

DNAnexus[®]

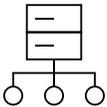
Enabling *Collaborative* Research to Support Drug Discovery

Trusted Research Environments Purpose-Built for
Clinico-Omics Data Integration and Collaboration

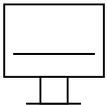
The Challenge

In the rapidly evolving pharmaceutical R&D landscape, it is increasingly necessary for organizations to get the most from available data so they may bring therapies to market faster and bolster their competitive advantage by reducing time-to-insight. At the same time, it is increasingly difficult to manage and extract value from the growing wealth of clinico-omics data (i.e. data comprising real world data [RWD] and biomolecular data).

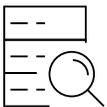
CRITICAL CHALLENGES THAT DEMAND ATTENTION ARE:



1. Data Standardization – Clinico-omics data are being generated in increasing and distributed ways, both within organizations and through various external data providers. Along with these disparate data sources comes a variety of data formats and ontologies. The challenge lies in harmonizing these data in a way that is normalized across data sources and usable for downstream analyses.



2. Data Accessibility, Security, and Regulatory Compliance – It is crucial that stakeholders of varying technical backgrounds have access to data and analysis capabilities. However, organizations struggle to provide a unified platform that i) allows non-coding users to access the utility of the full dataset through responsive dashboards with the ease of traditional, smaller scale BI tools, ii) provides powerful back-end infrastructure and modern informatics tools to enable complex data science at scale, and iii) meets all security and regulatory compliance requirements.



3. Interoperability – Rarely is a complete data catalog used by one group for a singular purpose. Multi-modal data provide value in a number of ways across functions, therapeutic areas, or geographical regions. With this versatility in data value comes variability in analysis systems and procedures as well as a diverse portfolio of sophisticated technological tools. Organizations encounter challenges with system interoperability and integration, as well as procedural standardization and analytical reproducibility across teams and regions.

Solving these challenges comprehensively requires a significant investment of time and resources. The adoption of new solutions or adaptation of existing solutions requires specialized knowledge and infrastructure that must be built and maintained over time.

