



EMEA/EFPIA WORKSHOP
Integrating Pgx Early into Drug Development:
PK as a working example

19th December 2008
EMEA Headquarters, Canary Wharf, London, UK
Meeting room 2A

FINAL AGENDA

08.00 – 08.30	Registration and welcome coffee	
08:30 – 09:00	Chairpersons opening statement, background and objectives	Co-Chair: Prof Bruno Flamion (SAWP-Chair, CHMP Member) Co-chair: Dr Duncan McHale (EFPIA/Astra Zeneca)
09:00-10:15	Session 1: Pgx in PK from various Perspectives	Speakers
	Applications of PGx in PK at EMEA: experience and expectations	Dr Mark Maliepaard: CHMP/PGEWP
	Applications of PGx in PK for drug development: the industry experience and expectations	Dr Brian Spear: (Abbott)
	Applications of PGx in PK at PMDA: experience and expectations	Dr Yoshiaki Uyama
	Applications of PGx in PK at FDA: experience and expectations	Dr Lawrence Lesko
	Panel discussion	
10:15-10:30	Coffee Break	
10:30-11:10	Session 2: How and when might PGx in PK be integrated and add value into drug development?	
	Gaining consensus on emerging science: the ADME panel as an exemplar	Dr Beena Koshy: GSK
	A worked example to introduce the Pgx clinical science in a variety of typical drug development situations.	Dr Linda Surh: GSK

11:10-12:45	Session 3: Breakout sessions Examples of Pgx from the Context of Drug Development Decisions around PK Variation	
	<p>Four Parallel Case Study Scenarios:</p> <ol style="list-style-type: none"> 1. First in Human trial design is being planned: How does in-vitro ADME data affect trial design? 2. Phase 2a trial design is being planned: How does pk variation observed in Phase 1 affect trial design? 3. A CTA is planned: What if the team wants to include Pgx data using a specific format and standard in the submission? 4. Phase 2 is ongoing: How does evolving data (PK and PD) affect Phase 2b trial design? 	<p>Dr Alun McCarthy: ABPI/ PGXIS Dr Magnus Ingelman-Sundberg: CHMP/PGEWP</p> <p>Dr Linda Surh: GSK Prof Spiros Vamvakas: (EMA)</p> <p>Dr Peter Groenen: (Schering Plough) Prof Giuseppe Novelli: CHMP/PGEWP</p> <p>Dr Jeroen Aerssens: (Johnson & Johnson) Dr Ann Daly: Newcastle University Medical School</p>
12:45-14:00	Lunch Break	
14:00-15:00	Plenary session: Debrief from breakout session with Q&A	Moderator: Dr Linda Surh: GSK
15:00-15:15	Coffee Break	
15:15-16:30	Session 4: Agreeing consensus and gaps, next steps	
	Application of PGx in PK in medical practice: how does PGx inform decisions?	Dr Munir Pirmohamed University of Liverpool
	Panel discussion : Overall conclusion	Moderators: Prof Bruno Flamion/ Dr Duncan McHale
16:30	Chairs' closing remarks and future actions	Prof Bruno Flamion/ Dr Duncan McHale