SAPIEN: Simpler and More Sophisticated (X4 and ALLIANCE)

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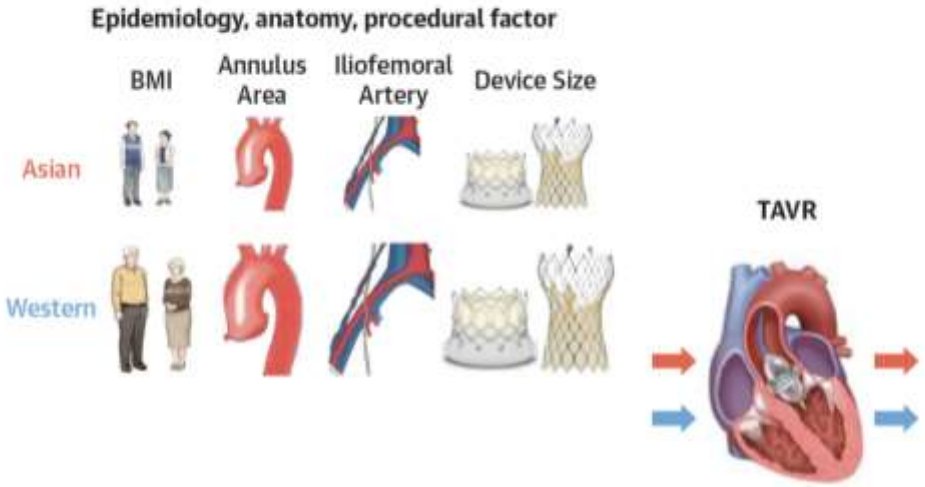
Current Score
UNITED STATES
65:75
EUROPE

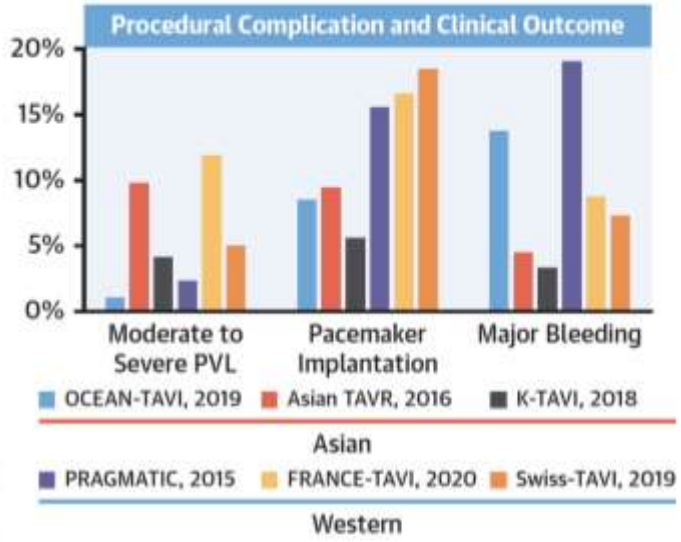
TAVR in Asia

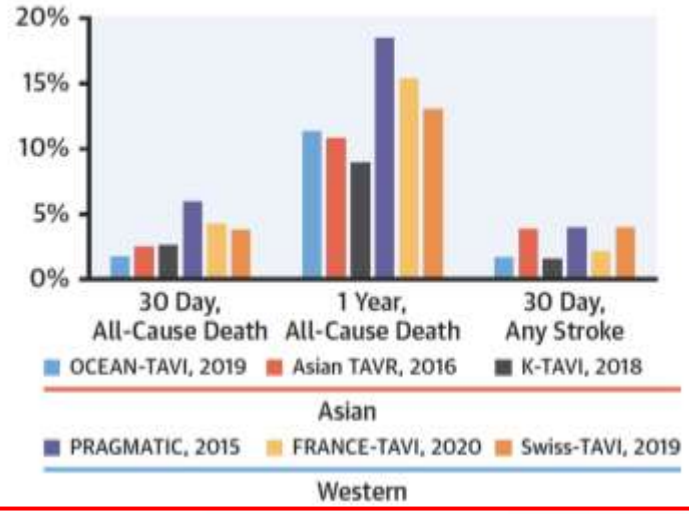
CENTRAL ILLUSTRATION Specific Clinical and Anatomic Features and Outcomes of Transcatheter Aortic Valve Replacement in Asian Populations



