

Industry Standard Good Programming Practice for Clinical Trials (using SAS)

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GPP for Clinical Trials

- What is Good Programming Practice?
- A collaborative approach to GPP (Wiki)
- What should we document?
- Maintaining the document
- Keeping it current



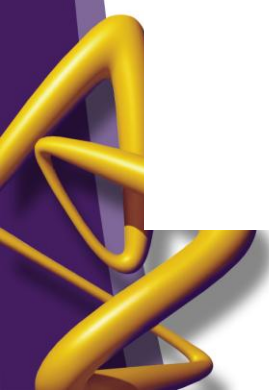
What Is GPP

- Code must be readable
 - Easy to understand, review, validate at a later date
- Maintainable and flexible code
 - Can be reused easily
 - » New data
 - » Ad hoc late change
 - » Next study



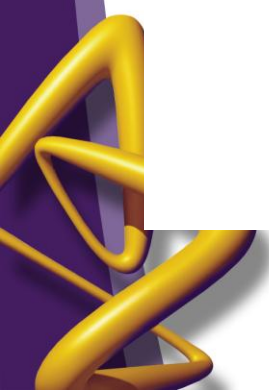
What Is GPP (2)

- Defensive code
 - Accommodate changes
 - Accommodate inaccuracies of binary representation
 - Write messages to log to flag data you hadn't coded for.



What Is GPP (3)

- Efficient code (read/write processing)
 - Where v if
 - Drop, keep
 - However -saving 2 hours programming time more important than 10 seconds processing time-



Implementing GPP

- Personal standards
 - Hints, tips, experience, courses, papers, discussion forums, style guides
- Company standards
 - SOP, WI, guideline
 - Pooled company experience
- This works well, but:
 - Do you do as much as you could?
 - Are you up to date— are your colleagues?
 - Relevant to your company- not all situations



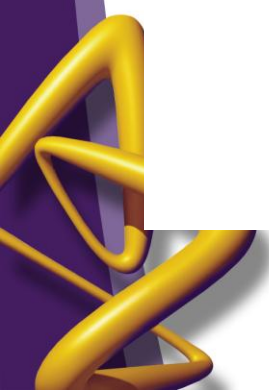
A Collaborative Approach to GPP

- One place to share ideas and experience in GPPCT
- Web based- accessible
- Anyone can author and justify ideas
 - Variety of/conflicting ideas
 - Peer review/ comments
 - Validation of ideas
- Relevant for all areas of clinical research
- Live document, current/up to date
- Wiki supports these ideas well



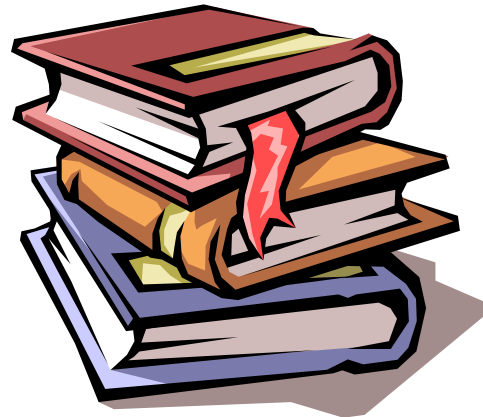
Benefits of a Collaborative GPP Document

- One reliable source of information
- Potential standard
 - Sharing code between companies
 - Sharing code with regulators
 - Support where no guidelines currently exist
 - E.G. open source projects (OS3A)



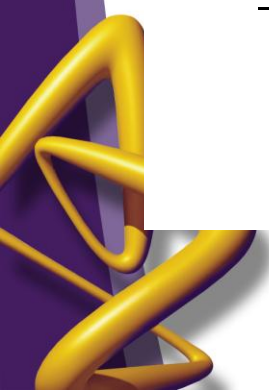
What Should This Document Contain?

- Focus on content relevant to clinical only?
- Cater for a wide range of users
- Comprehensive but not unwieldy



Clinical Trial Specific Code

- Hints, tips and ideas that relate to clinical trials in some way
- Specialist data
 - E.G. SF36, RECIST, SDTM, MedDRA
- Clinical regulations
 - Ideas for 21CFR11, item11/define.xml, IND annual reports, IMPDs
- Clinical programming principles
 - E.G. create all derived variables presented in output in an analysis dataset



Clinical Trial Relevant Code

- Clinical data and study design
 - Clinical data has relatively complex data structures
 - Reuse and modify from study to study Coding style (defensive)
 - Hard coding
 - Floating point errors – E.G. lab ranges
 - Incomplete and unpredictable clinical data
 - Aggregating /mapping data
- Relevant to other programming languages, but specific importance for clinical SAS



Wide Range of Users

- Varying programming/SAS experience
 - Experience with concepts of readability and maintainability
- Varying clinical experience
 - Experience with submissions, regulatory requirements and physicians?
- Varying work experience!

