

# First Report of Outcomes in the TRILUMINATE™ Pivotal Clinical Trial of TriClip™ in Patients with Tricuspid Regurgitation

## Insights From the Roll-In Cohort

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# Study Design

## BACKGROUND

The TRILUMINATE™ Pivotal trial is the first randomized, controlled clinical trial to evaluate the safety and effectiveness of transcatheter edge-to-edge repair (TEER) in patients with tricuspid regurgitation (TR)

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## SCIENTIFIC OBJECTIVE

To evaluate the safety and effectiveness of TriClip™ TEER System in improving clinical outcomes in symptomatic patients with severe TR

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## TRIAL DESIGN

- Prospective, multicenter, randomized, controlled, clinical trial
  - Randomized cohort (450+), single-arm cohort (200), and **roll-in cohort** (up to 3 per site)
  - **Principal Investigators:** Dr. David Adams, Dr. Paul Sorajja
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## PRIMARY ENDPOINTS

**Randomized Cohort:** Hierarchical composite of all-cause mortality or tricuspid valve surgery, heart failure (HF) hospitalizations, and quality of life (QoL) improvement assessed using the Kansas City Cardiomyopathy Questionnaire (KCCQ) at 12 months

**Single-Arm Cohort:** Survival at 12 months with KCCQ QoL increase  $\geq 10$  points compared to baseline.

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## KEY INCLUSION/EXCLUSION CRITERIA

### Key Inclusion Criteria:

- Symptomatic with severe TR despite medical therapy
- Intermediate or greater risk for tricuspid valve surgery

### Key Exclusion Criteria:

- Severe pulmonary hypertension or left-sided heart failure
- Untreated severe CV disease (e.g., MR, AS, CAD)

# 55 US Study Sites

- Abbott Northwestern Hospital
- Allegheny General Hospital-ASRI
- Arizona Cardiovascular Research Center
- Aurora Medical Group
- Austin Heart
- Baptist Hospital of Miami
- Baylor Scott & White Heart & Vascular Hospital
- Beth Israel Deaconess Medical Center
- Brigham & Women's Hospital
- Buffalo General Hospital
- California Pacific Medical Center - Van Ness Campus
- Cardiovascular Institute of the South
- Cardiovascular Research Institute of Kansas
- Carolinas Medical Center
- Cedars-Sinai Medical Center
- Centennial Heart Cardiovascular Consultants
- Christ Hospital
- El Camino Hospital
- Hospital of the University of Pennsylvania
- Inova Fairfax Hospital
- Intermountain Medical Center
- JFK Medical Center
- Kansas University Medical Center
- Los Robles Regional Medical Center
- Manatee Memorial Hospital
- MedStar Health Research Institute
- Methodist Hospital of San Antonio
- Montefiore Medical Center - Moses Division
- Morton Plant Valve Clinic
- Mount Sinai Hospital
- New York-Presbyterian/Columbia University Medical Center
- North Shore University Hospital
- Northshore University HealthSystem
- Novant Health Heart and Vascular Research Institute
- Ohio Health Research Institute
- Phoenix Cardiovascular Research Group
- Piedmont Heart Institute
- Providence Heart & Vascular Institute
- Providence Medical Foundation
- Rush University Medical Center
- Scripps Health
- Sentara Norfolk General Hospital
- St. Thomas Hospital
- Sutter Medical Center, Sacramento
- Swedish Medical Center
- Tallahassee Research Institute
- The Cleveland Clinic Foundation
- The Methodist Hospital
- Tucson Medical Center
- University Hospital - Univ. of Alabama at Birmingham (UAB)
- University of California - Davis Medical Center
- University of Colorado Hospital
- University of Pittsburgh Medical Center
- University of Virginia Medical Center
- Yale New Haven Hospital