	Age	Male	BMI	LVEF	STS score
Asian	◄►	◄►		◄►	◄►
Western	◄►	◄►	▲	◄►	◄►

	Valve area	Annulus area	Bicuspid	Device size	Transfemoral
Asian	◄►		▲		◄►
Western	◄►	▲		▲	◄►





CH Lee, T. Inohara, K. Hayashida, DW Park, JACC Asia: 2021 Dec, 1 (3) 279–293

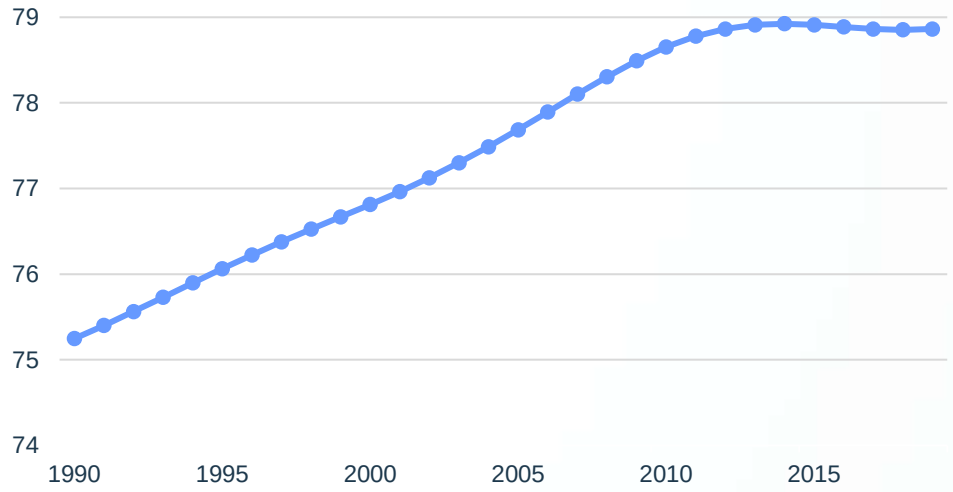
Today's TAVR patients have longer life expectancies

The TAVR patient population has expanded to younger patients

Low-risk patients in the PARTNER 3 trial are ~10 years younger than previous PARTNER trials

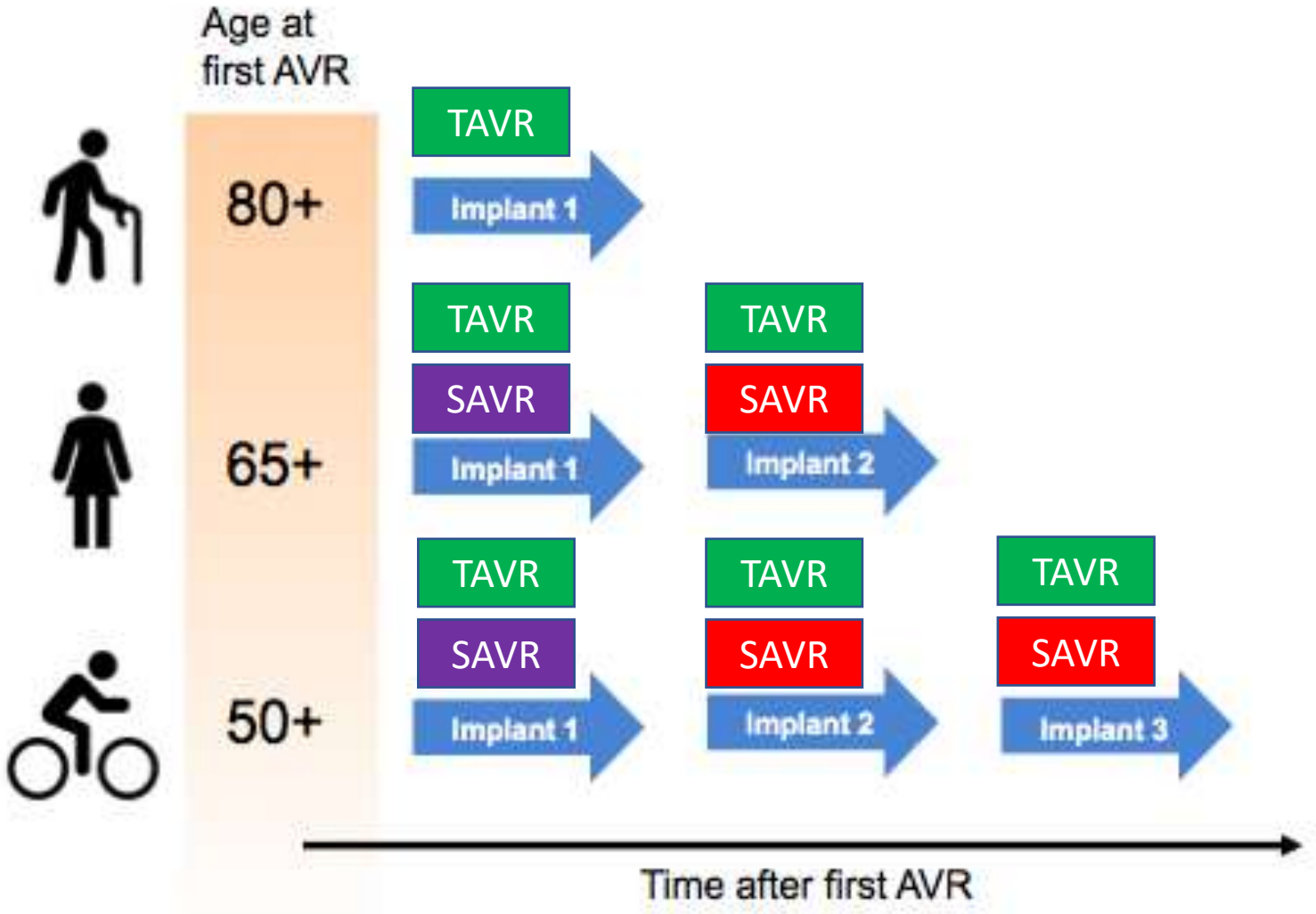
Even older patients have longer life expectancies

