

Questions?

submission readiness
validation

Submission quality report

study scorecard



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the CDISC compliance and data usability validation

to ensure electronic data quality for successful
submission





how to ensure

Eisai NDA submission high DataFit score

Eisai SDTM in-house project 2012 - 2014

Before start of this project, SDTM development process was outsourced.

The main goal of the project is to in-source SDTM conversion process, assess data quality by internal vs external teams; implement and apply newest technology to support FDA modern data review process.

Project Results:

- Converted to SDTM 30+ studies for 2 NDAs
- Implemented OpenCDISC Enterprise as SaaS cloud solution
- Implemented FDA expected derivations such as Baseline flag, Treatment emergent flag, Study Day and EPOCH
- Added CTC Grading

Project nominated as one of the best technology implementation in 2014

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Project Team



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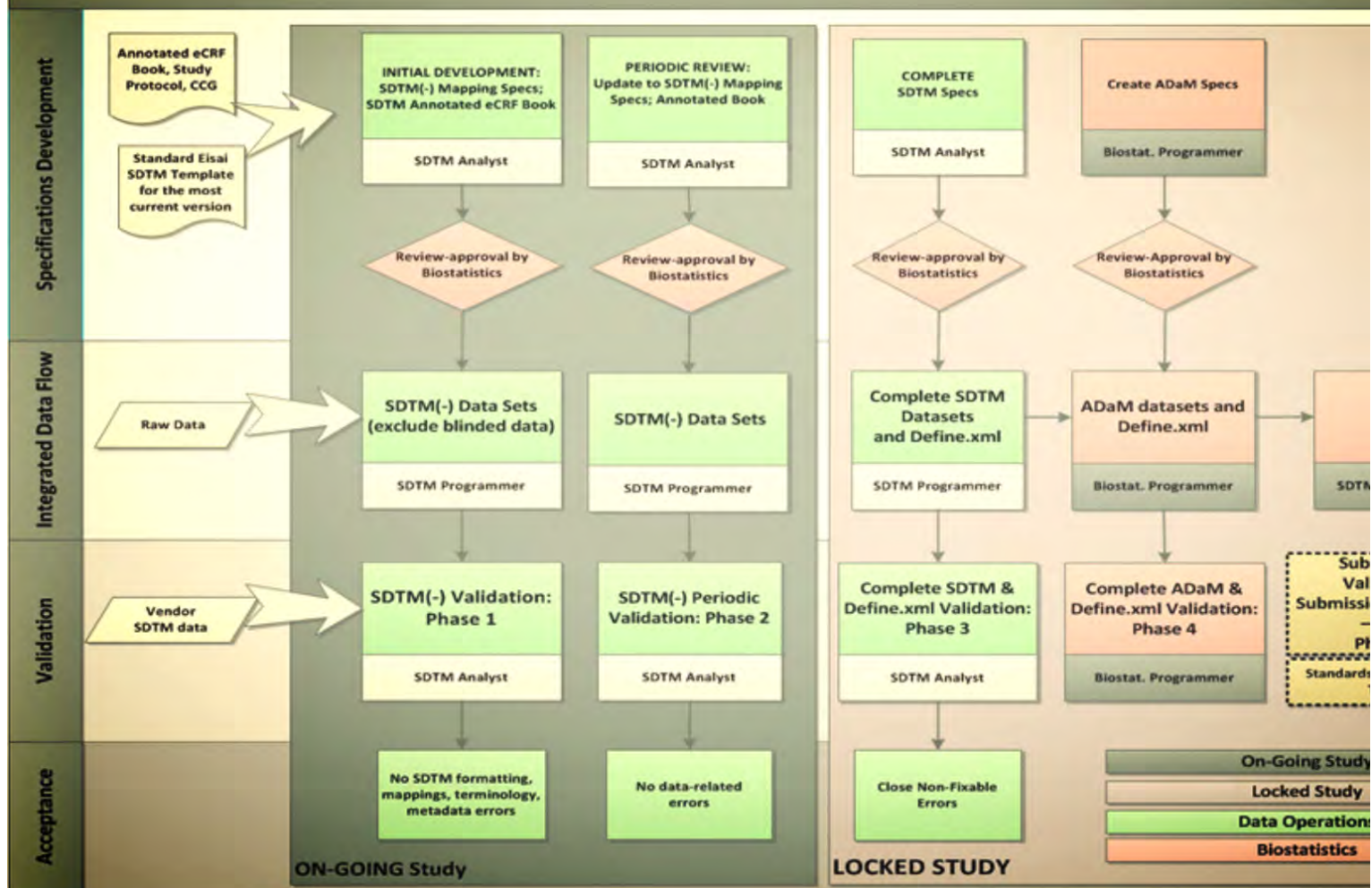
Chizuko Matsumura

Hiroko Tsukamoto



**Many
Thanks!**

The Journey From Raw Data to TLGs





a long journey from raw data to analytical panels

Tips for Data Integration Analyst



Define the submission standards version



Do not use obsoleted SDTM standard version 3.1.1, target to implement the most current version of SDTM v.3.1.3, Use standard oncology domains rather than custom. Implement Trial Design domains.



