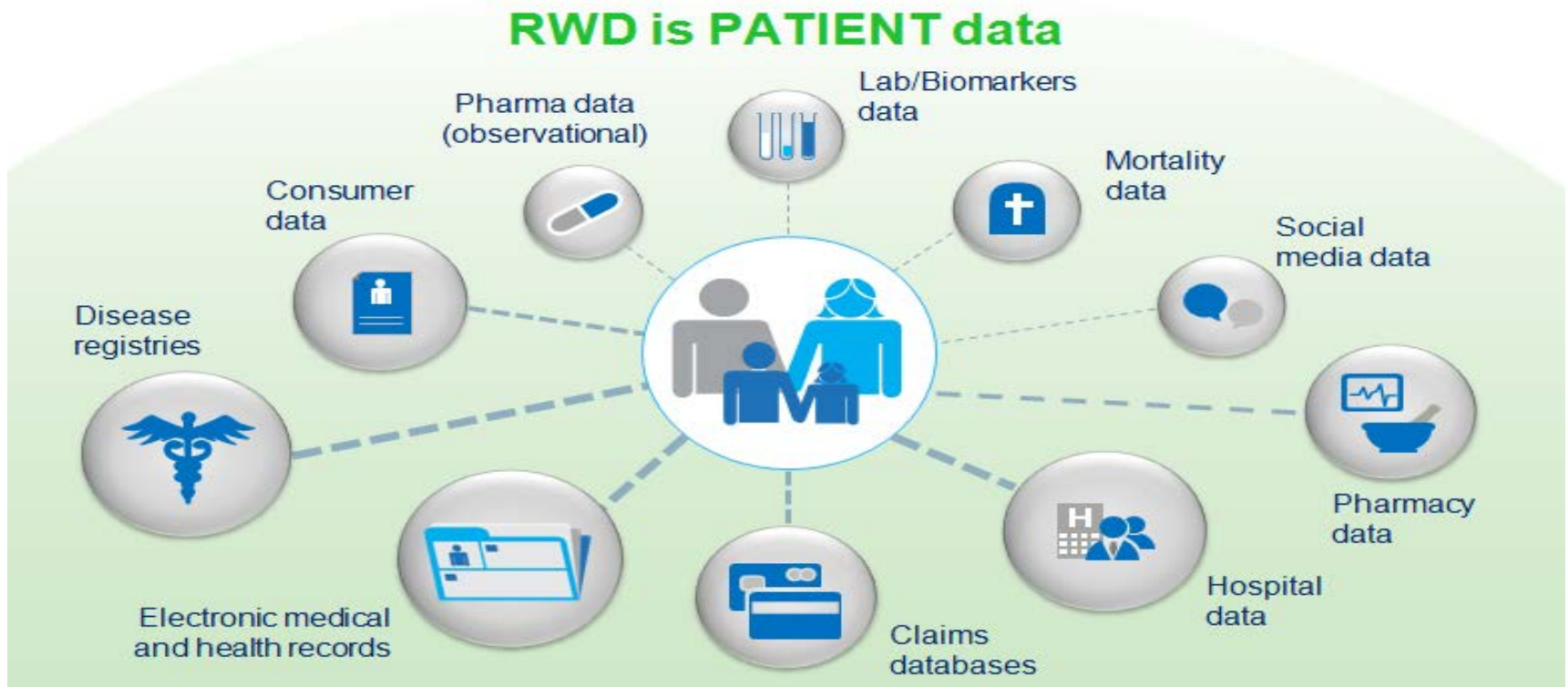


# Establishing Greece as a RWE excellence center

Antonis Karokis  
External Affairs Director MSD  
December 2015

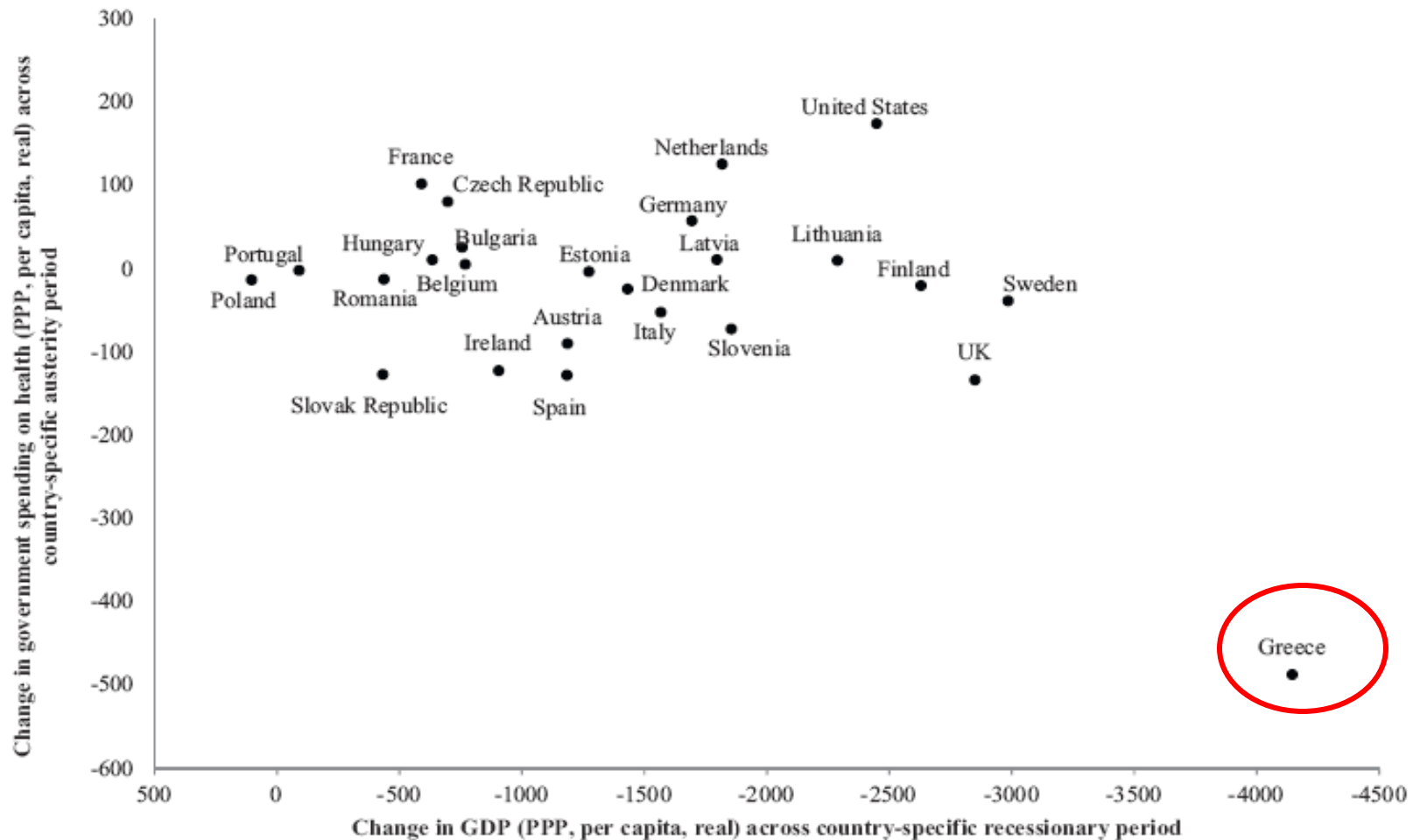
# Definition

## Real-World Data (RWD)



Real World Evidence: Insights generated by Real World Data using appropriate scientific and / or commercial analytics

