WHITE PAPER

10 Tips to Scale

Scale Your Diagnostics Business and Grow Your Test Portfolio Globally

DNAnexus®

Contents

ntroduction	01
Flexible Scaling	02
Ensure Quality & Uniformity	03
Enable Collaboration	04
Mitigate Risk: Security & Compliance	04
Optimize Your Pipeline	05
Reduce Turnaround Time	06
Expand Your Test Portfolio	07
Value Support	08
Reduce Capital Investment in Infrastructure	08
Future-Prooof Your Business	09
Key Takeaways	10
DNAnexus Platform	11
About DNAnexus	12

Introduction

You've jumped ahead of the curve, leveraging multiomics, including next generation sequencing (NGS), to advance precision medicine for better patient care. And now you are experiencing an explosion of demand. Well done!

It's time to expand and potentially go global. But how do you handle the increased test volume and the daunting regulations involved in offering your services in new regions and countries? Not to worry. Here are 10 tips to help accelerate your success as you scale up your business and grow your test portfolio.

1. Flexible Scaling to Unlock Your Full Potential

Eliminate Bottlenecks

Moving your NGS and multiomics analysis to the cloud will give you an environment that can flexibly scale to meet the demand for increased test volume, all while saving time and money. Cloud-based platforms enable you to optimize analysis pipelines for quality, speed, runtime, and cost. The cloud eliminates bottlenecks in processing queues and server capacity. Yet, not all cloud-based systems are created equal. NGS and multiomics analysis has unique requirements.

Purpose-built cloud platforms enable you to optimize analysis pipelines.

Look for vendors with solutions purpose-built for genomics. Who have proven track records supporting leading diagnostic testing organizations across a wide range of applications. Several leading diagnostic testing companies have chosen to partner with DNAnexus to move their pipelines to the cloud.

2. Ensure Quality and Uniformity Across All Your Sites: *From Regional to Global*

Safely Expand Your Footprint

Expand your footprint both locally and globally by bringing all production pipelines into a single, unified environment, with version-controlled pipeline updates rolled out simultaneously across your locales. Decentralize your sequencing among multiple sites or global lab partners while ensuring compliance and intellectual property (IP) protection by keeping your proprietary pipelines centralized in your home region.

CASE STUDY:

Noninvasive Prenatal Testing Company

When a leading genetic testing company decided to expand its NGS genetic test marketshare, it needed a global solution to decentralize the sequencing across partner laboratories, yet centralize the data analysis of the company's patented SNP-based algorithms. It selected DNAnexus for its flexibility to support the company's portfolio of genetic tests and expansion into other regions and countries.

3. Enable Instant Collaboration Between Labs and Customers

Share While Maintaining Control and Reproducibility

As you collaborate internally and with teams outside your organization, you don't want to be distracted by difficulties accessing data, sharing pipelines, and advancing your R&D efforts. You should look for a cloud-based informatics platform purpose built to share large datasets, version-controlled tools, notebooks, and analyses securely and efficiently, no matter where they are located. Select a vendor solution with fine-grain administrative controls and data provenance tracking to ensure auditability and reproducibility.

4. Mitigate Risk by Finding a Trusted Partner for Security and Compliance Hassles

The Ever-Changing Regulatory Landscape

It is difficult to expand business to new regions or countries while ensuring compliance with data sovereignty requirements and IP protection across locations. To make it work you will need to control access to IP, like pipeline algorithms and sensitive health data, and to comply with and continually monitor regionally-specific regulations.

In lieu of hiring staff to continually monitor the ever-changing regulatory landscape, work with a vendor that has a proven track record of helping customers succeed by building solutions that meet the industry's most strict compliance regulations, including:

FedRAMP

Cyber Essentials Plus

Strict Production

ISO 270001

Data Privacy

System Access

PCI DSS

Framework

Control

Cyber Essentials

HIPAA

CAP/CLIA

End-to-End

Encryption

21 CFR Part 11

GDPR

IVDR

Audit Trail

5. Optimize Your Pipelines

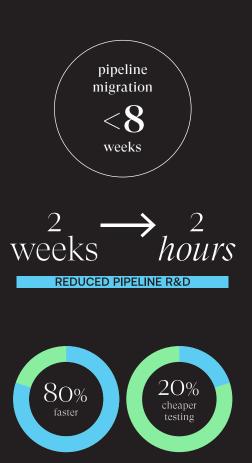
Your Pipelines Are Your Competitive Edge

Invest in your pipelines and look for ways to optimize performance as you move them to the cloud. Preserve and extend your analysis and ensure interoperability with CWL, WDL, Nextflow, and dockerized workflows that make cloud migration easy. Look for experts to help with computational optimization.

CASE STUDY:

DNAnexus and a Leading Molecular Diagnostics Company

The professional services team at DNAnexus helped our customer construct accurate, robust and efficient analysis pipelines, and to optimize pipelines for quality, speed, and runtime cost. Our customer was able to move its pipeline to the cloud, resulting in 80% faster informatics analysis for 20% less cost in a matter of a few months. In addition, their pipeline R&D was reduced from two weeks to two hours.



6. Automate and Integrate to Reduce Turnaround Time and Improve Traceability

Don't Put Turnaround Times at Risk

With patients' health tied to test results, you can't afford to put turnaround times at risk. Improving the informatics portion of your turnaround time can be achieved through automation and integration with systems for a seamless end-to-end solution.

