BioCelerate Toxicology Data Sharing initiative: Development of a centralized, searchable Preclinical Data Repository for the Biopharmaceutical Industry

W. Houser[1], **T.G. Bjerregaard**[2], M. Graziano[3], E. Vock[4], G. Kahlbaugh[5], C. Fish[6], T. Page[7], K. Mera[8], T. Fukushima[8], M. Kuzumoto[8], S. Frahm[9]

[1]Bristol-Myers Squibb, New Brunswick, NJ, US; [2]Novo Nordisk, Copenhagen, Denmark; [3]Bristol-Myers Squibb, Princeton, NJ, US; [4]Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, Germany; [5]Boehringer-Ingelheim Pharmaceuticals, Inc, Ridgefield, CT, US; [6]GlaxoSmithKline, Ware, UK; [7]Eli Lilly and Company, Indianapolis, IN, US; [8]Shionogi & Co., Ltd., Osaka, Japan; [9]BioCelerate, Conshohocken, PA, US

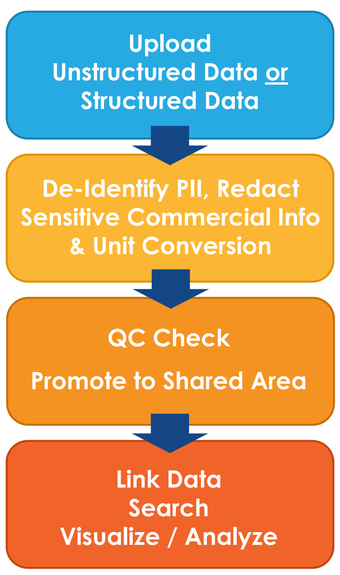
Introduction

BioCelerate, a subsidiary of TransCelerate, was formed in 2015 as a preclinical industry consortium to identify and implement initiatives driving efficiency in early stage R&D. Motivated in part by the FDA's 2011 Strategic Plan for Regulatory Science and binding guidance requiring CDISC SEND standard format for nonclinical data, the **Toxicology Data Sharing initiative has developed the DataCelerate platform, a centralized, searchable toxicology and background control animal data repository, enabling participants to make more informed decisions on compound progression based on increased understanding of on-target and off-target toxicity.**

Early data submissions are focused on FIH-enabling studies due to uniformity of design, abundance of toxicity findings for assessing on- and off-target effects, and capacity to be correlated more directly with early clinical safety data (Phase I). In addition to accepting SEND-formatted data, the system accepts unstructured (PDF) data to make legacy studies available and build database volume.

DataCelerate Workflow and Capabilities

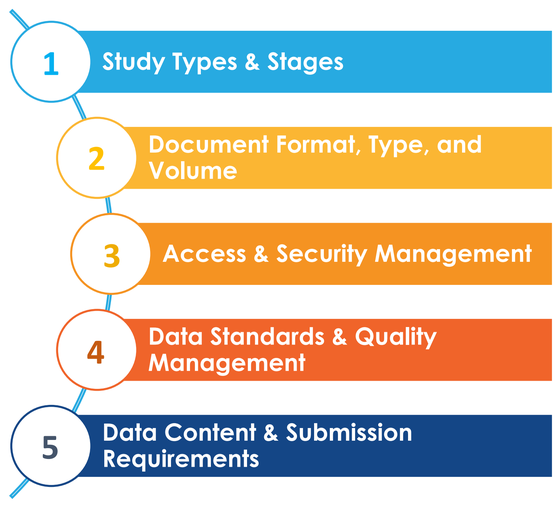
Workflow



Core Capability	Use Case Focus
Identity Management	▪ Semi-automated de-identification of PII (personally identifiable information) and redaction of commercially sensitive information for structured and unstructured data
Import & Export	▪ Import of structured (e.g. CDISC) and unstructured data (e.g. PDF) ▪ Unit conversion for lab values ▪ Export of full studies and filtered search results
Data & Document Management	▪ Separate background control & toxicology databases ▪ Linkages between associated toxicology data sets
Search	▪ Enhanced search & filtering capabilities across unstructured & structured data
Data Visualization	▪ Visualization tools for structured datasets

Data Sharing Guiding Principles & Agreement

Data Sharing Agreement Components



Data contribution and usage requirements are clearly outlined in the BioCelerate Data Sharing Agreement, ensuring high quality, meaningful data contributions, parity amongst participants, and risk management.

