Patient Engagement Task Force

Patient
Engagement
Enabler
Resource

A practical guide to overcoming barriers to patient involvement in publication activities

Version 1.0, 2025

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Objectives

- Prepare different stakeholders for common challenges to involving patients in industry-sponsored publication activities
- Outline key barriers and solutions, signposting to relevant evidence and other resources

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User Guide

- This Patient Engagement Enabler Resource has been designed using an FAQ format to allow all content to be keyword searchable
- The FAQs included in this Patient Engagement Enabler Resource represent typical barriers encountered by each of the key stakeholders involved in engaging patients in publication activities:
  - Patients*
  - Pharma and biotech companies
  - Agency
- The contents page outlines barriers for each stakeholder group, which are hyperlinked to individual barriers
- The home icon returns you to the contents page 🏠
- A glossary of terminology and a resources page can be found at the end of the document

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*Patients refers to patients, carers, advocacy groups, and patient representatives

Things to Consider

- The advice offered by this resource is for guidance only – please adapt it based on your specific circumstances
- Factors to consider include:
    - Prior experience of sponsor and patient contributor in engaging patients in different types of publication activity
    - Differences between company codes of conduct and other standard operating procedures
    - Regional differences (compliance, company processes, etc.)
    - Therapy area and unmet needs
    - Product approval status

Contents

Click on FAQs of interest and use the home icon to return to this page

Publication Process Understanding: I am not familiar with publication activities, scientific jargon, or my responsibilities as an author

- If you have no prior publications experience, **resources are available** to help you understand the publication development process and your role as a patient partner:
  - The WECAN Patients in Publications training course[1]
  - The Envision the Patient resources for Patient Authorship[2]
  - The ICMJE authorship criteria[3] and how patients meet these criteria[4]
- If you are **invited to author a publication:**
  - **Make the Pharma company aware** of any relevant details, such as your level of prior experience, whether you need any additional training and support, and what your preferred communication channels are
  - Make sure there is an **authorship agreement** in place that clearly states your role and responsibilities
  - Ask the Pharma company to provide **resources for onboarding patient authors**
    - These should cover company-specific processes for developing publications, company codes of conduct, and glossaries and lexicons of any scientific terms or language you are likely to encounter during the project
    - Resources should be accessible and written in plain language

WECAN, Workgroup of European Cancer Patient Advocacy Networks.

1. WECAN. Patients in Publications. https://wecanadvocate.eu/patients-in-publications/. (Accessed 6 November 2025)
2. Envision the Patient. https://www.envisionthepatient.com/patient-authorship. (Accessed 6 November 2025).
3. ICMJE. Defining the Role of Authors and Contributors. Available at: https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html. (Accessed 6 November 2025).
4. ISMPP. Patient Authorship: Three Key Questions (& Answers!) for Medical Communication Professionals [Part B]. https://www.ismpp-newsletter.com/2020/05/26/patient-authorship-three-key-questions-answers-for-medical-communication-professionals-part-b/. (Accessed 5 December 2025).

Expectations and Timelines: The publications process is time-consuming, and I'm worried that I won't be able to fulfil expectations and meet deadlines

- Ask the Pharma company to provide **clear descriptions of responsibilities and tasks** with corresponding **timelines** to make sure you are clear on expectations
    - You can request flexibility and buffers in the timelines
    - This can help you balance being a patient partner with other responsibilities and unexpected circumstances such as illness
- Make sure the Pharma company confirms a **key point of contact** for you to liaise with
    - Keep in clear and regular communication with this contact so they can guide you through the publication development process
- Don't be afraid to **advocate for yourself** and speak up if you are finding things too much or need more time for tasks

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Receiving Reimbursement: I am concerned that the reimbursement I have been offered may impact government benefits or have tax implications

