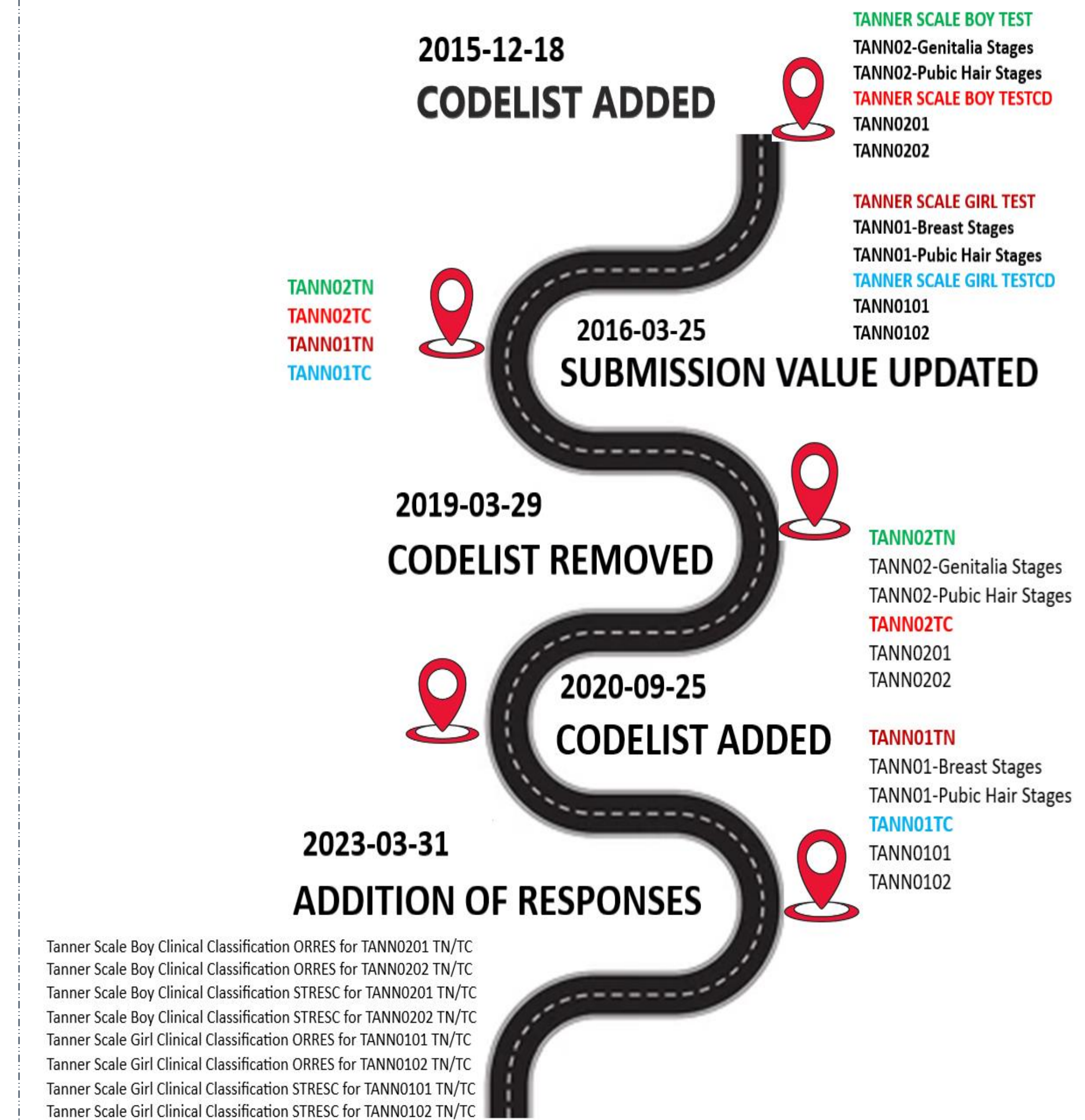


- CDISC regularly release new versions of its standards to improve data quality, interoperability, and efficiency of the data.
- Regulatory authorities require submissions that adhere to their guidelines, as it demonstrates a commitment to using the most up-to-date terminologies and ensures consistency across studies.
- Failure to update to the latest CDISC version, especially during the preparation of multi-study submissions, can lead to discrepancies and inconsistencies in terminologies across datasets, causing delays in the regulatory review process, potentially hindering their approval.



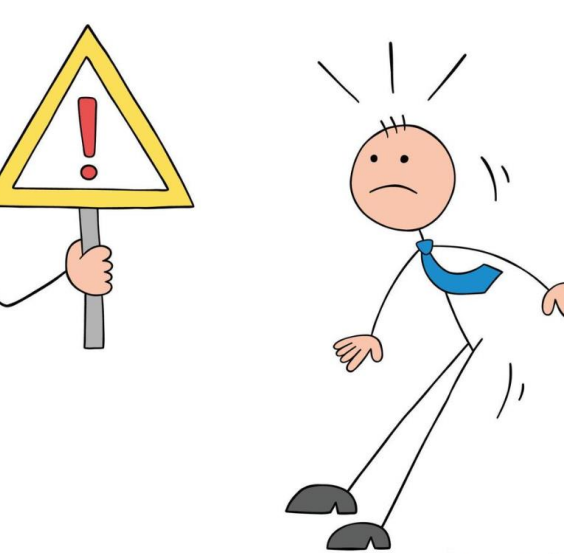
CASE STUDY: Tanner Scale Codelist



- Effective management of changes requires active participation with careful consideration during public review, monitoring new releases, evaluating effects, and addressing potential challenges.
- For instance, the Tanner staging code list underwent numerous changes over time, illustrating to develop mitigation strategies, organizations can effectively adapt and thrive in a constantly evolving standards and guidelines.

