WHITE PAPER

DNAnexus®

Build vs. Buy?

Six Questions to Consider when Evaluating Clinical Diagnostics Informatics Solutions

NGS data analysis management systems are the backbone of your lab, providing vital functionality for day-to-day workings of your business delivery. As a result, decisions about the tools to invest in can have far-reaching implications.

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Build or Buy?

Your lab has adopted the latest next-generation sequencing (NGS) technology and is on the cutting edge of clinical diagnostics. But the challenge is a deluge of data and the additional security and compliance considerations that come with it.

You may be deciding whether to improve, augment or entirely replace your existing systems. There are advantages and disadvantages to these approaches. Whichever you are considering, start with an evaluation of where you are today.

Should you improve, augment, or entirely replace your existing systems?

6 key success criteria that all lab leaders should evaluate as they plan for future growth:

1. Is the system scalable?
2. Can I improve my sample turnaround time?
3. How does the system handle quality, security, and compliance?
4. Can I expand globally?
5. Will I have the flexibility and extensibility I need?
6. How will this impact my operations support needs?

1. Is the System *Scalable?*

Feeling like a victim of your own success?

With the growth in genomic testing, many diagnostic providers find that their data management and analysis system was originally designed for a much lower volume of tests than they currently require. As demand and scale increases, complexity increases.

Existing systems experience unplanned downtime, difficulty deploying new pipelines, and challenges in finding and accessing data. Systemic issues that were once hidden start appearing and the system begins to fail, which bottlenecks future growth.

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.

If you experience a steep increase in workload you want a reliable system that is prepared to grow alongside you.

Cloud architectures provide scalability.

A cloud platform has the ability to auto-provision new workers as demand increases, which prevents production delays. However, most DIY cloud implementations don't parallelize easily. On a well-designed platform, you can run hundreds of assays in parallel, the overall execution time is slightly more than the timing of a single run.

Tracking and finding samples is crucial to running a lab. As data comes off the sequencer, you want to continue to track the sample through the dry lab. Applying metadata to your files is a key strategy to aid in data retrieval. Your informatics solution needs to be able to easily label data both for future retrieval and for traceability. A good system will have tools for easily automating the application of metadata to samples.

As demand and scale increase, complexity increases.

2. Can I Improve My Sample Turnaround Time?

You can't afford to put turnaround times at risk.

With patients' health on the line and your business service-level agreements, you can't afford to put turnaround times at risk. Your future growth also depends on being able to process more samples. To do this efficiently, you need to optimize your informatics pipeline, and minimize unplanned downtime.

Many homegrown solutions suffer from long processing queues, excessive compute times, and recurring downtime.

Get the best mileage out of your analysis pipeline.

Look for experts with experience in optimizing both the analysis steps and the computational backplane that the pipeline runs on. Benchmark your current analysis time to monitor your gains in efficiency.

More advanced pipelines can benefit from running each segment on the most appropriate computational server instance. By doing that, you not only improve performance, but you can also lower costs.

Case Study: Leading Molecular Diagnostic Company

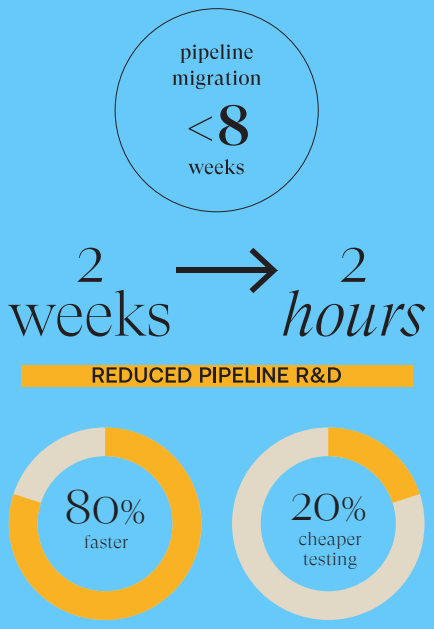
The Challenge

Designing a new or updated pipeline is an iterative process that involves running and re-running variations of the improved pipeline and validating the output results. To do this, labs need to re-test known samples in the newer pipelines. This can be time consuming and can incur compute expenses, increasing the time before a pipeline is ready for production.