# Greece was the country with the highest drop in GDP and Health Spending per capita during austerity times



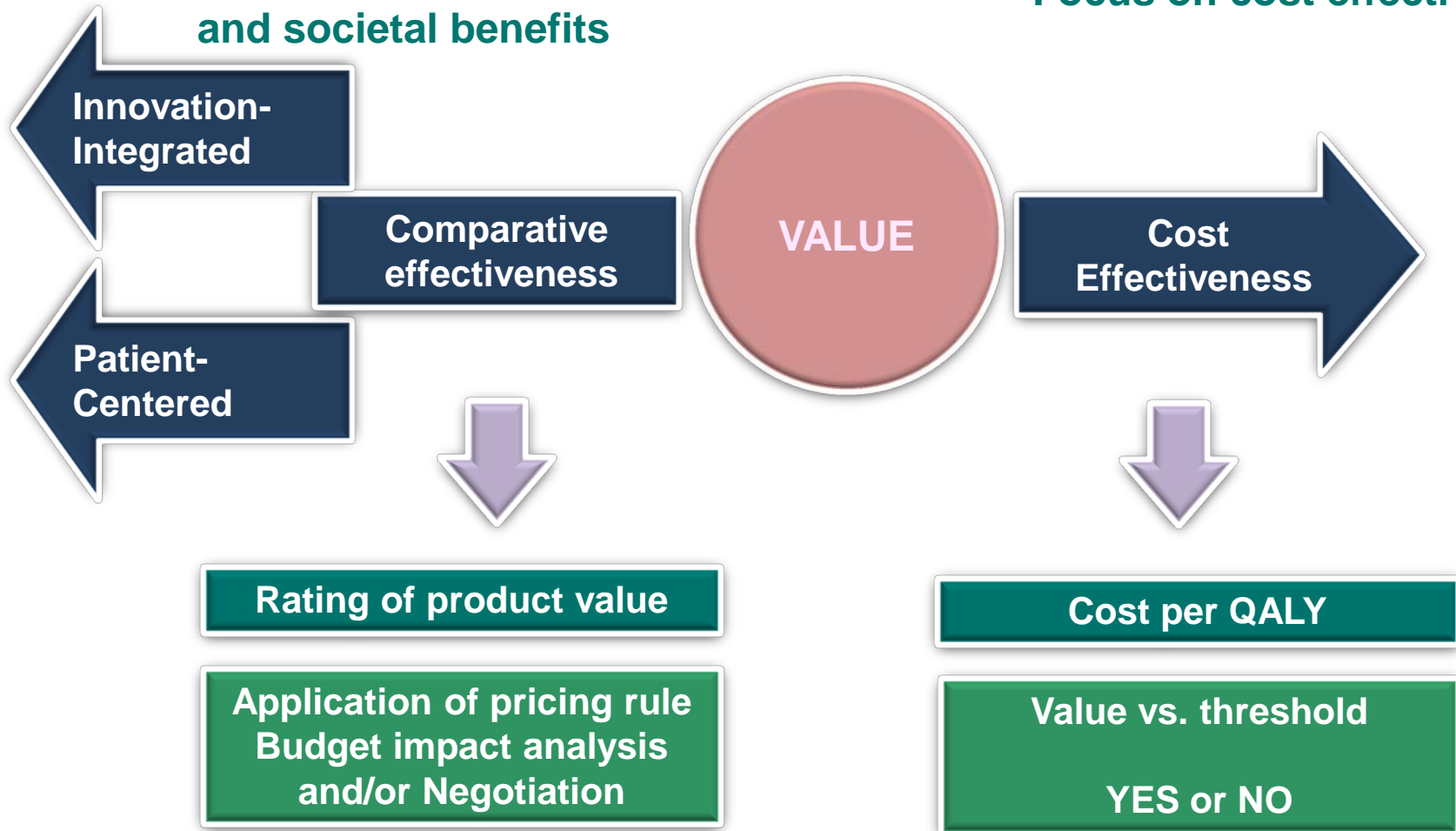
Reeves A., McKee M., Basu S., Stuckler D., et al, The political economy of austerity and healthcare: Cross-national analysis of expenditure changes in 27 European nations 1995–2011, Health Policy Vol. 115, Issue 1 (March 2014)

# We need to assess the value of health care resources

## The case of pharmaceuticals

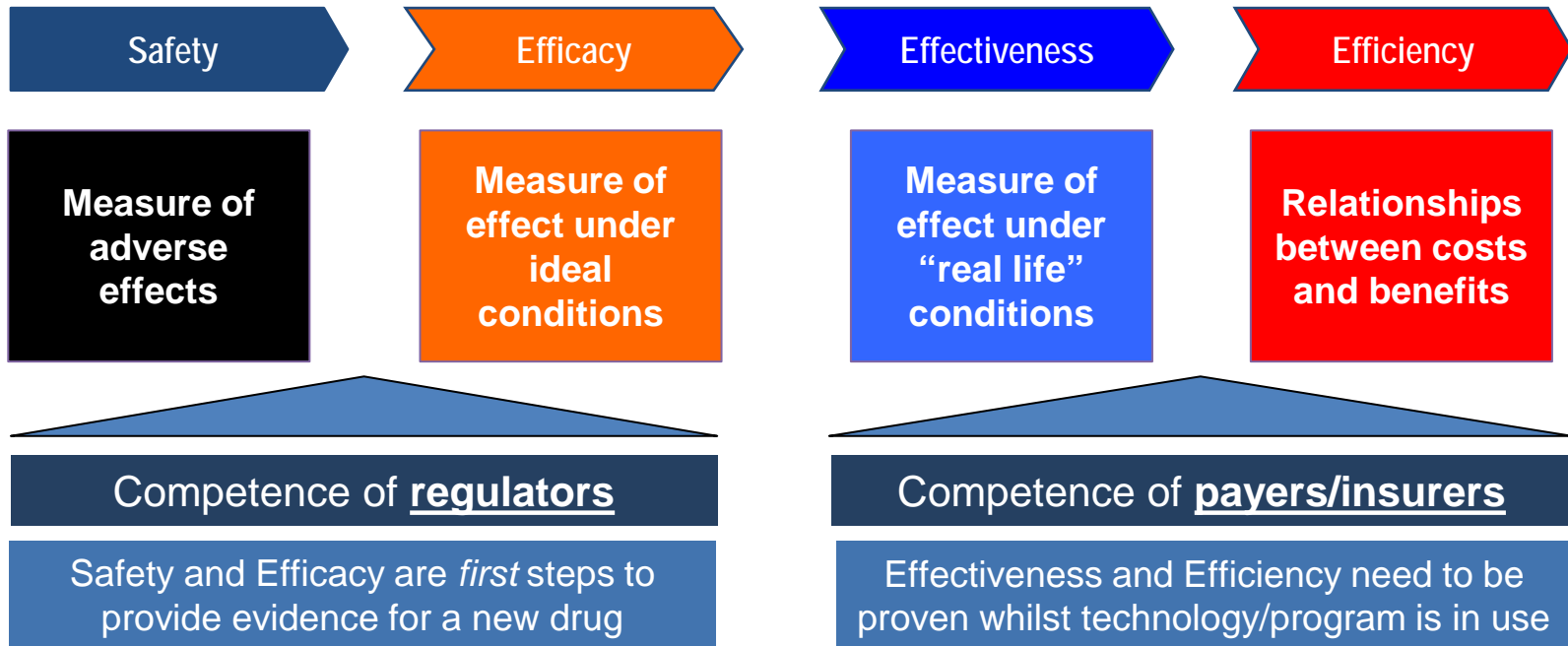
**Focus on clinical  
and societal benefits**

