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

Terek J. Peterson, MBA, Chiltern, King of Prussia, PA, USA
Brian Harris, MedImmune, Gaithersburg, MD, USA

ABSTRACT
When the ADaM Implementation Guide (ADaMIG) v1.0 was released in 2009, it was an exciting time for the standards community. There was now a standardized way to communicate and analyze study data, which had been done in many different ways by every company. Fast forward to 2016, the release of ADaMIG v1.1 has provided improvements and clarifications to the ADaM model. At the time that version 1.1 was released, a few items remained that required further research and were, therefore, reserved for a minor version v1.2 to be released soon after. This presentation will highlight those items and discuss the current status of ADaMIG v1.2 at the time of the PhUSE Annual conference.

To date, the working practices of the team editing the ADaMIG documents have used the tools that were available: the CDISC Portal, Word, and Email. Meeting agendas were sent via emails, and meeting minutes were taken in Word. The limitations of these tools often disrupted and slowed collaboration across the team. With the introduction of JIRA and WIKI to the CDISC volunteer teams, new opportunities for working and collaborating have emerged. Within the ADaM team, the ADaMIG v1.2 sub-team took a risk and decided to embrace the new tools to see if a more efficient and transparent way of working was possible. The second part of the presentation will describe how the team utilized JIRA to capture, assign, and track issues highlighted during working sessions, improving project management and providing transparency to the full ADaM team. The presentation will also highlight how the sub-team utilized WIKI for meeting agendas and minutes, collaboration areas to stress-test draft text and examples, and editing of the actual ADaMIG v1.2 document

INTRODUCTION
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History of ADaM Versions
A long time ago in a galaxy far, far away…

On December 17, 2009 the final version of the ADaMIG v1.0 was released, outlining fundamental ADaM principles, the requirement of traceability for the "verification of derivations", and the ADaM data structures. Subject-Level Analysis Datasets (ADSL) were designed to provide a "single location for key information for each subject in the trial" such as population flags and treatment variables.[1] The ADaM Basic Data Structure (BDS) contains a core set of variables, such as AVAL and PARAM, and could be derived from SDTM domains, other ADaM datasets, or a combination of both. While there is only one ADSL dataset per study, multiple BDS datasets could be created to accurately represent the analyzed data.[2]

Further definition and parameters for analysis datasets were released in May of 2012. The ADaM Basic Data Structure for Time-to-Event (TTE) analysis provided an outline for survival analysis data, "the statistical method for studying the occurrence and timing of events". This structure can be applied to a wide range of clinical outcomes, however "because recurrent event analyses require more than one analysis variable as a dependent variable, any analysis dataset for recurrent events is not compliant with the ADaM BDS". Along with the ADaM TTE structure, Adverse Events Analysis Data Model (ADAE) v1.0 was released in May of 2012. Analyses of adverse events fit closer within SDTM data modeling than to the Basic Data Structure model. ADAE offered a platform built on nomenclature from SDTM IG v3.1.2 and Amendment 1 of SDTM v1.2. When SDTM AE with SUPPAE was not sufficient to support the analysis of AE data, the ADAE model offered added attributes, variables, a naming guideline, and data structures needed to fill that gap.[3][4]

ADaMIG v1.1 was released on February 12, 2016 along with the introduction of a third ADaM data structure, Occurrence Data Structure (OCCDS) v1.0. This new data structure document superseded ADAE v1.0 and proved more generic and applicable to analysis outside adverse event data alone. Inclusions to the OCCDS were Medical History, Concomitant Medications, and Adverse Events ADaM datasets.[5]

