An Integrated Clinical Trial and Machine Leaning Operations Model for Artificial Intelligence Projects in Healthcare

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Abstract

Artificial Intelligence (AI) has been proven to have the capacity to match or outdo human beings in many healthcare tasks. That notwithstanding, AI solutions have not found their way into clinical practice and real-time decision making in healthcare (Goled, 2021). This challenge is occasioned by: the lack of randomized clinical trials to provide evidence of the applicability of the models developed in a real-world scenario, the lack of data for clinical trials and production stages. This is occasioned by the fact that most medical data is in inaccessible formats as well as restrictions on access to medical records on most countries due to privacy concerns, the 'Inapplicability' of models in out-of-lab settings, and the inability of models to be generalized beyond the development environments. This study seeks to address these challenges by proposing a model that integrates and sequences the salient aspects of a research process, the machine learning process, the development of software as a medical device, software testing and the clinical trial process. The methodology adopted in the study is design thinking.

Background

A case in point is a Blood Pressure Monitoring and Prediction solution developed by (*names withheld*) in Kenya. The project has developed a solution comprising of; (I) A smartwatch for ambulatory blood pressure data collection, (ii) A mobile application for receiving the readings from the smartwatch, for collecting mood data, activity data and calendar event data, and (iii) A machine learning model based on the Gradient Boosting Regressor model for blood pressure prediction. The solution works well in a research setup with data collection happening effectively and the machine learning predictions possible. However, the solution relies on manual data engineering, has not been subjected to a clinical trial and has not been deployed.

This lack of deployment is typical of a majority of solutions in Artificial intelligence across the globe. In this respect Andrew Ng, a pioneer of AI remarks that "*the entire cycle of the machine learning model goes beyond just modelling; it involves finding the right data, deployment, monitoring, and feeding data back to the model*." (Goled, 2021).

The challenges of finding real-time application of AI solutions in healthcare are further compounded by a silo approach to the advances in healthcare domain as well as in AI. The practice of clinical trials (World Health Organization, 2022) is well understood among the health fraternity as is the practice of Machine Learning Operations (MLOps) (Google Cloud, 2022) among the AI developer community.

1. ***Clinical trials*** study new medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments and preventive care and evaluates their effects on human health outcomes. The trials are carefully designed, reviewed and completed, and need to be approved before they can start. People of all ages can take part in clinical trials, including children.They are conducted in four stages; (i) Phase I studies to test new drugs for the first time in a small group of people to evaluate a safe dosage range and identify side effects, (ii) Phase II to test treatments that have been found to be safe in phase I but need a larger group of human subjects to monitor for any adverse effects, (iii) Phase III studies are conducted on larger populations and in different regions and countries, and are often the step right

before a new treatment is approved, and (iv) Phase IV studies take place after country approval and there is a need for further testing in a wide population over a longer timeframe (World Health Organization, 2022).

2. ***Machine Learning Operations (***MLOps) "*is an engineering discipline that aims to unify ML systems development (dev) and ML systems deployment (ops) in order to standardize and streamline the continuous delivery of high-performing models in production*" (Tyagi, 2021). The practice of MLOps is placed at the intersection of DevOps, machine learning, and data engineering. A typical approach to MLOps is presented in Figure 1.

