

Increasing Work Group Transparency: ADaMIG v1.2 Update and New Team Working Process Review

Brian Harris, MedImmune, Gaithersburg, MD, USA

Terek J. Peterson, MBA, Chiltern, King of Prussia, PA, USA





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- Review development stages of ADaM IGs up to ADaMIG v1.2
- Need for next ADaMIG, version 1.2
- New Tools available
 - WIKI
 - JIRA
- Utilization of CDISC JIRA/WIKI
 - Features
 - Process
 - Advantages
- Takeaways for JIRA/WIKI team Working Environment
 - How this will benefit future standards development teams

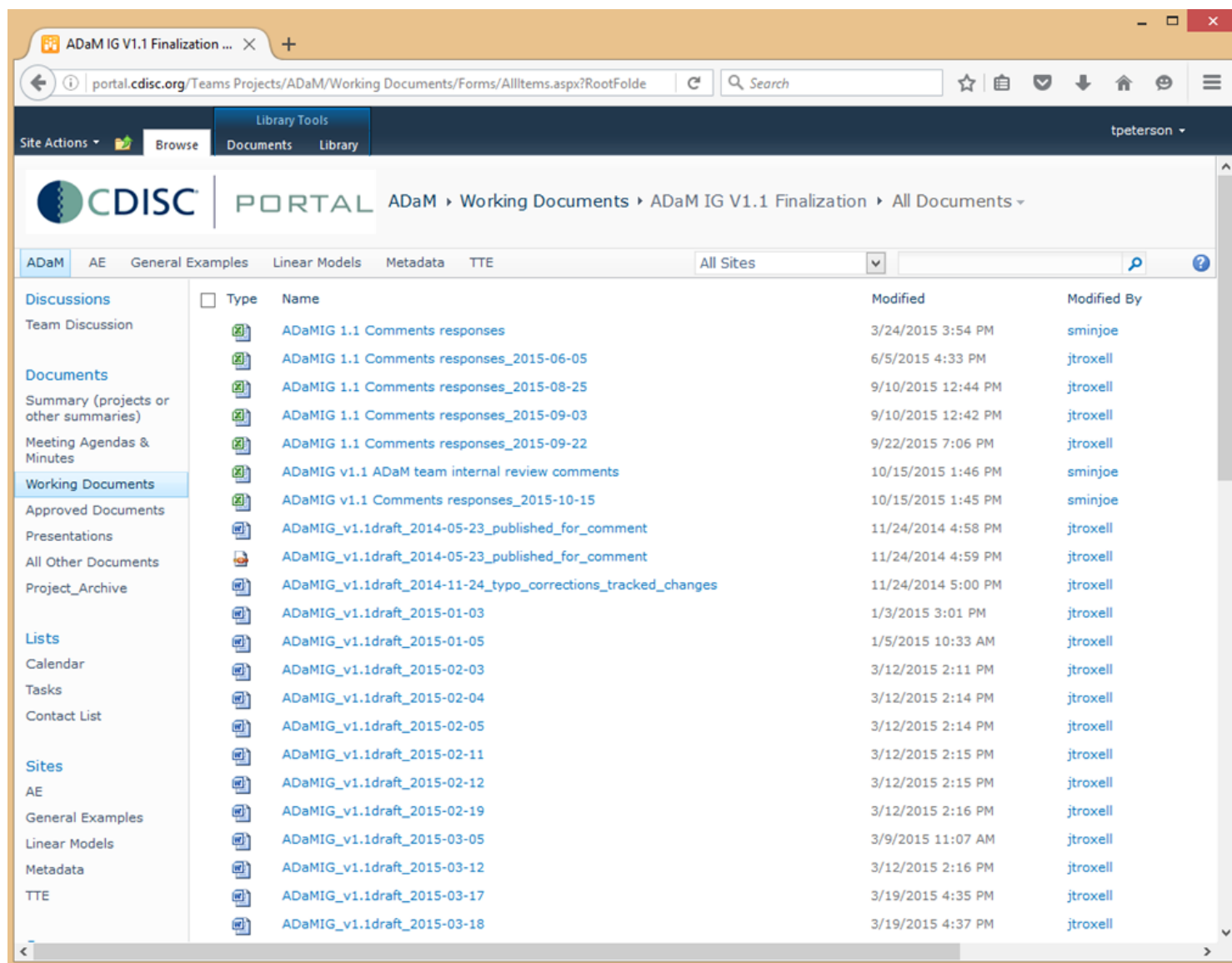
- ADaMIG v1.0 released late 2009
 - Two structures outlined
 - ADSL
 - BDS
- Supplemental parameters added for ADaM analysis datasets
 - BDS TTE v1.0 released mid-2012
 - ADAE v1.0 released mid-2012
- ADaMIG v1.1 released early 2016
 - Concurrently created is a third analysis data structure
 - OCCDS v1.0

