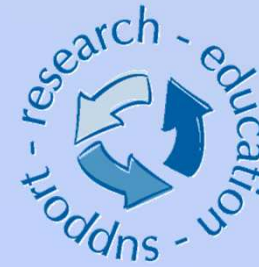


16th Annual Conference of the
National HIV Nurses Association (NHIVNA)



National HIV Nurses Association

Janey Sewell

University College London

26-27 June 2014- City Hall, Cardiff

HIV transmission risk through condomless sex if the HIV positive partner is on suppressive ART: PARTNER study

Janey Sewell
for the PARTNER Study Group

University College London



Background

- Important to understand the absolute risk of transmission of HIV through condomless sex (CL) for a person on ART with an undetectable plasma viral load
- Taking all studies in serodifferent couples to date, condomless sex is reported for only 330¹ cumulative couple-years of follow up (CYFU)
- There is no direct evidence at all for anal sex in men who have sex with men – HPTN 052 <2% couples were MSM

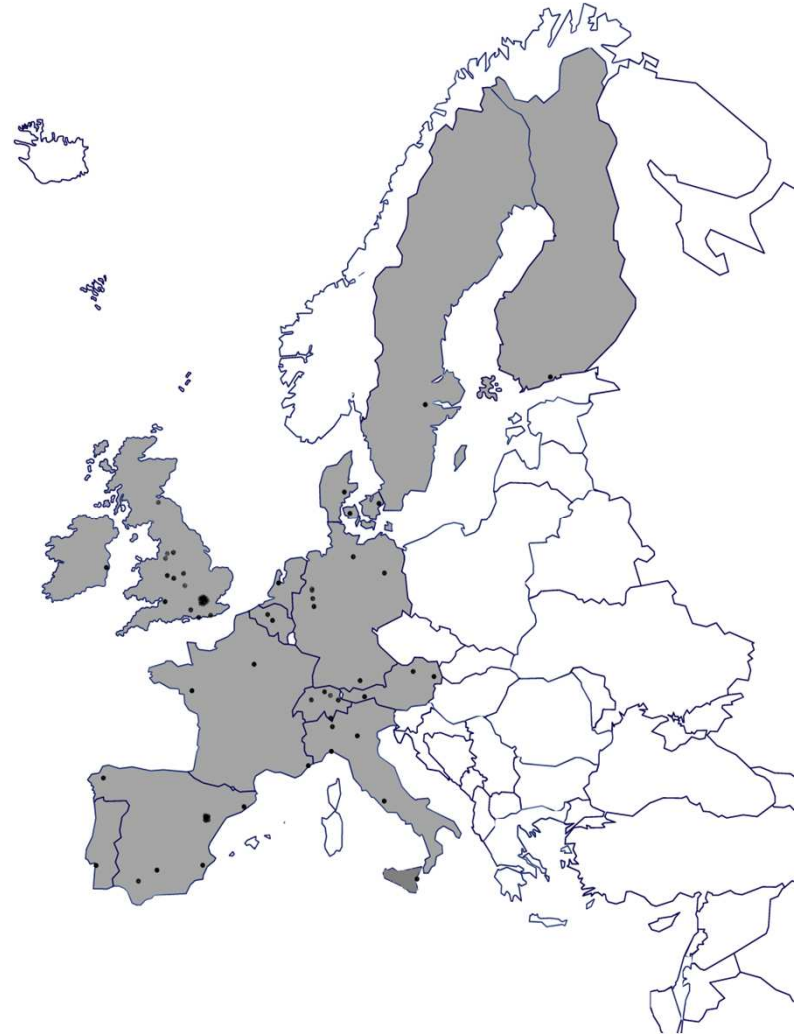
1. *Rodger et al. Antivir Ther. 2013;18(3):285-7*

PARTNER study

- The PARTNER study is an observational multi-centre study of HIV serodifferent couples in which the positive partner is on ART, taking place in 12 countries, 75 European sites, with 20 sites in the UK

Aim

- To evaluate the risk of within-couple HIV transmission (HT and MSM) during periods where condoms are not used consistently and the HIV positive partner is on suppressive ART



