Science Foundation Ireland For what's next

Principal Investigator Impact
Research in Medical Devices

CÚRAM
SFI Research Centre for Medical Devices

BECOMING A MEDICAL DEVICE PRINCIPAL INVESTIGATOR:

PLANNING FOR IMPACT TOOLKIT

James A Cunningham
Brendan Dolan
Caroline McGregor

ACKNOWLEDGEMENTS

The PI Impact project team wish to thank the following for their advice and support in the design and development of this toolkit:

- *Professor Abhay Pandit, Scientific Director, CÚRAM SFI Research Centre for Medical Devices*
- *CÚRAM team and CÚRAM Translation Platform*
- *UNESCO Child and Family Research Centre and School of Political Science and Sociology, National University of Ireland Galway*
- *Newcastle Business School, Northumbria University*
- *Our PI participants of our qualitative research study: Principal Investigator Impact Orientation of Medical Device Public Research*

The Principal Investigator Impact: Research in Medical Devices Project is funded by Science Foundation Ireland (SFI) and the European Regional Development Fund (Grant Number 13/RC/2073)

Any citation of this report should use the following reference:
Cunningham, J.A., Dolan, B. and McGregor, C. (2020) Becoming a Medical Device Principal Investigator: Planning for Impact Toolkit. Galway: CÚRAM SFI Research Centre for Medical Devices, National University of Ireland Galway.

ISBN: 978-1-905861-79-8

CÚRAM is co-funded by the European Regional Development Fund and Science Foundation Ireland under Ireland's European Structural and Investment Fund Grant Number 13/RC/2073

For further information, please contact:
CÚRAM SFI Research Centre for Medical Devices,
National University of Ireland Galway
Galway, Ireland
Tel: +353 91 495833
E-mail: info@curamdevices.ie
Web: www.curamdevices.ie

CONTENTS

FOREWORD

PROFESSOR ABHAY PANDIT
Scientific Director, CÚRAM SFI Research Centre for Medical Devices

Academic Principal Investigators (PIs) play a crucial role in developing research tools in medical device design and development, and so it is essential to increase our awareness and understanding of this critical position in the overall ecosystem. The PI role offers excellent potential for professional development and career enhancement, but also comes with numerous demands and challenges. One has multiple demands to contend with as a PI, as the scientific leader, project manager, budget holder, as well as seeking opportunities to create impact through knowledge and technology transfer.

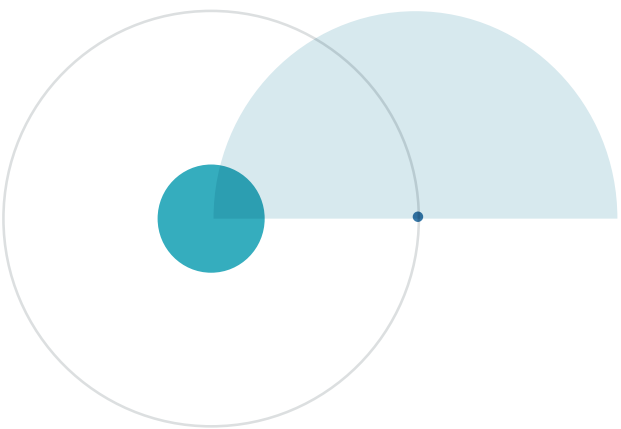
Effective collaboration is vital for a PI, developing lasting and trusting relationships with a wide variety of actors, within one's discipline, across domains one may have little or no expertise in, inside and outside academia, with industry partners and healthcare professionals. To be a successful PI, one must look to embrace these roles and responsibilities actively, and look to develop a diverse set of skills and behaviours, to further one's career and ultimately and most importantly, the impact of one's endeavours. As medical device scientists, we all want to create positive changes for patients, and the healthcare professionals who care for them.

At CÚRAM, we are focused on designing the next generation of 'smart' medical devices. We want to provide our researchers with extensive pathways or routes to impact, through the productive and focused industry, clinician and public engagement and collaboration.

One of the research themes within CURAM since 2015 has focused on Principal Investigator Impact through Research in Medical Devices. Led by Professor Caroline McGregor, in collaboration with Professor James Cunningham at Northumbria University, UK, a leading international expert on PI impact. With Dr Brendan Dolan as a postdoctoral research fellow, the project team have been building a body of original research in this area. Through their multidisciplinary expertise, along with their original research insights and extensive engagement with PIs in medical devices nationally and internationally, this has formed the basis for the development of a toolkit for becoming a PI and planning for impact, given that this was a gap identified in their research.

This toolkit offers a fantastic opportunity to begin to prepare for and plan one's journey as a successful PI and plan for impact. Moreover, the toolkit offers a novel approach to planning for impact, wherein one can plan one's collaborations to maximise impact. Furthermore, this toolkit provides one with an opportunity to engage with impact before it merely becomes a requirement of ones' role. The feedback from those who have used the toolkit as part of professional development sessions delivered by Professors McGregor, Cunningham and Dr Dolan has been very positive, as the toolkit has increased awareness of the PI role, provided tangible ways to think and act about becoming a PI as well providing real insights into the expanded roles and responsibilities of being a PI. Feedback from users identified that this toolkit has supported them in making the right decisions and how to expand their networks to support their research plans.

Finally, this toolkit provides support for scientists to reflect on and plan for becoming a PI and creating impact, thinking more holistically about the broader impact of their research endeavours. I would encourage all of you to use this toolkit as part of your professional and personal development.



INTRODUCING OUR TOOLKIT AND APPROACH

WHY SHOULD YOU ENGAGE WITH THIS TOOLKIT?

You might be at the stage in your career where you are thinking about becoming a principal investigator (PI). You may already be in the principal investigator role and find creating impact challenging. The PI role requires you to envision, create and realise impact. However, creating a patent is not impact. Having your work cited is not impact. Taking part in public engagement activities such as Pint of Science or RTE Brainstorm is not impact. These are routes or pathways to impact and require strategic planning and approaches to ensure that they are as productive, effective and efficient as possible in impacting or influencing the end beneficiaries of research, whether it be the patient, clinician, policymaker or broader society. Planning for and creating impact is now becoming a necessary part of any funded research project, particularly in the medical device research field and for those seeking to become or remain in the PI role.

Impact can feel very abstract, unattainable and complex. Based on extensive research carried out by the PI Impact project team on impact and PIs of medical device research, as well as PIs in other discipline areas, the purpose of this toolkit is to provide you as PI with a structure that enables you to contextualise and plan towards potentially impactful research. The toolkit provides a systematic and reflective approach that supports you to map the impact of your research, throughout the lifecycle of a project, and more importantly, throughout your research career, taking on the role of principal investigator.

WHO IS THIS TOOLKIT FOR?

- Do you plan to pursue a career in academic research?
- Do you plan to become a PI in order to lead your own publicly funded research programmes and projects?
- Does your research feed into the design of medical devices?

If you are thinking yes for any or all of these questions, then this toolkit can be of use to you.

LEARNING APPROACH UNDERPINNING THIS TOOLKIT

This toolkit is designed according to a *reflective learning approach* with an emphasis on supporting you to use the content we present to help you to think about, analyse and critique your own practices with regard to impact.

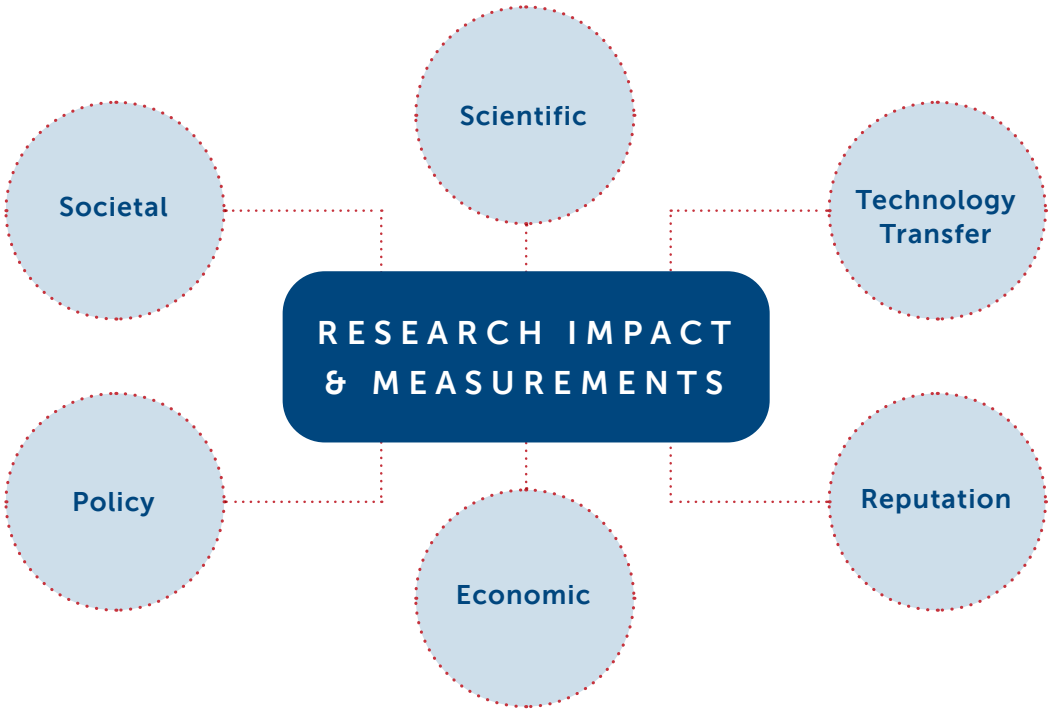
OUR REFLECTIVE LEARNING APPROACH EMPHASISES THE IMPORTANCE OF:

- Learning through your own lived experiences
- Identifying your own position and philosophy in relation to impact in your field of research
- Engaging in dialogue to test and explore your position vis-à-vis research findings and/or the views of others
- Using the questions and reflective exercises we pose to reflect on your own position and practice
- Developing a critically reflective approach to inform your own practices in relation to becoming a principal investigator and planning for impact

We want to support you to take a broader and more holistic view of impact, to take a step back and look at the wider picture. Taking an ecological approach allows you to understand and map the impact potential of your current and future research activities and how this relates to being a principal investigator.