Our Solution: A Comprehensive and Interoperable Precision Health Data Platform

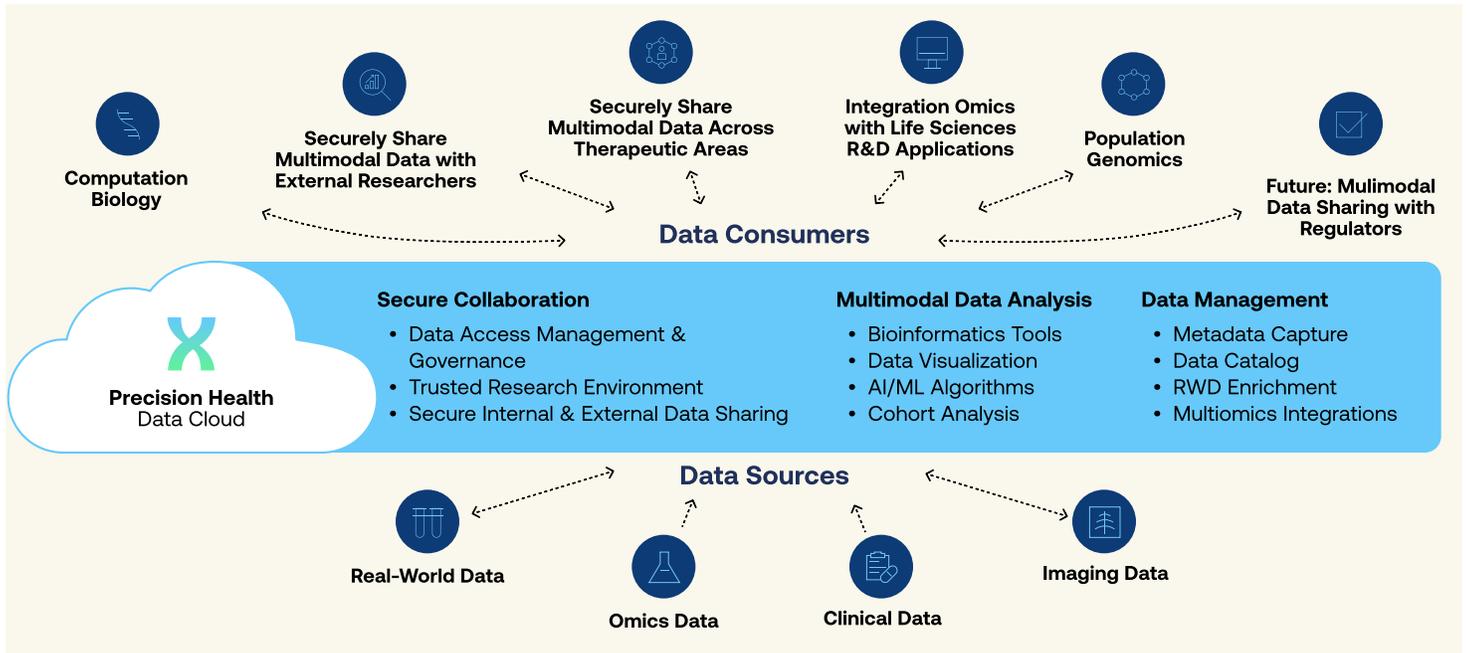


Figure 1. A Schematic Representation of the Precision Health Data Cloud

DNAexus empowers pharma teams with a cloud-native trusted research environment (TRE) that streamlines data integration, enables secure collaboration, and delivers IT-ready, turn-key GxP compliance, all while ensuring interoperability with existing systems. With DNAexus, teams gain a TRE that delivers:

Data Ingestion and Harmonization: DNAexus offers robust capabilities to ingest and harmonize clinico-omics data from various sources. Advanced data integration techniques — including data mapping, standardization, and normalization — streamline the integration process, ensuring high data quality and consistency.

User-Friendly Interface: DNAexus’ intuitive UI supports users of varying roles and technical backgrounds, facilitating easy data exploration, analysis, and collaboration. Interactive dashboards, customizable visualizations and user-friendly workflows make the platform easy to leverage by any data stakeholder, including decision makers, researchers, clinicians, and regulatory personnel. Additionally, the UI, underpinned by DNAexus’ industry-leading security and regulatory compliance features, serves as the foundation for a clinico-omics data dashboard that allows organizations to securely make available their data to a broader community of precision health stakeholders.

Secure, Collaborative Data Cloud Workspaces: DNAexus provides a variety of solutions for data collaboration and dispensal. We enable secure bi-directional interactions between team members, across cross-functional groups, or

between organizations. Our workspaces support users of all roles, providing programmatic access to clinico-omics data while enabling data stewards' full ability to control/lock down data access. Underscoring this offering is an unwavering commitment to data security and regulatory compliance through the implementation of robust encryption, access controls, and full audit trails and data provenance. Our platform facilitates secure, bidirectional data engagements with collaborators of all types while adhering rigorously to industry regulations such as GxP compliance, HIPAA, GDPR, and 21 CFR Part 11.

Interoperability with Organizational Software: DNAnexus seamlessly integrates with existing organizational software, enabling smooth data exchange. Whether electronic lab notebook (ELN) systems, laboratory information management systems (LIMS), or clinical data management software, our platform ensures seamless integration across different systems.

CASE STUDY 1: Integrating Clinical Trial Data For Secure Access Across Stakeholders

A top 3 pharma company approached DNAnexus based on their positive experience with the DNAnexus-powered UK Biobank Research Analysis Platform, the world's largest public clinico-genomic TRE. The company was generating large amounts of clinical trial (CT) data for therapeutics that are being brought to the market, but did not have a solution for integrating these data or making them accessible to internal and external stakeholders in a manner that was secure and compliant. Their key needs were to integrate disparate multi-site, multi-trial data and provide real-time interpretation of these data that would enable them to better understand the genetic and clinical features that underlie whether a patient responds to the various treatments in the CTs. However, after assessing the requirements, their team quickly concluded that the development of a do-it-yourself solution would require a significant investment of time and resources and, as one team member stated, "We are a pharmaceutical company - we could hire people to build (a solution), but our focus is on drug development, not software development."

Solution Requirements:

1. Integration of clinical trial datasets in a TRE
2. Cohort creation and real-time data interrogation
3. Versatile usability for programmers and non-programmers
4. Data access controls and support for data access proposals

