PhUSE CSS White Paper on Analyses and Displays Associated with Demographics, Disposition, and Medications

On behalf of the Development of Standard Scripts for Analysis and Programming,
PhUSE Computational Science Symposium (CSS) Working Group:

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History:
In March 2012 at a PhUSE symposium, a project was launched to set up an open source script repository to hold and to share programs that would be useful in medical research. The Computational Science Symposium (CSS) Development of Standard Scripts for Analysis and Programming Working Group is leading an effort to create several white papers providing recommended analyses and displays for common measurements, and has developed a Script Repository as a place to store shared code.

The working group leaders now are:
- Hamming Tu (Project Manager)
- Steve Wilson (FDA Liaison)
- Mat Soukup (FDA Liaison)
- Mary Nilsson (Industry co-lead)

White paper:
Demographics, subject disposition, and medications are commonly collected and summarized across clinical trials and across therapeutic areas. Why not have common approaches to analysis, reporting, and even scripts/source to produce them?

Overview White papers:
1. Analyses and Displays Associated with Measures of Central Tendency – With a Focus on Vitals, ECGs, and Labs in Phase 2-4 Clinical Trials and Integrated Submission Documents. (Final)
2. Analyses and Displays Associated with Outliers or Shifts from Normal to Abnormal – With a Focus on Vitals, ECGs, and Labs in Phase 2-4 Clinical Trials and Integrated Submission Documents. (Initial draft sent for team review)
3. Analyses and Displays Associated with Adverse Events and Deaths – With a Focus on Phase 2-4 Clinical Trials and Integrated Submission Documents
4. Analyses and Displays Associated with Demographics, Medications, and Disposition – With a Focus on Phase 2-4 Clinical Trials and Integrated Submission Documents (Initial draft sent for team review)
5. Analyses and Displays Associated with Hepatotoxicity – With a Focus on Phase 2-4 Clinical Trials and Integrated Submission Documents
6. Analyses and Displays Associated to Pharmacokinetics – with a focus on clinical trials (Initial draft sent for team review)