PROTECT PROJECT COMMUNICATION STRATEGY AND PLAN

Grant agreement n°:	115004
Project name:	Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium
Project acronym:	PROTECT
Start date of the project:	1 September 2009
Duration of the project:	60 months

Dissemination level:

Dissemination of this template and the communication plan that is derived from it is restricted to project participants (including the IMI Executive Office, European Commission service and EFPIA science policy department, ILG, RDG). It can also be shared with other IMI project coordinators upon agreement with the consortium.

Acknowledgement: This model communication plan has been prepared on the basis of a methodology prepared by Interface Europe in the framework of the IMI project SAFE-T.

Contents

1 Executive Summary

The main goal of PROTECT is to strengthen the monitoring of the benefit-risk of medicines in Europe. This will be achieved by developing a set of innovative tools and methods that will enhance the early detection and assessment of adverse drug reactions from different data sources, and enable the integration and presentation of data on benefits and risks. These methods will be tested in real-life situations in order to provide all stakeholders with accurate and useful information supporting risk management and continuous benefit-risk assessment.

PROTECT aims at explaining discrepancies between the reported outcomes from pharmacoepidemiology studies by studying combinations of drugs and adverse events in several databases. It will identify and further explore sources of variability that may currently affect drug safety studies. Modern ways of collecting data on medication, lifestyle and risk factors directly from consumers using internet and telephony will also be explored. The ability of these systems to collect regular, accurate and complete reporting without the intervention of health professionals will be tested. Good practice recommendations for the detection of safety signals are developed based on extensive testing of existing and new methods, creation of a database of known adverse drug reactions, and exploring the use of electronic health records and clinical trials data. In addition, PROTECT will use new modelling approaches to integrate existing information from various data sources to facilitate and enhance the continuous monitoring of the benefit-risk of medicines.

Throughout the project the outcomes will be disseminated to various audiences (see section 2.4 Who are they? (Target Audiences) through a number of means (see section 5.1 Communication tools and channels).

This communication strategy supports the overall goals of the PROTECT project.

2 Situation Analysis

2.1 Project in general

Project Name (short)	**PROTECT**
Project Name (full)	**Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium**
Dates	
Start date:	**01 September 2009**
Total duration:	**60 months**
End date:	**31 August 2014**
Coordination	
Coordinator (representative)	**European Medicines Agency** (Xavier Kurz)
Deputy Coordinator (representative)	**GlaxoSmithKline Research and Development LTD** (Elizabeth Swain)
Management	
PROTECT project support team	**Contact: protect_support@ema.europa.eu**
Project Information	
Website:	**http://www.imi-protect.eu**
Funding	
Funding scheme	**Innovative Medicines Initiative, Joint Undertaking (IMI JU) (http://imi.europa.eu)**
IMI JU funding	**~ 11 million Euros**
EFPIA in kind contribution	**~ 10 million Euros**

Important contact details for PROTECT are listed in Annex C.

2.2 Project objectives and key deliverables

The Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium (PROTECT) is a collaborative European project that comprises a programme to address limitations of current methods in the field of pharmacoepidemiology and pharmacovigilance.

The main goal of PROTECT is to strengthen the monitoring of the benefit-risk of medicines in Europe. This will be achieved by developing a set of innovative tools and methods that will enhance the early detection and assessment of adverse drug reactions from different data sources, and enable the integration and presentation of data on benefits and risks. These methods will be tested in real-life situations in order to provide all stakeholders with accurate and useful information supporting risk management and continuous benefit-risk assessment.

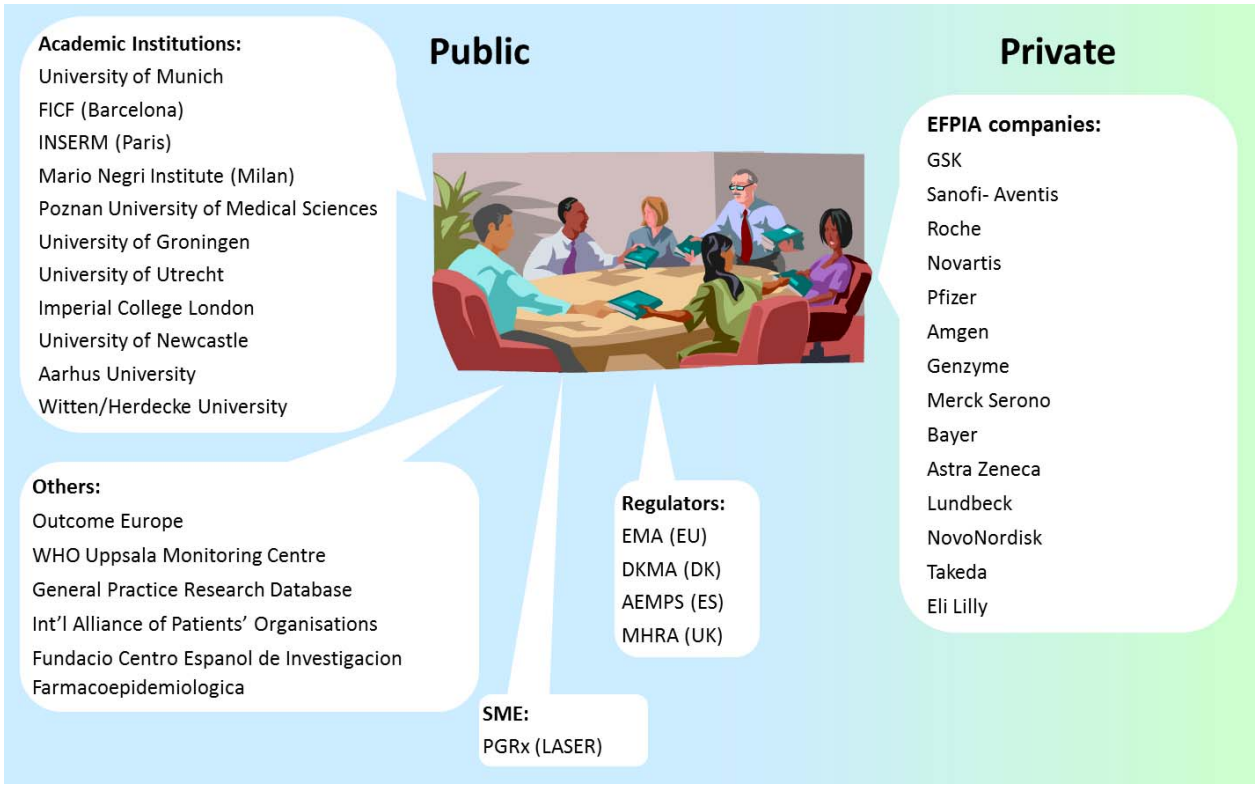
The main goal of PROTECT will be achieved by developing innovative tools and methodological standards aiming at:

