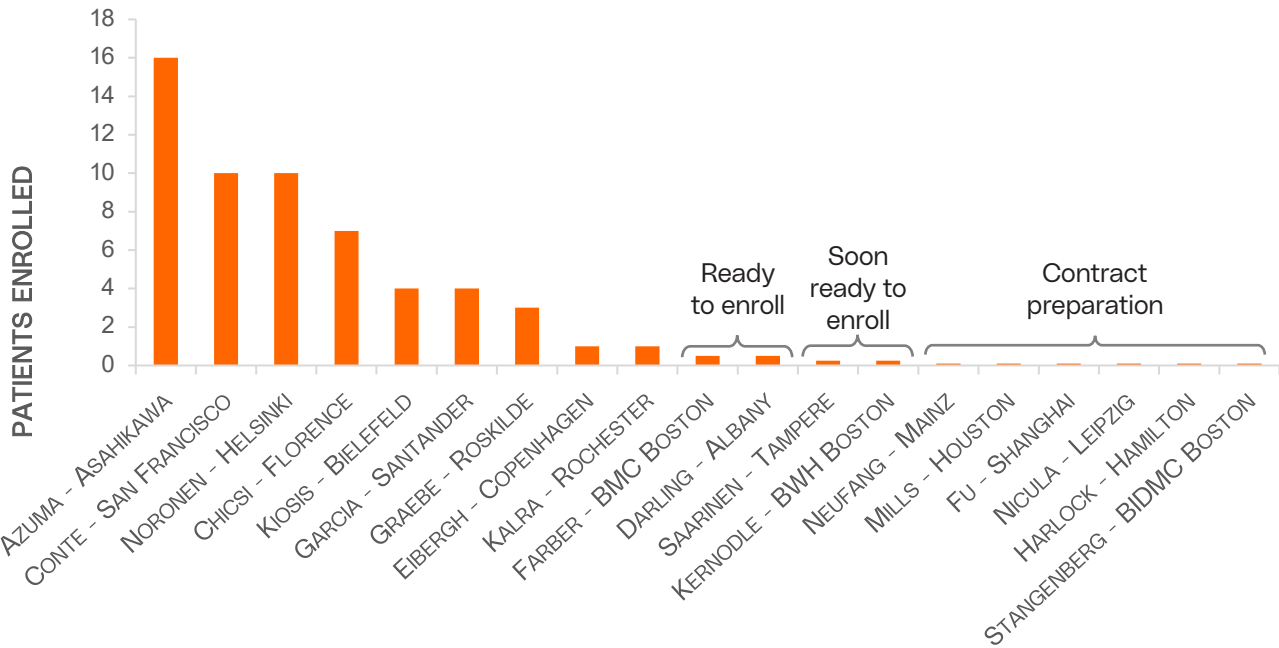


# PATENTstudy NEWSLETTER

Total # patients enrolled: **56/450**


Dear investigators and participants in the PATENT study!

This is the third Newsletter to keep you updated and engaged in PATENT. Nine centers are enrolling patients and 4 centers are soon ready to start enrollment. Six centers are not ready with the paperwork (IRB or contract). We have two new confirmed sites: Hamilton in Canada and Beth Israel Deaconess Medical Center in Boston.




## Surgeons who have performed the most cases

**5**




Michael Conte has been the leading surgeon on 5 out of the 10 patients at UCSF.

**9**




Shinsuke Kikuchi in Asahikawa has performed 9 surgeries out of the 16 enrolled patients at this site. He's thereby in the lead in enrollment for PATENT!


**4**



Katariina Noronen has performed 4 out of 10 surgeries in Helsinki, Finland.



Naoya Kuriyama has performed 4 out of 16 surgeries in Asahikawa, Japan.



Tito Garcia has performed 4 surgeries in Santander, Spain.

## PATENT Investigator meeting, Istanbul Sept. 24<sup>th</sup> 2025



Thank you for a great meeting and a lovely dinner during ESVS. Attending this meeting were: Emiliano Chisci and Cecilia Fenelli from Florence, Katariina Noronen, Petteri Kauhanen and Anita Mäkelä from Helsinki, Manju Kalra from USA, and Nobuyoshi Azuma from Japan. Medistim was represented by: Hæge Wetterhus, Andre Hagen, Stephanie Stenhagen, and Anne Waaler.

## PATENT Investigator meeting, New York Nov. 18<sup>th</sup> 2025



Thank you to everyone who participated at the Investigator meeting in connection to the VEITH meeting in New York.

Attending this meeting were: Michael Conte, Maarit Venermo, Katariina Noronen, Nobuyoshi Azuma, Clemence Darling, Manju Kalra, Joe Mills, Matt Menard and Mads Carstensen.

Medistim was represented by: Anne Waaler, Kari Krogstad and Tony Winter.

## Protocol amendment

Based on the input from the investigator meetings and from other PIs involved in the study, the Surgical Core Team has decided the following:

### PROTOCOL AMENDMENT:

We will modify the inclusion criteria to include any bypass below the knee and above the ankle in CLTI patients so that popliteal bypasses with more than one open run-off can be included. This will make recruitment easier, and the study population will be more representative to the real-world patient population. This will imply that we will make an amendment to the protocol, and some modifications to the CRF. The Amendment will be prepared shortly and must be submitted to the EC/IRB. Depending on local EC/IRB rules, the EC/IRB may regard this as a non-significant protocol amendment, or they may request a formal review process. Meanwhile, the study will proceed based on the current protocol.

### DUPLEX CRITERIA:

To avoid confusion and to keep it simple, all sites should stick to their standard criteria for grading graft stenosis in follow-up Duplex examinations.

## Clinical Coordinator corner:

### CRF guidance – how to deal with missing data

If data are missing, this is how to make a note of it in Viedoc

In this example ankle pressure is not possible to measure.

1. Select the + sign in the upper right corner
2. Select the field where data is lacking, confirm missing data and provide reason for this, click Ready.

The screenshot displays the Viedoc interface for the 'ABI / TBI' section. The main form includes fields for 'Brachial systolic pressure (BP) Right arm' (value: 110 mmHg) and 'Ankle systolic pressure in index (Use highest value for the index limb)' (value: mmHg). A red box highlights the empty input field for the ankle pressure. A modal dialog box titled 'Add new action' is open, showing a dropdown menu with 'AP limb - mmHg' selected. The 'Choose type of action' section has 'Confirm field is missing' selected. The 'Add reason for missing field here' text area contains the text 'AP not measured because arteries not compressable'. The dialog box has 'Ready' and 'Cancel' buttons. A red box highlights the '+' icon in the top right corner of the main form.

## Investigator meetings

We will plan for a Zoom Investigator meeting in January 2026.  
Date to be announced later.