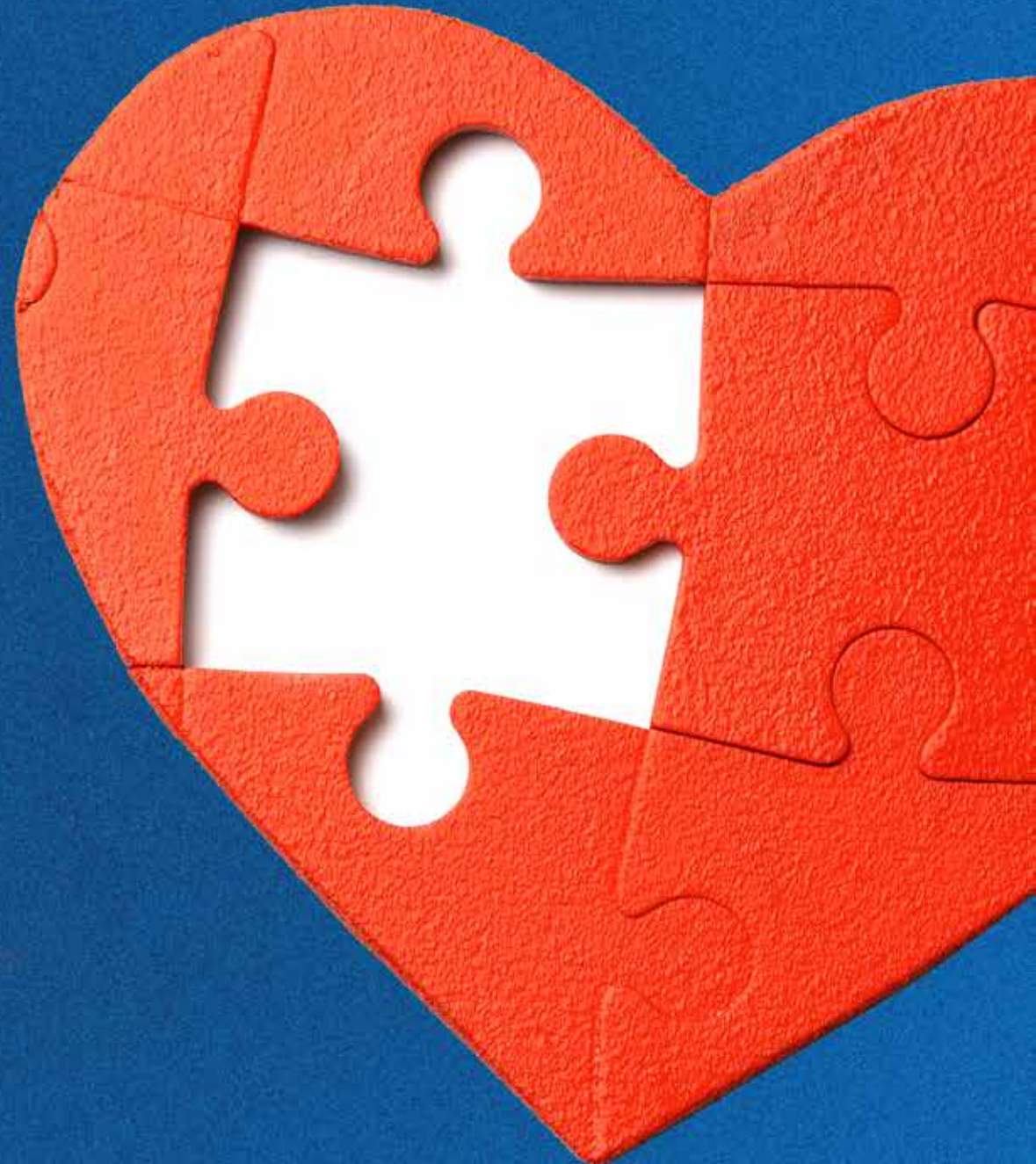


# 2020 Heart Valve Clinical Trial Report

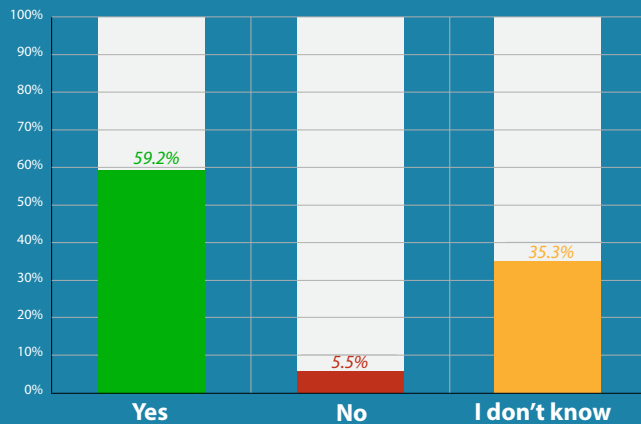
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Missed Opportunities for  
Patient Awareness & Enrollment





**Patient Question:**  
**Would you consider participating  
in a clinical trial?**



# Introduction

Developing, launching and completing a clinical trial for heart valve devices can be challenging. The consumption of resources and time needed to acquire a Food & Drug Administration (FDA) approval has led industry participants to, at times, call this process a “train wreck”.

Patient enrollment is commonly referred to as the Achilles’ heel of clinical trials. Interestingly, there are many unanswered questions whether direct-to-patient education is overlooked as an effective mechanism to stimulate clinical trial enrollment.

**To learn about patient awareness and patient perceptions specific to clinical trials, HeartValveSurgery.com conducted an online survey of 1,157 heart valve patients from October 13 to October 19, 2020.**

This report and the survey findings herein are designed to help our community better understand (i) patient interest for learning about clinical trials and (ii) patient interest for participating in clinical trials.

*Adam Pick*

Adam Pick, Patient & Founder  
HeartValveSurgery.com

# About HeartValveSurgery.com

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Founded in 2006, HeartValveSurgery.com (HVS) is the largest educational resource and community of patients with heart valve disease. This award-winning and HONcode certified website, which is sponsored by 40+ cardiac centers, has helped more than 10 million people manage and treat heart valve disease. The mission of HVS is to educate and to empower patients from diagnosis through recovery using novel technologies.



Adam Pick, the patient who founded HVS, has been featured by the American Heart Association for his work as a patient advocate. Over 350,000 people follow Adam on social media for his patient-centric coverage of heart valve disease. For the past 20 years, Adam has worked for leading technology companies and start-ups across the hardware, software and Internet sectors. Adam earned bachelor and graduate degrees from the University of Michigan.



# Physician Advisors

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Many thanks to Drs. Chikwe, Gillinov, Mack and McCarthy for their contribution to this report and their support of patients at HeartValveSurgery.com.



Joanna Chikwe, MD, serves as Chair of the Department of Cardiac Surgery in the Smidt Heart Institute at Cedars-Sinai Medical Center. Dr. Chikwe is a leading expert in cardiovascular outcomes research and has published over 125 contributions in peer-reviewed medical journals.



Marc Gillinov, MD, is a cardiac surgeon and Chairman of the Department of Thoracic and Cardiovascular Surgery in the Sydell and Arnold Miller Family Heart, Vascular & Thoracic Institute at Cleveland Clinic. Dr. Gillinov is the Chair of the NIH-funded Cardiothoracic Surgical Trials Network.



Michael Mack, MD, is a cardiac surgeon at Baylor Scott & White The Heart Hospital – Plano and Chairman of Baylor Scott & White Health Research Institute. Dr. Mack is the national co-principal investigator of the PARTNER 3 clinical trial of TAVR.



Patrick McCarthy, MD, is a cardiac surgeon and Executive Director at Northwestern Medicine Bluhm Cardiovascular Institute. Dr. McCarthy is the national co-principal investigator of the MitraClip REPAIR MR research study for patients with severe mitral regurgitation.

# Executive Summary

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Heart valve clinical trials can be expensive, multi-year programs typically associated with delays caused by missed patient enrollment timelines.

