EUFEPS BABP Network

The Global Bioequivalence Harmonisation Initiative

September 28, 2022

08:00 - 09:00 **Registration**

09:00 - 09:15 **Opening and welcome**
Mehul Mehta, US Food and Drug Administration, Silver Spring MD USA
Barbara Schug, SocraTec R&D, Oberursel, Germany

9:15 – 13:00
Session I: **Statistical considerations for BE assessment in specific situations**
Session co-chairs:
Gerald Beuerle, Teva, Ulm, Germany
Nilufer Tampal, US Food and Drug Administration, Silver Spring MD USA

2-stage, adaptive and replicate design: a regulatory update after the discussions at GBHI 2

09:15 - 09:40 **Re-cap from last meeting and new evidence comparing EMA, HC, FDA approach for highly variable drugs and replicate design; consumer risk?**
Wanjie Sun, US-FDA, USA

09:40 - 09:55 **News from EMA on requirements for highly variable drugs and replicate design**
Paulo Paixao, University Lisbon, Portugal

09:55 - 10:25 **Discussion**

10:25 - 10:40 **Adaptive design and alpha adjustment: FDA position**
Xiaojian Jiang, US-FDA, USA (TBC)

10:40 - 10:55 **Novel approaches in adaptive design and alpha adjustment, e.g. for parallel design studies, or integration of pilot into pivotal studies**
Helmut Schütz, BEBAC, Austria

10:55 - 11:25 **Discussion**

11:25 - 12:00 **Coffee and tea break**

Modeling & Simulation

12:00 - 12:20 **Introduction and example(s) to illustrate the opportunities of modeling & simulation to support virtual BE**
Paula Muniz, CTI, *Model Informed Development, Spain*

12:20 - 12:35 **Leveraging Model Integrated Evidence for Generic Drug Approval**
Liang Zhao, US-FDA, USA

12:35 - 12:50 **EMA perspective on model based BE**
Michiel van den Heuvel, PK assessor in MEB, member of EMA MSWP and MWP, The Netherlands

12:50 - 13:05 **IVIVC or PBPK, potential for waiver of in vivo BE studies from an innovator's perspective**
Sebastian Haertter, Boehringer Ingelheim, Germany

13:05 - 13:30 **Discussion**

13:30 - 14:30 **Lunch break**

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14:30 – 18:30 **Session II:**	**Fed vs fasting conditions in BE trials: current status and new insights** Session co-chairs: *Henning Blume, SocraTec C&S, Oberursel, Germany* *Jan Welink, MEB, Utrecht, The Netherlands*
	Introduction to Session II:
14:30 - 14:50	**Current regulatory thinking and where do we stand after GBHI-1 and GBHI-4?** *Jan Welink, MEB, The Netherlands*
14:50 - 15:10	**Fasted vs. fed state: what are the most essential differences in GI physiology which may affect the in-vivo performance of immediate release solid oral dosage forms?** *Mirko Koziolek, AbbVie, Germany*
15:10 - 15:20	**Discussion**
15:20 - 15:40	**Comparability of different capsule types: In-vivo performance of capsule shells in fasted vs. fed stomach and consequences for BE assessment** *Werner Weitschies, University Greifswald, Germany*
15:40 - 15:55	**Discussion**
15:55 - 16:30	**Coffee and tea break**
16:30 - 16:50	**Biopharmaceutical and pharmacokinetic characteristics of the active drug ingredient: which properties may be critical for comparability in fasted vs. fed state?** *Christos Reppas, National and Kapodistrian University of Athens, Greece*
16:50 – 17:05	**Discussion**
17:05 - 17:25	**New food trends: possible impacts on gastrointestinal function** *Clive Wilson, Strathclyde, UK*
17:25 – 17:40	**Discussion**
17:40 - 18:20	**Overall Discussion**
18:20 – 18:45	**Pearls of Bioequivalence Award 2022**
19:30 - 22:30	**Conference dinner**

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8:00 – 11:45 **Session III:**	**Equivalence assessment of topical products: product-dependent approaches** Session co-chairs: *Mehul Mehta, US Food and Drug Administration, Silver Spring MD USA* *Barbara Schug, SocraTec R&D, Oberursel, Germany*
08:00 - 08:20	**Introduction: why the site of action matters also for topicals** *Barbara Schug, SocraTec R&D GmbH, Germany*
08:20 - 08:35	**Which type of studies are needed for approval of generic topical products and in the case of major changes: Current position of FDA** *Wenlei Jiang, FDA, USA*
08:35 - 08:50	**Clinical endpoint studies, pharmacodynamic studies, cutanous PK studies and waiver option: EMAs current thinking and discussion process** *Evangelos Kotzagiorgis, EMA, The Netherlands*
08:50 - 09:05	**Which type of studies are needed for approval of generic topical products and in the case of major changes: Current position of ANVISA** *TBD*
09:05 – 09:20	**Discussion**
09:20 - 09:50	**Scientific background of appropriate comparative physicochemical characterisation, IVRT and IVPT of topical formulations** *Majella Lane, University College London - School of Pharmacy , UK*
09:50-10:20	**Requirements for a waiver of in-vivo studies based on qualitative, quantitative and structural similarity as well as IVRT and IVPT: example acyclovir topical cream** *Wenlei Jiang, FDA, USA*
10:20 - 10:35	**Discussion**
10:35 - 10:50	**Coffee and tea break**
10:50 - 11:10	**Promising technologies: Raman Spectroscopy and Thermodynamic and Functional Characteristics of Compositionally Different Topical Formulations** *Mehul Mehta, FDA, Rockville*
11:10 - 11:30	**Promising technologies: microperfusion** *Frank Sinner, Joanneum Research, Austria*
11:30 - 11:45	**Discussion**
11:45 - 13:00	**Lunch break**

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13:00 – 17:30 **Session IV:**	**Bioequivalence evaluation of narrow therapeutic index (NTI) Drugs** Session co-chairs: *Wenlei Jiang, US-FDA, Silver Spring, USA* *Yu Chung Tsang, Apotex, Toronto, Canada*
13:00 - 13:15	**Justification of the Current Regulatory Approach by EMA** *Jan Welink*
13:15 - 13:30	**Justification of the Current Regulatory Approach by U.S. FDA** *Wenlei Jiang, US-FDA, Silver Spring, USA*
13:30 - 13:45	**Justification of the Current Regulatory Approach by PMDA** *Toru Yamaguchi, PMDA, Japan*
13:45 – 14:15	**Panel discussion**
14:15 - 14:30	**Coffee and tea break**
14:30 - 14:50	**Statistical implication of divergent bioequivalence evaluation for NTI drugs** *Dr. Shein-Chung Chow, Duke University, USA (TBC)*
14:50 - 15:00	**Discussion**
15:00 - 15:20	**Challenges in global development of generic NTI drugs** *Dr. Gerald Beuerle, Teva, Germany*
15:20 - 15:30	**Discussion**
15:30 - 15:50	**Alternative thinking regarding bioequivalence evaluation of NTI drugs** *Dr. Paulo Paixao, University Lisbon, Portugal*
15:50 - 16:00	**Discussion**
16:00 - 16:20	**Debate the merit of pharmacokinetic variability comparison** *Dr. Leslie Benet, University of California, USA (TBC)*
16:20 - 16:30	**Discussion**
16:30 - 17:00	**Panel discussion**
17:00 - 17:15	**Closing remarks, Future of the Global Bioequivalence Harmonization Initiative**