

Tackling the Hard Topics: Shaping What's Next in Regulatory Science

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Vision for the future

- Maintain workshop format
- Build relationships (globally & cross functionally)
- Ensure appropriate share of voice
- Facilitate dialog, collaboration, and progress in the business of statistics / drug development policy

Why is this workshop different?

Workshop

Small

Plenary (Single-Track)

Narrow, Strategic

Quality

Longer Coffee Breaks & Lunches

Ours

Low Cost, High Value

Scale

Format

Focus

Networking

Structure

Outcome (Impression)

Cost / Value

Conference

Large

Parallel Sessions

Diverse, Technical

Quantity

Shorter Breaks & Lunches

Mine

High Cost, ??

Key themes

- Focus on OURS, not Mine
- Discussion is the primary focus
- Create a safe space to discuss hard things
- Create a lasting impact

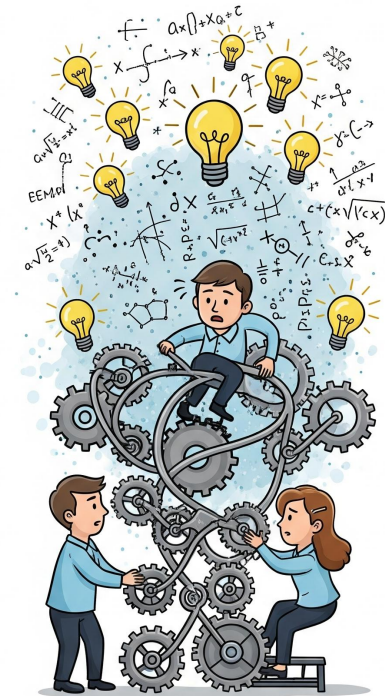
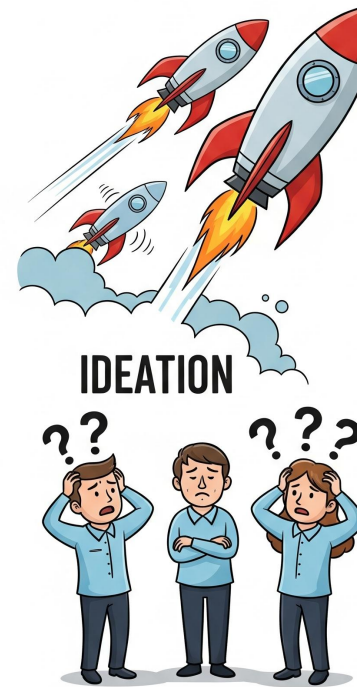
Ours, not mine

- Emphasizes "OUR" challenges over "My method"
- Single plenary track facilitates common focus vs. fragmented discussions
- Scientific Committee identifies and curates a program of the most important topics of mutual interest



Why is discussion the primary focus?

- Intentionally different: There are many other conferences where people can present their latest methods inventions
- Adoption of innovation is hard
 - Clear statement of the problem
 - Understand barriers
 - Create safe space for dialog
- Relationships take time to build



Why is scaling innovation so hard?

Time pressure

Perceived complexity

Penalty of being the guinea pig



Different values, priorities

Insufficient context

Over-valuing precedence

Why is implementing innovation so hard?

Industry Statistician

Works on the design and execution of studies

Is pragmatic and embedded in teams

Feels pressure to meet a timeline set by the environment, business, and (not the least) patients

Regulator Statistician

Works within a complex system that makes decisions through committees

Receives dossiers that are too lean in the wrong places (*don't explain WHY a novel approach was taken nor acknowledge the potential downsides*)

Feels pressure to meet a timeline set by the environment, regulation, and (not the least) patients

Splashing out comes with challenges

Dialogue to work through the root cause

“When two experts disagree about a policy question, it may be due to a different interpretation of the question they are being asked, or it may be due to a different judgment of which facts are most relevant for making a prediction about a future intervention.”

Source: <https://www.tandfonline.com/doi/full/10.1080/08913811.2020.1872948#d1e423>

Reiss, J. (2020). Why Do Experts Disagree? *Critical Review*, 32(1-3), 218-241. <https://doi.org/10.1080/08913811.2020.1872948>

Exploring the world as it actually is...

Are we talking about challenges we face enough?

Industry Statistician

Speed

Taking smart risks

Communication (timing, amount, etc)

Decision making (who's driving the car)

Regulator Statistician

Volume

Quality

Complexity

Wishful thinking

Creating something unforgettable

*Even when you don't remember the details,
you likely remember WHY something is important*

**winter IS
coming!**

***Speed never killed anyone,
standing still that's what gets you***

**We still believe in
randomization,
don't we?**

*It is not about data that is already there.
It is about the data that is needed to draw
the conclusion you want.*

What do you do when you leave the workshop?

- ❑ Share key ideas with statistician colleagues who couldn't attend
- ❑ Share key ideas and opportunities with nonstatistician colleagues to ensure alignment
- ❑ Initiate collaborations with fellow attendees to drive the field forward
- ❑ Plan your F2F attendance for next year
- ❑ Raise ideas / problems to the attention of the Scientific Committee and/or submit short topics
- ❑ Reflect about your favorite sessions on social media
- ❑ Purchase the winning wine from the tasting

Follow what's happening next

Engage and actively participate...

The workshop has a very informative website

<http://www.efspiworkshop.org>

The EFSPI organization has a new website

<https://www.efspi.org/>

So many posts on **LinkedIn**