To evaluate if patients are overlooked as an organic demand channel for clinical trial participation, HeartValveSurgery.com (HVS) conducted an online survey of 1,157 heart valve patients from October 13 to October 19, 2020.

Select survey findings:

- 73% of patients surveyed are “not very aware” of clinical trials.
- 90% of pre-operative patients want to learn about clinical trials.
- Only 4% of patients surveyed have participated in a heart valve clinical trial, yet 59% of patients would consider enrolling in a clinical trial.
- Just 13% of patients have visited ClinicalTrials.gov.
- 99% of patients would visit a new ‘Clinical Trials’ section at HVS.

While more research is needed, the survey results suggest that patients, doctors, hospitals and trial sponsors could benefit from the development of (i) new patient awareness initiatives, (ii) new patient education models and (iii) new patient enrollment paths specific to clinical trials.

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“Finding the right patients for clinical trials is a time-consuming, nightmare.”

- VICE PRESIDENT, CLINICAL AFFAIRS, HEART VALVE MANUFACTURER

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## **What can I do to accelerate patient enrollment for my clinical trial?**

That’s one of the most frequently asked questions by principal investigators and trial sponsors. And, for good reason, when you consider:

- 90% of clinical trials double enrollment times<sup>1</sup>
- 48% of clinical sites under-enroll patients<sup>2</sup>
- 11% of clinical sites fail to enroll a single patient<sup>3</sup>

SOURCES:

1,2. Patient Recruitment & Enrollment in Clinical Trials, Forte Research Systems, 2014

3. Impact Report, Tufts Center for the Study of Drug Development, Vol. 15, No. 1, Tufts University, 2013



“The cost to run a big clinical trial is easily over \$50 million dollars per year.”

- SENIOR EXECUTIVE, HEART VALVE MANUFACTURER

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## **Clinical trial expense and lost sales resulting from delayed commercialization is daunting.**

- The estimated cost for a delayed decision by the Food & Drug Administration (FDA) is \$24.1 million for a 30-employee company<sup>1</sup>.
- The median cost to conduct a clinical trial that leads to an approval is \$94 million on average, according to the FDA<sup>2</sup>.

SOURCES:

1. William H. Maisel, Transcatheter Cardiovascular Therapeutics Conference, 2014
2. Mass Device, Exploring FDA Approval Pathways for Medical Devices, Kirsh, 2019







“Our company does nothing to directly educate heart valve patients about clinical trials.”

- VICE PRESIDENT, CLINICAL AFFAIRS, HEART VALVE MANUFACTURER

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**Traditional strategies to stimulate clinical trial awareness and enrollment often fail to consider patient needs.**

While digital platforms and social media can provide scalable “self-referral” paths for patients to learn about and pre-screen for clinical trials, these capabilities are under-utilized.

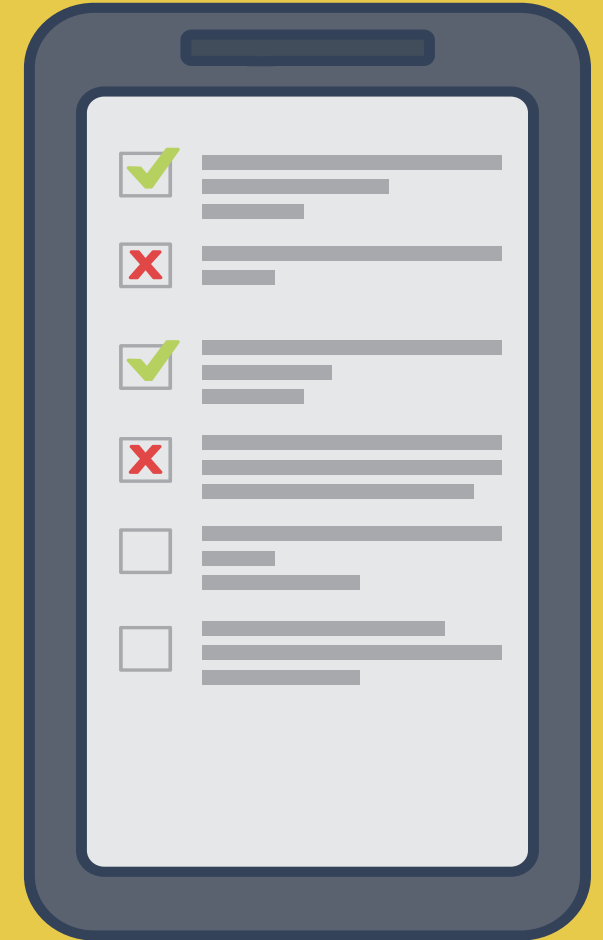
# Patient Survey

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## What do heart valve patients think about clinical trials? Are they aware? Do patients want to learn about or enroll in clinical trials?

To understand patient perspectives specific to clinical trial awareness and participation, HeartValveSurgery.com conducted an online survey.

The nationwide survey was conducted – from October 13 to 19, 2020 – among **1,157 patients** previously diagnosed with aortic, mitral, tricuspid and/or pulmonary valve disease.

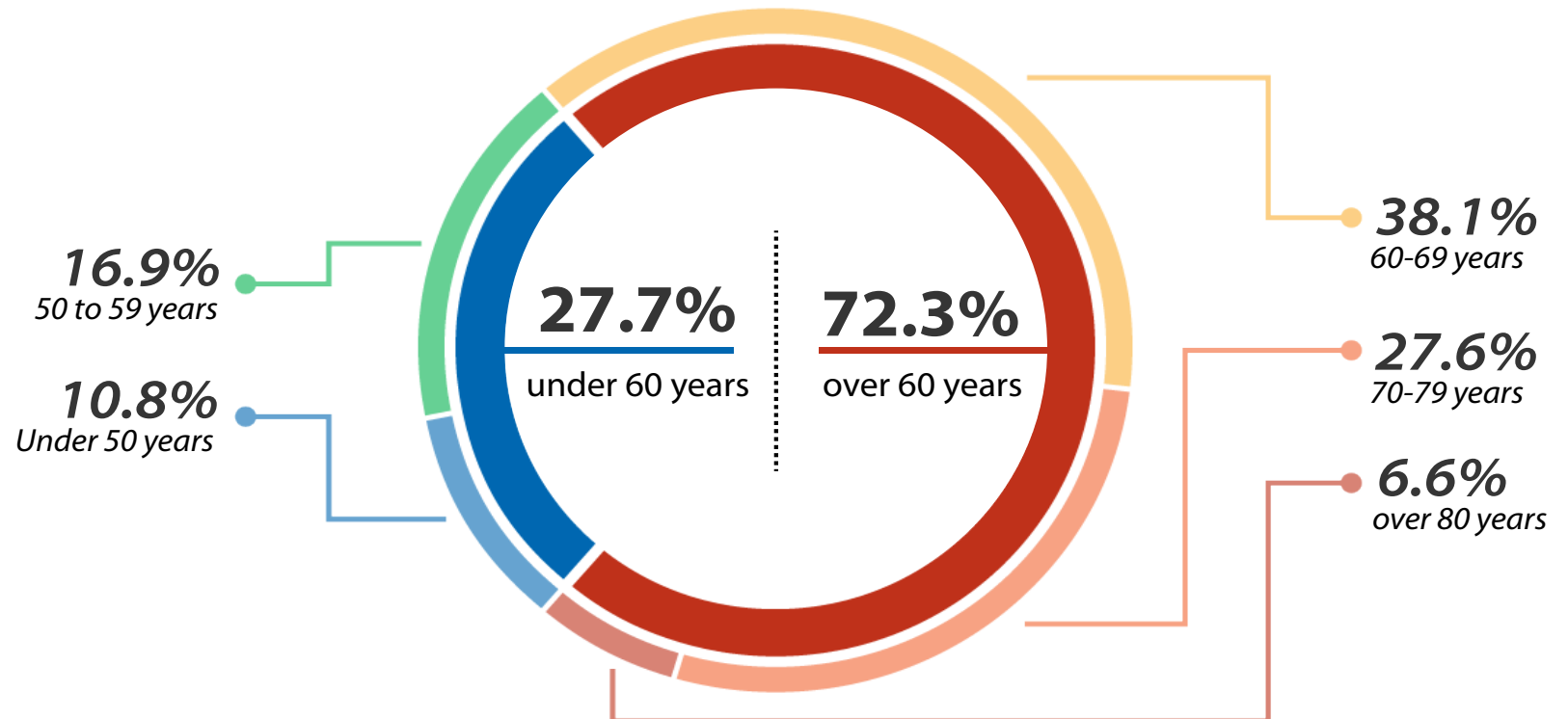




# Age of Patients Surveyed

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**Over 72% of the 1,157 survey respondents were 60 years of age or older.**



