

INNOVATION AND SECURING PATIENT ACCESS TO PERSONALISED MEDICINE

During the Irish Presidency

Dublin, October 2nd, 2026

09:00 - 17:00

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

Overview:

Europe has world-class science, strong regulatory expertise and leading life-sciences companies. Yet its ability to translate innovation into patient benefit is increasingly shaped not only by health policy, but also by industrial competition, trade tensions, tariffs, supply-chain resilience and international pricing pressures.

This conference will examine how personalised medicine can move from scientific promise to routine and equitable patient access. It will focus on the barriers between innovation and implementation, including fragmented reimbursement pathways, uneven diagnostic capacity, limited data infrastructure and insufficient 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 consider whether a dedicated European mechanism could de-risk early adoption, support evidence generation and prevent transformative technologies from being confined to the best-resourced health systems.

The second session, **“Liquid Biopsy and Digital Pathology,”** will examine the diagnostic infrastructure required to embed advanced molecular testing, digital pathology and AI-enabled workflows into routine care, enabling earlier diagnosis, more accurate stratification and better treatment selection.

The third session, **“Global Clinical Trials, Local Access,”** will explore how innovative trial designs, real-world evidence, regulation, HTA, reimbursement and diagnostic readiness can be better aligned so that successful research translates more rapidly into patient benefit.

The closing session, **“Personalised Medicine in an Age of Trade, Tariffs and MFN Pricing,”** will place these issues within the wider geopolitical and economic environment. It will ask how Europe can strengthen competitiveness, affordability and strategic autonomy without disrupting innovation, investment, supply chains or timely access for patients. The conference will conclude by identifying priorities for the Irish Presidency and by reaffirming that Europe's leadership should ultimately be measured by whether innovation reaches patients across all Member States.

Friday, October 2nd

8.30- 9.00: Registration

Moderators:

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

09.00: Welcome

- **Stephen McMahon**, Co-Founder and Director, Irish Patients' Association (*confirmed*)
- **Fergal O'Brien**, Deputy Vice-Chancellor for Research and Innovation, RCSI University of Medicine and Health Sciences (*confirmed*)
- **Colm Burke TD**, Leas-Chathaoirleach, Joint Committee on Health, Houses of the Oireachtas; Fine Gael TD for Cork North-Central

9.20: The Last Mile of Implementation

- **Marija Jakubauskienė**, Minister of Health, Ministry of Health, Republic of Lithuania (*invited*)
- **Spyridon-Adonis Georgiadis**, Ministry of Health, Greece (*invited*)
- **Vytenis Andriukaitis MEP**, Rapporteurs for the Biotech Act in the Public Health (SANT), European Parliament (*Confirmed*)

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

- **Ciarán NICHOLL**, Director Health & Food EC-Joint Research Centre (*confirmed*)
- **Lorraine Nolan**, Chief Executive, Health Products Regulatory Authority, Dublin, Ireland
- **Xose M. Fernandez**, Head of Digital Oncology Network for Europe, IQVIA (*confirmed*)

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

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

10.20: The promise and challenges of personalised medicine from a Patient Perspective: Lesson from EU council Conclusion on Personalised Medicine and Patient Access

- **Stephen McMahon**, Co-Founder and Director, Irish Patients' Association (*confirmed*)
- **Daniela Pia Rosaria Chieffo**, Associate Professor - General Psychology, Università Cattolica del Sacro Cuore, Rome, Italy (**ON-COME**) (*confirmed*)

10.30 – 12.00: 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 (*confirmed*)

- **Derek Tierney**, Secretary General, Department of Health, Ireland (*confirmed*)
- **Roisin Adams**, Head of HTA Strategy, National Centre for Pharmacoeconomics (NCPE); Trinity College Dublin (*TBC*)
- **Alexander Roediger**, Associate Vice President, Global Lead Oncology Policy, MSD / Merck & Co., Inc. (*confirmed*)
- **Nikki Gallagher**, Chief Executive Officer, Irish Cancer Society (*tentative*)
- **Gianpiero Cavalleri**, Professor of Human Genetics, School of Pharmacy and Biomolecular Sciences, Royal College of Surgeons (*confirmed*)

Q&A

Disease Perspective:

- **Declan Watson**, Board Member, Multiple Myeloma Ireland / Myeloma Ireland (*confirmed*)
- **Laura Cullinan**, Chief Executive Officer, Childhood Cancer Ireland (*confirmed*)
- **Jim Lucey**, Inspector of Mental Health Services, Mental Health Commission (*confirmed*)
- **William Gallagher**, Co-Lead, All-Island Cancer Research Institute (*confirmed*)

12.00-12.30: Coffee

12.30 -13.30: 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 (tentative)*
- **AstraZeneca**
- **Marc Van Den Bulcke**, *Head of service, Belgian Cancer Centre, Sciensano (JA PCM - SPARC) (confirmed)*
- **Amy Nolan**, *Chief Executive Officer, ARC Cancer Support (confirmed)*
- **Manuel Ottaviano**, *Scientific Coordinator, SPARC; Universidad Politecnica de Madrid (UPM) (confirmed)*

Q&A

13.30-14.30: Lunch

14.30- 15.45: 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:

- **Leo McAdams**, Head of Advanced Manufacturing, Construction & Life Sciences, Enterprise Ireland (*confirmed*)
- **Rachel Crowley**, Lead of the Rare Disease Research Catalyst Consortium, Co-Lead of the Rare Disease Clinical Trial Network (*invited*)
- **Patricia Maguire**, Director, UCD Institute for Discovery; Professor of Biochemistry, UCD School of Biomolecular and Biomedical Science; Fellow, UCD Conway Institute (*confirmed*)
- **Michael Twomey**, Senior Clinical Research Manager and Clinical Evaluation Lead, Health Innovation Hub Ireland, University College Cork (*confirmed*)
- **Ben Johnson**, Editor in Chief, Nature Health (*confirmed*)

15.45 – 17.00: Closing Session - From Innovation to Implementation: Delivering Personalised Medicine for Patients

The closing session will examine how tariffs, trade tensions, supply-chain pressures and Most-Favoured-Nation pricing policies could affect Europe's ability to deliver personalised medicine. The discussion will consider the implications for innovation, investment, product launches, diagnostics, targeted therapies and equitable access across Member States. It will also ask how Europe can strengthen competitiveness and affordability without creating new barriers for patients.

The central question is: **Can Europe pursue strategic autonomy, trade protection and price restraint while still ensuring timely access to personalised medicine?**

The session will conclude by identifying priorities for the Irish Presidency, including resilient supply chains, stronger European diagnostic and manufacturing capacity, and closer alignment between health, trade and

- **Stephen McMahon**, Co-Founder and Director, Irish Patients' Association (*Confirmed*)
- **Vytienis Andriukaitis MEP**, Rapporteurs for the Biotech Act in the Public Health (SANT), European Parliament (*Confirmed*)
- **Barry Andrews MEP**, Member of the European Parliament, Renew Europe Group; Chair, Committee on Development; Fianna Fáil Party, Ireland (*Tentative*)
- **Denis Horgan**, Secretary General, International Alliance for Personalised Medicine (*Confirmed*)