The Solution

This company leveraged a suite of features on the DNAnexus platform to address this challenge. On DNAnexus, it was able to run its newly created R&D pipelines in the same environment as their production data. This allowed the R&D team to easily access the data from production. In running the test pipelines, DNAnexus' Smart Reuse feature leveraged previous outputs for stages that don't have upstream modifications instead of running from scratch. This lowered the total development time to the amount of time it takes to develop and run only the modified part of the pipeline.

This customer's move to DNAnexus resulted in increased efficiencies.



3. How Does the System Handle Quality, Security, and Compliance?

Three Critical Dimensions

Clinical diagnostic companies must contend with. ever-increasing regulatory, security, and industry expectations. Consider three critical dimensions to examine in an informatics platform: Security, Privacy and Quality. Each of these dimensions are interdependent. While their importance may vary depending on specific use cases, each dimension is critical to sustain reproducible science.

A Future Proof System

When comparing the security, compliance, and quality requirements of a future-proof system, almost all depend upon robust authentication and authorization; track-and-trace functionality of people, objects, data, and information; clear data and object governance; and much more.

Quality, security, and compliance are required for reproducible science.

DIY System Management

Managing do-it-yourself systems increases the burden on your staff because it takes time and expertise to build compliant processes that are auditable and reproducible while protecting security and privacy. Depending on the regions where you do business, you'll be subject to different certifications and regulations, including HIPAA, CAP/CLIA, and 21 CFR Part 11 in the US; and GDPR and IVDR in Europe.

While many cloud providers offer some of these, building a compliant system on top of a horizontal cloud-provider still requires work and expertise to meet these requirements. Many diagnostic labs opt to work with companies such as DNAnexus, which have purpose-built genomics cloud infrastructure meeting all these requirements, and more out of the box.

4. Can I Expand Globally?

Expand Your Footprint and Protect Your IP

As your business grows, you may need the capability to expand to multiple locations in one country or around the world. Managing multiple sites requires quality and uniformity across the locations, adhering to data sovereignty requirements for each location while protecting your intellectual property (IP). Many diagnostic labs find their home-grown solutions hamper this growth.

Managing IT data process architecture and local compliance requirements is difficult on your own. Look for solutions that allow you to easily launch new sites while standardizing your pipelines and workflows to ensure consistency. You'll want to make sure you know what pipeline version is running, regardless of which site it's running in. To protect your pipeline IP if you expand into certain geographies, look for experienced professionals who have solved those challenges for other customers.

Managing IT data process architecture and local compliance requirements is difficult on your own.

