Governance structures for AsPEN

Asian Pharmacoepidemiology Network (AsPEN) is a Special Interest Group (SIG) of the International Society for Pharmacoepidemiology

Agreed on April 23, 2012 in the first AsPEN SIG AsPEN meeting

1.1. Mission, goals, and objectives of AsPEN (see Appendix I. SIG proposal to the Board for SIG application)

Mission :

Our mission is to develop and advance multi-national database research in Pharmacoepidemiology in the Asia/Pacific region.

Goals and objectives:

Goal 1:To conduct pharmacoepidemiologic research using databases from AsPEN sites

-Describe regional variations and challenges in multi-national database studies

-Develop appropriate infrastructure for cross national database research

-Conduct studies for drug utilization, signal detection and signal validation using existing databases

-Secure resources and funding for the activities

Goal 2: To provide educational opportunities for local and international researchers, policy makers, and healthcare practitioners

-Host symposia and workshops

-Provide opportunities for students and young researchers to receive formal or off-site training

Goal 3: To facilitate collaborations and communications across countries, regions, and research groups

- Meet regularly by phone (once in 1-2 months) and in person (1-2 times a year)

- Promote AsPEN and its mission through publications and presentations

- Provide opportunities for collaborative symposia and meetings

1.2. Members (see the proposal to the Board for SIG application)

Those given as members in the SIG proposal in the board meeting in April 2012 or those substantially involved in the PSSA/association studies for AsPEN workshops in 2011 (Beijing) or earlier are the initial members of AsPEN. Those qualified as initial members of AsPEN not listed on the SIG proposal should report to one of Co-chairs by the end of May 2012.

Those who wish to be a new member should have the recommendation from one current AsPEN member and should be acknowledged in one of regular meetings by phone or in person. The minimum responsibility of AsPEN members is to try to attend the regular meeting by telephone or in person.

1.3. AsPEN Co-chairs and other key roles

1.3.1. AsPEN Co-Chairs

BJ Park and Frank May are "past" co-chairs and Kiyoshi Kubota and Yea-Huei Kao Yang are current co-chairs at the outset, with secretarial responsibilities being equitably shared between current co-chairs. The first co-chairs elect will be selected in August 2012 in Barcelona.

Co-chairs will go through 3 terms (elect, current, and past).

Each term will be 2 years.

The current co-chairs will be tasked to lead and represent the group formally and to present and report at the Board meeting.

Supportive roles for the past and elect co-chairs: <not yet specified>

1.3.2. AsPEN administrative office

NPO Drug Safety Research Unit Japan will work as the administrative office for the time being (at least till March 2014). The administrative office after March 2014 will be discussed and decided sometime in 2013. The administrative office will maintain the web page for AsPEN and arrange the regular meetings.

1.4. Operation of AsPEN activities

AsPEN activities should be operated so that good AsPEN studies are designed, conducted and published. Criteria for a good AsPEN study include maintaining

transparency and scientific standard for unfunded and funded AsPEN studies. One additional criterion for a good AsPEN study is maintaining independency.

1.4.1 General operation

General aspects for AsPEN operation will be discussed and updated in the regular meetings. Those who wish to raise the issues related to administrative task and regulation should do so through the administrative office.

1.4.2 Intellectual property (IP) registry

The AsPEN administrative office will maintain and update a registry of intellectual property (IP) to clarify ownership and other features of IP used (or potentially used) in AsPEN studies, and to prevent misuse of IP.

IP used in AsPEN studies may include:

1) background IP developed prior to AsPEN studies (third party IP, such as databases owned by a third party, as well as other background IP including programming code developed by an AsPEN member prior to the study) and
2) foreground IP arising from individual ASPEN studies including joint programming code developed during the conduct of individual AsPEN studies, conference presentations and scientific papers.

The IP registry may include:

a) IP potentially used in AsPEN studies which is in the public domain: this will avoid misunderstandings that this type of IP is the property of any specific person/body.

AsPEN researchers will provide and update the relevant information in the AsPEN IP registry, and are responsible for keeping the registry updated.

Detailed information included in the IP registry will be shared by AsPEN members but will not be publicly available.

