

# **Project PRISM/Project CRYPTx**

## **Category:**

Best Digital Health Solution

## **Company Name:**

DNAnexus + Boehringer Ingelheim Joint Submission

## **Number of employees:**

> 1000

## **Turnover and/or Funding:**

N/A

## **Product/Solution Name:**

Project PRISM/Project CRYPTx

## **Corporate Name:**

Boehringer Ingelheim- DNAnexus

## **Date of Approval:**

2023-10-10

## **Indications:**

Applicable to all Indications

## **Therapeutic Areas:**

Applicable to all TAs

## **General Information File Document upload:**

[\*\*Boehringer Ingelheim DNAnexus \\_Prix Galien Nomination.pdf\*\*](#)

## **Background information and need for drug / device:**

In an era defined by geopolitical uncertainty, fragmented regulatory frameworks, and unequal access to healthcare, Boehringer Ingelheim embarked on a visionary initiative to bridge these divides: the creation of the Boehringer Ingelheim-Trusted Regulatory Spaces (TRS) leveraging the research outcomes from Project PRISM (Pharmaceutical Regulatory Information Service Module), a Research Collaboration Agreement with the US Food and Drug Administration (FDA) and the PrecisionFDA Platform. This centralized, open-source platform reimagines global pharmaceutical submissions as a collaborative, real-time process-bringing together regulatory agencies from around the world into a shared, secure digital environment that enables simultaneous review and transparent Q&A engagement. This supports the realization of global health equity dream, serving the underserved countries and uplifting their infrastructure through the open source model.

A robust and proven regulatory cloud platform represents more than just technological advancement-it is a trust-building mechanism in a fractured global landscape. By promoting transparency, harmonization, and mutual reliance, it fosters confidence among regulatory authorities, sponsors, and ultimately patients; TRS stands as a powerful equalizer.

At the forefront of this transformation is Dr. Vada A. Perkins, whose leadership has catalyzed a fundamental shift in regulatory science. With unwavering commitment to patient access and equity, he challenged longstanding industry limitations and delivered tangible innovation. While previous cloud submission efforts yielded minimal impact, Dr. Perkins' strategic vision led to the rapid integration of Boehringer Ingelheim-TRS (a.k.a, Project CRYPTx) achieved in just six weeks through close collaboration with DNAnexus, LORENZ, and Veeva.

This integration created a harmonized, cloud-based ecosystem that allows multiple health authorities to concurrently review a single marketing application to reduce redundancy, improve efficiency, and accelerate time-to-market transformative therapies. More critically, Boehringer Ingelheim-TRS is designed to lower technological barriers for both the pharmaceutical industry and regulatory bodies, enabling them to participate as equal partners in global review processes. This levels the playing field, supports regulatory capacity-building, and advances global healthcare equity.

By empowering health authorities to access the same tools, data, and collaborative networks as their high-resource counterparts, the Boehringer Ingelheim TRS initiative is reshaping the future of global health regulation. It ensures that no country is left behind in the delivery of safe, effective, and innovative medicines.

The rapid and successful results from Project PRISM and Project CRYPTx utilizing a robust, secure, and private regulatory cloud platform underscores its transformational impact for democratizing medication access to patients.

## **Background File Document upload:**

N/A

## History of the development of the solution/product:

The global regulatory ecosystem has long struggled with siloed workflows, redundant assessments, and uneven access to critical therapies. Fragmented submission processes increased costs, delayed access, and excluded under-resourced regulators from global decisions. Despite cloud investments, interoperability and equity remained unmet needs. A real-time, collaborative solution was essential to modernize regulatory science.

### The Solution: Project CRYPTx + FDA's Project PRISM

Boehringer Ingelheim (BI) addressed this with Trusted Regulatory Spaces (TRS)-a secure, open-source platform enabling global regulators to collaborate on a single marketing application within their own systems.

A breakthrough came through BI's year-long collaboration with the FDA's Project PRISM, aiming to transform regulatory review via secure cloud-based interoperability. Led by Dr. Vada Perkins, BI completed a six-week integration between TRS and PRISM using a secure gateway, CRYPTx. This created a first-of-its-kind \"data highway\" linking BI's RIM system, TRS, and PRISM-enabling real-time, secure regulatory data exchange while maintaining jurisdictional control.