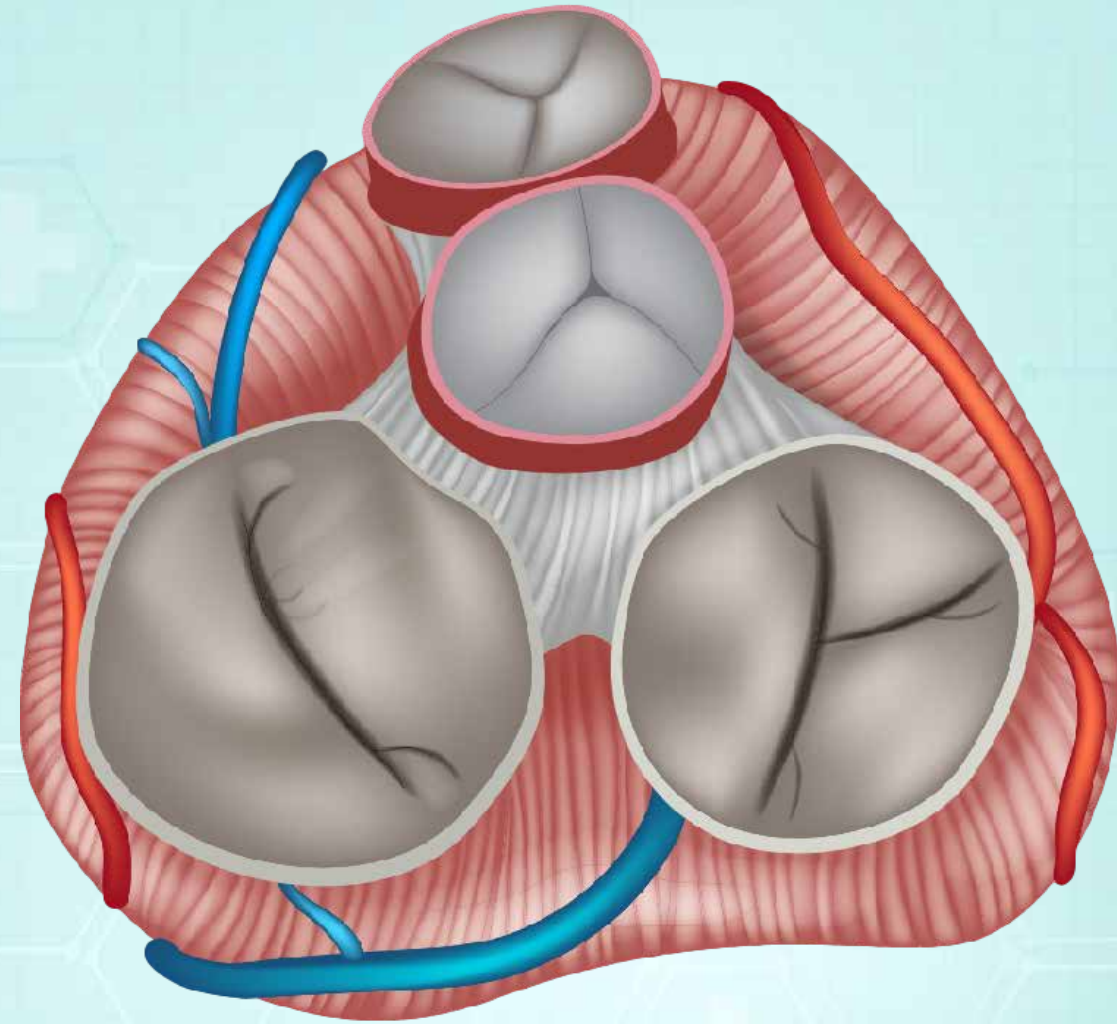


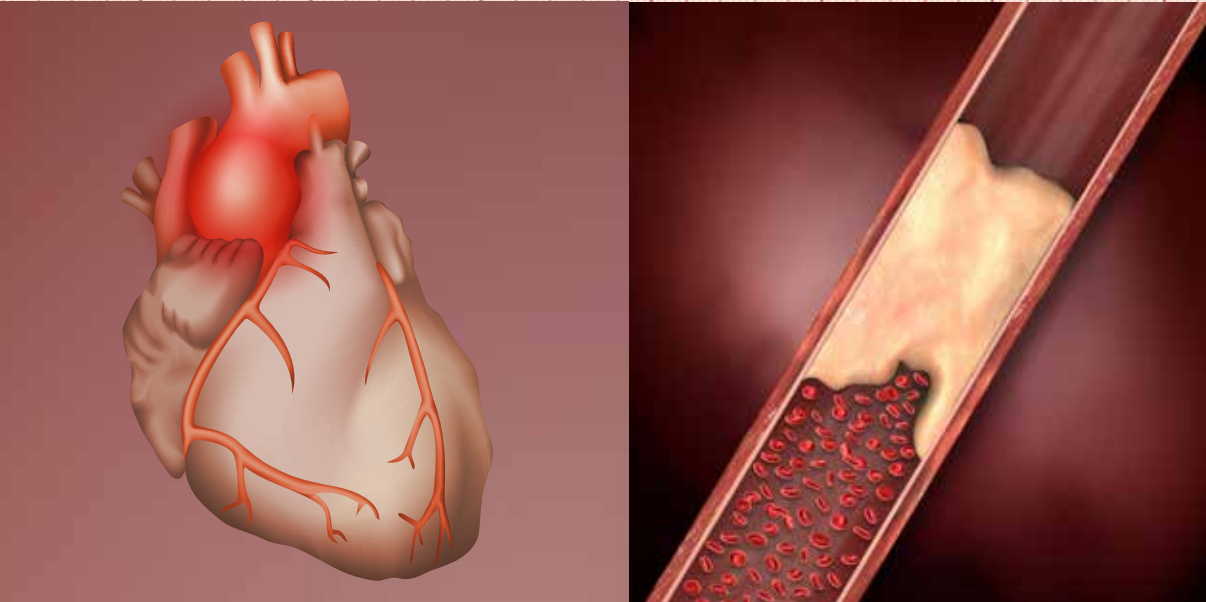
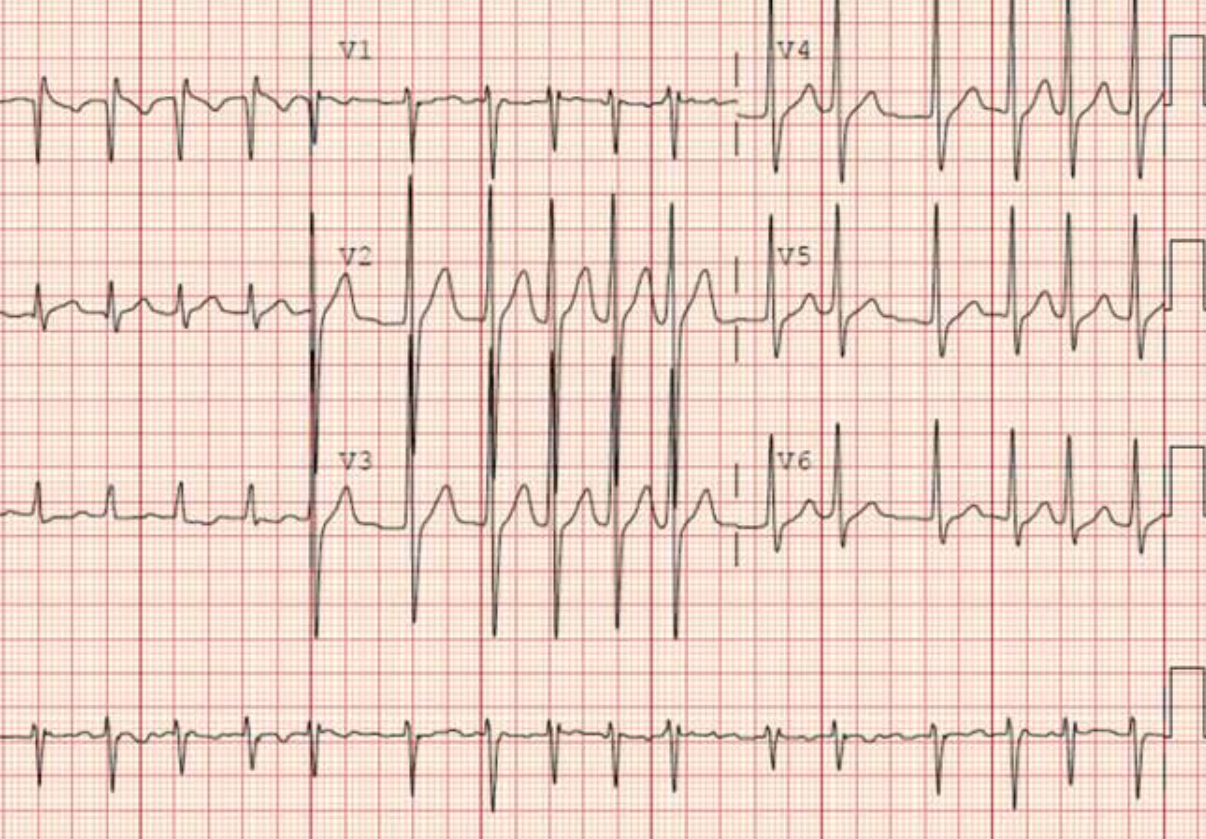
# Patient Diagnoses

