

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

**First published:** 28/04/2025

**Last updated:** 05/02/2026

Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000505

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### Study ID

1000000505

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### DARWIN EU® study

No

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### Study countries

 Poland

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### Study status

Planned

## Contact details

### Study institution contact

Mirosław Kociecki mirosław.kociecki@corza.com

Study contact

[mirosław.kociecki@corza.com](mailto:mirosław.kociecki@corza.com)

### Primary lead investigator

Piotr Czauderna

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 05/08/2024

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### Study start date

Planned: 01/07/2026

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### Date of final study report

Planned: 31/03/2031

## Sources of funding

- Pharmaceutical company and other private sector

## Study protocol

## Regulatory

**Was the study required by a regulatory body?**

Yes

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**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

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**Study type:**

Non-interventional study

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## Study drug and medical condition

**Medicinal product name**

TACHOSIL

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## **Study drug International non-proprietary name (INN) or common name**

HUMAN THROMBIN

HUMAN FIBRINOGEN

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## **Anatomical Therapeutic Chemical (ATC) code**

(B02BC30) combinations

combinations

## Population studied

### **Short description of the study population**

Infants and toddlers ( $\geq 28$  days -  $< 2$  years) on the day of signing the ICF

Children ( $\geq 2$  years -  $< 12$  years) on the day of signing the ICF

Adolescents ( $\geq 12$  years - less than 15 years) on the day of signing the ICF

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### **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**

No

## Data quality specifications

### **Check conformance**

No

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### **Check completeness**

No

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### **Check stability**

No

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### **Check logical consistency**

No

## Data characterisation

### **Data characterisation conducted**

No