19 Jun 2023

How LJMU's living lab is generating real world data to evaluate the feasibility or effectiveness of a business's innovation

The team from LJMU's Living Lab discuss their work on the Health Matters (ERDF funded) programme to help businesses demonstrate their product's practical and commercial benefits for the health and care markets

One of the main challenges faced by the NHS, industry and innovators in the UK is the ability for the health and social care system to adopt HealthTech innovations. It is widely recognised that if we want to see improvements in health outcomes there needs to be a drive to adopt innovative solutions to healthcare across the UK.

The LJMU Centre for Collaborative Innovation in Dementia, an accredited health Living Lab – European Network of Living Labs was a partner in the innovative Health Matters programme for the Liverpool City Region. This moved the centre from working exclusively within the dementia space to providing a unique environment where businesses could test and refine their ideas, products or services in a controlled yet realistic setting for the benefit of the health and social care sectors.

What do we mean when we talk about Real World Validation (RWV)

RWV is an observed study (no primary data collection) that validates all qualitative and quantitative data and benchmarking against bespoke health outcomes.

Healthcare commissioners are seeking more timely evidence than that provided by traditional research approaches to support the rapid adoption of effective innovations. The ERDF Liverpool City Region Health Matters programme developed a working definition of Real-world Validation as a methodology that uses real-world data (RWD) to determine, in a non-controlled environment (in the real-world), the effectiveness and the outcomes to patients, staff and the health economy, of a health innovation (Ganga,2021).

How collaboration with the Innovation Agency under the umbrella of the Health Matters programme enabled the Living Lab to co-create RWV for local businesses

Within the Northwest region of the UK, we are one of three partnerships attempting to support businesses with market-ready solutions to demonstrate how their product or service can make a difference. This is being done through collaboration with the Innovation Agency and Growth Platform – the Liverpool City Region Growth Company.

The Liverpool City Region Health Matters programme aimed to support local businesses, with innovative solutions, to access the health and care markets. LJMU provided knowledge and expertise for SMEs to develop an RWV protocol and analyse secondary data, they aimed to capture the complexities and costs of the innovation implementation process; staff and patient uptake of and satisfaction with the innovation; and realisation of claimed benefits of the innovation and financial impact on the organisation, the NHS, and the wider health economy.

This approach provided a holistic, structured validation health care commissioners can use to quickly identify, adopt and mainstream effective innovations.

Key methodology used in the various stages of RWV

At the Health Matters project, the LJMU team worked with health innovations that are in different stages of their development:

Pre-market stage

- The majority were in a pre-market stage and have deficient evidence of their effectiveness and health outcomes. They are still in the stage of describing logically, coherently and convincingly what they actually do. In these cases, we assess their product or service against evidence-based protocol and against market competition. We support companies in the pre-market stage to position themselves in the market with a robust value proposition. Furthermore, we also design an RWV methodology that will allow the business to collect RWD to evidence its product or service effectiveness and health outcomes when reaching the market.

Example of pre-markets stage

- One company we worked with wanted to create an innovation that would aid hospitalisation of dementia patients that would ensure their conformability and ultimately speed up their discharge from the hospital, thereby freeing up NHS hospital beds. Through pre-market research, as well as economic analysis, we were able to conceptualise the uniqueness and significance of the product and how it differs from those already on the markets. This enabled us to create a validation protocol for the business to undertake themselves. This work has now allowed the business to talk to hospitals in the region to set up protocols for dementia patients in their ward.

Growth phase

- Another group of businesses are the ones that have already launched their innovations to the market. They're in a growth phase and have collected some data. This group of businesses are already in the market and have already evaluated their products and services and can demonstrate a reasonable level of evidence showing that their innovation can induce some change. Still, they cannot prove that their innovation caused that change. In this case, the team designed a methodology that enables them to aggregate all the RWD available about the innovation, clean and validate that data – make it fit-for-purpose – and produce the Real-World Evidence (RWE) of the effects of innovation on pre-defined health outcomes. Equally, the team contextualise how the innovation is being used, and who benefits from the innovation, and we

validate its value proposition and/or make recommendations for further research. By validating the innovation's impact, the SME can securely sell and replicate the innovation in multiple locations.

Example of growth phase

- A business we worked with in the growth phase had already engaged in previous trials before joining the Health Matters programme, what they wanted now was to start a trail interviewing the individuals that were involved in their previous trials. To do this successfully the business wanted us to help them create an interview schedule that would coach them through semi-structured interviews. Alongside this the team also analysed some of their qualitative data as well as creating a new validation protocol.

Maturity stage

- Finally, the innovations that are in the maturity stage are the ones that have been faithfully replicated in different contexts, demonstrating advanced levels of evidence of their effectiveness, positive outcomes, and even efficacy. In this case, we need to demonstrate that the innovation can be scaled up whilst continuing to have a positive and direct impact on the health outcome whilst remaining a financially viable proposition.

