

Review

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Applying the Good Publication Practice 2022 Guidelines in the Asia-Pacific Region: A Practical Guide

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Keywords: Asia-Pacific; Authorship; Conflict of interest; Disclosures; Ethics; Good Publication Practice; Manuscript development



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Review

Applying the Good Publication Practice 2022 Guidelines in the Asia-Pacific Region: A Practical Guide

Blair R. Hesp ^{1,*}, Katsuhisa Arai ², Namita Bose ³, Rachael Profit ⁴, Malvika Katarya ⁵, Jonathan Lee ⁶, Ronnie Lin ⁷, Magdalene Chu ⁸, Andrew Sakko ⁹ and Hazel Fernandez ¹⁰

¹ Kainic Medical Communications Ltd., Dunedin, New Zealand

² Wiley Publishers, Tokyo, Japan

³ Cactus Communications Pvt Ltd., Mumbai, India

⁴ MIMS Pte Ltd (Taiwan Branch), Taipei, Taiwan

⁵ AMICULUM Asia Pte Ltd., Singapore

⁶ Takeda Pharmaceuticals International AG – Singapore Branch, Singapore

⁷ Hasten Biopharmaceutic Co., Ltd., Shanghai, China

⁸ MIMS (Hong Kong) Ltd., Hong Kong

⁹ Syneos Health, Gordon, NSW, Australia

¹⁰ Janssen Asia Pacific, a division of Johnson & Johnson Pte Ltd., Singapore

* Correspondence: blairh@kainicmedical.com; Tel.: +64-21-132-0854

Abstract: Objective: The Asia-Pacific region (APAC) represents a unique environment for the publication of biomedical research, particularly industry-funded research. Awareness and adoption of international guidelines on ethical publication practices continues to increase across APAC, but the reframing and expansion of many of the recommendations in the Good Publication Practice (GPP) 2022 guidelines versus GPP3 published in 2015 have important implications for publishing industry-funded biomedical research in the region. Methods: This manuscript provides practical guidance for stakeholders in APAC on interpreting and applying the recommendations made in the GPP 2022 guidelines. Results: Key focus areas include navigating new opportunities for communicating industry-funded research, such as plain language summaries, social media, and preprints; implementing formal processes to improve the integrity of published research in APAC; and methods of promoting transparency and inclusion when publishing industry-funded research. Key APAC-specific issues, including encore presentations, leadership on publication ethics in the region, access to professional resources, and support for educating regional stakeholders are also discussed. Conclusions: Overall, this manuscript offers a pragmatic guide for stakeholders in industry-sponsored research on applying GPP 2022 in practice with a focus on effectively integrating these guidelines in an APAC context.

Keywords: Asia-Pacific; Authorship; Conflict of interest; Disclosures; Ethics; Good Publication Practice; Manuscript development

Short title: GPP 2022 in the Asia-Pacific region

Introduction

The Asia-Pacific region (APAC) represents a unique environment for the publication of biomedical research. The plurality of cultures, dominance of English-language scientific communication, and guideline-issuing bodies generally residing in North America and Europe can make it challenging to apply ethical publication practices in APAC.

Historical investigations into ethical biomedical publication practices in APAC have suggested that practices are inconsistent with those in North America and Europe [1–7]. Notably, many of these studies benchmark practices in APAC against guidelines, expectations, and metrics that give limited consideration to the specific practices, cultures, and barriers encountered in this region. Indeed, the challenges of developing a universal definition of ethical publication practices are well known [8,9], and several initiatives have been developed to align expectations on ethical publication practices, particularly regarding industry-sponsored clinical research [10].

Therefore, it is heartening that improvements have been observed in APAC over the last decade, such as a reduction in the prevalence of unethical publication practices [11,12], alongside other efforts, such as benchmarking the time to publication of publicly funded research against international peers [13]. These improvements have been paralleled by increasingly frequent localized commentaries on publication ethics [10,14–16].

