

INFORMATICS FOR BIOLOGICS DISCOVERY AND DEVELOPMENT

Dotmatics provides a fully integrated informatics solution that supports biotherapeutics R&D workflows and helps to increase efficiency leading to faster research progress and more cost effective outcomes.

THE CHALLENGE OF BIOLOGICS R&D

Many pharmaceutical and biotech companies have rapidly shifted their research portfolios to have a much greater proportion of biologics versus small molecules. Biologics are attractive due to their superior efficacy, ability to hit targets that have so far proven intractable and, their premium pricing, superior patent protection and the difficulty of producing bio-similars. These biologics portfolios are currently dominated by antibodies, but a wide variety of other biologics are also being developed.

A critical challenge that these organisations now face is the implementation of informatics systems to support the complex workflows that are used to discover and develop biologics. It is essential to be able to track the processes, experiments, entities and huge volumes of data across the multiple teams, as well as provide analytics and decision support capabilities to help make the best decisions on project progression. In many organisations today, such an integrated system does not exist and research teams must contend with:

- Critical data being stored and shared in excel spreadsheets and other files
- Complex biological data and processes being forced into systems originally designed to support small molecules
- Ad-hoc, manual data collation and analysis for decision making
- A lack of inter-team collaboration capabilities
- Poor insight into project progression for scientific leaders

All of this effects the efficiency of the scientific teams as well as their ability to innovate.

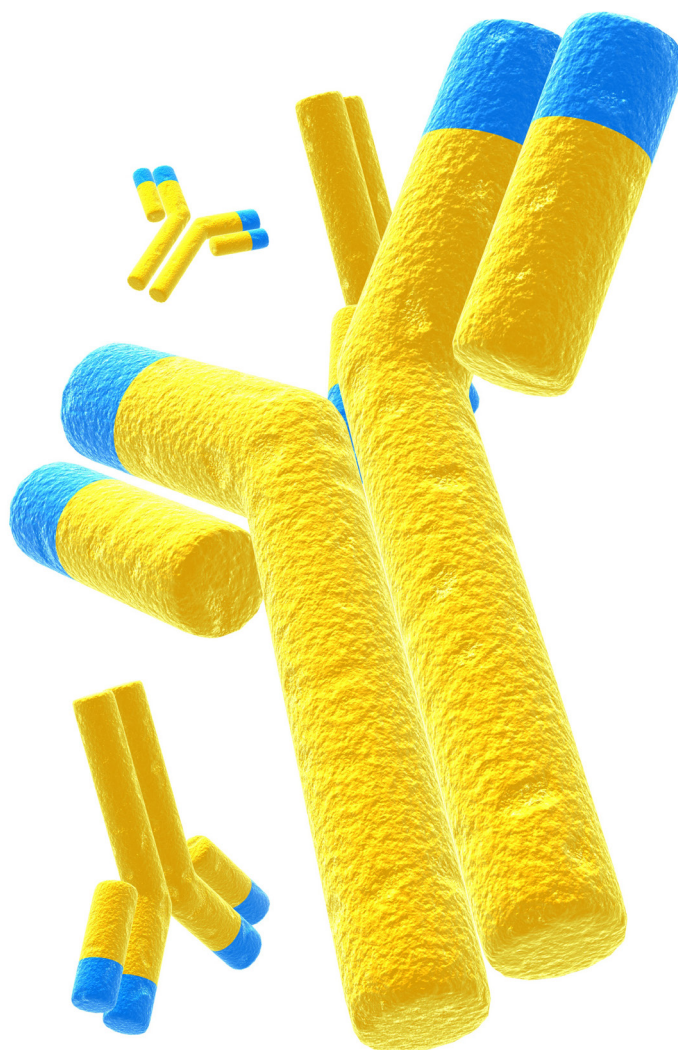
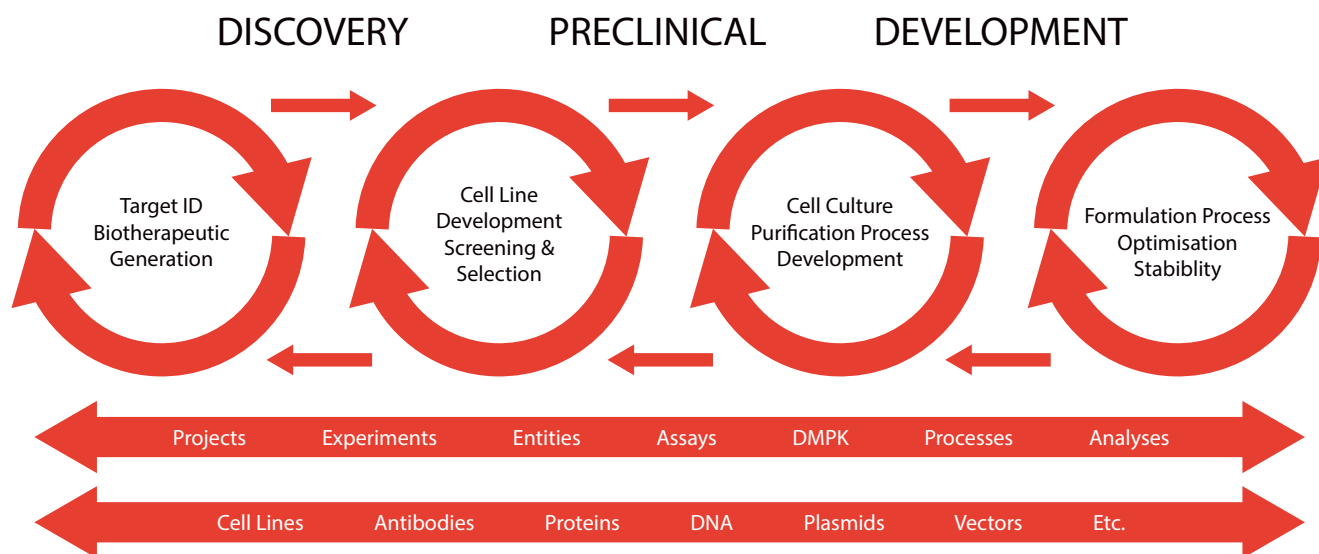


