



**CLINICAL  
EVALUATION  
STUDY**



**Above left:** Dr Shourjya Sanyal  
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**Think Biosolution** is a global innovation leader in building customised chronic disease prevention platforms for medical device suppliers in the USA and Ireland. Think Biosolution was founded in 2016, by two leading digital health and medical device experts in Dublin Ireland. They have five full-time staff in Ireland with expertise in medical device manufacturing, regulatory approval and medical device sales. Furthermore, Think Biosolution is ISO 13485 and ISO 14971 compliant.

Think Biosolution is a chronic disease prevention company offering hardware and software solutions for helping at-home geriatric patients live healthier lives. Think Biosolution's devices and digital health platform can detect hypertension, diabetes and cardiac conditions in mild stages. This early detection delays onset of severe chronic conditions, this reduces cost of care, helps patients live healthier and independent lives, helps avoid hospitalisation and increase length of stay at-home.

## About Health Innovation Hub Ireland

Health Innovation Hub Ireland (HIHI) was established by the Department of Business, Enterprise and Innovation and the Department of Health, supported by Enterprise Ireland (EI) and the Health Service Executive (HSE) to drive collaboration between the health service and enterprise. We offer companies the opportunity for pilot and clinical validation studies and the health service access to innovative products, services and devices that they may not otherwise be exposed to. HIHI is built on the recognition that collaboration with enterprise can benefit patient care, patient pathways and outcomes.



## The Healthcare Challenge

There are approximately 50 million patients in Europe with multimorbidity (two or more chronic conditions). The cost of chronic disease management in the EU is €700 billion per annum. 70-80% of healthcare costs are spent on chronic diseases. Multimorbidity is frequently first diagnosed in critical stages, due to lack of clinical staff time to analyse patient vitals and symptoms every week. Most models of care across the EU focus on a treating critical stage and a single disease approach, and are not adaptive to the needs of patients with multiple chronic conditions. Most

models of care are also repetitive (multiple appointments), inconvenient, inefficient, confusing (e.g., conflicting advice from different clinicians), burdensome, and potentially unsafe due to leading to poorly integrated and coordinated care (e.g., medication interactions).

There is a distinct need for easy to use and integrated system that can diagnose multiple chronic conditions (hypertension, diabetes, and chronic kidney disease) in mild stages and administer nonpharmacological treatment for reversal of conditions.



# The Healthcare Solution

Think Biosolution digital health platform is the next generation of remote patient monitoring. QuasaR™ measures multiple vitals including heart rate, respiratory rate, blood oxygen saturation, and heart rate variability. Additional sensors on the device can measure, core body temperature, movement (such as walking, number of steps, quality of sleep) and GPS location. The device's also has a conversational AI engine that can "talk" to patients, and give them medication reminders or lifestyle advice.

This digital health platform helps nurse managers review the patient's weekly vitals, symptoms and activity. The data collected from the device is stored in an Electronic Health Record. In addition, this digital

health platform can be integrated with any digital health platform using FHIR (Fast Healthcare Interoperability Resources); the industry standard for exchanging

healthcare information electronically. Nurse managers then can also schedule doctor's appointments or a telehealth appointment using our digital health platform.



## HIHI Role

Think Biosolution were seeking clinical experts to evaluate their clinical dashboard. HIHI facilitated a feasibility study to help the development team in Think Biosolution rank the relative importance of the features of the clinical dashboard. A focus group, comprising twenty healthcare professionals, was conducted in Cork.

The participants completed an online questionnaire to assess user experience and usability. The feedback from the clinical professionals was incorporated in the design plan by Think Biosolution. This was a critical step towards informing the design of their product to match the needs and expectations of healthcare professionals.

## Outcome Report

Think Biosolution's QuasaR™ device and platform is targeted at continuous monitoring of multiple chronic conditions of at-home patients. Think Biosolution is aiming to achieve one CE-Marking and three FDA 510(k) for the device and associated digital health platform in 2022.

Think Biosolution has secured four EU-funded projects in the last two years. DIGI-B-CUBE funded the development of a remote monitoring platform for COVID-19 patients using the QuasaR™ device. European Space Agency funded the addition of global navigation satellite system (GNSS) in the QuasaR™ device. C-Voucher funded the business plan validation of developing a modular QuasaR™ device for achieving circular economy outcomes. EIT Bridgehead funded commercialisation of the QuasaR™ device and platform in Canada.

### Testimonial

*"Health Innovation Hub Ireland provided critical support in the early days of Think Biosolution. The ability to do clinical validation of our platform and device, enabled us to accelerate our development process. Working with Health Innovation Hub Ireland not only helped us understand the challenges of deploying our solution in Europe, but helped us understand the key steps and timeline towards performing feasibility studies elsewhere in Europe and the USA."*

*"The Health Innovation Hub Ireland has an international team of experts who are super hands-on in helping digital health companies in every step of the process. It is a great opportunity for any innovative healthcare company in Ireland to validate their technology early on with real world clinical experts."*

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