TYPES AND MEASURES OF IMPACT

For your information, presented below are some of the commonly used measures of impact in research at present.[1] Impact is of course a complex and much debated concept to address. These measures give you an idea of the current state of affairs in terms of impact measurement and evaluation, while also highlighting the many issues, challenges and knowledge gaps at play, particularly in relation to the measurement and evaluation of societal impact of research. As such, funding bodies and research authorities are continually evolving how they measure and evaluate the impact of your research. As you progress through this toolkit, you will be provided with a more holistic, flexible and reflective approach to addressing impact in your work, thus moving above and beyond the current impact evaluation culture and narrow measures presented below.



[1]*Original Version: James Cunningham (2014) Positioning for Impact on Your Scientific Journey: Reflections and Action https://www.researchgate.net/publication/273126346_Positioning_for_Impact_on_Your_Scientific_Journey_Reflection_and_Action*

SCIENTIFIC IMPACT

How will your research work shape and influence scientific knowledge?

- *Some Measures:*
  - Citations
  - Alt-metrics
  - Number of academic papers
  - Co-authoring teams
  - Editorial Board positions
  - Special issues editorships
  - Journal editorships
  - Invited keynote talks

HUMAN

How will your research support the development of academic and industry talent? How does your research support the acquiring of new skills and knowledge?

- *Some Measures:*
  - Numbers employed in academic institutions, public research organisations and industry
  - Levels of qualifications
  - Research and industry mentoring programmes
  - Number of academic programmes
  - Job placement opportunities
  - Levels of international mobility between and in academic and industry environments

TECHNOLOGY TRANSFER

Should aspects of your research be protected and if so, what technology transfer mechanism best suits the exploitation of your intellectual property?

- *Some Measures:*
  - Material exchange agreements
  - Patents
  - Licenses
  - Spinouts
  - Spin-ins
  - Consultancy
  - Knowledge transfer agreements
  - Company directorships

REPUTATION

How will your research add to building your international reputation, as well as that of your research team and your institution? How will your research enhance the international reputation of your country?

- *Some Measures:*
  - Number of international collaborators;
  - Levels of international funding;
  - Professional esteem – visiting positions;
  - Research awards;
  - Best paper awards;
  - Invited keynote presentations;
  - Public advisory roles;
  - Membership of international academic association boards

ECONOMIC

How will your research support industry?

- *Some Measures:*
  - New jobs;
  - Creation of new roles within firms
  - New firm creation
  - New R&D collaborations
  - R&D investment
  - Skill acquisition
  - New organizational processes
  - Creation of new industry standards

POLICY

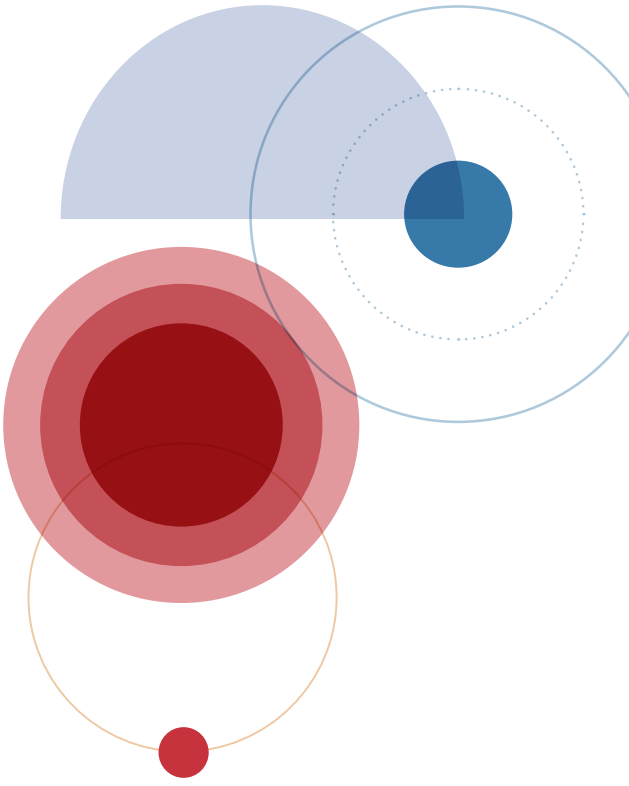
How will your research impact on the development and or implementation of public policy?

- *Some Measures:*
  - Participation in public policy consultation processes
  - Membership of policy review committee
  - Appointments to public bodies
  - Empirical research cited in government reports

SOCIETAL

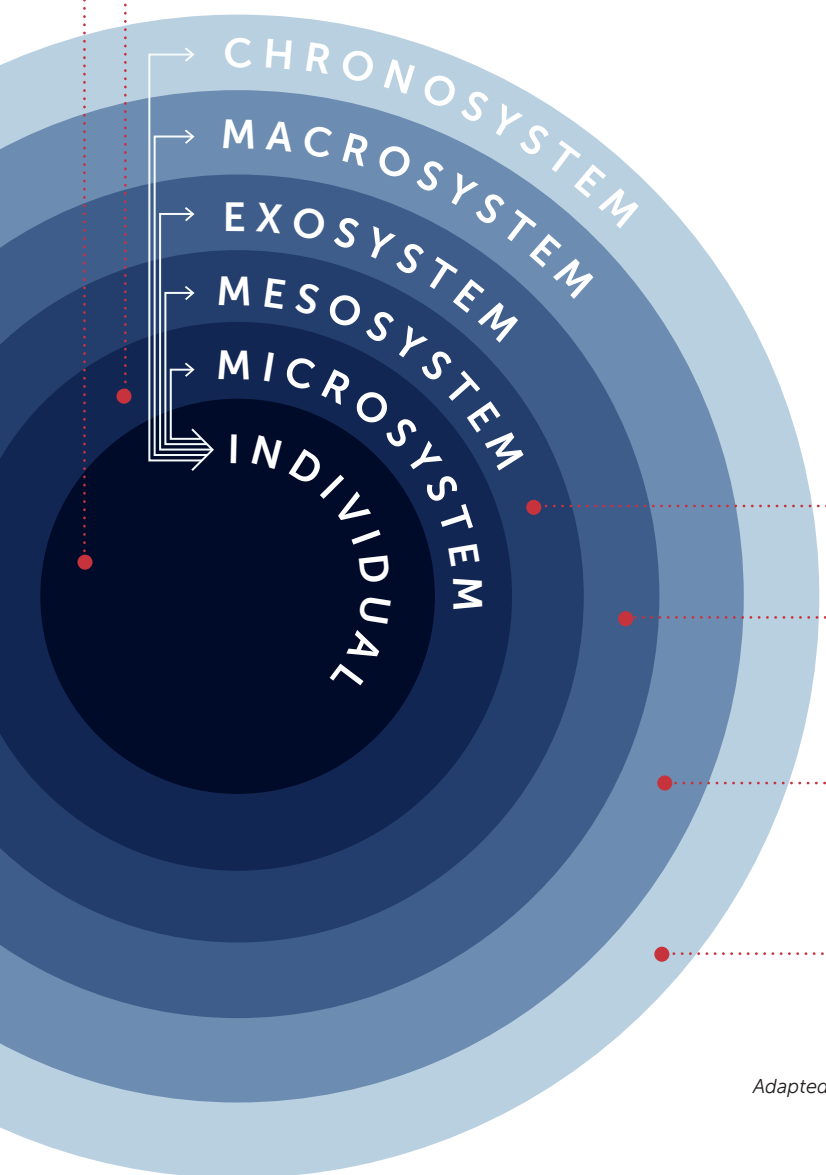
How will your research influence and shape society?

- *Some Measures:*
  - General public awareness of domain
  - Targeted outreach programmes
  - Media appearances
  - Media mentions



PLANNING FOR IMPACT: AN ECOLOGICAL APPROACH

This Planning for Impact Toolkit is designed using an ecological approach, which focuses on how the individual PI views, influences, and is influenced by the wider environment in which they operate. An ecological approach is most commonly used in social sciences to gain a more holistic understanding of the different spheres of influence that shape one's individual environment. At the forefront of ecological theory, Urie Bronfenbrenner's Ecological Systems Model (Bronfenbrenner, 1979; Bronfenbrenner & Morris, 2006) identifies the system levels that exist in an individual's environment, conceptualised as five expanding, interrelated, concentric circles. These can be viewed as spheres of influence. The individual at the centre has most influence on systems closest to them and the further outwards the impact of the person's research reaches the greater the expansion of their influence on the system as a whole. These systems can be viewed as having fluid boundaries, with the model incorporating also personal characteristics of the PI, time elements and the ongoing interactions between actors in the system.



