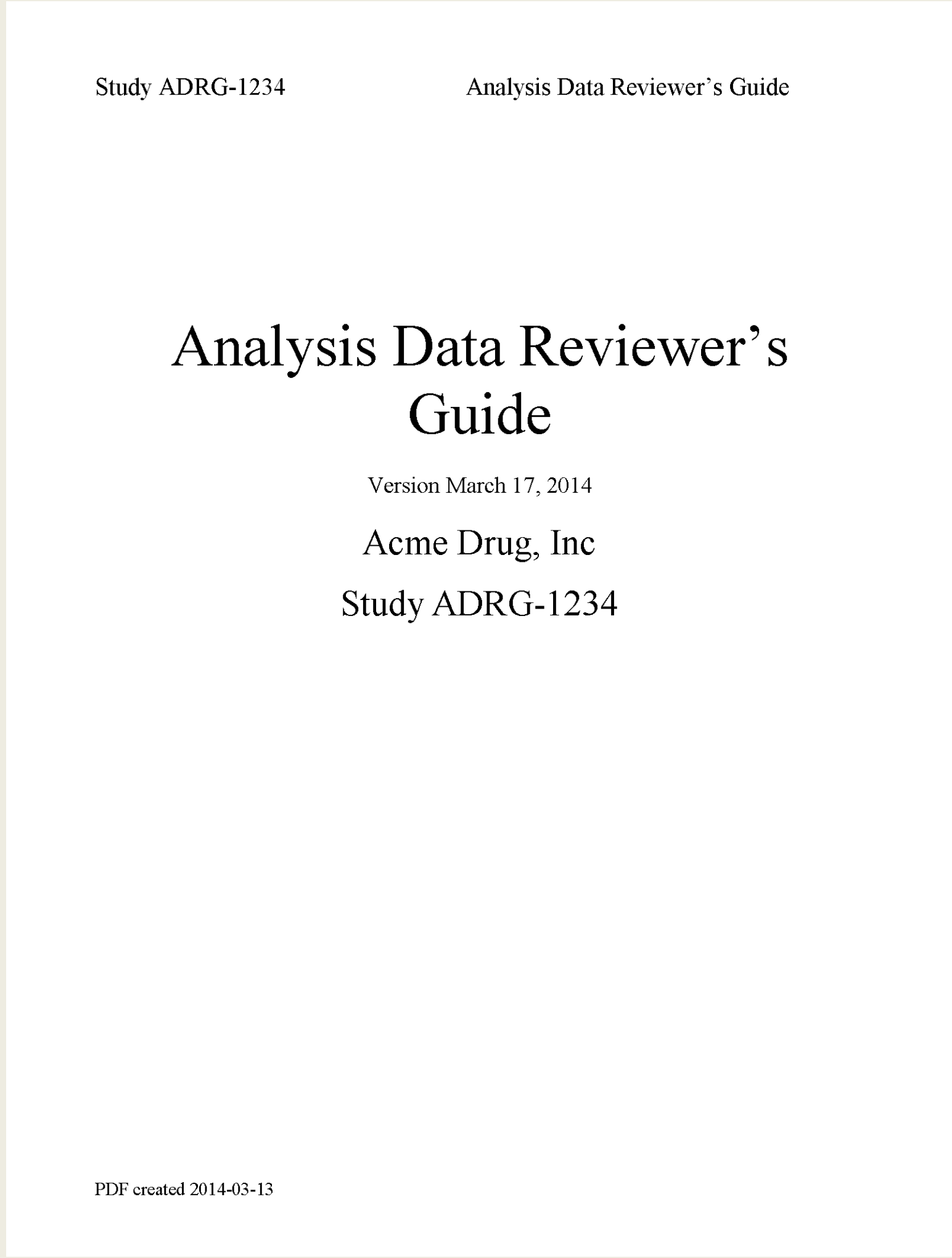


The Analysis Data Reviewer’s Guide (ADRG)

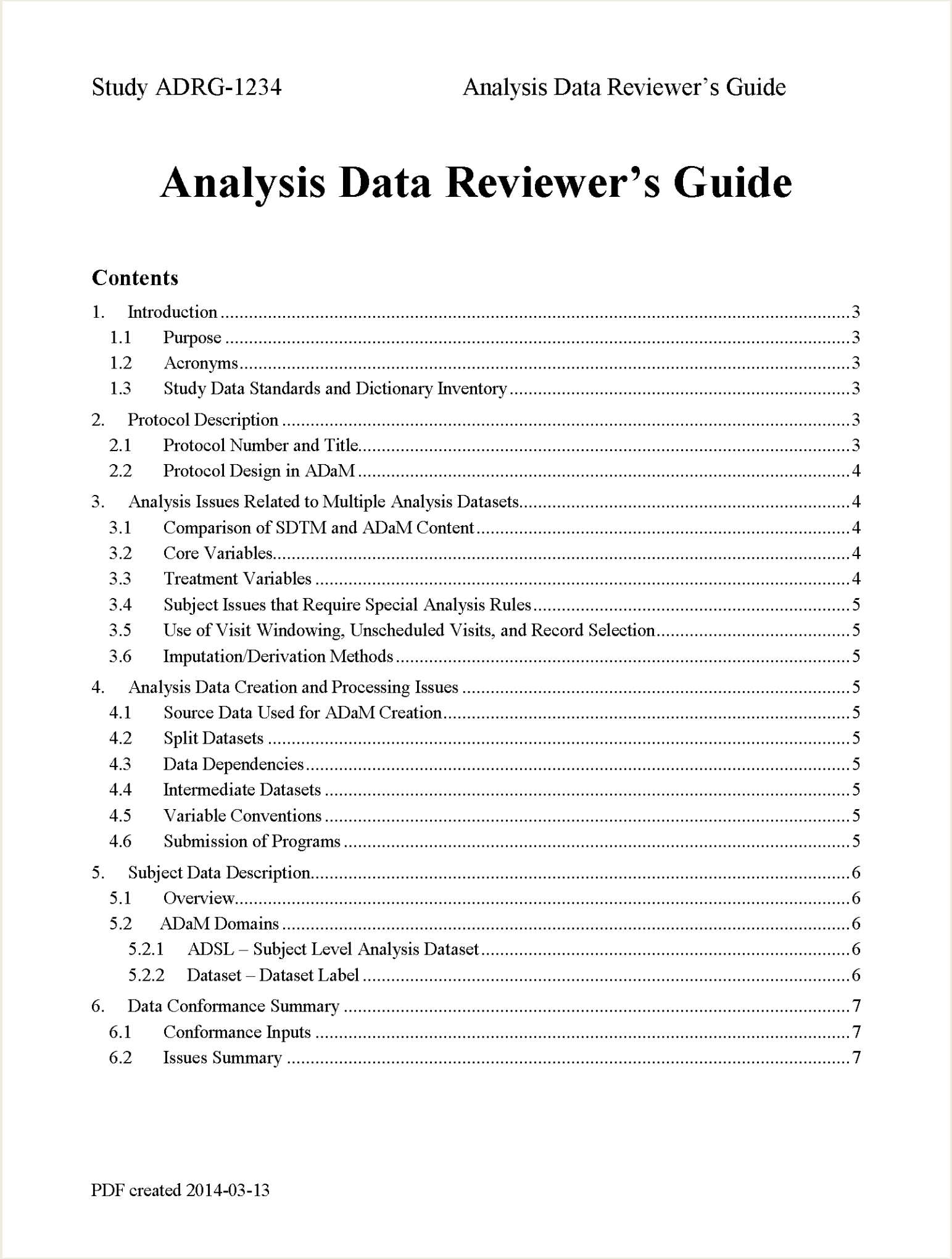
Presented on behalf of PhUSE Working Group 4:

Ben Vali (FDA), Mina Hohlen (FDA), Steve Wilson (FDA)

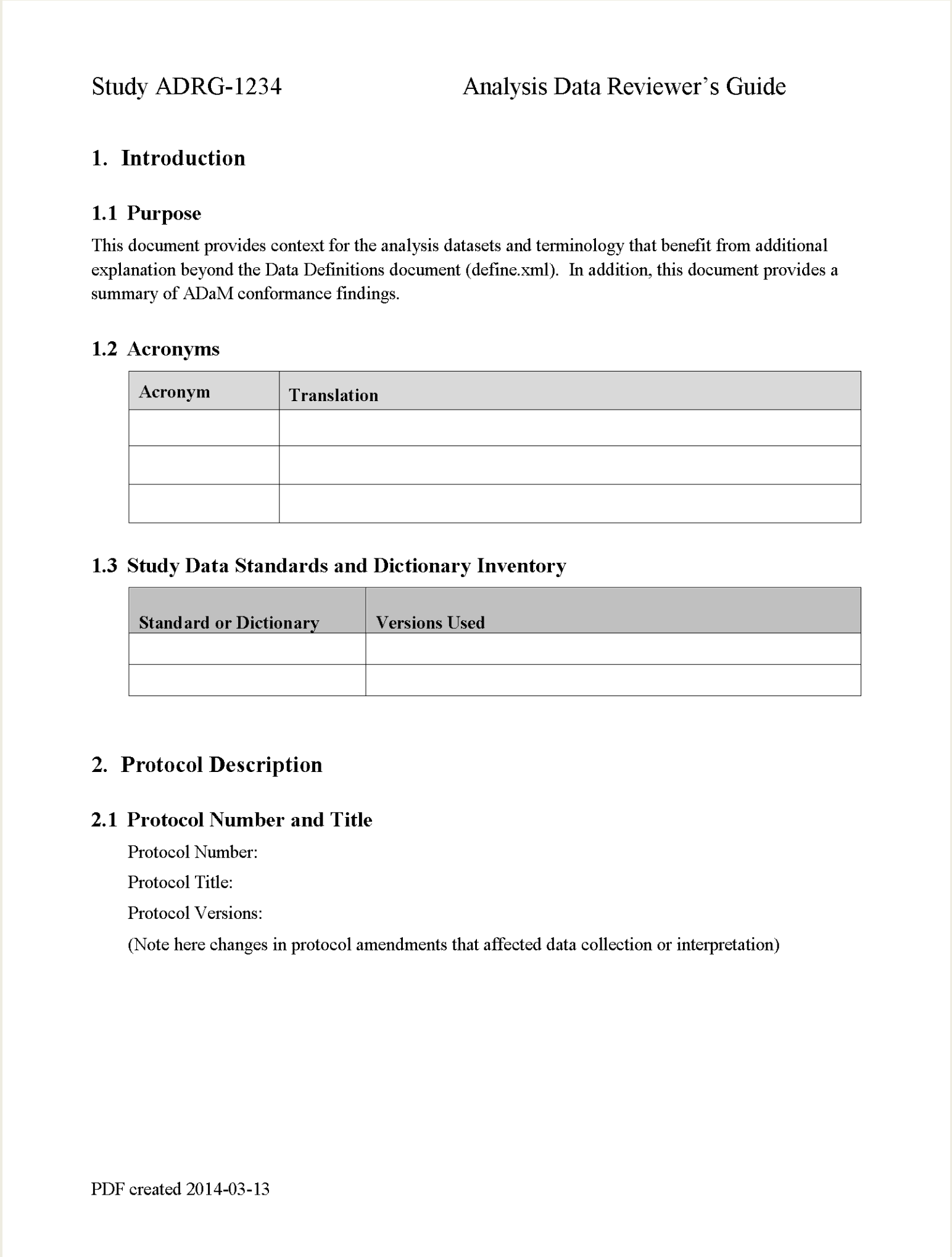
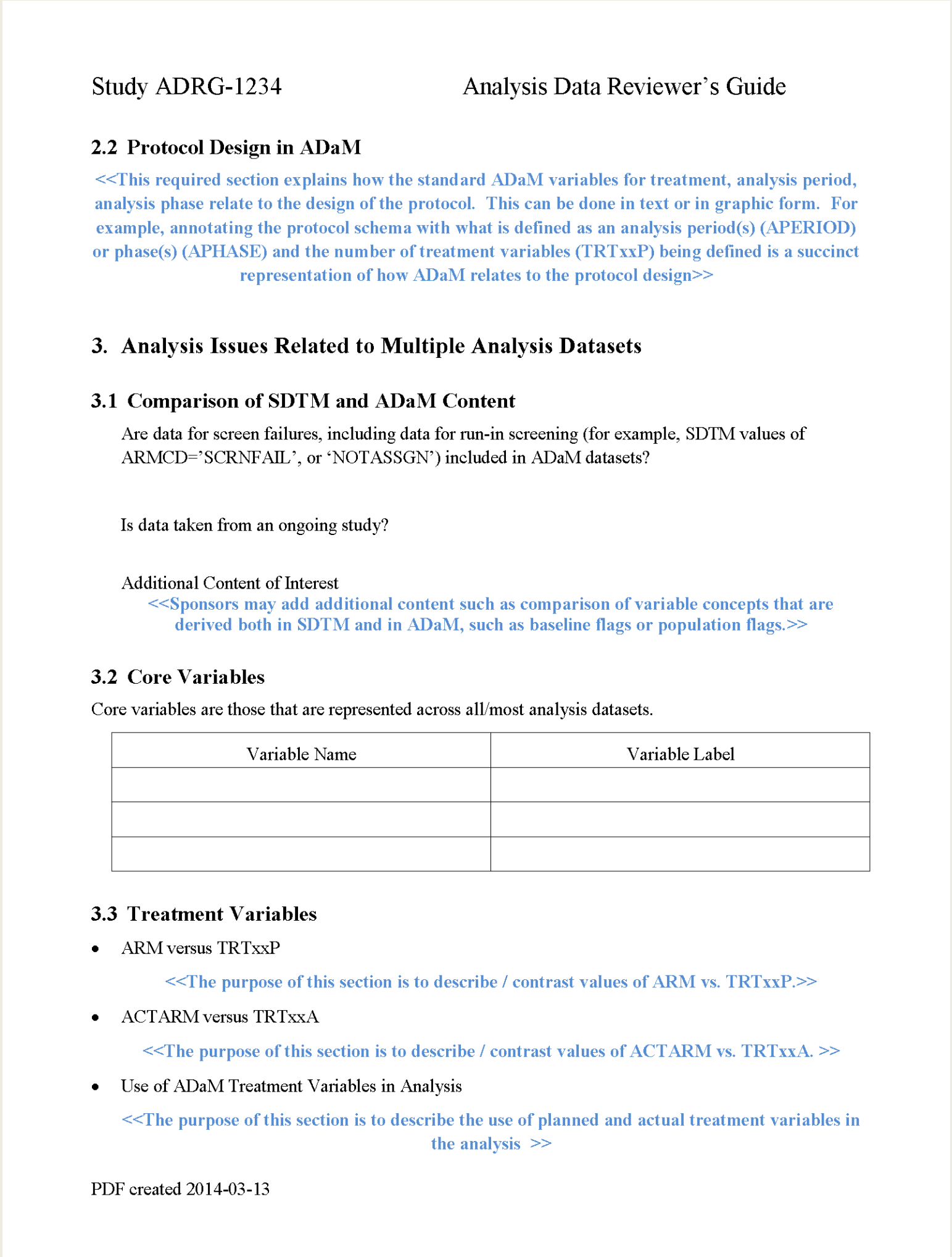
