

Implementing Bayesian augmented control designs into business practice

Insights and reflections on a journey from 'Why?' to 'Why not?'

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Inspired by **patients.**
Driven by **science.**



Next 15 minutes

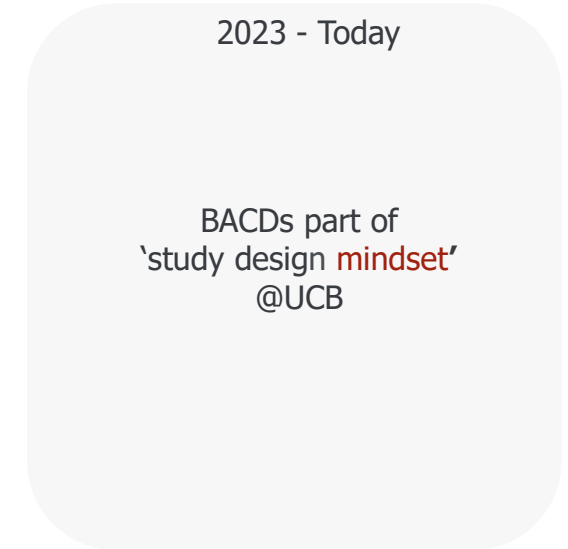
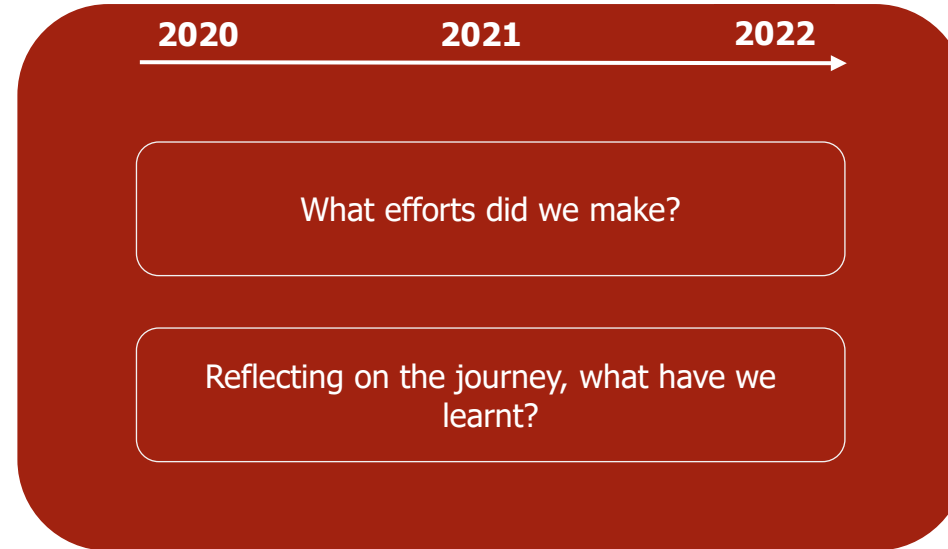
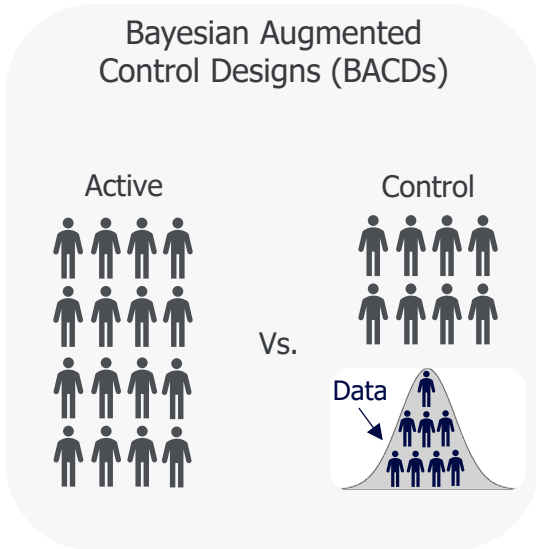
Invention

