Experience of randomization within a registry

From SwedeHeart & NICOR to EuroHeart

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EuroHeart
European Unified Registries for Heart Care Evaluation and Randomised Trials

www.escardio.org/euroheart

ESC
European Society of Cardiology

EuroHeart

The Mission of EuroHeart is:

1. To develop an international collaboration that provides common definitions of QoC indicators and the availability of an IT infrastructure for continuous online registration of high quality and harmonised patient data, supporting improvement of care and outcomes in patients with common cardiovascular diseases.
2. To provide an international infrastructure for cost-effective safety surveillance of new drugs and devices and registry-based randomized controlled trials in a general patient population across multiple geographies.

Monitoring QoC & Outcomes

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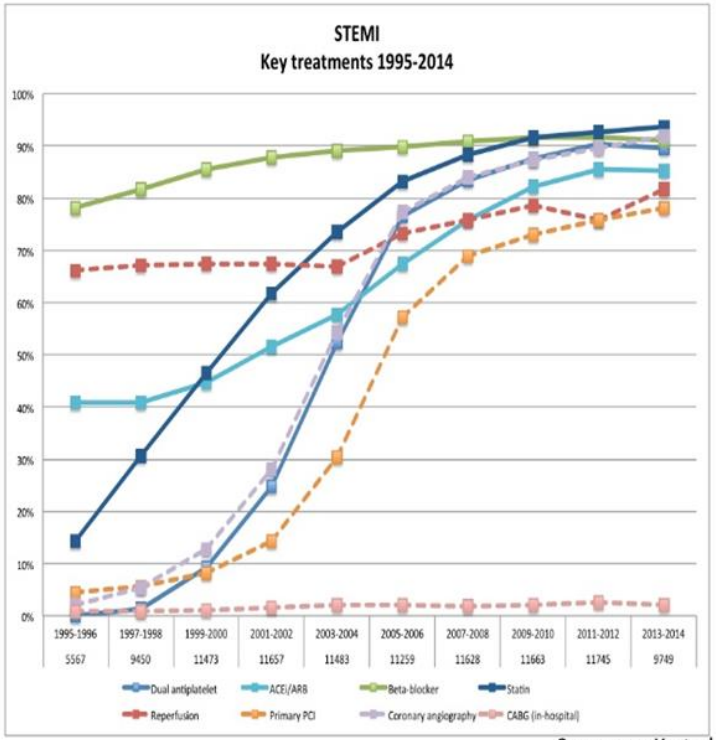
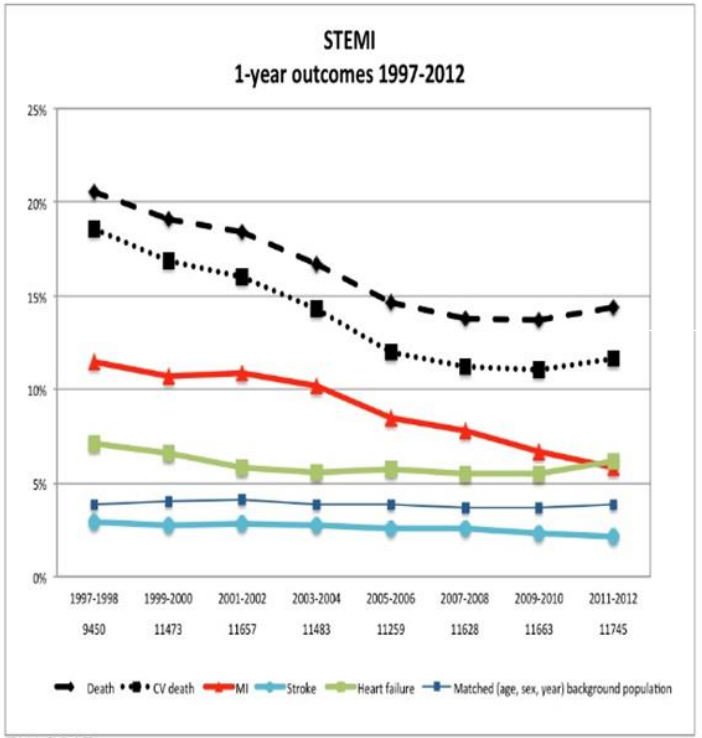
STEMI – Key treatments and 1-year outcomes
Results from SWEDEHEART 1994-2014



