

# Collaboration: Challenges and Opportunities for Biostatisticians



46th Annual Meeting  
Washington, DC - 2010

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# Outline

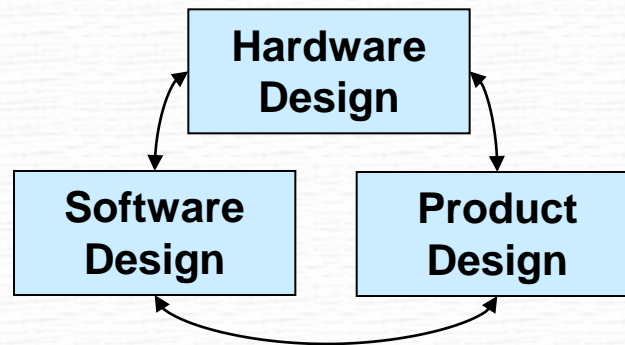
- I. Introductory Example**
- II. Defining Today's Environment
- III. Capitalizing on The Wiki Way
- IV. Working Towards a Solution



# Collaboration: A Tale of Two Companies

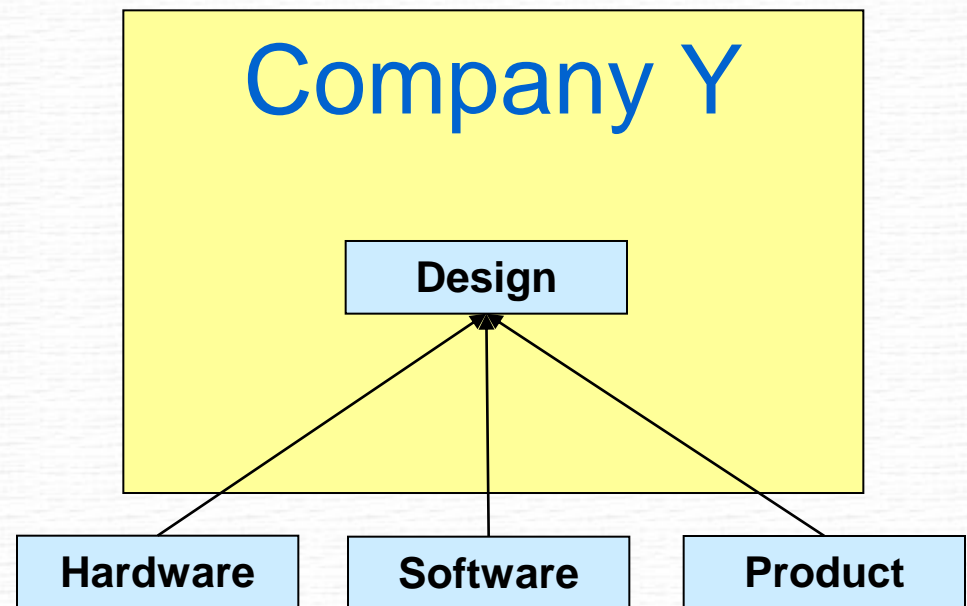
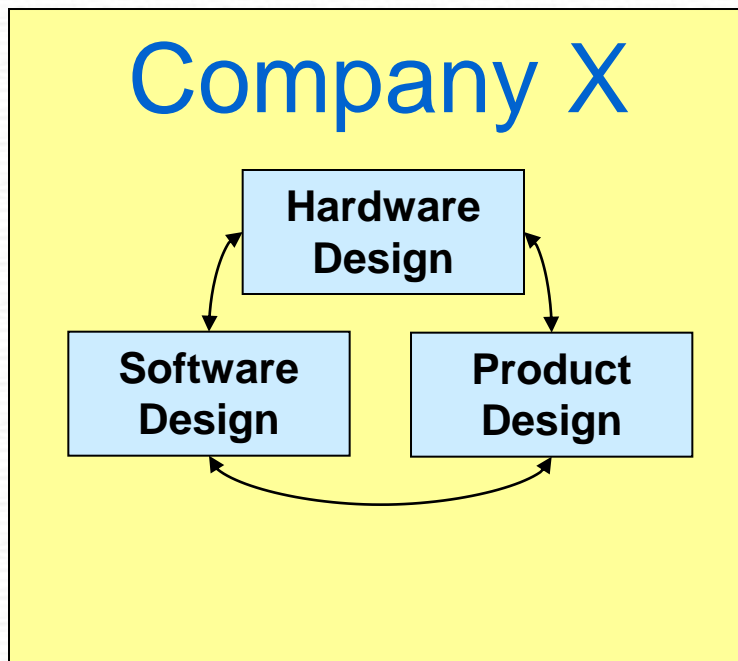
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- Goal: Develop a new electronic music device
  - For simplicity, assume 3 components need to be created/developed/modified/refined



