

# From SWEDEHEART to EUROHEART

**Lars Wallentin**

Senior professor of Cardiology  
Uppsala Clinical Research Centre  
Uppsala University Uppsala, Sweden



**EuroHeart**

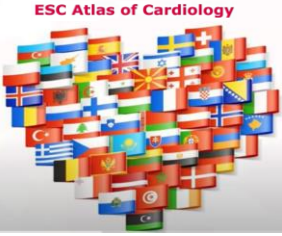
European Unified Registries for Heart Care  
Evaluation and Randomised Trials

[www.escardio.org/euroheart](http://www.escardio.org/euroheart)

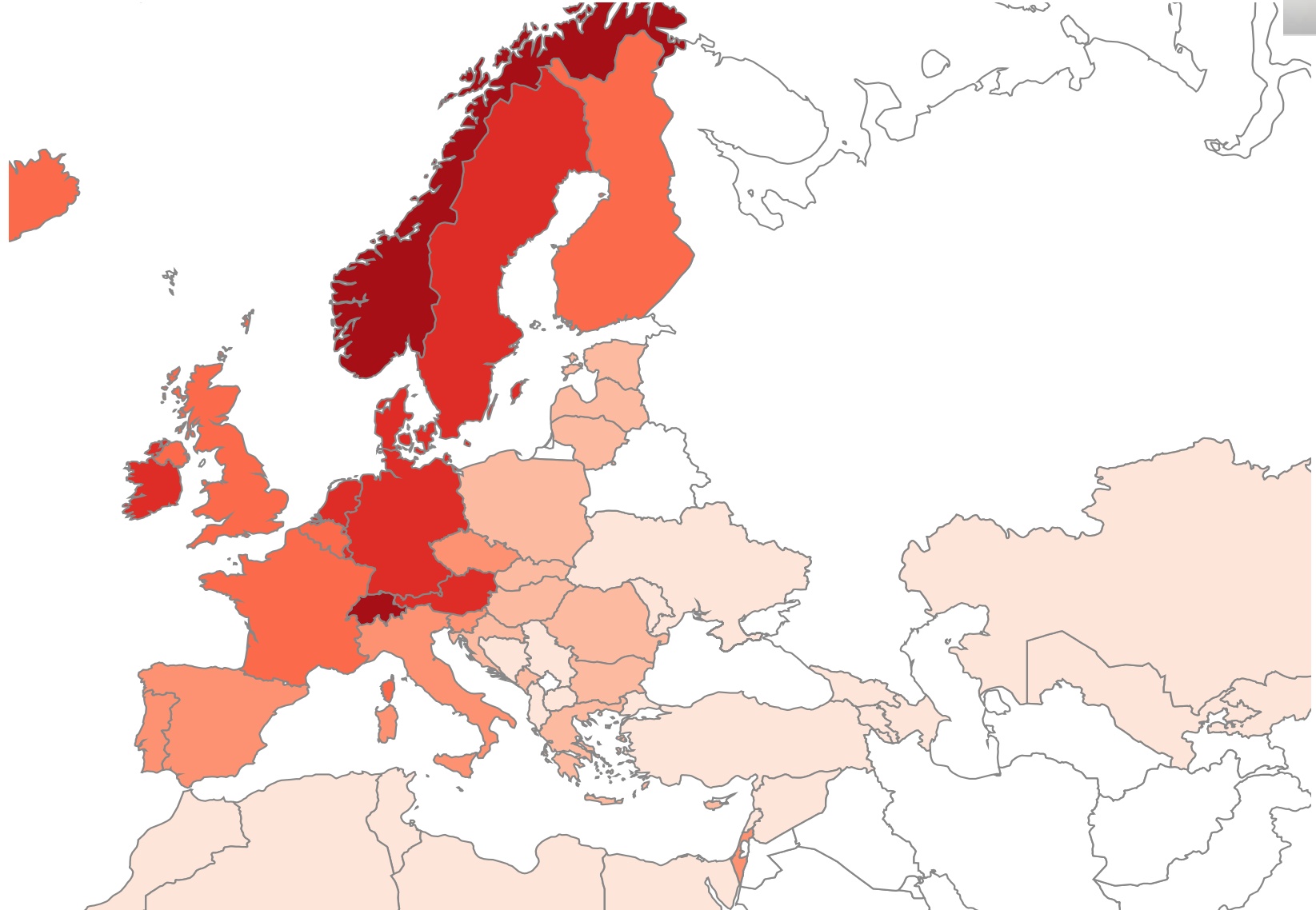
[www.ucr.uu.se](http://www.ucr.uu.se)

**UCR** 

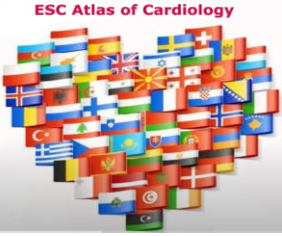
# Current health expenditure per capita



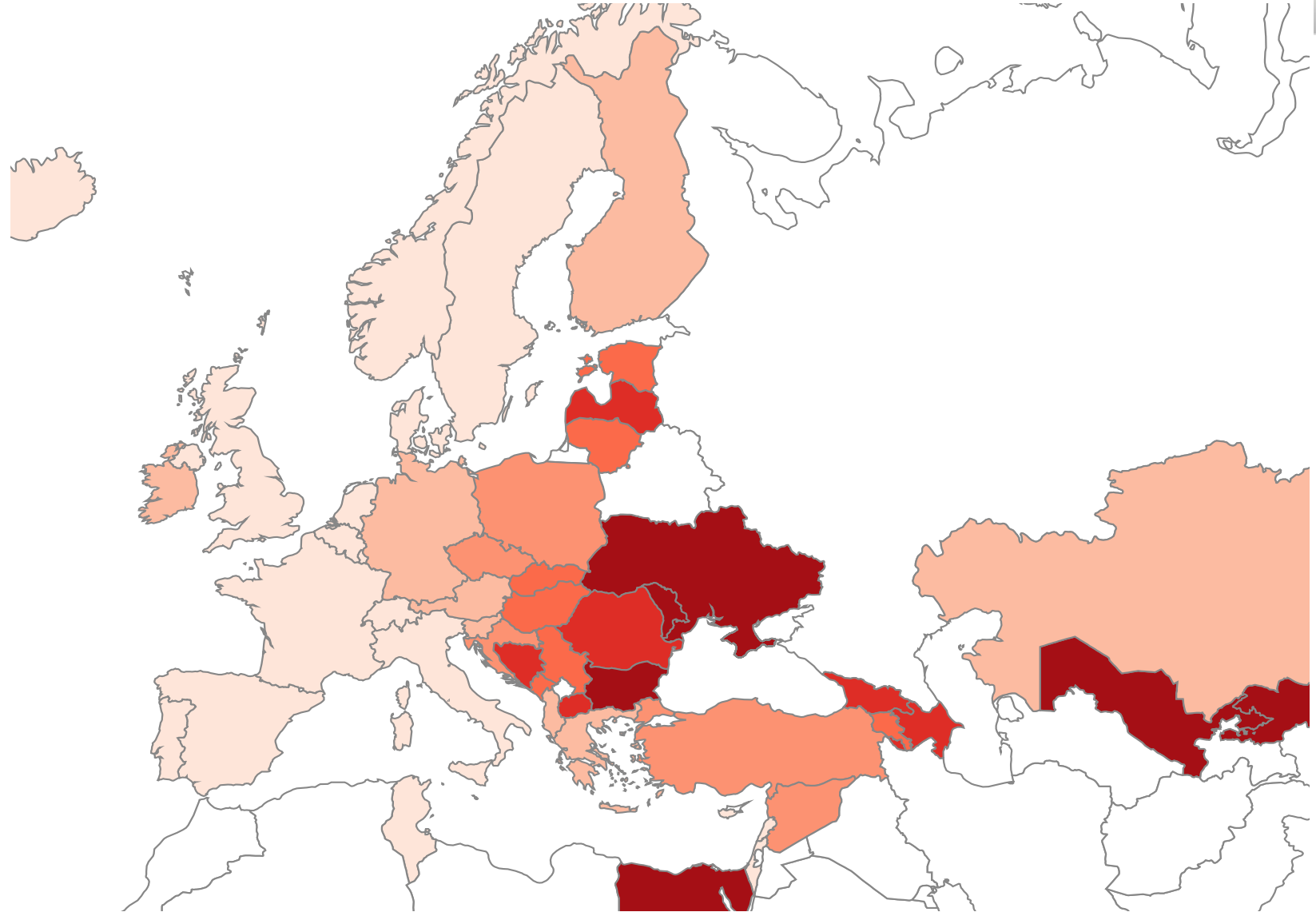
159.60 — 1485.32  
1485.33 — 2811.04  
2811.05 — 4136.77  
4136.78 — 5462.50  
5462.51 — 6788.22  
6788.23 — 8113.95



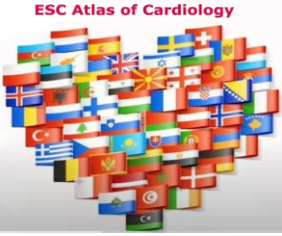
# Cardiovascular mortality men



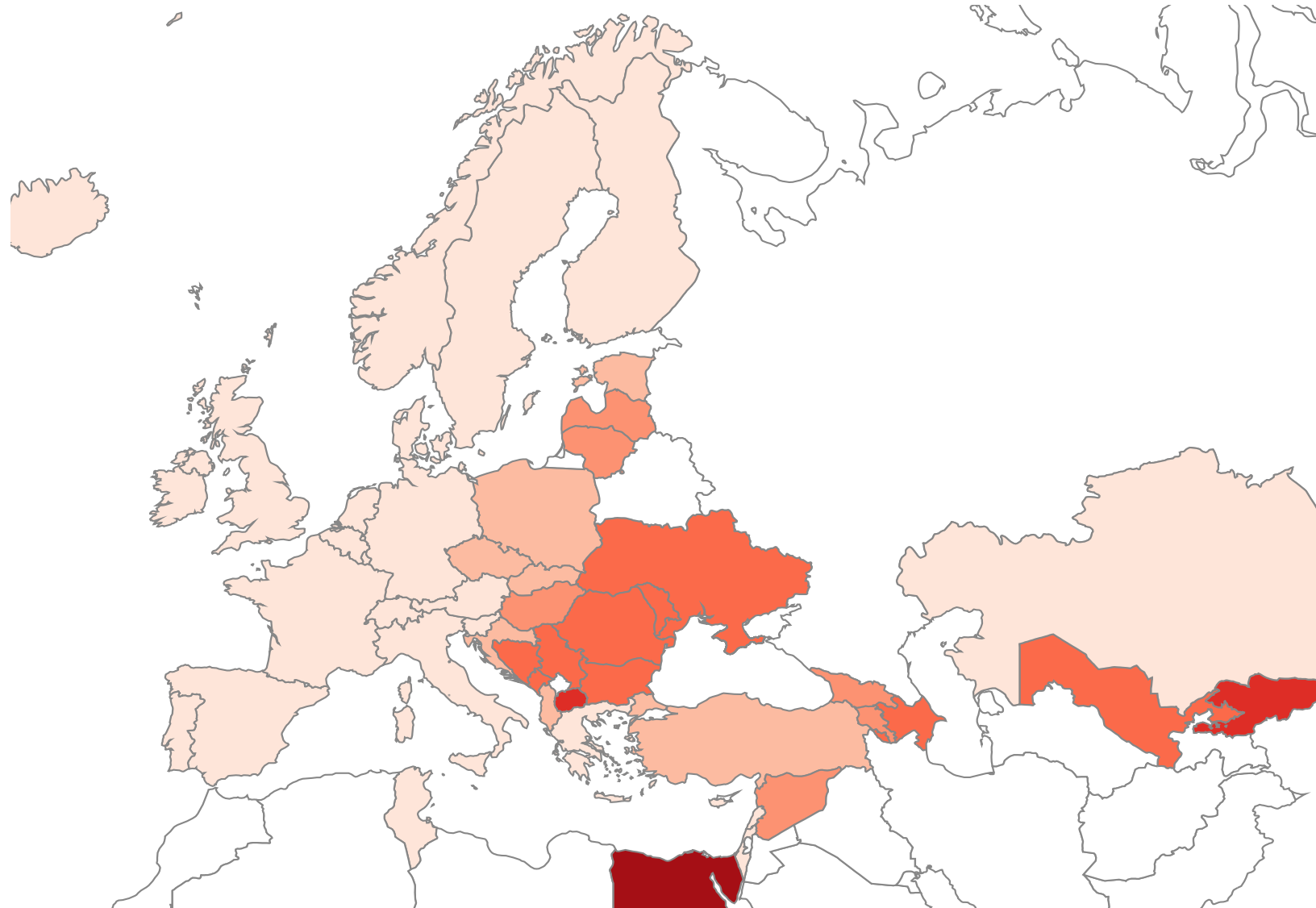
174.00 —374.92  
374.93 —575.84  
575.85 —776.77  
776.78 —977.70  
977.71—1178.62  
1178.63 —1379.55



# Cardiovascular mortality women



160.10 — 357.05  
357.06 — 554.01  
554.02 — 750.97  
750.98 — 947.93  
947.94 — 1144.89  
1144.90 — 1341.85

