

El projecte PROTECT

Pharmacoepidemiological Research on Outcome of Therapeutics
by a European Consortium

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

ACADÈMIA DE LES CIÈNCIES MÈDIQUES DE CATALUNYA I BALEARS

29 Abril 2015

Mònica Sabaté, Luisa Ibáñez
Fundació Institut Català de Farmacologia

Guió de la presentació

- Objectius i estructura del PROTECT
- Resultats (WP2-WG3):
 - Inventari bases de dades de consum
 - Mesura de l'impacte en salut pública dels efectes indesitjats.

Objectius

Consolidar l'avaluació del benefici-risc dels medicaments a Europa a través del desenvolupament de mètodes innovadors

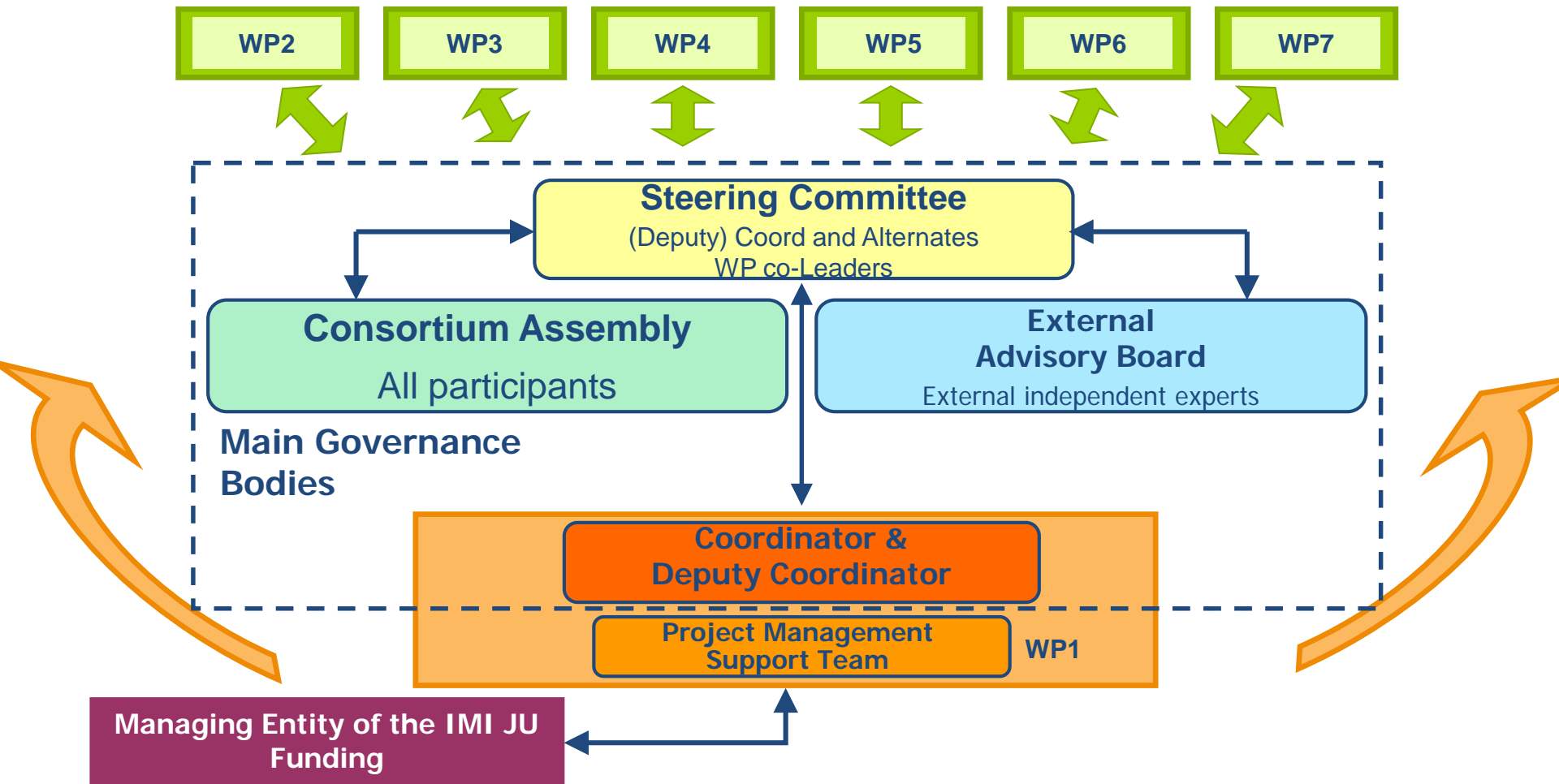


Millorar la **detecció i avaluació** de les reaccions adverses amb **diferents fonts de dades** (assajos clínics, estudis observacionals i notificació espontànea)