Life expectancy, 1990-2019*[4]



1. Leon MB, Smith CR, Mack MJ, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med. 2010;363(17):1597-1607.
2. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. N Engl J Med. 2016;374(17):1609-1620.
3. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med. 2019;380(18):1695-1705.
4. Roser M, Ortiz-Ospina E, Ritchie H. Life expectancy. Our World in Data. https://ourworldindata.org/life-expectancy. Accessed July 1, 2022.

AS Lifetime Management:
Why is TAVI Explant so important?



SAPIEN THV Design Evolution

SAPIEN valve

- Stainless Steel
- Bovine pericardium
- 23-26mm valves
- 22/24F access

SAPIEN XT valve

- Cobalt chromium
- Bovine pericardium
- 20-29mm valves
- 16-20F access

SAPIEN 3 valve

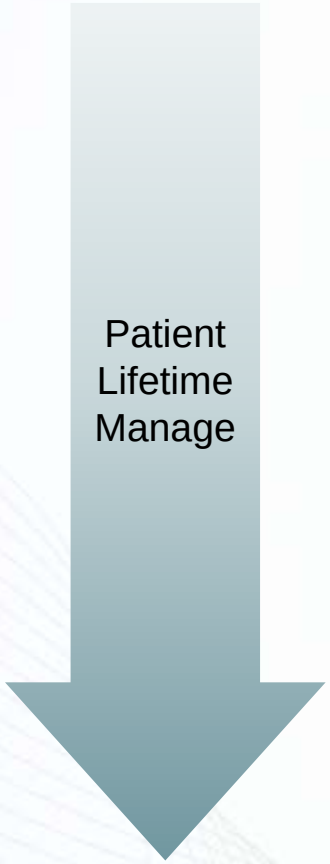
- Low profile valve design
- PET outer skirt
- 20-29mm valves
- 14-16F access