SIGNIFICANT CHANGES IN ADAMIG V1.1

In an effort to improve clarity and to address questions from the expanding user base, the ADaMIG v1.1 incorporated significant changes. A section was added to define the distinctions between analysis datasets, ADaM datasets, and non-ADaM analysis datasets. The text describing the contents of ADSL was further clarified. Explanations regarding standard naming fragments were added. A requirement was included, stating that if an ADaM standard variable name was identified for a specific concept, then that ADaM standard variable name must be used. Also included in ADaMIG v1.1 was clarification around the instructions for FL variables, as well as, to the concepts of anchor dates and times. New variables for "subperiod" and "phase timing" were added.
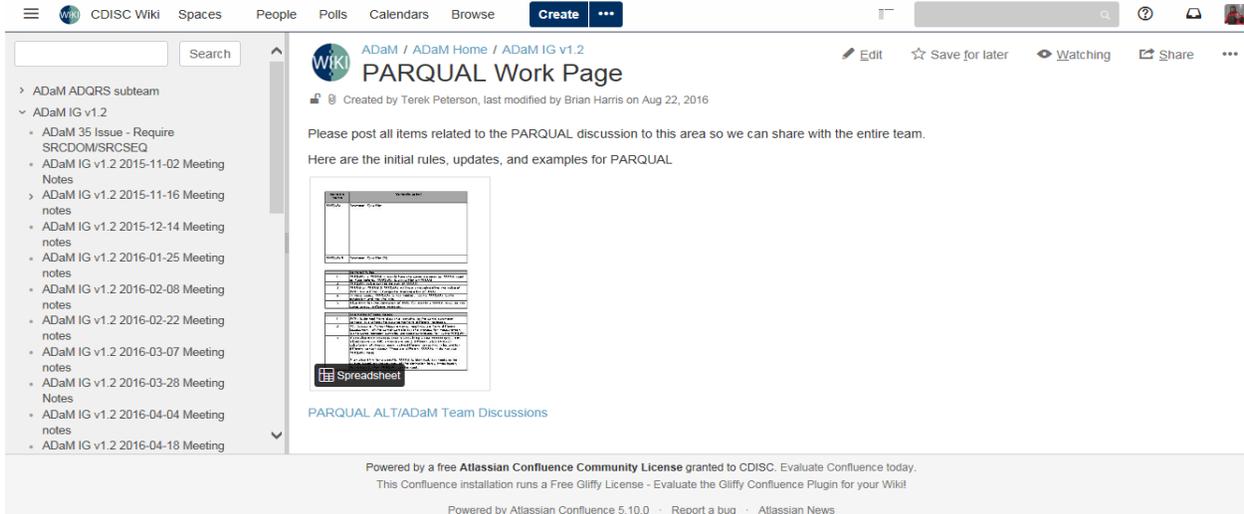
Tumble Weed: The Stuff Left Behind

Highly symbolic meaning in western films and visual media.

While finalizing version 1.1, a few issues arose that required further discussion by the ADaM team and would benefit public review. These issues were postponed to version 1.2 that would be finalized, ideally, within a year's time after publishing v1.1. Some examples of the issues were nomenclature for stratification variables within ADSL, the recommended approach for bi-directional toxicity grades, the addition of an example for PROC MI metadata, as well as minor clarifications across the sections. The most significant issue was with the addition of a new permissible variable within BDS called PARQUAL that would provide qualifying information for PARAM/PARAMCD. At the time of writing this paper, PARQUAL and some of the other issues are still being finalized; however, the v1.2 sub-team has had success implementing new collaboration tools, as can be seen in the displays below. Display 1 shows the JIRA entry of PARQUAL and Display 2 shows the PARQUAL work page in WIKI where ideas are vetted between team members.

Display 1 – JIRA Issue ADaM-6

Display 2 – Add new PARQUAL variable to BDS.

The Wild West: The Way It Was
Email. Email. Type. Wait. Email. Wait. Wait. Email. Reply All … Confusion.

To date, the working practices of the team editing the ADaMIG documents have used the tools that were available: the CDISC Portal (SharePoint), Word, Excel, and Email. Meeting agendas were sent via emails, and meeting minutes were taken in Word or Email. The limitations of these tools often disrupted and slowed collaboration across the team, but didn't hold back the team from getting the hard work done. That was just the way it was, there was a password to get on the CDISC website itself to get material like models, interpretation guides, presentations, etc as you do now with your company's yearly membership. Then an additional username and password for the CDISC portal, see Display 3.