- **Accepting reimbursement is a personal decision** based on your individual situation. Understand that your participation is valued regardless of whether you accept reimbursement, and that **your decision can change over time** if your situation changes
- If you **choose to accept reimbursement**, make sure you understand what role the reimbursement is for
    - Companies should reimburse patients by paying a fair market value (FMV), which is the reasonable amount for providing a service or activity based on the type of work, how much time it takes, the person's skills and experience, and where they live. Because of these factors, the amount can vary from one country or person to another for the same service[1,2]
    - Be aware than many companies have policies that don't allow reimbursement for authorship
- If you have **queries or concerns around reimbursement**, you can:
    - Refer to **general and country-specific guidelines** on patient involvement for information. Country-specific guidelines for patient engagement are available here;[3] these include the EFPIA principles[4] in Europe, and guidance from the NIHR[5] in the UK.
    - Ask your **key point of contact** to connect you with patient engagement team leads, or other relevant colleagues within the Pharma company
    - Understand that Pharma companies are unable to offer personal tax advice. Instead, please use a country-specific tax advice charity or citizen's advice bureau, such as TaxAid[6] in the UK and the Taxpayer Advocate Service[7] in the US

EFPIA, European Federation of Pharmaceutical Industries and Associations; NIHR, National Institute for Health and Care Research.

1. Determining Fair Market Value: Demystifying the methodology behind patient remuneration. https://patientfocusedmedicine.org/determining-fair-market-value-demystifying-the-methodology-behind-patient-remuneration/. (Accessed 16 December 2025). 2. Working with patients and patient organisations. https://www.abpi.org.uk/partnerships/patient-involvement/working-with-patients-and-patient-organisations-a-sourcebook-for-industry/. (Accessed 16 December 2025). 3. Patient Engagement Guidelines Country Codes of Conduct. https://patientengagement.synapseconnect.org/badge/patient-engagement-guidelines. (Accessed 4 December 2025). 4. EFPIA (2019). Working together with patients. https://www.efpia.eu/media/413114/workingtogetherwithpatients_patient-remuneration-principles.pdf. (Accessed 6 November 2025). 5. NIHR (2025). Payment guidance for researchers and professionals involving people in research. https://www.nihr.ac.uk/payment-guidance-researchers-and-professionals. (Accessed 6 November 2025). 6. TaxAid. https://taxaid.org.uk/ (Accessed 6 November 2025). 7. Taxpayer Advocate Service. https://www.irs.gov/taxpayer-advocate. (Accessed 6 November 2025).

Unintegrated Perspectives: I feel that my contribution to this publication has been separated out from the rest of the content

- Take time to understand at the outset **how your input will influence the paper.** For instance, you may be asked to contribute to a specific patient perspectives section, or your input may be integrated with that of the other authors
  - Refer to codes of conduct or charters of roles and responsibilities
  - There may also be limitations that need to be considered, such as journal instructions or reporting guidelines
  - **Discuss any concerns** about your role with your key point of contact
- Once publication development is underway, if you feel that **your contributions are not being taken into account, or your role is not what was originally communicated:**
  - **Raise your concerns as early as possible** in the publication development process
    - Ideally, have these discussions during early author calls, or when you are reviewing the publication outline before the full version is drafted
  - Keep in **regular communication with your key point of contact** to share your concerns, ensure your feedback is considered, and develop an action plan
  - Remember that **you have the right to remove your name as an author** at any stage if you aren't happy with the process

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Sharing Personal Experiences: I have experienced personal frustrations in medical contexts, but I have been told that the publications process is not a place to vent these

- Keep the **objective of the collaboration and shared purpose** as the main focus
- Understand agreed expectations regarding **appropriate and sensitive interactions and behaviours** for all parties from the outset
  - Refer to codes of conduct or charters of roles and responsibilities to align on the scope of the publication process
- Ask your point of contact if there is **an appropriate channel, support service, or time to discuss any personal frustrations or emotions** that may be coming through from discussing the publication

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Diversity and Representation: I do not feel that I adequately represent the wider patient community in relation to this publication

- Remember that **no individual patient can be fully representative** of the entire patient population
- Understand the **scope of the publication** and your role as a patient partner
  - For some types of publication, you may be representing your own perspective
  - If your role is to represent your wider community, you should consider the needs of this community and be able to blend your personal experiences with those of other individuals
    - Regular interactions with other patients and patient organizations can support this
- Before agreeing to be an author, have **early discussions with the Pharma company about your experiences** to help you both understand whether you are providing a relevant perspective
  - The IMI PARADIGM guidance[1] discusses skills and experiences that patient partners can bring to different types of patient engagement projects[1]
- Bear in mind that **companies may work with a range of authors**, including patients and healthcare professionals, to include diverse perspectives in a publication

IMI, Innovative Medicines Initiative; PARADIGM, Patients Active in Research and Dialogues for an Improved Generation of Medicines.

