International Society for Medical Publication Professionals

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GPP 2022

September 21, 2022

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Webinar will begin promptly at:
11 AM ET / 4 PM GMT

Good Publication Practice for Company-Sponsored Research: 2022 Update

September 21, 2022

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Executive VP, Strategic Collaborations
Suzann.Schiller@lumanity.com

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the following Titanium and Platinum Corporate Sponsors for their ongoing support of the Society:

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ISMPP Announcements

Applications for ISMPP CMPP recertification via credit are due September 30!

The ISMPP's Authorship Algorithm Tool is live. *Designate your Company Admin, who must be an ISMPP member, and have them sign-up today.*

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2023 EUROPEAN MEETING OF ISMPP

JANUARY 24–25 | LONDON, UK

Fueling Creativity

Session Proposal Deadline, October 3

Abstract Submission Deadline, October 10

Registration Opens Mid-October

Mark your diaries!

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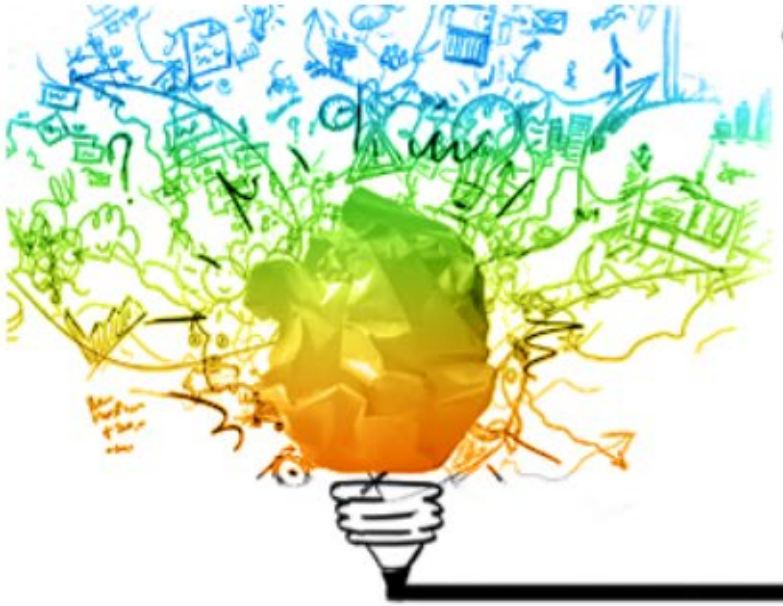
ISMPP U Webinar Proposals



ISMPP University

ISMPP International Society for Medical Publication Professionals™

The ISMPP U Committee invites proposals from groups and individuals for future ISMPP U sessions on topics of interest to ISMPP members.

Please visit ismpp.org/ismpp-u

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Acknowledgments

Anna Geraci oversaw the production of this beautiful slide template

Zoe Preston helped GPP 2022 with tireless copyediting, proofreading, referencing, and managing the typesetting process for the supplement

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How To Ask Questions

To ask a question, open the Q&A window, type your question into the Q&A box. Click Send

Note: Check Send Anonymously if you do not want your name attached to your question in the Q&A

We will make every effort to respond to as many questions as time will allow (live)

We are anticipating a high volume of questions. Please preface your question with the topic it is covering for ease of review by faculty

Examples:

Authorship: Are patients allowed to be authors?

Social Media: Is there a preferred social media platform among publishers?

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Faculty

(Moderator) Lisa DeTora
Associate Professor
Director of STEM Writing
Hofstra University

Faith DiBiasi
Director, Global Scientific Communication
Otsuka

Laura Dormer
Editorial Director
Becaris Publishing

Fiona Plunkett
Director of Client Services
Articulate Science

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Disclosures

- The opinions expressed are those of the authors
- No financial support was received for the development of GPP 2022
- Information presented reflects the personal knowledge and opinions of the faculty and does not necessarily represent the position of their current or past employers or ISMPP

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GPP 2022 Authoring Team

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- Leslie Citrome
- Lisa DeTora
- Faith DiBiasi
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- Trevor Lane
- Fiona Plunkett
- Angela Sykes
- Dikran Toroser
- Christine Vanderlinden

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Objectives

At the end of this session, participants should be able to:

- Understand some key principles of GPP 2022
- Identify new information
- Recognize the various sections of the GPP 2022 Supplement

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Hot Topics Poll Question

Which topic is most important to you?