# 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

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- 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



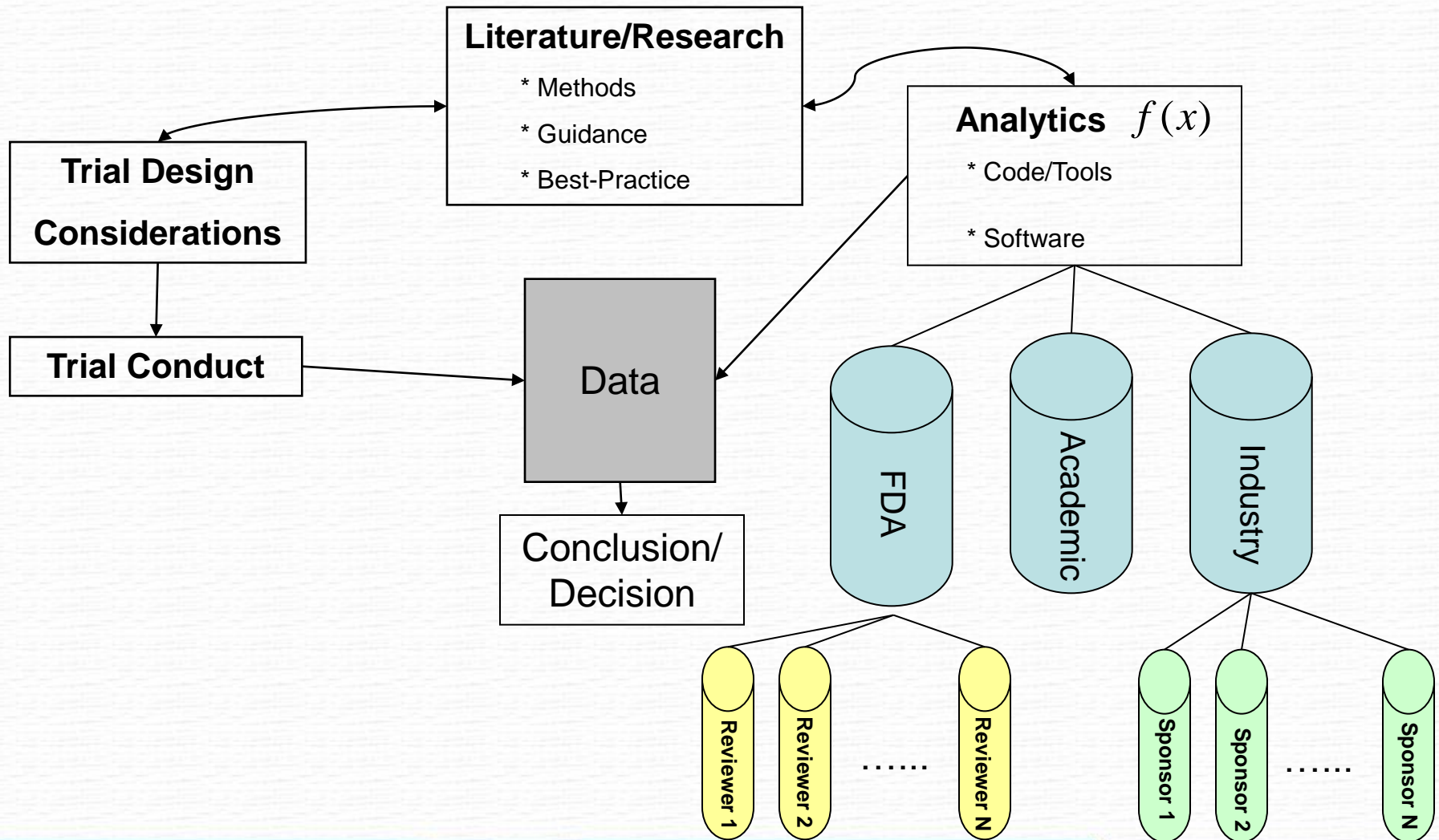
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# Simplistic yet Realistic Schematic



