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
Management’s expectations

- 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 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

Should smooth some of the efficacy analyses
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…)