

Welcome!

Putting the patient perspective into publications

The views expressed in this Webinar are those of the presenters, and are not an official position statement by MAPS, nor do they necessarily represent the views of the MAPS organization or its members.

This presentation is for informational purposes only and is not intended as legal or regulatory advice.

Introductions



Dawn Lobban

Global Lead, Patient Partnerships
Envision Pharma Group

*Dawn is an employee and shareholder
at Envision Pharma Group.*



Veronica Porkess

Publications Lead, Rare Diseases
UCB Pharma

*Veronica is an employee and
stockholder at UCB Pharma.*



Zack Pemberton-Whiteley

Chief Executive Officer at
Leukaemia Care, a UK based
blood cancer charity

Objectives and Agenda

Learning objectives

- Discuss the value of patient perspectives in company-sponsored medical publications
- Understand the opportunities for, and the barriers to, patient authorship
- Highlight some of the tools and training available to empower patients to become authors
- Describe a recent case study of patient co-authorship of a company-sponsored publication

The rationale for patients as authors

Dawn Lobban

Empowering patients to be authors

Zack Pemberton-Whiteley

Patient involvement in evidence generation and publication: a case study

Veronica Porkess

Polling question:

What is your experience of working with patients as co-authors of peer-review publications



I have never considered it



I am interested but have no experience yet



I have tried but it was a challenge to implement



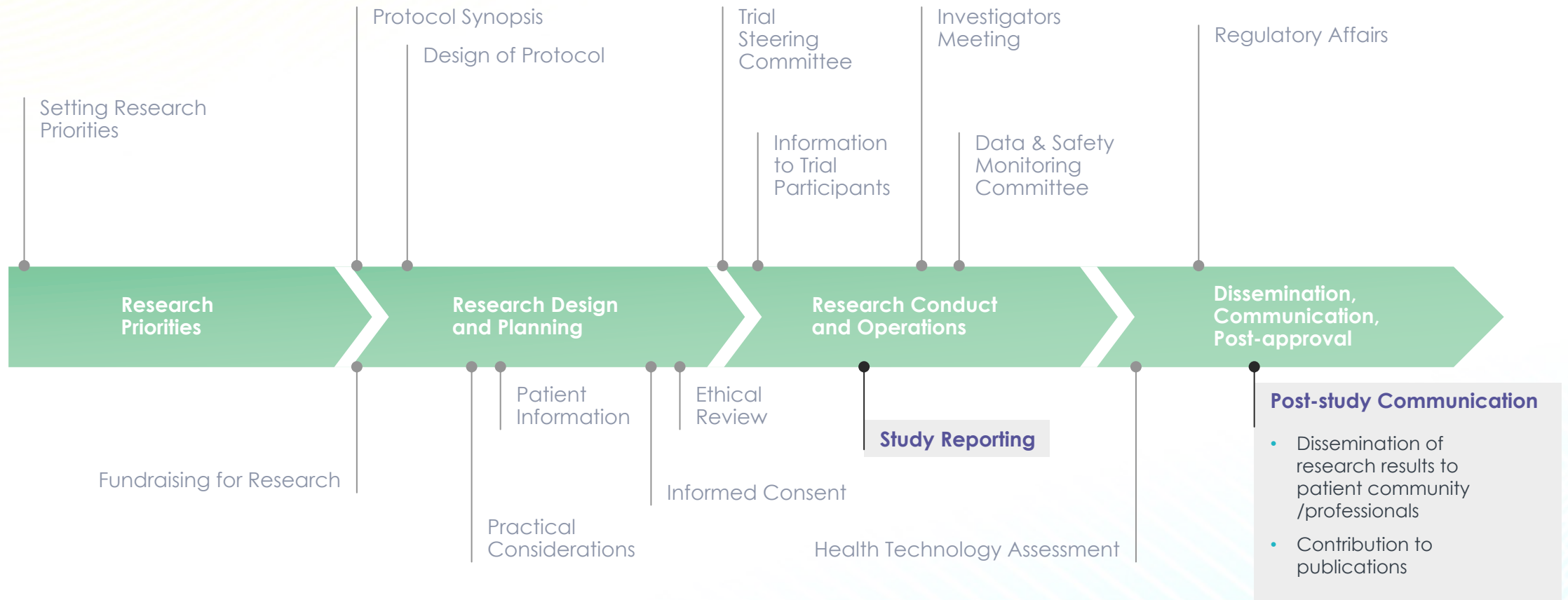
I have successfully collaborated with patient co-authors

Welcome!

