

KURZPROTOKOLL
241501 Obizur EU PAS

Öffentlicher Titel	Nicht-interventionelle Studie zu Obizur in der alltäglichen Praxis
Wissenschaftl. Titel	Prospektive und retrospektive, nicht-interventionelle Studie zur Bewertung der Sicherheit und Wirksamkeit von Obizur in der alltäglichen Praxis
Kurztitel	241501 Obizur EU PAS
Studienart	multizentrisch, prospektiv, offen/unverblindet, einarmig, nicht-interventionelle Studie
Studienphase	nicht zutreffend
Erkrankung	Blut: Gerinnungsstörungen (Koagulopathien)
Einschlusskriterien	<ul style="list-style-type: none">- Adult participant (or legal representative) is willing to provide informed consent- Participant is being treated or was treated (treatment initiation within 30 days) with Obizur in routine clinical practice
Ausschlusskriterien	<ul style="list-style-type: none">- Participant has known anaphylactic reactions to the active substance, hamster protein or to any of the following excipients: Polysorbate 80; sodium chloride; calcium chloride dihydrate; sucrose; Tris Base; Tris HCl; Tri-sodium citrate dihydrate; sterilized water for injections- Participant has participated in a clinical study involving a medicinal product or device within 30 days prior to enrollment or is scheduled to participate in another clinical study involving a medicinal product or device at study entry
Alter	18 Jahre und älter
Sponsor	Shire Pharmaceutical Development Ltd.
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03199794 (primäres Register)