

# HOW TO STREAMLINE AND ACCELERATE CLINICAL TRIALS



Conducting clinical trials is a time-consuming, expensive affair that involves close collaboration between multiple stakeholders (parties), often geographically distributed, and one that needs a high level of monitoring, regulation, and precision to maintain patient privacy and auditability. In this two-part blog series, **Lakshmi Shastry, Principal Solutions Architect at Brillio**, explains the challenges around clinical trials and how emerging multi-party workflow technology can be leveraged to improve the clinical trial process.

# 1 Challenges of conducting clinical trials



The multi-party and distributed nature of the clinical trials process brings along unique, intrinsic challenges such as:

- Multiple participating entities and workflows having disparate databases that must be constantly reconciled.
- Privacy and confidentiality considerations for each stakeholder and individual participant.
- Complex data collection, protection, sharing and reporting requirements across enterprise boundaries.
- Patient engagement over long periods.
- Data domicile and compliance needs.
- Multiple entities using different technologies for critical processing.
- Manual work that increases risk for data accuracy.

Using emerging multi-party workflow technology such as Daml, we can solve some of the problems described above. We will talk about Brillio's Blockchain-based Clinical Trial solution in the subsequent section and how it can be put in action.

*Nowadays, different steps of clinical trials are conducted independently of each other. This is partly because of legacy technology and legacy approaches to conducting clinical trials, and partly because of no better alternatives.*

The current process entails the following:

- Data gets created for multiple patients/participants from multiple networks – hospitals, clinical trials, smart devices.
- Data is then collected and entered into a Centralized Database Management System (DBMS) separately for each organization.
- Different pharmaceutical companies, hospitals, CROs, Biotech, laboratories have their own decentralized databases. Different organizations then collate and store data in their own preferred way and own preferred format in their own IT environments.
- Data is then analysed separately within each organization and exchanged in different forms between various organizations for regulatory reporting, business analytics, research and other purposes.

In this model, not only collaboration is difficult between participating organizations, it also complicates communication internally, resulting in more reconciliation and more human error. Additionally, effort expended to solve data consistency issues is large. the proverbial wheel is reinvented for each trial.

