Project Background

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I. Introduction

FHIR Studio is a web-based platform that simulates realistic clinical and patient data based on the Fast Health Interoperability Resource (FHIR) standard. The project will contribute to the Validitron Sandbox, eventually facilitating the development, design, validation and evaluation of other digital health innovations. Collecting these data is expensive and time-consuming and sometimes exposes collectors to legal risks. With the advent of FHIR Studio, the complexity of testing compatibility and validating digital health software further improved the digital health industry.

II. Problem Statement

Collecting real clinical and patient data is troublesome:

Collecting real clinical is always expensive and time-consuming, negatively impacting the project timeline. Medical checks like CT and blood tests need a few days to obtain the results, especially when a large amount of result data is needed. The cost of CT or blood test equipment is also expensive. Therefore collecting such medical data may increase the budget of the project and further decrease the ROI of the project. Therefore the traditional method used to collect actual clinical data becomes an obstacle in modern digital health application development.

Collecting real patient data may pose risks to data collectors and data users. Patient data is considered sensitive, so the organisation collecting these data should consider the risk of obtaining and keeping these data. Australia has stringent legislation protecting individual privacy, so collecting patient data may encounter many obstacles, such as patient agreement and sensitive data protection. The Medibank data breach implies that failing to protect sensitive data will be catastrophic. Therefore, collecting sensitive patient data may acquire the collectors' additional risk management and protection means, further occupying more project resources.

Obstacles in data collection cause a lack of evidence which leads to business decision-making:

Insufficient or weak evidence may lead the decision maker to make the wrong decision. Mathematically, smaller datasets result in higher uncertainty, meaning some biased evidence may be produced from the small datasets; and this biased evidence may eventually mislead the decision-maker. Nowadays, data plays a more and more critical role in modern project decision-making, such as the trending AB-test, which relies heavily on feedback data. Many organisations may not be capable of collecting and keeping large-scale sensitive clinical and patient data, so their decision-making may lack thoughtful and reliable evidence as an endorsement. Therefore if a digital health innovation is on the wrong track, without sufficient data for testing and validation, the project team may realise the mistake very late, and the sunk cost is irreversible. For some small businesses or organizations, such loss may be catastrophic.

FHIR Studio is the solution:

Testing and validating the digital health product with large amounts of actual data from patients and hospitals is elusive, inefficient, risky and expensive. FHIR Studio provides a solution to this industry pain point by simulating these data using specific algorithms that will resolve the issue. Moreover, FHIR Studio's simulated data could also help the project team investors to make better decisions.

III. Project Scope

Goal:

- Discuss what the project aims to achieve and how it will benefit the healthcare industry

The ultimate goal of FHIR Studio is to build a web-based UI tool for engineering simulated patient data to support the development, design, validation and evaluation of new digital health innovations. Specifically, the goal is to develop a "data scaper" to create realistic time-series clinical data that makes it easy to 'design' longitudinal data with particular trends or characteristics.

Deliverables:

1. Clear project plan, wireframes and related documentation.
2. Working MVP data platform implementing the data scaper workflow.
3. Well-architected and engineered codebase, leveraging technologies already in use by the project (e.g. Java Spring/Spring Boot for back-end services; Vue3 for front-end).
4. Devised and implemented testing strategy and appropriate documentation.
5. Generate usable dataset for Heart Rate, Blood Pressure, Oxygen Saturation.

Potential Impact on the health industry:

1. Reduce the budget for testing and validating the compatibility and functionality of the new digital health innovations.
    - Collecting testing data is cheaper and more feasible.
    - No risks of having genuine data that may be hacked.
2. Promote the usage of the FHIR standard
    - FHIR enables interoperability between different healthcare systems.
    - More interoperability may lead to a more flexible allocation of resources, improving the system's efficiency.
3. Reduce the sunk cost of project failure.
    - The time and labour costs will be reduced as the project validation becomes easier.
    - More testing and validating may discover the mistakes in time, which reduce the sunk cost of time and money.

IV. Fast Healthcare Interoperability Resources (FHIR)

What is FHIR?

The **Fast Healthcare Interoperability Resources** (**FHIR**, pronounced "fire"), developed by Health Level Seven International, is a standard for exchanging electronic healthcare data. It is designed to be flexible and adaptable so that it can be used in a wide range of settings and with different healthcare information systems. FHIR aims to enable the seamless and secure exchange of healthcare information between different systems so patients can receive the best possible care. Therefore FHIR plays a foundation role in the digital healthcare industry, becoming an infrastructure of digital health networks.

FHIR and FHIR Studio

FHIR standard is crucial to this project, enabling strong compatibility of various clinical systems. FHIR is designed to be flexible and adaptable, and FHIR is currently widely used in many healthcare systems. FHIR Studio produces realistic clinical data following the FHIR standards, which indicate that the output data would be able to interoperate with a wide range of health systems, resulting in more potential users of FHIR Studio. The development of the FHIR standard will strictly follow the rules and requirements of the FHIR standards.

V. Validitron Sandbox

What problems does Validitron solve:

For digital health new applications or innovations, it is really unclear about how to get implemented into the Healthcare System. Hospitals and clinics want to be innovative, but it is a very risky place to try innovations, as minor mistakes may affect people's health and life. Overall, Vliditron intended to create a new model of care where digital tool enables communication and decision-making across the healthcare team.

What is Validitron?

Validitron is a platform developed by the University of Melbourne's Centre for Digital Transformation of Health. Validitron provides an opportunity for companies to implement what they're doing into the healthcare market. There are two key components in the Validitron that support. One is the digital Sandbox, and another is the simulation lab. The simulation lab is a physical space with a GP office, a hospital room and a patient home, which is designed to be immersive and bridge the gap between the lab and the real world.

What is Validitron Sandbox?

The Sandbox is a digital replica of a health information ecosystem built on established and emerging data standards such as FHIR. It includes reusable elements such as hospital and general practice electronic medical records (EMRs), a telehealth environment, a secure messaging platform, and a clinician dashboard. These can be combined like LEGO bricks to rapidly build virtual infrastructure to test new tools for workflow and technical compatibility. The Sandbox is one component of Validitron, an end-to-end platform that supports developing, designing, validating, and evaluating digital health software innovations. Its unique approach is to apply an evidence-backed framework to assist innovators/product owners (i.e., sellers of digital health solutions) and digital health adopters (i.e., purchasers of digital health solutions) to:

a. explicitly anticipate and address issues that cause digital health innovations to fail during real-world implementation, such as poor compatibility with existing clinical workflows
b. generate the evidence that payers, regulators and clinical decision-makers need when deciding to approve or commission a product.

FHIR and Validitron Sandbox

FHIR Studio will enhance the Validitron Sandbox by providing a tool for users to create realistic simulated time series data for clinical measurements. This will allow for more comprehensive testing and validation of digital health solutions in a simulated environment, which can help to identify issues and improve compatibility with existing clinical workflows.