

THE USE OF COLLABORATIVE ENVIRONMENTS

WHERE WE ARE TODAY AND WHERE WE WANT TO BE IN
THE FUTURE

Mat Soukup, Ph.D.

Mat.Soukup@fda.hhs.gov

Mathematical Statistician, FDA/CDER

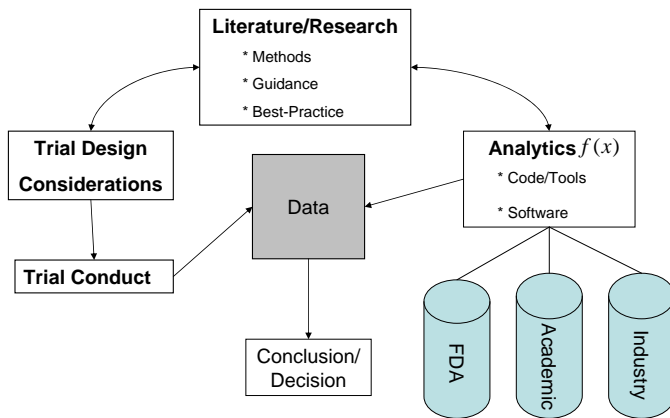
Outline

1 Where We Are Today

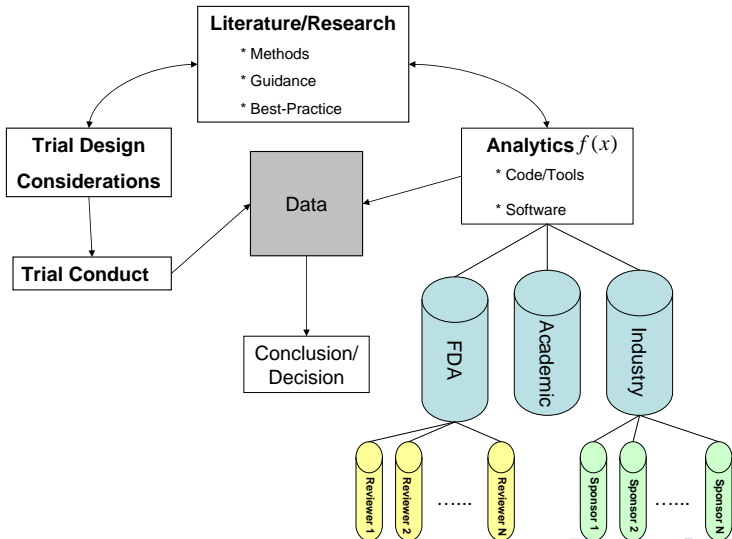
2 Finding a Solution

3 The Future

Defining Today: A Schematic



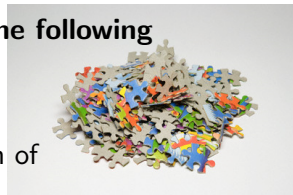
Defining Today: *More Realistic* Schematic



The Problem

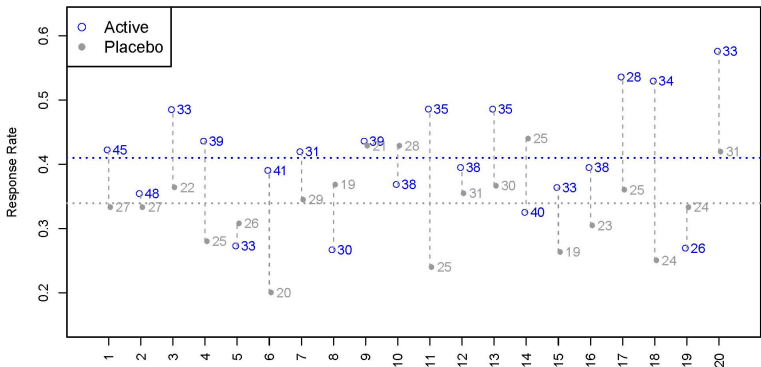
Based upon today's current practice, the following limitations may be present:

- 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 software sharing
- 4** Tendency to rely on antiquated methods
- 5** Difficult to improve the process for drug/biologic reporting

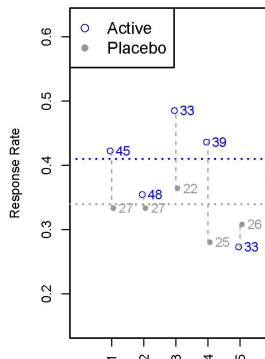


Illustrative Example: Efficacy By Site

A Graphic...



