

INTRODUCING

CLINICAL TRIALS SOLUTION

A Robust, Regulatory-Compliant Platform for NGS-Driven Clinical Trials

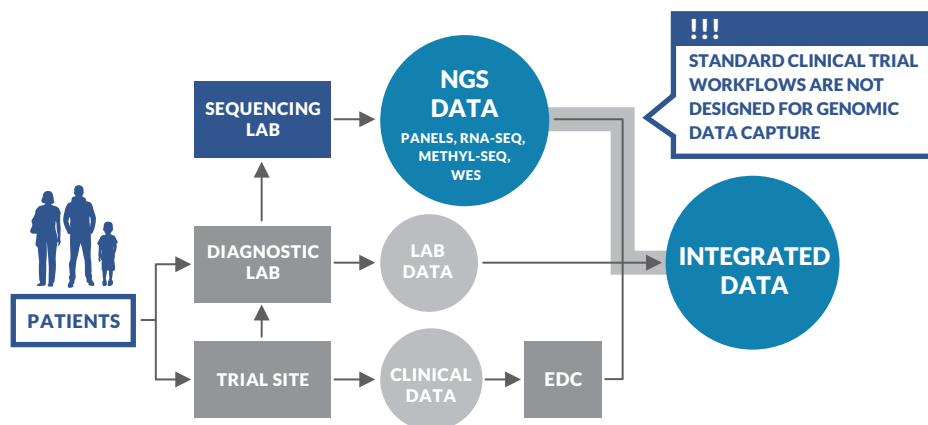
THE DNAnexus[®] CLINICAL TRIALS SOLUTION

Unlike general purpose data warehouses and clinical trials management software (CTMS), DNAnexus Clinical Trial Solution is optimized to handle the scale and the complexity of NGS data and is validated for use in drug discovery and development environments.

Security, privacy, quality, and compliance are core attributes of the Clinical Trial Solution, providing the versioning, tracking, logging, auditability, and reproducibility data required to effectively use NGS data for any purpose across the drug development continuum.

THE CHALLENGES WITH NGS-DRIVEN CLINICAL TRIALS

Bringing a drug through FDA approval can take 10+ years and cost over \$2 billion. By investing in next generation sequencing (NGS) in early-stage clinical trials, later phases can be optimized and de-risked. However, standard clinical trial workflows and tools are not designed to handle NGS data.



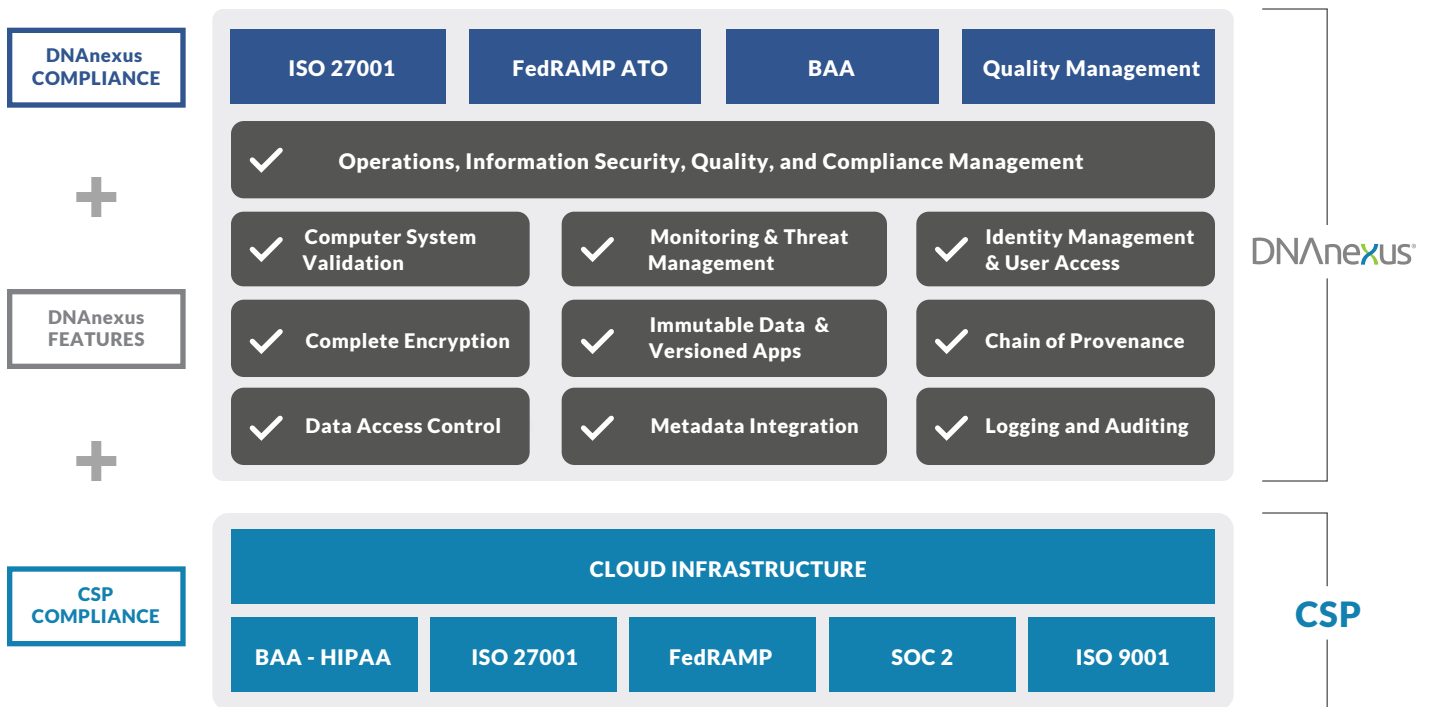
PLATFORM FEATURES

- GxP, 21CFR11, and 21CFR820 compliant
- Data encryption at rest and in transit
- Data provenance
- Submission portal for all NGS data
- Workflow audit trail

+ PROFESSIONAL SERVICES

- Computer system validation
- NGS analysis pipeline development and Qualification
- Study manager web portal
- Systems integration (LIMS, CTMS, EDC)

- ✓ **Cloud-Based Platform**
- ✓ **Regulatory-Compliant**
- ✓ **Data Management and Analysis Tools**
- ✓ **Scientific Expertise Required to Integrate NGS**
- ✓ **Increased Probability of Technical and Commercial Success**



USE CASE

A top 5 global pharmaceutical company is using the DNAnexus Clinical Trial Solution to forego the cost and time of setting up and maintaining GLP validated systems for handling NGS and other -omics data. They turned to DNAnexus to address the challenges of integrating genomics and study data to:

- Inform patient stratification and improve enrollment and trial accrual rates.
- Assign patients to appropriate intervention pathways.
- Mine genomic and clinical outcome data to discover biomarkers of response and/or resistance.

ABOUT DNAnexus®

DNAnexus, the leader in biomedical informatics and data management has extensive experience managing large-scale genomics projects in the cloud, helping NGS-driven clinical diagnostics companies, and powering the community portals for both precisionFDA and the St. Jude Cloud.

Contact DNAnexus to learn more about how the Clinical Trial Solution can help you validate bioinformatics pipelines and integrate NGS and other omics data to improve the efficiency and outcomes of NGS-driven clinical trials.

Please visit www.dnanexus.com
or follow the company @DNAnexus