1. Trial Subjects and Compliance With Trial Protocol
   1. DISPOSITION OF SUBJECTS

* 1. DATASETS ANALYSED
  2. PROTOCOL DEVIATIONS
  3. DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS
     1. Demographic characteristics
     2. Medical history and concomitant therapies
  4. EXTENT OF EXPOSURE
  5. MEASUREMENTS OF TREATMENT COMPLIANCE

1. Pharmacokinetic, Pharmacodynamic, and Immunogenicity Evaluation
   1. Data Sets Analyzed
   2. Demographic and Other Baseline Characteristics

* 1. Measurements of Treatment Compliance
  2. Pharmacokinetic Results
     1. Statistical/Analysis Issues
     2. Pharmacokinetic Conclusions
  3. Pharmacodynamic Results
     1. Statistical/Analysis Issues
     2. Pharmacodynamic Conclusions
  4. Immunogenicity Results
     1. Analysis of Immunogenicity
     2. Immunogenicity Conclusions

1. SAFETY EVALUATION
   1. ADVERSE EVENTS
      1. Brief summary of adverse events
      2. Display of adverse events
         1. Treatment-emergent adverse events
         2. Adverse events that led to premature discontinuation of trial drug
         3. Drug-related adverse events
   2. SERIOUS ADVERSE EVENTS INCLUDING DEATHS
   3. CLINICAL LABORATORY EVALUATION
   4. VITAL SIGNS - PHYSICAL FINDINGS AND OTHER OBSERVATIONS RELATED TO SAFETY
      1. Vital signs
      2. Electrocardiograms
   5. SAFETY RESULTS SUMMARY
2. Discussion and Overall Conclusions
   1. Discussion
      1. Pharmacodynamics
      2. Pharmacokinetics
      3. Immunogenicity
      4. Safety1
   2. Conclusions
      1. Pharmacodynamics
      2. Pharmacokinetics
      3. Immunogenicity
      4. Safety2
3. Tables, Figures, and Graphs Referred to But Not Included in the Text
   1. Disposition, Demographic, and Exposure Data
      1. Disposition
      2. Demographics
      3. Exposure
   2. Pharmacokinetic Data
   3. Pharmacodynamic Data
   4. Immunogenicity Data
   5. Safety Data
      1. Adverse Events
      2. Listing of Deaths and Other Serious Adverse Events
      3. Narratives of Deaths and Other Serious Adverse Events
      4. Clinical Laboratory
      5. Other Safety Parameters
4. References

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1. Appendices

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