- Developing a comprehensive set of signal detection recommendations applicable to different databases based on extensive retrospective and prospective testing of existing and new methods for SD, creation of a structured database of known adverse drug reactions, and testing SD in electronic health records and clinical trials.
- Better explaining discrepancies between PE studies of adverse drug events (AE), by developing a framework for PE to test and compare analytical methods to control for confounding and study 5 drug/AE pairs in several EU databases to identify and further explore sources of variability (i.e. hip fracture and antidepressants/benzodiazepines, acute liver injury and antibiotics, myocardial infarction and anti-asthmatic drugs, suicide and antiepileptics and cancer and calcium channel blockers). This includes exploring the best use of drug utilisation data in PE studies.
- Exploring the feasibility and acceptability of early data collection on medication, lifestyle and risk factors directly from consumers via the internet and interactive voice response system in a study with 5,600 pregnant women from 4 countries, including data linkage to other sources where possible.
- Developing methods for collating and integrating benefits and risks of medicines from various data sources as well as novel modelling approaches to allow continuous modelling of the benefit-risk along the lifecycle of products and its graphical representation for use by patients, healthcare prescribers, regulatory agencies, and drug manufacturers.
- Testing and validating various methods developed in PROTECT using a large variety of different sources in the EU (including disease registries) in order to identify and help resolve operational difficulties linked to multi-site investigations.
- Disseminating the methodologies developed in PROTECT. This will be enhanced by making use of existing and also developing new training and educational activities.

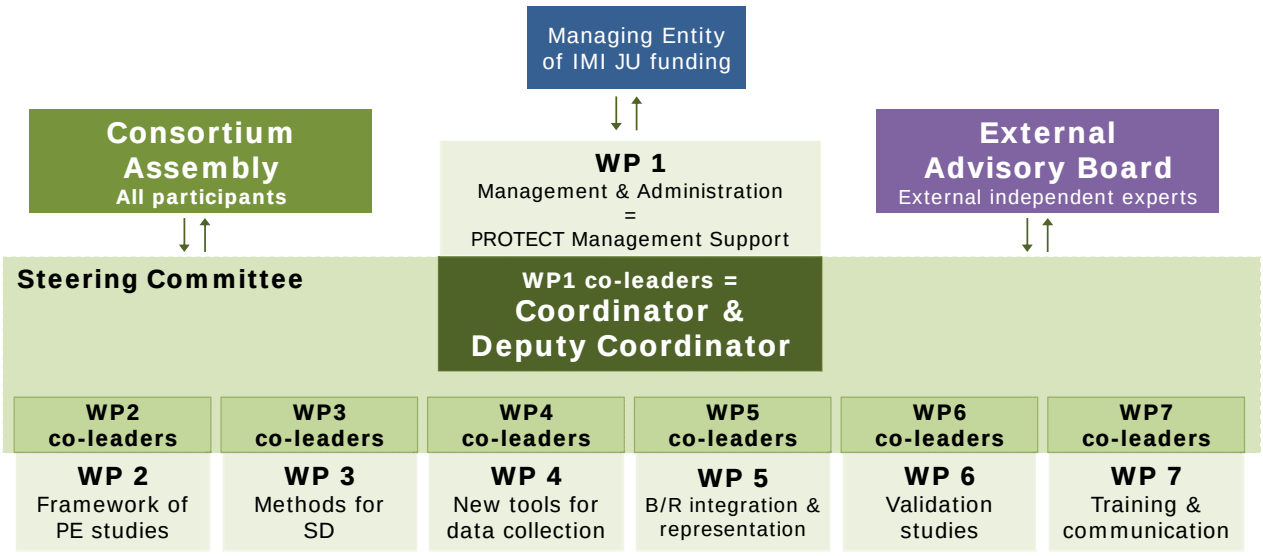
2.3 Who are we?

PROTECT is a multi-national consortium of 34 public and private partners including academics, regulators, SMEs and EFPIA companies with extensive experience in pharmacovigilance.

PROTECT Communication Strategy and Plan



In order to efficiently manage the PROTECT project, the research agenda was split into 7 sub-projects – work packages (WPs) which are complemented by a multi-layer management and governance structure including Consortium Assembly, Steering Committee and external expert group (External Advisory Board). Project coordination and management consists of (Deputy) Coordinator, PROTECT Management Support Team and Managing Entity of the IMI JU funding. The relationship between individual entities is shown in the diagram below.



Seven WPs are subdivided into six scientific (each addressing one of the objectives above) and one managerial packages which are distinct from one another by their specific objectives, their methodologies, the type of data they use and the required expertise, but complimentary with regard to the overall project. These WPs can be described as

- *one WP concerned with the aspects of the organisation and management of PROTECT:*

  WP1: Project management and administration

- *four "vertical" WPs targeting the specific scientific objectives and methodological developments*

