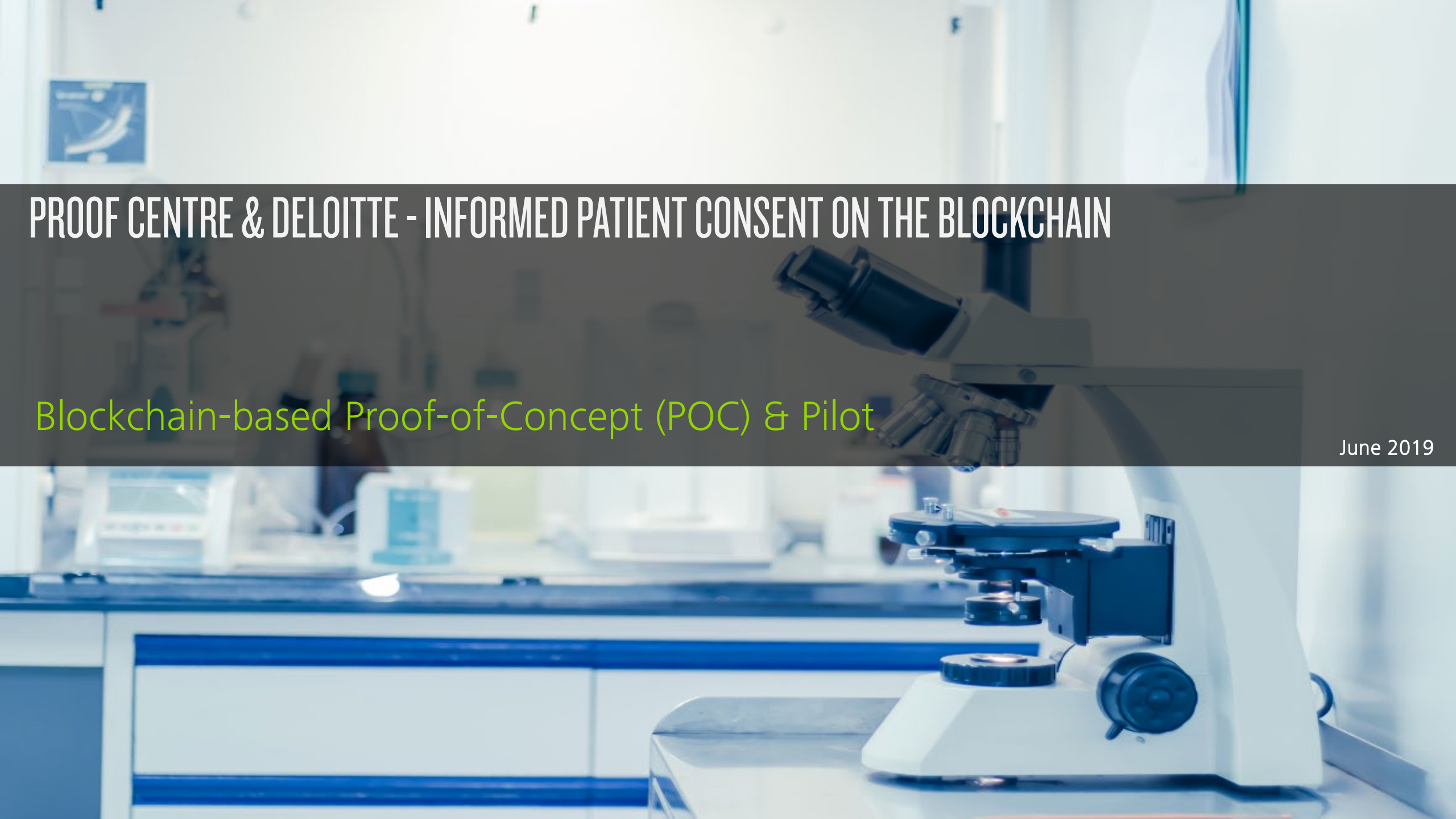


PROOF CENTRE & DELOITTE - INFORMED PATIENT CONSENT ON THE BLOCKCHAIN

Blockchain-based Proof-of-Concept (POC) & Pilot

June 2019

WHY IS THIS NECESSARY?