**Focus on cost effectiveness**





# Scientifically credible debate is driven by decision-makers in healthcare and they demand four types of evidence



Efficacy does not imply effectiveness and effectiveness does not imply efficiency, therefore decision makers use:

**Health Technology Assessment (HTA)**

which requires evidence generated through

Clinical and **Outcomes (observational) Research**

which requires

**Reliable and Valid Data Sources**

# Care pathway optimization is necessary because services are often disconnected and fail to truly address patient and provider needs

## Challenges along a patient's journey

### Awareness



**Early symptoms not recognized**

### Diagnosis



**Diagnostics not part of all check-ups or not reimbursed**



**Poor physician-patient communication**

**Fear & anxiety**

### Therapy

**Complex medication for co-morbid patients**



**Side effects and drug-drug interactions**



**Intentional & non-intentional non-adherence**



### Monitoring

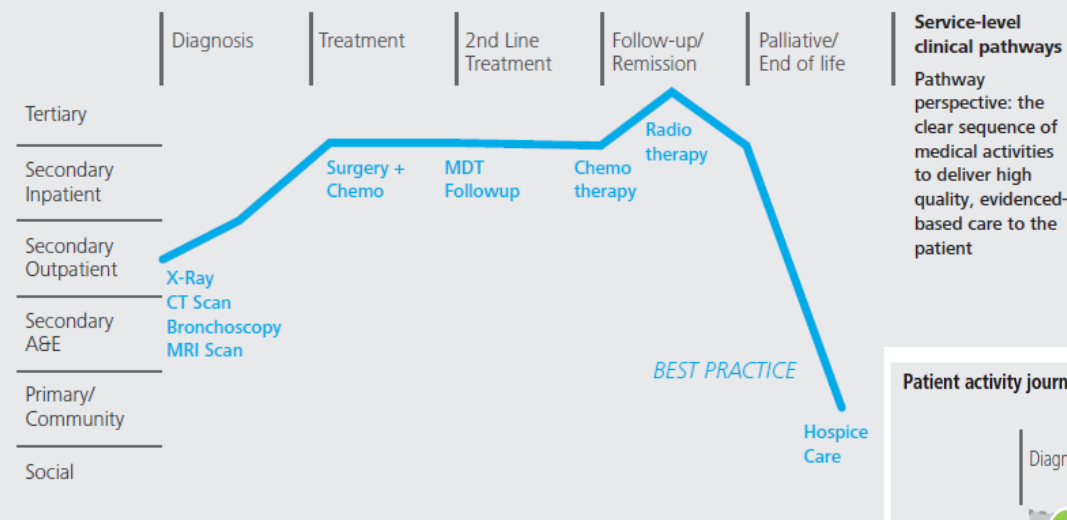
**Social withdrawal, avoidance, isolation**



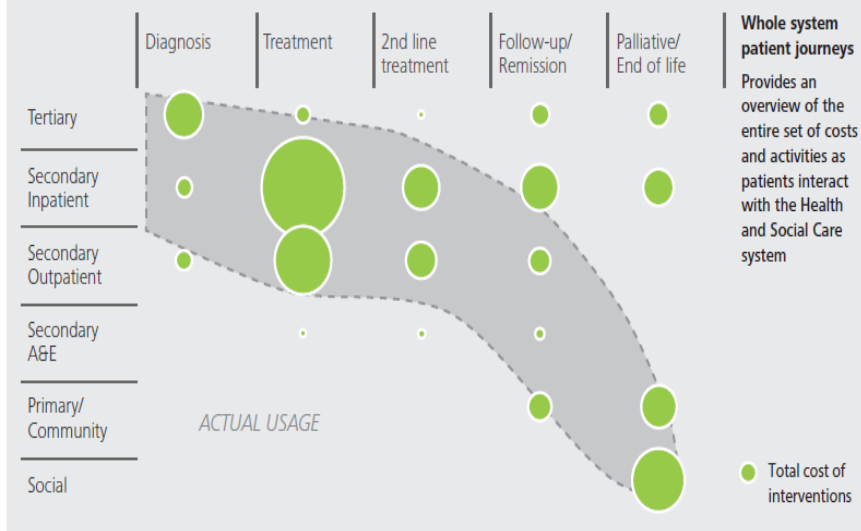
**Connectivity of patient records enables analytics, understanding and evaluation of inefficiencies in the system. Afterwards, co-creation of appropriate interventions to improve patient outcomes and system efficiency is feasible!**

# Identifying patient care pathways and spending patterns

## Clinical pathways



## Patient activity journeys



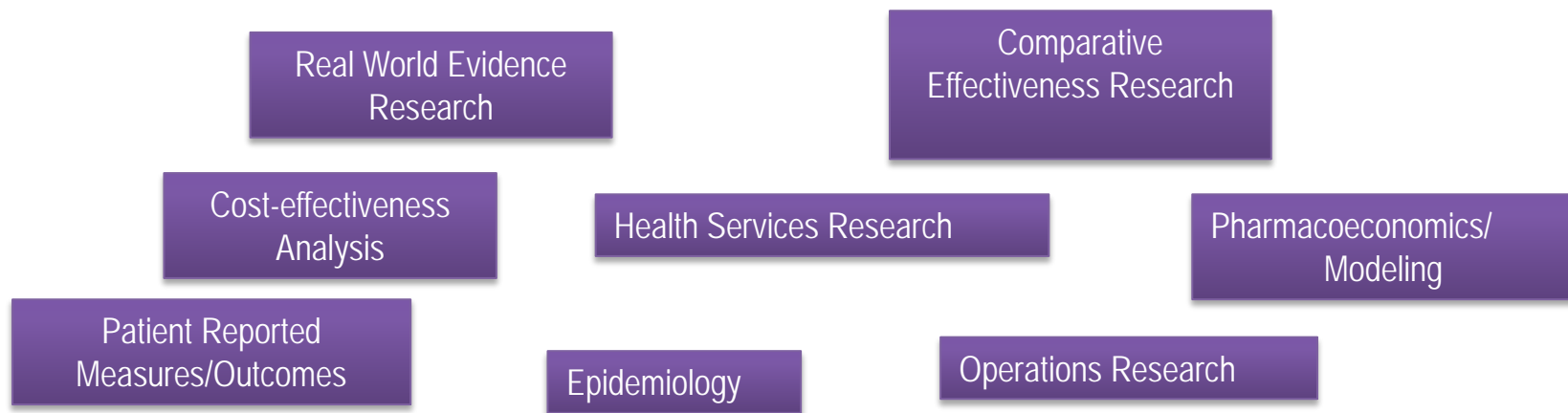
# What is Health Outcomes Research?

