



**Minutes of the PARTNER Investigator Meeting
Monday 18th July 2011, IAS Rome**

Agenda

Chair: Prof. Antonella d'Arminio Monforte

1. Welcome
2. Enrolment Status in PARTNER:
 - Open sites
 - Enrolled pairs
3. Recruitment and feedback from the questionnaires
4. Panel discussion on recruitment
5. Update on HPTN 052

1. Welcome

Professor Antonella Monforte welcomed everyone to the meeting and reviewed the agenda as well as introducing the executive committee and the national coordinators.

Wim Vandeveldt introduced himself and discussed the role of ECAB (Community Advisory Board) in contributing to studies by reviewing and advising related to the community perspective. ECAB will be the CAB for PARTNER and will be active in collaboratively identifying ways to recruit and manage the study related to the patient perspective.

2. Enrollment Status in PARTNER:

Michelle Ellefson from CHIP updated the group on the current status of enrollment. With 67 centres total, 58 are able to recruit. Overall the study has 322 partnerships enrolled. The goal by end of 2011 is 900 partnerships (which would average 60 pairs per month for a steady recruitment). The attached slides show national projections and enrolment numbers.

3. Recruitment and feedback from the questionnaires

The coordinating centre distributed a questionnaire to the national coordinators to get more insight into the recruitment obstacles and overall procedures at the centres. The results of the questionnaire are elaborated on in the attached slide set. Jens Lundgren presented the recurring themes (based on the questionnaire results as well as teleconferences held over the last several months with the nat'l coordinators). In summary:

- There is a barrier when physicians talk about sex without condoms with their patients. One way to overcome this is to de-link the conversation so that the physician only asks about whether or not they have an HIV neg partner. Thereafter, a neutral person (study nurse) can ask them if they are having "safe sex without a condom." Pietro stressed the language here is important and suggests to avoid "unsafe sex" and instead say "sex without a condom"
- Additionally, the barrier among clinical colleagues of the lead investigator in each clinic needs to be lessened so that they feel comfortable with the study and the dialogue and that they feel the study is an important contribution.
- One suggestion here was to develop some e-learning material to make it easier for investigators to "sell" the study both to colleagues and to participants. The Coordinating Centre will explore how to develop some short

slide sets to ease communication. As this study is more behavioral and not biomedical, there is more reluctance experienced in the field.

- Finally, in the questionnaire and the teleconferences, it was apparent that it has been difficult for some centres to allocate appropriate resources to the study. To increase recruitment it will be important to get colleagues on board as it will require more than the individual lead investigator in each clinic.

4. Panel discussion on recruitment

The investigators had a good discussion about the experiences at their centres and how to increase recruitment. Although there are obstacles for some centres, other smaller centres are able to meet the targets, so it is possible and that is a positive sign. All the efforts of lead clinic investigators were highly appreciated.

5. Update on HPTN 052

Pietro Vernazza presented the 052 study and his slide set is attached to the minutes. Results from this study will be available at 4pm today at NEJM. In summary, the study experienced 28 transmissions. 27 of them were in the deferred treatment arm and 1 was in the immediate treatment arm (overall recruitment was at 1763 in 13 centres).

- The study only enrolled 4% MSM.
- Reported condom use was not yet disclosed (reported in the subsequent presentation is 92% at baseline)
- The study had VL measurements in the positive partner and an HIV test in the negative partner every 3 months
- PYFU will be disclosed this afternoon at the presentation
- No transmission while suppressed
- Even if no transmission under ART:
 - Extent of condom use not known
 - Not yet clear how many person years are with VL < 50 and with couple having unprotected sex (as is required in PARTNER study)
 - 95%-CI of trx risk for partnerships in this situation still needs to be narrowed with accumulation of more person years
 - Results essentially not informative for MSM

Pietro stressed that PARTNER, as an observational study, is the only tool that can contribute more information to the field. Additionally, the number of MSM enrolled in PARTNER will provide information that 052 cannot.