Look for a solution that automatically captures and manages sample-level metadata, so you can efficiently search for and filter data and samples when you need them. Integrate your pipeline analysis with upstream and downstream systems, such as LIMS, clinical reporting and visualization apps using open APIs and SDKs.

End-to-End Visibility and Consistency

A robust streamlined solution will automatically upload sample data from sequencing instruments and deliver results immediately when the analysis is done – all without manual processing steps. Achieve end-to-end visibility, operational consistency, auditability, and reproducability by tracking all data, tools, and workflows.

Achieve end-to-end visibility, operational consistency, auditability and reproducability by tracking all data, tools, and workflows.

Get to market faster.

7. Reduce Time to Market for New Tests

Rapidly Expand Your Test Portfolio

As you add new tests to your existing offerings, you don't want to be slowed down by the complexity of managing multiple tools, systems, and data streams when creating, refining, and validating pipelines. Working at unprecedented speeds requires secure access to millions of your production samples without manual file transfers so you can quickly assess and validate pipelines.

For example, features such as Smart Reuse on the DNAnexus platform significantly reduce development time by applying compute resources only to the downstream parts of the pipeline you're optimizing. This allows for the reuse of outputs from earlier steps that were unchanged, and thus decrease the time and cost of iterating on a pipeline code, ultimately letting you get to market faster.

8. Don't Underestimate the Need for Support

Avoid Bottlenecks

Slow compute times, backlogged queues and cumbersome processes for accessing test data creates bottlenecks that can delay your turnaround time. Premium production support helps maintain business continuity for enterprises running mission-critical processing. Select a provider with deep domain expertise in advanced bioinformatics. Make sure the provider offers 24/7 technical support to continually optimize your workflow and computational approach.

9. Reduce Capital Investment in Infratructure

Consider the Best Use of Your Resources

Beware of hidden costs associated with managing your own NGS informatics infrastructure. Consider how your business will grow in the next 3-5 years and the impact on your organization. Do you want to continue to invest time, money, and people in operating, scaling, maintaining, securing, and providing support on secondary genomic analysis infrastructure?

Revisit your options for purchasing a purpose-built NGS bioinformatics platform and compare the total cost of ownership between those systems and your current costs. Also consider the lost opportunity costs by tying up your resources and headcount on software development.

When you consider features of your bioinformatics platform, ensure it has spend management tools. Tools to monitor and reduce costs and enforce budget limits will help you be more efficient and eliminate waste. Advanced forecast analysis and budgeting tools will support your spend planning and decision making.

10. Future-Proof Your Business

A Long Term Solution

It's paramount to select a vendor that not only meets your immediate needs, but can grow with your future expansion goals. You need a long-term solution that can scale with the increases in your computational and storage demands, as well as changes in lab and analysis workflows.

The velocity of technological innovation requires a partner who keeps pace to ensure you are at the forefront of the industry. Select a vendor that enables your teams to continually push the boundaries and focus on what they do best: test development and delivery of results to improve outcomes for patients.

The velocity of technological innovation requires a partner who keeps pace.

10 Key Takeaways

- o1 | Using the cloud for analysis eliminates bottlenecks in processing queues and server capacity, enabling you to optimize analysis for quality, speed, runtime, and cost.
- 02 | Cloud-based informatics solutions enable sequencing to be decentralized to take place in multiple global laboratories, while keeping the analysis pipelines centralized in your home region.
- o3 With a cloud platform, you can easily share datasets, version-controlled tools, and analyses securely and efficiently among your research team.
- o4 With a seamless end-to-end solution, you can optimize the informatics portion of your research and production analysis, reducing turnaround time for customers.
- 05 There are hidden costs associated with building and maintaining your own NGS informatics infrastructure. Partnering with a trusted vendor can save you time and money.

- o6 When evaluating enterprise-scale genome informatics solutions, look for a vendor that meets necessary industry compliance regulations, including HIPAA, CAP/CLIA, 21 CFR Part 11, GDPR, and more.
- o7 Don't fret about migrating your pipelines to the cloud. Look for a platform that ensures interoperability with CWL, WDL, and dockerized workflows. This makes migrating your pipelines to the cloud easy so your analysis can be up and running quickly.
- o8 | Look for tools that stay updated with the latest engineering advancements to continually optimize your processes for efficiencies so you can plan for expansion.
- og | Select a provider with 24x7 technical support from experts with domain expertise and advanced bioinformatics skills.
- Find a long-term solution that will scale with your increasing computational and storage demands, as well as changes in lab and analysis workflows.

DNAnexus®

Take the first step to optimize your operations. See how DNAnexus can help your lab do more, with less.

info@dnanexus.com
dnanexus.com/clinical-diagnostics

About DNAnexus

DNAnexus is a pioneer in providing cloud-based data analysis and management solutions tailored for the life sciences industry. Our platform empowers all life science data stakeholders by offering advanced tools for clinico-omics data analysis, fostering insights into disease mechanisms, therapeutic target discovery, and precision medicine. DNAnexus emphasizes collaboration, security, and compliance, ensuring that data handling meets the highest standards, thus accelerating scientific discovery and innovation in healthcare.

www.dnanexus.com