EMEA/EFPIA Workshop

Integrating PGx early into drug development

PK as a working example

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Objectives for today

1. To exchange knowledge about the various approaches on the application of PGx in early drug development, using PGx in PK studies as an example and special breakout/workshop sessions
2. To give this reflection a global perspective
3. To agree on the need for potential future regulatory guidance(s) in this area, and on their aim
4. To determine whether next steps for this workshop would be a collaborative effort on a white paper and/or on any future regulatory guidance

Steps to reach the objectives

1. PGx in PK studies *(1h15)*
   - The CHMP Reflection Paper (adopted May 2007)
   - The EFPIA experience and expectations
   - The PMDA experience and expectations
   - The FDA experience and expectations
2. Does PGx/PK add value to drug development? *(40 min)*
3. Four breakout sessions *(1h35)* + debriefing / Q&A *(1h)*
4. PGx/PK in medical practice: does it help? *(35 min)*
5. Panel discussion – conclusions *(40 min)*

16 h 30

The 4 breakout sessions (case scenarios)

Observation :	*Does this impact…*
PK variation in preclinical studies	first in Human study design ?
PK variation in phase I studies	phase II design ?
Specific PGx knowledge before clinical trial	planning/submission of a clinical trial application (CTA) ?
Newly published PGx data with potential influence on PK/PD	ongoing phase II study ?