



ΠΑΝΕΛΛΗΝΙΑ  
ΕΝΩΣΗ  
ΦΑΡΜΑΚΟΒΙΟΜΗΧΑΝΙΑΣ

# Real World Data: Generating them in partnership with patients

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# Real World Data (RWD) and Real World Evidence (RWE)

**Real World Data** are **observational data** related to patient health status and/or the delivery of healthcare rather than data gathered in an experimental setting.

- **Derived from** electronic health records, claims and billing activities, product and disease registries, etc.
- **Quality assessments are challenging** due to **these data being complex and heterogeneous**.

*The goal of working with RWD is to generate RWE.*

- **Real World Evidence** is **clinical evidence derived from analysis of RWD** regarding the usage and potential benefits or risks of a medical product.



# Real World Data (RWD) and Real World Evidence (RWE)

- RWD can be a **powerful tool for life science** researchers.
- RWD can **help researchers gain insights into how therapies are performing in the real-world.**
- Incorporating RWD into clinical research can help provide **evidence for drug/treatment repurposing.**

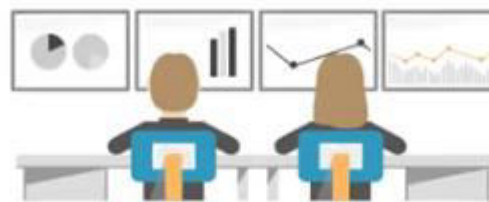


# Real World Data sources



**RWD**

- Electronic Medical Records
- Patient Registries
- Large Surveys
- Insurance Claims
- Social Media
- Online Forums
- Wearables/sensors



Analyzed according to  
research plan



**Real-World Evidence**

# Why should we focus on Real World Data

- Because now we are fit to do so.
- There are now a large quantities of health data generated and stored:
- *computers, smart phones, wearable devices, biosensors*
- These data have the potential to benefit research.
- The Real World Evidence coming out from the analysis of Real World Data can complement traditional Randomized Controlled Trials.

## Clinical trial



Inclusion and exclusion criteria  
make the groups very  
homogeneous

## RWD



Real World Data captures  
everyone

- Real World Data captures everyone
- Can address questions that require large numbers of patients.
- Can satisfy longer follow-up periods.
- Can replace research that cannot be done due to ethical or feasibility reasons.
- Evidence reflecting real-life treatment and/or disease management

# RWD/RWE Case Examples

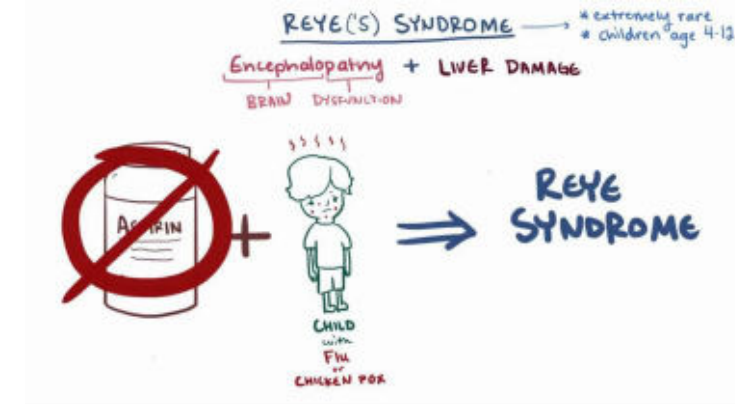
## International stop-smoking efforts

- Death certificate & hospital data
- Rate of lung cancer deaths among heavy smokers (men) was 20 times higher than for non-smokers



## Identification of aspirin as the cause of Reye's Syndrome

- Registry data
- Over 90% of children afflicted with Reye's syndrome had recently used aspirin

