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Automate the detecting, reporting of raw data issue from eCRT package validation

Yu Zhu, Boehringer Ingelheim

ABSTRACT

Raw data issues have negative impact on programming logic, statistical result review, study timeline, etc. If incorrect data is analyzed, study team could draw wrong or inaccurate conclusions regarding drug's safety and efficacy.

Raw data issues can be detected during data validation, edit checks, SDTM development, ADaM creation and TLF result review. However in previous projects experiences, a good amount of the row data issue were identified through eCRT package validation. This paper will introduce a method to detect and report raw data issue through Pinnacle 21 report automatically. This can help efficient data cleaning and reduce the possibility of unnecessary database relock due to raw data issue.

INTRODUCTION

REGULATORY REQUIREMENT

FDA announced on December 17, 2014 that applications must be submitted electronically, and that submissions will be required to contain study data in conformance with CDISC standards. The industry has been given 2 years from the publication of the final guidance documents to comply, at which point the FDA may refuse to file (RTF) any submission that isn't received in electronic form and/or doesn't conform to the required FDA study data standards, formats, and terminologies.

FDA needed a way to leverage automated analytics and data-driven tools to assess data from clinical trials more efficiently. This meant that data had to be standardized to enable development of a new generation of review, analysis, and data visualization tools that could work with data from any submission. This would enable reviewers to spend less time trying to analyze data and more time ensuring that safe and effective drugs are approved quickly and seamlessly for public use.

PINNACLE 21 BRIEF INTRODUCTION

In October 2008, OpenCDISC was launched as an open source community dedicated to building extensible tools and frameworks for the implementation of CDISC standards. OpenCDISC validator later became the open source software of choice at the FDA, the momentum shifted and OpenCDISC popularity increased dramatically. Therefore, in 2011 members of OpenCDISC formed Pinnacle 21, the commercial arm of OpenCDISC. This new company created OpenCDISC Enterprise, a commercial, enterprise-wide version of the software designed to support large organizations with many users, providing all the tools, bells, and whistles advanced users needed.

PROJECT TEAM 'PAIN POINT'

According to the regulatory requirement, project team must ensure the SDTM Pinnacle 21 report 'clean' before e-submission. 'Clean' means no error in the PINNACLE 21 report, and the remaining warnings can be explained clearly in the Reviewers' Guide section 4.2 Issues Summary. The warnings and errors normally caused by SDTM mapping issue or the raw data issue. For SDTM mapping issues, programmers can update mapping logic and mapping program to correct them. That is under programmers' control. However, for raw data issues, it requires cross function collaboration to solve them. Firstly programmers identify the issue and report the issue the way DM colleagues can understand. Then DM check the issue and send out the query as needed. Some may need site correction and database

updates. It normally takes quite long time to have the issue solved. An unpredictable factor is, the issue or new issue may happen during the life cycle of clinical trial. Programmers need to keep a close eye on them and regularly run the validation.

Even though DM claims that all queries are closed and confirms data base lock achieves. Worst case scenario is after DBL when preparing the eCRT package, programming team noticed one/some Pinnacle 21 errors/warnings are caused by data issue. A database unlock will have very negative impact on the whole trial progress. That even may delay the process to fulfill patient unmet medical needs.

DETECTING RAW DATA ISSUE FROM PINNACLE 21 REPORT

After checking the SDTM/ADaM data sets using Pinnacle 21 validator, findings are made available to the user in Excel format. The findings report consists of four tabs: Datasets Summary, Issue Summary, Details, and Rules. The Datasets Summary tab provides an overview of the contents for each input file and contains summary information about the total number of records, errors, warnings, and notices for each domain. The Issue Summary tab breaks down issues by severity (error, warning, and notice) and by type for each domain. Each issue type is categorized by FDA Publisher ID, which represents the FDA's published business rules. A description of each rule can be found on the Rules tab. The Details tab includes all issues in an expanded format and is presented on the record level. This tab includes the domain, record number, count, variables, values, rule ID, message, category, and severity for each issue.