Afavorir la integració i la presentació de les dades sobre **els beneficis i els riscos dels medicaments**

Tots aquests mètodes es testaran en situacions reals

Gestió del projecte



WP

- WP1: Coordinació i gestió (*X Kurz, EMA/E Swain, GSK*)
- WP2: Marc per a estudis farmacoepidemiològics (*O Klungel, UU/R Reynolds, Pfizer*).
- WP3: Mètodes per detecció de senyals (*N Noren, UMC/M Kayser, Bayer*).
- WP4: Nous mètodes per recollida de dades a partir dels consumidors (*O de Mol, Genzyme*).
- WP5: Representació gràfica de la relació risc-benefici (*D Ashby, Imperial/A Micallef, ME*).
- WP6: Estudis de replicació (*L Abenhaim, PGRx-LASER/L Auclert, SARD*).
- WP7: Formació i comunicació (*JR Laporte, FICF/E Rivero, Novartis*).

WP2: Marc per als estudis farmacoepidemiològics

Objectiu:

- desenvolupar
- testar
- disseminar

estàndars metodològics per al:

- disseny
- realització
- anàlisis

d'estudis farmacoepidemiològics aplicable a

- diferents estudis farmacoepidemiològics
- diferents fonts de dades

WP2: Pla de treball

3 Grups de Treball (WG):

- WG 1: Bases de dades

- Mark de Groot (UU) /Raymond Schlienger (Novartis)*

- WG 2: Factors de confusió

- Rolf Groenwold (UU), Nicolle Gatto (Pfizer)*

- WG 3: Ús de medicaments

- L Ibàñez (FICF)/H Petri (Roche), J Fortuny (Novartis)*

Selecció parells fàrmac-reacció

- Inhaladors beta2 de llarga durada i IAM.
- Antibiòtics i hepatotoxicitat.
- Antidepressius i benzodiacepines i fractura de maluc.
- Antiepil·lèptics i suïcidi.
- Bloquejadors del canal del calci i neoplàsies.

Send Orders for Reprints to reprints@benthamscience.net

130

Current Clinical Pharmacology, 2014, 9, 130-138

Bridging Differences in Outcomes of Pharmacoepidemiological Studies: Design and First Results of the PROTECT Project

Victoria Abbing-Karahagopian¹, Xavier Kurz², Frank de Vries^{1,3}, Tjeerd P. van Staa^{1,4}, Yolanda Alvarez², Ulrik Hesse⁵, Joerg Hasford⁶, Liset van Dijk^{1,7}, Francisco J. de Abajo⁸, John G. Weil⁹, Lamiae Grimaldi-Bensouda¹⁰, Antoine C.G. Egberts^{1,11}, Robert F. Reynolds¹² and Olaf H. Klungel^{1,13,#,*}

AE	Non-Fatal /Fatal Incidence		Regulatory Triggers/Action	Seriousness	Ascertainment	Feasibility of Ascertainment in EHR
Acute myocardial infarction	Non-fatal Fatal	803/100,000 hospital discharges due to CHD in 2009 [33] 76 {range: 30-313}/100,000 in 2010 [34]	Drug withdrawal/ Boxed warning [30]	10% disability-adjusted life years lost by CHD in 2010 [33] 28-day case fatality of IHD: 34%-88% [35]	Clinical, laboratory and ECG criteria	Moderately Easy
Idiopathic acute liver injury	Non-fatal Fatal	1-41/100,000 person years [36-38] 10% of all AE [39] 0.8/million person-years [36]	Drug withdrawal/ Boxed warning [30, 40, 41]	6 months case fatality: 12% [36] 29% of patients acute jaundice [42]	Diverse clinical, laboratory and histological data [43]	Moderately Difficult
Hip fracture	Non-fatal Fatal	80-200 /100,000/yr [44] 20-24% fatality rate within 1 yr [45,46]	Warning in product information of antiretrovirals [47] & thiazolidinediones [48, 49]	3.3 years: mean interval between fractures [50]	Hospital admission	Easy
Suicide/suicide attempt	Non-fatal Fatal	50-100/100,000/yr attempts [51] 10 /100,000/yr [52]	Drug withdrawal/Boxed warning [30]	-	Cause of death Hospital admission due to self-harm	Difficult
Cancer	Non-fatal Fatal	414-600/100,000 new cases/yr [53] 170/100,000/yr [34]	For biologicals [41]	5-year fatality rate: 43%-71% [53]	Tumour diagnosis cancer registry	Moderately Easy

WP2-WG3: Objectius

- ü Descriure i actualitzar les principals característiques dels grups de recerca multinacionals Europeus en l'àmbit de l'ús de medicaments
- ü Descriure i actualitzar les principals característiques de les bases de dades administratives (healthcare utilisation databases) disponibles a Europa
- ü Avaluar i disseminar la metodologia dels estudis d'ús de medicaments per poder estimar l'impacte en salut pública dels efectes adversos.