x

Commercialization

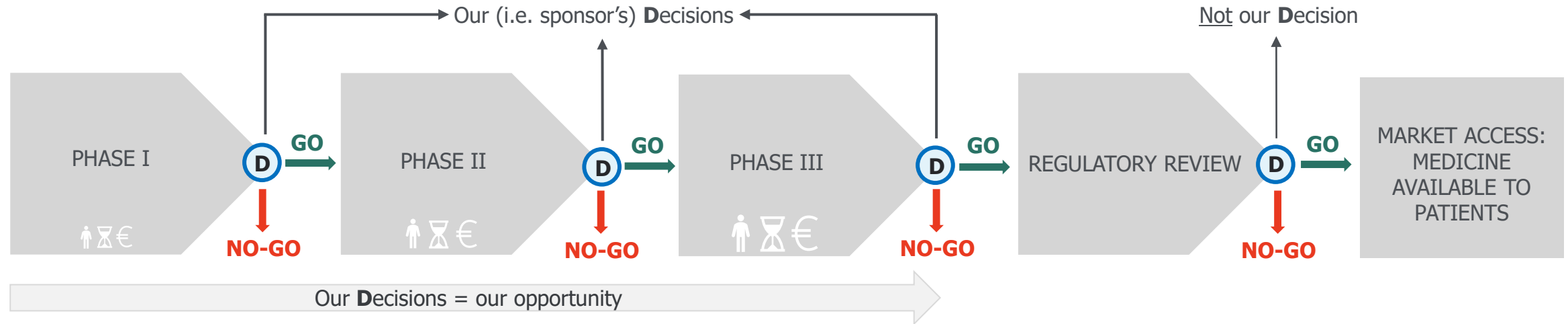
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Innovation*



Positioning BACDs in a first step: contribution to a greater mission

High-level schematic of clinical trial phases and **D**ecisions **D** involved:



Greater mission: **decision making** (next **study**, whole **program**, **portfolio**) with **confidence & efficiency**.

BACDs contribute to this mission by reducing

- *patients-to-decision,*
- *time-to-decision,*
- *cost-to-decision.*

Our slogan:

Think Twice – Design Once.

Reducing barriers through tailored software: Smart Study Design tool

Smart Study Design Tool

Welcome & News

Overview & Help ▾

Meta-Analytic Predictive (MAP) Prior

Expert Elicitation (SHELF) ▾

Design OCs

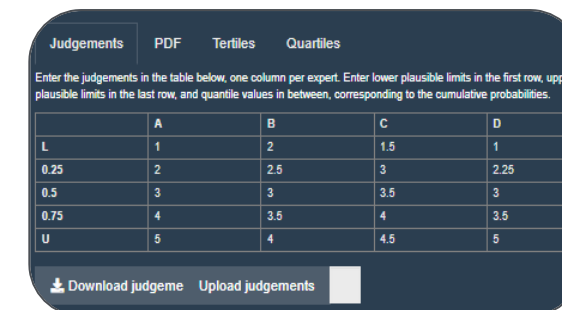
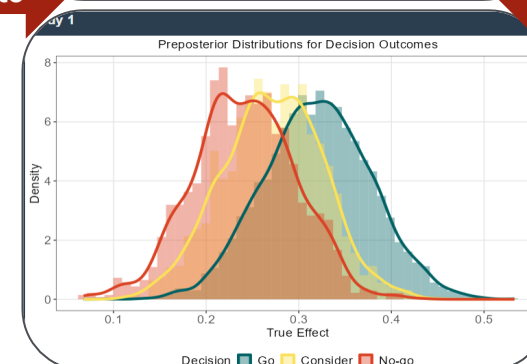
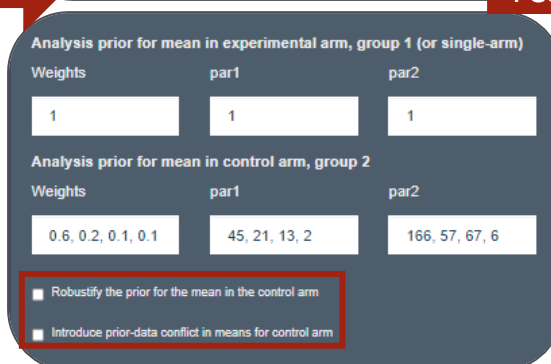
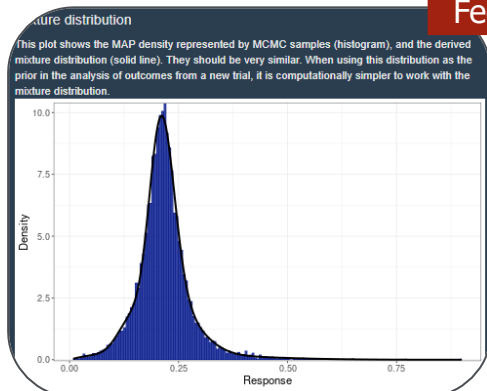
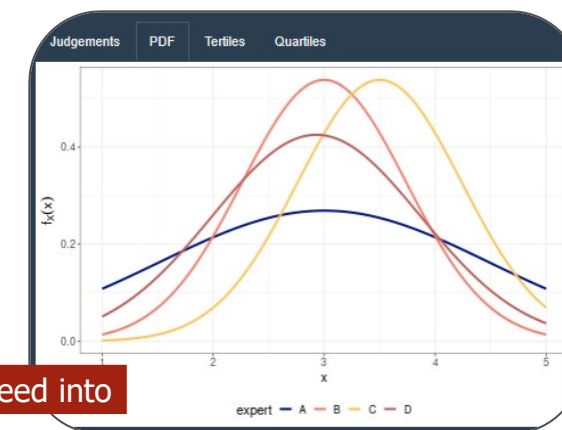
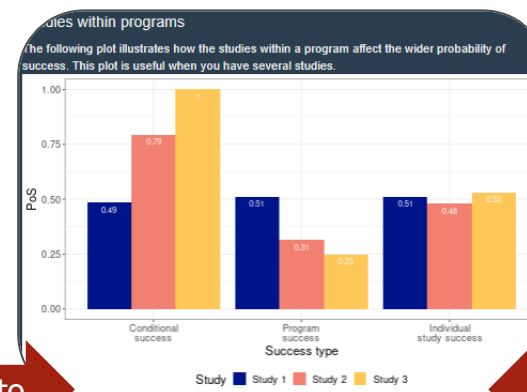
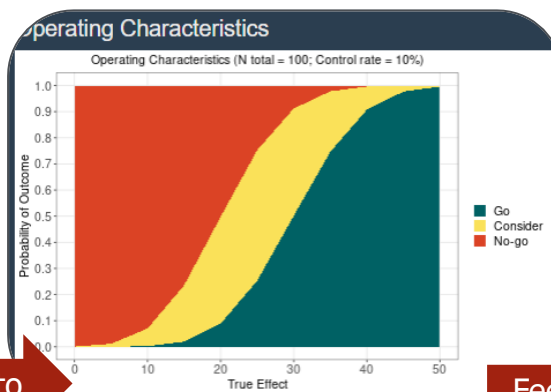
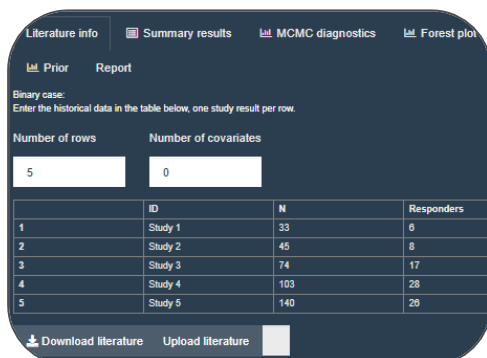
PoS & Pre-posteriors