- **Individual** – intrapersonal factors. Characteristics such as knowledge and expertise, attitudes, behaviours, self-concept, experience, skills and personal development.
  E.g. previous experience with industry, multidisciplinary expertise, translation knowledge, reputation inside and outside discipline
- **Microsystem** – immediate environment. Formal and informal social networks/supports and the work environment.
  E.g. Close departmental colleagues, project team members, academic supervisors
- **Mesosystem** – direct environment, connections and community. University system, administration.
  E.g. University department, academic partners (outside of discipline), clinician partner, funding body liaison, patient advocacy groups, industry partners
- **Exosystem** – indirect environment. Regulations, technological breakthroughs in the field.
  E.g. regulation and compliance agencies, activities of competing centres/research groups/industry
- **Macrosystem** – social and cultural values. Public opinion, government mandates, economic factors.
  E.g. Government policy, societal values and needs, ethical issues
- **Chronosystem** – Time relevant considerations. Current trends or matters of concern
  E.g. COVID 19 impact, environmental issues

Adapted from Bronfenbrenner (1979) & Bronfenbrenner and Morris (2006)

BECOMING A PRINCIPAL INVESTIGATOR (PI)

> ***The PI role is about enabling other people, influencing other people, and bringing the best out of them... So I go back to the fact that me as a PI am a drop in the ocean, but every drop counts."***

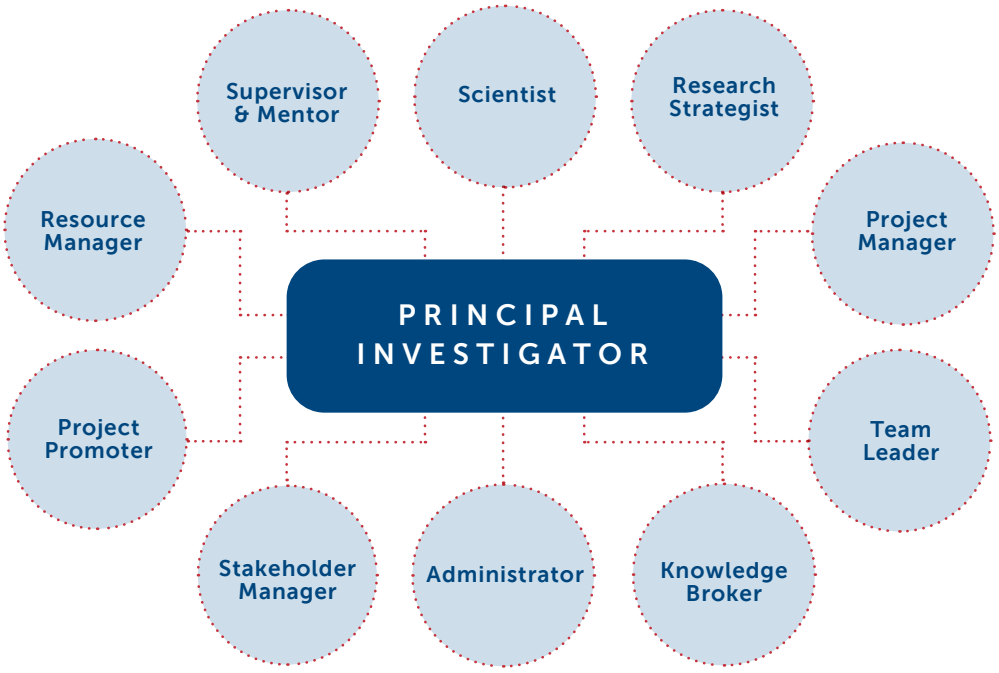
The term principal investigator (PI) is a commonly used term between scientists, research funding agencies and professional research career supports amongst others. For the individual scientist, becoming a PI is widely understood as an important step in their career progression. Becoming a PI for a scientist is career enhancing and prestigious among peers. Being a PI is a complex role involving more than just research leadership (see Figure 1). In the PI role, scientists are now expected to deliver and realise multiple impacts beyond their scientific field. Our research focus has been on understanding the role realities that scientists experience when they become a PI and must plan for impact within the medical device research field. In particular, we have examined PI attitudes and approaches to research impact as well as identifying the factors and barriers that may influence, enhance, or hinder PI impact orientation or impact mindset.

The PI is the person charged with direct responsibility for completion of a funded project, directing the research and reporting directly to the funding agency[2].

Becoming a PI entails taking on additional roles and responsibilities, with scientists, based on our research, not receiving dedicated PI role preparation. In the PI role, scientists have to balance role tensions:

- Balancing scientific and economic activities
- Balancing governance and fiduciary responsibilities
- Managing market shaping expectations

Figure 1: Principal Investigator Roles



[2]*Cunningham et al, (2016) Publicly Funded Principal Investigators as Transformative Agents of Public Sector Entrepreneurship, in (ed)David Audretsch and Albert N. Link, Essays in Public Sector Entrepreneurship, Springer, pp.67-93*

We are privileged people, privileged but mad busy. There is a responsibility that goes with that privilege."

WHY SCIENTISTS CHOOSE TO BECOME A PI?

Pull Factors:

- *This sub-group of factors detailed where the PI had more choice in choosing to become a PI.*
  - Control
  - Career ambition and advancement
  - Drive and ambition

Push Factors:

- *This sub-group of factors detailed where the PI had less choice in choosing to become a PI.*
  - *PI skills and experience*
  - *Lack of options*
  - *Pressure of the role*

PRINCIPAL INVESTIGATORS: WHAT WE KNOW[3]

Did you know that PIs...

- are considered the linchpin for scientific transformation and advancement
- have a clear vision of scientific contribution
- strategize consistently about achieving vision
- adopt a proactive strategic posture to shape new scientific avenues
- are focused and highly selective in relation to research funding
- are open to all forms of collaboration
- are motivated by the prioritisation of new knowledge
- open new scientific trajectories or choose to enhance existing ones
- accumulate role practices
- learn about the role on the 'job'
- experience role identity changes within the PI role
- face managerial challenges (project management and project adaptability)
- identify potential impact on society as one of the top three motivations for scientists to be a PI
- identify technology transfer and commercialization as the most challenging tasks
- need to be effective at identifying, creating and delivering value for stakeholders
- consists of four role identities - science networker, research contractor, project manager and entrepreneur

[3]*This is based on peer reviewed publications listed on pages 33 and 34*

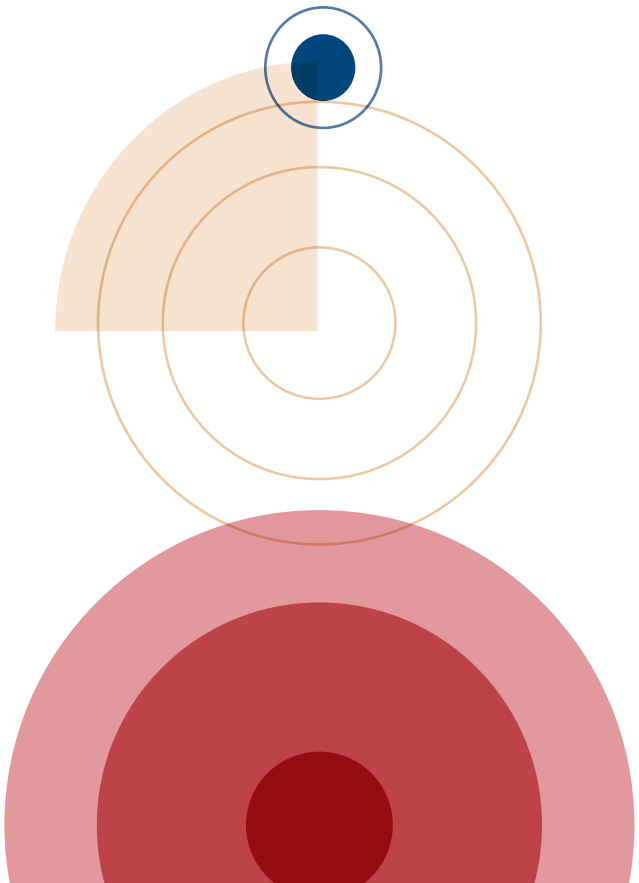
MEDICAL DEVICE PIS AND IMPACT

Medical Device PIs' views on impact:

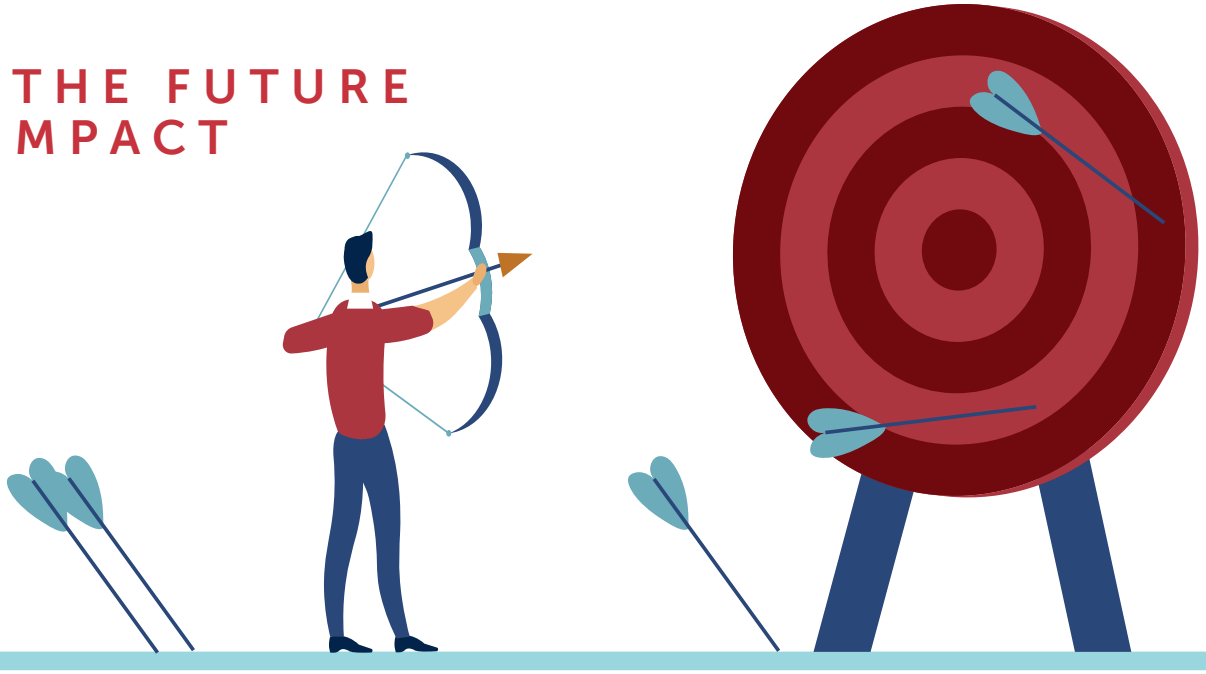
- Can be delineated along two lines of thought:
  1. Scientific impact, and
  2. Broader impacts, which include economic, human capital and, to a lesser extent, health and societal impacts.
- Emphasise first and foremost the scientific and economic impacts of their research, as well as human capital impact.
- Present health and societal impacts as hybrid impacts resulting primarily from commercialisation and collaboration activities.
- Include issues of the conflicting requirements of economic and scientific impacts (i.e. commercialisation and publications), confusions and misunderstandings in relation to impact, PI positioning on the translation continuum, and time constraints inherent in the PI role.
- Are influenced and facilitated by antecendent factors including previous work experience (e.g. industry, international), team competencies, effective collaboration and project preparation strategies, and long-term career strategising, alongside the supportive role of cooperative research centres such as CÚRAM.
- Incorporate deliberate strategies for collaboration with clinician partners, patient groups, industry partners and multidisciplinary academic research teams.

> *Unless you can actually tell me how is that going to impact the patient, or impact the next generation of devices, there has to be reason for what you are doing, or the path you are taking, always have in the back of your mind, how is this going to impact clinically or impact the patient."*

> *One of the things about being a PI is being able to brush off the negative stuff that happens, and it happens frequently, failed grants, rejected papers."*



YOU, THE FUTURE AND IMPACT



REFLECTIVE EXERCISE:

YOU AND IMPACT

What does impact mean to you?

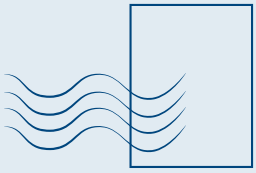
Why do you want to create impact from your research?

What impact do you want to achieve from your research?

REFLECTIVE EXERCISE:
POSTCARD FROM THE FUTURE

Imagine you are at the end of your professional career. The last day. Write yourself a postcard from that future. On your postcard describe what you have achieved, its importance and relevance to science and beyond academia?

POSTCARD

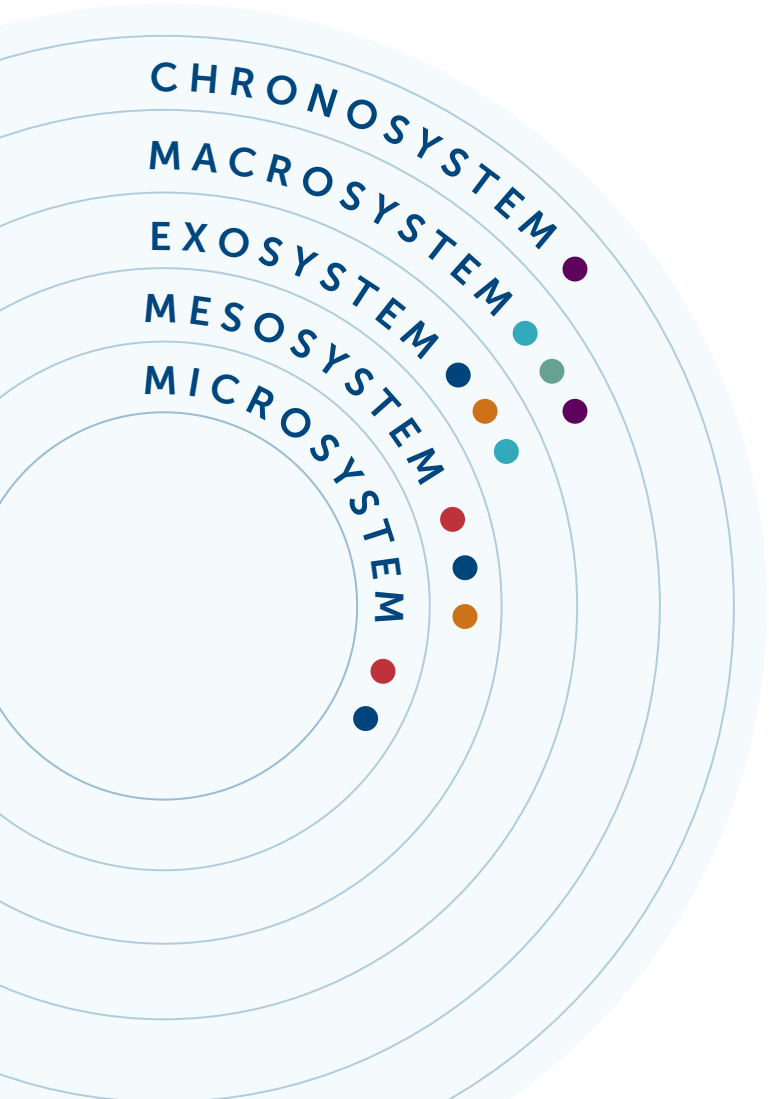


I think because that can be a very blue skies long term goal, I try to make sure that I see where we are making small steps in impact that are important along that route."

THE COLLABORATIVE JOURNEY OF A NEW MEDICAL DEVICE

> ***Genius is in the idea. Impact, however, comes from action."***
>
> **Simon Sinek,**
> *Organisational Consultant.*

When you become a PI, you have the opportunity and are given the responsibility to lead your own research agenda and the impact potential of your medical device research activities. However, new technologies often spend many years in development before making it onto the market to have a chance of success and impact. While an invention, breakthrough research or an idea may emerge from the work of a single PI or a small team of scientists. For an invention to make it to the marketplace it requires the inputs and support of a range of people and stakeholders who play different parts in an idea's journey to implementation. The input of multidisciplinary academics (e.g. engineers, biomaterial scientists, molecular biologists, pharmacists), clinicians, patient or end-user groups, Technology Transfer Offices (TTOs), and industry partners can be instrumental to the new medical device or technologys success and legitimacy. PIs may need to collaborate with groups of different stakeholders, all with varying skills, interests and abilities, bringing their technology through the various TRL levels. Medical device scientists regularly use the 'Technology Readiness Level' (TRL) scale to estimate the maturity of technology developments. This toolkit can support medical device PIs to effectively engage with relevant stakeholders as they bring their medical device from invention to market, moving from the microsystem to the macro- and chronosystem.



TECHNOLOGY READINESS LEVEL

- **Invention (1&2)**

  Important Stakeholders/Groups:
  E.g. PI, project members, clinicians, patient groups

- **Concept Validation (3&4)**

  Important Stakeholders/Groups:
  E.g. Research community, stakeholder groups, funding body

- **Prototyping and Incubation (4-6)**

  Important Stakeholders/Groups:
  E.g. TTO, university incubation centre, end-user, clinicians

- **Pilot Production and Demonstration (5-7)**

  Important Stakeholders/Groups:
  E.g. Industry, regulatory bodies

- **Initial Market Introduction (7-9)**

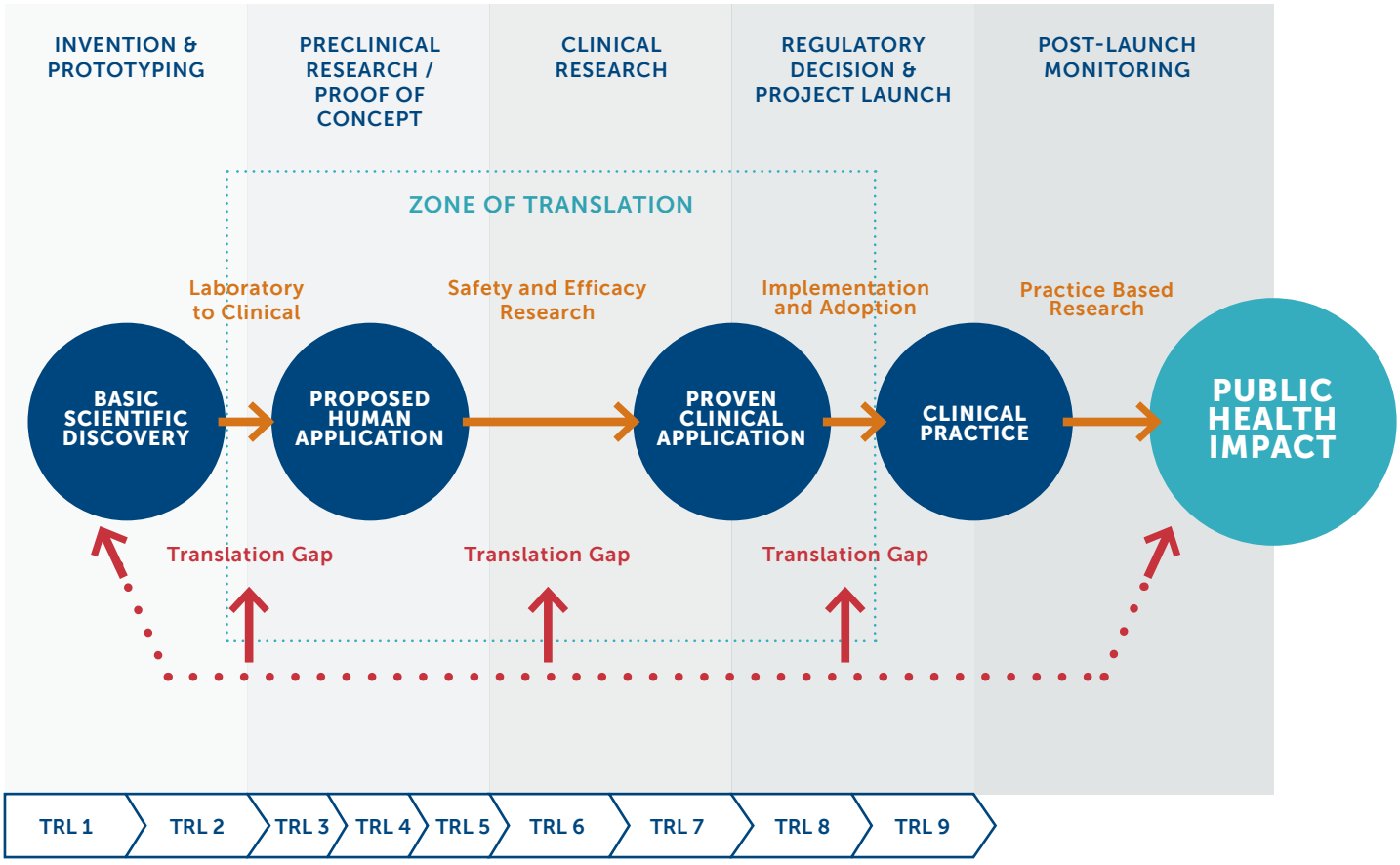
  Important Stakeholders/Groups:
  E.g. Government policy, university structures and process

