Introduction to Certara

@D360UM **8 Oct, 2019**

Certara is the global leader in advancing modern, efficient drug development.

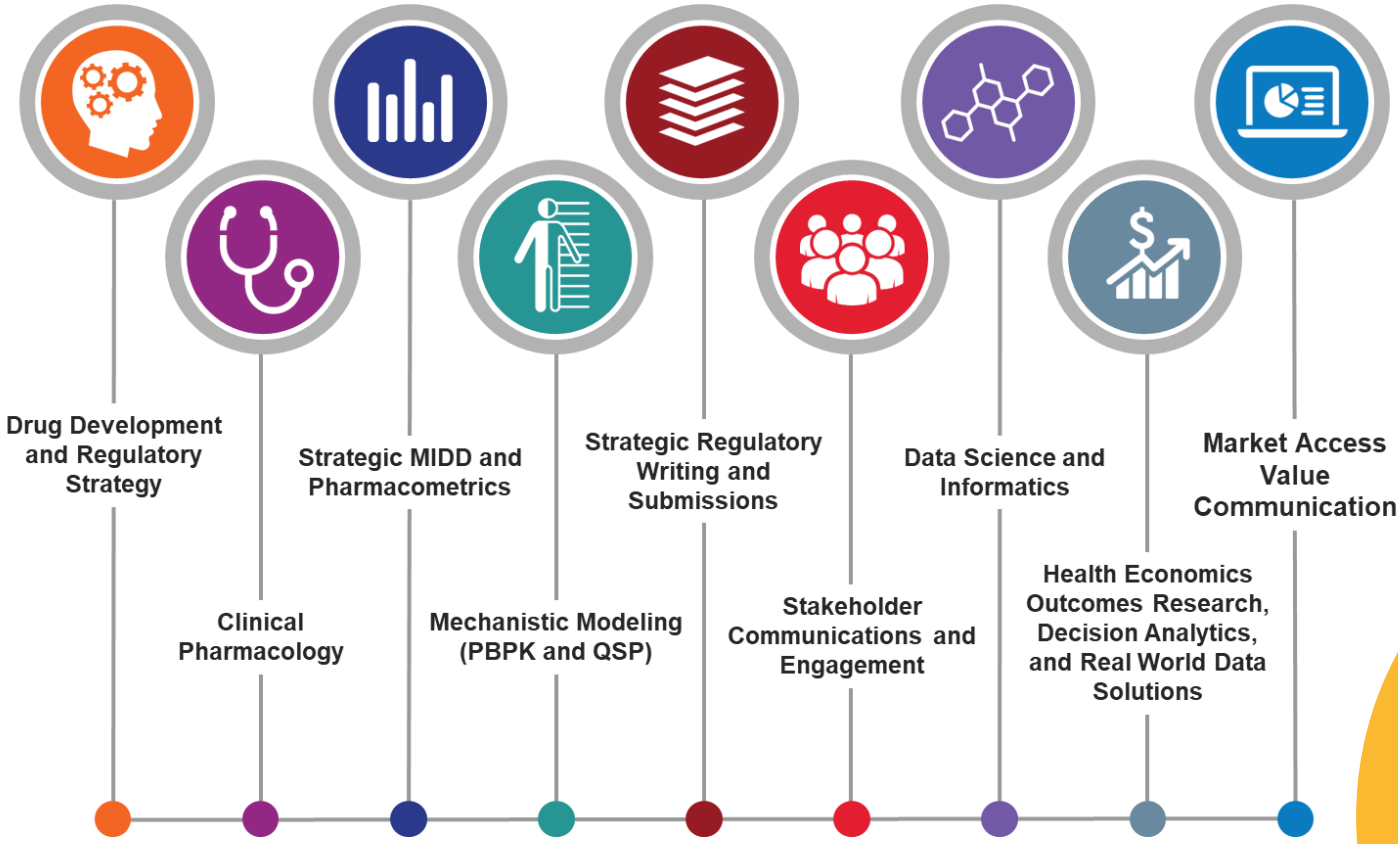
In partnership with our clients, we provide proven modeling & simulation, regulatory science, and real-world assessment software and services to help our clients reduce clinical trial burden, accelerate regulatory approval and increase patient access to medicines.