1. IMI PARADIGM (2020). https://imi-paradigm.eu/PEtoolbox/identification-of-patient-representatives-bw.pdf. (Accessed 6 November 2025).

Lack of Guidance: My company does not have an established framework for involving patients in publications

- While your company may not involve patients in publications, patients may already be engaged earlier in the clinical development process, e.g., to inform protocol/study design. **Connect with other internal teams to understand what level of patient engagement already exists elsewhere within your company**, and what framework might already be in place.
- If there is no framework available elsewhere in your company, **create a company-specific framework** by adopting or adapting existing guidance and relevant publications. These include the 2022 GPP guidelines,[1] the ICMJE authorship criteria,[2] the GRIPP2 reporting guidelines,[3] a 2025 patient-authored publication providing practical steps to advance patient authorship,[4] and a 2025 article on facilitating patient involvement in publications[5]
- Collaborate with colleagues to **co-create guidance documents**
  - **Key topics** include identifying and engaging patient partners, authorship eligibility, and compensation policies
  - **Adapt publicly available documents** where possible, such as the PFMD contract templates[6]
  - **Adapt existing company documents** where possible, e.g., an authorship agreement could be rewritten in plain language for patient authors
  - Define **separate roles and responsibilities** for patients involved in publications in different capacities – as authors, reviewers or advisors
  - Ensure that all **externally-facing plain language documents** undergo relevant cross-functional alignment before use
- **Build internal awareness** through existing training on ethical patient involvement, such as the PFMD[7] and DIA[8] courses
- Consider setting up a **dedicated Patient Engagement Team** to facilitate patient partnership
- **Make a start!** Identify an appropriate pilot project, collect feedback to demonstrate value and refine your framework

DIA, Drug Information Association; ICMJE, International Committee of Medical Journal Editors; GPP, Good Publication Practice; GRIPP2, Guidance for Reporting Involvement of Patients and the Public, Version 2; PFMD, Patient Focused Medicines Development.

1. DeTora LM, et al. *Ann Intern Med.* 2023; 176:eL220490. 2. ICMJE. Defining the Role of Authors and Contributors. Available at: https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html. (Accessed 4 November 2025). 3. Staniszewska S, et al. *Res Involv Engagem*. 2017;3:13. 4. Bharadia T, et al. *Patient.* 2025; 18:403-414. 5. Cooksey K, et al. *BMC Med Res Methodol*; 25;39. 6. PFMD. https://pemsuite.org/legal-and-contractual-tools/. (Accessed 6 November 2025). 6. PFMD. https://pemsuite.org/patient-engagement-training/. (Accessed 6 November 2025). 8. DIA. https://www.diaglobal.org/en/course-listing/certificate-program/patient-engagement. (Accessed 6 November 2025).

Lack of Alignment Between Partners: My alliance partners do not have an established framework for involving patients in publications, or their framework is different to mine

- Work with your publication counterparts to **align on processes and guidance before approaching any potential patient partners.** This aims to prevent any confusion
- **Compare existing policies and frameworks** from either alliance partner
  - Leverage existing materials and identify any gaps
  - Highlight any differences between materials and discuss these with compliance colleagues from both companies
- **Co-create revised policies** that meet the needs of both alliance partners
  - Ensure that all policies are approved by compliance colleagues from both companies
  - Ensure that the policies are also available in plain language
- Ensure that **patient partners are clear about the aligned process** and who their key point of contact is
  - To prevent confusion during the development of a publication, identify **one key point of contact** who takes overall responsibility for communicating with patient partners
- **Document and share learnings** to continuously refine the alliance framework and support consistency in future projects

