Response #12

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1.

1. Your contact details

First name : John
Last name : Diaz-Decaro
Email : jdiazdecaro@gmail.com

2. Briefly describe the potential strategic effort (e.g., “respond to [x] draft guidance document” or “develop new [y] principles.”)

Respond to the European Medicines Agency (EMA) "Reflection Paper on Patient Experience Data" (EMA/CHMP/PRAC/148869/2025), which is open for public consultation until January 31, 2026. The response would highlight pharmacoepidemiology's contributions to generating, validating, and applying patient experience data (PED), including patient-reported outcomes, patient preference studies, patient engagement data, and real-world data across the medicinal product lifecycle.

3. Briefly describe why this could be of strategic importance for ISPE.

This is a unique opportunity for ISPE to position itself at the center of regulatory discussions on the integration of patient experience data into medicines development, evaluation, and lifecycle management. ISPE members bring expertise in study design, data quality, bias mitigation, real-world data integration, and regulatory science. By contributing, ISPE can influence EMA's evolving methodological and regulatory expectations and elevate pharmacoepidemiology's role in bridging traditional clinical trial evidence with patient-centered real-world outcomes.

4. Which objective(s) in Strategic Plan 2024-2029 are addressed through this effort?

Inspire 1 & 2: Advance emerging and innovative topics by integrating patient experience data into pharmacoepidemiology, showcasing novel methodological contributions.

Prepare 5 & 6: Build global capacity and leadership by fostering scientific exchange across disciplines (regulators, patient groups, developers) and creating opportunities for ISPE members to engage.

Empower 7 & 8: Strengthen inclusivity and external partnerships to ensure diverse patient perspectives inform evidence generation and regulatory policy worldwide.

5. Are you interested in being part of the ISPE effort?

No

Describe your interest in participation in this effort (i.e., why do you want to be involved). Include in your comments any experience and/or skills you possess relevant to participation.

Do you have previous experience in participating in a similar effort? If so, please describe.

Do you have previous experience leading a similar effort? If so, please describe.

6. Is this a short-turn around/time bound (up to 120 days) potential strategic effort?

No

What would a successful outcome look like for this effort?

7. Please provide any additional information that would aid in deciding the strategic purpose of this effort for ISPE.

The reflection paper acknowledges gaps in systematic patient experience data use, particularly around methodological standards, data quality, representativeness, study design, and global alignment. ISPE is well-positioned to provide expert commentary on these areas. An ISPE-coordinated response could also highlight how PED aligns with pharmacoepidemiology's mission of evaluating medical product benefits and risks in real-world populations.

8. Do you wish to receive a copy of this form?

Yes

2. Thank You!

Thank you for completing this form. This information will be provided to the ISPE Executive Secretary for consideration in the ISPE Process for Coordination of Strategic Efforts.