The National Academy of Sciences
The Innovation Policy Forum
Medical Devices Innovation:
Opportunities, Threats, and Challenges

Accelerating Pre-Market Approval for Medical Devices

Michael J. Mack, MD
Baylor Scott & White Health
Dallas, TX

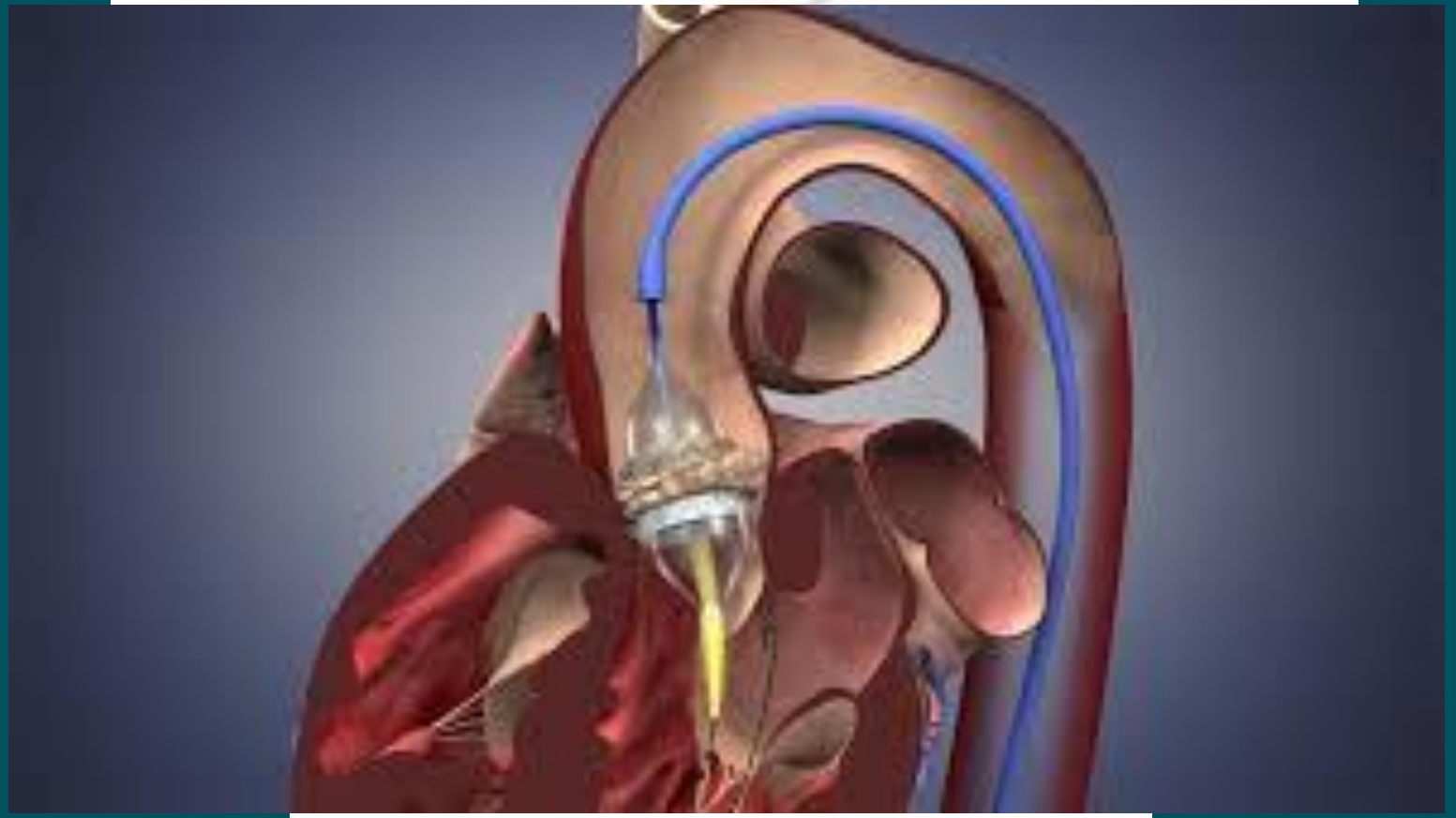
The Problem

Current regulatory processes are impeding medical device innovation in the US

How ?

- PMA process for device approval is long
- Pivotal IDE trials for approval typically cost >$100M
- Pathway and timelines can be uncertain
- Once approved, reimbursement can be problematic

Case Study
TAVR –Transcatheter Aortic Valve Replacement



Relationships
Two hearts as one? Couple married nearly 74 years have heart surgery on same day

Health
Death by Exercise: Preventing

Relationships

Two hearts as one? Couple married nearly 74 years have heart surgery on same day

Susan Donaldson James
TODAY contributor

Sep. 5, 2014 at 9:53 AM ET

Courtesy of Cleveland Clinic

Raymond "Huggie Bear" Huggins, 96, and his wife, Mazie Leota, 93, both had life-saving heart surgery on the same day. The couple will celebrate their 74th wedding anniversary next month.

