EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SYMPOSIUM
PROTECT

Monitoring benefits and risks of medicines:
PROTECT results and recommendations, 18-20 February 2015, EMA, London

Dates

Training courses:
18 February 2015
14:00-18:00

PROTECT Symposium:
19 February 2015,
09:00-18:00

20 February 2015,
08:30-15:00.

Place

European Medicines Agency, 30 Churchill Place, Canary Wharf, London E14 5EU

The Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium (PROTECT) is a 5-year public-private partnership of 34 partners initiated in 2009 to enhance the monitoring of the safety of medicinal products and contribute to better evaluate and communicate their benefit-risk profile throughout their lifecycle. To this end, PROTECT planned to develop and test methodological standards and innovative tools.

The objective of the Final PROTECT Symposium is to present the main results and recommendations of PROTECT and discuss their implications from a methodological perspective and for the evaluation of the benefits and risks of medicines. Four parallel pre-symposium training courses will provide in-depth training on specific aspects of the research work performed in PROTECT.

The main topics will include methods to collect data directly from consumers, signal detection, methods to improve consistency between pharmacoepidemiological studies and benefit-risk integration and representation.

Registration

Free.

Places are limited and registration will be made on a "first come, first served" basis.

Applications can be submitted for the entire programme or for a specific day, but registration to the entire programme is preferred.

To apply, please fill the form which you will find here: ***Registration Form***

Visit our website

Further information about the PROTECT project is available on our website:

http://www.imi-protect.eu/

Aknowledgments

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PROTECT
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Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium

Pre-symposium training

18 February 2015, 14:00-18:00

Parallel sessions

1. Benefit-risk assessment: concepts and methods *Leaders: Deborah Ashby, Steve Hobbiger, Sharhul Mt-Isa*

This session will review and discuss structured methodologies for the assessment and visualisation of the benefit-risk of medicines and explain how they can support benefit-risk decision-making. Methods and examples for patients and public involvement will be described. PROTECT resources for further learning will be presented.

2. Application of MCDA to real-life decision-making *Leaders: Mireille Goetghebeur, Billy Amzal*

This training will familiarise the audience with structured benefit-risk assessment of medicines using a hands-on exercise based on multicriteria decision analysis (MCDA) and evidence synthesis to handle data heterogeneity similar to that encountered in a product's lifecycle. Based on a real-life example, participants will perform a structured elicitation of weights and performance scores for benefit and risk criteria and discuss the challenges and opportunities of this approach in real life settings.

3. Statistical signal detection *Leaders: Niklas Norén, Jim Slattery, Michael Kayser*

This training will explain the role of statistical signal detection (SD) in pharmacovigilance and the concept, methods and pitfalls of disproportionality analysis. It will address the need and methods for empirical evaluation of measures, propose factors to be considered for the choice of methods and provide a view of SD processes applied to different information sources. Specific topics in SD will be covered.

4. Methods to control for confounding *Leaders: Olaf Klungel, Rolf Groenwold, Nicolle Gatto*

Starting from an overview of methods to control for confounding and of their importance in epidemiology, this training will address more specifically propensity scores and the use of balance measures; time-dependent confounding and the use of marginal structural models; and the use of instrumental variables. These methods will be illustrated with case studies performed in PROTECT.

Format

Pre-symposium training courses will explain methods developed and tested in PROTECT, starting from basics and progressing towards more advanced knowledge. The audience will be engaged in interactive discussions to ensure good understanding of the concepts and methods.

Each session of the symposium will open with a presentation of the knowledge gaps which PROTECT intended to address, provide the main results of case studies and discuss the implications of the findings for the benefit-risk monitoring of medicines.

Throughout the symposium, posters developed by PROTECT and presented in various conferences will be displayed, giving opportunities for direct discussions during breaks. Websites and databases developed by PROTECT will be made available on laptops to allow one-to-one explanation of their use.

Faculty

For each topic, objectives, results and recommendations will be presented by researchers of the involved work package(s). Non-PROTECT international speakers will be invited for some topics.

Day 1, 19 February 2015, 09:00-18:00

1. Welcome – Introduction
X. Kurz

2. Regulatory sciences: the role of the European Medicines Agency
G. Rasi (tbc)

3. PROTECT: shaping objectives into a work programme
L. Swain

4. Signal detection
Chairs:tbc

PROTECT Work package 3

- Use of ontologies in signal detection:
  - Grouping of ADR terms
  - The PROTECT structured SPC-ADR database

- Statistical signal detection (SD) from spontaneous reports:
  - Evaluation of disproportionality analysis methods across databases held by pharmaceutical companies, national competent authorities, EMA and the WHO, including an evaluation of stratification and subgroup analysis
  - PROTECT recommendations for duplicate detection, grouping of ADR terms, unmasking strategies and statistical interaction detection.

- Real-world signal detection in longitudinal electronic health data: lessons from PROTECT and perspectives from related projects:
  - Signal detection from clinical trials
  - Panel discussion: key recommendations and future priorities

5. Improving consistency between pharmacoepidemiological studies
Chairs:tbc

PROTECT *Work packages 2 and 6*

- PROTECT recommendations in a global perspective
- Objectives and methods
- Outcomes of studies for six adverse event-drug pairs and five databases: what did we learn?
- Comparison of methods to control for confounding: review of findings and lessons
- Measuring the public health impact of adverse drug reactions
- Panel discussion

Day 2, 20 February 2015, 08:30-15:00

6. Welcome – Introduction to Day 2

X. Kurz

7. Pilot study of Direct-to-Patient pharmacovigilance

Chairs: tbc

PROTECT Work package 4

- Background and objectives of the PROTECT Pregnancy Study.
- Development of novel multi-lingual pharmacovigilance tools for direct-to-patient data collection.
- Recruitment strategy.
- Study results: recruitment, lifestyle behaviour, medications use and pregnancy outcomes.
- Comparative overview of Pregnancy Study and routine electronic healthcare databases in Denmark and United Kingdom.
- Participation in the Pregnancy Study among a sample of women: a qualitative study.
- Lessons learned and recommendations for future direct-to-patient pharmacovigilance studies.

8. Benefit-risk integration and representation

Chairs: tbc

PROTECT Work packages 5 and 6

- Formalising benefit-risk assessment: a road map to data integration and visualisation.
- A real-life experience of benefit-risk assessment: a case study.
- The challenges in assessing benefit-risk balance of older medicinal products.
- In sickness and in health, and for the greater good: involving patients and the public in benefit-risk decision-making.
- Measuring patients' preferences in a multi-criteria benefit-risk assessment.
- Communicating benefit-risk balance for informed decision-making.
- Panel discussion: the past, the present and the future.

9. Review of experience and lessons learnt

Chairs and speakers: tbc

- Contribution from PROTECT to regulatory practice: from science to process improvement.
- The Innovative Medicines Initiative: lessons learnt from public-private partnerships and future directions.

10. Wrap-up and conclusions

L. Swain, X. Kurz