Currently, the clinical research sector faces problems with study participant participation and time-intensive, paperwork-heavy data collection processes.

THE PROBLEM

The Researcher / Data Requestor is the intermediary coordinating with other stakeholders

Stakeholders, like Study Participants and Patients, have limited visibility in how their data is used

Current approval processes for data share requests between stakeholders is inefficient and paper-intensive

IMPLICATIONS

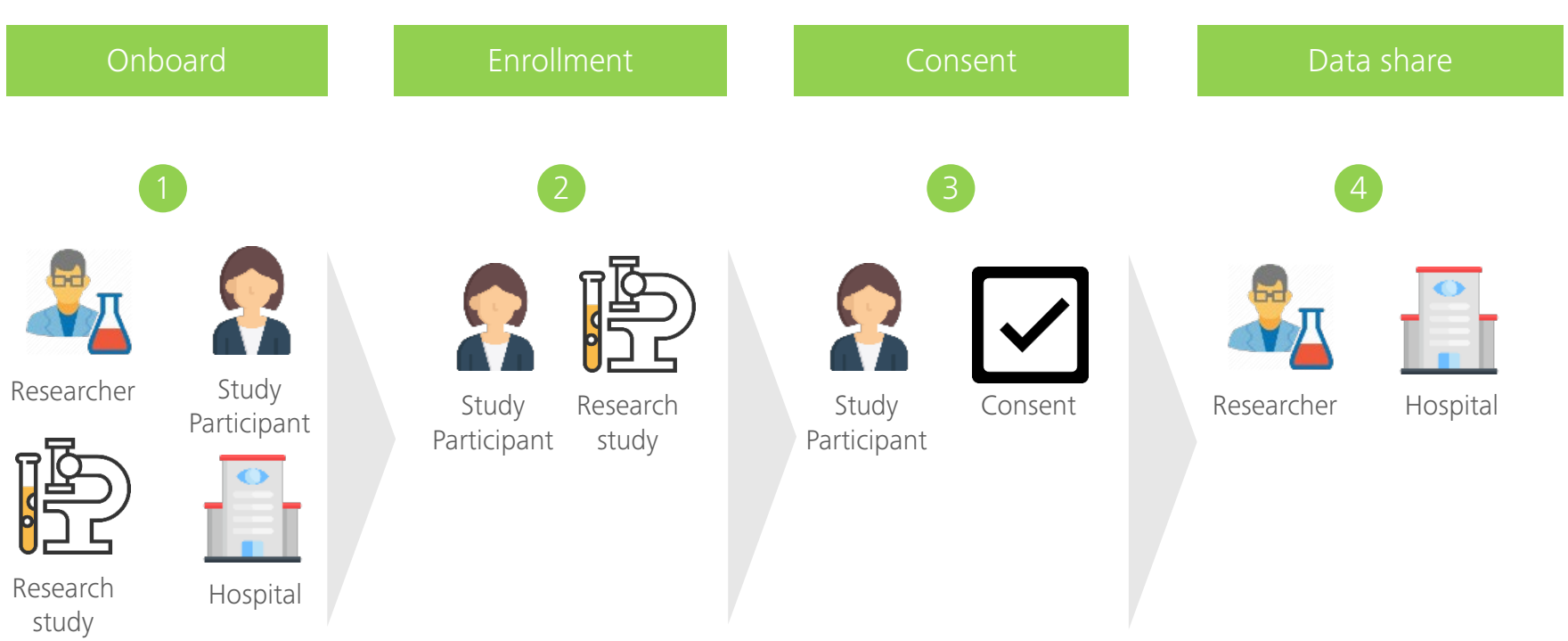
Limited participant pool and no central platform to communicate with participants