Participants

WG3

Coordinators: Luisa Ibáñez.....FICF
Joan Fortuny.....Novartis

Justyna Amelio	Amgen
Joan-Ramon Laporte	FICF
Mònica Sabaté	FICF
Elena Ballarin	FICF
Pili Ferrer	FICF
Joerg Hasford	LMU-München
Marietta Rottenkolber	LMU-München
Sven Schmiedl	Witten-Herdecke University
Iain Tatt	Roche

Inventory drug consumption databases in Europe

35 European countries, 45 databases

Armenia	Hungary	Romania
Austria	Iceland	Russia
Bosnia-Herzegovina	Ireland	Serbia
Belgium	Israel	Slovakia
Bulgaria	Italy	Slovenia
Croatia	Latvia	Spain
Czech Republic	Lithuania	Sweden
Denmark	Montenegro	Turkey
Estonia	Netherlands	United Kingdom
Finland	Norway	
France	Poland	
Germany	Portugal	

Inventory drug consumption databases in Europe

<http://www.imi-protect.eu/drugConsumption.shtml>

Home | Contact Us | Search

PROJECT
About PROTECT
Objectives
Governance structure
Partners
Work programme

News

Results

PROTECT Symposium NEW

General Presentations

eRoom - partners only

Links
General Links
Collaborations
Training Opportunities
Pregnancy Study
Adverse Drug Reactions Database NEW
Drug Consumption Databases in Europe NEW
PROTECT Benefit-Risk Website NEW

Drug Consumption Databases in Europe

The inventory of **Drug Consumption Databases in Europe** is a comprehensive and structured source of information on drug consumption in Europe. It comprises two documents. The master document contains a detailed report of the available information, methods to retrieve this information, a description of the validity of national drug consumption data and a discussion. The country profile document summarizes the main results by country.

DRUG CONSUMPTION DATABASES IN EUROPE: MASTER AND COUNTRY PROFILE DOCUMENTS

These documents are the result of reviewing, compiling and updating knowledge about European sources of data on drug utilisation in the out- and inpatient healthcare sector. Two documents are available to view. A master document, organised as a scientific article, contains a detailed report of the information already available, methods to retrieve this information, and a discussion. The country profile document summarizes the main results by country.

Summary of the included information:

Master document and country profile document	List of non-commercial providers of drug consumption data in Europe
	List of national medicines agencies, reimbursement and pricing agencies
	List of sources of information about medicines
Master document	List of nationwide drug consumption databases in Europe with a description of the main characteristics and accessibility
	Summary of data provided by IMS Health, Inc.
	Exploration of the availability of nationwide inpatient drug consumption data
	Outline of validity and degree of inter-country comparability of drug consumption data
	International networks and research working groups in pharmacoepidemiology

Information is available for Belgium, Federation of Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Montenegro, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, The Netherlands, The United Kingdom and Turkey. Information was last updated in February 2015.

These documents are a shared resource for researchers, regulatory agencies, and pharmaceutical companies. We encourage all readers to review and comment on these documents.

Inventory drug consumption databases in Europe

Country profile

(Spain as an example)

SPAIN

Population	47,190,493 (1/1/2011) http://www.ine.es/welcoing.htm
Health care provider	Public health sector. Universal access to health services.
Population coverage	In 2005, 99.5% including low-income inhabitants. Civil servants can opt out of the public financed system. 88% of this population and their beneficiaries are covered for-non-for-profit private sector. 13% of the Spanish population are covered by private-for-profit voluntary health insurance, with an important regional variation.
Model of health care financing	Highly decentralised model with the allocation of block grants –obtained through taxation-, from the central government to the autonomous communities, except for Navarre and the Basque Country with high autonomy taxation. Taxation represents 94.1% of the funding of the social security system.



