Nonclinical Common Templates

Driving efficiencies and improving overall quality for all stakeholders through the development of common protocol and report templates for repeat-dose toxicology studies

Initiative Status:

Benefits:

- A common protocol template can:
  - Decrease user time spent looking for key content
  - Decrease study errors and improve data quality, leading to reductions in animal usage due to fewer studies having to be repeated
  - Lead to more rapid protocol development, allowing studies to get started more quickly
- A common report template can:
  - Allow reports to be written and reviewed more quickly – resulting in more rapid data delivery and development timelines
  - Lead to the development of automation opportunities further improving efficiency and decreasing cycle times

Solutions:

Protocol Template (Q4 2019):
Published V 1.0 of Protocol Template for voluntary public use

Implementation Toolkit (Q4 2019):
Go Live of Implementation Toolkit to support voluntary adoption of the Nonclinical Protocol Template

Report Template & Implementation Toolkit (Q3 2020):
Published V 1.0 of Report Template for voluntary public adoption and implementation Toolkit to support voluntary adoption of the Nonclinical Report Template

V1.1 of Protocol & Report Template (Q1 2022):
Published V 1.1 of the Templates replacing V 1.0 to include updates based on feedback

Last Update: January 2022