# Accelerated Precision Antibody Discovery

## Why scalable cloud data platforms are the future of biologic drug development

Research and development processes to bring new antibody therapeutics to market are becoming increasingly fast, large-scale and data-driven. This creates both challenges and opportunities for biopharma enterprises. This white paper discusses how a cloud computing data platform that combines data management with scientific and data analysis workflows can enhance speed and accuracy in antibody candidate selection. When such platforms enable collaboration and integration of data across discovery, pre-clinical and clinical development operations, valuable information can be leveraged organization-wide to further drive competitive advantage and ultimately ensure the availability of more effective and safe antibody drugs for patients.

## Rapid market growth anticipated for mAb therapeutics

Since the commercialization of the first therapeutic monoclonal antibody (mAb) in 1986, global sales of mAb drugs have grown faster than any other class of therapeutics, owing to their highly targeted specificity and efficacy in treating disease.

The monoclonal antibody drug class includes therapeutic monoclonal antibodies and antibody-related products such as Fc-fusion proteins, bispecific antibodies, antibody fragments and antibody-drug conjugates (collectively referred to in this white paper as mAb therapeutics or mAb products [1]). Sales of mAb products almost trebled from ~$31 billion in 2007 to ~$92 billion in 2015 [2]. There are now over 60 mAb products approved for clinical use in the US and Europe, and nearly 500 in development, including a highly active late-stage pipeline that will deliver numerous mAb products to the global market in the near future [3,4]. Many of these mAb products are providing much needed treatments for unmet medical needs, including in autoimmune disease, cancer, viral infections and orphan conditions.

At present market growth rates, sales of currently approved mAb therapeutics plus sales from new products approved in the coming years may drive the world-wide sales of mAb products to more than $140 billion by 2020. As illustrated in Figure 1, this would amount to more than half of all biologic drug revenues and 15% of total global prescription drug sales [5].

While the introduction of new mAb therapeutics to the market is increasingly a major driver of biopharma revenues (21 mAb products achieved sales of more than $1 billion each in 2015 [2]), on the flip side the average cost to develop a drug (including the cost of failures) is now estimated to be more than $2.6 billion [6]. Reducing time to market and improving the ability to identify promising candidates and ‘fail early’ in the drug discovery phase is therefore more critically important than ever.

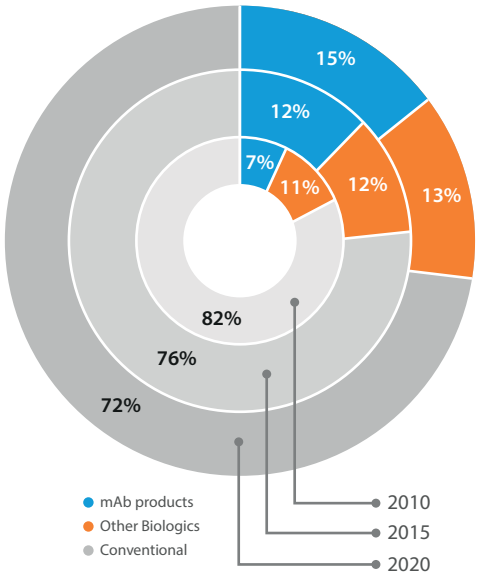


**Figure 1.** Global sales of mAb products are forecast to account for over half of all biologic drug revenues and 15% of total prescription drug sales by 2020. (Forecasts based on reference [5] plus Biomatters analysis of current market trends.)

## Big data challenges and opportunities in potent therapeutic development

The development of potent mAb therapeutics is an iterative design process that involves generating, filtering and optimizing antibodies to improve their clinical potential. Strides forward in next generation technology innovations such as massively parallel high-throughput DNA sequencing now allow the speed and accuracy of these drug discovery and development processes to be greatly increased. However, like many other areas of scientific and industrial activity, these technological advances in high throughput methods have created a 'big data' challenge and opportunity, as well as the potential to add further cost to drug development if not leveraged effectively. Heterogeneous data sets of large size, complexity and velocity need to be processed, analysed and interrogated in order to derive critical information from the data to reduce the cost and increase the speed of drug discovery and development by identifying the most promising drug candidates and doing this earlier and more cost-effectively.

> *Technological advances in high throughput laboratory methods have created a 'big data' challenge*

> *The average cost to develop a drug is now estimated to be more than $2.6 billion.*

Solving this problem requires next generation informatics platforms to support the future of mAb product development. The needs of modern biopharma enterprises demand scalable data platforms that are flexible and customizable to integrate with their specific data requirements and workflows.

> *Next generation informatics platforms are needed to support the future of mAb product development*

The architecture of cloud software delivers scalable data management and computation, enabling organizations to maximize the potential of antibody sequence data, together with other laboratory data and metadata, for the acceleration of drug discovery. In this white paper we outline some of the important areas that cloud software vendors are addressing with their solutions and how those solutions deliver the power and flexibility needed to advance the development of life saving mAb drugs.