The rationale for patients as authors

Dawn Lobban

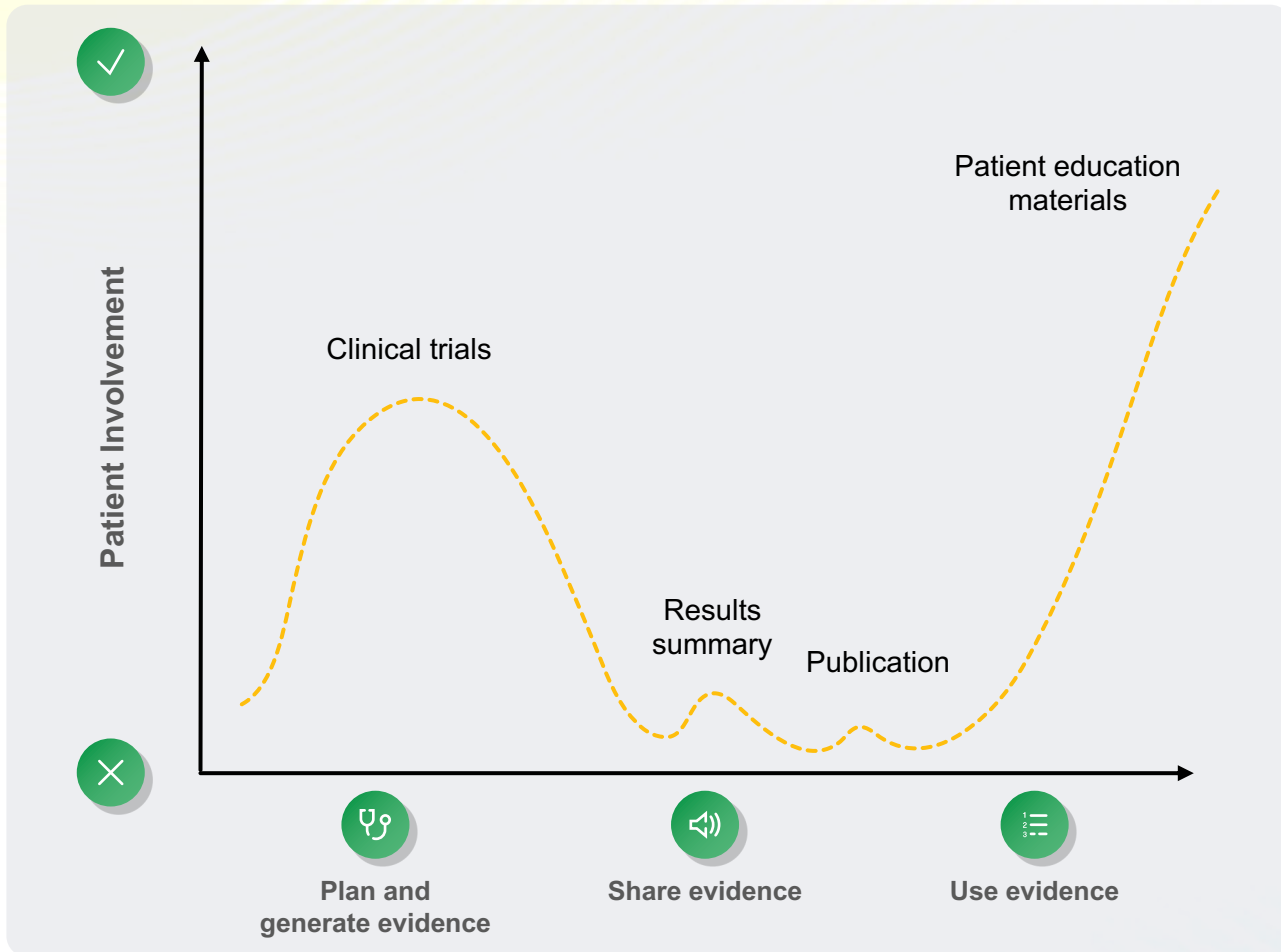
Patients can be involved throughout the medicine development life cycle – including publications^{1,2}



¹ Geissler J, Ryll B, di Priolo SL, Uhlenhopp M. Improving Patient Involvement in Medicines Research and Development: A Practical Roadmap. Ther Innov Regul Sci. 2017;51(5):612-619. doi:10.1177/2168479017706405, and at www.eupati.eu

² Woolley KL, et al. Insights from patient co-authors in a systematic review of patient involvement in publications. Oral presentation ISMP Annual Meeting USA 2019. Curr Med Res Opin. 2019;35(suppl 2)

Patient involvement in publications is lagging – but is on the increase



Factors driving an increase in patient authorship

Recognition by major funders

Increase in patient-led research

Increasing involvement with congresses and journals

Patient publication steering committees

Plain language summaries

Patient demand

Awareness of the value!

Growing support...

Patient authors add real value to peer-reviewed publications

Representative

Applicable

Relevant

Understood

Trusted

Disseminated

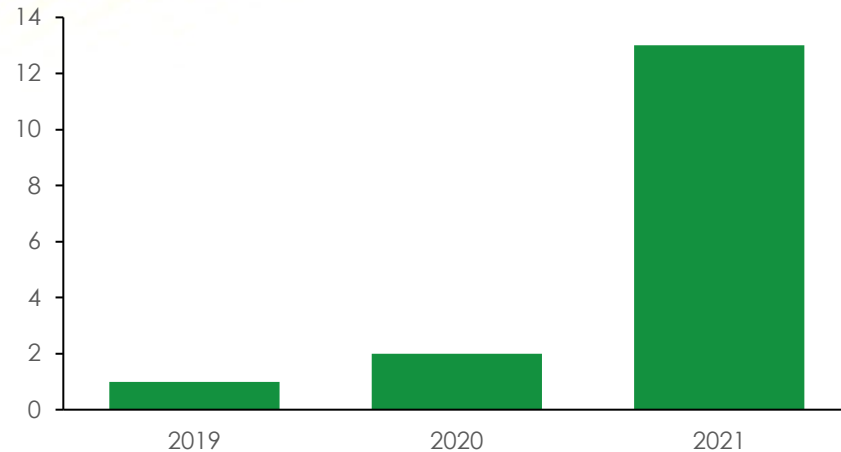
Identifying patient authors

Who are they?

A person who:

- Lives with (or is affected by) a disease or condition
- Provides a patient perspective to the publication
- Meets all the criteria required for authorship, eg, criteria from the International Committee of Medical Journal Editors (ICMJE)

Publications including a patient author



Includes publications where patients were sole or lead author reinforcing that patient authorship is not and should not be tokenistic



Affiliation = 'Patient Author'

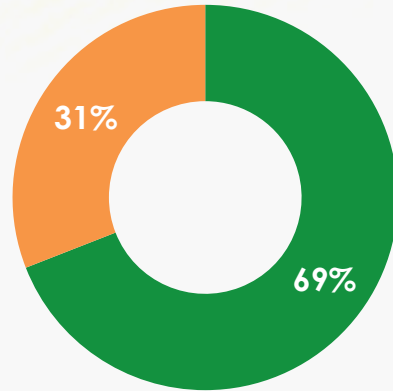
Why do we want to identify them?