Figure 1: Dotmatics captures the Antibody research workflow



THE DOTMATICS SOLUTION

The biologics discovery and development workflow (see graphic above) is complex, highly iterative and requires many handoffs between different scientific teams within a company or across collaborating organisations. Dotmatics provides a fully integrated informatics solution that supports such workflows and addresses the informatics challenges research teams face. The solution benefits different parts of the organisation:

Leaders in R&D organisations will see improved efficiency and faster innovation from their scientific teams, thus delivering more and better biologic candidates faster into clinical development. They will have the ability to track the progression of the projects in real-time even across external collaborators and make rapid decisions to optimise project progression

Research IT organisations will achieve lower total cost of ownership (TCO) with systems that are easy to deploy, maintain and come out-of-the-box, already fully integrated. They will see satisfied customers in their research organisations through their ability to rapidly configure solutions to their scientists' evolving workflows

Scientists engaged in biologics research will become more productive and innovative by having ready access to all of their data, informatics systems that follow their workflows, analysis tools designed for making the most of their data, and the ability to collaborate effectively with all members of the extended research team

Key capabilities of the suite include:

Notebook for Biologics – A compliant multidisciplinary ELN with capabilities specifically tailored to Biologics discovery and development experiments facilitates collaboration across multiple scientific teams.

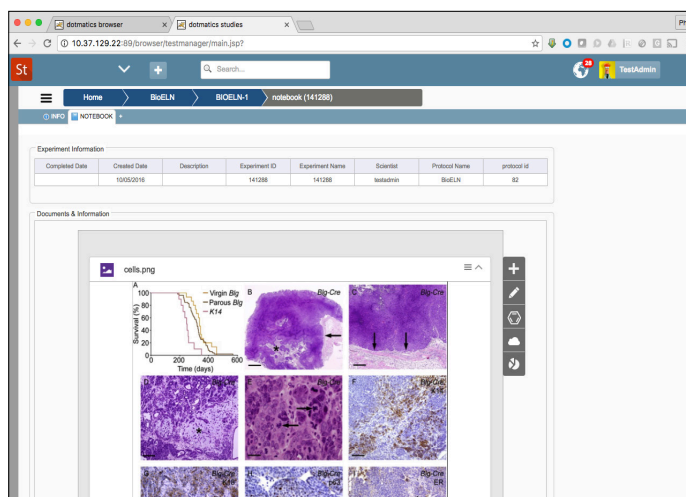


Figure 2: Studies Notebook flexibly captures Biologics data

- data, documents and images and provides the ability to add annotation
- Provides digital signature and audit trail for IP protection
- Fully integrated with registration, sample and assay management to support the molecular biologists' workflows

Biological Registration – provides for the registration and lineage tracking of all the biological entities and material batches used or produced within a biologics R&D project:

- Supports proteins, antibodies, DNA, siRNA, expression vectors and cell lines
- Maintains data integrity such as gene names, with tools designed for the job.
- Integration with Dotmatics (or any other Oracle based) chemical registration system allows registration of antibody drug conjugates and other chemically modified biologics

- Allows for the creation of new user defined entities
- Provides sequence analysis, property calculation and visualisation capabilities

