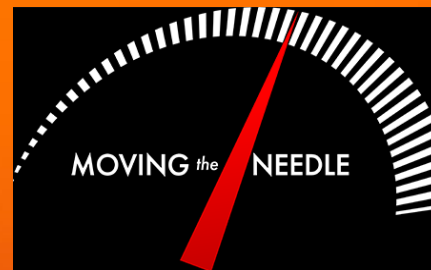




Implementing Statistical Innovations in the Pharmaceutical Industry: Moving the needle on use of Bayesian methods



Nicky Best

Statistics and Data Science Innovation Hub, GSK

Successful implementation of Bayesian approaches at GSK

GSK's Boostrix for pertussis cleared by FDA for use in pregnancy



FDA Approved Product Label

BDB primary analysis of real-world data led to the inclusion of BDB results in the FDA-approved label for maternal Boostrix vaccination

GSK's Nucala for severe eosinophilic asthma gains approval in China

The Nucala antibody targeting IL-5 was initially approved in the US for severe asthma with an eosinophilic phenotype.

January 11, 2024



CDE Approved Product Label

BDB design used for a confirmatory bridging trial that supported the approval of Mepolizumab for severe asthma in China.

Rheumatology > Lupus
Belimumab Benefits Kids With SLE, Data Confirm
— First placebo-controlled trial shows efficacy, safety in pediatric lupus patients

by Nancy Walsh, Contributing Writer, MedPage Today
July 24, 2020



Pediatric Efficacy Extrapolation

BDB in a pediatric efficacy trial facilitated FDA approval of Belimumab for pediatric lupus

BDB is routinely proposed for clinical efficacy extrapolation in paediatric studies at GSK



Governance Boards

Bayesian quantitative decision making (QDM) framework is embedded as a core part of GSK's Clinical Development Planning and Governance processes

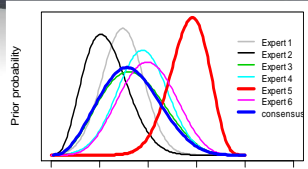
Road to “commercialisation”: Bayesian Quantitative Decision Making



Main Paper | [Full Access](#)

Assurance in clinical trial design

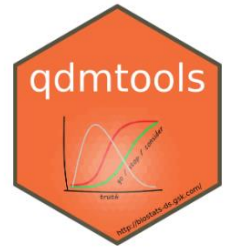
Anthony O'Hagan | [John W. Stevens](#), [Michael J. Campbell](#)



GSK Chief Scientific Officer Hal Barron (GSK)



GSK Keep Growing Campus
QDM Technical Training



MAIN PAPER | [Open Access](#) | [CC](#) [BY](#) [NC](#) [ND](#)

Conditional assurance: the answer to the questions that should be asked within drug development

Jane R. Temple | [Jon R. Robertson](#)



Road to “commercialisation”: Bayesian Dynamic Borrowing (BDB)



Robust Meta-Analytic-Predictive Priors in Clinical Trials with Historical Control Information

Heinz Schmidli, Sandro Gsteiger, Satrajit Roychoudhury, Anthony O'Hagan, David Spiegelhalter, Beat Neuenschwander

Belimumab Benefits Kids With SLE, Data Confirm
— First placebo-controlled trial shows efficacy, safety in pediatric lupus patients

By Henry Mark, Contributing Writer, STATista Today
July 16, 2019



- Daprodustat Type C meeting
- Belimumab Information Request



Statistics in Biopharmaceutical Research
Beyond the Classical Type I Error: Bayesian Metrics for Bayesian Designs Using Informative Priors

Nicky Best, Maxine Ajimi, Beat Neuenschwander, Gaëlle Saint-Hilary & Simon Wandelon behalf of the PSI/EFSPi special interest group "Historical Data"



Qualification of novel methodologies for medicine development



MAIN PAPER [Open Access](#)
Assessing efficacy in important subgroups in confirmatory trials: An example using Bayesian dynamic borrowing
Nicky Best, Robert G. Price, Isabelle J. Pouliquen, Oliver N. Keene



R&D Data Hub > Capabilities > Bayesian Dynamic Borrowing

Bayesian Dynamic Borrowing Technical Training

There is enormous potential to boost the decision-making power of our clinical trials if we are smart about how and when to re-use clinical data. It can help us to increase the precision of our treatment effect estimates or reduce the number of patients, costs and timelines of our clinical development programmes.