Study Procedures

Enrolment of couples in sero-different relationship (+ve partner on ART) who had condomless penetrative sex in the past 4 weeks

Baseline visit:

- Informed consent with reference to positive partner's HIV status - transmission risk.
- Consistent condom use is the most effective way to prevent transmission
- Self completed confidential questionnaire for both partners
- HIV test for the –ve partner
- Recording of clinical data of +ve partner (CD4/VL/ART)

Study Procedures

Follow-up visit:

- 4-6 monthly self completed confidential risk behaviour questionnaire
- HIV test for the –ve partner
- Recording of clinical data of +ve partner (CD4/VL/ART)
- Re-consented after 2 years of study participation

If, during the course of the study, the -ve partner has a positive HIV test result, blood samples are obtained from both partners for delinked anonymised viral sequencing

This planned interim analysis reports phylogenetically linked transmissions only, the total number of transmissions will remain blinded until the end of the study



Study Procedures

Overall 1,110 couples were recruited by 1st Nov 2013, of which 767 couples contributed 894 eligible CYFU (586 in HT and 308 in MSM)

- Eligible CYFU:
 - condomless sex
 - not using PEP or PrEP
 - latest HIV VL <200 copies (within max past 12 m)
- Reasons couples provide no eligible CYFU:
 - no follow-up visit (71%)
 - VL>200 (16%)
 - no HIV test (5%)
 - PEP/PrEP (3%)
 - no CL sex reported (3%)

