WHITE PAPER

Looking Forward: The Case for Intelligent Design (and Infrastructure) in Life Science Biologics R&D

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IN THIS WHITE PAPER

In the shadow of the industry transformation brought on by blockbuster patent expirations, leading life science companies have made significant progress in their efforts to pursue new business models. Efforts to institutionalize operational efficiency and excellence as core business drivers have resulted in the elimination of excess capacity, the externalization of noncore competencies, and efforts designed to better utilize organizational data, information, and knowledge to reduce risk and improve productivity.

The life science industry's information ecosystem is currently undergoing a radical transformation as organizations seek to create business and IT resources and infrastructure that can deliver value over the near term by better utilizing data, information, and knowledge within their domain. Concurrent with internal company efforts, the industry is continuing to change, with advances in science, increasing globalization, and the expansion of the industry into adjacent spaces (e.g., healthcare providers, healthcare payer spaces, and directly into patient homes) driving additional complexities into the new life science world. These changes are creating new opportunities for life science research and development (R&D), with new tools, resources, and infrastructure helping both discovery researchers and product developers better succeed in an increasingly resource-constrained, global, collaborative work environment.

Building on its foundational strengths in product life-cycle management (PLM) and supplemented by both internal and acquisition-derived life science–specific capabilities, Dassault Systèmes has recognized the need for a more comprehensive, holistic approach to new drug R&D with a focus on the highly complex, rapidly growing biologics space.

This white paper highlights the key (and different) issues facing biologics discovery researchers and product developers today and the new capabilities being brought forth by advances in science and technology. A discussion of how Dassault's new offering helps address these issues follows, along with anticipated potential barriers to adoption.

SITUATION OVERVIEW

The life of a life science researcher has changed significantly since the days when all of his/her experiments would be conducted on his/her lab bench and results were physically entered into a paper notebook. Complex experiments (e.g., whole genome sequencing or high-throughput screening) are now regularly performed centrally (either onsite or at a partner's facility). Project teams are increasingly global and may include team members that are external to the organization. Organizational and extra-organizational data, information, and knowledge are more important than ever and need to be easily accessible in volumes never before seen. While technological and scientific innovation to date has significantly advanced researcher capabilities, there is a need for further innovation to both improve researcher productivity and ensure that they are neither overwhelmed by data overload nor stifled by analysis paralysis.

From an operational perspective, product developers have encountered a similarly transformative level of change. Paper master batch records and quality monitoring Excel spreadsheets are being supplanted by biologics-specific electronic laboratory notebooks (ELNs) and quality management systems (QMSs) from an operational perspective in the same way that eClinical applications and platform solutions have replaced paper-based clinical trials processes. Formulation development, biologics production scale-up, stability testing, regulatory compliance and reporting, and pilot manufacturing are increasingly being performed and managed by partners, extending the enterprise beyond traditional boundaries and reducing direct product developer control over efforts. In parallel to researcher gains, technological and scientific innovations have yielded significant productivity improvements to date, but there are significant opportunities to further reduce susceptibility to performance lapses, improve project transparency (including better oversight), better exploit available organizational data (including elimination of data silos), and improve regulatory compliance without adding to product developer workloads.

In addition, data access across the life science R&D ecosystem (and beyond) is becoming increasingly important in cases where it can be used to better inform and accelerate biologics discovery research, clinical development, and strategic decision making in general, taking into account access limitations required to maintain regulatory compliance (and protect IP).

For the purposes of this document, the data, processes, and regulatory requirements associated with the execution of clinical trials are considered separate from the clinical product development for new biologics-based drugs. This area is extensively described and discussed in other research from the author but is not included in this document.

The Increasingly Complex R&D Ecosystem

Until recently, ongoing scientific and technological advances have allowed both biologics researchers and product developers to keep up with the increasing demands of life science R&D. The transformational shift to externalize noncore competencies and increasingly work with partners, the rapid growth of technology-enabled data often exceeding 4x Moore's law, and much tighter overall resource management in pursuit of optimal operational efficiency have all contributed to breaking the traditional R&D model, forcing both researchers and developers to begin to embrace change and seek new paths moving forward. Some of the key issues currently facing professionals in the life science R&D ecosystem today are captured in Table 1.