Reimbursement characteristics

Method of payment	The National Health System (SNS) partially pays reimbursed medicines. Patients pay the rest.
The beneficiaries	All Spanish residents. Exemptions to copayment for people with specific diseases, with low income, or for treatments due to a job injury or occupational disease.
Categories of reimbursable drugs	Based on negative lists that exclude pharmaceuticals with low treatment value or not proved to have adequate increased cost-effectiveness. Reimbursement of medicines depends upon the age and income of the patient. Special reimbursement category for people with specific treatments.
Structure of reimbursement to the patient (patient copayment)	<i>Retired people</i> pay 10% of the medicines price with a monthly maximum depending on annual income : > €100,000, copayment is 60%; < €18,000 (max per month €8), between ≥€18,000-<€100,000 (max per month €18), ≥€100,000 (max per month €60). <i>Employees and beneficiaries</i> copayment rate based on their annual income: < €18,000 40% of the medicines price; >€18,000-<€100,000 50%; >€100,000 (60%). Exemptions for people with toxic syndrome and other disabilities, on social cash aid, retired with non-contributory pensions, unemployed not receiving any social aid, work derived diseases or injuries. For specific treatments copayment is 10% up to a maximum of €4.13/package dispensed. Some food products no copayment after a medical application and approval. There are regional variations in flat-fees per prescription. Reimbursable scheme applied in 2012.
Reimbursement level for drugs	There are 4 main reimbursement levels: For employed and their beneficiaries between 40 to 60% of the medicines are reimbursed depending on their annual income. For pensioners between a 40-90% is reimbursed depending on their annual income and up to a maximum expenditure per month fixed also by population's level of annual income. For specific treatments, reimbursement is 90%.

Inventory drug consumption databases in Europe

PROTECT Drug consumption databases in Europe – Countries summary

List of national website of interest

National Medicine Agency	Agencia Española de Medicamentos y Productos Sanitarios-AEMPS. Spanish Agency for Medicines and Medical Devices. Ministerio de Sanidad , Política Social e Igualdad	www.aemps.gob.es
Pricing Agency	Dirección General de Farmacia y Productos Sanitarios. Ministry of Health and Social Policy. Directorate of Pharmacy and Health Products.	www.msc.es/profesionales/farmacia/organizacion.htm
Reimbursement Agency	Ministerio de Sanidad, Política Social e Igualdad. Dirección General de Farmacia y Productos Sanitarios. Ministry of Health and Social Policy. Directorate of Pharmacy and Health Products.	www.msc.es/profesionales/farmacia/organizacion.htm
Pharmaceutical data source	Consejo General de Colegios Oficiales de Farmacéuticos Catálogo de Especialidades Farmacéuticas. Edited reference drug information book.	No online information.
	Database with information about drugs by region (summary of product characteristics, patient leaflet, patient counselling).	https://botplusweb.portalfarma.com/ (No free access).
	Agencia Española de medicamentos y productos sanitarios (AEMPS). CIMA database. Information on all drugs marketed in Spain.	http://www.aemps.gob.es/cima/fichasTecnicas.do?metodo=detalleForm

National drug consumption database: DGFPS database

Organisation	Ministry of Health, Social Policy, and Equity. DGFPS: Dirección General de Farmacia y Productos Sanitarios (General Directorate of Pharmacy and Health Products)
Web	www.msc.es/profesionales/farmacia/organizacion.htm
Source	Drugs dispensed by community pharmacies reimbursed by the National Health System. Data is collected at regional level and centralised in the Ministry of Health. Not included are medicines consumption reimbursed by other health insurances that specifically cover civil servants or military personnel.
Setting	Outpatient
Population coverage	100%
Accessibility	Application to data provider farmacoepi@aemps.es (If of interest, data may be applied for at regional level with a list of the regional health authorities available on the website).
Drug codification	ATC
Data	Region, DDD, turnover, prescriber's code, national pharmaceutical code, pharmacist's code, strength, dosage form. Some regions collect data on age and gender.
Record period	Since 1985 (computerised data)
Language	Spanish
Record linkage	No

Sources of European drug consumption data at a country level

Pili Ferrer · Elena Ballarín · Mònica Sabaté · Joan-Ramon Laporte ·
Marieke Schoonen · Marietta Rottenkolber · Joan Fortuny ·
Joerg Hasford · Iain Tatt · Luisa Ibáñez

Information was collected on data providers, websites, sources of medicines consumption data, healthcare settings, population coverage (the proportion in a particular database of a country's inhabitants from which DU figures were compiled), information related to the medicines (packages, dosages, medicines codifications, measurement units, dates of prescription and dispensing, indications for which the medicines were dispensed or prescribed), sociodemographic and clinical characteristics of the patients, prescriber information, internal validity of each database, periods covered, potential record linkages with other databases, and external accessibility of the databases for research purposes.