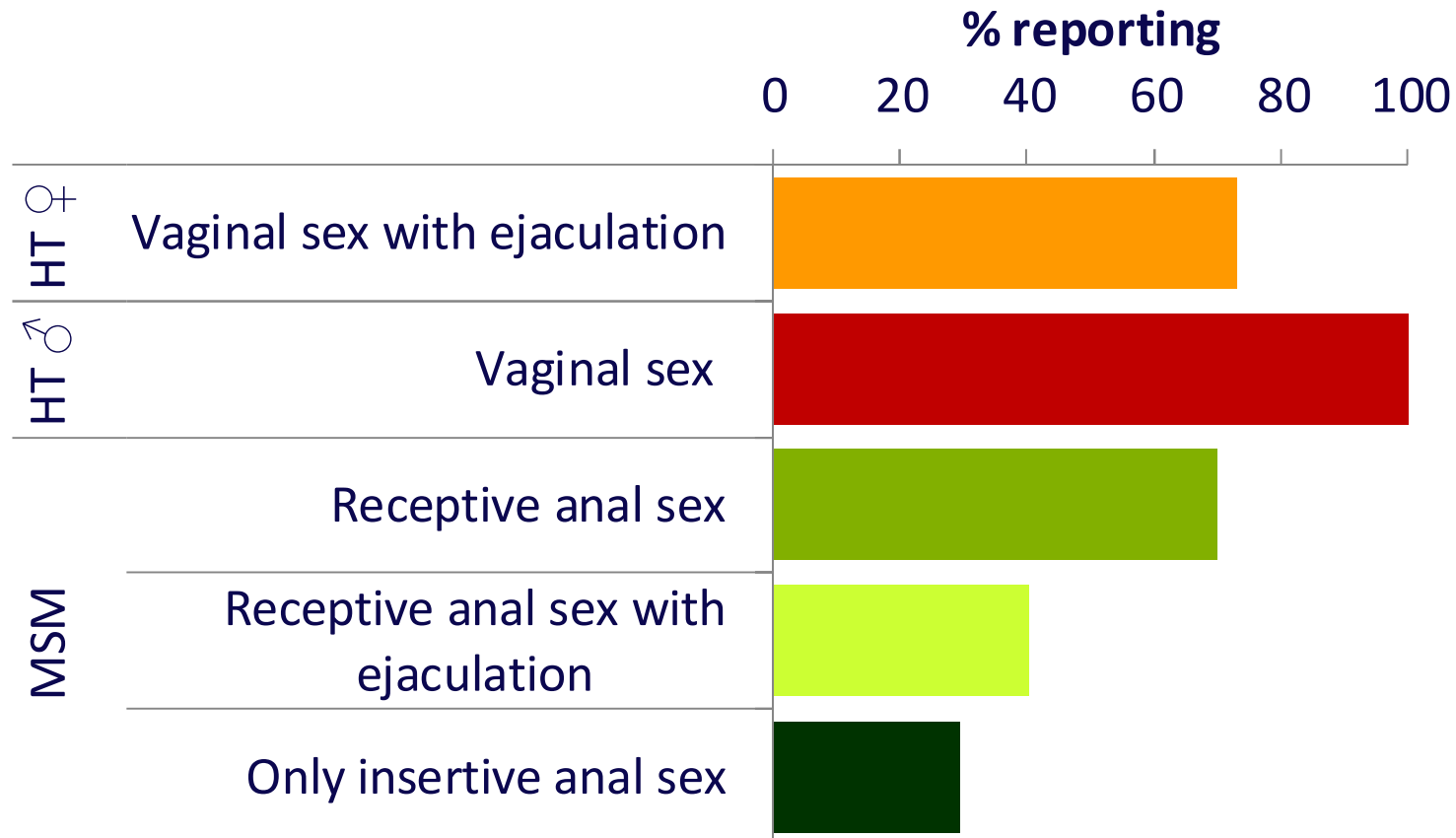
HIV negative partners: Characteristics

	MSM couples (n=282)	Heterosexual couples (n=445)	
		M -ve (n=245)	W -ve (n=240)
At study entry			
Age, median (IQR)	40 (32-47)	45 (37-50)	40 (34-46)
Years CL sex, median (IQR)	1.5 (0.5-3.5)	2.7 (0.6-6.9)	3.5 (0.7-10.6)
During follow up			
Years in the study, median (IQR)	1.1 (0.7-1.9)	1.5 (1.0-2.0)	1.5 (0.9-2.0)
Diagnosed with STI, %	16%	5%	6%
CL sex with other partners, %	34%	3%	4%
CL sex acts/year, median (IQR)	43 (18-79)	37 (14-77)	38 (14-71)
Estimated total number CL sex acts	16,400	14,000	14,000