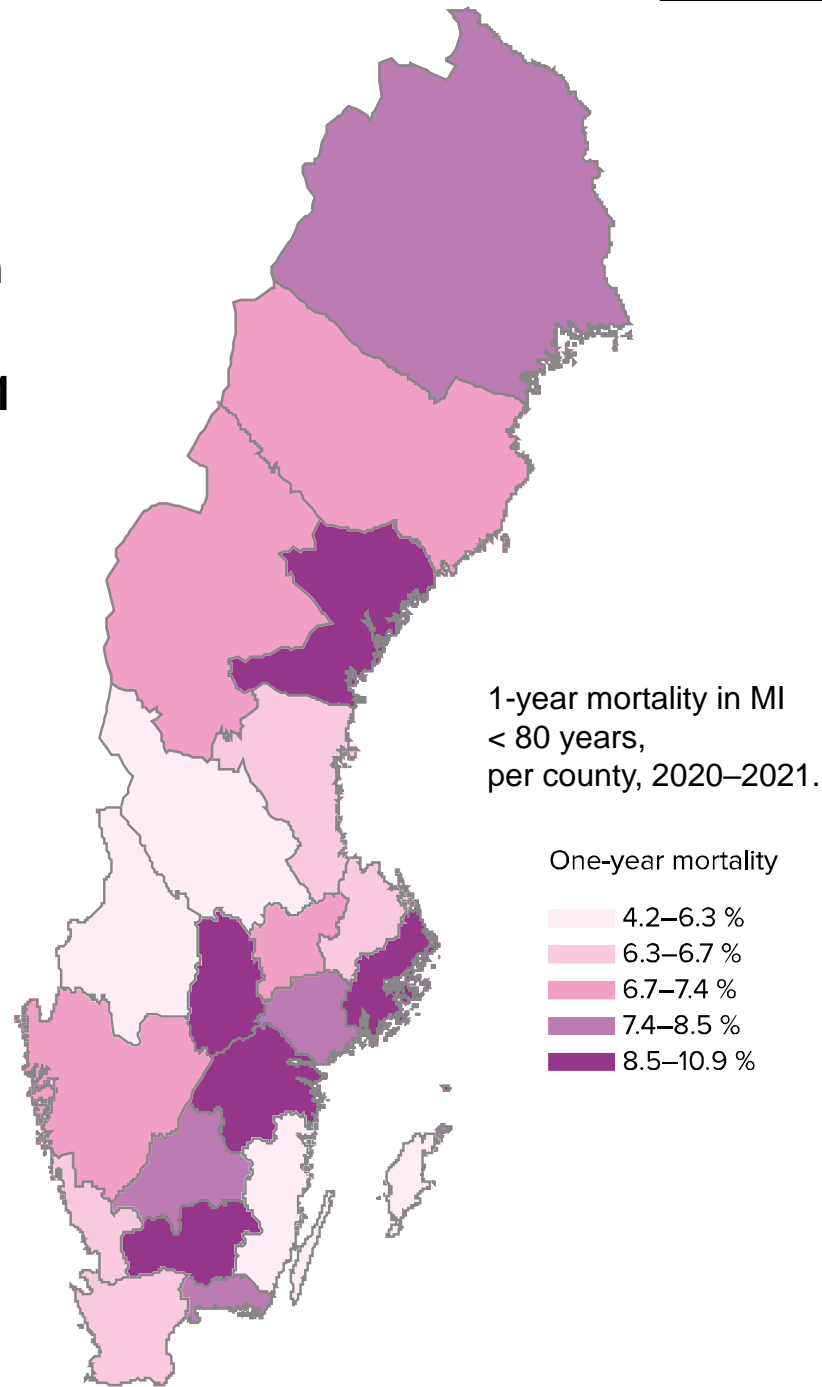




# 1 year mortality

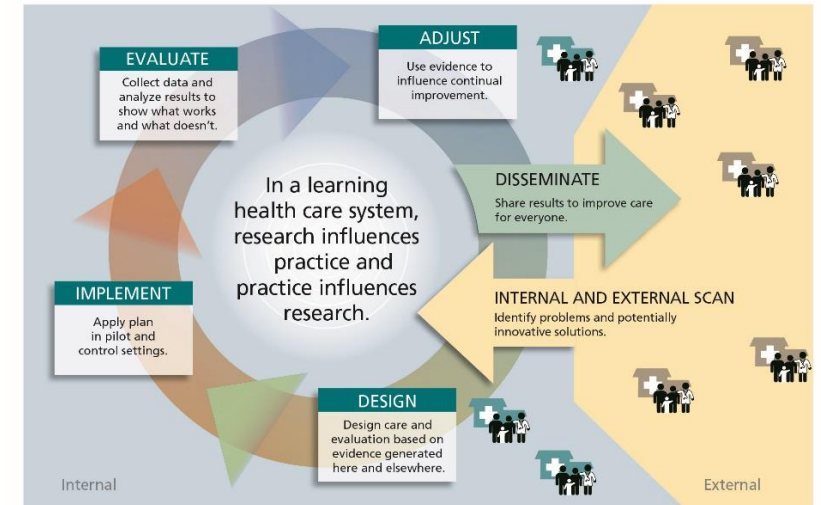
in patients with myocardial infarction  
< 80 years of age admitted 2020 - 2021

2022  
Issued in 2023



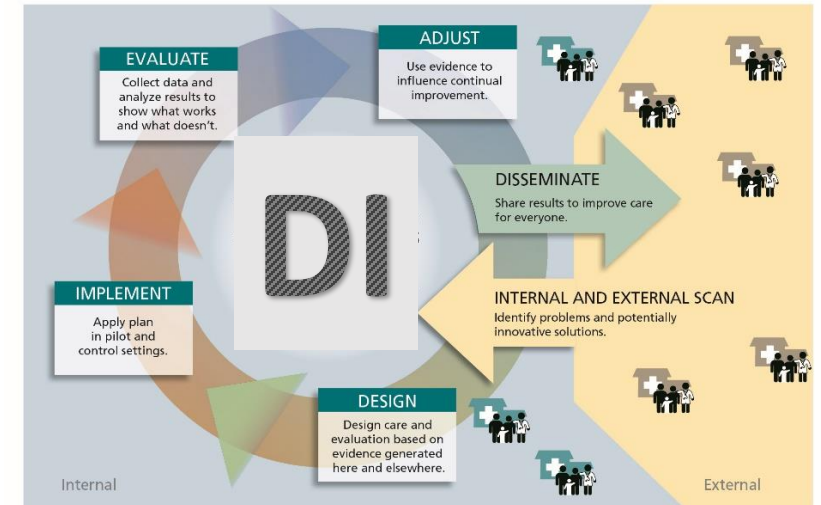
# What is a Quality registry?

- Contains individual structured data on patients, medical interventions, and outcomes
- Integrated into the clinical workflow
- Capacity to generate reports in real time
- Supported by an organization of health care professionals, researchers, patient reps
- Used for continuous learning, quality improvement, research and randomized trials
- Might be integrated with EHR



# Development Intelligence

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- Capacity to generate reports in real time
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**Immediately  
actionable  
data**



# SWEDEHEART – History

SWEDEHEART registries started during the 1990s

- Swedish heart surgery registry
- RIKS-HIA (heart intensive care)
- SCAAR (coronary angiography and PCI)
- SEPHIA (cardiac rehabilitation and secondary prevention)
- SWEDEHEART (all 4 registries combined)
- SWENTRY (transcatheter valvular interventions)
- SNKR (cardiogenetic registry)



1992

1995

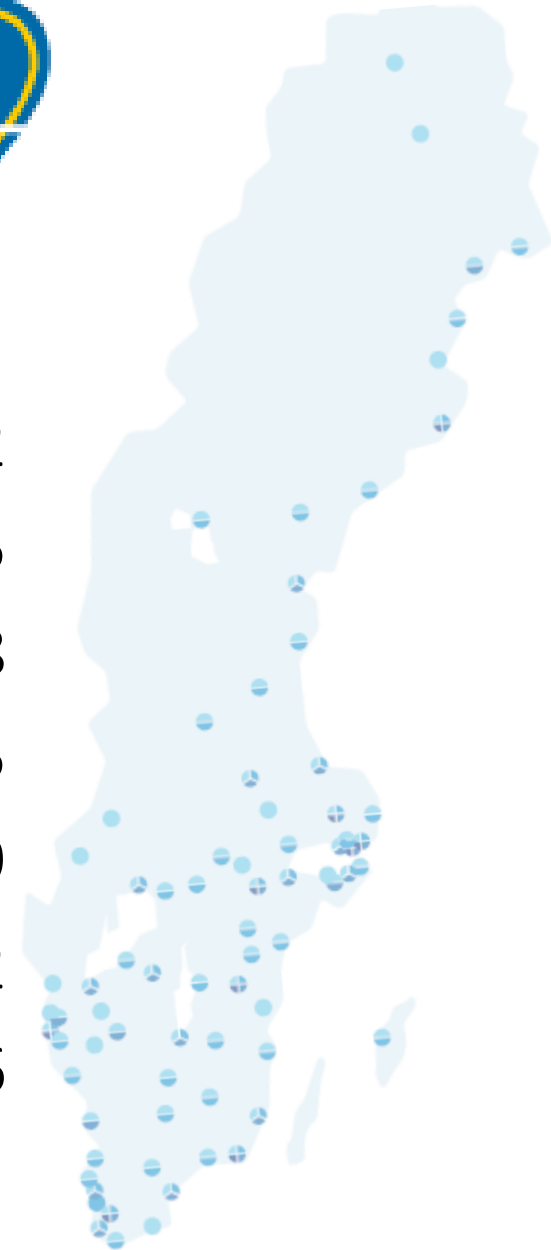
1998

2005

2009

2012

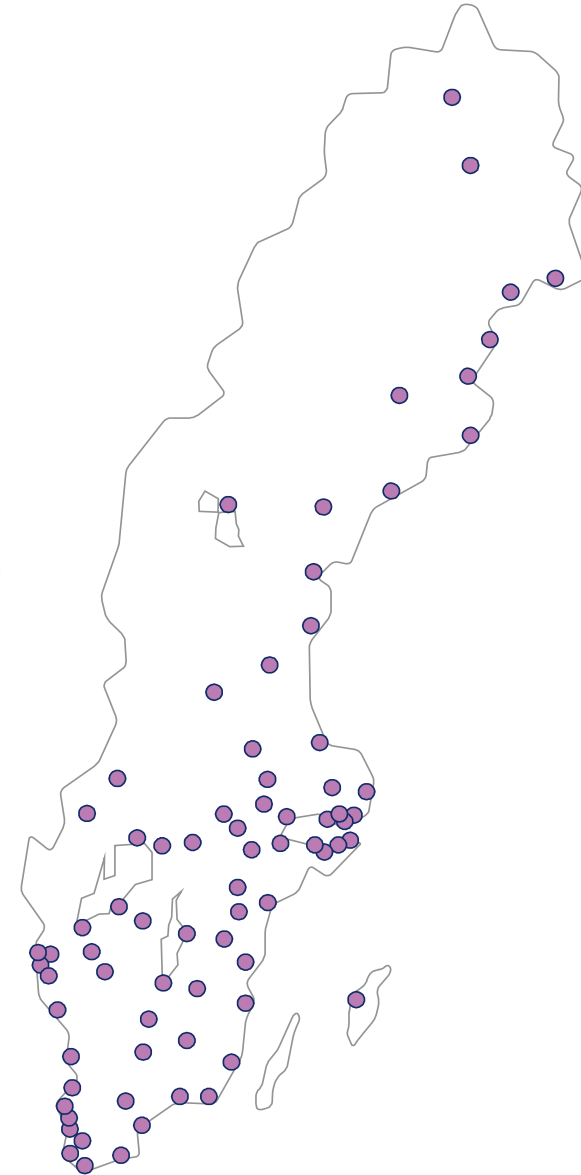
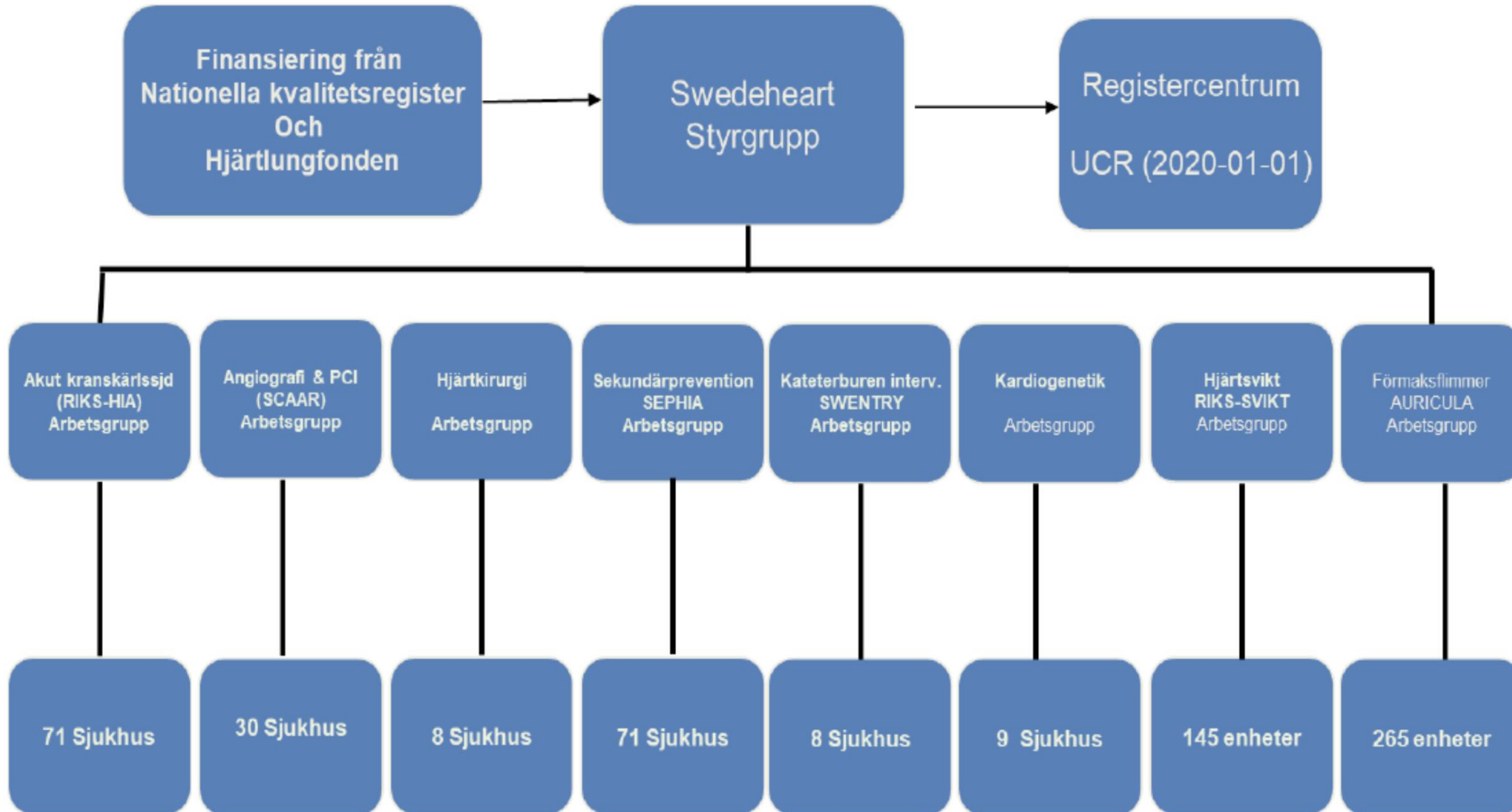
2016







