

# Registries – how we can ensure the EHDS has data worth sharing

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# Why are health data and EHDS important for the ESC?

- Guidelines
- Collaborative Data Collection activities
  - Registries
  - Surveys
  - CV Disease Statistics (ATLAS)

# ESC Strategic Aims 2023-2028



**A Welcoming  
Society with Fair  
and Transparent  
Governance**



**Trusted Knowledge,  
Effectively Delivered**



**A Membership  
Experience Rich in  
Rewards and Benefits**



**A Focus on  
Person-Centred  
Healthcare**



**High Quality Data  
and Research**



**Environmental  
Sustainability**

# The plurality of evidence

## ESC Classes of recommendations

	Definition	Wording to use	
Classes of recommendations	<b>Class I</b>	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.	Is recommended or is indicated
	<b>Class II</b>	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.	
	Class IIa	Weight of evidence/opinion is in favour of usefulness/efficacy.	Should be considered
	Class IIb	Usefulness/efficacy is less well established by evidence/opinion.	May be considered
	<b>Class III</b>	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.	Is not recommended

## ESC Levels of evidence

Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

## ESC Levels of evidence

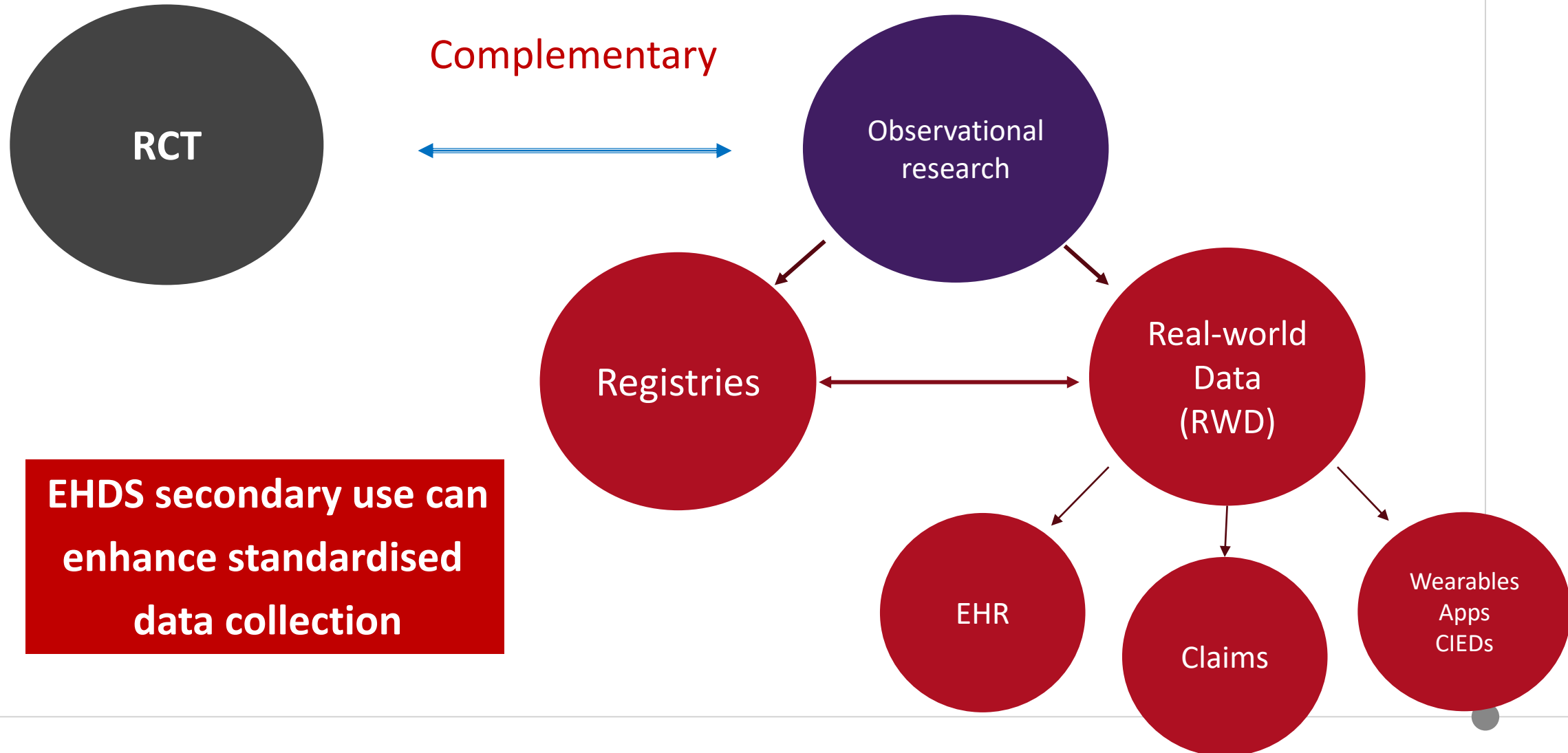
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Randomised clinical  
Trial (RCT)

