Feedback : SDRG Trial

CJUG-SDTM (LISaS Sub Team)
9th August 2013

Study Data Reviewer's Guide

- SDRG provides;
  - Additional explanation beyond the Data Definitions document (define.xml).
    - e.g., SDTM IG version, OpenCDISC version
  - A summary of SDTM conformance findings.
    - e.g., OpenCDISC Error/Warning issue list
- SDRG will be proposed as a component of the eCTD's Module 5 data documentation.
  - Analysis Data Reviewer's Guide will be handled in a future project.

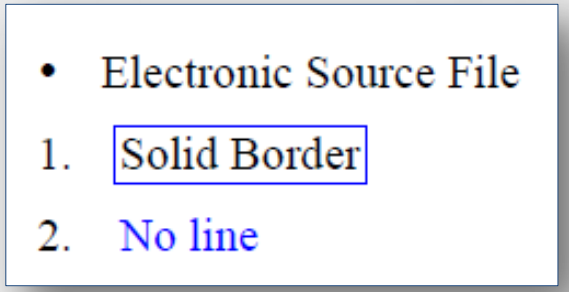
1. Guideline and Sample: http://www.phusewiki.org/wiki/index.php?title=Study_Data_Reviewer's_Guide
2. Poster: http://www.phusewiki.org/docs/Posters2013CSS/PP21%20.pdf
3. Study Data Tabulation Model - Metadata Submission Guidelines (SDTM-MSG), Page 7

Trial Overview

- Study data: HTT-55-MA2AC (virtual)
  - Created by CJUG in 2012
- Process:
  1. Each member created respective SDRGs.
  2. The SDRGs were shared and reviewed by each member.
  3. One new SDRG was created and fixed.
  4. Send FDA/PhUSE Working Group - SDRG Core Team our feedback.

Update v1.0->v1.1 during the Trial

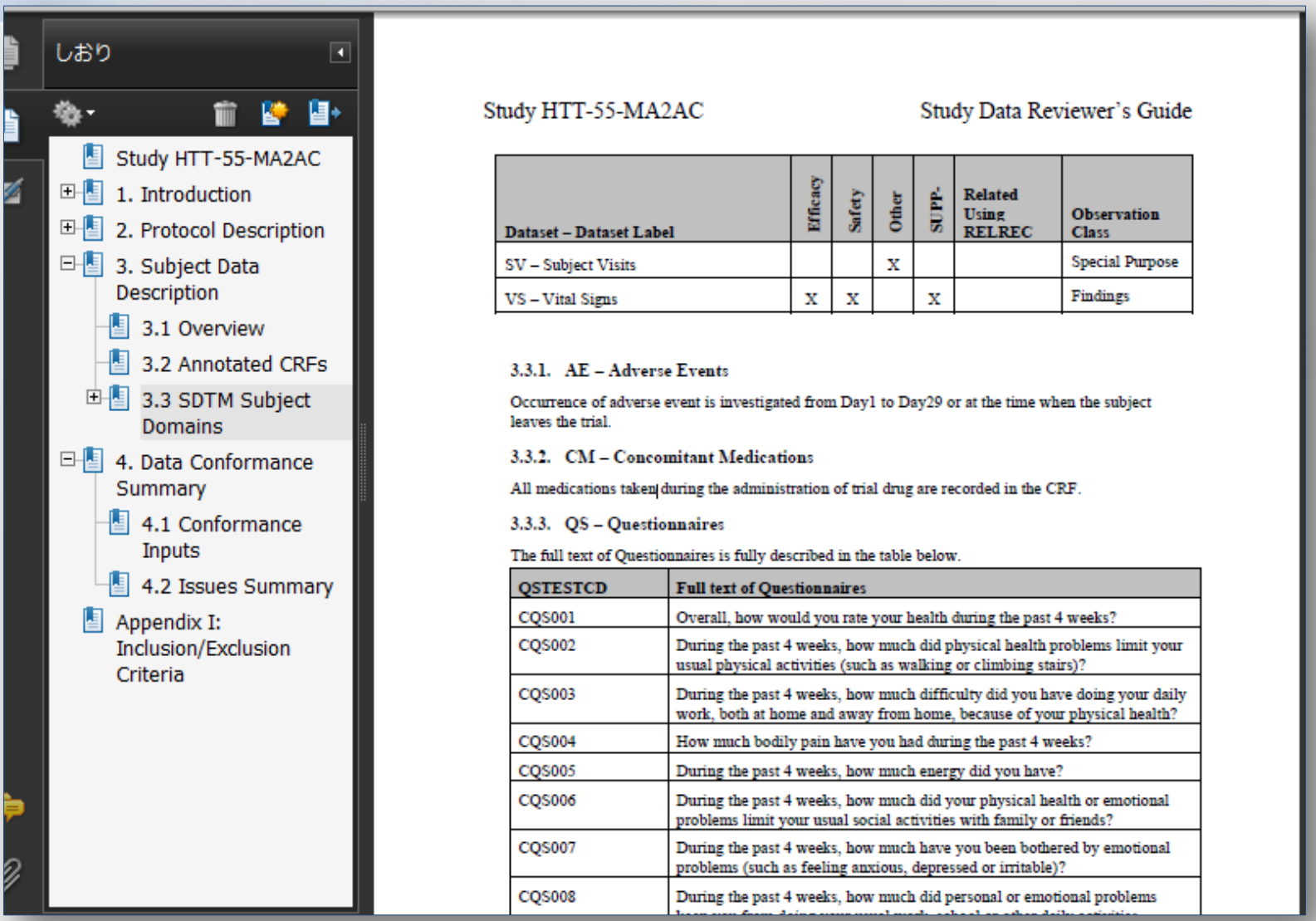
- FDA Portable Document Format PDF Specifications;
  - Black is the recommended font color except that blue can be used for hypertext links.
  - Hypertext links in text can be designated by rectangles using thin lines or by blue text.