1.4.3 Data Access Plan

a. The AsPEN administrative office will maintain the data access information covering the following issues listed below associated with acquisition and transfer of data. The list of information will be provided from the AsPEN administrative office to those who need it (e.g., possible PIs who wish to develop a new study plan).
   1) Nature of databases
      a) Size of data and period covered,
      b) patient demographics,
      c) type of data (e.g., claims data or electronic health record),
      d) codes used for drugs, diagnoses, and medical procedures, and

e) information on cost.

2) Ethical issues

f) Need for approval from a data custodian/ethics committee,

g) any problem in use of data in studies funded by industry, and

h) type of data that can be sent to the international co-ordinating study center.

b. Before developing an individual study plan, potential principal investigators (PIs) should obtain information from the AsPEN administrative office concerning data access policies in individual study sites regarding restrictions/conditions for data acquisition. Proper arrangement should then be made in advance for encryption of any data to be transferred between sites, and any other issues that may otherwise pose problems for AsPEN members in their particular settings.

1.4.4 Registry/disclosure of studies

Individual AsPEN studies (particularly those funded by the industry) should be registered with the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) or other publicly accessible registers of studies.

As a minimum requirement, the outline of studies should be disclosed on the AsPEN homepage before the start of data acquisition. The information to be disclosed includes:

a. Names of PIs and participating AsPEN members with their respective tasks and responsibilities.

b. Objectives, methods and milestones of the study.

c. Funding source, if applicable.

d. An outline of the contract with any funding source (particularly when funded by the industry) including:

1) Involvement of the funder in protocol development.

2) Conditions of the funder's access to the study data

3) Payment schedule (to clarify that the schedule will not be affected by the study results)

4) Ownership of foreground IP

5) Researchers' unrestricted freedom to publish the results

1.4.5 Operation for specific projects

Those who wish to work as the PI of either unfunded or funded study should design and propose the individual study. If applicable, the PI may also make the contract with funding body (see also 1.6). The researchers in individual study sites may or may not participate in the study according to their interest and capacity to do so. The PI

has the responsibility to develop research protocol. The PI also has the responsibility to develop or to take the lead of developing analytical tool as well. The PI should report the progress of the individual study to co-chairs and in regular discussion. The PI should be allowed to make the final decision on the operation of the individual study. In general, the intellectual property (IP) of any analytic tools developed through AsPEN activity will remain the property of the PI or their associated institution as appropriate.

1.5. Authorship for manuscripts

As for the protocol proposal, the PI should propose authorship including the criteria to be co-authors for the individual manuscripts before the initiation of the study. The PI is allowed to make the final decision on the authorship for the individual manuscript. In case two or more manuscripts are made by different corresponding authors in one study, the PI should select each lead author for each manuscript. In such a case, how to make the final decision for the authorship will be discussed and agreed between the PI and lead author for each manuscript and the results should be reported to co-chairs and in regular discussion.

1.6. Funding (grants, contracts, and donations)

1.6.1 Funding of individual studies

Any funding and potential contractual obligations for the individual study should be administered through the academic institution of the PI or PI's collaborator. However, general consensus that the study is accepted as an AsPEN study in terms of the criteria for good AsPEN study (1.4) should be achieved among the AsPEN members before the initiation of the study.

1.6.2 Funding of AsPEN activities as a whole

Any funding and potential contractual obligations for the AsPEN group as a whole but not for the individual study should be also administered through the academic institution of one of the current co-chairs or somebody agreed in the regular discussion. In such a case, funding and contractual obligations should be fully agreed by the majority of AsPEN members.

1.7. Database infrastructures

To achieve efficient environment for the collaborative studies, common data model and other data structure may be achieved in each study site. Details and milestones will be discussed and agreed in the future meetings.

The original governance structure was issued when AsPEN was recognized as a SIG in ISPE in the board meeting held in April 2012.

The governance structure was updated on July 3rd, 2013 in the regular SIG AsPEN teleconference.

- Following 3 new sections were added;

  1.4.2 Intellectual property (IP) registry

  1.4.3 Data Access Plan

  1.4.4 Registry/disclosure of studies

- Following section number was changed;

  [Original] 1.4.2 Operation for specific projects

  [Updated] 1.4.5 Operation for specific projects