

Poster presentation

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## **P15-02. Participation in immune-based therapy trial excludes participation in future trials: solving this problem**

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### **Background**

Participation in clinical trials to evaluate immune-based therapies generally results in subjects being excluded from participating in any other trials. Reasons include trial-required structured treatment interruptions and possible bias due to persistent effects of the immune therapy. They include preventive vaccine, specific immunotherapy trials such as Quest and Remune/ALVAC, dendritic cell therapy and cytokine-based trials such as Esprit and Silcaat(IL-2) and IL-7. Therefore, there is a need to look for ethically justifiable ways whereby immune-based trials can continue to recruit participants successfully and participants can be allowed to enter subsequent trials.

### **Methods**

Ethicists, clinicians and HIV-infected spokespersons, from France and Quebec, were asked to examine this problem and identify particular issues that merit analysis.

### **Results**

Whether participation in future clinical trials should continue to be prohibited elicited positive and negative responses, qualified by whether the future trial is a drug or immune-based one and by the immune intervention to which participants had been exposed. There was agreement that exclusion has to be thoroughly disclosed for participation in a first immune-based trial. There was concern that exclusion could reduce or skew first trial recruitment. Interim ways to allow future participation are needed, such as incorporating a parallel or roll-over arm in a trial. This would also offer long-term, ongoing surveil-

lance of the effects of the earlier immune-based intervention or treatment interruptions.

### **Conclusion**

Exclusion of subjects in immune-based trials from future trials is a concern for participants and investigators that includes: 1) full disclosure of exclusion is required for valid consent to participate in immune-based trials; 2) impact of exclusion on recruitment to a first immune-based trial is unknown; 3) the potential impact of immune-based interventions on a clinical trial were participants allowed to enter future trials is undefined; 4) studying this problem will help define, analyze and show how to accommodate it in future trials.