**A scientific discipline that evaluates the effect of health care interventions on patient health status, often involving economic, clinical or humanistic outcomes\***

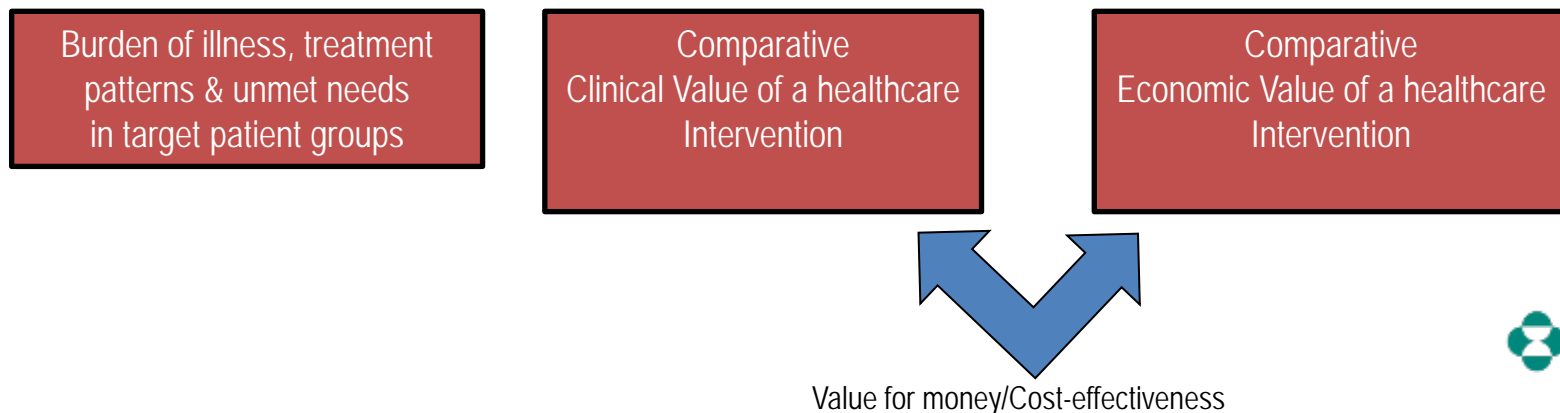
\* Definition from ISPOR Book of Terms



# Several (*and many more than listed here*) terms are used in connection with Health Outcomes



...but in general three key areas appear in published scientific literature and are required in healthcare decision making



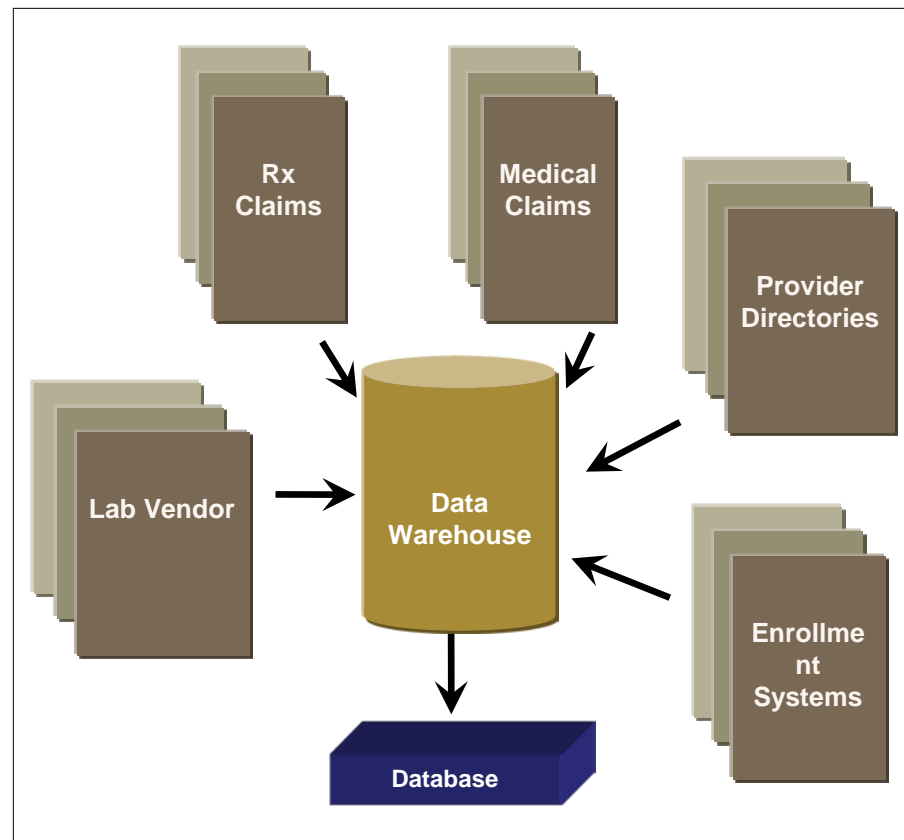
# Outcomes Research (OR) Methods are versatile and interdisciplinary

- Observational studies incl. comparative effectiveness research
  - Prospective (incidence)
  - Cross-sectional (prevalence)
  - Retrospective (case series, case-control)
- Economic Models
  - Budget impact (Rx and Dir. Medical costs)
  - Cost effectiveness
- Disease progression models
- Naturalistic trials
- Other Approaches
  - Literature reviews/synthesis & meta analyses
  - Indirect comparisons
  - Patient/Provider Preference Methods and surveys

# Key Data Sources for Outcomes Research (OR)

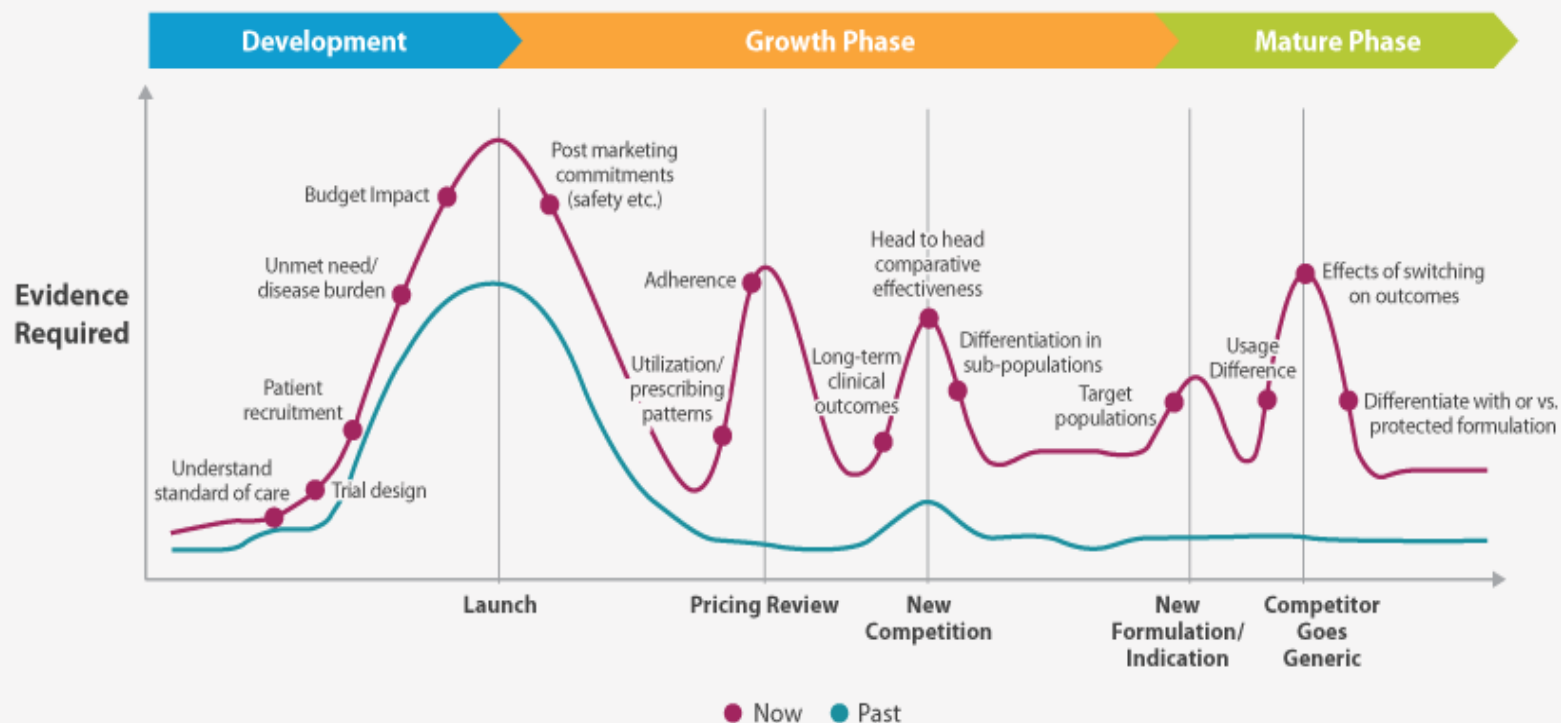
1. Randomized Clinical Trials (combined in meta-analysis or post-hoc analyses)
2. Primary Data Collection (e.g. chart reviews, surveys)
3. Secondary data sources
  - Disease and product registries
  - Administrative databases
    - De-identified health data collected as a by-product of patient care
    - Data are collected from insurance carriers, health plans, third-party administrators, pharmacy benefit managers, etc.
      - Claims data (INGENIX, Marketscan, CERNER, RAMQ)
      - Electronic Health Records (GE Healthcare, CPRD)

