



An update on PrEP research in Europe

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Current European PrEP trials



Study design	name	intervention	location	N	Primary Outcome	closes
RCT	PROUD	Daily truvada	UK	544 (356)	HIV incidence	Oct 16
RCT	IPEGAY	Event driven truvada	France	400	HIV incidence	No placebo
Cohort	Be-PrEP-ared	Choice	Belgium	200	Uptake, acceptability	2018
Cohort	AMPrEP	choice	Holland	370	Uptake, acceptability	2018

Results from PROUD and IPERGAY



- **High HIV incidence in control groups**
- **High Effectiveness : 86%**
- **High STIs** – but no different between arms in PROUD

Planned European PrEP research



Study design	name	intervention	location	N	Primary Outcome	Opens
RCT double-dummy	DISCOVER	Truvada vs F/TAF	EU	5000		2016
implementation research to upscale PrEP in Paris area	ANRS Prevenir	Truvada	France	>3000		Nov 2016
Ex vivo challenge	TAP R-PrEP	FTAF Raltegravir +/- 3TC	UK	24 24	Ex vivo infection	2017

Current European high risk cohorts



At least 8 countries have high risk cohorts of MSM, transgender, sex worker and/or PWID populations

- HIV incidence
- STI incidence in some
- No PrEP offered
- “in readiness” for PrEP



PrEP provision in Europe



France:

- only country providing PrEP
- numbers been limited as must be prescribed by HIV physician
- So far > 800 individuals have received PrEP and numbers are increasing steadily Now PrEP can be also prescribed in STI clinics

UK:

- plans being made for provision of PrEP within a £2M budget
- Judicial review outcome due July 2016 to determine if NHS England is responsible for commissioning PrEP. If they are not then it is not clear who is!
- meanwhile increasing use of generic drug imported for personal use

Diverse health systems in Europe affect the organisation and delivery of health care



Countries differ on healthcare provision

- National health systems
- Mixed health insurance
- Private insurance
- Out-of-pocket payment

How health care is organised and financed will affect decisions on the payment threshold for PrEP