MiniReview

Inpatient Drug Utilization in Europe: Nationwide Data Sources and a Review of Publications on a Selected Group of Medicines (PROTECT Project)

Mònica Sabaté^{1,2,3}, Pili Ferrer¹, Elena Ballarín^{1,2}, Marietta Rottenkolber⁴, Justyne Amelio⁵, Sven Schmiedl^{6,7}, Robert Reynolds⁸, Olaf Klungel⁹, Luisa Ibanez^{1,2,3} and on behalf of PROTECT Work Package 2

¹Fundació Institut Català de Farmacologia, Barcelona, Spain, ²Department of Clinical Pharmacology, University Hospital Vall d'Hebron, Barcelona, Spain, ³Department of Pharmacology, Toxicology and Clinical Therapeutics, Hospital Universitari Vall d'Hebron, Univ Autònoma de Barcelona, Barcelona, Spain, ⁴Institute for Medical Information Sciences, Biometry and Epidemiology, Ludwig-Maximilians Universitaet-Muenchen, Munich, Germany, ⁵Amgen, Uxbridge, UK, ⁶Philipp Klee-Institute for Clinical Pharmacology, Helios Klinik Wuppertal, Wuppertal, Germany, ⁷Department of Clinical Pharmacology, School of Medicine, Faculty of Health, Witten-Herdecke University, Witten, Germany, ⁸Epidemiology, Pfizer Research & Development, New York, NY, USA and ⁹Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht University, Utrecht, The Netherlands

(Received 18 July 2014; Accepted 19 November 2014)

Inventory drug consumption databases in Europe: inpatient drug consumption databases

Table 1. National public databases providing information on hospital drug consumption in Europe.

Countries	BELGIUM	BULGARIA	CROATIA	DENMARK	ESTONIA	FINLAND	FRANCE	HUNGARY	ITALY	ICELAND	LATVIA	NORWAY	PORTUGAL	SWEDEN
Database name	Minimum Basic dataset (MDDS)	Not provided	Not provided	Register of medicinal products statistics	SAM Database	Drug sales register	ANSM database	Not provided	OsMED database	Not provided	Not provided	Wholesalers drug statistics	Informed database	Since January 2014 under re-structuration. Apoteket AB database up to 2013
Data provider	Federal Public Service (FPS) Health, Food Chain Safety and Environment	Bulgarian Medicines Agency	Croatian Drug Agency	Danish Health and Medicines Authority	State Agency of Medicines	Finnish Medicines Agency	The French National Agency for Medicines and Health Products Safety (ANSM)	Directorate General of National Institute of Pharmacy	Italian Medicines Agency	Icelandic Medicine Agency	State Medicines Agency of Latvia	Norwegian Institute of Public Health	National medicines agency	Since January 2014 Ehdsoymyndigheten. National Corporation of Swedish Pharmacies up to 2013.
Website	http://www.health.belgium.be/sportal/health_care/itsalthcare/facilities/Registrationsystems/index.htm	http://en.bda.bg/	www.almohar.com	http://laegemiddelstyrelsen.dk	www.som.ee	www.fimea.fi	www.ansm.sante.fr	www.ogvi.hu	http://www.agenziafarmaco.gov.it/en	www.lm.co.is	http://www.vsm.gov.lv/index.php?id=305&pg=305&to=298	www.fhi.no	www.infarmed.pt	http://www.ehdsoymyndigheten.se/
Accessibility	adhoc_admin@sanite.belgium.e.be	Application Medicines use control department maria.popova@bda.bg	Application viola.malovic@halmmed.hr	Free online www.medstat.dk Further data upon request	Application ott.laius@eriimiamet.ee	Application communications@fimea.fi	Application communication@ansm.fr	Application ogvi@ogvi.hu	Application farmaciline@agenzia.gov.it	Free online http://www.lm.co.is/sais/fmca/statistiks/vr/235	Application info@eva.gov.lv	Application Infira@fhi.no	Application demoss@infarmed.pt	Application: registrator@ehdsoymyndigheten.se
Data source	Prescribed and dispensed	Sales	Sales	Sales	Sales	Sales	Sales	Sales	Dispensed	Sales	Sales	Sales	Prescribed Dispensed HOM ^a	Sales
Population coverage	21.5% of hospitals	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% up to 2013.
Data by age/gender	Yes	No	No	Yes	No	No	No	Yes	Yes	Yes	No	Yes	No	Yes
Record linkage	Yes	No	No	Yes	No	No	No	No	Yes at regional level	No	No	No	No	No

^a Hospital only medicines.