Meanwhile, greater adherence to the Enhancing the QUality and Transparency Of health Research (EQUATOR) Network guidelines [17], for example, remains desirable, and efforts to translate EQUATOR guidelines into more Asian languages continue. However, reporting of improved adherence to guidelines may take several years to become evident and can be confounded by multidecade reporting times [13].

While the overarching understanding of ethical publication practices within APAC is difficult to delineate and compare with practices in Western countries, surveys suggest that knowledge of the International Committee of Medical Journal Editors (ICMJE) and other publications ethics guidelines remains low in parts of APAC [1,2,18–20]. Regardless, ongoing education efforts are required within APAC to support stakeholders in biomedical research to improve their publication quality and awareness, and adherence to ethical practices. The latest iteration of the Good Publication Practice guidelines issued in 2022 (GPP 2022) [21] updated and extended guidance in the Good Publication Practice 3 (GPP3) guidelines (2015) [22] and the Good Practice for Conference Abstracts & Presentations (GPCAP) guidelines (2019) [23].

Many of the recommendations have been reframed and expanded with implications for stakeholders in industry-funded biomedical research in APAC. A number of innovations in biomedical publishing, such as patient authorship and plain-language summaries (PLS), have also been introduced, which create new challenges and opportunities for stakeholders in APAC.

This manuscript aims to provide a practical guide on applying the GPP 2022 guidelines for developing biomedical publications and implementing innovative publication practices for authors, publication professionals, and study sponsors in APAC, as well as other stakeholders who collaborate with authors and publication professionals. It is important to note that this manuscript does not replace earlier recommendations for applying ethical publication practices in APAC [10]. Instead, it provides practical guidance for applying these guidelines in the context of situations that are relevant to stakeholders in APAC. Where necessary, key terms have been defined in **Table 1**.

Table 1. Definitions of common terms used in this manuscript.

Criteria	
Asia-Pacific region (APAC)	Asia, the Middle East, Australia, New Zealand, and the Pacific Islands.
Consensus statement	A publication presenting a set of recommendations agreed by a group of healthcare professionals for consideration by their peers regarding the optimal method of diagnosing, managing, or treating a condition [24].

Honorary authorship	Authorship granted to an individual who does not meet the ICMJE authorship criteria, out of respect for that individual.
Honorary citation	A reference that lacks clear relevance to the subject of a manuscript, but has been incorporated into the manuscript following a direct request for insertion by a peer reviewer who co-authored the citation (or has another relevant interest).
Plain-language summary (PLS)	Summary of medical research presented in a way that is easily accessible and understood by a broader readership, including non-specialist HCPs and lay audiences, compared with a traditional publication. May include enhanced content, such as graphical abstracts, infographics, videos, and other non-traditional formats of presenting scientific data.
Plain-language summary publication (PLSP)	A full scientific publication in plain language, usually published in a separate journal to the primary manuscript.
Publications	Information published in manuscript form in peer-reviewed journals, as well as abstracts and presentations at scientific conferences. GPP 2022 includes enhanced content and plain-language summaries to be a component of the publications they accompany [21].
Publication plan	Plans for communicating research, including information such as the timing of submitting publications (both to conferences and peer-reviewed journals), selection of target conferences and journals, and proposed authors for each publication, amongst other relevant information.
Publication professional	Various professional roles of colleagues who manage and advise on publication activities, as defined in GPP 2022 [21].
Stakeholder	Any person or company who has an interest in the publications process, such as an author or study sponsor.
APAC, Asia-Pacific region; GPP, Good Publication Practice; ICMJE, International Committee of Medical Journal Editors; HCP, healthcare provider; PLS, plain-language summary; PLSP, plain-language summary publication	

General Principles for Ethics and Good Publication Practice

1. *Biomedical publications and the research they report must adhere to appropriate accepted ethical research principles. Principles outlined in the Declaration of Helsinki and country-specific works, such as the Belmont Report, should be consulted.*

Publications should include statements that ethical principles were followed when conducting the underlying research. The authors and study sponsor must then confirm the accuracy of these statements, including appropriate institutional ethical approvals being granted, patients providing written informed consent, and any research performed being within the scope of research defined in ethical approvals and consent forms. Country-specific works that represent both formal and informal guiding principles for reporting biomedical research performed in APAC should be considered (Table 2).