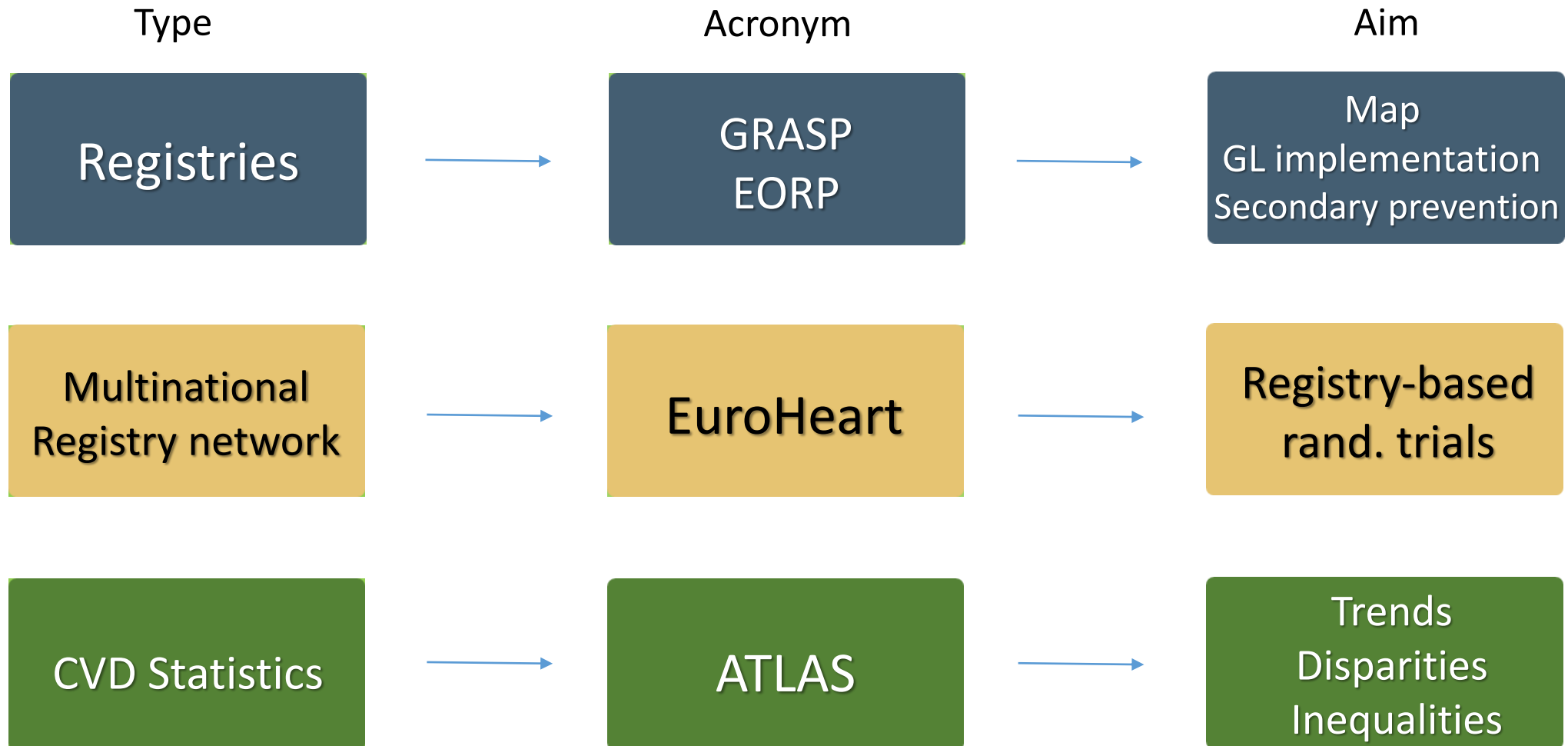
Non-randomised  
studies

Retrospective studies  
Registries

# Clinical Evidence



# Data collection in the ESC



## Study objectives

- Assess **contemporary patterns** of disease management in practice
- Assess **adherence to /** implementation of current **ESC Guidelines**
- Collect information on **evidence-based treatments** as recommended by ESC

## Snapshot studies - 2 per year

- Short recruitment period - limited follow up
- Reduced workload for participating sites

## Registry studies - 1 per year

- Rare diseases and prevention
- Reports on real-world clinical evaluation



# GRASP: Topics proposal

	Proposed registries	ESC Guidelines
Short term Priority (2023)	<b>Chronic coronary syndromes</b> (snapshot)	2019 & 2024
	<b>Cardiac Pacing</b> (snapshot)	2021
	<b>Heart Failure</b> (snapshot)	2021
	<b>EuroAspire</b> (prevention)	2019 Diabetes & Dyslipidaemias 2023: Diabetes
Medium term Priority (2024)	<b>Atrial Fibrillation</b> (snapshot)	2020 & 2024
	<b>Acute coronary syndromes</b> (snapshot)	2020 & 2023
	<b>Valvular disease</b> (snapshot)	2021
	<b>Cardiomyopathies</b> (including HCM amyloidosis) <b>and myocarditis</b> (rare disease)	2023

# EuroHeart

- Develop and maintain a **collaboration** of countries with **continuous online registration of high-quality, harmonised patient data** at admission and over time.
- Create **an international infrastructure** for cost-effective **safety surveillance** of new drugs and devices and **registry-based randomised clinical trials** in a representative patient population across multiple geographies.