Significant Changes in ADaMIG v1.1

- Distinctions are defined between analysis datasets, ADaM datasets, and non-Adam analysis datasets
- The contents of ADSL is clarified
- Standard naming fragments are further explained
- A requirement for the use of an ADaM standard variable name was added
- Clarification added for FL variables
- New variables for “sub-period” and “phase timing”

- New Issues came up during the finalization period for v1.1
 - Discussion and public review needed, so postponed to v1.2
- Examples of New Issues:
 - New Permissible variable within BDS: PARQUAL
 - Nomenclature for Stratification variables within ADSL
 - Recommended approach for bi-directional toxicity grades
 - Needed example for PROC MI metadata
- Issues are still being finalized

The Wild West: The Way It Was



ADaM IG V1.1 Finalization ... X

portal.cdisc.org/Teams Projects/ADaM/Working Documents/Forms/AllItems.aspx?RootFolde Search

Site Actions Browse Library Tools Documents Library tpeterson

CDISC PORTAL ADaM Working Documents ADaM IG V1.1 Finalization All Documents

ADaM AE General Examples Linear Models Metadata TTE All Sites

Discussions Team Discussion

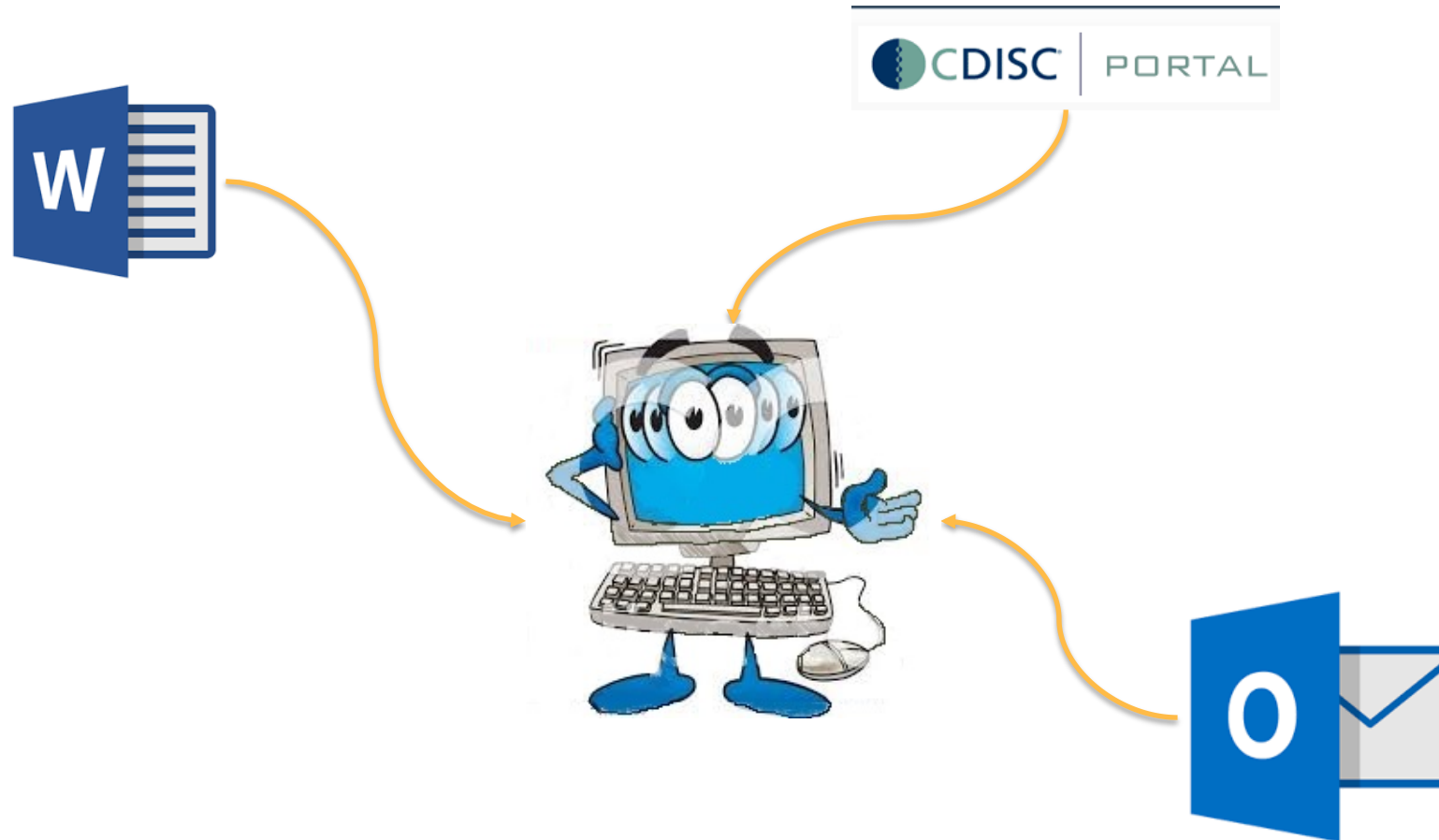
Documents Summary (projects or other summaries) Meeting Agendas & Minutes Working Documents Approved Documents Presentations All Other Documents Project_Archive

