Patient-Centred Outcome Measures in Research & Healthcare
IPPOSI Outcome Report

Patient-centred outcomes in research and healthcare

Keywords: Patient-reported outcomes, patient-centred outcome measures, health-related quality of life, patient & public involvement in research, patient experience

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# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>4</td>
</tr>
<tr>
<td>Snapshot</td>
<td>5</td>
</tr>
<tr>
<td><strong>Part 1:</strong></td>
<td></td>
</tr>
<tr>
<td>Patient-Centred Outcome Measures - An Introduction</td>
<td>6</td>
</tr>
<tr>
<td><strong>Part 2:</strong></td>
<td></td>
</tr>
<tr>
<td>Patient-Centred Outcome Measures - Highlights + Challenges</td>
<td>8</td>
</tr>
<tr>
<td><strong>Part 3:</strong></td>
<td></td>
</tr>
<tr>
<td>The Future of Patient-Centred Outcome Measures in Ireland</td>
<td>9</td>
</tr>
<tr>
<td>Conclusions &amp; Links</td>
<td>10</td>
</tr>
<tr>
<td>Appendix: Biographies</td>
<td>11</td>
</tr>
</tbody>
</table>
“Measuring my mobility, my hearing, my sight is easy, but have you considered measuring my empowerment, my sense of wellbeing, my independence? These are equally as important. Put time and money into my personhood - because at the end of the day my quality of life will have a profound effect on my healthcare.”

- Helen Rochford-Brennan

Chair, European Working Group of People with Dementia

The 2018 IPPOSI Annual General Meeting and Conference was a milestone event for IPPOSI. Our new chairperson, several new board members as well as record numbers of IPPOSI members participated in an event focused on ‘Patient-Centered Outcome Measures’.

In all, over 160 people - speakers, panellists and contributors - attended an insightful and sometimes passionate meeting that incorporated perspectives from right across the health sector – from policy-makers, clinicians, patients, academia and industry – who spoke about what patient-centered outcome measures mean to them.

It was truly inspiring to see the passion and good intent with which issues in this area are being approached, despite significant challenges at a local and national level.

IPPOSI would like to thank everyone who contributed to the event, including our sponsors. We hope this report captures the positivity and striking determination of those working to place the patient voice and experience firmly at the heart of outcome measures development, and the embracement of a more value-based healthcare approach towards meeting Irish healthcare challenges.

As the Slaintecare vision for healthcare in Ireland drives innovation forward, it is clear these conversations and conclusions are more timely and important than ever.

Outputs from the meeting are available on a dedicated page on our website.

Dr Derick Mitchell
Speaker snapshots

- **Helen Rochford Brennan**
  - EWS/PWD
  - @rochfordbrennan
  - "I have Alzheimer’s and I have never been asked by a medical professional about comfort or attachment."

- **Rishi Hazarika**
  - ICROM
  - @ICHOM_ORG
  - "The patient voice is essential. We need to capture those outcomes which are most important to patients, in a standard way so that we can compare them. Falling to measure the right outcomes can leave us hitting the target, but missing the point."

- **David Galvin**
  - IPCOR
  - @IPCOR_Ireland
  - "By measuring outcomes in prostate cancer, we will know if we are providing patients with high quality care and if we are meeting patients’ needs. We are establishing a ‘Patient Panel’ to involve patients in our outcomes measurement work."

- **Aíne Carroll**
  - UCD
  - @AinemCarroll
  - "To measure what is important in health, what has value, we need to ask patients in a meaningful way about their experience and about their hopes for person-centred, coordinated healthcare. There is still a culture ‘them’ and ‘us’, but really there is only an ‘us’. We need to all figure out what is important, together, as citizens of this country!"

- **Declan Devane**
  - HRB TMRN
  - @decdevane
  - "We know there is inconsistency in the outcomes reported in clinical trials. We know there is variety in the value attached to outcomes, from different stakeholders. We need to have a standardised set of outcomes that we all agree are important to measure."

- **Abaigéal Jackson**
  - Cystic Fibrosis Registry of Ireland
  - @Abaigéal_Jackson
  - "We know that registries need to measure patient reported outcomes, but we are still learning about how we can best do this. We need to know what outcomes are important for the pathway of care and we need to know how to capture this data."

- **Éidín Ni Shé**
  - UCD
  - @EidinNiShe
  - "Simple things make a difference to frail patients in hospital, like having access to water and the bell and reading glasses. We are studying how co-designed pathways, plans and education include what matters to patients."