People often met situation to report issue to DM for correction when dealing with Pinnacle 21 issues. The general way is to find out the specific subject and pick the record out to inform DM. Remember, strictly avoid any workaround programming to get rid of errors and warnings e.g. no date imputation on SDTM level to avoid any warning related to date. General perspective, Errors always have High severity; whereas Warnings have either Low or Medium severity. Errors must be corrected; however, Warnings should be corrected in order to assist with the submission, even though some warning and errors may be acceptable depending on the study.

For example, there are some MedDRA coding issues reported in the Pinnacle 21 validation. A programmer firstly will check the rules according to the issue ID (see Display 1). Once he/she confirms they are coding issue, a response "Coding issue, report to DM" will be provided in the issue details (see Display 2). Then the specific records will be entered into a data issue tracker sending to DM.

Pinnacle 21 ID	Publisher ID	Message	Description	Category
SD1061	FDAC012	Missing MB dataset, when MS dataset is present	Microbiology Specimen (MB) dataset should be included, when a Microbiology Susceptibility Test (MS) dataset is present.	Presence
SD1062	FDAC211	AESER is not 'Y', when AESOD equals 'Y'	Serious Event (AESER) variable value is expected to be 'Y', when Occurred with Overdose (AESOD) variable value equals 'Y'.	Consistency
SD1063	FDAC023	Dataset is not present in define.xml	Datasets included in study data must be described in the data definition document (define.xml).	Metadata
SD1064	FDAC219	Duplicate ETCD value	The value of Element Code (ETCD) variable must be unique within Trial Elements (TE) domain.	Consistency
SD1065	FDAC160	Missing RDOMAIN value, when IDVAR is populated	Value of Related Domain Abbreviation (RDOMAIN) variable must be populated, when value of Identifying Variable (IDVAR) variable is populated.	Presence
SD1066	FDAC157	IDVARVAL value is populated, when RELTYPE values is populated	Variable Value (IDVARVAL) variable value should not be populated, when Relationship Type (RELTYPE) variable value is populated.	Presence
SD1067	FDAC166	USUBJID value is populated, when RELTYPE values is populated	Unique Subject Identifier (USUBJID) variable value should not be populated, when Relationship Type (RELTYPE) variable value is populated.	Presence
SD1068	FDAC218	Duplicate ELEMENT value	The value of Element (Description of Element) variable must be unique within Trial Elements (TE) domain.	Consistency
SD1069	FDAC087	Inconsistent value for --PARM within --PARMCD	All values of a Parameter (--PARM) variables should be the same for a given value of a Parameter Short Name (--PARMCD) variables.	Consistency
SD1070	FDAC088	Inconsistent value for --PARMCD within --PARM	All values of a Parameter Short Name (--PARMCD) variables should be the same for a given value of a Parameter (--PARM) variables.	Consistency
SD1071	FDAC016	Dataset is greater than 1 GB in size	Large datasets should be split into smaller datasets no larger than 1 GB in size.	Metadata
SD1072	FDAC204	Missing IDVAR value, when RDOMAIN value is provided	Value of Identifying Variable (IDVAR) variable must be populated, when Related Domain Abbreviation (RDOMAIN) variable value is provided, with the only exception of 'DM' value for RDOMAIN.	Consistency
SD1073	FDAC028	Variable prohibited for use in SDTM	Variables described in IG as inappropriate for usage must be not included in the dataset.	Metadata
SD1074	FDAC029	Variable which can be used only in SEND	Variables designed only for SEND pre-clinical studies must be not included in the SDTM dataset.	Metadata
SD1075	FDAC030	Variable not recommended for use	Variables described in IG as not recommended for usage should be not included in the dataset.	Metadata
SD1076	FDAC031	Model permissible variable added into standard domain	SDTM model variable may be added into standard domains according its domain general class, if there are no restrictions on their usage specified in IG.	Metadata

