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

PROOF
PROOF's UI

St Paul’s Hospital (SPH), Vancouver
SPH’s UI

University of Nebraska Medical Centre (UNMC)
UNMC’s UI

Patients

Mobile App on Patient’s Smartphone
(Web interface will be used as proxy)

Legend

- APIs
- Web / Mobile Interface
- Blockchain Node
- Database

Blockchain Middleware

OMICS Data
API
Clinical Data
API
Clinical Data
API
Clinical Data

PRIVATE ETHERNET NETWORK (NUCO)

Blockchain Middleware

Secure Storage / Transfer (S3)

Smart Contracts
Consent
Hospital Visit
Data Share
REB
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.

**Phase 1: PoC**
- Developed Proof of Concept
- Defined and detailed Use Case and User Journeys
- Modelled High-level Solutioning Strategy

**Phase 2: Pilot**
- Assess the existing solution by replacing current simulated dummy data with real patient data and simulate cross-border data flows
- Gather requirements for integrating with other Clinical / Research / Hospital Information Systems
- Conduct end-user testing and iteratively develop user interface to create an optimal experience

**Phase 3: Commercialize**
- Identify other ecosystem partners and form go-to-market consortium
- Develop a Go To Market Strategy, Sales / Marketing Strategy, Pricing Model/Strategy

**MARKET OPPORTUNITY**

- ~$60B Global Clinical Trial / Research Industry in the USA¹
- ~56% of health care executives intend on implementing blockchain -based consent, information sharing solution by 2020²
- 10% of clinical trial studies have issues related to patient consent³

---

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.

<table>
<thead>
<tr>
<th>Regulation / Legislation / Policy</th>
<th>Key Requirements for Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HIPAA (Federal)</strong></td>
<td>• Health data held by a covered entity must be encrypted</td>
</tr>
<tr>
<td>Title CFR 45 Part 164</td>
<td>• Identity verification is required to authenticate digital signatures for consent</td>
</tr>
<tr>
<td></td>
<td>• Participants / Patients must be provided sufficient information and options to provide Informed Consent</td>
</tr>
<tr>
<td></td>
<td>• Participants / Patients may need to sign Authorization Form for health data sharing</td>
</tr>
<tr>
<td><strong>FIPPA (Federal / Provincial)</strong></td>
<td>• Participants / Patients must consent to have their health data stored in and / or accessed from another country (incl. cloud)</td>
</tr>
<tr>
<td></td>
<td>• The onus is on the Researcher / Data Requestor to ensure Informed Consent is granted</td>
</tr>
<tr>
<td></td>
<td>• Ensure that hospital access has security measures to avoid breaches</td>
</tr>
<tr>
<td><strong>PIPA (Provincial)</strong></td>
<td>• Ensure that Researcher / Data Requestor's access has security measures to avoid breach</td>
</tr>
<tr>
<td></td>
<td>• Participation / Patients provided consent for their personal information to be collected, used and disclosed; and ability to revoke consent</td>
</tr>
<tr>
<td><strong>E-Health Act (Provincial)</strong></td>
<td>• Participation in a study may be frozen when a complaint is made by Participant</td>
</tr>
<tr>
<td><strong>PHSA Research Conflict of Interest Policy (Provincial)</strong></td>
<td>• All material Conflicts of Interest must be disclosed by Researcher before Participant is enrolled in Study</td>
</tr>
<tr>
<td><strong>Financial Conflict of Interest Regulations (Federal)</strong></td>
<td>• All material Conflicts of Interest must be disclosed by Researcher before Participant is enrolled in Study</td>
</tr>
<tr>
<td><strong>FDA Regulation Title CFR 21 Part 11</strong></td>
<td>• Participants must be provided sufficient information, time and options to provide Informed Consent</td>
</tr>
<tr>
<td></td>
<td>• Identity verification is required to authenticate digital signatures for consent</td>
</tr>
<tr>
<td></td>
<td>• Participants must have ability to revoke or amend their consent</td>
</tr>
</tbody>
</table>
# APPENDIX 2: Completed Solution Updates

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

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