- **Rachel Flynn**
  - HRQA
  - @mrachelflynn
  - "The National Patient Experience Survey has shown that patients want healthcare professionals to improve communication with them and their family members, and patients want to be more involved in decisions about their care."

Design by Rachel Lynch, FibroIreland and EUPATI Patient Fellow
1. Patient-Centred Outcome Measures - An Introduction

The first session highlighted the importance and impact of patient-centred outcome measures in research and healthcare. The voices of patients, researchers and clinicians were represented. Several key points emerged from the presentations and discussions during this session.

**The patient perspective needs to be considered** - Helen Rochford Brennan, Chairperson of the European Working Group of People with Dementia, spoke about her experience of being a person with dementia and the lack of value-based healthcare she had experienced. When she got her diagnosis, there was no pathway nor plan, nor support, it was a case of just getting on with it, going home and getting on with your life. A more value-based healthcare approach towards meeting healthcare challenges will allow people with dementia to contribute their knowledge from experience, and ensure their human rights are upheld.

**Patients are not experiencing patient-centred care** - Results from the HSE-funded Patient Narrative Project, which surveyed 584 (predominantly female) respondents, indicate issues in patient care around co-ordination and communication. Professor Aine Carroll, University College Dublin, described how two-thirds of the patients reported appointments being changed or cancelled (and the frustration this engenders); that the information discussed with patients was focused on their medical needs whereas they or their families may have been worried about something else, and that one quarter of the patients in the survey were left with a limited understanding of what to watch out for after discharge. Against this, 50% of respondents noted that the information they received was practical and / or easy to understand.

**Patient-centred outcome measures improve care** - As patient outcome measures become more transparent, patients and payers will vote with their feet. Rishi Hazarika of the International Consortium of Health Outcomes Measurement (ICHOM) gave the example of the Martini Klinik in Germany, which specialises in the treatment of prostate cancer. Its patient-centred outcomes far exceed national averages for several countries, and patients are going there because it delivers the best outcomes and has incorporated new surgical methods that deliver benefits for patient quality of life. Measuring patient-centred outcomes can also refine care for sub-populations of patients, such as the case of cataract surgery in Sweden, which spotted a decline in vision for a percentage of patients despite good clinical outcomes.

**Patient information needs to be properly managed and used** - We are collecting patient-related information for good reasons, but what else is happening to the data? We need to ensure that on the one hand the personal information shared by patients is protected, and also that patients learn about the benefits of sharing that information, how it is being used to improve their care and that of others. We also need to be careful what we are collecting, otherwise we will end up automating things that don’t matter to the patient.

**Patient-centred outcomes need to be comparable** - Rishi Hazarika spoke about the need to measure patient-centred outcomes in a manner such that they can be compared. ICHOM makes standard sets or guides on what outcomes to measure, how, and what time points. At the moment, we measure things in lots of different ways, so it is difficult do the comparisons. “Hospitals need to focus on outcomes, not just processes,” he said.

**Patient-reported outcomes in prostate cancer enrich our understanding of the disease** - Dr David Galvin of the IPCOR (Irish Prostate Cancer Outcomes Research) project, which is funded through the Irish Cancer Society and Movember, is collecting an extensive clinical dataset looking at time to diagnosis, outcomes, complications and recurrence and, importantly, patient-reported outcomes. It is already showing that prostate cancer diagnosis happens in a proportion of working-age men, not just retired men, and that the majority of patients are diagnosed when symptomless. There is also a need to carry out more trans-perineal procedures for patients with prostate cancer in Ireland, as opposed to transrectal procedures, and data show that patients are voting with their feet for robotic surgery in private hospitals.

**Some patients may fear reporting outcomes** – This is particularly a risk in the area of mental health. Emotional support and building of trust can help, and trust can be strengthened by showing that the reported information is used to improve the design and delivery of healthcare and has practical benefits.

**Leadership is key to enable patient-centred outcome measurement** - Rishi Hazarika from ICHOM pointed out that leadership is a driving force to enable the measurement of patient-centred outcomes. The most fantastic IT system in the world will not achieve its potential without leadership, commitment and engagement - and with the right leadership even capturing information with pen and paper can make a difference.
Patient-Reported Outcomes

Patient Reported Outcomes (PROs) are data reported directly by a patient on his or her own health condition, without interpretation by a doctor or anyone else. They are based on a patient’s perception of a disease and its treatment. The findings or outcomes can be measured in absolute terms (e.g. severity of a symptom, sign, or state of a disease or condition) or as a change from a previous measure.