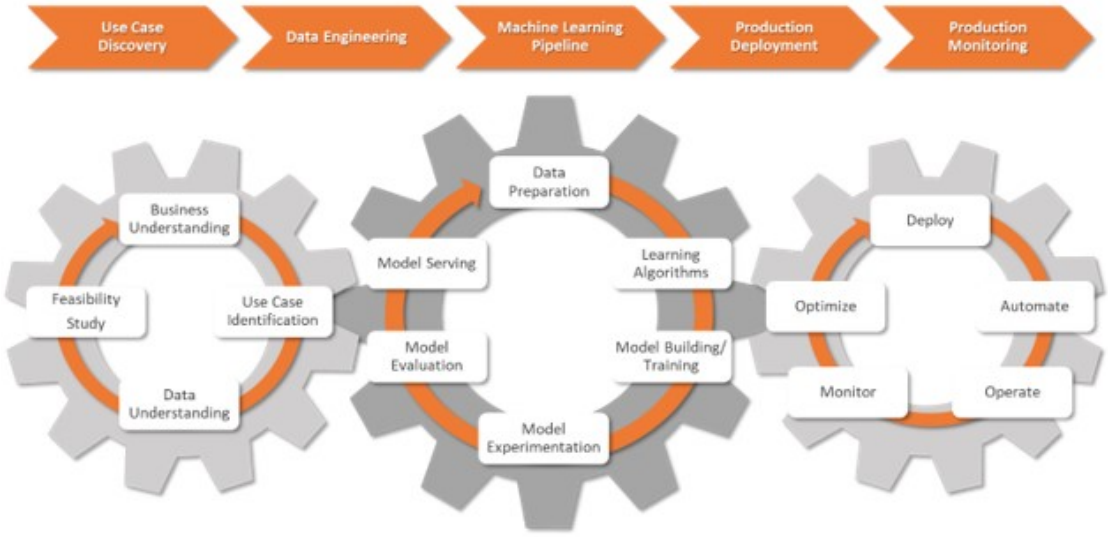


Figure 1: Machine Learning Operations Framework (Bose & Aggarwal, 2020)

The convergence of these two robust practices presents great promise to the actualization of AI solutions in the healthcare domain.

Problem

The development of machine learning solutions for heathcare has shown great promise for improved service delivery. However, these solutions have not found their way into the mainstream clinical practice for among other reasons the lack of clinical trials, lack of adequate testing and production stage data and the lack of deployment of the solutions. These challenges point to a gap in knowledge and skills among AI practitioners on the end to end AI solution development process for healthcare that must include clinical trials and climax in a deployment. This study therefore seeks to develop and test a model that integrates the practice of clinical trials from the healthcare domain and the Machine Learning Operations (MLOps) approach in AI.

Proposed Solution

This study seeks to develop an Integrated Clinical Trial and Machine Leaning Operations Model for AI projects in Healthcare.

The study will seek to implement the MLOps Level 1 - Pipeline Automation depicted in Figure 2.

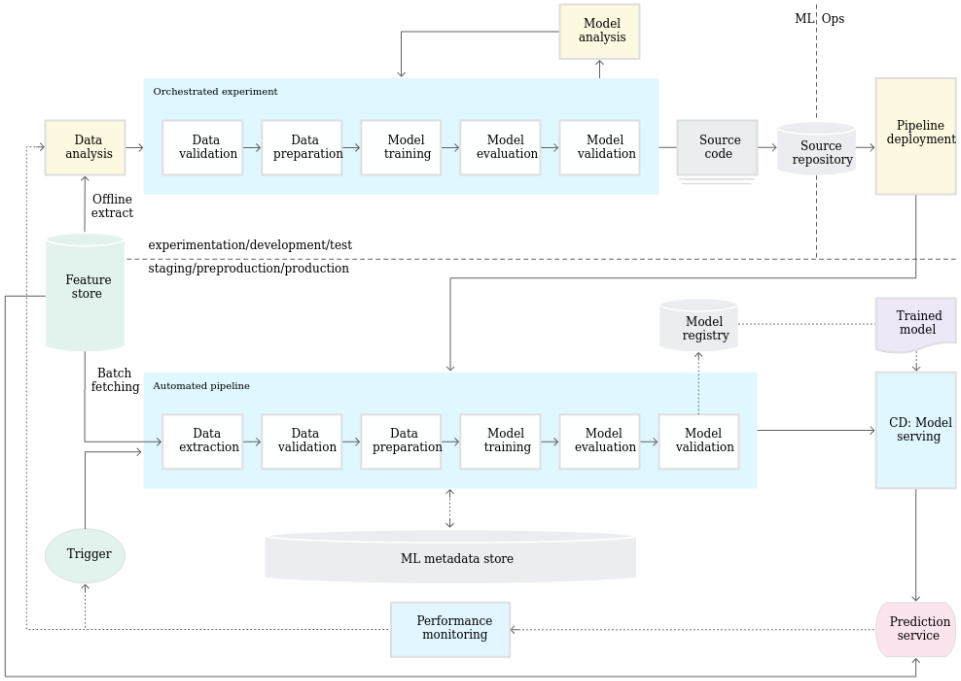


Figure 2: MLOps Level 1 – Pipeline Automation (Google Cloud, 2022)

