

Good Programming Practices at Every Level

PhUSE GPP Steering Board



The GPP Steering Board is a voluntary industry group with representatives from a diverse array of health and life sciences organizations

- Working to develop common good programming practices applicable to statistical programming for the development of high quality and efficient programming code
- Focus on analysis and reporting of clinical trial data; data integration; preparation of clinical data for e-submissions
- This Poster explores the topic of good programming practices in the pharmaceutical industry at different levels – at the level of individual programs, at the study level, and at the compound or therapeutic area level. At each level, there are different yet complementary practices that a programmer should follow.



PhUSE GPP Guidance is found on PhUSE Wiki

The Wiki is a place to share your ideas and post your contributions.
Please provide your comments!



http://www.phusewiki.org/wiki/index.php?title=Good_Programming_Practice_Guidance

Individual Program Level

- Always include a program header
- Write comments that clearly explain the rationale of the code
- Follow consistent coding conventions, e.g.
 - Do not overwrite existing datasets
 - Use 'data=dataset' option in procedure statements
 - When converting character variables to numeric or vice versa, use the put and input functions to explicitly convert the variables
 - See full list of recommended coding conventions at http://www.phusewiki.org/wiki/index.php?title=Good_Programming_Practice_Guidance
- Write programs to be reusable
 - Do not include study-specific values in programs
 - Use macros parameters to allow flexibility



Avoid or Document/Encapsulate

Study-Specific Code:

If visitnum = 70 then ...

If upcase(extrt) = "DRUG A" then ...

Benefits of GPP

- Other programmers and regulators can easily understand programs and data
- Leads to consistency across programs
- Improves programmer efficiency
- Produces more robust programs
- Increases the reuse of programs

Study Level

Study Programmer: Responsible for overseeing all programs for a study and ensuring they work together

Principle 1: Understand the study and data



- Study Protocol
- Annotated CRF
- SAP & Shells
- Data Standards
- Data Specifications

PhUSE GPP Steering Board recommends "Defensive programming"

- Write programs that anticipate future changes of data
- Understanding data helps with defensive programming

Principle 2: Organize the Programs

- One main program per analysis dataset
- Analysis-ready datasets so TLFs can be produced with minimal programming
- One main program per TLF

Principle 3: Follow industry and company standards

CDISC

- Run OpenCDISC checks early, prior to final CSR output

Programming Standards

- Know and use standard tools and macros

Principle 4: Consistency across programs and data cuts

- Naming conventions
- Consistent algorithms across programs and data cuts
- Common variables have same values in all datasets

Principle 5: Document data and programs

Documentation is just as important as programs!

- Program header and comments
- Documentation of all data cuts for study (purpose, date, location)
- Documentation of all data sources for study, especially non-CRF sources
- Analysis dataset specifications
 - Can use specs as the basis for Define file
 - Good practice to complete specs before programs are QCed so QCer can QC both programs and specs at same time



Compound or Therapeutic Area Level

Project/Compound Programmer: Responsible for compound-wide consistency in data structure and programming algorithms

Additional Responsibilities at Compound or TA Level

- Compound or Therapeutic Standards
 - Coalition for Accelerating Standards and Therapies (CAST) developing TA standards
- Compound-level macros
- Cross-Compound interrogations of data

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