Example of maturity stage

- The business in the maturity stage already had their product in-market which had previously been tested in different contexts. The business was now looking for us to analyse data they had been collecting from a trial site. The Health Matters team analysed the available, data providing statistical outputs and results. Alongside this the team conducted a literature and markets search, a SWOT and economic analysis,. all of which was collected into a in-market report. From this, the team recommended that the business carry out further trials to a larger population that would enable them to have more data to analyse.

The benefits of using RWV

Validating a health innovation using RWE is being increasingly perceived as a valid methodological approach by the AHSN Network, NHS Innovation Agency, but also by other funding bodies such as the NIHR through the Invention for Innovation (i4i) programme. The NIHR i4i is a translational research funding scheme aimed at de-risking early-to-late-stage medical devices, in vitro diagnostics and high-impact patient-focused digital health technologies for ultimate NHS use. This programme of funding aims to address the translational gap between the clinical evaluation of technologies and their adoption, by funding the assessment of MedTech innovations in real-world healthcare settings.

Currently, the Centre for Collaborative Innovation in Dementia is the leading academic partner of NIHR-funded "CYP as One – Investigation in how to further support the community through digital service". The research programme aims to co-design and use real-world data to determine the effectiveness, and the outcomes to patients, staff and the health economy, of the digital single point of integrated access into specialist provision in Liverpool and Sefton, pioneered by Alder Hey Children's NHS Foundation Trust (Smith, et al., 2021).

In terms of relevancy for regulatory purposes, the U.S. Food and Drug Administration (FDA) uses RWD and RWE to monitor post-market safety and adverse events and to make regulatory decisions; and accepts clinical trial and observational studies designs in which RWD and RWE are used to generate innovative and new approaches.

The Medicines and Healthcare products Regulatory Agency published in December 2021 new guidance on the use of RWD to support regulatory decisions in clinical studies and randomised controlled trials.

The challenge of RWV in a pandemic

The COVID-19 pandemic has been our major challenge for several reasons. Mainly, the SMEs that engage with us on pre-market and growth stages are struggling to access health and social care sites, and, as such, it has been quite challenging to access RWD data.

Fit-for-purpose good quality RWD is another major challenge. If RWV can be a more cost-effective methodological design, it is also more demanding in terms of data curation, cleaning, validation, and standardisation. So, another major challenge is the awareness that RWV does not collect primary data, but supports SMEs to develop a data infrastructure that will help them to collect data themselves.

Future work at LJMU Living Lab

From a Higher Education (HE) point of view, the nearly created (2017) Knowledge Exchange Framework (KEF) aims to increase efficiency and effectiveness in the use of public funding for knowledge exchange (KE) and to further a culture of continuous improvement in universities. Under this new framework, beyond evidencing research outputs, universities need to explore effective ways of collaborating with external partners and demonstrate evidence of the economy and society benefit of those collaborations.

Knowledge production is not enough any longer. KEF pushes HE to work with the NHS, local authority, care businesses and other users to translate research and expertise into real-world change. Subsequently, research policy, priorities and funding are also shifting.

The Centre for Collaborative Innovation in Dementia is an accredited health Living Lab – the European Network of Living Labs (ENoLL). The Centre is widening its reach by working with co-creation groups across health and social care, including working with people with specific needs that are not dementia-related to working with partners committed to co-created product design and testing. Furthermore, the Centre is bridging the gap between innovation co-creation and validation by pushing further the novel methodology of RWV. The Centre has applied to a series of externally funded research-to-innovation programmes using the Living Lab and RWV methodologies namely:

- “Improving the quality of life in older people through reducing alcohol harm and improving social connection” – Economic & Social Research Council (ESRC)
- “Social Robots as a Cognitive Stimulation Therapy for Dementia Patients” – Economic & Social Research Council (ESRC)
- “Validation of the Electronic Routine Nutritional Screening Tool – NIHR i4i Product Development Awards” – National Institute for Health Research (NIHR) i4i PDA

- “Responsible Innovative Network plus for Integrated Neurorestoration: RESTORE+” – Economic & Social Research Council (ESRC), Medical Research Council (MRC)
- “The SPARKLE Project Studying the Prevention of Dementia Across the Lifecourse: a Research and Knowledge Co-operative Across Liverpool” – National Institute for Health Research (NIHR) PDG
- “FusedVision – using multiple ocular biomarkers for the differential diagnosis and early detection of dementia” – National Institute for Health Research (NIHR) i4i
- “Evaluation of the Children and Young People Integration Test Sites” – Cheshire and Merseyside Health & Care Partnership

In conclusion

By leveraging the Living Lab, businesses can gain valuable insights into the real-world viability of their innovations before making substantial investments or launching them in the market. LJMU’s collaborative and data-driven approach has helped businesses assess risks, refine their strategies, and enhance the chances of success for their innovative initiatives.

Find out more information on the work at the Centre for Collaborative Innovation in Dementia at Liverpool John Moores University