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FROST & SULLIVAN BEST PRACTICES AWARD

NGS INFORMATICS AND DATA MANAGEMENT NORTH AMERICA

Enabling Technology Leadership 2019

DNAnexus®

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2019

BEST PRACTICES AWARD

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Background and Company Performance

Industry Challenges

Recent advances in next-generation sequencing (NGS) technologies, increasing cost pressures, and regulatory uncertainties have driven pharmaceutical (pharma) and healthcare business models from curative to preventive. A molecular-level understanding of the root causes of diseases is paramount to developing targeted drugs and companion diagnostics. Affordable DNA sequencing is encouraging companies to switch from traditional to NGS for commercial diagnostic and translational research, thus promoting the adoption and growth of NGS informatics technology and driving precision medicine.

Frost & Sullivan estimates the 2016 revenue for the United States (US) NGS informatics market at $416.2 million, projected to $992 million by 2021, with a compound annual growth rate of 19% from 2016 to 2021. With a slight increase in interpretation cost over the next 3 to 4 years, companies look to host various paid and free phenotyping, genotyping and multi-omics interpretation databases on their platforms.[1] Driven by pharmaceuticals' high adoption rates, the cloud-based solution segment accounts for 50% to 60% of the total bioinformatics market - potentially reaching 80% to 90% over the next 5 to 7 years.[2]

NGS Data Explosion—Handling, Analysis, and Integration Challenges

Applying an NGS data-driven approach to drug development research has become crucial to developing therapeutics quickly and successfully. Frost & Sullivan points out that affordable DNA sequencing simultaneously has led to an explosion in NGS data volumes. The scale and complexity of genomic, multi-omics and phenotypic data precluded ad-hoc environments. As genomic and clinical data grew massively over the years, researchers faced a data deluge; organizing large cohorts and querying combined data posed a major technical problem. Furthermore, researchers needed a collaborative space to apply tools, conduct data analytics, and gain explainable insights from correlating genotypic and phenotypic data. The need for a method of dealing with large datasets integrating phenotypic and genotypic data became more evident.

However, legacy tools were becoming obsolete and not just costly, but difficult to manage, analyze, and interpret Big Data. A flexible cloud-based informatics platform, capable of handling the enormous scale and providing a complex data processing infrastructure while limiting data storage costs for genomics, multi-omics and clinical research, became critical. Finally, the Big Data challenge with large-population clinical studies demanded automation and scalability in data management and assessment processes.

A Need for Large-Scale, Secure, and Compliant Research Collaboration

Successful translational research initiatives demand seamless collaboration, communication and data integration; however, Frost & Sullivan notes that the volume and variety of multi-omics data can hamper collaboration across global research teams.

With multiple ongoing research projects and novel molecules in the research and development (R&D) pipeline, scientists with variable expertise require a single informatics platform to view, query and analyze data at different scales and individual expertise level. Adhering to industry regulations, standards and infrastructure requirements are vital for clinical research compliance and can involve significant resources, cost and time. Data accessibility (depending on the clinical data's source and variability in informed consent)

and protection and privacy rules mandate engaging an informatics platform with a robust authentication and authorization framework governing data access, usage and sharing across R&D teams. Accordingly, Frost & Sullivan believes that NGS informatics tool vendors providing sequencing-to-reporting capabilities more cost-effectively will emerge as market leaders.

Technology Leverage and Customer Impact

Founded in 2009 and headquartered in Mountain View, California, DNAnexus is one of the leading cloud computing and informatics platform providers for genomic-based translational research. The company provides a secure and scalable platform that allows for scientific collaboration and enables massive genomic and multi-omics data handling and complex processing. DNAnexus operates in 33 countries across North America, Europe, China, Australia, South America and Africa, and supports researchers' diverse genomics programs, such as biopharmaceutical, healthcare, bioagricultural, sequencing services, clinical diagnostics, as well as government and research consortia.

