Visit 5 – Day 35 (± 3) and End of Study

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

Visit Type: ☐ On-Site Visit

DISCHARGE:

Has the patient been discharged since Visit 4? ☐ No / previously discharged ☐ Yes

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 Infusion 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

<u>SIGNATURE SECTION</u> – Physical Examination Completed by:

_____ _____ ____/____/___

Printed Name and qualification(s) Signature Date

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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

Date Central Lab Samples drawn, if different from Day 35 visit.

Date of Visit: _____/_____/_____ Time completed: _____am / pm

Visit 5 – Day 35 (± 3) and End of Study

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

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

_____

- ☐ 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

PREGNANCY TEST

Serum Pregnancy Test Collected ☐No ☐Yes ☐N/A comment: _____

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*

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**If yes, complete the applicable worksheet*

TRIAL COMPLETION

Date of Trial Completion ____/____/____ *(date of last contact with patient or date of death)*

Did the subject complete the treatment as planned? ☐ Yes ☐ No if no: please check one of the reasons:

- ☐ Adverse event (specify): _____
- ☐ Death
- ☐ Medication Error
- ☐ Withdrawal by Subject
- ☐ Other: _____

Did Subject Complete Study as Plan (to day 35)? ☐ Yes ☐ No if no: please check one of the reasons:

- ☐ Study terminated by sponsor
- ☐ Death
- ☐ Lost to follow-up
- ☐ Informed consent withdrawn
- ☐ Lack of efficacy
- ☐ Non-compliance with study drug
- ☐ Physician decision
- ☐ Pregnancy
- ☐ Protocol Violation
- ☐ Adverse event
- ☐ Other: _____

VITAL STATUS

Reminders: *Patients who withdraw from the study early should be requested to be contacted for vital status at the end of their planned study period (Day 35).*

The status of this patient is: ☐ Alive ☐ Deceased* ☐ Lost to follow-up

*If patient has died, complete an SAE report

Date of death: _____ Cause of death: _____

_____

<u>SIGNATURE SECTION</u> –Source Documents Completed by:

_____ _____ ____/____/____
Printed Name and qualification(s) Signature Date

Visit 5 – Day 35 (± 3) and End of Study

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

_____	_____	____/____/____
Printed Name	Signature	Date