## Nonclinical Common Protocol and Report Templates V1.1 Release

FEBRUARY 2022



### V1.1 Release of BioCelerate Nonclinical Templates Summary

#### BioCelerate is pleased to announce the release of V1.1 of the Nonclinical Protocol and Nonclinical Report Templates

- V1.1 replaces V1.0 of both the Nonclinical Protocol and Report Templates and are currently available for public download and use at <u>www.biocelerate.org</u>.
- Updates in V1.1 are based on stakeholder feedback collected through online feedback forms and a voluntary pilot of participating companies utilizing the BioCelerate V1.0 Templates
- The Table of Contents structure with Level 1 and 2 headers remains the same as V1.0 which will continue to allow all users to easily find information

#### V1.1 Release of BioCelerate Nonclinical Templates Background

- Since the V1.0 releases, the team has been collecting feedback via public feedback forms and recently completed a voluntary pilot utilizing the BioCelerate V1.0 Templates.
- The objective of the voluntary pilot was to assess the value and functionality of the BioCelerate Templates by comparing them with templates used by participating companies. Feedback from this experience assisted in identifying points of variation and helped to inform V1.1 as well as future versions.
- Key results from the pilot were presented at the American College of Toxicology Annual Meeting and included consensus on the value of a common template for nonclinical studies to all stakeholders. Targeted revisions provided by companies will increase overall usability and ease of implementation. For additional information on the pilot please visit www.biocelerate.org
- Feedback is collected on an ongoing basis for both publicly available Templates. Feedback can be provided online <u>here</u>.
- > Have questions or need more information? Check out our <u>FAQs.</u>

### What has changed in V1.1? Outline of Updates

#### Updates included in V1.1 are based on collected feedback provided through online forms and detailed feedback received from a voluntary pilot

Updates in V1.1 focus on increasing Template usability and ease of implementation for the user\* and include:

- Quality Assurance section added based on participant feedback
- > Approval section moved up front for quick access to this important page
- Updated instructional and suggested text for clarity
- Formatting updates for consistency
- Editorial revisions to resolve wording and/or grammatical errors

\*A track changes version of V1.0 is available upon request at info@biocelerate.org

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for more information visit www.biocelerate.org