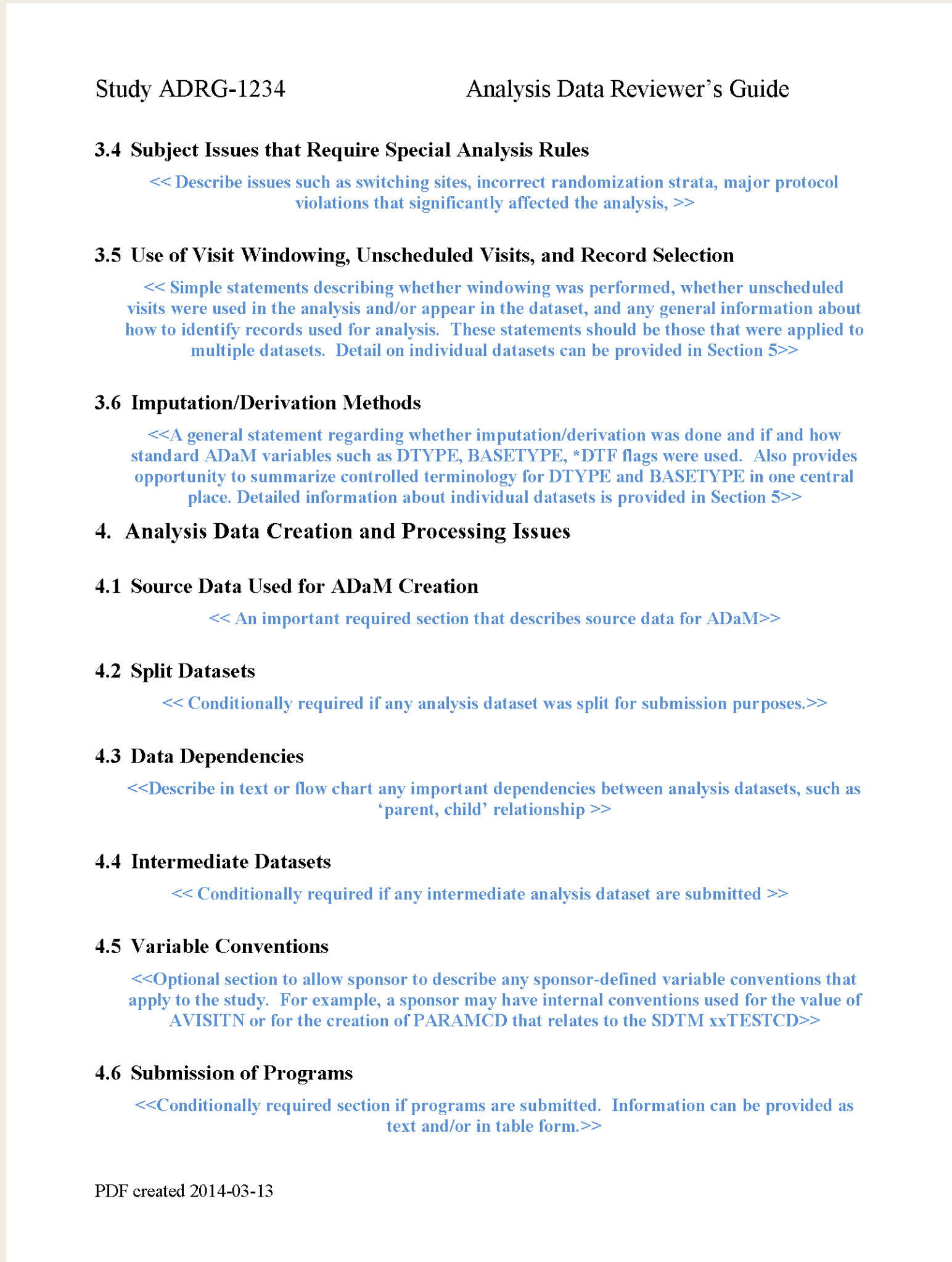
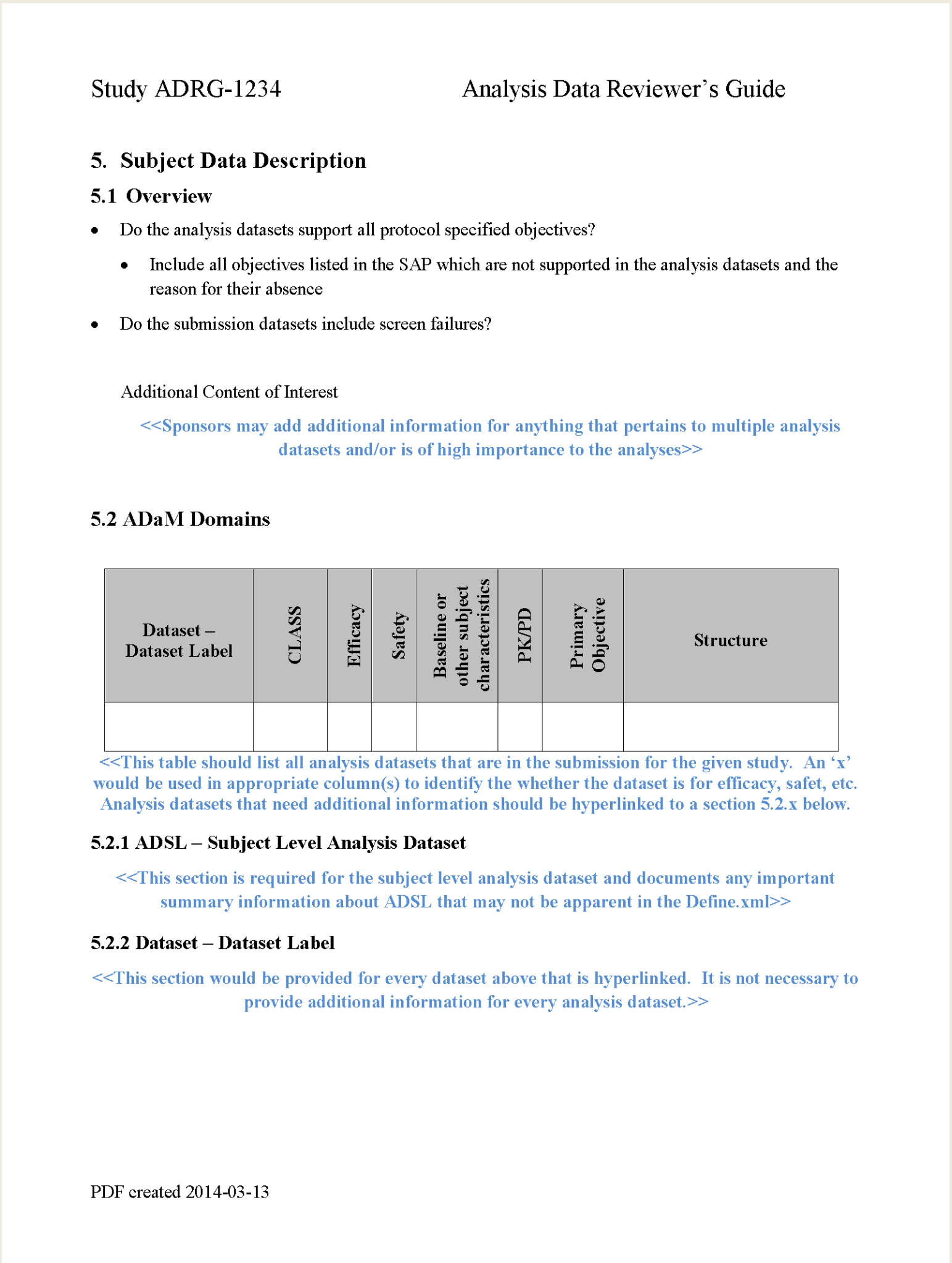
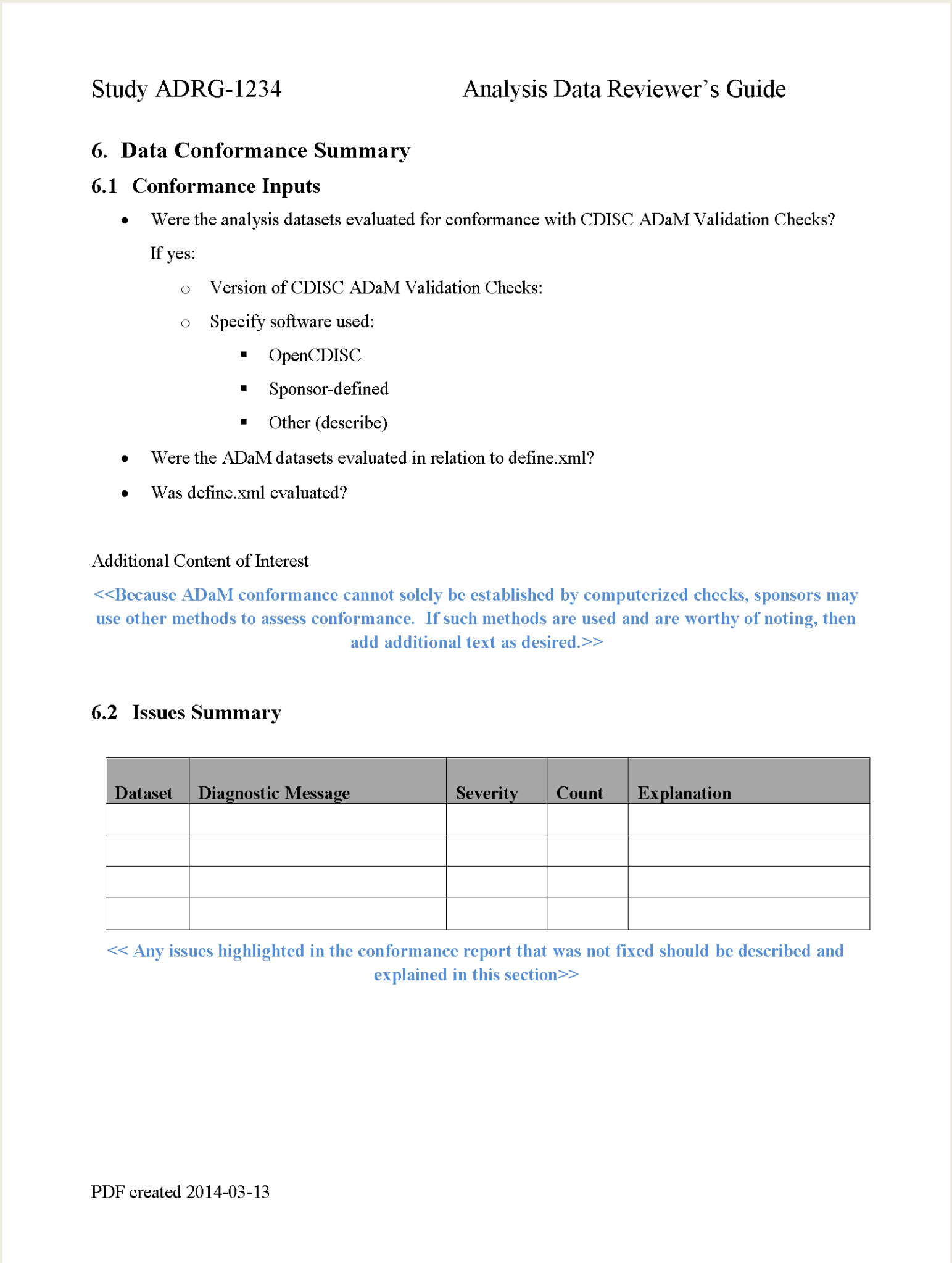
Susan Kenny (Amgen), Gail Stoner (J&J), Linda Collins (PharmaStat), Chris Price (Roche), Jennifer Montello (J&J), Nancy Friedland (IBM) and Team



- ❖ To complement the Submission Data Reviewer’s Guide (SDRG), the