Retrovirology

Poster presentation

P06-01. Developing a sponsor-initiated clinical guidance for AIDS vaccine research

F Priddy, J Becker and J-L Excler*

Address: Medical Affairs, International AIDS Vaccine Initiative, New York, USA
* Corresponding author

from AIDS Vaccine 2009
Paris, France. 19–22 October 2009

Published: 22 October 2009

Retrovirology 2009, **6**(Suppl 3):P90 doi:10.1186/1742-4690-6-S3-P90

This abstract is available from: http://www.retrovirology.com/content/6/S3/P90

Background

Existing ICH-Good Clinical Practices guidelines provide well established guidance for organizations conducting AIDS vaccine research. However, some important processes related to conduct of clinical studies and issues specific to AIDS vaccine research are not addressed by GCP. We developed an institutional clinical guidance document for research partners discussing essential processes and practices required to conduct IAVI-sponsored research that aims to support adherence to high ethical and quality standards. This guidance document applies to clinical trials and observational and behavioural research studies.

Methods

The document describes practices that have been developed and applied over the past decade of IAVI-sponsored clinical studies. To identify key topics, we reviewed existing guidance from GCP-related documents, the UNAIDS/WHO guidance documents ''Ethical considerations in biomedical HIV prevention trials'' (2007) and ''Good participatory practices for biomedical HIV prevention trials'' (2007), national regulations and guidance documents from other research organizations. A framework and list of key topics was circulated to collaborating investigators and stakeholders for input.

Results

The guidance document currently addresses 17 key topics: community engagement, informed consent and protection of human subjects, HIV VCT, risk reduction counseling, male circumcision, family planning services, sexually transmitted infections, screening and treatment, counselling and referral for HIV-infected individuals, referral for health services, quality assurance/quality improvement for service delivery, laboratory management, vaccine-induced HIV antibodies, treatment and compensation for physical harm, post-exposure prophylaxis (PEP) for study staff, social impact, gender, and post-trial access. Challenges encountered were to use language broad enough to recommend but not require when specific procedures may conflict with local practices or national requirements, and to determine how to effectively disseminate the guidance.

Conclusion

The clinical guidance document communicates expectations for conduct of studies, including processes responsive to the needs of study staff, study volunteers and communities, to clinical research collaborators as well as stakeholders and the larger research community.