Lack of Internal Alignment: There is limited collaboration between the Patient Engagement and Publications teams within my company

- **Establish a framework for collaboration** between Patient Engagement and Publications teams
  - Identify key barriers to effective collaboration
  - Establish a cross-functional working group to overcome these barriers.
  - Actions could include:
    - Defining clear roles, responsibilities, and shared objectives in relation to patient involvement
    - Ensuring all colleagues are trained on patient involvement and relevant internal/external guidance
    - Addressing compliance concerns
    - Establishing the need for further policies or guidance
    - Identifying where to involve patients in the publication lifecycle, including involvement in strategic publication planning where relevant
    - Raising awareness between functions of current and upcoming patient involvement activities
- Review where patients may already be engaged elsewhere within your company (e.g., to inform protocol/study design), **what collaborations already exist with your Patient Engagement team**, and leverage key learnings
- Consider relevant metrics applicable across functions to measure the success and value of patient involvement
  - PFMD,[1] IMI PARADIGM[2] and the ISMPP Patient Engagement Task Force have developed guidance on metrics for patient engagement

IMI, Innovative Medicines Initiative; PARADIGM, Patients Active in Research and Dialogues for an Improved Generation of Medicines, PFMD, Patient Focused Medicines Development.

1. PFMD. Your first step towards advanced patient engagement intelligence. https://pemsuite.org/monitoring-to-learn-tools/. (Accessed 6 November 2025).
2. IMI PARADIGM. Patient engagement monitoring and evaluation framework. https://imi-paradigm.eu/petoolbox/monitoring-evaluation/. (Accessed 6 November 2025).
3. ISMPP Patient Engagement Task Force. https://www.ismpp.org/assets/ISMPP%20PETF%20Impact%20Metric%20Tools_Final.xlsx. (Accessed 6 November 2025).

PLS Compliance Concerns: I am worried that PLS and PLSPs could be perceived as promoting to patients

- PLSs are summaries of scientific articles and congress abstracts **written in easy-to-read, non-technical language**[1] and are usually published within the article or congress poster
- PLSPs are standalone, peer-reviewed articles summarising one or more previously published articles in plain language[2]
- PLSs and PLSPs do not introduce any new data
- Publication of PLSs and PLSPs in the peer-reviewed medical literature has **increased exponentially** during the last decade
  - PLS are encouraged by the 2022 GPP guidelines[3]
- **PLS and PLSPs aim is to democratise data** by making the medical literature accessible to non-technical audiences, including non-specialist healthcare professionals, patients, and the public
  - Patients are increasingly involved in authoring or collaborating on PLS and PLSPs, both during development and peer review
- **PLS and PLSPs are not promotional materials**
  - PLS and PLSPs are based on peer-reviewed publications, which by definition are robust, credible and balanced information sources without promotional intent
  - In common with their source publications, PLS and PLSPs published in medical journals are developed in line with GPP guidelines and undergo rigorous peer review to ensure accuracy and quality

GPP, Good Publication Practice; PLS, plain language summary; PLSP, plain language summary publication.

1. https://researchinvolvement.biomedcentral.com/articles/10.1186/s40900-022-00358-6. 2. https://files.taylorandfrancis.com/plsp%20guidelines%20for%20authors.pdf. 3. DeTora LM, et al. *Ann Intern Med.* 2023; 176:eL220490.