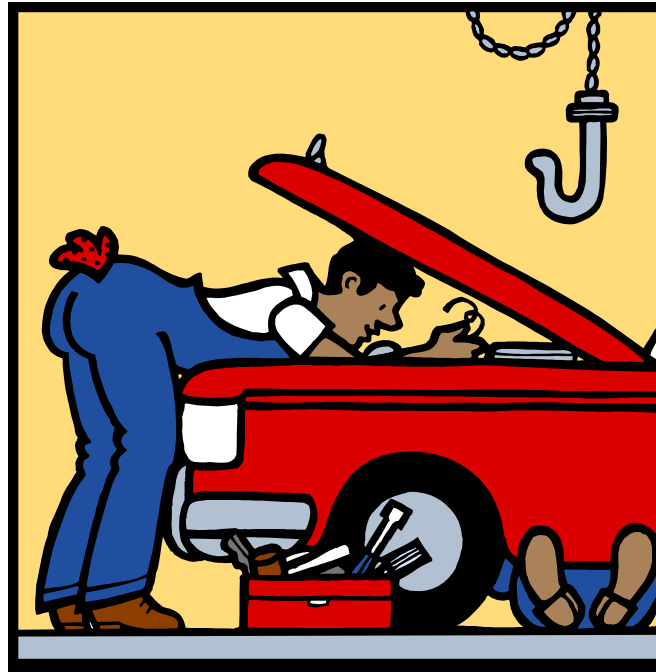


How Does This Affect GPP Document Structure

- Include GPP relevant for new programmers as well as experienced?
 - Clinical/more specialised tips only or more general SAS GPP
- Browse or read thoroughly?
 - Could link to some documents elsewhere in wiki?
 - Increase usefulness with hyperlinking
- Your ideas and suggestions are welcomed



Maintaining the document



Editorial Board

- Provide guidance rather than content
 - Mission
 - Review contributions
 - Present to conferences
 - Seek endorsement from PhUSE/Pharmasug
 - Request contributions
 - Propose solutions where opinions conflict
 - Guidance for contributors to OS3A
 - Promotion of page
 - Stimulate discussion
 - Drive document structure



– Is the GPP page being used?



Wiki Page Usage

- Views (October 3rd)
 - » May 2009 16 000+
 - » June 19 200+
 - » July 20 400+
 - » Aug 23 000
 - » Sept 25 900
 - » Oct 28 300
- One of most popular pages on SAS community Wiki



Wiki Page Usage

- Edits
 - 109 edits 5th highest on SasCommunity
 - » May: 18
 - » July: 2
 - » August: 6
 - » Sep: 2



So, is the **GPP** page being used?

- A lot of views
- Fewer edits
 - Expected...
 - but would like more



What Next?

- Q4
 - Review current content
 - Restructure, put in place outline to encourage contributions, edit
- Invite contributions and show people how easy it is to edit!



How Can You Contribute?

- Go to SasCommunity getting involved page
 - [Http://www.sascommunity.Org/wiki/getting_involved](http://www.sascommunity.Org/wiki/getting_involved)
- Set up an account if you do not have one already
- Get editing
 - Wiki uses a mark up language



Editing the wiki

- Wiki tracks all edits
- You can put individual pages on a watchlist
- Discussion tab
 - Have a new idea – add it!
 - Ideas about structure or other content



[page](#)[discussion](#)[edit](#)[history](#)[move](#)[unwatch](#)

Good Programming Practice for Clinical Trials

Feel free to comment on the related "Discussion" tab/page and/or to contribute changes directly to this page (preferentially with a rationale).

CALL FOR CONTRIBUTIONS: WE NEED YOUR INPUT [Good Programming Practice for Clinical Trials - Your input needed!](#)

The following are **draft recommendations** a Good Programming Practice for Clinical Trials using SAS.

The purpose is to *encourage contributions from across companies, non-profit organizations and regulators* in an attempt to create a **consensus recommendation**. The ambition is that this page becomes recognized by the Pharmaceutical Industry, Clinical Research and Health Care Organizations as well as Regulatory Authorities.

The hope is that **the Practice can be reviewed and endorsed** by the relevant management teams of several Pharmaceutical companies and major Contract Research Organizations and promoted through relevant professional organizations such as PharmaSUG, PhUSE, PSI, CDISC.

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[2.4 Naming Conventions](#)

[2.5 Code Structure](#)

[2.6 Style conventions](#)

[2.7 Use of analysis datasets](#)

This is an example- the first page of the document

page discussion edit history move unwatch

Editing Good Programming Practice for Clinical Trials

B

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== Introduction ==

This is the editing version for same page

[page](#) [discussion](#) [edit](#) [history](#) [move](#) [unwatch](#)

Good Programming Practice for Clinical Trials

(Difference between revisions)

Revision as of 16:10, 24 September 2009 ([edit](#))
[Mark Foxwell](#) ([Talk](#) | [contribs](#))
[← Older edit](#)

Current revision as of 16:16, 24 September 2009 ([edit](#)) ([undo](#))
[Mark Foxwell](#) ([Talk](#) | [contribs](#))

Line 169:
"Draft section : this may not be specific to clinical programming, but may be of use when considering a general standard for sharing programs."
-

== Macros ==

Line 169:
"Draft section : this may not be specific to clinical programming, but may be of use when considering a general standard for sharing programs."
+ **=== Use of analysis datasets ===**
+ **" For discussion of why programming output directly from raw data is generally avoided. "**
+
== Macros ==

This shows comparison of two versions of the page

Conclusions

- GPP helps programmers develop robust and easy to maintain code
- GPP for clinical trials wiki provides facility to develop a central repository of industry best practice that is peer reviewed and critically assessed
- The editorial board looks to steer development and ensure that the document is relevant and current
- Your contributions are needed to make this successful and useful document



Any Questions?