### Key Features and Impact

- Real-time, multi-agency review: Enables concurrent assessments, cutting redundancy and delays.
- Seamless cross-agency communication: Centralized feedback and traceability eliminate manual exchanges.
- Supports global initiatives: Interoperable with Health Canada's ACCESS, EMA's CTIS, and others.
- Solves infrastructure gaps: Provides secure, compliant access for under-resourced regulators.
- Accelerates access: Speeds time-to-market for innovative therapies.
- Scalable & adopted: Growing uptake across the industry demonstrates its utility.

### Value to Regulatory Professionals

- Streamlined workflows reduce administrative load.
- Shared visibility enhances collaboration and reduces duplication.
- Mutual reliance is strengthened for global efficiency.
- Uplifts regulatory maturity in emerging markets via shared infrastructure.
- Standards-based interoperability future-proofs regulatory systems.

### Value to Patients & Society

- Faster medicine access through shortened approval timelines.
- Reduced development costs lower barriers to innovation.

- Increased availability in underserved regions.
- Greater transparency and global trust in the regulatory process.

Advances health equity through inclusive access and participation.

### Vision Realization is In progress: A Single Global Submission

We've long envisioned a world where one product application supports global access. That's Project PRISM's foundation: data stored centrally, accessible to a network of regulators who collaborate in real time-sharing insights, aligning decisions, and accelerating patient access.

More than a technological shift, this is a transformation in how we work together-democratizing innovation, expanding equity, and shaping the future of medicine.

### **Development File Document upload:**

N/A

### **Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:**

This digital health innovation marks the first secure, private, end-to-end cloud integration of regulatory workflows-seamlessly linking Boehringer Ingelheim's Trusted Regulatory Spaces (TRS), internal RIM system, and the FDA's precisionFDA via a scalable, interoperable regulatory cloud platform. It sets a groundbreaking global standard for managing submissions and assessments.

#### Broad Implications for Future Research:

Real-time, multi-agency review: Enables concurrent assessments by multiple regulators, eliminating sequential delays.

Dynamic information exchange: Instant feedback sharing replaces siloed, manual processes, supporting data reuse and AI-driven regulatory science.

Supports global reliance models: Compatible with Health Canada's ACCESS, EMA's CTIS, MHRA, and WHO-led frameworks, enhancing harmonization.

Catalyzes innovation: Open-source architecture fosters interoperable workflows, paving the way for global data standardization and digital dossier ecosystems.

Impact on Patients & Society:The public-private partnership between Boehringer Ingelheim and the FDA represents a transformative leap in global therapeutic innovation. Leveraging digitalization and interoperability, it aims to cut over two years from the drug development timeline-reshaping how therapies reach patients.

**Time Saved:** Traditional regulatory reviews are often redundant and slow. This platform provides the ability to convert millions of pages of unstructured documents into structured content, enabling faster evaluations and accelerating time-to-market by at least two years.

**Cost Reductions:** With drug development averaging \$2 billion per asset, digital workflows reduce regulatory costs by 30-50%, potentially saving \$10 billion globally each year (estimation based on BI processes). These efficiencies benefit both industry and healthcare systems. TRS and PRISM have shown that even a one-day acceleration in approvals can yield €10 million in value for high-revenue therapies.

**Faster Patient Access:** By eliminating duplicative reviews and aligning global standards, the model ensures timely, equitable access to therapies-especially in underserved regions. Centralizing patient-related data enhances transparency and global accessibility.

**Strategic Industry Impact:** This interoperable, digital-first framework positions stakeholders at the forefront of regulatory transformation. Automation and standardization improve submission quality, reduce risk, and streamline approvals-delivering unmatched financial, operational, and societal value.

**Democratizing Access:** The open-source TRS model allows any regulatory body-regardless of resources-to join a secure, shared ecosystem. It aligns with calls for FDA-led modernization and open digital infrastructure.

**Global Infrastructure:** PRISM's cloud-based platform is accessible to low- and middle-income countries, enabling faster approvals without costly system development. This shared ecosystem reduces duplication and speeds global access.

**Health Equity & Research:** Lowering regulatory barriers accelerates access to therapies in underserved regions. Cost savings can be reinvested in high-impact research for neglected diseases, aligning innovation with societal goals.

