Minutes from General Principles subteam of

FDA/Industry/Academia Safety Graphics

**Meeting Date/Time:** April 5, 2010, 2-3pm EDT

**Present:** Larry Gould, Markus Yap, Mat Soukup, Richard Forshee, Qi Jiang, Susan Duke
(Brenda Crowe was on holiday)

**Agenda:**

1. Introductions
2. Examples of items to consider including on the wiki
3. Brief review of Safety Graphics team objectives
4. Brainstorm/discuss scope, breadth, depth of what Graphics Principles subteam wants to cover (ie, subteam objectives)

**Actions:**

1. Mat to find out if a private area can be set up in the wiki for the subteam’s work (and if so, to set it up and communicate to the subteam)
2. Susan to request availability for subsequent subteam meetings and set them up

**Minutes:**

1. Introductions were made by all. Collectively we have a broad and deep breadth and depth of graphics knowledge and interest. It was nice for all to meet and consider motives and interests for being part of the subteam.
2. Items considered for inclusion on the wiki:
* Reference links (eg, Tufte, Cleveland, Robbins, Heiberger, etc)
* Best practice (right way to ‘do graphs’)
	+ Guide audience in appropriate ways of graphing for common purposes, eg count data
	+ Common mistakes in graphing (eg too many bells/whistles, chart junk, etc)
	+ Graphical perception
	+ Risk communication
1. A brief review of Safety Graphics objectives was undertaken to identify which objectives our subteam is aligned. We propose the subteam is aligned to the team’s objectives in the following ways:
	1. Identify areas particularly applicable or useful to regulatory review in which graphics can enhance understanding of safety information.
	2. Develop a palette of statistical graphics for reporting on clinical trials safety data. *Post-meeting suggestion for this team from Mat: Define a standard template to be used for graphics entries on the wiki.*
	3. Recommend graphics for clinical data based on good scientific principles and best practices. *Identify general graphics principles that will aid readers of graphs to better design and interpret them, especially those principles that may aid in safety data interpretation.*
	4. Create a publicly-available repository of sample graphics (ensuring appropriate credits are given for contributions), including data sets and code.
	5. Educate and engage stakeholders through outreach activities.
	6. Consider publishing with authorship/acknowledgments as is consistent with contributions and policy of the affiliated institution. *A possible outcome of the General Principles subteam’s output is a white paper (to be determined after the wiki takes shape).*
2. Discussion of scope, etc for this subteam is included in italics above (after each Safety Graphics objective). In addition, Mat offered to follow up on whether the wiki can be made available for an initially private area for the team to begin their work.

There was discussion of software and interactive graphics. Several members noted that the purpose of the Safety Graphics team is to identify good graphic design for particular safety questions. If vendors or users choose to create interactive versions of these designs, that will be a beneficial additional outcome of Safety Graphics team’s identification of the graph design. However creation of interactive graphs or identification of a specific software as the only way to render the graph is outside the scope of this team.

The team agreed to meet on a monthly basis, preferably during the first week of the month. Susan has an action to request availability and set up future meetings.

1. Post-meeting note: Frank Harrell has asked to join this subteam. Welcome Frank! Good to have you on board.