TAVR Timeline

- 1992- [illegible] Idea
- 19[illegible]
- 20[illegible]
- 20[illegible]
- 20[illegible]
- 20[illegible]
- 2[illegible]
- 2[illegible]
- 2012- NCD Issued by C[illegible]
- 2014- >20,000 implanted in US [illegible]

TAVR Approved in US

- ✓ *9 years after FIM*
- ✓ *4 Years after Approval in Europe*
- ✓ *43rd Country to Approve*
- ✓ *Behind Brazil / Ahead of Albania*

The Current Regulatory Path

Positives

- A very safe device has been introduced into the US
  - Technology iterations and procedure learning curve happened outside US
- Evidence base is firm
  - Only randomized trials done worldwide were those required by the FDA

Negatives

- Significant delay in Americans having access to life saving technology
- The cost of getting these devices into the US has now exceeded $2B
- Many patients not studied in the pivotal trials , e.g., dialysis

Other Consequences

- Capital investment for early stage medical device companies has diminished
- Venture capital is avoiding the medical device space
- Development of medical device industry OUS, e.g., Israel, Germany
- Whereas the US has traditionally represented half of the world medical device market, many early stage companies now ignore the US market altogether
- Access to innovative medical devices by the US population is significantly delayed

Possible Solutions

- Strengthen Postmarket Surveillance Thereby Shortening Approval Timeline
- Use Registries for IDE Studies to Expand Indications and Approve Device Iterations
- Tie Reimbursement to FDA Approval
- Use Registries to Perform Randomized Trials
- Build Global Registries to Use OUS Data

Post Market Surveillance

"The FDA should develop a comprehensive medical device post-market surveillance strategy to collect, analyze and act on medical device postmarket performance information"

FDA

STRENGTHENING OUR NATIONAL SYSTEM FOR MEDICAL DEVICE POSTMARKET SURVEILLANCE

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
U.S. FOOD AND DRUG ADMINISTRATION

SEPTEMBER 2012

- UDI system incorporated into EHR
- National and international device registries
- Modernize adverse event reporting
- New methods for evidence generation, synthesis and appraisal

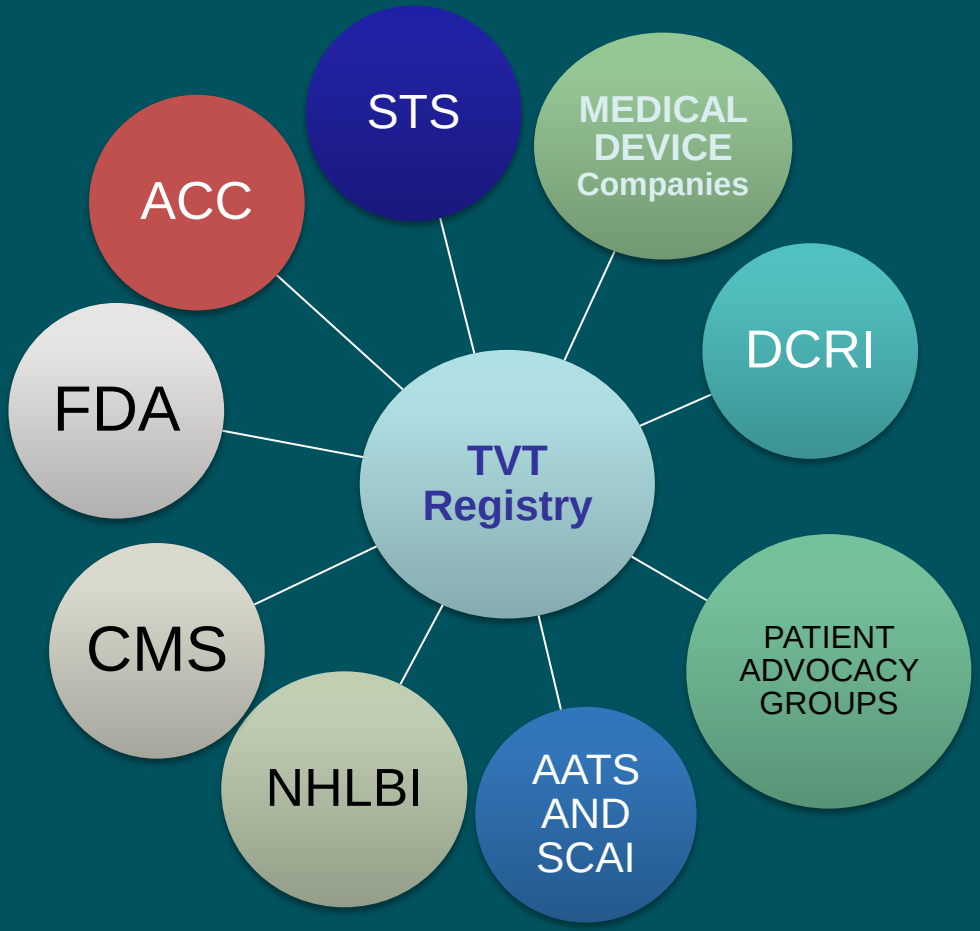

David Holmes
President American College of Cardiology 2011
Jeff Shuren
Director CDRH FDA
Michael Mack
President Society of Thoracic Surgeons 2011

