Nonclinical Common Templates for Toxicology Studies: Nonclinical Protocol Template (NCPT) and Nonclinical Report Template (NCRT)

Frequently Asked Questions

Last Updated March 2021

GENERAL

Q: Is use of the NCPT and NCRT limited to BioCelerate member companies?
A: No. The nonclinical common templates and Supporting Materials are posted on the BioCelerate website, making them available for download and use by any interested party.

Q: How will nonclinical common templates like the NCPT and NCRT benefit organizations?
A: Consistent use of protocol and reporting templates help to drive greater efficiency for all stakeholders, including investigators, sites, sponsors, and regulators. An organization could see potential efficiencies including less time spent on low-value customization, reduced time managing template maintenance and increased efficiency of the QC check of SEND datasets, all of which leave more time to focus on the science. Benefits of the NCPT and NCRT may include the elimination of duplicative protocol and report formats across organizations, resulting in more efficient protocol and report authoring and reviews by stakeholders. Many stakeholders, including health authorities, believe this will contribute to an environment where information is more connected and streamlined from one stage to the next. Please see the NCPT & NCRT: Initiative Overview available under "Supporting Materials" on the BioCelerate website for additional information: www.BioCelerate.org

Q: Are there any foreseen hurdles to these nonclinical templates being used?
A: Change is hard at any scale. BioCelerate is monitoring feedback to surface any unanticipated hurdles. To address adoption challenges please see the "Approaches to Implementation in Your Organization" document available at www.BioCelerate.org for additional information.

Q: How has the Nonclinical Common Protocol Template (NCPT) evolved to become this version?
A: The process to develop the first working draft of the protocol template utilized the OECD/FDA GLPs as a starting point and excluded process instructions where large variations in internal processes and preferences may exist. An early survey with CROs was completed for initial input as well. In addition to posting two subsequent working drafts on the BioCelerate website for public feedback, two 2019 webinars introduced the draft template and were used to collect CRO feedback on the working drafts. Feedback from US FDA was also solicited. Version 1.0 of the protocol was released publicly in Q4 2019. For more information, there is a background document available on the BioCelerate website under the NCPT "Supporting Materials" www.BioCelerate.org

Q: How has the Nonclinical Report Template (NCRT) for Toxicology Studies evolved to become this version?
A: The process to develop the initial report template utilized both common report structure and the NCPT outline as a starting point. In addition to member company input, feedback on the main structure of the NCRT was also solicited from a few pharm/tox reviewers with the US FDA. In April 2020, a virtual workshop convened key stakeholders including CROs, tech vendors and sponsors which provided further feedback on the working draft. V0.1 was posted on the BioCelerate website for public feedback. Version 1.0 was released publicly in Q4 2020.

For more information, there is a background document available on the BioCelerate website under "Supporting Materials" www.BioCelerate.org

Q: What are some of the most important components to the NCPT?
A: The most important aspect of the Nonclinical Protocol Template is the Table of Contents with Level 1 and 2 heading structure which will allow all users to easily find information. A focus has been to keep the template simple, therefore enabling organizations to reduce unnecessary complexity in their existing template requirements.

Q: What are some of the major issues the common protocol template will address?
A: Protocols have become increasingly complex and difficult to navigate. Responses to survey questions answered by CROs and sponsors indicated that a majority of stakeholders used multiple repeat-dose toxicology protocol templates, and experienced problems associated with protocol inconsistency including process/time inefficiencies and reduced quality of study execution. The NCPT also facilitates the efficient quality control of the SEND datasets through the addition of certain SEND terminology which can be referenced in the protocol.

Q: Why is the BioCelerate workstream recommending that organizations carefully consider deviations from the common text?
A: In the end, each sponsor and CRO must decide whether and how to best use the template to meet their needs, including whether and how much to alter proposed common content. More consistent adoption within organizations will allow stakeholders to derive maximum benefit. For example, sites and CROs will save more time if sponsors use the same structure, so protocols can be followed more easily with less confusion.

Q: What are the next steps for the Nonclinical Common Templates Initiative?
A: In the short term we hope to build awareness and encourage adoption in order to increase the value of both templates. We also hope to measure the usability and benefits achieved through template use. We will continue to work with collaborators and stakeholders in evaluating adoption and implementation options as well as recommendations for content and structural improvements. Input from all stakeholders will help us develop the next-generation templates as well as shape our next steps.

Adoption of the NCPT and NCRT

Q: Why should an organization adopt the NCPT and NCRT?

A: An organization could see potential benefits including less time spent on low-value customization, reduced time managing template maintenance, and increased efficiency of the QC check of SEND datasets. Broad adoption of BioCelerate common templates supports the elimination of duplicative protocol and report formats across organizations, resulting in more efficient protocol and report authoring and reviews by stakeholders. Many stakeholders, including health authorities, believe this will contribute to an environment in which information is more connected and streamlined from one stage to the next.