Table 2. Examples of formal and informal guiding principles for reporting biomedical research in APAC.

Country	Guiding document
Australia	National Statement on Ethical Conduct in Human Research 2007 (updated 2018) [25]
	Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders [24]

India	National Ethical Guidelines for Biomedical and Health Research Involving Human Participants [26]
Japan	See Table 8.1 [27] for a comprehensive list of relevant Japanese administrative legislation
New Zealand	Guidelines for Researchers on Health Research Involving Māori [28] Pacific Health Research Guidelines [29]
Singapore	Ethics Guidelines for Human Biomedical Research (2021 Revised) [30]

APAC, Asia-Pacific region

2. *Publication of biomedical research in peer-reviewed journals is an ethical responsibility; AND*
3. *Publication development should be conducted solely for the purposes of scientific exchange and should follow best practices to meet public health and medical needs, in keeping with the principles of research ethics as well as applicable laws and guidelines.*

Researchers have an obligation to ensure that scientific data generated through the volunteer efforts of participants in clinical research studies are publicly communicated via presentations at internationally recognized scientific conferences and peer-reviewed publications (i.e., at conferences and in journals that have a legitimate standing in the scientific community and are not ‘predatory’). The obligation to publish also extends to data generated via other means that may not involve direct patient engagement, such as real-world evidence, systematic reviews, and health economics outcomes research.

However, publications should be justified by their need to fill a knowledge gap or unmet need in the literature and not published solely for commercial purposes, such as increasing share of voice or publication count, or as a reward for collaborators. Encore presentations, or translations, in APAC should be done for the purpose of increasing access to data that may be otherwise inaccessible due to geographic and/or language barriers. Congress organizers in APAC should aim to clearly communicate whether they are willing to accept encore presentations, the circumstances under which they would accept such presentations, and their expectations regarding authorship, including addition of non-author presenters, and disclosure of prior presentation.

Depending on the circumstances, a 12–18-month timeframe has been recommended for submitting primary outcomes data to a peer-reviewed journal [31], with full publication expected within 24 months [32]. Subgroup analyses, local-language translations, and encore presentations relevant to APAC should be expedited where possible, although encore presentations are not appropriate after data are published in a peer-reviewed journal. APAC data may be expected to be published some time after the primary publication, especially if drug approval in countries in APAC occurs after approval in other markets. We recommend encore presentations within 12 months and submission of APAC subgroup analyses within 24 months of submission of the primary manuscript. However, there may be circumstances where these timelines need to be extended.

In addition, allowances must be made for delayed publication of data generated in APAC. Anecdotal evidence suggests that post-hoc/retrospective analyses and observational data from APAC may be considered of a lesser priority by many peer-reviewed journals. Accordingly, authors should aim to clearly communicate the clinical implications of APAC-specific analyses to demonstrate their value and elevate their priority.

For company-sponsored articles, open-access publication is commonly selected by the authors. Care should be taken to ensure that an appropriate copyright license is granted when selecting an open-access option.

Publication in a peer-reviewed journal confirms that data sets and their accompanying commentary have been scrutinized by subject matter experts and increases discoverability for healthcare professionals and patients. Peer-reviewed publication also offers positive feedback to clinical trial participants and related parties (e.g., their families and friends) by demonstrating the value of their contribution. Accordingly, investigators and study sponsors should consider making

peer-reviewed publications available to clinical trial participants in APAC, including providing translations in languages other than English.

Routinely disseminating industry-sponsored content on preprint servers or accepting journal invitations to pre-publish content that is under review, should be avoided unless delaying data dissemination is unethical and alternate forms of communication (e.g., at biomedical conferences) are not available, or do not provide adequate context or supporting information (e.g., press releases).