TABLE 1

Challenges Facing the Life Science R&D Ecosystem

Discovery Research Issues	Product Development Issues
▪ The need to access new research capabilities, enabled by technology (often accessible through external collaborators) ▪ Complex biological models that are not easily visualized or modeled ▪ Lack of standardization in experiments ▪ Rapid growth of data, information, and knowledge ▪ What to do with a diversity of isolated scientific and technology tools intended to support specific research or process problems ▪ An increasingly complex data ecosystem that includes internal data, both public and private external data, and proprietary partner data ▪ Ineffective data mining capabilities that make it easier to repeat studies rather than exploit previously completed work ▪ Unwieldy, oversized data resources resulting in increased potential to overlook key insights ▪ Globally distributed teams, making collaboration more difficult and complex to both manage and execute	▪ How to efficiently leverage new product development information, knowledge, and best practices from outside the organization ▪ What to do with a diversity of isolated scientific and technology tools intended to support specific product development problems ▪ Managing globally distributed teams that make collaboration more difficult and complex to both manage and execute ▪ Dealing with rapidly growing and evolving regulatory compliance and reporting requirements ▪ Addressing the ongoing need to improve operational efficiencies in a tightly resource-constrained ecosystem ▪ Accommodating decreasing resources in an environment with increasing workloads ▪ Finding ways to deliver increased transparency to support senior management decision making ▪ Delivering meaningful project oversight for complex projects ▪ Improving technology transfer within product development, with other departments, and with outside collaborators

Source: IDC Health Insights, 2015

Evolving for Long-Term Sustainability

Taken individually, the challenges and opportunities facing biologics researchers and product developers are all manageable over the near term, with specific technological or process solutions regularly able to help them accommodate change. Taken together, however, the challenges become much larger and more difficult to manage.

From a big picture perspective, it is clear that the traditional status quo has gone the way of the dodo bird. In the future, it will become necessary to forgo individual point solutions and look toward more holistic and integrated approaches that deliver near-term value to everyone involved while concurrently integrating approaches that take into account longer-term needs, requirements, and expectations. A number of scientific, technological, and process advances should help move us in a direction that will help support long-term sustainability in the industry. That said, the key factors defining long-term sustainability are different depending on the specific area of focus.

Emerging Capabilities in Biologics Discovery Research

Within the unregulated area of biologics discovery research, the role of the researcher is changing, and tech-enabled capabilities promise to help deliver new discoveries faster, reduce the cost of research, and increase the likelihood that discoveries will translate into new medical innovations. These capabilities include:

- **Collaborating more securely.** With the continued externalization of discovery research and the increased use of specialty vendors to conduct specific research efforts (e.g., whole genome sequencing services from BGI or Illumina), the emergence of more secure, industry-specific collaboration platforms is allowing researchers to better interact with each other and share data and insights as effectively as if they were all in the same room. From a process standpoint, these secure collaboration platforms are better enabling team interactions and data sharing while concurrently enabling more transparent metadata and IP capture, more standardized data analyses, and better data sharing across applications. In addition, these platforms are also more systematically managing participants and access as individuals shift in and out of projects.
- **Enhancing organizational data use (and reuse).** One of the key productivity issues affecting discovery research is the inability to leverage organizational knowledge, resulting in wasted efforts through replication of failed experiments and pursuit of efforts with a low probability of success. The growing availability of an increasingly integrated research infrastructure (potentially in the cloud) is helping researchers work more efficiently and effectively. This enabling infrastructure is typically further enhanced by a common foundation of connectors and tools, including laboratory information management systems (LIMSs), ELNs, and common analytics platforms (usually with the capacity for individual researcher add-ons [e.g., custom genomic algorithms]). Searching through an organizationwide accessible ELN makes it possible to determine beforehand whether an experiment has already been done and what the outcome was, rather than reproducing the experiment.

  From an application perspective, the creation of a common data foundation for researchers to connect their research (either through a common data repository [either a consolidated data warehouse or a federated data mart] or through direct access in place) offers significant potential. With access to a common accessible data resource, research applications are more efficiently executed, delivering results that more directly support follow-on efforts (and analyses).

- **Automating best practices.** The use of automated workflows to institutionalize best practices (including commonly performed experimental procedures) helps reduce the effort needed by researchers to perform their work while transparently capturing supporting experiment metadata. In addition to improving researcher efficiency and reducing process errors, the implementation of automated workflows to exploit best practices also delivers better data that is more likely to have lasting value to the organization.
- **Empowering the researcher.** While still relatively early in their adoption, a number of technological advances promise to significantly improve researcher effectiveness. Easy-to-use biologics modeling tools are empowering researchers to better visualize complex biological interactions and share these insights with their collaborators. Cognitive computing efforts are providing early capabilities to more effectively and systematically mine global knowledge resources and present researchers with all data relevant to their specific efforts, even in cases where the specific topic of discussion is not explicitly mentioned. Advances in predictive analytics are empowering researchers with powerful modeling capabilities that can more routinely extend their data beyond its direct experimental boundaries and provide earlier insights on research potential.

