Collaboration: Challenges and Opportunities for Biostatisticians

Mat Soukup, Ph.D.
Acting Team Lead Biometrics 7
FDA/CDER
Disclaimer

- The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to Drug Information Association, Inc. (“DIA”), its directors, officers, employees, volunteers, members, chapters, councils, Special Interest Area Communities or affiliates, or any organization with which the presenter is employed or affiliated.

- For work prepared by US government employees representing their agencies, there is no copyright and these work products can be reproduced freely. All rights reserved. Drug Information Association, DIA and DIA logo are registered trademarks or trademarks of Drug Information Association Inc. All other trademarks are the property of their respective owners.
Outline

I. Introductory Example

II. Defining Today’s Environment

III. Capitalizing on The Wiki Way

IV. Working Towards a Solution
Collaboration: A Tale of Two Companies

• Goal: Develop a new electronic music device
  – For simplicity, assume 3 components need to be created/developed/modified/refined

![Diagram showing the relationship between Hardware Design, Software Design, and Product Design]
Collaboration: A Tale of Two Companies

• Two Companies (X and Y)
Collaboration: A Tale of Two Companies

• What company is likely to be more successful?
Collaboration: A Tale of Two Companies

• Lessons Learned
  – Both companies collaborated
    • Company X used mostly internal resources
    • Company Y relied on external components and designed them for their needs
  – Collaboration was not the only thing, BUT...
    • For complex activities, effective collaboration is a necessity for success
    • Collaboration should be embraced and given enough resources in order for it to have success
  – Collaboration can have negative consequences
Outline

I. Introductory Example

II. Defining Today’s Statistical Environment

III. Capitalizing on The Wiki Way

IV. Working Towards a Solution
Simplistic yet Realistic Schematic

Trial Design Considerations

Literature/Research
* Methods
* Guidance
* Best-Practice

Data

Analytics $f(x)$
* Code/Tools
  * Software

Conclusion/Decision

Trial Conduct

FDA

Academic

Industry

Reviewer 1
Reviewer 2
Reviewer N
Sponsor 1
Sponsor 2
Sponsor N
The Problem

Based upon today’s current practice, the following limitations may be present:

1. **Redundancy** in analytic development
2. Slow for **cross-organization** application of literature/guidance/best-practice
3. **Quality Control/Validation** NOT maximized with limited to no code/open-source sharing
4. Tendency to rely on **traditional** methods
Illustrative Example: Efficacy by Site

A Graphic....
Illustrative Example: Efficacy by Site

```
"efficacy.by.site" <-
function(yy, site, trt, type="b", legend=FALSE, ...){
  nms <- names(list(...))
  ss <- summarize(yy, llist(site, trt), mean)
  n <- summarize(yy, llist(site, trt), length)

  sdat <- data.frame(ss, n[,3])
  names(sdat) <- c("Site", "Trt", "Mean", "N")

  if(type="b"){
    nsn <- length(unique(sdat$Site))
    ut <- unique(sdat$Trt)
    rnx <- tabulate(as.factor(sdat$Site))
    # Creation of the figure.
    if("ylab" %in% nms)
      plot(c(.5, nsn+.5), c(min(sdat$Mean) -.05, max(sdat$Mean) +.05),
           type="n", axes=FALSE, ...)
    else plot(c(.5, nsn+.5), c(min(sdat$Mean) -.05, max(sdat$Mean) +.05),
             type="n", ylab=paste(deparse(substitute(yy))), axes=FALSE)
    axis(1, at=1:nsn, labels=as.character(unique(sdat$Site)), cex.axis=.75, las=3)
    axis(2)
    box()
    for(k in 1:length(ut)){
      subdat <- subset(sdat, sdat$Trt==ut[k])
      points(subdat$plotx, subdat$Mean,
             pch=trellis.par.get("superpose.symbol")$pch[k],
             col=trellis.par.get("superpose.symbol")$col[k])
      for(j in 1:length(subdat$N)){
        text(subdat$plotx[j]+.3, subdat$Mean[j], labels=subdat$N[j],
             col=trellis.par.get("superpose.symbol")$col[k], cex=.7)
      }
    }
  }
  for(i in 1:nsn){
    subdat <- subset(sdat, sdat$Site==unique(sdat$Site)[i])
    lines(c(i,i), c(min(subdat$Mean), max(subdat$Mean)), lty=2, col='gray60')
  }
}
```
Illustrative Example: Efficacy by Site

• Is the approach publicly available or does the public know about it?
  – Potentially, it’s been presented at several professional meetings.