Lists Calendar Tasks Contact List

Sites AE General Examples Linear Models Metadata TTE

Type	Name	Modified	Modified By
	ADaMIG 1.1 Comments responses	3/24/2015 3:54 PM	sminjoe
	ADaMIG 1.1 Comments responses_2015-06-05	6/5/2015 4:33 PM	jtroxell
	ADaMIG 1.1 Comments responses_2015-08-25	9/10/2015 12:44 PM	jtroxell
	ADaMIG 1.1 Comments responses_2015-09-03	9/10/2015 12:42 PM	jtroxell
	ADaMIG 1.1 Comments responses_2015-09-22	9/22/2015 7:06 PM	jtroxell
	ADaMIG v1.1 ADaM team internal review comments	10/15/2015 1:46 PM	sminjoe
	ADaMIG v1.1 Comments responses_2015-10-15	10/15/2015 1:45 PM	sminjoe
	ADaMIG_v1.1draft_2014-05-23_published_for_comment	11/24/2014 4:58 PM	jtroxell
	ADaMIG_v1.1draft_2014-05-23_published_for_comment	11/24/2014 4:59 PM	jtroxell
	ADaMIG_v1.1draft_2014-11-24_typo_corrections_tracked_changes	11/24/2014 5:00 PM	jtroxell
	ADaMIG_v1.1draft_2015-01-03	1/3/2015 3:01 PM	jtroxell
	ADaMIG_v1.1draft_2015-01-05	1/5/2015 10:33 AM	jtroxell
	ADaMIG_v1.1draft_2015-02-03	3/12/2015 2:11 PM	jtroxell
	ADaMIG_v1.1draft_2015-02-04	3/12/2015 2:14 PM	jtroxell
	ADaMIG_v1.1draft_2015-02-05	3/12/2015 2:14 PM	jtroxell
	ADaMIG_v1.1draft_2015-02-11	3/12/2015 2:15 PM	jtroxell
	ADaMIG_v1.1draft_2015-02-12	3/12/2015 2:15 PM	jtroxell
	ADaMIG_v1.1draft_2015-02-19	3/12/2015 2:16 PM	jtroxell
	ADaMIG_v1.1draft_2015-03-05	3/9/2015 11:07 AM	jtroxell
	ADaMIG_v1.1draft_2015-03-12	3/12/2015 2:16 PM	jtroxell
	ADaMIG_v1.1draft_2015-03-17	3/19/2015 4:35 PM	jtroxell
	ADaMIG_v1.1draft_2015-03-18	3/19/2015 4:37 PM	jtroxell