Dataset Summary | Issue Summary | Details | Rules

Display 1. Rules Tab View

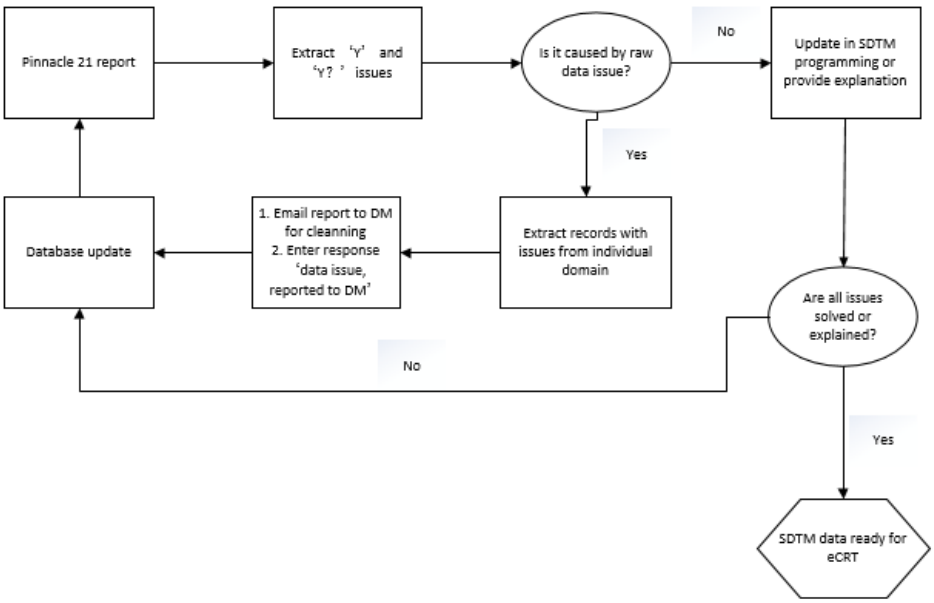
Doma	Reco	Cou	Variables	Values	innacle 2	Publisher I	Message	Category	Severit	Response
MH		62	MHBODSYS	Allergies	SD1114	FDAC348	Value for MHBODSYS not found in MedDRA dictionary	Terminology	Error	Coding issue, report to DM
MH		37	MHBODSYS	Blood/Lymphatic	SD1114	FDAC348	Value for MHBODSYS not found in MedDRA dictionary	Terminology	Error	Coding issue, report to DM
MH		84	MHBODSYS	Cardiovascular	SD1114	FDAC348	Value for MHBODSYS not found in MedDRA dictionary	Terminology	Error	Coding issue, report to DM
MH		76	MHBODSYS	Endocrine/Metabolic	SD1114	FDAC348	Value for MHBODSYS not found in MedDRA dictionary	Terminology	Error	Coding issue, report to DM

Display 2. Raw Data Issue Detected from PINNACLE 21 Report

However, there are some limitations and disadvantages in the manual checking and reporting. The manual checking is time consuming if the issues are many. For long run trials, the number of validation might be huge. Therefore the total hours spent on the manual checking will be tremendous. The second limitation is the manual step dependent heavily on programmers' experience. If the trial is transferred to others, the experience may not be easily transferred. So a systematic macro can help reduce manual work, improve efficiency as well as save a lot of time.

MACRO DESIGN

The macro function design generally follows the manual checking/reporting steps (see Display 3 below). The first step is run Pinnacle 21 validator. The Pinnacle 21 Validator command line interface can be called directly from SAS. The rules can be classified as directly data issue related (issuefl='Y') or suspicious data issue related (issuefl='Y?') or NOT related. Below 'selection issue records' session will describe how to classify the rules. For the issuefl='Y?' issues, programmers need to double check if they are caused by data issue. After the issuefl='Y' errors/warnings are selected, the next step is to 'pick' them out according to the record number. A DO loop macro will be used to extract all issue records from each domain. Finally an email communication with DM step is also designed to achieve automatically through SAS.



