How to complete the abstract form

Submission Title

Enter the FULL TITLE. This will be used for the final program. 200 character max and 75 words max

Category

Select one (1) from the following

- Oral preferred
- Oral only
- Poster preferred
- Poster only
- Symposium*
- Workshop

*selecting this would take the submitter to a slightly different set of specifications

1. Affirmation

Please answer the following questions by checking the box for each question

☐ This abstract is being submitted as an Oral/Poster submission only. This abstract will not be submitted as a Workshop or Symposium.

☐ The results in this submission have not been published (not in abstract form) either on-line ahead of print, or in printed version before January 1, 2021.
Results that have been published (except in abstract form) either on-line ahead of print, or in printed version before January 1, 2021, are not eligible for submission. Results that have been presented at meetings of other scientific societies are eligible for presentation, provided that they have not been published (except in abstract form) either on-line ahead of print, or in printed version before January 1, 2021.

2. Authors

You must add at least 1 author and no more than 50. You must have 1 presenting author for this submission. Authors: mandatory information

- First name
- Last name
- Email
- Country
- Role: presenting author and corresponding vs co-author

3. Disclosure

Each author is required to submit a Conflict of Interest Disclosure. You can access each author's form by clicking on the "Edit Form" button below each name listed. In addition, the "Invite" button below each name will create an automatic email to that speaker inviting them to complete the form.
Once an Author completes their disclosure, this will carry over to other abstracts they submit or are listed on.

4. Abstract

Submission Topic - Required

Select one

- Benefit Risk Assessment, Communication and Evaluation (BRACE)
- Biologics and Biosimilars
- Disease Epidemiology/Clinical Course
- Drug Effectiveness
- Drug Utilization Research
- Geriatric Pharmacoepidemiology
- Health Economics/Outcomes Research
- Informatics
- Medical Devices
- Methods on Pharmacoepidemiology
- Molecular Epidemiology/Biomarkers/ Pharmacogenetics
- Pediatric Pharmacoepidemiology
- Pharmacovigilance
- Pregnancy and Lactation
- Rare Disease
- Safety End Points
- Vaccines

Secondary Submission Topic - Optional

Same as the list above

Sub-Submission Topic - Optional

- Cancer
- Cardiovascular
- Neurological/Mental Health
- Diabetes
- Other

If your abstract focuses on a specific exposure, please select the type
Optional

- Alimentary tract and metabolism therapeutic area
- Antiinfectives for systemic use and vaccines
- Antineoplastics and immunomodulating agents
- Antiparaitic products insecticides and repellents
- Blood and blood forming organs therapeutic area
- Cardiovascular therapeutic area
- Dermatologicals
- Genitourinary tracts medicines and sex hormones
- Musculoskeletal therapeutic area
- Nervous system therapeutic area
- Sensory organs therapeutic area
- Systematic hormonal preparations
- Other

If your abstract focuses on a specific outcome, please select an outcome
Optional

- Allergic reaction
- Birth defect
- Cancer
- Cardiovascular
- CNS/Neurological
- Endocrine/Diabetes
- Gastrointestinal
- Hematological
- Liver Injury/Hepatic
- Respiratory Disorder
- Rheumatological Disorder
- Skin Discorder
- Treatment Failure
- Other

Please note that there is a character limit of 2,350 combined for these fields below, plus title, not counting spaces

Background - Required

One or two sentences that describe the clinical (or other) importance of the study

Objectives - Required

The main objective(s) or study question should be explicitly stated (e.g., "To determine the rate of"). If study was to test an a priori hypothesis, it should be stated.

Methods - Required

Should include statements that address: Design: Basic study design, source population, follow-up; For new analyses of existing data the data-set should be disclosed; statement of criterion standard if study of screening or diagnostic test and any blinding; analysis type (e.g., cost-effectiveness, cost-benefit, etc.) if an economic analysis. Matching and selection of controls, if relevant, also should be included.

Setting: To assist readers in determining the relevance of the findings to their own circumstances, the setting or source population should be described including statements regarding generalization to a larger or more representative population. This may include eligibility, inclusion/exclusion criteria, and for surveys and follow-up studies should include the number eligible versus the number/proportion remaining in the analysis.