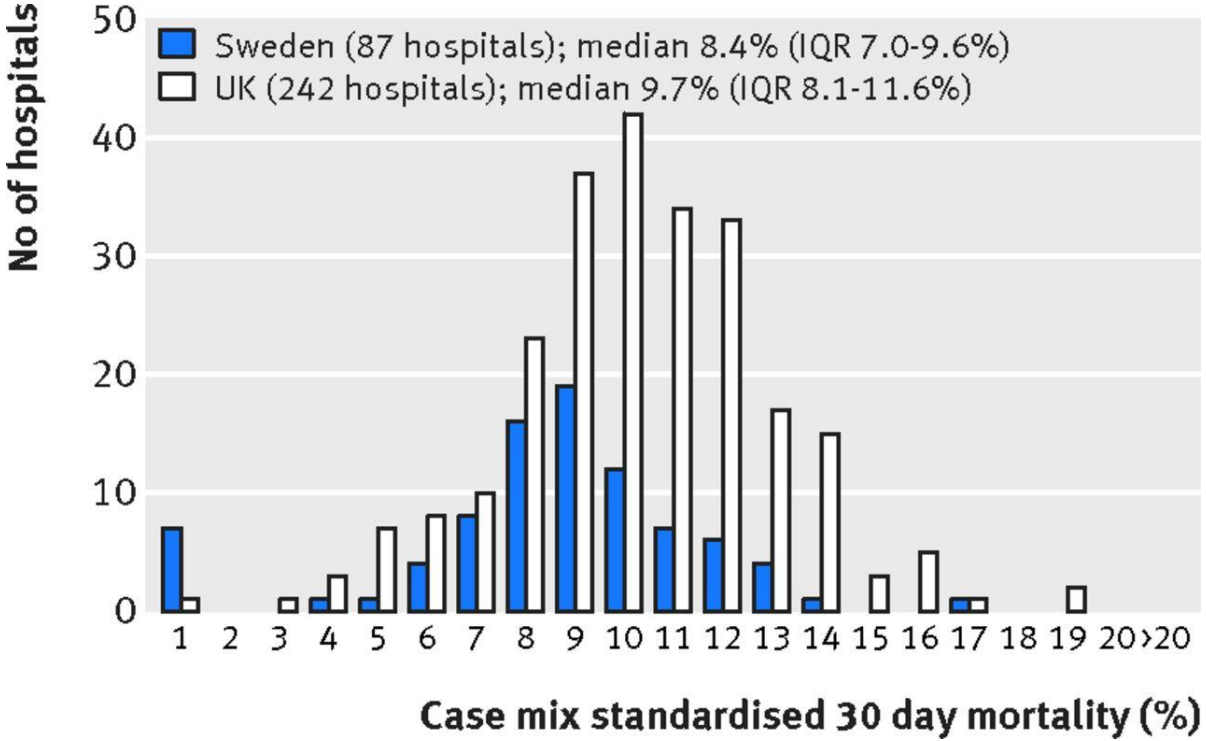


Szummer K et al EHJ 2017

Monitoring implementation of new treatments and its impact on patient outcomes

Benchmarking

Hospital variation in standardised 30 day mortality (%) in Sweden and UK 2004-2010.



Sheng-Chia Chung et al. BMJ 2015;351:bmj.h3913

Why should one be eager to randomize?

EuroHeart

1. Is an essential tool for testing the efficacy of the treatment;
2. It eliminates the selection bias;
3. Balances the groups with respect to many known and unknown confounding or prognostic variables;
4. Proper randomization ensures no a priori knowledge of group assignment. Knowledge of group assignment creates a layer of potential bias that may taint the data;
5. Studies with inadequate or unclear randomization tend to overestimate treatment effects up to 40% compared with those that used proper randomization.

Why should one be eager to randomize within registries?