Display 3. Program Flowchart

COMMAND LINE INTERFACE

The CLI has long been a feature of Pinnacle 21 products and the latest software release includes new syntax and more options. The most used parameters for all users are depicted in Table 1 and a full list can be found by running the following code from the command line:

```
java -jar -p21-client-{version}.jar –help
```

The latest CLI is a robust tool and can easily be integrated into SAS programs. In the following examples, the core features of the CLI are depicted by calling the CLI using the X statement in SAS. Let's start by assigning some key pieces of information to macro variables so we can reference them later:

```
/* Pinnacle 21 Parameters */
/* Note: the configuration file folder should be in the same location
as p21-client- {version}.jar */
%let jarpath = C:\Users\p21-client ;
%let jarfile = p21-client-1.0.7.jar ;
%let configpath = C:\Users\p21-client\config ;
/* CDISC Data Parameters */
%let sdtmpath = C:\Users\study-123\sdtm\xpt ;
%let adampath = C:\Users\study-123\adam\xpt ;
%let sdmtdefine = C:\Users\study-123\sdtm\Define ;
%let adamdefine = C:\Users\study-123\adam\Define ;
/* Validation Report Parameters */
%let reportpath = C:\p21-client\reports;
x
java -jar "&jarpath.\&jarfile." ^
--standard=sdtm ^
--standard.version=3.2 ^
--source.sdtm="&sdtmpath." ^
--source.define="&sdmtdefine." ^
--cdisc.ct.sdtm.version=2017-12-22 ^
--unii.version=2017-11-15 ^
--ndf-rt.version=2018-02-05 ^
--meddra.version=21.0 ^
--report="&reportpath.\0123.abc_sdtm.xlsx "
;
```

SELECTING ISSUE RECORDS

The Pinnacle 21 Rules contain 5 categories, Terminology, Presence, Consistency, Limit and Format. Each category has some rules which the root cause is data issue. Below is a brief summary of the key rules which need to be reported. The full list of the rules caused by data issue are provided in the Appendix.

Terminology

Value for --DECOD not found in MedDRA dictionary (SD0008, FDAC346)

Value for --BODSYS not found in MedDRA dictionary (SD1114, FDAC348)

Value for --LLT not found in MedDRA dictionary (SD2008, FDAC351)

……

Coded and Decoded values do not have the same Code in CDISC CT (CT2003, FDAC342)

Presence

NULL value in variable marked as Required (SD0002, FDAC018)

No Disposition record found for subject (SD0069, FDAC052)

No Exposure record found for subject (SD0070, FDAC053)

Consistency

Inconsistent value for Standard Units (SD0007, FDAC084)

Missing value for --DTC, when --ENDTC is provided (SD0024, FDAC119)

Missing value for --ORRESU, when --ORRES is provided (SD0026, FDAC154)

Missing value for --DOSU, when --DOSE, --DOSTXT or --DOSTOT is provided (SD0035, FDAC183)

AE start date is after the latest Disposition date (SD0080, FDAC208)

RFSTDTC is not provided for a randomized subject (SD0087, FDAC109)

Duplicate records (SD1117, FDAC212)

Limit

--STDTC is after –ENDTC (SD0013, FDAC107)

Negative value for –DOSE (SD0014, FDAC081)

Value for --STNRHI is less than value for –STNRLO (SD0028, FDAC215)

Format

Unexpected character value in variable (SD1021, FDAC216)

Non-ASCII or non-printable characters in variable (SD1029, FDAC214)

CONVERTING TO 'READABLE' LISTING FOR DM

After detecting the issues from PINNACLE 21 report, one of the challenge is to provide the 'readable' listings for DM to solve. The general practice is to describe the issue with detailed subject number in a data issue tracker then send to DM colleagues. Since the PINNACLE 21 issue report has the SDTM record number of each issue, it provides the opportunity to use a DO loop to 'extract' all suspect issues to each individual issue dataset. The sample code and example output are provided below.

```
data issue_&&domain&i;
  format record 8.;
  set test.&&domain&i;

  select;
    %do cnt=1 %to &cnt_rcd;
      when (_n_ = &&rcd&cnt) record = input("&&rcd&cnt", best.);
    %end;
    otherwise delete;
  end;

run;


proc sql;
  create table issue2_&&domain&i as
  select a.message, a.description, b.*
  from issue_1 as a right join issue_&&domain&i as b
  on a.record eq  b.record;
quit;
```