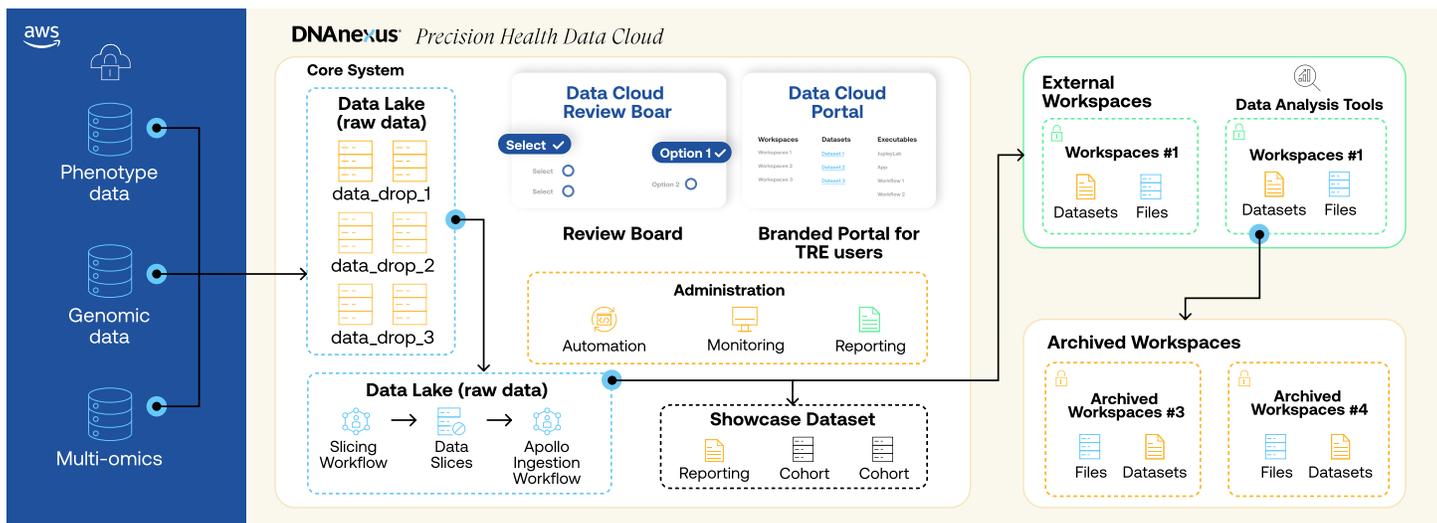


Figure 2. Solution Architecture Diagram

The technical capacity and agility of the DNAnexus platform along with the company’s wealth of experience in standing up enterprise TREs were key differentiators that led to the selection of DNAnexus as the partner to achieve their ambitious goals. Our solution provides researchers the ability to select data, create a cohort, submit this cohort to a proposal review board, and then dispense the relevant data types in a ready-to-use translational informatics environment, all within a secure and regulatory compliant platform that prohibits data from leaving the environment.

CASE STUDY 2: Ingesting, Harmonizing And Updating Multimodal Clinico-Omics Data From 700,000+ Patients For Secure Access And Collaboration

The ingestion and harmonization of diverse real world and clinico-omics data into a usable, integrated dataset requires deep domain knowledge and data science skill. Data often originates from multiple sources, each with their own schema and format. The disparate nature of these data, coupled with their growing volume and complexity, makes the data difficult to integrate and analyze effectively.

