PROTECT

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Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium

The PROTECT project

An Innovative Public-Private Partnership for New Methodologies in Pharmacovigilance and Pharmacoepidemiology

Xavier Kurz, MD, MSc, PhD

European Medicines Agency

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 real-life situations.

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: Framework for pharmacoepidemiological studies

Adverse event –drug pairs

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

Databases

Danish national registries	British THIN databases
Dutch Mondiaan database	Spanish BIFAP project
British GPRD database	German Bavarian claims database

Protocols

Cohort, nested case-control, population-based case-control, case-crossover, self-controlled case series

Manuscript Bridging differences in findings from observational pharmaco-epidemiological studies: the PROTECT project

Work Package 2 – Confounding Drug utilisation

Simulation studies and methods to quantify balance of confounder distributions with propensity score methods

Manuscripts:

- Measuring balance and model selection in propensity score methods
- Selection of confounding variables should not be based on observed associations with exposure
- Balance measures for propensity score methods: a clinical example on beta-agonist use and the risk of myocardial infarction

Evaluation and dissemination of methodologies for drug utilisation studies in order to estimate public health impact of adverse drug reactions

– Inventory of data sources on drug utilisation data for several European countries

– Collaboration with EuroDURG

Work Package 3: Signal Detection

Objective:

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

Work Package 3: Sub-projects

1. Merits of disproportionality analysis
2. Structured database of known ADRs
3. Concordance with risk estimates
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

Structured database of product information on adverse drug reactions

- Objective:

  Making available, in a **structured** format, already known ADRs

- All 375 SPCs of CAPs (substances). Addition of non-CAPs under discussion.

- Proof-of-concept analysis of free text extraction algorithm
  - Initial match rate increased from 72% to 98%

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

Work Package 4 - Project Definition

- Prospective, non interventional study which recruits pregnant women directly without intervention of health care professional
- Collect data from them throughout pregnancy using either web based or interactive voice response systems (IVRS):
  - medication usage, lifestyle and risk factors for congenital malformation
- Compare data with that from other sources and explore differences
- Assess strengths and weaknesses of data collection and transferability to other populations

Work package 4 - Study population

- 4 countries:

Denmark 

United-Kingdom 

The Netherlands 

Poland 

- 1400 pregnant women per country
  - Self identified as pregnant
  - Volunteers may not be "typical" of pregnant population – can characterise

Work Package 4: Patient workflow overview

Study subject picks up a leaflet in a pharmacy or browses specific web sites to find out about the study in one of 4 countries.

Study subject enrolls for the web or phone (IVRS) method of data collection.

Web

n = 1200 per country

Study subject completes the surveys online.

IVRS

n = 200 per country

Study subject completes the surveys via an outbound reminder or by inbound call she initiates.

Final outcome survey is completed at the end of pregnancy.

Work Package 5: Benefit-Risk Integration and Representation

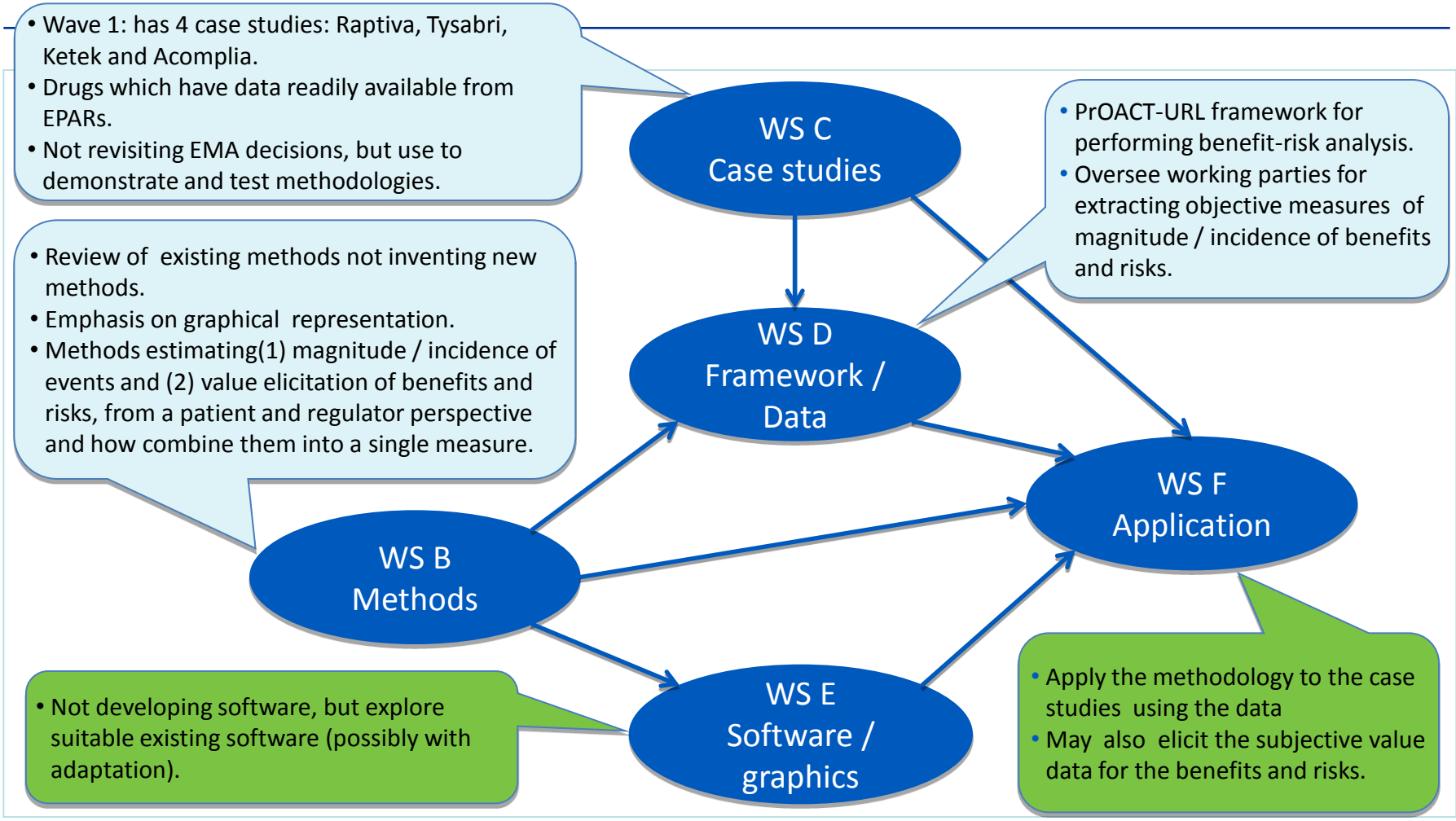
Objectives:

- 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

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

➔ From pre-approval through lifecycle of products

Work Package 5: Overview

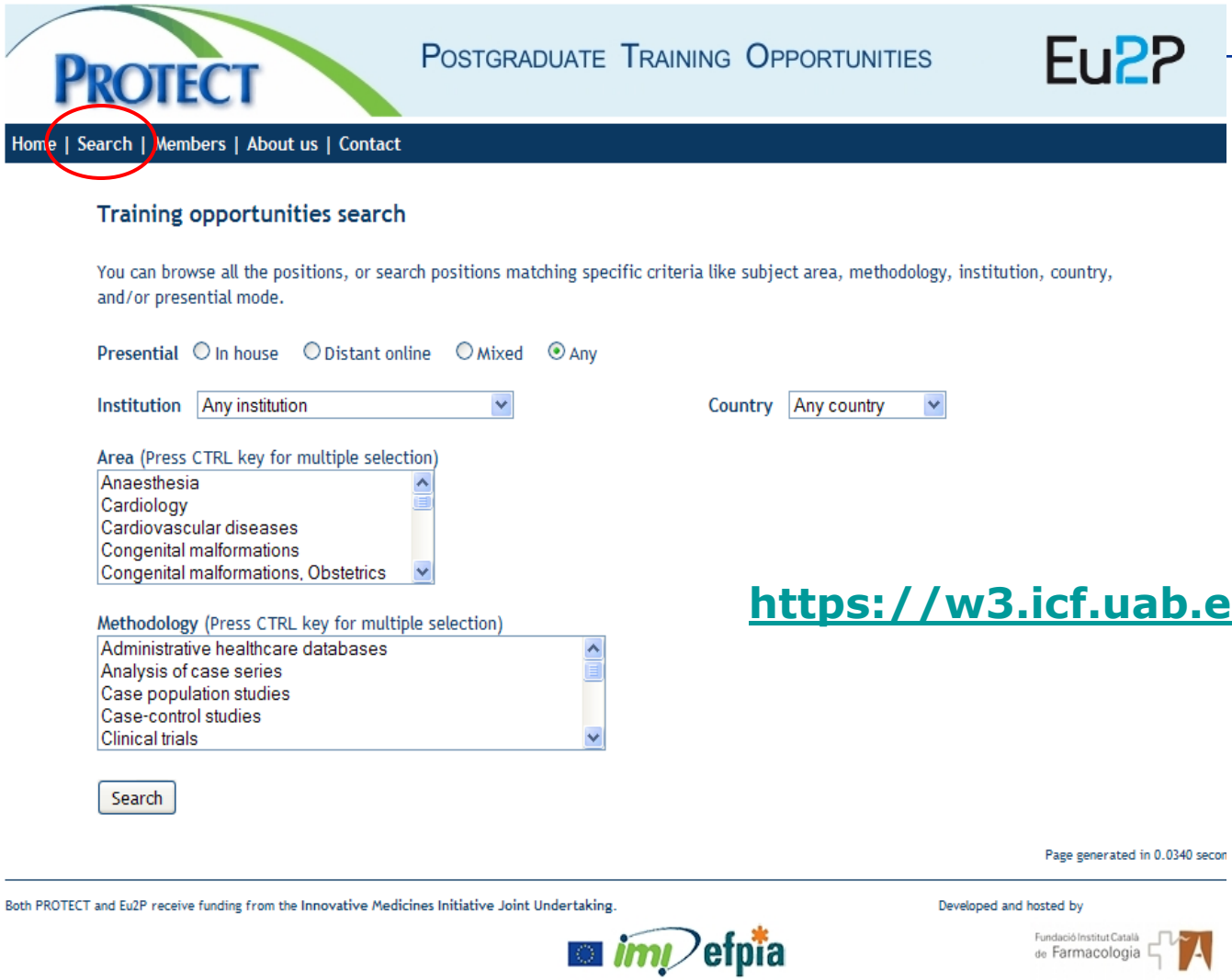


Work Package 6: Validation

Objectives:

- To validate and test the transferability and feasibility of methods developed in PROTECT to other data sources and population groups
- To determine the added value of using other data sources as a supplement or alternative to those generally used for drug safety studies, in order to investigate specific aspects or issues.

Work Package 7: Training Platform



https://w3.icf.uab.es/trainingopp

More information?

Website: www.imi-protect.eu

Email: Protect_Support@ema.europa.eu