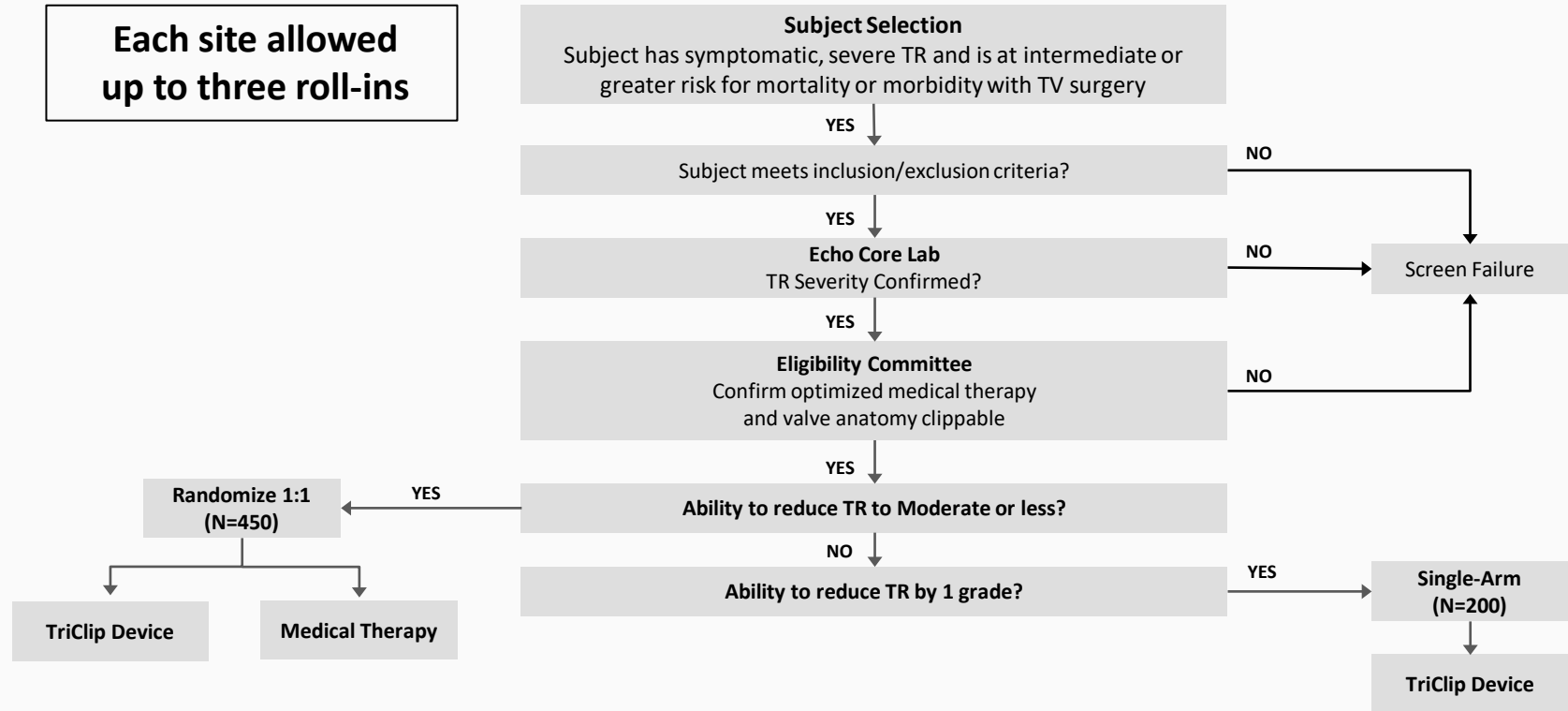
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# 12 International Study Sites

- Hamilton Health Science Centre
- Herzzentrum Leipzig GmbH
- Hospital Clinic de Barcelona
- Institut de Cardiologie de Montreal (Montreal Heart Inst.)
- Munchen Grosshadern
- Ospedale San Raffaele - Cardiac
- Ottawa Heart Institute
- St. Michael's Hospital
- St. Paul's Hospital
- Sunnybrook Health Sciences Centre
- Universitätsklinikum Bonn AdoR
- Universitätsmedizin der Johannes Gutenberg-Universität Mainz

# Enrollment Pathway



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# TriClip™ G4 TEER Delivery System