The risk of substantial changes being incorporated into the publication, including changes to data, between preprint upload and final peer-reviewed publication must be considered [33]. Preprints are not a substitute for publication in a peer-reviewed journal. The lack of restrictions in word count or other quality control measures with preprints have also been highlighted as risk factors for poor-quality publications [34,35].

4. *Consistent with journal guidelines, sponsors and communications agencies, as well as individuals, have a duty to adhere to ethical practices for all publication activities. This duty includes the responsibility to ensure that medical writers and other colleagues who support publications are treated ethically and enabled to follow the ethical practices of the field.*

All participants in manuscript preparation have a duty to adhere to ethical publication practices, including the authors, sponsors, reviewers, journal staff, and publication professionals. Author agreements should be executed for all authors and expectations regarding ethical practices should be set by the study sponsor as part of an authorship agreement before initiating a publication.

The responsibility to act ethically extends to the peer review process where all interested parties should aim to develop the most scientifically robust manuscript possible in a manner that is consistent with the ICMJE authorship guidance. Accordingly, all authors should participate in preparing a response to peer review and re-approve the final version.

However, a pragmatic approach must be taken to obtaining approval for a response to peer review. A failure to object to a response after a genuine effort has been made to seek input from authors may need to be interpreted as implied approval. Relying on implied approval should only be done after all other options have been exhausted, such as requesting an extension to the deadline for submitting a response. When unable to contact an author prior to submitting a response, efforts to contact the author should continue until it is impossible to make further changes (i.e., final approval of proofs). In the event of an author not responding to multiple attempts to contact them, it may be necessary to re-assess whether the author continues to meet the ICMJE authorship criteria in consultation with the journal editor. Despite the ICMJE authorship criteria not explicitly referring to post-submission expectations, failure to contribute to drafting and reviewing a response to peer review, providing suggested amendments, or approving the final version of the manuscript could bring authorship into question. All authors who approve re-submission may include a statement in their response to reviewers indicating their approval and agreement to proceed with the current author byline, provided that the journal agrees. While not establishing precedent, and subject to different circumstances, this recommendation is consistent with the pragmatic suggestions regarding balancing authorship against a time-sensitive need to submit publications during the COVID-19 pandemic [36].

Authors should also carefully consider comments from peer reviewers for 'guest or honorary citation' of a reviewer's work [37]. Authors may not be able to readily identify requests for honorary citation during blinded peer review, but should consider and respond to requests to insert new citations on their merits.

The independent role of publication professionals, particularly those employed by third parties (e.g., professional medical writers contracted to support a study sponsor) should be recognized and respected. Professional medical writers often have expertise in developing publications to international best practice and are generally capable of improving the outcomes for all stakeholders, especially if they have formal qualifications issued by internationally recognized industry bodies (e.g., International Society of Medical Publication Professionals (ISMPP) Certified Medical Publication Professional [CMPP] or the American Medical Writers Association (AMWA) Medical Writer Certified [MWC] qualifications).

Professional medical writers should not be subject to undue influence that may affect their objectivity or willingness to adhere to ethical publication practices when preparing a manuscript. Medical writers should be at liberty to provide professional opinions on matters within the scope of their responsibilities, including publication ethics, journal selection (including avoiding predatory journals), authorship, and other procedural matters. Accordingly, mechanisms for ethical conduct and dispute resolution between all stakeholders should be considered and agreed to before beginning to develop a publication.

Study sponsors should be prepared to provide professional medical writers with supporting documents that are reasonably requested to enable them to meet their obligations in following ethical publication practices. Ideally, relevant content and/or additional analyses required to prepare a publication should be identified and finalized before development starts. Access to information that a medical writer requires to perform their duties with due skill and care should not be unreasonably withheld.

