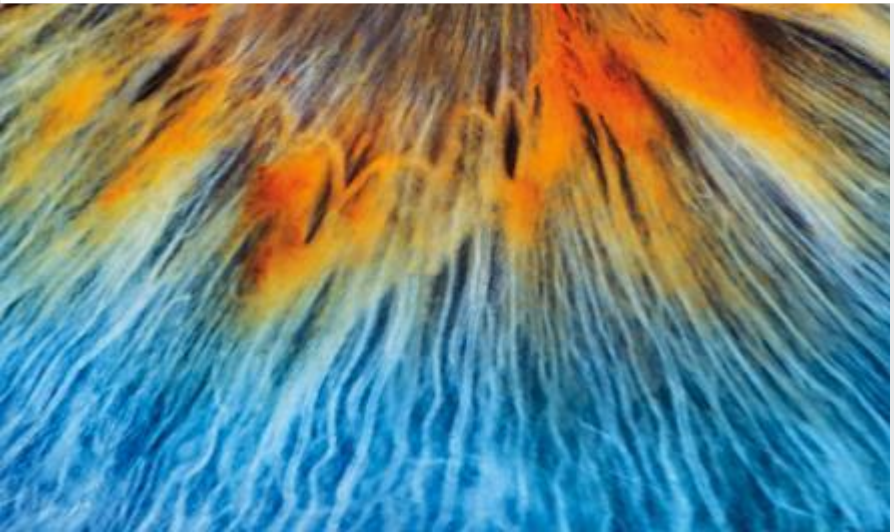

CHANGES IN FDA TECHNICAL CONFORMANCE GUIDE V4.0

20-Feb-2018, Print Media Academy - Heidelberg
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DEFINITION

- **This Study Data Technical Conformance Guide provides specification, recommendations and general considerations on how to submit standardized study data using FDA–support**

- **The guide is separated in the same sections as before:**

Section 1: **Introduction** – provides information on regulatory policy and guidance background, purpose, and document control.

Section 2: **Planning and Providing Standardized Study Data** – recommends and provides details on preparing an overall study data standardization plan, a study data reviewer's guide and an analysis data reviewer's guide.

Section 3: **Exchange Format - Electronic Submissions** – presents the specifications, considerations, and recommendations for the file formats currently supported by FDA.

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DEFINITION - CONTINUE

Section 4: **Study Data Submission Format: Clinical and Nonclinical** – presents general considerations and specifications for sponsors using, for example, the following standards for the submission of study data: Study Data Tabulation Model (SDTM), Analysis Data Model (ADaM), and Standard for Exchange of Nonclinical Data (SEND).

Section 5: **Therapeutic Area Standards** – presents supplemental considerations and specific recommendations when sponsors submit study data using FDA-supported therapeutic area standards (TA).

Section 6: **Terminology** – presents general considerations and specific recommendations when using controlled terminologies/vocabularies for clinical trial data.

Section 7: **Electronic Submission Format** – provides specifications and recommendations on submitting study data using the electronic Common Technical Document (eCTD) format.

Section 8: **Data Validation and Traceability** – provides general recommendations on conformance to standards, data validation rules, data traceability expectations, and legacy data conversion.

