

Patient Registration

1 Purpose

- 1.1 This standard operating procedure (SOP) describes the procedure for determining patient eligibility for the PaTK02 clinical trial and the process for registering a patient with the sponsor.
- 1.2 To describe the procedure for receiving registration confirmation, protocol case number and randomization assignment from the sponsor.

2 Determining Eligibility and Registering Patient (to be performed by clinical site)

- 2.1 Pretreatment evaluations listed in the Investigational Protocol are required. Eligibility Criteria are listed in the protocol and in the Eligibility Criteria form.
- 2.2 The process of obtaining informed consent will be in accordance with the Investigational Protocol and in compliance with applicable regulations and institutional requirements.
- 2.3 The Eligibility Criteria Form, any supporting documents and the signed Informed Consent form will be submitted to the sponsor as soon as they are available.
- 2.4 In patients with biliary obstruction, AST and bilirubin must be confirmed to meet eligibility criteria prior to injection as described in the protocol. Lab results may be submitted to sponsor after the injection along with additional studies not previously sent such as Quality of Life Questionnaire.

3 Eligibility Verification and Enrollment (to be performed by Sponsor)

- 3.1 The Registration form will be reviewed to verify that all criteria are met and that the pretreatment evaluations are complete.
- 3.2 Once eligibility is verified, the patient will be enrolled, and randomization will be performed. The protocol case number will be assigned, and the Patient Registration will be sent to the site. For patients on the Test arm a Drug Assignment and Dispensing record (DA) will be sent.