- Improve affiliation transparency
- Validate researcher claims of patient involvement
- Facilitate patient authorship research
- Act as role models to encourage others

Editors support patients as authors but some question the applicability of ICMJE authorship criteria

In your view, is it appropriate for patient partners to be authors or co-authors on published biomedical research articles? (N = 107)

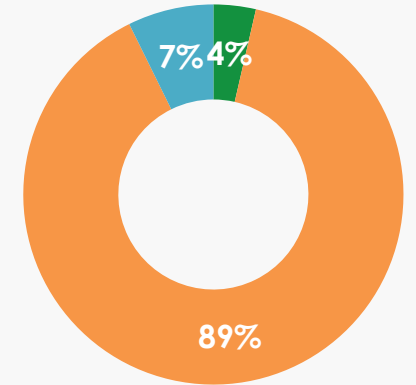
■ Yes
■ No



"In many cases, they make significant contributions to data acquisition and analysis or perform critical functions, without which, the studies could not be completed"

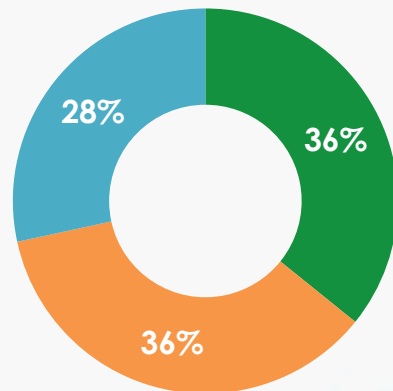
Does your journal have an authorship policy which specifies how patients or patient partners should be considered as authors? (N = 110)

■ Yes
■ No
■ Unsure



In your view, do you think the ICMJE authorship criteria should be revised to be more inclusive to patient partners? (N = 109)

■ Yes
■ No
■ Unsure



"Unless the patient was involved in the design and analysis of the data I do not think the subject should be considered to be co-authors."

- Two journals had a policy similar to ICMJE criteria
- One noted that their journal encourages patient authorship and described sections in their journal relevant to patients but did not specifically describe a policy

The (efficient) pathway to successful patient authorship

Nil or rare patient authorship

Successful patient authorship

TRIAL AND ERROR

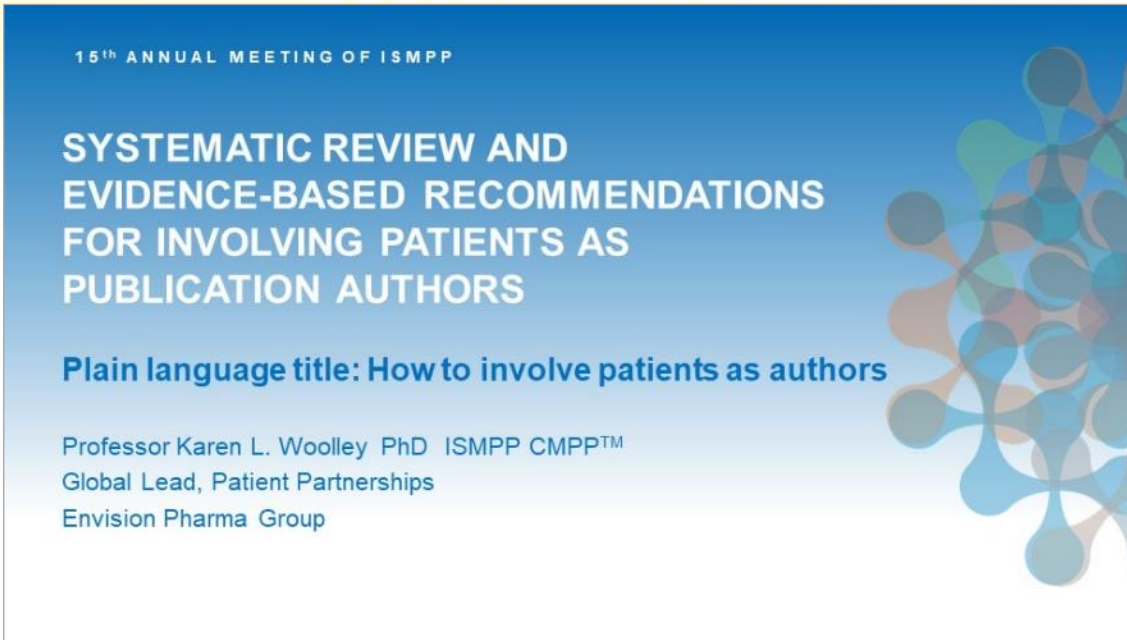


Evidence-based approach



Evidence on benefits and risks of patient authorship

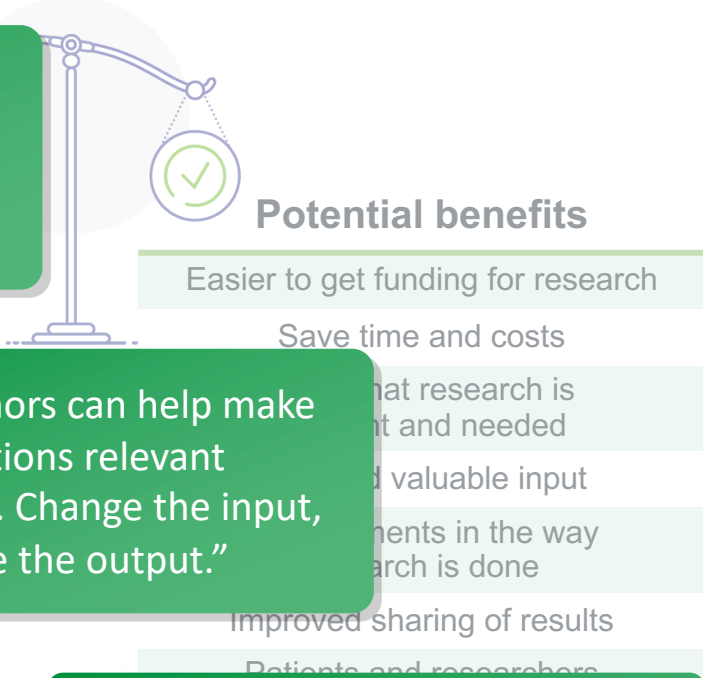
World-first systematic review... with patient authors^{1,2}



“Of course patients should be involved as co-authors of medical research papers. It’s our story you’re telling.”