Data sharing guiding principles in five strategic areas were established early to serve as a framework for successful collaboration amongst participants. In parallel with an extensive legal assessment, these data sharing principles evolved into a formal Data Sharing Agreement (DSA) governing the secure, controlled exchange of data and addressing potential legal risk. **Executing the Data Sharing Agreement is a requirement for member company participation.**

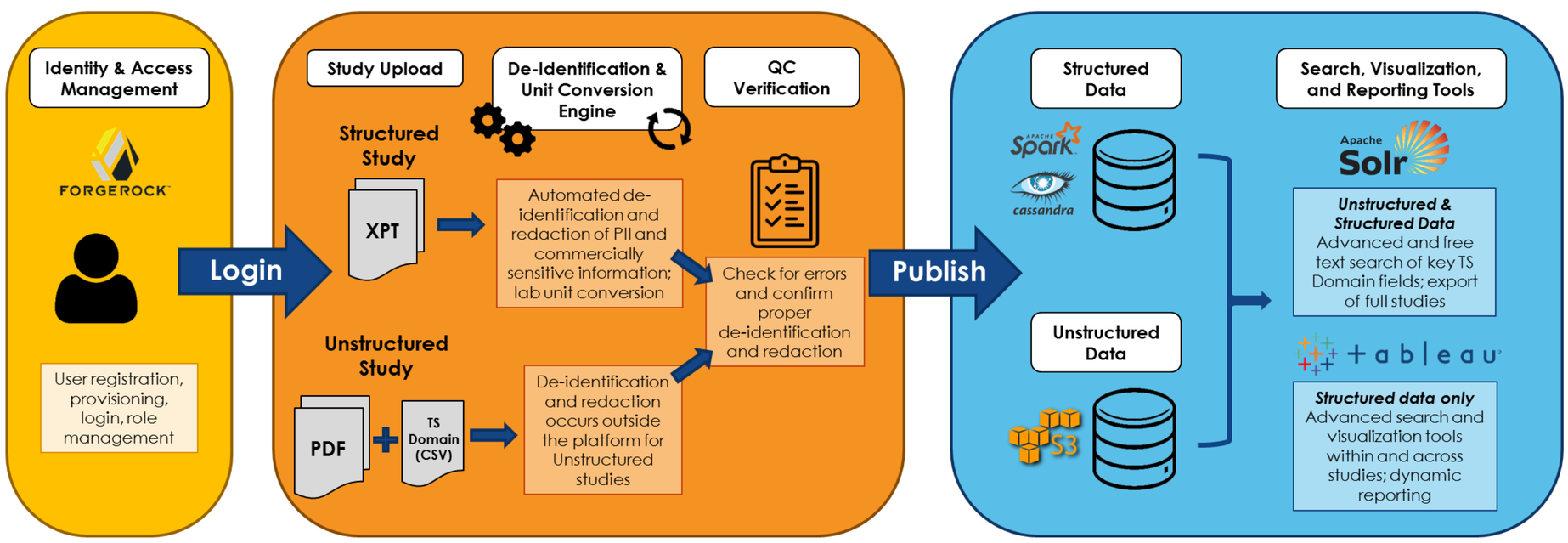
Example data contribution requirements:

- *Inclusion of primary intended biological target, compound type and class*
- *Exclusion of sponsor identity information, compound structure, personal data*
- *Submissions are restricted to compounds for which a patent is filed & verified by external counsel*

Summary & Future State

BioCelerate's Toxicology Data Sharing initiative has developed a user-friendly data sharing platform allowing participants to easily upload, search for, visualize, and download toxicology and background control data of interest. With a future vision of linking de-identified data across the entire R&D continuum, the innate flexibility and modularity of the underlying data lake will serve as a foundation for all future TransCelerate preclinical and clinical data contributions, expediting the discovery of translational insights and predictive outcomes in order to bring new medicines to patients faster.

DataCelerate System Architecture



BioCelerate
Contact: info@biocelerate.org

Boehringer Ingelheim · Bristol-Myers Squibb · gsk · Lilly · novo nordisk · SHIONOGI