- **Market Expansion (9)**

  Important Stakeholders/Groups:
  E.g. Societal needs

THE TRANSLATIONAL RESEARCH CONTINUUM

PIs leading medical device research projects must operate along a complex, multidisciplinary translation continuum from basic scientific discovery to point-of-care application, from invention and prototyping through preclinical and proof of concept research, following the complex and onerous phases of clinical trials, overcoming many regulatory hurdles along the way. Awareness and understanding of this translational research (TR) process is essential to effectively plan for impact in your research activities. Consider: where do you sit on the TR continuum? Where are the translation gaps, or potholes? An ecological approach offers novel opportunity to conceptualise your position in the TR process between bench and bedside, enhancing the impact potential of your research activities.



Adapted from Drolet and Lorenzi (2011)

REFLECTIVE EXERCISE:
YOUR ROLE IN TRANSLATION

Where do you currently sit on the Translational Research Continuum?

Who do you know/ what connections do you have at each point in the continuum? (Go to page 17 (Who's in your network) for support with this)

What do the arrows signify?

Where do you see yourself positioned on this continuum in five / ten / fifteen years' time?

KEY QUESTION

Is your idea clinically applicable and how do you know?

SKETCHING EXERCISE:

Use this space to sketch what your own translation continuum would look like, the stages of translation to bring your idea to fruition, the gaps in between...

You might have something, the in-depth biomechanics of a smooth muscle cell, and yes, in one way it's important, but there's no point in going down that rabbit hole unless at the end of that rabbit hole, there's something that's clinically applicable."

INDIVIDUAL LEVEL CONSIDERATIONS OF IMPACT

First, consider yourself, the individual scientist, and your personal characteristics that could influence the impact potential of your research. These characteristics can play a vital role in the types and quality of productive interactions you engage in, how you plan for research impact, and, ultimately, the impact potential of your research activities. As such, self-awareness of these characteristics is very important for PIs in effective planning for impact.

REFLECTIVE PROMPTS:

What strengths do you have to support creating impact?

How do you demonstrate and measure the impact of your research?

REFLECTIVE EXERCISE:

YOUR SHAPERS OF IMPACT

Three types of personal characteristics for you to think about:

FORCE	
What are your internal motivations for what you do? (e.g. your disposition, inner drive, capacity for resilience, sense of self-efficacy)	

Your natural tendency is to think that to be successful you have to have the same attributes as your first PI has, when that's not the case at all."

RESOURCE

What resources or assets (mental, emotional, social & material) do you possess that could enhance impact potential?

- What prior experience (e.g. industry experience, international, previous commercialisation experiences) provide benefits for my research?
- What resources do I possess/need to further my research's potential for impact?
- What knowledge and experience do I have of the commercialisation process?

DEMAND

What characteristics do you possess that can influence another person's reactions to and expectations of you?

- What characteristics do I possess that may influence how others view me?
- How could your present reputation within discipline/ institute/ with industry partners aid or hinder your research's impact potential?
- Think of this as a critical eye to your LinkedIn profile - How would others view this?

YOUR RESEARCH NETWORK: FROM THE MICRO TO THE MESO

The micro- and meso-levels can be viewed as the formal and informal interactions you have in your day-to-day research activities.

IT IS OF VITAL IMPORTANCE TO THINK FROM STAKEHOLDERS' PERSPECTIVES... TO WALK IN THEIR SHOES

Our research highlights the importance of stakeholder engagement and analysis for impact for medical device PIs. Researchers need to develop effective collaboration strategies, strong multidisciplinary networks of academics, clinicians and industry partners. Research stresses the importance of establishing and maintaining these networks and relationships, involving reciprocal and mutually beneficial interactions between project stakeholders that build in complexity over time.

> *Don't stay in your silo, go talk to someone."*

> *It has to be mutually beneficial."*

> *I think networking is absolutely vital and is a massive part of what we do."*

REFLECTIVE PROMPTS

- **What matters to your team members?**
- **What are their interests, strengths and priorities? How do you know?**
- **Who is my target audience and how do I know what they need and demand?**
- **How do I reach them?**
- **When? Before the project, during, after...?**

REFLECTIVE EXERCISE:

MAPPING YOUR RESEARCH NETWORK

Use this table to map all of your formal and informal networks in your day to day research activities

Stakeholder	What are the benefits for you?	What are the benefits for them?	Type and Level of Interaction	Time spent	Directionality
	E.g. access to material resources	*E.g. Input into device design*	*Ongoing or transactional? High/Med/Low*	*Regular/sporadic*	*Who is contacting who? Who is benefiting?*

What he looks for in people is always someone who is smarter than him, like don't ever be the smartest person in the room... If you bring the correct expertise on board, they will enhance your project, and will open up things to you that you never would have thought of."

INDIRECT INFLUENCES: THE EXOSYSTEM

The exosystem level can be understood as the indirect influences and influencers on your research, that could affect the impact potential of your research – It can be viewed as an extension of your mesosystem

Our research highlighted the indirect influence of various stakeholders on PI impact orientation. PIs without direct connections to expert scientists in other disciplines, clinicians, industry, etc must identify intermediaries or brokers who can provide a bridge to these stakeholders. These intermediaries can then become part of your mesosystem, strengthening your research's impact potential.

REFLECTIVE PROMPTS

- **Who have you not spoken to that can influence the direction of your research project?**
- **What stakeholders, or beneficiaries, of your research do you have difficulty engaging with?**
- **Who do you know that could engage with this person/group?**
- **Who do I want to reach and how do I get to them?**
- **When? Before the project, during, after...?**

REFLECTIVE EXERCISE:
ENVIRONMENTAL SCANNING

Successful PIs are constantly strategizing and constantly undertaking environmental scanning activities. The purpose of environmental scanning is to broaden your knowledge and understanding of your environment and key trends and drivers relevant to your research. *These indirect actors, those in your exosystem, could include, for example, regulatory bodies, general practitioner groups, patient advocacy groups.*

Environment Scanning Activities				
Indirect actors / organisations	*Why?*	*What are their needs?*	*How do you know what they want?*	*How do they know what you want?*

You need to know that you are not a marketing person, that you are not a business person, but you need to know that you should go to these types of people to ensure that your research becomes a successful product, because it would be extremely rare for the PI or the scientist to actually push it all the way."

MACROSYSTEM TO CHRONOSYSTEM: SOCIETAL AND GOVERNMENTAL FACTORS

The *macrosystem* can be viewed as the wider governmental and societal influences on your research, the cultural and social values that you must consider in your research planning and strategising activities.