There is an opportunity for increased transparency between patients and clinicians

Researcher’s workflow is entirely manual

OVERVIEW OF THE CASE IN SCOPE

PROOF, St. Paul's Hospital (Vancouver) and University of Nebraska Medical Center were chosen due to rich resources and existing heart transplant program knowledge



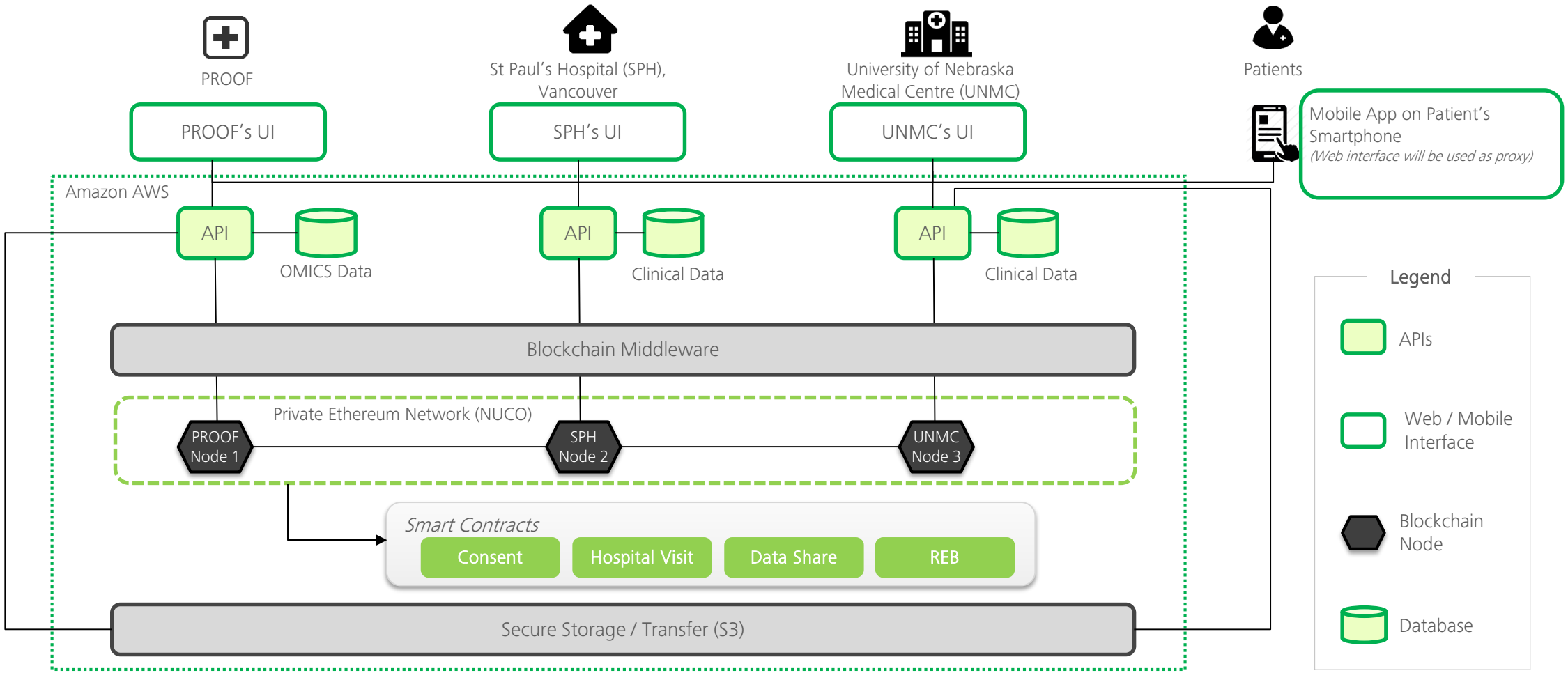
Key Actions

1. Researcher, Study Participant and Hospital are on-boarded in the solution database. Research study is added to the PROOF database and is available to the assigned researchers to start enrollment
2. Study Participant registers in a Research study on the PROOF website
3. Study Participant provides consent for Researcher to access their clinical data
4. Researcher receives Study Participant's clinical data from the Hospital