• How to reproduce this visual representation?
  – Write your own code; ask the author.

• What if there are ways to improve the representations?
  – Publish/present at public meetings

• What if you have written sleek code, can you share it?
  – Not really; potentially with the author

• What if the code is written in a language my closed system does not run?
  – Rewrite it!
What We Know

1. Current environment can be improved upon
2. There is a large pool of talented and experienced researchers/biostatisticians that can be utilized
3. Collaboration among FDA, academia, and industry has the potential to alleviate/solve some of the current problems.

But **HOW** do we solve it?
Outline

I. Introductory Example
II. Defining Today’s Environment
III. Capitalizing on The Wiki Way
IV. Working Towards a Solution
The Wiki Way

- **Definition**: A wiki is a website that uses wiki software, allowing the easy creation and editing of any number of interlinked Web pages, using a simplified markup language [source: Wikipedia].
- Creation/Editing is done via the web browser - no fancy software is required.
- **Community** of users add/edit content → pages/website is not static but ALIVE!
- *Invokes* user participation to create or collaborate.
- Subject to GNU-GPL regulations making them free software programs.
Wiki Strengths and Weaknesses

• **Bad content** may appear from time to time
  – 50% of mass deletions were modified in less than 3 minutes (Wikipedia, CHI 2004)
• **Lack** of contributions to important topic areas
• Topics which are emerging can **evolve quickly**
• **Rewards** contributor to know their efforts are being utilized by others
• **Lack** of citation/recognition for wiki contributions
  – Recently; more acknowledgement for such contributions
• **Development** in topics not otherwise planned by originators
What We Learned

1. Wikis provide open access to information which is provided by a community of users
2. The technology is straight-forward and can be easy to use
3. The technology is dynamic and offers advantages to static websites
4. A wiki *can be* highly successful as a medium for others to collaborate

But *HOW* do we apply it to our problem?
Outline

I. Introductory Example
II. Defining Today’s Environment
III. Capitalizing on The Wiki Way

IV. Working Towards a Solution
Collaborative Schematic

Collaborative Environment

- Literature/Research
  * Methods
  * Guidance
  * Best-Practice

- Analytics Repository
  * Code/Tools
  * Software

Data

Trial Design Considerations

Conclusion/Decision

Trial Conduct
Relying on a Community

• **Advantages**
  – Transparency
  – Increase in the talent pool
  – Current; documents/materials/code can evolve
  – Efficient; evolution towards improvement (not reproduction)
  – Addresses needs of participants; tailored towards them

• **Disadvantages**
  – Trustworthiness?
  – Lack of authority?
  – Content is driven by willingness of the community to share
  – Too much information?
Keys to Success

- Identify **KEY** stakeholders
- Develop an environment that meets the needs of **ALL** potential contributors/consumers
  - Site organization/structure
  - Ease of use
- **Publicity** of the environment
- Provide **incentives** to contribute
- Provide **metrics** on environment usage
- Ensure **quality** of contributions (rating system)
- Environment **monitoring**
Challenges

- Identifying the **KEY** stakeholders
- Identifying **resources**
  - Hosting the environment (*financial*)
  - Building the environment (*financial and human*)
  - Monitoring the environment (*human*)
- **Culture change**
  - Move from *internal sharing* towards one where non-proprietary information is *shared publicly*
  - *Acceptance* of open/public information
  - *Adoption* of a collaborative culture from **ALL** parties
Stay Tuned....

• Any questions or willingness to participate please email me:
  – Mat.Soukup@fda.hhs.gov

• Any move towards a community-driven collaborative environment can only be as successful as the willingness of the community to participate!
Special Thanks

<table>
<thead>
<tr>
<th>FDA</th>
<th>CTSA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sue Bell</td>
<td>Mary Banach</td>
</tr>
<tr>
<td>Joan Buenconsejo</td>
<td>Laurel Beckett</td>
</tr>
<tr>
<td>Chuck Cooper</td>
<td>Frank Harrell</td>
</tr>
<tr>
<td>Gary Gensinger</td>
<td>Jeffrey Horner</td>
</tr>
<tr>
<td>Ted Guo</td>
<td>Sally Thurston</td>
</tr>
<tr>
<td>Don Salzer</td>
<td></td>
</tr>
<tr>
<td>Norman Stockbridge</td>
<td></td>
</tr>
<tr>
<td>Chris Tornoe</td>
<td></td>
</tr>
<tr>
<td>Steve Wilson</td>
<td></td>
</tr>
</tbody>
</table>