Display 3 – CDISC Portal on www.CDISC.org

Once on the CDISC portal like Display 4 on the next page, documents were organize like they probably are at every company in one form or another in logical subfolders and some type of version control scheme. This method works and the ADaM team has been producing industry changing documents for over a decade. As can be seen on the next page, during the finalization of ADaMIG v1.1 there were many working versions needed due to the substantive additions and clarifications being added to this version as in Display 4. Versioning was tracked by track changes and version dates of the documents. This method works however one member of the team must be the champion of the version and can only work on it one person at one time.

Display 4 – Organization of ADaMIG on Portal

Baby Steps: First JIRA Issue

Baby steps get on the bus, baby steps down the aisle, baby steps…

ADAM-1 was the first JIRA issue entered into the system at the E2E breakout session at the 2015 Winter IntraChange in Silver Spring, Maryland. It was during that meeting the ADaM team started investigating how the existing CDISC tools could be used to improve the ADaM teams' working practices. For the ADaMIG v1.2 project, the team decided the number of tasks was small enough it could experiment with the tools and recommended the use of JIRA during the project.

JIRA Software from Atlassian is a cloud based collaborative platform that can be used to plan and assign tasks, track issues, prioritize tasks, and generate progress reports. It offers the flexibility to design tasks unique to any project and define the task's parameters for completion. Within JIRA, a requester would create the specified task summary. The sub-team co-leads will be notified and the task is assigned to the appropriate team member. JIRA allows for customized workflows to be created, however this team kept the process very simple via the assignment function in JIRA. Display 5 shows the system dashboard when logging into JIRA summarizing tasks assigned one of the authors.

Display 5 – JIRA System Dashboard

With customized interfaces, the task is color-coded and assigned a timeline. Using the software, project issues can be addressed at any phase. Transparency will increase since all of these steps will be observable to both the sub-team and the full ADaM team as well as CDISC volunteers across the entire community. At weekly meetings with the sub-team members, the co-leads will review progress using JIRA's real-time reports and, if needed, a task can be reprioritized. Reprioritization and report generation can occur any time it is necessary. The progress of all releases can be viewed simply as shown in Display 6.
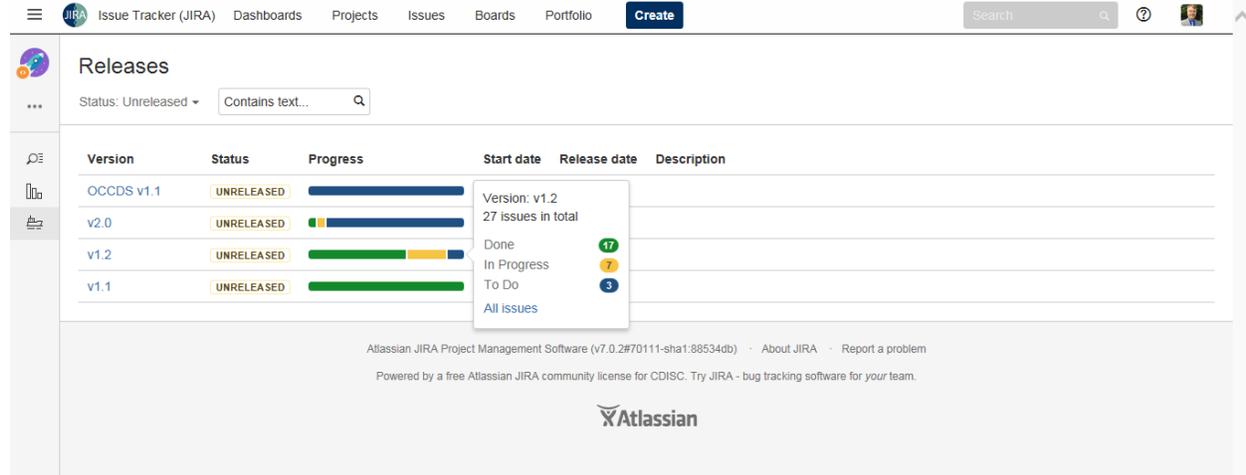
Display 6 – ADaMIG Releases and Issue Progress