Solution Components

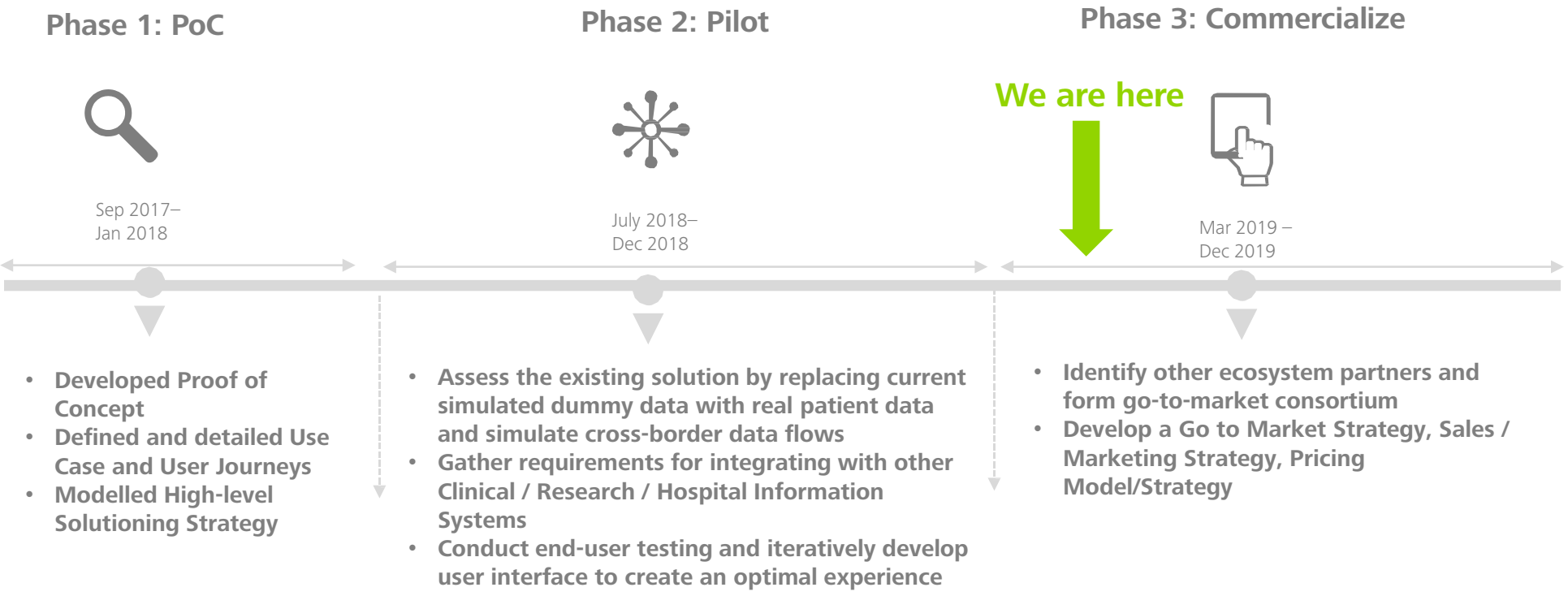
- Web UI (Study Participant)
- Web UI (hospitals & PROOF)
- Blockchain nodes
- Smart contracts
- Data storage

SOLUTION ARCHITECTURE



THE ROAD AHEAD...