Acknowledgement of the contribution of publication professionals should also be performed in a manner that is consistent with the ICMJE authorship guidelines (i.e., all contributors who meet the criteria for acknowledgement should be acknowledged) [38]. This should include naming the individual, their affiliation, and their specific contribution to the publication [39].

5. *Publication professionals, authors, and steering committees have a responsibility to seek out and share knowledge on relevant standards and guidelines and to educate their teams on an ongoing basis.*

All stakeholders should take reasonable steps to educate themselves on the relevant standards and guidelines to be applied when developing a publication. For example, all stakeholders should ensure they are aware of the instructions to authors promulgated by conference organizers and journals. Additional guidelines issued by overarching bodies, such as the ICMJE authorship criteria [40], EQUATOR Network guidelines [18], GPP 2022 [21], and GPCAP [23] should also be considered and proactively disseminated by publication professionals. In addition, informal communications, such as ISMPP's MAP newsletter, may help increase awareness of guideline updates and recommendations.

These obligations are not equal for all parties; publication professionals are expected to have a deeper knowledge of ethical publication practices than other individuals whose expertise lie elsewhere, and should actively share their knowledge with other stakeholders. Publication professionals in APAC should aim to actively participate in professional development opportunities and strive to achieve formal qualifications that have assessed and confirmed their skill set, such as the ISMPP CMPP or the AMWA MWC.

National or regional publications steering committees are relatively rare in APAC. Instead, national or regional publication plans may be developed independently and aligned and/or integrated with study sponsors' global publication plans, so authors are likely to rely on publication professionals for guidance on ethical publication practices rather than peers. Publication professionals should also consider opportunities for outreach and education in APAC to improve the overall understanding of ethical publication practices within clinical research.

6. *Company policies and other procedural documents for publication planning and authorship should include ethical principles. Sponsor and communications agency policies do not supersede journal or scientific guidelines or requirements.*

All parties participating in the publication process should strive to meet international best practices, and study sponsors and medical communications agencies should assess and review their internal policies regularly to ensure that they remain consistent with the current biomedical publications environment. By developing internal policies and procedures that meet industry best practice, the process of publication development can be streamlined by minimizing the degree of adaptation required to meet individual journal requirements.

Journal guidelines should represent the minimum standard of ethical publication practices adhered to. Acknowledgements, disclosures, and funding statements should be included in all

publications, regardless of whether they are requested in journal instructions for authors. Such statements should also be included in conference presentations and posters.

Appropriate journal and congress selection is also a key component to ensuring ethical publication practices are followed. Objective criteria should be considered when selecting a journal or conference, including relevance of the data set to journal/conference scope, readership, publication restrictions (e.g., word count, article type, etc.), rejection rates, timelines for editorial and peer review, opportunities to submit publication enhancements and PLSs, open-access options (and accompanying fees, especially for authors who reside in nations within APAC who may be eligible for reduced fee schemes), and methods of assessing publication impact (e.g., impact factor, downloads, CiteScore, Altmetrics, etc.) [41].

Differentiating between generally respected and predatory journals (and conferences) can be challenging, particularly when attempting to publish research that may be geographically limited in scope or one of many subgroup analyses. The absence of statements regarding ethical publication practices and adherence to principles defined by organizations such as the ICMJE or Committee on Publication Ethics (COPE) is as an adverse factor when selecting a journal.

Checklists should be used to aid journal selection that identify objective minimum requirements for journal selection to avoid inadvertent publication in predatory journals. For example, checklists for journals are available in many languages used in APAC [42–44], and a checklist for book chapters is also available, although Asian-language translations are limited [45]. However, caution must still be exercised to avoid predatory checklists. Accordingly, journal selection should be approved by more than one author and a ‘cooling off’ period applied between selecting a journal and submitting a publication because even experienced publication professionals can have difficulty identifying predatory journals and conferences. Likewise, all authors should approve the final choice of target journal(s)/conference(s).