Patient-Reported Outcome Measures

Patient-reported outcome measures (PROMs) are the tools used to measure and collect data on PROs. Generally, findings are measured by a well-defined and reliable questionnaire. The use of a PRO questionnaire (also called an instrument) is advised when measuring an aspect of the disease or condition that is best known by the patient or is best measured from the patient perspective.

PROM questionnaires are designed to be either generic or condition-specific and may measure symptoms, physical function, mental health, and quality of life. A number of generic instruments have been developed and validated in different populations including EQ-5D, Health Utilities Index, Quality of Well Being, Short Form, PROMIS.

Patient-Centred Outcome Measures

As a relatively new concept, Patient-Centred Outcome Measures (PCOMs) aim to place patients, their families and carers at the heart of decisions concerning the most valuable criteria in health assessment, rather than leaving assessments solely to clinicians.

PCOMs should provide evidence on the impact of a disease and treatment on patients. PCOMs include but are not limited to self-reporting instruments: they embrace all forms of clinical outcome assessments (COAs), namely ‘patient-reported outcomes’ (PRO), clinician-reported (ClinRO), observer-reported (ObsRO) and performance outcome (PerfO) measures.

PCOMs may be used for several purposes, such as: efficacy endpoints in clinical trials, outcome measures in registries, guides to treatment choices for daily care, or tools to monitor care delivery. PCOM identification and validation require rigorous planning, methodology, and partnership between investigators and patient organizations.

Health-related Quality of Life

Health-related quality of life (HRQoL) is a specific type of PRO and is a broad concept which can be defined as the patient’s subjective perception of the impact of his/her disease and its treatment(s). This can include the impact on his/her daily life, physical, psychological and social functioning and well-being. The notion of multidimensionality is a key component of the definition of HRQL.

Patient (& Public) Involvement in Research

INVOLVE (UK) have defined PPI in Research as “research being carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them”. The goal of effective PPI is to create a valued partnership between the public, patients & researchers to ultimately improve research quality, relevance & outcomes.

Patient Experience

In addition to the length and quality of life, one important outcome of care and research is peace of mind for the patient. When a care episode or a research initiative is over, it matters to patients whether they feel confident that all that should have been done was done, independent of other outcomes.

From a perspective of patient-centred healthcare, exploring patients’ (a) preconceptions, (b) treatment experiences, (c) quality of life, (d) satisfaction, (e) illness understandings are all critical components in improving health care and research. Utilizing qualitative approaches to discover patients’ experiences can provide valuable information for practitioners and investigators alike.
A series of ‘lightning presentations’ were delivered from Irish-based speakers about patient-centred outcome measures in their work and initiatives.

**Professor Declan Devane** from the HRB Trials Methodology Research Network spoke about the wide diversity in the outcomes researchers choose to measure in their research. He cited examples of difficult-to-analyse situations, such as the 72 different primary outcome measures in a suite of 103 randomised controlled trials about how to stop pre-term birth, and the relative lack of quality-of-life outcomes in reviews of obesity. We need to have agreed core outcome sets to measure and compare – these could be specific for a disease or condition but should be measured and reported by researchers to enable more study and comparison.

**Dr Abigail Jackson** from the Cystic Fibrosis Registry of Ireland spoke of the need to capture information that matters to patients, and how patient-reported outcomes have the potential to be of value alongside the clinical outcomes. A new project between the CF Registry, UCD, Boston Children’s Hospital and Harvard Business School will explore value-based healthcare in this context. The registry has also developed a portal to allow cystic fibrosis patients (or their parents where appropriate) to log in and access their own information on the registry, and this offers a potential route to find out more about the patient outcomes that matter to patients and their families.

**Dr Éidín Ní Shé** from UCD Health Systems spoke about the systematic approach for improving care for frail older people in hospital (SAFE) study. The project at St Vincent’s University Hospital involved clinicians and patients in the co-design and production of the study and gathered information partly through shared workshops. The pilot study highlighted the need for relatively simple changes such as ensuring that patients had access to water and their reading glasses in the hospital. Addressing these issues via intentional rounding process correlated with a small but important reduction in falls, and it is now being implemented more widely in the hospital.