Illustrative Example: Efficacy By Site



R Code

```

"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)
    rxn <- tabulate(as.factor(sdat$Site))
    sdat$plotx <- rep(1:nsn, rxn[rxn>0])
    # 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$Site)), cex.axis=.75, las=3)
    axis(2)
    box()
    if(length(ut)==2) sdat$plotx <- sdat$plotx + rep(c(-.05, .05), length(sdat[,1])/2)
    if(length(ut)==3) sdat$plotx <- sdat$plotx + rep(c(-.1, 0, .1), length(sdat[,1])/3)
    if(length(ut)==4) sdat$plotx <- sdat$plotx + rep(c(-.15, -.05, .05, .15), length(sdat[,1])/4)
    for(k in 1:length(ut)){
      subdat <- subset(sdat, sdat$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$Mean)), lty=2, col='gray60')
    }
  }
  if(type=="monly"){
    nsn <- length(unique(sdat$Site))
    ut <- unique(sdat$Trt)
    rxn <- tabulate(as.factor(sdat$Site))
    sdat$plotx <- rep(1:nsn, rxn[rxn>0])
    # Creation of the figure.
    if("ylab" %in% nms)
      plot(c(.5, nsn+.5), c(min(sdat$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)
  }
}

```

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 meeting
- 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!

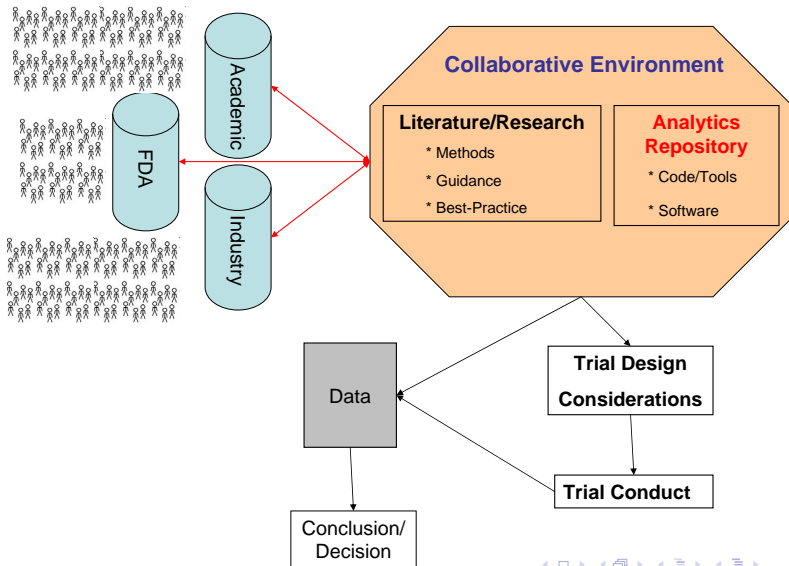
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Collaborative Schematic



Rely on a Community *not* Individual Organizations

Advantages

- Transparency
- Increase 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
- Abundance of information; potentially redundancy

Solution: The **Wiki Way?**



- Most popular and HIGHLY successful Wiki: **Wikipedia**.
- **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
 - Can improve by rewarding important efforts
- **Lack** of citation/recognition for wiki contributions
 - Recently; may be better acknowledgements of such contributions
- **Development** in topics otherwise not known to originators

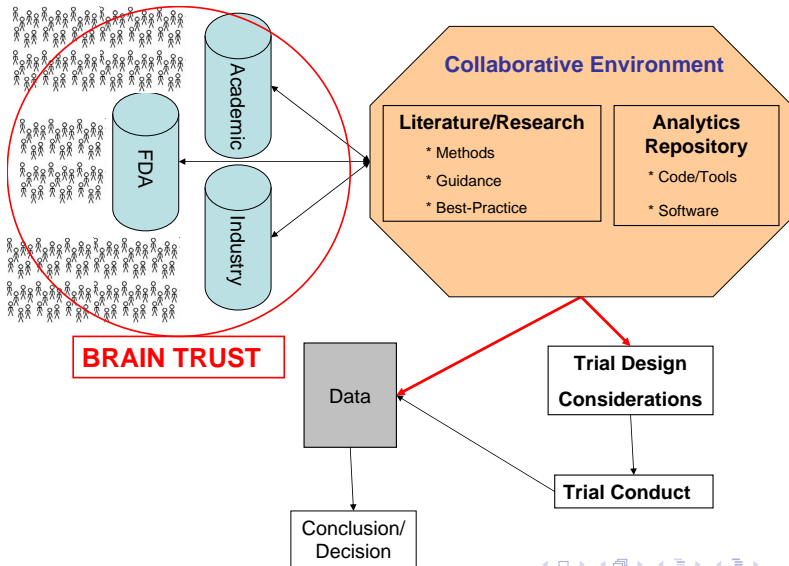
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Bringing Stakeholders Together