## Example of Data Resources Used to Create an Administrative Database



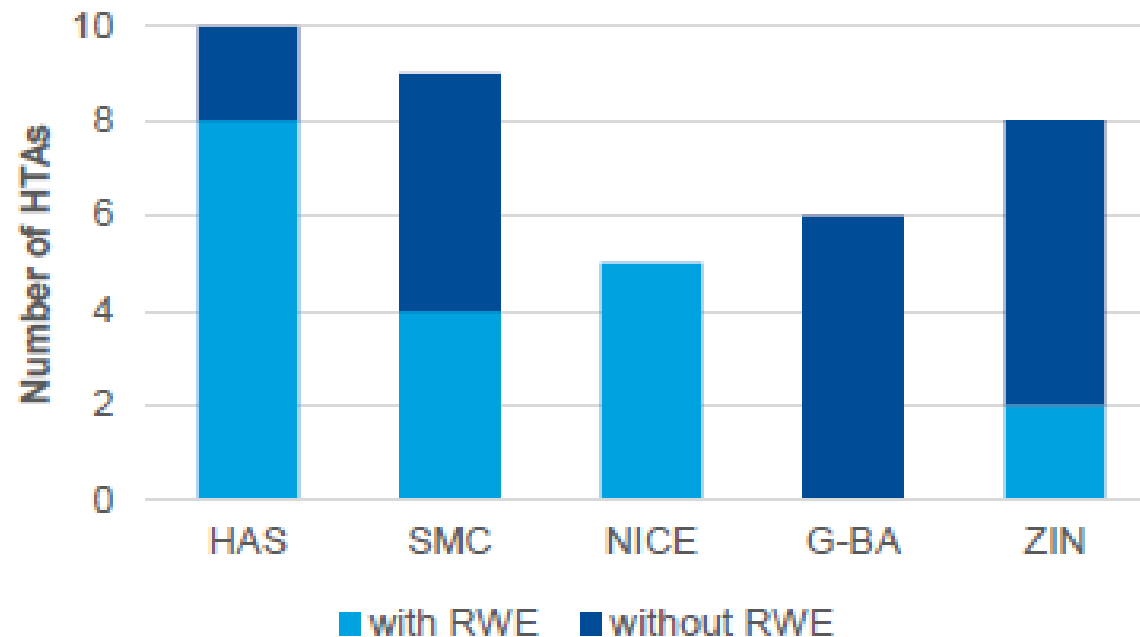
# Product lifecycle proves an unfailing source of RWE

## RWE Intensifying Across Product Lifecycle



Source: [IMS Health](#)

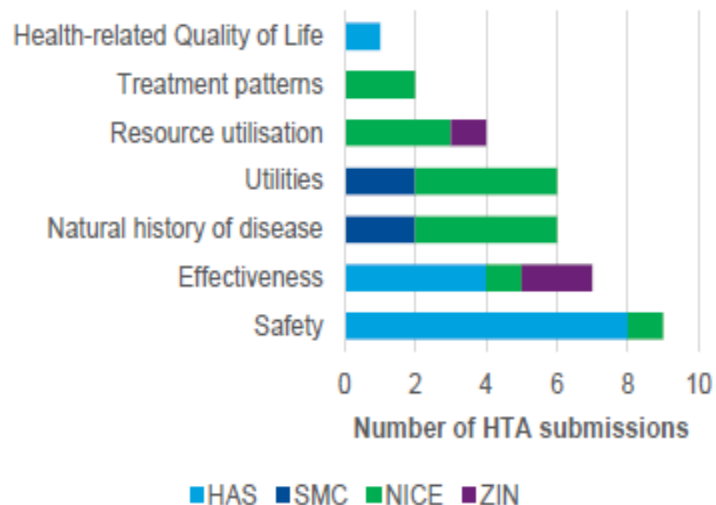
# Real World Evidence in Health Technology Assessment



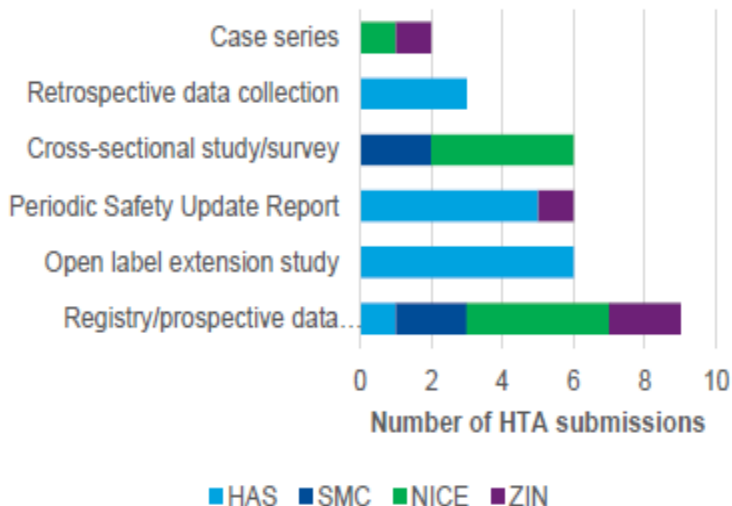
Number of HTAs between 2011 and 2014. in France, UK, Germany