**Barbara Skerritt** from ICON plc spoke about their collaboration with ICHOM on the first global outcomes benchmarking pilot program. From the outset, it was apparent that there is huge variation between hospitals as not all collect patient-reported outcome measures. The benchmarking project captured and analysed data from hospital sites worldwide and ICON has developed a minimal viable product to analyse and visualise the data. Overall learnings from the pilot are that data collection, variation and interpretation are challenging, and the migration in hospitals from paper to electronic records can cause difficulties. There is a need for solid legal frameworks and adherence to data protection legislation.

**Dr Rachel Flynn** from HIQA spoke about the National Patient Experience Survey, a pioneering initiative in Ireland which captures the experiences and thoughts of patients at the point of discharge from hospital. Overall satisfaction with their experience was high, but there were areas for improvement such as communication and what to watch out for after discharge (when to call the doctor etc). The survey has led to several local initiatives in hospitals to address the identified areas that need improvement and the HSE is rolling out a communications skills training programme for staff in response. The survey will be carried out again this year and hopes to include non-hospital settings.
Several issues were raised during a forward-looking panel and audience discussion about how to support measuring outcomes of relevance for Irish patients. The panel included Ava Battles, CEO of Multiple Sclerosis Ireland, Dr Darrin Morrissey, CEO of the Health Research Board, Dr Lorraine Nolan, Chief Executive of the Health Products Regulatory Authority and, in place of Professor Martin Curley, Fran Thompson, Assistant National Director at the Office of the Chief Information Officer in the HSE.

Quality of life (QoL) outcomes are seen as vital by patients yet appear to remain secondary to funders – Quality of life is hugely important to patients and their families, as articulated by Helen Rochford Brennan, who has Alzheimer’s disease, and Anne Lawlor, whose adult child has a chromosomal condition called 22q11. Yet Trinity College Dublin researcher Dr Catherine Darker noted that when she designs a project and seeks funding for it, she needs to argue the case for QoL measures to be included. If she is successful, these are generally classified as secondary outcome measures. There is a need for a minimum dataset that includes QoL measures.

We need sustainable structures rather than reliance on champions – While it is encouraging to hear the success stories of patient-centred outcomes being measured, it often happens thanks to the efforts of a champion, noted Caitríona Dunne from Fighting Blindness. The lack of systemic structure in Ireland and the reliance on individual personalities to take the initiative leads to progress in pockets. To tackle this, we need more systemic inclusion of public and patient involvement (PPI) and patient-reported outcome measures in funding awards, more education on outcome measurement even as early as undergraduate level, and the need to set up appropriate ‘touch points’ for patients to engage.

Data need to be embedded and to make sense – Data collection elements must be part of a patient-centered process, otherwise they will fail, and the value of the data must be obvious to the person collecting it. Electronic Health Records that are developed in partnership with patients will make data more patient-centric and will allow patients to get involved by recording data of use to themselves or to clinicians. The national electronic health record being developed in Ireland is seeking to provide a more patient-centric record that allows access with consent for both patients and medical professionals about the care to date and referrals.

Clarity and transparency are key for patients – Patients need less jargon and clearer explanations about the outcomes being measured, and they need to hear back about any research to which they have contributed, in particular to learn about how their participation makes a difference.
Conclusions

- Patient-centred outcome measures improve and refine care, and improve our fundamental understanding of living with a condition.
- Healthcare providers and researchers have a responsibility to include the patient voice as early as possible in the development of outcome measures.
- Outcomes need to be measured in a manner that allows them to be compared. Utilise standard sets and core outcome sets to select what outcomes to measure, how and at what time points.
- Build trust with patients to encourage reporting outcomes by showing that their reported information is used to improve the design and delivery of healthcare.
- Patient Experience Data and Quality of Life measures need to move up the hierarchy of evidence considered relevant by research funders and healthcare providers.
- Electronic Health Records will make data more patient-centric and will allow patients to get involved by recording data of use to themselves or to clinicians.

