# INTERNATIONAL SOCIETY FOR PHARMACOEPIDEMIOLOGY

## CALL FOR MANUSCRIPT PROPOSALS

***DEADLINE: September 27, 2019***

***Submit to ISPE Office (info@pharmacoepi.org)***

ISPE seeks proposals for manuscripts that could be used for guideline development or reference documents for pharmacoepidemiology, including pharmacovigilance, drug utilization research, outcomes research, comparative effectiveness research, and therapeutic risk management.

Suggested topics of interest to the Society include:

- Real world evidence
- Precision medicine
- Patient-generated health data
- Signal detection in emerging large data sets such as EHR or social media
- Use of use of pharmacological / mechanistic data in pharmacoepidemiologic studies
- Methodological differences in data mining and causal inference
- New methods in pharmacoepidemiology
- Best practices related to specific approaches in pharmacoepidemiology
- Formal evaluation of risk mitigation approaches
- Measuring impact of pharmacovigilance activities
- Guidance/methods (design/analysis) of multi-database studies
- Any topic contributing to ISPE's strategic mission

**Manuscript Proposals Accepted**

2018 (Approved)

- Propensity Scores in Real World Evidence.
- Guidelines for Best Practices in Validation Studies in Pharmacoepidemiologic Studies that Use Routinely Collected Data.
- Guidance for the Application of Longitudinal Methods for Exposure Profiling in Pharmacoepidemiologic Studies in Pregnancy.
- Developing a Framework for Combining Randomized Controlled Trial and Non-Randomized Data in Evidence Synthesis for Informed Health Care Decision Making.
- Observational External Comparator Cohorts as Controls for Long-Term Uncontrolled Extensions to Randomized Clinical Trial.

2017 (approved)

- Quantifying the impact of outcome misclassification on the results of pharmacoepidemiology database studies (Database SIG)
- Digital Patient Generated Data (Digital Epi SIG)
- Developing a set of best-practice standards for the communication of risk in pharmacoepidemiological research
- Publicly Available Data Sources for Drug Utilization Research in Latin American (LatAm) countries

(LA-DURG).
- Requirements for Conducting Multi-Country Safety Surveillance of Vaccines in the Asia-Pacific region (AsPEN SIG)
- Guidance for the Application of Pharmacoepidemiological Research and Methods to Best Inform Therapeutic Decision Making for Off-Label Medicines Use

2016 (in process)
- Importance of Pharmacoepidemiology for Advancing Precision Medicine
- Guidance for the Application and Reporting of Self-Controlled Study Designs in Pharmacoepidemiology
- Reporting of Pharmacoepidemiology Research Using Routinely-Collected Real World Evidence
- Good Practices of Drug Utilization Studies in Countries from Latin America and African Regions
- Linking Electronic Health Data in Pharmacoepidemiology.

2015 (in process)
- ISPE Best Practices on the Conduct of Active Surveillance in Resource-Limited Countries
- Good Practice Guidelines for Conducting and Reviewing Cross-National Drug Utilization Studies
- Patient Engagement in Observational Pharmacoepidemiology Research and Registries: Where Are We, Where Do We Need to Be, And What Are the Steps for Getting There?

2014
- Managing Change for Good Pharmacoepidemiology Practice in Healthcare Databases and Related Tools (**Published** Bourke A, Bate A, Sauer B C, Brown J S, & Hall G C, Evidence generation from healthcare databases: recommendations for managing change. Pharmacoepidemiol Drug Saf, 25: 749–754. doi: 10.1002/pds.4004. 2016 )
- Importance Of Feasibility Assessments Before Implementing Non-Interventional Pharmacoepidemiologic Studies Of Vaccines: Lessons Learned And Recommendations For Future Studies (**Published** - Pharmacoepidemiol Drug Saf. 2016 Dec;25(12):1397-1406. doi: 10.1002/pds.4081. Epub 2016 Sep 7.]

**OVERVIEW**

The Society will fund several Working Groups to develop manuscripts consistent with the topic proposed. Working Groups will be comprised of experts representing the interests involved. Responses will be reviewed by the Society's Strategic Planning Committee and Publications Committee, then referred to the ISPE Board/Executive Committee for a decision. The Committees may suggest changes in the proposal to the applicants. The selected Working Groups will develop manuscripts that will be reviewed by the ISPE membership consistent with the ISPE public policy process as specified in the ISPE Policy Manual.