The STS-ACC Transcatheter Valve Therapy National Registry

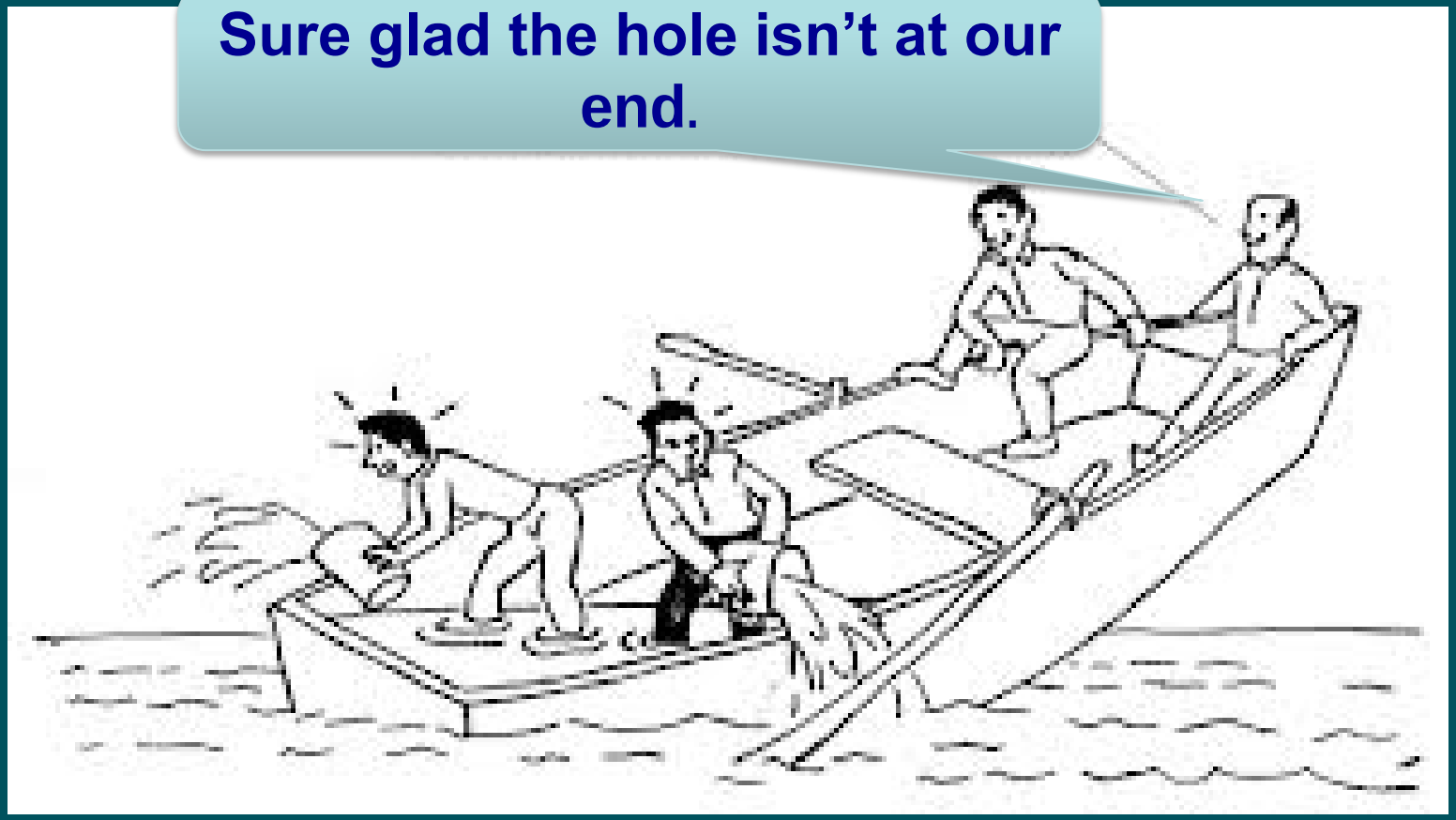
A New Partnership and Infrastructure for the Introduction and Surveillance of Medical Devices and Therapies

John D. Carroll, MD,* Fred H. Edwards, MD,† Danica Marinac-Dabic, MD, PHD,‡ Ralph G. Brindis, MD, MPH,§ Frederick L. Grover, MD,* Eric D. Peterson, MD, MPH,‖ E. Murat Tuzcu, MD,¶ David M. Shahian, MD,# John S. Rumsfeld, MD, PHD,** Cynthia M. Shewan, PHD,†† Kathleen Hewitt, MSN, RN,‡‡ David R. Holmes, JR, MD,§§ Michael J. Mack, MD‖‖

A Unique Public- Private Collaboration



We (STS-ACC-FDA-CMS-Industry) Have Realized That We Are in the Same Boat



Establishing the TVT Registry

February 2011
- FDA, ACC and STS met about the need for real world safety and efficacy data

July 2011
- TVT Registry proposed at the FDA Advisory Panel for Edwards Sapien Valve

