

**Category**

Best Startup

**Product/Solution Name**

Bloqcube(R) and BloqBridge

**Date of Approval**

N/A

**Indications**

Accelerating Decentralized Clinical Trials cheaply worldwide

**Therapeutic Categories**

All

**Attached Files:**

- Bloqcube\_ RamaKRAO\_May 23 Galien.pdf

**Background information and need for solution/product**

Clinical Trials take over 7 years, utilize multiple systems ( average over 6) have data integrity issues ( ~17%), require multiple peoples in multiple countries to supervise it, requiring Source Data Verification almost manually via an army of Monitors, causing a lack of data in real time, delayed payments to doctors/patients ( over 4 months and 41 % churn rate) and now are exposed to Ransomware attacks (\$21 billion lost in 2020). Companies spend over \$100 billion per year in clinical trials development of which approximately \$26 billion is spent on Clinical Trials Operations. Current systems have a key vulnerability in the entire data is in a data warehouse making it vulnerable to Ransomware hacking that can cripple operations as was done in 2020 during Covid for three companies. Finally Study coordinators and Monitors have around 2 years experience and have high churn making consistency in execution a challenge. Glassdoor has a litany of the demotivation issues. Finally Success rates are low varying across Phases of trials. Phase 1 eg 75%; Phase 2 :50% etc. and these failure rates require agile rapid systems

**Attached Files:**

- ERG article on Clinical trial costs CTJ625964.pdf

**History of the development of the solution/product**

2017: Ideation; company setup. Technical PoC with Hyperledger fabric V0.6 built. Philosophy of LEAN Startup fail fast/cheap

2018: MVP - Minimum Viable Product and IP development

2019: MMP- Minimum marketable Product/ Beta built

2020: Covid shutdown however Beta tested with 2 customers

2021: Covid shutdown. Commercial Product FDA Part 11 compliant built

2022: Customer 3 acquired and system built; BloqBridge built and launched

2023: Commercial Customer purchased our system

Attached Files:

- Bloqcube\_ RamaKRAO\_May 23 Galien Product journey.pdf

**Why this solution/product is innovative, the broad implications for future research, and/or how it will improve the human condition**

The solution is innovative as it includes three key elements - Ipad/Mobile Web solution, Cloud and a Private Permissioned Blockchain. The Blockchain delivers an algorithmic structure of trust alongwith cryptographically anchored security and ensures auditable immutable data. Additionally by using a "Smart Contract" or "ChainCode" we have built a unique finance module that ensures SOX controls, the clinical trials agreement's performance metrics are enshrined in the algorithm so that we can automate a manual process of payments approval, decreases transaction costs for payments using a ecommerce payment rail (STRIPE) then an accounting record is output to the Accounting ERP software and the data brought back to do a Budget versus Actuals calculation. The documents below show an incredible improvement in efficiency.

We used it in rural India pre Covid and demonstrated we can leap frog technology barriers and ensure diversity of trial subjects are ensured. This has huge benefits as the FDA has emphasized the need for diversity in clinical trials. Given that we tested it in Rural India it can help bridge the digital divide anywhere in US or the developing world. We are laying the foundational rails to implement our vision to transform healthcare consumers to healthcare producers in a Web 3 world.

Attached Files:

- IBM Cuomo Testimony Blockchain Copy.pdf
- JAMA Remote Research and Clinical Trial Integrity During and After the Coronavirus Pandemic jama 421.pdf
- JAMA Ransomware attacks in healthcare 2016-2021.pdf
- Lancet article on Blockchain and Observational studies.pdf
- BMJ article blockchain and crypto currency Brian Till et al.pdf
- Mehdi article on Blockchains in Clinical trials.pdf
- JMIR on Blockchain in Clinical trials.pdf

**Please provide appropriate references (ie Pubmed links)**

Attached below

Attached Files:

- 2020 Lifesciences in Blockchain Extract not for circulation.docx