Engineered to navigate the right heart anatomy

**F/E KNOB**  
Flexes and extends deliver catheter to steer down to the valve plane

**S/L KNOB**  
Enables movement in septal or lateral direction

**+/- KNOB**  
Provides the height needed above the valve plane

**DISTAL CURVE**  
Anatomically designed for direct access to the valve

**CONTROLLED GRIPPER ACTUATION**

Ability to optimize leaflet grasping if needed

## 4 CLIP SIZES

Broad range of sizes for tailored treatment



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# Baseline Characteristics

VARIABLE	n=97
Age, mean (years)	79 ± 9
Male/Female	62 %/38 %
NYHA Class III/IV	68 %
KCCQ score	55.3 ± 21.5
6MWD (m)	234 ± 116
Left Ventricular Ejection Fraction	59.8 ± 10.2
Functional Tricuspid Regurgitation	91 %
Baseline TR Severity	
Grade 2 (moderate)	2%
Grade 3 (severe)	37 %
<b>Grade 4 (massive)</b>	<b>24 %</b>
<b>Grade 5 (torrential)</b>	<b>37 %</b>

VARIABLE	n=97
Hypertension	80 %
Atrial Fibrillation	90 %
Prior Left-sided Intervention	39 %
Prior CABG	21 %
Diabetes	25 %
Chronic Renal Disease	27 %
Chronic Obstructive Pulmonary Disease	19 %
Peripheral Vascular Disease	14%
Prior Stroke	6 %
<b>Permanent Pacemaker/ICD</b>	<b>9 %</b>
Prior Myocardial Infarction	7 %

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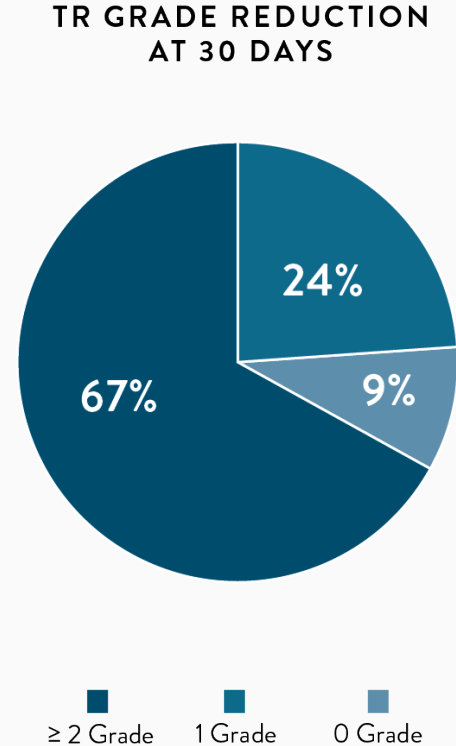
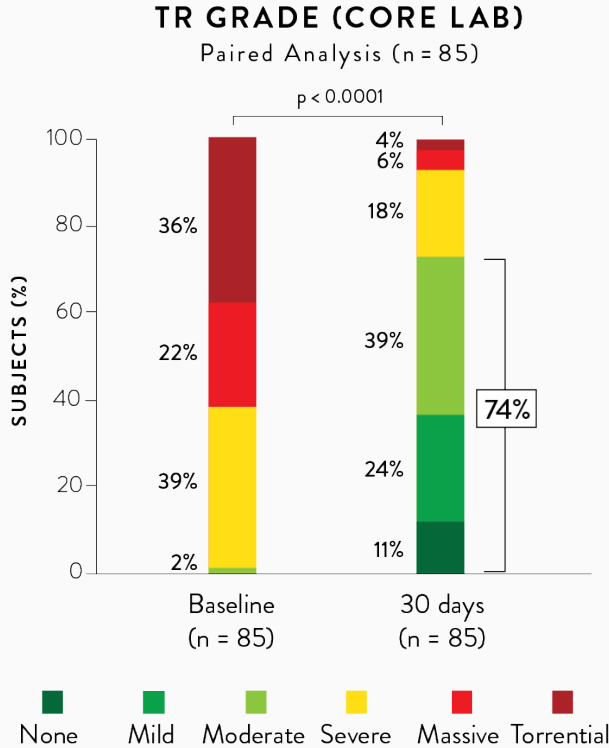
# Acute Procedural Outcomes

PARAMETER	(N=97)
Implant Success (at least 1 clip placed)	99 %
Mean Device Time (min)	105 ± 67
Median Device Time (min)	89 (50, 146)
# of clips per patient	2.3 ± 0.7
Devices Implanted*	
NT	21%
XT	79%

