DM (Demographics) SV (Subject Visits)

Dummy Case Report Form (CRF)

Visit 1 - Demographics VISIT

Subject ID: SUBJID _____

Visit Date (DD-MMM-YYYY): SVSTDTC/SVENDTC DMDTC _____

Subject Initials: SUPPDM.QVAL when QNAM = SUBJINIT _____

Date of Birth (DD-MMM-YYYY): BRTHDTC _____

Sex (M/F): SEX _____

Race: RACE _____

Ethnicity: ETHNIC _____

Investigator Signature: NOT SUBMITTED _____

Date: NOT SUBMITTED _____

SV (Subject Visits) VS (Vital Signs)

Dummy Case Report Form (CRF)

Visit 1 - Vitals VISIT

Subject ID: NOT SUBMITTED _____

Visit Date (DD-MMM-YYYY): SVSTDTC/SVENDTC VSDTC _____

Height (cm): VSORRES/VSORRESU when VSTESTCD = HEIGHT _____

Weight (kg): VSORRES/VSORRESU when VSTESTCD = WEIGHT _____

Systolic BP (mmHg): VSORRES/VSORRESU when VSTESTCD = SYSBP _____

Diastolic BP (mmHg): VSORRES/VSORRESU when VSTESTCD = DIABP _____

Pulse (bpm): VSORRES/VSORRESU when VSTESTCD = PULSE _____

Investigator Signature: NOT SUBMITTED _____

Date: NOT SUBMITTED _____

MH (Medical History) SV (Subject Visits)

Dummy Case Report Form (CRF)

Visit 1 - Medical History VISIT

Subject ID: _____ NOT SUBMITTED

Visit Date (DD-MMM-YYYY): _____ SVSTDTC/SVENDTC

Condition: _____ MHTERM

Date of Onset: _____ MHSTDTC

Ongoing? (Y/N): _____ MHENRF = ONGOING if Yes is checked

Treatment Given: _____ SUPPMH.QVAL when SUPPMH.QNAM = MHTRT

Outcome: _____ SUPPMH.QVAL when SUPPMH.QNAM = MHOUT

Investigator Signature: _____ NOT SUBMITTED

Date: _____ NOT SUBMITTED

CM (Concomitant Medications) SV (Subject Visits)

Dummy Case Report Form (CRF)

Visit 1 - Concomitant Medications VISIT

Subject ID: _____NOT SUBMITTED_____

Visit Date (DD-MMM-YYYY): _____SVSTDTC/SVENDTC_____

Medication Name: _____CMTRT_____

Indication: _____CMINDC_____

Dose: _____CMDOSE_____

Route: _____CMROUTE_____

Start Date: _____CMSTDTC_____

End Date: _____CMENDTC_____

Investigator Signature: _____NOT SUBMITTED_____

Date: _____NOT SUBMITTED_____

AE (Adverse Events) SV (Subject Visits)

Dummy Case Report Form (CRF)

Visit 1 - Adverse Events VISIT

Subject ID: NOT SUBMITTED _____

Visit Date (DD-MMM-YYYY): SVSTDTC/SVENDTC _____

Event Term: AETERM _____

Start Date: AESTDTC _____

End Date: AEENDTC _____

Severity: AESEV _____

Related to Study Drug? (Y/N): AEREL _____

Investigator Signature: NOT SUBMITTED _____

Date: NOT SUBMITTED _____

See Page 1 for annotations

Visit 2 - Demographics

Subject ID: _____

Visit Date (DD-MMM-YYYY): _____

Subject Initials: _____

Date of Birth (DD-MMM-YYYY): _____

Sex (M/F): _____

Race: _____

Ethnicity: _____

Investigator Signature: _____

Date: _____

See Page 2 for annotations

Visit 2 - Vitals

Subject ID: _____

Visit Date (DD-MMM-YYYY): _____

Height (cm): _____

Weight (kg): _____

Systolic BP (mmHg): _____

Diastolic BP (mmHg): _____

Pulse (bpm): _____

Investigator Signature: _____

Date: _____

See Page 3 for annotations

Visit 2 - Medical History

Subject ID: _____

Visit Date (DD-MMM-YYYY): _____

Condition: _____

Date of Onset: _____

Ongoing? (Y/N): _____

Treatment Given: _____

Outcome: _____

Investigator Signature: _____

Date: _____

See Page 4 for annotations

Visit 2 - Concomitant Medications

Subject ID: _____

Visit Date (DD-MMM-YYYY): _____

Medication Name: _____

Indication: _____

Dose: _____

Route: _____

Start Date: _____

End Date: _____

Investigator Signature: _____

Date: _____

See Page 5 for annotations

Visit 2 - Adverse Events

Subject ID: _____

Visit Date (DD-MMM-YYYY): _____

Event Term: _____

Start Date: _____

End Date: _____

Severity: _____

Related to Study Drug? (Y/N): _____

Investigator Signature: _____

Date: _____

See Page 1 for annotations

Visit 3 - Demographics

Subject ID: _____

Visit Date (DD-MMM-YYYY): _____

Subject Initials: _____

Date of Birth (DD-MMM-YYYY): _____

Sex (M/F): _____

Race: _____

Ethnicity: _____

Investigator Signature: _____

Date: _____

See Page 2 for annotations

Visit 3 - Vitals

Subject ID: _____

Visit Date (DD-MMM-YYYY): _____

Height (cm): _____

Weight (kg): _____

Systolic BP (mmHg): _____

Diastolic BP (mmHg): _____

Pulse (bpm): _____

Investigator Signature: _____

Date: _____

See Page 3 for annotations

Visit 3 - Medical History

Subject ID: _____

Visit Date (DD-MMM-YYYY): _____

Condition: _____

Date of Onset: _____

Ongoing? (Y/N): _____

Treatment Given: _____

Outcome: _____

Investigator Signature: _____

Date: _____

See Page 4 for annotations

Visit 3 - Concomitant Medications

Subject ID: _____

Visit Date (DD-MMM-YYYY): _____

Medication Name: _____

Indication: _____

Dose: _____

Route: _____

Start Date: _____

End Date: _____

Investigator Signature: _____

Date: _____

See Page 5 for annotations

Visit 3 - Adverse Events

Subject ID: _____

Visit Date (DD-MMM-YYYY): _____

Event Term: _____

Start Date: _____

End Date: _____

Severity: _____

Related to Study Drug? (Y/N): _____

Investigator Signature: _____

Date: _____