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**The 1,157 survey respondents were previously diagnosed with at least one type of heart valve disease.**

Aortic stenosis:	48.8%
Bicuspid aortic valve:	32.9%
Mitral regurgitation:	31.0%
Aortic regurgitation:	23.3%
Mitral valve prolapse:	18.1%
Tricuspid regurgitation:	5.8%
Pulmonary regurgitation:	1.2%





# Comorbid Diagnoses

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**56% of survey respondents indicated they suffered from heart valve disease and one of the following cardiac disorders:**

Atrial Fibrillation:	24.2%
Aortic Aneurysm:	19.7%
Coronary Artery Disease:	12.2%

Survey Finding #1

**Heart Valve Patients Are Not  
Aware of Clinical Trials**

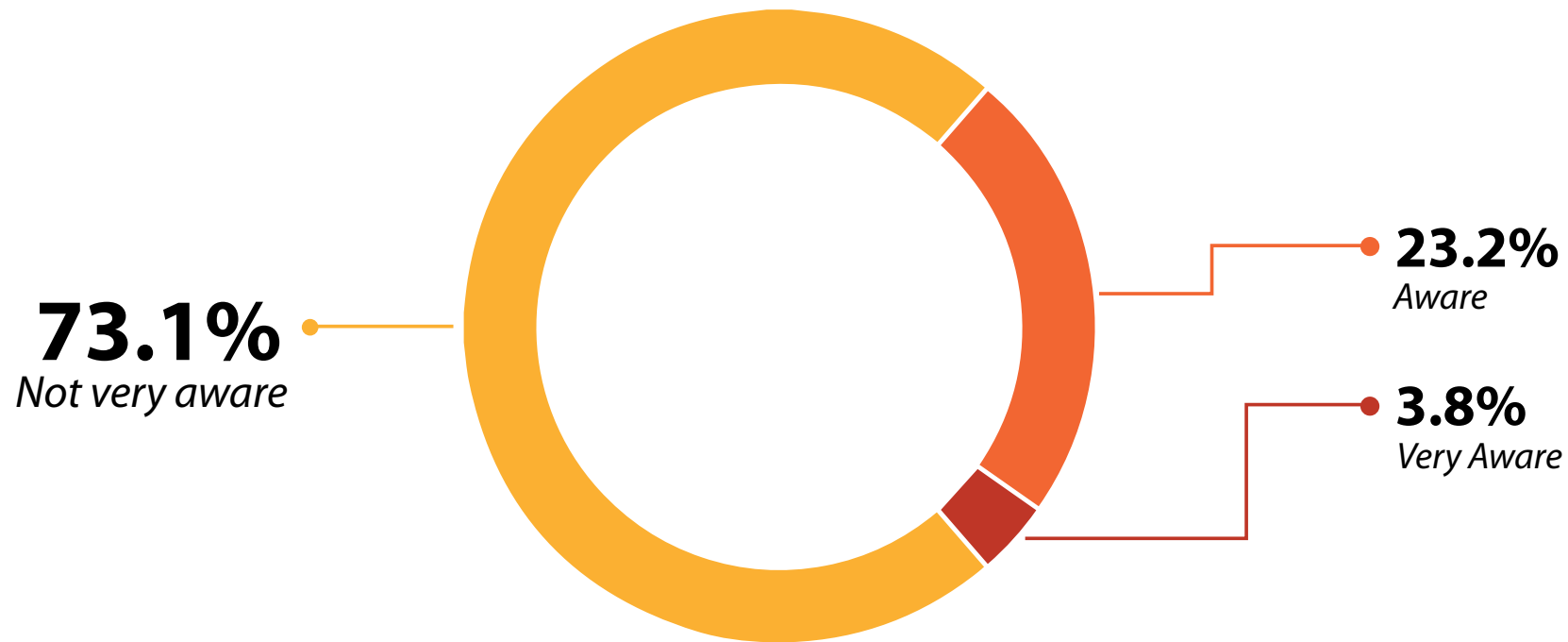


# Patient Awareness Levels for Clinical Trials

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When patients were asked, "What is your current level of clinical trial awareness specific to heart valve disease?", 73% of respondents answered, "Not very aware".

Question: What is your current level of clinical trial awareness specific to heart valve disease?