Resource Implications: I have inadequate budget, staffing, and time to involve patients in publication development

- **Identify publication activities that would benefit most** from patient engagement
- Embed patient involvement within the publication plan **as early as possible**, enabling budget and resource to be allocated to it
  - This can help to establish the value of patient involvement, and avoid it being seen as a ‘nice to have’ tactic in response to a gap in data flow
  - When selecting tactics, consider the target audiences and the intent of the tactic (the 'so what'), as well as what could also be used by other internal teams
- Identify quick wins that **show the value of communicating in lay terms** to ensure plans for patient involvement in publication development are implemented
  - For example, when developing content for presentations at congresses, include a PLS on a slide at the end of a presentation or as part of a poster, as well as a PLS infographic behind a QR code; then, use audience feedback and usage data to demonstrate the value of communicating in a different way to help to get buy in on other tactics that clearly communicate on a key subgroup where a patient partner would be required (e.g., a PLSP).
- Ensure you have robust processes in place to make patient involvement **as efficient as possible** to minimise burden on internal stakeholders

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Inclusive Engagement: I am uncertain how to tailor my approach for the specific needs of the patients I am partnering with

- **Ask your Patient Engagement team** for their advice
- Create a **culture where patients feel supported and comfortable** to express their views and ask questions
  - Ask patients what they would like to see put in place to feel supported
- Offer **flexibility within your process** to consider individual needs, for example adaptable timelines
  - Identify one key point of contact who takes overall responsibility for communicating with patient partners
- Ensure **effective communication**
  - Use plain language and avoid jargon so all communication is understandable
  - Develop internal resources, such as a therapy area-specific patient lexicon, to support all colleagues to use appropriate language
- Offer **flexible communication channels** to meet individual preferences whilst balancing resources and other goals
  - Virtual meetings, email correspondence, text messaging, etc., are regular communication options for informal catch-ups and project correspondence
- **Refine your approach using feedback** from patients and evaluate the quality of patient involvement in your project. For example, using the PFMD Patient Engagement Quality Guidance[1] and a published patient author experience tool[2]

PFMD, Patient Focused Medicines Development.

1. PFMD (2018). Patient Engagement Quality Guidance. https://patientfocusedmedicine.org/peqg/patient-engagement-quality-guidance.pdf. (Accessed 6 November 2025).
2. Arnstein L, et al. *Res Involv Engagem.* 2020;24:34.

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Identifying Opportunities: I am unable to identify opportunities to involve patients in publication activities, or to identify the right patients to partner with

- **First identify topics for which a patient perspective would add value**
  - Understanding unmet treatment needs; what its like to live with the condition; how clinical data translate into a real-life setting; review of PROs; impact of endpoints that have a meaningful impact to patients (vs. what a KOL/HCP may consider important); impact to care partners and the needs of care partners
- **Then identify key touchpoints throughout the publication lifecycle** where patient perspectives could add value
  - These could include concept development, authorship, writing and/or reviewing PLS, and dissemination planning
  - Use patient perspectives to augment your publication plan, by including patients in publication steering committees and working groups
- **If you're struggling to find the right patients** to partner with:
  - Define the **relevant skills and level of experience** that will be required
  - Leverage **existing relationships**
    - Identify and work with internal stakeholders who have established external relationships with individual patients and/or patient organizations, such as the Patient Engagement and Medical Affairs teams
  - Build **new relationships**
    - Guidance is available from IMI PARADIGM on identifying patient representatives[1]
  - Once you have **identified patient partners**, make sure you understand their motivations for participation (including previous experience working with Pharma), and their practical ability to contribute

IMI, Innovative Medicines Initiative; PARADIGM, Patients Active in Research and Dialogues for an Improved Generation of Medicines.

1. IMI PARADIGM (2020). https://imi-paradigm.eu/PEtoolbox/identification-of-patient-representatives-bw.pdf. (Accessed 6 November 2025).

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Reimbursement Considerations: My company has no clear policy related to patient reimbursement, or is unable to reimburse patient authors for their contribution

- Ensure that you are **clear with the patient partner upfront** about your reimbursement policy for the specific activity planned
- If your company **permits patient authors to be paid** for their contribution, ensure that the reimbursement process is clear
  - Ensure early, upfront communication about roles and responsibilities, scope of work and the estimated hours required
  - Guidance is available regarding fair market value, for example from PFMD[1] and the NHC[2]
- If your company policy **does not permit reimbursement for authorship:**
  - Ensure that the patient partner is given the option to withdraw from the project
  - You could consider an alternative form of engagement. For example, patients could be paid for their involvement in study design and interpretation
  - Discuss with compliance colleagues whether policies could be amended to incorporate patient involvement – for instance differentiating between types of authors (e.g. patients vs healthcare professionals)
- If **patients are participating as authors without reimbursement**, still ensure that roles and responsibilities and the expected level of effort are clarified upfront

NHC, National Health Council; PFMD, Patient Focused Medicines Development.