SAPIEN 3 Ultra valve

- Enhanced PVL solution
- 20-26mm valves
- 14F access

2007 — 2020

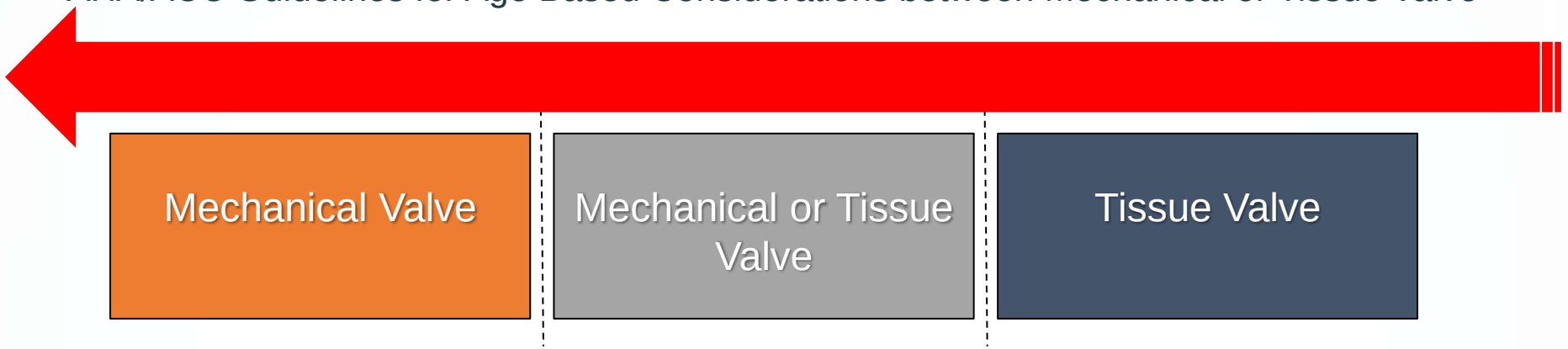
Next Generation THV design with a focus on Lifetime Management of Aortic Stenosis



Optimize index procedure	Safety, reproducibility, low access profile, personalized valve sizing, PVL solution
Extend valve longevity	Novel tissue technology, valve design
Maintain coronary access	Short frame height, commissural alignment
Plan for THV-in-THV	Control of valve orientation relative to anatomy

New Tissue Technologies Are Changing our Treatment Considerations for Patient with Longer Life Expectancy

AHA/ACC Guidelines for Age Based Considerations between Mechanical or Tissue Valve[1]



Mechanical valves offer durability

But …

- May require lifetime anticoagulant treatment
- Limits future intervention options if needed

Tissue valves offer quality of life

But …

- Relatively shorter expected valve life increases the potential need for replacement when patients are older and more prone to complications

1. Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2021;77(4):e25-e197.

SAPIEN X4 Transcatheter Heart Valve System

Novel frame and leaflet design

- Enables adjustable sizing while maintaining valve performance over the deployment diameter range
- Maintains high radial strength cobalt chromium balloon-expandable design

Low frame height and large cells

- Facilitates future coronary access

RESILIA tissue

- Offers enhanced anti-calcification technology and enables dry storage
- Maintains bovine pericardial leaflets matched for thickness and elasticity

Enhanced PET outer skirt

- Designed to further minimize PVL
- Maintains low profile access

RESILIA tissue calcium-blocking technology*

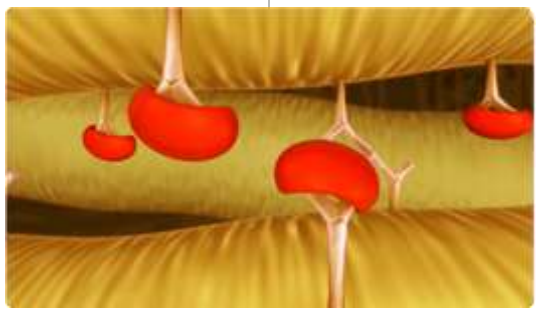
Proprietary tissue technology

SAPIEN 3 Ultra valve

Stable capping
permanently blocks calcium binding sites within tissue*[1]

Glycerolization
enables dry tissue storage

SAPIEN X4 valve



RESILIA tissue technology blocks the receptors that enable calcium to bind to tissue*[1]

*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.

1. Flameng W, Hermans H, Verbeken E, Meuris B. Randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. *J Thorac Cardiovasc Surg*. 2015;149:340-345.

SAPIEN X4: Provides Adjustable Valve Sizing

SAPIEN 3 Ultra

4 valve sizes (3 mm increments)

20 mm

23 mm

26 mm

29 mm

SAPIEN X4

3 valve sizes, 16 unique deployment diameters (0.5 mm increments)