Links

1. Video recordings of speakers: https://vimeo.com/album/5571058
2. Presentations (slides): https://www.slideshare.net/ipposi/presentations
3. Photos from the event: https://www.flickr.com/photos/136386396@N03/albums/72157702281289405
4. IPPOSI website page dedicated to this event: http://www.ipposi.ie/2018/12/03/annual-theme-2018-access-medicines-update-2
SESSION 1 Speakers:

Helen Rochford-Brennan is the current Chairperson of the European Working Group of People with Dementia and is the group’s nominee to the Board of Alzheimer Europe; she is former Chair of the Irish Dementia Working Group. Helen is on the Monitoring Committee of Ireland’s first National Dementia Strategy and a Global Dementia Ambassador. Helen was diagnosed after a five-year struggle with Early Onset Alzheimer’s at the age of 62 and has since written very personally about living with Alzheimer type of dementia. She hopes her participation in research will one day help find a cure. Throughout Helen’s life she has been a Rights and Social Justice Campaigner and today advocates for the Rights of people with Dementia in particular Alzheimer’s.

Dr Derick Mitchell is the Chief Executive of IPPOSI. Derick has over ten years experience of working in patient engagement, scientific communications, multi-stakeholder management and advocacy at both the national and European level. Derick leads IPPOSI’s participation in EUPATI - a unique initiative to develop an EU-wide Patient Training Academy. He is also a member of a number of national committees including the eHealth Ireland committee, the Medical and Life Sciences Committee of the Royal Irish Academy as well as the oversight group on implementation of the National Rare Disease Plan for Ireland. Derick has a PhD in Molecular Medicine from University College Dublin, as well as a BSc in Biotechnology from NUI Galway.

Dr Rishi Hazarika leads ICHOM’s implementation and courses work globally. Rishi originally trained as a surgeon and prior to ICHOM worked at Monitor, the economic regulator for the NHS, where he was responsible for the turnaround and restructuring of hospitals in financial and quality difficulties. He has a background of working in provider organisations in senior roles including the Associate Medical Director for Strategy at Birmingham Children’s Hospital, one of four specialist children’s hospitals in England. Rishi has trained in health policy at Imperial College London and studied at Harvard, INSEAD and London Business School.

Dr David Galvin Graduated from the Royal College of Surgeons in Ireland. He completed his Higher Surgical Training in Urology and was awarded the Urology Fellowship in June 2008. In December 2010 he completed a Fellowship in Urological Oncology at Memorial Sloan Kettering Cancer Centre in New York, and was then appointed a Consultant in Urological Oncology in the Essex Cancer centre (2011). Also in 2011 he was appointed to both the Mater Misericordiae and St. Vincent’s University hospitals as part of the Dublin Academic Medical centre in April 2011. David is Chair the National Prostate cancer Leads Network, Head of Research within the Irish Society of Urology, an Associate Professor in University College Dublin and Principal Investigator on the Irish Prostate Cancer Outcomes Research study (IPCOR) funded by Movember and the Irish Cancer Society to the value of €1.5 million.

Professor Áine Carroll has recently completed her role as the Irish Health Services Executive’s National Director for Clinical Strategy and Programmes, a division encompassing the National Clinical Programmes, Integrated Care Programmes and The Office of the Nursing & Midwifery Services (ONMSD). During her tenure, Professor Carroll established the Integrated Care Programmes for older persons, chronic disease, children and patient flow to promote coordinated care and team work across services and specialties, ensuring that care is provided effectively and seamlessly to patients as they move through the system. Áine is acknowledged Internationally for her expertise in large-scale change and implementation. An experienced Improvement advisor, she has provided advice, guidance and training on quality improvement and change to leaders of healthcare systems across the world. She is passionate about Person Centred Coordinated Care and Implementation Science. She has recently taken up a role as Professor of Healthcare Integration and Improvement at University College Dublin.
SESSION 2 Speakers:

Prof. Declan Devane is Professor of Midwifery at NUI Galway and Director of the Health Research Board - Trials Methodology Research Network (HRB-TMRN). He is an Editor with the Cochrane Pregnancy and Childbirth Group and an Honorary Senior Lecturer at Cochrane UK. Declan has a particular interest in the implementation and evaluation of models of maternity care. His methodological areas of expertise are randomised trials, systematic reviews and meta-analyses. He has published over 140 papers including numerous Cochrane systematic reviews. He has led a number of clinical trials recruiting from 100 to over 3000 participants.

