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## Issue Management in P21E

Jane Wang, Principal Statistical Programmer,  
GSP, Parexel  
Haili Yang, Manager,  
GSP, Parexel



## Meet the Speaker

Jane Wang, 王婵

**Title:** Principal Statistical Programmer

**Organization:** Parexel

I worked in some local CROs at the beginning after graduation from university, and then moved to Parexel. Have some experiences in statistical programming and project management in general medicine and oncology area.



# Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *The author(s) have no real or apparent conflicts of interest to report.*



## Agenda

- Introduction of Issue Management in P21E
- Examples: Fix and/or Explain Issues



# Introduction of Issue Management in P21E



# Introduction of Issue Management in P21E

- What is Issue Management in P21E
- Importance of Issue Management
- How to Support Issue Management in P21E
- Issue Status and Issue Progress
- Impact, Severity and Type
- Types of Issue Sources



# What is Issue Management in P21E

Issue management in P21E is study team's cloud-based workbench for fixing or explaining noncompliant data.

All your teamwork.

All in one spot.

Never lost in an inbox.



# Importance of Issue Management

- ❑ Improve submission data package readiness in an ongoing way.
- ❑ Identify quality issues early and fix with collaborators.
- ❑ Improve data quality throughout clinical trial life cycle.

Goal:  $\geq 90$  by the time of submission



# How to Support Issue Management in P21E

- Overview dashboard online/dynamic, check issue progress, identify critical issues
- Default or customized fix tips and customized explanations

The screenshot displays the P21E Issue Management interface. The main panel shows details for issue SD2232: Missing SSTDC Trial Summary Parameter. It includes a description, dataset information (TS), impact (Reject), affected count (1), and type (Error). A 'Fix Tips' section provides instructions on updating the mapping of the Trial Summary domain. The 'Manage Issue' panel shows the status as 'Open' and lists sources like Design, Data, Mapping, Metadata, Process, and False Positive. The 'Progress' section shows a 20% completion rate with a 'Keep Going' indicator. The 'Explanation' section at the bottom provides a demo explanation and a table of suggestions.

Explanation	Reason	Action
<Demo Explanation, noting how this represents the data as collected.>	Used in 1 study (this one)	Copy/Paste

# Issue Status and Issue Progress

Issue Status	Contents
Open	Default, newly open OR once fix then later reopen
Fix Now	Plan to fix before next data transfer, programmer fix immediately
Fix Later	Plan to fix after next data transfer but before next milestone, naturally fix itself by EOS
To Close	Ready to be Closed, need approval
Closed	Cannot be fixed, must explain
Fixed	Truly resolved, or fixed in datasets

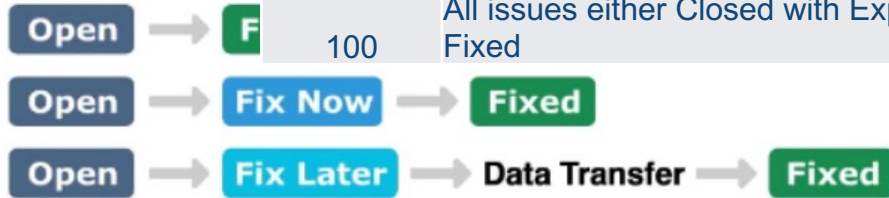
# Issue Status and Issue Progress

## Typical Issue Lifecycles

### Unfixable Issues



### Fixable Issues



Progress	Meaning
0	All issues open with no explanations/comments
...	Not 100% Closed with Explanation or Fixed
100	All issues either Closed with Explanation or Fixed

Explanations

Comments

# Impact, Severity and Type

## Review Impact

**Reject**

**High**

Medium

Low

## PMDA Severity

**Reject**

**Error**

Warning

## Message Type

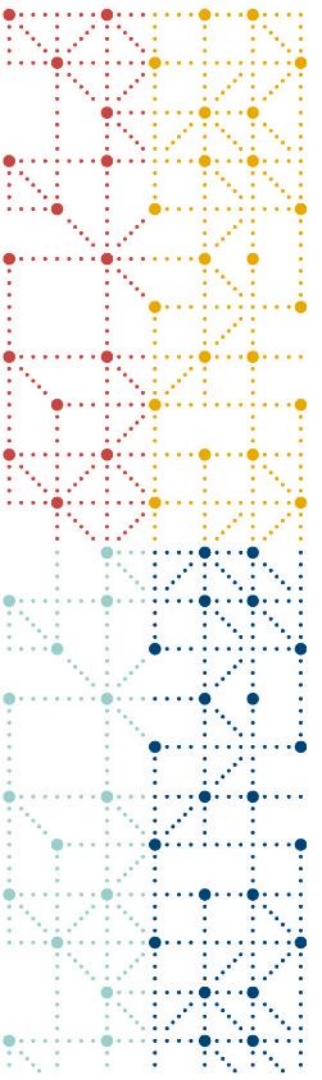
Error

Warning

Notice

# Types of Issue Sources

Type of Sources	Contents
Design	Data collection design
Data	Error in data entry or lack of data in an ongoing study
Mapping	Specification or programming
Metadata	Define.xml, e.g., a misnamed aCRF file
Process	User's validation process, e.g., a missing aCRF file
False positive	P21 enterprise validation rule sensitivity or error



## Examples: Fix and/or Explain Issues

# Examples: Fix and/or Explain Issues (1)

Rule ID	Message	Description
SD0002	NULL value in variable marked as Required	Required variables (where Core attribute is 'Req') cannot be NULL for any records.