# The Problem

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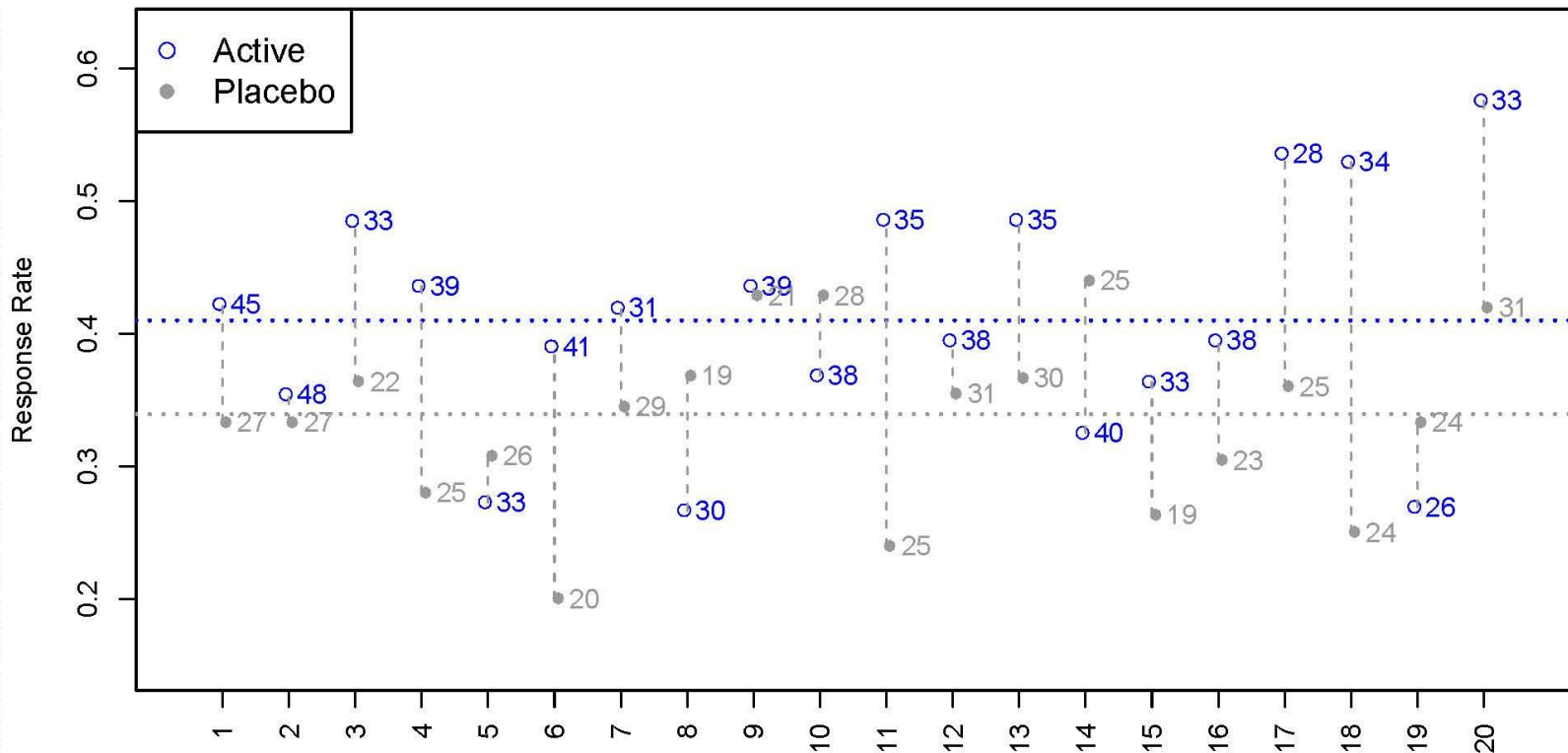
**Based upon today's current practice, the following limitations may be present:**

