PVClinical

PROJECT OVERVIEW

Dr. Vassilis Koutkias
PVClinical Project & Scientific Coordinator
Principal Researcher | Researcher Grade B'
Institute of Applied Biosciences (INAB)
Centre for Research & Technology Hellas (CERTH)

Presentation Outline

Introduction – Background

Project Identity & Scope

Project Approach

Project Structure

Expected Outcomes

Contact Details | Further Information

PVClinical

Project Identity (1/2)

- Project Title: **PVClinical – Ενεργή Φαρμακοεπαγρύπνηση σε Κλινικά Περιβάλλοντα**
- Funding Body: **EPAnEK 2014-2020 Operational Programme co-financed by Greece and the European Union**
- Reference Code: **T1EDK-0789**
- **Consortium**:
  Project & Scientific Coordinator: Institute of Applied Biosciences (INEB), Centre for Research and Technology Hellas (CERTH)
  Partners: PHARMASSIST Ltd, Papageorgiou General Hospital, European Interbalkan Medical Center

Project Identity (2/2)

- Call: **II. Synergies between Companies and Research Centers**
- Axis: **Health and Medicines**
- Topic: **5.5 Electronic Health: Services and Systems for Patients/Citizens and Healthcare Professionals**
- Priority: **5.5.4 Decision Support Systems for Detection, Prevention and/or Surveillance of Adverse Drug Events in the Clinical Environment**
- Duration: **36 months**
- Total funding: **917.200,00€**

European Union
European Regional Development Fund

HELLENIC REPUBLIC
MINISTRY OF ECONOMY & DEVELOPMENT
SPECIAL SECRETARY FOR ERDF & CF

EPAnEK 2014-2020
OPERATIONAL PROGRAMME
COMPETITIVENESS ENTREPRENEURSHIP INNOVATION

ΕΣΠΑ 2014-2020
ανάπτυξη - εργασία - αλληλεγγύη
Partnership Agreement 2014 - 2020

Pharmacovigilance

- *"... the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems"* [1]
- *It is being carried out by:*
  - Regulatory authorities (e.g. EOF in Greece, FDA in the US, EMA in Europe)
  - Drug Monitoring Organizations (e.g. Uppsala Monitoring Centre – WHO Collaborating Centre for Drug Monitoring / WHO-UMC)
  - Pharmaceutical companies
  - Contract Research Organizations (CROs)

[1] World Health Organization, W. C. C. for I. D. M. (2002). *The importance of pharmacovigilance.* World Health Organization Available at: http://apps.who.int/medicinedocs/en/d/Js4893e/

Adverse Drug Effects: *Problem Dimensions*

Contents lists available at ScienceDirect

Review Article

ELSE

Clini

Adver

and c

René A

Janet Sul

Journal of Pha

The Costs of Adverse Drug Events in Hospitalized Patients

Adverse Drug Events in Hospitalized Patients

David W. Ba

Author A

Excess Length of Stay, Extra Costs, and At-

JAMA. 1997

tributable M

David C. Classen, MD, MS; S

Author Affiliations

JAMA. 1997;277(4):301-30(

Taylor & Francis

Expert Opinion on Drug Safety

ISSN: 1474-0338 (Print) 1744-764X (Online) Journal homepage: http://www.tandfonline.com/loi/ieds20

The economic burden of preventable adverse drug reactions: a systematic review of observational studies

D Formica, J Sultana, PM Cutroneo, S Lucchesi, R Angelica, S Crisafulli, Y Ingrasciotta, F Salvo, E Spina & G Trifirò

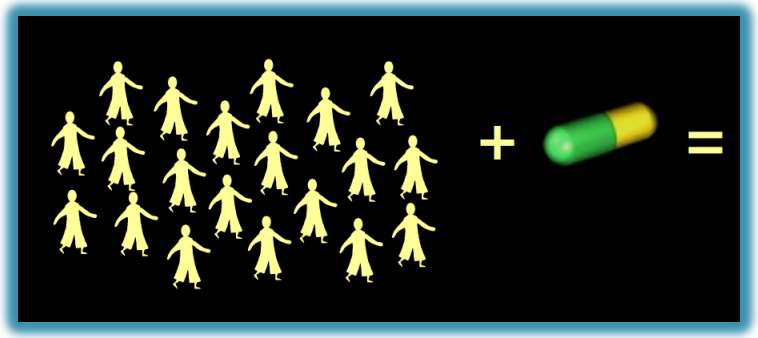
The Estimated “Impact” of Adverse Drug Effects

- In the US:
  - 4^{th}-6^{th} most frequent cause of deaths, with more 100,000 deaths annually in hospitals
  - Cause for 7% hospital admissions
  - Financial burden of 137-177 billion$ annually
- In Europe:
  - Cost of preventable adverse drug effects account between 2,851-9,015 € in hospitalized patients
  - Prolonged hospital stay of 6,1 ± 2.3 days

→ A serious Public Health problem!