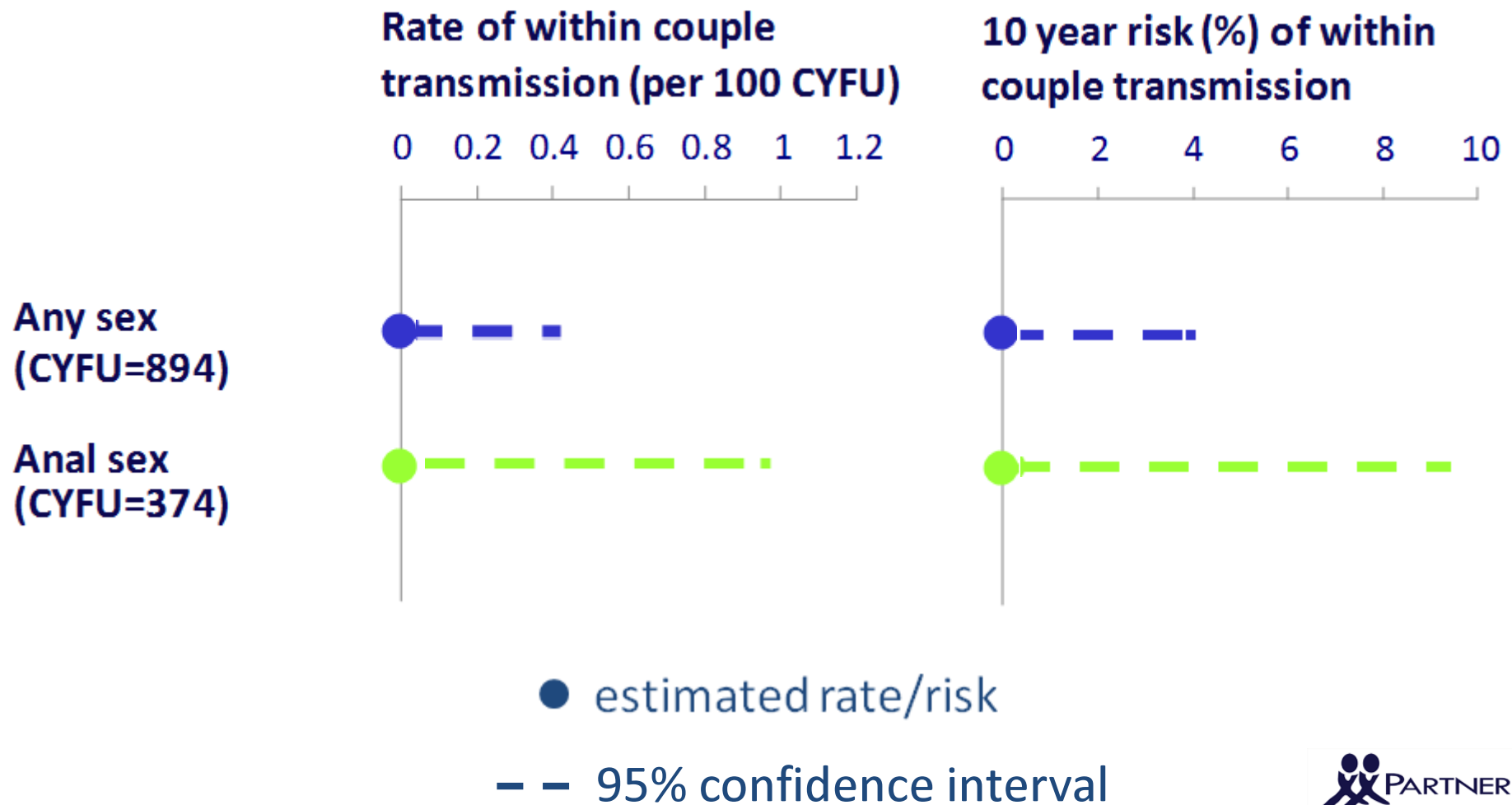
HIV positive partners: Characteristics

	MSM couples (n=282)	Heterosexual couples (n=445)	
		W +ve (n=245)	M +ve (n=240)
At study entry			
Age, median (IQR)	42 (36-47)	40 (34-46)	45 (40-49)
Years on ART, median (IQR)	5 (2-11)	7 (3-14)	10 (4-15)
Self-reported adherence $\geq 90\%$, %	97%	94%	94%
Self report undetectable VL, %	94%	86%	85%
CD4 >350 cells/mm ³ , %	90%	88%	84%
During follow-up			
Having missed ART for more than 4 consecutive days, %	2%	7%	4%
Diagnosed with STI, %	16%	4%	5%

