IMPRESS: ECPA funded project 'Improving exposure assessment methodologies for epidemiological studies on plant protection products'

Project governance v2

Document dated:
Version 2 (final): 16th February 2020

Changes made to Version 1

- Section 2: Minor edits to reflect Advisory Board has been convened.
- Appendix 1, Section B, point 7. Addition of "(or their delegate)"
- Appendix 1, Section B, new point 8. Concerns Advisory Board member attendance to the IOM / ECPA progress teleconferences.
- Appendix 1, Section C, point 3. Addition of text to reflect number of participants for quorum.
- Appendix 2, Section D, point 1. Addition of sentence identifying where details of teleconference procedures can be obtained.
- Appendix 2, new Section G. This details the procedures in the event of progress meetings held via teleconference.
- Appendix 2, new Section H. This details the procedures when responding to formal written comments from ECPA.

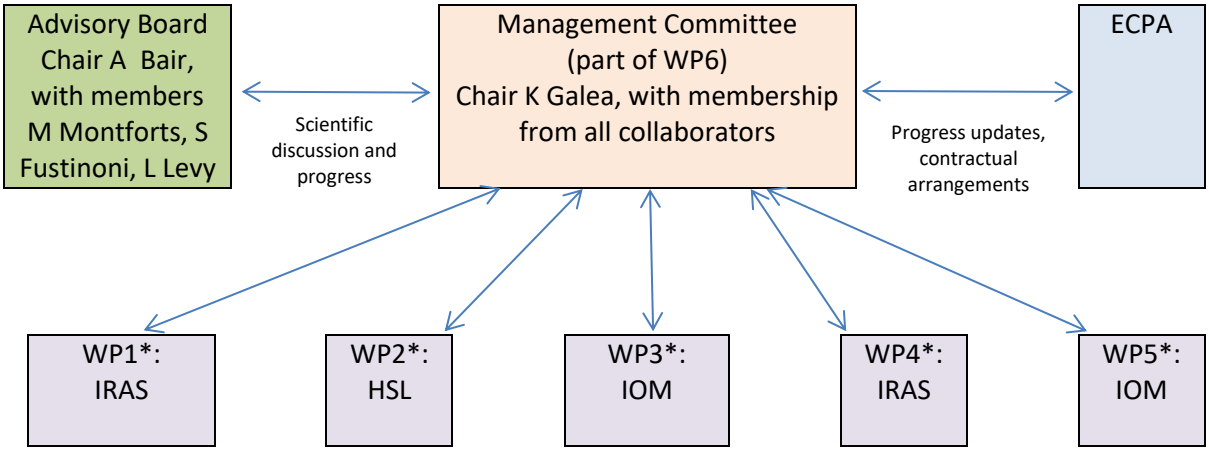
The contents of this document have been agreed upon by:

- the research team (Institute of Occupational Medicine (IOM), Institute of Risk Assessment Sciences, Utrecht University (IRAS); Health and Safety Laboratory (HSL) and the Centre for Occupational and Environmental Health, University of Manchester (CEOH (UoM))),
- representatives of the European Crop Protection Association (ECPA), the project Sponsor, and
- the current independent Advisory Board.

1. Remit of document

The IOM and all the project collaborators (IRAS, HSL and CEOH (UoM)) are committed to undertake research projects in an independent and impartial manner, publically making available the research findings in a transparent manner. This is particularly important when funding is from an industry source where potential conflicts of interest may be perceived by the wider scientific community and other stakeholders.

The purpose of this document is to clearly define the roles, responsibilities and interactions of the key actors within the ECPA funded project, these being the essential independent Advisory Board, the project collaborators (IOM, IRAS, HSL and CEOH (UoM)), (represented by the Management Committee) and representatives of the Sponsor (ECPA). These relationships are summarised in Figure 1 and expanded upon in the subsequent sections.



* WP lead collaborator stated

Figure 1: ECPA project structure

2. Advisory Board

In the proposal we stated:

"The project consortia propose to establish one or more project Advisory Boards that will provide independent scientific advice and stakeholder input to the project. We consider that the (scientific) Advisory Board should consist of 3-4 independent scientific experts….<removed possible names>*…. Travel and subsistence for their attendance at any in-person meetings will be covered by the project. In addition, we also propose to set up a separate stakeholders group, inviting representatives of ECPA and EFSA and other bodies to provide input into the project".*

The Management Committee have convened one completely independent Advisory Board for the project, the Terms of Reference being specified in Appendix A. No separate stakeholder group will be convened.

Invitation to join and membership of the Advisory Board will be solely at the prerogative of the Management Committee. The Advisory Board will decide who will Chair and act as deputy Chair from those invited to participate on the Advisory Board.