Several proposals will be funded; estimated award per work group is between $9,000-$13,000. Announcements of accepted proposals are expected to be made in late October 2019; ideally the manuscripts should be available in draft form before ICPE 2019/Philadelphia (August 2019).

**FORMAT OF RESPONSE (Maximum - 2 pages excluding any CVs, biosketches, budget, and references)**

1. Title: Identify how the proposed manuscript addresses the need for guideline development or reference documents for pharmacoepidemiology, including pharmacovigilance, drug utilization

research, outcomes research, comparative effectiveness research, and therapeutic risk management.

2. Background: Provide information on the proposed topic; describe the issues concerning the need for guidelines or a good practice document or a reference manuscript.
3. Objective: Identify the purpose/goal of the working group
4. Rationale/Priority: Include a statement on how the manuscript/topic is consistent with ISPE's strategic plan, mission statement and why it should be a priority for the Society
5. Issues to be addressed: What issues will the Working Group address?
6. Content: Working Group reports must include specific recommendations or guidelines or practices and supporting information
7. Composition of Working Group. Include a list of all members of the Working Group (name, title, affiliation, & a brief description of their expertise), and Work Group Chair. Work group members must be current ISPE members; no exceptions. Composition should address, to the extent possible, membership diversity by geographic region, work sector and organization. NOTE: Proposals including working group members exclusively from one organization/institution will not be considered responsive to the call for manuscripts.
8. Conflict of interest. Each member of the Working Group must submit a conflict of interest statement. Download guidelines here.
9. Budget. Estimated expenses.[1] Several proposals may be funded; estimated award per work group is generally between $9,000-$13,000. Most of the work groups will be conducted by conference calls and email. Appropriate expenses include:
    a. Administrative/logistical expenses such as conference calls, meeting notes, library research & drafting manuscript
    b. ISPE does not pay overhead
    c. ISPE expects that manuscripts are published in an open access format so they are accessible on the ISPE website. The budget should therefore incorporate adequate funds for open access publishing.
    d. One face-to-face meeting (Work Group is responsible for logistics & arrangements)
        i. Travel. Funding will not cover ISPE members' travel to a scheduled meeting; i.e. Mid-Year Meeting, ICPE. However, funds can be used to cover an extra night if needed to ensure participation at a manuscript team meeting.
        ii. Food/beverage; AV; Room rental
10. Target journal(s) for publication. Rationale for selection.

**NOTE:** The Strategic Planning Committee expects that the final manuscript will be made available to the ISPE membership through the Society's public policy process, revised appropriately, then the revised draft will be submitted to the Board for action. This review is separate and distinct from any journal required peer review process. The Committee encourages the Work Group to submit the ISPE-endorsed manuscript to PDS or another professsional journal for publication. The authors should state clearly that the manuscript has been endorsed by ISPE in both the cover letter and manuscript. "Endorsement" by the ISPE

[1] As a rule, ISPE does not make payments to members for their work for the Society.
Exceptions to this rule include activities commissioned by the Board or Executive Committee. In general, when commissioned activities are to be undertaken, expenditure and income budgets must be approved by the Executive Committee. Reimbursements for reasonable expenses will only be made on production of receipts and attested statements of time taken, as well as evidence of work completed. (SOURCE: ISPE Policy Manual)

Board does not mean that PDS (or another journal) will automatically accept the manuscript; PDS (and other journals) has an independent review process.

11. Bibliography. Provide recent relevant articles on the topic.
12. Timeline. Define specific work activites from the outline. Timeline should extend to the end of the Working Group process.
13. The Working Group will complete an Annual Impact Report to help the Committee monitor the success of the manuscript initiative.

**REVIEW CRITERIA**

Each proposal will be assessed against the following criteria.

a) Appropriateness of proposal for the general ISPE membership.
b) General interest of topic to ISPE membership (i.e., limited to broad audience).
c) Feasibility to accomplish the stated objectives.
d) Importance (or significance) of proposal to the field of pharmacoepidemiology.
e) Visibility – the extent to which the proposed guidelines will be used and if so, raise the visibility of pharmacoepidemiology.
f) Collaboration among multiple organizations, work sectors, and geographic regions.
g) Consistent with ISPE strategic goals, objectives and priorities.

There is no 'official' application; maximum length is 2 pages (excluding supporting documentation such as CV or budget documents). Submit your final manuscript according to the criteria above in PDF form to info@pharmacoepi.org by **September 27, 2019** (no exception).