Cloud-based NGS Informatics Platform Accelerates Research and Discovery

The evolution of DNAnexus was motivated by meeting customers' demand for merging genomic and phenotypic data through NGS informatics to accelerate drug discovery research. The company's ability to rapidly integrate with disparate cloud architectures such as Amazon Web Services and Microsoft Azure, has helped drive precision medicine research and provides tools to gain insights for a variety of healthcare and pharma applications. The company launched its cutting-edge, cloud-based platform to reliably process the massive volumes of raw sequence data into actionable high-quality genomic data and to allow extreme-scale storage, sharing and data processing for genomics, multi-omics, phenotypic and other biomedical data. The platform is designed to support global collaboration within or across organizations while ensuring security and privacy standards. Standout products include:

DNAnexus Apollo™ Platform allows data science exploration, analysis, and discovery by correlating structurally complex genomic data with phenotypic data, such as demographics, patient history and treatment outcomes. By tracking information such as disease progression and severity, the platform enables life science organizations to link genetics to potential clinical outcomes, identifying novel drug targets and biomarkers – all serving to advance precision medicine. The Regeneron Genetics Center and UK Biobank (RGC UKB) consortium leveraged the DNAnexus Apollo Platform to deliver 800,000 files associated with the initial UKB exomes release. Designated individuals from each of the seven participating pharma companies were able to access the complete, analysis-ready dataset. The innovative browser for clinico-genomic cohorts seamlessly explores and navigates combined genotypic and phenotypic data at-scale in seconds. RGC deployed the browser on thousands of phenotypic fields extracted from the UKB and millions of genetic variants computed through their scientific pipelines. The cohort browser enables the researchers to easily and quickly survey the data landscape and zoom in to datasets of interests, which will accelerate their research process.

DNAnexus Titan™ Platform provides high-performance NGS data analysis for research and clinical pipelines, eliminates bottlenecks in development and production systems, and brings NGS data and analytical pipelines together in one place for streamlined analysis.

Additionally, DNAnexus Titan automatically tracks data provenance for uniform reproducibility of pipelines, and enables seamless sharing of data and tools, as well as access to a JupyterLab environment to streamline collaboration with local and global partners. The Titan Platform is leveraged by genomic R&D teams and clinical diagnostic test providers to power advancements in precision medicine.

DNAnexus Portals™ delivers customized private and collaborative online environments to foster internal or external partnerships and fuel scientific advancements. DNAnexus Portals provides a space for organizations to showcase projects with special datasets, proprietary tools, analysis results, help documentation, and other important news and updates. Portals remove the burden of data storage, scalable analysis and security hurdles, which accompany sharing or distributing molecular and clinical data. PrecisionFDA.gov leverages DNAnexus Portals to deliver its online, cloud-based, virtual research space for members to collaborate and advance NGS regulatory standards. DNAnexus Portals also powers the St. Jude Cloud, an online data-sharing and collaboration platform that provides researchers access to the world's largest public repository of pediatric cancer genomics data.

Actionable and Intelligent Analysis Empower Researchers

Frost & Sullivan acknowledges DNAnexus' commitment to enabling researchers around the world access to large and diverse datasets through a single, purpose-built informatics platform that unlocks the power of genomics to accelerate clinical research and drug development. Platform capabilities such as flexible metadata and data schemas, interactive visualizations, and project-based sharing, facilitate meaningful value derived from large volumes of genomic and disparate biomedical data. Specific tools embedded in the platform such as JupyterLab Notebooks for interactive investigation and Apache Spark for large-scale distributed analyses are also available.