- Enhanced Content
- Policies & SOPs
- Preprints
- Social Media
- Training
- Working with patients

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Key GPP principles

Reporting and publication of biomedical research should follow all applicable laws and guidelines

All biomedical research must be published in peer-reviewed journals in an accurate, balanced and timely manner

Research and data integrity must be protected from commercial influence

Promote data and other transparency

Authors require access to relevant study data to make informed decisions and be accountable for the work

Form steering committees/working groups before data are available; define member roles & responsibilities up front

All funding sources and other interests of authors & sponsors must be disclosed, including competing interests

GPP, Good Publication Practice; https://www.acpjournals.org/doi/full/10.7326/M22-1460
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Key principles: New in GPP 2022

Patients and patient advocates should be included in publication planning and development, where appropriate

Support communication of scientific information to lay audiences and other interested parties

Pay attention to inclusivity and address needs of marginalised and minority groups

Use enhanced content and plain languages summaries to reach lay audiences

Use open access or free to access options wherever possible

Reflect all regions in which research is conducted

Show leadership via policy/SOP development and team training

GPP, Good Publication Practice; https://www.acpjournals.org/doi/full/10.7326/M22-1460
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Finding changes and other information

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What's new in GPP 2022?

GPP 2022 builds on the previous guidance to reflect the changing role of the publication professional and strengthens the core values of GPP such as ethics, transparency, inclusivity, accountability and responsibility

- Updated guidance on the types of studies that should be published (e.g., HEOR, RWE, translational and biomarker studies)
- Information added on the role of patients as authors
- Improved and detailed guidance on author agreements, including the removal of the recommendation to limit author numbers
- Guidance on working with alliance partners
- Advice on the role of social media in publication planning
- Guidance on enhanced content and PLSs for publications
- Clarity of the timing of data sharing to improve transparency

GPP 2022 has been reorganised and contains a detailed supplement that includes practical help on key aspects of publication planning, including:

- Publication types
- Publication professional roles and professional development
- Steering committees
- Publication plans
- Publication working groups
- Authorship and contributorship determination
- Publication processes
- Documentation guidelines

GPP, Good Publication Practice; HEOR, health economics and outcomes research; ISMPP, International Society for Medical Publication Professionals; PLS, plain language summary; RWE, real-world evidence. https://www.acpjournals.org/doi/full/10.7326/M22-1460

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GPP 2022: List of changes (Main manuscript)

GPP3 Appendix Section	GPP 2022 Update: New Location	Additions and Deletions
1: Publication Processes	Supplement	–
1.1: Publication Planning	Section E of the Supplement	–
1.2: Publication Steering Committees	Section D of the Supplement	Additions: Enhanced process information, role of patients, alliances, types of SCs, contents of charter Deletion: Recommended number of participants
1.3: Studies That Should Be Published	Section E of the Supplement	Additions: Translational and biomarker studies, nonclinical research, health economics, real-world evidence, and outcomes research studies (Sections A and E of the Supplement)
1.4: Premature Publication 1.5: Redundant (or Duplicate) Publication 1.6: Plagiarism	No longer mentioned Ethical Principles Ethical Principles	Addition: Enhanced guidance on acceptable encore presentations (Section A of the Supplement) Deletion: Explanations of poor practice
1.7: Trial Registration and Public Posting of Data	Supplement Table 3	Additions: Information on registration of studies other than clinical trials, and preregistration of clinical protocols
1.8: Documentation	Section I of the Supplement	Additions: Retain copyright permissions, review process details, maintain auditable records

AMWA = American Medical Writers Association; EMWA = European Medical Writers Association; GPCAP = Good Practice for Conference Abstractsand Presentations; GPP = Good Publication Practice; ISMPP = International Society for Medical Publication Professionals; ORCID = OpenResearcher and Contributor ID; SC = steering committee. GPP, Good Publication Practice
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GPP 2022: List of changes