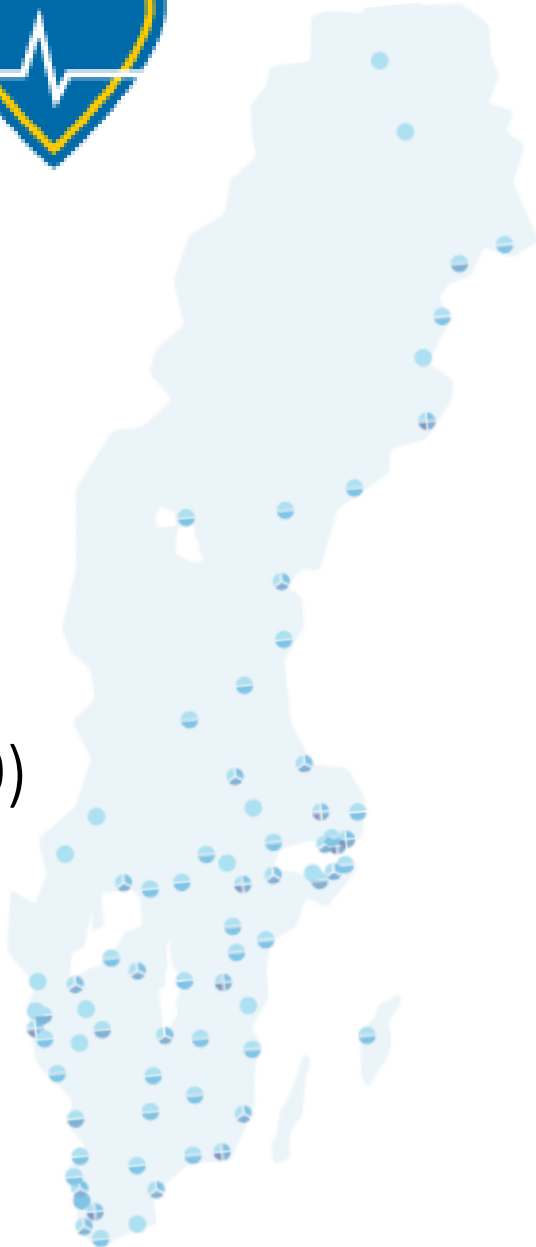
# SWEDEHEART – Organisation





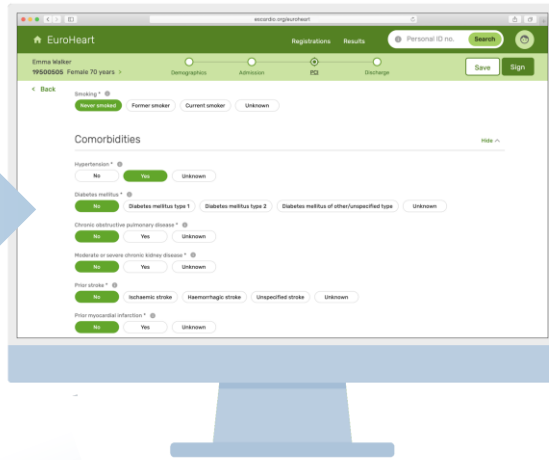
# SWEDEHEART – Coverage

	<u>Hospitals</u>	<u>Patients</u>
Heart surgery registry	100 % (n = 8)	100% (n ≈ 7,000)
RIKA-HIA (ACS)	100% (n = 69)	92% (n ≈ 30,000)
SCAAR (PCI)	100% (n = 29)	100% (n ≈ 40,000)
SEPHIA (Sec. prev)	85% (n = 65)	80% (n ≈ 5,000)
SWENTRY (TAVR, TMVR)	100% (n = 7)	100% (n ≈ 500)

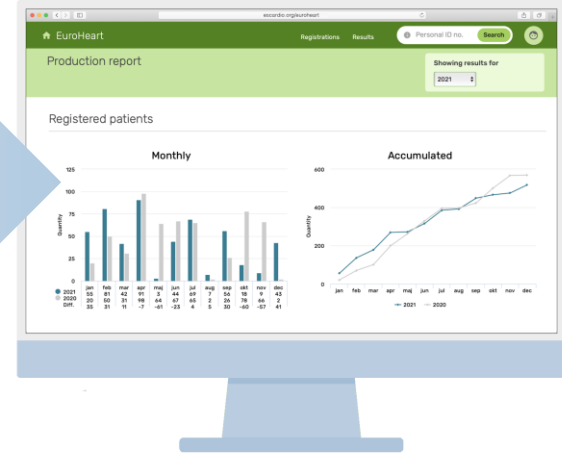


# How do Quality registries work?

Data recorded by healthcare providers



Data presented in real time and as regular reports

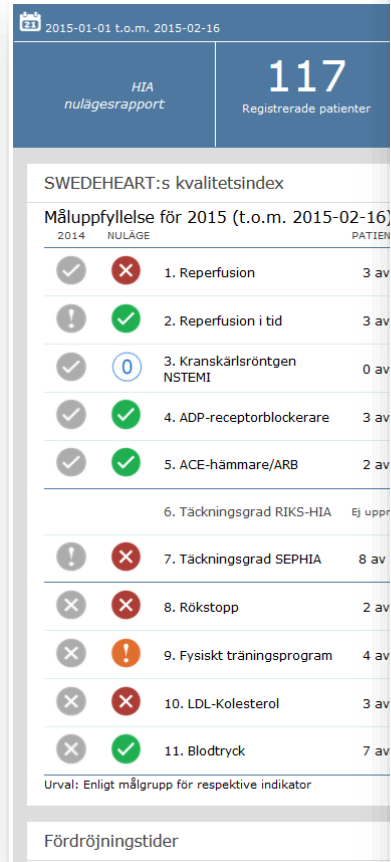


Data warehouse



# SWEDEHEART - feedback for quality improvement

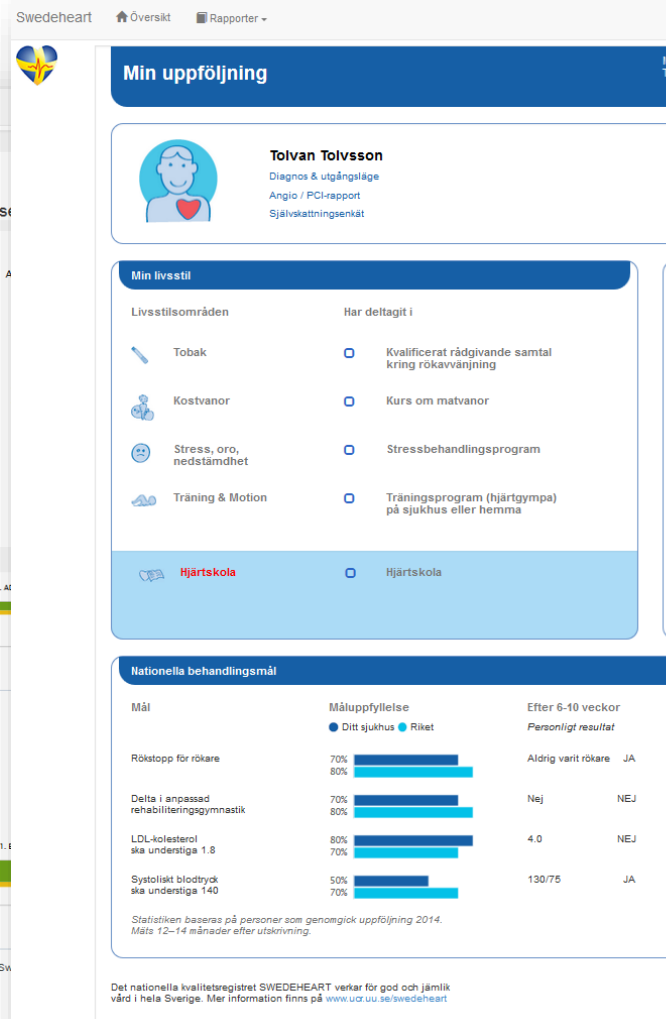
To staff



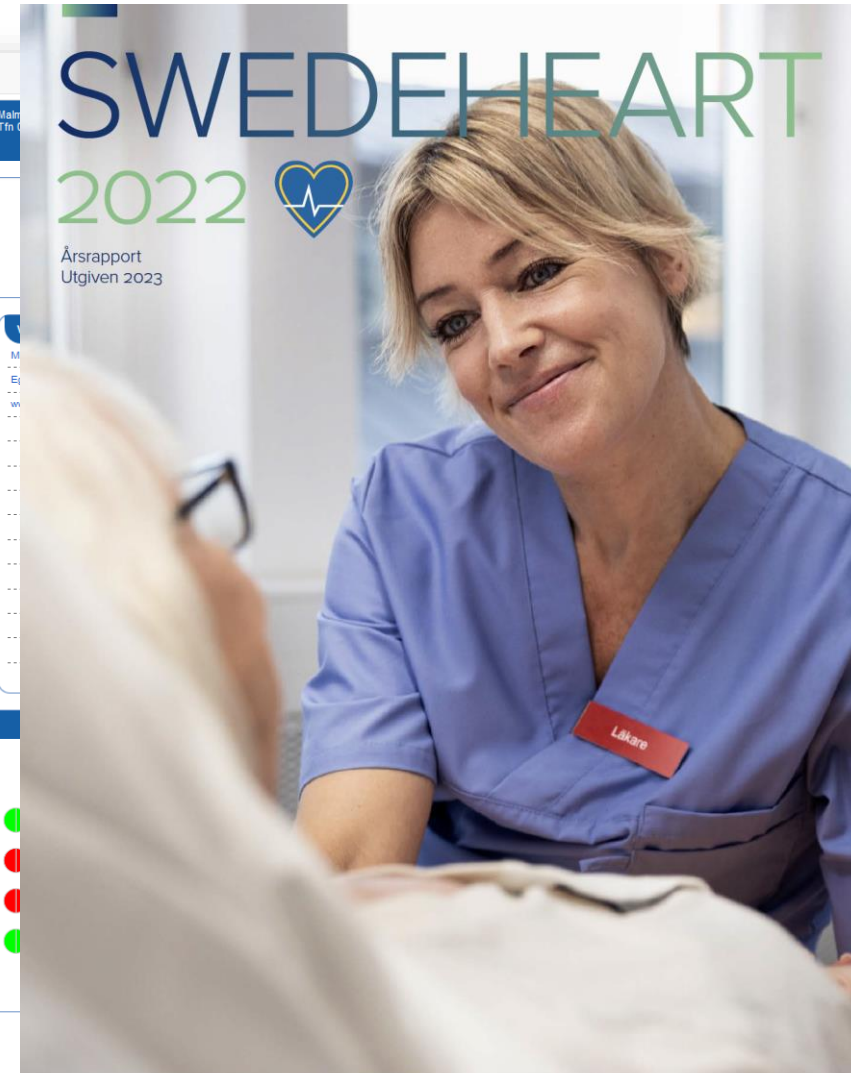
To leadership



To patients

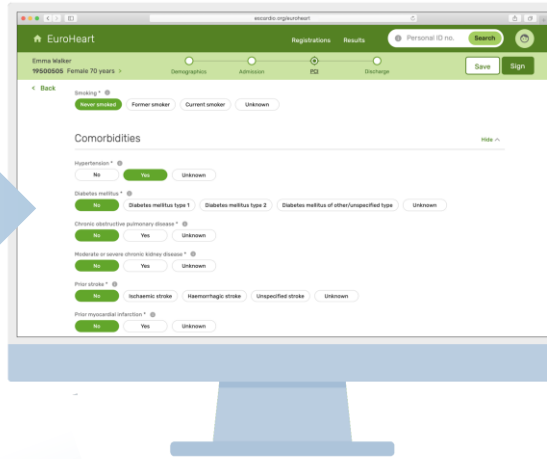


To the public

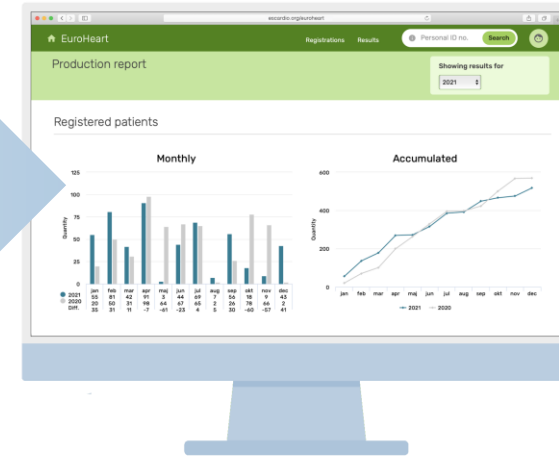


# Quality registries for observational research!

Data recorded by healthcare providers



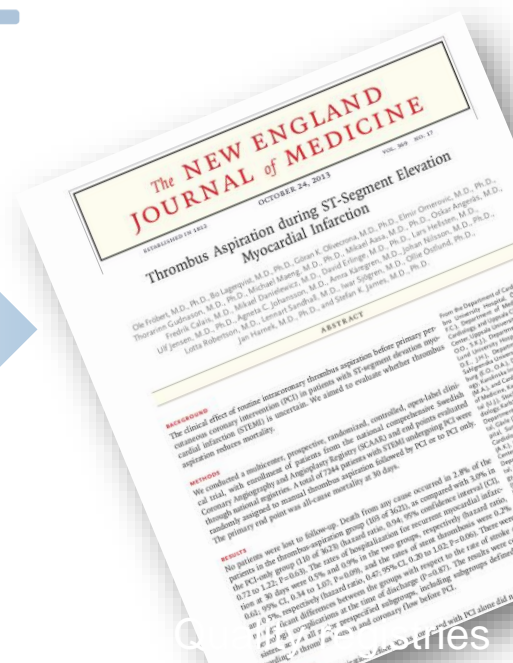
Data presented in real time and as regular reports