Our Mission

Enable superior drug development and patient care decision-making

through model-informed drug development, regulatory science, real world evidence and knowledge integration,

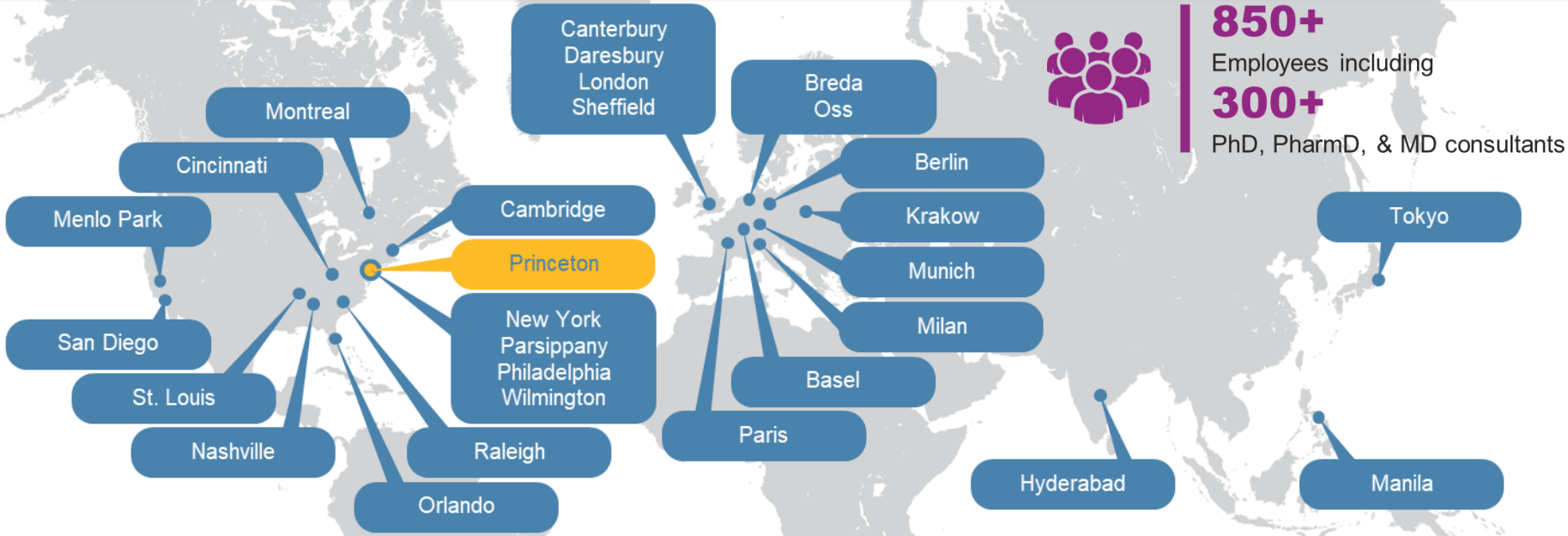
thus optimizing R&D productivity, commercial value and patient outcomes



© Copyright 2018 Certara, L.P. All rights reserved.

CERTARA

Our Impact delivered via a global footprint



850+
Employees including
300+
PhD, PharmD, & MD consultants

200+
Global submissions written and approved in the last 3 years from team of
250+
Regulatory science consultants
100+
Market access specialists

Certara software is used by major regulatory agencies and considered a "gold standard" by the US FDA

>90%
of all novel drugs approved by the US FDA in the past 4 years were supported by Certara software or services

1,700
companies, academic institutions, global non-profits, and leading regulatory agencies in
60
countries partner with Certara

© Copyright 2018 Certara, L.P. All rights reserved.