MESSAGE	DESCRIPTION	RECORD	STUDYID	DOMAIN	USUBJID	AETERM	AELLT	AELLTCD
AE start date is after the latest Disposition date	Start Date/Time of Adverse Event (AESTDTC) should be less than or equal to the Start Date/Time of the latest Disposition Event (DSSTDTC).	2	1199-0247	AE	1199-0247-01022017	HEADACHE	Headache	10019211
Missing End Time-Point value	One of End Time-Point variables values is expected to be populated when an event or an intervention occurred. (E.g., one of End Date/Time of Event or Intervention (--ENDTC), End Relative to Reference Period (--ENRF), and End Relative to Reference Period (--ENRTPT) variables values should not be missing, or Occurrence (--OCCUR) variable value should be 'N').	3	1199-0247	AE	1199-0247-01022017	JOINT PAIN	Joint pain	10023222
AE start date is after the latest Disposition date	Start Date/Time of Adverse Event (AESTDTC) should be less than or equal to the Start Date/Time of the latest Disposition Event (DSSTDTC).	4	1199-0247	AE	1199-0247-010220177	HEADACHE	Headache	10019211
Missing End Time-Point value	One of End Time-Point variables values is expected to be populated when an event or an intervention occurred. (E.g., one of End Date/Time of Event or Intervention (--ENDTC), End Relative to Reference Period (--ENRF), and End Relative to Reference Period (--ENRTPT) variables values should not be missing, or Occurrence (--OCCUR) variable value should be 'N').	11	1199-0247	AE	1199-0247-02052017	HEADACHE	Headache	10019211

Display 4. Output Example

SEND EMAIL FROM DATA STEP

Once the excel file is generated. Email communication with DM colleagues is needed. As an important part of automation, sending email through SAS is expected. The DATA step can write information to virtually any destination. But email can also function as a destination.

One of those destinations may be an email server, meaning that you can send emails directly from the DATA Step. In order to do that, you first have to define the email environment that SAS will use. This environment is defined in a number of system options.

Once the environment is set up, sending email is like writing information to an external destination, using FILENAME, FILE and PUT statements.

```
filename sendmail email ATTACH='C:\SASUtil\123.abc_issues_&sysdate.xlsx'
    from=("matt.zhu@boehringer-ingelheim.com")
    to=("lanjin.jin@boehringer-ingelheim.com ")
    Subject="Study 0123.abc data issue report from P21 &sysdate."
    ;

data _null_;
    file sendmail;
    put "Hello Lanjin,";
    put "";
    put "Please check the latest data issues detected from Pinnacle 21
         validation tool for Study 0123.ABC";
    put "Your timely response is highly appreciated.";
    put "";
    put "-Pinnacle 21 Data Issue Autorun";
    put "V1.0";
run;
```

After setting the SAS program ready, an auto-run can be schedule in Window scheduled task.

CONCLUSION

Quality of data is the basis of accurate analysis and reporting, and making informed decisions. Every function in the trial team shall make effort to ensure the data quality. Statistical programmers are capable of using programming technologies to make some manual work more efficient. Programmers can follow the examples and recommendations in this paper to detect, understand, and report common issues found in Pinnacle 21 validator to play a data quality ‘gatekeeper’ role in the whole trial team.

REFERENCES

Amy Garrett, Aleksey Vinokurov, 2018.“How to Automate Validation with Pinnacle 21 Command Line Interface and SAS®” *Proceedings of the PhUSE US Connect 2018, paper CT03*.

Gupta Ajay, 2016. “Enhanced OpenCDISC Validator Report for Quick Quality Review” *Proceedings of the PharmaSUG 2016 Conference, paper AD07*.

Sergiy Sirichenko, 2017. “Common Programming Errors in CDISC Data” *Proceedings of the PharmaSUG 2017 Conference, paper DS15.*

Pinnacle 21 Community. Available at www.pinnacle21.net/download

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Yu Zhu (Matt)
Boehringer Ingelheim
+86 21 52880408
matt.zhu@boehringer-ingelheim.com
https://www.boehringer-ingelheim.com