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1. Pressing clinical questions;
2. Rapid recruitment;
3. Large size;
4. Representative patients;
5. Inexpensive;
6. Longer follow-up (with linkage to administrative data).

Point-of-Care Randomization

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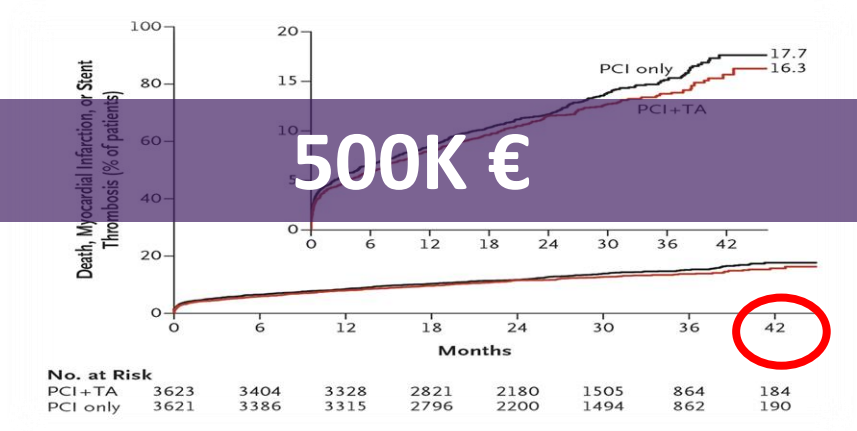
STEMI Thrombectomy