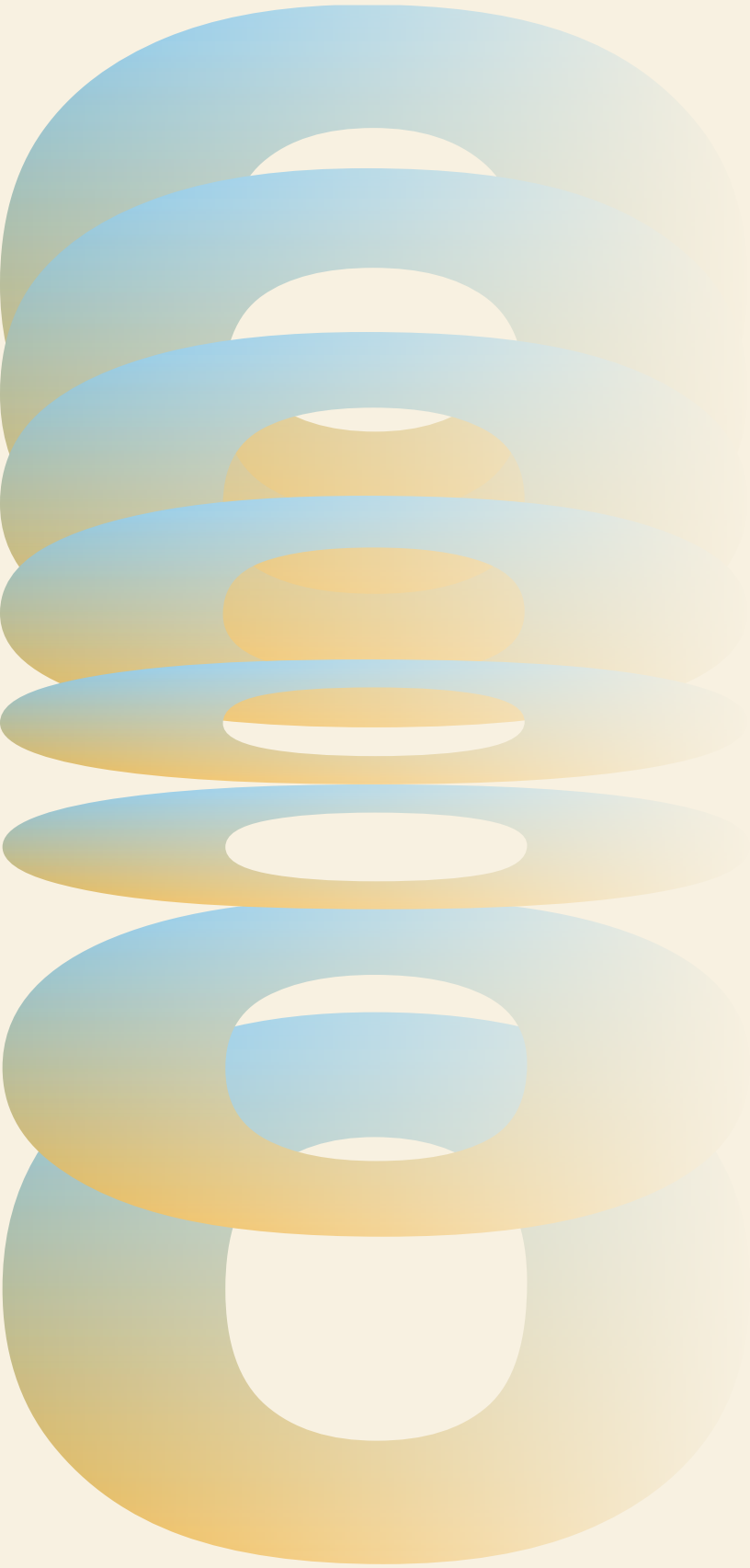
Case Study: Noninvasive Prenatal Testing Company

Future-Proofing Their Investment

When a leading genetic testing company decided to go global, the DNAnexus platform enabled them to easily navigate European Union and US regulations. The platform includes compliance tools for industry-specific certifications and regulations, such as HIPAA, CAP/CLIA, FedRAMP, GxP, ISO27001, and GDPR. These are continually updated to stay in line with new and updated regulations, future-proofing the company's investment.

The DNAnexus platform also comes pre-built with features that provide transparency and accountability by tracking access and interactions with data and tools across the customer's global network. DNAnexus achieves compliance with current and future regulations, standards, and industry frameworks to understand:

- Overlap of control points
- Congruence of security privacy, and quality design principles
- Continuous monitoring of compliance to provide robust guard rails for scientists



5. Will I Have the Flexibility and Extensibility I Need?

Focus On What Matters Most

Improving the informatics portion of your overall turn-around-time can be achieved through automation. You want to remove all manual steps and quickly move data off the sequencer and through your analysis pipeline. A good solution will automate the uploading of data from the sequencer to the informatics platform, perform necessary QC steps and run analyses, all without human intervention. Working with an established informatics platform provider removes this technical burden, allowing your team to focus on what matters most: the science.

While some NGS informatics solutions offer integrations, they can often be too rigid when it comes to the analytic offerings. If you're accustomed to building and hosting your own analyses, then you'll want an easy way to port them to an NGS platform. Look for systems that have an open API and SDK, as well as support industry standards like Docker, Nextflow, CWL, or WDL that will give your pipelines portability. Flexible solutions should include all of this, as well as a development workstation in the cloud where your bioinformaticians can work close to the data while refining your application, simulating your local development environment.