PhUSE Working Group 4 developed an Analysis Data Reviewer’s Guide (ADRG) Template to provide information pertaining to the analysis datasets that supplements the information found in the define.xml. This reviewer’s guide would be included in Module 5 of the eCTD with the study’s analysis datasets.
- ❖ This poster presents the ADRG Template with description of the type of information (in blue) that would be provided in each section. Text in black is required.
- ❖ The ADRG is nearing completion and the Working Group is in the process of gathering comments from industry reviewers.



- ❖ This template was produced with FDA input. The SDRG and the ADRG template will help both the industry and the FDA by providing a consistent standard to use for the format and content these reviewer guides.
- ❖ In some sections of the ADRG Template, there is required text that is formatted as a question. This Q&A format helps drive consistency and helps direct the reviewer to the information they need.
- ❖ All sections of the ADRG are open-ended so that sponsors can add or subtract information as necessary.



- ❖ In addition to this Template, the ADRG working group has developed a Completion Guideline document. The Completion Guideline document helps guide the user of the Template to understand what information should be presented in each section.
- ❖ The ADRG team has developed 3 ADRG samples to illustrate real use cases.

- ❖ This ADRG Template and Completion Guidelines are targeted for completion by the end of April.
- ❖ Please provide your comments by **March 28** to susan.kenny@amgen.com and gstoner@its.jnj.com