# Current Challenges In Antibody Discovery And Development

## Scaling up to achieve world-changing breakthroughs

Effective processes in antibody discovery are increasingly based on high-throughput scientific workflows, supported by automated technologies including robotics and sophisticated laboratory instrumentation for parallelized sample preparation and analysis. These workflows generate data sets that are both large and complex.

As a result, and after more than a decade of talk about its potential, 'big data' is beginning to have a real impact on biopharmaceutical research and development. The technological advances that have taken place in areas such as genomics as well as computing over the last decade have made enormous amounts of data available to scientists and engineers, creating both opportunities and challenges.

> *Cloud based sequence and data repositories provide biologic drug developers with an easy-to-use yet powerful platform for antibody bioinformatics analysis*

These developments will see cloud-based software solutions pushed to the forefront as organizations look to streamline and automate the processes of mAb drug development. Cloud computing and big data are complementary technological paradigms with a core focus on scalability, agility and on-demand availability [7].

Cloud computing has proven, across many industries, how important it is to have the flexibility to upscale as and when needed, while limiting the requirements for on premise hardware solutions for large scale computational analyses and data warehousing and personnel for maintenance of this.

Cloud based sequence and data repositories provide biologic drug developers with an easy-to-use yet powerful platform for antibody bioinformatics analysis. As data processing needs increase, for example during antibody discovery, laboratories can seamlessly scale up their cloud capacity, with remote servers hosted and maintained offsite. This level of agility will give enterprises using cloud computing a real advantage over competitors.

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## Leveraging complexity gives precise access to the right information

Information is a strategic asset, and perhaps no more so than in the biopharmaceutical industry where competition around the generation and protection of intellectual property is highly critical to business success. As one of the most information-intensive industries, biopharma has much to gain from big data analytics.

> *Insights from cloud-based analytics can be directly and continuously fed back into operational applications to enhance decision making*

Cloud technologies now offer enterprises unprecedented opportunities to apply data analytics to large and complex data sets in order to make better data driven decisions and enhance competitive advantage.

New generation software platforms that create a convergence between cloud computing and big data are bringing analytics and operational applications together to deliver robust, scalable and cost-effective solutions.

Biopharmaceutical enterprises are generating huge volumes of data throughout the discovery, pre-clinical and clinical stages of development of new antibody based therapeutics, but face multiple challenges in leveraging that data, including data accuracy, data completeness, difficulties combining data that comes from different sources, and the speed and complexity of implementing data analytics.

Cloud computing offers an agile and comprehensive solution to these challenges. Cloud computing allows organizations to consolidate data from multiple sources at scale, and to do so in real time so that data is current and complete. In a well built and comprehensive cloud solution, insights from cloud-based analytics can be directly and continuously fed back into operational applications to enhance decision making.

> *Cloud computing allows organizations to consolidate data from multiple sources at scale, in real time so that data is current and complete*

Employing these kinds of approaches in research and development environments is still in its infancy today, but will become an increasing source of competitive advantage for organizations that adopt this new paradigm early.

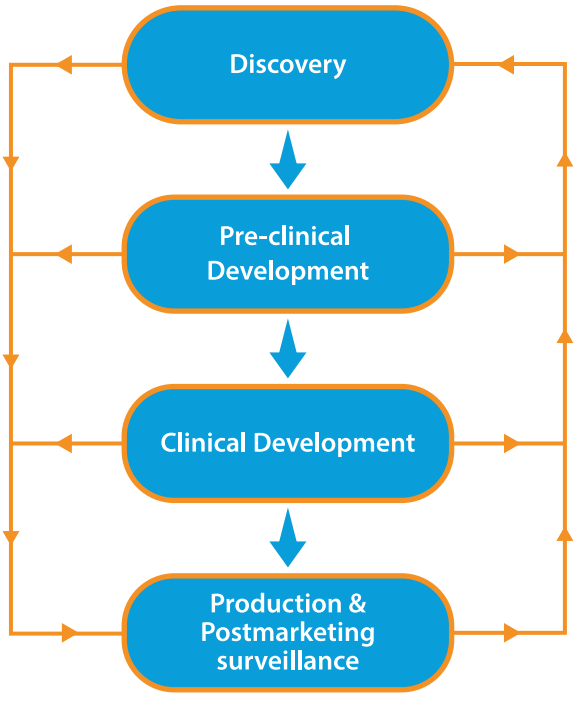


**Figure 2.** An integrated cloud platform facilitates data flow across the drug development process, making information available to support decision making both upstream and downstream of all stages

## Minimizing misses by enabling better data integration and collaboration

Using cloud services will enable mAb therapeutic developers to collaborate on their findings and work together more effectively on company-wide projects, while improving quality control for high throughput data analysis.

For biopharma companies to fully realise the business value that comes from an easy flow of data and the implementation of advanced data analytics, it is essential that data is consistently and reliably captured across the research and development process and is well integrated. Data is the foundation upon which value-adding analytics are built, and relies on effective end-to-end integration of all relevant data sets.