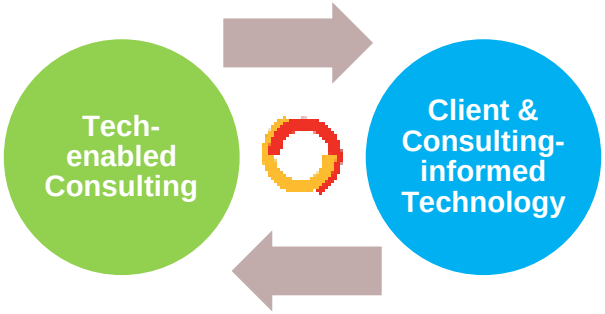
CERTARA

Certara Tech-enabled Integrated Drug Development Solutions

Spanning Discovery to Patient Access

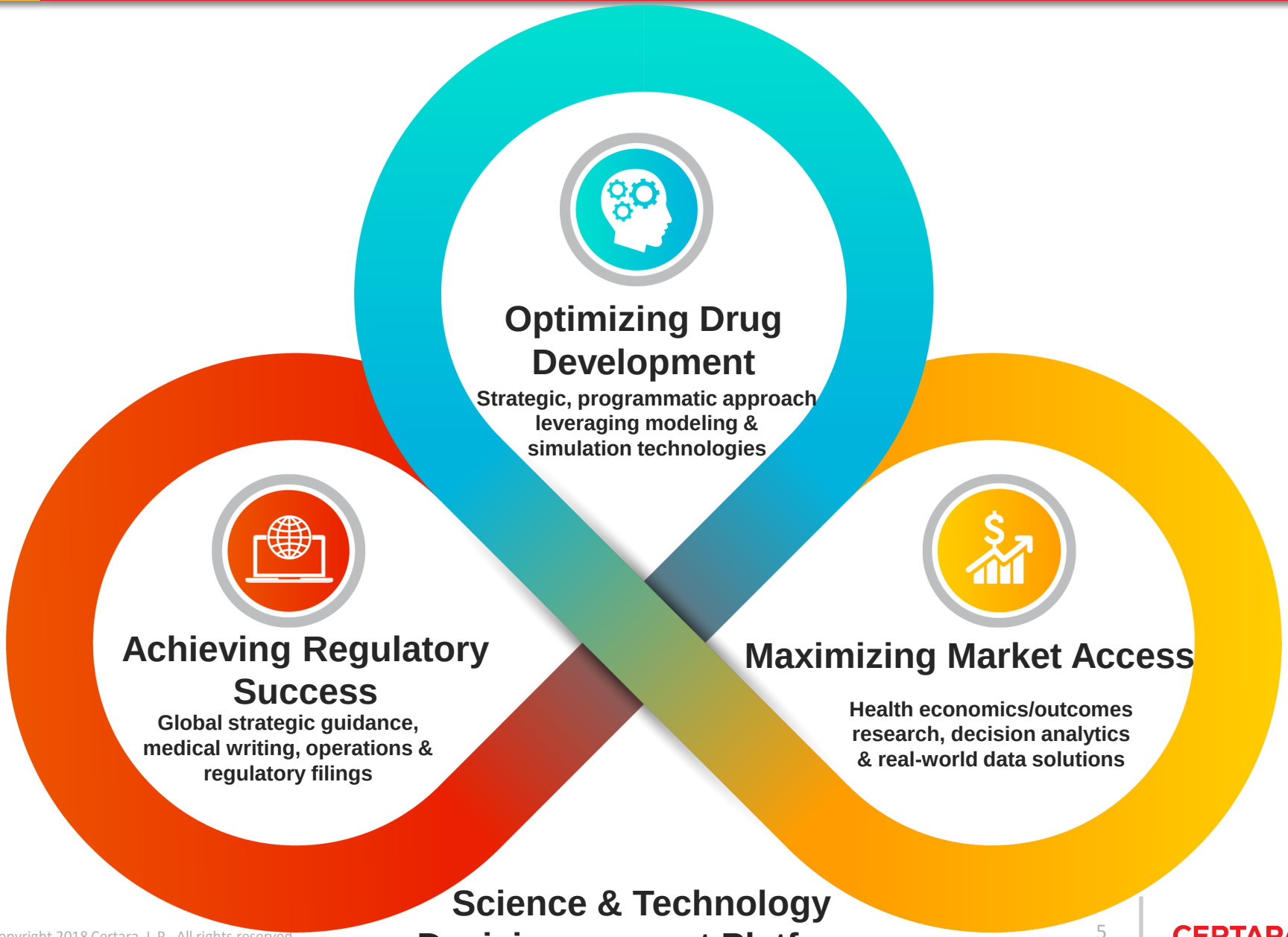
Discovery | Preclinical | Phase I | Phase II | Phase III | NDA | Phase IV

