PB2452-PT-CL-0004

Source Document List Version 4.0, August 2021

These study-specific Source Documents are designed to help organize information, serve as a guideline for study procedures and provide a means to capture medical information that may not be recorded elsewhere.
Please note:

- Each study visit and some protocol assessments have an individual set of source documents to assist with the implementation and completion of study procedures
- Once a visit/assessment has been completed, source documents should be reviewed and signed by the PI and filed in the patient's study file/chart
- The use of source documents is not meant to replace the protocol or the patient's medical record/chart. Line through and initial duplicate sections and indicate where source is located
- The source documents may be customized to suit your needs
- All source documents, along with the relevant medical records and images are to be de-identified and sent for adjudication review after Day 35. The site assigned CRA will assist with this process

Provided Source Documents	Additional Information
Dosing and assessments schematic 18g and 36 g	*Overview of key items for first 24 hours – 2 versions – non CYP3A inhibitor (18g) regimen and with CYP3A inhibitor (36g) regimen*
Visit 1 Screening	*Visit 1 (Screening and eligibility)*
Lab Draw Worksheet	*Central Lab collection documentation for first 24 hours*
Visit 2.1. to 2.6 Vital Signs, AEs, ISRs	*Vital Sign, AES and ISR documentation for first 24 hours*
Infusion 1	*Administration of bolus infusion*
Infusion 2	*Administration of loading infusion*
Infusion 3	*Administration of maintenance infusion*
Infusion 4	*Administration of extended dosing if required*
Visit 2.5 – 12 hours	*12 hours (visit 2.5) source document worksheet (in addition to lab draw worksheet)*
Visit 3 – Day 3	*Visit 3 source document worksheet*
Visit 4 – Day 7	*Visit 4 source document worksheet*
Visit 5 – Day 35 End of Study_Full Visit	*Visit 5 source document worksheet for Full On-Site visit*
Visit 5_Day 35_End of Study_ Telehealth Visit	*Visit 5 source document worksheet if performed as a Telehealth Visit*
Visit 5_End of Stud yvisit_Rescheduled On-Site Visit	*Visit 5 source document worksheet_End of Study On-Site Visit rescheduled within 30 days of Telehealth Visit*
Bleed Location and time hemostasis achieved	*Patients enrolled for bleeding - this page is required each time they experience a bleed.* *Patients enrolled for surgery - this page must be completed if patient had unexpected bleeding, before during or post-surgery.*
Surgery Invasive Procedure	*Patients requiring urgent surgery or invasive procedure - this page is required for each procedure.* *Patients enrolled for bleeding - this page must be completed if patient had unexpected surgery or procedures.* *This page is to include minor, beside supportive measures conducted during the trial as well as estimated blood loss 12 hours post-surgery.* *Patients who have abnormal bleeding during or post procedure, also complete Bleeding Assessment*

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Adverse Event Worksheet	*Complete one worksheet per adverse event, review for Adverse Events at every visit.*
Prior/Concomitant Therapy Worksheet	*Cumulative log to record prior/concomitant therapy for use throughout the study.*
Protocol Deviation Log	*Record all protocol deviations and actions regarding deviations.*