PAREXEL

UPDATES 4.0

October 2017	4.0	Section 1.5 (Relationship to Other Documents) – Updated references Section 2.1 (Study Data Standardization Plan) – Clarification on SDSP and added footnotes Section 2.2 (Study Data Reviewer's Guides) – Clarification on Reviewer Guides Section 4.1 (Clinical Data Interchange Standards Consortium) – Clarification on terms SDTM, ADaM, and SEND Section 4.1.1.2 (SDTM General Considerations) – Updated and clarified text Section 4.1.1.3 (SDTM Domain Specifications) – Added QS Domain (Questionnaires) Section 4.1.2.4 (Subject Level Analysis Data) – Updated and clarified text on baseline characteristics Section 4.1.2.10 (Software Programs) – Updated and clarified text Section 4.1.3.1 (Definition) – Updated and clarified text Section 4.1.3.2 (General Considerations) – Clarification on variable usage Section 4.1.3.3 (SEND Domain Specification) – Clarification and added text Section 4.1.4.1 (Variables in SDTM and SEND: Required, Expected, and Permissible) – Added text Section 4.1.4.6 (Annotated Case Report Form (aCRF) for SDTM) – Updated and clarified text. The recommendation to use the SDTM Metadata Submission Guidelines was removed pending further FDA review. Section 5.2 (Supported Therapeutic Areas) –Added TA sections Section 6.3.1.1 (General Considerations) – Updated and clarificated text Section 6.7.1.1 (General Considerations) – Added clarification text Section 8.3.2 (Legacy Study Data Conversion to Standardized Study Data) – Added clarification text Section 8.3.2.2 (Legacy Data Conversion Plan and Report) – Added clarification text

PAREXEL

CHANGES FROM GUIDE V3.3 TO GUIDE V4.0 (RELEASED OCTOBER 2017) – UPDATES IN SECTION 1.5

V3.3: **1.5 Relationship to Other Documents**

- Guidance to Industry Providing Regulatory Submissions in Electronic Format: *Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act*[7]

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[7] http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm384686.pdf

V4.0: **1.5 Relationship to Other Documents**

- Specifications for File Format Types Using eCTD Specifications[7]

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[7] See https://www.fda.gov/downloads/drugs/developmentapprovalprocess/formssubmissionrequirements/electronicsubmissions/ucm347471.pdf

Link and references have changed

PAREXEL

CHANGES FROM GUIDE V3.3 TO GUIDE V4.0 (RELEASED OCTOBER 2017) – UPDATES IN SECTION 2.1

V3.3:

2.1 Study Data Standardization Plan

template is available.[10] A SDSP should include, but is not limited to the following:

1. List of the planned studies
2. Type of studies (e.g., phase I, II or III)
3. Study designs (e.g., parallel, cross-over, open-label extension)
4. Planned data standards, formats, and terminologies and their versions or a justification of studies that may not conform to the currently supported standards

[10] A specific template for a Study Data Standardization Plan is not specified. However, an example of a Study Data Standardization Plan (template, completion guidelines and examples) can be found at http://www.phusewiki.org/wiki/index.php?title=Study_Data_Standardization_Plan_%28SDSP%29

V4.0:

2.1 Study Data Standardization Plan

plan. Although a specific template is not specified, an example of a SDSP is available.[10]

For clinical studies that will be submitted to CBER, the SDSP and an appendix should be provided to the review office no later than the end-of-phase 2 meeting. The CBER SDSP appendix should include tables of proposed SDTM domain/variable usage, supplemental domain usage and proposed analysis.

[10] A specific template for a Study Data Standardization Plan is not specified. However, an example can be found at http://www.phusewiki.org/wiki/index.php?title=Study_Data_Standardization_Plan_%28SDSP%29. The PhUSE SDSP template has been reviewed by FDA and published in the Federal Register https://www.federalregister.gov/documents/2016/11/08/2016-26913/intent-to-review-a-study-data-standardization-plan-template-notice-of-availability-establishment-of. FDA prefers but does not require its use.

PAREXEL

CHANGES FROM GUIDE V3.3 TO GUIDE V4.0 (RELEASED OCTOBER 2017) – UPDATES IN SECTION 2.2

V3.3:

2.2 Study Data Reviewer's Guides

The preparation of relevant Reviewer Guides (RG) is recommended as an integral part of a standards-compliant study data submission. An RG should describe any special considerations or directions that may facilitate an FDA reviewer's use of the submitted data and may help the reviewer understand the relationships between the study report and the data.[11]

[11] For submissions to CBER, sponsors and applicants should continue to provide the Validation and Data Interpretation Report. The report can be incorporated into the Study Data Reviewer's Guide. For more information see http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/ucm209137.htm.

