Nonclinical Common Protocol and Report Templates

Initiative Overview

BioCelerate

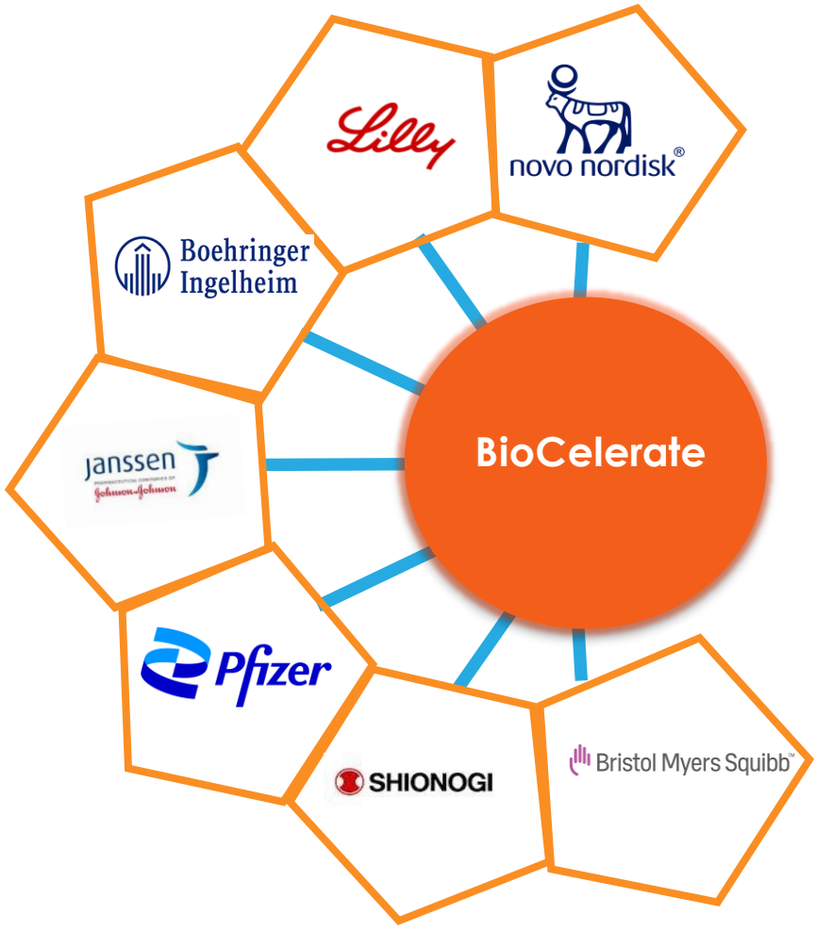
BioCelerate
History and Current Participation

2016 BioCelerate was created with the goal to identify, develop, and deliver industry initiatives designed to make nonclinical R&D efforts more efficient, starting with toxicology data sharing (TDS)

2017-2021 BioCelerate launched two additional Initiatives, expanded membership, and established a working group with the FDA to advance nonclinical initiatives

2022-Onwards Future efforts will continue to build upon the current, foundational initiatives to enable predictive toxicology and translational efficacy across the R&D ecosystem

BioCelerate Members include:



Why Common Templates for Nonclinical Studies?

The Challenge

The **variety** and **complexity** of nonclinical template formats across organizations introduce errors, delays, increased workload for both CROs and sponsors. The errors may lead to decreased data quality and delays in bringing medications to patients.

Our Opportunity

Broad adoption of nonclinical common templates could help to **drive greater efficiency** for many key stakeholders: technical staff, investigators at test sites, study directors, sponsors, QA, and regulators; **structure is a logical place to harmonize**

Long Term Opportunity

Templates are a first step toward better **enabling structured, computer readable** protocols and reports

Core Design Principles
Focus on Users

Purpose

- Focus on process efficiency and quality study execution / conduct
- Eliminate content better suited for inclusion in other documents
- Make it easier for users to do their jobs
- Simplify Sponsor-CRO expectations

Structure

- Order sections intentionally for easy reference and navigation
- Focus on layout and format to minimize redundancy
- Use consistent terminology & follow standards of OECD and FDA/GLP guidance
- Avoid process instructions where large variations in preferences exist
- Allow flexibility within the defined high-level sections

Scalability

- Enable agility across stakeholder types or geographies
- Minimize the need for major customizations
- Allow for evolution based on need
- Link to templates (e.g., report) or to available data standards (e.g., SEND)
- Lead to the development of automation opportunities further improving efficiency and decreasing cycle times

Benefits Many Stakeholders
with progress towards automation

CROs

- Protocols streamlined and organized with technician/lab needs in mind
- More consistent documentations
- Greater efficiency in study start-up and conduct, leading to less delay
- Enables greater automation and reuse of content in downstream processes, like reporting and analytics