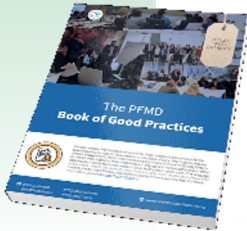
Lost opportunity to carry out other research
 Imbalance of power between researchers and patients
 Insights may not be shared with wider groups

“Patient authors can help make publications relevant and readable. Change the input, enhance the output.”



“Patients should be involved as authors – it’s a no-brainer!”

- Oral presentation at the 15th Annual Meeting of ISMPP
- Selected for the 2019 Book of Good Practices, issued by Patient Focused Medicines Development
- Published by *Research Involvement and Engagement*



1. Arnstein L et al. *Res Involv Engagem.* 2020; 6:34.
 2. Arnstein L et al. *Curr Med Res Opin.* 2019. <https://www.tandfonline.com/doi/full/10.1080/03007995.2019.1587943>.

An evidence-based approach to empowering patients to co-author publications

21 evidence-based recommendations

for manuscript
preparation

Key recommendations

Before

Ideally, involve patients in the question formulation stage to ensure publications address unmet needs that are relevant and important to patients

Consider providing a publication induction guide and training for patient authors (eg, plain language summary of GPP3, glossary of publication terms, overview of process)

Identify patient author candidates who are interested in contributing, have relevant expertise, and can meet authorship criteria

During

Recognize and respect diversity in the authorship team. Patient authors can provide unique and useful input from their lived experience

Consider presenting key results at authorship meetings and in publications that could make it quicker and easier for patients to understand (eg, use data visualization, flowcharts)

After

Involve patients in the publication dissemination plan (eg, raising awareness, contributing to plain language summaries, ensuring cultural and linguistic appropriateness)

Tools in plain language to help patients understand authorship

Developing an infographic with and for patient partners about conference abstracts

The Basics about Conference (and Other) Abstracts

What is an Abstract and its Purpose?

- 01** A brief summary of research work you have done or will do. Make abstracts as concise as possible. Use the word limit to your advantage. Let the rest of the world know about your work.
- 02** Submitted to conference organizers before a conference to get "pre-approval" of the abstract.
- 03** Typical presentation format. You can report:
 - Presenting a poster at a research conference
 - Presenting a poster at a medical conference
 - Presenting a poster at a patient-focused research conference
 - Presenting a poster at a patient-focused research conference
 - Presenting a poster at a patient-focused research conference
- 04** The abstract is reviewed by a committee of experts on the day of the conference. You will be notified of the results.
- 05** Anyone can write an abstract. Patient partners are encouraged to write abstracts.
- 06** A way to share knowledge. Research abstracts are published in a journal or conference program.

Parts of an Abstract

- 1** **Title of Your Presentation**
- 2** **Authors:** Contribution to the work and their affiliations (often ordered from who contributed the most to the work. Patient partners may or may not have an affiliation. Highlight the experience closest to feasibility. A Presenting author is the person who will present the work if accepted).
- 3** **Main Body:** Instructions about sections or headings, word count, and anything else required are provided in the call for abstracts. Consider the study goals and abstract format.
- 4** **Goal / Objectives:** why you did the research and what you hoped to accomplish.
- 5** **Background:** why the goal is important (eg, an area that patients have indicated is an unmet need).
- 6** **Methods / Approach:** how the work was done. For example, was there a review of the scientific literature or current knowledge? This is a very diverse field. Do you have any specific responsibilities? Were there focus groups? Were patient partners part of the team, and if so, how were they involved?
- 7** **Results and Discussion:** highlights of the findings and why you found them interesting or maybe the findings weren't what you expected and you don't think that's your thought.
- 8** **Conclusion or Summary:** The take-away or one of two things that you found and want people to remember.
- 9** **Potential conflicts of interest:** Any relationships that may be perceived to influence the research and report for transparency (eg, employment, a consultancy, being paid to do the research, relationships with for-profit companies, etc.).

Good luck with your abstract! We hope you have found this to be helpful and informative!

Thank you for your input!
Brenda Andreas, Mary Brachanec, Rachel Cooper, Jennifer Daly-Cyr, Trudy Flynn, Erin Gilmer, Kathy Koshin, Delane Linkewich, Zal Press, Laurie Proulx, Maureen Smith, Linda Wilhelm, and Andy Wong

http://blogs.ubc.ca/imhablog/files/2021/08/Infographic_Abstract-Preparation-for-Conferences.pdf

Summary of GPP guidelines for patient partners

ENVISION THE PATIENT
Good Publication Practice (GPP) Guidelines
SUMMARY FOR PATIENT AUTHORS

What is the purpose of this summary?
This summary can help patients understand the 'rules' of becoming an author of a research report (eg, a presentation at a medical conference or a publication in a medical journal). The summary was created with patients and one of the authors of the GPP guidelines.

WHAT ARE THE GPP GUIDELINES?
The GPP guidelines help authors prepare research reports that can be trusted. These guidelines focus on how to report research funded by healthcare companies. You can read the full guidelines, for free, at: <http://annals.org/aim/futurecare/2424869/good-publication-practice-communicating-company-sponsored-medical-research-gpp>

WHAT IS A PATIENT AUTHOR?
Patients can provide unique and valuable input to research and research reports

Patients — Patient Partners (Help with the research study) — Patient Authors (Help with the research report)

A patient author represents patients' views in the report and meets the 4 requirements to become an author (table)

REQUIREMENTS TO BE AN AUTHOR	HAVE YOU MET THIS REQUIREMENT?	
	Yes	No
1. Provide a valuable contribution to the report (eg, use your experience as a patient to help design the study, or to help identify and describe the research findings that are most important to patients)		
2. Provide useful comments at each stage of writing the report		
3. Read and approve the final version of the report		
4. Be willing to take responsibility for the accuracy and integrity of the report and help to answer questions about the report		

Page 1 of 2 | January 2018

KEY POINTS
Patients can offer unique and valuable input to research reports. If you are asked to be a patient author on a research report, use this summary to help you:

- 1** Meet the requirements to be an author
- 2** Know your author rights
- 3** Know your author responsibilities

What are your rights as a patient author?