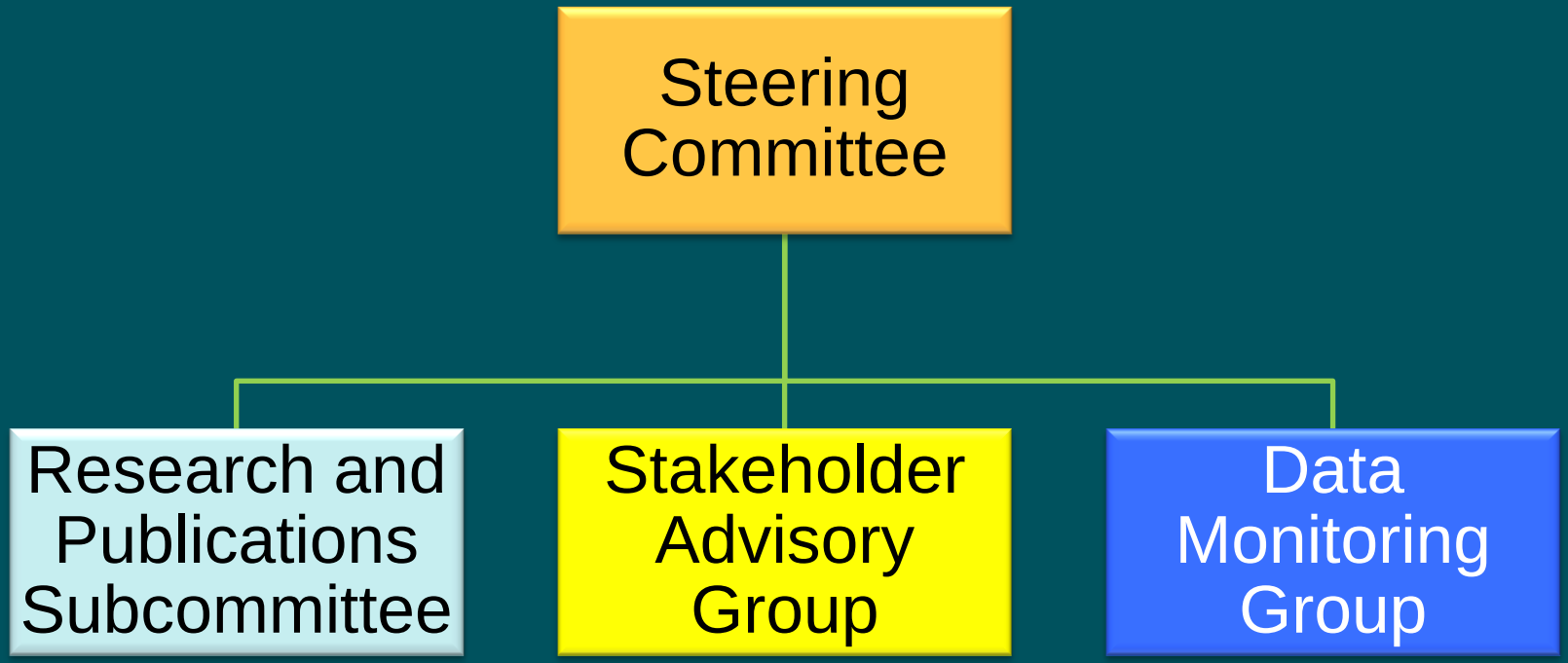
November 2011
- Edwards Sapien THV approved in U.S.

Dec 2011
- STS/ACC TVT Registry launched

May 2012
- CMS issued NCD for transcatheter valves mandating participation in a national registry as a requisite for reimbursement

May 2013
- New IDE AA for Inop Patients

Governance


Steering Committee
Research and Publications Subcommittee
Stakeholder Advisory Group
Data Monitoring Group

STAKEHOLDER ADVISORY GROUP

Society Representatives

- Murat Tuzcu, MD TVT Registry Steering Committee liaison
- Larry Dean, MD SCAI e
- Joseph Bavaria, MD AATS Public and

Consumer Representatives

- Bray Patrick-Lake PFO Research Foundation
- John Santa, MD Consumer Reports
- Fmr. Rep. Tony Coelho Public Member