Largely based on **RBest** package;
S. Weber et al. (2021)

Based on **RBest** package +
in-house functionalities

In-house functionalities;
R. Walley et al. (2015), A. Grieve (2022)

Largely based on **SHELF** package;
J. Oakley & T. O'Hagan (2015)



A tool is not enough

Commitment is key.

To quality throughout. To statisticians. To non-statisticians.
To senior management. To ourselves.

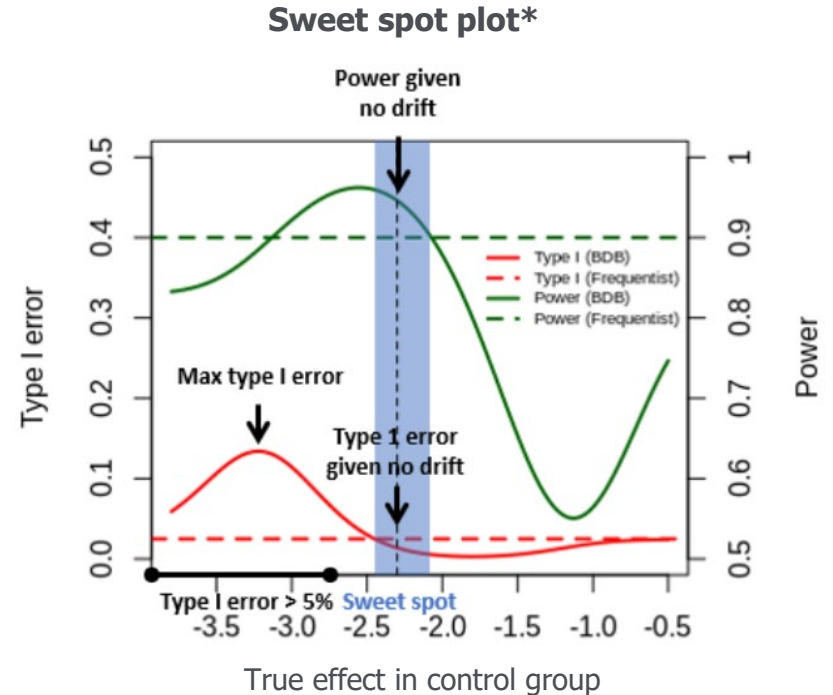
In the following: will share some **reflections** on our
journey from **tool to mindset**.