As can be seen in Display 7 below, when creating an issue, the JIRA Create Issue feature has a simple interface to enter the necessary information to complete the task, including attachments. Enter in the Project, Issue Type, Summary, and the Description. Attachments are always helpful when describing a new improvement needed in an implementation guide. The Fix Version and Priority were generally filled out by the ADaMIG v1.2 team leads once the new issue was discussed during the weekly meeting. Once a new issue is entered, as can be seen in Display 6 above, it will initially be assigned to "To Do" progress until it is assigned to an individual and the issue then becomes "In Progress". As can be seen, the process becomes very systematic and organized for the sub-team.
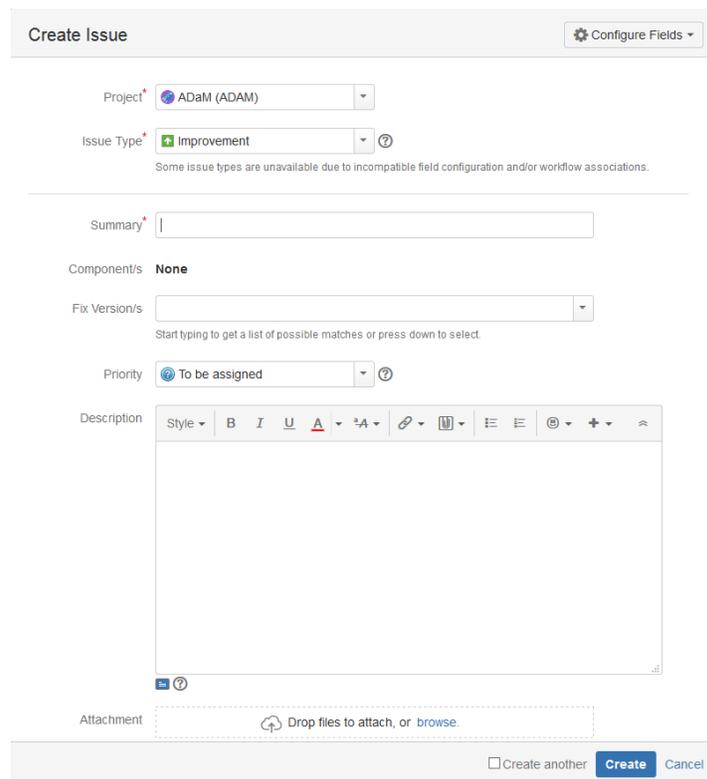
Display 7 – Create Issue in JIRA

5

Embracing WIKI and JIRA

Louis, I think this is the beginning of a beautiful friendship

Along with CDISC JIRA, the CDISC WIKI further increases transparency into the group's workings. The sub-team decided that it would try to present as much information as possible to the rest of the ADaM team so that they could keep track of the progress of this version. The CDISC WIKI was used for three primary purposes (1) capture meeting minutes, (2) vet issues before editing the ADaMIG, and (3) editing the ADaMIG v1.2.

As can be seen below in Display 8, meeting minutes are easily captured during the meeting in WIKI. It was easy to go back and forth between JIRA and WIKI during the meeting to discuss each issue. With the team new to both systems, updates might be better documentation for JIRA. The important point, the information was being documented and accessible by anyone. Once updates were made the minutes were automatically emailed.

Display 8 – Meeting Minutes in CDISC WIKI

WIKI was used for vetting issues before editing the ADaMIG with the proposed text. One example can be seen in Display 9 below. Sometimes this was due to the complexity of the items like toxicity grades or a new proposed parameter qualifier.

