

Mapping Table Exercise - Instructions

Purposes: To facilitate use of the NCPT within your organization by ensuring alignment of your company’s protocol content needs to the BioCelerate Nonclinical Protocol Template (NCPT) by

- mapping the location of content in the NCPT as compared with your company template – this will facilitate populating the NCPT
- determining if content used in your company template is missing in the NCPT - this
 - allows for identification of any gaps (information in your company template that does not appear in the NCPT)
 - triggers the need to identify where (other than the protocol) within your organization this information is found (eg, Standard Operating Procedures, policy and procedure documents).

Mapping Instructions: Map your protocol template to the BioCelerate NCPT

1. Compare the headings and subheadings of your protocol template with those in the BioCelerate NCPT (see example below) – this will allow users to easily find the appropriate sections where content should be included in the NCPT
2. Compare the content of corresponding sections (your protocol template to those in the BioCelerate NCPT). Identify any missing information (gaps) that are important to your company.
3. If gaps are identified, work with your internal functional representatives to identify if this information is adequately covered elsewhere within your organization (eg, Monitoring Guidelines, SOP/Policy documents), where else in your company it can be captured, or if it needs to be included in your protocol template.

Below is an illustrative example of how a company’s template might map to the BioCelerate template.

BIOCELERATE NCPT HEADING	SECTION IN TOC		COMMENTS/GAPS
	BIOCELEATE NCPT SECTION #	COMPANY X SECTION #	
Objective	1	2	Includes study rationale and dose justification
Proposed Study Schedule	2	5	Report date not included, is it needed?
Sponsor/Test Facility/Test Site Information	3	4	No gaps
Key Personnel	4	1	Key personnel is a very exhaustive list, is that necessary in our organization to ensure communication?
Test Item/Article and Vehicle Control Item/Article	5	6	Is characterization needed?