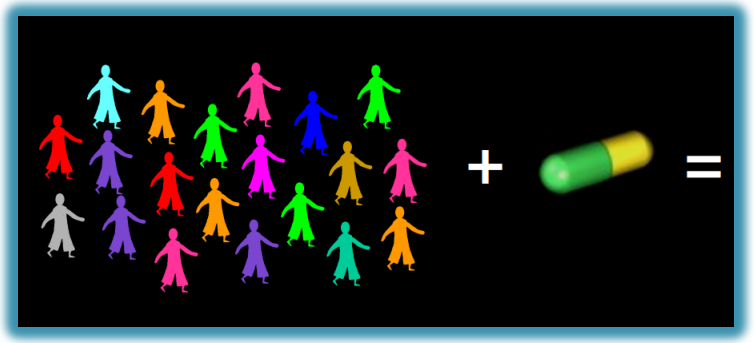
Prevention of Adverse Drugs Reactions:
Do we Have the Required Knowledge?

CLINICAL STUDIES FOR DRUG DEVELOPMENT



Drug tested in a specific population in normal dosages

POST-MARKETING DRUG EXPOSURE



Exposure to the drug by an extremely larger and heterogenous population under different conditions

Prevention of Adverse Drugs Reactions:
Do we Have the Required Knowledge?

PVClinical

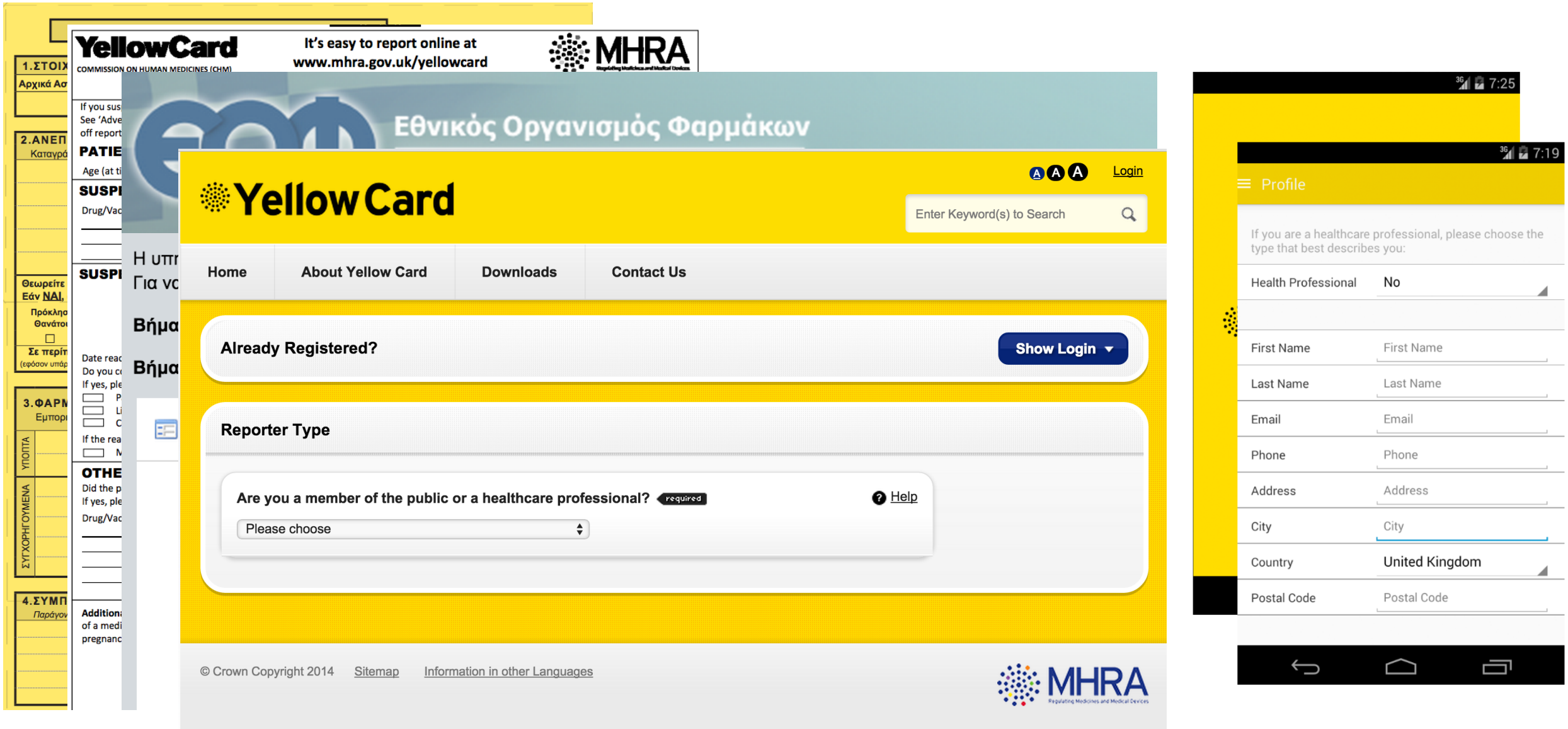
Need for: Real-World Evidence!!!

