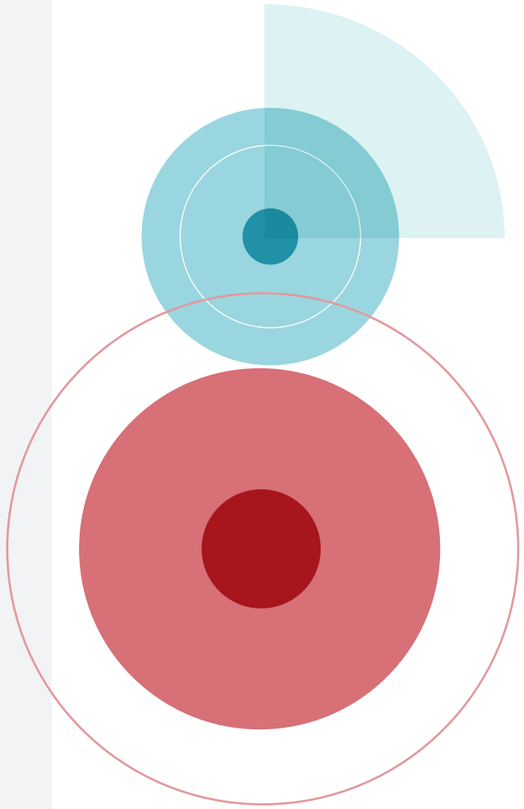


PI IMPACT PROJECT RESEARCH OBJECTIVES

- Exploring the understanding, attitudes and approaches to research impact from the micro-level perspective of the principal investigator (PI)
- Identifying the antecedent, organisational, project and individual factors and barriers that may influence, enhance, or hinder PI impact orientation
- Designing professional development supports for the PI role in addressing and demonstrating impact from research
- Developing policy and practice-based recommendations

The PI Impact Project team have also developed the '**Becoming a Principal Investigator: Planning for Impact Toolkit"** to support early career researchers and nascent PIs involved in medical device research to take on the PI role and plan effectively and more holistically for impact. For more information on the PI Impact project, and to download your copy of the toolkit, visit:

http://www.curamdevices.ie/curam/research/translational-research/



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Scientists in the Principal investigator (PI) role are key actors driving medical device research from bench to the marketplace. For such a vital and pivotal role in medical device research processes, there has been a lack of research, policy and practice-based attention to date in this regard. This white paper seeks to address this by outlining the current state of the art with respect to the PI role in general as well as outlining key empirical insights with respect to PIs in the medical device arena that have been found by the Principal Investigator Impact Project Team. The White Paper sets out key policy and practice recommendations that focus on how to prepare scientists for the PI role, and the need for more targeted and effective supports for scientists in medical device research to become successful and impactful in their PI role.

For more information on the PI Impact: Research in Medical Devices Project, please visit: **http://www.curamdevices.ie/curam/research/translational-research/**