APPENDIX

Pinnacle 21 ID	Publisher ID	Message	Category	Severity	Issuefl
CT2001	FDAC340	Variable value not found in non-extensible codelist	Terminology	Error	Y
CT2003	FDAC342	Coded and Decoded values do not have the same Code in CDISC CT	Terminology	Error	Y
CT2004	FDAC343	Variable value not found in non-extensible codelist when value-level condition occurs	Terminology	Error	Y
CT2006	FDAC345	Coded and Decoded values do not have the same Code in CDISC CT when value-level condition occurs	Terminology	Error	Y
SD0008	FDAC346	Value for --DECOD not found in MedDRA dictionary	Terminology	Error	Y
SD0008C	FDAC347	Value for --DECOD is in incorrect case	Terminology	Error	Y
SD0013	FDAC107	--STDTC is after --ENDTC	Limit	Error	Y
SD0014	FDAC081	Negative value for --DOSE	Limit	Error	Y
SD0015	FDAC082	Negative value for --DUR	Limit	Error	Y
SD0024	FDAC119	Missing value for --DTC, when --ENDTC is provided	Consistency	Warning	Y
SD0025	FDAC108	--DTC is after --ENDTC	Limit	Error	Y
SD0026	FDAC154	Missing value for --ORRESU, when --ORRES is provided	Consistency	Warning	Y
SD0027	FDAC168	Missing value for --ORRES, when --ORRESU is provided	Consistency	Warning	Y
SD0028	FDAC215	Value for --STNRHI is less than value for --STNRLO	Limit	Error	Y
SD0029	FDAC169	Missing value for --STRESU, when --STRESC is provided	Consistency	Warning	Y
SD0030	FDAC170	Missing value for --STRESC, when --STRESU is provided	Consistency	Warning	Y
SD0035	FDAC183	Missing value for --DOSU, when --DOSE, --DOSTXT or --DOSTOT is provided	Consistency	Error	Y
SD0036	FDAC171	Missing value for --STRESC, when --ORRES is provided	Consistency	Error	Y
SD0047	FDAC178	Missing value for --ORRES, when --STAT or --DRVFL is not populated	Consistency	Warning	Y
SD0048	FDAC179	Value for --ORRES is populated, when --STAT is 'NOT DONE'	Consistency	Warning	Y
SD0080	FDAC208	AE start date is after the latest Disposition date	Consistency	Error	Y
SD0082	FDAC050	Exposure end date is after the latest Disposition date	Consistency	Warning	Y
SD0084	FDAC083	Negative value for AGE	Limit	Error	Y
SD0087	FDAC109	RFSTDTC is not provided for a	Consistency	Warning	Y

		randomized subject			
SD0088	FDAC110	RFENDTC is not provided for a randomized subject	Consistency	Warning	Y
SD1002	FDAC111	RFSTDTC is after RFENDTC	Limit	Error	Y
SD1011	FDAC039	Invalid ISO 8601 value for variable	Format	Error	Y
SD1021	FDAC216	Unexpected character value in variable	Format	Warning	Y
SD1029	FDAC214	Non-ASCII or non-printable characters in variable	Format	Error	Y
SD1039	FDAC161	Redundancy in paired variables values	Consistency	Warning	Y
SD1045	FDAC095	Inconsistent values for IEORRES/IECAT	Consistency	Error	Y
SD1046	FDAC096	Inconsistent values for IEORRES/IECAT	Consistency	Error	Y
SD1114	FDAC348	Value for --BODSYS not found in MedDRA dictionary	Terminology	Error	Y
SD1114C	FDAC349	Case for --BODSYS is in incorrect case	Terminology	Error	Y
SD1117	FDAC212	Duplicate records	Consistency	Warning	Y
SD1123	FDAC180	--ORRES value is populated, when --STAT is 'NOT DONE'	Consistency	Warning	Y
SD1124	FDAC176	Missing value for --REASND, when --STAT is 'NOT DONE'	Consistency	Warning	Y
SD2006	FDAC165	Unexpected MedDRA coding in the SUPPQUAL domain	Consistency	Error	Y
SD2007	FDAC350	Value for --PTCD not found in MedDRA dictionary	Terminology	Error	Y
SD2008	FDAC351	Value for --LLT not found in MedDRA dictionary	Terminology	Error	Y
SD2008C	FDAC352	Value for --LLT is in incorrect case	Terminology	Error	Y
SD2009	FDAC353	Value for --LLTCD not found in MedDRA dictionary	Terminology	Error	Y
SD2010	FDAC354	Value for --HLT not found in MedDRA dictionary	Terminology	Error	Y
SD2010C	FDAC355	Value for --HLT is in incorrect case	Terminology	Error	Y
SD2011	FDAC356	Value for --HLTCD not found in MedDRA dictionary	Terminology	Error	Y
SD2012	FDAC357	Value for --HLGT not found in MedDRA dictionary	Terminology	Error	Y
SD2012C	FDAC358	Value for --HLGT is in incorrect case	Terminology	Error	Y
SD2013	FDAC359	Value for --HLGTCD not found in MedDRA dictionary	Terminology	Error	Y
SD2014	FDAC360	Value for --BDSYCD not found in MedDRA dictionary	Terminology	Warning	Y
SD2015	FDAC361	Value for --SOC not found in MedDRA dictionary	Terminology	Error	Y
SD2015C	FDAC362	Value for --SOC is in incorrect case	Terminology	Error	Y
SD2016	FDAC363	Value for --SOCCD not found in MedDRA	Terminology	Error	Y