1. PFMD. Discover the tools to support fair remuneration of the patient community for interactions with the pharmaceutical industry. https://pemsuite.org/fmv/. (Accessed 6 November 2025). 2. NHC. Access the NHC Patient Compensation Tools. https://nationalhealthcouncil.org/access-the-fmv-calculator. (Accessed 6 November 2025).

Flexible Timelines: The patients I am partnering with are facing personal issues such as illness, which could affect our ability to meet project deadlines

- Consider how to **adapt your project timelines to accommodate patient needs** while still meeting your objectives – patient centricity is key
- **Communicate sensitively** around deadlines
- Build additional **flexibility into timelines**
  - Include buffer time to compensate for unexpected circumstances
- Build **flexibility into tasks**
  - Instead of requiring patient partners to provide feedback via email or a publication management system, consider different ways in which they can provide their feedback – virtual meetings, email correspondence, text messaging, etc.
  - Consider how to make contributions more manageable, for example breaking larger tasks down into smaller ones
- **Emphasize that all contributions are valuable**, regardless of scale or timing
  - If patient partners are unable to review every draft, make reasonable adjustments/concessions that align with patient needs whilst adhering to authorship criteria
  - If patient partners cannot approve a final version of the publication because of a serious worsening of their condition or death, adopt the procedure used for any author who is unable to approve the final version

Lack of Decision Oversight: Decisions on patient engagement are made by my client; my agency is not involved in the process

- You have a role in making sure your client **considers engaging patients** in publication activities
  - As early as possible, ask if the client company has a patient engagement framework in place, and if patients have already been engaged in the clinical development program (e.g., provided input into a protocol design or participated in a patient insights activity)
  - Encourage them to maximise patient involvement in line with their company framework
- Make your client aware of **your patient engagement capabilities**
  - You may be acting as an intermediary between the client and patient partners, and will help to guide ethical collaboration and inclusive publication practices
- **Educate clients on the value** of patient involvement in publications
  - Share evidence on the benefits of patient involvement in publications[1]
  - Provide case studies that demonstrate successful patient involvement in publications, such as examples from the PFMD Book of Good Practices[2]

PFMD, Patient Focused Medicines Development.

1. Bharadia T, et al. *Patient.* 2025; 18:403-414. 2. PFMD. Discover inspiring patient engagement initiatives.
2. https://pemsuite.org/bogp/. (Accessed 6 November 2025).

Lack of Guidance: My client does not have an established framework for involving patients in publications

- Ensure you and your colleagues have the **skills to support patient involvement** in the absence of client frameworks
- Make the client **aware of publicly available resources** and relevant patients/patient organizations who may be able to support framework development
  - Resources include the 2022 GPP guidelines,[1] the ICMJE authorship criteria,[2] the GRIPP2 reporting guidelines,[3] a 2025 patient-authored publication providing practical steps to advance patient authorship,[4] a 2025 article on facilitating patient involvement in publications[5] and PFMD contract templates[6]
- Work with the client and relevant patients/patient organizations to **co-develop a framework** for patient engagement in publications
- If the client has a Patient Engagement team, suggest that they **involve this team** in framework development

ICMJE, International Committee of Medical Journal Editors; GPP, Good Publication Practice; GRIPP2, Guidance for Reporting Involvement of Patients and the Public, Version 2; PFMD, Patient Focused Medicines Development.

1. DeTora LM, et al. *Ann Intern Med.* 2023; 176:eL220490.
2. ICMJE. Defining the Role of Authors and Contributors. Available at: https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html. (Accessed 4 November 2025).
3. Staniszewska S, et al. *Res Involv Engagem*. 2017;3:13.
4. Bharadia T, et al. *Patient*. 2025; 18:403-414.
5. Cooksey K, et al. *BMC Med Res Methodol*; 25;39.
6. PFMD. https://pemsuite.org/legal-and-contractual-tools/. (Accessed 6 November 2025).