SHORT REPORT

Open Access

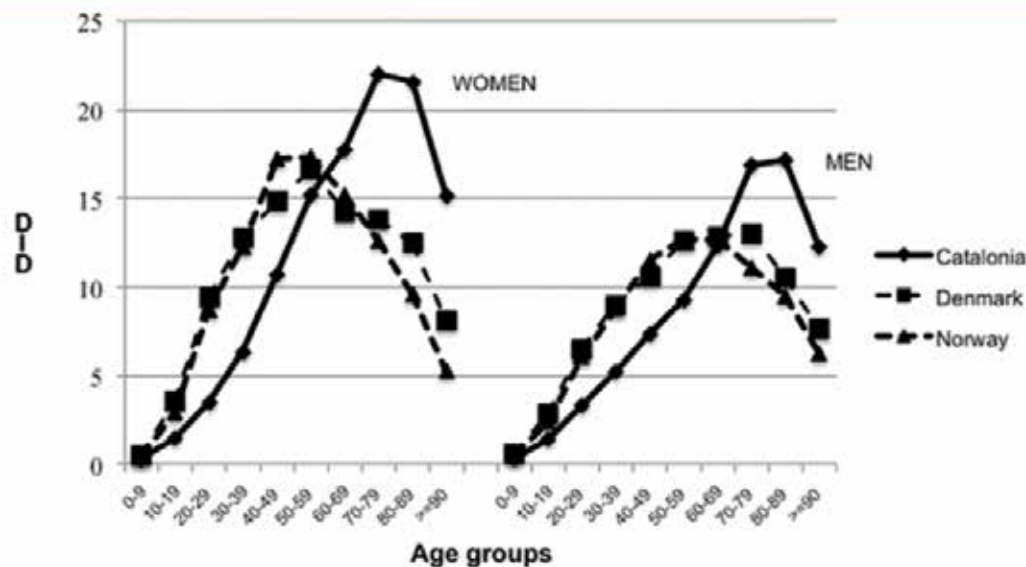
A compilation of research working groups on drug utilisation across Europe

Mònica Sabaté^{1,2,3}, Juan Fernando Pacheco^{1,2,3}, Elena Ballarín^{1,2,3}, Pili Ferrer¹, Hans Petri⁴, Joerg Hasford⁵, Marieke Wilma Schoonen⁶, Marietta Rottenkolber⁵, Joan Fortuny⁷, Joan-Ramon Laporte^{1,2,3}, Luisa Ibáñez^{1,2,3*}
and On behalf of the PROTECT Work Package 2

Cross-national comparison of antiepileptic drug use: Catalonia, Denmark and Norway, 2007-2011

PILI FERRER^{(1)*}, CONCITA RAFANIELLO⁽²⁾, MÒNICA SABATÉ^{(1,3)*}, ELENA BALLARÍN^{(1,3)*}, ANNA COMA⁽⁴⁾, CORINNE ZARA⁽⁴⁾, ANNALISA CAPUANO⁽²⁾, FRANCESCO ROSSI⁽²⁾, JOAN-RAMON LAPORTE^{(1,3)*}, LUISA IBÁÑEZ^{(1,3)*}

"OTHER AEDS" GROUP CONSUMPTION IN CATALONIA, DENMARK, AND NORWAY BY AGE AND GENDER, YEAR 2011.



Dades de consum de medicaments: validesa i confiabilitat (reliability)



Podem avaluar la verdadera ingesta de medicaments que fan els pacients amb aquestes bases de dades administratives?

Recullen aquestes bases de dades administratives, de forma no esbiaixada, la informació en ús de medicaments a un nivell geogràfic determinat/per a una població determinada/i amb els anys?

Dades de consum de medicaments: validesa i confiabilitat (reliability)

PROTECT QUESTIONNAIRE

INSTRUCTIONS¶

The questionnaire is intended to collect information on databases registering out- and inpatient drug consumption at national level. ¶

The questionnaire is divided into four sections: ¶

(1) Definition of out- and inpatient drug consumption: The type of information on pharmaceutical monitoring included as outpatient healthcare or inpatient healthcare. ¶

(2) Population coverage: The proportion of the population of the country for which the database collects information. ¶

(3) Drug-based information: Information collected regarding the active ingredient/pharmaceutical package ¶

(4) Other information. ¶

Each of the sections collect different characteristics of out- and inpatient pharmaceutical monitoring databases at a national level. In addition, there is the option of writing free comments. Also, there is the possibility of pointing out that the information requested is not collected or not applicable to the database. Further instructions are provided throughout the questionnaire. ¶