Exposures or interventions: Explicit naming of medications or other interventions. Non-proprietary names should be used.

Main outcome measures: The primary and secondary outcome measurement(s) as determined prior to data collection. If hypothesis was formulated after data collection, this should be stated.

Statistical analysis: The statistical methods should be described.

Results- Required

The main outcomes of the study should be provided and quantified, including confidence intervals and/or other significance tests. If differences are not significant, the clinically important difference sought should be stated and the confidence interval for the difference between the groups should be given. When risk changes or effect sizes are reported, absolute values should be included so that the reader can determine the absolute as well as relative impact of the result. Screening and diagnostic test studies should report sensitivity, specificity, and likelihood ratio and if predictive value or accuracy is given, prevalence or pretest likelihood should be provided.

Conclusions - Required

Only those conclusions that are directly supported by the reported data should be provided, along with their implications (avoiding speculation and overstatement of findings). Emphasis should be given equally to positive and negative findings of equal scientific merit.

Please note that there is a character limit of 2,350 combined for these fields above, plus title, not counting spaces

5. Special Interest Groups

Special Interest Groups (SIGs) are created to facilitate interactions among ISPE members with interests in specialized areas of activity within Pharmacoepidemiology. SIGs may host Spotlight Poster Sessions as part of 2021 ICPE. The following question will guide the scientific program to identify appropriate abstracts in consideration for SIG poster walks.

Does your abstract fit with the interests of one of the Special Interest Groups (SIGs)? - Required

SIG definitions and mission statements are listed at the end of this document

If "YES" please select appropriate SIG:

- Adherence
- AsPEN
- Benefit Risk Assessment, Communication and Evaluation (BRACE)
- Biologics and Biosimilars
- Cancer
- Comparative Effectiveness Research (CER)
- Databases
- Digital Epidemiology
- Drug-Drug Interaction
- Drug Utilization / Health Services Research
- Genomics & Precision Medicine
- Geriatric Pharmacoepidemiology
- Medical Devices
- Medications in Pregnancy & Lactation
- Pediatrics
- Rare Disease
- Vaccines

Please select a secondary SIG option:

Same as list above

6. Lightning Forum Preference - Required

Answer: yes or no

If you selected Oral Presentation Only, Oral Presentation Preferred, or Poster Presentation Preferred as a presentation option, please indicate if you would like to also be considered for a Lightning Forum(described below)? *ISPE's Lightning Forums is a 90-minute session that will organize 3 sets of 4 speakers that have been grouped based on shared themes that emerge from the submitted abstracts.
Each set of 4 speakers will be led by a single moderator with expertise in the theme's area. Presenters will be asked to prepare a 3-minute "lightning/rapid" oral presentation. For this session, speakers will be required to prepare: a) title slide, b) disclosure slide, and c) 2 slides highlighting the key scientific question and rationale of the abstract, the main methods used, key results, and the main conclusions. The Scientific Program Committee will require that the moderator of each grouped theme email in advance each of the presenters in their grouped theme and request their slides and abstract so as to have time to prepare questions, lead the discussion, and prepare a summation slide.
Within each of the 3 grouped themes, each presenter will deliver their 3-minute, 4-slide presentation. Upon completion of the presentation, there will be 2 minutes allowed for questions by the moderator and audience. With four speakers for each theme, there will be 20 minutes of time for the oral presentations for each grouped theme. The final 10 minutes for the grouped theme will be led by the moderator, who will direct questions to and between the speakers and allow additional questions from members of the audience to foster a more interactive oral abstract session. The moderator for a particular theme will conclude with a short 1-slide summation of the presentations and highlight important aspects that emerged during the discussion. Abstracts will be scored as per the Technical Appendix D of the ISPE Policy Manual. The committee will select 4 abstracts for each theme of interest for the lightning forum.