Health System and Health Plans

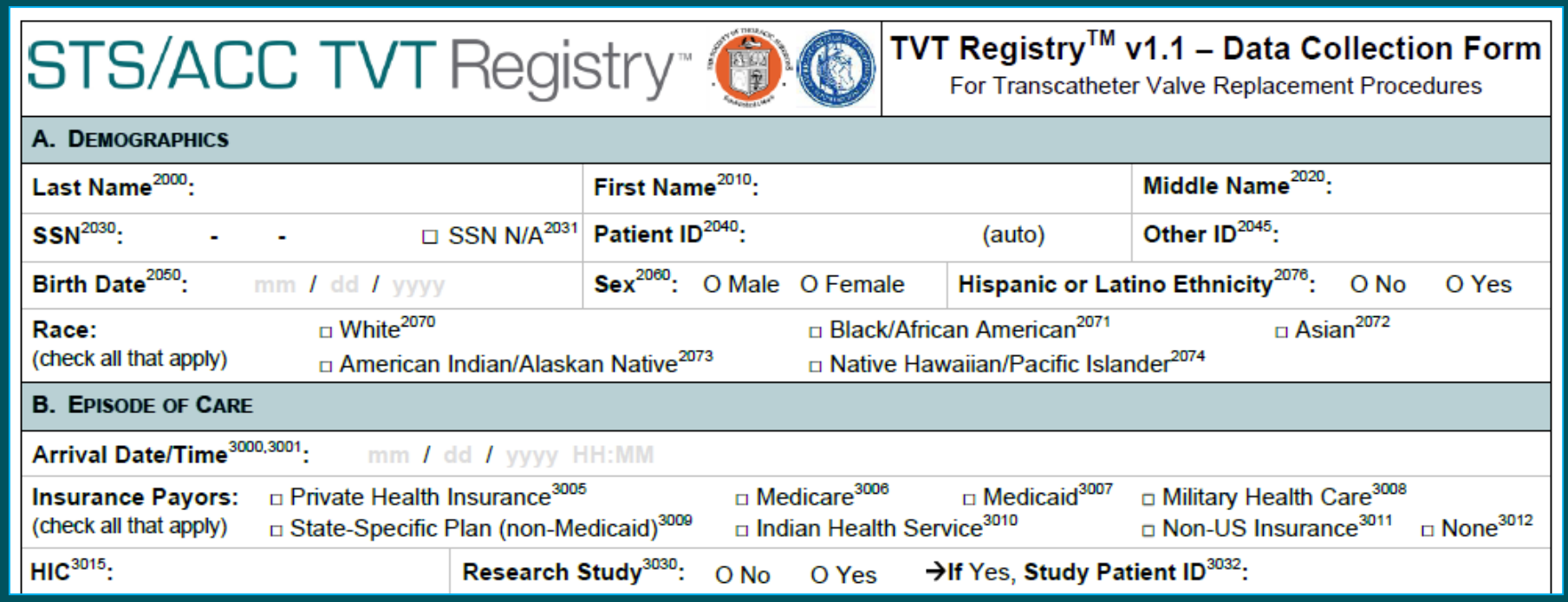
Tom Priselac Cedars-Sinai Hospital System

Industry Representatives

- Chuck Simonton, MD Abbott Vascular
- Larry Wood Edwards Lifesciences
- Nusrath Sultana, MD St. Jude Medical
- Tom Armitage, MD Medtronic
- Keith Dawkins, MD Boston Scientific

Government Representatives

- Bram Zuckerman, MD FDA liaison
- John Laschinger, MD FDA liaison
- Danica Marinac-Dabic, MD FDA liaison
- Marissa Miller, DVM NIH liaison
- Marie Casey CMS liaison



STS/ACC TVT Registry™

TVT Registry™ v1.1 – Data Collection Form
For Transcatheter Valve Replacement Procedures

A. DEMOGRAPHICS

Last Name[2000]:	**First Name**[2010]:	**Middle Name**[2020]:
SSN[2030]: - - ☐ SSN N/A[2031]	**Patient ID**[2040]: (auto)	**Other ID**[2045]:
Birth Date[2050]: mm / dd / yyyy	**Sex**[2060]: O Male O Female	**Hispanic or Latino Ethnicity**[2076]: O No O Yes

Race: (check all that apply)
☐ White[2070] ☐ Black/African American[2071] ☐ Asian[2072]
☐ American Indian/Alaskan Native[2073] ☐ Native Hawaiian/Pacific Islander[2074]

B. EPISODE OF CARE

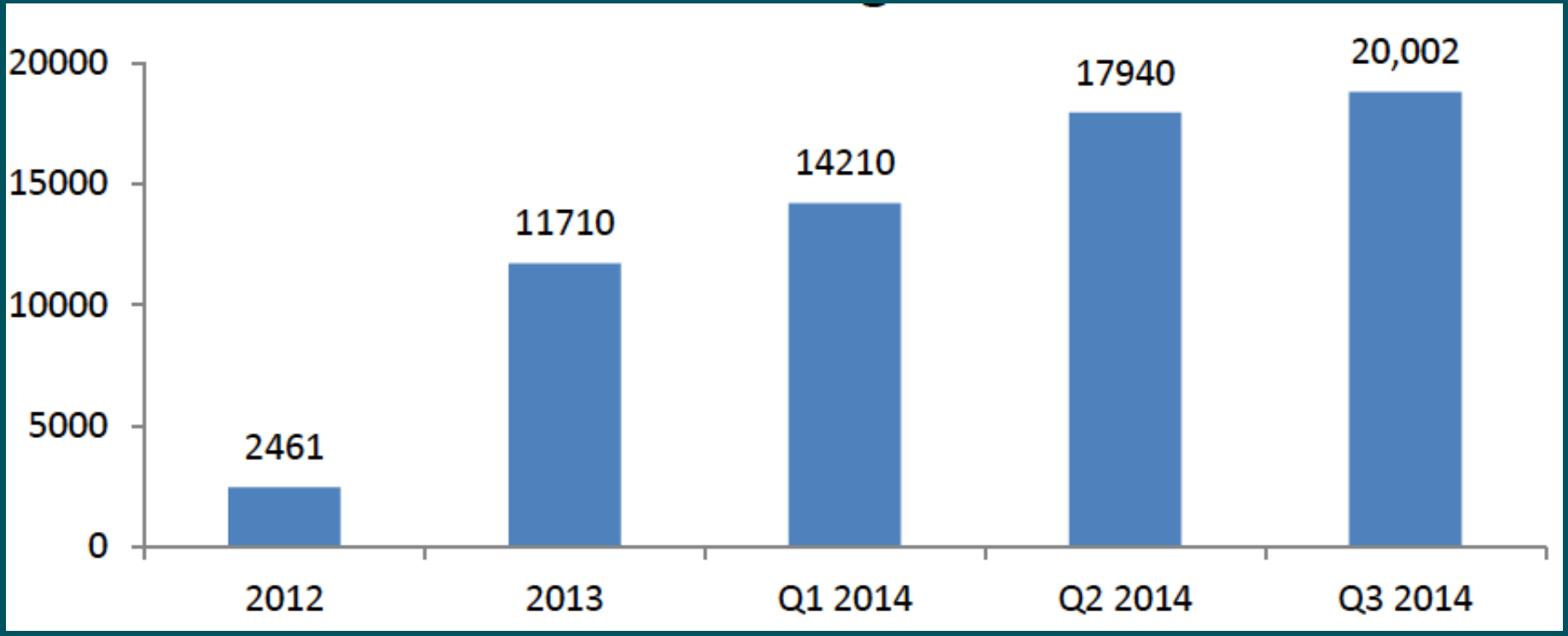
Arrival Date/Time[3000,3001]: mm / dd / yyyy HH:MM