# 2 Current implementation of the clinical trial process



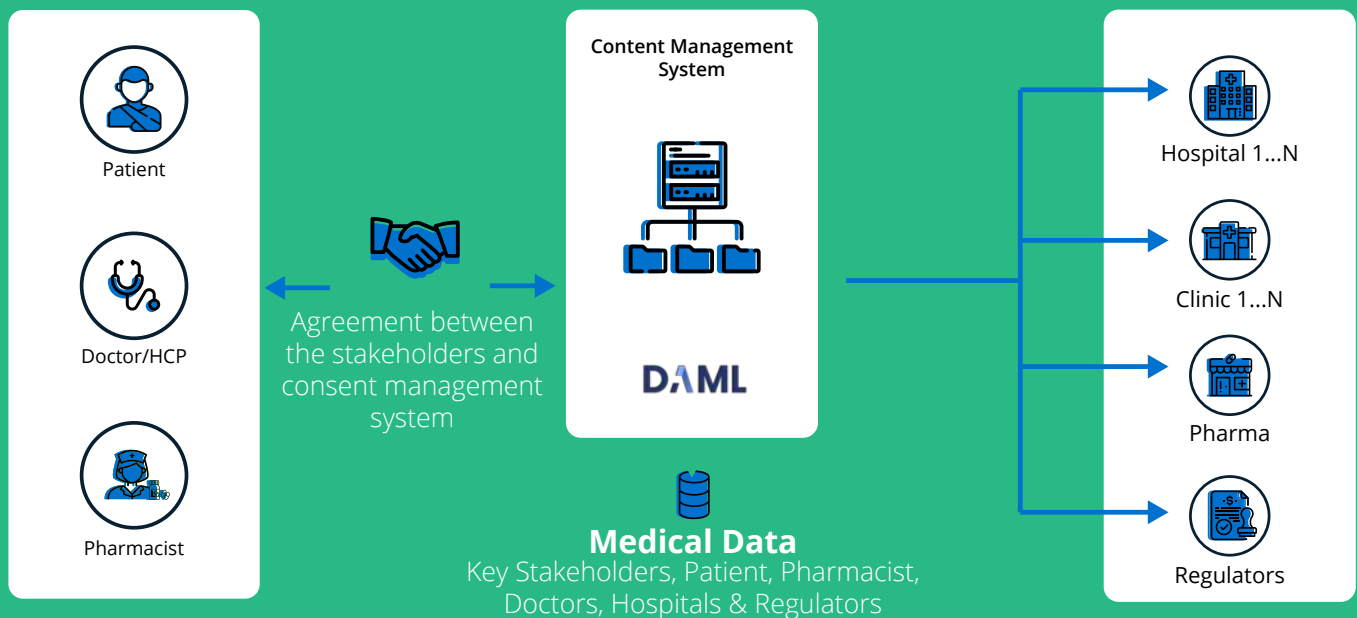
# 3 Brillio's Solution



Brillio's solution is a permissioned multi-party network in which:

- Various Stakeholders such as pharma companies (sponsors), CROs, regulators (FDA, EMA, etc.), clinics, and patients participate within a network.
- Data sharing and clinical trial execution takes place in a distributed and secure manner with custom Daml workflows based on the Clinical Trial Protocol.
- All Stakeholders maintain their own local, private version of the data which is automatically synced under the hood by Daml based on workflows and privacy rules agreed between parties (i.e. no more reconciliation or checks and balances).
- Each party remains in sync in real-time with the latest state of the clinical trials business process, seeing only the data they are supposed to see. This avoids costly privacy gaps because no tack-on authorization models are needed. Azure cloud is leveraged to provide high performance and scalability. However, the solution can meet each participant's cloud preferences if needed.

## Trial Patient Portal Solution



## 4

Key parts of  
Brillio's solution

- Parties**  
 Parties refer to the pharmaceutical companies (sponsors), regulators, CRO's, and hospitals that participate in the network. For instance, each pharmaceutical company is a party. Similarly, each Hospital and each regulator (i.e. FDA, EMA) is a party.
- Network**  
 Networks represent multiple organizations, different identities, and associated data visibility rules. Data is shared only within a network between the participants.
- Transaction History**  
 Transaction History is the historical log of all the transactions on the network. Since the underlying ledgers are append-only, all the transactions can be replayed to arrive at the current state. Each participant in the network stores their version of the Ledger which is automatically synced as required based on the privacy and data sharing rules. Transaction History is available to view for all allowed participants in the network in real-time.
- Smart Contracts**  
 Smart contracts or multi-party workflows of Daml change and control the state of the ledger within the network. These rules also automatically enforce authorization as well as the physical domicile of the data thus simplifying compliance.

*Brillio uses Microsoft Azure that offers frameworks and tools to simplify the development of this network on the cloud. From integration to monitoring, network configurations, multi-party workflow developments, privacy, and distributed computing capabilities, Microsoft Azure powers data-driven approaches in clinical trials.*

Brillio's three step approach using Microsoft Azure and Daml is to:

**STEP 1**

*Build a multi-party network using a rights and obligations model.*

**STEP 2**

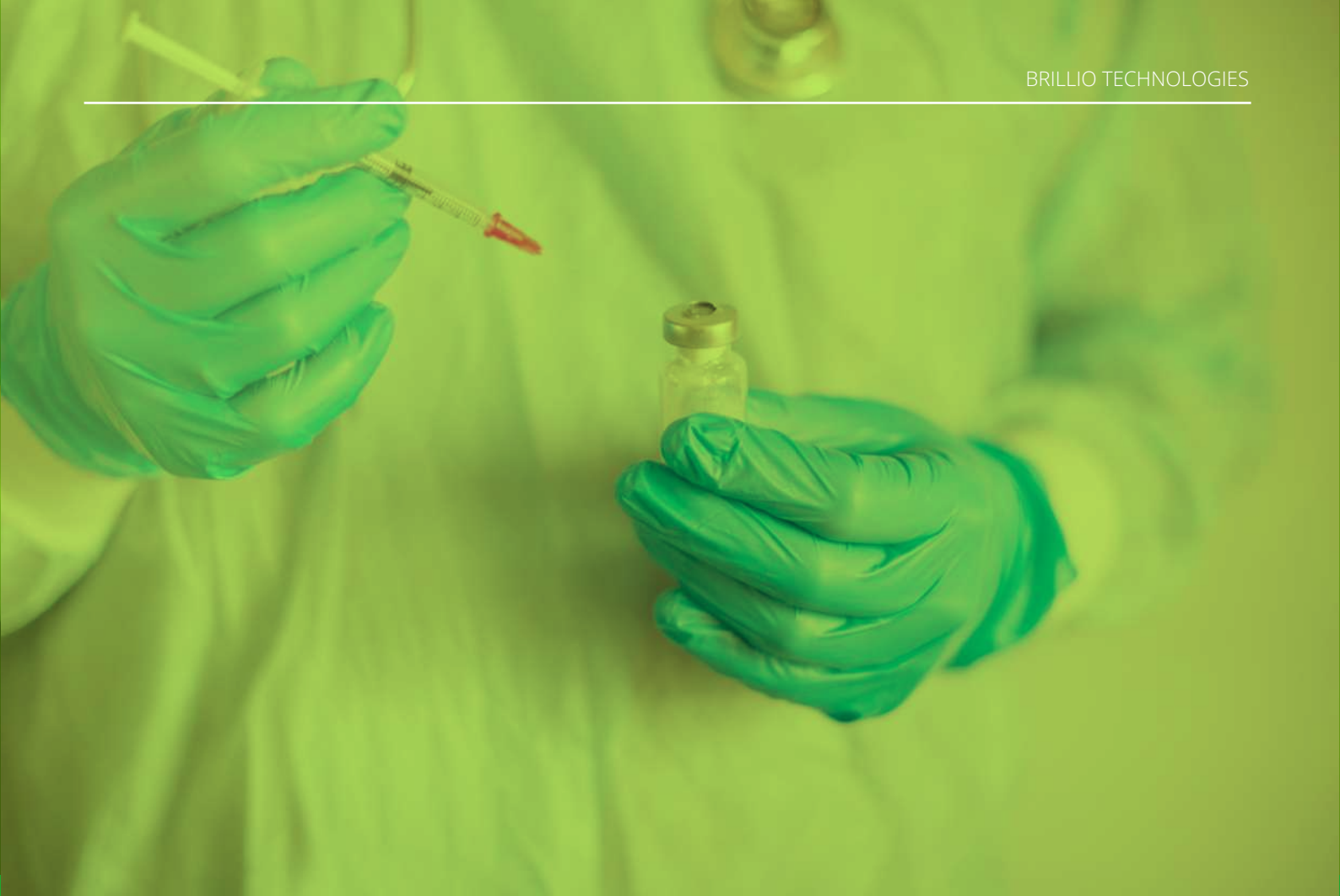
*Simplify governance and management respecting each party's technology choices.*

**STEP 3**

*Integrate solutions with existing systems and tools to reduce IT roadmap complexity.*

Daml is an open-source runtime designed specifically for building distributed, multi-party workflows, allowing applications to work across multiple underlying data storage platforms (databases or blockchains) with interoperability between different networks. Daml integrations, APIs, and run-time features are built-in safeguards that protect data integrity and privacy and create an interoperable system in which multiple parties, including pharmaceutical companies (sponsors), regulators, CRO's and hospitals can connect with absolute trust in their Clinical Trial Process. Daml thus provides significant benefits beyond traditional technology, positioning users as the provider of choice with the given market.

Microsoft Azure serves as the foundation to manage these networks for digitized workflows shared across clinical trial stakeholders.



## Summary

We believe such a solution that preserves privacy while allowing for seamless collaboration has the ability to transform clinical data collection, data sharing, and operations. Clinical Trial Processes based on blockchain technology can streamline data transfer, ensure real-time data access across clinical trial participants, reduce data entry errors, and simplify the clinical trial audit and compliance process.

### ABOUT US

At Brillio, our customers are at the heart of everything we do. We were founded on the philosophy that to be great at something, you need to be unreasonably focused. That's why we are relentless about delivering the technology-enabled solutions our customers need to thrive in today's digital economy. Simply put, we help our customers accelerate what matters to their business by leveraging our expertise in agile engineering to bring human-centric products to market at warp speed. Born in the digital age, we embrace the four superpowers of technology, enabling our customers to not only improve their current performance but to re-think their business in entirely new ways. Headquartered in Silicon Valley, Brillio has exceptional employees worldwide and is trusted by hundreds of Fortune 2000 organizations across the globe.

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