DNAnexus®

Accelerating External Innovation: Trusted Research Environments (TREs) for Biopharma

Executive Summary:

Biopharma increasingly depends on external innovation, with over 60% of new drugs originating externally through partnerships with biotech startups, academia, and consortia. Yet, securely managing sensitive data and maintaining compliance remain critical hurdles. Trusted Research Environments (TREs) from DNAnexus address these challenges, enabling pharma leaders to rapidly access high-quality external assets while maintaining stringent security, compliance, and collaboration standards.

The Challenge: Overcoming Barriers to External Innovation

External collaborations have become essential for filling pharma pipelines, driving nearly 70% of new pipeline assets. However, these partnerships face significant obstacles:
Data Security Risks: Sharing sensitive genomic, clinical, and proprietary data externally risks data breaches, IP loss, regulatory penalties, and reputational damage.

- **Complex Regulatory Compliance:** Navigating evolving regulations (e.g., HIPAA, GDPR, GxP) complicates multi-party data sharing.
- **Fragmented Collaboration Tools:** Different IT systems, incompatible data formats, and manual processes impede efficient, scalable collaboration.
- **Heterogeneous Data Integration:** Multi-modal datasets (clinical, genomic, imaging) are often siloed, impeding meaningful analysis and insight generation.

Why TREs Matter for Biopharma:

- Rapidly integrate external innovation assets
- Secure sensitive multi-modal data
- Maintain robust compliance with industry regulations
- Enable scalable, real-time collaboration
- Accelerate drug discovery and reduce time-to-market

The Opportunity with Trusted Research Environments

TREs provide secure, cloud-based platforms specifically designed for sensitive biopharma data, enabling safe, compliant collaboration without data leaving the controlled environment.
DNAnexus TREs utilize the "Five Safes" framework, ensuring:

1. **Safe People:** Robust identity verification, role-based permissions, and user training.
2. **Safe Projects:** Ethically justified research with strict data use approvals.
3. **Safe Settings**: End-to-end encryption, continuous monitoring, and certifications (HIPAA, GxP, GDPR, FedRAMP).
4. **Safe Data:** Anonymized, pseudonymized, securely managed datasets with granular visibility controls.
5. **Safe Outputs:** Rigorous reviews ensuring compliance before any data leaves the environment.

Key Capabilities of DNAnexus TREs:

Secure Multi-Stakeholder Collaboration: Unified, virtual collaboration spaces eliminate data silos, streamline workflows, and enhance real-time data access and version control.

Built-In Regulatory Compliance: Automatically ensures adherence to HIPAA, GxP, GDPR, and FedRAMP standards, simplifying audits and compliance processes.

Advanced Data Integration: Unified integration of multi-modal datasets enables comprehensive, cross-modal analyses (e.g., correlating genomic mutations with clinical outcomes).

Embedded Analysis Tools: In-platform bioinformatics and data science tools streamline analysis, promote reproducibility, and reduce dependency on external IT resources.

Proven Value to Pharma Pipelines:

Faster Time to Market: Accelerate project workflows by up to 50%, enabling quicker progression from discovery to market.

Significant Productivity Gains: Reduce developers' workload by 50% and bioinformaticians' workload by 40%, translating into substantial productivity and efficiency gains.

Robust Compliance Management: Leverage built-in compliance certifications, reducing risk of regulatory fines and enhancing global collaboration ease.

Enhanced Data Security: Secure cloud-based environment significantly lowers risk of data breaches, ensuring safer data handling and transfer.

High Return on Investment (ROI): Realize substantial financial benefits through operational efficiencies, productivity gains, and reduced risk of compliance issues.

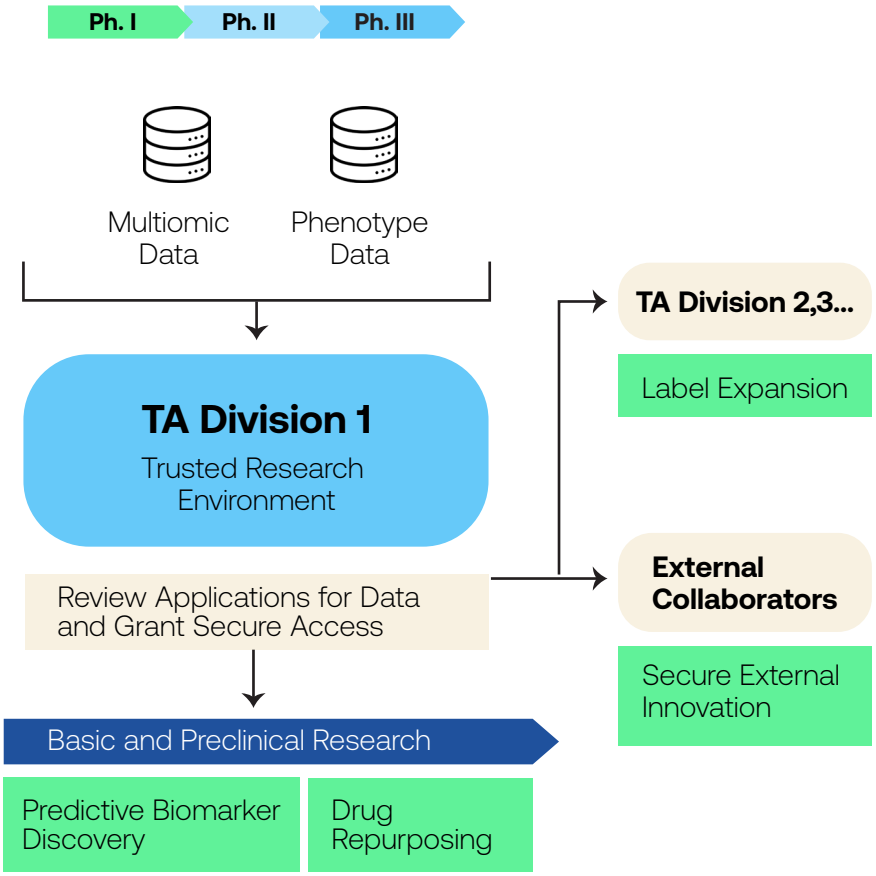
Case Example

Customer's Goals:

1. Inform therapeutic improvement
2. Accelerate drug repurposing and label expansion
3. Identify better predictive biomarkers

Solution Benefits:

1. De-risking clinical trials
2. Reduce development times
3. Outpacing competition



A top 3 pharma company leveraged DNAnexus TRE to integrate disparate multi-site, multi-trial clinical trial data securely. Facing significant challenges in integrating these data and making them securely accessible to internal and external stakeholders, the company quickly recognized the inefficiency of developing an internal solution. By partnering with DNAnexus, the company streamlined data integration, enabled real-time interpretation, and significantly accelerated their understanding of genetic and clinical features influencing patient treatment responses. The secure, compliant, and scalable DNAnexus platform allowed researchers to rapidly access integrated data, fostering quicker, more informed therapeutic decisions.

Partner with DNAnexus to *Unlock* Secure External Innovation

Accelerate your organization's external innovation pipeline by leveraging the proven capabilities of DNAnexus TREs. Contact us today to learn how we can help you securely access, analyze, and integrate high-value external assets—rapidly filling your pipeline and bringing transformative therapies to market faster.

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