This effective data integration of phenotypic variables and genomic datasets is an essential component of precision medicine. The platform capabilities, empowers researchers to accelerate delivering novel medical innovation to patients. The powerful computational and data management solution is customizable and flexibly integrates other NGS technologies into a customer specific pipeline. DNAnexus supports the data management and genomic analysis for global research consortia. For instance, Stanford University's Data Coordination Center for the National Institutes of Health (NIH) funded ENCyclopedia of DNA Elements (ENCODE) Project, selected the company's cloud genomics platform to support data analysis and sharing for the project's third phase. Highly scalable, the collaborative DNAnexus Platform facilitated processing thousands of datasets and allowed researchers at several institutions worldwide to leverage and apply ENCODE's analysis pipeline and data to advance genomic medicine.

Global Research Collaboration At-Scale, Reliably, and Securely

While Frost & Sullivan independent research reveals that other competitors' platforms face data reliability issues with scale, DNAnexus can easily scale petabytes of data rapidly and reliably, delivering matchless efficiencies. Certified and compliant to security, quality and regulatory frameworks such as ISO 27001, HIPAA, 21 CFR Part 11, CAP/CLIA, GxP, and GDPR guidelines, the platform safeguards cloud-based private data and enables clients to perform clinical workflows, such as diagnostics interpretation and reporting.

In addition, its genome informatics platform was the first to receive Authority to Operate under the Federal Risk and Authorization Management Program (FedRAMP) for the handling Moderate level data — a designation fortifying the company's commitment to enforcing stringent security and compliance frameworks for customer data.

Customized Solutions Deliver Time and Cost Efficiencies

"For many years now, one of the company's [DNAnexus] core value propositions is its science quality."—Richard Daly, CEO, DNAnexus

Based on a consultative model, the DNAnexus xVantage Group™ provides deep domain expertise to solve some of the most complex research problems. The experts enable seamless cloud migration and workflow development as well as data harmonization, genome assembly and GxP services. Pipelines provide a competitive edge. The xVantage Group works with clients not only to construct accurate, robust and efficient analysis pipelines, but also to optimize them for quality, speed and runtime cost. They have worked with leading molecular diagnostics companies to move their pipelines to the cloud, resulting in 80% faster informatics analysis for 20% less cost, in a matter of months.

Deploying, qualifying and validating bioinformatic tools for genomic data analysis and operating GxP-compliant services are specialized tasks that are required for discovery and use of genome-based insights in clinical trials. The xVantage Group works with clients to support clinical trial applications, including app and workflow qualification sufficient for regulatory submissions.

Frost & Sullivan firmly believes that DNAnexus delivers unprecedented value through time and cost efficiencies compared to developing an equivalent genome informatics system in-house. Furthermore, the company's proven expertise in enterprise deployments helps clients take aim on larger and more diverse datasets in pursuit of improving outcomes for patients.

Conclusion

Affordable DNA sequencing creates enormous genomic data volumes with data handling challenges. Consequently, researchers require a solution to relate phenotypic and genotypic data, conduct intelligent data analytics, and gain insights more cost-effectively.

DNAnexus provides researchers with an extremely scalable, cloud-based genome informatics and data management platform to seamlessly explore and analyze high-volume multi-omics and clinical data rapidly and cost-effectively. The collaborative platform enables researchers to gain intuitive and actionable insights from diverse datasets and allows for secure and compliant data sharing for global researchers and projects. By allowing customers to partner with deep domain experts, DNAnexus customizes and optimizes the cloud to deliver the best solution with measurable customer value.

With its strong overall performance and powerful platform accelerating translational research and discovery, DNAnexus earns the 2019 Frost & Sullivan Global Enabling Technology Leadership Award.

Significance of Enabling Technology Leadership

Ultimately, growth in any organization depends on customers purchasing from a company and then making the decision to return time and again. In a sense, then, everything is truly about the customer. Making customers happy is the cornerstone of any successful, long-term growth strategy. To achieve these goals through enabling technology leadership, an organization must be best in class in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.

Understanding Enabling Technology Leadership

Product quality (driven by innovative technology) is the foundation of delivering customer value. When complemented by an equally rigorous focus on the customer, companies can begin to differentiate themselves from the competition. From awareness, to consideration, to purchase, to follow-up support, organizations that demonstrate best practices deliver a unique and enjoyable experience that gives customers confidence in the company, its products, and its integrity.