7. *Detection of serious problems (such as plagiarism, duplicate publication, or inadequate disclosures) must result in swift action to correct or retract the work.*

Requests for post-publication correction should be limited to minor errors, such as typographical errors in data values or updating disclosures, which must be corrected to maintain accuracy and integrity in the scientific record. Furthermore, the scope of unsolicited changes that may be accepted by a journal during the peer review process is likely to be limited. Substantial unsolicited changes to a manuscript may bring the quality of a publication into question, requiring additional peer review. The window available for reviewing proofs is unlikely to facilitate adequate review and approval of any changes by all authors.

Retraction may be necessary in cases of scientific misconduct (e.g., plagiarism or duplicate publication) or major quality control failure, and should be prevented by implementing appropriate checks and balances to ensure ethical publication practices are followed when developing a publication. Study sponsors should consider developing a policy for investigating and managing situations relating to potential scientific misconduct in biomedical publications.

Furthermore, efforts should be made to detect and address any serious scientific integrity problems prior to submitting a publication for peer review. Best practice dictates that data checking should be performed by an experienced individual who was not involved in the initial publication development. In APAC, consulting a native English speaker may also be advisable for English-language publications.

Applying standard operating procedures, such as an individual not directly involved in drafting a manuscript performing a data check prior to submission, and utilizing the expertise of publication professionals or other suitably qualified individuals (e.g., sponsor legal and/or medical review teams) can help detect instances of plagiarism, inadequate reporting (e.g., missing data, ethics statements, or other quality control issues), and citation of retracted articles or content from predatory sources. The benefits of improved quality associated with the involvement of publication professionals in manuscript drafting have been highlighted previously [46,47].

Any requests for amendment identified during the data checking process should be adjudicated by the authors, who have ultimate responsibility for the accuracy of a manuscript. Publication

professionals or other third parties should also have the opportunity to deny permission to be acknowledged if they disagree with the accuracy of statements in a publication [38].

8. *Ethical standards for individual publications do not alter during public health or other emergencies. Publication activities may be adjusted in response to emerging health care situations to align with medical and public health needs and ethics.*

Adhering to ethical publication practices can have increased importance during public health or other emergencies because of the reliance on limited and frequently updated information [38]. This may include situations where data from a multinational clinical trial has been published but is not generalizable to APAC. 'Publication by press release' should be avoided.

While preprints should generally be avoided for company-sponsored research, the need for rapid dissemination of data may justify alternative methods of publication. However, if publishing in preprint format prior to formal peer review, the preprint should be updated as soon as new iterations are generated. Individual journal policies on preprints should be consulted, but uploading updated iterations that incorporate amendments made in response to a journal-facilitated peer-review process (i.e., potentially publishing the final version of a manuscript as a preprint) is not recommended. Comments offered on any preprint publication should be monitored and considered during development of each new iteration of a publication.

When submitting a manuscript to a peer-reviewed journal, journal editors should be alerted to the existence of any preprint publication at the time of submission and an appropriate link and/or digital object identifier (DOI) provided. Comments on preprints received in parallel to peer review should be considered when responding to peer review.

Citing preprints in the references section is only acceptable in the absence of alternative peer-reviewed content. During the publication development process, regular checks should be performed with the aim of replacing any reference to a preprint with the final published manuscript because substantial changes can occur [33].

Preprints should not be cited if they have not been published in a peer-reviewed journal within 12 months of the original upload date. Failure to publish in a peer-reviewed journal within this timeframe suggests that the data were either not of adequate quality to survive peer review or have been superseded by more recent and relevant data.

Principles for Protecting Research and Data Integrity

1. *Appropriate controls should be put in place to protect the integrity of research and data reported in publications; commercial interests should not be permitted to influence such integrity or the publications process.*

Publication development should only begin once any study database has been locked and a final report has been prepared. Whenever possible, publications should not be prepared in the context of an evolving or interim data set, except when prespecified in the study protocol.

