

Secure Platforms for Distributed RWE-based Clinical Studies

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Background

The growth of real world evidence (RWE) to support clinical trials has been greatly accelerated by the COVID-19 pandemic, but even post-COVID the value of RWE will remain. Hospitals generating this data are interested in becoming research ready to drive advances in clinical research and provide their patients with most effective treatment quickly. However, there is still no common operating picture for distributed provider/researcher network due to the disparate data sources, interoperability issues and security and privacy concerns.

Objective

Create a secure system for harvesting and applying advanced analytics to RWE and RWD from patients, hospitals, labs, clinics and medical groups to reduce the time to approve existing drugs for new indications, with out compromising security.

Methods

- Collaborating with academic medical institutions and private EHR aggregators to evaluate technological solutions that support RWE clinical research
- Creating a framework to interoperability and security capabilities by using an actionable query on patient data.
 - Synthetic data do not represent the complexity of the research
 - Successfully running this query provides evidence for a submission of a new indication for an existing drug

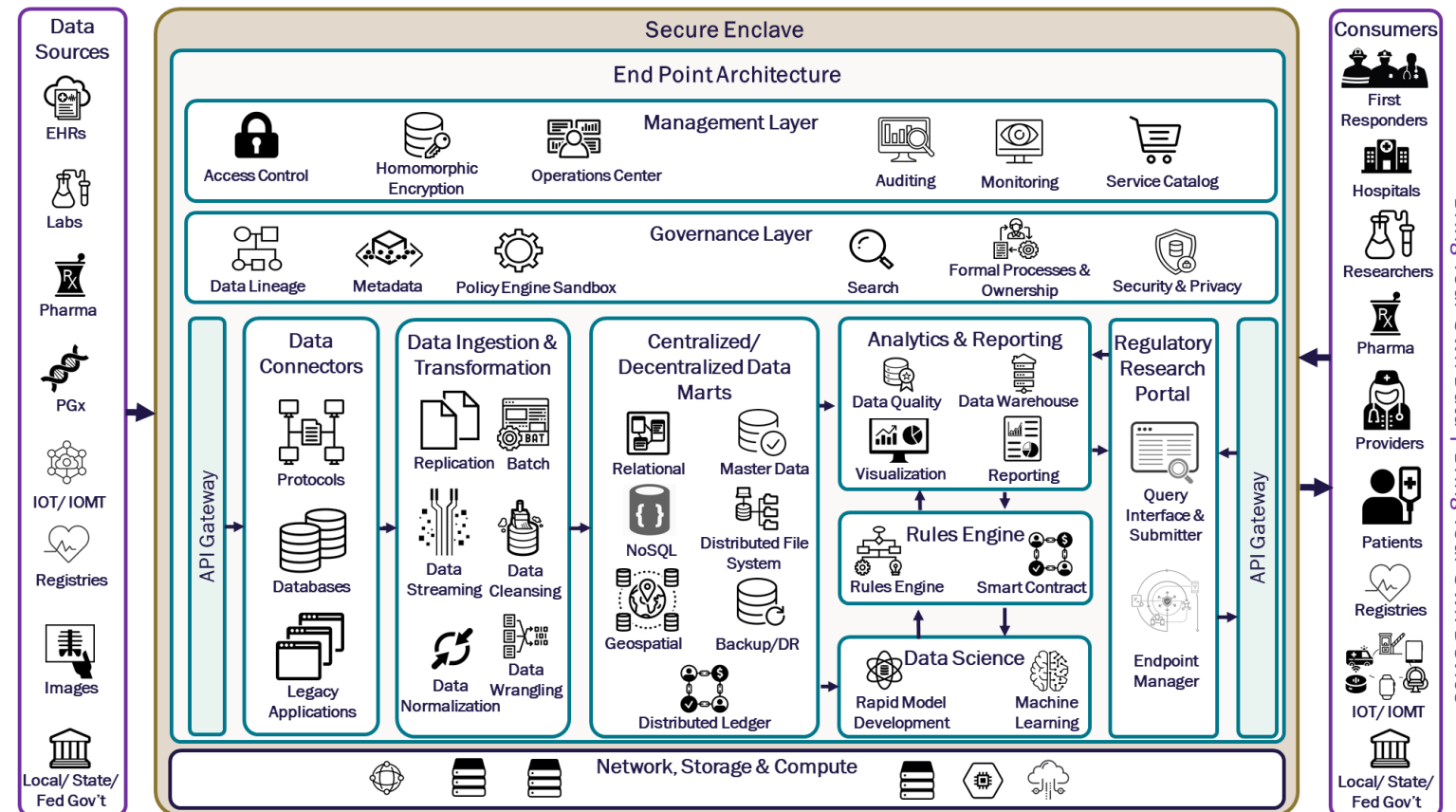
Results

- Leidos created RWE Service Offering: Secure Hardware and Software Platform As A Service, Data As A Service – including a RWE Reference Architecture, RWD Core Framework and Uses
- Leidos is finalizing the cryptographic framework to securely access and query PHI/PII in the native EMR/EHRs, with both secure enclave technology and homomorphic encryption showing significant potential. Secure enclave technology likely to achieve broad acceptance.

Conclusion

Leidos developed a secure, RWE system with the following capabilities: central research portal, centralized query generator and aggregator, decentralized data analytics and exploration, tamper-proof auditing, API gateway, endpoint management, IOT and IOIMT device management, security and privacy, Leidos is working with a group of clinical researchers and health systems to implement a RWE only clinical trial and file an IND on the use of an existing drug for a new indication.

Securely Unlocking RWE for Faster Regulatory Decision Making



Acknowledgements

Intel Corporation, Academic collaborators

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