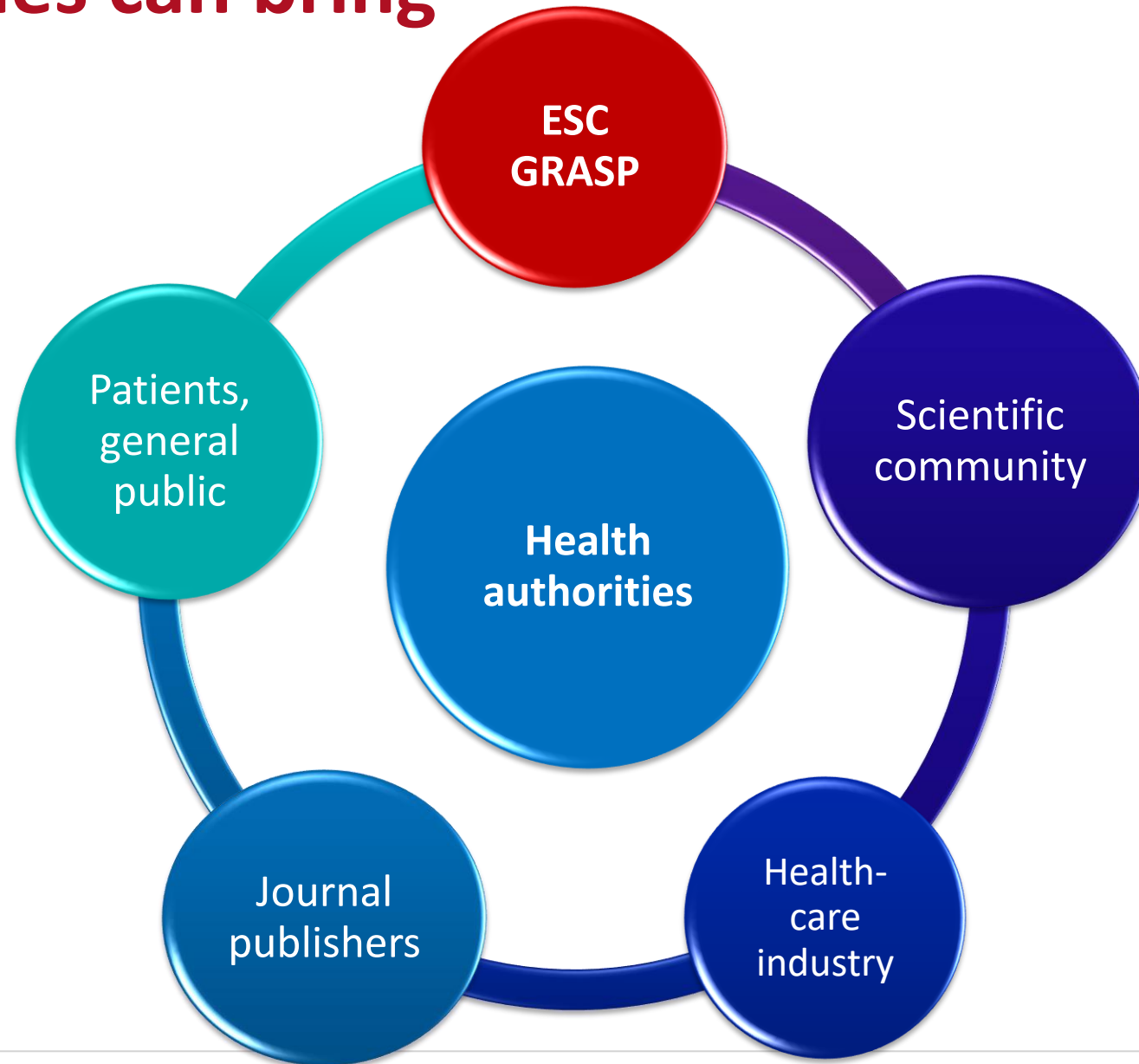
# The EuroHeart Data Standards

Developed data standards for **4** common cardiovascular disease domains

- **Acute Coronary Syndromes & Percutaneous Coronary Intervention (ACS-PCI)**
- **Heart failure – CRT, ICD**
- **Atrial fibrillation – Ablation**
- **Valve disease – TAVI**



# What registries can bring



# Registries – the struggles

- Data entry by dedicated staff versus daily routine
- Consecutive patients
- Voluntary versus mandatory
- Standardised data variables
- Data transfer
- Data protection regulations (anonymised/ pseudonymised data)
- Funding

# EU4health – the instrument we need

**FINANCIALLY SUPPORTING THE EU AS THE HEALTHIEST REGION  
IN THE WORLD**

**EU4Health Programme worth EUR 9.4 billion for 2021-2027**  
with a health in all policies approach 



European Social Fund Plus (ESF+)



European Regional and Development  
Fund



Horizon Europe



Union Civil Protection Mechanism/rescEU



Digital Europe Programme



Connecting Europe Facility



Recovery and Resilience Facility

#EU4Health  
#EUBudget



***Funding is needed to enable independent research  
supporting a functioning EHDS in the patients' interest***