Key Benchmarking Criteria

For the Global Enabling Technology Leadership Award, Frost & Sullivan analysts independently evaluated Technology Leverage and Customer Impact according to the criteria identified below.

Technology Leverage

Criterion 1: Commitment to Innovation
Criterion 2: Commitment to Creativity
Criterion 3: Stage Gate Efficiency
Criterion 4: Commercialization Success
Criterion 5: Application Diversity

Customer Impact

Criterion 1: Price/Performance Value
Criterion 2: Customer Purchase Experience
Criterion 3: Customer Ownership Experience
Criterion 4: Customer Service Experience
Criterion 5: Brand Equity

Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan analysts follow a 10-step process to evaluate Award candidates and assess their fit with select best practice criteria. The reputation and integrity of the Awards are based on close adherence to this process.

STEP	OBJECTIVE	KEY ACTIVITIES	OUTPUT
1 **Monitor, target, and screen**	Identify Award recipient candidates from around the globe	• Conduct in-depth industry research • Identify emerging sectors • Scan multiple geographies	Pipeline of candidates who potentially meet all best-practice criteria
2 **Perform 360-degree research**	Perform comprehensive, 360-degree research on all candidates in the pipeline	• Interview thought leaders and industry practitioners • Assess candidates' fit with best-practice criteria • Rank all candidates	Matrix positioning of all candidates' performance relative to one another
3 **Invite thought leadership in best practices**	Perform in-depth examination of all candidates	• Confirm best-practice criteria • Examine eligibility of all candidates • Identify any information gaps	Detailed profiles of all ranked candidates
4 **Initiate research director review**	Conduct an unbiased evaluation of all candidate profiles	• Brainstorm ranking options • Invite multiple perspectives on candidates' performance • Update candidate profiles	Final prioritization of all eligible candidates and companion best-practice positioning paper
5 **Assemble panel of industry experts**	Present findings to an expert panel of industry thought leaders	• Share findings • Strengthen cases for candidate eligibility • Prioritize candidates	Refined list of prioritized Award candidates
6 **Conduct global industry review**	Build consensus on Award candidates' eligibility	• Hold global team meeting to review all candidates • Pressure-test fit with criteria • Confirm inclusion of all eligible candidates	Final list of eligible Award candidates, representing success stories worldwide
7 **Perform quality check**	Develop official Award consideration materials	• Perform final performance benchmarking activities • Write nominations • Perform quality review	High-quality, accurate, and creative presentation of nominees' successes
8 **Reconnect with panel of industry experts**	Finalize the selection of the best-practice Award recipient	• Review analysis with panel • Build consensus • Select recipient	Decision on which company performs best against all best-practice criteria
9 **Communicate recognition**	Inform Award recipient of Award recognition	• Present Award to the CEO • Inspire the organization for continued success • Celebrate the recipient's performance	Announcement of Award and plan for how recipient can use the Award to enhance the brand
10 **Take strategic action**	Upon licensing, company is able to share Award news with stakeholders and customers	• Coordinate media outreach • Design a marketing plan • Assess Award's role in future strategic planning	Widespread awareness of recipient's Award status among investors, media personnel, and employees

The Intersection between 360-Degree Research and Best Practices Awards

Research Methodology

Frost & Sullivan's 360-degree research methodology represents the analytical rigor of our research process. It offers a 360-degree-view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan's research methodologies. Too often companies make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry participants and for identifying those performing at best-in-class levels.

360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS

About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, enables clients to accelerate growth and achieve best-in-class positions in growth, innovation and leadership. The company's Growth Partnership Service provides the CEO and the CEO's Growth Team with disciplined research and best practice models to drive the generation, evaluation and implementation of powerful growth strategies. Frost & Sullivan leverages more than 50 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on six continents. To join our Growth Partnership, please visit http://www.frost.com.