GPP3 Appendix Section	GPP 2022 Update: New Location	Additions and Deletions
2.0: Roles and Responsibilities	Section B of the Supplement (publication professionals, medical writers) Section D of the Supplement (steering committee members) Sections F and G of the Supplement (authors and contributors)	Additions: The potential role of patients in various groups, alliances
2.1: Written Agreement	Supplement Table 4	Additions: Enhanced guidance for authors, sponsors, collaboration, medical writers, disclosures, and confidentiality
2.2: Authors' Access to Data	Ethical Principles, Section F of the Supplement, Supplement Table 4, Section H of the Supplement	Additions: Timing for data sharing with authors, mention of appropriate data sharing in author agreements
2.3: Authorship 2.3.1: Qualifications for Authorship 2.3.2: Application and Guidance	Section G of the Supplement, Supplement Table 4	Additions: Suggested Author Agreement Contents provides guidance summarizing author agreements as well as highlighting key obligations of both the sponsor and authors; information provided regarding patients as authors; use of ORCID recommended Deletion: Recommendation for 10 or fewer authors Change: Process steps moved to Section H of the Supplement

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GPP 2022: List of changes

GPP3 Appendix Section	GPP 2022 Update: New Location	Additions and Deletions
2.3.3: Author Payment and Reimbursement	Section G of the Supplement	Additions: Salaried employees are not disqualified from authorship, reimbursement for time permitted, especially for SC members, patients, patient advocates
2.4: Professional Medical Writers	Sections B, F, and G of the Supplement	–
2.4.1: Role of the Professional Medical Writer	Section B of the Supplement	Addition in main manuscript to enable professional medical writers to follow ethical practices
2.4.2: Working With Authors	Section F of the Supplement	Addition: Reference to relevant AMWA/EMWA/ISMPP joint statement
2.4.3: As Authors	Section G of the Supplement	Addition: Paid employment as a medical writer is not "payment for authorship"
2.5: Contributorship and Acknowledgments	Section G of the Supplement	–
2.6: Disclosures	Section G of the Supplement, Supplement Table 4	Additions: Enhanced detail provided
3.0: Recommendations for Specific Types of Publications and Presentations	Sections A and E of the Supplement	–
3.1: Primary and Secondary Publications	Section A of the Supplement	–
3.2: Presentations at Scientific Congresses	Section A of the Supplement	Additions: Alignment with GPCAP
3.3: Review Articles	Section A of the Supplement	Additions: Guidance expanded and clarified for narrative reviews, methodology papers, case reports, letters to the editor, and supplements
4.0: Reporting Standards	Sections A and F of the Supplement	Additions: Guidance given as appropriate in various appendixes
5.0: Data Sharing	Section H of the Supplement	Additions: More detailed guidance provided

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Guide to Supplement Sections

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Publication Types

- Plain language summaries should be prepared for all clinical trial publications and preferably published in the same journal as the manuscript
- Any enhanced content must be in line with the publication and must not be promotional
- Guidance expanded and clarified for narrative reviews, methodology papers, case reports, letters to the editor and supplements

GPP, Good Publication Practice; SOP, Standard Operating Procedure.
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Publication Professional Roles and Professional Development

- As every situation cannot be planned for, GPP 2022 has included information to help build a team's education and develop standard operating procedures and policies
- Includes recommendations on what should be considered when developing publication policies and SOPs
- Highlights key organizations that can provide training to your team and encourage best practice sharing

GPP, Good Publication Practice; SOP, Standard Operating Procedure.
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Publication steering committees

- Detailed guidance on the life cycle of the steering committee as well as who qualifies for membership, including for those from alliance programs and patient groups
- Each committee should agree to a charter that encourages consensus building, and should also agree on schedule and communication plans
- The supplement provides an overview of this life cycle as seen on the next slide