- D360
- Physiology-Based Pharmacokinetic Modeling
- Quantitative Systems Pharmacology
- Quantitative Systems Toxicology/Safety
- Virtual Bioequivalence
- Integrated Drug Development Strategy
- Regulatory Strategy
- Regulatory Ops, Writing, Submissions
- Population Pharmacokinetic-Pharmacodynamic Modeling
- Non-Compartmental Analysis of Pharmacokinetics
- Clin Pharmacology Gap Analysis
- Model-Base Meta-Analysis
- Trial Design
- Real World Evidence
- Health Economics & Outcomes Research
- Evidence, Value, and Access



© Copyright 2018 Certara, L.P. All rights reserved.

Increasing the Reliability & Predictability of Key Decisions

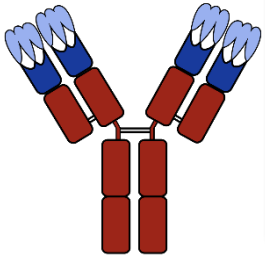


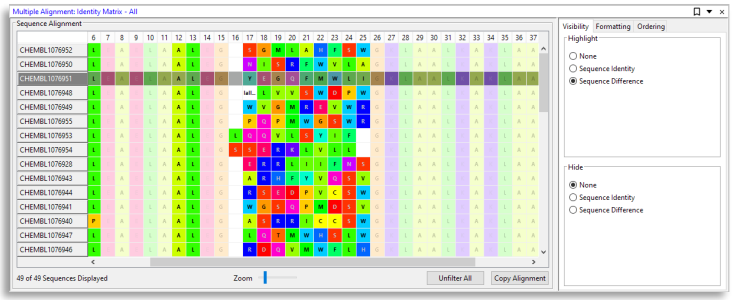
© Copyright 2018 Certara, L.P. All rights reserved.

CERTARA

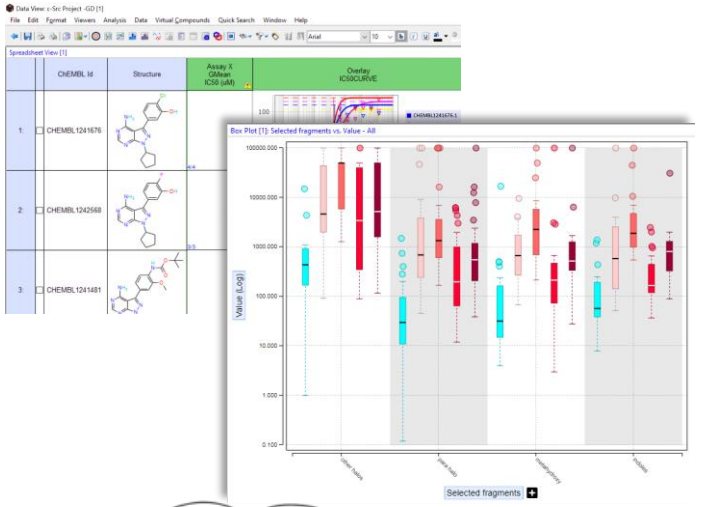
D360 Major Initiatives

- Biologics: Support for research on new modalities
  - Antibodies
  - ADCs
  - Peptides
  - Oligos

