# MMV Portfolio: discovering, developing and delivering innovative products

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*MMV Portfolio: discovering, developing and delivering innovative products*
Implementation-safety study with ASAQ in Côte d’Ivoire

- Collaboration with Sanofi and DNDi in the district of Agboville
- **Implementation-safety study** in 15,000 patients to enable, with a 95% likelihood, the detection of an adverse event occurring with a rate of 1/5000 (classified as “rare” adverse event)
- End of January 2013:
  - 13,018 patients recruited,
  - 85 SAEs reported,
  - signal detected and SmPC updated: extrapyramidal symptoms
  - between 10 and 40% of the patients reporting AEs to Community Health Workers
Implementation-Safety (INESS) Study with Eurartesim® (DHA-piperaquine)

- Collaboration with Sigma-Tau and INESS in Tanzania, Mozambique, Burkina Faso, and Ghana
- **Implementation-cohort event monitoring study** in 10,000 patients to enable, with a 95% likelihood, the detection of an adverse event occurring with a rate of 1/3,000 (classified as “rare” adverse event): *safety focused on cardiotoxicity and QT*
- Registration granted in Ghana in January 2013, study expected to start in Q2 2013
Implementation-Safety Study with Pyramax® (pyronaridine/artesunate) in the Mekong

- Collaboration with Shin Poong and WHO in Western Cambodia and Eastern Thailand
- Implementation-cohort event monitoring study in 3,000 patients to enable, with a 95% likelihood, the detection of an adverse event occurring with a rate of 1/800 to 1/1,000 (classified as “uncommon” to “rare” adverse event): safety focused on hepatotoxicity
- Protocol in development
EDCTP Longitudinal Repeat Dose Study

- Phase IIIb/IV randomized, comparative, open, multi-centre study of the safety, efficacy, and impact of repetitive treatment with four artemisinin-based combination therapies (AS-PYR (Pyramax), DHA-PQP (Eurartesim), AS-AQ, and AR-L) on the incidence of uncomplicated malaria in children
- This design will clarify the safety profile of Pyramax and Eurartesim in a context similar to large-scale deployment of these new drugs in sub-Saharan Africa
- Study started in October 2011
- January 2013, hepatic safety IDMC review of 59 patients retreated at least once with Pyramax:
  - No difference between first and following treatments
  - No difference compared to the safety profile observed during the development of Pyramax
Effectiveness and Cohort Event Monitoring with AS-SP in Orissa, India

- Collaboration MMV, NIMR and NVBDCP
- Effectiveness and cohort events monitoring study in the region of Orissa
- Treatment:
  - AS+SP + Single-dose PQ for *P. falciparum*
  - CQ+ 14 day PQ for *P. vivax*
- Then in collaboration with DNDi: AS-AQ, AS-MQ and DHA-PQP?
- Programme should start in June 2013
Injectable artesunate

• 19 cases of delayed hemolysis reported in five publications with the Guilin injectable artesunate
• One anecdotal report with the WRAIR injectable artesunate
• Meeting on 19 March in Vienna to discuss:
  • reported cases,
  • data from SEAQUAMAT, AQUAMAT and SMAC,
  • possible mechanism of action and
  • next steps:
    • amendment to the current implementation protocol on-going in DRC, weekly hematological follow-up until D28 added to the initial protocol
    • cohort event monitoring study with Swiss TPH in Central Africa (DRC, CAR, Congo, Gabon, Cameroon, Chad)
    • severe malaria registry in hospitals from West and East Africa
THANK YOU
MERCI