Data warehouse

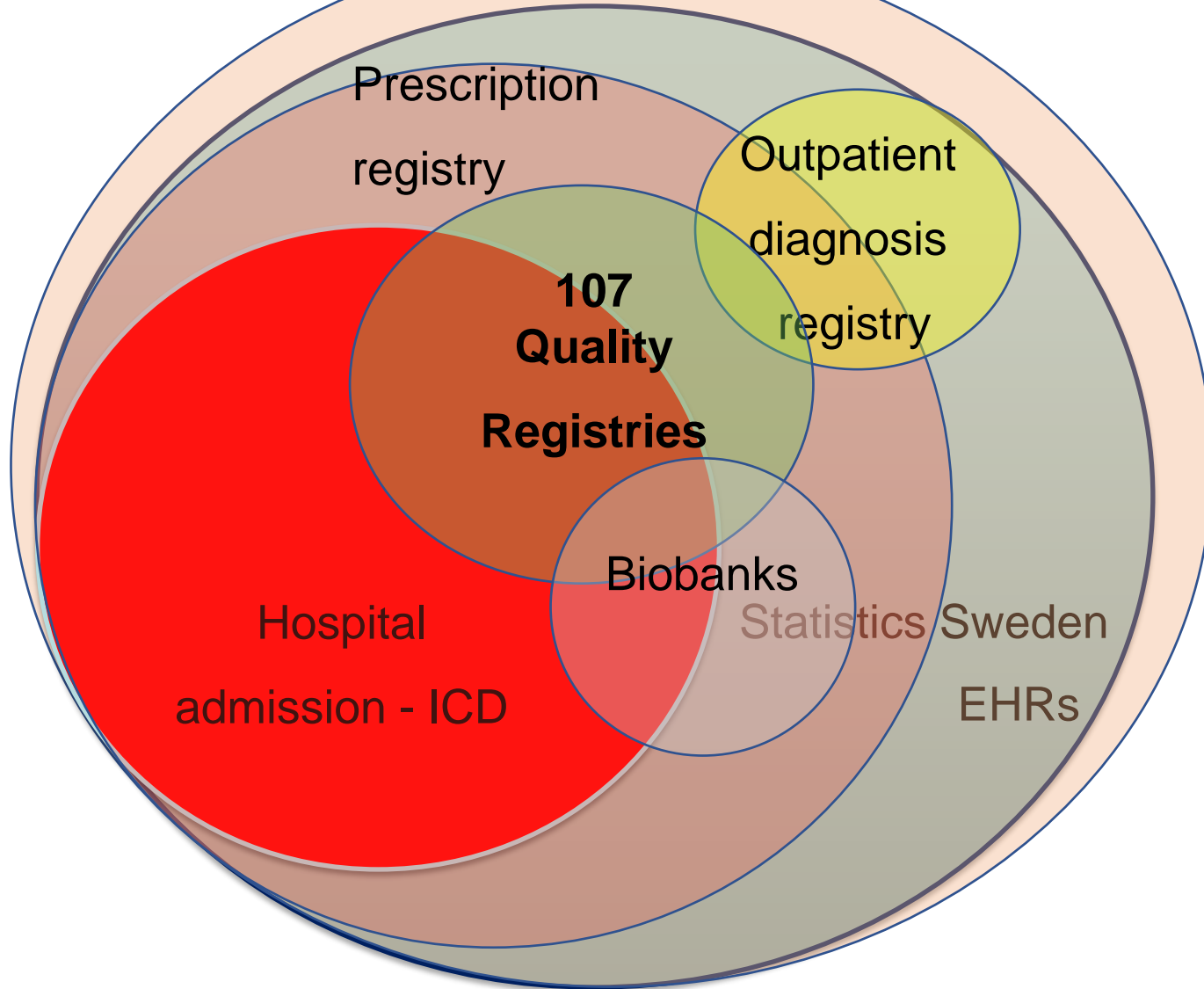


Research database



# Swedish national registries based on personal number yyyymmdd-nnnn

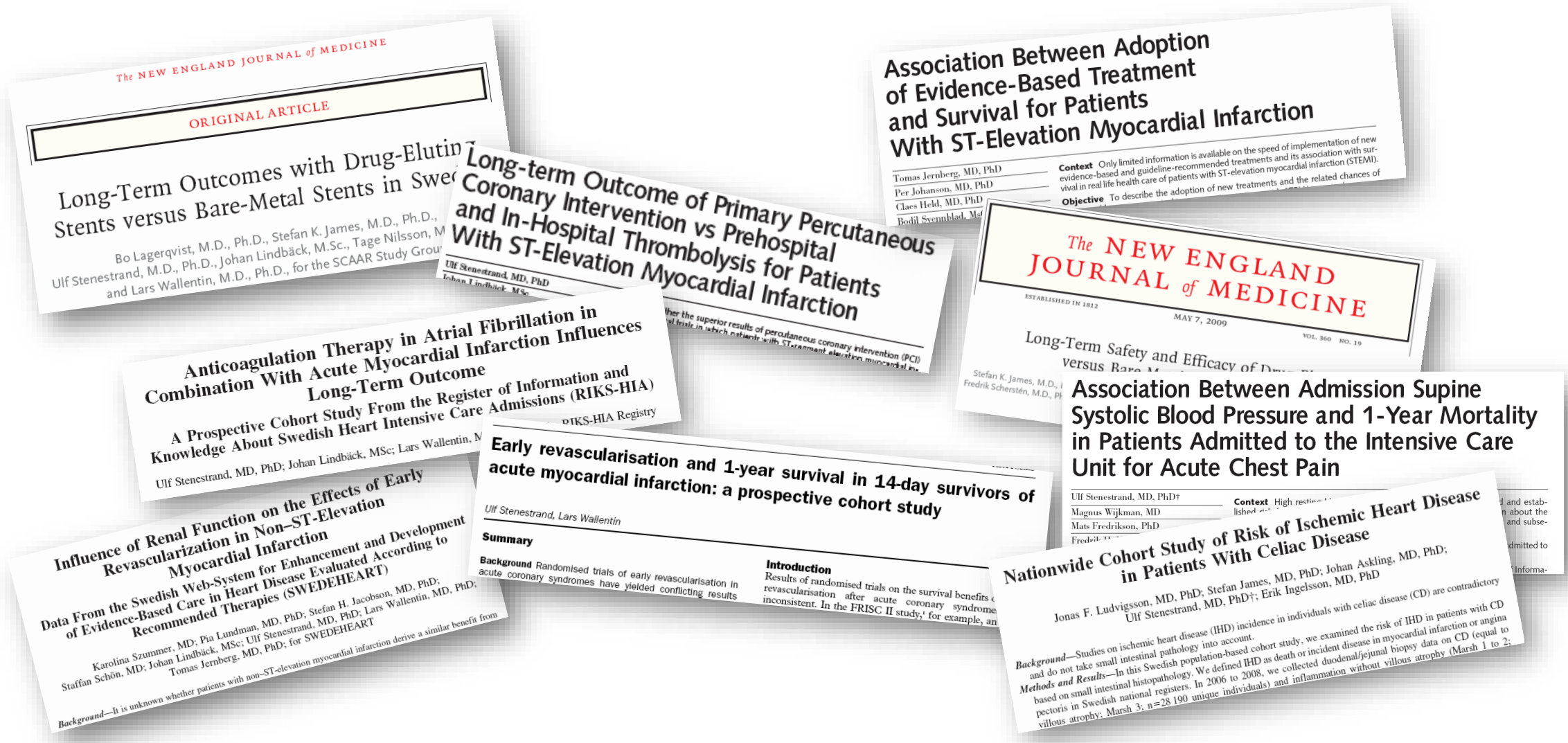
Population registry (vital status). Cause of death registry



Registry	Contents
Swedish Population Registry	Place of residency; country of own and parents' birth; marital status
Swedish Censuses	Socioeconomic group; education; income; sick leave
Swedish National Insurance Agency	Sick leave, pensions
Swedish Education Registry	Highest education
Swedish 9th Grade Registry	Junior high school grades
Swedish Multi-Generation Registry	Number of children and siblings; identity of parents if born after 1932
Swedish Medical Birth Registry (since 1973)	Numbers of pregnancies and births; pregnancy outcomes
Swedish Prescription Registry (since 2005)	Pharmacy-expedited drug prescriptions
Swedish In-Patient Registry (since 1987)	All diagnoses of all hospitalisations; surgical and other procedures
Swedish Cancer Registry (since the 50's)	All cancer diagnoses
Swedish Cause-of Death Registry	Causes of death, including contributing factors
Swedish Out-Patient Registries (since 2005)	Hospital-based -> mandatory; primary care -> voluntary

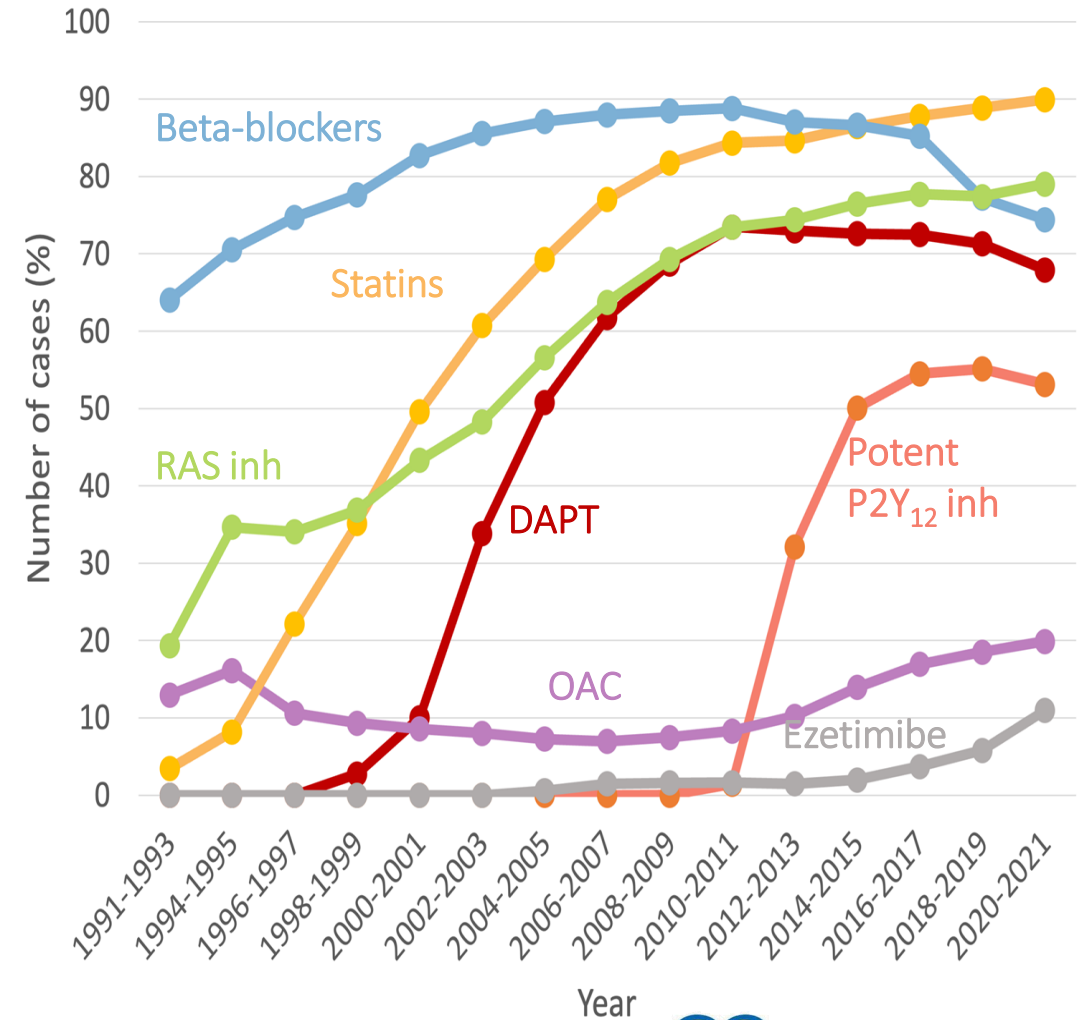
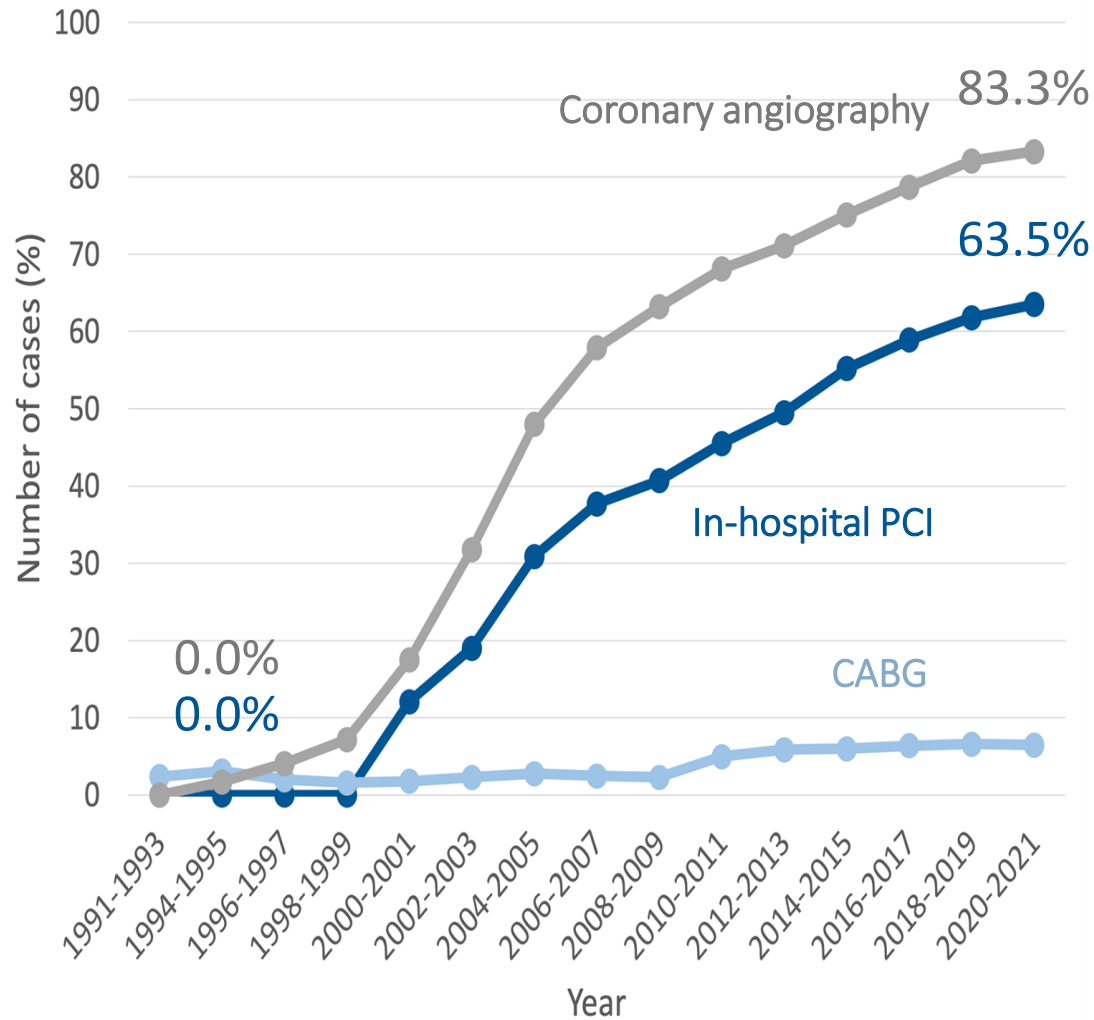