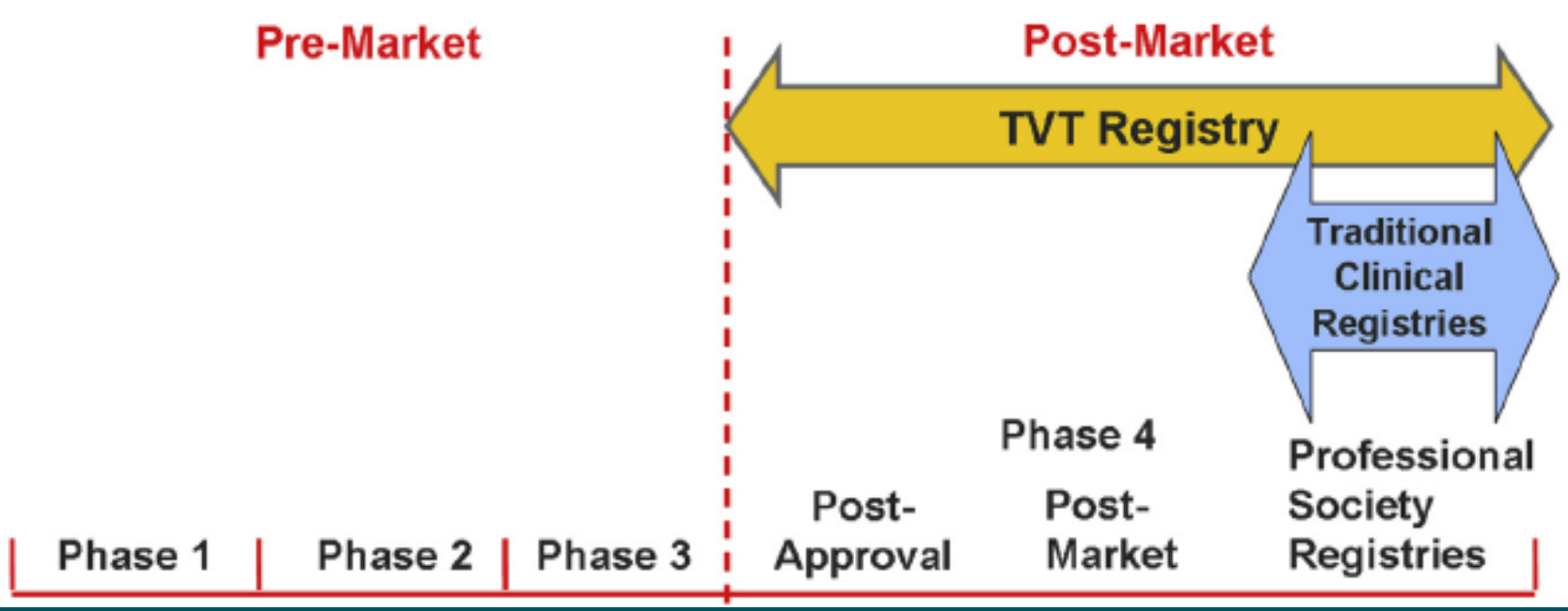
Insurance Payors: (check all that apply)
☐ Private Health Insurance[3005] ☐ Medicare[3006] ☐ Medicaid[3007] ☐ Military Health Care[3008]
☐ State-Specific Plan (non-Medicaid)[3009] ☐ Indian Health Service[3010] ☐ Non-US Insurance[3011] ☐ None[3012]

HIC[3015]: **Research Study**[3030]: O No O Yes →**If Yes, Study Patient ID**[3032]:

- **Comprehensive prospective observational database (7-page CRF)**
- **FU includes 30-days, 1-year (incl. QOL measures)**
- **TVT compliance linked to reimbursement**

Cumulative Number of Patient Records Entered in the STS-ACC TVT Registry From 318 Clinical Sites