\* All roll=ins completed prior to G4



# 30-day TR Reduction



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# Safety Outcomes at 30-days

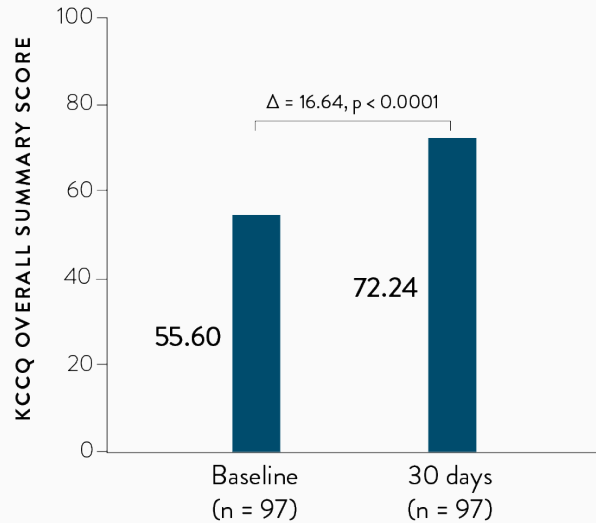
EVENT	n=97
MAEs	1.0% (1)
Cardiovascular Mortality	1.0% (1)
New Onset Renal Failure	1.0% (1)
Endocarditis Requiring Surgery	0
Non-Elective Cardiovascular Surgery for Device-Related AE	0

EVENT	n=97
Other Clinical Safety Endpoints	15.5 % (15)
All-cause Mortality	1.0% (1)
Stroke/TIA	0
TV Surgery	1.0% (1)
TV re-intervention	1.0% (1)
Major Bleeding*	7.2% (7)
Device Embolization	0
Single Leaflet Device Attachment (SLDA)	7.2% (7)

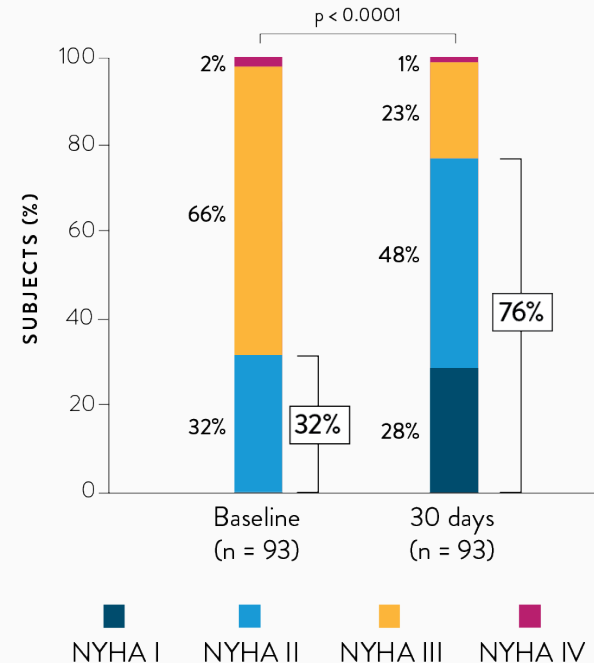
\* Major defined as bleeding BARC Type 3A.

# Functional and Quality of Life Measures

## KCCQ-OS



## NYHA FUNCTIONAL CLASS



# Summary

- TRILUMINATE™ Pivotal Trial is a landmark randomized, controlled clinical trial to evaluate the safety and effectiveness of TriClip™ across a broad range of tricuspid anatomies
- Early TriClip™ experience in the roll-in cohort demonstrated successful TR reduction in most patients, despite the majority having massive and torrential TR severity at baseline.
- Few subjects experienced a major adverse event within 30 days.
- Most experienced a clinically meaningful improvement in functional status and quality of life at 30-day follow-up, with an average increase in KCCQ score of ~17 pts at 30-day follow-up.
- Results from the ongoing TRILUMINATE Pivotal Trial randomized cohort will provide insight into the impact of TriClip™ TEER on clinical outcomes in symptomatic patients with severe TR

**SOURCE: ESC 2022, August 26-29**

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