- To read and discuss information (eg, the research protocol) that will help you understand the research findings.
- To share your skills (eg, experience as a patient) to help analyze, interpret, and report research findings.
- To suggest conferences and journals you think would be suitable for sharing the research findings. More conferences and journals are encouraging patient authors and patient-focused research.
- To be paid to cover costs of being an author (eg, travel to author meetings). Authors are not usually paid for writing time.
- To ask for help from a publication professional who is trained to help authors prepare reports and to follow relevant guidelines. Help is not guaranteed, but you can ask.

What are your responsibilities as a patient author?

- To sign a written Authorship Agreement at the start of the project. The Agreement should describe your rights and responsibilities and state that the healthcare company cannot interfere with authors' rights.
- To report the research findings in a complete, accurate, non-biased, and timely way, whether you think the findings are good, bad, or uncertain, you must report the findings.
- To provide useful feedback at each stage of preparing the report (eg, reading each draft, sharing your comments) and to approve the final version of the report.
- To follow GPP guidelines and other reporting guidelines relevant to your work.
- To respect the privacy of patients involved in the research and include a thank you to the patient group in the presentation or publication.
- To report your name, your role, and any financial or nonfinancial relationships you have that could be perceived as influencing the presentation or publication.

Page 2 of 2 | January 2018

Woolley K. Plain language summary of Good Publication Practice guideline. *Figshare*. 2019. doi:10.6084/m9.figshare.11292047.v1.

Welcome!

Empowering patients to be authors

Zack Pemberton-Whiteley

Putting the public into publications

PUBLIC

“of the people”

PUBLIC-ation

“of the people,

BY the people,

FOR the people!”

wecanadvocate.eu/patients-in-publications/

Copyright:

The 'Patients in Publications' Training Course by WECAN (<https://wecanadvocate.eu/>) and Envision Pharma Group (<https://www.envisionpharmagroup.com/>) is licensed under CC BY 4.0.

This generous license means you are free to share and adapt the content in a reasonable manner for non-commercial purposes, but you must give appropriate credit to © WECAN and Envision Pharma Group 2021 and indicate if changes were made.



PATIENTS IN PUBLICATIONS

TRAINING COURSE

ABOUT THE COURSE

The 'Patients in Publications' Training Course was co-created by WECAN and Envision Pharma Group for patient advocates.

- Learn **HOW** to plan and prepare publications
- Investigate case studies
- Gain tips and insights

WE PROVIDE

- A strong foundation
- A well-defined curriculum
- Open-access material
- Access to a community



Who is the training course for?

Inexperienced patient authors

Patient authors publishing their own data

Patients involved in authoring an abstract

Experienced patient authors

Patients co-authoring with industry
/ HCP / academia

Patients involved in planning
multiple publications

Making it happen: Roles and responsibilities

WECAN team

Course initiation, content review and programme management

Envision

Course content development and programme management

Patient Editorial Board

Course content direction and review

Funders

Funding was obtained from multiple industry and non-industry funders: The funders had no role in course development.

Amgen

Bayer

Ipsen

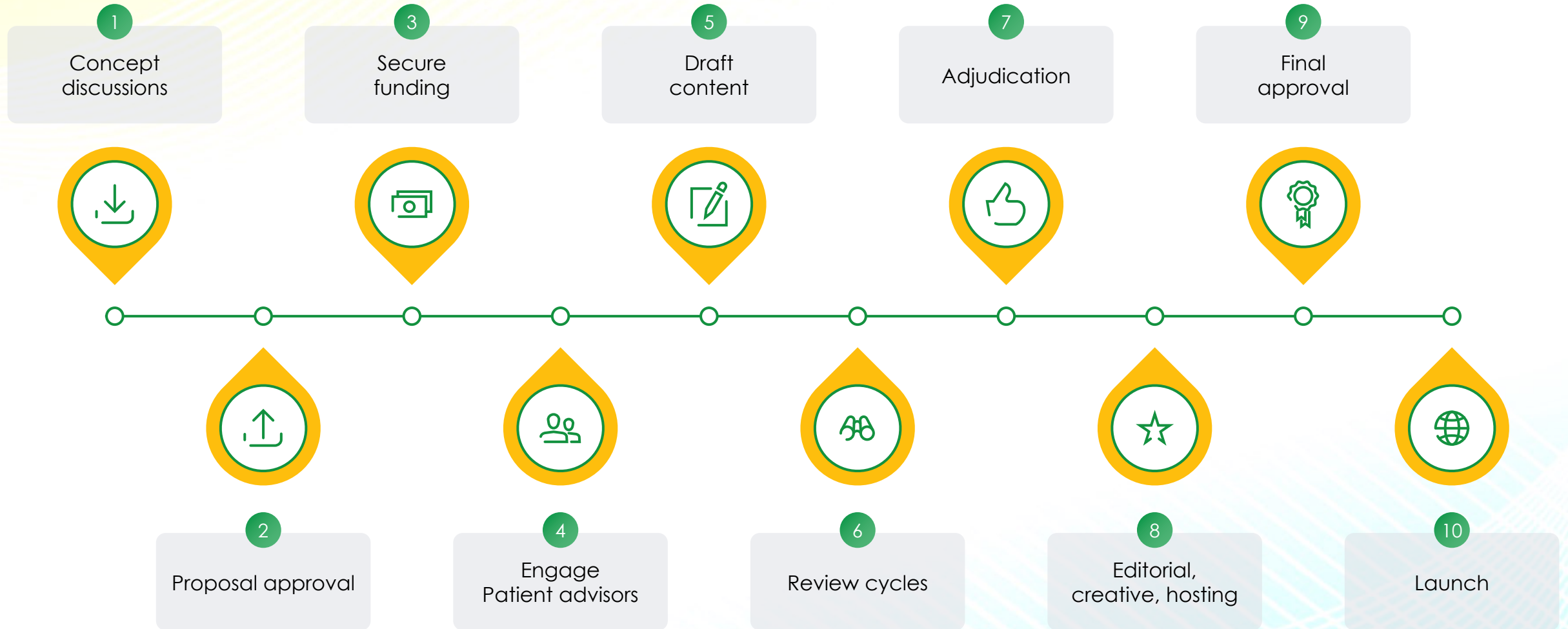
Pfizer

Novartis

Roche

Eupati

A robust development process



What is in the course?

