

INNOVATION AND SECURING PATIENT ACCESS TO PERSONALISED MEDICINE

during the Irish Presidency

Dublin, October 2nd, 2026

8:00 - 16:00 (CET)

**RCSI University of Medicine and Health Sciences
123 St Stephen's Green, Dublin 2, Ireland**

Overview:

Europe has world-class science, strong regulatory expertise, leading companies and a clear ambition to become a global life sciences leader. Yet too often, innovation does not reach patients quickly, consistently or equitably. The challenge is no longer whether Europe can generate breakthrough science; it is whether Europe can build the pathways to scale, fund and deliver that innovation across health systems.

This conference will examine how personalised medicine can move from promise to routine patient benefit. It will focus on the practical barriers that still stand between innovation and access: fragmented reimbursement pathways, uneven diagnostic capacity, slow evidence-to-implementation processes, limited data infrastructure, and the need for stronger alignment between research, regulation, HTA, clinical practice and patient needs.

The first session, **“From Innovation to Access: Why Europe Needs a Health Innovation Fund,”** will explore whether a dedicated European mechanism could help de-risk early adoption, support evidence generation, and ensure that transformative technologies are not limited to the fastest-moving or best-resourced health systems.

The second session, **“Liquid Biopsy & Digital Pathology,”** will look at the diagnostic infrastructure needed to make precision oncology real. It will consider how advanced diagnostics, digital pathology, AI-enabled workflows and molecular testing can be embedded into routine care so that patients can be diagnosed earlier, stratified more accurately, and matched to the right treatment at the right time.

The third session, **“Clinical Trials,”** will address the gap between clinical evidence and patient access. It will examine how innovative trial designs, real-world evidence, regulatory pathways, HTA, reimbursement and diagnostic readiness can be better aligned so that successful trials translate more rapidly into real-world benefit.

The closing session will bring these discussions together and ask what political and policy commitments should be taken forward under the Irish Presidency. The central message is clear: Europe should measure its leadership in personalised medicine not only by the innovations it discovers or approves, but by whether patients across Member States can benefit from them in routine care.

Friday, October 2nd

8.00- 9.00: Registration

9.00: Welcome

- **Marcel Tanner**, Board Chair, International Alliance for Personalised Medicine; Director Emeritus, Swiss Tropical and Public Health Institute (Swiss TPH); Professor Emeritus of Epidemiology and Medical Parasitology, University of Basel
- **Michael J. Kerin**, President, RCSI; Professor and Head of Surgery, University of Galway; Director, Cancer Managed Clinical Academic Network (MCAN), HSE West and North West

9.15: Key note address:

- **Colm Burke TD**, Leas-Chathaoirleach, Joint Committee on Health, Houses of the Oireachtas; Fine Gael TD for Cork North-Central
- **Ruggero de Maria**, President, Alliance Against Cancer, Italy

9.30: Personalised Medicine and the Innovation Agenda: An Integrated Approach:

- **Olivér Várhelyi**, European Commissioner for Health and Animal Welfare, European Commission

9.45: International Collaboration: The International Alliance for Personalised Medicine:

- **Denis Horgan**, Secretary General, International Alliance for Personalised Medicine

10.00: The promise and challenges of personalised medicine from a Patient Perspective:

- **Stephen McMahon**, Co-Founder and Director, Irish Patients' Association

10.15 – 11.45: Session 1 - From Innovation to Access: Why Europe Needs a Health Innovation Fund

Europe is at a decisive moment. As negotiations on the next MFF intensify, health must be recognised as central to competitiveness, resilience and economic security—not crowded out by them.

Yet Europe's health innovation pathway remains fragmented. Scientific excellence does not consistently translate into patient access, and regulatory approval does not guarantee reimbursement. This creates delays for patients and uncertainty for innovators.

This session will explore whether a dedicated European Health Innovation Fund could bridge the gap between research, regulation, reimbursement and real-world access. Designed as a time-limited, strategic de-risking mechanism, it could support early deployment of transformative technologies, real-world evidence generation, adaptive payment models and more equitable access across Member States.

Drawing on national examples such as the Italian Innovation Fund and the UK Cancer Drugs Fund, the discussion will ask how Europe can move from fragmented access to a true innovation-to-patient pathway.

The core question is simple: can Europe afford not to invest in health innovation?

Moderator: Stephen McMahon, Co-Founder and Director, Irish Patients' Association

- **Derek Tierney**, Secretary General, Department of Health, Ireland
- **Elizabeth Kuiper**, Associate Director and Head of the Health and Societal Resilience Programme, European Policy Centre
- **Alexander Roediger**, Associate Vice President, Global Lead Oncology Policy, MSD / Merck & Co., Inc.
- **Nikki Gallagher**, Chief Executive Officer, Irish Cancer Society

Q&A

Disease Perspective:

- **Declan Watson**, Board Member, Multiple Myeloma Ireland / Myeloma Ireland
- **Diabetes Ireland**
- **Debbi Onolememem**, Patient Voice and Advocate, Sickle Cell Society Ireland
- **Laura Cullinan**, Chief Executive Officer and Parent of a Survivor, Childhood Cancer Ireland
- **Jim Lucey**, Inspector of Mental Health Services, Mental Health Commission?

