



Partner Study

Investigator meeting CROI
Atlanta 4th March 2013

Agenda

- Welcome - Andrew Phillips
- Status of PARTNER - Andrew Phillips
 - Open sites
 - Recruitment
 - Follow up
- Follow-up data and projections PARTNER - Valentina Cambiano
- PARTNER until April 2014 and forward - Alison Rodger
- Funding for PARTNER stage 2 - Jens Lundgren

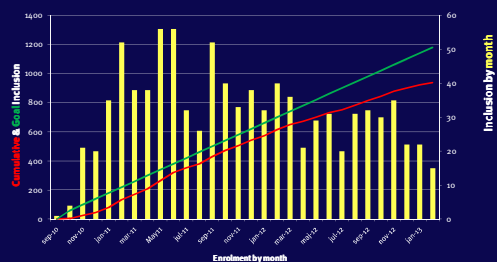


Welcome



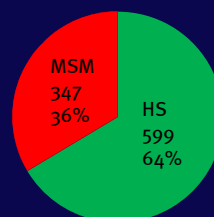
Study update

Enrolment by month Sep. 2010 to Feb. 2013



Couples enrolled and MSM/Hetero

Total enrolment: 946



Global overview

Update on enrolled partnership as of 28 February 2013

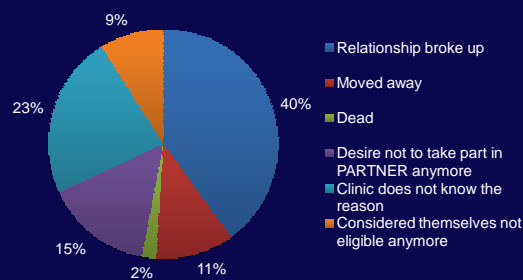
Country	Open sites	In last 2 weeks	No. of pairs enrolled		
			Total	Projected total	% of projected enrolled
Austria	4	0	50	60	83
Belgium	3	0	12	45	27
Denmark	4	2	62	67	102
Finland	1	0	15	15	100
France	5	2	70	130	54
Germany	8	2	103	99	104
Ireland	1	0	12	20	60
Italy	6	2	55	118	47
Portugal	1	1	15	20	70
Spain	12	5	194	312	62
Sweden	2	0	38	40	95
Switzerland	5	0	96	90	107
Netherlands	3	2	37	45	82
UK	21	4	167	357	52
Total	75	20	946	1412	67%



PARTNER Follow-up data and projections Valentina Cambiano

Retention in PARTNER

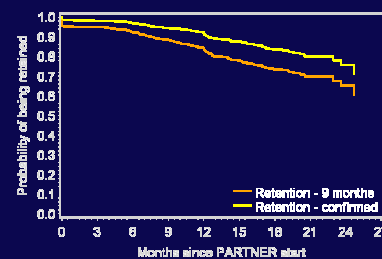
100 couples dropped out (clinics confirmed with Tina)



Retention in PARTNER

100 couples dropped out (confirmed with Tina)
+69 couples, at least 1 member of the couple has not been seen for at least 9 months

169 / 845 CYFU = 20 drop-out rate per 100 CYFU



PARTNER – What do we need to estimate the risk of transmission?

Number of new HIV infections
Couple-years of eligible follow-up

1 couple-year of follow-up

= follow 1 couple from when both have the 1st CRF filled for 1 year

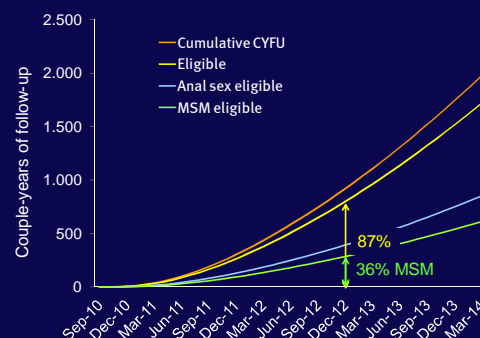
= follow 12 couples from when both have the 1st CRF filled for 1 month

Which information do we need for a couple-year to be **eligible**?