V4.0:

2.2 Study Data Reviewer's Guides

The preparation of relevant Reviewer Guides (RG)[11] is recommended as an integral part of a standards-compliant study data submission. An RG should describe any special considerations or directions or conformance issues that may facilitate an FDA reviewer's use of the submitted data and may help the reviewer understand the relationships between the study report and the data.

[11] For the purposes of this document, the term 'Reviewer Guide' refers only to those located in the m4 or m5 eCTD folders.

PAREXEL

CHANGES FROM GUIDE V3.3 TO GUIDE V4.0 (RELEASED OCTOBER 2017) – UPDATES IN SECTION 4.1

V3.3:

4.1 Clinical Data Interchange Standards Consortium

Data format specifications for the tabulation datasets of clinical and nonclinical toxicology studies are provided by SDTM and SEND, respectively, while data format specifications for the analysis datasets of clinical studies are provided by ADaM. It should be noted that data format specifications for the analysis datasets of nonclinical toxicology studies have not been developed yet. As noted in section 1.1, the *Standards Catalog* provides a listing of the currently supported data standards with links to reference materials.

V4.0:

4.1 Clinical Data Interchange Standards Consortium

Data format specifications for the tabulation datasets of clinical and nonclinical toxicology studies are provided by SDTM and SEND, respectively, while data format specifications for the analysis datasets of clinical studies are provided by ADaM. It should be noted that data format specifications for the analysis datasets of nonclinical toxicology studies have not been developed yet. As noted in section 1.1, the Catalog provides a listing of the currently supported data standards with links to reference materials. For the purposes of this Guide, the terms SDTM, ADaM, and SEND apply to versions only listed and supported by FDA in the Catalog.

PAREXEL

CONTINUE – UPDATES IN SECTION 4.1 (ONGOING)

V3.3:

4.1.1.2 SDTM General Considerations

It is recommended that sponsors implement the SDTM standard for representation of clinical trial tabulation data prior to the conduct of the study. The use of case report forms that incorporate SDTM standard data elements (e.g., Clinical Data Acquisition Standards Harmonization (CDASH)) allows for a simplified process for the creation of SDTM domains.

V4.0:

4.1.1.2 SDTM General Considerations

It is recommended that sponsors implement the SDTM standard for representation of clinical trial tabulation data prior to the conduct of the study.

PAREXEL

CONTINUE – UPDATES IN SECTION 4.1 (ONGOING)

V3.3:

-Not available-

V4.0:

4.1.1.3 SDTM Domain Specifications

QS Domain (Questionnaires)

Some items in an instrument may be logically skipped per the instrument's instructions. Responses for logically skipped items should be (1) recorded and/or scored according to the instructions provided in the instrument's user manual, scoring manual, or other documentation provided by the instrument developer and (2) included in the submission dataset.

If instructions on how to record and/or score responses to logically skipped items are available from the instrument developer, then records for logically skipped items should be included in the submission dataset with the following:

- QSSTAT = "NOT DONE";
- QSREASND = "LOGICALLY SKIPPED ITEM"; and
- QSORRES, QSSTRESC, and QSSTRESN would be assigned according to the instrument's instructions.

If instructions on how to record and/or score responses to logically skipped items are not available from the instrument developer, then records for logically skipped items should be included in the submission dataset with the following:

- QSSTAT = "NOT DONE";
- QSREASND = "LOGICALLY SKIPPED ITEM"; and
- QSORRES, QSSTRESC, and QSSTRESN all set to null.

CONTINUE – UPDATES IN SECTION 4.1 (ONGOING)

V3.3:

4.1.2.4 Subject Level Analysis Data

....(ISO) formats.

