

Summary

Simple, intuitive visualization and validation tools are necessary to review and disseminate the results of large-scale biopharmaceutical datasets

User-defined traffic lights represented in a microtiter plate format quickly relate laboratory operations to processed results.

Byosphere web analysis brings trusted mass spectrometry data processing tools to the cloud for high-throughput, automated data exploration and management

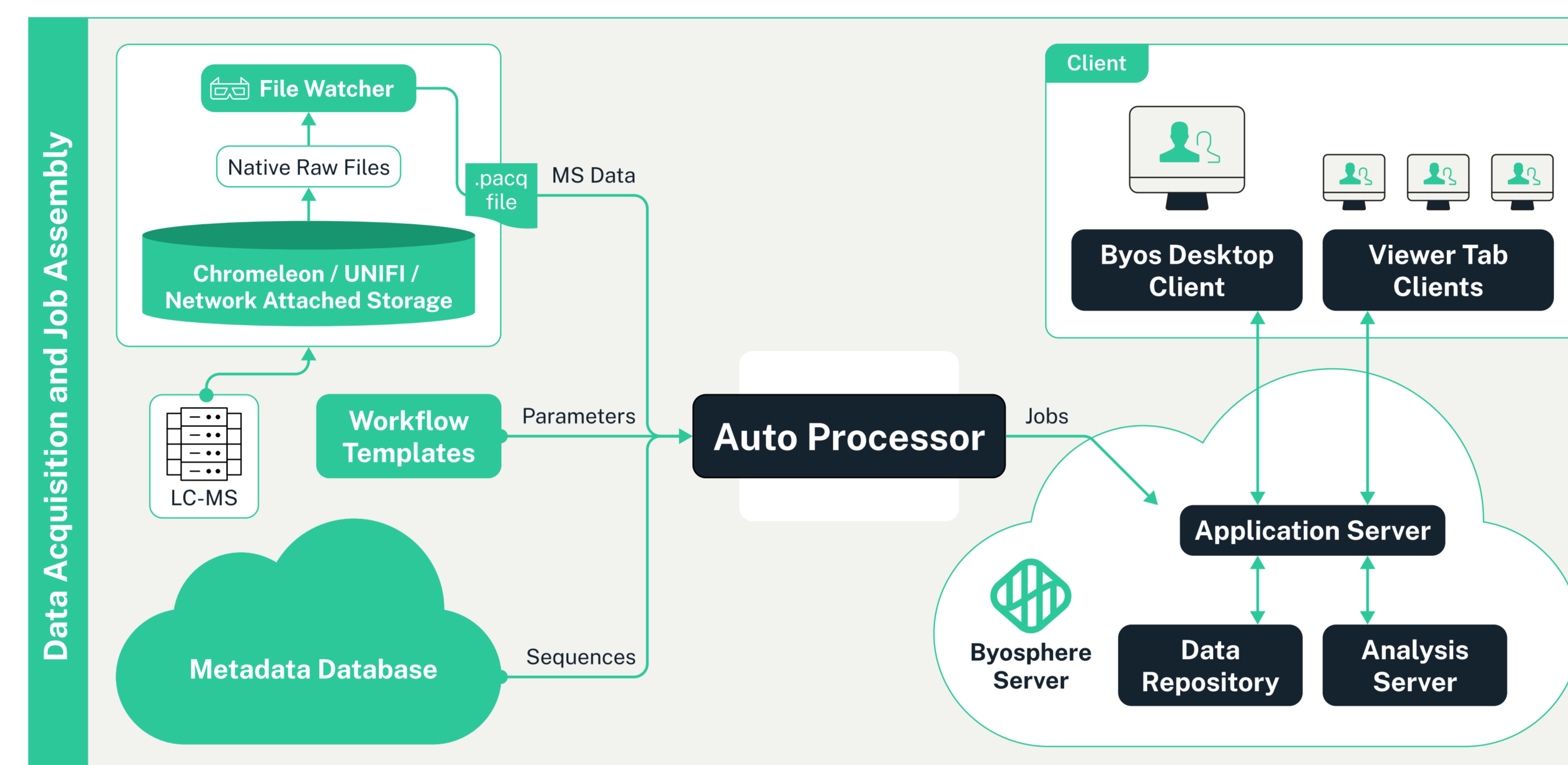
Introduction

As more multispecific antibodies reach the clinic, with 1274 in clinical trials and 25 in late-stage clinical trials by 2024 the amount of data to review for characterization becomes overwhelming for any human^{1,2}. Therefore software and interfaces designed to aid and automate the review are paramount to speeding up development. Methods for expressing hetero-IgGs in a single cell-line can produce undesired "shuffled" combinations. For example, an undesired product can contain regions and chains that are not correctly paired. To enable molecule design optimization, as well as expression/purification optimization of multispecific constructs, mass spectrometry can accurately and efficiently identify desired and undesired chain combinations. Protein Metrics has designed an automated system that deconvolves intact-mass spectra, labels and quantifies desired and undesired peaks, and prepares reports for human inspection and validation.