Note: New standard implementation time requirements: 36 month for IND and 24 month for NDA

SDTM minus phase





resolve all
formatting,
metadata,
terminology
issues

validation rules for Complete
SDTM shall be suppressed (Ex.
spacing rules)

Acceptance criteria: Standard compliance, General rules, Terminology and Metadata profiles - no issue

Periodic Data Review



cooperate with the study data manager to clean data-related issues through study until close out



avoid resolution of data errors after study database is locked

OpenCDISC Enterprise validate and track "Red flags" - data quality issues that must be resolved before database lock

review phase



Complete SDTM,
Define xml
& SDRG phase



*OpenCDISC Enterprise enables
issue tracking
and cross-unit teams
communication*



Validate, analyze and
resolve all issue/s;
enter resolution
details to Study Data
Reviewer's Guide



Evaluate data in the latest
OpenCDISC Validator version
1.5

Note: higher OpenCDISC
Validator version – more
rules published. Refer to:
[http://www.opencdisc.org/
download](http://www.opencdisc.org/download)



a long journey from raw data to analytical panels

Tips for Data Integration Analyst



Why

creating consistent
metadata for all studies



is preferable

Consistent domain, variables and value data metadata for all studies pooled for submission supports data usability

cross-review data

save time
to integrate
in ADaM



utilize
standard
programs



scientific conclusion
in shortened time

"Data that are not standardized diminish the Agency's ability to review the data efficiently, resulting in manual, labor-intensive processes and inherent inefficiencies in the review."
FDA Guidance.