  WP2: Framework for PE studies

  WP3: Methods for signal detection

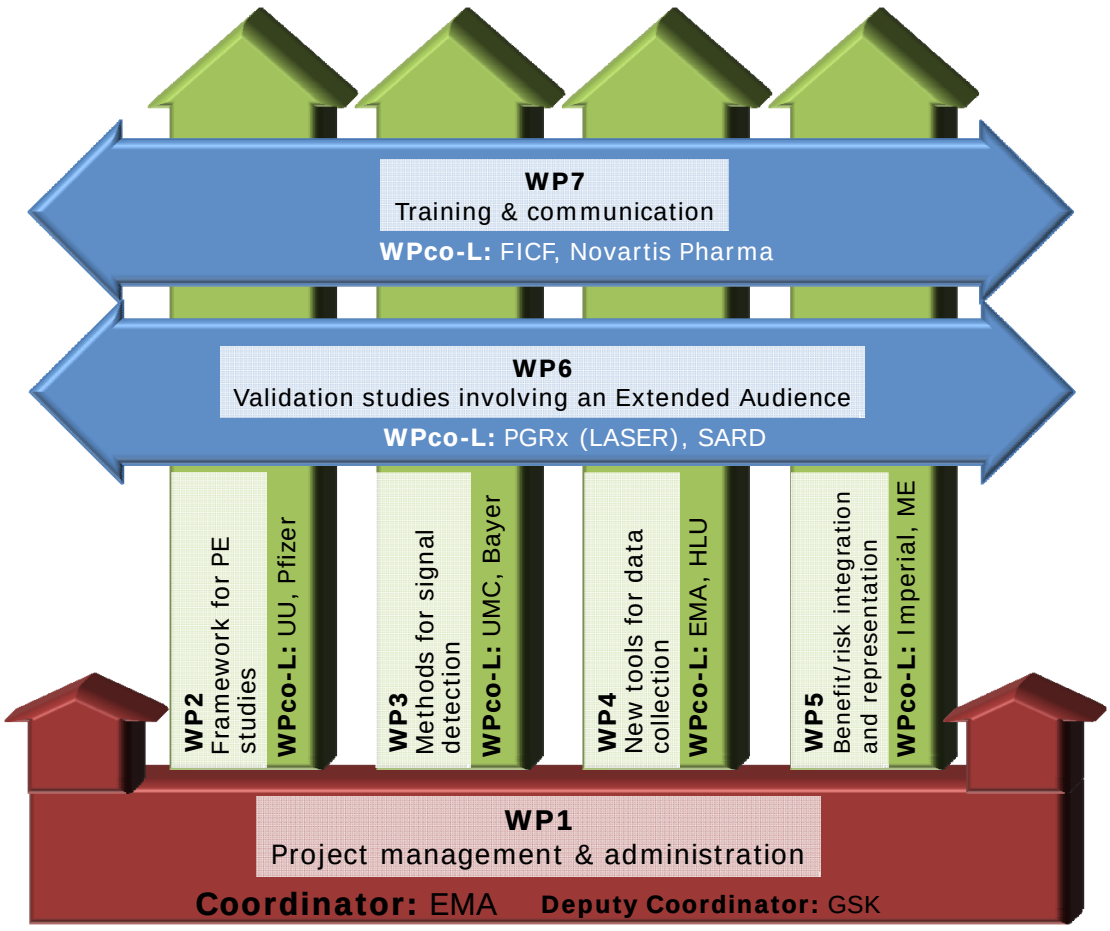
  WP4: New methods for data collection from consumers

  WP5: Benefit-risk integration and representation

- *two "horizontal" WPs concerned with the communication, validation and integration of the scientific work into an integrated and cohesive European activity*

  WP6: Validation studies involving an Extended Audience

  WP7: Training and communication



Common grounds of interest and common goals of consortium partners

- Strengthen the monitoring of the safety of medicinal products
- Enhance the monitoring of the benefit-risk of medicines
- Better evaluate and communicate medicinal products' benefit-risk profile throughout their lifecycle
- Develop modern ways of collecting data on medication, lifestyle and risk factors directly from consumers
- Enhance the early detection and assessment of adverse drug reactions

2.4 Who are they? (the target audience)

PROTECT's target audience can be divided into two subgroups:

- Internal:
  - Consortium members
  - Governance bodies
  - IMI JU
- External:
  - Patients, patients' organizations
  - Clinicians, academic researchers
  - Students of pharmacovigilance
  - SMEs
  - Healthcare professionals
  - EFPIA
  - Pharmaceutical industry
  - Academia
  - EU/national health authorities
  - EU/national regulators
  - EU/national policy makers
  - International organizations
    - WHO
    - ICH
  - Initiatives related to PROTECT objectives (see also Annex A)
    - Observational Medical Outcomes Partnership (OMOP)
    - FDA's Sentinel Initiative
    - PhRMA Benefit-Risk Action Team Initiative (BRAT)
    - European Programme in Pharmacovigilance and Pharmacoepidemiology (Eu2P)
    - European Drug Utilization Research Group (EuroDURG)
    - Exploring and Understanding Adverse Drug Reactions by Integrative Mining of Clinical Records and Biomedical Knowledge (EU-ADR)
  - General audience
    - Citizens
    - Media

PROTECT Communication Strategy and Plan

Target audiences and their interest, impact and opportunities

Stakeholders	Stakeholders' interest(s) in the PROTECT project	Assessment of the impact High / medium / low	Information / communication needs of this stakeholder	Communication opportunities to / with this stakeholder
Consortium members	Knowing in detail what is going on in the project: its progress, future plans	High impact: if they contribute to the project extensively and take over the goals of the project as the goals of their organization. The success of the project depends on them.	Regular update on the progress of the work, decisions of the governance bodies, future plans of the project	Via consortium meetings, work package meetings, personal communication with project coordinator's team; eRoom; project website
Governance bodies	Knowing the general progress of the project and its future plans.	High impact: by fulfilling their role of steering the project into its successful end by providing expertise and advice.	Regular update on the progress of the work	Via consortium meetings; project website; eRoom
IMI JU	Knowing the general progress of the project and its future plans.	High impact: by creating the framework (legal and financial) within which the project can progress, by funding the public participants, by promoting the project's outcome.	Regular update on the progress of the work	Via periodic reports,
Patients and patients' organisations	To improve the monitoring of the safety of medicinal products taking into consideration needs of the patients. To make the patients' voice be heard.	High impact: if they participate in the IMI projects. Medium impact: if they make (other) patients aware of the possibilities of participation in the IMI project	Opportunities of participation in the project. Benefits of the project for patients.	Scientific conferences/seminars/ workshops; website; publications in scientific journals; patients' organisations included in PROTECT; members of the EMA's Patients and Consumers Working Party (PCWP);word of mouth;
Clinicians, academic researchers	Knowing about the project its results and its impact on the state of art in PhV.	Medium impact: by applying the outcomes of the project in their own work; Low impact: by making other researchers aware of the project and its outcomes	Results of the project. Opportunities of participation in the project.	Via: Scientific conferences/seminars/ workshops; website; publications in scientific journals; health care professionals' association included in EMA's Health Care Professionals Working Party (HCPWP);word of mouth;
Students of Pharmacovigilance	Knowing about the project its results and its impact on the state of art in PhV.	Low impact: by making other students aware of the project and its outcomes	Results of the project.	Via: Scientific conferences/seminars/ workshops; website; publications in scientific journals; word of mouth;