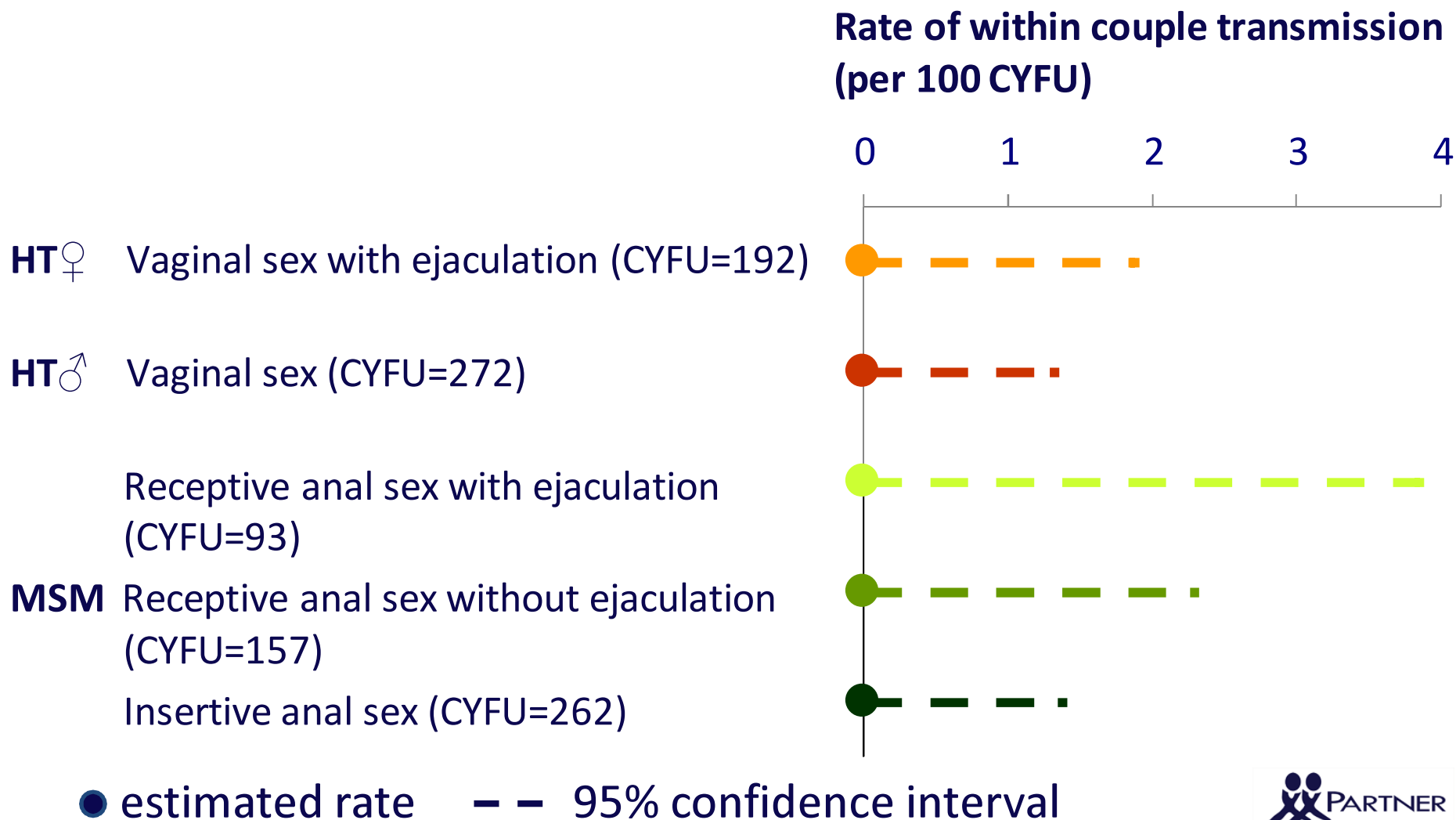
HIV-ve partners reporting condomless penetrative sex during eligible CYFU



Rate of HIV transmission according to sexual behaviour reported by the negative partner



Rate of HIV transmission according to sexual behaviour reported by the negative partner



Conclusions

- Interim results: 894 eligible CYFU report an overall HIV transmission rate of zero through condomless sex with a plasma VL < 200 copies/mL on ART, despite a significant number of sexual acts.
- However uncertainty over the upper limit of risk remains, particularly over receptive anal sex with ejaculation
- Additional follow-up in MSM is needed through PARTNER2 (2014-2017) to provide more precise estimates for transmission risk to inform policy and also individual choice on condom use

Acknowledgments

Thank you to all PARTNER study participants

PARTNER sites

Spain : Hospital Virgen del Rocío, Sevilla, Pompeyo Viciano. Hospital Universitario de Elche, Felix Gutiérrez. Hosp. Universitari Germans Trias i Pujol, Bardalona, Bonaventura Clotet. Hospital La Paz, Madrid, José María Peña. Hospital Universitario San Carlos, Madrid, Vicente Perez Estrada. Hospital Universitario Reina Sofia De Cordoba, Antonio Rivero. Hospital Clínico Universitario de Santiago de Compostela, Antonio Antela. Hospital Clínic de Barcelona, Barcelona, Jose M. Gatell Artigas. Centro Sanitario Sandoval, Madrid, Jorge Del Romero Guerrero. Hospital Ramon y Cajal, Madrid, Fernando Dronza. Hospital Carlos III, Madrid, Vincente Soriano.