The *chronosystem* consists of the temporal issues you must consider when planning for impact, the changing societal trends that could influence or affect your research. For example, impact could be viewed as a current trend in research processes and governmental policy

> ***What's topical and what's the correct agenda at the right time, is very important."***

REFLECTIVE PROMPTS

- **What is the current cultural and social climate like?**
- **Thinking of the grand challenges dominating society, is there a way your research can alleviate them or contribute to the discussion?**
- **How do these values and trends affect your research ambitions?**
- **How does your research align with these values and trends?**
- **What are your strategies to keep up to date with these trends? E.g. podcasts, news features**

REFLECTIVE EXERCISE:

SOCIAL AND CULTURAL VALUES AND TRENDS

Take some time to think about the broader influences on your research and its potential for impact

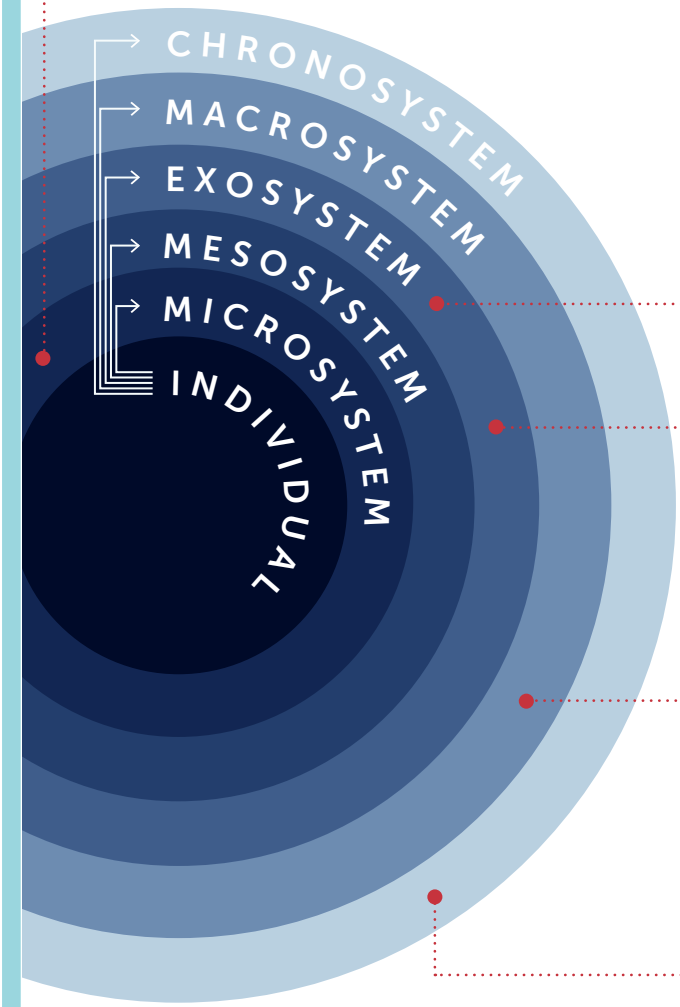
MACROSYSTEM	CHRONOSYSTEM
Social values: *E.g. Social debate in relation to access to health and inequalities*	Changing social values: *E.g. Social debate in relation to access to health and inequalities*
Cultural values: *E.g. Debates in relation to utilisation of stem cell research*	Changing cultural values: *E.g. Debates in relation to utilisation of stem cell research*

ALIGNING YOUR VISION AND MAPPING YOUR IMPACT

REFLECTIVE EXERCISE:

MAPPING YOUR OWN IMPACT

Now you have completed the above exercises, working between the micro- to chrono-levels, you can begin to map these productive interactions for impact.



Microsystem

Mesosystem

Exosystem

Macrosystem

Chronosystem

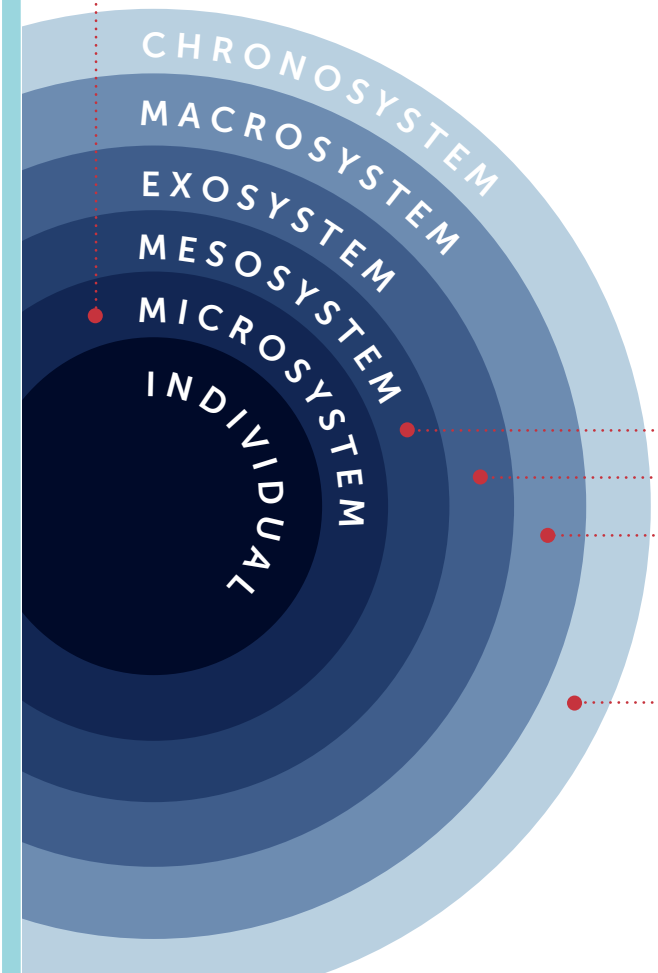
REFLECTIVE PROMPTS

- **Who are the stakeholders currently in your research environment?**

- **Where can you envisage impact across these systems?**

- **Where are the gaps?**

ILLUSTRATIVE EXAMPLE OF PI IMPACT MAP



Microsystem
- PI
- Project Team

Mesosystem
- Funding Body
- Department
- University
- End-User
- Stakeholder Groups

Exosystem
- Regulatory Bodies
- Competing Researchers
- Industry

Macrosystem
- Societal Calues & Needs
- Government Policies
- University Processes & Structure

Chronosystem
- Time dependent issues Prevalent in Public Consciousness

E.g. Carbon Emissions, Austerity etc.

REFLECTIVE PROMPTS

Now you have your visual map, what next?

How does this align to your impact goals?

How will you monitor your progress?

Use the exercises that follow to assist you in completing this table

Impact Goals	Stakeholders to engage with	Routes to impact (Activities)	Monitoring (measurement)	Personal strengths	Gaps identified
E.g. influencing government policy on MD regulations	*Local TDs*	*Policy brief*	*Presentations to Dail. Number of views Feedback from TDs*	*Reputation in Galway*	*Lack of experience dealing with politicians*

REFLECTIVE EXERCISE:
YOUR IMPACT GOALS

- Reflecting on your 'postcard from the future', what are your impact goals from your research?

- What impact pathways (and associated activities) will enhance your potential to achieve these goals?

- Who in your research environment can help you achieve these goals? E.g. who do I need to persuade?

- Using your ecological model, who are the stakeholders you need to engage with at each level?

- Looking back at your micro-level considerations of impact (page 15) what have I learned in terms of personal characteristics can I utilise in planning for impact?

- What are the risks/ potential pitfalls to be aware of in planning for impact?

- What are the impact gaps? What do I need to improve on/training required?

REFLECTIVE EXERCISE:
FROM PLANNING TO ACTION

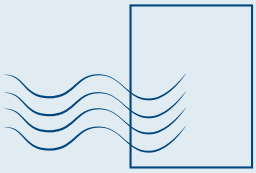
Where to next? Let's list your core actions for the short term (Horizon One) and long term (Horizon Two). How do you plan to link between these two horizons (medium term)

Horizon One	Horizon Two
Short Term - Core Actions	Medium to Long Term - Core Actions

REFLECTIVE EXERCISE:
REVISITING YOUR POSTCARD

Now back to your postcard from the future. What can you add following your reflections? What would you change?

POSTCARD



We would spend an awful lot of the time analysing the project before we ever start it. So the phrase I always say is, if you've got seven hours to chop a tree, you spend the first five sharpening the axe."

CONCLUDING REFLECTIONS

While the Principal Investigator role can be personally rewarding, it can also be very challenging. Creating actual impact from medical device research, and research in general, is complex. Therefore, impact should not be thought of simply as the final destination of your research. Impact is about the journey, the process of working towards wider societal contributions, beyond the traditional outputs of academia (e.g. publications and citations, patenting and licensing).

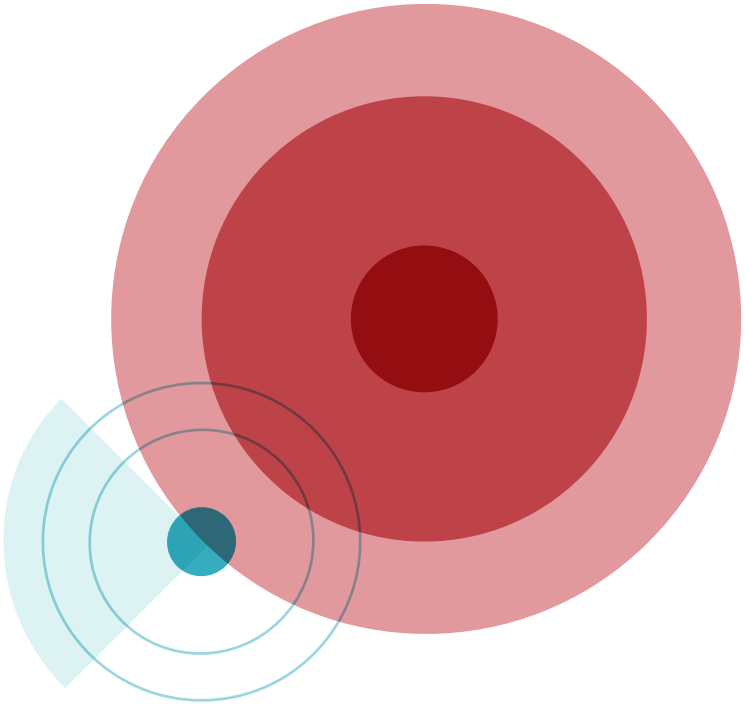
PIs need to develop their impact orientation, or impact mindset, to think strategically about how they engage in research and plan for impact. This impact mindset can influence how the PI operates on a day to day basis, to think more holistically about the relevance and impact of their work. This toolkit encourages PIs to reflect on their priorities and their research ecosystem, to cultivate a more nuanced understanding of impact, to encourage PIs to be more impact-oriented, whatever that might be to each individual scientist.