V4.0:

4.1.2.4 Subject Level Analysis Data

numeric date variables in non-International Standards Organization (ISO) formats. Some examples of baseline characteristics for vaccine studies include, but are not limited to, past medical history (e.g. prior infection history), immunosuppressive conditions, prior vaccination history and concomitant medications/vaccines.

PAREXEL

CONTINUE – UPDATES IN SECTION 4.1 (ONGOING)

V3.3:

4.1.2.10 Software Programs

Sponsors should provide the software programs used to create all ADaM datasets along with the tables and figures associated with primary and secondary efficacy analyses in order to help reviewers to better understand how the datasets, tables and figures were created. The specific software utilized should be specified in the ADRG. The main purpose of requesting the submission of these programs is to understand the process by which the variables for the respective analyses were created and to confirm the analysis algorithms. Sponsors should not submit software programs with executable file extensions. Sponsors should submit in ASCII text format.

V4.0:

4.1.2.10 Software Programs

Sponsors should provide the software programs used to create all ADaM datasets and generate tables and figures associated with primary and secondary efficacy analyses. Furthermore, sponsors should submit software programs used to generate additional information included in Section 14 CLINICAL STUDIES of the Prescribing Information (PI)[26] if applicable. The specific software utilized should be specified in the ADRG. The main purpose of requesting the submission of these programs is to understand the process by which the variables for the respective analyses were created and to confirm the analysis algorithms. Sponsors should not submit software programs with executable file extensions, and these programs should be submitted in ASCII text format.

[26] https://www.fda.gov/downloads/drugs/guidances/ucm075082.pdf

PAREXEL

CONTINUE – UPDATES IN SECTION 4.1 (ONGOING)

V3.3: **4.1.3.1 Definition**

The Standard for Exchange of Nonclinical Data (SEND) provides the organization, structure, and format of standard nonclinical (animal toxicology studies) tabulation datasets for regulatory submission. Currently, the SEND Implementation Guide (SENDIG) supports single-dose general toxicology, repeat-dose general toxicology, and carcinogenicity studies.

V4.0: **4.1.3.1 Definition**

The Standard for Exchange of Nonclinical Data (SEND) provides the organization, structure, and format of standard nonclinical (animal toxicology studies) tabulation datasets for regulatory submission. The SEND Implementation Guide (SENDIGv3.0) supports single-dose general toxicology, repeat-dose general toxicology, and carcinogenicity studies. SENDIG v3.1 additionally supports respiratory and cardiovascular safety pharmacology studies.

PAREXEL

CONTINUE – UPDATES IN SECTION 4.1 (ONGOING)

V3.3:

4.1.3.2 General Considerations

The SENDIG provides specific domain models, assumptions, conformance and business rules, and examples for preparing standard tabulation datasets that are based on the SDTM. If there is uncertainty regarding SEND implementation, the sponsor should discuss the issue with the review division.

Sponsors should use the VISITDY variable if findings, which were intended to be analyzed together, were collected across multiple study days. For postmortem findings in MA, MI, and OM, indicate groupings of grace day data collections using the VISITDY variable in the DS domain. For in-life findings domains like LB or EG, add VISITDY to the domain to indicate grouping of measurements across grace days when measurements are grouped in the Study Report. For example, an ECG might be collected on Day 20, determined to be uninterpretable, and repeated on Day 21. If those ECG findings are grouped for analysis in the Study Report, VISITDY should be provided and set to Day 20 for both ECG collections to provide traceability in the SEND dataset.

V4.0:

4.1.3.2 General Considerations

The SENDIG provides specific domain models, assumptions, and examples for preparing standard tabulation datasets that are based on the SDTM. If there is uncertainty regarding SEND implementation, the sponsor should discuss the issue with the review division.

The ideal time to implement SEND is prior to the conduct of the study as it is very important that the results presented in the accompanying study report be traceable back to the original data collected. Each submitted SEND dataset should have its contents be described with complete metadata in the define.xml file (See section 4.1.4.5) and within the nSDRG as appropriate (See section 2.2).

