



Main challenges for a SAS programmer stepping in SAS developer's shoes

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Terminology used in this presentation

■ SAS programmer:

- Creation of Derived datasets, Tables, Listings and Figures
- Experienced user of the company standard tools
- Very good understanding of the clinical data

■ SAS developer:

- Implementation of company standards
- Responsible for upgrades, technical support, training, etc..

A bit on the background and the expectations

Description of the needs

- Oncology – Implementation of the Response Evaluation Criteria In Solid Tumor (RECIST)
- Used for the derivation of key efficacy endpoints (Progression free survival, Best overall response, etc..)
- Standard approach is a must for the company – would also be appreciated by the agencies for later submission

A bit on the background and the expectations

Description of the needs

- Older programs were available.
 - Had been developed on previous versions of the paper
 - Code was made of 8 large macros
 - Limited flexibility to the user (a lot of Y/N macro variables with no default values)
- The tool needed to overcome the following hurdles:
 - Paper CRF and electronic CRF
 - Different study designs
 - Different study particularities (very specific to RECIST derivation):
 - Different frequencies in tumor assessments
 - Allowance or not of patients with no target lesions at baseline
 - Parts of the tool could be reused for data derivation in other indications

A bit on the background and the expectations

Management's expectations

Minimise the cost, maximise the functionalities

- Standard data derivation is just a start
- Ultimate goal - a complete standard tool, including standard reports – Kaplan Meier plots, standard tables, listings, etc...
- Their decision was to
 - Free 2 study programmers of their study work
 - Ensure the tool gets tested on several studies
 - Use older available code for the validation

A bit on the background and the expectations

The user's expectations

Should smooth some of the efficacy analyses

- Should simplify the derivation of those datasets to the use of a calling program
- Should gain some time when delivering efficacy analyses
 - A bit less pressure
 - More time to review outputs
 - More time to work on other data

A bit on the background and the expectations

Developer's expectations in his new role

Extend technical expertise + knowledge on the matter

- Exciting challenge
- Intensive programming for a few months and that will be it
- Nothing more than a big macro
- A bit of documentation, some slides.. And that'll be it

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A standard program versus single use programs

From a general paper to some SAS code

- Every little word in the guideline had to be weighted
 - 1st reading – Start paying attention to details you'd never heard of
 - 2nd reading – everything looks straight forward - you start replacing words with macro parameters / variable names / %IF , etc...
 - After several readings – potential lack of clarity in the paper appears.
 - And then, the more your read the guideline, the more questions you have
- Every little pieces of the algorithm needs to be thought of, coded and tested
- Implement extensive defensive code

A standard program versus single use programs

Serious thoughts on inputs and outputs of the tool

- Allow flexibility in the use of the tool
 - How to ensure flexibility?
 - Use self-explanatory macro variable names
 - Implement default values whenever possible / relevant
 - Ensure users know the different options they have
 - Ensure users can check the options applied during execution
- Contents of the output datasets
 - Meaningful variables, labels, formats
 - Keep only variables needed/requested by user

A standard program versus single use programs

An endless process

- Always room for improvement, new features to be added
 - 6 major updates in just over a year
 - some corrections to be considered
- When additional requests come
 - Needs to assess what is making sense to be implemented as a global standard
 - Which level of priority to give to its implementation
 - Ensure backward compatibility of the tool

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When will this be over?

Subject Matter Expert

- Your input is requested whenever the subject is mentioned.
 - Changes in the standard CRF pages
 - Implementation of new listings for cleaning the raw data
 - Changes in the contents of the data collected

- You're regularly contacted for questions like:
 - Can the macro handle that? Does the macro do that? How would the macro treat this?
 - When user have tricky designs or data, they will come to you for advice

When will this be over?

Subject Matter Expert and technical support

- The natural first contact when somebody is facing an issue when using the macro
 - How to set the programming up based on their trial specificities?
- A natural shift of perspective between you, the developer, and the users:
 - Users tend to think there might be something wrong with the macro
 - The developer prefers thinking that the user's implementation is incorrect

When will this be over?

The documentation and communication about the tool

- Having a very detailed documentation is a must that will be expected :
 - By the agencies when the data get submitted
 - By the users when they are offered to use the tool
 - By the developers responsible for upgrading the tool
- Having a good documentation will also help support the implementation of the tool
 - Users will have more confidence in this than in a black box
 - This helps in developing efficient training on the tool
 - Eases the work of technical support
 - Eases the validation work

Conclusion

- Challenging experience
 - Not just a technical challenge
 - Need to imagine and test all possible scenarios
- If I was to give one recommendation
 - Spend time on documentation
 - This will be of benefit later (it means less technical support, it facilitates any update to the code, facilitates the use of the tool, etc...)