Reflection 1: seeing the opportunity for **technical leadership**

- **Seeing the startup behind the project**
 - What is the product?
 - Who are the customers?
 - Who are the investors?
- **Seeing people development behind task completion**
 - Effort is long-distance run
 - People-focused vs. task-focused planning ('talent factory')
- **Seeing the space & need for methodological competence**
 - Effort is technical AND creative AND operational
 - Crucial for effective advertising

Reflection 2: acting like a **partner** to **non-statisticians**

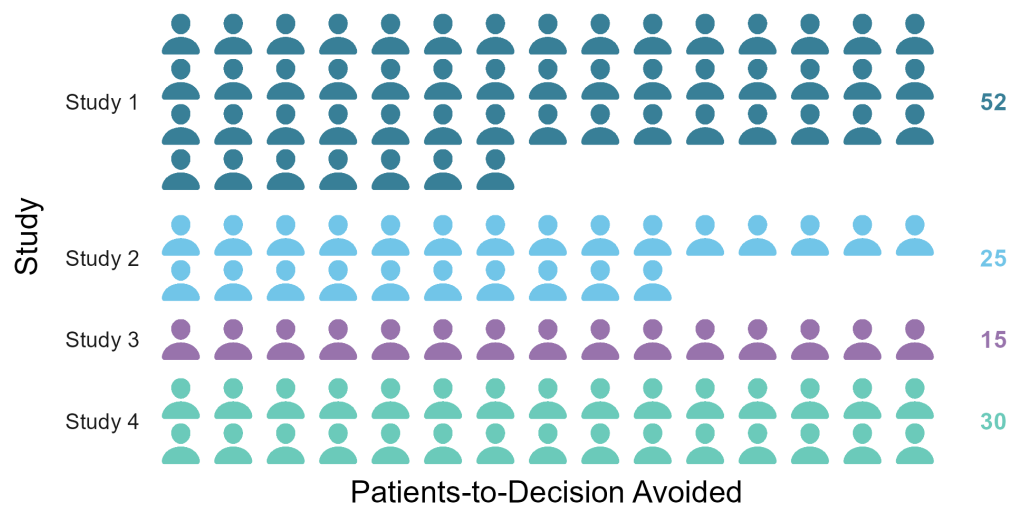
- **Being proactive about possible concerns**
 - Not wanting to innovate OR just not understanding the invention?
 - Deep dive into prior-data conflict often door-opening
 - Helpful material by Historical Data SIG (e.g. 'Sweet spot plot')
- **Non-statisticians DO appreciate details**
 - They actually need them
 - Not done in one or two sessions BUT
 - Demystification = catalyst for engagement
- **Communication success depends on BOTH sides**
 - Non-statisticians need to improve too
 - Expect (willingness to increase) statistical literacy






Reflection 3: acting like a **partner** to **senior management**

- **Transparency** is key.
- **Interest in business questions:** we linked BACDs to UCB's data strategy key driver 'Algorithms As Assets (AAA)'
- **Metrics:** quantification of implementation success and impact

Example (dummy data):



Overall avoided **by re-using historical data:**

- **122** patients-to-decision, 
- **10.3** M EUR cost-to-decision, and 
- **21** months time-to-decision. 

Reflection 4: acting in line with goals, not **Egoals**

Def. **Egoal**:

noun ; UK /'i:.gəʊl/ ; US /'i:.goʊl/

goal with a slightly irritating capital E standing in front of it, making the goal difficult to be seen, understood or supported by others than capital E itself

• **Transparency on novelty of BACDs**

- 'Andy Grieve was doing this in the 80s.'
- Boosts credibility and openness to try

A. Racine-Poon, A. P. Grieve, H. Fluehler, C. Bartlett and A. F. M. Smith (1985): '[...] such information might serve either to boost the current information provided by very small trials, or to permit some reduction in current sample sizes if experimental resources are scarce.'

• **Repetition is OK**

- Does not say one can only do this one thing
- Only says this one thing needs to be repeated

• **Embracing ALL opportunities**

- It does not have to be Ph3 from the start
- Use PoC to generate knowledge, experience, and trust
- Prioritize 'innovation readiness'

• **Selling is ~~un~~helpful**

- Fear of overselling inspires systematic underselling
- Systematic underselling is NOT more responsible

Your turn!

Acknowledgements

Many (former) UCB statisticians, collaborators & advocates:

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- Quentin Surdiacourt
- And many more ...



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Thank you.

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