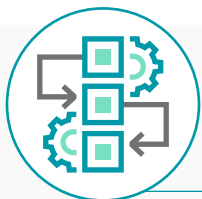




The Power of Collaboration

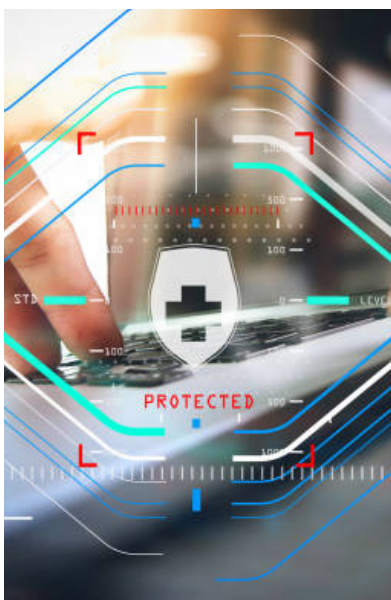
The Pistoia Alliance is a global, not-for-profit members' organization collaborating to lower barriers to innovation in life science and healthcare R&D. Now more than ever, the world needs our industry to work together to solve common challenges and achieve scientific advances and breakthroughs. The fruits of our collaborative innovation can be seen across our portfolio of member-driven global projects, made possible through our legal framework for pre-competitive collaboration that enables companies to share resources, data, expertise and best practices.



PROJECT OPPORTUNITY TO DELIVER VALUE THROUGH PRE-COMPETITIVE COLLABORATION

Informed Consent Blockchain Project

This project seeks to demonstrate the value of blockchain technology as part of a decentralized digital identity solution for the Informed Consent process in clinical trials.



"70 percent of our survey participants think blockchain has the potential to make a real difference in patient data management and sharing. Blockchain's ability to instantly create tamper-proof records will become a key part of increasing patient participation as more clinical trials are conducted remotely because of the pandemic. We hope the security advantages can both improve patient trust and facilitate further knowledge sharing across the life science community."

– Dr. Steve Arlington
Advisory Board Member
Pistoia Alliance



UPCOMING EVENTS

Don't miss these opportunities to connect with other advocates for life sciences innovation.

Explore more of our educational webinar series at www.pistoiaalliance.org/events



PROJECT RESOURCES

[Webinar on Demand: Implementing Blockchain Applications in Healthcare](#)

[Webinar on Demand: Informed Consent in Clinical Trials - Application of Blockchain Technology](#)

Why is this project important to the life science R&D industry?

Obtaining consent is a fundamental requirement for enrolling participants on to clinical studies, yet the Informed Consent process is not participant-friendly and involves multiple stakeholders, documents and transactions, meaning it is often quoted as being in the top ten cited regulatory deficiencies in the clinical operations landscape.

Some of this complexity, which uses paper-based methods for obtaining consent through Informed Consent Forms (ICFs), is being removed by the adoption of digital electronic-Consent (eConsent) solutions which streamline the process to a more participant-centric approach. Despite the benefits eConsent platforms are centralized, raising questions around the privacy and access to participant data during and after a clinical trial.

Our solution for Informed Consent in clinical trials (BlockSent), implements key components of decentralised digital identities: Decentralised Identifiers (DIDs), Verifiable Credentials (VCs) and a blockchain registry. BlockSent enables participants to provide consent, be re-consented and withdraw their consent to participate in a clinical trial.

BlockSent provides participants, clinicians and sponsors with an audit trail of all the transactions between relevant stakeholders in the clinical trial informed consent process ensuring regulatory compliance and enabling real time overview of the approvals and signature process. The project has developed the learning and system requirements so that others could adopt or build on BlockSent based on their own approach.

What will this project achieve?

The project will build a solution for Informed Consent in clinical trials (BlockSent), implements key components of decentralized digital identities: Decentralized Identifiers (DIDs), Verifiable Credentials (VCs), and a blockchain registry. BlockSent will:

- > Provide participants with a simple system to participate in a clinical trial.
- > Create an immutable audit trail for the Informed Consent process which is tamper-proof.
- > Have the ability to integrate with existing third-party clinical trial data management systems.
- > Deliver a publication highlighting BlockSent as a conceptual solution based on blockchain technology to enhance the electronic informed consent process in clinical trials.



Be a part of that future by joining one of these developing projects!

Reach out to us at ProjectInquiries@PistoiaAlliance.org to learn more or join the next member meeting.

AstraZeneca 

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