Process Data Management – manages the data at all stages of the protein production processes as biological entities are produced:

- Tracks expression vectors, cell lines, expression levels, purification protocols
- Integrates with Inventory Management for sample storage and distribution

Assay Data Management – captures, processes and stores assay protocols and results as the biological entities are tested for potency and safety:

- Out-of-the-box templates for assay development, HCS, HTS, MIC and secondary screening and DMPK data in plate and non-plate formats
- %inh, IC/EC50, KI and user defined analysis, automatic curve fitting with optional manual validation
- Tightly integrated with the Notebook capabilities

Inventory Management – sample and material inventory that tracks biologic samples, lab resources and all associated data:

- Manages samples in a wide variety of containers including bottles and plates
- Manages unlimited numbers and classes of biological (and chemical) samples
- Integrates safety and hazard information

Search, Browse and Reporting – provides a single, fully integrated search capability across all of the data relevant for a biologics project including experiments, entities, samples, reagents, assay results, and documents:

- Provides the project team with a complete, accurate, real-time view of their project
- Provides a single search across data in Dotmatics and third party scientific informatics systems
- Powerful browsing and reporting capabilities allow rapid understanding and dissemination of the project data and results

Analytics and Data Visualisation – advanced analytics and data visualisation allow scientists to very quickly and easily gain deep insight into their project data and make well informed decisions as a team on the progression of the project:

- Visualise, manipulate and refine large volumes of research data
- Analyse activity data to identify most promising candidate biologics
- Built-in property and sequence analysis calculations
- Built-in drug antibody ratio analysis from mass spectrometry data

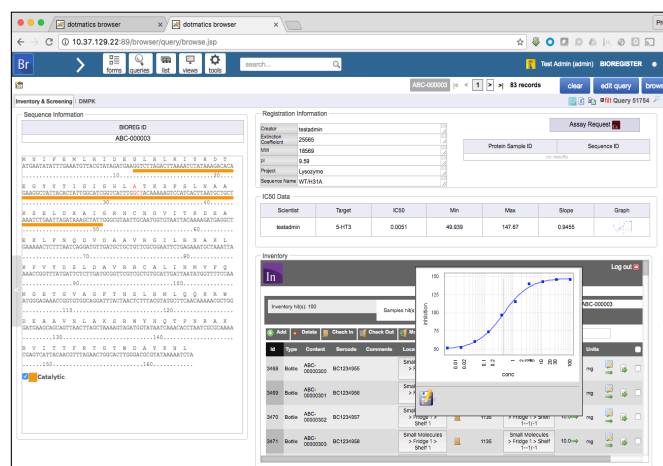


Figure 3: Flexible dashboard for querying and reporting biological information

Collaboration and Document Exchange – key to successful collaboration is the ability to exchange and discuss ideas across multidisciplinary teams that may be separated by geographic and/or company boundaries. The collaboration capabilities provide document exchange to share data, reports and literature as well as engage in an electronic discussion around the key scientific objects and topics in the research project.

Integrated Workflow – all of the capabilities described here are fully integrated and out-of-the-box so that all scientists engaged in a biologics project can:

- gather all of the data they need at any time from across multiple sources
- easily follow their laboratory workflow as they move, for example, from the documentation of their experiment, into the registration of the resulting entity and then into management of the physical sample
- use the requesting capability to efficiently hand-off to the next scientific team to progress the overall workflow forward

Web, Mobile and Cloud enabled – the capabilities can be accessed through web and mobile devices allowing access when and where required. The capabilities can be provided both to in-house scientists and, with a high level of granular access, to external collaborators:

- Systems are supported on-premises or on highly secure Cloud-hosted systems
- Web and mobile applications with out-of-the-box integration minimise deployment and maintenance costs ensuring a low total cost of ownership
- All capabilities are highly configurable and extensible without large customisation service engagements allowing IT to tailor systems to specific company or research project workflows

PROVIDING VALUE TO OUR CUSTOMERS

The Dotmatics Biologics solution has proven its value in a number of pharmaceutical and biotech research organisations.

One of the world's largest biotech companies uses the visualisation and analytics capabilities to automate the analysis of intact protein mass spec data for complex antibody-drug conjugates. Replacing a manual labour-intensive and error-prone excel-based process allowed them to save significant time (and therefore cost) and greatly increased throughput removing a processing bottleneck whilst minimising manual errors. In addition, they consolidated on a single best practice analytical procedure across data from multiple instrument vendors.

In the analysis of screening data, a customer was able to perform a complex procedure using the assay data management capabilities in less than ten minutes. In their experience this would have taken three hours using one alternative software offering and overnight in another.

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