Sponsors should use the VISITDY or --NOMDY variable appropriate to the selected SENDIG version if findings, which were intended to be analyzed together, were collected across multiple study days. For postmortem findings in MA, MI, and OM, indicate groupings of grace day data collections using VISITDY or DSNOMDY variable in the DS domain. For in-life findings domains like LB or EG, add VISITDY or --NOMDY to the domain to indicate grouping of measurements across grace days when measurements are grouped in the Study Report. For example, an ECG might be collected on Day 20, determined to be uninterpretable, and repeated on Day 21. If those ECG findings are grouped for analysis in the Study Report, VISITDY or EGNOMDY should be provided and set to Day 20 for both ECG collections to provide traceability in the SEND dataset.

PAREXEL

CONTINUE – UPDATES IN SECTION 4.1 (ONGOING)

V3.3: **4.1.3.3 SEND Domain Specification**

Sponsors should ensure that the transformation of findings from MIORRES to MISTRESC closely adheres to the instructions in the SENDIG. Non-neoplastic findings in MISTRESC, where controlled terminology is not required, should be standardized and limited to only the base pathological process to ensure that data can be tabulated. For suggestions as to what constitutes a base pathological process, refer to the CDISC NONNEO Controlled Terminology list. Details and severities for which there are variables available (e.g. MISEV, MILAT, MIANTREG, etc.) should be placed appropriately and not duplicated in MISTRESC or SUPPMI.

V4.0: **4.1.3.3 SEND Domain Specification**

Microscopic Findings (MI) Domain

Sponsors should ensure that the transformation of findings from MIORRES to MISTRESC closely adheres to the instructions in the SENDIG. When controlled terminology is not required for MISTRESC, non-neoplastic findings should be standardized and limited to only the base pathological process to ensure that data can be tabulated. For suggestions as to what constitutes a base pathological process, refer to the CDISC NONNEO Controlled Terminology list. Result qualifiers for which there are variables available (e.g. MISEV,MIDTHREL, MICHRON) should be placed appropriately and not duplicated in MISTRESC or SUPPMI.

When histopoathology severety data are collected on a severity scale that cannot be represented using the CDISC MISEV codelist without a loss of scientific accuracy (e.g. data were collected on 3 levels or 4 levels but MISEV specifies 5 levels), severity scores may be represented in MISEV as "1 of 4" "2 of 4" or "1 of 3" as appropriate, where the first number is the score and the second is the number of available severities in the scale. A score of 1 should be the least severe finding. Extend the non-extensible MISEV codelist with the necessary terms to describe the alternative severity scores, include these extended values in the define.xml and nSDRG, and explain any resulting validation error(s) in the nSDRG.

PAREXEL

CONTINUE – UPDATES IN SECTION 4.1 (ONGOING)

V3.3: **4.1.3.3 SEND Domain Specification**

Clinical Observations (CL) Domain

Only Findings should be provided in CL; ensure that Events and Interventions are not included. Sponsors should ensure that the standardization of findings in CLSTRESC closely adheres to the SENDIG. The information in CLTEST and CLSTRESC, along with CLLOC and CLSEV when appropriate, should contain sufficient information to ensure traceability between counts in tables, listings, and figures to the unique terms in CLSTRESC. For example, if "vomitus, food" and "vomitus, clear" are tabulated separately in the study report, CLSTRESC should be standardized to "vomitus, food" and "vomitus, clear" rather than "vomitus". Differences between the representation in CL and the presentation of Clinical Observations in the Study Report should be mentioned in the NSDRG.