Stakeholders	Stakeholders' interest(s) in the PROTECT project	Assessment of the impact High / medium / low	Information / communication needs of this stakeholder	Communication opportunities to / with this stakeholder
SMEs	Knowing about the project its results and its impact on the state of art in PhV.	High impact: if they participate in the IMI projects.	Results of the project. Opportunities of participation in the project.	Via: website, publications in scientific journals; word of mouth;
Pharmaceutical industry (EFPIA)	Knowing about the project its results and its impact on the state of art in PhV.	High impact: if the companies participate in the IMI projects; impact on regulatory activities.	Results of the project. Opportunities of participation in the project.	Via: Scientific conferences/seminars/ workshops; website; publications in scientific journals; word of mouth;
Academia	Knowing about the project its results and its impact on the state of art in PhV.	High impact: by conducting studies on behalf/under contract of the industry; by making their students aware of the project and its outcomes	Results of the project.	Via: Scientific conferences/seminars/ workshops; website; publications in scientific journals; participation in expert committees at national and European levels; word of mouth;
EU / national regulators	Speed up and facilitate the process of drug approval, for instance through direct involvement in the development phase	Great, if they participate in the IMI project, or if they connect to the project as external advisory body	Opportunities for interaction with project leaders. Info of potential role of regulators in the project	Scientific conferences, direct meetings with project leaders, participation in scientific and regulatory meetings at national and European levels.
International organizations	Knowing about the project its results and its impact on the state of art in PhV.	Medium impact: by providing forum where the results could be shared	Results of the project.	Scientific conferences/seminars/ workshops; direct meetings with project leaders
Similar initiatives to PROTECT	Knowing about the project its goals and results	Medium impact: by cooperating with the project the better outcomes can be achieved	Results of the project.	Via: Scientific conferences/seminars/ workshops; website; publications in scientific journals; word of mouth; direct meetings with project leaders
General audience	Knowing about the project its goals	Medium impact: by making other people aware of the project and its goals	Results of the project.	Via: website; word of mouth

3 Communication Objectives

3.1 Main objectives

- Promote project and its participants
- Promote project results and its impact on the state of the art in PhV
- Build synergies with other similar initiatives
- Seek support and advice of healthcare professionals, clinicians and academic researchers

- Secure continued commitment of all partners and seeking new contributions where necessary
- Align all partners between work packages
- Give all consortium partners information required to perform their tasks
- Use synergies between work packages

3.2 Expected impact

- Raise awareness of the project's participants and their involvement in the project
- Raise awareness of the project in its priority target groups,
- Raise awareness of the project's results and its impact on the state of the art in PhV
- Gain target groups' active support and involvement,

4 Communication Strategies

4.1 Key message

PROTECT Tagline:

PROTECT: strengthening the monitoring of the benefit-risk of medicines in Europe

PROTECT Standard text for communications:

The PROTECT project will enhance the monitoring of the safety of medicinal products. It will also contribute to better evaluate and communicate their benefit-risk profile throughout their lifecycle. To this end, innovative tools and methodological standards will be developed. The European Medicines Agency coordinates PROTECT and manages a Consortium of 34 public and private participants.

PROTECT aims at explaining discrepancies between the reported outcomes from pharmacoepidemiology studies by studying combinations of drugs and adverse events in several databases. It will identify and further explore sources of variability that may currently affect drug safety studies. Modern ways of collecting data on medication, lifestyle and risk factors directly from consumers using internet and telephony will also be explored. The ability of these systems to collect regular, accurate and complete reporting without the intervention of health professionals will be tested. Good practice recommendations for the detection of safety signals are developed based on extensive testing of existing and new methods, creation of a database of known adverse drug reactions, and exploring the use of electronic health records and clinical trials data. In addition, PROTECT will use new modeling approaches to integrate existing information from various data sources to facilitate and enhance the continuous monitoring of the benefit-risk of medicines.

PROTECT Success stories:

For example:

WP2 has created a unique Drug Consumption Databases (Inventory on Drug Utilisation). Information is available on Denmark, Finland, France, Germany, Italy, Netherlands, Norway, Poland, Spain, Sweden and United Kingdom. It describes the characteristics of non-commercial drug consumption data providers in Europe, with special emphasis on pricing and reimbursement agencies. It reports the features of each country health policy systems and lists several pharmaceutical data sources. It includes a brief summary of data provided by Intercontinental Marketing Services (IMS Health).

4.2 Communication opportunities

PROTECT communication opportunities include:

- At launch of the project
  - press release
  - launch of website
- During the implementation of the project
  - Key events conferences/events organised by third parties or target audiences (see Annex B)
  - IMI periodic events (info days, stakeholders' forums, etc.)
  - Deliverables (results) (see also Annex E)

4.3 Roles and Responsibilities

WHO PREPARES	COMMUNICATION TASK
Steering Committee	• Communication strategy and dissemination policy • Approval for project publications on partners' websites • Preparing input for the IMI Scientific Committee,
Coordinator	• Spokespersons for media, • IMI conferences, • Liaison to IMI Executive Office communication team • Identification of communication opportunities and target audiences
Project Consortium	• Approving publications and presentations and annual reports
Communication group (*Work package 1*)	• Drafting press releases, newsletter, project leaflets etc. • Keeping the Communication Plan and web site updated
WP Leaders	• Ensure timely dissemination of outcomes of their WP • Responding to ad hoc questions, • Review and approval of scientific publications and conference presentations Input on progress and achievements • Drafting, editing and approving scientific articles and presentations • Initiate publications on success stories, support drafting of communication materials as appropriate • Disseminate project achievements at scientific conferences etc.
Communication experts from partner organisations	• Provide info on company, logo and other visual identity/visuals as appropriate
IMI Executive Office Communication Team	• General guidance on Communication • Providing overall IMI key messages • Providing helpful communication material (brochures, slide sets …) • Approval + advise on draft project publications

4.4 Tracking of the Communication

The PROTECT Management Support Team has put in place a Presentation and Publication Tracking Tool. Tracking tables for presentations and publications of results are held by the PROTECT Management Support Team in house (at EMA) and also online (restricted to participants) at the PROTECT eRoom. The tables are updated on an on-going basis to always reflect the current status as regards planned,

submitted and published/held journal publications and presentations as well as any other dissemination of project results or to present the project in general.

