

Deliverables



Regulatory Deliverables

These documents below are referenced in the FDA Study Data Technical Conformance Guide (click [here](#) to view FDA Study Data Standards Resources). These are also referenced in the PMDA Technical Conformance Guide on Electronic Study Data Submissions (click [here](#) to view PMDA New Drug Review with Electronic Data).

Integrated Analysis Data Reviewer's Guide (iADRG) Package Version 1.0, 18 September 2023	The cSDRG and ADRG apply to a single study. Sponsors have used these templates when creating a reviewer's guide for integrated Study Data and reviewer's guide for integrated Analysis Data. The template has to be changed in order to document the information for multiple studies.
Bio-research Monitoring Data Reviewers Guide (BDRG) Package Version 3.0, 28 June 2023	The BDRG provides regulatory agency reviewers an orientation to the submitted Bioresearch Monitoring (BIMO) data in a consistent way and usable format. The BDRG Package includes Introduction and Overview, Template, Completion Guidelines and Examples.
Nonclinical Study Data Reviewer's Guide (nSDRG) Package Version 1.2 08 April 2022	The nSDRG provides regulatory agency reviewers with additional context for nonclinical tabulation datasets received as part of a regulatory submission. The nSDRG Package includes the template and completion guidelines.
Analysis Data Reviewer's Guide (ADRG) Package Version 1.2, 18 July 2019	The ADRG provides regulatory agency reviewers an orientation to the submitted analysis data in a consistent way and usable format. This Package includes information on the Legacy Data Conversion Plan and Report (LDCP) appendix. The ADRG Package includes the template, completion guidelines, and examples.
Clinical Study Data Reviewer's Guide (cSDRG) Package, including Legacy Data Conversion Plan and Report (LDCP) appendix Version 1.3, 2 November 2018	The cSDRG provides regulatory agency reviewers an orientation to the submitted tabulation data in a consistent way and usable format. This Package includes information on the Legacy Data Conversion Plan and Report (LDCP) appendix. The cSDRG Package includes the template, completion guidelines, examples, and example traceability diagrams.
Study Data Standardisation Plan (SDSP) Package Version 1.0, 16 January 2018	The SDSP documents the data standardisation approach for clinical and nonclinical studies within a development program. This Package includes information on the CBER appendix, with proposed domain /variable usage. The SDSP Package includes the template, completion guidelines, sponsor implementation guide, and examples.

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