General Considerations

In the development of a collaborative environment (wiki) the following considerations should be made.

- Target the consumer - meet the needs of the end-user
- Move from a culture of a lack of information to a culture of **information overload** - site organization/knowledge management is essential.
- Hierarchy is horizontal - does *not* **require** authoritative approval for participating (may be some guidelines within institutions)
- General acceptance that content does not have to be “finished” to be published
- Training of wiki use may be required
- Requires buy in from upper management

Utilizing CTSpedia

- Building on the work of the CTSA, advance CTSpedia for a broader audience
- Faces several challenges
 - 1 Site needs to meet the **needs** of all users
 - 2 Limited Resources: financial and human - will need to increase as content grows to ensure organization of site maintains its intended functionality
 - 3 Reorganization
 - 4 Employees within an organization should be encouraged to **freely** contribute - potential culture change
- May need to limit the scope - to start! Keep initial development towards targeted needs

Partnering CTSpedia and FDA

- Computational Science Center (CSC) Project Team 17 proposed to “Establish a **collaborative environment** for development of specialized program code (like SAS or SPLUS scripts or compiled code) for analytical tools.”
- CTSpedia approached by FDA CSC Project Team 17 in September 2009
- Since January of 2010, CTSpedia and FDA core members have been participating in restructuring CTSpedia.
- Several challenges need or needed to be addressed
 - 1 Reorganization of an active wiki towards one planned for a wider audience
 - 2 Legal considerations (FDA)
 - 3 Increasing resources available to the project
- **Continues to move forward**

What the Future *Might* Look Like



Repository Title Name

Institution

[Register](#) [Log In](#)

Home Page

[Tools](#)

[Graphics](#)

[Best Practice](#)

[Development](#)

[Other Links](#)

Wiki Links

[Sandbox](#)

[Frequently Asked](#)

[Questions](#)

[Others](#)

Analytical Tools

Tool Repository

Recently Added Tools

Most Used Tools

Highest Rated Tools

Tool Development

Tool Needs

Tools Being Developed

Tools Completed

Graphics

Graphic Tools

Recently Added

Highest Rated

Best Practices

Listing

Recently Added

Other Links

Announcements

Others...

[Edit](#) | [Attach](#) | [Print Version](#) | [History: ...](#) | [Backlinks](#) | [Raw View](#) | [Raw Edit](#) | [More topic actions](#)



How a Tool Page *Might* Look

GeniusMIApproach

Description

[Link to article](#)

This tool allows one to implement the multiple imputation procedure developed by Billy published in [Journal for Cool Statistics](#). The strength of this approach is for count data collected over a series of visits.

Code Information

Program Language: R version 2.8

Tool Version: Version 1.1

Tool Meta Data: [GeniusMIApproach-Meta](#)

[Link to Meta Data Page](#)

Tool Example: [Coding Examples](#)

[Link to Examples in Meta Data Page](#)

Tool Code: [GeniusMIApproach](#)

[Link to read-only code](#)

Key Words

Multiple Imputation, missing data

Author

Email: Billy@StatsRock.org

Organization: StatsRock, Ltd.

User Reviews

Number of Reviews: [10](#)

[Link to reviews](#)

Average Rating: ★★☆☆☆ (4 of 5)

[Discussion](#)[Edit](#)[History](#)

Number of page views:

0 0 4 1



Special thanks to the following people

FDA

Sue Bell

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Ted Guo

Don Salzer

Norman Stockbridge

Chris Tornoe

CTSA

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Laurel Beckett

Frank Harrell

Jeffrey Horner

Sally Thurston

Thank You!