01 The Opportunity

Towards an All-Island Digital Health Validation and Regulatory Sandbox

The feasibility study explores the potential to establish a Digital Health Validation and Regulatory Sandbox (DHVRS) in Ireland, with the longer-term ambition of creating an All-Island model spanning the Republic of Ireland and Northern Ireland.

Commissioned by Dundalk Institute of Technology through the Connected Health & Wellbeing Cluster, the study responds to a recognised gap in the digital health innovation pathway. Ireland has strong research, MedTech and digital health capability, but innovators can still face fragmented routes from development through clinical validation, regulatory readiness and adoption.

> **The study concludes that a DHVRS is both feasible and timely, and recommends progressing to full business case development.**

Why is it needed?

The proposed DHVRS would help create a more coordinated environment in which digital health technologies can be tested, validated and prepared for clinical and regulatory requirements. It would not act as a regulator or replace existing regulatory, ethics or conformity-assessment processes.

- More structured routes from innovation to clinical validation and regulatory readiness.
- Earlier access to clinical, technical and regulatory expertise.
- Improved access to appropriate data and realistic testing environments.
- Reduced duplication and fewer late-stage barriers to implementation.
- A clearer pathway from successful pilots towards adoption and scale.

Learning from international models

The study reviewed six international approaches: Melbourne Validitron, Glasgow clinical innovation, TEF Health, Singapore health sandboxes, Mayo Clinic Platform Accelerate and the NHS AI Lab.

Overview & Comparison of Global Validation Labs

Six models, assessed consistently on the same six dimensions

Model	Governance	Infrastructure	Regulatory	Funding	Validation	Data Governance
Melbourne	University-led, multi-stakeholder	Physical + digital simulation	Indirect, TGA-informed	University & grant funded	Structured, not gated	Institutional (AU + EU GDPR)
Glasgow	University + NHS Scotland	Hospital-based clinical studies	Evidence-focused, not a sandbox	Public + MedTech retainers	Clinical immersion & testing	NHS Scotland frameworks
TEF Health	EU 9-country consortium	Distributed EU test infra	High, AI Act aligned	€60m EU Digital Europe	Services marketplace model	GDPR + AI Act core
Singapore	Top-down, MOH + Synapxe	National cloud, synthetic data	Highest, formal sandbox	Gov't-backed, AWS-enabled	Gated: intake → scaling	HEALIX synthetic data
Mayo Clinic	Provider-led, single institution	Enterprise data trust (7m+)	FDA pathway support	Equity-in-kind, no cash grants	Embedded lifecycle model	HIPAA + LLM de-ID
NHS AI Lab	NHS England + local trusts	NHS testbeds & SDEs	Advanced (AI Airlock/DRS)	£170m public, cyclical	Four-phase funding model	UK GDPR, federated SDEs

Across these models, the strongest approaches combine clinical access, regulatory expertise, secure data infrastructure, clearly defined pathways, strong governance and strategic partnerships. The report recommends adapting these lessons to Ireland rather than copying any single international model.

Strategic opportunity

The opportunity is to create a national and ultimately All-Island gateway that connects innovation, clinical validation, regulatory readiness and adoption, while complementing existing healthcare, research and enterprise supports.

02 What Would the DHVRS Do?

A coordinated pathway from innovation to adoption

The proposed DHVRS would operate as a structured, needs-led validation environment rather than a generic accelerator or open testing facility. It would bring together innovators, clinicians, researchers, health-service partners, regulators and industry around clearly defined validation pathways.

01 National Gateway & Intake

A structured entry point assessing maturity, relevance, system need and readiness to progress.

02 Clinical Validation Network

Access to clinical expertise, simulation and real-world settings to evaluate solutions within genuine workflows.

03 Regulatory & Compliance Support

Earlier support around regulatory and evidence requirements, helping innovators identify issues before costly redesign.

04 Digital & Physical Test Environments

Secure digital environments combined with physical and simulated settings for usability, interoperability and validation.

05 Adoption & System Integration

Support beyond the pilot stage, with a stronger focus on implementation, procurement and scale.

06 Sustainable Platform & Partnerships

A not-for-profit model combining public support, service income and strategic industry partnerships.

