Estimands addendum is final: Anything new for oncology?

Joint webinar EFSPI & BBS
29th June 2020
Kaspar Rufibach, on behalf of BBS and the organizing committee

Supporting organizations

Basel Biometrics Section

http://bbs.ceb-institute.org

European Federation of Statisticians in Pharma Industry

www.efspi.org

Industry working group "Estimands in Oncology"

www.oncoestimand.org

Organizing committee

Bibiana Blatna (Novartis)

Marie-Laure Casadebaig (Celgene)

Evgeny Degtyarev (Novartis)

Lynda Grinsted (AstraZeneca)

Lorenzo Guizzaro (EMA)

Wolfgang Kothny (Novartis)

Giusi Moffa (Uni Basel)

Kaspar Rufibach (Roche)

Hans-Jochen Weber (Novartis)

E9(R1) EWG Addendum: Statistical Principles for Clinical Trials

This topic was endorsed by the ICH Steering Committee in October 2014.
An Addendum was proposed to provide clarification on E9 and an update on the choice of estimand in clinical trials to describe an agreed framework for planning, conducting and interpreting sensitivity analyses of clinical trial data. This Addendum is proposed to focus on statistical principles related to estimands and sensitivity analysis, not on the use or acceptability of specific statistical procedures or methods. While a variety of mid-stage and late-stage clinical trials may be in scope, the primary focus of the Addendum will be on confirmatory clinical trials.

Rapporteur: Mr. Frank Petavy (EC, Europe)

Regulatory Chair: Dr. Yuki Ando (MHLW/PMDA, Japan)

Date of *Step 4*: 20 November 2019

Status: *Step 5*

Implementation status:

ANVISA, Brazil - Not yet implemented; Reference: N/A

EC, Europe - Implemented; Date: 30 July 2020; Reference: EMA/CHMP/ICH/436221/2017

FDA, United States - In the process of implementation;

HSA, Singapore - In the process of implementation;

MFDS, Republic of Korea - Not yet implemented; Date: 1 January 2021;

MHLW/PMDA, Japan - In the process of implementation;

NMPA, China - In the process of implementation;

Swissmedic, Switzerland - Implemented; Date: 30 November 2019;

TFDA, Chinese Taipei - In the process of implementation;

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Goal today:

engage stakeholders
beyond statistics

Joint EFSPI / BBS Seminar: Estimands addendum is final: Anything new for oncology?

Basel Biometrics Section webinar
Basel, 29th June 2020

Kaspar Rufibach (Roche, member of BBS board)
Welcome and scene setting

Regulator's view (Anja Schiel, Norwegian Medicines Agency)
Experience with the estimand framework in oncology

Renaud Capdeville (Novartis), Tina Nielsen (Roche)
Challenges and open questions in hematology: RATIFY and GALLIUM