scientific conclusion in shortened time

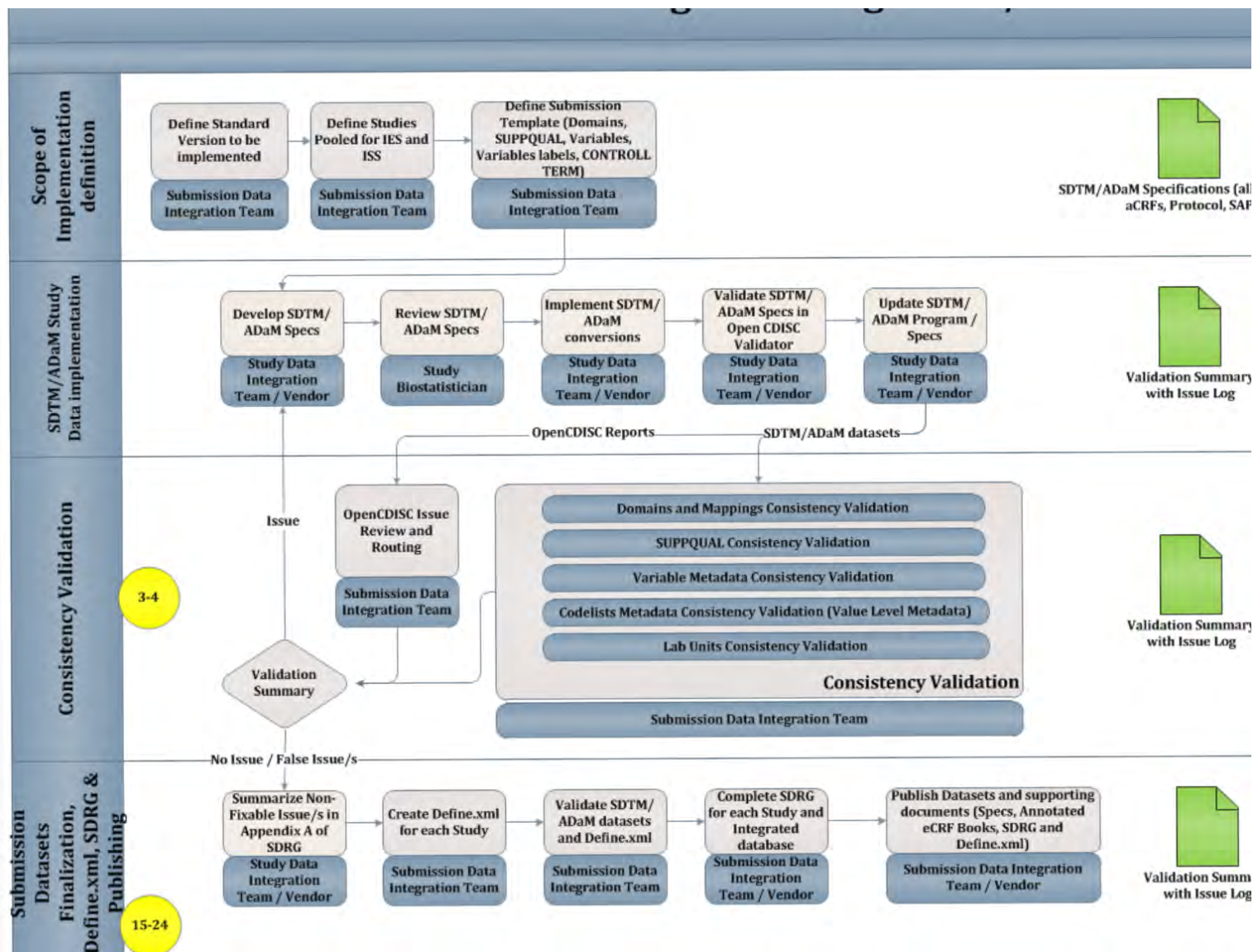


"Data that are not standardized diminish the Agency's ability to review the data efficiently, resulting in manual, labor-intensive processes and inherent inefficiencies in the review."

FDA Guidance.

how to make it?







excellence in data quality

supports FDA modern data review
of drug safety and efficacy



Refer to:

**FDA-2014-D-0092 - Study Data Technical Conformance Guide
and Data Standards Catalog**

**FDA-2012-D-0097 - Guidance on Electronic Submissions:
Standardized Study Data**

**FDA-2014-D-0085 - Guidance on Submissions in Electronic
Format--Submissions under the Federal Food, Drug, and
Cosmetic Act**

6 February 2014

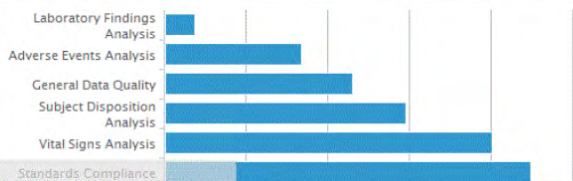
Study Quality Report: E7080-G000-303

Dashboard Scores Domains Issues Rules History

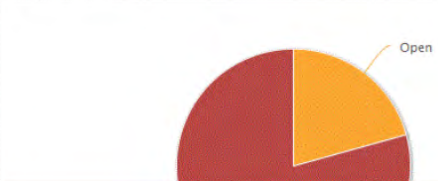
Key Metrics



Quality Dimension Scorecard



Issue Status



1%

Issue Rate

0%

50

Score

0%



0%

0%

0%

0%



Quality Dimension Scorecard

Laboratory Findings
Analysis

Adverse Events Analysis



General Data Quality

Subject Disposition
Analysis

Vital Signs Analysis



Standards Compliance



Study Quality Report: E7080-G000-303

Dashboard Scores Domains Issues Rules History

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Validation Spec	Score	Pass/Fail	Domains	Issues	Failures	Errors	Warnings	Notices
Exposure Analysis (1 Profiles)								
Exposure Analysis Panel	100	Pass		3	1	13	13	0
General Data Quality (2 Profiles)								
CDER Common Data Standards Issues	0	Fail		41	570	570	236	211
SDTM v3.1.2 General Data Quality	92	Pass		41	51	345,552	3,258	342,294
Laboratory Findings Analysis (6 Profiles)								
JReview Labs Baseline vs Max/Min Scatter Plots	0	Fail		3	2	784	392	392
JReview Hy's Law Patient Listing	0	Fail		3	2	784	392	392
Liver Function Analysis Panel	0	Fail		3	12	17,711	457	17,254
Found 29 records								

Fail

92
Pass

Fail

Details

SD0091: AEOUT is not 'FATAL', when AESDTH='Y'

Domain: AE | **Severity:** Warning | **Category:** Consistency

Open

1 comme

Tags:

Risk:

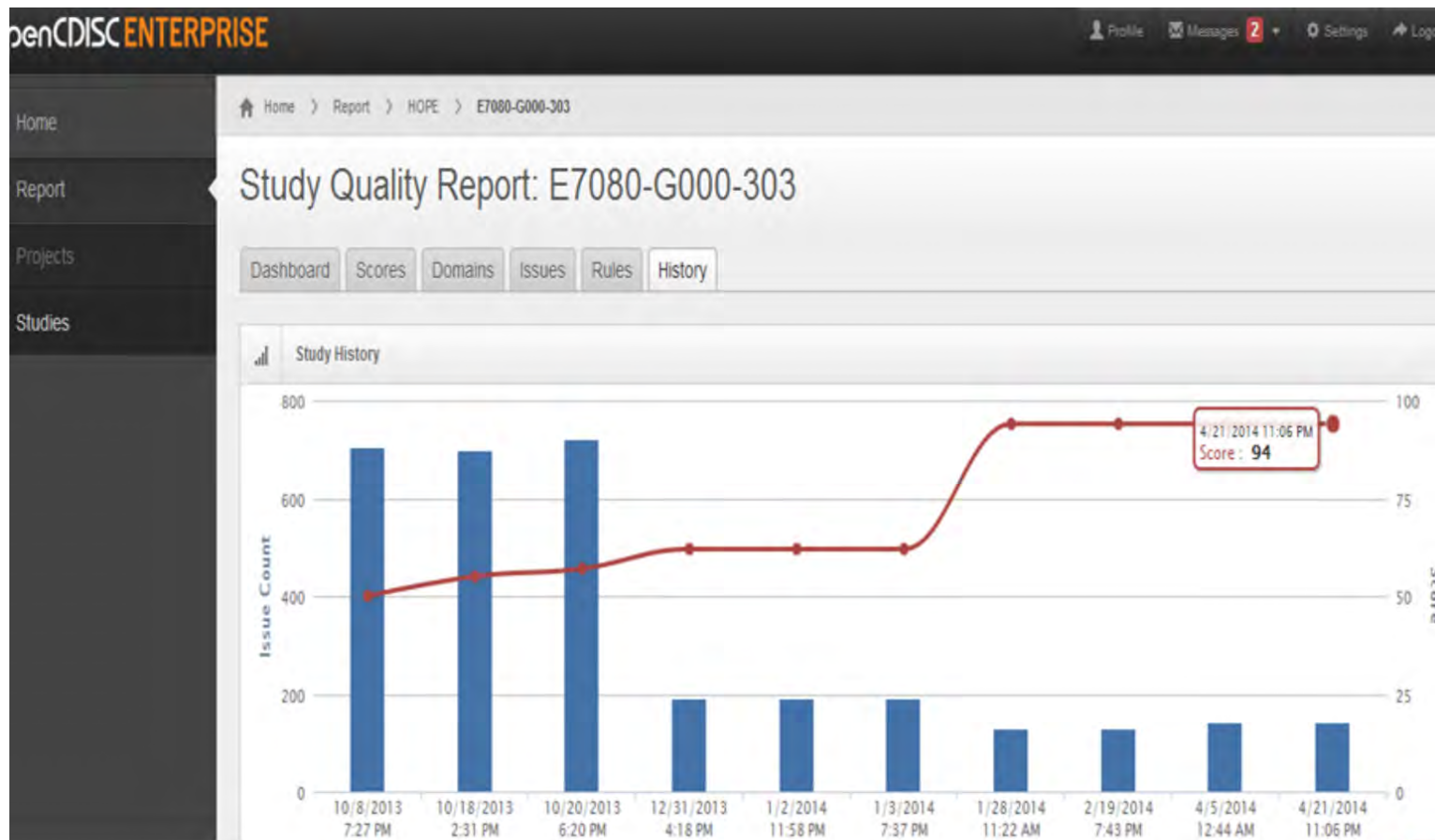
Medium



10 days ago

Please contact EISAI DM team for the issue resolution

Enter your comment...



Pivotal study score increased from 50 to 94

Report

Study Quality Report: E7080-G000-303-ISS

Define

Dashboard

Scores

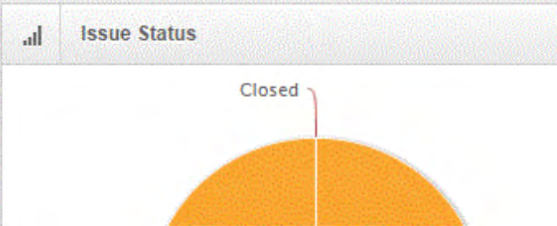
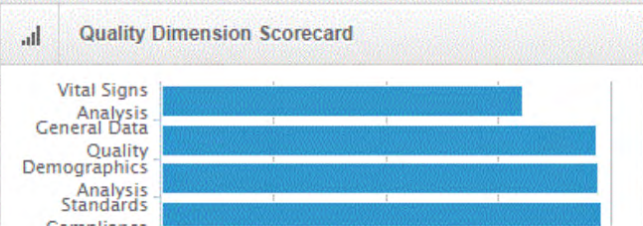
Domains