The Wild West: The Way It Was



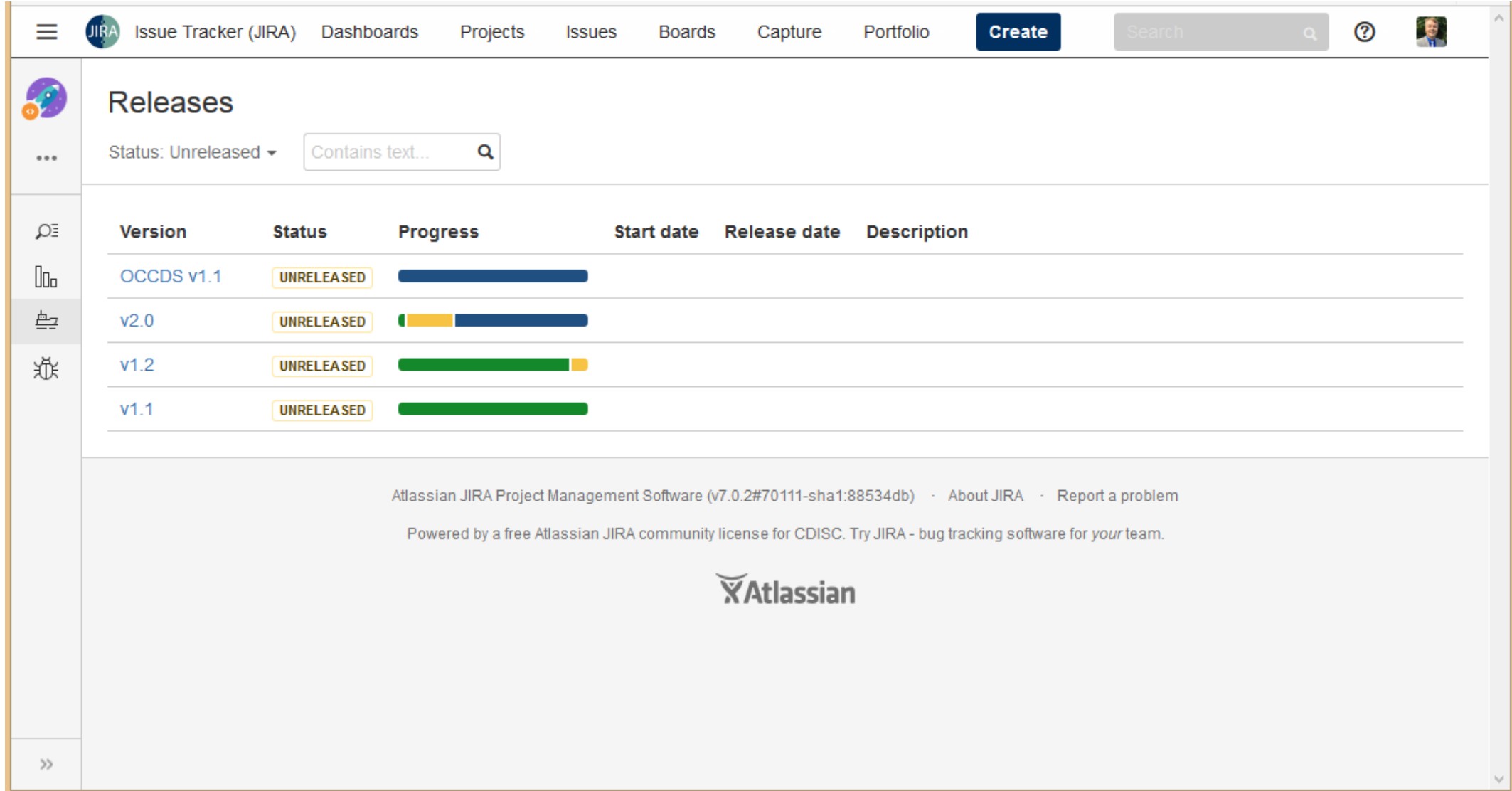
JIRA and the first baby step

- ADaM Team explores new tools available
 - JIRA Issue ADAM-1 is entered into system at the 2015 Winter IntraChange