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



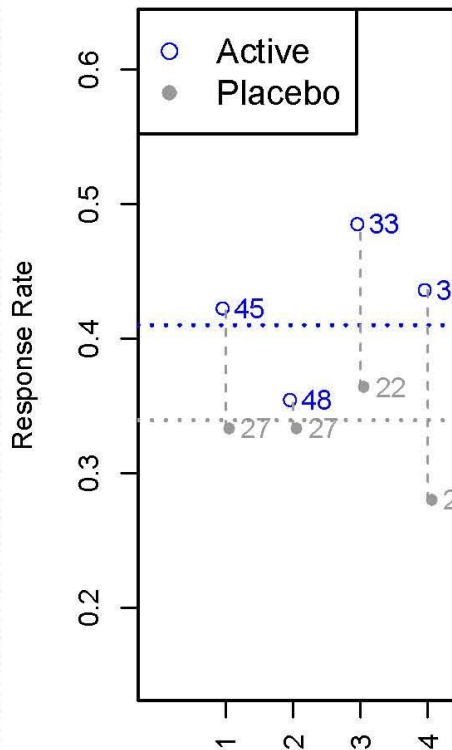
# Illustrative Example: Efficacy by Site

## A Graphic....



# Illustrative Example: Efficacy by Site

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)  
    rnx <- tabulate(as.factor(sdat$Site))  
    sdat$plotx <- rep(1:nsn, rnx[rnx>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$Mean)), lty=2, col='gray60')  
    }  
  }  
  if(type=="nonly"){  
    nsn <- length(unique(sdat$Site))  
    ut <- unique(sdat$Trt)  
    rnx <- tabulate(as.factor(sdat$Site))
```

# Illustrative Example: Efficacy by Site

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- 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

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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?



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# The **Wiki** Way

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- 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.





# Wikipedia Screenshot

The screenshot shows the Wikipedia article for "Statistics". Red callouts highlight several key features:

- Discussion**: A red box highlights the "discussion" tab in the article navigation bar.
- Edit**: A red box highlights the "edit this page" button in the article navigation bar.
- History**: A red box highlights the "history" button in the article navigation bar.
- Navigation**: A red box highlights the "navigation" section in the left sidebar, which includes links for "Main page", "Contents", "Featured content", "Current events", and "Random article".
- Search**: A red box highlights the search box in the left sidebar, including the "Go" and "Search" buttons.