Publications should be prepared in the context of any instructions to authors from peer-reviewed journals or conference organizers. Relevant EQUATOR Network guidelines should also be consulted when preparing manuscripts [18]. Submitting a completed EQUATOR checklist alongside a manuscript to peer-reviewed journals is recommended to demonstrate adherence to these guidelines and assist journal editors and peer reviewers in assessing the integrity of a manuscript. Other sources, such as guidelines for preparing manuscripts disseminating data from randomized clinical trials published by *The Lancet* [48], may also have universal applicability and can help improve the overall quality of publications prior to submission.

All content in publications must be developed under the guidance of the authors and reviewed and approved by all authors prior to submission or presentation [40]. Biomedical publication activities should be conducted independently of the study sponsor's sales and marketing activities.

2. *Publication planning, development, review, and approval should preserve research integrity by including only colleagues with appropriate qualifications (for example, medical, scientific, professional, or relevant experience) for their respective roles.*

Industry sponsors must take responsibility for the integrity of the scientific publication process, for example, by developing standard operating procedures for publication development.

Appropriate publication planning may assist with maintaining the integrity of the publication process by prespecifying when and how support may be required from specific functions within the study sponsor. For example, relevant employees of the study sponsor who are expected to qualify for authorship should be identified prior to initiating publication development. Employees of the study sponsor who commit to participating in publication development should be conscious of their involvement extending beyond their term of employment, namely that authors are held responsible for the accuracy and integrity of a publication indefinitely. Appropriate professional reviewers, such as medical and legal experts, and the timing of their review should be specified as part of any publication plan.

Principles to Promote Transparency

1. *Publication is only one form of data transparency, which also includes appropriate protocol and data sharing with authors and journals and posting to trial and results registries.*

For studies conducted solely in APAC, publication professionals should consult with the study sponsor's clinical team regarding when data may be publicly disseminated on clinical trial registries or any other public data-sharing platform to ensure compliance with individual journal requirements and to avoid prior publication. However, recent updates to the ICMJE's definition of prior publication to exclude reports published in health technology assessment and regulatory reports should be noted [49]. Efforts should also be made to ensure consistency in data sets across biomedical publications and data repositories or registries. Where discrepancies are evident, authors should consider acknowledging this and providing an explanation in relevant publications.

For regional subgroup analyses, publication professionals should coordinate with relevant national, regional, and/or global clinical teams to ensure that appropriate documentation requested by peer-reviewed journals, such as study protocols and statistical analysis plans, are available to support submission. Relevant teams within the study sponsor should be made aware of, and agree with, any data sharing statements incorporated into publications, such as raw data sets being made available upon reasonable request. Study sponsor contact details for data sharing should include a permanent generic email address for data sharing requests, not the contact details of an individual. Accordingly, genuine attempts should be made to provide data sets requested by authors for review.

2. *Data transparency associated with publication activities must be achieved in such a way as to protect patient privacy.*

All data disseminated in publications should be presented in a manner that prevents the identification of individual patients. Case reports relating to an individual or small numbers of patients should only be published when the clinical need is justified, not because of curiosity about an individual's condition. Furthermore, case studies and case series are associated with an elevated risk in cherry-picking and publication bias towards cases with favourable outcomes, so caution should be exercised by commercial entities considering sponsoring or funding medical writing support for case reports, which should generally be prepared independently by healthcare professionals [21]. For studies that have low sample sizes, authors also need to be aware of potential direct and indirect identifiers of individual patients and present data in a manner that minimizes the risk of individual patient identification [50].

If publishing details about an individual could allow for identification of that individual, but is otherwise unavoidable, such as in case studies, written consent should be obtained from the patient or their legal representative. Particular effort should be made to conceal patients' identities when presenting images (e.g., by censoring identifying features). If sharing individual patient data with

third-party researchers, steps should be taken to ensure that the requestor also protects patient confidentiality, such as preparing a formal data-sharing agreement that confirms that the researcher will not attempt to use the data to identify individual patients and restricting access to the data to the defined purpose [51].

