

# MEETING THE NEEDS OF PATIENTS ENROLLED IN CLINICAL TRIALS



These tools and resources are designed to make it easier for you to participate in a clinical trial

CHALLENGES	SOLUTIONS
<b>Can't afford to come to visit.</b>	Ask your care team about options for covering your travel expenses.
<b>It's too hard to get to the doctor's office – public transportation, traffic, parking, etc.</b>	A car service can drive you to and from your visits at no cost to you. Leave the planning to us. All you have to do is wait for your car at the door.
<b>I don't want to come back to the doctor's office for my follow-up visits.</b>	<ul style="list-style-type: none"> <li>• With your doctor's approval a trained professional can complete certain study visits in the comfort of your home.</li> <li>• Your study doctor receives a full report of the visit and will review all the information.</li> </ul>
<b>I live too far for a day trip study visit.</b>	Ask your care team about making travel arrangements at no cost to you. A travel agent will book airfare and hotel reservations for you. Take advantage of the concierge service!
<b>This seems like a lot of work and time.</b>	As recognition for the extra effort to participate in this complex study, you may be offered compensation for your time.



## LIFE-BTK PHARMACOKINETICS (PK) SUB-STUDY PATIENT INFORMATION

CAUTION: Esprit™ BTK System is an investigational device limited by Federal (US) law for investigational use only. Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

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 LIFE-BTK PK Patient Brochure CL1016753



**See Important Safety Information referenced within.**

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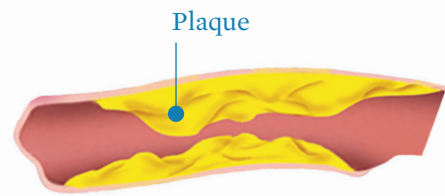


# CLI DISEASE

## AND CURRENTLY AVAILABLE TREATMENTS

### WHAT IS CRITICAL LIMB ISCHEMIA (CLI)?

In patients with CLI, blood vessels in the legs are blocked, drastically reducing blood flow to the feet



### HOW DOES CLI AFFECT YOU?

- Pain or numbness in the feet
- Absent or reduced pulse in the legs or feet
- Wound(s) in the leg or feet that will not heal



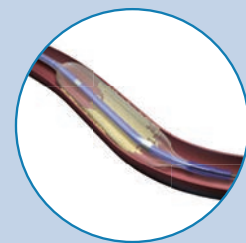
### WHAT DOES TREATMENT PROCESS LOOK LIKE?

#### DIAGNOSIS OF CLI

##### ANGIOGRAM (X-RAY)

Looks for blocked vessels in the leg

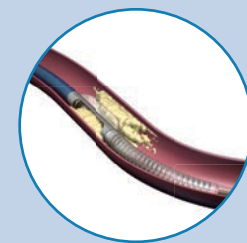
#### MOST COMMON TREATMENT



##### PTA

- Percutaneous transluminal angioplasty (PTA)
- A small balloon is inserted into the vessel and inflated to open the blockage, and re-establish blood flow to the lower leg and feet
- The balloon is then removed from the vessel

#### OTHER POTENTIAL TREATMENTS



##### ATHERECTOMY

- Method used to remove significant blockages and/or calcium buildup that could prevent the vessel from opening
- PTA is then performed to completely open the vessel

##### SURGERY

Operation performed on your artery to clean out or bypass the narrowed part of your artery

### LIFE-BTK PK SUB-STUDY

- If you have been diagnosed with CLI, you may qualify for the LIFE-BTK PK study
- This is a study to understand the pharmacokinetics (PK) of a drug called everolimus, during and after implantation of a drug-eluting investigational new device named “Esprit™ BTK”, for treatment of CLI.
- Pharmacokinetics is the study of what the body does to the drug. It describes how much the body absorbs and the way it gets rid of the drug over a time period.

*You can still see your personal physician for regular checkups and care.*

### WHAT IS INVOLVED IF I CHOOSE TO PARTICIPATE?

Before you are enrolled, you will be screened to make sure you are a good candidate for the study. You will also have to sign a consent form to participate in the study.

#### The screening may include:

- Review of your medical history with a study representative
- Laboratory tests
- Assessment of wound(s) on the leg or feet (if applicable)
- Angiogram (type of X-ray) to diagnose where the blockage is in your vessel

### WHAT HAPPENS IF I PASS THE SCREENING PROCESS?

- 1 You will be assessed in-person at the treatment center and then registered in the study
- 2 You will have the procedure to treat your blocked vessel with Esprit™ BTK
- 3 You will have blood draws, about the amount of a tablespoon, starting on the day of the procedure up to 60 days
- 4 You will have 16 study visits over a 5-year period, some matching the same time points for your blood draws

### WHAT DOES TREATMENT WITH ESPRIT™ BTK LOOK LIKE?



- 1 Device inserted into blocked vessel to open up the blockage.
- 2 Device holds your vessel open, and releases a small amount of drug to help your vessel heal.



- 3 Device slowly goes away over time, so that nothing is left behind in your vessel, after about 3 years.

### WHERE CAN I LEARN MORE ABOUT THE LIFE-BTK PK STUDY?

For any questions, please contact the study team at the below information:

- Visit [www.LIFE-BTK.com](http://www.LIFE-BTK.com). The website includes:
  - Information related to the LIFE-BTK trial of which LIFE-BTK PK is a sub-study
  - Videos about the disease
  - Information on the Esprit™ BTK device
  - FAQs

**See Important Safety Information referenced within.**