There are 4 modules in this course

- Introduction
- Publication planning
- Publication writing
- Submission, peer-review and beyond

Each module is enhanced by

- Case-study based learning activity
- Helpful handouts
- Summary and top tips

Audio and notes

'It won't turn you into a professional medical writer – but will give you a good start!'

After completing each module, patient advocates should be able to:



Module 1 Introduction

1. Assess the likelihood of publishing your research
2. Describe the key stages in the publication process
3. Identify the major guidelines that provide information on ethical publication practices
4. Describe the main responsibilities of being an author



Module 2 Publication planning

5. Explain what a Publication Steering Committee is
6. Recognise the value of preparing a publication plan
7. Estimate the time required to prepare a publication plan
8. Recall the main factors that should be considered when selecting a journal or a conference



Module 3 Publication writing

9. Identify the major guidelines that provide information on what should be reported in a publication
10. Describe the type of content that should be included in each section of a publication
11. Follow a logical sequence of steps to write a publication
12. Explain the difference between professional medical writing support and ghostwriting



Module 4 Submission, peer review, & beyond

13. Use a quick and free online artificial intelligence tool to help 'check' your publication
14. Prepare a suitable cover letter
15. Explain how to prepare a document to respond to peer-reviewers' comments
16. Propose practical ways to raise awareness of your published research (eg, plain language summaries of publications)

Module 1: Introduction



Relevant case study

- A patient advocate had no publishing experience
- She was invited to author a publication
- She was asked to focus on her personal story
- She faced several challenges
 - No ‘publication mentor’ within patient community
 - Limited time and capability (voluntary hours dedicated to patient advocacy!)
 - Language barriers



Useful handouts

Process for preparing a publication
Time estimate – about 6 months from starting the publication process

Legend: Author/writer task (yellow), Author task (grey), Writer task (red)

If a professional medical writer is not available, authors will need to complete the writer's tasks

Flowchart steps: 1. Confirm there is a... 2. Invite potential... 3. Obtain a signed... 4. Hold a call with patient author(s) to help prepare them for the first, all author call (ie. kickoff meeting) 5. Kickoff meeting – authors discuss: What should be included in the publication, Target journals, Timelines 6. Prepare an outline of the proposed content, based on author input 7. Send authors a summary of the kickoff meeting, including next steps for authors. Answer patient author questions during or after the call.

A tool to help you assess your publication potential – for current or future research

Please read each statement, then rate how strongly you agree or disagree (tick the circle)

Scale: Strongly disagree, Disagree, Neutral, Agree, Strongly agree

Statements:
1. My research focuses on an important question
2. My research is novel
3. My research can be trusted
4. I can report my research clearly and concisely
5. I have the time and skills required to publish my research
6. I have chosen a journal that is likely to be interested in my research
7. I have read, understood, and can meet the journal's requirements

Checklist: Evidence-based recommendations for successful patient authorship¹ – share with research teams

Before manuscript preparation

1. Ideally, involve patients in the question formulation stage (eg, involve patients in publication planning to ensure publications address unmet needs that are relevant and important to patients)
2. Identify patient author candidates who are interested in contributing, have relevant expertise (eg, lived experience), and can meet authorship criteria (ie, no guest authorship); document consented contact details for patient authors in publication management software
3. Clarify and document author and contributor roles and responsibilities (eg, signed authorship agreements should help ensure expectations are clear and understood; patient involvement should be substantial; archive signed agreements)
4. Ensure support for patient authors from nonpatient authors, especially the primary author and publication guarantor
5. Appoint a designated contact person for patient authors to reach out to with queries (eg, a Certified Medical Publication Professional who has publication expertise, project knowledge, and time to support patient authors)
6. Identify relevant publication and patient involvement guidelines that will be followed (eg, CONSORT, GRIPP2, GPP3)
7. Check that funding facilitates patient author involvement (eg, upfront payment of travel expenses for author meetings and conference presentations, translator fees if necessary)
8. Prepare a publication timeline that facilitates patient author involvement (eg, early delivery of materials to review; contingency time for unexpected unavailability – illness, employment, other commitments)
9. Consider providing a publication induction guide and training for patient authors (eg, plain language summary of GPP3, glossary of publication terms, overview of publication process)
10. Consider how to proactively and systematically evaluate the effect of patient involvement (eg, document feedback via publication management software; administer patient authorship experience tools)

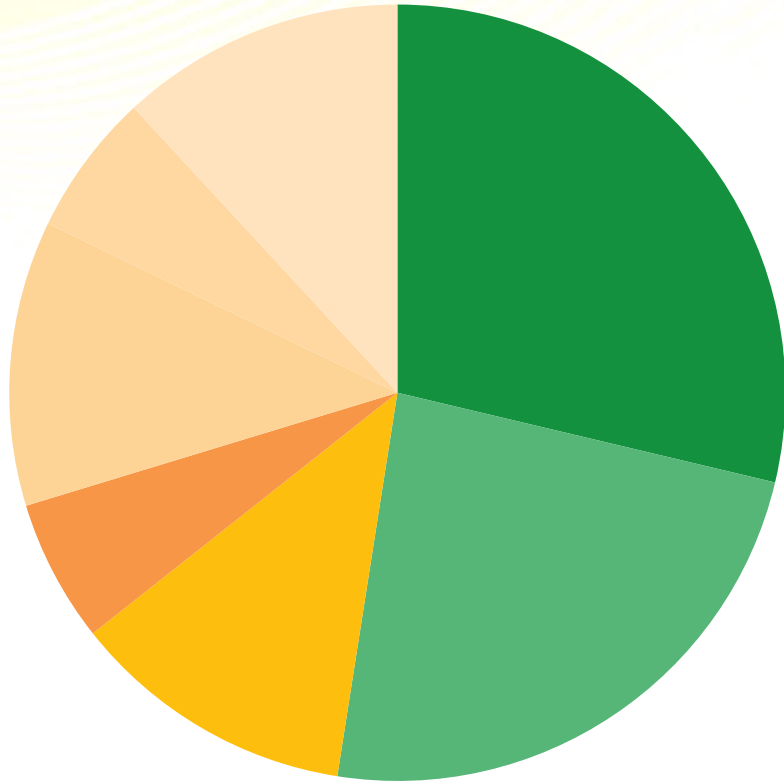
Before you start your research and before you start writing, please consider and share these recommendations with your team. Try to answer 'yes' to as many as possible!