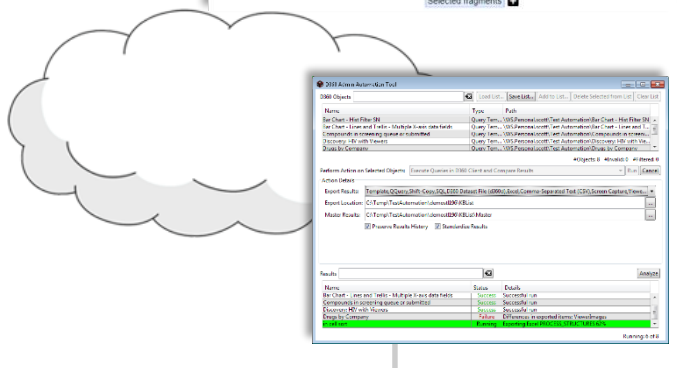




- Data Visualization
  - Completion of data visualization initiative



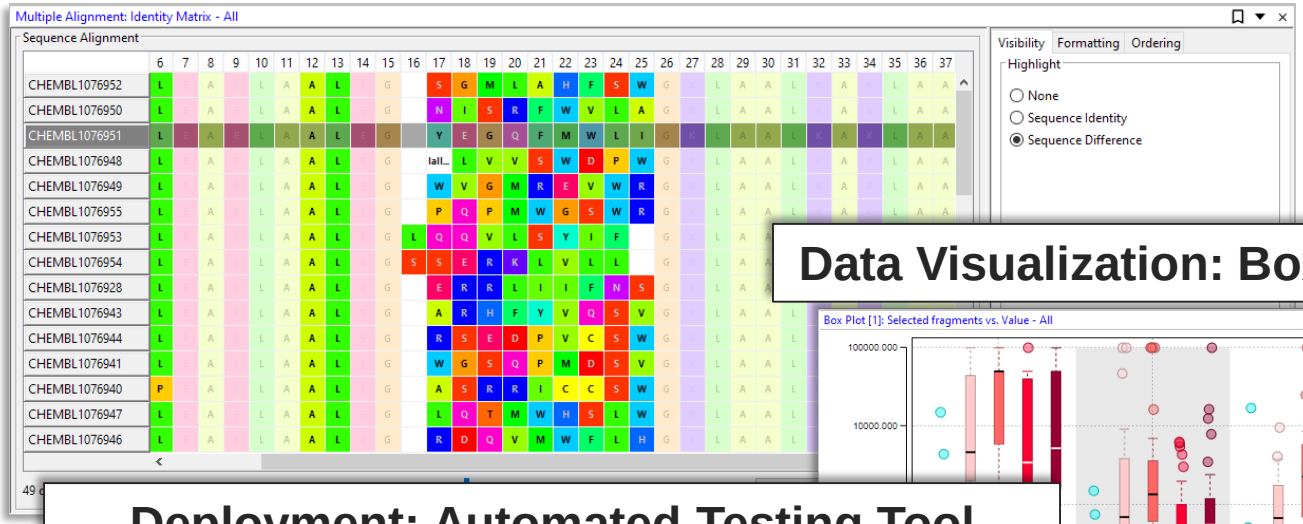
- Simplifying deployment
  - Automated testing for new versions
  - Expansion in cloud deployment capabilities