V4.0: **4.1.3.3 SEND Domain Specification**

Clinical Observations (CL) Domain

Only Findings should be provided in CL; ensure that Events and Interventions are not included. Sponsors should ensure that the standardization of findings in CLSTRESC closely adheres to the SENDIG. The information in CLTEST and CLSTRESC, along with CLLOC and CLSEV when appropriate, should be structured to permit grouping of similar findings and thus support the creation of scientifically interpretable incidence tables. Differences between the representation in CL and the presentation of Clinical Observations in the Study Report which impact traceability to the extent that terms or counts in incidence tables created from CL cannot be easily reconciled to those in the Study Report should be mentioned in the nSDRG.

PAREXEL

CONTINUE – UPDATES IN SECTION 4.1 (ONGOING)

V3.3:

4.1.3.3 SEND Domain Specification

Pharmacokinetics Concentrations (PC) Domain

If the nominal times are provided in PCELTM, nulls should be avoided.

When a measurement is identified as being above or below a limit or quantitation threshold in PCSTRESC and/or PCLLOQ, standardized units for the threshold should be provided in PCSTRESU.

V4.0:

4.1.3.3 SEND Domain Specification

Pharmacokinetics Concentrations (PC) Domain

If the nominal times are provided in PCELTM, nulls should be avoided for plasma concentrations used to calculate a profile.PCDTC and PCDY variables should be populated with actual/collected information when it available; however, for GLP single dose, repeat dose, or carcinogenicity studies where actual/collected information are documented on paper and not available electronically, these variables may be left null or populated with calculated or nominal dates/times. The use of calculated or nominal dates and times should be mentioned in the nSDRG.

When actual dates or date/time values are available for PCRFTDTC/PPRFTDTC, they can be included.

When a measurement is identified as being above or below a limit or quantitation threshold in PCSTRESC and/or PCLLOQ, standardized units for the threshold should be provided in PCSTRESU; PCLLOQ should be populated.

PAREXEL

CONTINUE – UPDATES IN SECTION 4.1 (ONGOING)

V3.3: **4.1.3.3 SEND Domain Specification**

Custom Domains

To provide study data that does not fit into an existing SEND domain, consider creating a custom dataset aligned with the CDISC Study Data Tabulation Model (SDTM).

V4.0: **4.1.3.3 SEND Domain Specification**

Custom Domains

To provide study data that does not fit into an existing SEND domain, draft SEND domain, or published SDTM domain, consider creating a custom dataset aligned with the Study Data Tabulation Model (SDTM). Questions about custom domains should be addressed in pre-submission meetings and documented in the SDSP.

PAREXEL

CONTINUE – UPDATES IN SECTION 4.1 (ONGOING)

V3.3:

4.1.3.3 SEND Domain Specification

Tumor Dataset

Carcinogenicity studies should include an electronic dataset of tumor findings to allow for a complete review. At this time sponsors should include a tumor.xpt file while following the specification in the SENDIG for its creation regardless of whether or not the study is in SEND format (See www.cdisc.org/send).

V4.0:

4.1.3.3 SEND Domain Specification

Tumor Dataset

Carcinogenicity studies should include an electronic dataset of tumor findings to allow for a complete review. At this time sponsors should continue to include the tumor.xpt and associated define.pdf files regardless of whether or not the study is in SEND format (See tumor.xpt file specification and mappings to the SEND standard available in the SENDIG). When both tumor.xpt and SEND are submitted, the sponsor should ensure that data are traceable between tumor.xpt and the SEND datasets. Any information needed to establish traceability should be presented in the nSDRG.

CONTINUE – UPDATES IN SECTION 4.1 (ONGOING)

V3.3:

4.1.4 General Considerations: SDTM, SEND, and/or ADaM

4.1.4.1 Variables in SDTM and SEND: Required, Expected, and Permissible

Expected; therefore, both SVSTDY and SVENDY should be included.