As a PI, you will have to deal with challenges, setbacks and rejections. Your plans will change. Impact can be both positive and negative, and it is vital to acknowledge failure. This is all part of the research translation process, bringing your research towards point-of-care application, bridging the many translation gaps and chasms. Having a clear and considered perspective as to the impact that you are seeking to realise can have a directional resilience that can be used to overcome failure and setbacks.

The *Becoming a PI & Planning for Impact Toolkit* offers medical device scientists, and scientists in general, an opportunity to reflect on their own impact orientation, or impact mindset, how they understand and approach impact in their research activities, and the stakeholders of research that they must engage with. The fluid and flexible nature of the toolkit provides the chance for you, throughout your career, to regularly reflect on the direction in which you are going.

This framework serves as a support mechanism to current impact metrics and models, it is not a replacement. Scientists must look to every opportunity to enhance the impact potential of their work, whether through increased PPI (Public and Patient Involvement in Research) and Engaged Research activity, science communication, or entrepreneurship training.

At the end of the day, not every research project can achieve impact. Most impactful projects require a certain level of serendipity or luck. Impact cannot be guaranteed by using this, or any other, toolkit, or in combination with other impact planning models, whether it be, for example, an impact logic model or theory of change. We can, however, improve our chances of enhancing our impact by increasing our awareness of the context in which we operate, the stakeholders involved and the ultimate relevance of our work.



SOME IMPACT RESOURCES

FUNDING BODIES IMPACT POLICIES

Science Foundation Ireland
https://www.sfi.ie/funding/award-management/research-impact/

Health Research Board
https://www.hrb.ie/funding/evaluation/how-we-monitor-and-evaluate/

Irish Research Council
http://research.ie/what-we-do/societally-oriented-research/

Research Excellence Framework
https://www.ref.ac.uk/guidance/

Wellcome Trust
https://wellcome.ac.uk/sites/default/files/wtp052364_0.pdf

EU Commission
https://ec.europa.eu/programmes/horizon2020/en/tags/impact-assessment

IMPACT SUPPORTS

MedTechTranslate
https://crdi.ie/research-curam/medtechtranslate-2/

PPI Ignite – NUI Galway
https://www.nuigalway.ie/ppi/

NUI Galway Research Community Portal - Research Impact Supports
www.nuigalway.ie/researchcommunityportal/

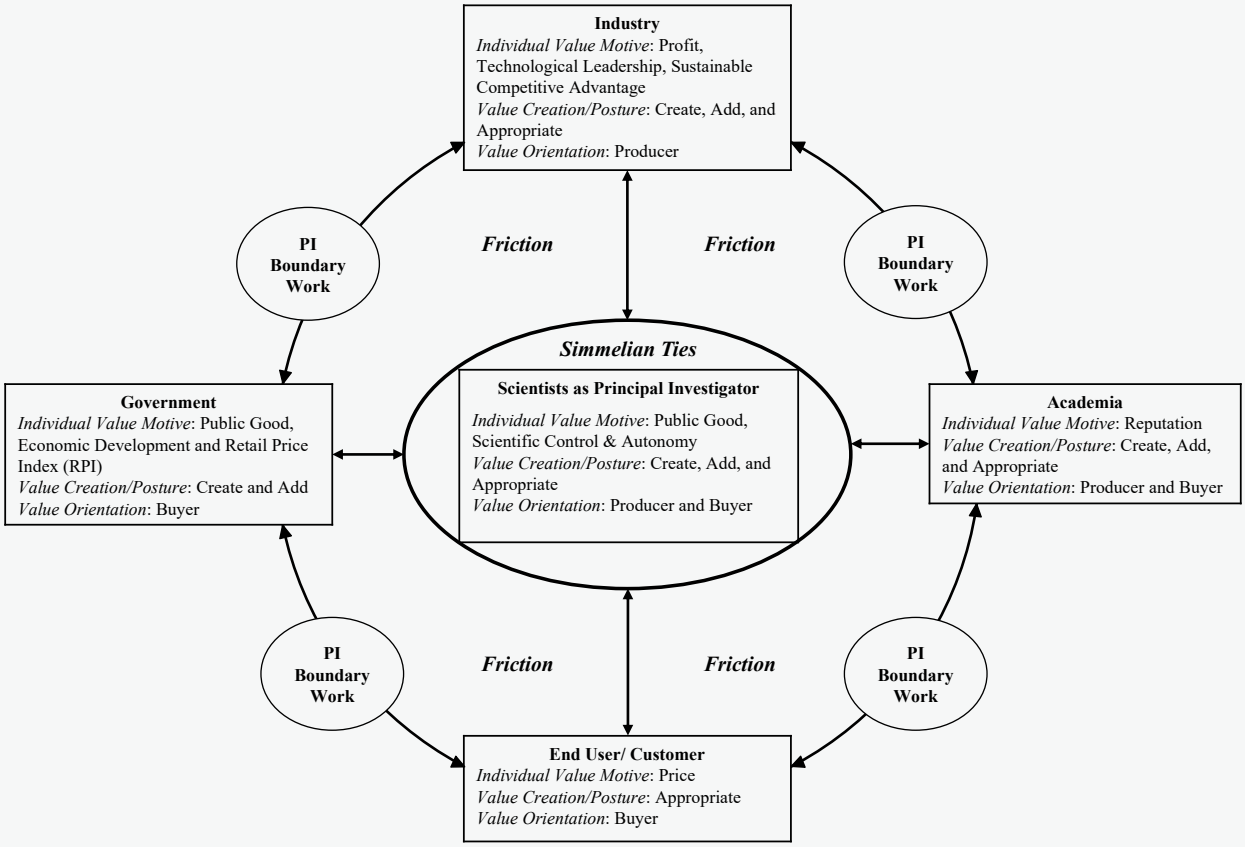
Campus Engage - Making an Impact through Engaged Research
http://www.campusengage.ie/our-work/making-an-impact/engaged-research/

PI ROLE AND IMPACT: RELEVANT RESEARCH

PRINCIPAL INVESTIGATORS AND VALUE CREATION

This conceptual model capture the value motives for key stakeholders that PIs need to consider when planning for impact.

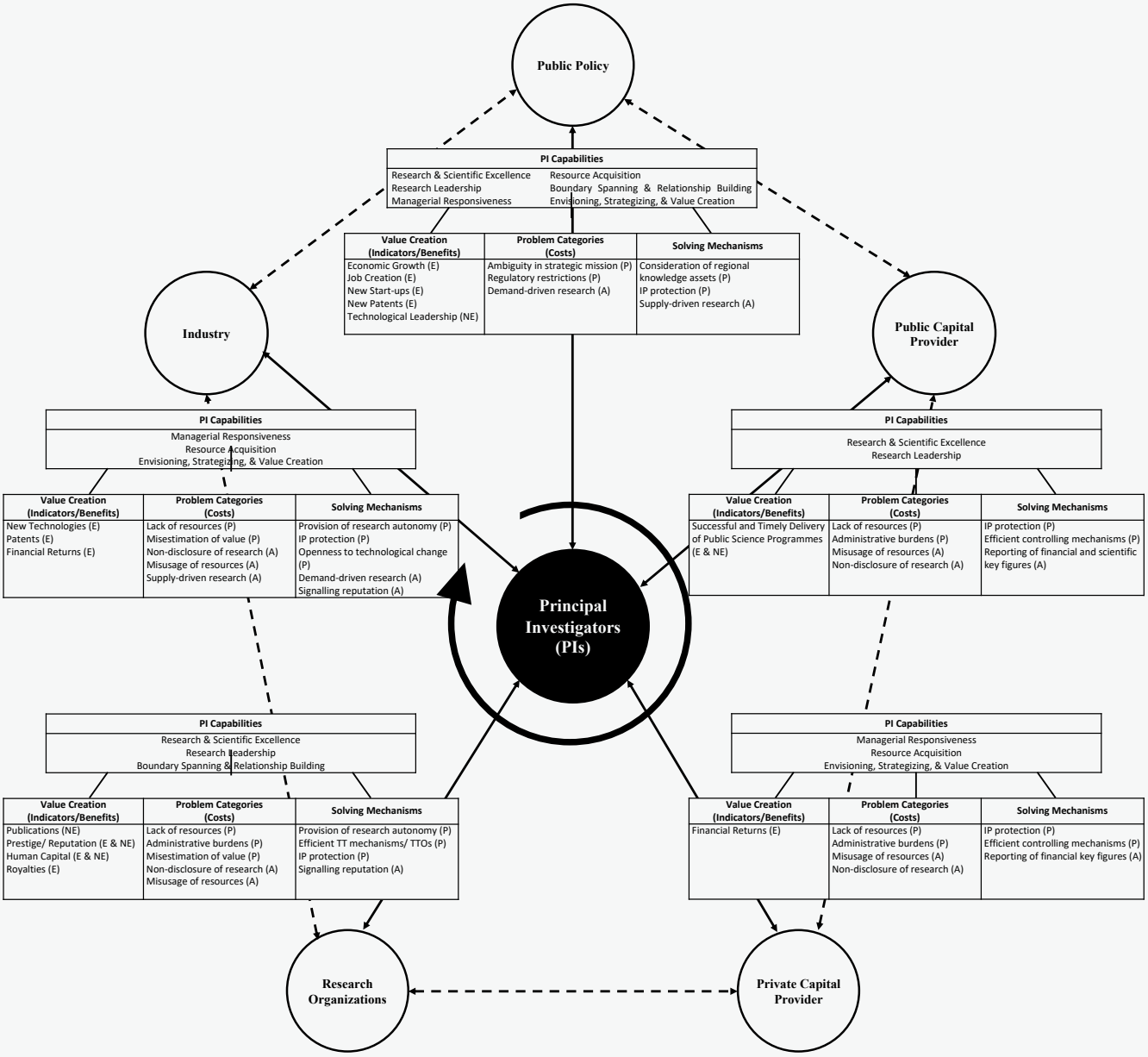
A Conceptual Model of Principal Investigators as Quadruple Helix Value Creators



Source: Cunningham, J.A., Menter, M., and O'Kane, C., (2018) Value Creation in the Quadruple Helix, *R&D Management*, 48(1):136-147

PRINCIPAL INVESTIGATOR CENTRED ENTREPRENEURIAL ECOSYSTEM GOVERNANCE

This provides an overview of the PI capabilities that are required to engage effectively with different stakeholders.



