

# Participant Journey

For participants: This tool is to help you understand what to expect during the **SBT777101-01/Regulate-RA** trial.

1



## INFORMED CONSENT

You will need to read and sign the Informed Consent Form (ICF) before you receive any trial assessments.

2



## SCREENING PERIOD

You will receive trial health assessments to find out if you qualify further for the trial. This is called the Screening Period.

3



## APHERESIS PROCEDURE

Once you qualify, you will have an apheresis procedure using an approved apheresis machine, which separates cells in your blood.

4



## OPTIONAL JOINT BIOPSY FOR SYNOVIAL TISSUE

You will be asked if you want to complete an optional biopsy, where a needle is used to collect a sample of synovial fluid and tissue from your joint.

5



## SBT777101 TRIAL CELL THERAPY INFUSION

You will receive an IV infusion of the trial cell therapy (made from your own cells).

6



## FOLLOW-UP PERIOD

You will attend follow-up visits for a total of about 11 months, including 1 more optional joint biopsy.

# Participant Journey

For site staff: These talking points are to help you review the **SBT777101-01/Regulate-RA** trial with potential participants.



## 1. INFORMED CONSENT

- Before you receive any trial assessments, you will review and sign the Informed Consent Form (ICF). The ICF explains the trial and what you can expect in more detail.
- Study staff will review the ICF with you and answer any questions about the trial. You can also discuss the information in the ICF with friends and family before signing.
- Participation is completely your choice, and you can leave the trial at any time.



## 2. SCREENING

- You will receive screening health assessments to confirm if you further qualify to join.
- You will answer questions about your medical history, symptoms, and current medications.
- You will also give blood and urine samples, have a physical exam, and may have an ultrasound.
- The trial doctor will let you know after screening is over if you qualify to continue in the trial.



## 3. APHERESIS PROCEDURE

- The apheresis procedure will allow the trial doctor to collect the cells from your blood to make the trial cell therapy.
- Nursing staff will place one needle in each arm. If your veins are not large enough to support a standard size needle, a central venous catheter may be used instead.
- During apheresis, your blood will be drawn into the apheresis machine from one arm (or catheter) and separated into components. White blood cells will be removed, and the plasma and red blood cells will be returned into the other arm. The procedure typically lasts about 2-4 hours.

Apheresis procedures are considered safe and are used regularly for collecting certain blood components.



## 4. OPTIONAL JOINT BIOPSY FOR SYNOVIAL TISSUE

- If you agree to it, you will have a biopsy of your joints once before and after receiving the trial cell therapy.
- Synovial tissue is the connective tissue that lines your joints. Synovial fluid works with the synovial tissue to keep your joints lubricated.



## 5. SBT777101 TRIAL CELL THERAPY INFUSION

- After more health assessments, you will receive an IV infusion of the trial cell therapy through a needle in your arm.
- You will need to remain at the clinic for at least 1 night so the trial doctor can monitor your health.



## 6. FOLLOW-UP PERIOD

- You will be asked to stay within 1 hour of the trial clinic for the first week after the trial cell therapy infusion (for example, do not travel far enough away that you could not return to the trial clinic quickly if necessary).
  - As a precaution, you will be asked to identify a trial companion to watch over you for at least 28 days after the trial cell therapy infusion.
  - It is recommended to not drive or operate heavy machinery for at least 28 days after the trial cell therapy infusion.
- You will return to the trial clinic for several safety follow-up visits during the first month after your infusion.
- You will need to attend about 15 visits over the course of about 11 months.
- Follow-up visits will include more trial health assessments, including physical exams, blood and urine samples, and another optional joint biopsy.
- You will be asked to continue with the long-term follow-up period for up to 15 years (you will receive more information from the trial staff).