4.1.4.6 Annotated Case Report Form (aCRF) for SDTM

An Annotated Case Report Form (aCRF) is a PDF document that maps the clinical data collection fields used to capture subject data (electronic or paper) to the corresponding variables or discrete variable values contained within the SDTM datasets. Regardless of whether the clinical database is legacy or SDTM compliant, an aCRF should be submitted. The aCRF should be provided as a PDF with the file name "acrf.pdf."[31] The SDTM Metadata Submission Guidelines should be used for additional information on annotated CRFs.[32]

V4.0:

4.1.4 General Considerations: SDTM, SEND, and/or ADaM

4.1.4.1 Variables in SDTM and SEND: Required, Expected, and Permissible

Expected; therefore, both SVSTDY and SVENDY should be included.

As mentioned in section 4.1.3.3, in certain GLP nonclinical studies submitted in SEND, PCDTC and PCDY may be imputed.

4.1.4.6 Annotated Case Report Form (aCRF) for SDTM

An Annotated Case Report Form (aCRF) is a PDF document that maps the clinical data collection fields used to capture subject data (electronic or paper) to the corresponding variables or discrete variable values contained within the SDTM datasets. Regardless of whether the clinical database is in a format supported by the Catalog, an aCRF should be submitted preferably at the time a protocol is submitted. The aCRF should be provided as a PDF with the file name "acrf.pdf."[32]

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CHANGES FROM GUIDE V3.3 TO GUIDE V4.0 (RELEASED OCTOBER 2017) – UPDATES IN SECTION 5

V3.3:

5.2 Supported Therapeutic Areas

both components of the ISARIC CORE Dataset when conducting EVD clinical trials.

5.2.6 Kidney Transplant

The Kidney Transplant TAUG does not address two important data elements. First, the

V4.0:

5.2 Supported Therapeutic Areas

both components of the ISARIC CORE Dataset when conducting EVD clinical trials.

5.2.6 Influenza

5.2.7 Kidney Transplant

….

5.2.12 Virology

PAREXEL

CHANGES FROM GUIDE V3.3 TO GUIDE V4.0 (RELEASED OCTOBER 2017) – UPDATES IN SECTION 6

V3.3: **6.3 Adverse Events 6.3.1 MedDRA 6.3.1.1 General Considerations**

MedDRA should be used for coding adverse events. The spelling and capitalization of MedDRA terms should match the way the terms are presented in the MedDRA dictionary (e.g., spelling and case). Common errors that have been observed include the incorrect spelling of a System Organ Class (SOC) and other MedDRA terms.

Generally, the studies included in an application are conducted over many years and may have used different MedDRA versions. To avoid potential confusion or incorrect results, the preparation of the adverse event dataset for the ISS should include MedDRA Preferred Terms from a single version of MedDRA. The reason for an ISS based on a single version of MedDRA is that reviewers often analyze adverse events across studies, including the use of Standardized MedDRA Queries.[39] In addition, sponsors should use the MedDRA-specified hierarchy of terms. The SDTM variables for the different hierarchy levels should represent MedDRA-specified primary SOC-coded terms.

V4.0: **6.3 Adverse Events 6.3.1 MedDRA 6.3.1.1 General Considerations**

MedDRA is used for coding adverse events.[39] Generally, the studies included in an application are conducted over many years and may have used different MedDRA versions. The expectation is that sponsors or applicants will use the most current version of MedDRA at the time of study start. However, there is no requirement to recode earlier studies

The spelling and capitalization of MedDRA terms should match the way the terms are presented in the MedDRA dictionary (e.g., spelling and case). Common errors that have been observed include the incorrect spelling of a System Organ Class (SOC) and other MedDRA terms.

To avoid potential confusion or incorrect results, the preparation of the adverse event dataset for the ISS should include MedDRA Preferred Terms from the latest version of MedDRA at the time that data across studies are pooled. The reason for an ISS based on

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CHANGES FROM GUIDE V3.3 TO GUIDE V4.0 (RELEASED OCTOBER 2017) – UPDATES IN SECTION 6

V3.3:

6.7 Laboratory Tests 6.7.1 LOINC 6.7.1.1 General Considerations

The Logical Observation Identifiers Names and Codes (LOINC) is a clinical terminology housed by the Regenstrief Institute.[48] LOINC codes are universal identifiers for laboratory and other clinical observations that enable semantically interoperable clinical data exchange. The laboratory portion of the LOINC database contains the categories of chemistry, hematology, serology, microbiology (including parasitology and virology), toxicology, and more.