3. Working / Liaison with ECPA

In the proposal we stated:

"The PL will regularly report technical and financial progress during the course of the project, in a format and frequency to be agreed with ECPA. It is considered that at least four in person meetings will be held with ECPA in Brussels (kick–off meeting, report progress at end of Year 1, 2 and also final project meeting) and that these meetings will involve representatives from all project collaborators. It is likely that in addition to these formal meetings, communications will be via email or teleconference. Appropriate contractual arrangements in relation to the project will also be put in place".

To ensure that the independence, impartially and integrity of the project is protected it is vital that there is a clear understanding of the engagement and interactions between the Management Committee and ECPA of what will and will not be discussed. Our proposal, in relation to contractual, financial and reporting obligations is presented in Appendix B.

4. ***Working with the consortium***

In the proposal we stated:

"A project Steering Committee (SC) [1]*, led by the overall PL, and involving a representative from each consortium organisations will be established. The role of the SC is to ensure that the aims and objectives of the project are realised across all the WPs in an efficient, streamlined, timely and cost effective manner. The project team will convene regularly to discuss technical progress in relation to project aims and objectives and timescales. The team make use of web-conferencing facilities where required and will communicate regularly via email. It is anticipated that several in-person meetings will be held by the SC at key stages of the project (e.g. kick-off)".*

Karen Galea (IOM) will be the overall PL. Representatives from each collaborator who will sit on the Management Committee are: Roel Vermeulen and Hans Kromhout (IRAS); Kate Jones and Anne Helen Harding (HSL); Andrew Povey and Martie van Tongeren (CEOH, UoM); Ioannis Basinas and John Cherrie (IOM).

[1] This is now referred to as the Management Committee

Appendix 1: Advisory Board Terms of Reference

Role and Purpose

To provide independent and impartial expert advice to the Management Committee (IOM, IRAS, HSL, CEOH (UoM)) on the ECPA funded project 'Improving exposure assessment methodologies for epidemiological studies on plant protection'.

A. Members, Chair, Attendees, Secretary, Terms of Office

1. The Advisory Board is not a legal entity, and members of the Advisory Board will not have legal or contractual responsibility for the project or the information associated with it.

2. The Advisory Board will normally consist of 4 members.

3. Membership will be invited scientific / academic experts in the field of epidemiology, biomonitoring and exposure assessment in the field of pesticides and health.

4. Advisory Board members will be asked to declare any conflicts of interest (COI) (Appendix 3) and to advise the Management Committee of any changes to this during the lifespan of the project. Declarations of any COI will also be made at the start of Advisory Board meetings.

5. Invitation to join and membership of the Advisory Board will be at the prerogative of the Management Committee.

6. The Advisory Board will nominate the Chair and Deputy Chair of the Board, each of whom will serve in this post for the duration of the project.

7. The current Chair, Deputy Chair and members of the Advisory Board are, as discussed at the 1st Advisory Board meeting, 15th December 2017:

Role in AB	Name	Affiliation	Primary area(s) of expertise in relation to project
Chair	Aaron Blair	National Cancer Institute (USA)	Epidemiology, exposure assessment
Deputy Chair	Mark Montforts	RIVM (The Netherlands)	Regulatory science, risk assessment, toxicology
Member	Silvia Fustinoni	University of Milan (Italy)	Biomonitoring, epidemiology
Member	Len Levy	Cranfield University (UK)	Occupational and environmental toxicology

8. Members can publically disclose their role on the Advisory Board.

9. Members may terminate their role in the Advisory Board in writing (by email or letter) to the Chair. A replacement will be arranged at the prerogative of the Management Committee, following advice from the Advisory Board.

B. Duties of the Advisory Board

1. To advise on the development and implementation of the Description of Work (DOW) for the project[2] so to ensure that the project objectives are achieved and delivered by providing appropriate and constructive guidance in relation to the overall shape and direction of the research programme.

2. To monitor project progress and advise on any issues or problems arising during the course of the project.

3. To advise on the development of policies, protocols and procedures associated with the collection, use and disclosure of data within the project.

4. To advise on publications and other outputs (e.g. protocols) arising from the project, with a view to ensuring timely publically availability of relevant data. To ensure process transparency and results integrity, all main publications of the project will be distributed to the Advisory Board for final review prior to submission and following comments from ECPA.

5. To comment on reports to ECPA (non-financial), protocols and publications to be submitted for peer-reviewed publication from the project.

6. To attend the Advisory Board meetings, which will normally meet once a year.

7. The Advisory Board Chair (or their delegate) will also be invited to chair project progress meetings held between the Management Committee and ECPA. These meetings will be held separately to the Advisory Board meetings (and discussed in Appendix 2). The intention would be that the Advisory Board and ECPA meetings would be held back-to-back to minimise travel commitments and costs. Acceptance of this invitation is at the discretion of the Advisory Board Chair.

