Who may be eligible to join the trial?

You may be able to join the trial if you meet the following key criteria (other criteria may apply):

- Age 18 to 70 years old
- Diagnosed with moderate to severe adult-onset RA
- Have tried at least 3 approved therapies for RA that were not effective
- Have someone who can act as a trial companion to watch for side effects

What are clinical trials?

Clinical trials help scientists and doctors explore whether a therapy is safe and whether it works. Before a doctor can prescribe a new therapy, it must go through several phases of clinical research:



Phase 1: First research of the therapy in people



Phase 2: Research of the therapy in people with the condition the therapy is for



Phase 3: Research confirming how well the therapy works



Phase 4: More research after the therapy is approved



Clinical trials rely on volunteers. Remember that taking part in the trial is your choice. Know that the rules and ethics that doctors must follow to practice medicine also apply to clinical trials.



Is your RA not well managed by medication?

Talk to your doctor about the SBT777101-01 clinical trial, which is researching a possible new option for people with rheumatoid arthritis (RA).

For more information about the SBT777101-01 trial, contact:



What is the purpose of the trial?

Researchers in the SBT777101-01 trial are studying a possible cell therapy for people with RA who do not benefit from the standard therapies.

What is the trial cell therapy?

The trial cell therapy is called SBT777101 and is made from a participant's own cells.

By adding new DNA (instructions that tell cells how to do their job) to certain immune cells, the SBT777101 cell therapy may help reduce inflammation, joint damage, and other symptoms in people with RA.

The SBT777101 cell therapy is considered **investigational**, which means it can only be used in clinical research studies. It has not been approved by any regulatory authorities as an effective therapy for RA.



What is cell therapy?

The goal of cell therapy is to use your own cells to improve your condition. In many cases, the original cells taken from the participant are 'engineered' so that the cells can be directed to manage the disease. For example, cells can be directed to fight cancer cells or directed to improve the immune system.

How is the trial cell therapy made?



1. The participant's blood is drawn into a machine that separates certain immune cells from other cells in the blood





2. Scientists genetically modify the immune cells





3. Cells are left to grow and multiply for 2 weeks





4. Scientists check the cells for quality





5. Participant receives an infusion of trial cell therapy

What can trial participants expect?

If you decide to participate, you can expect to do the following periods:

- Screening (about 4 weeks)
 - Complete screening assessments for about 4 weeks to find out if you qualify for the trial
 - Includes a joint biopsy (a needle is used to collect a sample of synovial fluid and tissue)
- SBT777101 cell therapy preparation (about 6 weeks, but up to 6 months is allowed)
 - Before the cell therapy treatment is given, you will complete the following:
 - Apheresis (blood is drawn into an approved apheresis machine to separate the cells used for the SBT777101 cell therapy)
 - Pre-trial health assessments to confirm that it is safe to receive the SBT777101 cell therapy
- SBT777101 cell therapy and trial health assessments (about 11 months)
 - If you qualify, receive the SBT777101 cell therapy as a one-time IV infusion on Day 1 of the trial
 - You will be asked to stay overnight at the trial clinic, so the trial doctor and staff can monitor your health closely
 - Receive trial health assessments for 48 weeks (about 11 months) that include, but are not limited to, the following:
 - Joint biopsy (a needle is used to collect a sample of synovial fluid and tissue)
 - Vital signs, blood tests, questionnaires, urine tests, heart tests, and physical exams
- Long-term Follow-up (up to 15 years)
 - Continue to the long-term follow-up period for up to 15 years (you will receive more information from the trial staff)