Resource Implications: My client is concerned that patient involvement will negatively impact publication timelines and budget

- Remember that the **benefits of patient involvement offset the potential impact** on budget, timelines and resources
  - Potential benefits include greater relevance, clarity, and accessibility of the publication, stronger trust with patient communities, and broader dissemination of the publication
- Work with clients to understand budget needs associated with patient involvement, such as honoraria and support costs
  - Where needed, share guidance on patient remuneration such as those from PFMD[1] and the NHC[2]
- Involve patients and establish roles and responsibilities **as early as possible** in the publication process, to align expectations and minimize delays later on
  - Discuss typical publication timelines upfront to help manage both client and patient expectations
- When **preparing the publication timeline**, ensure it facilitates patient involvement
  - For example, allowing sufficient time to review materials and including buffer time for unexpected delays
- **Communicate with the journal Editor regarding timelines**, and keep them informed if extensions will be required, for example to manage revisions

NHC, National Health Council; PFMD, Patient Focused Medicines Development.

1. PFMD. Discover the tools to support fair remuneration of the patient community for interactions with the pharmaceutical industry. https://pemsuite.org/fmv/. (Accessed 6 November 2025).
2. NHC. Access the NHC Patient Compensation Tools. https://nationalhealthcouncil.org/access-the-fmv-calculator. (Accessed 6 November 2025).

Negative Experiences: My client has had a previous negative experience in a patient engagement project

- Discuss with your client to understand **why their experience was negative**
- Educate your client on the **benefits of patient engagement** in the publication lifecycle, and provide published case studies highlighting the value
- **Share your team's own experiences** of patient engagement in publications, demonstrating the feasibility
- **Identify an internal company advocate** who has had a positive experience for your client to connect with

Identifying Opportunities: I am struggling to find opportunities to discuss patient involvement in publications with my client

- Be aware that your client may be **familiar with certain activities** such as PLS and patient authorship, **but struggling to look more broadly and strategically**, for example at patient involvement in publication planning and steering committees
- Educate your client on the **different opportunities to involve patients** throughout the publication lifecycle
  - Help them to identify topics for which a patient perspective would add value: understanding unmet treatment needs; what it’s like to live with the condition; how clinical data translate into a real-life setting; review of PROs; impact of endpoints that have a meaningful impact to patients (vs. what a KOL/HCP may consider important); impact to care partners and the needs of care partners
  - Consider sharing slides and case studies on how this can be done for different activities, particularly for planning activities where the patient perspective tends to be overlooked, such as in steering committees[1,2]
- **Review existing publication plans** with your client to identify opportunities for patient involvement
  - Schedule a specific meeting to discuss these opportunities and clarify what they need from you
- Proactively offer to address internal barriers by offering to talk to the relevant teams directly (such as Patient Engagement and compliance teams)
- Link the value of patient engagement with key performance indicators that your client is working towards

PLS, plain language summary.

1. Establishing a patient publication steering committee: A case study with insights for medical writers. https://journal.emwa.org/writing-for-patients/establishing-a-patient-publication-steering-committee-a-case-study-with-insights-for-medical-writers/. (Accessed 10 December 2025). 2. https://figshare.com/articles/poster/Patient_Publication_Steering_Committees_-_feasibility_case_study/12561935?file=23415485. (Accessed 10 December 2025).