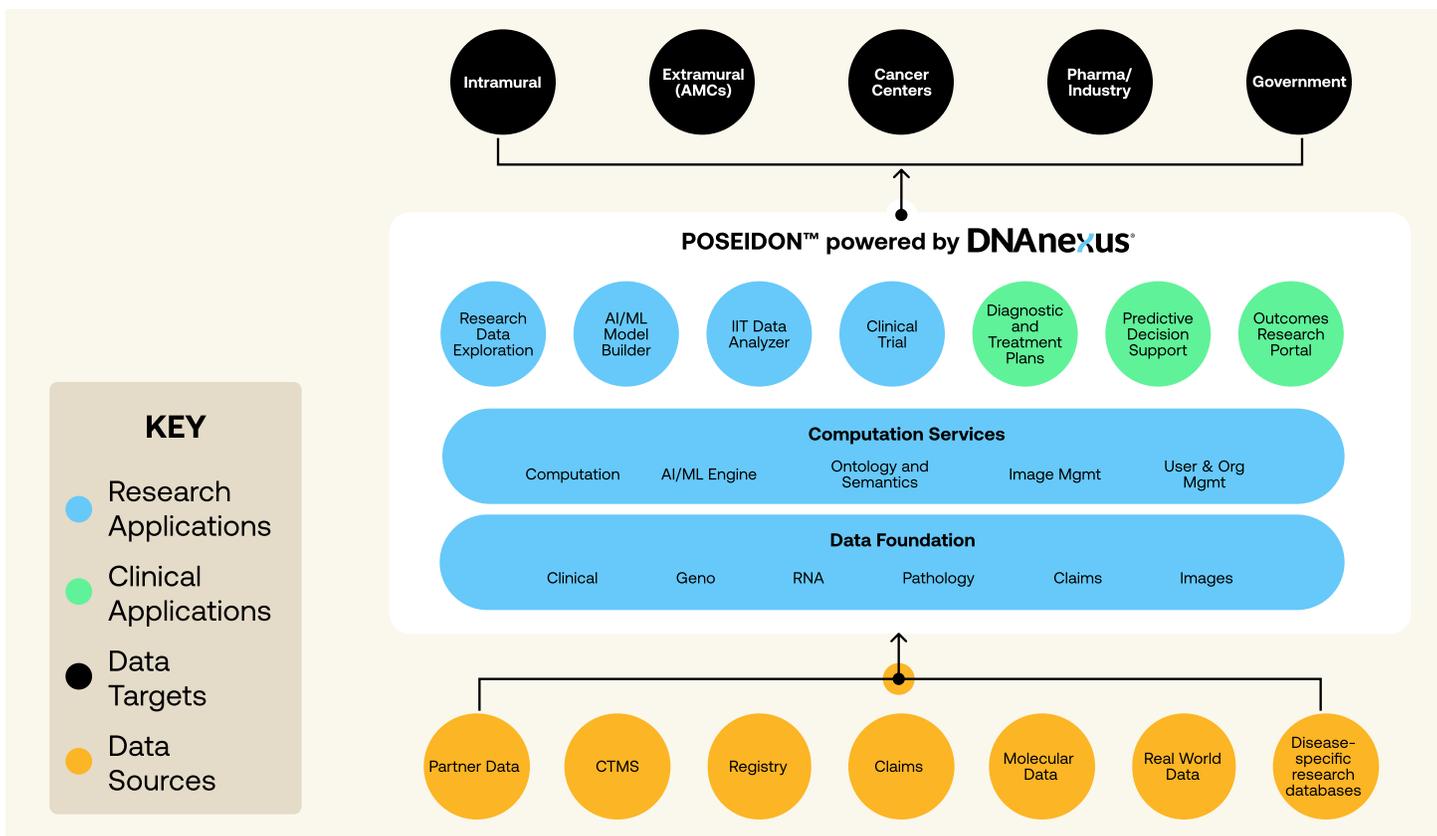
City of Hope, one of the world’s leading comprehensive cancer care centers, needed a precision oncology data and analysis ecosystem that could be updated with the latest patient data on a daily basis to support research and ensure high-value data emanating from varying sources was protected and FAIR (findable, accessible, interoperable, and reusable). City of Hope partnered with DNAnexus to develop a powerful cloud-based precision health data solution – the Precision Oncology Software Environment Interoperable Data Ontologies Network (POSEIDON™). POSEIDON™ harnesses the capabilities of DNAnexus’ platform to wrap multimodal data in a secure and compliant research environment where clinicians and researchers can explore, analyze and visualize de-identified, clinico-genomic data from over 700,000

hospital patients, as well as data from public sources. Automated nightly updates ensure that users are always accessing the most up-to-date patient data. POSEIDON™ provides data stakeholders with insights that inform in-house drug development, spark new research ideas, improve clinical trial matching, enable AI and machine learning model development and training, provide critical decision support for tumor boards, and more.

Solution Requirements:

1. Integration of multi-modal clinico-omics and imaging data
2. Support clinical and non-clinical users with an intuitive dashboard
3. Command line experience that supports client-led customization
4. Cohort creation and real-time data interrogation

POSEIDON™ has become a critical strategic asset for City of Hope. It enables better patient care, simplifies data integration, and makes an invaluable ecosystem of up-to-date precision oncology data accessible to users of diverse roles and responsibilities. Using the POSEIDON™ platform, researchers are extracting unprecedented value from precision health data to accelerate advances in cancer screening, diagnostics, and therapeutics that benefit patients everywhere.



Conclusion: DNAnexus has the experience and capabilities to address the critical challenges faced by pharma groups in ingesting and harmonizing multimodal clinico-omics data, and integrating diverse clinical trial data. By providing a secure and compliant solution that supports collaboration, is interoperable with existing organizational software, and deploys user-friendly interfaces, we empower all stakeholders across the drug discovery and development value chain to drive analyses to data-driven insights, streamline research processes, and accelerate the discovery of new therapies.

Trusted by:



Interested in learning more about moving multi-omics analysis to the cloud? Contact DNAnexus (info@dnanexus.com)

ABOUT DNANEXUS

DNAnexus is a leading provider of secure, scalable, and intuitive biomedical data analysis software and bioinformatics applications for the life sciences and healthcare industries. We actively manage and support more than 80 petabytes of complex genomic, multi-omic, and clinical datasets on behalf of a growing network of collaborations with large-scale biobanks, as well as leading pharmaceutical, clinical diagnostic, academic research, and government organizations. Scientists across 48 countries are now using our platform to gain data-driven insights that can advance scientific discovery, accelerate precision medicine, and improve patient care.