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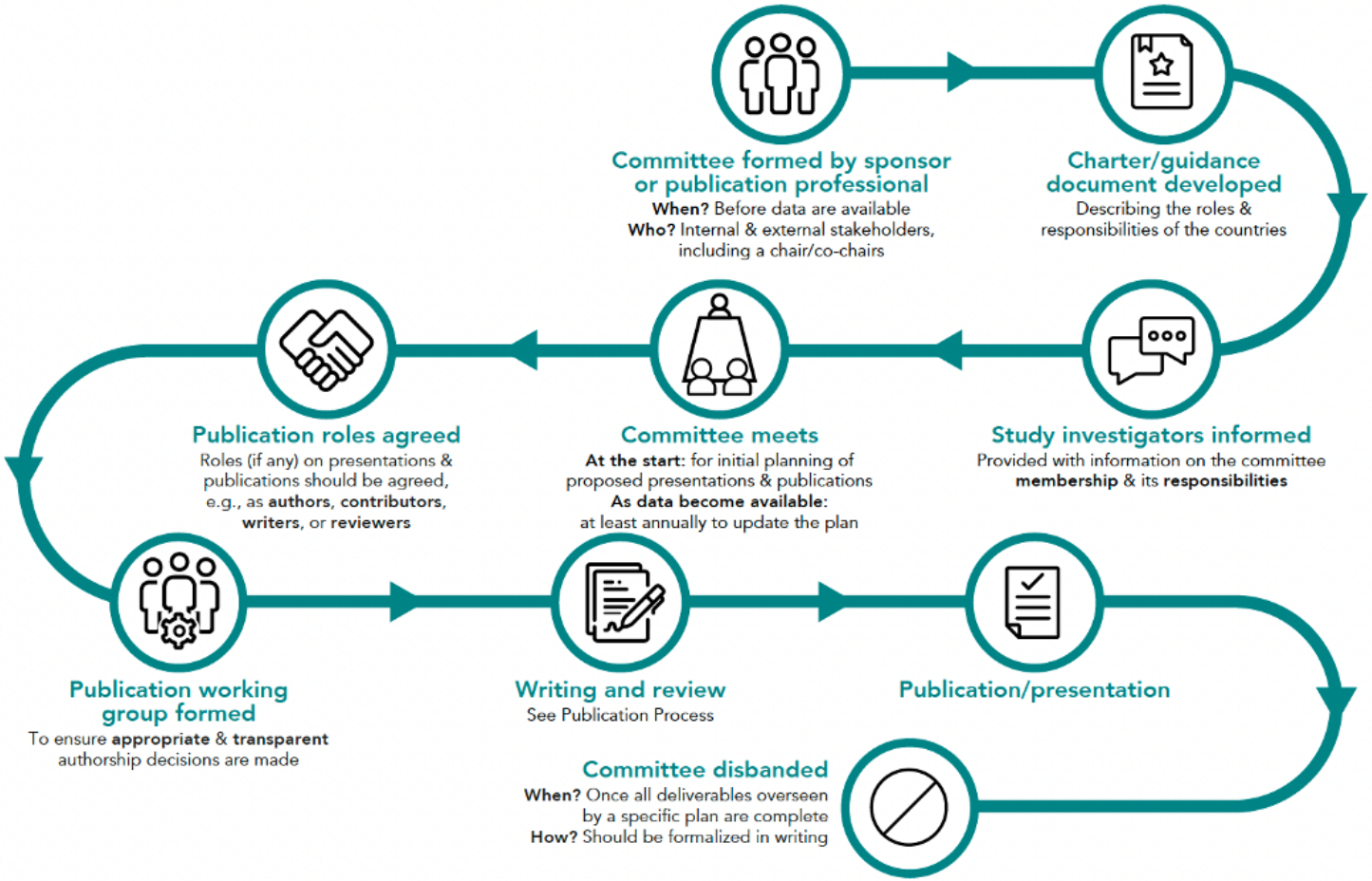
Life Cycle of a Publication Steering Committee

Supplement Figure 1. Suggested Life Cycle of a Publication Steering Committee



GPP, Good Publication Practice
https://www.acpjournals.org/doi/full/10.7326/M22-1460

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Publication Plans

- The key principles for a publication plan are clearly laid out in Supplementary Table 2 to ensure industry standards are met
- Primary and key secondary findings from all Phase II and III clinical trials should be submitted for publication in a peer-reviewed journal, regardless of outcome
- Additional guidance is provided on timings of publications, access to data, use of preprint servers and development costs
- Sponsors may reimburse presenting authors for reasonable out-of-pocket expenses

GPP, Good Publication Practice; HEOR, health economics and outcomes research; ICMJE, International Committee of Medical Journal Editors; RWE, real-world evidence.
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Principles for Publication Plans