Lack of Interest: My client is not interested in patient involvement in their specific therapy area

- Remember that **patient perspectives are relevant in most therapy areas.** It is your job to work with your client to identify the most relevant potential opportunities to involve patients in publications – open up a discussion by asking why they are not interested
- Use **case studies from other therapy areas** to show your client how patient involvement can lead to more impactful publications and publication plans
- If the client company has a **Patient Engagement team**, suggest they link in with this team discuss how patient involvement can support publications in their therapy area
- Support your client to **find relevant patients and patient organizations** that may be able to participate in publications development
- Demonstrate **what competitors are doing** with patient engagement in the same therapy area

Unintegrated Perspectives: My client only asks patient authors to review sections of publications, leaving them separated from the author group

- **Encourage clients to involve patients from the outset**
  - Use guidelines to support this suggestion, including GPP 2022, ICMJE authorship criteria, and other industry guidelines
- Use client codes of conduct or charters of roles and responsibilities to **manage shared expectations** and encourage integration of patient authors
- Make sure the **remit of patient engagement within the publication** is clear
  - Ensure alignment at the publication outline stage
- Provide **context and background** on the types of opportunities available to integrate the patient voice into publications, and any limitations or guidelines that need to be adhered to (e.g. journal instructions or reporting guidelines)
- Suggest **asking patient authors for feedback** on the process during and after publication development to improve future patient engagement
  - For example, using the PFMD Patient Engagement Quality Guidance[1] and a published patient author experience tool[2]

PFMD, Patient Focused Medicines Development.

1. PFMD (2018). Patient Engagement Quality Guidance. https://patientfocusedmedicine.org/peqg/patient-engagement-quality-guidance.pdf. (Accessed 6 November 2025).
2. Arnstein L, et al. *Res Involv Engagem.* 2020;24:34.

Promotional Perceptions: My client is concerned that involving patients in publication activities could be seen as promotional

- Remember that perceptions of promotion are valid and reflect a **broader industry tension between meaningful patient engagement and regulatory compliance**
  - Sensitivities exist around accessibility of publications to broader audiences than specialist healthcare professionals
- Show your client that you **understand the potential sensitivities** surrounding patient involvement in publication activities, especially when patients are using the sponsor's product or taking it in the context of a clinical trial
- Share established **industry guidelines that support patient engagement** when it is transparent, well-documented, and scientifically grounded – 2022 GPP guidelines,[1] EFPIA, FDA
- **Highlight the value of peer review** in ensuring robust, balanced, and accurate publications – all publications that go through peer review are by definition non-promotional
- Make **clear recommendations** on how to avoid any potential promotional perceptions, such as:
  - Ensuring the patient's role in the publication is clearly and transparently defined and disclosed
  - Avoiding the use of promotional language
  - Include the compliance team in framework development
  - Inclusion of an internal compliance review step as part of the publication development process

ISMPP International Society for Medical Publication Professionals™

To be populated

Glossary

- Advisors
- Authorship
- Compliance
- Cross-functional working group
- Data gaps
- Eligibility
- Ethical patient involvement
- Gap analysis
- GPP
- ICMJE
- Onboarding

To be populated

Glossary (cont.)

- Medical affairs
- Metrics
- PAGs
- Patients
  - People having or at risk of having medical condition(s), whether or not they currently receive medicines or vaccines to prevent or treat a disease; and family and those voluntarily caring for those with the medical condition(s), patient advocates and patient groups
- Plain language
- PRO
- Reviewers
- Publication plan
- Scope of work
- Stakeholders
- Strategies
- Tactics

To be populated

Resources

- **The what:** Guidance supporting pt involvement
  - In publications – GPP 2022
  - More broadly – refs
- **The why:** Specific benefits of pt involvement in publications – do we have quantitative evidence for this?
- **The how:**
  - Generate the right skill sets
    - Patient: WECAN course, EtP authorship resources
    - Agency/client
  - Follow the right policies & processes
    - General guidance (EFPIA, NIHR etc)
    - How patients can meet ICMJE authorship criteria
    - Remuneration & tax guidance
    - Contract templates
    - Plain language writing & PLS
    - Reporting PI in publications - GRIPP2
  - Find the right patient for the right opportunity
    - Pt involvement in pubs lifecycle
    - Patient ID (IMI PARADIGM)
  - Measure the impact & incorporating learnings – inc PEQG
  - Case studies

Case studies

- https://journal.emwa.org/writing-for-patients/establishing-a-patient-publication-steering-committee-a-case-study-with-insights-for-medical-writers/