Emerging Capabilities in Biologics Product Development

In the transition from discovery research to product development, biologics drugs face a much more complex path than their chemically based, small molecule counterparts. Because of their complexity, biologics drugs are defined by their production process in addition to their composition. As a result, data associated with the biologic carries additional weight, and the need to capture, track, and manage this data (and its supporting metadata) is key to effectively and efficiently bringing a new biologics drug to market. From an operational perspective on biologics drug development, the life science product developer is responsible for taking the chemical (and other physical), production, and test data collected during discovery and preclinical research and translating this data into manufacturable biologics drug products and processes. Historically and not unlike traditional discovery research, many of the processes involved in advancing and commercializing have been manual, siloed, and error prone. While similar in some ways to conventional chemical drug development, the development of biologics is much more complex, based on the complexity of the biological molecules themselves, the additional complexity associated with biologics drug testing, and the need to address biologics regulatory compliance concerns early in the development process.

As with biologics discovery research, the role of the biologics product developer is changing, and tech-enabled capabilities promise to improve the overall product development process, including optimizing operational efficiency and effectiveness, reducing costs, and helping accelerate time to market, all while operating in a highly regulated environment. These capabilities include:

- **Making biologics data collection and regulatory compliance more transparent.** As with the automation of best practices in discovery research, the ability to automate repetitive processes and transparently capture data and supporting metadata, wherever possible, reduces the burden of low-value, repetitive activities on product developers, enabling them to better focus on more strategic and higher-value activities. Automation also reduces the potential for manual errors and improves overall regulatory compliance by ensuring that critical data, including its supporting metadata and audit trail, is always captured, tracked, shared, and reported as required to better ensure data integrity.

- **Enhancing organizational data use (and reuse).** As with discovery research, the ability to better leverage prior product development data (as well as information and knowledge) has a high potential to help streamline product development. New biologics are routinely based on common biological foundations (e.g., monoclonal antibodies or proteins) that use common production processes. Data, information, and knowledge developed from prior related efforts are likely to be directly relevant to follow-on new biologics development, allowing biologics product developers to more quickly identify best practices moving forward and avoid pitfalls encountered previously.
- **Enabling global collaborative product development.** As part of the industry transformation, the externalization of noncore competencies has resulted in significant outsourcing of activities across the product development spectrum. Clinical trials, product manufacturing, and regulatory reporting can now be easily conducted by third parties on behalf of sponsor organizations. In support of these efforts, a robust, regulatory-compliant, global collaboration and data infrastructure is needed to ensure that the work being done is aligned with sponsor needs, is fully regulatory compliant, and is designed to efficiently advance product development efforts. Current collaborative infrastructure approaches are largely piecemeal, with ad hoc analytics dashboards and scheduled reporting the primary source of communications between sponsor and vendor and regular, scheduled audits as the primary face-to-face interaction.
- **Maximizing process reusability.** In contrast to discovery research, biologics product development is more routinely expected to produce outputs that are regular and reproducible. In moving in this direction, development processes can often benefit from the reuse of proven processes, including common biologics product testing approaches, common report formats, more standardized nomenclatures, and intelligent workflows. This approach enables biologics product developers to work more efficiently and effectively overall while again reducing the potential for manual errors.

Delivering Value to Key Stakeholders

In a time when operational efficiency and effectiveness remain key drivers of internal organizational investment, the ability to effectively share data across the life science R&D ecosystem is increasingly being recognized as a foundational requirement. It is clearly time to consider a more holistic approach that begins to connect biologics discovery research with product development. With more intelligent supporting infrastructure reducing the overhead cost associated with IP capture in discovery research and regulatory compliance in product development, it should be possible to breach the wall between research and development to both smooth the biologics transition from research to development and better exploit the potential benefits of bidirectional data, information, and knowledge sharing. From a people perspective, successful adoption will depend on recognition by key stakeholders of the direct near-term benefits that they will receive from a more unified approach. Key metrics supporting key stakeholder benefits are likely to originate from the automation of low-value efforts; reduced error generation; better access to data, information, and knowledge; more effective collaborative efforts; and improved regulatory compliance. Simply put, it becomes possible using a comprehensive, holistic approach to life science biologics R&D to make many efforts transparent to both discovery researchers and product developers while making infrastructure more intelligent on a life science–specific basis.