Supplement Table 2. Principles for Publication Plans
Auditable publication plans are developed in compliance with GPP and sponsor policies, as applicable
All clinical trial data and other relevant research (including regional studies) are reflected in the publication plan
Primary publications reporting prespecified primary endpoints or objectives are prioritized over secondary publications and reviews, and any background information needed to contextualize clinical data (e.g., new methods or techniques) is published before clinical data
All publication components, including plain language summaries (PLSs) and enhanced content (and technical support needed to produce them) are included in planning and budgeting
Scientific and clinical needs are identified for planned publications of secondary or subgroup analyses, pooled data analyses, or systematic reviews
Journal and conference selection is appropriate and realistic; submission opening dates and deadlines for relevant conferences should be aligned with anticipated data availability; open-access and free-to-access options are prioritized
Encore publications, translations, and re-publications are included only to meet specific scientific and medical needs and/or reach audiences who lack access to the original publication (which should be cited)
Authors are notified in a timely manner of their roles and responsibilities, and appropriate working groups are formed to support publication development
Authors have access to relevant study data
Datasets are generally consistent across publications for a single study (e.g., abstract, poster, manuscript) and trial identifiers are used in all publications
Journal and conference embargoes are respected

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Publication Working Groups

- Publication working groups are responsible for ensuring the development follows all appropriate guidelines
- When appropriate, patients and patient advocates should be included
- Commercial colleagues must not influence content development, review or approval of any publications
- Colleagues within HEOR and RWE functions should be classed as researches, regardless of reporting structure

GPP, Good Publication Practice; HEOR, health economics and outcomes research; ICMJE, International Committee of Medical Journal Editors; RWE, real-world evidence.
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Authorship and Contributorship Determination

- The ICMJE should be the default for authorship
- Paid employment is not a disqualification from authorship
- ORCID IDs should be used to increase transparency
- Tables detail considerations for authorship and encourage ongoing assessment as well as suggested content for author agreements

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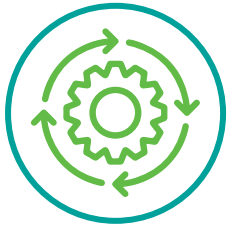
Publication Process



- Additional guidance is provided on data sharing highlighting that authors should have time to review any data before a kick-off call or first draft development
- Supplement Table 6 lists the criteria for journal /congress selection
- Each journal publication should be accompanied by
- a PLS which should be developed with the initial draft
- PLS and any enhanced content must be consistent with the final publication content and peer reviewed
- An overview for developing a publication is illustrated in the next slide