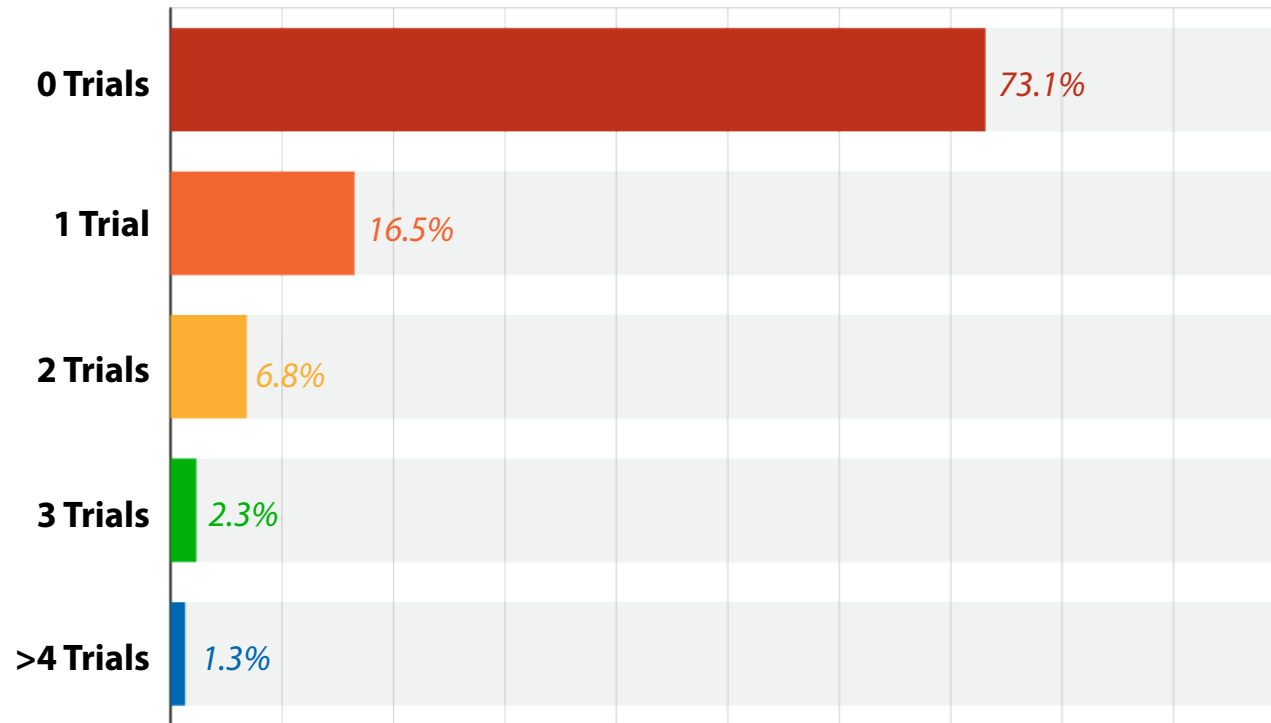


# Identifying & Describing Clinical Trials

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When patients were asked, “Specific to heart valve disease, how many clinical trials can you specifically name and describe?”, 73% of respondents answered “0”.

Question:  
Specific to heart valve  
disease, how many clinical  
trials can you name and  
describe?

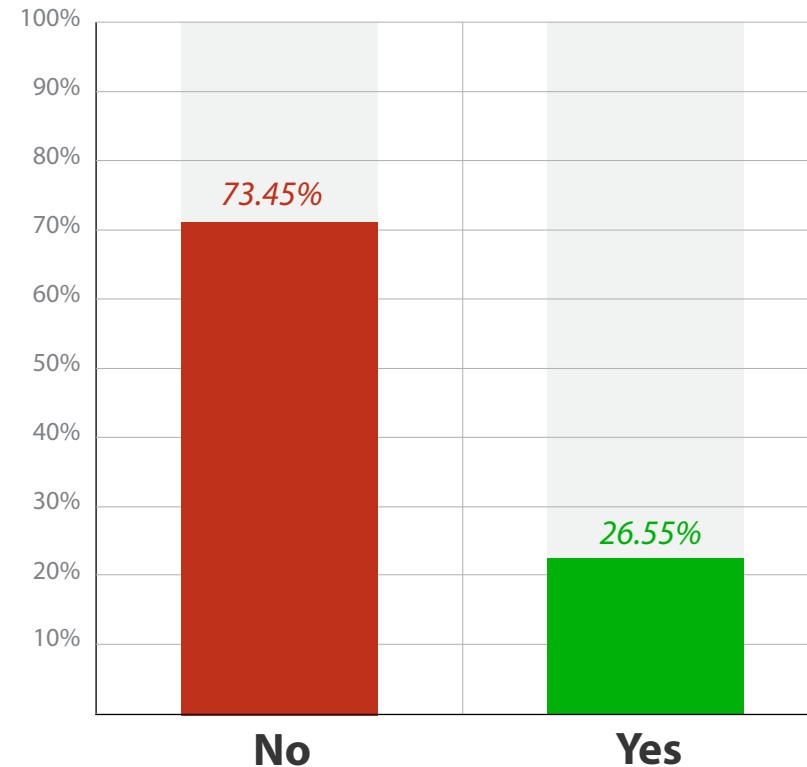


# Clinical Trial Awareness Before Surgery

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Prior to surgery, 73% of heart valve patients were not aware of clinical trials.

Question:  
Were you aware of clinical  
trials for heart valve patients  
before your surgery?





Survey Finding #2

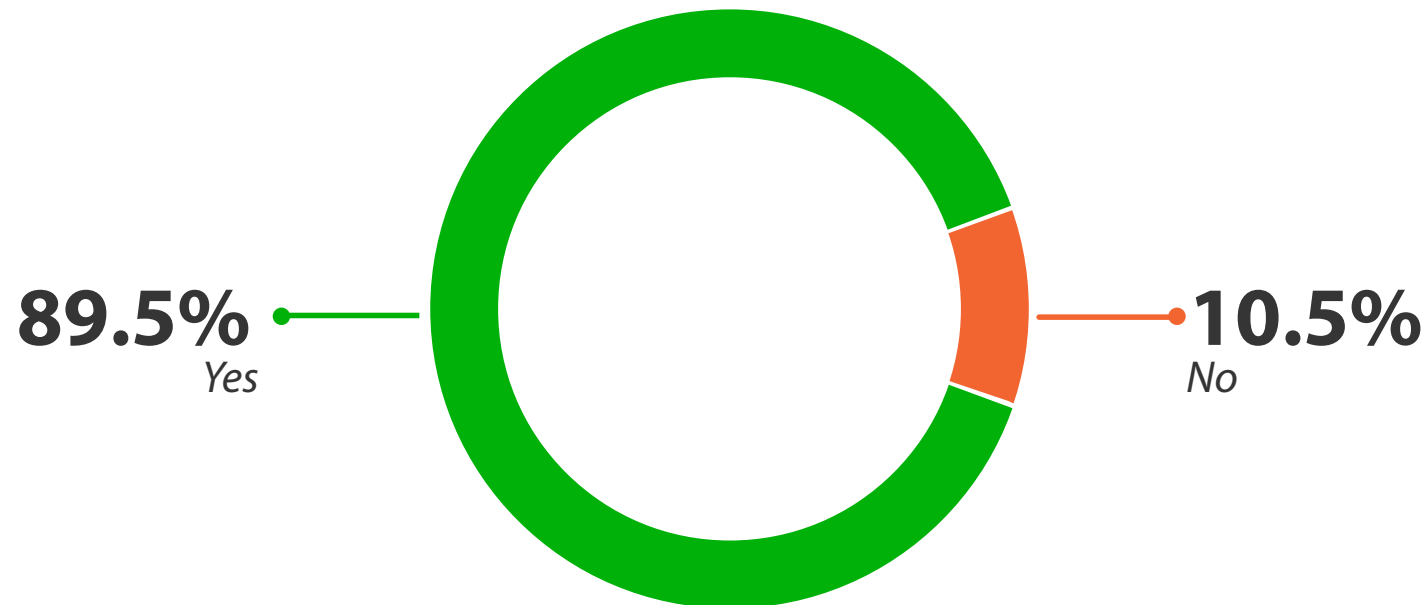
# **Heart Valve Patients Want To Learn About Clinical Trials**

# Patients Want to Learn About Clinical Trials

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According to survey respondents, **89.5% of pre-operative patients** want to learn about clinical trials.