- The PoC was successful in showcasing that the blockchain-enabled patient consent empowers patients to own and provide informed consent to share health data in an easy way
- The Pilot Phase used a minimum viable data set to explore regulatory and privacy constraints around health data transfer



MARKET OPPORTUNITY

~$60B Global Clinical Trial / Research Industry in the USA[1]

~56% of health care executives intend on implementing blockchain -based consent, information sharing solution by 2020[2]

10% of clinical trial studies have issues related to patient consent[3]

[1] Grandviewresearch.com (2018). Clinical Trials Market Analysis by Phase, By Study Design, By Indication And Segment Forecasts, 2018-2025, GVR-1-68038-975-3 [online] https://www.grandviewresearch.com/industry-analysis/global-clinical-trials-
[2] Sujay Jadhav. (2018). Blockchain Technologies Poised To Disrupt Stagnant Trial Timelines. Forbes. [online] https://www.forbes.com/sites/forbestechcouncil/2018/02/02/blockchain-technologies-poised-to-disrupt-stagnant-trial-timelines/#32b92f2e7390
[3] Hashed Health (2018). Consent, Clinical Trials, and The Blockchain, [online] https://hashedhealth.com/consent-clinical-trials-blockchain/

APPENDICES

APPENDIX I: Relevant Frameworks in Scope

The PROOF Platform is set to meet the regulatory requirements of a North American health data platform. Regulatory compliance is critical to meet the needs of the market targeted by the PROOF Platform

Regulation / Legislation / Policy	Key Requirements for Compliance
HIPAA (Federal) Title CFR 45 Part 164	• Health data held by a covered entity must be encrypted • Identity verification is required to authenticate digital signatures for consent • Participants / Patients must be provided sufficient information and options to provide Informed Consent • Participants / Patients may need to sign Authorization Form for health data sharing
FIPPA (Federal / Provincial)	• Participants / Patients must consent to have their health data stored in and / or accessed from another country (incl. cloud) • The onus is on the Researcher / Data Requestor to ensure Informed Consent is granted • Ensure that hospital access has security measures to avoid breaches
PIPA (Provincial)	• Ensure that Researcher / Data Requestor's access has security measures to avoid breach • Participation / Patients provided consent for their personal information to be collected, used and disclosed; and ability to revoke consent
E-Health Act (Provincial)	• Participation in a study may be frozen when a complaint is made by Participant
PHSA Research Conflict of Interest Policy (Provincial)	• All material Conflicts of Interest must be disclosed by Researcher before Participant is enrolled in Study
Financial Conflict of Interest Regulations (Federal)	• All material Conflicts of Interest must be disclosed by Researcher before Participant is enrolled in Study
FDA Regulation Title CFR 21 Part 11	• Participants must be provided sufficient information, time and options to provide Informed Consent • Identity verification is required to authenticate digital signatures for consent • Participants must have ability to revoke or amend their consent

APPENDIX 2: Completed Solution Updates

During Phase 2, the PROOF Platform underwent crucial solution updates.

Copy Implementations	Functional Implementations	Technical Implementations
• Update Request Consent Box text • Study Participant side: Change 'Rejected Studies' to 'Declined Studies' under participant profile. • Update Notifications for request enrollment decline • In Account Settings, update text on medical history page	• Show Study Participant's contact information in Study Participant's name card • Notification to Researcher when enrolled Study Participant deletes account • Add buffering / loading icon to notify user that their request is being processed • Display user's name in right-hand corner of screen • Removed blockchain view from Study Participant portal	• Stabilize the existing Nuco environment to maintain operational state • Enable SSL on PROOF solution domain (proofpoc.com) • Implement security and performance enhancements on server side • Refactoring existing code to create modules related to specific actions • Separating Researcher and Study Participant code functions • DevOps changes to server configuration to run processes in forever mode • Set up docker environment for different components within the solution • Set up dockerized CI / CD environment using Jenkins to enable faster deployments and testing • Set up template codebase for Node.JS and Ethereum migration*