SAPIEN X4 Delivery System

Commander-like system

- Articulation for tracking and coaxiality

On-balloon valve preparation

- Enables commissural alignment
- Streamlines procedure

Low profile access

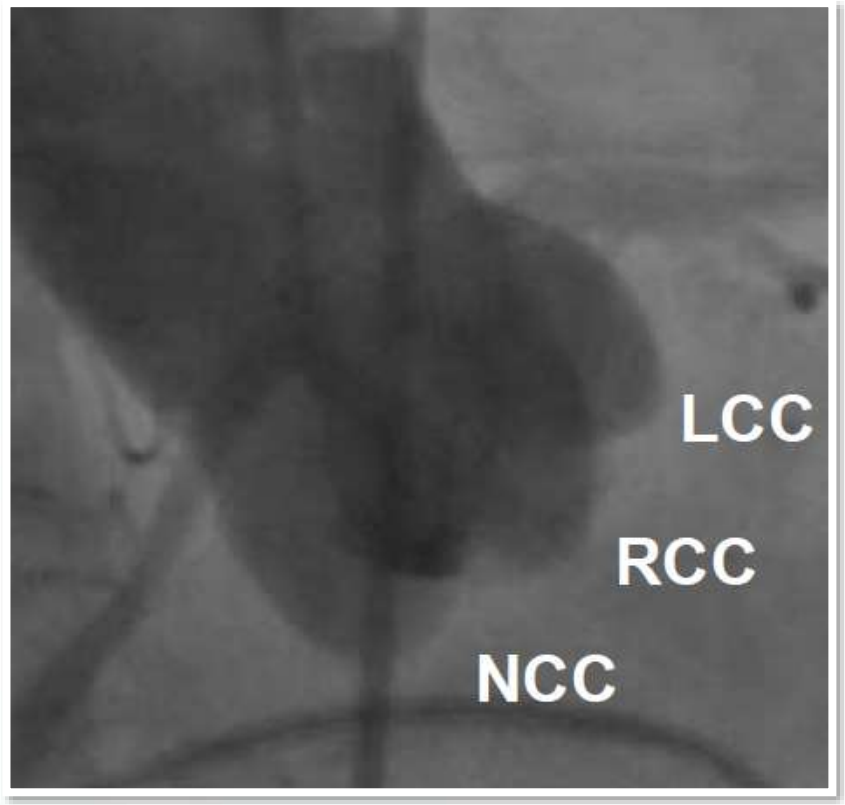
- 14/16F expandable sheath compatibility

Valve Rotation Control

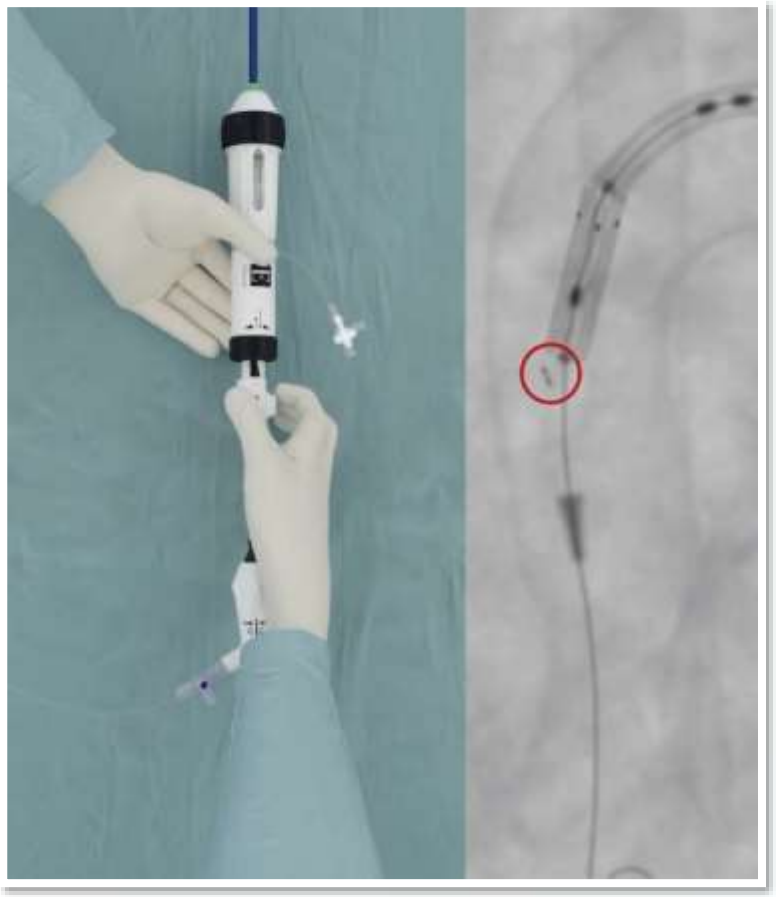
- Control for commissural alignment
- Independent control of valve orientation