8. The Advisory Board Chair (or their delegate) will also be invited to attend and Chair project progress meetings between the IOM (as representatives of the Management Committee) and ECPA, which are held on a quarterly basis via teleconference. These teleconferences are typically 1-1.5 hours in length.

C. Meetings: Frequency, Quorum, Duration

1. The work of the Advisory Board will be based to some extent upon virtual communication and consultation. However, it is anticipated that the Advisory Board will meet face-to-face with representatives of the Management Committee at least once a year.

2. In-person meetings will typically take up no more than one working day and will be scheduled to take place in Europe at a location convenient for travel.

3. Quorum for meetings will be attendance by a simple majority (currently three) of Advisory Board members including the presence of either the Chair or Deputy Chair.

4. The Advisory Board will remain in place for the lifespan of the project. The project was originally foreseen to be 3 years (upon signing of contract), however this has been formally

[2] The Description of Work (DOW) for the project has been drafted, with detailed project protocols produced.

extended by an additional year. The Advisory Board may be extended in the event of the project timescales being further extended or scientific publications being drafted beyond the timeframe of the project.

D. Administration

1. The Project Leader (or their assigned deputy) shall be responsible for arranging the administrative support for the Advisory Board meetings.

2. The agenda for all meetings will be circulated two weeks in advance of the meetings.

3. Papers for all meeting shall be made available to the Advisory Board members no later than one week in advance of the meeting.

4. The project leader (or their assigned deputy) shall record the minutes of every meeting; such minutes being circulated, and agreed as accurate by email but then formally approved and signed at their subsequent meeting. The minutes shall summarise the proceedings to reflect the advice offered.

5. Minutes will be circulated to Advisory Board members and Management Committee. Once agreed, copies of the scientific and progress related components of the minutes will be made available to ECPA for information. These minutes can then become publically available documents as they will not contain any sensitive/confidential information or preliminary results.

6. The role of an Advisory Board member is unpaid but the IOM (as the lead contractor within IMPRESS) will reimburse members for reasonable economy travel and subsistence costs (upon submission of relevant receipts) that cannot be recovered from their own organisation.

Appendix 2: Terms of Reference for interactions between project team and ECPA

Role and Purpose

To provide a transparent overview of what interactions and discussions will take place between ECPA and the Management Committee so to i. protect the independent and impartial work of the project; ii. minimise any perceived conflicts of interest arising; iii. ensure the objectives of the project as specified by ECPA and agreed by the Management Committee are met. This document will be reviewed and updated in light of contractual discussions as necessary.

A. Contractual arrangements

1. IOM will enter a direct contractual agreement with ECPA (pending review and agreement).

2. IRAS, HSL and CEOH (UoM) will be sub-contractors to IOM and will operate under separate contracts (pending review and agreement). IRAS, HSL and CEOH (UoM) will not have any direct contractual obligations with ECPA.

B. Management Committee and Advisory Board

1. A Management Committee, led by the overall Project Leader, and involving a representative from each consortium organisation will be established. The role of the Management Committee is to ensure that the aims and objectives of the project are realised across all the WPs in an efficient, streamlined, timely and cost effective manner.

2. The Management Committee will convene an independent Advisory Board to discuss and advise on the scientific undertaking of the project.

3. A Description of Work (DOW) for the project will be issued to ECPA (for inclusion as an Appendix to the agreed contract) so that transparent progress and adherence to this can be followed.

C. Financial reporting

1. IOM will provide financial reports, as required and stated in the agreed contract, to the identified point of contact for ECPA.

D. Progress reporting

1. IOM will provide progress reports (in relation to the agreed DOW), as required and agreed with ECPA, to the identified point of contact. When progress reporting takes place via an in-person meeting, the procedures listed in Section F will apply. When reporting takes place via teleconference, the procedures in Section G will apply.

E. Scientific reporting / project dissemination

1. A dissemination plan for the project will be drafted by the Management Committee and updated during the life course of the project. This will detail the planned publications (along with details of planned journals), conference presentations and any other dissemination activities. A copy of this will be made available to ECPA for information.

2. All scientific reports, protocols, abstracts of presentations, and proposed publications will be issued to the independent Advisory Board for review and comment before being finalised. If time scales allow, conference abstracts will also be made available for comment prior to submission but will be provided for information thereafter.

3. ECPA will be advised of the planned dissemination activities and will receive a draft copy of the protocols and publications (journal papers, abstracts, conference presentations) prior to submission[3]. ECPA will have the opportunity to provide comment (within an agreed timeframe) on the protocols, scientific articles, and copies will be made available by the Management Committee for this purpose. The Management Committee will review any provided comments, which are non-binding and will reserve the right to take these into account (or otherwise) when finalising the documents for submission.

