Visit 4 – Day 7 (± 1)

Reminder: *The Day 7±1 visit (Visit 4) should be performed on Day 7±1 if the enrolled patient is still in the hospital or as a Discharge Visit (within 24 hours of discharge) if the patient will be discharged before Day 7±1. If enrolled patients are discharged after Day 7±1, an additional Discharge visit is not needed*

Date of Visit: _____/_____/_____ Comment if not completed: _____

_____

DISCHARGE:

Has the patient been discharged since Visit 3? ☐ No ☐ Yes ☐ NA

If yes, discharge date: _____/_____/_____ Discharge time: _____ am / pm

Facility to which patient was transferred or discharged:

- ☐ Home
- ☐ Nursing facility
- ☐ Rehab
- ☐ Hospice facility
- ☐ Other hospital unit: specify: _____

PHYSICAL EXAMINATION:

Body System	Overall interpretation, findings, abnormalities etc.	*Clinically Significant?
Skin (Record Injection Site Assessment)		
Lungs		
Cardiovascular		
Abdomen		
Upper Extremities		
Lower Extremities		
Other:		

*If any abnormal findings are clinically significant and are changes from baseline, record as AEs

SIGNATURE SECTION – Physical Examination Completed by:

_____ _____ ____/____/___

Visit 4 – Day 7 (± 1)

Reminder: *The Day 7±1 visit (Visit 4) should be performed on Day 7±1 if the enrolled patient is still in the hospital or as a Discharge Visit (within 24 hours of discharge) if the patient will be discharged before Day 7±1. If enrolled patients are discharged after Day 7±1, an additional Discharge visit is not needed*

Printed Name and qualification(s)	Signature	Date

VITAL SIGNS

Time completed: _____am / pm

Blood pressure: _____ / _____mmHg Location: ☐ Arm ☐ Leg ☐ Right ☐ Left

Heart rate: _____bpm Respiratory rate: _____breaths / min

Temperature: _____ ☐°F or ☐°C

Temperature Method: ☐ Oral ☐ Rectal ☐ Axillary ☐ Tympanic (Ear) ☐ Cutaneous Infrared ☐ Other: _____

Please record any clinically relevant findings on the Adverse Event page

ECG

Was the ECG taken? ☐ Yes ☐ No: Reason: _____

Time of ECG: _____

Subject Position:

☐ Supine ☐ Semi-Recumbent

☐ Sitting ☐ Other: _____

Tracing to be reviewed/assessed as clinically significant or non-clinically significant and initialized and dated by investigator; file original and record any findings judged clinically relevant as AEs Transcribe all findings from the ECG in EDC. QTcF and QTcB will be auto calculated in EDC

INFORMED CONSENT FOR GENETIC TESTING

Has the patient consented to sampling for genetic testing ☐ No ☐ Yes ☐ NA (previously taken)

If yes, was sample collected? ☐ No ☐ Yes – *record detail on re-consent page in EDC*

CENTRAL LABORATORY SAMPLES

Have central lab samples been completed per protocol? ☐ Yes ☐ No

If no, record reason and add as a protocol violation: _____

_____

Visit 4 – Day 7 (± 1)

Reminder: *The Day 7±1 visit (Visit 4) should be performed on Day 7±1 if the enrolled patient is still in the hospital or as a Discharge Visit (within 24 hours of discharge) if the patient will be discharged before Day 7±1. If enrolled patients are discharged after Day 7±1, an additional Discharge visit is not needed*

☐	Plasma Biomarker	Time completed: _____am / pm
☐	PK Ticagrelor Total	Time completed: _____am / pm
☐	PK MEDI2452	Time completed: _____am / pm
☐	PK Ticagrelor Free	Time completed: _____am / pm
☐	Chemistry	Time completed: _____am / pm
☐	Coagulation	Time completed: _____am / pm
☐	Immunogenicity	Time completed: _____am / pm

INFUSION SITE ASSESSMENT

Time completed: _____am / pm

Did the subject have any reactions? ☐ No ☐ yes- record as Adverse Events

ANTICOAGULANT THERAPY:

Did patient restart antiplatelet therapy since last visit?

☐ No - reason not restarted:

- ☐ Not indicated
- ☐ Continued bleed risk
- ☐ Pending surgery or other procedure
- ☐ Other _____

☐ Yes – record details on Concomitant medication page

Name of antiplatelet therapy started: _____

CONCOMITANT MEDICATIONS:

Any new, or changes, in Concomitant Medications, Adverse Events or Infusion Site Reactions since last visit? ☐ No ☐ Yes*

**If yes, complete the applicable worksheet*

VISIT REMINDERS!

Please complete the following additional source documents if applicable

- Bleeding Location and Hemostasis Assessment ☐ No ☐ Yes

Visit 4 – Day 7 (± 1)

Reminder: *The Day 7±1 visit (Visit 4) should be performed on Day 7±1 if the enrolled patient is still in the hospital or as a Discharge Visit (within 24 hours of discharge) if the patient will be discharged before Day 7±1. If enrolled patients are discharged after Day 7±1, an additional Discharge visit is not needed*

- Surgery/Invasive Procedure Assessment ☐ No ☐ Yes
- Adverse Events / Serious Adverse Events ☐ No ☐ Yes
- Concomitant Therapies ☐ No ☐ Yes
- Blood Products and / or additional supportive treatments ☐ No ☐ Yes

Do not transcribe data points already captured in patient's medical records. Line through and initial duplicate sections above and indicate where source is located.

Additional Information:

_____

_____

_____

_____

SIGNATURE SECTION –Source Documents Completed by:

_____ _____ ____/____/____

Printed Name and qualification(s) Signature Date

PI SIGNATURE SECTION – Principal Investigator signature is required below to signify review:

_____ _____ ____/____/____

Printed Name Signature Date