Display 9 – Vetting Issues in CDISC WIKI

The third way the team used WIKI, was by editing the ADaMIG v1.2 in WIKI. After working through some of the mindful concerns of the ADaM Leadership Team regarding access issues, the sub-team was willing to give it a go. It was bit of a slow start as there were issues with getting the original ADaMIG v1.1 ported to WIKI. This version would not allow the WIKI database to have unique entries for certain sections based on past editing styles. With a couple of meetings with the CDISC WIKI experts that was resolved and the team got moving on April 14, 2016.

Editing in WIKI is not that same as Word, so for example adding a table or an example needs to be thought of as adding a Web page. Let's say you are looking at the entire document and find a section you want to edit, you cannot simply edit from there you must find the smaller section or table in the document hierarchy then hit the Edit button. As can be seen in Display 10, the edit screen does have a few familiar editing features like Word but that is where editing is different. In the example below there were extra spaces in front of Cond and Perm. To remove those spaces required editing the section as shown then editing the macro that makes the nice text box "Values of ADaM "Core" Attributes". The great thing about WIKI, it stores the incremental changes so the first time the changes were made they did not stick because they were not done correctly but the second time they did. Once this change was made the team members watching this editing will get an email that an update has been made to the master document.

Editing the ADaMIG in this manner allowed team members to work on the document simultaneously without the need to worry about having the latest draft from the team. The latest draft is always present on the WIKI and recovering to an earlier version is simple to do if the change made needs to be rolled back.

Display 10 – Editing the ADaMIG v1.2 in WIKI

Finally, once an edit was made to the ADaMIG that was now complete, a team member would reference the original JIRA issue to confirm it was fully addressed. Any meeting minutes or vetted WIKI pages were reviewed to confirm all items were entered. To close the item, the JIRA issue was set to Resolved.

What Worked and What Didn't
In the end, we think it will be better

Transparency will increase since all steps will be observable to both the sub-team and the full ADaM team as well as CDISC volunteers across the entire community. The ADaM Rules (Compliance) and Questionnaire Rating and Scales (QRS) sub-teams have started using these tools with some guidance from the v1.2 sub-team. There has been a noticeable reduction in emails, as compared to other sub-teams, produced by an individual; instead emails are primarily system produced. Communication has been eased. The WIKI has allowed for white boarding of ideas that are retained until the next time volunteers have time to discuss.

Using new tools do not work easily the first time. Getting out of the mindset of editing in a Word or Excel document and to the idea of basically creating a web page to express your thoughts takes retooling the way people have worked since frankly these two Microsoft software packages have been created. Easily tracking difference between versions was said to be easy, but we have not found that to be so. Particularly when having to show others on the ADaM team who are used to track changes in a Word document. Since WIKI divides up the document into smaller segments, getting the grand difference document has not come easy. This could be a learning curve item that we still need training on.

CONCLUSION
Techniques and approaches for collaborating continue to evolve. There is some reluctance from ADaM team members to use tools that they may not have familiarity with as part of their "Day Jobs". Nonetheless, the experience of the ADaM v1.2 sub-team has been positive, and the team has been complemented for members of the full ADaM team for increasing transparency. These tools are being used by other ADaM sub-teams as well, namely ADQS and ADaM rules, and the trend will continue as more team members become familiar with the tools. All of these efforts, are ultimately bringing the ADaM team closer to the CDISC community by having them collaborate in a similar fashion as the other work groups.

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

Terek J. Peterson, MBA
Chiltern
1016 W 9th Ave.
King of Prussia / 19406
Work Phone: +1 610 627 9436
Email: Terek.Peterson@Chiltern.com

Brian Harris
MedImmune
One MedImmune Way
Gaithersburg / 20878
Work Phone: +1 301 398 4275
Email: HarrisB@MedImmune.com

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