Bioequivalence for Immediate-Release Solid Oral Dosage Forms Category (M) New GL

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Problem statement

- **What is the main issue proposed to be addressed? (1 slide)**
  - We propose to develop a series of new ICH guidelines to address topics related to bioequivalence (BE) assessment for immediate-release (IR) solid oral dosage forms
  - This proposal represents an important next step for harmonization of generic drug standards as proposed in the FDA, United States Reflection Paper endorsed by the ICH Assembly in November 2018
- **Why is this a problem? (brief and practical description of current effects deriving from lack of harmonisation in the field – can be a case study – 1-3 slides)**
  - Differences in guidance on BE studies between jurisdictions hamper global harmonization of generic drug development
    - Duplicative BE studies to support requirements from more than one jurisdiction
    - Additional development time

Main technical/scientific challenges foreseen in the process

- **Where are the differences in current practice between ICH members/views within the expert community? (1-2 slides)**

1. **Study design**
-e.g., crossover vs. parallel, subjects (healthy vs. patients), sample size, fasting vs. fed, replicate vs. nonreplicated design, single dose vs. multiple dose, analyte to be measured (e.g., parent vs. metabolite)

2. **Provisions for waiving BE study requirements (e.g., granting biowaivers) for IR solid oral dosage forms**

3. **Statistical Analysis**
-e.g., statistical methods for BE assessment, handling of outlier data, average bioequivalence vs. scaled bioequivalence

4. **Data interpretation and BE acceptance limit**
-e.g., BE standards for narrow therapeutic index (NTI) drugs are different across jurisdictions

Objective(s) of the new topic proposal

- **What will the new topic aim to achieve? (1 slide)**
  - Create common study design and assessment methodologies for BE evaluation to streamline generic drug development

Objective(s) of the new topic proposal

- **How will these achievements bring an improvement in the field/positive impact on public health? (1 slide)**
  - The generic drug industry could use one study design for multiple jurisdictions
  - Innovator companies may also benefit in the cases where BE principles are used to establish links among formulations
  - Reduce potentially duplicative work
  - Maintain rigorous standards of BE requirements
  - Enable the timely approval of safe, effective and high quality generic drugs
  - May facilitate entry of high quality generic drugs in developing countries

→ Improve patient access to high quality and affordable generic drugs

Objective(s) of the new topic proposal

- **What resources/expertise will be needed to achieve this? (1 slide)**
  - Most jurisdictions have published their own guidances/guidelines on BE assessment for IR oral dosage forms
    → can serve as the foundation for harmonization
  - Need experts who have knowledge in bioequivalence, pharmacokinetics, PK study design, biostatistical methods for BE evaluation, biopharmaceutics, and in vitro dissolution
  - Collaborate with the "to-be-established" informal generic drug discussion group (IGDG) on the scope and prioritization of BE topics to be included in the ICH guidelines

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Thank You!

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