# Real World Evidence data can adapt to individual country needs



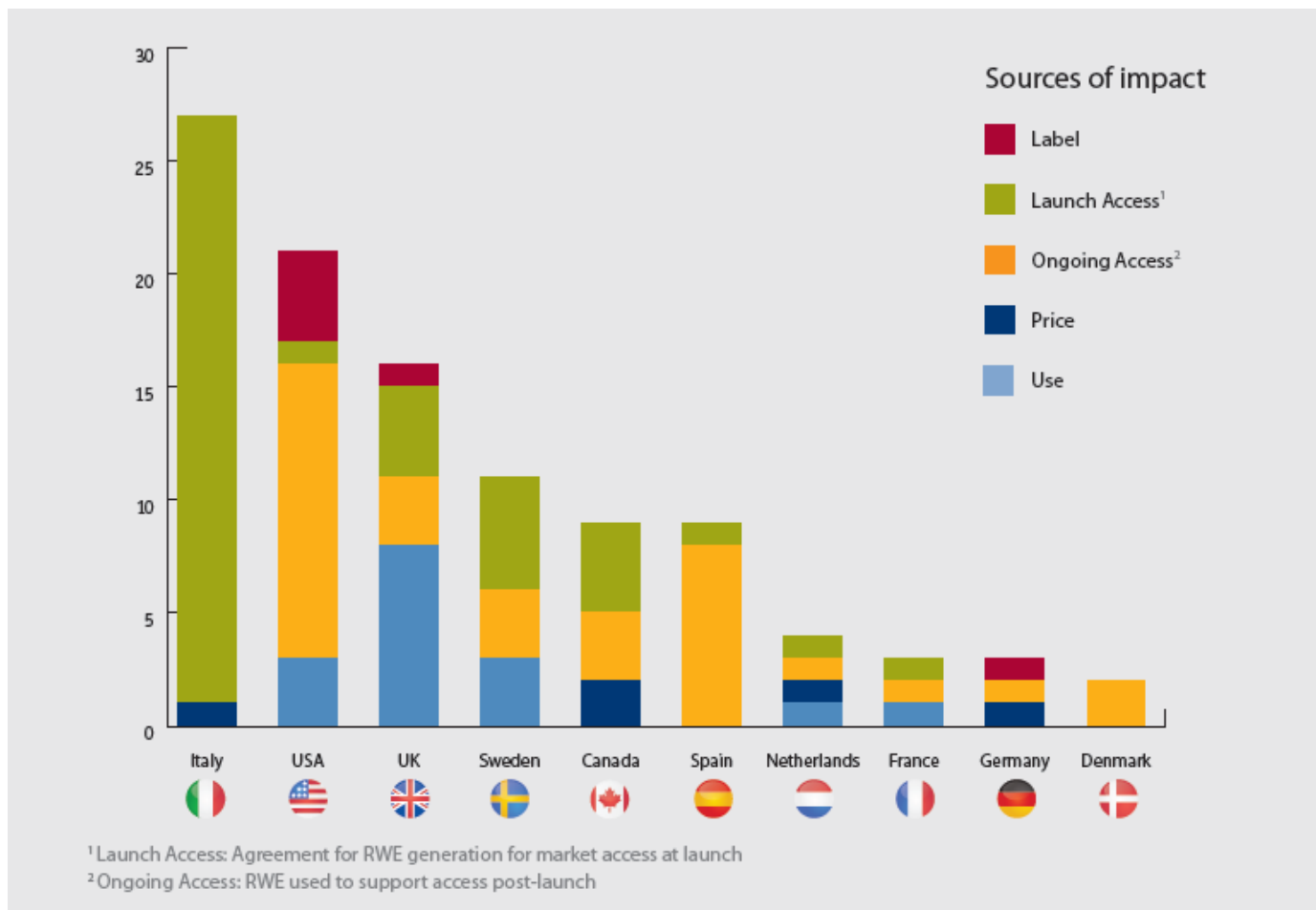
Type of RWE



Data collection methods

# Big data development as an enabler for integrating care

RWE is the gateway to market access



Source: RWE Market Impact on Medicines: A Lens for Pharma International comparisons of the impact of Real World Evidence on creating value from medicines IMS Health 2013

# Η σύμπραξη Ε.Ε. και ΕΦΡΙΑ (IMI) περιλαμβάνει και έρευνα στον τομέα των RWE

**innovative medicines initiative**



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## GETREAL

Incorporating real-life clinical data into drug development



### Summary

Incorporating data from 'real life' clinical settings into drug development and associated decision-making represents a serious challenge for pharmaceutical companies, regulators, and health authorities alike. By bringing together all key stakeholder groups (namely industry, academia, regulatory agencies, reimbursement agencies, healthcare budget holders, and patient groups) to share their insights and know-how, GETREAL will develop new approaches for incorporating real life data into drug development, and pave the way for a greater consensus on this issue.

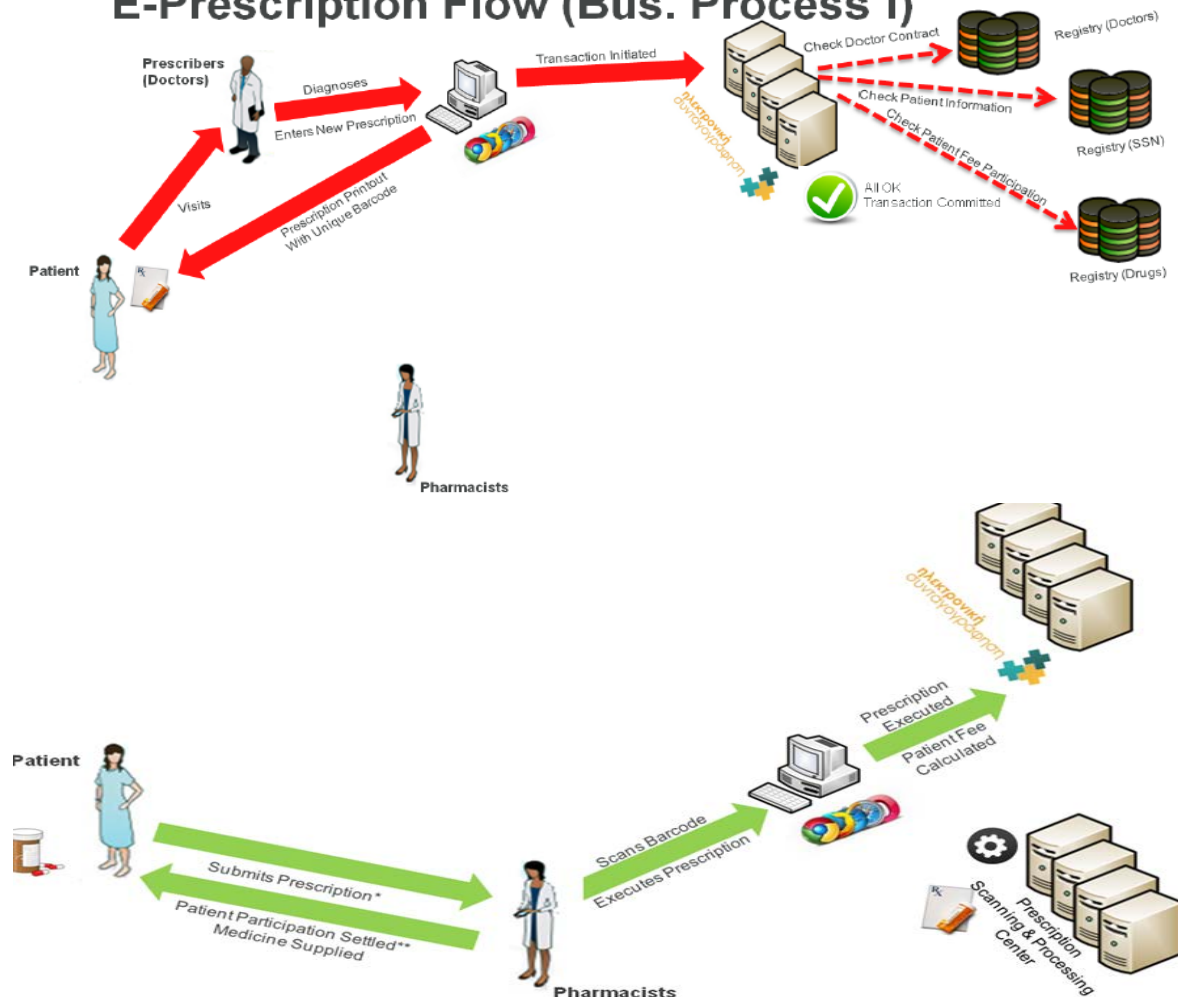
[more](#) 