Source	Root Cause	Resolution
Design	CRF design unclear	Improve CRF design or clarify in CRF completion guide in study start up in future
Data	Data incomplete or CRF page to be inactivated in database	Notify DM to follow and fix

## Examples: Fix and/or explain issues (2)

Rule ID	Message	Description
SD0021	Missing End Time-Point value	One End Time-Point variable is expected to be populated when an event or an intervention occurred. (E.g., End Date/Time of Event or Intervention (--ENDTC), or End Relative to Reference Period (--ENRF), or End Relative to Reference Period (--ENRTPT) should not be missing, or Occurrence (--OCCUR) = 'N' or Completion Status (--STAT) != "" or Duration (--DUR) != "").

For issues triggered by AE.AEENDTC

Source	#	Root Cause	Resolution
Design	1	For subject ended study, AE not resolved	Explain
Data	2	For sites with limited resources, data not yet entered for resolved AE	Follow up till fixed or explain
Data	3	For subject on treatment/study, data may be not yet observed	Follow up

For ongoing studies: 1 & 2 & 3

For interim analysis: 1 & 3

For final analysis: 1

Special case for Source # 2:

Data unable to be cleaned due to site early closure.



# Examples: Fix and/or explain issues (3)

Rule ID	Message	Description
SD1344	Value for --DECOD not found in WHODrug dictionary	Value for the Standardized Medication Name (--DECOD) variable must be populated using a Drug Name from the WHO Drug dictionary version specified in the define.xml.

For issues triggered by CM.CMDECOD

Source	Root Cause	Resolution
Mapping	Truncation of values	Fix in program
Mapping	Not split values > 200 char with semicolon <sup>a</sup>	Fix in program
Process	Wrong version of the dictionary configured in the data package prior to validation	Reset the configuration
False positive	Values exactly 200 char in length are being identified as too long because the conformance logic is looking for a semicolon closest to 200 char to represent a split value <sup>b</sup>	Explain

# Examples: Fix and/or explain issues (4)

Rule ID	Message	Description
SD0060	Variable in dataset is not present in define.xml	Variables included in the dataset must be described in the data definition document (define.xml).

Source	Root Cause	Resolution
Mapping	Variable is inappropriate in the data	Fix in program to remove it
Metadata	Variable is appropriate in the data, but not in define	Update define to add it

# Examples: Fix and/or explain issues (5)

Rule ID	Message	Description
DD0114	Invalid usage of split datasets for non-general-observation-class datasets	Split datasets can only be used for general-observation-class datasets (Events, Findings, Interventions).

## For issues triggered by FA

Source	Root Cause	Resolution
False positive	Per SDTMIG3.2, the Findings About (FA) domain can be split either by --CAT values or relative to the parent domain of the value in --OBJ, For example, FAMH would store Findings About MH records, sponsor's implementation is in line with SDTMIG recommendation (section 4.1.1.7 of SDTMIG3.2).	Explain with standard template

## Examples: Fix and/or explain issues (6)

Rule ID	Message	Description
AD1024	Traceability rules not executed due to missing DM dataset	When validating ADaM datasets, the DM dataset must also be included to ensure traceability. Note: For the final submission the eCTD structure should be maintained. Therefore, the SDTM and ADaM datasets should be submitted in their appropriate locations. Do not include the DM dataset in the ../analysis/adam/datasets folder.

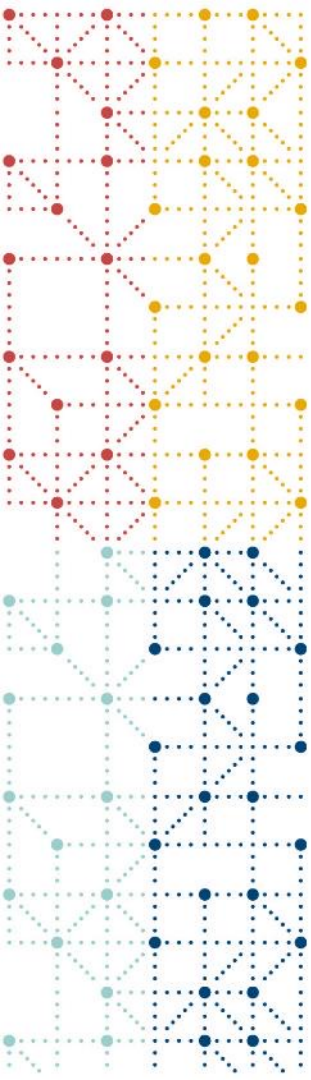
Source	Root Cause	Resolution
Process	Missing DM xpt file in ADaM data package	Include it to ensure traceability

Similar issues like AD1025 for AE, AD1026 for EX

# Examples: Fix and/or explain issues (7)

Rule ID	Message	Description
AD1012	Secondary custom variable is present but its primary variable is not present	In a pair of corresponding character and numeric variables, the primary or most commonly used variable must be present if its secondary version describing it (*N or *C) is present. This is the generic rule to capture all instances of custom variables. Specific rules AD0064, AD0066, AD0070, AD0075, AD0097, and AD0201 exist for some standard ADaM variables. AD1012A rule covers all other standard ADaM variable.

Source	Root cause	Resolution
Mapping, Metadata	The secondary variable is provided but the primary is not. E.g. AREL01N in dataset, AREL01 not.	Add the primary variable
Design, False positive	This issue is usually triggered by Sponsor standard variables such as ADOMAIN, as the variable name ends in 'N' P21E is assuming it contains a numeric version of a character variable.	Explain with standard template



**Thank You!**



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