The screenshot shows the JIRA Issue Tracker interface for a project named "Issue Tracker (JIRA)". The top navigation bar includes links for Dashboards, Projects, Issues, Boards, Capture, and Portfolio, along with a "Create" button and a search bar. The main content area displays the "Version v1.2" page, which is marked as "UNRELEASED". Below the version name, there are links for "Start date not set", "Release date not set", and "Release Notes". A progress bar is shown, indicating the progress of the version. Below the progress bar, there are statistics: 22 Issues in version, 20 Issues done, 2 Issues in progress, and 0 Issues to do. A table lists the issues, showing their priority (P), type (T), key, summary, assignee, and status. The issues are sorted by priority, with the highest priority issues at the top.

P	T	Key	Summary	Assignee	Status
↑	↑	ADAM-6	Addition of PARQUAL	Richann Watson	IN PROGRESS
↑	↑	ADAM-7	Stratification variables	Isaac Swanson	RESOLVED
↑	↑	ADAM-9	Add example of PARCATy to IG	Richann Watson	IN PROGRESS
↑	↑	ADAM-43	CRITy and compound criteria	Terek Peterson	RESOLVED
↑	↑	ADAM-44	CRITy variables in Table 4.7.1.3	Terek Peterson	RESOLVED
↓	↑	ADAM-15	ATOX/BTOX for capturing event associated with grade	Richann Watson	RESOLVED
↓	○	ADAM-26	Definition of "scope"	Terek Peterson	RESOLVED

JIRA (continued)



The screenshot shows the JIRA web interface. The top navigation bar includes links for Issue Tracker (JIRA), Dashboards, Projects, Issues, Boards, Capture, and Portfolio, along with a 'Create' button and a search bar. The left sidebar contains icons for navigation. The main content area is titled 'Releases' and features a filter for 'Status: Unreleased' and a search box. Below this is a table with columns for Version, Status, Progress, Start date, Release date, and Description. The table lists four versions: OCCDS v1.1, v2.0, v1.2, and v1.1, all with a status of 'UNRELEASED' and varying progress bars. At the bottom, there is a footer with version information, links to 'About JIRA' and 'Report a problem', and the Atlassian logo.

Version	Status	Progress	Start date	Release date	Description
OCCDS v1.1	UNRELEASED				
v2.0	UNRELEASED				
v1.2	UNRELEASED				
v1.1	UNRELEASED				

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ADaM ADQRS subteam

ADaM IG v1.2

ADaM 35 Issue - Require SRCDOM/SRCSEQ

ADaM IG v1.2 2015-11-02 Meeting Notes

ADaM IG v1.2 2015-11-16 Meeting notes

ADaM IG v1.2 2015-12-14 Meeting notes

ADaM IG v1.2 2016-01-25 Meeting notes

ADaM IG v1.2 2016-02-08 Meeting notes

ADaM IG v1.2 2016-02-22 Meeting notes

ADaM IG v1.2 2016-03-07 Meeting notes

ADaM IG v1.2 2016-03-28 Meeting Notes

ADaM IG v1.2 2016-04-04 Meeting notes

ADaM IG v1.2 2016-04-18 Meeting

	Review of Action Item Table	All	See below table for updates			
	Wrap-up	Brian	Brian confirm with everyone attending that this meeting time seems to work well (For those not in attendance, please let Brian or Terek know if there are any issues). The next meeting will be Monday, February 8th.			