### Facts & Figures

<b>Start Date</b>	01/10/2013
<b>End Date</b>	31/12/2016
<b>Contributions</b>	<b>€</b>
IMI funding	8 000 000
EFPIA in kind	6 910 397
Other	2 041 883
<b>Total cost</b>	<b>16 952 280</b>

# In Greece we are unique in having developed the e-prescription system

## E-Prescription Flow (Bus. Process I)



With the addition of appropriate clinical data the GR e-prescription system can become one of the best live observational studies lab for all categories of medicines giving health in Greece an enormous investment opportunity

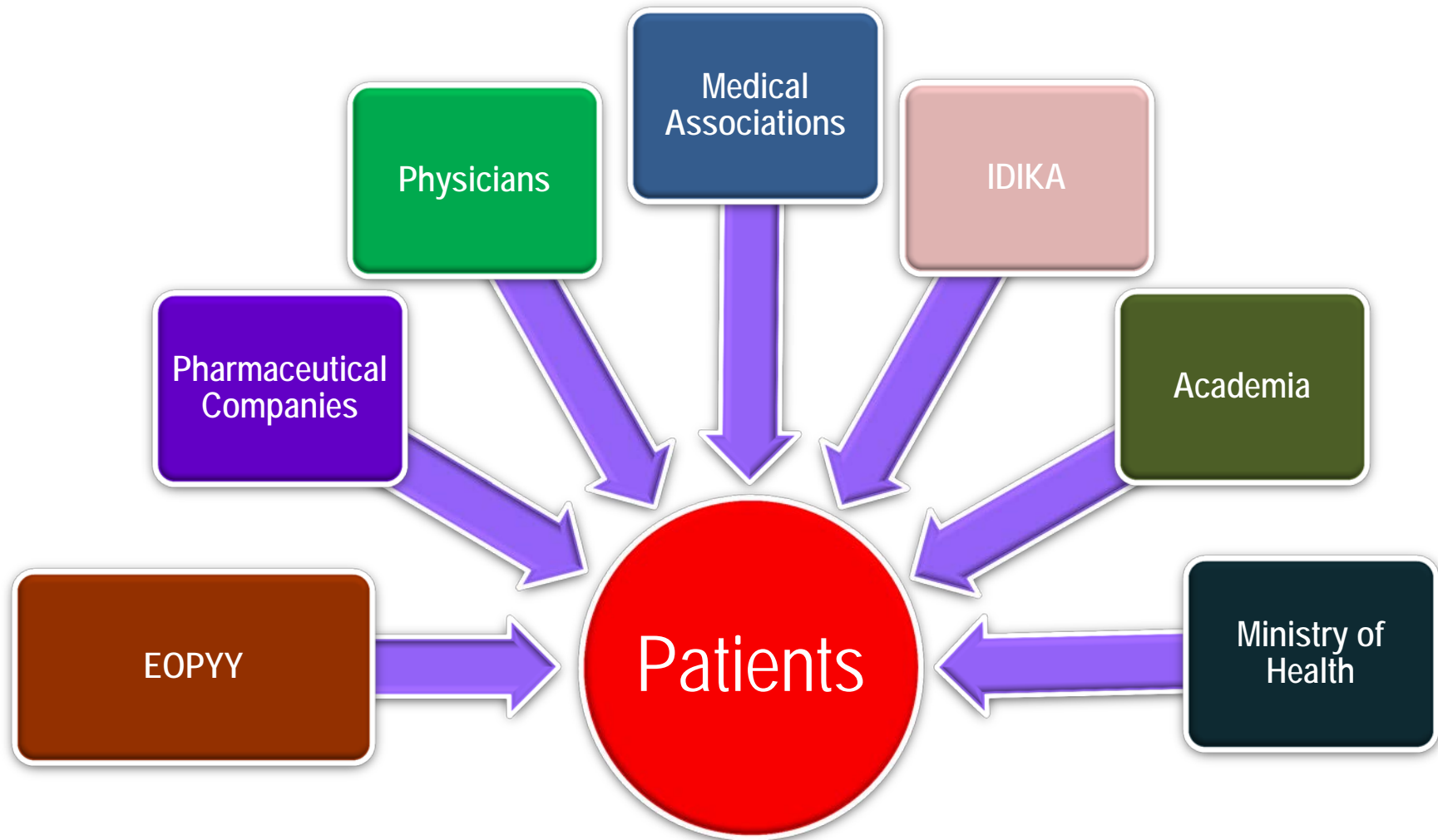
The e-prescription database uniquely combines almost all providers, patients and services in the same platform