# SWEDHEART – Gold mine for observational research

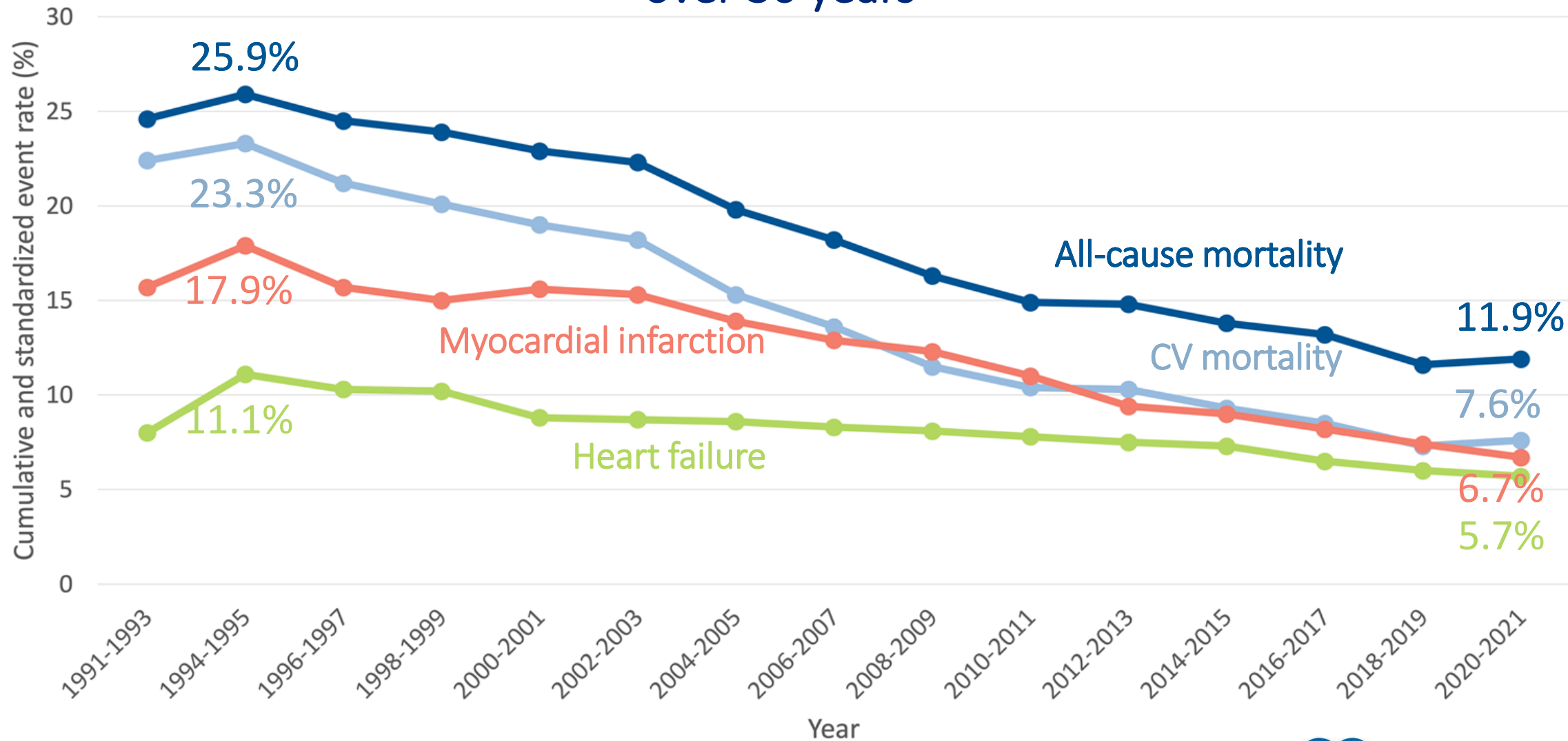




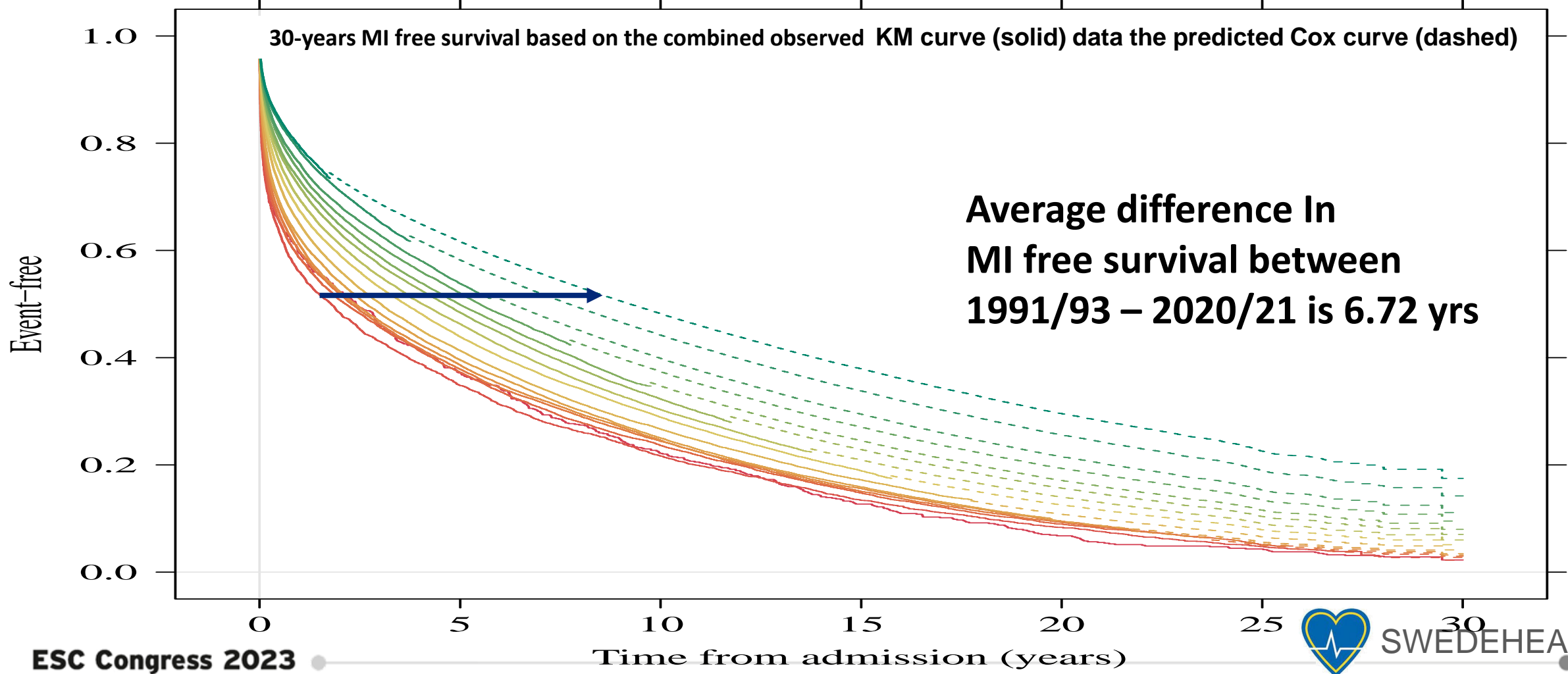
# Implementation of treatments in Non ST-elevation myocardial infarction over 30 years



# 1-year outcomes in Non ST-elevation myocardial infarction over 30 years



# NSTEMI – Changes in MI free survival over 30 years



## Registry-based randomized clinical trials—a new clinical trial paradigm

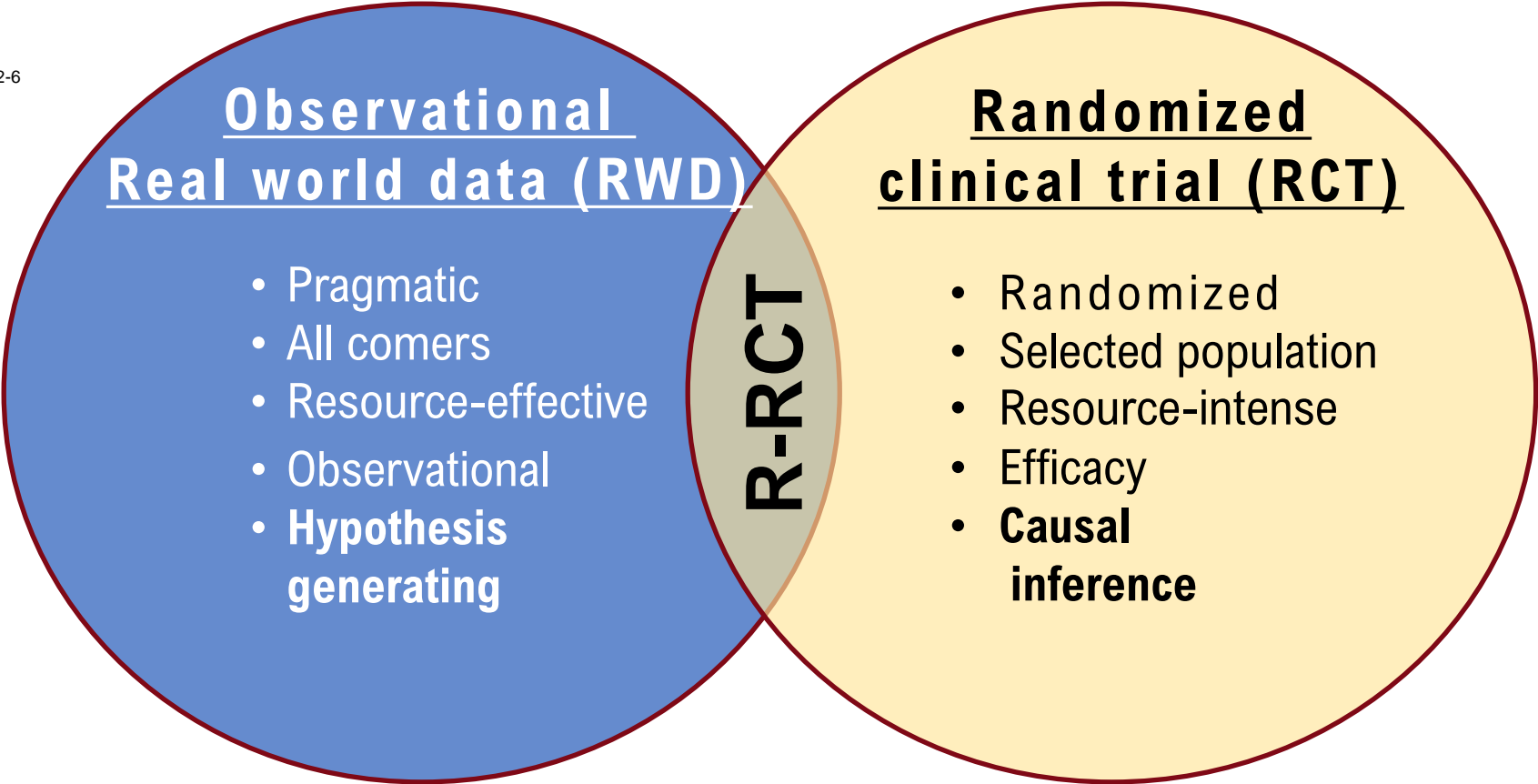
Stefan James, Sunil V. Rao and Christopher B. Granger



Nature Rev Cardiol. 2015 May;12(5):312-6

# Registry-based Randomized Clinical Trial - R-RCT

Prospective randomized trial that uses a clinical registry for one or several major functions for trial conduct and outcomes reporting.



