



# Eighth International Congress on Drug Therapy in HIV Infection

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## **[PL3.5] THE NEED FOR PHARMACOVIGILANCE IN THE RESOURCE-LIMITED SETTING: AN INDUSTRY PERSPECTIVE**

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**Purpose of the Study:** Traditionally clinical research has been mainly performed in the “Western World” where medical infrastructures are available. Drug development in resource poor setting was limited by lack of capacities but also by ethical and access challenges. Globalisation of the R&D is a new reality firstly to fulfil the unmet medical needs of 80% of the world population and of the HIV patients in particular but it is also attractive from a drug development point of view. The population diversity, the top quality centres now available associated with the development of health care systems make the implementation of clinical trials in many of these countries possible and cost effective.

But performing clinical trials in these countries is only the first step. The drug will then be registered and marketed in countries where the studies were performed. To make drug available safely in these countries, a key challenge is the weakness or even the lack of pharmacovigilance systems allowing a continuous monitoring of the benefit/risk of drugs. Many initiatives of education, capacity building and cohort follow up are ongoing but there are still limited in scope. These initiatives must be supported, new one must be taken.

**Plenary Session:** New Challenges in Providing ART [IAS Session]

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