

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.