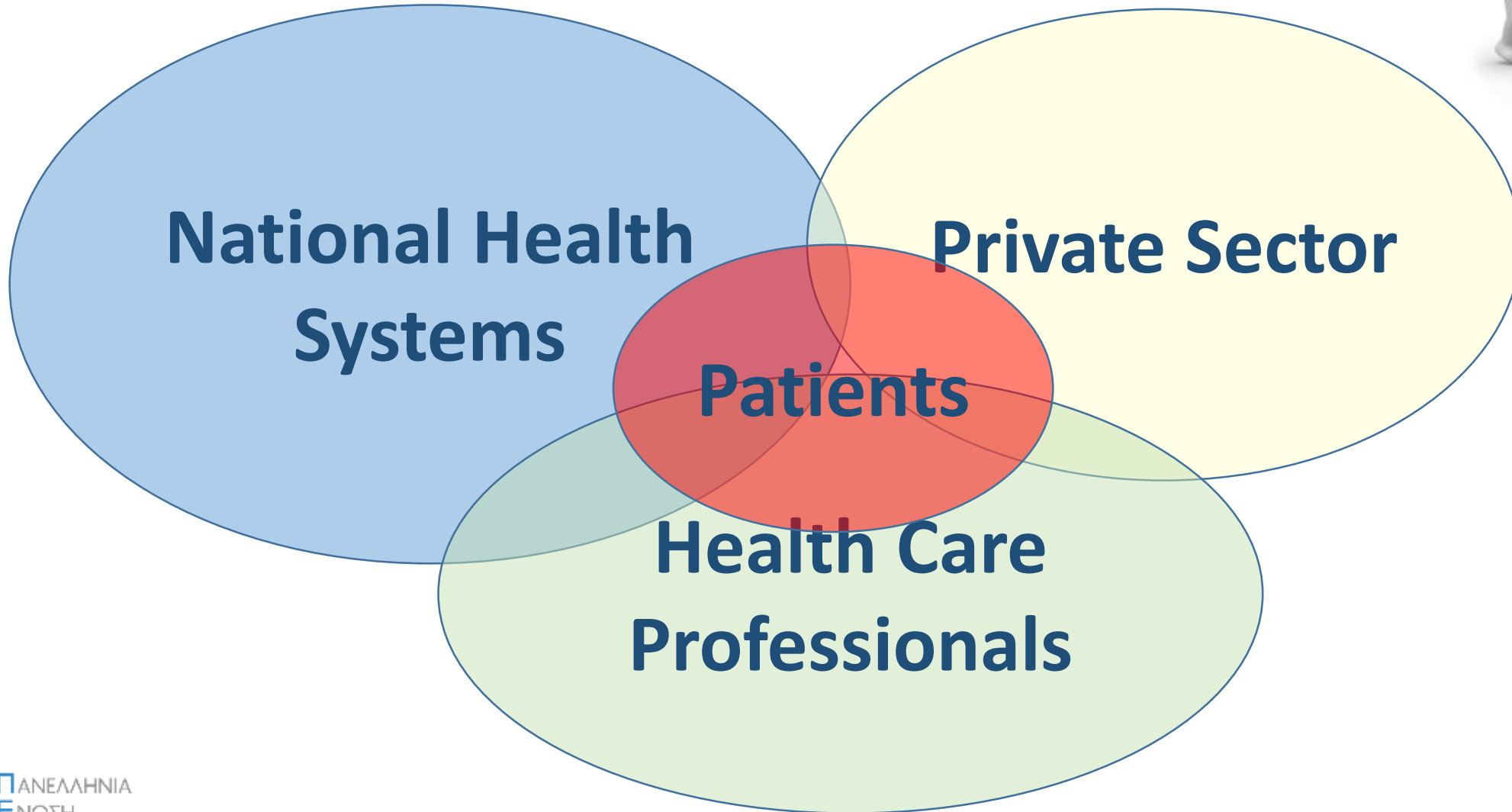


## Establishing the use of beta-blockers in heart attack patients

- Electronic medical records
- Beta blockers use linked to 40% reduction in death after a heart attack



# Key players



# Key players



## National Health Systems

- **Legislate** on RWD **secure collection** and **use**
- **Provide incentives** for **health care professionals** to actively participate in RWD collection
- **Educate** the public (hence patients) on the **benefits** from RWD/RWE accumulation
- **Educate** the public (hence patients) on their **rights** but also their **moral obligation** as patients
- **Fund** the efforts towards RWD/RWE accumulation



# Key players



## Private Sector

- Aim towards the **production of reliable tools** for RWD
  - 1) Collection
  - 2) De-identification and Security
  - 3) Combination for the production of useful RWE

# Key players



- **Understand** the **benefits** from RWD/RWE accumulation
- Use their **expertise** in efficient and beneficial RWD **collection**
- Use their **expertise** in efficient and beneficial RWD use **to produce RWE**
- **Actively participate** in RWD/RWE **legislation formation** on security and usage

**Health Care  
Professionals**

# Key players



## Patients

- **Understand** the **benefits** from RWD/RWE accumulation
- **Understand** their **rights** but also their **moral obligation** as patients
- **Actively participate** in RWD/RWE **legislation formation** on security and usage
- **Actively participate** in RWD/RWE **collection**

# The Challenges



- 1) Real world data **exists in multi-structured formats** and is **stored within disparate, internal and third-party data silos.**
- 2) **Data governance and security** issues.

# Goals



## Standardized data collection

- Patient registries must be uniform and comprehensive
- Registry data should be available to combine
- Registry data must be subject to strict quality requirements

## Data security

- Patient privacy
- Data safety
- Data security
- Cybersecurity

## Patient Consent

- Patients must be well informed
- Patients must understand the benefits of RWD
- Patients must be willing to aid gathering of RWD

# Conclusion



- Ensuring **patient safety** is a **international priority**.
- **Everyone** involved in the healthcare system **has a role**.
- **This includes the patient!**
- **RWD/RWE** are **key tools** in the hands of **modern medical practice**.
- **Patients** involved in RWD collection **can help make their healthcare experience safer and fruitful**.

