



AGENCE NATIONALE DE RECHERCHES SUR LE SIDA  
NATIONAL AGENCY FOR AIDS RESEARCH

# Pre-exposure prophylaxis in France

**Jean-Michel Molina**  
**Jean-Pierre Aboulker**  
**Jean-Marie Le Gall**  
**Bruno Spire**



Membre de la Coalition Internationale Sida



**Inserm**

Institut national  
de la santé et de la recherche médicale

**SE42**

UMR 912 / Inserm / IRD  
Université AIX-MARSEILLE

# **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