Spontaneous Reporting Systems: The Main Data Source for Adverse Drug Reactions

Reports of potential Adverse Drug Reactions from healthcare professionals/citizens sent to:

- National authorities (e.g. E.O.F. in Greece, Food and Drug Administration in the US)
- International drug monitoring organizations (e.g. European Medicines Agency, Uppsala Monitoring Centre – WHO Collaborating Centre for Drug Monitoring)
- Pharma companies / Contract Research Organizations

Spontaneous Reporting Systems: *The Main Data Source for Adverse Drug Reactions*



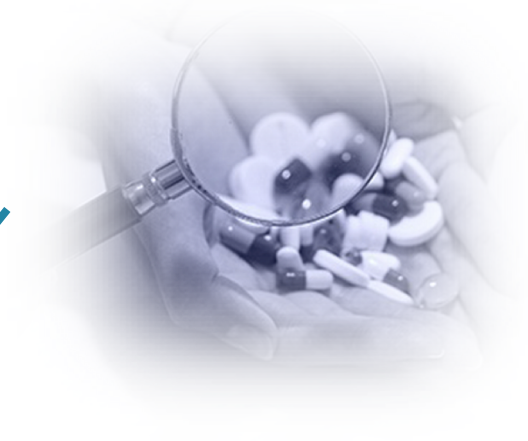
Limitations of Spontaneous Reporting Systems

- They gather a very low number of reports, given the magnitude of the problem (many studies account this below 5%)
- Missing data
- Allegations of biased reports
- ...

→ Spontaneous Reporting Systems are not enough for effective Pharmacovigilance!

The Need for a Paradigm Shift: *From Passive to Active Pharmacovigilance*

PHARMACOVIGILANCE



Passive

No other measures are taken to search for potential Adverse Drug Reactions besides encouraging reporting

Active

search other electronic databases for any information that can be useful

Continuous Learning Health System

Exploitation of Further (including Emerging) Data Sources

- Secondary data use acquired during the clinical practice (e.g. in the Electronic Medical Record of hospitals/clinics)
- Other data sources:
  - Scientific bibliography
  - Mobile health (mHealth) apps
  - Social media platforms
- Major Pros/Cons:
  - ⬆️ Availability of big data
  - ⬇️ Data heterogeneity

The PVClincal Scope

- **Active pharmacovigilance** in the clinical environment via appropriate support IT tools for:
  - Concurrent exploitation of multiple data sources, i.e. Spontaneous Reporting Systems, Bibliography, Social Media, Electronic Medical Records
  - Emphasis on the investigation of new, potential Adverse Drug Reactions
- **Enabling Technologies**:
  - Knowledge Engineering
  - Linked Data
  - Standard terminologies/thesauri
  - Big data management and analytics
- **Extensions**:
  - Beyond clinical environments (e.g. Drug Monitoring Organizations, Pharmaceutical Companies, Contract Research Organizations, …)

The PVClinical Approach (1/2)