By combining analytics and operations in a unified cloud platform with a common data foundation, data driven decision making becomes a seamless and collaborative experience across an organization. On-premise big data deployments can involve significant operational risks and expensive infrastructure, and have a history of failure and poor organizational adoption as systems and applications tend to remain disconnected from one another. Instead of data residing in different silos where it is difficult to exploit, a unified cloud platform can enable data to be captured automatically and to flow easily between discovery and clinical development, and between internal functions and external partners such as contract research organizations.

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This requires the development and deployment of data analysis platforms for antibody screening that integrate with the wider ecosystem of processes and systems.

Ultimately such systems need to be developed with analytical intelligence to exploit the meaning that can be derived from the convergence of multiple heterogeneous but related data sets, including data streamed directly from instruments and devices.

> *Cloud-based workflow and file sharing, helps scientists share findings in real time, across global organizations and, ultimately, identify and discard sub-optimal candidates or projects earlier*

Improved collaboration is not only a key factor in reducing cost. Given the vast amounts of data processed in antibody discovery, it will also improve accuracy. Cloud-hosted data and analysis tools allow teams to do more together, faster and better. Cloud-based workflows and file sharing help scientists share findings in real time, across global organizations and, ultimately, identify and discard sub-optimal candidates or projects earlier. Otherwise enterprises run the risk of missing rare and valuable antibody drug candidates, while assigning time and resources to the development of less efficacious antibodies.

## Freeing up resources to invest back into antibody discovery and therapeutic development

Increasing competition in the mAb therapeutic industry means enterprises involved in their development need to quickly find innovative solutions to keep pace with their peers.

C-level executives at therapeutic development enterprises will be increasingly required to find ways to reduce the cost of antibody discovery in order to free up resources and people, allowing them to focus on innovation and other high value tasks. Improving the ability to identify quality antibody candidates and reduce time spent on sub-optimal antibody candidates will deliver major cost savings in the development of future mAb products.

More and more executives are looking to cloud computing to reduce the high cost of hardware, hosting and maintenance. Biopharma companies are adopting cloud services because they offer state-of-the-art security mechanisms that are difficult and expensive to deploy on premise. The scalability and elasticity of cloud computing allows computational power to be accessed on demand, without the uncertainties of long term investment in computing hardware. Subscription software is becoming ever more popular as it allows executives to more accurately manage cash flow and better quantify the return on their technology investment. Additionally, ease of setup and maintenance make managed cloud services appealing to many IT managers and users involved in biologic drug development.

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The companies now emerging as leaders in the biologic therapeutics industries recognize the issues identified in this paper and are channelling their resources to address them.

However, moving to the cloud is not restricted to the most successful large enterprise players. In fact cloud computing allows smaller businesses, with limited resources to invest in on-premise computing infrastructure, to act as fast as, if not faster, than big, established competitors by giving them access to this highly scalable enterprise-class technology.

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# Conclusion

Scientific analysis globally is becoming increasingly fast, large-scale and data-driven. In antibody discovery and selection, workflows that leverage new high-throughput analyses have massive potential to increase speed and accuracy in identifying optimal mAb therapeutic candidates and reduce wastage and cost associated with failures. In order to make timely and effective data-driven decisions, it is vitally important that data and metadata are captured, accurately processed, rendered visible and deployed into a data platform that facilitates both user-based scientific insights and computational deduction and inference to generate data intelligence.

> *Scientific analysis globally is becoming increasingly fast, large-scale and data-driven*

> *A unified cloud computing data platform that combines data management with scientific and data analysis workflows provides an optimized framework for antibody research and development.*

The convergence of big data and cloud computing provides tremendous opportunities for the discovery and development of mAb therapeutics. A unified cloud computing data platform that combines data management with scientific and data analysis workflows provides an optimized framework for antibody research and development. Such a platform offers a future-proof solution that will not only enhance speed and accuracy in pre-clinical candidate selection, but will also allow the entirety of that rich information to be linked to both upstream discovery work and downstream clinical development for end-to-end business efficiencies.

# Biomatters' Geneious Biologics

Biomatters is renowned for its Geneious software used in molecular biology research. The company has delivered biotech researchers the best of class software for more than a decade and with this knowledge has expanded its software solutions to include support for the discovery and development of biologic therapeutics, especially monoclonal antibodies and their derivatives.

Biomatters' next generation cloud Geneious Biologics platform has been specifically designed and purpose-built as an enterprise solution for commercial antibody discovery and screening, in collaboration with industry partners. The platform is flexible and customizable to integrate with specific customer data requirements and workflows. Delivered through a modern intuitive, user-friendly web interface, the platform provides a fully managed data platform and informatics system in a secure cloud computing infrastructure. The architecture of the software delivers scalable data management and computation, enabling organizations to increase their process efficiencies and thus accelerate their drug discovery.

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