The article content includes a definition of statistics, a description of a statistician, and a table of values for the normal distribution curve.

Standard Deviations From The Mean	Cumulative %	Z Scores	T Scores
+3σ	99.73%	+3.00	+60
+2σ	97.72%	+2.00	+40
+σ	84.13%	+1.00	+20
0σ	50.00%	0	0
-σ	35.87%	-1.00	-20
-2σ	22.28%	-2.00	-40
-3σ	9.73%	-3.00	-60

# Wiki Strengths and Weaknesses

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- **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

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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?

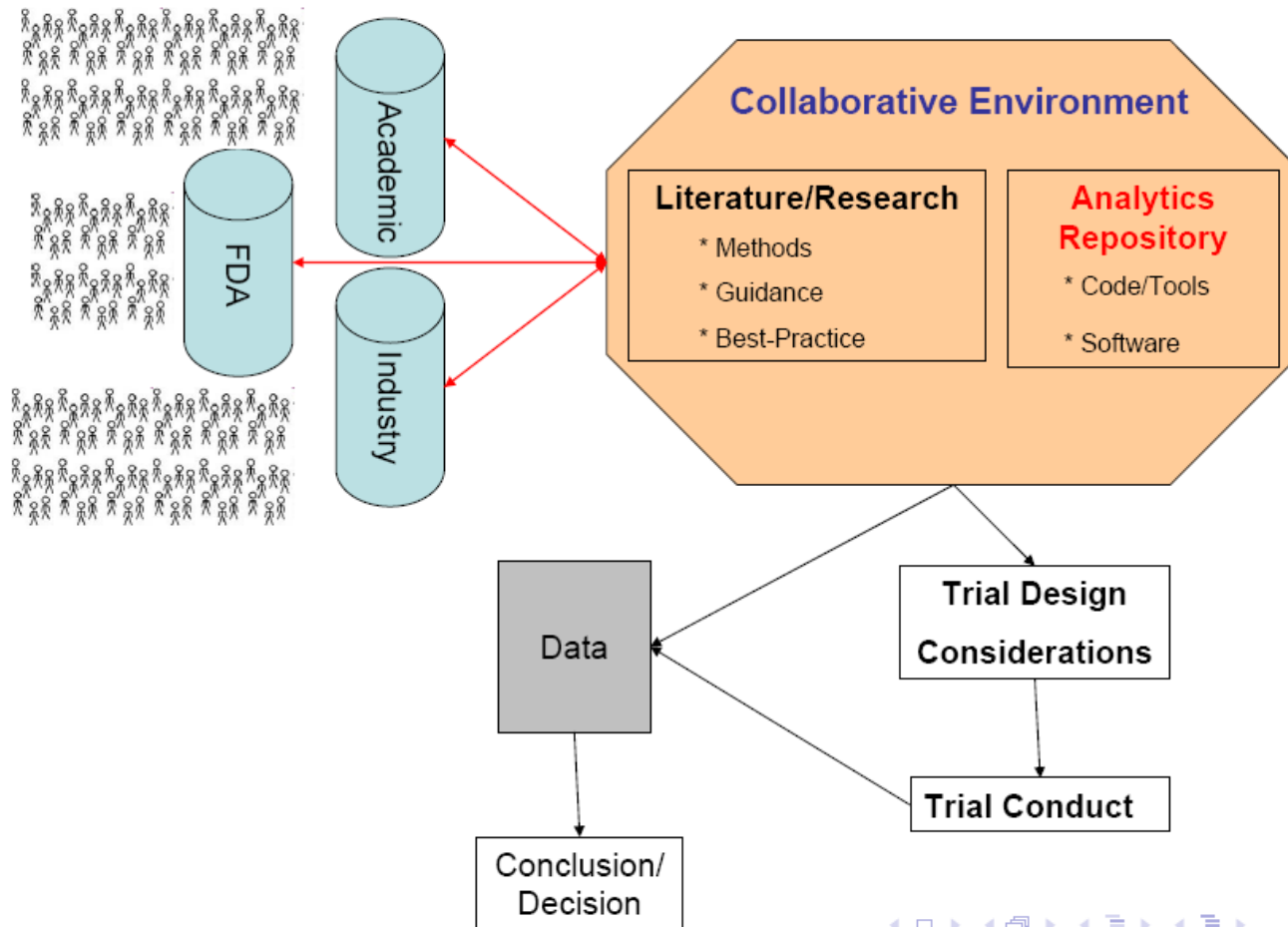


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# Collaborative Schematic



# Relying on a Community

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- **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

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- 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

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- 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....

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- Any questions or willingness to participate please email me:
  - [Mat.Soukup@fda.hhs.gov](mailto: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

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## **FDA**

Sue Bell

Joan Buenconsejo

Chuck Cooper

Gary Gensinger

Ted Guo

Don Salzer

Norman Stockbridge

Chris Tornoe

Steve Wilson

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## **CTSA**

Mary Banach

Laurel Beckett

Frank Harrell

Jeffrey Horner

Sally Thurston