Commissural Alignment with SAPIEN X4

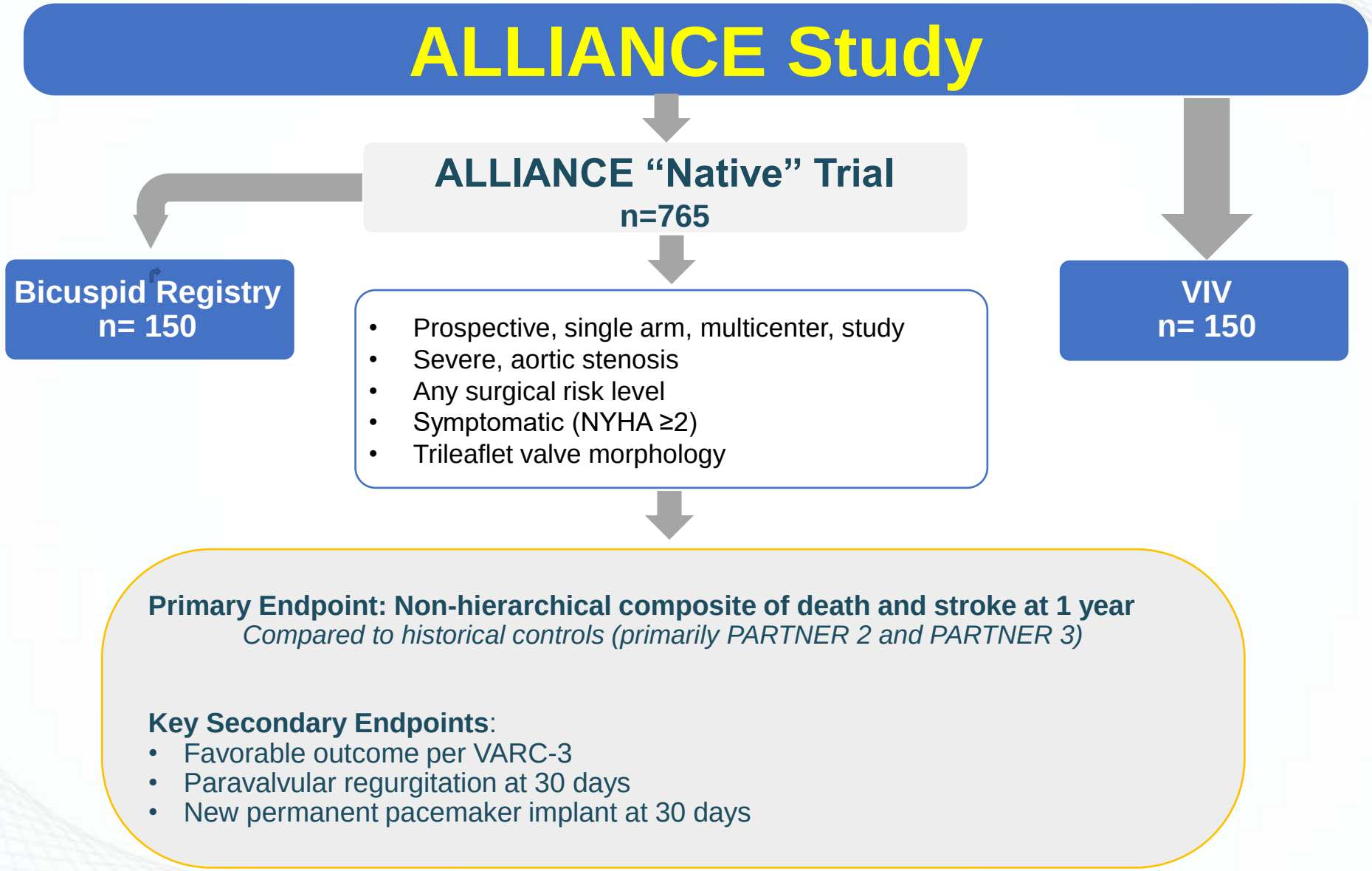
1. Standard 3 cusp view



2. Align radiopaque marker prior to deployment



SAPIEN X4 Clinical Research Program



Key Messages

- Long-term valve durability is a most important issue for AS lifetime management using TAVR, particularly for younger patients with few comorbidities.
- Tissue technology has a material impact on the long-term durability of bioprosthetic valve: RESILIA tissue is designed to increase valve durability.
- The SAPIEN X4 is a next generation balloon-expandable THV
  - Seeks to optimize a safe, reproducible index TAVR procedure
  - Focuses on lifetime management with personalized valve sizing, new RESILIA tissue leaflets, PVL solution, and commissural alignment
- ALLIANCE study program will assess the safety and efficacy of the SAPIEN X4 in a broad patient population, including any surgical risk level, bicuspid anatomy, and valve-in-valve.