If you have any questions, please do not hesitate to contact us at: ¶

Information retrieved from the PROTECT questionnaire

Items	Danish Registry of Medicinal Products Statistics (Denmark)	ANSM (France)	OsMed (Italy)	NorPD (Norway)
Data included in drug consumption data	Community pharmacies, hospital pharmacies, dental care, nursing homes, etc.		Drugs dispensed to patients while in hospital.	Dental care, specialist care to outpatients, drug abuse centers and private institutions. Nursing homes sent data to the register on an aggregated level.
If applicable, sampling or weighting methodology	n/a	n/a	n/a	n/a
Possibility to estimate the time intervals of drug exposure (days of supply, quantity of drug dispensed, dose and DDD)	Yes	Yes	Yes (Quantity)	Yes
ATC/DDD updates	Yearly, all data updated retrospectively.	Yearly, all data updated retrospectively.	Yearly, all data updated retrospectively.	Yearly, all data updated retrospectively.
Coding of drugs with non ATC/DDD assigned	National codes	Yearly updated. Very few databases provided information	Yearly updated. Very few databases provided information	No information provided
Other variables collected	Number of people treated, number of packages, and indication of the prescriptions.	Prescriber's, pharmacy characteristics, number of users, indication for use	Prescriber's, pharmacy characteristics, number of users, indication for use	Information on prescribers and the community pharmacy.
Internal validity	Monthly, large validation process	Data is contrasted with other sources of data	Reimbursed data is handled at the national level	Monthly and every 6 months.
Proportion of missing prescriptions	No information provided.	Quality checks of the database	Quality checks of the database	Very few databases provided this information

What is out- and inpatient drug consumption data?

Differential aspects: nursing homes (DK, IT, CR, SE), hospital-only medicines dispensed to outpatients (SE), or other long-term healthcare settings, dental care.

Weighing and/or sampling methodology if population coverage <90%

Time intervals of drug exposure?

Possibility to estimate time intervals of drug exposure in database

ATC/DDD updates/national codes

Other variables

Quality checks of the database

Table 1. Studies published on sensitivity and specificity of national drug consumption databases



COUNTRY	DATABASE	REFERENCES
Denmark	The Danish National Prescription Registry	<p>Kildemoes et al. 2011.(29)</p> <p>For hormone replacement therapy (patient questionnaire gold standard), sensitivity 74.8% and specificity 98% in 1999.</p>
Finland	The Finnish National Prescription Registry	<p>Rikala et al 2010(30)</p> <p>Psychotropic drugs in elderly (patient questionnaire). <i>No access</i></p> <p>Haukka et al 2007(31)</p> <p>Psychotropic drugs in patients with schizophrenia (patient questionnaire as gold standard, Cohen's κ 0.96 for Li to 0.37 for BZD)</p>
France	Reimbursement databases	<p>Noize et al. 2009(32)</p> <p>Comparison of health insurance claims and patient interviews in assessing drug use: data from the Three-City (3C) study.</p> <p>All classes of drugs in the general population (patient questionnaire as gold standard). Values of correlation and sensitivity/specificity varied with reimbursement time frame. 30-day κ= 0.03-0.59; Se 2.4%-47.4%; Sp 89.1-99.9%.60-dayκ= 0.05-0.20; Se 70%; Sp 77.6-99.8%</p>
Germany	Health insurance medication claims data	<p>Hoffmann. 2009(33)</p> <p>Review article on use of German Health Insurance data. None of the articles published conducted a validation study about drug exposure.</p>

COUNTRY	DATABASE	REFERENCES
		biologic register and people receiving tx with <u>etanercept</u> and <u>adalimumab</u> from the Swedish prescribed register (gold standard).
United Kingdom	<u>ePACT</u>	Langley et al. 2010(37) Validation of prescription in THIN database compared with <u>ePACT</u> (gold standard)



Inventory drug consumption databases in Europe: Limitacions

- Gran quantitat de feina
- Actualització de l'inventari
- Molt pocs països tenen dades no agregades *online*.
- Manca d'informació clínica.
- Consum intrahospitalari és en forma de dades de vendes agregades

Inventory drug consumption databases in Europe: Conclusions

- Estudis d'ús de medicaments comparatius entre països.
- Marc de la recerca en ús de medicaments a nivell europeu.
- Bases per a futures col.laboracions a nivell europeu.
- Determinar ús medicaments per poder avaluar l'impacte en salut pública d'un efecte advers.
- Informació útil per als acadèmics, agències reguladores i indústria farmacèutica.

WP7 formació i comunicació



POSTGRADUATE TRAINING OPPORTUNITIES



[Home](#) | [Search](#) | [Members](#) | [About us](#) | [Contact](#)

Training opportunities matching your query

Click position title for further details, including contact form

Training in clinical pharmacology (4-year residency programme)

Catalan Institute of Pharmacology	Barcelona, Spain	4 years	In house
-----------------------------------	------------------	---------	----------

Exposure to suspected teratogens and subsequent obstetric and perinatal follow up.

Catalan Institute of Pharmacology	Barcelona, Spain	6 months	In house
-----------------------------------	------------------	----------	----------

Intracranial haemorrhages analysis of hospital data.

Catalan Institute of Pharmacology	Barcelona, Spain	12 months	In house
-----------------------------------	------------------	-----------	----------

Utilization of beta2-adrenergic agonists (National Drug Consumption Databases NDCDB).

Catalan Institute of Pharmacology	Barcelona, Spain	7-12 months	In house
-----------------------------------	------------------	-------------	----------

Utilization of calcium channel blockers (National Drug Consumption Databases NDCDB).