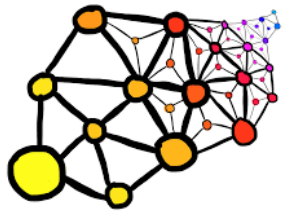
Primary Data

twitter

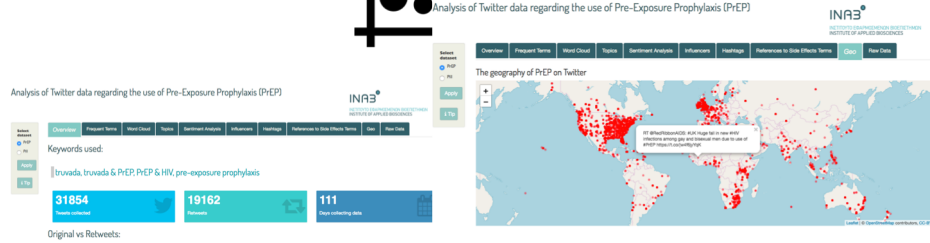
PubMed

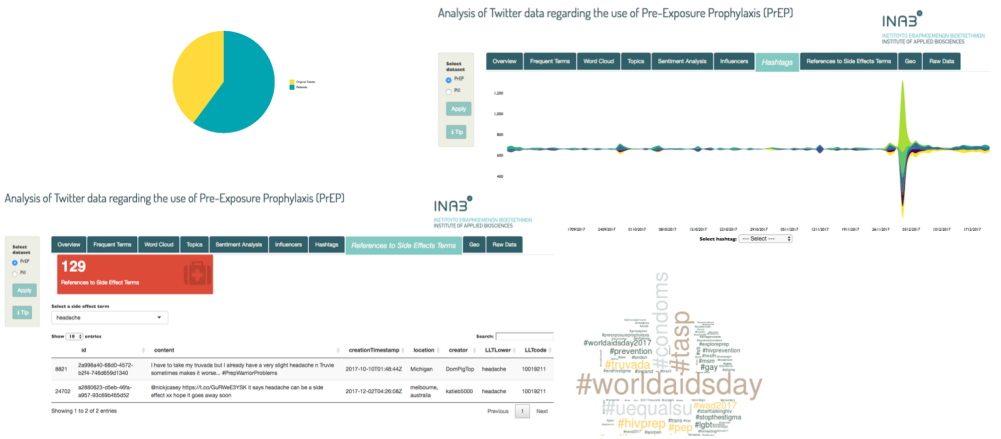
OHDSI
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

