

# Participation in a TAVR Clinical Trial — Shared Decision Making Aid

This shared decision aid is for patients who are interested in participating in an Edwards Lifesciences TAVR (Transcatheter Aortic Valve Replacement) clinical trial. The goal of this decision aid is to help you and your doctor make a shared and informed decision about a treatment option for managing aortic valve disease.

A clinical trial is a voluntary study that researches the safety and effectiveness of a medical device or therapy. By participating, you may receive a treatment option or medical device that is not available to everyone. There may be potential risks and complications, which will be explained to you by your doctor and will be listed in the informed consent form. This form will have all of the information you need in order to make an informed decision before you agree to participate in the trial. It is important to understand the possible benefits and risks of each option and how they may affect your personal lifestyle and goals.

This decision aid should be reviewed with your physician to help you understand the information and potential risks and benefits. You may also wish to share this information with loved ones and other healthcare professionals for their shared input into your decision.

This decision aid includes the following sections:

- Questions to ask your doctor
- Options for managing your disease, including risks and benefits
- Next steps

## Questions to Ask Your Doctor

- What are my treatment options for my disease?
- Am I a candidate for a clinical trial?
- What types of screening tests will be done?
- What are the possible risks and benefits of the TAVR procedure?
- What is the recovery time for TAVR?
- How long is a clinical trial?

## Options for Managing Your Aortic Valve Disease

If you have aortic valve disease and you're interested in participating in a clinical trial, there may be different management/treatment options available to you. Below are some options to review with your doctor:

	Replace Your Diseased Aortic Valve		Closely Monitor the Disease
	Option 1: Open Heart Surgery	Option 2: Transcatheter Aortic Valve Replacement (TAVR)	Option 3: Clinical Surveillance
What does each option involve?	Removing the diseased valve and inserting a new valve through an incision across the full length of the breastbone.	Placing a new valve within your diseased valve using a catheter, usually through a small incision in the groin. TAVR is a less invasive procedure than surgery.	Monitoring the progress of your disease until you develop symptoms, or your doctor determines that you need to have your valve replaced.
Is this treatment option available if I participate in a clinical trial?	No – You do not need to participate in a clinical trial to receive open heart surgery.	Possibly – Depending on the severity and symptoms of your aortic valve disease, a TAVR clinical trial may be a treatment option for you.	Possibly – Some clinical trials compare the safety and effectiveness of TAVR to clinical surveillance. If your disease worsens, your doctor may decide to treat you with TAVR.
What are the advantages of this option?	Replacing your diseased aortic valve may relieve your aortic valve disease and may prevent worsening of your heart function.	Participating in a clinical study may or may not provide any direct medical benefit to you. Depending on the severity of your aortic valve disease, TAVR may or may not improve your symptoms or quality of life with a faster recovery time than surgery.	You do not undergo a procedure. Depending on the severity of your aortic valve disease, clinical surveillance may be recommended by current guidelines.
What are the major risks associated with this option?	Some potential risks of having your aortic valve replaced include death, stroke, and major bleeding.	Some potential risks of TAVR include death, stroke, and major bleeding. The specific risks of participating in a clinical trial are described in detail in the Informed Consent Form. Please carefully review the form and ask your research nurse any questions before deciding to participate.	Some potential risks of monitoring your disease include sudden death, progression of irreversible heart damage, and increased risk of complications for a future aortic valve replacement procedure.

## Next Steps

It is important that you understand your disease, your options, all of the potential risks and benefits of each, and how these factors align with your lifestyle and values. If you feel that you do not have enough information to make an informed decision, your doctor may be able to refer you to others for additional support.

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