Q: How do organizations adopt the NCPT and NCRT?
A: Each organization must decide how best to implement. We have developed materials to facilitate implementation that are available under the "Common Templates for Nonclinical Studies Initiative" at www.BioCelerate.org.

Q: What will companies need to change/update to implement the NCPT and NCRT?
A: Organizations might want to compare their current protocol templates with BioCelerate's NCPT and assess if any differences require action/alignment. To facilitate this exercise, a Mapping Tool and Instructions are available for the NCPT under "Common Templates for Nonclinical Studies Initiative" at www.BioCelerate.org. Once a company has adopted the NCPT, the transition to using the NCRT should be easier as the NCRT follows a similar structure as the NCPT and elements can be easily linked. Additionally, organizations may need to communicate with partners to facilitate adoption and approaches to implementation.

Q: What should we do if gaps/differences are identified between our company's current protocol/report and the common templates?
A. If gaps are identified, work with your internal functional representatives to identify if this information is adequately covered elsewhere within your organization (e.g., Monitoring Guidelines, SOP/Policy documents) or if it needs to be added to the NCPT/NCRT. Feedback can be provided to BioCelerate (www.biocelerate.org) for consideration of additional text in future versions of the template(s).

Stakeholder Input to NCPT and NCRT Development

Q: How can users provide feedback?
A: On the BioCelerate website, complete an online feedback form or send an email with your specific feedback to info@biocelerate.org. The online feedback form can be found at www.biocelerate.org. The team welcomes feedback as it is critically important to creating robust, sustainable templates.

Q. Is there any documentation around the decisions made about specific content, headers, etc.?
A: Decisions for the NCPT about specific content, headers, etc. were made based on a review of relevant guidelines regarding GLP, regulatory testing, animal welfare and relevant regulations, CRO feedback as well as a review and comparison of anonymized sample protocol templates in use at the BioCelerate member companies. The NCRT is based first on the organization of the NCPT high level headings as a base and then incorporated stakeholder feedback.

Q: Was the NCPT content checked to conform to regulations and guidelines?
A: The latest GLP, regulatory testing and animal welfare regulations were used to guide the design of the NCPT content, however, nothing in the template should be construed as providing legal advice and all individuals and organizations using this template bear responsibility for complying with the applicable laws and regulations for the relevant jurisdiction.

Q: What is the timing of incorporating additional input from CROs, sponsors and regulators?
A: Input from key stakeholders is assessed on an ongoing basis and will be addressed in future versions.

Nonclinical Common Protocol Template Content

Q: Can a tabular format be used for the common core text to represent the text information in a different manner than text sentence structure?

A: Each company must decide if and how they want to implement the templates. A tabular format is used in some areas, particularly appendices, for a more clear and concise presentation of the information. A mechanism for feedback and suggestions for template improvements is available on the BioCelerate website for those implementing the template. www.BioCelerate.org

Q: Is there any documentation around text types, font sizes, colors, etc. that have been used in the NCPT?

A: No, harmonization around text types, font sizes, colors, etc. has not been in scope for the NCPT. However, a mechanism for feedback and suggestions for template improvements is available on the BioCelerate website.

Q: Has there been any discussion on how best to handle protocol amendments?

A: There is variability in the approaches taken by users. For example, a company could update the entire protocol and issue this as an amendment. Within the NCPT, a cover page is provided under the Appendix section with instructional text that can be used, if applicable.

Q: Is the order of the assessments meant to be fixed as they are currently presented in the Schedule of Activities (SoA)?

A: The order of the SoA is aligned with the order of the sections within the protocol and is recommended to remain as such. However, it can be modified as needed for the study and sponsor preferences. Please note: it is strongly recommended that if the table is re-arranged, the protocol section numbers remain associated with the appropriate parameter.

Q: Can the APPENDICES be deleted if not applicable, or does the word 'Not Applicable' need to be inserted to retain the sequence/order of the Appendices numbering?

A: The decision about whether to modify, delete or add appendices rests with the individual Organization. Appendices provide additional information that can be accessed when needed (e.g., abbreviations, company specific content). Individual Appendices are to be omitted if not applicable. **This is a different expectation than applies to the body of the document, where Level 1 and 2 section headings should not be deleted to maintain the template structure, but rather should be marked "Not Applicable", if appropriate.**

Nonclinical Study Report Template Content

Q: Is there any documentation around text types, font sizes, colors, etc. that have been used in the NCRT?

