



**The need for pharmacovigilance in the
resource limited setting:
an industry perspective**

Madrid

March 2006

Didier Lapierre MD

Benefit/Risk evaluation and drug development

- Traditionally clinical research has been performed in the “Western World”
 - Availability of infrastructure
 - Regulatory environment
 - IP protection
 - Access to market, return on investment
- Drug development in the Developing World was limited by Ethical and Access Challenges

Globalisation of R&D

- Why to go there ?
 - Medical Unmet needs of 80% of the population
 - Favourable political and economical environment in some countries
 - Political pressure and corporate image
- Why it is attractive ?
 - Population diversity
 - Paediatric population
 - Top quality medical centres are available in many countries like India, China, or Latin America
 - Patient have access to some healthcare system
- Many Challenges
 - Ethical eg. patient consent
 - Price and access to medicine
 - IP protection
 - Drug safety assessment

Assessment of benefit/risk : HIV treatments

- Large phase 3 ran in the developed world
- Ongoing post marketing pharmacovigilance
- Numerous phase IV trials in the DW
- Availability of treatment becomes a pharmacovigilance challenge
 - Education (eg HSR management), Capacity Building, support to local initiatives, cohorts, sentinel centres...

An even more challenging case : Disease of the Developing World (DDW)

Malaria

Mainly paediatric, 1-2 millions deaths

Safety evaluation is critical, drugs are more often used “OTC”

No PV infrastructure allowing a continuous evaluation of drug safety

Assessment of benefit/risk can only be obtained from clinical trials from phase I to phase IV

Moving forward

- FDCs are in phase III, new molecules are coming
- Phase III and phase IV planned and supported via private-public partnerships
- Lessons learned in HIV should be applied for DDW
 - Negotiation with authorities
 - Use of existing and new Networks
 - Education
 - Capacity building
- Need to “piggy bag” on large HIV initiative
- Encourage countries to develop PV system