4. The responsibility for the content of all dissemination materials (reports, publications, conference presentations etc) and study protocols lies solely with the project Management Team.

F. Meetings with ECPA: Frequency, Quorum, Duration

1. In-person meetings will be held periodically between ECPA and the Management Committee to discuss project progress and delivery in relation to the DOW. The Management Committee may ask that a representative of the Advisory Board attend these meetings.

2. In-person meetings will typically take no more than one working day and will be scheduled to take place in Europe at a location convenient for travel.

3. The Advisory Board Chair will be invited to Chair the progress meetings.

4. The agenda for all meetings will be circulated to those invited to attend the meeting two weeks in advance of the meetings and agreed upon.

5. Papers for all meetings shall be made available to ECPA and the Management Committee no later than one week in advance of the meeting.

6. If any meeting attendee believes that there is an undue attempt to influence the impartiality and independent nature of the research then this should be immediately raised with the meeting Chair and that particular line of discussion will be stopped.

7. The project leader (or their assigned deputy) shall record the minutes of every meeting; such minutes being circulated, and agreed as accurate by email but then formally approved and signed at their subsequent meeting.

8. Minutes will be circulated to ECPA and the Management Committee. Once agreed, copies the minutes will also be circulated to the Advisory Board members for information.

[3] With respect to the study protocols this refers to submission to the relevant ethics committee

G. Meetings with ECPA via teleconference: Frequency and Duration

1. Teleconference progress meetings will be held quarterly between ECPA and IOM project team representatives on behalf of the Management Committee to discuss project progress and delivery in relation to the DOW.

2. The Advisory Board Chair (or their delegate) will also be invited to attend and Chair project progress meetings between the IOM (as representatives of the Management Committee) and ECPA, which are held on a quarterly basis via teleconference. .

3. Teleconference will typically be no more than 2 hours in length and scheduled at a time to maximise participation by attendees.

4. The agenda will be circulated to those invited to attend the teleconference one week in advance of the teleconference and agreed upon.

5. Any papers to be discussed at the teleconference shall be made available to those invited to attend no later than one week in advance of the teleconference.

6. If any teleconference attendee believes that there is an undue attempt to influence the impartiality and independent nature of the research then this should be immediately raised with the meeting Chair and that particular line of discussion will be stopped.

7. The project leader (and / or their assigned deputy) shall record the minutes of every teleconference; such minutes being circulated, and agreed as accurate by email but then formally approved and signed at their subsequent meeting.

8. Once approved, minutes will be circulated to the wider IMPRESS management Committee and Advisory Board members.

H. Responding to formal ECPA comments

1. ECPA may choose to provide written feedback to the IMPRESS management committee on protocols, publications as well as project progress in relation to the description of work.

2. As stated in Section E, point 3, the Management Committee will review any provided comments in relation to protocols and publications, which are non-binding and will reserve the right to take these into account (or otherwise) when finalising the documents for submission. The Management Committee will provide ECPA with a written response to the comments received. The Advisory Board will receive a draft of this response prior to its submission to ECPA.

3. The Management Committee will respond in writing to formal written feedback that ECPA representatives provide on project progress in relation to the description of work. This response will be circulated to the Advisory Board for comment before being issued to ECPA. The Advisory Board may also choose to provide their own independent response to the matter raised.

Appendix 3: Conflict of Interest form

In the interests of transparency, Advisory Board members should declare any conflicts of interest. A conflict of interest is a situation in which an Advisory Board member has competing interests or loyalties in relation to the IMPRESS project.

Conflicts of interest can arise in a variety of circumstance, for example (but not limited to),

• when an Advisory Board member has a position of authority and /or interests in one organisation which conflicts with his or her interests in the IMPRESS project

• when an Advisory Board member has personal interests outside of work that conflict with his/her professional position on the Advisory Board

• where an Advisory Board member has a close friend or family member whose personal or professional interests conflict with those of the IMPRESS project

• where an Advisory Board member works for or carries out work on ECPA, IOM, IRAS, HSL or UoM behalf, and also has personal interests – paid or unpaid – in another business which uses the aforementioned organisations services.

For the purposes of this statement, the phrase 'conflict of interest' encompasses actual, perceived (i.e. as perceived by a reasonable person) and potential conflicts of interest.

Conflict of Interest Declaration

I, the undersigned, declare that I have read and understood the above and that I understand my responsibilities with respect to this form.

I wish to declare the following actual, potential or perceived conflicts of interest:

(Describe the nature of any such conflicts, identify the organisations or individuals that give rise to the conflict, and describe the business or personal relationship you have with them)

If you **DO NOT** have any conflicts to declare, please tick this box: ☐

Name: ……..

Signature: ……

Date: ……