## Registry-based randomized clinical trials—a new clinical trial paradigm

Stefan James, Sunil V. Rao and Christopher B. Granger



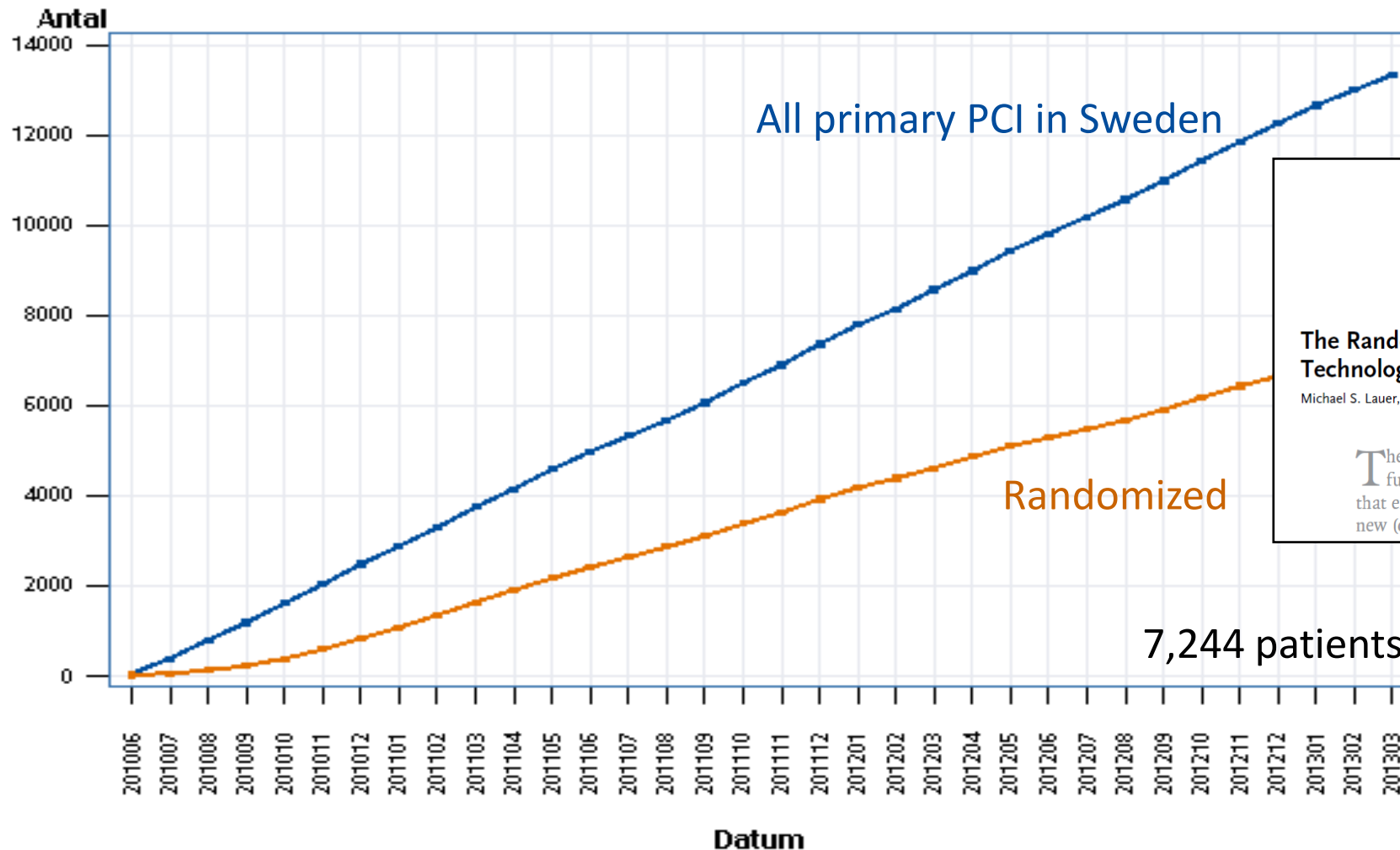
Nature Rev Cardiol. 2015 May;12(5):312-6

# Registry-based Randomized Clinical Trial - R-RCT

Prospective randomized trial that uses a clinical registry for one or several major functions for trial conduct and outcomes reporting.

- **Pragmatic**
- **All comers**
- **Resource-effective**
- **Randomized**
- **Efficacy - effectiveness**
- **Causal inference**

# TASTE trial – Inclusion rate



### Perspective

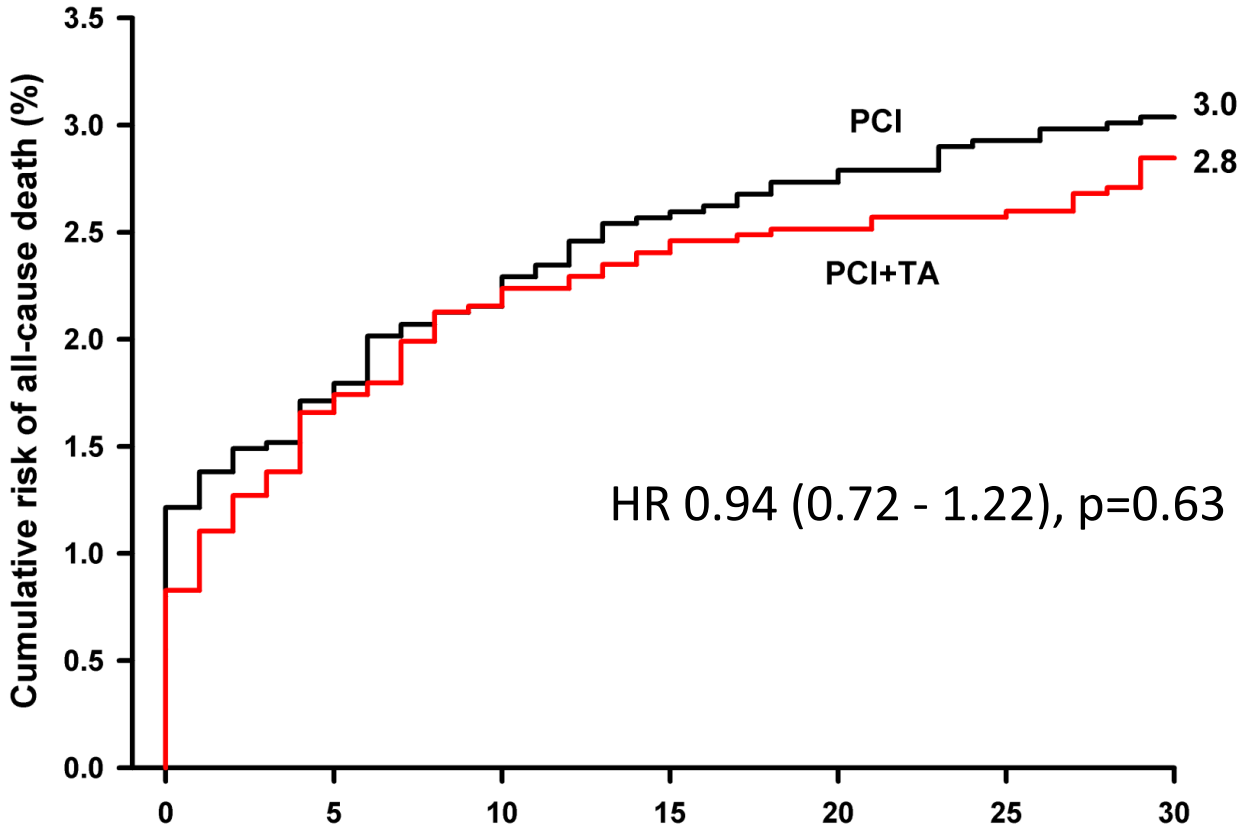
**The Randomized Registry Trial — The Next Disruptive Technology in Clinical Research?**  
Michael S. Lauer, M.D., and Ralph B. D'Agostino, Sr., Ph.D.

The randomized trial is one of the most powerful tools clinical researchers possess, a tool that enables them to evaluate the effectiveness of new (or established) therapies while accounting for

United States and abroad have collected vast amounts of data from patients with acute coronary syndromes, stable coronary disease, and heart failure, as well as



# TASTE trial – All-cause mortality at 30 days



No. at Risk		0	5	10	15	20	25	30
PCI+TA	3621	3568	3540	3532	3526	3524	3519	3519
PCI	3623	3567	3545	3530	3523	3517	3513	3513

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Thrombus Aspiration during ST-Segment Elevation Myocardial Infarction

Ole Fröbert, M.D., Ph.D., Bo Lagerqvist, M.D., Ph.D., Göran K. Olivecrona, M.D., Ph.D., Elmir Omerovic, M.D., Ph.D., Thorarinn Gudnason, M.D., Ph.D., Michael Maeng, M.D., Ph.D., Mikael Aasa, M.D., Ph.D., Oskar Angerås, M.D., Fredrik Calais, M.D., Mikael Danielewicz, M.D., David Erlinge, M.D., Ph.D., Lars Hellsten, M.D., Ulf Jensen, M.D., Ph.D., Agneta C. Johansson, M.D., Amra Käregren, M.D., Johan Nilsson, M.D., Ph.D., Lotta Robertsson, M.D., Lennart Sandhall, M.D., Iwar Sjögren, M.D., Ollie Östlund, Ph.D., Jan Harnek, M.D., Ph.D., and Stefan K. James, M.D., Ph.D.

ORIGINAL ARTICLE

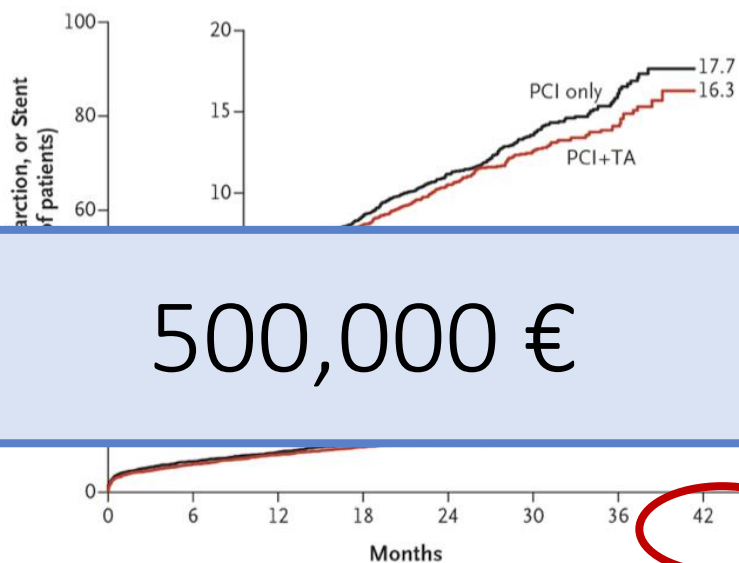
## Outcomes 1 Year after Thrombus Aspiration for Myocardial Infarction

Bo Lagerqvist, M.D., Ph.D., Ole Fröbert, M.D., Ph.D., Göran K. Olivecrona, M.D., Ph.D., Thorarinn Gudnason, M.D., Ph.D., Michael Maeng, M.D., Ph.D., Patrik Alström, M.D., Jonas Andersson, M.D., Ph.D., Fredrik Calais, M.D., Jörg Carlsson, M.D., Ph.D., Olov Collste, M.D., Matthias Götzberg, M.D., Ph.D., Peter Härdhammar, M.D., Dan Ioanes, M.D., Anders Kallryd, M.D., Rickard Linder, M.D., Ph.D., Anders Lundin, M.D., Jacob Odenstedt, M.D., Elmir Omerovic, M.D., Ph.D., Verner Puskar, M.D., Tim Tödt, M.D., Ph.D., Eva Zelleröth, M.D., Ollie Östlund, Ph.D., and Stefan K. James, M.D., Ph.D.





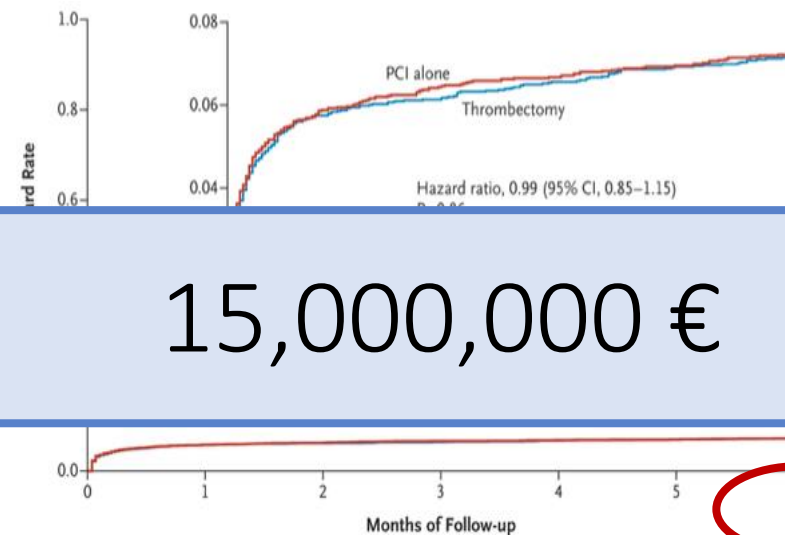
# R-RCT (*TASTE* trial) vs RCT (**TOTAL** trial)



500,000 €

1<sup>st</sup> patient: June 2010  
30 centers  
22 months to full enrollment

Fröbert et al. NEJM. 2013;369:1587-1597  
Lagerqvist et al. NEJM. 2014;371:1111-1120