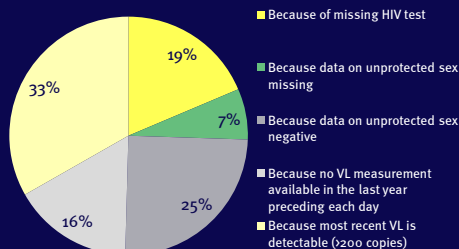
- Viral load <200 copies/ml measured in the last 12 months
- HIV test for the non-index partner
- Unprotected sex reported (by the HIV- partner)



Couple-years of follow-up accumulated



Why only 87% of CYFU are eligible for primary analysis?



PARTNER - until April 2014 and onward PARTNER Stage 2

PARTNER stage 1 and stage 2 -what will be achieved

Stage 1: Hypothesis to be addressed mid 2014:

*The risk of HIV transmission with condom-less penetrative sex is very low when the HIV positive partner has an undetectable viral load.**

In other words, the study will at the completion of the first stage be able to establish the average risk of transmission for couples having condom-less sex, amongst which around 48% are practising condom-less penetrative anal sex.*

Stage 2: Hypothesis to be addressed by 2017:

*The risk of HIV transmission with condom-less penetrative sex is very low when the HIV positive partner has an undetectable viral load regardless of sexual practice**.*

In other words, the study will at the completion of the second stage be able to establish the risk of transmission for couples practising condom-less penetrative anal sex as well as the risk for couples practising only vaginal sex.

* since the proportion of couples followed having anal sex is only around 40%, there will be less certainty over whether the rate is low specifically for anal sex.

** ie including anal sex



PARTNER stage 2 April 2014-April 2017

- Continues to follow up both hetero sexual couples having anal sex and MSM?
- Follow up couples/MSM having anal sex?
- Continue to recruit only MSM couples



HPTN 052, PARTNER stage 1 and stage 2

Table 2: Comparison of results generated by HPTN 052, and projected for PARTNER stage 1 and 2

	HPTN 052	PARTNER stage 1 (by March 2014)	PARTNER stage 2 (by March 2017)
Number of serodiscordant couples	1763	App 1350	App 1780
Number MSM couples	37	App. 500	App. 950
Condom-less sex	96% reported regular condom use 5-6% reported having unprotected sex prior to enrolment	Only couples reporting having sex without condom will be included in the final analyses.	Only couples reporting having (anal) sex without condom will be included in the final analyses.
PYFU overall	1585	2015	3590
PYFU eligible	1145	1753*	3124*
PYFU of condomless sex	Estimated <200 PYFU	1753*	3124*
MSM/Anal sex	2%	48%	100%
PYFU from anal sex couples	Unknown < 50	879	2250



HPTN 052, PARTNER stage 1 and stage 2 -cont

Table 2: Comparison of results generated by HPTN 052, Partner 1 and 2

	HPTN 052	PARTNER stage 1 (by March 2014)	PARTNER stage 2 (by end March 2017)
PYFU receptive anal sex with ejaculation	Unknown	282	726
upper 95% confidence limit for Risk of transmission – overall	If no transmissions occur in the study: 1/54 couple years combined	If no transmissions occur in the study (**): 1/474 couple years combined	If no transmissions occur in the study (**): 1/847 couple years combined
upper 95% confidence limit for Risk of transmission – anal sex	If no transmissions occur in the study: 1/14 couple years anal sex	If no transmissions occur in the study (**): 1/238 couple years anal sex	If no transmissions occur in the study (**): 1/610 couple years anal sex

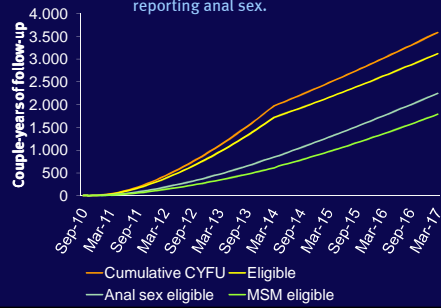
* Eligibility criteria: HIV negative reporting condom-less sex; HIV+ VL<200 in the last year

** These numbers will be lower if one or more linked transmissions are observed (see table 1 above for details)



Projections of couple-years of follow-up: stop recruitment of heterosexual couples

Scenarios: (1) continue to recruit and follow **only MSM**
 (2) continue to follow MSM and heterosexual couples reporting anal sex.



FUNDING strategy for PARTNER stage 2

- Total cost for PARTNER stage 2 (2014-2017)
 - **637.000 €**
- The funders can be :
 - Industry
 - Global funds
 - National/local funders