GPP, Good Publication Practice; PLS, Plain Language Summary; ICMJE, International Committee of Medical Journal Editors.https://www.acpjournals.org/doi/full/10.7326/M22-1460
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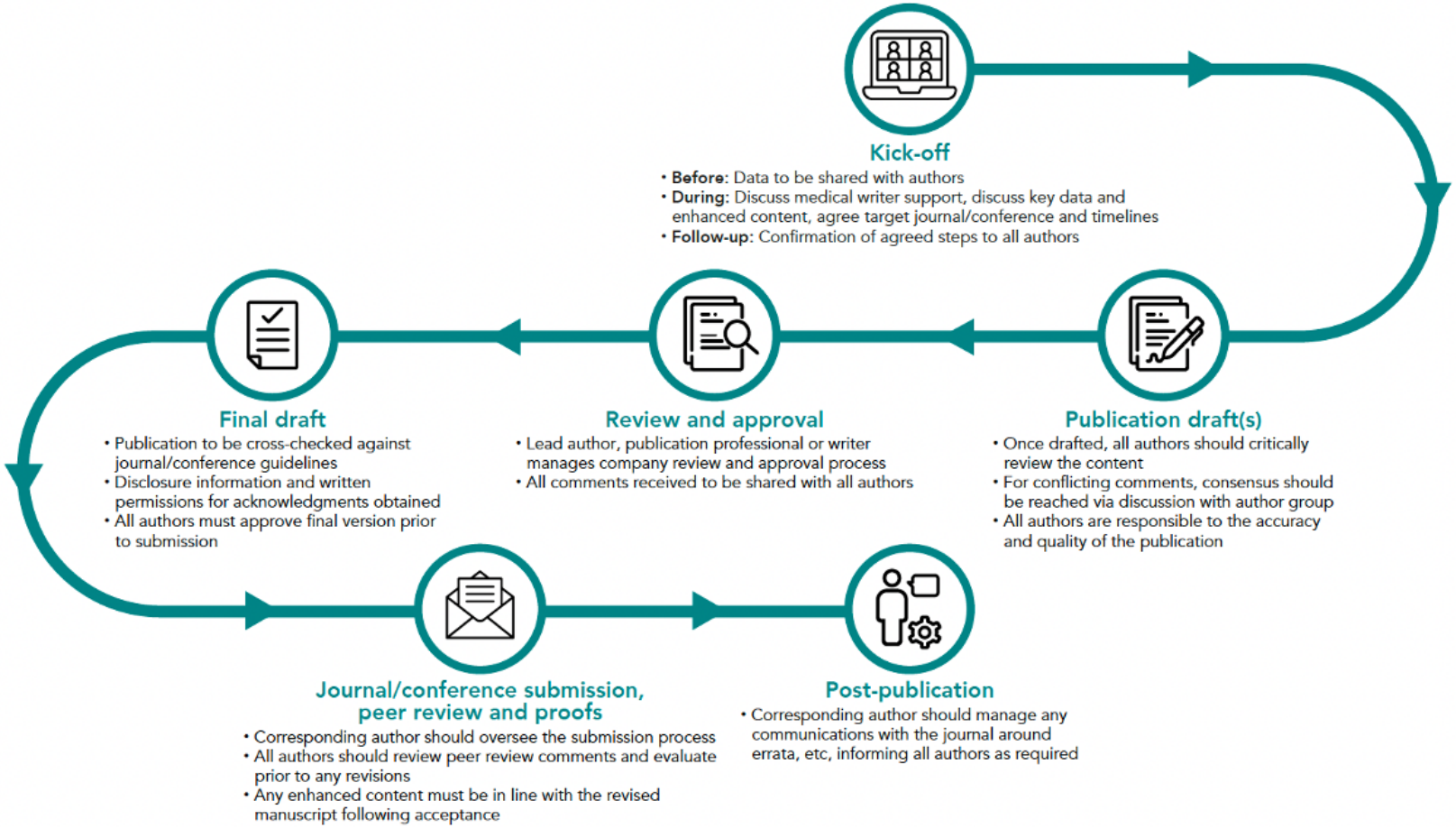
Overview of the publication process

Supplement Figure 2. Overview of the Publication Process



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Documentation

- Detailed guidance given on what documents need to be retained for auditing purposes
- Recommendation to keep records for at least 10 years, in line with ICJME guidelines for primary data and analytical results

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Audience Q&A

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Upcoming ISMPP U Webinars

October 19, 2022
Data Visualization

October 26, 2022
CMPP Certification & Recertification Update

November 16, 2022
Omnichannel Considerations for Publication Professionals

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Faculty Bios

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Lisa DeTora

- Lead author of GPP 2022
- Long-time member of the ISMPP Ethics and Standards Committee
- Research interests include medical humanities, studies of embodiment, graphic narrative research, publication ethics, and narrative medicine

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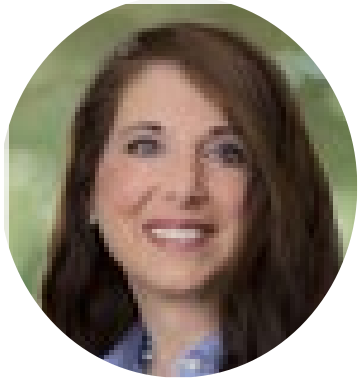
Faith DiBiasi



- >25 years of experience in academia, biotech, diagnostics and pharma
- Member of the GPP4 Steering Committee
- CMPP Since 2010
- Member of the CMPP Credentialling Board

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Laura Dormer

- GPP4 steering committee member and member of the PFMD ‘How to’ Guide for PLS working group
- Previously Editorial Director at the Future Science Group, first publisher of standalone Plain Language Summary of Publication articles
- Interest in patient engagement in publications and publication ethics

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Fiona Plunkett, PhD, CMPP

- GPP4 steering committee member and author
- ISMPP Board of Trustees and European Programme Committee member
- >15 years of experience in publications and communications

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