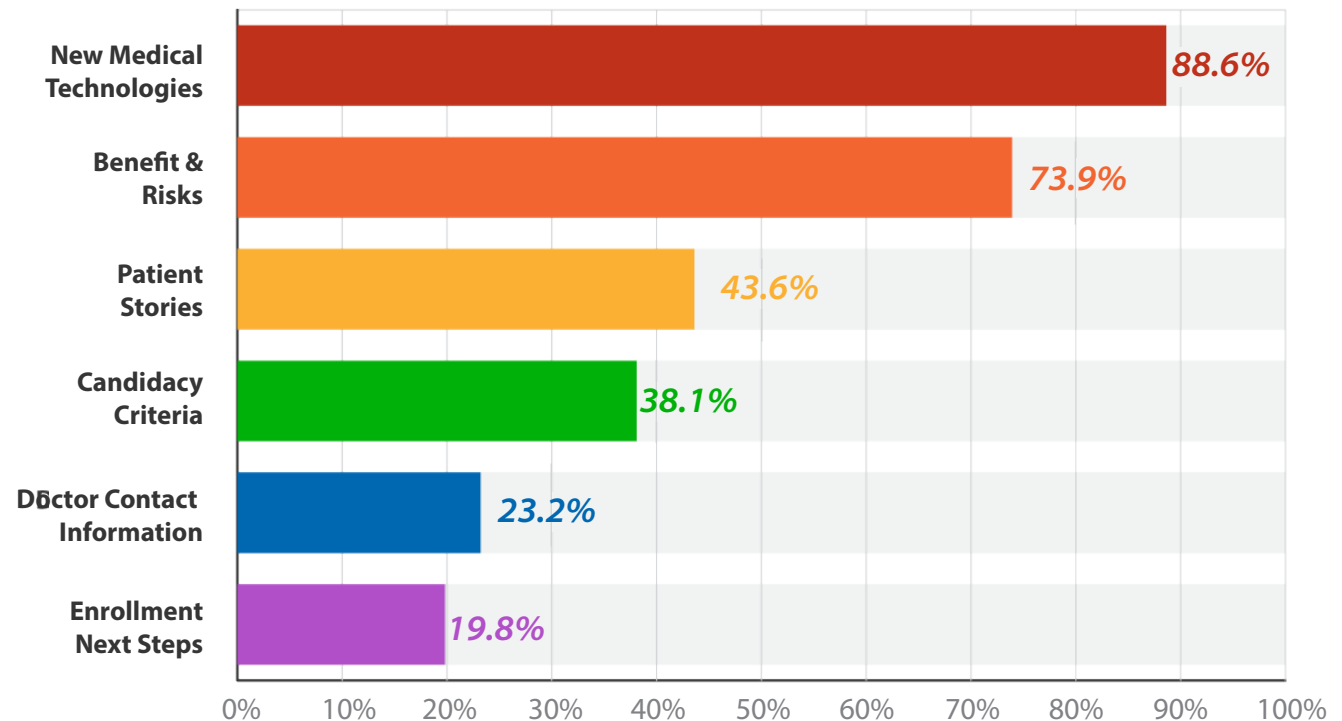
Question to Pre-Operative Patients: Would you like to learn about clinical trials for heart valve patients?



# What Do Patients Want to Learn About?

Patients want to learn about new medical technologies (89%), the benefits and risks of clinical trials (74%), patient stories about a clinical trial (44%), candidacy criteria (38%), doctor contact information (23%), and enrollment next steps (20%).

Question:  
What would you like to  
learn about heart valve  
clinical trials?





Survey Finding #3

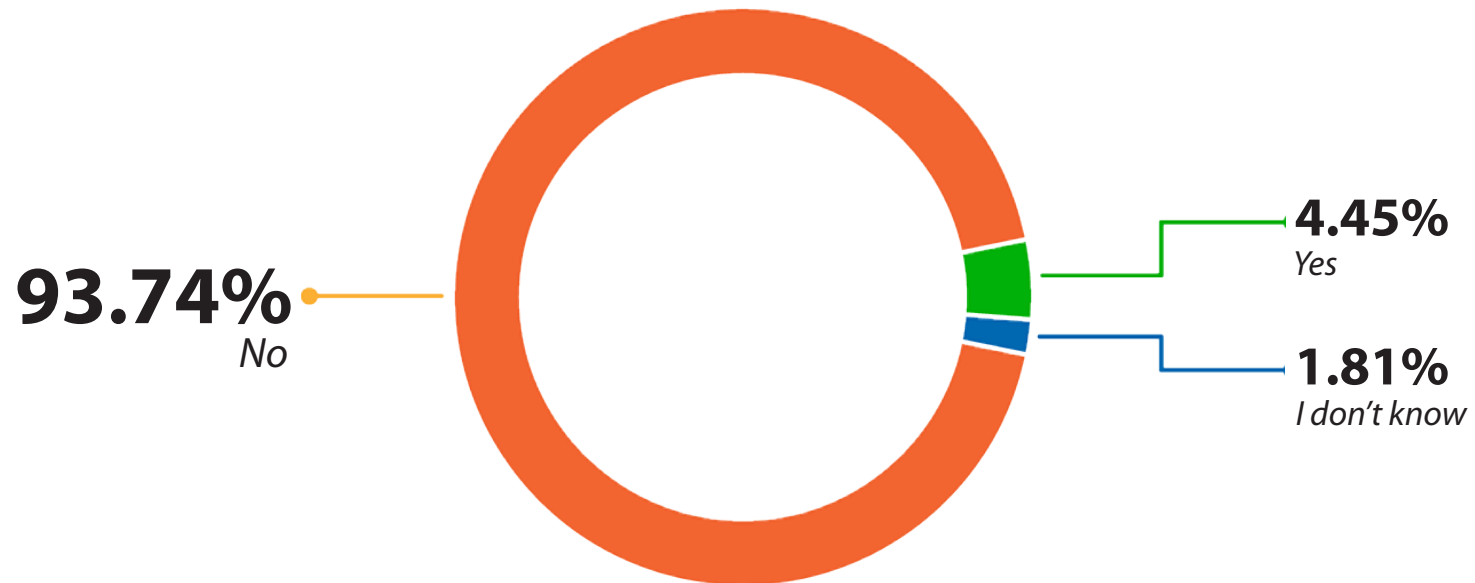
# **Heart Valve Patients Want To Participate In Clinical Trials**

# Previous Participation in Clinical Trials

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When patients were asked, “Have you previously participated in a heart valve clinical trial?”, 93.7% of respondents answered “No”.

Question: Have you previously participated in a heart valve clinical trial?