TASTE

- Registry-based Follow-up



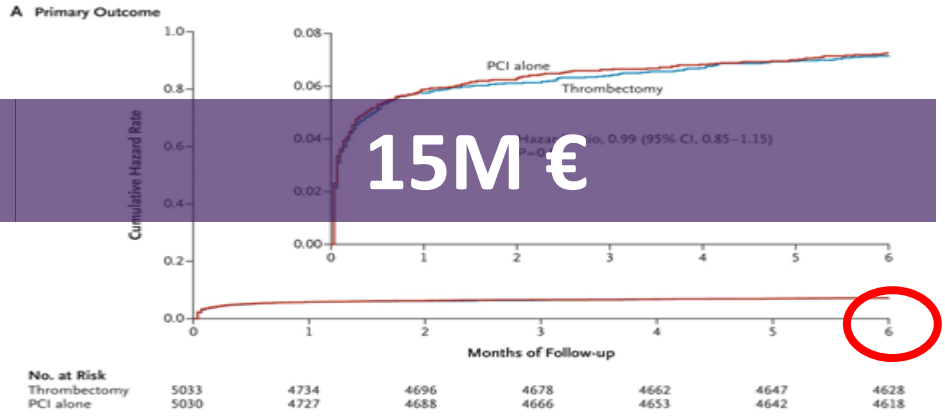
500K €

1st patient: June 2010
30 centers
33 months to full enrollment

Fröbert et al. *N Engl J Med* **2013**
Lagerqvist B et al. *N Engl J Med* 2014

TOTAL

- Standard site-based follow-up



15M €

1st patient: August 2010
87 centers
48 months to full enrollment

Jolly SS et al. *N Engl J Med* **2015**

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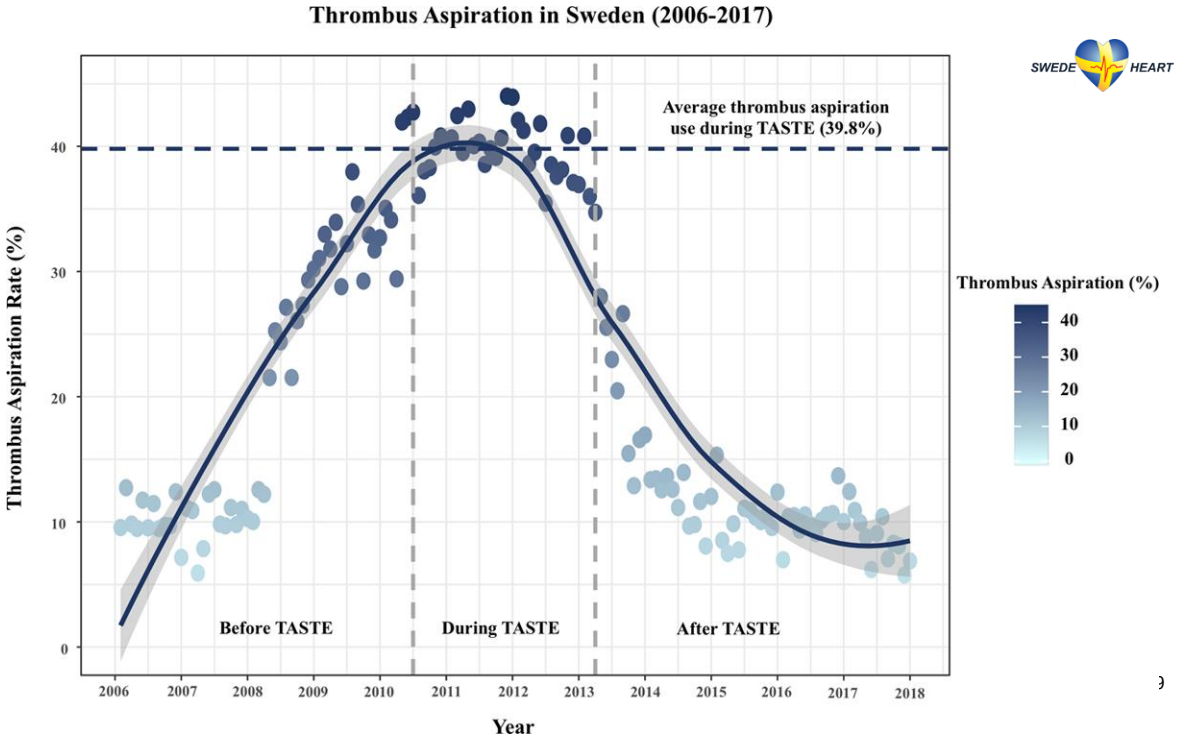
Impact of TASTE results on routine patent care



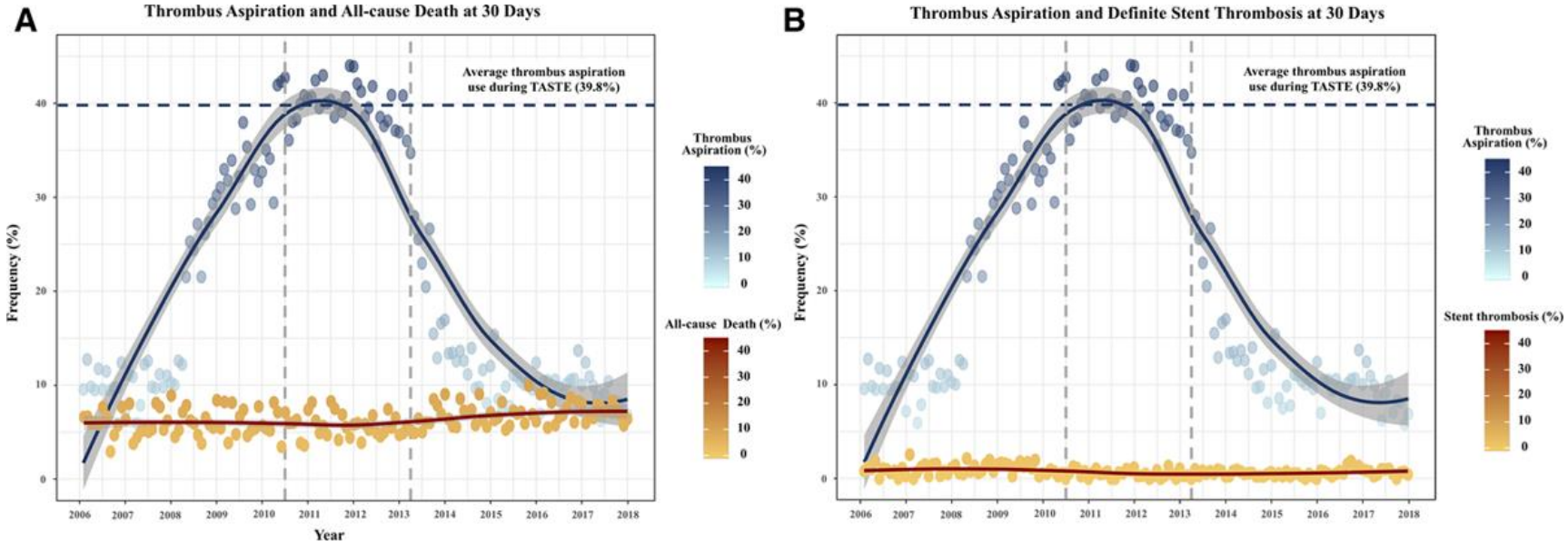
Buccheri et al *Circ Cardiovasc Interv.* 2019

