



Pre-Exposure Prophylaxis

Challenges of Clinical Trial Designs, Degree of Evidence and Recommendations

9h. Where are we, what do we know, what do still don't know?

Overview of the ongoing PrEP Trials (pipeline, phase I, phases II, phase III)
Towards implementation: demonstration projects, regulatory issues and beyond
Outstanding issues: adherence, drug concentrations and levels of protection

11h. Ongoing researches: objectives, designs, levels of evidence and ethical issues

Which standard of prevention is applied in the PrEP trials? Does it correspond to the local standards?
Does placebo in Prep intermittent trials counteract the Helsinki Declaration?
Will it still be feasible to conduct phase III trials?
What are the alternative designs?

14h: Recommendations' production

What kind of evidence can be drawn from researchers others than phase III efficacy trials
(observational studies, phase II studies, adaptive etc.)?
Is it possible to make recommendations on their basis?
When does evidence becomes standard of care or standard of prevention?
What are the rules usually applied? Are there scales of evidence and scales of recommendations?

15h30: Round Table and concluding remarks

29 janvier 2013 – Mairie du 10^e arr. de Paris