11.45-12.15: Coffee

12.15 -13.15: Session 2 - Liquid Biopsy and Digital Pathology: Building the Diagnostic Backbone of Precision Oncology

Precision oncology depends on the ability to diagnose earlier, profile disease more accurately, and match patients to the right treatment at the right time. Liquid biopsy and digital pathology are two of the most important enablers of this shift. Together, they can support faster diagnosis, improved molecular stratification, treatment selection, disease monitoring, recurrence detection and access to clinical trials.

Yet their potential is not being realised equally across health systems. Access to advanced diagnostics remains fragmented, reimbursement is inconsistent, laboratory capacity varies, and many countries still lack the data infrastructure, interoperability standards, quality frameworks and workforce readiness needed to embed these tools into routine care.

This session will examine how liquid biopsy and digital pathology can move from promising technologies to core components of modern cancer systems. It will explore how they can improve patient pathways, strengthen multidisciplinary decision-making, support real-world evidence generation and enable more efficient use of innovative therapies.

The discussion will focus on what is needed to scale adoption responsibly and equitably: clinical validation, regulatory clarity, reimbursement models, pathology



and laboratory capacity, data governance, AI-enabled workflows and integration into national cancer strategies.

The central question is clear: how can Europe and other health systems build the diagnostic infrastructure needed to turn precision oncology into routine patient benefit?

Moderator: *Ruggero de Maria, President, Alliance Against Cancer, Italy*

- **John Sheehan**, *Consultant Radiologist, Blackrock Clinic, Blackrock Health; Clinical Director of Radiology, Hermitage Clinic, Blackrock Health*
- **Derek Tierney**, *Secretary General, Department of Health, Ireland*
- **John Longshore**, *Head of Scientific Affairs, Global Oncology Diagnostics, AstraZeneca*
- **Amy Nolan**, *Director of Clinical Affairs, Irish Cancer Society*
- **Nina Carberry MEP**, *Member of the European Parliament; Group of the European People's Party (Christian Democrats); Fine Gael Party, Ireland*
- **Manuel Salto-Tellez**, *Chair of Molecular Pathology, Queen's University Belfast; Clinical Consultant Pathologist, Belfast Health and Social Care Trust*

Q&A

13.15-14.00: Lunch

14.00- 15.15: Session 3 - Global Clinical Trials, Local Access

Modern clinical trials are transforming personalised medicine, but too often the evidence they generate does not translate quickly into patient access. Multinational trials may satisfy global regulatory standards, yet patients still face delays because national registration, HTA, reimbursement, diagnostic readiness and implementation systems apply different rules, expectations and capacities.

This session will examine the growing disconnect between global clinical trial evidence and local access. It will explore why innovative trial designs—such as biomarker-defined cohorts, adaptive trials, single-arm studies, surrogate endpoints and real-world evidence—often sit uneasily with existing national assessment and reimbursement frameworks. The discussion will focus on cancer, neurology, cardiology and obesity as four areas where innovation is moving rapidly, but where health systems are not always ready to evaluate, fund and implement new approaches. It will also consider the equity implications of current evidence-to-access pathways, including gender, paediatric and geriatric dimensions.

The session will ask how countries can better align clinical evidence, regulatory pathways, HTA, reimbursement and diagnostic access so that trial success leads more quickly to real-world patient benefit. The aim is to move beyond identifying barriers and towards practical policy solutions that support faster, fairer and more consistent access to personalised medicine.

Moderator:

Setting the Scene: Vivek Subbiah, *Associate Director for Drug Development and Precision Oncology, Stanford Cancer Institute; Professor of Medicine, Stanford University*



- **Patrick Kivlehan**, *Patient Advocate; Chair, Patient Consultation Committee, Cancer Trials Ireland*
- **Louise Callanan**, *eHealth Director and Chief Information Officer, HSE South West; Assistant National Director, Health Service Executive*
- **Patricia Maguire**, *Director, UCD Institute for Discovery; Professor of Biochemistry, UCD School of Biomolecular and Biomedical Science; Fellow, UCD Conway Institute*
- **Michael Twomey**, *Senior Clinical Research Manager and Clinical Evaluation Lead, Health Innovation Hub Ireland, University College Cork*
- **Eibhlín Mulroe**, *Former Chief Executive Officer, Cancer Trials Ireland*

15.15 – 16.00: Closing Session - From Innovation to Implementation: Delivering Personalised Medicine for Patients

The closing session will draw together the key messages from the day and focus on how Europe can move from scientific and technological promise to real patient access. Discussions will reflect on the need for a stronger bridge between innovation, evidence generation, reimbursement, diagnostics, clinical trials and health-system implementation.

Building on the themes of the European Health Innovation Fund, liquid biopsy and digital pathology, and the alignment of clinical trials with access pathways, the session will ask what practical steps are needed to make personalised medicine a routine and equitable reality across Europe.

The session will conclude with a call for clear political and policy follow-up under the Irish Presidency: investing in diagnostic readiness, supporting earlier access to transformative innovation, improving evidence-to-reimbursement pathways, and ensuring that patient benefit becomes the central measure of European leadership in personalised medicine.

- **Jennifer Carroll MacNeill**, *Minister for Health, Government of Ireland*
- **Ruggero de Maria**, *President, Alliance Against Cancer, Italy*
- **Barry Andrews MEP**, *Member of the European Parliament, Renew Europe Group; Chair, Committee on Development; Fianna Fáil Party, Ireland*
- **Stephen McMahon**, *Co-Founder and Director, Irish Patients' Association*
- **Denis Horgan**, *Secretary General, International Alliance for Personalised Medicine*