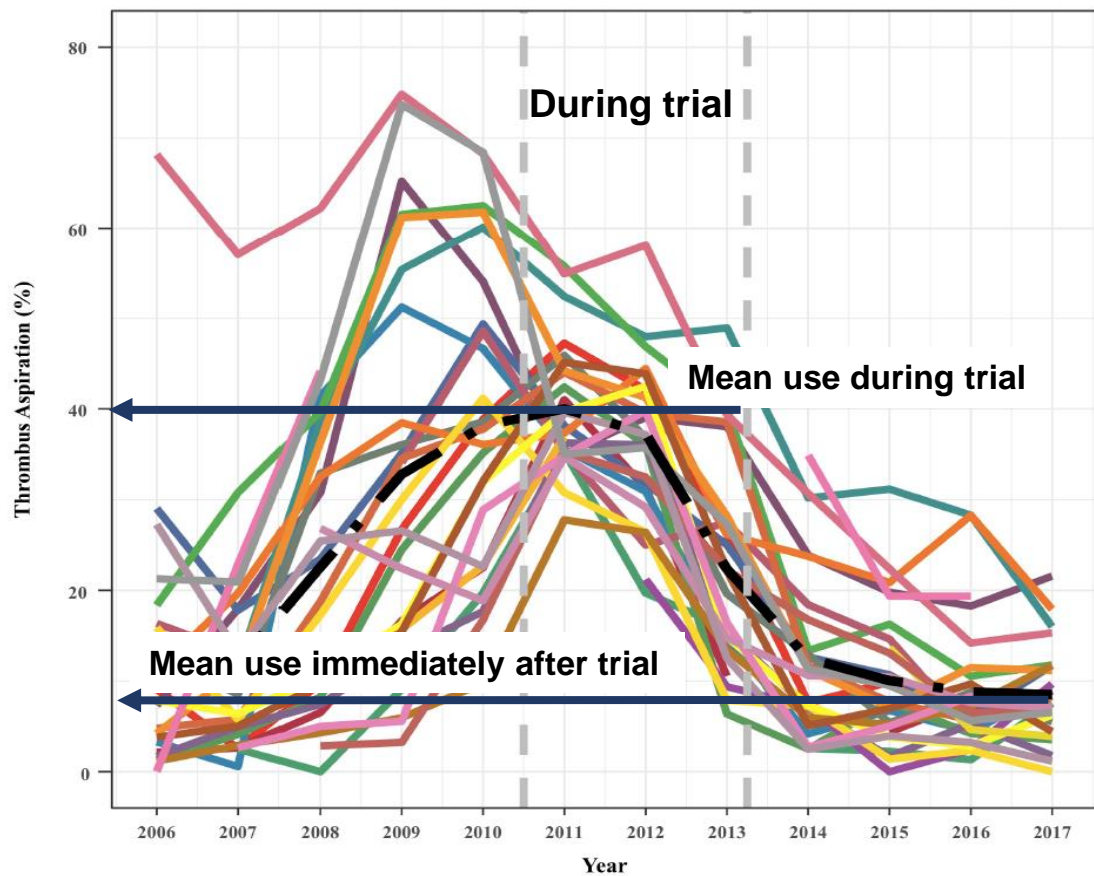
15,000,000 €

1<sup>st</sup> patient: August 2010  
87 centers  
48 months to full enrollment

Jolly et al. NEJM. 2015;372:1389-1398

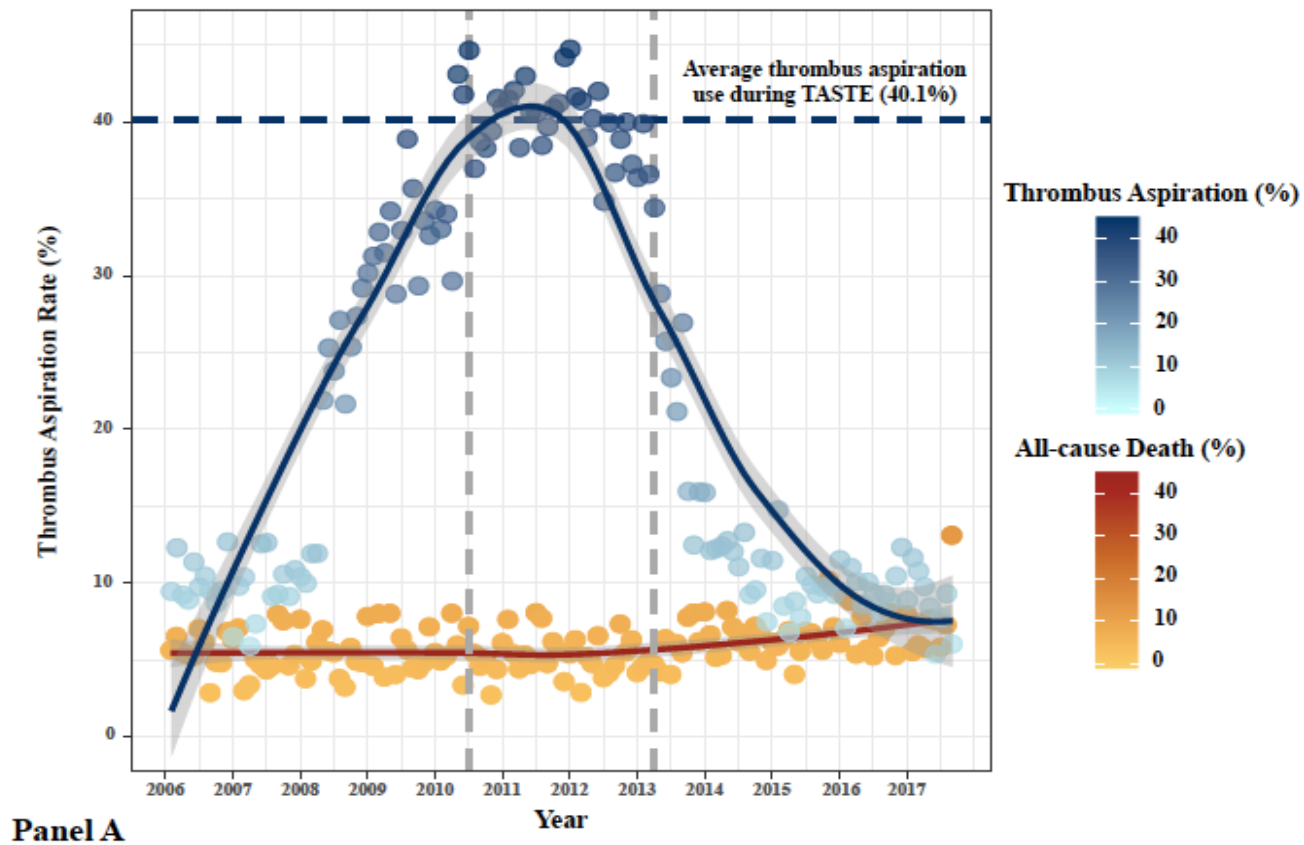


# Thrombus aspiration before and after the *TASTE* trial



Bucciari Circ CV Int 2019

### Thrombus Aspiration and All-cause Death at 30 Days



Panel A

### Assessing the Nationwide Impact of a Registry-Based Randomized Clinical Trial on Cardiovascular Practice

The TASTE Trial in Perspective

# Strategy trial with simple endpoints



## DETO<sub>2</sub>X – AMI



**Eligible patient\***  
In ambulance, ED or cath lab  
N=6600

- \*Inclusion criteria:**
- symptoms suggestive of AMI within 6h
  - SpO<sub>2</sub> ≥ 90%
  - ≥ 30y
  - ECG changes indicating ischemia and/or elevated troponin levels

R  
1:1

**Oxygen**  
6l/min for (6-)12h  
via Oxymask

**Air**

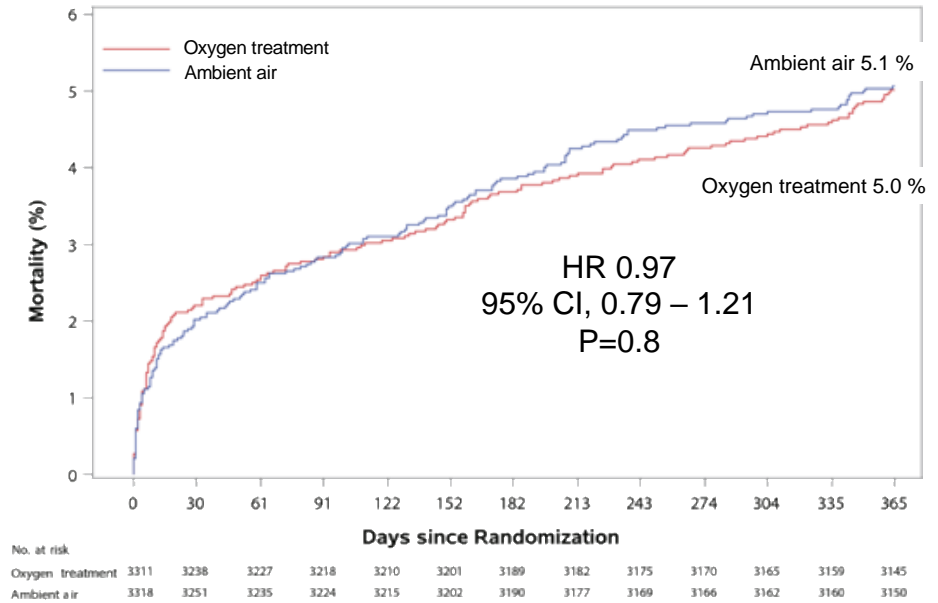
### Primary Endpoint: 1-year total mortality

Additional secondary endpoint and sub studies  
Data analysis through SWEDEHEART registry and national mortality registry

Funding: Swedish Research council (VR)



## Primary Endpoint up to 365 days



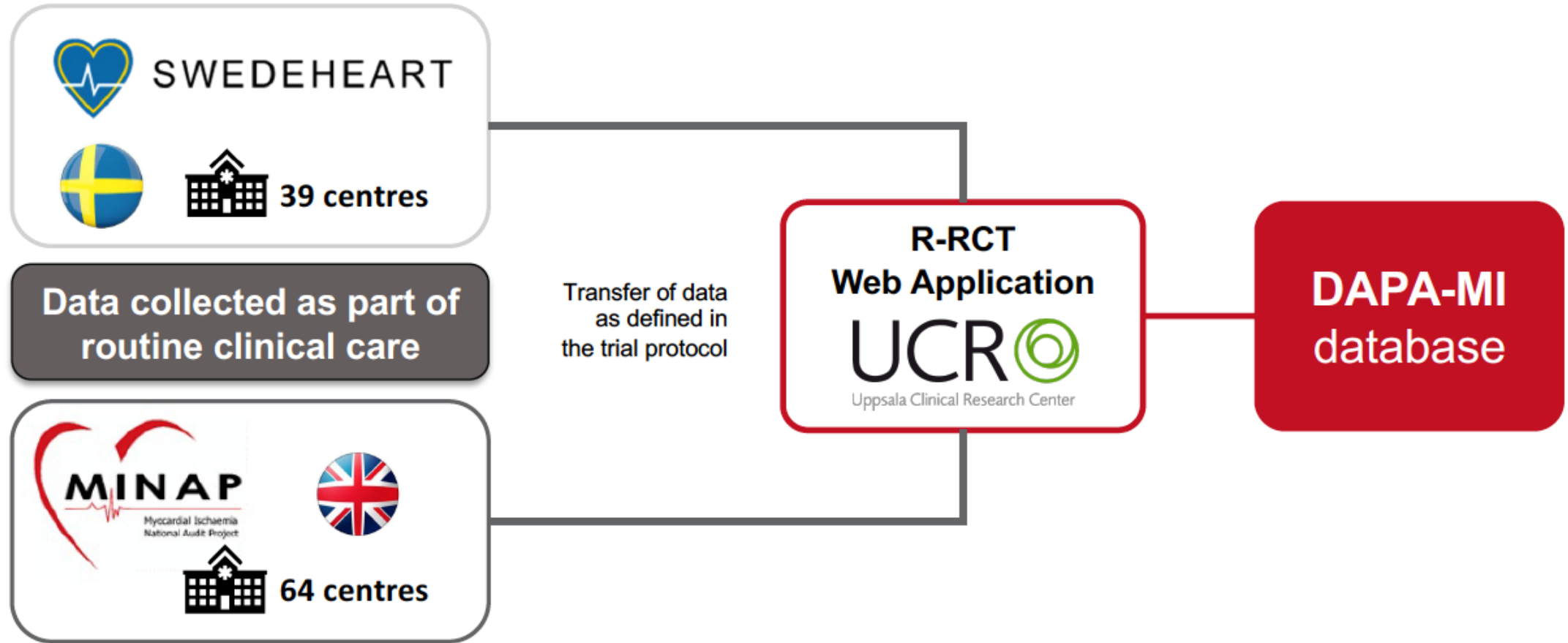
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

### Oxygen Therapy in Suspected Acute Myocardial Infarction

Robin Hofmann, M.D., Stefan K. James, M.D., Ph.D.,  
Tomas Jernberg, M.D., Ph.D., Bertil Lindahl, M.D., Ph.D.,  
David Erlinge, M.D., Ph.D., Nils Witt, M.D., Ph.D., Gabriel Arefalk, M.D.,  
Mats Frick, M.D., Ph.D., Joakim Alfredsson, M.D., Ph.D.,  
Lennart Nilsson, M.D., Ph.D., Annica Ravn-Fischer, M.D., Ph.D.,  
Elmir Omerovic, M.D., Ph.D., Thomas Kellerth, M.D., David Sparv, B.Sc.,  
Ulf Ekelund, M.D., Ph.D., Rickard Linder, M.D., Ph.D.,  
Mattias Ekström, M.D., Ph.D., Jörg Laueremann, M.D., Urban Haaga, B.Sc.,  
John Pernow, M.D., Ph.D., Ollie Östlund, Ph.D., Johan Herlitz, M.D., Ph.D.,  
and Leif Svensson, M.D., Ph.D., for the DETO2X-SWEDEHEART Investigators\*

# REGISTRY-BASED RANDOMIZED CLINICAL TRIAL – R-RCT



# R-RCT in Sweden 2023

	Active	Published
Cardiology	8	7
Bariatric surgery	1	1
Vascular surgery	1	1
Stroke		1*
Obstetrics	1	
Gynecology	2	
Pulmonary medicine	1	
GI cancer	1	
Orthopedic surgery	4	
Diabetes	1	
Renal failure	1**	



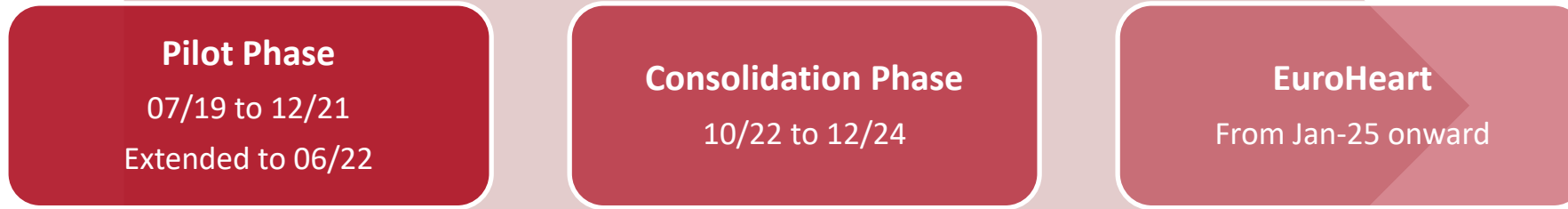
# EuroHeart mission

- develop an **international collaboration** of countries with **continuous online registration of high-quality, harmonised patient data** at admission and over time *supporting continuous improvement of care and outcomes in patients with common cardiovascular diseases.*
- create an **international infrastructure** for cost-effective **safety surveillance** of new drugs and devices and **registry-based randomised clinical trials** in a representative populations across multiple geographies.