- We updated the SDRG;
  - Change the blue header fonts to black
  - Use the hyperlink with no underline

FDA Portable Document Format (PDF) Specifications:
http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163565.pdf
Changing PDF Link Color for Regulatory Submissions
http://blogs.adobe.com/acrobatforlifesciences/2009/08/changing_pdf_link_color_for_re/

Deliverable



Dataset – Dataset Label	Efficacy	Safety	Other	SUPP-	Related Using RELREC	Observation Class
SV – Subject Visits			X			Special Purpose
VS – Vital Signs	X	X		X		Findings

3.3.1. AE – Adverse Events

Occurrence of adverse event is investigated from Day1 to Day29 or at the time when the subject leaves the trial.

3.3.2. CM – Concomitant Medications

All medications taken during the administration of trial drug are recorded in the CRF.

3.3.3. QS – Questionnaires

The full text of Questionnaires is fully described in the table below.

QSTESTCD	Full text of Questionnaires
CQS001	Overall, how would you rate your health during the past 4 weeks?
CQS002	During the past 4 weeks, how much did physical health problems limit your usual physical activities (such as walking or climbing stairs)?
CQS003	During the past 4 weeks, how much difficulty did you have doing your daily work, both at home and away from home, because of your physical health?
CQS004	How much bodily pain have you had during the past 4 weeks?
CQS005	During the past 4 weeks, how much energy did you have?
CQS006	During the past 4 weeks, how much did your physical health or emotional problems limit your usual social activities with family or friends?
CQS007	During the past 4 weeks, how much have you been bothered by emotional problems (such as feeling anxious, depressed or irritable)?
CQS008	During the past 4 weeks, how much did personal or emotional problems

