Retrovirology

BioMed Central

Poster presentation

P15-14. Assuring data quality of the phase III vaccine trial of ALVAC vaccine priming and AIDSVAX vaccine boosting in Thailand

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

Published: 22 October 2009

Retrovirology 2009, **6**(Suppl 3):P215 doi:10.1186/1742-4690-6-S3-P215

This abstract is available from: http://www.retrovirology.com/content/6/S3/P215

Background

Data collected for a clinical trial should have errors at the minimum level; high rates of data discrepancy or incompleteness may affect validity of the trial conclusions. Proof of data quality is also an essential requirement for regulatory bodies. The study objectives were to present best practices and assess data management process and data quality of the largest trial.

Methods

Data were extracted from phase III vaccine trial conducted among Thai adults. This study began in 2003 and closed out in July 2009. To meet scientific and ethical standards, good clinical data management practice (GCDMP) had been implemented to obtain high quality data.

Results

The CDM process was prepared at the trial initiation. The systems were routinely validated; the data, IT and quality assurance staff were trained to complete their responsibilities effectively. The data collected in this study met CDM metrics in both quantity and quality. In this study, 16,402 healthy volunteers enrolled into the study for 3 years follow-up. Of the 1,148,839 case record forms (CRFs), there were 82,502 QCs composed of 21% missing data and 22% inconsistent values; time to QC resolved ranged from 7 to 11 days. There were 2,691 events of protocol deviation captured and all get resolved timely. Data coding was done for 27,714 AEs and 2,925 SAEs using MedDRA; the AE and SAE databases were reconciled prior to the study closure. Source document and CRFs were 100% verified; the accuracy assessment for efficacy and safety data was performed before declaration of clean databases for final analysis.

Conclusion

The trial had been conducted under GCDMP; best practices in quality assurance and quality control was crucial in making this trial analysis datasets valid and reliable. The results of this study were scientifically sound and in compliance with the protocol and all aspects of trial conduct.