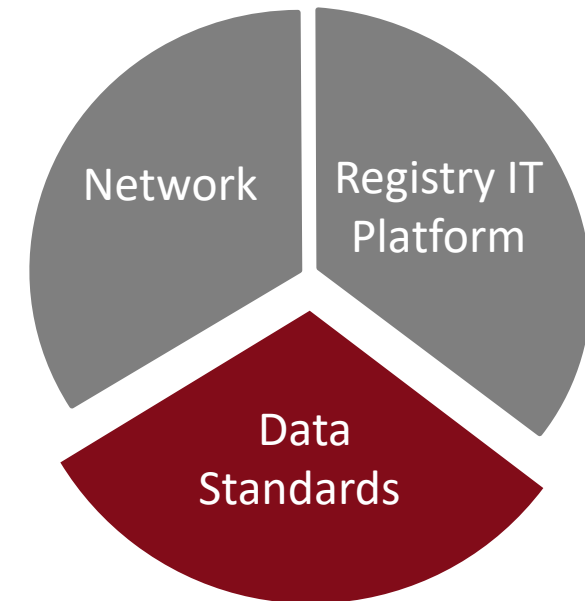


# EuroHeart Data Standards



## EuroHeart Data Standards:

- **4** common CV disease domains developed in collaboration with ESC Associations, NCS and other relevant stakeholders
  - **ACS-PCI** (EHJ 2022)
  - **Heart failure – CRT, ICD** (EHJ 2022)
  - **Atrial fibrillation – Ablation** (EHJ-QCCO) 2022)
  - **Valve disease – TAVI** (EHJ-QCC 2022)



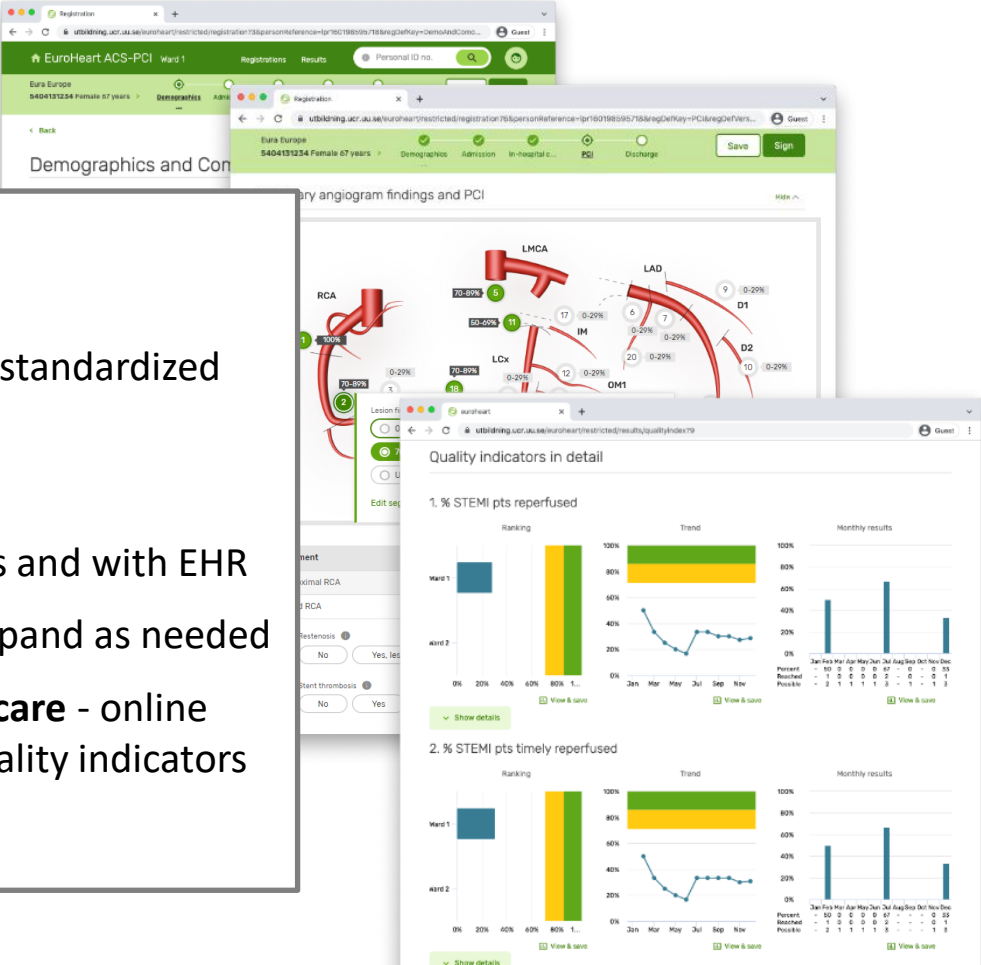


# EuroHeart Data Entry

**Pilot Phase**  
07/19 to 12/21  
Extended to 06/22

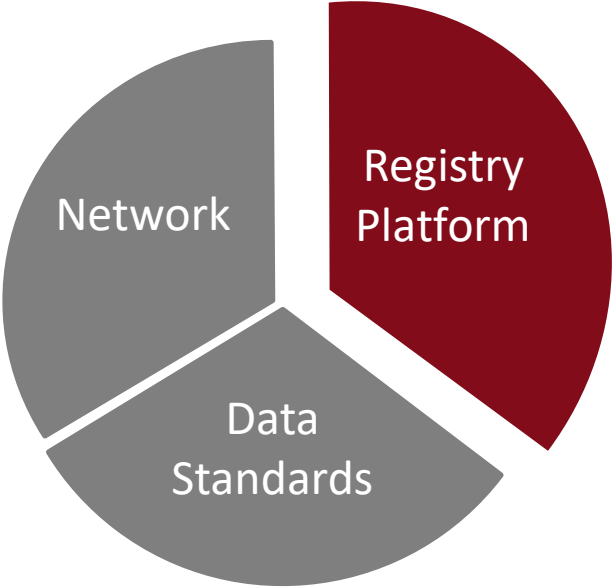
**Consolidation Phase**  
10/22 to 12/24

**EuroHeart**  
From Jan-25 onward

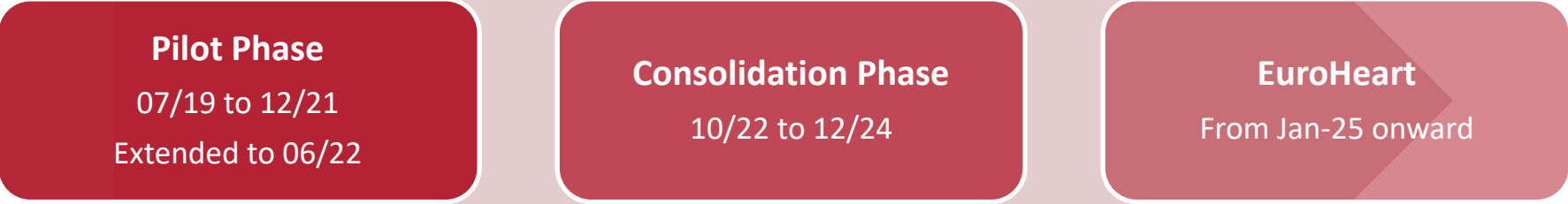


## EuroHeart Registry IT-platform:

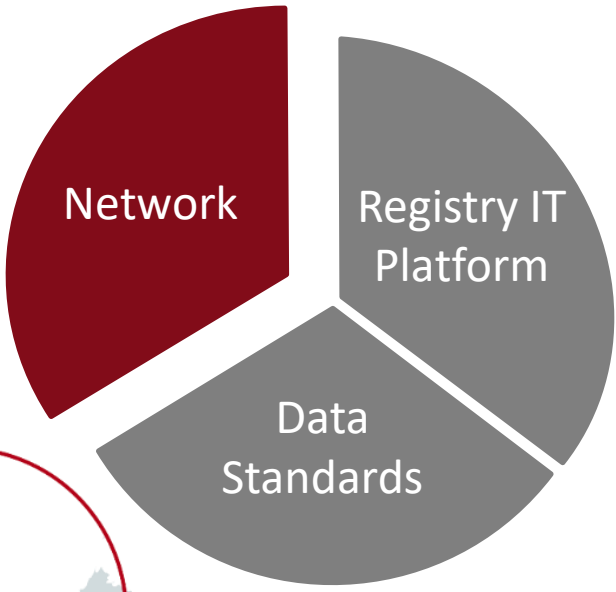
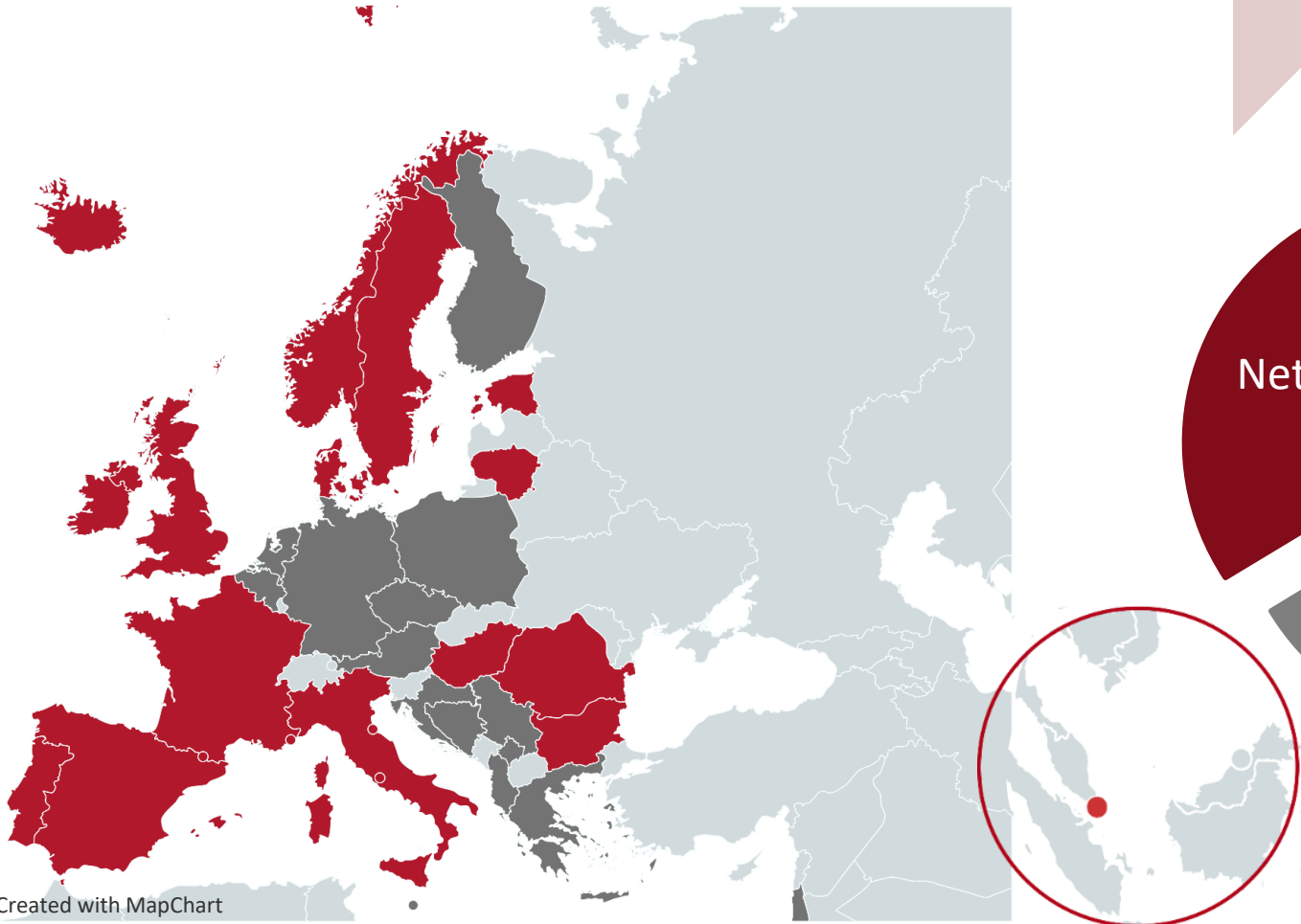
- Internet-based **direct entry** of standardized data
- **Intuitive** – no manual needed
- **Interactive** - on-line definitions and with EHR
- **Adaptive** – fields/questions expand as needed
- **Direct feedback on quality of care** - online graphical/tabular statics on quality indicators



# EuroHeart Network 2024



■ EuroHeart Countries  
■ In Communication

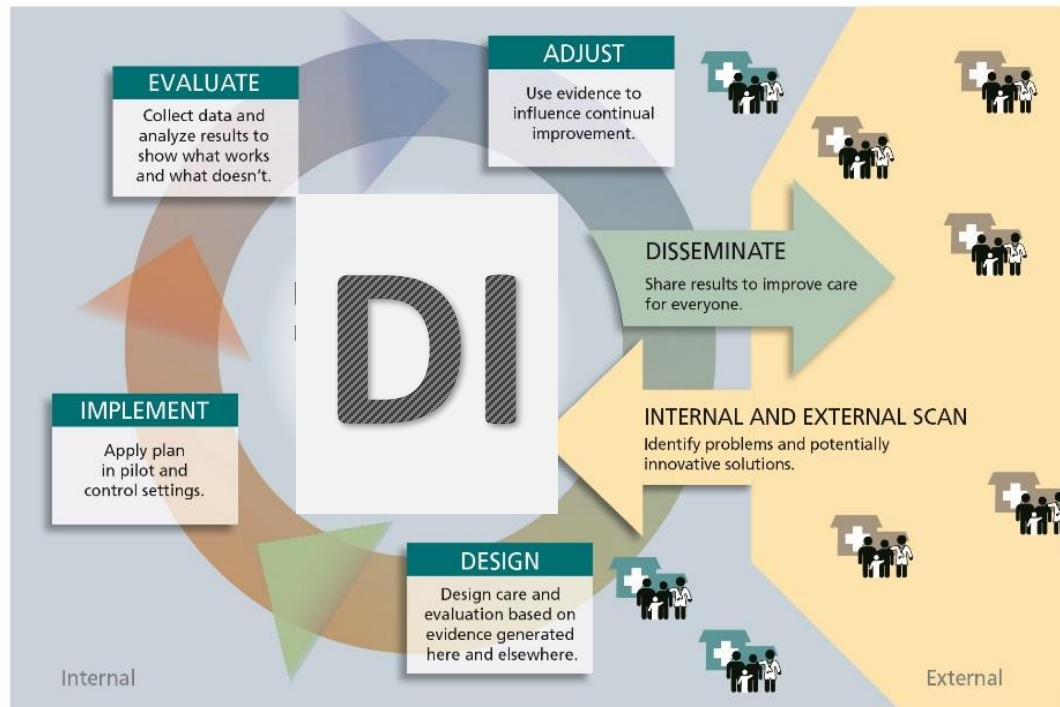


# From



# SWEDHEART

# to



# EuroHeart