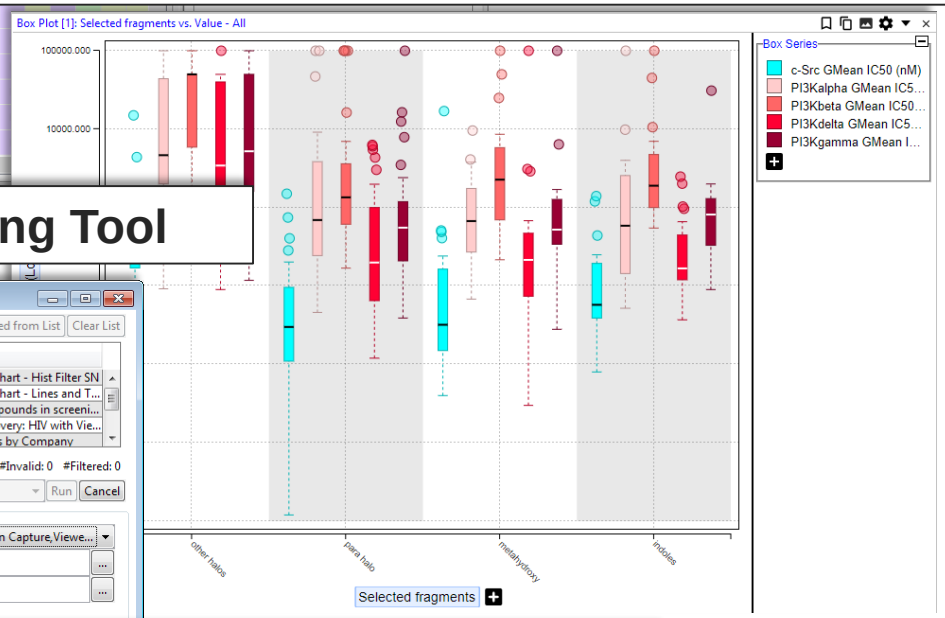
© Copyright 2018 Certara, L.P. All rights reserved.

D360 19.6 – Released June 30th 2019

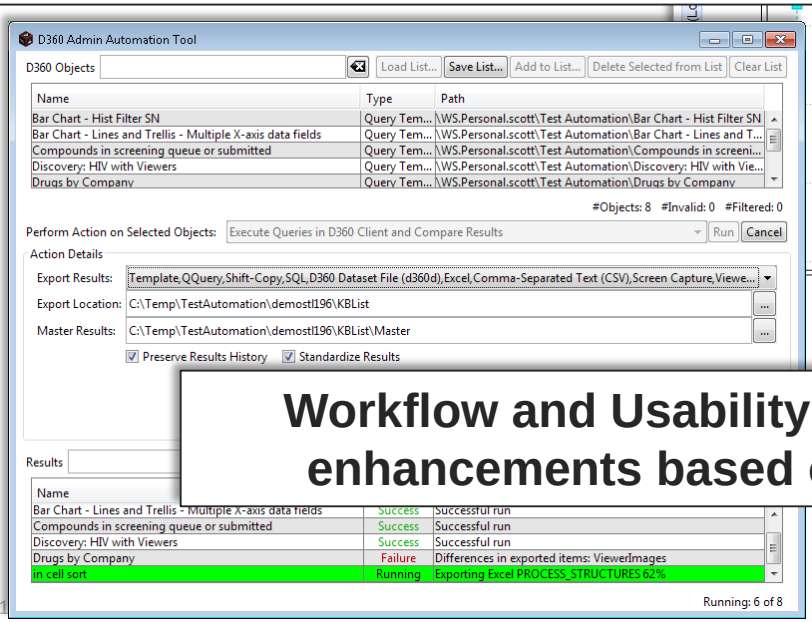
Biologics: Sequence Alignment/Analysis



Data Visualization: Box plots and usability



Deployment: Automated Testing Tool



Workflow and Usability Testing Tool: > 75 enhancements based on user feedback

© Copyright 201

CERTARA