**Societal Transformation:** Project PRISM exemplifies a new regulatory paradigm-delivering high-quality, accelerated submissions, reducing development costs, and expanding equitable access. Its replicable model offers a sustainable, global solution to healthcare challenges.

## **Innovation File Document upload:**

N/A

## **Please provide appropriate references (PubMed, Abstract, Website):**

### Project PRISM

Lorenz Press Release - PRISM Overview

<https://www.lorenz.cc/News/press-releases/press-release.cfm?ID=386>

### Project PRISM Summary Page PDF

[https://20779781.fs1.hubspotusercontent-na1.net/hubfs/20779781/FDA/PRISM%20RCA-FDA\\_CBERR\\_CDER\\_ODT\\_Bayer\\_BI-%20FINAL%2020231005%20SUMMARY%20PAGE%20-%20RELEASABLE.pdf](https://20779781.fs1.hubspotusercontent-na1.net/hubfs/20779781/FDA/PRISM%20RCA-FDA_CBERR_CDER_ODT_Bayer_BI-%20FINAL%2020231005%20SUMMARY%20PAGE%20-%20RELEASABLE.pdf)

### PhUSE US CSS 2024 - PRISM Presentation

[https://phuse.s3.eu-central-1.amazonaws.com/Archive/2024/CSS/US/Silver%20Spring/PRE\\_03.pdf](https://phuse.s3.eu-central-1.amazonaws.com/Archive/2024/CSS/US/Silver%20Spring/PRE_03.pdf)

### PRISM Press Page (DNAnexus / BI / FDA)

<https://www.the-prism-project.com/prism-press>

### □□ FDA / Marty Makary

AgencyIQ: Five Critical Challenges Awaiting Marty Makary

<https://www.agencyiq.com/analysis-life-sciences-five-critical-challenges-awaiting-marty-makary/>

### □□ EMA / CTIS Modernization

EMA Modernizes CTIS

<https://informaconnect.com/ema-modernizes-trial-system-to-make-eu-more-attractive-for-studies/>

### Revised CTIS Transparency Rules

[https://accelerating-clinical-trials.europa.eu/newsroom/news/launch-revised-ctis-transparency-rules-2024-04-22\\_en](https://accelerating-clinical-trials.europa.eu/newsroom/news/launch-revised-ctis-transparency-rules-2024-04-22_en)

### Core Reference Summary

<https://www.core-reference.org/news-summaries/february-2024/>

### □□ Patient-Centric Initiatives

FDA CDER Patient-Focused Drug Development (PFDD)

<https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development>

### CTTI - Patient Engagement Collaborative

<https://ctti-clinicaltrials.org/about/ctti-projects/patient-engagement-collaborative/>

TransCelerate - Patient Technology Implementation Framework

<https://www.transceleratebiopharmainc.com/assets/patient-technology-implementation-framework/patient-technology-assets/>

DIA & Tufts - Patient-Centric Metrics Study (PubMed)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9848715/>

TrialX Blog - Enhancing Clinical Trial Participation

<https://trialx.com/4-patient-centric-approaches-by-which-trialx-is-enhancing-clinical-trial-participation/>

☐☐ Thomson Reuters (TRS)

TRS Whitepaper on Structured Content Authoring

<https://www.thomsonreuters.com/en-us/posts/legal/structured-content-authoring-white-paper/>

TRS Joins FDA Project PRISM - Press Release

<https://www.thomsonreuters.com/en/press-releases/2023/december/thomson-reuters-joins-fda-initiative.html>

☐☐ DNAnexus & FDA Collaboration

DNAnexus Regulatory Submissions Platform

<https://www.dnanexus.com/solutions/regulatory-submissions>

DNAnexus Joins FDA PRISM - Blog Announcement

<https://www.dnanexus.com/blog/dnanexus-joins-fda-prism-to-accelerate-drug-approvals>

☐☐ Cloud Adoption in Life Sciences

Deloitte - Cloud in Life Sciences Industry Report

<https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/life-sciences-cloud-computing.html>

AWS - Life Sciences Solutions

<https://aws.amazon.com/health/life-sciences/>

## **References File Document upload:**

N/A