Action items

#	Date Raised	Action	Description	Assigned to	Updates	Status
1	2Nov2015	Jira	Add version number and determine how to add people to assigned field.	@Nancy Brucken	Version numbers are now added to all issues in JIRA. It will not be possible to add individual team members to the assigned field.	Complete
2	2Nov2015	ADaM-6 / ADaM-9	Add text for new proposed standard variable of PARQUAL and update text for existing PARCATy variable.	@Richann Watson	The Parqual team hasn't met yet this year. Richann will follow up with Shelly Dunn and provide an update at our Feb 8th meeting.	In Progress
3	2Nov2015	ADaM-7	Stratification variables	@Isaac Swanson	Material was posted on Wiki. Team to review and discuss before next meeting Feb 8th. (Note: Action require by whole team: Review	In Progress

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ADaM IG v1.2 2016-03-07 Meeting notes

ADaM IG v1.2 2016-03-28 Meeting Notes

ADaM IG v1.2 2016-04-04 Meeting notes

ADaM IG v1.2 2016-04-18 Meeting

ADaM / ADaM Home / ADaM IG v1.2

ADaM 35 Issue - Require SRCDOM/SRCSEQ

Created by Cindy Stroupe on Dec 11, 2015

Document

Document: "Translating Variability"

Guidelines to support data management activities. The purpose of this document is to provide a common understanding of the variability concepts and the associated data management activities. This document is intended for use by all CDISC staff and is a living document. It will be updated as needed.

Table 3.30.3 defines additional variables and their associated data management activities. They are used to support the data management activities described in this document.

If a variable is not in the ADaM dataset, the variable name and the ADaM value of the variable should be documented in the ADaM dataset.

If all values of a variable are the same, the variable should be documented in the ADaM dataset.

Guidelines to support data management activities are provided in this document.

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Analysis Data Model Implementation Guide

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Analysis Data Model Implementation Guide

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ADaMIG examples

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General Identification 1

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General Identification 1

Identification of rows used for analysis – multiple visits that fall within a visit window.

This example (Table 4.5.4.1) illustrates the use of the analysis flag variable ANLZZFL to indicate the rows that were chosen for analysis from among the multiple visits that fall within the analysis timepoint windows of "Baseline" and "Week 2". Subject 1001 had two observed Baseline and Week 2 analysis timepoints according to analysis window definitions. The one that is used in analysis is flagged with ANL01FL=Y. This approach is used because all original visits (rows) are included in the dataset, and those selected for analysis must be identified. For traceability reasons, the AWTARGET and AWTDIFF columns are included in order to indicate more clearly how the analyzed rows were selected from among the candidate rows within each analysis window. In this example, the record that falls closest to the scheduled visit day is the one that will be analyzed.

Table 4.5.4.1 Example 1: ADaM Dataset with Identification of Rows Used for Analysis When Multiple Visits Fall Within a Visit Window

Dataset | HasFormatting = true

Row	<u>USUBJID</u>	VISIT	<u>AVISIT</u>	<u>ADY</u>	<u>PARAM</u>	<u>AVAL</u>	<u>DTYPE</u>	<u>ANL01FL</u>	<u>AWTARGET</u>	<u>AWTDIFF</u>
1	1001	Screening	Baseline	-5	SUPINE <u>SYSBP</u> (mm Hg)	144			1	5
2	1001	Baseline	Baseline	1	SUPINE <u>SYSBP</u> (mm Hg)	145	Y		1	0
3	1001	Week 1	Week 1	7	SUPINE <u>SYSBP</u> (mm Hg)	130	Y		7	0
4	1001	Week 2	Week 2	12	SUPINE <u>SYSBP</u> (mm Hg)	133	Y		14	2
5	1001	Week 3	Week 2	17	SUPINE <u>SYSBP</u> (mm Hg)	125			14	3
6	1001	Week 4	Week 4	30	SUPINE <u>SYSBP</u> (mm Hg)	128	Y		28	2

What did you change?

☒ Notify watchers

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What Worked and What Didn't

- Increased Transparency
 - Influencing other sub-teams
 - Ease of Communication
 - Increased Collaboration
-
- Learning new platforms
 - Editing took more time
 - Publishing is still a mystery
 - Posting IG to the WIKI required Help
-
- In the end, we think it will be better

- Transparency
- Collaboration made easier
- More ADaM groups adopting these methods
- Recommend to use these tools
- Need more training to use the tools
- Need experience using WIKI effectively

Contact Information

Terek J. Peterson, MBA
Chiltern
1016 W 9th Ave.
King of Prussia, PA
Terek.Peterson@Chiltern.com

Brian Harris
MedImmune
One MedImmune Way
Gaithersburg, MD
HarrisB@MedImmune.com