



Enabling Secure, Integrated Global Collaboration with *Trusted Regulatory Spaces*


DNAxenus Trusted Regulatory Spaces (TRS) offers a unifying framework to enable health authorities, sponsors, and standards and trade organizations to use the cloud to modernize regulatory workflows. TRS aims to reduce review and approval times through early sponsor-agency interaction, sharing of data and tools, and parallelization of submissions across markets. TRS is built using the same open-source technology powering precisionFDA and PRISM, both developed and operated by DNAxenus for the FDA to address the unique challenges of global regulatory interaction.




Isolated systems with limited integration create data siloes.




Multiple fragmented platforms complicate access and compliance requirements.




Inconsistent security levels hinder interoperability.



Greater coordination is required across global participants.



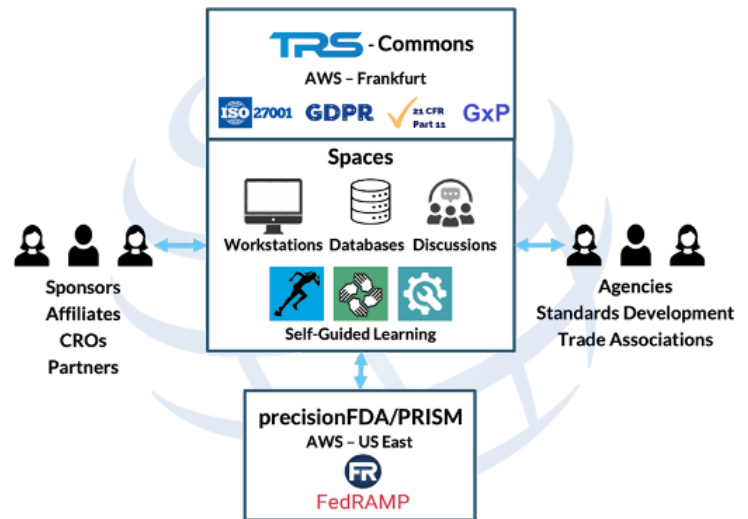
Varying submission systems and processes increase administrative burden.



Incompatible tools contribute to redundancy and inefficiency.

KEY FEATURES AND BENEFITS INCLUDE:

- Members-only Spaces for secure sharing of data, tools, and discussions between sponsors, agencies, and standards development and trade organizations
- Cloud workstations and databases to enable all parties to view submissions and data in real-time through the same lens
- Regulatory-grade security, privacy, and quality: ISO 27001, FedRAMP, FISMA, GDPR, GxP, 21 CFR Part 11 CSV
- Integrations with Veeva RIM, LORENZ docuBridge, SAS, R, Jupyter, CDISC, HL7 FHIR, RAG-LLM AI
- Compatibility with precisionFDA/PRISM user experience and data interchange protocols
- Platform-embedded regulatory use case and tools training for a self-guided learning experience
- Multi-tenant and private deployment models to address data sovereignty, privacy, and security requirements unique to each stakeholder



Trusted Regulatory Spaces form a regulatory-grade cloud network that connects sponsors to multiple agencies with a common user experience and data interchange protocols.

Investigate, Innovate and Translate Insights into Action!

COME JOIN THE TRS EARLY ADOPTER PROGRAM

We've kicked off the TRS Early Adopter Program, providing sponsors with the opportunity to pilot TRS and help guide its evolution to meet their specific requirements.

As an early adopter, you will:

- Pilot the TRS secure cloud collaboration framework through real regulatory use cases.
- Gain early access to new tools for structured data submissions, AI-driven document analysis, digitalization and visualization of protocols, and CMC reliance.
- Help shape TRS development through your participation, so it better meets your needs.