Post-baseline subpopulation analyses:
Known to be improper, but frequently done. Can we fix them?

Basel, Biozentrum - 14th Sep 2022

Agenda

1. Introduction by Khadija Rantell (MHRA), 5 mins
2. Presentation by Björn Bornkamp (Novartis), 25 mins incl. Q&A
3. Presentation by Anja Schiel (Norwegian Medicines Agency), 25 mins incl. Q&A
4. Panel discussion moderated by Mouna Akacha (Novartis), 65 mins incl. Q&A
   - Björn Bornkamp (Novartis)
   - Florian Klingelmüller (Austrian Agency for Health and Food Safety)
   - Fabrizia Mealli (University of Florence) – virtual
   - Khadija Rantell (MHRA)
   - Stephen Ruberg (Analytix Thinking)
   - Kaspar Rufibach (Roche)
   - Anja Schiel (Norwegian Medicines Agency)
   - Mats Stensrud (Swiss Federal Institute of Technology in Lausanne – EPFL)
   - Wanje Sun (FDA) – virtual

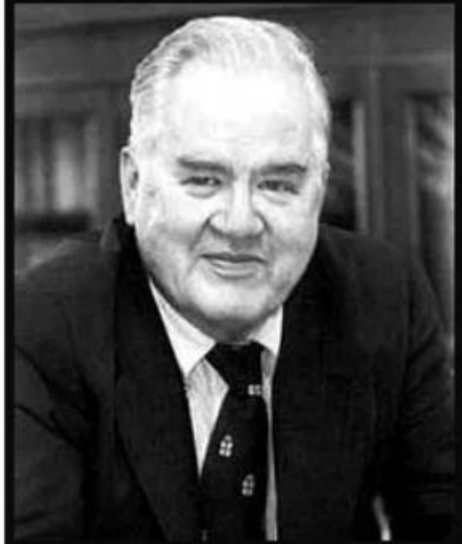
Panel questions

Do you think that trial objectives/ estimands focusing on post-baseline subpopulations are relevant?

Can the discussed trial objectives/ estimands be the primary estimand of a confirmatory trial? Yes/No - explain why

Could you share some high-level considerations on design, trial conduct, analyses and reporting?

Is there a common set of trial objectives/ estimands that are of interest to all parties? Or, do we have to cater for multiple estimands to satisfy different "customers"?



Far better an approximate answer to the right question, which is often vague, than an exact answer to the wrong question, which can always be made precise.

(John Tukey)

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