[redacted] Study [redacted]

[redacted]: Submitter Validation and Data Interpretation Report

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 STDM or from pre-validation activities.

A. Trial design

a. Trial Inclusion/Exclusion (TI)

- **No violation of in- or exclusion criteria was seen, thus no Domain IE was generated.**

b. Trial Summary (TS)

c. Trial Visits (TV)

B. Special Purpose

a. Comments (CO)

b. Demographics (DM)

- **RFSTDTC was populated with the screening date.**
- **RFENDTC was populated with the completion/termination date.**

c. Subject Visits (SV)

C. Interventions

a. Concomitant Medications (CM)

- **Original verbatim terms of the investigator were not available in the legacy database, but only coded according to a dictionary or free coding list or a mix of both. These coded texts were used as 'verbatim' and were re-coded with the latest dictionary if applicable.**
- **Information on concomitant medications were retrieved from several different legacy datasets. Dose, Units, routes and indications were not available in some of the legacy datasets.**
- **In the legacy data for 6 observations, patients [redacted] three times and [redacted] three times only a textual dose description was available (populated into CMDOSTXT). Where possible these entries were split into a dose (CMDOSE) and a unit (CMDOSU). Only the original entry 'AFTER INR' with no further information was set to blank, because this was not considered to be a dose.**

b. Exposure (EX)

- **Only actual administered doses from the legacy database were used to populate this domain. The information in the legacy dataset on administrations not performed (in treatment arm 'NO PLASMA') was not transferred to this domain, because these patients have not been exposed to any substance (not even Placebo). Thus 29 subjects of the DM-Domain have no entry in the EX-Domain.**

D. Events

a. Adverse Events (AE)

- **Documentations were done on both AE- and SAE-Form in the CRF. These were combined into the domain AE. All supplementary information was captured in the domain SUPPAE.**
- **On the AE-Form no field was planned for start and end year of an AE, but only for month and day. The year could be inferred without doubt from the domain DM and SV.**
- **Original verbatim terms of the investigator were not available in the legacy database, but only coded according to a dictionary or free coding list or a mix of both. These coded texts were used as 'verbatim' and were re-coded with the latest dictionary if applicable.**
- **According to legacy data, the variable AESHOSP was populated in each case a admission/discharge date was documented or the question for hospitalization was ticked.**
- **For subject [redacted] the SAE 'Death' occurred, but only little information was documented in the CRF. The start date of the SAE was denoted as 'unknown' in the CRF and was thus left blank in the data, but an 'end date'='death date' was documented. Therefore the end date has been populated, but the start date was left empty in the domain AE.**

b. Disposition (DS)

c. Protocol Deviations (DV)

E. Findings

a. Laboratory (LB)

- **In case of a missing year of blood sample but available month and day, the year 2000 was inferred from earlier or later samples.**
- **For subject [redacted] the year of the virology date was documented as 200 in the legacy database. It could be inferred without doubt, that the year was 2000.**
- **Laboratory dates/times documented in the CRF could not clearly be combined with the corresponding result datasets. Because in the results datasets dates/times were also available only these were used in the domain LB.**

- Laboratory results in the categories 'Immune Hematology', 'Viral marker' and 'Urine' do not have a unit. The corresponding unit fields have not been populated.
- Virology markers were obtained as follow-up information 6 months after the clinical part of the study (i.e. 6 months after individual trial completion/withdrawal). These results determined after study completion were intended to provide additional safety information on the patients. This resulted in dates of laboratory samples after the latest disposition date in domain DM. However, the inclusion of these measurements in the domain LB is considered to be the most appropriate place for their presentation and is seen also to provide the reviewer with relevant information
- All supplementary information was captured in domain SUPPLB.

b. Physical Exam (PE)

- Original verbatim terms of the investigator were not available in the legacy database, but only coded according to a dictionary or free coding list or a mix of both. These coded texts were used as 'verbatim' and were re-coded with the latest dictionary if applicable.

c. Subject Characteristics (SC)

d. Vital signs (VS)

F. Relationships

a. Supplemental Qualifiers

- SUPPAE

  Contains information on adverse events not included in AE
- SUPPHO

  Contains information on adverse events not included in HO
- SUPPLB

  Contains information on adverse events not included in LB
- SUPPOP

  Contains information on adverse events not included in OP

G. Custom

a. Hospitalizations (HO)

- This domain was generated as an Event domain to capture the basic information from the hospitalization documentation.

- **All supplementary information on hospitalizations was captured in domain SUPPHO**

b. Surgeries (OP)

- **This domain was generated as an Intervention domain to capture the basic information from the surgery documentation.**
- **All supplementary information on surgeries was captured in domain SUPPOP**