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After a new CDISC SDTM version, how to update and manage ADS/SDS DEFINE files at company team level

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ABSTRACT

In the objective of anticipating the requirements of the health authorities' agencies, after each new CDISC version, a review of the Standard of our team is necessary. So, following the company flow chart, we need to update our standard ADS/SDS definition files. The aim of this poster is to show how we manage in our team the standard definition files using a data base and how to create or to update automatically a standard document.

INTRODUCTION

As there is a new CDISC SDTMIG version (v 3.1.2) available and therefore a new Biostatistic Internal reference document version (Sanofi-Aventis ADS/SDS standard definitions), a review of all defines had to be done to identify all differences and to decide whether they should be taken into account in our Phase 1 studies. In a past situation, this comparison was made manually. But now, we have some programs to do it automatically, except the decision step *(to keep or not a variable)*. This tool can be very helpful to make as often as possible a new comparison, considering that CDISC model could be updated over the time.

CONTEXT

The Biostatistic department is in charge of preparing all SDS/SUPPQUAL datasets for a study. Therefore, we have a Standard document (Sanofi-Aventis ADS/SDS standard definitions) built on CDISC SDTMIG v3.1.2. Also, a Biostatistic tool (SuSADS2) is available to help programmers to produce ADS/SDS datasets. The tool requests to have an Excel definitions file by domain that lists all variables which must remain in the final dataset. Since in Phase 1 we have many studies to conduct through a whole year with always the same specificities to apply, we created a phase 1 ADS/SDS standard definitions file for each domain based on the global Sanofi-Aventis ADS/SDS standard definitions file. For the past reviews, a manual update of each definitions file (.xls) was made by visual comparison with the global standard definitions file (.doc). It was time consuming and brought about a lot of feedback from several users.

GOAL

To manage easily all definitions files in our Phase 1 team considering the following requirements:

- Make a comparison as often as possible to follow frequent updates done in the Sanofi-Aventis ADS/SDS standard definitions file
- Make the comparison the most automatic as possible
- Create a data base to simplify the validation of the contents
- Simplify the analysis and decision steps
- Track changes between two Standard document version
- Create Phase 1 ADS/SDS standard definitions files to be used directly by Biostatistic tool
- Create a Phase 1 ADS/SDS standard definitions guideline
- Involve only few people to participate to the Global review

CONSTRAINTS

To put in application all requirements, some constraints must be taken into account:

- Different files structures for the comparison components.
- Create a definitions file (.XLS) by domain for study programmers with a specific structure for the Biostatistic tool

PROPOSAL

The new concept to manage easily all definitions files in our Phase 1 team is divided in three parts. The first one concerns only the comparison and the update of Phase 1 data base. The second one corresponds to review all changes and to decide which one we keep or not in the Phase 1 ADS/SDS standard definitions guideline. And the third one represents the creation of definitions files by domain and a Phase 1 ADS/SDS standard definitions guideline, after an extraction of the updated data base. Therefore, SAS programs are developed to make those tasks easier, especially the first and the third ones.

But before that, considering our pre-requirements and constraints, we should compile all Phase 1 ADS/SDS standard definitions files into one base using Excel. And at the same time, the Standard Biostatistic team should give the reference document in Excel or SAS format.

