Pre-exposure prophylaxis in France

Jean-Michel Molina
Jean-Pierre Aboulker
Jean-Marie Le Gall
Bruno Spire
Rational for an intermittent PrEP trial in France

- Higher incidence in the MSM group
- Possible better acceptability of intermittent treatment vs. continuous
- Expected better adherence, tolerance and costs
- Allows an individual risk management according to lifestyle
- Need in the community: 40% of MSM interested
Study design

- PREP on demand

- A comprehensive risk reduction intervention including HIV testing, counseling, HBV vaccination, STI treatment and randomization Tenofovir/FTC vs. placebo

- 2 tablets 24h before exposure, followed by 1 tablet 24 hours after the first intake, every 24 hours during risk exposure period and 24h after the end of the period of exposure

- Principal outcome criteria: HIV incidence

- 1900 participants are needed
Enrolment & follow-up

- >18 years old, MSM, HIV, HCV HBV negative
- High risk
  - Unprotected anal sex with at least 2 partners in the last 6 months
- At month 1, 2 and every 2 months
  - HIV test
  - STI diagnosis
  - ARV Tolerance
  - Self-administered questionnaire (through internet)
- Basic counseling for all participants
- Motivational counseling proposed to all participants
Socio-behavioural and economical issues

- Risk compensation
- Adherence to PREP (skipping doses, respect of timing and number of pills...)
  - Self-administered questionnaires
  - Pill count
  - Hair dosage
- Impact of motivational counseling
- Cost-effectiveness: cost / infection avoided & cost / life additional year
Recruitment

- Outreach through community and testing sites
- Phase 1: 300 participants recruited until Feb 2013
- Challenge: ideological obstacles