WE CAN Academy

¹ Anstee L, et al. Patient involvement in preparing health research peer-reviewed publications or results summaries: a systematic review and evidence-based recommendations. *Res Involv Engagem*. 2020;5:24. <https://doi.org/10.1186/s13054-020-01325-w>

Who is taking the course?*

*Limited data available



- Patient or Carer, 29%
- Patient Advocate, 24%
- Medical Writing Professional, 12%
- Pharmaceutical Industry, 6%
- Academics, 12%
- Researcher, 6%
- Unknown, 12%

Patient involvement in evidence generation and publication: a case study

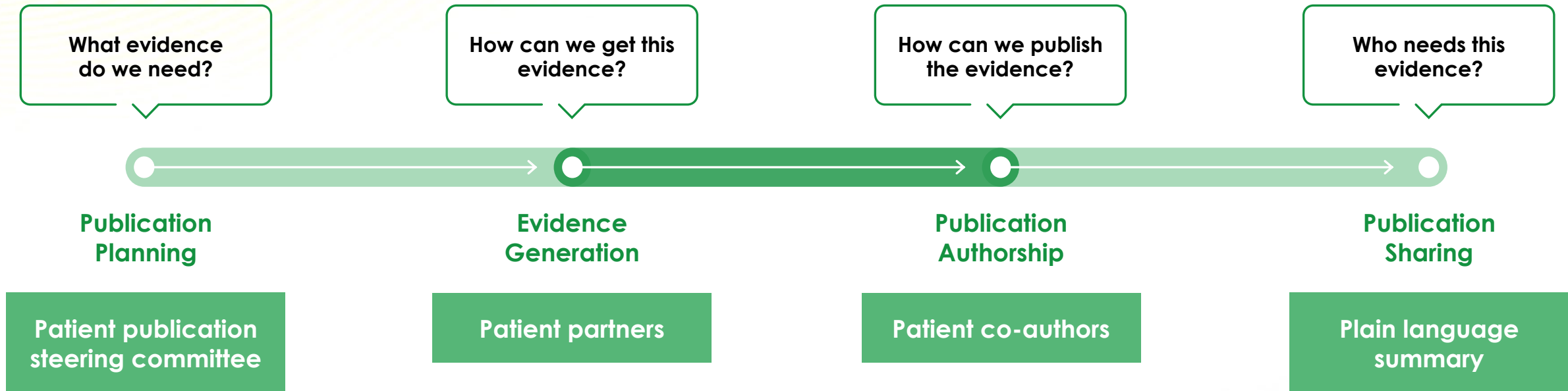
Veronica Porkess

Publications Lead, Rare Diseases, UCB Pharma

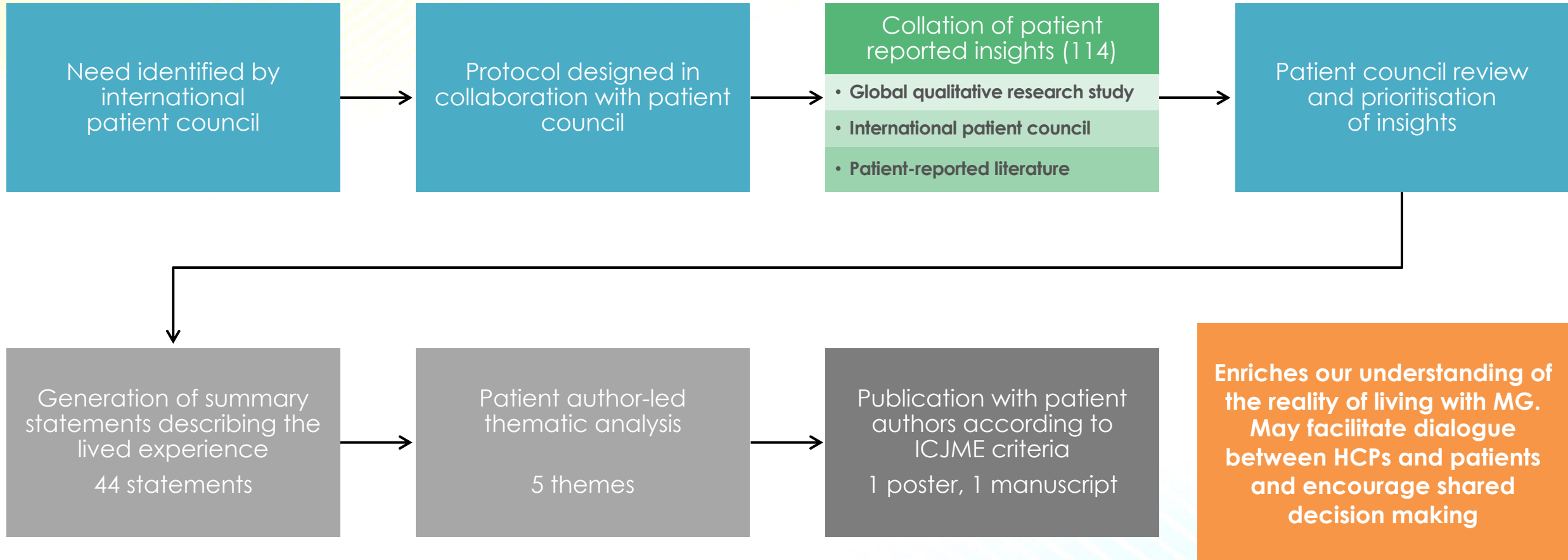
US-S-DA-2100072

Date of preparation: November 2021

Patient involvement in the publications life cycle



Case study: understanding the lived experience of myasthenia gravis (MG)