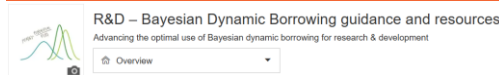
This course is aimed at Biostatistics statisticians applying QDM principles.
Join us to explore how we can use historical information to design more efficient clinical trial



GSK's Nucala for severe eosinophilic asthma gains approval in China

The Nucala antibody targeting IL-5 was initially approved in the US for severe asthma with an eosinophilic phenotype.
January 10, 2024

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GSK's Boostrix for pertussis cleared by FDA for use in pregnancy



Ingredients for Success (1)

A good idea



business
A problem to solve

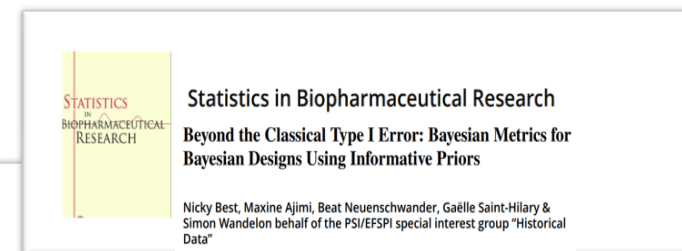


Ingredients for Success (2)

A good idea

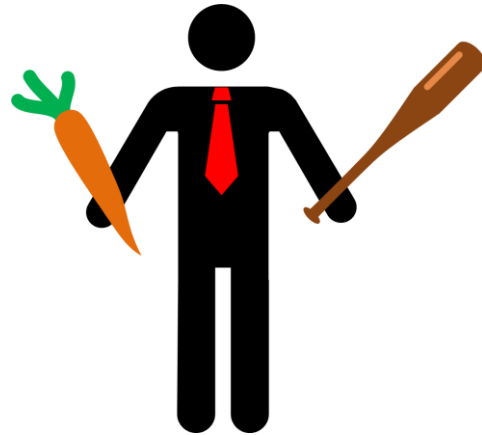


A good ~~idea~~ solution



Ingredients for Success (3)

Adoption



Find in video from 00:20 The Role of the First Follower

First Follower: Leadership Lessons from Dancing Guy

Ingredients for Success (4)



QDM Tools Hub

[Home](#)

Evolving QDM

QDM R

$$\left[\begin{array}{c} R \end{array} \right]$$

Rethinking QDM and Engaging with the Community

AUTHOR

Ben Arancibia

PUBLISHED

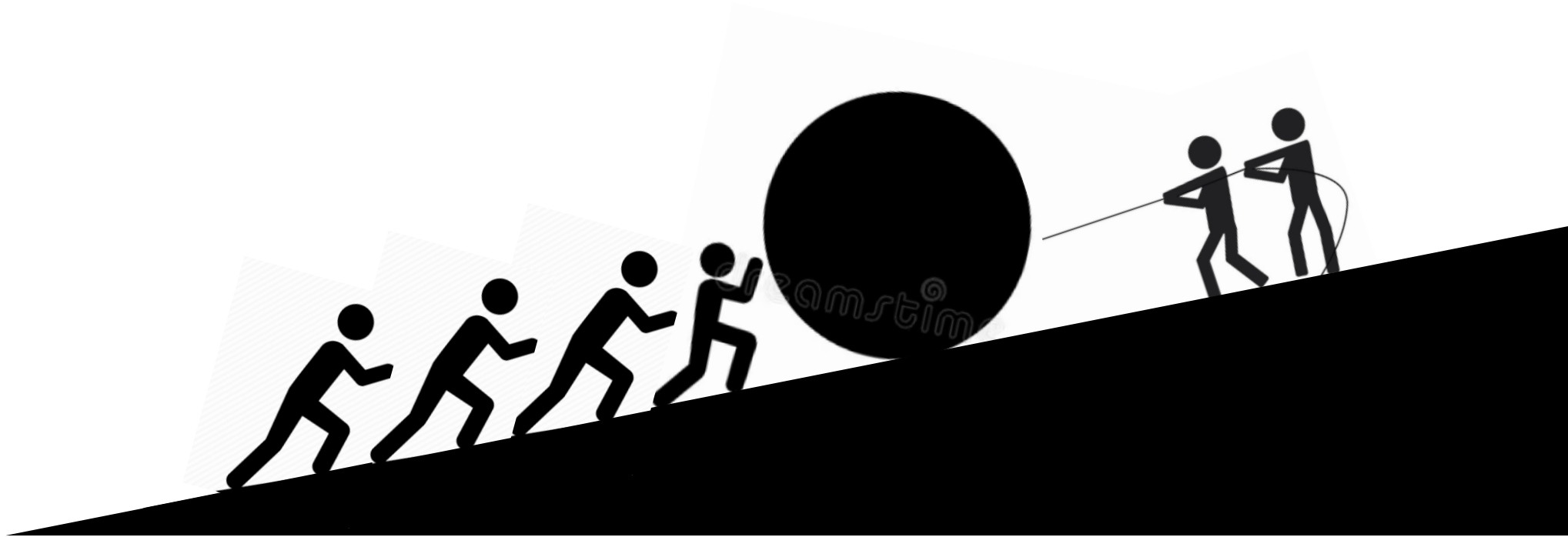
November 11, 2024

QDM has gone through different phases and the QDM development team is excited for a revamp. This revamp is focused on making sure Clinical Statistics knows and understands the scope of all current tools – as well as ensuring that the community can effectively steer the future development of our tools.

Below is a list of the current known tools that are available to use for QDM.

Tool Name	Description	URL
QDM Tools	R package for deriving conditional and unconditional probabilities of success for standard designs. Users are able to	https://probable-guide-690d873.pages.github.io/

Innovation in a Regulated Environment



Commercialising Innovation is a Team Science