DID YOU KNOW?

From SDTM Terminology Version 2015-06-26 to 2023-12-15	
318 Codelists Added	
13 Codelists Removed	
361 NCI Preferred Terms Updated	
2 Updates In Extensibility Of Codelists	
285 Submission Values Updated	
6109 Codelist Names Updated	
6500 Terms Added	
1041 Terms Removed	
351 CDISC Definitions Updated	



CT Requirements: Regulatory Insights

NEW STUDIES

FDA Guidelines: Latest version to be used at the start of the study

PMDA Guidelines: Refer PMDA's website for versions of the CDISC standards, controlled terminologies, and dictionaries that are accepted by the PMDA.

ONGOING STUDIES

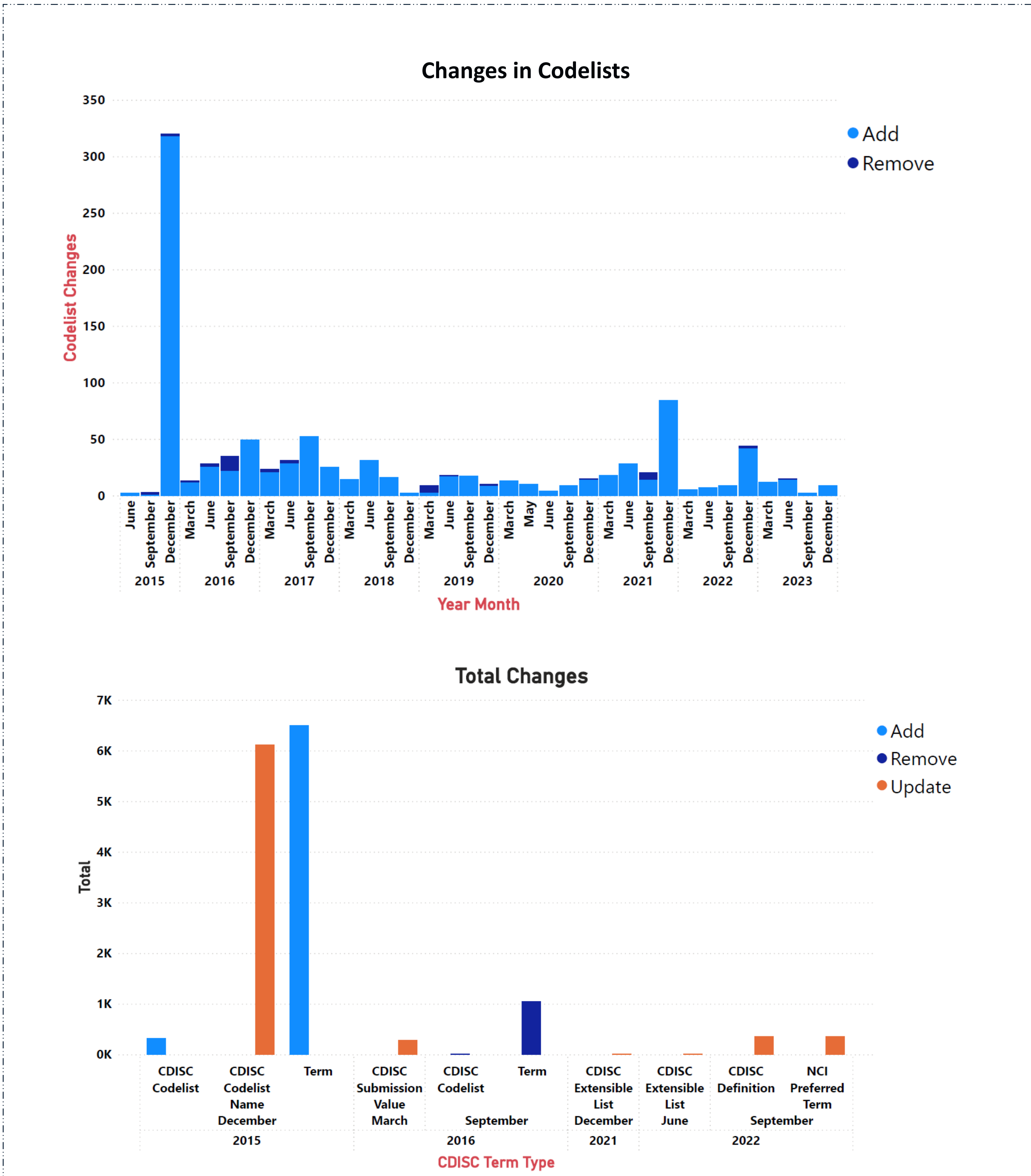
FDA Guidelines: New version released post study commencement; most current version may be used. Impact to be described of the use of different versions on the study results

PMDA Guidelines: Same version of CT be used within the same clinical study

POOLED STUDIES

FDA Guidelines: Single version across studies, current version should be used at the time that data across studies are pooled.

PMDA Guidelines: Same version for datasets of integrated analyses of multiple clinical studies, even if different versions were initially used. Detail the rationale for selecting a specific version and considerations for conversion in the data guide.



STAY INFORMED

STAY UPDATED

SUBMIT WITH EASE