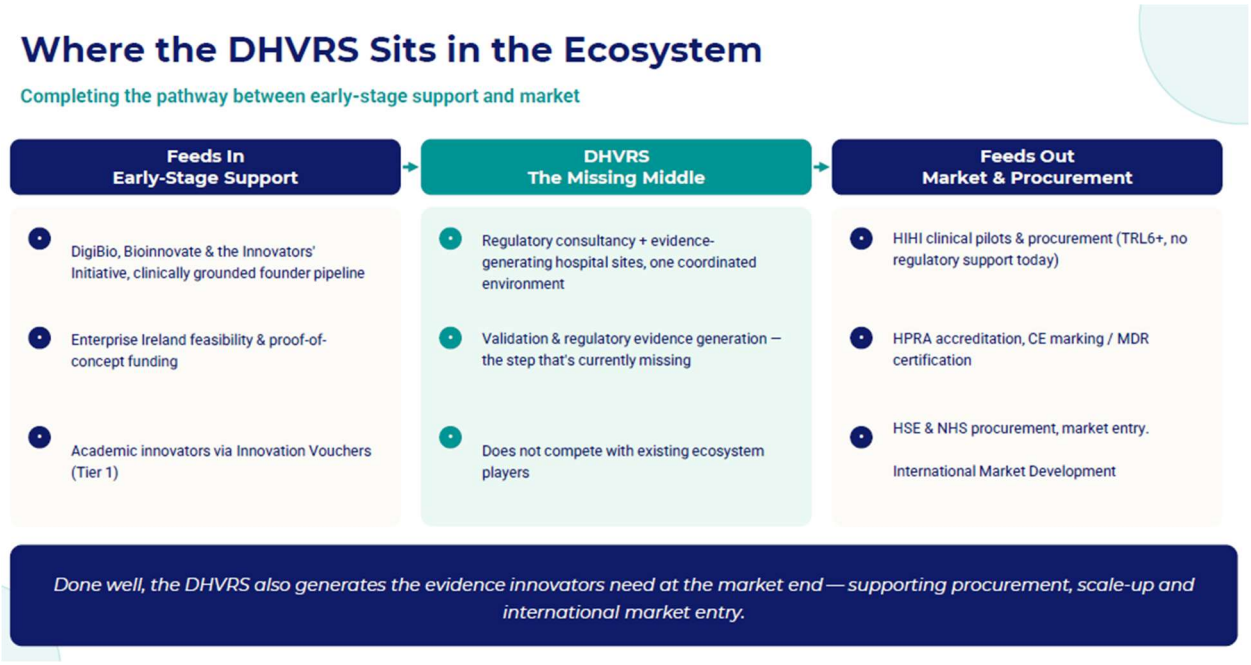
A distinctive All-Island proposition

A significant opportunity is the potential to create an aligned pathway across the Republic of Ireland and Northern Ireland. Rather than creating one integrated health system, the DHVRS could support interoperable approaches that help innovators navigate different healthcare, governance, data and market-access environments.

This could strengthen Ireland's proposition for indigenous and international companies seeking to validate technologies across EU and UK contexts, while reducing unnecessary duplication where common methodologies can be developed.

How could it be delivered?

The report proposes a hub-and-spoke approach, with DkIT as the proposed anchor institution and Tallaght University Hospital as the founding clinical site, supported by clinical, academic, regulatory and industry partners.



Phased development

01	02	03	04
Design & Mobilisation	**Build & Deploy**	**Pilot**	**Scale**
Governance, scope and partnerships	Clinical, digital and cyber infrastructure	Test the pathway and evaluate performance	Expand network, capability and All-Island activity

The model is designed to scale progressively, with investment and infrastructure added as demand, partnerships and system readiness are demonstrated.

Thank you to all participants of the Working Group from the Connected Health & Wellbeing Cluster, and the supporters of the Feasibility Report:

03 Stakeholder Insights & Next Steps

Key themes from the September 2026 roundtable

The feasibility study was launched at a stakeholder roundtable at Enterprise Ireland, Eastpoint, bringing together representatives from healthcare, research, regulation, industry and innovation. The discussion tested the report's direction and highlighted where the proposition could add most value.

What we heard

Needs-led first	Start with clearly defined clinical, operational and health-system needs, while retaining a route for promising innovator-led ideas.
Pilot to scale	Do not measure success only by the number of pilots. The stronger opportunity is helping validated technologies progress into adoption, procurement and scale.
Whole ecosystem	The model should create value for start-ups, SMEs, scale-ups, academia and larger industry partners — not just one part of the innovation pipeline.
Build in trust	Regulation, data governance, interoperability and cybersecurity need to be embedded from the outset, with clear roles for health-system and regulatory partners.
All-Island edge	Participants saw real potential in an aligned EU–UK pathway that could reduce duplication and create a distinctive proposition for Ireland and Northern Ireland.

What happens next?

The report recommends progressing to a full business case. The next phase should build on both the feasibility study and stakeholder feedback, with further work focused on:

- Deeper engagement with health-system and government partners across both jurisdictions.
- Clear priority use cases and a well-defined role alongside existing initiatives and sandboxes.
- A stronger proposition for scale-ups, academia, SMEs and multinational companies.
- Strategic partnerships across healthcare, MedTech, pharma, technology, cloud and cybersecurity.
- Further development of the All-Island proposition and common validation methodologies.

> **The ambition is to build a practical pathway that helps promising digital health innovations move from development to evidence, regulatory readiness, adoption and meaningful scale.**

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