Pre-Market
Post-Market
TVT Registry
Traditional Clinical Registries
Phase 4
Professional Society Registries
Post-Approval
Post-Market
Phase 1
Phase 2
Phase 3

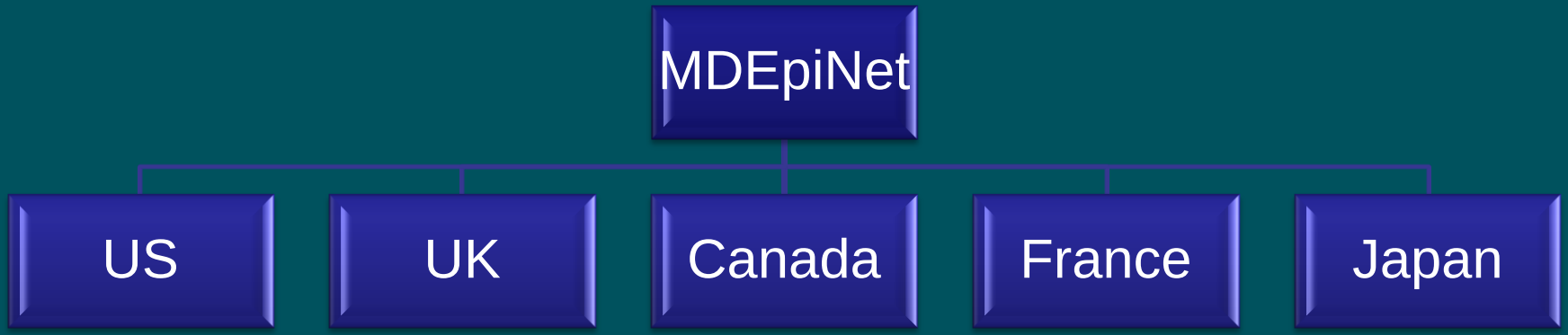
- TAVR approved under “coverage with evidence development”
- Approved for treatment of severe symptomatic aortic stenosis
- FDA approved indication and with an FDA approved device
- Two cardiac surgeons approve
- Performed in facility with
  - >50surgical AVR’/year (~400 centers)
  - >400 caths/50PCI/year
  - >20 TAVR/year
  - Mortality <15%
  - Stroke <15%
- Multidisciplinary Heart Team
- Mandatory National TVT Registry participation

