PASS TachoSil Evaluation (PasTel): Shortand long-term safety evaluation of TachoSil in paediatric population

First published: 28/04/2025

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Study status

Planned



Administrative details

EU PAS number	
EUPAS1000000505	
Study ID	
-	
100000505	
DARWIN EU® study	
No	
Study countries	
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Poland	
Poland	

Contact details

Study institution contact

Miroslaw Kociecki miroslaw.kociecki@corza.com

Study contact

miroslaw.kociecki@corza.com

Primary lead investigator

Piotr Kalicinski

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/08/2024

Study start date

Planned: 31/12/2024

Date of final study report

Planned: 30/06/2029

Sources of funding

Pharmaceutical company and other private sector

Regulatory

Was the study required by a regulatory body? Yes	
Is the study required by a Risk Management Plan (RMP)? EU RMP category 3 (required)	
Methodological aspects	
Study type	
Study type list	
Study topic: Human medicinal product	
Study type: Non-interventional study	
Study drug and medical condition	
Name of medicine TACHOSIL	
Study drug International non-proprietary name (INN) or common name HUMAN THROMBIN HUMAN FIBRINOGEN	
TIOPIAN TIDMINOULIN	

Anatomical Therapeutic Chemical (ATC) code

(B02BC30) combinations combinations

Population studied

Short description of the study population

Infants and toddlers (>=28 days - < 2 years) on the day of signing the ICF Children (>=2 years - < 12 years) on the day of signing the ICF Adolescents (>=12 years - less than 15 years) on the day of signing the ICF

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025.

The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Use of a Common Data Model (CDM)

CDM mapping

Data quality specifications

Check conformance

No

Check completeness

No

Check stability

No

Check logical consistency

No

Data characterisation

Data characterisation conducted

No