

Written evidence submitted by Health Innovation Research Alliance – Northern Ireland (HIRANI), relating to the Investment in Northern Ireland inquiry (INI0028)

The Health Innovation Research Alliance Northern Ireland (HIRANI) represents the Northern Ireland Health and Life Sciences Sector (NI H&LS Sector) which includes industry, the two universities and the health service (HSC). HIRANI is well-placed to advocate for the Health and Life Sciences sector and work over the last year has identified some regional differences which will be important to recognise in future investment considerations to ensure this sector can deliver on its potential.

For the purposes of this consultation, we have identified 3 areas where investment in Health and life sciences in Northern Ireland could accelerate economic growth and prosperity in Northern Ireland 1) Regulatory Advocacy 2) Trusted Health Innovation Networks similar to those in England 3) A Strength in Places Diagnostics Cluster. These largely represent infrastructure which is already available in England and represent an opportunity to level up the health and life sciences sector to promote health and skills equality and prosperity for the citizens of Northern Ireland.

1) Investment in Regulatory Advocacy to mitigate losses due to uncertainty and divergence of GB from NI for the Health and Life Sciences Sector.

HIRANI is highlighting a serious concern, namely, current UK regulatory uncertainty and flux, which is having an alarming impact on this sector's ability to make critical business decisions, attract investment and remain competitive for the next few years. This is an important growing sector in Northern Ireland which supports 18,000 jobs, with a Gross Value added (GVA) of £1.1Billion (The Association of British Pharmaceutical Industry ([ABPI](#)) [Fraser of Allander, 2020](#)).

Feedback from sector stakeholders to HIRANI has emphasised that the lack of leadership and support for Northern Ireland, particularly from the UK Competent Authority (the Medicines and Healthcare products Regulatory Agency (MHRA)) as a major issue, mainly since Northern Ireland alone within the UK has been obliged to follow EU regulations (January 2021). Eighty-seven percent said that MHRA leadership and communications were rated as less than good with 66% saying that these were poor or irrelevant. Critically as the MHRA can no longer represent Northern Ireland at the EU in this respect, Northern Ireland has become de-prioritised.

Without investment in Regulatory advocacy in Northern Ireland for Medicines and medical devices, HIRANI believes the following risks to this sector and to the NI economy will remain at an elevated level:

- 1) the Northern Ireland Life & Health Sciences sector will not deliver on its potential and the ambitions of the 10X strategy including attracting foreign direct investment into the City Deals, for this sector is critical.

- 2) There will be a loss of investment resulting in experienced companies reporting they will be compelled by customers to move their businesses outside Northern Ireland, in order to remain agile and competitive, with the associated loss of up to 1000 jobs;
- 3) SMEs & spin outs will be unable to raise financial support due to regulatory uncertainty, resulting in loss of investment to the innovation pipeline. With Life Sciences Innovation a strong regulatory pathway is required for Series A and follow-on investment in lieu of the ability to secure revenues ahead of clinical validation.
- 4) There will be a substantial reduction in access of NI patients to innovative medicines and devices due to regulatory dealignment with GB, causing a decrease in recruitment to NI clinical trials (As of 2020, upwards of 600 patients annually in Northern Ireland participated in Clinical Trials which test innovative drugs and medical devices).
- 5) Northern Ireland needs will not be considered by the UK government in its current Regulatory for Growth Strategy which could result in platforms and processes being developed for the sector which are unfit for use here.
- 6) Northern Ireland is unable to foster appropriate connections with the MHRA and a NI seat at the table of the European Medicines Agency, whose regulatory processes Northern Ireland (not GB) has to follow (rather than those of the MHRA). This means we are unable to horizon scan for future EU regulatory changes and how these impact in Northern Ireland e.g., changes to the EU Clinical Trials Regulations and data regulations, and new regulations such as the In vitro Diagnostics Regulations, AI Regulation and others which affect this sector.

2. Encourage investment that addresses the health inequality and skills gap through Trusted Health Innovation Networks

Since their introduction, the Academic Health Sciences Networks and Biomedical research centres have boosted cross-sectoral engagement, encouraged employment to address the innovation skills gap and promoted health service adoption of innovation and industry investment, in England.

However, HIRANI has noted that in **Northern Ireland, these structures do not exist, and we are missing out on opportunities to connect the academic-health and industry-economic sectors.** These **trusted**, publicly funded cross-sectoral structures which create a **transparent environment** for knowledge and skills exchange do not exist here.

This means, there are still significant gaps between the health and life sciences industry and the local health systems, creating a bottle-neck for accessing investment to identify and translate place-based innovation to address health and economic inequality. This also represents an opportunity to upskill and empower health workers to collaborate and engage in activity that serves to improve health and acts as an economic multiplier.

3. A strength in Places Diagnostics Cluster to build on recognised strengths and bring together a space for industry collaboration and creates skilled jobs.

Public investment for life sciences for the SIP wave 2 application UKRI from Nov 2020, that **narrowly missed out on £30M funding despite meeting the highest success criteria to qualify**. This **builds on our strengths in biomarker and diagnostic development** which will enable a never-before-seen collaboration aligns 2 global life sciences industry leaders based in Northern Ireland and 5 other cutting edge indigenous SMEs locally in NI, with academic capabilities from both universities and the health service to engage along the pipeline of diagnostics development (from Biomarker – to test – analytics).

Funding this £30M investment **will be a critical foundation to underpin levelling up** in the innovative life sciences sector, to leverage NI's recognised strengths in diagnostics and analytics and unlock >£23M in-kind investment in industry-academic-clinical collaboration to deliver opportunities for the citizens and businesses of Northern Ireland and support the UK Life Sciences Vision. This will create a proposed **50% leap in productivity (>£850M GVA) and creating nearly 200 jobs over the next 5 years**, providing local solutions to global health problems.

This creates recognized “spillover effects to benefit the local community and create employment opportunities across a wide area of society to develop Life Sciences supporting skills, which will be important for future growth of the sector.

- 1) it brings together industry external to Belfast along a corridor between Randox and Almac, Queen's University Belfast, & Ulster University and pulling in expertise over a wider area
- 2) It offers skills training from 16yrs apprentice up to Post-doc in Life science supply chain roles – Biobank technician, ethics, regulation, operations – to promote accessibility into this field from all educational levels.

The Future medicines institute based adjacent to the QUB Precision Medicines centre enables a landing pad for them to collaborate with the best minds, techniques and companies from across the world who want a UK base to expand into EU to create the next generation of diagnostics for both health and wealth benefits.

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