Monitoring, Randomization and Implementation:

A Learning Health System

EuroHeart

Impact of TASTE results on patient outcome



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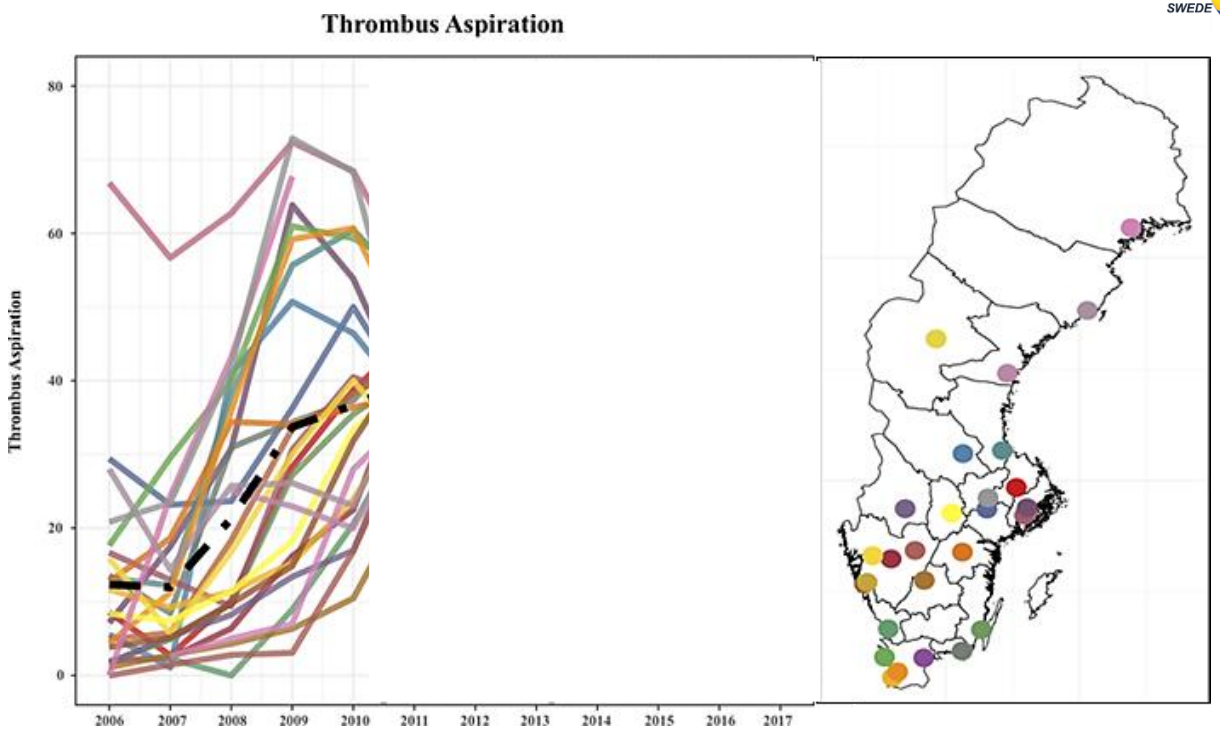
Impact of TASTE results on routine patent care