United Kingdom: Chelsea & Westminster, London: David Asboe, Nneka Nwokolo, Serge Fedele and Tracey Sturt. Mortimer Market Centre, London: Richard Gilson, Nahum de Esteban and Kate Tudor. Southmead Hospital, Bristol: Mark Gompels and Louise Jennings. Coventry and Warwickshire Hospital: Sris Allan and Abayome Shomye. King's College Hospital: Michael Brady and Lucy Cambell. Brighton and Sussex: Martin Fisher, Nicky Perry and Elaney Youssef and Louise Kerr. Leicester Royal Infirmary: Jyoti Dhar and Linda Mashonganyika. Newham : Rebecca O'Connell and James Hand. Birmingham Heartlands: David White and Gerry Gilleran. St Thomas's Hospital, London: Julie Fox and Alice Sharp. St Mary's Hospital, London: Sarah Fidler and Kristin Kuldaneck. Bradford: Phillip Stanley and Sue Kimachia, Earnsdale Clinic, Redhill: Usha Natarajan. Northampton: Mohamed Ghanem and Leanne Holman. North Middlesex University Hospital, London : Jonathan Ainsworth and Anele Waters. North Manchester General Hospital: Ed Wilkins and Yvonne Clowes and Andrew Thompson. St James's, Leeds: Jane Minton and Jamie Calderwood. Hastings: Harish Patel. Whipps Cross Hospital, London: Monica Lascar.

Germany: University Clinic, Hamburg Eppendorf: Jan van Lunzen. University Hospital, Cologne Gerd Fätkenheuer. Praxis Driesener Straße, Berlin Ivanka Krznaric. Medizinische Poliklinik, Munich, Johannes Bogner. Universitäts-Hautklinik, Bochum, Norbert H. Brockmeyer. ICH Study Center, Hamburg, Hans-Jürgen Stellbrink. Gemeinschaftspraxis Jessen-Jessen-Stein, Berlin, Heiko Jessen. University Hospital, Bonn, Jürgen Rockstroh.

Switzerland: University Hospital Zürich, Rainer Weber. University Hospital Bern, Hansjakob Furrer. University Hospital Basel, Marcel Stoeckle, Kantonsspital, St. Gallen, Pietro Vernazza. Ospedale Regionale Di Lugano, Enso Bernasconi.

Denmark: Rigshospitalet, Copenhagen, Jan Gerstoft. Hvidovre Universitets Hospital, Lars Mathiesen. Aarhus universitetshospital, Skejby Lars Oestergaard. Odense Universitetshospital, Svend Stenvang.

Finland: Helsinki University Central Hospital, Matti Ristola.

Sweden: Karolinska University Hospital Huddinge, Stockholm, Katarina Westling. Södersjukhuset, Venhälsan, Stockholm, Anders Blaxhult.

Ireland: St. James' Hospital, Dublin Gráinne Cortney.

Belgium: CHU Saint-Pierre, Bruxelles, Nathan Clumeck. University Ziekenhuis, Gent, Linos Vandekerckhove

The Netherlands: AMC, Amsterdam, Jan Prins. OLVG, Amsterdam, Kees Brinkman. Medisch Centrum Jan van Goyen, Amsterdam, Dominique Verhagen. DC Klinieken, Amsterdam, Arne van Eeden.

France: Hopital de l' Archet 1, Nice, Christian Pradier. CHU Hotel-Dieu, Nantes, Francois Raffi. Hopital Tenon, Paris, Gilles Pialoux. "190", Paris, Michel Ohayon. AIDES, Vincent COQUELIN.

Austria: Medical University of Vienna, Armin Rieger. Medical University Innsbruck, Robert Zangerle. FA für Dermatologie/Venerologie, Linz, Maria Geit

Italy: San Paolo Hospital, Milna, Terease Bini. Ospedale Spallanzani, Roma Adriana Ammassari. Malattie Infettive Università di Catania, Maurizio Celesia. Università degli Studi di Modena Cristina Mussini. Universitaria San Martino, Genova, Antonio Di Biagio.

Portugal: Hospital Santa Maria, Lisabon, Nuno Janerio.

The PARTNER study presents independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research funding scheme (RP-PG-0608-10142). The views expressed in this presentation are those of the authors and not necessarily those of the NHS, NIHR or the Department of Health