A learning experience for everyone



Provide **technical support** as required, eg, online discussion platforms



Consider **translation** services for an international patient council



Get internal **compliance** teams on board early and keep them informed throughout



Ensure all relevant **ethics** approvals are obtained at the outset
Journal requirements may be more stringent than local market research rules



Schedule sufficient **time** for review and analysis of data by the patient council who may have other commitments



Provide detailed **feedback** to the patient council on the findings



Provide relevant **authorship support**

- Lay versions of GPP3 and authorship agreements
- Explain publication development process



Schedule sufficient **time** for review of manuscript by patient authors

Patient co-authored peer-reviewed publication

Neurol Ther
<https://doi.org/10.1007/s40120-021-00285-w>

ORIGINAL RESEARCH

The Lived Experience of Myasthenia Gravis: A Patient-Led Analysis

Nancy Law · Kelly Davio · Melissa Blunck · Dawn Lobban ·
Kenza Seddik

Manuscript co-authored with patients and
published in Neurology and Therapy October 2021

[Law N et al. Neurol Ther. 2021 Dec;10\(2\):1103-1125](#)

1029 accesses



Audio-enhanced poster presented at the
American Association of Neurology 2021

<https://miasthenia.org/wp-content/uploads/2021/04/Law-AAN-2021-Poster-2272-MG-Lived-experience-UPLOADED.pdf>

The lived experience of myasthenia gravis: A patient-led analysis

Institutions: ¹MG patient advocate, Parker, CO, USA; ²MG patient advocate, Richmond, London, UK; ³UCB Pharma, Smyrna, GA, USA; ⁴UCB Pharma, Paris, France

AAN Virtual Annual Meeting | April 17–22, 2021 Poster 2272

Background
Myasthenia gravis (MG) is a rare autoimmune disease that clinically manifests as muscle weakness and fatigability.
There are few published data on the patient perspective of how MG impacts life.

Objective
This study set out to reveal the lived experience of MG from the patient perspective.

Methods
The qualitative analysis was led by an international patient council (see page 2 for method overview).

Results
114 patient insights
50 patient quotes
44 summary statements across 9 domains
5 overarching themes describing the lived experience of MG

Summary
This patient-driven analysis enriches our understanding of the reality of living with MG.
A greater understanding of what it means to live with MG could help health care professionals (HCPs) to better communicate with patients.

Overarching themes identified by patient authors
(see page 3 for detailed themes)

- 1 Living with fluctuating and unpredictable symptoms**
"Every patient will have muscle weakness, but the difficulty to live with is that it is so unstable, the fluctuation is even worse to live with than the muscle weakness itself"
- 2 A constant state of adaptation, continual assessment, and trade-offs in all aspects of life**
"You feel it from the moment you wake up and you have to adjust your routines and expectations; I live day by day. Those bad days you need to prioritize the most important activities, or the most basic, and try to work with your medication"
- 3 Treatment inertia, often resulting in undertreatment**
"Yes, if you don't know something is going to work, and it doesn't work, you feel like you've wasted 6 months, which can be very frustrating"
- 4 A sense of disconnect with HCPs**
"He may think I'm in remission, but I'm taking 20-30 mg of prednisone, I have all these side effects. It's not adequate control"
- 5 Feelings of anxiety, frustration, guilt, anger, loneliness, and depression**
"I remember a time when I couldn't go out for dinner with friends after the theatre because I was so exhausted. I cried a lot that evening"

9 individuals living with MG who serve as local or national patient advocates across Europe and the United States

3 data sources analyzed:
Qualitative research study
Previous patient council
Literature review

Physical
Psychological
Social
Reproductive & parenting
Activities & participation
Controlled & not controlled
Flare-ups & myasthenic crises
Treatment burden
Unmet needs

Representative quote by person living with MG
References: ¹Miller AM, et al. *Neurological Clin* 2020;39:831–8. **Author Contributions:** All authors contributed to preparation of the poster.
Author Disclosures: N.L., K.D., members of the patient council; M.B., K.S. employees of UCB Pharma, which funded the study. **Acknowledgements:** We give special thanks to the people with MG who participated in the qualitative research during and patient councils. This study was approved by UCB Pharma. The authors acknowledge Neurologica Purchase, PDC, UCB Pharma, for publication and editorial support. Medical writing support was provided by Sarah Holberry, Clinician Pharma Group, Warrilow, UK, and funded by UCB Pharma, in accordance with Good Publications Practice (GPP) guidelines (<https://www.elsevier.com/locate/S014067362030011>). All users associated with development of this poster were funded by UCB Pharma.

A successful outcome...!

... for the community

Presented at a leading
neurology conference

AAN Virtual Annual Meeting
April 17–22, 2021

Published in a peer-reviewed,
PubMed Indexed journal

Law N et al. *Neurol Ther.* 2021
Dec;10(2):1103-1125.

... for the patient partners

“I felt there was a willingness to
listen and hear the vision of patients,
without judgment and without a priori.
It feels good. It was nice.”
Patient council member

“It has been a great experience.
We could share a lot of things about
people living with MG from different
countries of the world. Many thanks
for this opportunity!”
Patient council member

... for UCB

A landmark study at UCB

Key learnings to optimise
the approach

Increased patient collaborations in
evidence generation and potential
publication in other therapy areas

Inspired colleagues

Polling question: Do you think it is currently practical to involve patients as co-authors of company-sponsored, peer-reviewed publications



No – I don't think it is ever appropriate for patients to be authors



No – more guidance and training is needed



Yes – but there is still a lot of work to do to facilitate this



Of course – let's go!

Q&A