5 Tactics / Communication Channels and Tools

5.1 Communication tools and channels

1. Personal interactions: Personal contacts, professional contacts

All partners are encouraged to engage in the interactions to promote the project.

2. Events: Standard presentations, conferences, workshops, seminars, training materials

WP co-leaders of relevant work package decide when to present the project or its results. It is also at the discretion of WP co-leaders to nominate the presenter(s). Each presentation containing new results has to be approved by the Consortium before going public (see PROTECT publication policy in Annex D). The notification of the presentation held has to be recorded in the project's presentation tracking table, and the presentation saved in eRoom.

3. Publications: Articles, open access publications, newsletters, e-articles, brochures/flyers.

WP co-leaders manage publication activities of their work package and regularly inform the Steering Committee of their activities. Publications containing new results have to be approved by the Consortium before going public (see PROTECT publication policy in Annex D). The notification of the planned/submitted/accepted publication has to be recorded in the project's publication tracking table. The published publication has to be saved in eRoom.

4. Press releases:

The EMA released a first press release at the launch of the project.

5. Website:

The PROTECT website is used for external communication only. The PROTECT management support team is responsible for keeping it up-to-date and for managing its content, with the project coordinator being the final approver.

The PROTECT web portal is available at http://www.imi-protect.eu and includes three components:

1. A webpage accessible to the general public that provides a general presentation of the project, its research programme and status, as well as the participants involved. Deliverables for public use and public consultation are posted on the webpage for dissemination. The PROTECT website consists of a number of sections:
    - Homepage with brief description of the project and latest news
    - 'About PROTECT' section with more detailed description of project's goals and project's composition
    - 'Objectives' section describes the main objectives of the project.

- o 'Governance structure' section describes the different governance bodies of the project and their roles.
- o 'Partners' section provides brief description of the organizations and key staff involved in the project.
- o 'Work programme' section describes the 7 work packages and their interactions.
- o 'Results' section provides overview of what the project has accomplished so far.

2. A password protected domain with access only for participants in PROTECT (eRoom). The eRoom serves as a forum to post and exchange information and announcements aimed at PROTECT participants only, including internal guidance documents, meeting dates, arrangements and minutes, other group or WP specific information, and documents for consultation by PROTECT members. Documents can be shared whilst ensuring version control;

3. A platform for training opportunities; this platform will be accessible to PROTECT participants looking for training opportunities within the Consortium, as well as to the members of the Eu2P consortium (the IMI funded project in response to the 1st IMI Call, topic no. 18, call identifier: IMI_Call_2008_1_06) as a possible source of training resources for the Masters programme and the PhD programme on benefit-risk communication.

The website is hosted by the European Medicines Agency with the eRoom being maintained by Bayer.

6. Social media:

Currently, WP4 is planning to use social media (Facebook) for promoting their study and recruiting women.

The PROTECT Management Support team is planning to use social media (Twitter, LinkedIn, Facebook) to promote PROTECT to a general audience.

7. Other internal communication tools:

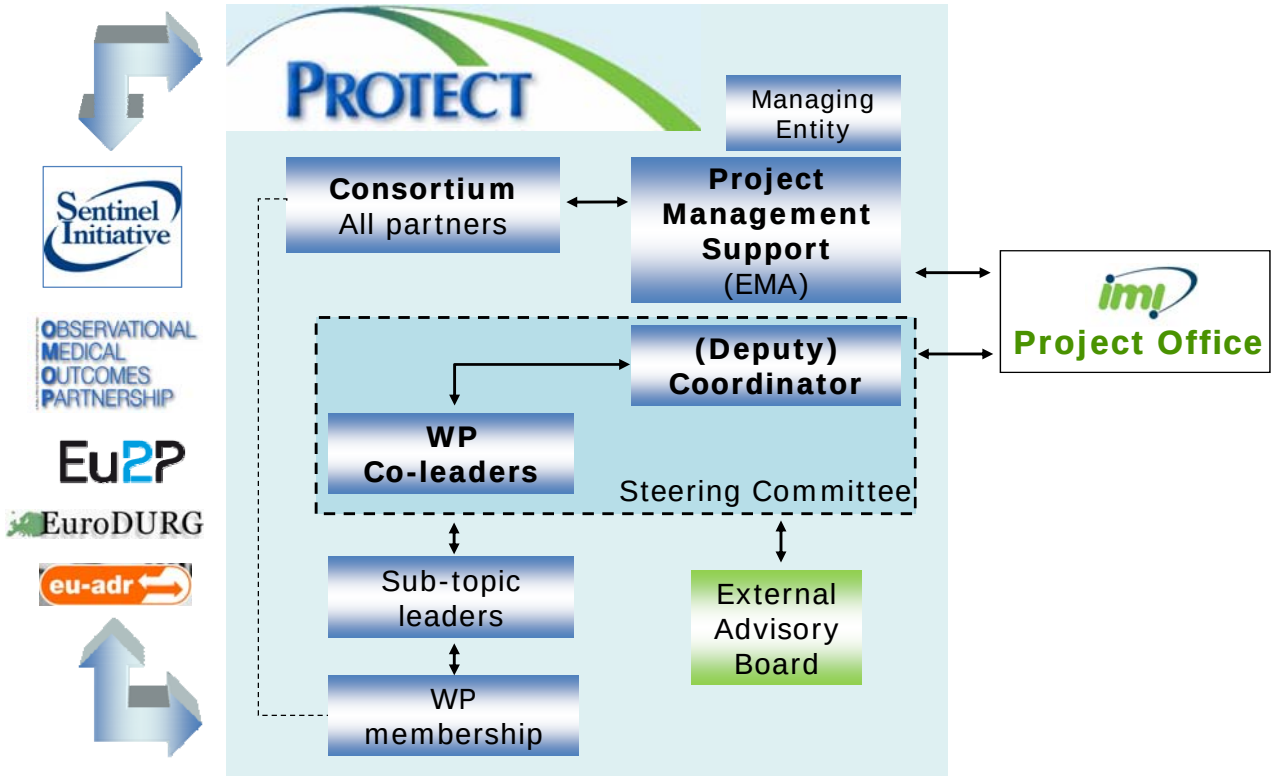
Day-to-day communication within the consortium is mainly based on electronic means. In order to ensure a smooth interaction and exchange of information within the consortium, means and routes for communication have been agreed and established as follows:

- **PROTECT support inbox:** A central email address is used for communication from and with the Coordinator or Management Support Team (protect_support@ema.europa.eu). Participants may use this address to provide information e.g. in relation to publications or reporting, or in case of technical, administrative or financial queries.
- **PROTECT eRoom:** A forum and electronic document management system is used as a central accessible document repository, discussion forum to facilitate group related communication, as well as for sharing of documents and remote editing of documents with version control. The eRoom is available at the PROTECT website or directly at https://eroombayer.de/eRoom/. It is open to all individuals participating in PROTECT who can request an invitation from the Management Support Team. Groups are created to enable specific exchange of the different bodies and WP in PROTECT. The full content of the eRoom is accessible even if an individual is actually not a member of a specific group; however, in that case documents will only be available in 'read-only' mode, thereby preventing unauthorised and uncontrolled involvement of non-members. It is possible to activate notifications for any activities or changes to the eRoom or a particular part of it.

- **Partners' database and email distribution lists:** A central partners' database is kept by the Management Support Team comprising details of all individuals involved. The list provides information, if available, on the contact details (email, telephone, fax, and postal address), job title, affiliation and involvement in WPs or other PROTECT bodies. The list as well as email distributors for all governance bodies and Work Packages are available through the eRoom to all consortium members.

In addition to the above-described routes of communication, regular meetings of the Work Packages and their sub-groups, the Steering Committee and the Consortium Assembly ensure a continuous knowledge and information flow within the Consortium. The type and frequency of meetings during the course of the project reflects what is needed to ensure effective governance and exchange of information. Modern technology is used in the form of virtual meetings where appropriate to facilitate frequent communication between participants. Meeting minutes including tables of decisions are placed on the eRoom and are accessible to all participants whether or not they form part of the respective body or group. In case of decisions by the governance bodies, such as adoption of guidance or policies, or other information of general application, in addition to placing the information on the eRooom, an email notification is sent by the (Deputy) Coordinator or Management Support Team to all participants.

Illustration of the communication and interaction routes within the Consortium and between the Consortium and external programmes and bodies:



Within PROTECT, the WPs operate to a large extent independently as regards the execution of their work programme. Communication between individuals who together perform the work of a sub-package to a WP is led by the respective sub-package leader who is reporting to the respective WP co-leaders. The

WP co-leaders interact with the sub-package leaders as well as individual participants as necessary and report to the (Deputy) Coordinator and the Steering Committee during the regular SC meetings. The SC is also the point of interaction with the External Advisory Board.

In case of any general issues or administrative or financial issues participants should communicate directly with the Coordinator or the Management Support Team using the PROTECT Support email address.

If the (Deputy) Coordinator and/or the Support Team need to communicate to the Consortium or a specific participant, the nominated scientific, administrative and/or legal contact person, as appropriate, should be involved. In case of written adoption of revisions of legal documents, the participants' authorised persons will be addressed. On request by a participant, also other persons can be included such as administrative or managerial support. When communicating with the Work Packages, the (Deputy) Coordinator and/or the Support Team should involve all co-leaders including the alternates as well as the managers and administrative support, if available.

If necessary, the Support Team will liaise with the Managing Entity of the IMI JU funding.

Interaction with **other research programmes** can in principle be initiated by any participant. The (Deputy) Coordinator and the SC should be informed and should be involved in the initial phase. Once the contact is established, relevant WP co-leaders and other participants and individuals of the consortium should be involved. The (Deputy) Coordinator and the SC should be updated by the lead contact from PROTECT on a regular basis. International and European initiatives similar to the project are listed in Annex A.

Correspondence with the **IMI JU office** is restricted to the Coordinator and the Managing Entity of the IMI JU funding through contacts defined in the grant agreement. The PROTECT Support team will forward any request of the IMI JU to concerned participants, collect all information in relation to the periodic project reporting and dissemination of results etc and forward the compiled information as well as any individual requests to the IMI JU project office.

5.2 Validation/approval for all communications

Approval for all communications is governed by the PROTECT Publication policy (see Annex D) which adheres to the IMI JU rules for communications and which was adopted by the PROTECT Steering Committee.

There are three different routes for approval of communications:

A. ***approval by the whole consortium*** (publications, presentations, abstracts)
   Each publication/presentation/abstract which includes new results has to go through a Consortium review as specified in the PROTECT publication policy (see PROTECT publication policy in Annex D)
B. ***approval by the PROTECT coordinator*** **and SC (if needed)** (website, press releases, interactions with other research programmes in first instance)
   Decisions regarding updates of the PROTECT website, issuing of a new press release and interaction with a new research programme are at the discretion of the PROTECT Coordinator and deputy Coordinator.
C. ***approval by WP co-leader(s)*** (personal interactions, interactions with other research programmes in second instance)
   It is at the discretion of WP co-leaders to initiate and give approval for personal interactions of WP members with external audiences. Once the PROTECT (deputy) coordinator decides on interaction

with a new research programme it is up to the WP co-leaders to manage further collaboration with research programmes relevant to the WP.

5.3 Visual identity and acknowledgements

1. Project Logo

- The PROTECT logo is used on all communications (articles, project websites, presentations, flyers, press releases etc.).
- In addition, the **IMI, EU and EFPIA logos** are also included on all communication products.
- **Project participants' logos** are used on PROTECT website and may be used on communication products (such as posters, presentations, etc.) where relevant participant significantly contributed to the communication product.

2. Templates

Templates for project's presentations, meeting agendas and minutes, posters, leaflets, etc. are available on eRoom.

3. Acknowledgements

All publications or any other dissemination relating to the project shall include the acknowledgement statements as instructed in the PROTECT publication policy (see PROTECT publication policy in Annex D)

6 Budget for Communication

Communication budget (funds covering attendance at conferences, preparation of publications or presentations, etc.) is part of the budgets of individual PROTECT participants. Governance meetings are organized by the PROTECT Coordinator (EMA). All eligible costs incurred by PROTECT participants with relation to PROTECT communication activities are reimbursable by IMI JU.