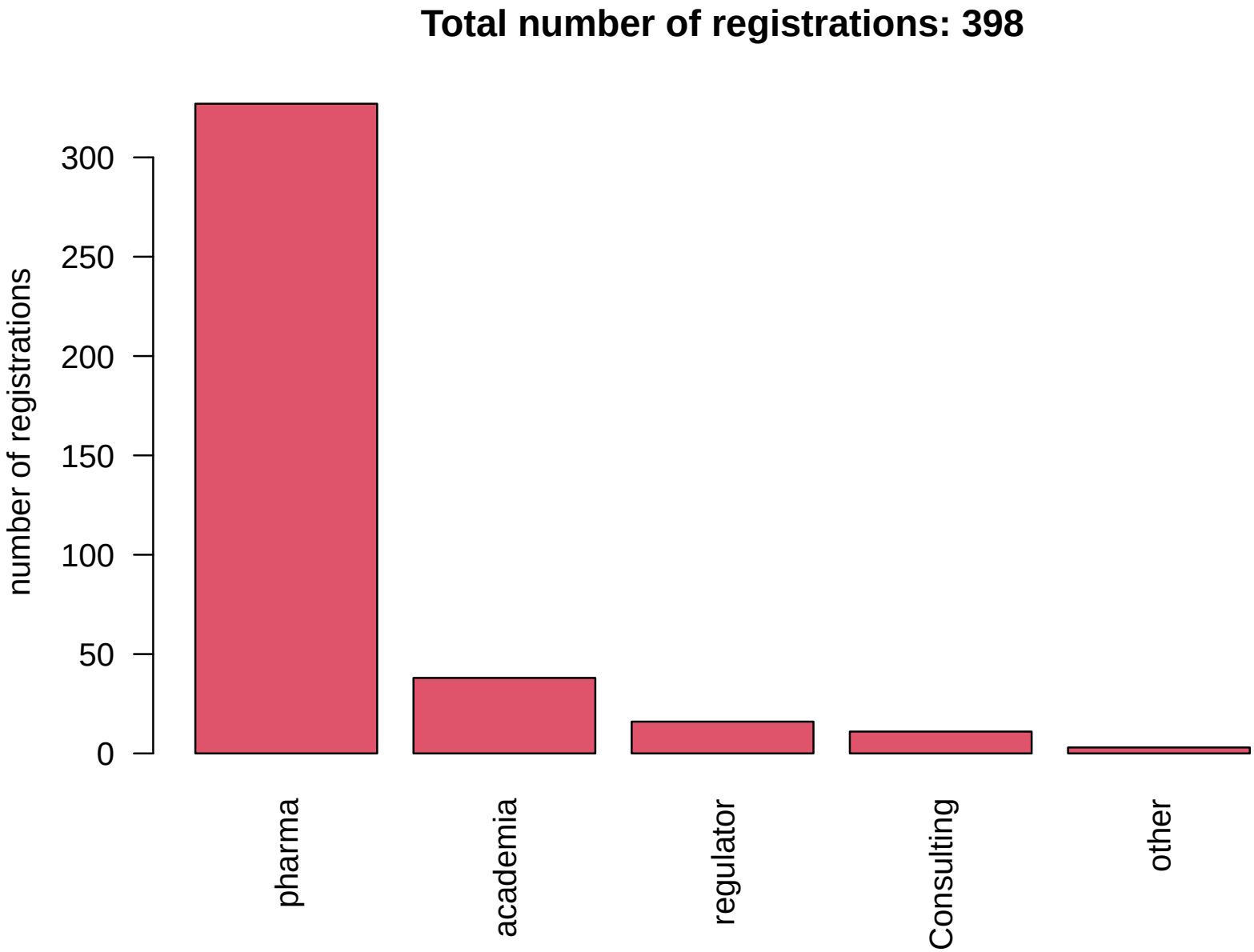
Break

Hannes Buchner (Staburo) & Ingolf Griebsch (Boehringer Ingelheim)
Treatment switching: challenges, estimands, and estimators

Stefan Englert (AbbVie)
Commentary on previous talks taking COVID-19 into account

Break

Panel discussion
(all speakers + Rob Hemmings from Consilium, Michael Wenger from Novartis)
Estimands – after first experiences anything new for oncology? If at all, what does it add?


Total number of registrations: 398
number of registrations
300
250
200
150
100
50
0
pharma
academia
regulator
Consulting
other


Total number of registrations: 398
number of registrations
0
20
40
60
80
100
120
Novartis
Roche
Bayer
AstraZeneca
BMS

Webinars under discussion

Estimands in CNS

Causal inference methods in drug development after the ICH E9 addendum

One year of ICH E9 addendum - examples of application and open problems

Principal stratification - examples in drug development

Thank you for your attention.

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numbersman77

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Doing now what patients need next

R version and packages used to generate these slides:

R version: R version 4.0.0 (2020-04-24)

Base packages: stats / graphics / grDevices / utils / datasets / methods / base

Other packages: dplyr / readxl

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