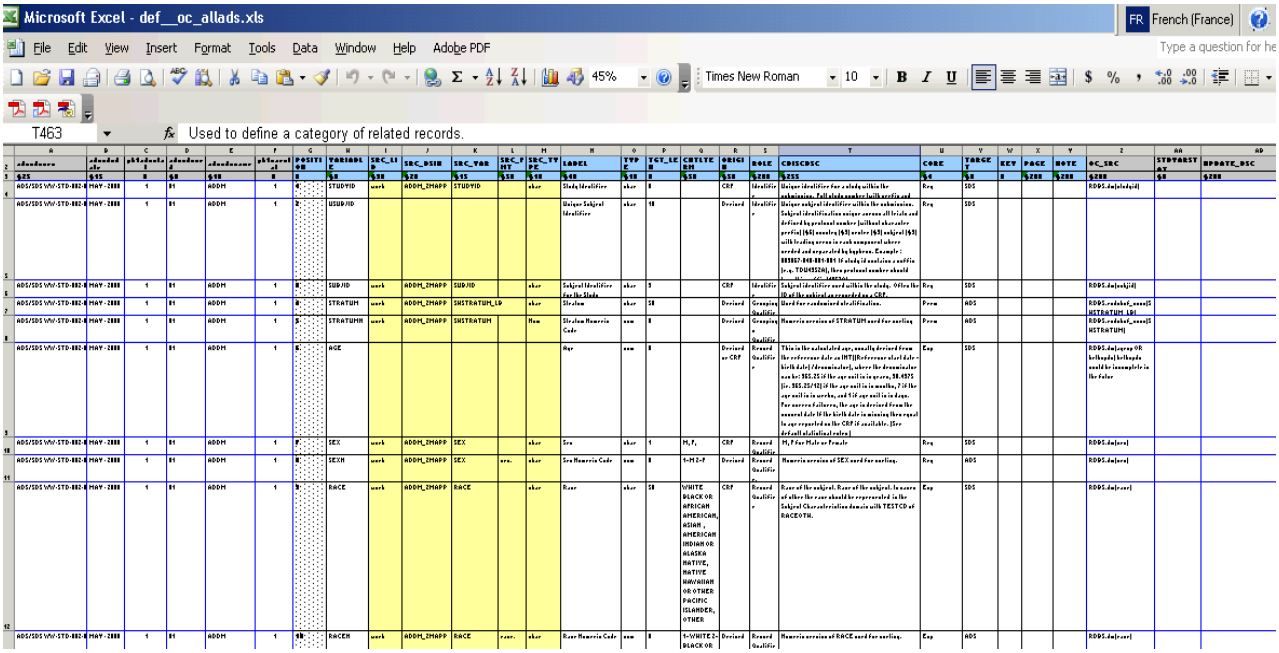
CREATION OF AN EXCEL DATA BASE

- Regroup all domains in the same sheet to obtain a Phase 1 ADS/SDS standard definitions base

- Contents :

  # Sanofi-Aventis ADS/SDS standard definitions file structure :
    - **Blue columns :** POSITION, VARIABLE, src_lib, src_dsin, src_var, src_fmt, src_type, LABEL, TYPE, TGT_LEN, CNTLTER, ORIGIN, ROLE, CDISCDS, CORE, TARGET, KEY, PAGE, NOTE

