[redacted] **Submitter Validation and Data Interpretation Report for** [redacted]

The following explanations are being provided to assist in interpreting known issues with the data identified in the course of converting legacy data to CDISC SDTM or from pre-validation activities.

OpenCDISC Validator Version 1.2.1 with Java Runtime 1.6.0_24 on Windows XP 5.1 x86 operating system was used for SDTM compliance check.

define.xml

Validation of the define.xml yields the error about Invalid Codelist for 'AEOUT' variable. The CRF for this study were developed using legacy procedures; therefore, the CDISC controlled terminology codelists were not applicable.

A. **Trial Design**
   a. Trial Arm (TA)
   b. Trial Elements (TE)
   c. Trial Inclusion/Exclusion (TI)
   d. Trial Summary (TS)
      - TSVAL not found in TTYPE controlled terminology codelist. This rule applies to record where TSPARMCD='TTYPE'. Currently, the validation program does not have a way to supply user-defined codelist to a subset of records.
   e. Trial Visits (TV)

B. **Special Purpose**
   a. Comments(CO)
   b. Demographics(DM)
      - No baseline result in EG and LB for subjects. Screen failed subjects [redacted] are not present in EG and LB domain.

C. **Interventions**
   a. Concomitant Medications (CM)
   b. Exposure (EX)

D. **Events**
   a. Adverse Events (AE)
      - AEOUT values are not found in OUT controlled terminology codelist. The CRF for this study were developed using legacy procedures; therefore, the CDISC controlled terminology codelists were not applicable.
   b. Clinical Events (CE)

- Invalid CESTRTPT value. Start relative to reference time point inadvertently is used instead of planned time point CETPT.

c. Disposition (DS)

d. Protocol Deviation (DV)
   - Invalid EPOCH. EPOCH has value '2' refers to the second treatment epoch.
   - DVSTDY label does not match the SDTM specifications.
     - DVSTDY label is "Study Day of Start of Deviation" instead of "Study Day of Start of Protocol Deviation".

e. Medical History (MH)
   - Start dates are expected when end dates are provided. Start dates were not available for some medical history records and are therefore null.
   - MHBODSYS values are not found in SOC controlled terminology codelist. The CRF for this study were developed using legacy procedures; therefore, the CDISC controlled terminology codelist were not applicable.

E. **Findings**

a. ECG Test Results (EG)
   - Observation date must be less than or equal to latest disposition date. The end of study date does not have the time; therefore the validation program interprets it as less than the date/time of ECG.

b. Inclusion/Exclusion Criteria (IE)

c. Laboratory (LB)
   - Observation date must be less than or equal to latest disposition date. The end of study date does not have time, therefore the validation program interprets it as less than the date/time of specimen collection.
   - Inconsistent value for lab assay names. The lab test code LBTESCD='BILI' is used for lab assays 'BILIRUBIN, TOTAL' and 'BILIRUBIN'.
   - Invalid value for --TESTCD variable. Lab test codes have special characters (e.g. META#, U-SQEP). These were transferred from central lab.
   - Missing units on value. Unit does not exist for the following assays
     - 2009 H1N1 INFLUENZA A
     - ANA INDEX VALUE
     - ANA INTERPRETATION
     - ANA PATTERN
     - ANTI-HAV, IGM
     - ANTI-RHUPH20 ANTIBODIES
     - BACTERIA
     - BENZODIAZEPINE CONFIRM
     - BILIRUBIN
     - C3 AB INTERP.
     - CMV IGG AB
     - CMV IGM AB

- COLD AGGULTININ SCREEN
- COLOR
- CRYSTAL-CA OXALATE
- CRYSTALS
- CRYSTALS-AMORPHOUS
- DIRECT COOMBS
- EARLY AG, IGG
- EBNA IGG
- EBV VCA AB, IGM
- GLUCOSE
- HEMOLYSIS
- HEMOSIDERIN, U
- HEPATITIS B VIRUS SURFACE ANTIGEN
- HEPATITIS C VIRUS SURFACE ANTIBODY
- HIV-1/2 ANTIBODY
- IGG AB INTERP.
- INFLUENZA A
- INFLUENZA A/B ANTIGEN
- INR
- KETONES
- LEGIONELLA ANTIGEN, URINE
- LEUKOCYTE ESTERASE
- MACROAMYLASE
- MONOTEST
- MUCOUS THREADS
- MYCOPLASMA IGM AB
- NITRITE
- OCCULT BLOOD
- PH
- PREGNANCY TEST, URINE
- PROTEIN
- RHUPH20 NEUTRALIZING ACTIVITY
- RHUPH20 RELATIVE TURBIDITY
- SPECIFIC GRAVITY
- UR SPERMATAZOA
- URINE CULTURE
- VCA AB, IGG
- VCA AB, IGM

- Missing value of LBORRES and LBSTRESC although units provided. It is a standard for this study to show units when there is no result.

d. Physical Exam (PE)
e. Vital Signs (VS)
   - Observation date must be less than or equal to latest disposition date. The end of study date does not have time, therefore the validation program interprets it as less than the date/time of vital sign.

F. Relationship
   a. Related Records (RELREC)
   b. Supplemental Qualifiers for AE (SUPPAE)
   c. Supplemental Qualifiers for CE (SUPPCE)
   d. Supplemental Qualifiers for CM (SUPPCM)
   e. Supplemental Qualifiers for DS (SUPPDS)
   f. Supplemental Qualifiers for DV (SUPPDV)
   g. Supplemental Qualifiers for EG (SUPPEG)
   h. Supplemental Qualifiers for EX (SUPPEX)