Health Authorities

- Increased consistency between nonclinical study-related documents to facilitate efficient review
- Increased use of data standards enabling end-to-end traceability

BioPharma/ Sponsors

- Opportunity to consolidate existing, varying templates
- More streamlined protocol authoring and review
- Improved quality / efficiency
- Enables greater automation and reuse of content in downstream processes, like reporting and analytics

Standards Bodies/ Users

- Opportunity for further application of available data standards and terminology, for end-to-end consistency across processes, i.e., protocol development to study reporting

BioCelerate Nonclinical Templates
Scope

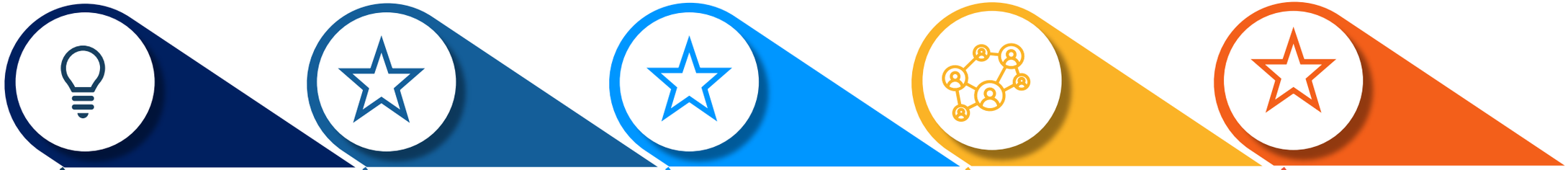
Protocol Template

- GLP or Non-GLP single-dose or repeat-dose toxicology studies
- Multiple species (rodent, non-rodent) Version 1.1
- Additional future versions (v2.0, etc.) may be considered based on user feedback and changes to regulatory guidelines

Report Template

- Follow the order of BioCelerate V1.1 Protocol
- Option to link the protocol for the majority of the study methods
- Option to link to Contributor Reports (PI reports), summary and data tables in report

Template Development Journey
Stakeholder input along the way



2018 - 2019

Ideation: Nonclinical Protocol Template

- Member Company Best Practices
- CRO Roundtables Input
- Public feedback
- Draft version published for input

2019

V1.0 Protocol Template Published

Included:

- Member Best Practices
- FDA CDER feedback
- Stakeholder Roundtable
- Public feedback period

2020

V1.0 Report Template Published

Included:

- Member Best Practices
- FDA CDER feedback
- Stakeholder Roundtable
- Public feedback period

2021

Voluntary Internal Pilot

- Participating companies applied the publicly available BioCelerate-developed Nonclinical Protocol Template and corresponding Report Template to prior trials in which they had used their organization's current templates.
- Results aggregated and shared at ACT

2022

V1.1 Protocol & Report Templates Published

Updates Included:

- Pilot results feedback
- FDA CDER feedback
- FDA CDER feedback

Next Steps:

- Industry engagement for scoping future of nonclinical templates

Internal Pilot with BioCelerate Templates
Assessing Usability

All BioCelerate participating companies **voluntarily completed a pilot** by applying the publicly available BioCelerate-developed Nonclinical Protocol & Report Templates to prior studies that utilized their organization's current templates.

A **detailed pilot feedback form was completed** by representatives across various company departments and in accordance with BioCelerate policies, survey information was aggregated, blinded, and summarized.

Key results include:

Consensus on the value to all stakeholders of a common template for nonclinical studies

All companies reported that their organization's study templates compared somewhat similar or very similar to the BioCelerate developed Templates

Reported Template differences were considered to be both positive e and negative which is to be expected when developing a common template

Consensus that aligning on Templates' structure (i.e., level 1 headers) allows or flexibility within sections

Targeted revisions provided by companies will increase overall usability and ease of implementation

All companies reported potential barriers to broad adoption; cited most often was internal and external resistance to change

What can the Templates Offer Organizations?

IMPROVE EFFICIENCY

- Decrease time spent looking for key content by aligning format which can decrease study errors and improve data quality
- Leads to more rapid protocol development

IMPROVE QUALITY

- Reduces multiple report formats across organizations, resulting in more efficient report authoring and reviews by CROs, Sponsors, and regulators
- Spend less time on low-value customization and reduce time managing template maintenance

FACILITATE COMPLIANCE

- Consistent format across protocols simplifies the QC check of the SEND package

What Next?

- Check out more information on the BioCelerate Common Templates Initiative

- Create a Plan to Consider Adoption at your Organization
  - Download the Templates
  - Review the available supporting materials under 'Available Assets' on the website

For more information on BioCelerate visit: *www.biocelerate.org*