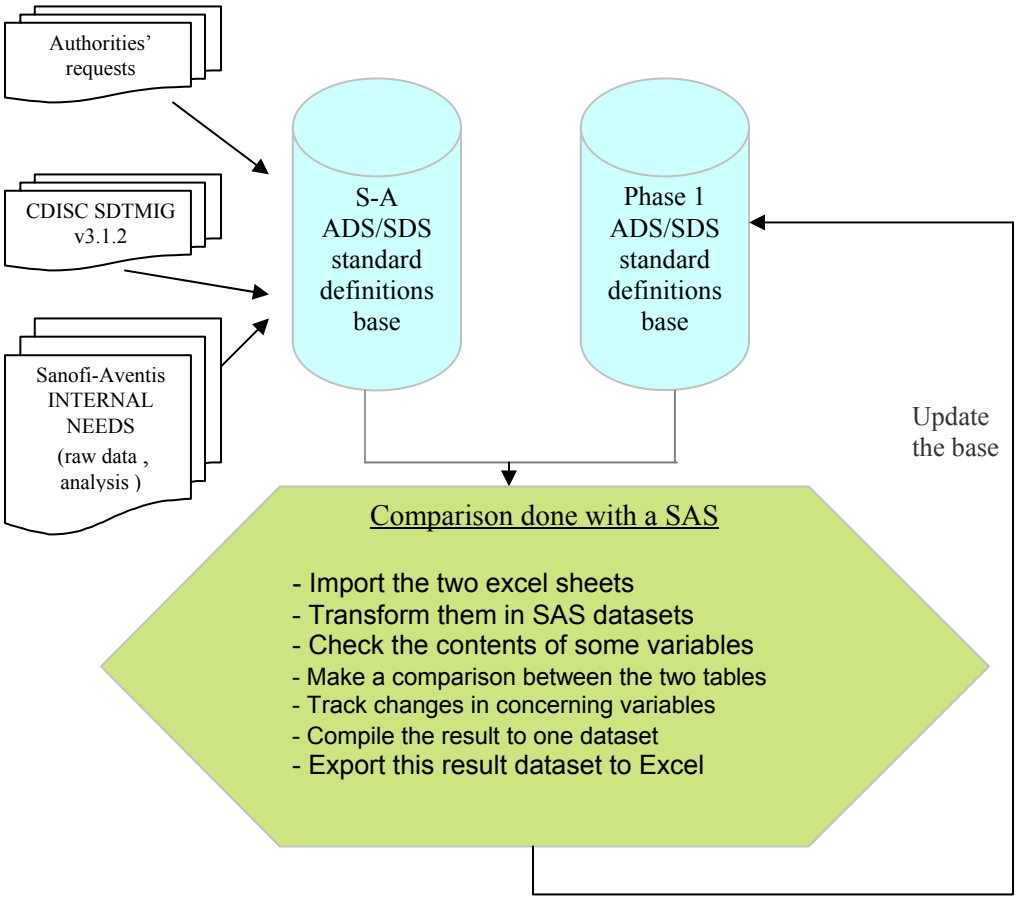
  # Additionnals columns :
    - **Grey columns :** ADSSDSSRC, ADSSDSDATE, PH1ADSSTAT, ADSSDSORD, ADSSDSNAME(domain), PH1VARSTAT, OC_SRC, STDVARSTAT, UPDATE_DSC, reviewvarstat, diff_LABEL, diff_TYPE, diff_LENGTH, ...