ANNEXES

A. List of international and European initiatives similar to the project

Name of the initiative	Short description and mission	Potential synergy with your project
Observational Medical Outcomes Partnership (OMOP)	The partnership is conducting a two-year initiative to research methods that are feasible and useful to analyze existing healthcare databases of patient medical records and health insurance claims to identify and evaluate safety and benefit issues of drugs already on the market.	Common interest areas e.g. comparing the outcome of the investigations related to the selected drug-event pairs in OMOP and PROTECT WP2 and exploring differences between the US and Europe as regards the databases used or safety issue detected.
FDA's Sentinel Initiative	The Initiative aims to develop and implement a national electronic system to improve tracking of reports of adverse events linked to the use of FDA-regulated medicinal products. The Sentinel system would enable to simultaneously query diverse automated healthcare data holders like electronic health record systems, administrative and insurance claims databases, and registries to evaluate possible medical product safety issues more quickly and securely.	Sentinel and PROTECT are complementary and it will be useful to exchange information as regards the characterisation and differences of the databases used.
PhRMA Benefit-Risk Action Team Initiative (BRAT)	The objective of the Initiative is to establish a structured, transparent benefit/risk framework to be integrated into the regulatory approval process. The BRAT framework is a set of processes and tools to guide decision-makers in selecting, organizing, interacting with and summarizing data relevant to benefit-risk decisions. Three main steps apply: (1) customizing relevant benefit and risk attributes into a value tree; (2) completing the data source table; and (3) associating elements from the data source table to the tree.	The strongest area for collaboration between BRAT and PROTECT would be how best to communicate the output from benefit/risk evaluation especially to patients and as regards the work being conducted in PROTECT WP5 on graphical representation as well as the efforts of BRAT on how to systematically incorporate patient preferences.
European Programme in Pharmacovigilance and Pharmacoepidemiology (Eu2P)	The project focuses on the development of courses in PhV and PE for both specialists and non-specialists with the possibility of specialization in benefit/risk assessment, regulatory aspects, risk quantification, public health and risk communication. The Eu2P e-learning platform will enable to combine face-to-face lectures with web based learning using a modular approach.	WP7 in PROTECT will closely work together with Eu2P aiming at integrating the methodologies and recommendations developed under PROTECT in the various training programmes of Eu2P.
European Drug Utilization Research Group (EuroDURG)	EuroDURG's mission is "to promote drug utilization research as a means to improve use of drugs by providing an	A collaboration has been established with PROTECT's WP2-WG3 (Drug utilisation) to exchange information and

	international forum for communication and cooperation between people interested in drug utilization research". EuroDURG's focuses on classical drug monitoring at national levels as well as quantitative research in drug use, and intervention research to improve the quality of prescribing with special focus on prescribing quality indicators.	experience with a particular view to the work done in PROTECT regarding the overview of drug consumption databases.
Exploring and Understanding Adverse Drug Reactions by Integrative Mining of Clinical Records and Biomedical Knowledge (EU-ADR)	The project aims to develop an innovative computerized system to detect adverse drug reactions (ADRs), supplementing spontaneous reporting systems. To achieve this objective, EU-ADR will exploit clinical data from electronic healthcare records (EHRs) of over 30 million patients from several European countries.	EU-ADR has kindly agreed to share with PROTECT WP3 work done on disease mapping, coding and grouping of medical terms. A further exchange, including statistical signal detection such as Baysian methods, is envisaged.

B. List of key conferences/events relevant to project

- DIA Annual EuroMeeting
- DIA Annual meeting
- World Drug Safety Congress Americas
- ISPE Mid-year meeting
- ISPE Annual meeting
- ICPE
- Post-approval Summit - Harvard Medical School/Outcome
- ISPOR Annual Int'l Meeting
- ISPOR Annual European Congress
- HTAi (Health Technology Assessment International) Annual Meeting
- North American Congress of Epidemiology
- ISoP Annual Meeting
- World Drug Safety Congress Europe
- EUFEPS PharmSciFair
- ENCePP Plenary
- Etc.

C. Important contact details for PROTECT

Name (role)	Contact details	Area
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Xavier Kurz (Coordinator representative, EMA scientific lead)	xavier.kurz@ema.europa.eu	*scientific or general coordination*
Elizabeth Swain (Deputy Coordinator representative, GSK scientific lead)	Elizabeth.J.Swain@gsk.com	*scientific or general coordination, particularly EFPIA*
Jim Slattery (Alternate Coordinator representative)	jim.slattery@ema.europa.eu	*replaces Coordinator repr. in absence*

PROTECT Communication Strategy and Plan

Name (role)	Contact details	Area
Laurent Auclert (Alternate Coordinator representative, SARD scientific lead)	laurent.auclert@sanofi-aventis.com	*replaces Deputy Coordinator repr. in absence*
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Managing Entity of the IMI JU funding		
Anne Marie Clemensen (primary financial contact)	AMC@dkma.dk	*IMI funding account*
IMI JU project office		
Fatiha Sadallah (PROTECT project officer)	Fatiha.Sadallah@imi.europa.eu	*general, GA Annex I, progress reporting*
Antoine Juliens (IMI Financial Manager)	Antoine.Juliens@imi.europa.eu	*payments* *financial guidance*
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D. PROTECT Publication Policy

