Agenda for General Principles subteam of

FDA/Industry/Academia Safety Graphics

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

**Present:** Larry Gould, Markus Yap, Mat Soukup, Richard Forshee, Qi Jiang, Susan Duke, Brenda Crowe, Frank Harrell, Fabrice Bancken

**Agenda:**

1. Welcome to Frank Harrell and Fabrice Bancken
2. Last month’s minutes – any discussion or accept as written
3. Actions
   1. Update from Mat on private area, progress on setting up of the site itself
   2. Update from Susan on future standing meeting times
4. Discuss template for graphics entries (GSK’s template may be used as a starting point if the team so chooses)

**Actions:**

1. Mat offered to send out a template for the team to discuss, based on today’s discussion (agenda item 4)
2. Susan offered to draft brief biosketches on each of us, based on notes from each of our introductions
3. Welcome to Frank Harrell and Fabrice Bancken

*Frank, Fabrice and Brenda (who was on holiday last month) gave a brief introduction. Susan offered to write up a biosketch based on notes from intros at both meetings*

1. Last month’s minutes – any discussion or accept as written

*Minutes accepted as written*

1. Actions
   1. Update from Mat on private area, progress on setting up of the site itself

*At the last general safety graphics meeting, it was decided that a private area was not needed. So no discussion of this topic was needed in this meeting.*

* 1. Update from Susan on future standing meeting times

*Standing meetings will take place on the first Monday of the month from 2-3 Eastern (unless there is a holiday, etc – will be rescheduled to another time)*

1. Discuss template for graphics entries (GSK’s template may be used as a starting point if the team so chooses)

*Susan provided an example entry, which generated good discussion.*

*Mat subsequently sent out a version for discussion, which is progressing with the subteam in an email stream.*

Draft biosketches (please review/revise as needed – I wasn’t planning to share these so they are obviously incomplete!)

**Larry Gould, Merck** – has taught short courses on graphics. Believes it is important to frame the question – what are you trying to do, what are the questions the graph is to answer?

**Rich Forshee, FDA, Center for Biologics Evaluation and Research, Office of Biostatistics and Epidemiology** – Rich is a member of the risk assessment team, and he develops quantitative, probabilistic computer simulations to support regulatory decision-making. High-quality statistical graphs are one of the most important tools for communicating the results of the team's risk assessments. He joined the FDA in 2008, and he has more than 12 years of experience in academia at Georgetown University, Virginia Tech (National Capital Region), and most recently the University of Maryland. Rich has been interested in statistical graphics since his graduate school days at the University of Michigan.

Interests for the General Principles Group: Help to develop a set of general guidelines; Consider how to make graphs effective communication tools; Explore how to use graphs to convey the essence of the analysis.

**Qi Jiang, Amgen** – Has many years experience in early and late stage clinical development across a spectrum of therapeutic areas. Has worked both in the pharmaceutical industry and in an academic setting, and so has seen a number of organizations’ processes. Very interested in safety graphics presentation. Safety graphics is an efficient way to visualize complex information – well designed graphs help to understand the safety data.

**Markus Yap, FDA** – New to the FDA, commissioner’s fellow in medical informatics, 15 yrs in medical devices and strategy consulting for life sciences companies. Interested in visualization, medical imaging, data mining, business intelligence, and other analytical tools aiding the clinical decision making process. Opportunistically seeking collaborative opportunities for this team w.r.t. data mining, signal detection and BI

**Mat Soukup, FDA** – 6 yrs at FDA, currently acting team lead in safety group. Would like to see emphasis of good graphics principles.

**Susan Duke, GSK** – half of experience has been in biotech, the other half at GSK. Have co-lead an internal graphics team since 2004, which delivered the Amit, et al paper on safety graphics and an internal graphics catalogue website. Is interested in graphic design, also in furthering collaboration amongst statisticians to increase the value and speed of our collaborative efforts via electronic means.

**Brenda Crowe, Lilly** – Leads a statistics group that support's Lilly's Global Patient Safety.  The general statistics group has a library of statistics tables, but very few standard graphs.  She would like to get more graphics being used.

**Frank Harrell, Vanderbilt** – was with DCRI for many years, now at Vanderbilt. Has consulted on many pharma and FDA issues. Has participated on a number of DSMBs, which are typically focused on safety – sees need for more use of graphs in this setting.

**Fabrice Bancken, Novartis** – based in Switzerland, Fabrice makes ours an international group. Statistician in a quantitative safety group. Prior position as statistician at BMS also included leading the development and roll out of standards graphs, best practices for graphics as well as a system to produce standard and custom graphics.