Dr Abi Jackson is the Research Lead at the Cystic Fibrosis (CF) Registry of Ireland, which was established to collect and analyse information in order to facilitate research and contribute to the improvement of the quality of care of persons with CF. She manages a portfolio of research projects examining cystic fibrosis epidemiology, health service utilisation, health economics, and pharmacovigilance. She is the lead Principal Investigator of a European study ‘CFView’ investigating the benefit of patient access to registry health records and was appointed chairperson of the European CF Registry Patient Registry Scientific Committee in 2015. Abi graduated with a B.A. Mod (Natural Sciences) from Trinity College Dublin, and a PhD in Public Health from the University of Glasgow in 2006.

Dr Éidín Ní Shé is a Research Fellow in the UCD School of Nursing, Midwifery and Health Systems. She is currently leading on the UCD PPI Ignite program focused on enabling and supporting seldom heard voices in health and social care research. She has developed strong qualitative and applied research skills by collaborating, co-designing and working in complex policy development, research and evaluations across federal, state and local government agencies and with the NGO sector in Ireland and internationally. Her research experience covers a diverse range of fields including regional community development, public and patient involvement, stakeholder engagement and multi-agency collaborations and policy implementation.

Barbara Skerritt has 25 years experience in the CRO environment, encompassing in-depth project management, data management, eCOA (Electronic Clinical Outcome Assessment) and also strategic business development. She is a member of ICON’s core innovation team. The innovation team keep abreast of current and future state health care initiatives. Barbara is currently leading the partnership with ICHOM and in 2017 completed their Global Outcomes BEnchmarking (GLOBE) Pilot Program where ICHOM and ICON collected clinical and patient reported outcome data from Providers across the globe as an innovative new initiative. Outcomes data can help to answer questions for Stakeholders, from Patients, Providers, Payers, to entire health systems.

Rachel Flynn is the Director of Health Information and Standards. She joined the Authority in November 2007. She is responsible for overseeing the implementation of the National Patient Experience Survey. The National Patient Experience Survey is a nationwide survey asking people for feedback about their recent stay in hospital. She is also responsible for setting Standards and developing guidance for Health and Social Services. This involves developing person centred standards, based on evidence and best international practice, for health and social care services in Ireland. She is also responsible for setting standards for all aspects of health information, monitoring compliance with those standards, evaluating the quality of the information available and making recommendations to improve the quality and filling in gaps where information is needed but is not currently available.
Dr Darrin Morrissey took up the position of Chief Executive at the Health Research Board in July 2018. Immediately before joining the HRB, Darrin was the Director of Programmes and Investments with Science Foundation Ireland, where he led the delivery of funding to science & technology research across the Irish public sector research institutions. Darrin’s prior experience includes 16 years spanning research, manufacturing and commercial success in the pharmaceutical and biotech industries. Darrin qualified with a BSc in Microbiology and he holds a PhD from University College Cork. His PhD research focused on the molecular mechanisms that underlie the spread of cancer. He also worked as a postdoctoral researcher, managing clinical research into the effects of microbial-based foods on the human gut microbiome.

Dr Lorraine Nolan is the CEO of the Health Products Regulatory Authority. She is also a chemist, having completed her Ph.D. and post-doctoral research at Trinity College Dublin in transdermal drug delivery. She worked for a number of years in private industry in the area of enhancing and developing drug delivery systems, and also within the state forensic science services. Lorriane joined the HPRA in 2001 and since that time has held a number of different roles at senior level within the organisation across a range of areas including inspection and authorisation of human medicines, medical devices, cosmetics and controlled substances. Prior to assuming the role of Chief Executive she was Director of Human Products Authorisation & Registration. Ms Nolan is a member of the Management Board of the European Medicines Agency.

Professor Martin Curley is Chief Information Officer of the Irish Health Services Executive (HSE) and CEO of eHealth Ireland enabling the digital transformation of Ireland’s health service. Most recently he was Senior Vice President and group head for Global Digital Practice at Mastercard. Previously Martin was vice president at Intel Corporation and Director/GM of Intel Labs Europe. He is the chair of the EU Open Innovation and Strategy Policy group, and the author of numerous books on technology management for value, innovation and entrepreneurship. Martin has a bachelor’s degree in electronic engineering and a master’s degree in business studies, both from University College Dublin, Ireland. He received his Ph.D. in information systems from the National University of Ireland, Maynooth.

NOTE: On the day Fran Thompson, Assistant National Director at the Office of the Chief Information Officer in the HSE deputised for Professor Martin Curley.
This event was made possible through a combination of IPPOSI resources and a number of unrestricted grants from the following IPPOSI Industry members:

AbbVie, GSK, ICON plc, Novartis, Roche