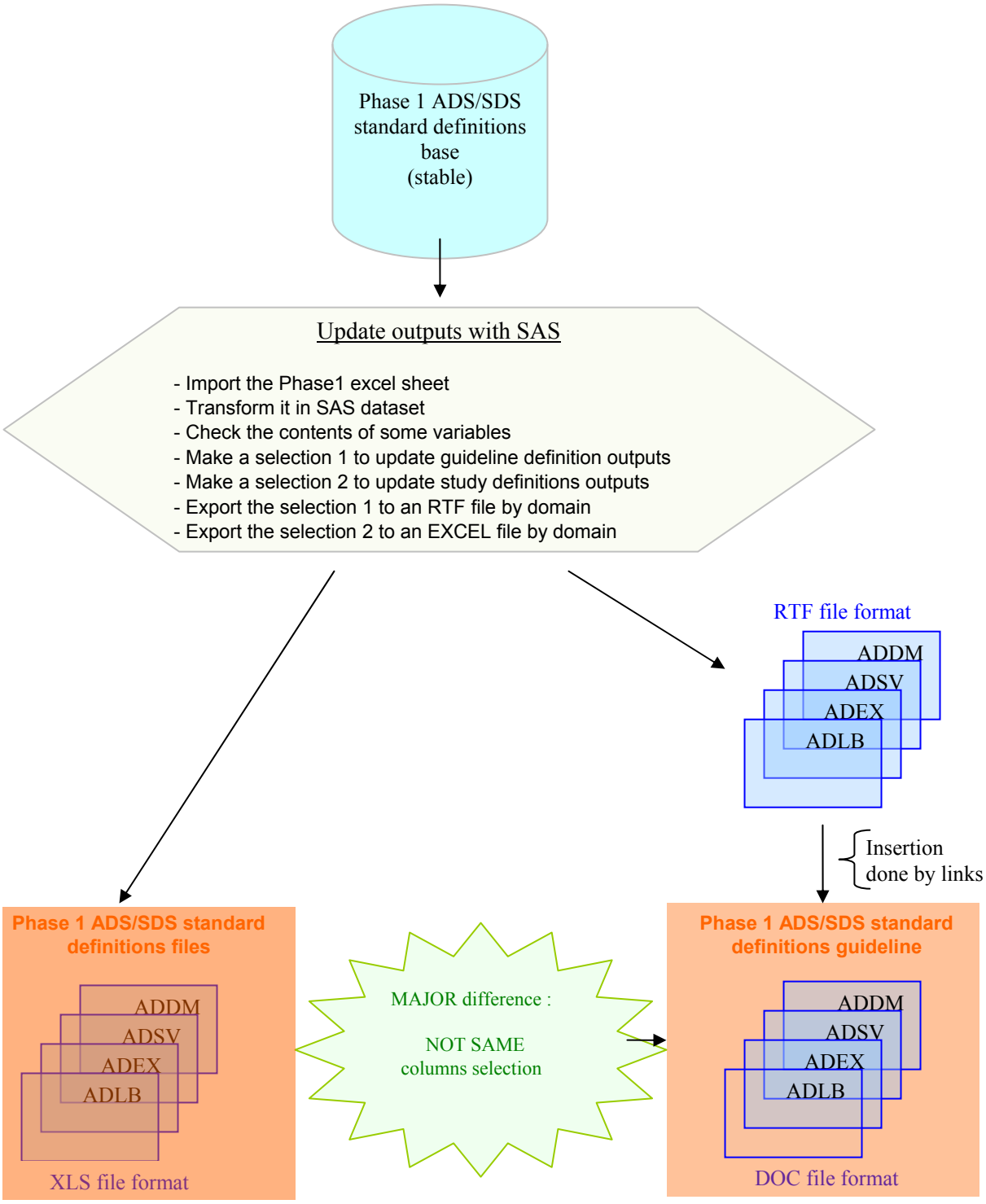
- Creation of conventions to fill in the Grey columns
  - *ADSSDSSRC* = Sanofi-Aventis ADS/SDS standard definitions document version
  - *ADSSDSDATE* = Sanofi-Aventis ADS/SDS standard definitions document date
  - *PH1ADSSTAT* = Phase 1 ADS/SDS status
  - *ADSSDSORD* = ADS/SDS order (more for programs execution)
  - *ADSSDSNAME* = ADS/SDS name correspond to DOMAIN in CDISC model
  - *PH1VARSTAT* = Phase 1 variable status
  - *OC_SRC* = Oracle Clinical source raw data
  - *STDVARSTAT(*)* = Standard variable status
  - *UPDATE_DSC(*)* = Update description
  - *Reviewvarsat* = Variable updated automatically with the comparison program
  - *All diff_xxx (*)* = Variables updated automatically with the comparison program

(*) : variables used for analysis and decision steps

HOW TO MAKE A COMPARISON AND UPDATE THE PHASE 1 DATA BASE



HOW TO UPDATE DIFFERENT TYPES OF OUTPUTS



Outside of the program :

- For the Phase 1 ADS/SDS standard definitions guideline (manually),
  * Open Word mock-up
  * Update all links

* Save modifications

- For the Phase 1 ADS/SDS standard definitions files (manually),
  * Open each Excel file
  * Save it at .CSV format using comma as separator

CONCLUSION

This new process is helpful to maintain Phase 1 ADS/SDS standard definitions files with frequent updates. It allows involving fewer people to make the review and allows saving working time. Also this new process uses common softwares (Excel, Word,SAS) and is easy to manage. As possible improvement, it could be to obtain a CDISC SDTMIG model with an other format as PDF.

CONTACT INFORMATION

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

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