		dictionary			
SD0002	FDAC018	NULL value in variable marked as Required	Presence	Error	Y?
SD0007	FDAC084	Inconsistent value for Standard Units	Consistency	Error	Y?
SD0012	FDAC106	--STDY is after --ENDY	Limit	Error	Y?
SD0021	FDAC117	Missing End Time-Point value	Consistency	Warning	Y?
SD0022	FDAC118	Missing Start Time-Point value	Consistency	Warning	Y?
SD0031	FDAC122	Missing values for --STDTC, --STRF and --STRTPT, when --ENDTC, --ENRF or --ENRTPT is provided	Consistency	Warning	Y?
SD0056	FDAC017	SDTM Required variable not found	Metadata	Error	Y?
SD0057	FDAC020	SDTM Expected variable not found	Metadata	Warning	Y?
SD0069	FDAC052	No Disposition record found for subject	Presence	Warning	Y?
SD0070	FDAC053	No Exposure record found for subject	Presence	Warning	Y?
SD0083	FDAC041	Duplicate USUBJID	Consistency	Error	Y?
SD1001	FDAC048	Duplicate SUBJID	Consistency	Error	Y?
SD1017	FDAC225	VISITNUM value does not match TV domain data	Cross-reference	Warning	Y?
SD1018	FDAC226	VISITNUM/VISIT/VISITDY values do not match TV domain data	Cross-reference	Warning	Y?
SD1061	FDAC012	Missing MB dataset, when MS dataset is present	Presence	Warning	Y?
SD1077	FDAC021	FDA Expected variable not found	Metadata	Warning	Y?
SD1083	FDAC124	Missing --DY variable, when --DTC variable is present	Presence	Warning	Y?
SD1085	FDAC126	--DY variable value is imputed	Presence	Warning	Y?
SD1087	FDAC128	Missing --STDY variable, when --STDTC variable is present	Presence	Error	Y?
SD1089	FDAC130	--STDY variable value is imputed	Presence	Error	Y?
SD1091	FDAC132	Missing --ENDY variable, when --ENDTC variable is present	Presence	Error	Y?
SD1093	FDAC135	--ENDY variable value is imputed	Presence	Error	Y?
SD1106	FDAC005	Missing AE dataset	Presence	Warning	Y?
SD1107	FDAC006	Missing LB dataset	Presence	Warning	Y?
SD1108	FDAC007	Missing VS dataset	Presence	Warning	Y?
SD1109	FDAC004	Missing EX dataset	Presence	Warning	Y?
SD1110	FDAC003	Missing DS dataset	Presence	Warning	Y?
SD1111	FDAC008	Missing SE dataset	Presence	Warning	Y?
SD1118	FDAC146	Neither --STDTC, --DTC nor --STDY are populated	Presence	Warning	Y?
SD2024	FDAC042	Missing or redundant values for USUBJID and POOLID	Presence	Error	Y?