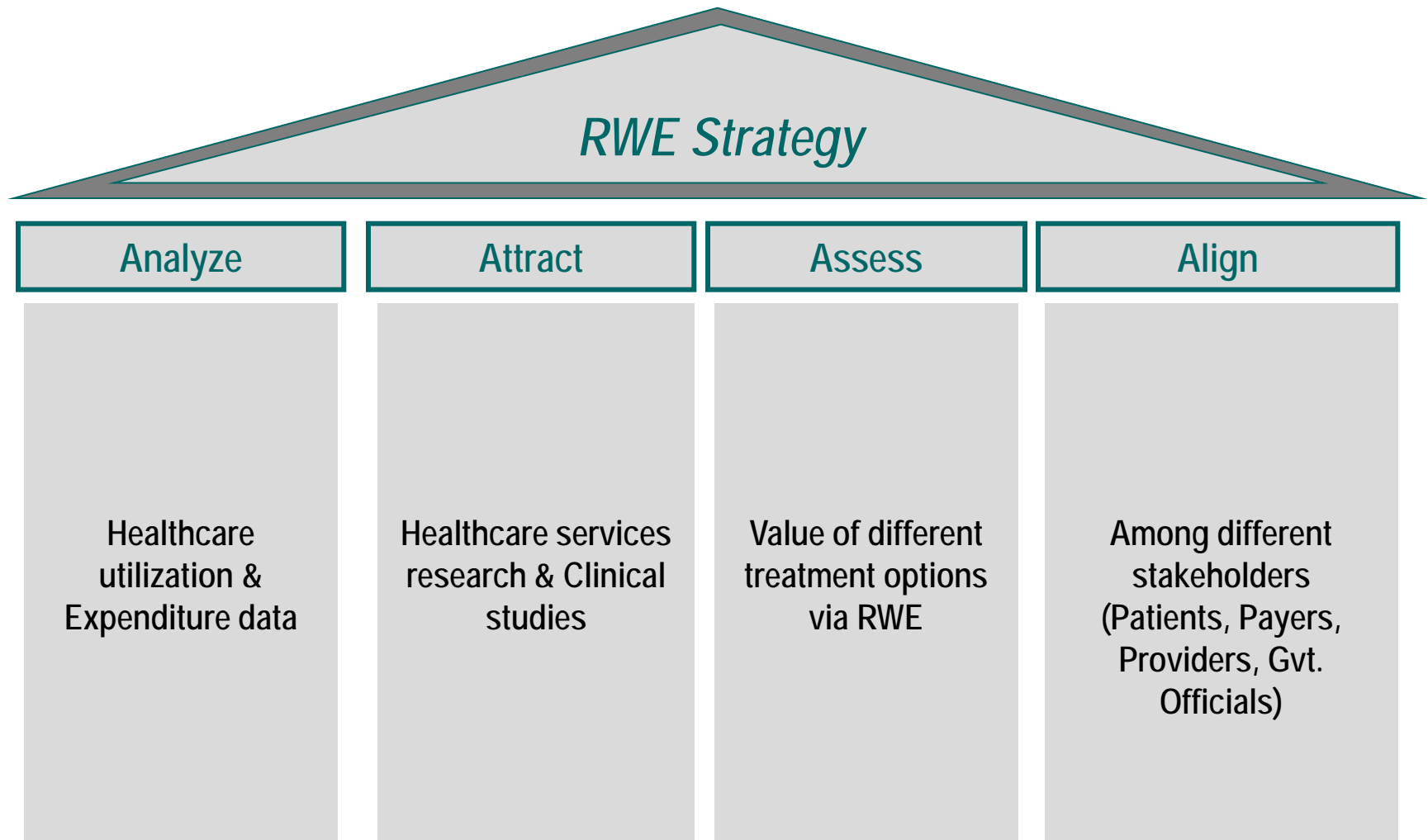
A live database of 11 million users



# Clever Partnerships can improve governance and data quality



# Greece as a World Class Excellence Centre for Real World Evidence



# A Vision and a Roadmap based on collaboration

- 
- Building Capabilities
  - Academia, Public Sector, Private entities

- 
- Establishing collaborating frameworks
  - Institutional Developments

- 
- Focus on value and health care priorities
  - Innovation and quality drive

# Key prerequisites for successful registry development & research are in place in Sweden

- Strategic, financial and legal support by the government

**Facts:** A decline in clinical research, ageing population, increase in rate of HC expenditure

**Actions taken in 2009:**

- 1) A national strategy to build a world-leading platform in value based health care within 10 years was established
- 2) Annual governmental financial support to quality registries

- High quality data & oversight (annual monitoring)
- Framework for collaborative registry research

*"Health care needs transformational changes in order to improve productivity and secure that the broader population can get access to high quality care and innovation."*

# The Swedish system

## National longitudinal health registries

- Catch patients and their use of health care

Personal identification number, pID

*Swedish example*

81 12 18 - 98 7 6

YY MM DD      Region      Sex      Control number

&



### National health registries (ex)

Prescription databases

Medical birth registries

Cancer registries

Cause of death registries

Hospital discharge registries

### Other data sources

Background information, education, income, occupation etc.

Biobanks

Patient records

Health surveys

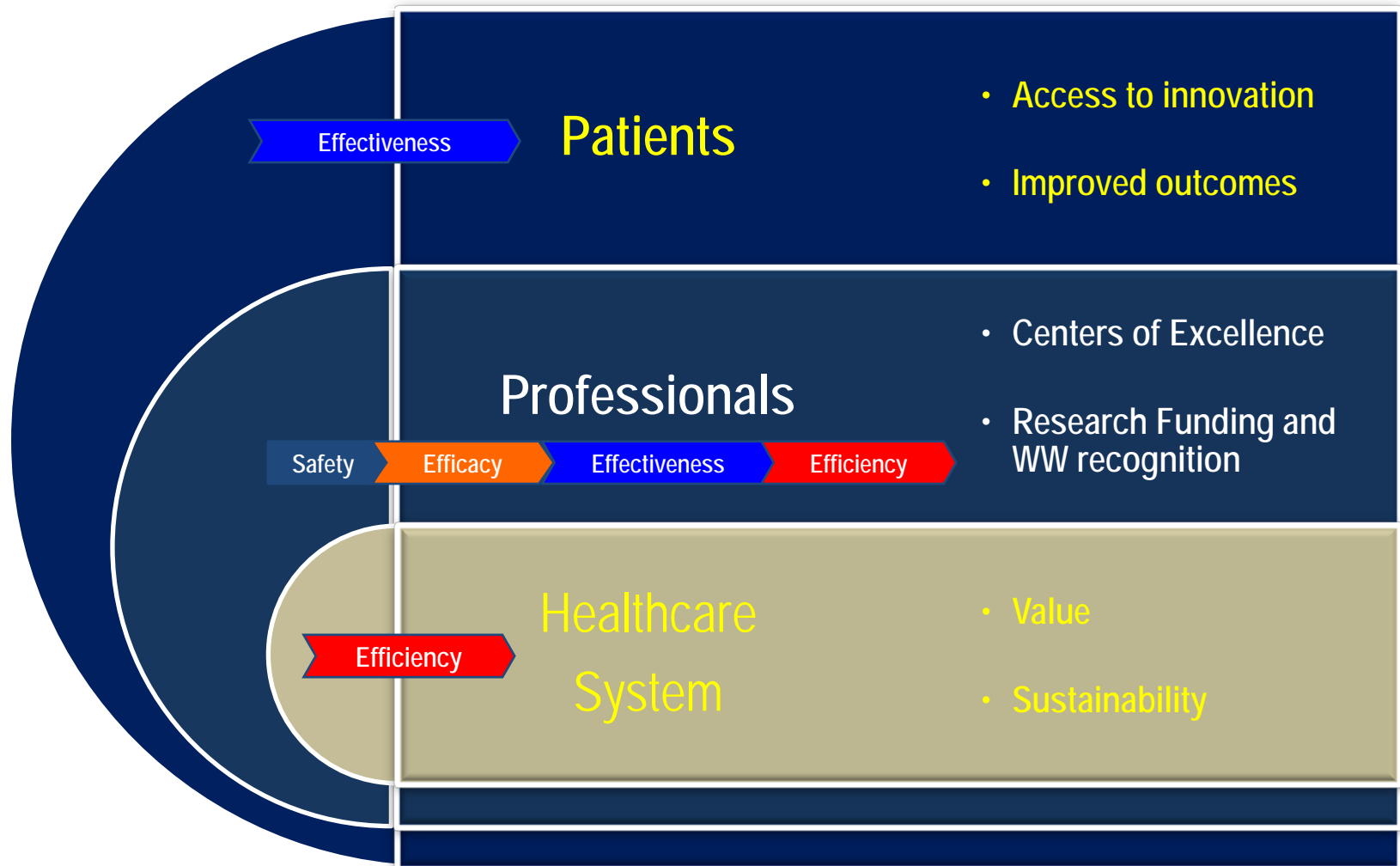
Quality registries

## Disease-specific quality registries

- Their purpose is to improve patient care
- In Sweden approx 100 nation-wide health care disease specific quality registries



# There are benefits of developing infrastructure for observational/health outcomes research for all



- Thank you