Monitoring, Randomization and Implementation:

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“Quality of data won’t be as good…”

Minimal impact on RCT findings of randomly distributed errors

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	Active (10,000)	Control (10,000)	OR (& 95%CI)	P-value
True events	800	1000	0.78 (0.71-0.86)	<0.00001

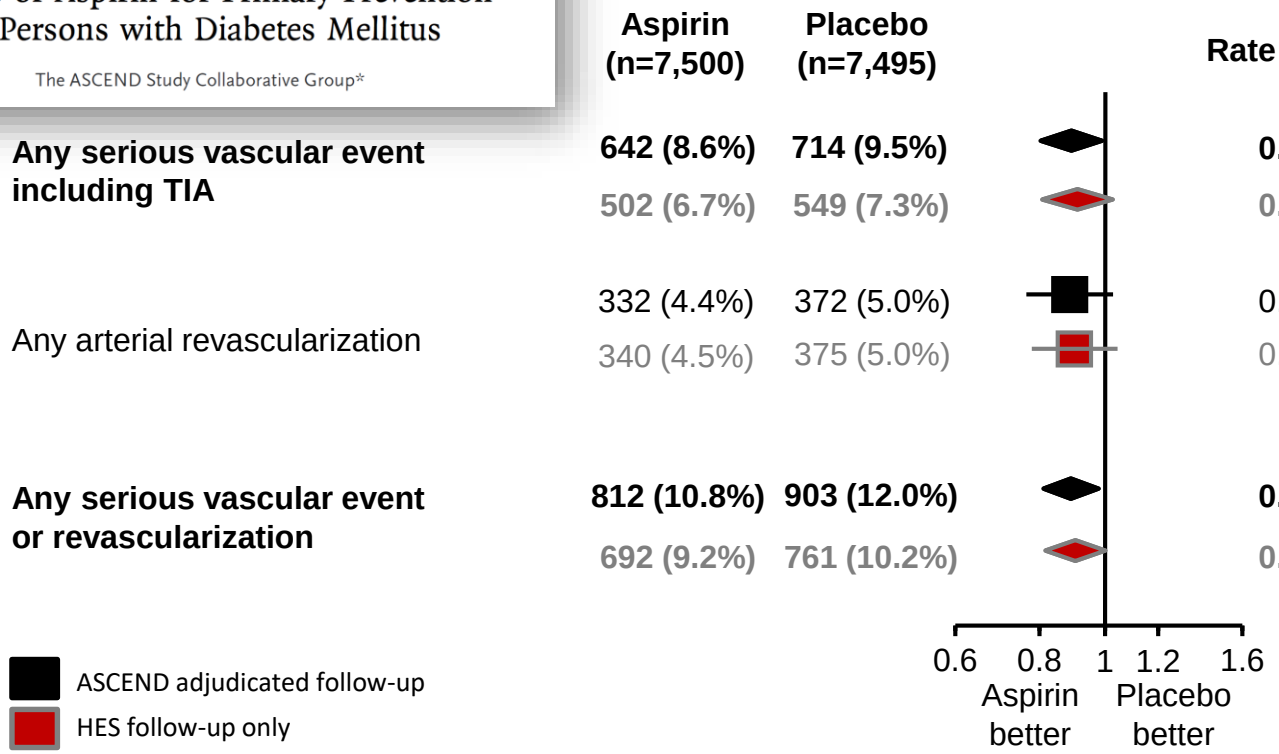
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Effects of Aspirin for Primary Prevention in Persons with Diabetes Mellitus

The ASCEND Study Collaborative Group*

EuroHeart



Aspirin vs Placebo in ASCEND (excluding Scotland)

Unpublished data – not for reproduction or circulation

A federation of continuous patient registries on common CV diseases across Europe is an opportunity to:

EuroHeart

- Harmonise QoC definitions;
- Monitor, benchmark and improve QoC and outcomes;
- Carry out cost-effective safety surveillance of new drugs and devices;
- Undertake more affordable RCTs in a general patient population across multiple geographies;
- Increase industry investment (in Europe and in CVD) and patient access to new treatments.