7. Presentation Release

Answer yes or no

I approve of ISPE posting this abstract (if selected) in the ISPE Education Center section of the ISPE website after the conference.*

By selecting "No" below, you are not allowing ISPE to post your presentation on the ISPE website

8. Newcomer Track

Answer yes or no

Do you meet the eligibility AND wish to participate in the Newcomer Track?*

Details on Newcomer track

The Newcomer Track is designed to encourage researchers submitting for the first time to the International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), regardless of native language or country of origin. By taking advantage of the Newcomer Track option, researchers will receive feedback from a reviewer on scientific quality, style and language once and will have the opportunity to resubmit their abstract before the final abstract deadline of February 12, 2021. All abstracts submitted to the Newcomer Track before the deadline of January 11 will be reviewed. Early submission is encouraged to provide sufficient time for review and revision of the abstract.

Who is eligible to submit through the Newcomer Track?

This track is recommended for researchers submitting for the first time to ICPE regardless of native language or country of origin.

How does the Newcomer Track work?

Researchers will receive feedback from a reviewer on scientific quality, style and language once and will have the opportunity resubmit their abstract before the February 12, 2021 deadline. All abstracts submitted by the Newcomer Track deadline of January 11 will be reviewed. Early submission is encouraged to provide sufficient time for review and revision of the abstract. Any abstract submitted after the January 11 Newcomer Track deadline will automatically go through the standard abstract review process.

What are the important dates?

Newcomer Track Abstract Submission Deadline: January 11.
Revision Deadline: February 12. Abstract must be revised by this date to ensure consideration for 2021 ICPE.

If you choose "Yes" to the Newcomer Track question below, you must follow this procedure:

- After you submit your abstract, the status will be set to “Pending Review”.
- The deadline to submit the first draft of your abstract is: January 11, 2021 at 11:59PM EST.
- You must return to the submission site to make any changes (online) to the abstract. After you have applied and saved your updates, review the abstract summary to confirm all updates were saved and confirm the submission status is “Complete”. You can send yourself a confirmation email or print a PDF of your submission for your records.
- Remember, the deadline to submit your final abstract is: February 12, 2021 at 11:59PM EST. ISPE suggests that you submit the revised abstract several days prior to the February 12 deadline if possible.

Questions or comments about this track:
Please email info@pharmacoepi.org; the subject line should state "NEWCOMER TRACK"

Once all the abstract submission steps are completed, save your submission by clicking the save submission button at the top or bottom of the page.
From here you will be able to preview your submission by clicking the option at the bottom of the page.
If you are ready to submit, click submit on the upper right hand corner of the page.

You will receive a confirmation email with the subject line: Call for Papers --- Submission Details.
You may edit your abstract anytime before the deadline of February 12, 2021 at 11:59pm EST.

SIG Definition, Mission Statemennt

Adherence

Mission Statement

Adherence to pharmacotherapy is central to the effectiveness of self-administered medication regimens. Yet, non-adherence is exceedingly common, with upward of 50% of patients not taking their medications as prescribed. There are a number of challenges unique to adherence research that require specialized skills which will benefit from innovative collaborative approaches to solutions. Historically, adherence research has been siloed into the disease content such that methodologic work has been carried out in parallel, limiting synergy.

More info HERE

AsPEN, Asian Pharmacoepidemiology Network

Mission Statement

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

More info HERE

Benefit Risk Assessment, Communication and Evaluation (BRACE)

Mission Statement

To provide an interactive and collaborative forum for education, training and development among ISPE members with an interest in BRACE.

More info HERE

Biologics and Biosimilars

Mission Statement

The ISPE Biologics Special Interest Group provides a forum to discuss, develop, and improve the use of pharmacoepidemiologic techniques for biologic agents.

More info HERE

Cancer

Mission Statement

To identify existing oncology data sources and professional and research networks that may be considered in peri-approval and observational research;

To identify issues unique to cancer pharmacoepidemiology, and to explore methodological approaches to address these issues; and

To serve as a resource to the ISPE membership by providing expertise in cancer pharmacoepidemiology and educational content in the area.

