Series 1: Bad science

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2017-11-09T21:59:45+01:00

Estimands and regulatory statistics

Following up on the 2nd EFSPI Workshop on Regulatory Statistics, on October 5-6th 2017 in Basel

- Multiple Endpoints in Clinical Trials: FDA Issues Draft Guidance
  Announcement on RAPS (Regulatory Affairs Professionals Society)
  EMA Guideline on multiplicity issues in clinical trials Draft
- ICH E9 Addendum
- Per-Protocol Analyses of Pragmatic Trials
  Miguel A. Hernán and James M. Robins
  Statistics in Medicine, 2017
- Estimands and Their Role in Clinical Trials
  Mouna Akacha, Frank Bretz, David Ohlssen, Gerd Rosenkranz & Heinz Schmidli
  Statistics in Biopharmaceutical Research, 2017
- A taxonomy of estimands for regulatory clinical trials with discontinuations
  Thomas Permutt
  Statistics in Medicine, 2015

@permutt_taxonomy_2016

- Estimands in clinical trials broadening the perspective pdf
  with *Comments on Estimands in clinical trials broadening the perspective*
  Thomas Permutt
  pdf
  Peter Bauer
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  Frank Rockhold
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- Editorial: Estimands in clinical trials a challenge to intention to treat?
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- Cytel - Estimands 101: Interview with Mouna Akacha