The Society of Thoracic Surgeons

AMERICAN COLLEGE of CARDIOLOGY FOUNDATION

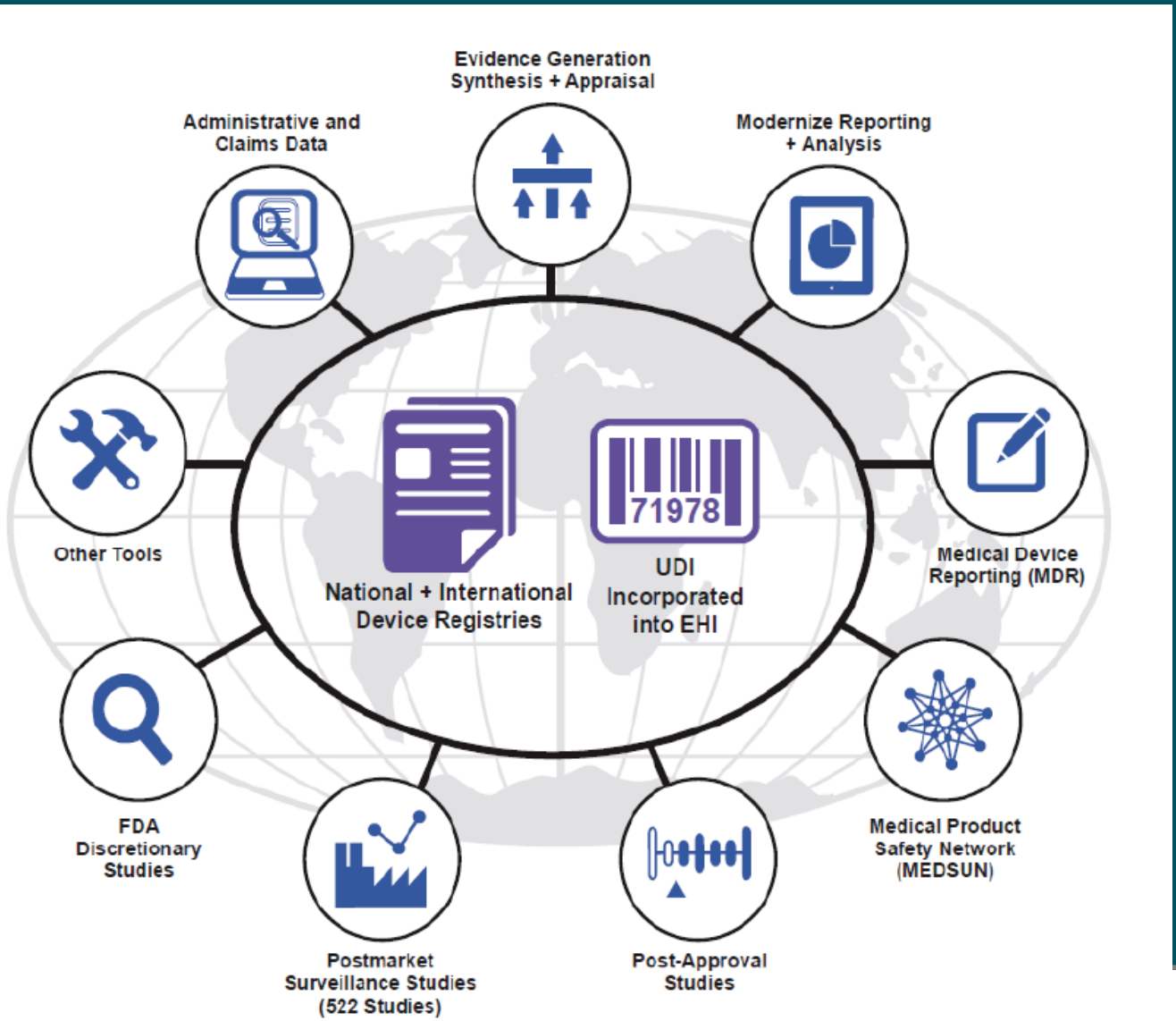
VIEWPOINT

The International Registry Infrastructure for Cardiovascular Device Evaluation and Surveillance

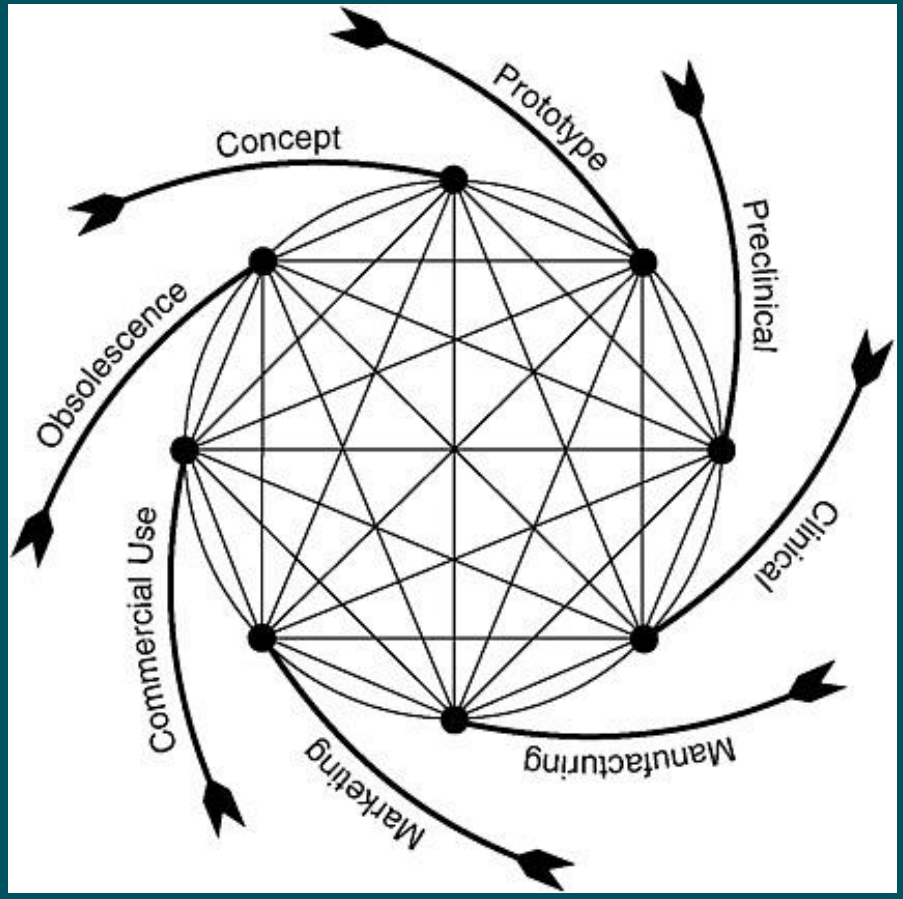


JAMA July 17, 2013 Volume 310, Number 3

Role of Device Registries in FDA Vision for the Future



Common Data Infrastructure For Total Product Lifecycle



Why Is STS/ACC TVT Registry Innovative?

- Shared public-private responsibilities
- Multiple stakeholders with different needs
  - FDA- safe and effective
  - CMS- reasonable and necessary
  - Clinicians- quality assessment, performance improvement
  - Industry- PAS, device performance, label expansion
- Reimbursement tied to FDA approved indications
- “Rational dispersion” of new technology

Why Is STS/ACC TVT Registry Innovative?

- Registry participation is a condition of reimbursement
- Complete, real time assessment of device performance in virtually all patients
- Clinical data allowing “risk adjustment”
- Linkage to CMS data for long-term outcomes
- Establishment of OPC’s (Objective Performance Criteria)
- Linkage with other national registries for global outcomes assessment

Concerns / Questions

- Burdensome
- Expense
- Carrot- stick incentives
- Sustainability
- Which devices –Class III ?
- What can go away- MDR ?
- Role of professional societies
- Will pre-approval timeline be shortened with a more robust post approval surveillance system in place?