The SDTM already supports the exchange of LOINC codes using the LBLOINC variable.

V4.0:

6.7 Laboratory Tests 6.7.1 LOINC 6.7.1.1 General Considerations

The Logical Observation Identifiers Names and Codes (LOINC) is a clinical terminology housed by the Regenstrief Institute.[49] LOINC codes are universal identifiers for laboratory and other clinical observations that enable semantically interoperable clinical data exchange. The laboratory portion of the LOINC database contains the categories of chemistry, hematology, serology, microbiology (including parasitology and virology), toxicology, and more.

The SDTM already supports the exchange of LOINC codes using the LBLOINC variable. LOINC codes should not be added to SEND datasets.

PAREXEL

CHANGES FROM GUIDE V3.3 TO GUIDE V4.0 (RELEASED OCTOBER 2017) – UPDATES IN SECTION 8

V3.3:

8.3 Study Data Traceability 8.3.2 Legacy Study Data Conversion to Standardized Study Data

Sponsors should use processes for legacy data conversion that account for traceability. Generally, a conversion to a standard format will map every data element as originally collected to a corresponding data element described in a standard. Some study data conversions will be straightforward and will result in all data converted to a standardized format. In some instances, it may not be possible to represent a collected data element as

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Although not strictly a legacy conversion, for nonclinical studies where data is converted to SEND from a previously established collection system, instances may arise where it is not possible to represent a collected data element as a standardized data element. In these cases, there should be an explanation in the nSDRG as to why certain data elements could not be fully standardized or were otherwise not included in the standardized data submission. As the Study Report should contain a complete representation of the study data, no non-standardized data should be submitted.

V4.0:

8.3 Study Data Traceability 8.3.2 Legacy Study Data Conversion to Standardized Study Data

Legacy study data are study data in a non-standardized format, not supported by FDA, and not ever listed in the Catalog. Sponsors should use processes for legacy data conversion that account for traceability. Generally, a conversion to a standard format will map every data element as originally collected to a corresponding data element described in a standard. Some study data conversions will be straightforward and will result in all data converted to a standardized format. In some instances, it may not be possible to

....

For nonclinical studies where data is converted to SEND from a previously established collection system, instances may arise where it is not possible to represent a collected data element as a standardized data element. In these cases, there should be an explanation in the nSDRG as to why certain data elements could not be fully standardized or were otherwise not included in the standardized data submission. As the Study Report should contain a complete representation of the study data in the

PAREXEL

CONTINUE - UPDATES IN SECTION 8 (ONGOING)

V3.3:

8.3.2.2 Legacy Data Conversion Plan and Report

include all versions and all forms used in the study.

3. Record significant data issues, clarifications, explanations of traceability, and adjudications in the RG. For example, data were not collected or were collected using different/incompatible terminologies, or were collected but will not fit into, for example, SDTM format.

4. Legacy data (i.e., legacy aCRF, legacy tabulation data, and legacy analysis data) may be needed in addition to the converted data.

V4.0:

8.3.2.2 Legacy Data Conversion Plan and Report

include all versions and all forms used in the study.

3. Record significant data issues, clarifications, explanations of traceability, and adjudications in the RG. For example, data were not collected or were collected using different/incompatible terminologies, or were collected but will not fit into, for example, SDTM format.

4. Legacy data (i.e., legacy aCRF, legacy tabulation data, and legacy analysis data) may be needed in addition to the converted data.

Submission of a Legacy Data Conversion Plan and Report is not expected for nonclinical studies where data were collected in a previously established data collection system.

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THANK YOU

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