The specific objectives of the study are;

1. To establish the challenges faced in transitioning AI projects to production among AI developers, AI researchers and Clinicians.
2. To identify areas of potential convergence between Clinical Trails and Machine Leaning Operations.
3. To develop an Integrated Clinical Trial and Machine Leaning Operations Model.
4. To test the Integrated Clinical Trial and Machine Leaning Operations Model with an AI solution in healthcare.

Justification

Monumental losses have been made in the recent past from the development of AI solutions for healthcare that have ended up being suspended or discarded altogether. A case in point is the IBM Watson for Oncology program that was suspended arising from problematic clinical recommendations. At the point of suspension USD 62 Million had been invested in the solution. Another example is that of Google's machine learning solution for detecting diabetic retinopathy that was unable to work when it encountered poorer images in practice compared to the ones used in its training and testing. (Cohen et al., 2021). These and other AI projects would benefit greatly from an approach that integrates best practices in healthcare and AI research.

Methodology

This study follows the design thinking process depicted in Figure 3

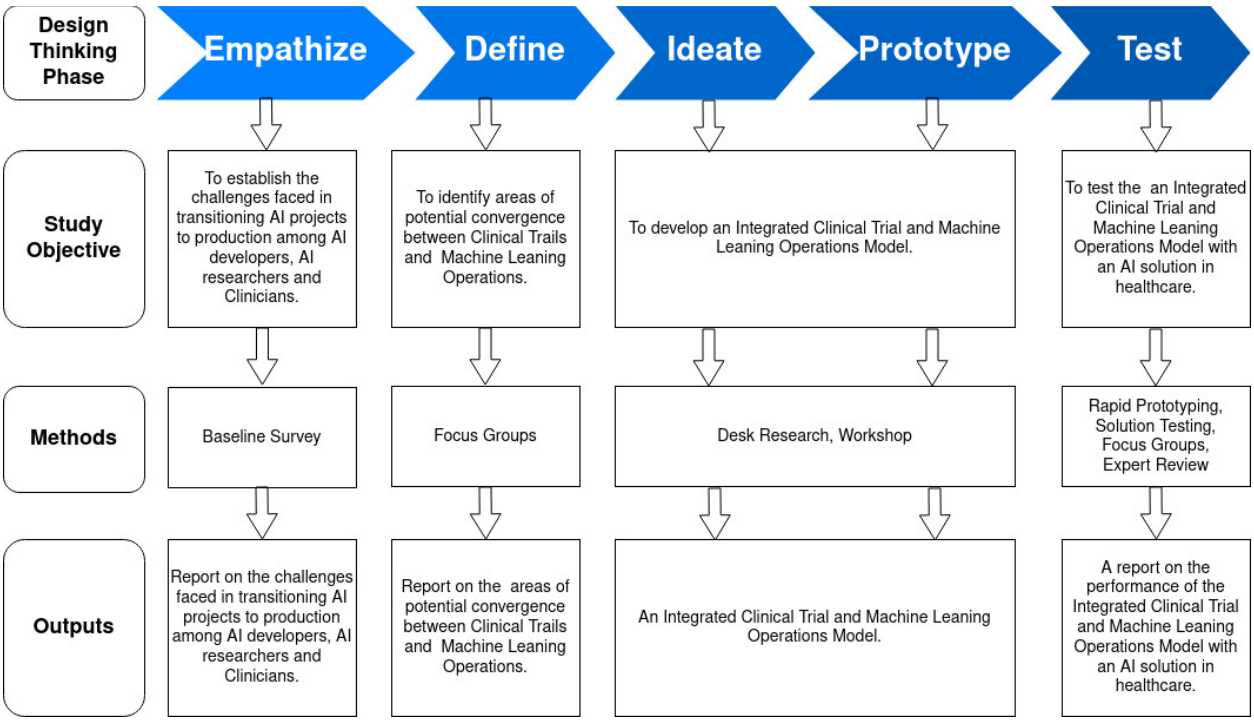
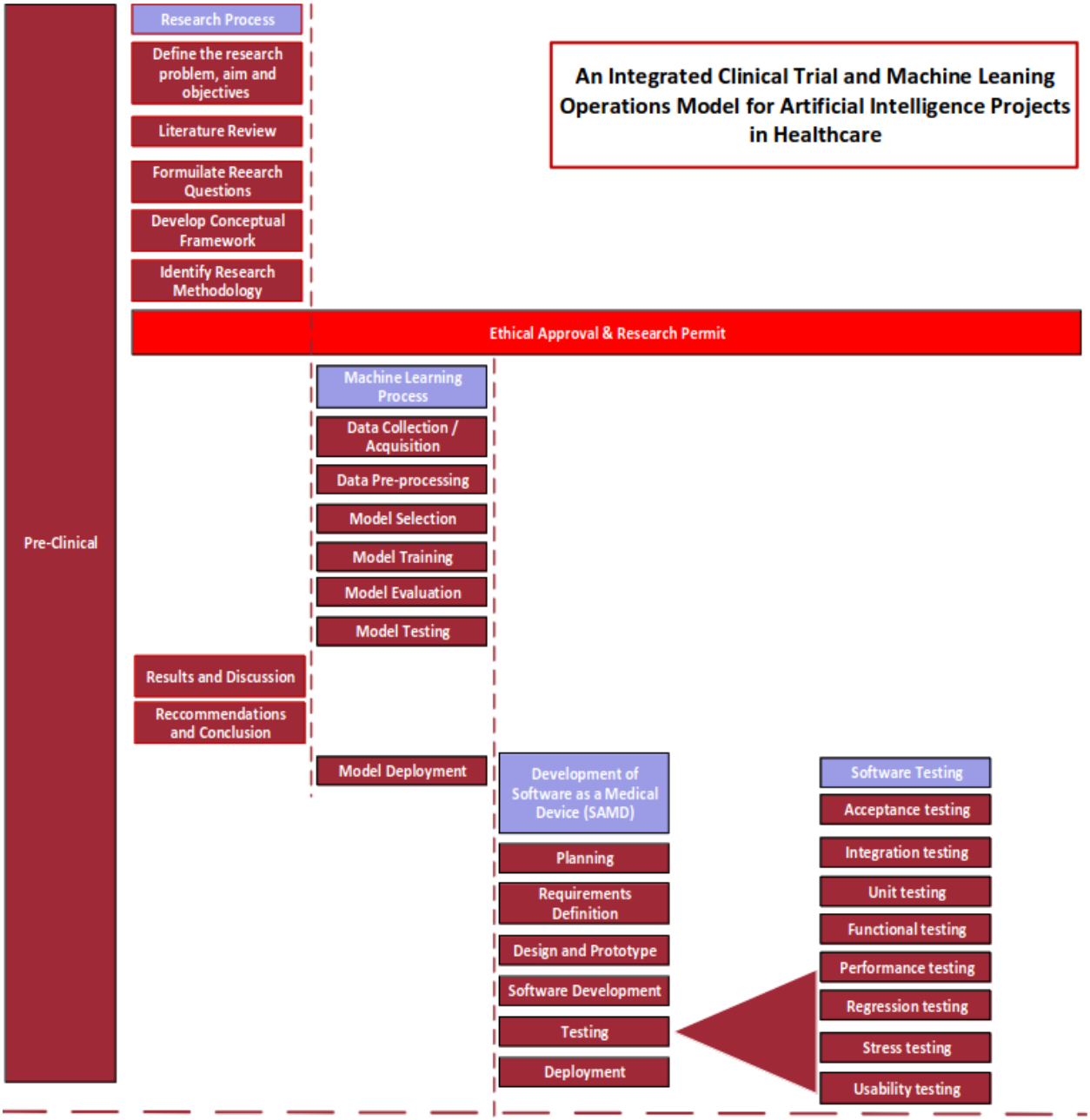
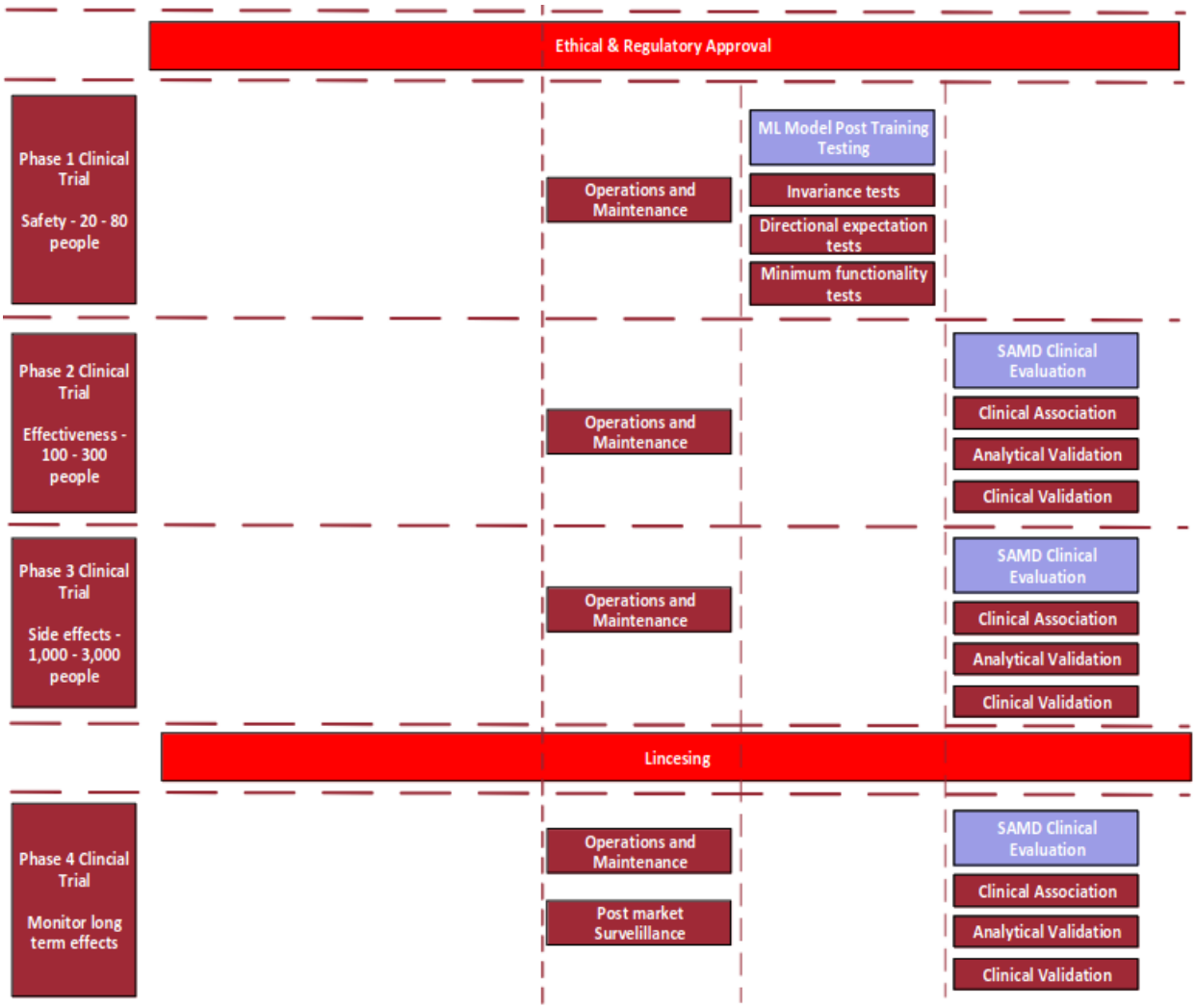


Figure 3: Study Methodology

Preliminary Results

The work has so far output a process that combines the salient aspects of a research process, the machine learning process, the development of software as a medical device, software testing and the clinical trial process.





Next Steps

The proposed model will be subjected to expert review for validation before publication for adoption.

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