Integrated Semantically-enriched Data Model

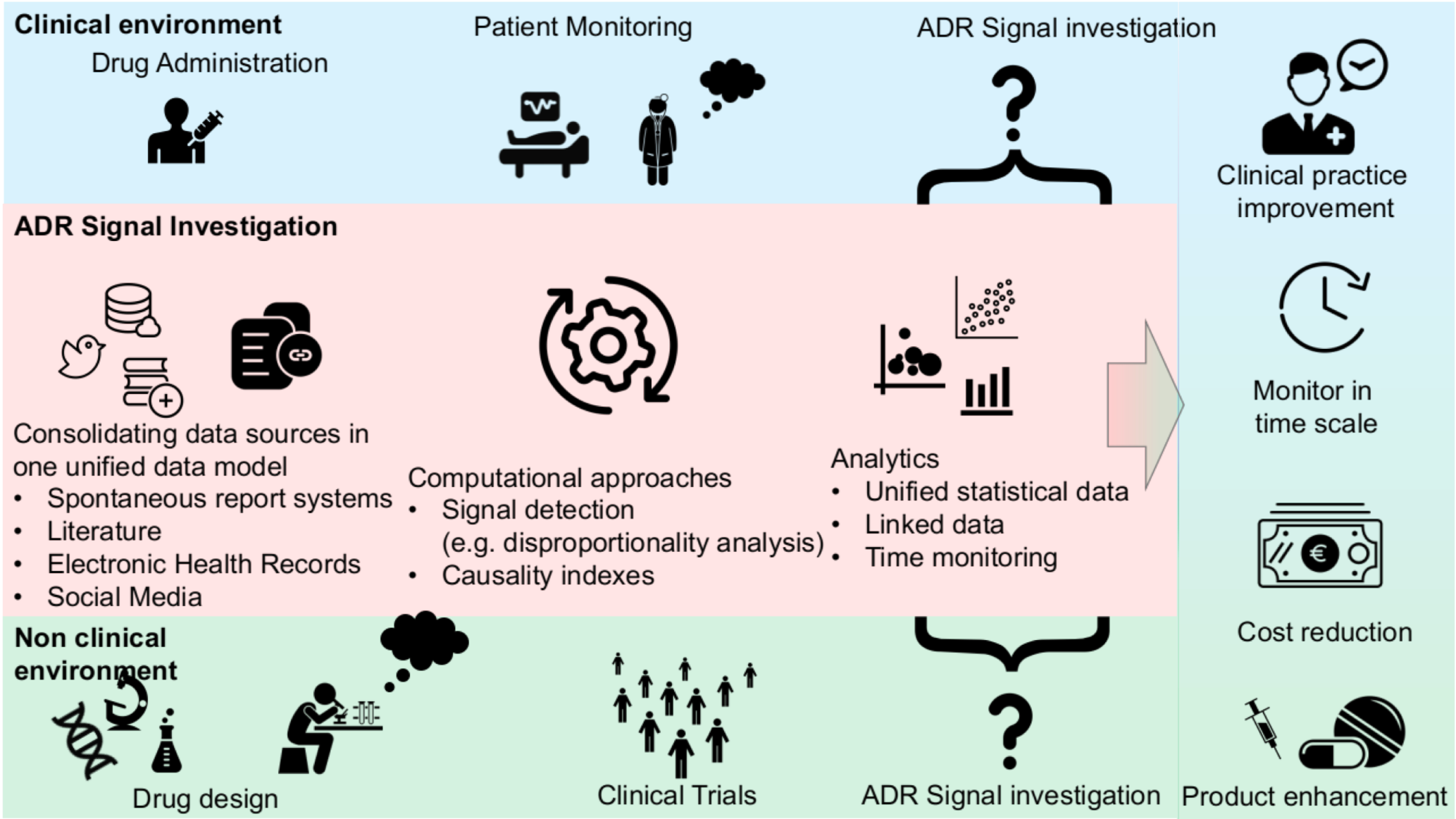


Data Analytics





The PVClinical Approach (2/2)



Project Structure: Work Packages

Work Package (WP)	Leader	Duration
WP1: User Requirements Analysis, Specifications and System Architecture	PHARMA	M1-M12
WP2: Design and Development of Data Collection Infrastructure	CERTH	M2-M24
WP3: Design and Development of Data Analysis Methods	CERTH	M3-M18
WP4: Implementation of the Web Platform	CERTH	M11-M30
WP5: Evaluation and Pilot Applications	PHARMA	M13-M36
WP6: Feasibility Study on Commercial Applicability	CERTH	M15-M33
WP7: SME Participation in Exhibitions	PHARMA	M15-M36

Expected PVClinical Contribution to Clinical Environments

The primary aim is the introduction of the proposed platform in the clinical environment, offering the potential to **systematize and automate/guide the investigation of potential Adverse Drug Reaction signals**.

This will enable hospitals to implement active pharmacovigilance with **major benefits for public health** (patient safety, quality of care) and a **cost reduction as regards the management of Adverse Drug Reactions**.

Primary users of the PVClinical platform are **clinicians** (*pharmacists, clinical pharmacologists and pharmacovigilance experts*)

Extending the PVClinical Scope Beyond Clinical Environments

Monitoring Organizations / Drug Regulatory Authorities: May use the PVClinical platform to detect and **assess potential Adverse Drug Reaction signals**, saving cost and time for the entailed analysis.

Pharmaceutical Companies / Contract Research Organizations: May use the PVClinical platform for **post-marketing surveillance of the products of interest**, or for **drug repositioning studies**, aiming to save cost and time for the entailed analysis.

During Clinical trials: The detection of Adverse Drug Reactions is an important part of clinical trials. The PVClinical platform may **reinforce the capabilities of reporting and documenting potential Adverse Drug Reactions**, enhancing the quality of the procedure and potentially contributing to **cost reduction in clinical trial conduction.**

PVClinical

Contact & Further Information

Dr. Vassilis Koutkias, PVClinical Coordinator

vkoutkias@certh.gr, tel.: +30 2311 257615

https://pvclinical-project.eu/

Acknowledgment: This research has been co-financed by the European Union and Greek national funds through the Operational Program Competitiveness, Entrepreneurship and Innovation, under the call RESEARCH – CREATE – INNOVATE (project code: T 1 ΕΔΚ-03789)