PROTECT

imi efpia

Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium

The PROTECT project

Introduction

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Partners

Public

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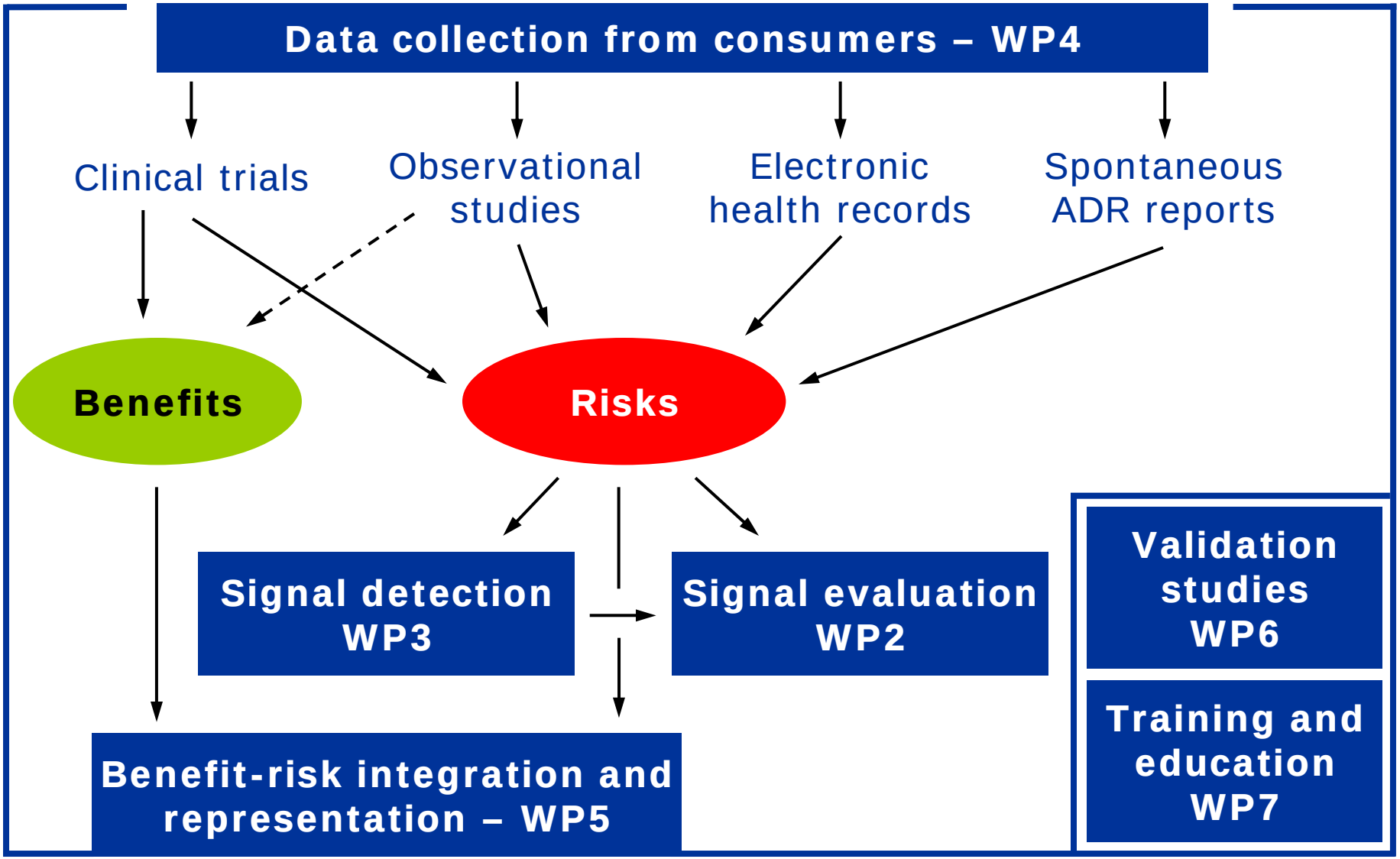
PROTECT Goal

To strengthen the monitoring of benefit-risk of medicines in Europe by developing innovative methods

to enhance early detection and assessment of adverse drug reactions from different data sources (clinical trials, spontaneous reporting and observational studies)

to enable the integration and presentation of data on benefits and risks

These methods will be tested in case studies.


Data collection from consumers – WP4
Clinical trials
Observational studies
Electronic health records
Spontaneous ADR reports
Benefits
Risks
Signal detection WP3
Signal evaluation WP2
Validation studies WP6
Training and education WP7
Benefit-risk integration and representation – WP5

WP 2: Framework for pharmacoepidemiological studies

Objectives:

To:

- develop
- test
- disseminate

methodological standards for the:

- design
- conduct
- analysis

of pharmacoepidemiological studies applicable to:

- different safety issues
- using different data sources

Work Package 2 – WG1 Databases

- Conduct of 5 adverse event - drug pair studies in different EU databases
  - Selection of 5 key adverse event - drug pairs
  - Development of study protocols for all 5 pairs
  - Compare results of studies
  - Identify sources of discrepancies

Antidepressants (incl. Benzodiazepines) **- Hip Fracture**
Antibiotics - **Acute liver injury**
Beta2 Agonists **- Myocardial infarction**
Antiepileptics - **Suicide**
Calcium Channel Blockers - **Cancer**

Work Package 3: Signal Detection

Objective:

To improve early and proactive signal detection from spontaneous reports, electronic health records, and clinical trials.

PROTECT

Work Package 3: Signal Detection

Scope

- Develop new methods for signal detection in Individual Case Safety Reports.
- Develop methods and guidelines for signal detection and strengthening in Electronic Health Records.
- Evaluate signal detection based on Suspected Unexpected Serious Adverse Reactions from clinical trials.
- Recommendations for good signal detection practices.

Work Package 3: Sub-projects

1. Merits of disproportionality analysis
2. Structured database of known ADRs
3. Risk estimates from trials
4. Signal detection recommendations
5. Better use of existing ADR terminologies
6. Novel tools for grouping ADRs
7. Other information to enhance signal detection
8. Signal detection based on SUSARs
9. Subgroups and risk factors
10. Signal detection in Electronic Health Records
11. Drug-drug interaction detection
12. Duplicate detection

Work Package 4: Data collection from consumers

Objectives:

To assess the feasibility, efficiency and usefulness of modern methods of data collection including using web-based data collection and computerised, interactive voice responsive systems (IVRS) by telephone

WP 4 will address limitations of data capture through conventional methods such as health care professionals and electronic health records.

Work Package 5: Benefit-risk Integration and Representation

Objectives:

- To assess and test methodologies for the benefit-risk assessment of medicines
- To develop tools for the visualisation of benefits and risks of medicinal products

Considerations given to:

➔ Perspectives of patients, healthcare prescribers, regulatory agencies and drug manufacturers

➔ From pre-approval to post-approval B-R assessment

➔ Individual and population-based decision-making

Wave 1 case studies: Tysabri, Accomplia, Raptiva, Ketek

More information?

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