Catalan Institute of Pharmacology	Barcelona, Spain	7-12 months	In house
-----------------------------------	------------------	-------------	----------

PROJECT

[About PROTECT](#)

[Objectives](#)

[Governance structure](#)

[Partners](#)

[Work programme](#)

News

Results

PROTECT Symposium NEW

General Presentations

eRoom - partners only

Links

[General Links](#)

[Collaborations](#)

[Training Opportunities](#)

[Pregnancy Study](#)

PROTECT Symposium

In this section you will find all presentations given at the PROTECT Symposium, which was held at the European Medicines Agency in London, on the 18-19-20 February 2015.

Also, recordings from the event, which are available at the EMA YouTube Channel, can be accessed through the links below.

Finally, a list of participants is available at the bottom of the page.

FULL PROGRAMME

[PROTECT Symposium_18-20 Feb 2015_programme](#)

RECORDINGS

[PROTECT pre-Symposium Training Sessions - 18/02/2015 \(20 videos\)](#)

[PROTECT Symposium day 1 and 2- 19-20/02/2015 \(28 videos\)](#)

PRESENTATIONS

1. Training Session Benefit-Risk Assessment: Concepts and Methods

1.1 [Benefit-Risk Integration and Representation](#)

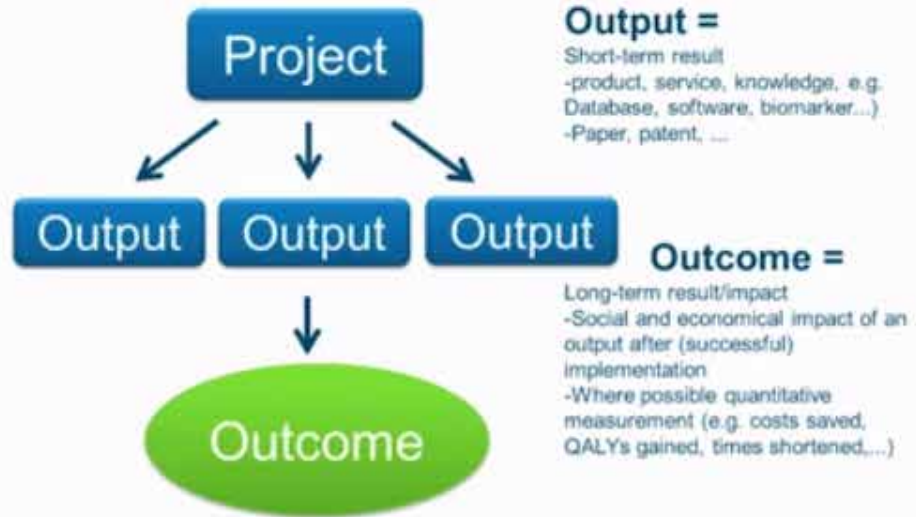
1.2 [Patient Preferences](#)

2. Training session Application of MCDA to real-life decision-making

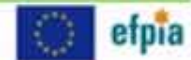
2.1 [Overview of multicriteria and statistical methods applied to regulatory decisions](#)

<https://www.youtube.com/watch?v=jfhxRuUopNQ&index=25&list=PL7K5dNgKnawbCbddbpOxfDG7C4Eqdoks9>

Translation of outputs into outcome



Source: Angela Wittelsberger, ADVANCE 3rd General Assembly meeting, 18-19 September 2014



PROJECT[About PROTECT](#)[Objectives](#)[Governance structure](#)[Partners](#)[Work programme](#)**News****Results****PROTECT Symposium** NEW**General Presentations****eRoom - partners only****Links**[General Links](#)[Collaborations](#)[Training Opportunities](#)[Pregnancy Study](#)[Adverse Drug Reactions Database](#) NEW[Drug Consumption Databases in Europe](#) NEW[PROTECT Benefit-Risk Website](#) NEW

Key achievements of PROTECT

Framework for pharmacoepidemiology studies

- [Presentations](#) (35)
- [Publications](#) (7)
- [Reports and Databases](#) (1)

Methods for Signal Detection

- [Presentations](#) (14)
- [Publications](#) (6)
- [Reports and Databases](#) (2)

New Methods for data collection from consumers

- [Presentations](#) (3)
- [Publications](#)
- [Reports and Databases](#)

Benefit- Risk integration and representation

- [Presentations](#) (16)
- [Publications](#)
- [Reports and Databases](#) (14)

Replication studies

- [Presentations](#) (1)
- [Publications](#)
- [Reports and Databases](#) (1)

Training and Communication

- [Presentations](#)
- [Publications](#)
- [Reports and Databases](#) (1)

Més informació: www.imi-protect.eu