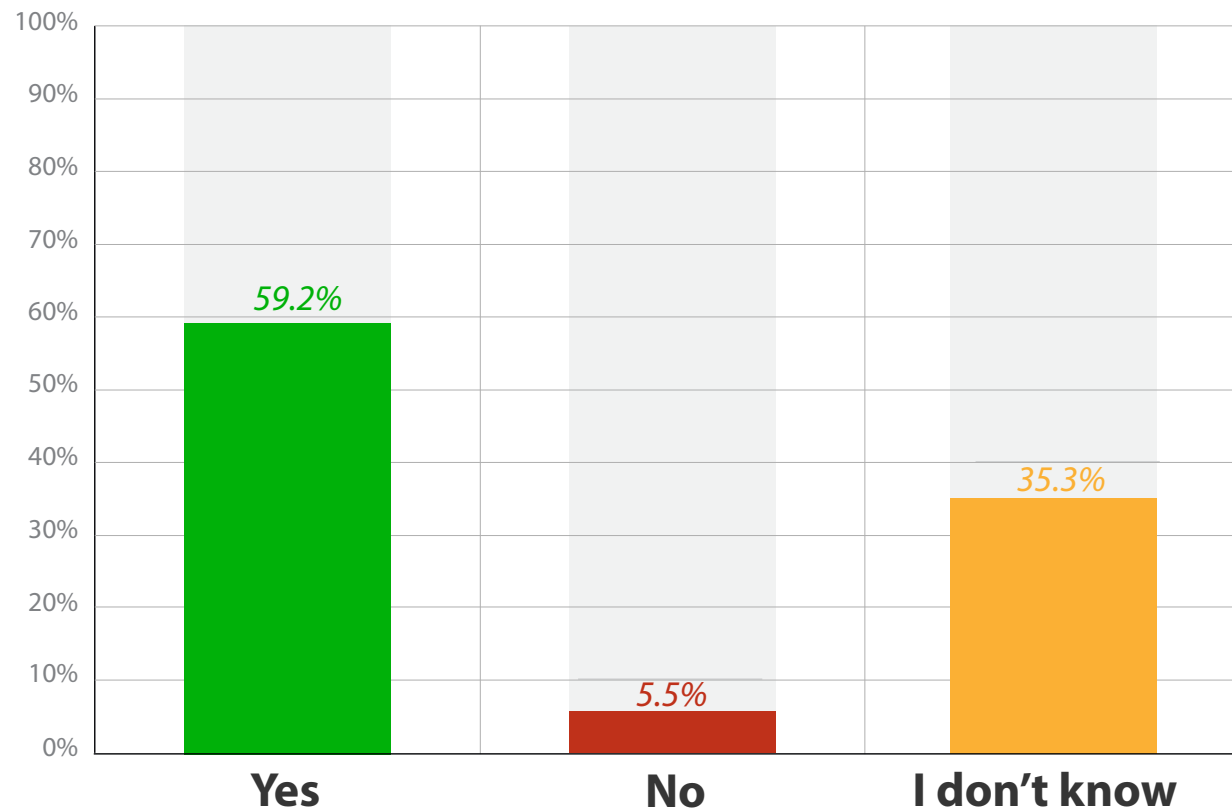


# Patient Interest for Clinical Trial Participation

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When patients were asked, “Would you consider participating in a heart valve clinical trial?”, 59.2% of respondents answered “Yes”.

Question:  
Would you consider  
participating in a  
heart valve clinical trial?



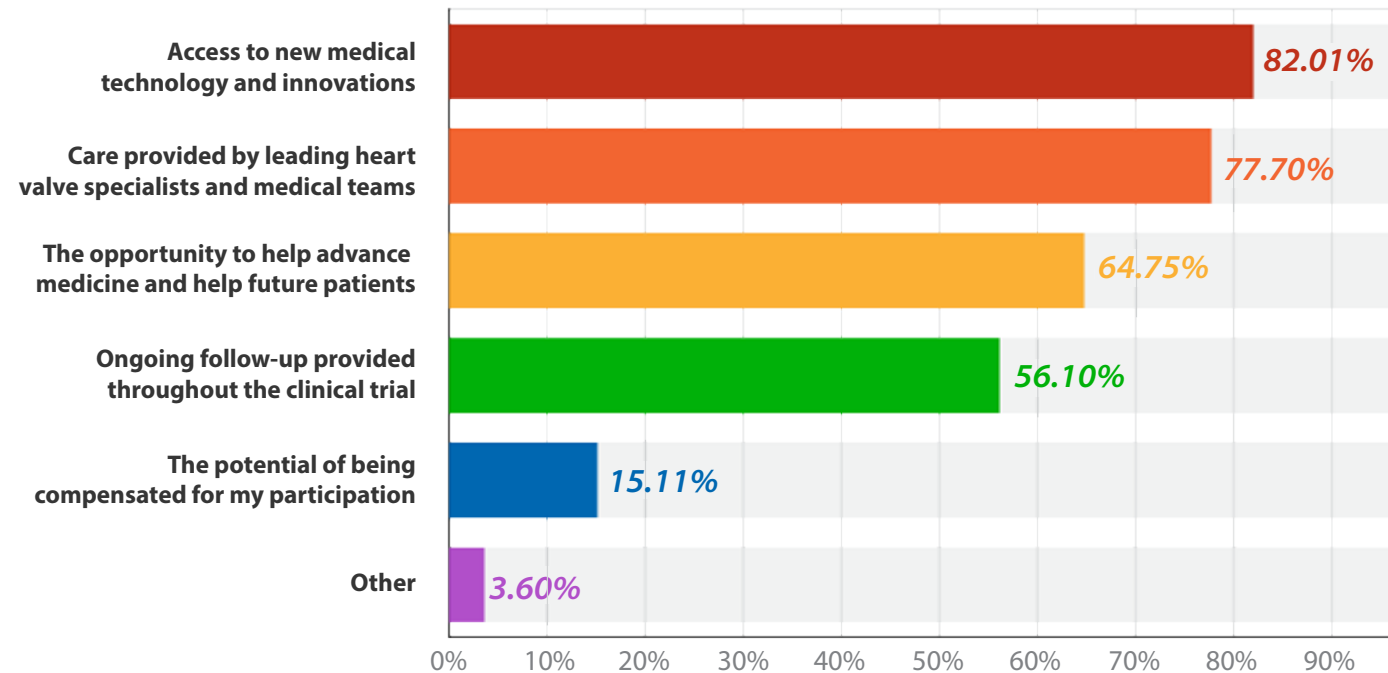
Survey Finding #4

**Patients Know Why They Want  
To Participate In Clinical Trials**

# Why Participate In A Clinical Trial?

The top four reasons patients want to participate in clinical trials include access to new medical technology (82%), care provided by leading heart valve specialists (78%), the opportunity to help advance medicine and future patients (65%), and ongoing follow-up provided throughout the clinical trial (56%).

Question:  
Why would you consider  
participating in a heart  
valve clinical trial?





Survey Finding #5

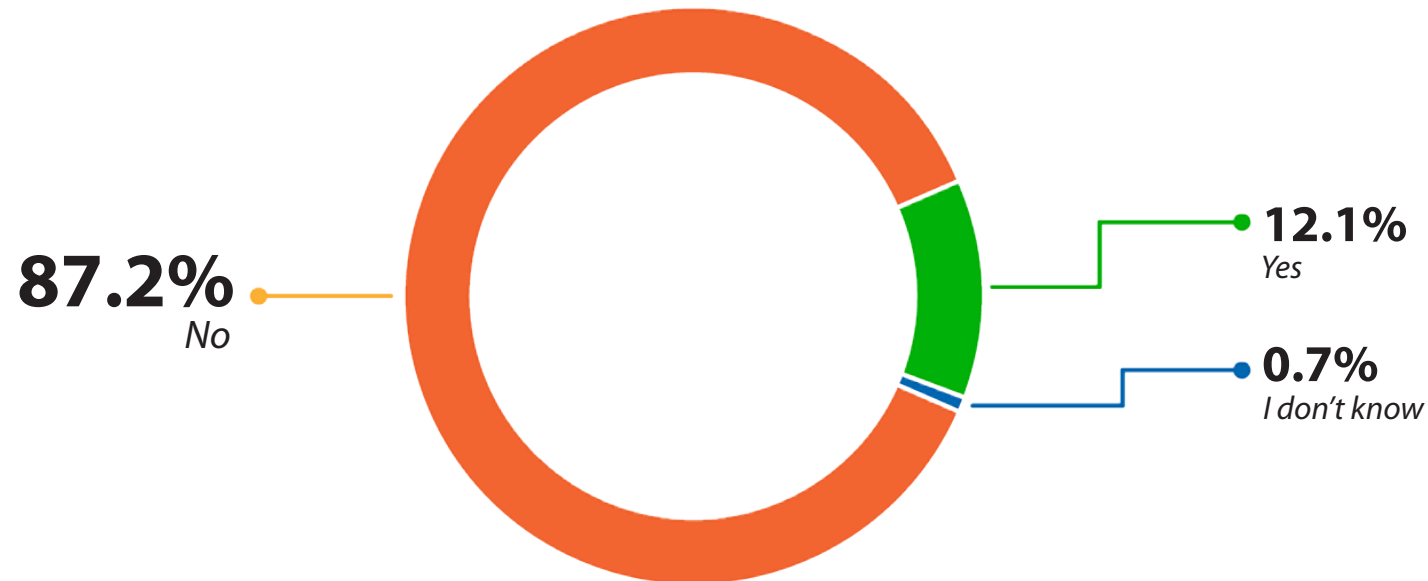
**Existing Educational Resources For  
Clinical Trials Are Under-Utilized**

# Existing Educational Resources Are Under-Utilized

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87% of patients have never visited ClinicalTrials.gov, the largest clinical trials website managed by the U.S. National Library of Medicine.

Question: Have you ever visited ClinicalTrials.gov?