More info HERE

Comparative Effectiveness Research (CER)

Mission Statement

To provide a forum for the development, application, and dissemination of comparative effectiveness research activities, education, and methods.

More info HERE

Databases

Mission Statement

To provide a forum on the use of individual patient databases (medical claims databases, electronic health record databases, and other publicly available cross-sectional and longitudinal-linked patient databases) in pharmacoepidemiological research in order to discuss, develop, and improve methods, approaches, and dissemination of results and to improve the science and transparency of pharmacoepidemiology database research.

More info HERE

Digital Epidemiology

Mission Statement

The Digital Epidemiology Special Interest Group provides an interdisciplinary forum for discussion of challenges and opportunities from digitalization developments.
It also develops, and aims to ensure that sound scientific pharmacoepidemiological methods and techniques become available in this evolving digital space.
Electronic Medical Records (EMR) and claims data are the backbone of our research, however the role and integration of patient generated data, methods for its collection, transmission, analysis and optimization are also a priority. This work will enhance the value of patient-generated data for patients, providers and healthcare systems.

More info HERE

Drug-Drug Interaction

Overview and Mission

Pharmacoepidemiologic studies are essential to confirm (or refute) and elucidate the health effects of potential drug-drug interactions (DDIs). In addition to applying principles for good pharmacoepidemiology practice, researchers conducting DDI studies must consider nuances in design and interpretation that follow from a focus on the health effects of combinations of multiple exposures rather than single medical products. The DDI Special Interest Group will serve as a collaborative community of ISPE members with an interest in the design, analysis, interpretation, and translation of pharmacoepidemiologic studies of drug interactions.

More info HERE

Drug Utilization / Health Services Research

Mission Statement

To create a global forum for discussion and cooperation between drug utilization researchers

More info HERE

Genomics & Precision Medicine

Mission Statement

To create a global forum for discussion and cooperation between pharmacoepidemiologic researchers interested in genetic, genomic and biomarker research (i.e., molecular epidemiology, genetic epidemiology, pharmacogenetics, and genomic and protein-based biomarkers, and imaging biomarkers). Specifically, this special interest group is interested in research involving the intersection of genetics, genomics, and biomarkers with pharmacovigilance, drug utilization research, comparative effectiveness research, therapeutic risk management, risk communication, health economics and health policy, where the intersection issues relate to drug development, drug delivery, drug use, drug costs, and drug effects.

More info HERE

Geriatric Pharmacoepidemiology

Mission Statement

Older adults are the main consumers of drugs but are rarely included in pivotal RCTs. Hence, pharmacoepidemiology is central to understanding drug safety in elderly patients. The mission of the Geriatric Pharmacoepidemiology Special Interest Group is therefore to provide a collaborative forum to discuss, develop, and improve the methods, applications, and dissemination of geriatric pharmacoepidemiology.

More info HERE

Medical Devices

Mission Statement

To determine the evidence gaps and questions, datasets and approaches for conducting robust analytic studies and improve our understanding of the performance of medical devices. Methodological discussions and real world comparative effectiveness and safety studies will be one of the main areas of concentration.

More info HERE

Medications in Pregnancy & Lactation (MiPaL)

Mission Statement

The Medications in Pregnancy Special Interest Group seeks to enhance communication, improve the quality of science, and expand knowledge related to the use and safety of the wide range of medications taken by pregnant women.

More info HERE

Pediatrics

Mission Statement

Advance research and share knowledge for safe and effective use of medicines in pediatric populations to inform policies and clinical practice, to promote safe use, and to improve child health outcomes.

More info HERE

Rare Disease

Mission Statement

To provide an interactive and collaborative forum to discuss, develop and improve the use of epidemiological approaches for rare disease research.

More info HERE

Vaccines

Mission Statement

The SIG strives to achieve these goals by offering a platform for interested ISPE members to plan educational activities for the ICPE pre-conference courses together with the education committee, shared national and international projects and grant proposals, and joined presentation in form of workshops, symposia or poster walks at annual ICPE meetings. Whenever possible, the VAX SIG will seek to maximize synergy with existing vaccine institutions and stakeholders.

More info HERE