Issues

Rules

History

Key Metrics



Study Quality Report: E7080-G000-303

Dashboard Scores Domains Issues Rules History Comparison *

Comparison

Search Print Copy Download			
Key Metric	10/8/2013 11:27 PM	4/22/2014 3:06 AM	Percent Change
Domains	41	47	14.6%
Subjects	612	612	0%
Records	950,776	1,474,190	55%
Rules Executed	484	483	-0.3%
Checks Executed	5,948	5,383	-9.5%
Issues	705	140	-80.2%
Issue Rate	1.1%	0.8%	-27.4%
Score	50	94	88%

Data quality score is derived based on number of issues, issue rates and issue severity

Vendor's Study

Study Quality Report: E7080-702

Dashboard Scores Domains Issues Rules History

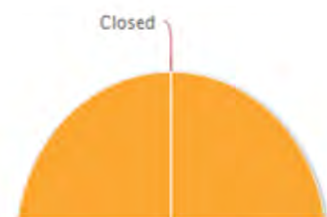
Key Metrics



Quality Dimension Scorecard



Issue Status

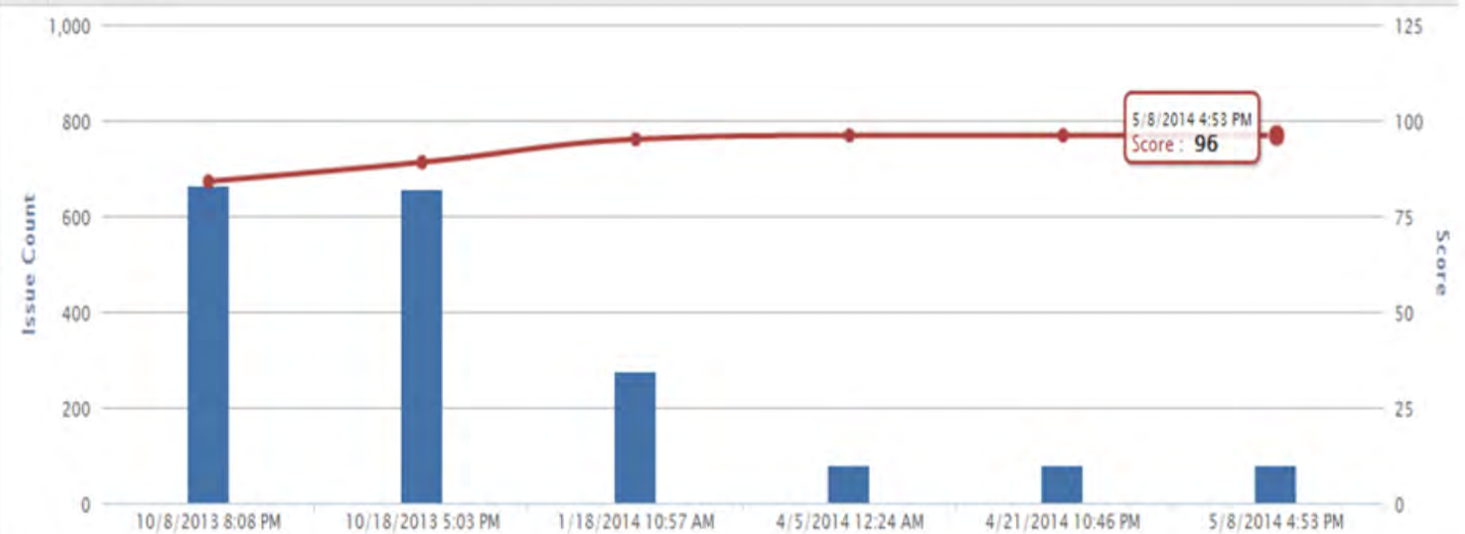


Japanese Team Work

Study Quality Report: E7080-J081-208

Dashboard Scores Domains Issues Rules History

Study History



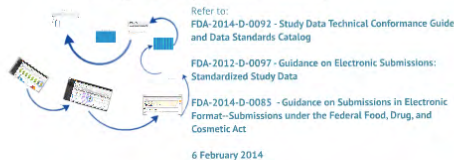
new drug may offer hope

to many people's quality of life

DO NOT compromise

excellence in data quality

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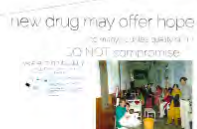


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