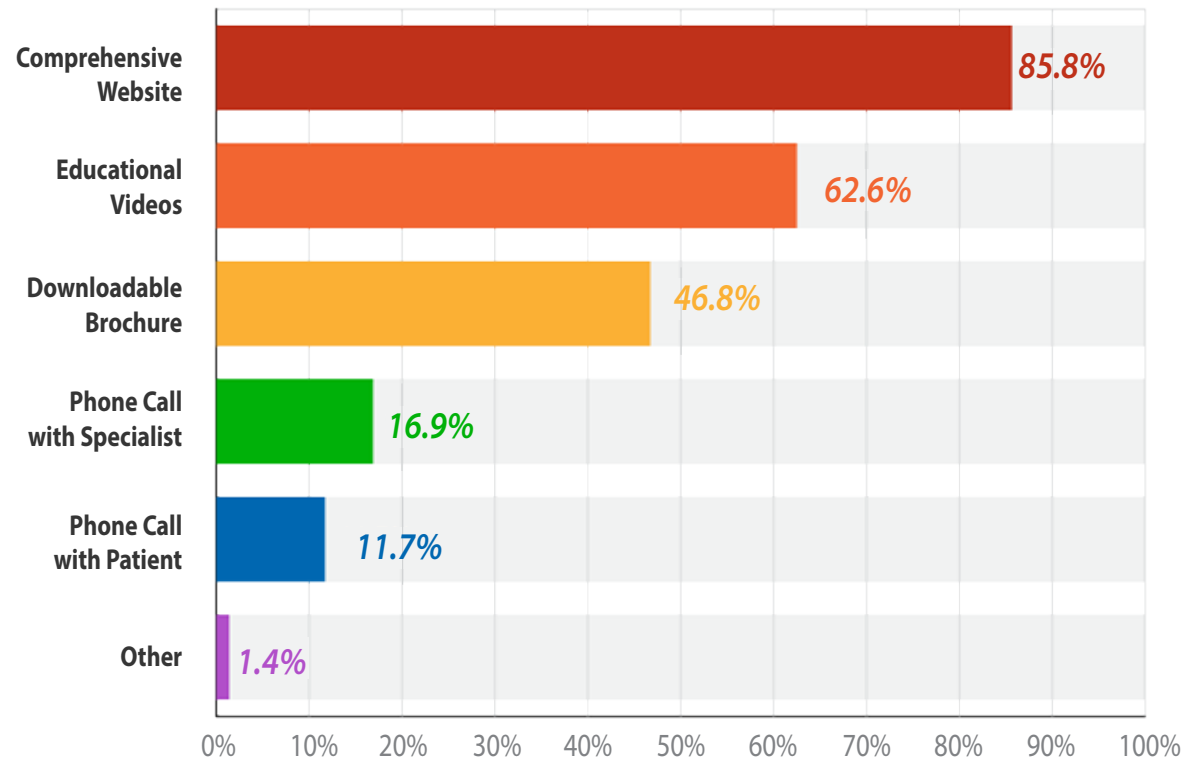
Survey Finding #6

**Patients Know How They Want  
To Learn About Clinical Trials**

# What Educational Resources Do Patients Want?

To enhance awareness and education specific to clinical trials, patients want comprehensive websites with detailed information about clinical trials (86%), educational videos with doctors describing clinical trials (63%), downloadable brochures about clinical trials (47%), a phone call with a clinical trial specialist (17%), and a phone call with a patient already enrolled in a clinical trial (12%).

Question:  
Which resources would  
help you learn about  
heart valve clinical trials?



Survey Finding #7

**Patients Know Where They Want  
To Learn About Clinical Trials**

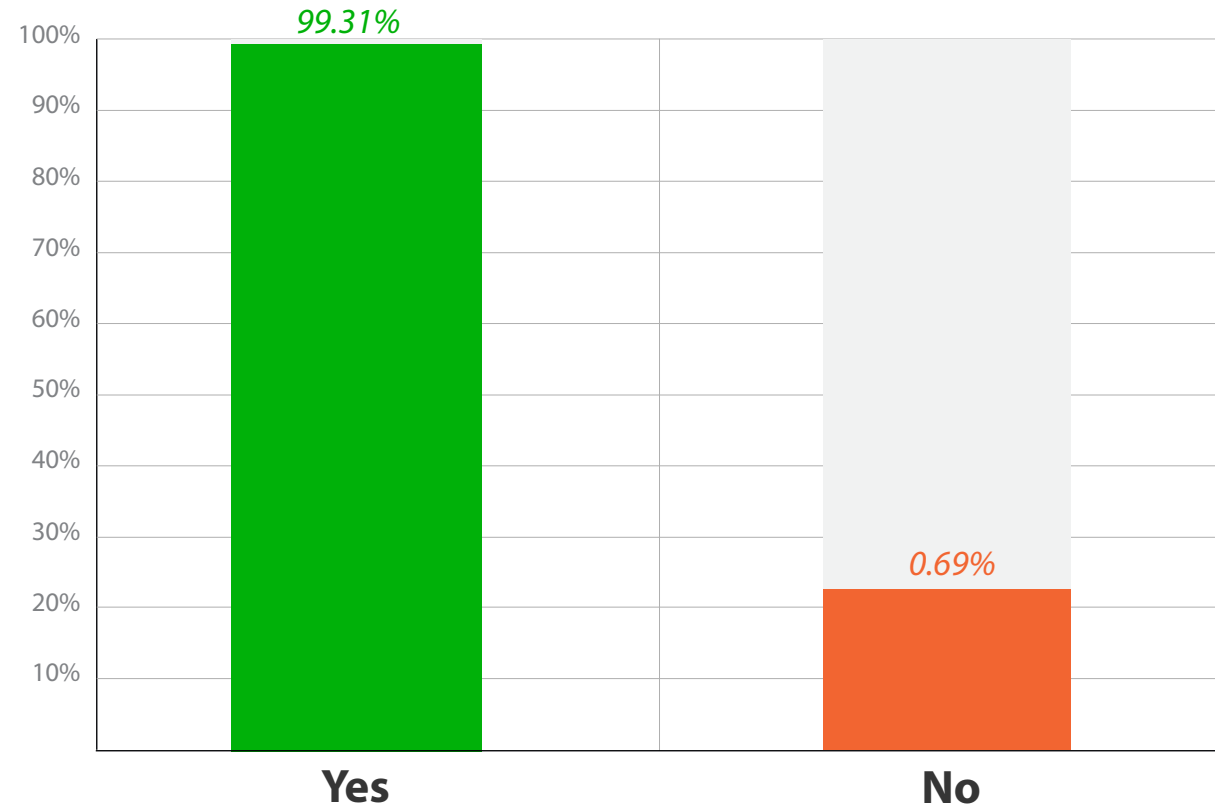


# Where Do Patients Want to Learn About Trials?

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99% of patients surveyed would visit a new “Clinical Trials” section at HeartValveSurgery.com.

Question:  
If HeartValveSurgery.com started  
a new section of the website to  
educate patients about clinical trials,  
would you visit that section?



# Heart Valve Patient Survey Takeaways

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- Nearly three out of four (73%) heart valve patients are “not very aware” of clinical trials.
- 73% of patients surveyed cannot name and describe one clinical trial.
- 90% of pre-operative patients want to learn about clinical trials.
- Only 4% of patients surveyed have participated in a clinical trial, yet 59% of patients would consider enrolling in a clinical trial.
- Just 13% of heart valve patients have visited ClinicalTrials.gov.
- 99% of patients would visit a new ‘Clinical Trials’ section at HeartValveSurgery.com to learn about clinical trials.



## Questions? Need Help?

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If you have any questions or need help with your clinical trial awareness initiatives, please contact:

Email: [info@heartvalvesurgery.com](mailto:info@heartvalvesurgery.com)

Phone: (888) 725-4311



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# 2020 Heart Valve Clinical Trial Report

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Missed Opportunities for  
Patient Awareness & Enrollment