PROTECT Publication Policy - Revision 2.pd

E. List of main deliverables

WP involved	Deliverable	Delivery date*	Means of communication
1	PROTECT Management Plan	Oct-10	Submission to Consortium Assembly; submission to IMI
1	PROTECT web portal	Sep-09	Internet access
1	Periodic report incl. financial report	Oct-10; Oct-11; Oct-12; Oct-13; Oct-14	Submission to Consortium Assembly and to IMI JU
1	Publication Record	Oct-10; Oct-11; Oct-12; Oct-13; Oct-14	Submission to Consortium Assembly and External Advisory Board
1	Communication plan	Aug-14	Submission to Consortium Assembly and to IMI JU
2	Select Key AE-drug pairs	Mar-10	eRoom, SC, CA; PROTECT web;
2	Study protocols for pilot PE studies	Mar-12	eRoom, SC, CA; PROTECT web;
2	Conduct pilot PE studies	Feb-13	eRoom, SC, CA; PROTECT web; publications to external audience
2	Develop Inventory on drug utilisation data	Aug-14	eRoom, SC, CA; PROTECT web; publications to external audience
2	Develop Methods to control for confounding	Feb-14	eRoom, SC, CA; PROTECT web; publications to external audience
2	Public health impact analysis of ADRs	Feb-14	eRoom, SC, CA; PROTECT web; publications to external audience
2	Analysis of discrepancies between studies	Feb-14	eRoom, SC, CA; PROTECT web; publications to external audience
2	Develop Statistical methods for multi-database studies	Feb-14	eRoom, SC, CA; PROTECT web; publications to external audience
2	Guidelines for PE and drug utilisation studies	Aug-14	Guidelines and methodological standards to be presented to scientific community and industry for conceptualization of PE studies.
3	Evaluation of disproportionality analysis	Feb-13	eRoom, SC, CA; PROTECT web; publications to external audience
3	Risk estimates compared with disproportionality statistics	Feb-13	eRoom, SC, CA; PROTECT web; publications to external audience
3	ADR Repository	Aug-14	eRoom, SC, CA; PROTECT web; Presented at International Conference on Pharmacoepidemiology & Therapeutic Risk Management 2011 and at Medical Informatics Europe 2012
3	Recommendations (Report of analyses using signal detection methodologies in international, national and EFPIA databases.)	Aug-14	eRoom, SC, CA; PROTECT web; Presented at International Conference on Pharmacoepidemiology & Therapeutic Risk Management 2012; publications to external audience
3	Existing ADR terminologies	Mar-12	eRoom, SC, CA; PROTECT web; presented at International Conference on

			Pharmacoepidemiology & Therapeutic Risk Management 2012 and at Medical Informatics Europe 2012
3	Novel groupings for ADRs	Feb-14	eRoom, SC, CA; PROTECT web; presented at ACM International Health Informatics Symposium 2012, at MIE - Medical Informatics Europe 2011, 2012
3	Other Information to enhance signal detection	Feb-14	eRoom, SC, CA; PROTECT web; publications to external audience
3	Subgroups and risk factors	Feb-14	eRoom, SC, CA; PROTECT web; publications to external audience
3	Signal detection based on SUSARs	Oct-13	eRoom, SC, CA; PROTECT web; publications to external audience
3	Signal detection in EHRs	Aug-14	eRoom, SC, CA; PROTECT web; publications to external audience
3	Drug-drug interaction	Feb-14	eRoom, SC, CA; PROTECT web; publications to external audience
3	Duplicate detection	May-13	eRoom, SC, CA; PROTECT web; publication to external audience
4	Development of study protocol	Mar-12	eRoom, SC, CA; PROTECT web;
4	Recruitment tools	Apr-12	eRoom, SC, CA; PROTECT web; recruitment web; Printed leaflet and content of publicly accessible web-page
4	Development of data collection platform	May-12	eRoom;
4	Ethical approval	May-12	eRoom, SC; PROTECT web;
4	Development of linkage methodology	Jul-11	eRoom, SC; PROTECT web;
4	Completion of data cleaning	Oct-13	eRoom, SC
4	Preparation of datasets	Jan-14	eRoom, SC
4	Report on results of data collected directly from pregnant women including comparative evaluation with data from other databases	Aug-14	eRoom, SC, CA; PROTECT web; publication to external audience
4	Exploration of feasibility of linkage with malformation regstries	Aug-14	eRoom, SC, CA; PROTECT web; publication to external audience
4	Report describing 1) the user requirements and formats for consumer-based tools, 2) the assessment of the efficiency, usefulness of and satisfaction with these tools, 3) recommendations on future development to facilitate the collection of drug utilisatio	Aug-14	eRoom, SC, CA; PROTECT web; publication to external audience
4	Report on transferability of methodology to other target populations and pharmacovigilance situations	Aug-14	eRoom, SC, CA; PROTECT web; publication to external audience
5	Develop framework for benefit-risk analyses	Jun-10	eRoom, SC, CA;
5	Review of methodologies used to model effects of medicines, elicidation of preferences and integrating effects and preferences	Jul-11	eRoom, SC, CA;
5	Review of and reporting on methodologies for graphical representation	Mar-12	eRoom, SC, CA; PROTECT web; publication to external audience
5	Determine and gather data for case studies	Jun-12	eRoom, SC, CA; PROTECT web; publication to external audience
5	Carry out case studies (wave 1 + 2)	Aug-12	eRoom, SC, CA; PROTECT web; publication to external audience
5	Further methodological development as necessary to finalise tools for benefit-risk integration and representation	Dec-12	eRoom, SC, CA; PROTECT web; publication to external audience
5	Deliver recommendations on methodologies for B-R integration and representation	Dec-12	eRoom, SC, CA; PROTECT web; publication to external audience (in the

			medical and statistical literature.)
5	Develop protocol for validation studies	Nov-12	eRoom, SC, CA; PROTECT web;
5	Writing of reports and scientific publications	Feb-13	eRoom, SC, CA; PROTECT web; publication to external audience
6	Establishment of database of interest	May-11	eRoom, SC, CA;
6	Establishment of a list of data sources in the Extended Audience	Apr-11	eRoom, SC, CA; PROTECT web;
6	List of outcomes for validation	Aug-11	eRoom, SC, CA;
6	Establishment of a new revised Extended Audience	Apr-11	eRoom, SC, CA; PROTECT web;
6	Study protocols, work plan and budget proposals	Aug-12	eRoom, SC, CA;
6	Participating centres identified	Aug-12	eRoom, SC, CA; Submission IMI JU
6	Conduct of studies	Aug-13	eRoom, SC, CA;
6	Results of validation studies	Feb-14	eRoom, SC, CA; PROTECT web; publication to external audience
6	Revised recommendations and methodological standards	Aug-14	eRoom, SC, CA; PROTECT web; Submission to IMI JU; publication to external audience
7	Questionnaire on training needs and opportunities	Nov-08	eRoom, SC, CA;
7	Platform of Training Opportunities	Dec-10	eRoom, SC, CA; PROTECT web; Submission to IMI JU; available to external audience
7	List of deliverables agreed with Eu2P Consortium	Aug-14	eRoom, SC, CA; PROTECT web; Eu2P
7	Training modules developed with Eu2P Consortium	Aug-14	eRoom, SC, CA; PROTECT web; Eu2P; training modules

* Note: Delivery date as reported with 3rd interim report (March 2012)