6. How Will This Impact My Operations and Support Needs?

Building a Dedicated Informatics System

Building a dedicated informatics system might seem like a straightforward task. Yet when you consider the significant investment of time, money, and human resources, it may not be the right tradeoff. Pain and financial burden comes with maintaining, scaling, and supporting the system.

Software maintenance and technical support is a continuous commitment. You have to keep the platform up to date with ever-changing security and compliance regulations, software patches and technology updates, which becomes added work for your existing staff and an ongoing resource drain. These challenges can increase business costs by needing to hire additional experts to manage operations, unplanned system downtime, extended turnaround times, and delays in getting new offerings to market.

Pain and financial burden comes with maintaining, scaling, and supporting the system.

Future-Proof Your Investment

Get Ahead of Innovation

You don't want to trail innovation, with insufficient time and focus to build a solution that incorporates all the latest technological advances, and miss out on must-haves and latest developments in cloud computing, analytics, knowledge management, or rich visualization. Compare this with a pre-built NGS genomics platform. By not needing to spend your resources creating your own environment, your team can focus on what they do best – test development and delivery of results – while leveraging the expertise of commercial companies' cloud engineers to optimize and customize the solutions.

An outside vendor comes with engineering excellence offering tailored solutions. These engineers also bring a high degree of industry know-how and experience gained from offering solutions to similar organizations. Additionally, a good vendor will provide 24x7 technical support, training, clear service-level agreements (SLAs), and have system uptime above 99%.

As opposed to the common notion that buying a solution is more expensive than building it, in the long term the total cost of execution and ownership can turn out to be much lower than building a system internally - especially when factoring in maintenance and talent costs. Most times, the commercially available solution will have a vastly lower total cost of ownership, not even considering the opportunity cost of the resources that could have been directed at other priorities, rather than building and maintaining a custom software application.

Conclusion: Build or Buy? Or Both?

Build

Companies that choose to build their own infrastructure generally do so because they think it will be faster, cheaper, and better customized to their specific needs. While this can be true for smaller, ad hoc systems, if you plan to scale and expand your test portfolio, the time, effort, and expense of building and maintaining the system to support complex applications far exceeds these projected benefits. As technology advances, cloud-based genomics platforms must evolve and be highly configurable in terms of workflow, integrations, and extensibility.

Buy

Choose a vendor that offers an out-of-the-box cloud-based enterprise architecture enabling precision health data analysis at scale. Selecting a user-friendly platform allows you to build, automate, and centralize end-to-end bioinformatics workflows - from alayisis to insights. Make sure the interface helps ensure ease of use for non-programmers. A fully-managed security and compliance infrastructure, including 21 CFR Part 11, is a must. In addition, you may need a partner with a platform that offers a data analysis-ready trusted research environment (TRE). This allows you to provide data access to your community of collaborators, customers, and other external users without data ever needing to leave your environment.

Build *and* Buy

But why not get the best of both worlds? Buy a platform that lets you build upon it. A purpose-built NGS platform can save valuable time and resources, as well as provide the flexibility to scale your business while ensuring regulatory compliance and reproducibility. Advanced tooling allows you to build your new pipelines and new offerings quickly, so your bioinformatics team can keep innovating without the need to also build the underlying system. Reputable genomics cloud vendors can provide additional benefits through platforms designed to simplify, enrich and secure your cloud experience.

Key Takaways

DIY Pitfalls

- Unplanned erratic downtimes, processing queues, and excessive compute time leading to unreliable turnaround times
- Burden on internal staff to build and maintain regulatory compliant and auditable processes
- Inability to expand service to new sites, limiting growth
- Hidden costs of infrastruction maintenance and technical support

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Benefits of an Enterprise Bioinformatics Solution

- End-to-end process from data upload from sequencer to informatics platform through QC and analyses
- Integrated features that enable tracking of access and interactions with data and tools
- Continually updated security measures for compliance with ever-changing regulations
- Scalability of cloud architecture for local and global expansion

DNAnexus®

Dedicated to Enabling Your Success

Start the process with a brief scientific consultation to find out how we can help. Contact us at: info@dnanexus.com

For more information about DNAnexus solutions, visit dnanexus.com/clinical-diagnostics

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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.

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