Biologics R&D on the Dassault 3DEXPERIENCE Platform

The Dassault BIOVIA Biologics R&D Solution

In applying its product life-cycle management expertise to biologics R&D, Dassault Systèmes is among the first companies to seek to create a comprehensive, unified solution designed to help advance science, better manage data and processes, and deliver improved operational efficiencies across the entire life science biologics R&D enterprise.

For its BIOVIA Biologics R&D solution, Dassault brings together strong life science application capabilities from its acquisition of Accelrys, QUMAS, and Aegis as well as its own capabilities developed internally. From Accelrys, Dassault delivers industry-leading ELN, LIMS, scientific workflow, biologics registration, sample management, bioprocessing management, and bioinformatics solution capabilities. From QUMAS, Dassault adds a life science-specific, leading quality management solution. From Aegis, Dassault incorporates a validatable process management informatics solution with the ability to deliver real-time, on-demand data access, analysis, and reporting of manufacturing and process development data to end users (during both pilot manufacturing and commercial production). In integrating these applications into a single comprehensive integrated BIOVIA Biologics R&D solution, Dassault believes that it has created the first comprehensive discovery-to-commercialization platform capable of addressing the full needs of the life science biologics R&D enterprise.

Key capabilities of the BIOVIA Biologics R&D solution include more transparent data (and metadata) capture and management (including data supporting IP creation and protection), intelligent workflows designed to automate laboratory best practices (reducing low-value repetitive activities), transparent data sharing (between both researchers and scientific applications), and process optimization designed to encourage reuse and more standardized approaches to both discovery research and product development.

With a view toward the industrywide shift toward the virtual enterprise, the BIOVIA Biologics R&D solution is available on-premise today and is expected to be available soon on the BIOVIA ScienceCloud. In addition, considering the new opportunity for smaller and midtier life science companies to access industry-leading, enterprise solutions previously accessible only by top life science companies, the BIOVIA Biologics R&D solution on the ScienceCloud should enable these smaller organizations to rapidly and easily transition their organizations from a historically haphazard collection of diverse disconnected applications and platforms to a powerful integrated solution.

Caveats for Dassault

As with all transformational approaches, there are a number of hurdles that Dassault will need to overcome to enable more industrywide adoption of the Dassault BIOVIA Biologics R&D solution. Potential hurdles include:

- Traditional organizational inertia hampering change
- Shifting both researchers and product developers away from their well-established processes and procedures (which, in many cases, may be paper based)
- Accommodating the need for company-specific application configurations, especially in discovery research where processes, best practices, and analyses are evolving on a continuous basis

FUTURE OUTLOOK

If properly implemented, the Dassault BIOVIA Biologics R&D solution has the capability to transform the infrastructure supporting the entire R&D enterprise by creating a more seamless approach to biologics R&D. The solution is a transformational shift away from traditional management of the R&D enterprise and could help organizations accelerate progress in transforming life science biologics R&D both now and over the long term.

The potential benefits of the Dassault BIOVIA Biologics R&D solution are clear and include:

- In discovery research:
  - Cost savings from automation of data (and metadata) capture, including savings from reduced errors generated by manual data entry
  - More standardized analyses through the use of common scientific and analytical applications
  - Simplified data sharing between applications
  - Ability to create intelligent workflows specific to discovery researcher needs, including researcher-specific (sharable) libraries of commonly used data analyses
  - Automated and integrated biologics registration
  - Ability to easily integrate third-party discovery research applications with the solution
- In product development:
  - Improved operational efficiency and regulatory compliance produced by the increased reuse of processes and workflows where appropriate
  - Ability to create intelligent workflows specific to product development needs, including both regularly reused R&D analyses and analyses supporting project oversight
  - Access to a full suite of life science–specific biologics product development applications with full access to data from across the R&D enterprise
  - Better product insight and improved experiment design linking experiments as well as entities
  - Ability to easily integrate third-party product development applications with the solution
- Across the R&D enterprise:
  - Integration of discovery research and product development infrastructure onto a common R&D solution
  - Easier sharing of scientific data, information, and knowledge both across the organization and with external partners and collaborators
  - The ability to create reusable intelligent workflows at all levels of the organization (e.g., laboratory, project management, and senior management)
  - More systematic control and increased effectiveness of collaborative efforts

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