Shaping patient involvement in publications: Identifying and overcoming barriers through expert insights

Shweta Rane[a], Dawn Lobban[b], Trishna Bharadia[c,d,e] and Bradley Meehan[f]

a. BridgeBio Pharma, Inc., San Francisco, CA, USA
b. Amica Scientific, Stockport, UK
c. Patient author, Buckinghamshire, UK
d. The Spark Global, Buckinghamshire, UK
e. Centre for Pharmaceutical Medicine Research, King's College London, London, UK
f. OPEN Health Communications LLC, London, UK

Poster #42

ISMPP Patient Engagement Task Force

Key findings

- All groups identified a lack of guidance, frameworks, and onboarding tools as key barriers to effective patient involvement (PI) in publications
- Impact on timelines and budget considerations were identified as barriers by agencies and industry, whereas lack of clarity on processes and timelines was a key barrier for patients

Conclusions

- A greater understanding of the barriers and potential solutions will shape development of tools and resources to support compliant and effective PI in publication activities

The challenge

Despite growing interest and GPP 2022 Guidelines encouraging PI in publication activities, such as in authorship, steering committees, publication planning, etc., challenges for compliant PI still persist.[1-3]

As part of the International Society for Medical Publication Professionals (ISMPP) Patient Engagement Task Force (PETF), we sought to understand the barriers to PI in medical publications.

The PETF conducted a virtual workshop (Oct 30, 2024) with 3 key stakeholder groups: Agency (medical communications and freelance publication professionals), Industry (pharmaceutical, biotech, and medical device), and Patients (including patient organizations and advocates).

Insights and examples based on stakeholder experiences were gathered ahead of the workshop and mapped on a virtual whiteboard for discussion.

Agency, Industry, and Patient representatives identified the top 3 barriers to compliant PI in publications and potential solutions

Agency

6 representatives | 8 barriers mapped



Agency is not directly involved in the decision-making process; decisions are made by the client

- **Educate clients** on the benefits of PI in publication activities
- **Provide examples** of cases demonstrating successful PI

Lack of processes or frameworks for identifying and training patients established by the client to support PI

- **Partner with patients** to develop a framework for effective PI in publications, and **share with clients** who lack an established framework
- **Co-develop onboarding materials** with patients

Impact on publication **timelines and budget** considerations

- **Establish roles and responsibilities** and typical timelines to help manage client and patient expectations
- **Work with clients** to understand budget needs and FMV reimbursement

Industry

6 representatives | 7 barriers mapped



Limited resources (money, staffing, and time) and inability to identify the right patients, especially in rare diseases

- **Establish company guidance** for working with PAGs to identify patients
- **Work with legal and compliance leads** to establish a framework for protecting patient identity (if part of a clinical trial) and disclosing payment (FMV guidance, etc.)

Lack of an established framework and guidance for PI in publications within the company or for alliance partners

- **Work with legal and compliance leads** to establish a framework for PI
- **Develop guidance** to aid alignment of policies between alliance partners
- **Establish alternative routes** for PI, including using anonymous patient authors and liaising with an agency

Navigating **compliance barriers** associated with promotional vs non-promotional publications

- **Establish a Code of Conduct** for appropriate and sensitive interactions with patients
- **Onboard patients** to ensure PI is ethical, objective, unbiased, and provides no promotional perspective
- **Provide guidance for working with legal or compliance leads** to establish guardrails for mitigating risks of bias or subjective opinions, and promotional perspectives, and to establish ethical engagement between patients and HCPs

Patients

4 representatives | 14 barriers mapped



Lack of understanding of publication activities, industry/scientific jargon, and responsibilities

- **Educating/onboarding patients** for effective engagement
- Developing glossaries, dictionaries, etc.
- **Discuss** the company Code of Conduct and **encourage informal catch-ups**

Process is too technical and can be burdensome, overwhelming, and time consuming, leading to a fear of inability to meet timelines or expectations due to illness, death, etc.

- Onboarding tools, clear timelines, and roles and responsibilities may help to **better manage expectations**
- **Establish a key point of contact** and regular touchpoints to guide patients through development processes
- Agency/Industry to **build flexibility and buffers** into timelines

Payments offered **may impact benefits**, have **tax implications**, etc.

- **Educate the patient** on available guidelines, such as EFPIA
- Connect with patient engagement team leads to address patient questions or concerns upfront

Client is defined as an industry partner. EFPIA, European Federation of Pharmaceutical Industries and Associations; FMV, fair market value; HCP, healthcare professional; PAG, patient advocacy group.

Considerations

No validated model was used to determine the top 3 barriers and the associated solutions; these were determined through discussion within the PETF. Due to the small sample size, these findings cannot be generalized. Further work is required to understand how the solutions will be realized to provide the relevant guidelines, frameworks, and training materials needed to maximize the impact of PI.

Acknowledgments

The authors thank the members of the ISMPP Patient Engagement Task Force for their valuable participation, and Anna Geraci, ISMPP United States, for operational support and courtesy review. Studio support was provided by Catharine Snell and Sandrine Grillon, OPEN Health Communications LLC. Editorial support was provided by Rebecca Middleburgh, OPEN Health Communications LLC.

References

1. Harrison JD, Auerbach AD, et al. Patient stakeholder engagement in research: a narrative review to describe foundational principles and best practice activities. *Health Expect.* 2019;22(3):307-316; doi: 10.1111/hex.12873.
2. The Publication Plan. https://thepublicationplan.com/2020/01/17/patient-involvement-in-medical-publishing-insights-from-a-publication-professional/. Accessed on Apr 28, 2025.
3. DeTora LM, Toroser D, et al. Good Publication Practice (GPP) Guidelines for company-sponsored biomedical research: 2022 update. *Ann Intern Med.* 2022;175(9):1298-1304; doi: 10.7326/M22-1460.

Presented at the ISMPP 21st Annual Meeting, Washington, DC, May 11-14, 2025.