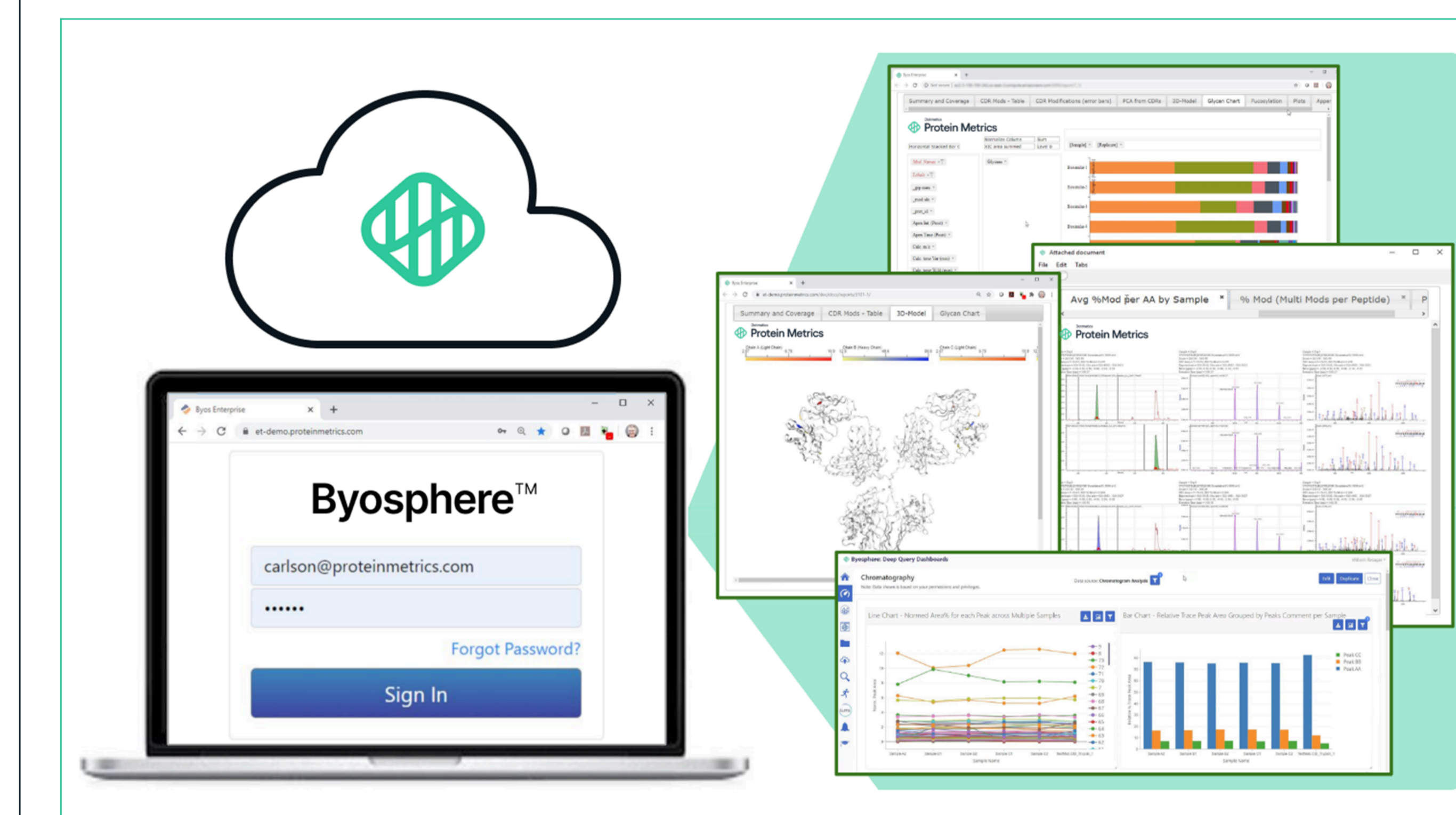
The simple concept of assigning certain combinations by mass as "undesired" enables the software to match not only the correctly formed (hetero-IgG) molecules, but also the various mis-formed molecules. Additionally, a category of "unexpected" mass allows the software to use business rules to assign each sample to one of three categories (Pass, Fail, and Review), color coded in an intuitive "traffic light system" and this can be displayed in a micro-titer/96WP format in a browser view. That browser view can also be shared within a closed, GxP-compliant system, and provide rapid review for non-experts.



Automated Cloud-Based Data Processing & Analysis



Globally Accessible & Notifications



Visualize, inspect, and review results in a format that reflects input data

Sample Status Review

Sample Name	Sample No.	Desired	Undesired	Unexpected	Status	Comment	Volume
F4	54	3.073	0.040	53	Review		Pass
F2	55	3.073	0.040	52	Review		Pass
F3	56	3.073	0.040	51	Review		Pass
F7	67	3.073	0.040	58	Review		Pass
F8	68	3.073	0.040	59	Review		Pass
F9	69	3.073	0.040	60	Review		Pass
G1	70	3.073	0.040	61	Review		Pass
G2	71	3.073	0.040	62	Review		Pass
G3	72	3.073	0.040	63	Review		Pass
G4	73	3.073	0.040	64	Review		Pass
G5	74	3.073	0.040	65	Review		Pass
G6	75	3.073	0.040	66	Review		Pass
G7	76	3.073	0.040	67	Review		Pass
G8	77	3.073	0.040	68	Review		Pass
G9	78	3.073	0.040	69	Review		Pass
G10	79	3.073	0.040	70	Review		Pass

Microtiter Plate

User-defined criteria automates initial data review process

After inspection, user can set validation status to Pass, Fail, Review.

Interactive microtiter plate allows user to quickly view status of a data set, observe edge effects if present, and quickly navigate to underlying results.

References

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