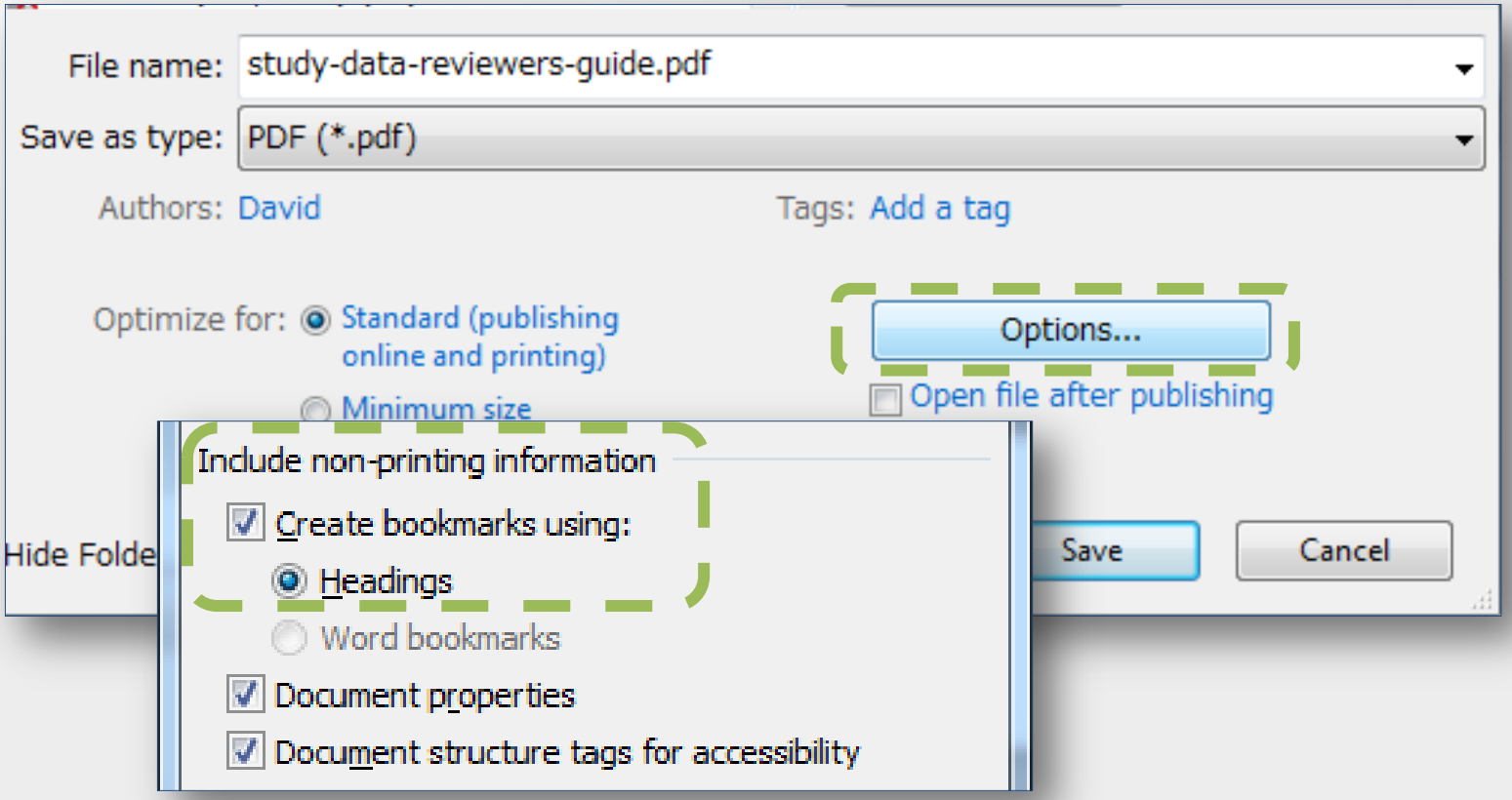
Findings -1: Japanese Application

- The study number in the header is NOT updated automatically.
  - Because the field code="Title" doesn't work in the MS Word Japanese version. The code "Title" in the header should be replaced by "表題".

Note: The potential risk caused by the double-byte or Local language software should be considered of implementing any tools related to the CDISC/FDA standards.

Findings -2: Bookmarks

- Bookmarks should be created.
  - Not mentioned in the Completion Guideline.



Findings -3: SDTM Subject Domains

- Specify the functional category or categories for each domain.
  - Include categories of Efficacy, Safety, and Other.
  - Additional categories may be defined at the discretion of the sponsor.

- Difference of opinion;

Dataset – Dataset Label	Person	Efficacy	Safety	Other
CM – Concomitant Medications	Person A, C, D		X	
	Person B, E			X
VS - Vital Signs	Person B	X		
	Person A, E	X	X	
	Person C, D		X	

Note that Primary Endpoint is Change from day 1 to end of treatment in blood pressure (SBP/DBP).

- Should it be categorized by Statistical Analysis Plan?

Comments from FDA/PhUSE Working Group - SDRG Core Team

- *The functional categories were intended to provided the FDA Reviewer with a high-level overview of the content of the SDTM domains.*
- *Ideally, these should be aligned with the protocol objectives and analysis plan, but this is not required.*
- *Additionally, more than one category may be indicated for a given domain.*

Note that the slide deck (previous version v1.0, Page 1 - 9) was sent to the FDA/PhUSE WG - SDRG Core Team and we received the feedback.

Findings -4: Creation Timing

- It's strongly recommended that SDRGs or similar documents should be prepared through Clinical development process.
  - If SDRGs are created just before a submission, It may need huge resources to clarify context of data or conformance details.