Source: Cunningham, J. A., Menter, M., & Wirsching, K. (2019). Entrepreneurial ecosystem governance: A principal investigator-centered governance framework. Small Business Economics, 52(2), 545-562.

ADDITIONAL READINGS AND REFERENCES

David Audretsch, James A Cunningham, Donald F Kuratko, Erik E. Lehmann, and Matthias Menter (2019) Entrepreneurial Ecosystem: Economic, Technological and Societal Impacts, *Journal of Technology Transfer*, 44(2):315-325.

James Cunningham, Brendan Dolan, Matthias Menter, Conor O'Kane, & Paul O'Reilly (2020) How Principal Investigators' Commercial Experience Influences Technology Transfer and Market Impacts. *Research Technology Management,* October-November, 48-56 -DOI: 10.1080/08956308.2020.1790244

Conor O'Kane, Vincent Mangematin, Jing A. Zhang, James A. Cunningham (2020) How University-Based Principal Investigators Shape a Hybrid Role Identity, *Technology Forecasting and Social Change*, 159, 120179.

Conor O'Kane, Jing A. Zhang, James A. Cunningham and Lawrence Dooley (2020) Value Capture Mechanisms in Publicly Funded Research, *Industrial Marketing Management*, 90:400-416.

James Cunningham, Paul O'Reilly, Daire Hooper, Daniel Nepelski and Vincent Van Roy (2020) *The Role of Project Coordinators in European Commission Framework Programme Projects. Results of the Innovation Radar PC Survey in FP R&I Projects* EUR 30131 EN, Publications Office of the European Union, Luxembourg, 2020, ISBN 978-92-76-17304-5, doi:10.2760/709126, JRC120015

James Cunningham & Paul 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, 2019, ISBN 978-92-76-11711-7, doi:10.2760/55062, JRC117576

Brendan Dolan (2019) *Principal Investigator Impact Orientation in Medical Device Public Research*, Unpublished doctoral dissertation, National University of Ireland Galway

James Cunningham (2019) *Principal Investigators and Boundary Spanning Entrepreneurial Recognition: A Conceptual Framework* (eds) David Audretsch and Albert N. Link, A Research Agenda for Entrepreneurship and Innovation, Edward Elgar, pp.55-74.

Brendan Dolan, James Cunningham, Matthias Menter, Caroline McGregor (2019) The Role and Function of Cooperative Research Centers in Entrepreneurial Universities: A Micro Level Perspective, *Management Decision, Vol. 57 No. 12, pp. 3406-3425.*

James Cunningham, Matthias Menter and Katharine Wirsching (2019) Entrepreneurial Ecosystem Governance: A Principal Investigator Governance Framework, *Small Business Economics*, 5, 545-562.

James Cunningham, Matthias Menter and Conor O'Kane (2018) Value Creation in the Quadruple Helix, *R&D Management*, 48(1):136-147

James Cunningham, Paul O'Reilly, Conor O'Kane, Vincent Mangematin and Brendan Dolan (2017) *Female Publicly Funded Principal Investigators*, in Al Link Gender Issues in Entrepreneurship, Edward Elgar, pp.221-252

Conor O'Kane, Jing A. Zhang James A. Cunningham and Paul O'Reilly (2017) What factors inhibit principal investigators's commercialization activities?/ *Small Enterprise Research,* 24(3):215-232.

Paul O'Reilly, and James A. Cunningham. (2017). Enablers and barriers to university technology transfer engagements with small and medium-sized enterprises: Perspectives of Principal Investigators, *Small Enterprise Research*, 24(3) pp. 274-289.

James Cunningham, Paul O'Reilly, Conor O'Kane and Vincent Mangematin, (2016) *Publicly Funded Principal Investigators as Transformative Agents of Public Sector Entrepreneurship in* David Audretsch and Al Link, Essay in Public Sector Entrepreneurship, Springer, pp.67-93.

James A. Cunningham, Paul O'Reilly, Brendan Dolan, Conor O'Kane and Vincent Mangematin, (2016) Publicly Funded Principal Investigators Allocation of Time for Public Sector Entrepreneurship Activities, *Economia e Politica Industriale (Journal of International Business & Economics)*, 43(4):383-408.

James A. Cunningham, Vincent Mangematin, Conor O'Kane and Paul O'Reilly (2016) At the Frontiers of Scientific Advancement: The Factors that Influence Scientists to Become or Choose to Become Publicly Funded Principal Investigators, *Journal of Technology Transfer,* 41(4): 778-797.

Conor O'Kane, James Cunningham, Paul O'Reilly and Vincent Mangematin (2015) Underpinning Strategic Behaviours and Posture of Principal Investigators in Transition/Uncertain Environments, *Long Range Planning*, 43(3): 200-214.

James Cunningham, Paul O'Reilly, Conor O'Kane and Vincent Mangematin, (2015) Managerial Challenges of Publicly Funded Principal Investigators, *International Journal of Technology Management*, 68(3-4):176-202.

Vincent Mangematin, Paul O'Reilly and James Cunningham, (2014) PIs as boundary spanners, science and market shapers, *Journal of Technology Transfer*, 39(1):1-10.

James Cunningham, Paul O'Reilly, Conor O'Kane and Vincent Mangematin, (2014) The Inhibiting Factors that Publicly Funded Principal Investigators Experience in Leading Publicly Funded Research Projects, *Journal of Technology Transfer,* 39(1):93-110.

Brian Drolet & Nancy Lorenzi (2011). Translational research: understanding the continuum from bench to bedside. *Translational Research*, 157(1), 1-5.

Jack Spaapen & Leonie Van Drooge (2011). Introducing 'productive interactions' in social impact assessment. *Research Evaluation*, 20(3), 211-218.

Urie Bronfenbrenner & Pamela A. Morris (2006) 'The bioecological model of human development', in Damon, W. & Lerner, R. M. (eds.), *Handbook of child psychology, Vol. 1: Theoretical models of human development*, 6th edn., New York: Wiley, pp. 793-828.

Urie Bronfenbrenner (1979) *The ecology of human development: Experiments by nature and design*, Cambridge, MA: Harvard University Press.

PRINCIPAL INVESTIGATOR IMPACT PROJECT: OVERVIEW AND TEAM

RESEARCH PROGRAMME OVERVIEW

- 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

For more information on the project, visit: http://www.curamdevices.ie/curam/research/translational-research/

OUR MULTIDISCIPLINARY TEAM

Prof James Cunningham is a Professor of Strategic Management at the Department of Entrepreneurship, Innovation and Strategy, Newcastle Business School, Northumbria University, UK. His research intersects the fields of strategic management, innovation and entrepreneurship. His research focuses on strategy issues with respect to scientists as principal investigators, university technology transfer commercialization, academic, public sector and technology entrepreneurship, entrepreneurial universities and business failure. He has papers published in leading international journals such as *Research Policy, Small Business Economics, R&D Management, Long Range Planning, Journal of Small Business Management, Journal of Technology Transfer, Technological Forecasting and Social Change, International Marketing Management* and the *Journal of Rural Studies* among others.
Email: james.cunningham@northumbria.ac.uk

Dr Brendan Dolan is a Postdoctoral Researcher on the Principal Investigator Impact: Research in Medical Devices research program at CÚRAM Centre for Research in Medical Devices at National University of Ireland Galway, Ireland. His research interests include impact research theory, principal investigator research, applied ecological theory, and research process dynamics. This work follows on from Brendan's PhD thesis: Principal Investigator Impact Orientation in Medical Device Public Research.
Email: brendan.dolan@nuigalway.ie

Prof Caroline McGregor is Professor at the School of Political Science and Sociology, NUI Galway with lead responsibility for social work. She is a senior Researcher at the *UNESCO Child and family research Centre* within the School and part of the wider *Institute for Life Course and Society*. Her main research is within the fields of child welfare, family support and social work alongside wider critical social scientific research and publication. Caroline has published widely in her field (see https://www.nuigalway.ie/our-research/people/political-science-and-sociology/carolinemcgregor/). Her particular contribution to this research programme has been to introduce the use of Uri Bronfenbrenner's Ecological and bio-ecological theory, used widely in the social work and child welfare field, to the study of impact and impact orientation. She is PI for Principal Investigator Impact: Research in Medical Devices research program at CÚRAM Centre for Research in Medical Devices at National University of Ireland Galway, Ireland.
Email: caroline.mcgregor@nuigalway.ie

Becoming a Principal Investigator (PI) and planning for impact from research requires in-depth planning and stakeholder engagement across many disparate environments. This toolkit supports researchers of medical device research to reflect on and think holistically and strategically about becoming a PI and impact. Grounded on the experiences of PIs in medical device research and other scientific domains, this toolkit takes a reflective learning approach. Through reflective exercises and prompts it provides researchers with a flexible approach to understand and engage with impact, exploring how you, in the role of PI, can influence the direction and ultimate success of your research to benefit the public, patients and clinicians.

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