Eg: Germany: private healthcare does not cover prevention

A medicine for treatment and prevention



HIV prevention often occurs via NGOs and public health authorities



HIV medicines for treatment often via clinical bodies, hospitals

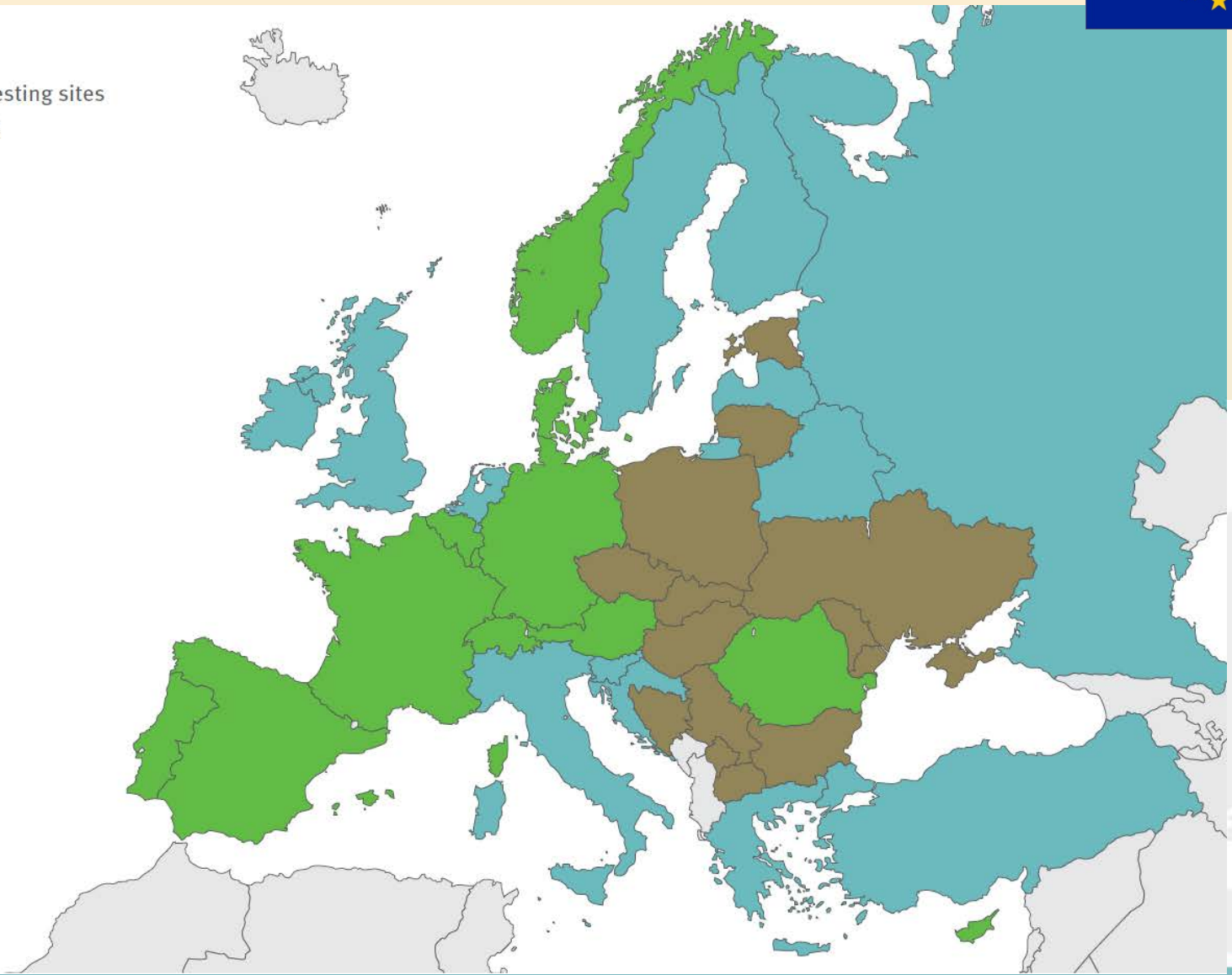


Settings for HIV testing varies across Europe



- Private practices
- Hospitals
- Community based testing sites
- Missing or excluded

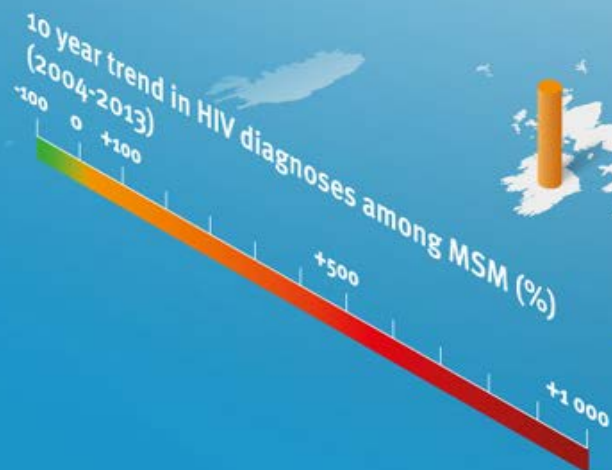
- Non-visible countries
- Luxembourg
 - Malta



Largest proportional increases in new HIV diagnoses among MSM are in countries in Central and Eastern Europe

HIV and MSM

In Europe, sex between men is still the predominant mode of HIV transmission. Men who have sex with men (MSM) are the only key population not to see a decline in new infections during the last decade: new diagnoses increased by 33% compared to 2004.



Number of cases among MSM increased in all but 4 countries

EU PrEP meeting July 2016



need to discuss trial designs that could be implemented in Europe where healthcare systems differ and PrEP is not funded

Concern : The size of non-inferiority designs may be prohibitive and interpretation of results difficult without knowing population incidence.

Areas to discuss:

- quicker/ better approaches for PrEP clinical research
- Whether PK/PD with animal or human challenge can provide a path to licensure,
- An agreement made about how to extrapolate efficacy from smaller studies of very high risk individuals

Overall



Momentum is growing in Europe with regard to the use of PrEP but different health systems make decisions on funding and implementing PrEP complex

Demonstration projects are needed in most countries as comprehensive sexual health provision including HIV testing are rarely integrated

Facilitating PrEP trials in Europe needs further work and this will be discussed in July 2016

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