A: No, harmonization around text types, font sizes, colors, etc. has not been in scope for the NCRT. However, a mechanism for feedback and suggestions for template improvements is available on the BioCelerate website at www.biocelerate.org.

Q: Has there been any discussion on a template for a contributing scientist/ principal investigator report?

A: Creating a template for contributing scientist/prinicpal investigator reports was not in the original scope of the BioCelerate Nonclinical Common Templates initiative. However, the team recognizes the potential value of a CR/PI template and will consider revisiting this at a future date.

Q: How was the format of the NCRT developed?

A: The NCRT was developed based on the structure of the BioCelerate nonclinical protocol template. Additionally, in attempting to reduce copy/paste repetition, the team proposed the use of links to the latest protocol amendment rather than repeating the Materials and Methods text in past tense. The team recommendation to further support reduction in copy/paste is for each results section to link directly to the applicable Contributing Report Results Section and may also include a high-level summary. Repetition of text from the Contributor Report should be avoided. For those results that are interpreted by the Study Director and not accompanied by a Contributing Report, a summary and link to the results tables/figures will be included. The Discussion Section is considered optional and is placed just after the summary section. The Discussion Section should not be a copy/paste of the Summary Section but should provide information to further contextualize the study findings described in the summary, the MOA/pharmacology of the test article, and/or may include references to literature to support this.

Implementation of the NCPT and NCRT by the Sponsor

Q: Can organizations alter the content of the NCPT and/or NCRT to their liking? Can we use some sections of the NCPT and not others?

A: BioCelerate initiatives are voluntary, meaning that organizations, including BioCelerate member companies, decide whether and how they will use deliverables like the NCPT and/or NCRT. Many of the benefits of the project are increased by template consistency. To achieve maximum benefits, it is strongly recommended that all Level 1 and 2 Headers be left intact, and if no content is needed for a section, that section is to be marked as "Not Applicable

Q: Is the expectation that a company would use the templates for all its nonclinical studies or perhaps just for certain types of studies?

A: The NCPT and NCRT were originally designed to be used for general toxicology studies, including study types such as antigenicity, metabolite, and impurity studies that follow similar study designs. However, all implementation is voluntary, and if an organization chooses to adopt the templates, they can choose their own strategies for implementation.

Q: Why should the headers remain unchanged?

A: The intent is that all Level 1 and 2 Headers be left intact, so that the template structure remains consistent. If they are not applicable, you can mark them N/A.

Q: Will there be special software required to implement?

A: No special software will be needed. The template utilizes functionality native in MSWord.

Q: Is there a mechanism for organizations working to adopt the BioCelerate NCPT and NCRT templates to know that the content is aligned with the content in their current templates?

A: There is a Mapping Table tool publicly available on the BioCelerate Website where an exercise that can be performed to ensure alignment between your company protocol/report templates and the latest BioCelerate NCPT/NCRT. Within the mapping table, the headings and subheadings are compared to identify where content is located. In addition, the content can be compared to identify any gaps, which will help trigger if there is another mechanism in place within your organization to capture this information (e.g., Monitoring Guidelines, Master Service Agreements, Standard Operating Procedures) or if and how the gap needs to be addressed.

Q: Will there be additional guidance for authors provided with the NCPT and NCRT or will it be a standalone document?

A: Instructional Text (guidance for authors) has been embedded into the NCPT and NCRT and will be visible as *italicized red text* in the Templates.

Q: How will organizations know that the BioCelerate templates are being utilized by their contract research organization partners?

A: The templates are intended for voluntary adoption across industry. As a best practice, individual sponsors and CROs should discuss the implementation and adoption with each other.

Metrics

Q: What are the BioCelerate Nonclinical Common Template Workstream's metrics for success around implementation of the NCPT and NCRT? How will these be measured and reported?

A: Metrics measurement is currently being discussed. We welcome users who wish to share their ideas and experiences with implementation of the templates to info@biocelerate.org.

Updates to the NCPT and NCRT

Q: What are the expectations for future releases of the nonclinical common templates? Will there be major changes?

A: V1.0 of both the NCPT and NCRT will remain stable throughout 2021 to facilitate implementation conversations and adoption and allow sufficient time for companies to use the template so that we can evaluate their effectiveness. In the future, once the templates have been in use and are in business continuity (i.e., maintenance) mode, the team is planning that the templates would be updated periodically by BioCelerate based on any external regulation changes or user feedback. The frequency of templates update will be influenced by the feedback received and the criticality of the updates, but in general we would target releasing updates no more than once annually. The next planned major release is intended for early 2022. Please note that the structure of the templates does allow for flexibility in use and any updates will include a marked-up version for user review and comparison prior to implementation. Feedback, including suggestions for future releases, may be submitted via the BioCelerate website: www.BioCelerate.org