3. *Publications must include the role, if any, of any funding sources and disclose other interests of authors and sponsors, such as the role of the sponsor in research and publication activities and competing financial or other author interests.*

The study sponsor's involvement in funding any study must be disclosed in all publications. The involvement and source of funding for any medical writing, English-language editing or translation, or statistical analysis support should also be disclosed in all publications.

As discussed previously [10], proactive efforts should be made to ensure transparency by seeking disclosures from authors regarding any relationships or potential competing interests relating to the research on both an individual and institutional level. Disclosures should include any financial, personal, social, or other interests that may be perceived to directly or indirectly influence the conduct of the author(s) when developing a publication [52,53]. Defaulting to authors having no conflicts of interest is not recommended [39].

4. *Publications should support communication of scientific information to lay audiences through PLSs and other accessible formats.*

PLSs (sometimes called lay or patient summaries [54]) are often interpreted as being written summaries of publications in abstract form using 'plain English'. However, the scope of the term 'plain-language summary' has been formally defined to include other 'enhanced content', such as graphical abstracts, infographics, videos, and other non-traditional formats of presenting scientific data [21]. A PLS should not be confused with standalone plain-language summary publications (PLSPs), which represent a full scientific publication in plain language, usually published in a different journal to the primary manuscript. Permission must be sought from the primary journal before submitting a PLSP to another journal.

In many cases, a PLS may be offered as an optional add-on to a publication by a journal or conference organizer [54]. Options provided by each journal, and the timing of submission, should be considered during the journal selection process. Some journals may allow enhanced content to be developed after acceptance to avoid consuming resources in developing unique content without a guarantee of acceptance. Such content should still be peer-reviewed prior to publication. The Enhanced Publication Options Navigator [44] can assist in identifying journals that accept PLS and other enhanced content options. PLSs should be published open access whenever possible.

In the absence of a formal method of submitting a PLS, authors and study sponsors should engage journal editors or conference organizers to discuss options for presenting a PLS, such as including a PLS in supplementary material or using a QR code on a poster that directs readers to web-hosted PLS content. For conference-related PLS content that is not peer reviewed and is hosted by a third party (i.e., not part of the conference presentation itself and not hosted on the official conference website), consideration should be given to the most appropriate form of access to ensure compliance with local regulations and the study sponsor's internal policies, including guidance on the length of time QR codes should remain active following a conference. However, discoverability remains challenging for PLSs in the absence of a central database, registry, or universal marker of a PLS being available.

Developing content in plain language can be complicated because of the requirements defined by journals to maintain scientific accuracy while adhering to variously phrased requirements, such as meeting the reading level of a teenager, using active versus passive voice, using person-centered language, and using 'language that does not patronize the reader' [54]. If engaging external support to develop a PLS, due diligence should be performed to ensure that individuals providing support are suitably skilled in writing for non-expert audiences. Additional design and/or digital expertise may also be required to supplement writing skills when communicating with a non-expert audience. In some cases, journals will offer specialist support in developing a PLS. Engaging patients or other

laypersons who are affected or have an interest in a publication to review a PLS should also be considered to improve accessibility. When journals exclusively develop PLSs internally, authors should be given an opportunity to review and approve the PLS before publication.

No facility for delivering PLSs in a language other than English appears to be available at the time of publication of this manuscript, but translation may be assisted by, for example, ensuring written subtitles or transcripts are available for video and audio PLSs, respectively. Likewise, publishing PLSs in languages other than English represents an opportunity for future innovation in biomedical publishing.

When contemporaneous peer-reviewed publication of a PLS is not feasible or access is limited by paywalls, copyright, and/or language barriers, authors and study sponsors may consider developing PLS content independently, including in languages other than English. Scientific accuracy, proper attribution, and appropriate copyright permissions should be applied to any PLS that has not been published as part of a peer-reviewed publication. However, any publicly disseminated informal PLS should identify itself as not peer-reviewed and provide clear direction to the full peer-reviewed publication. The scientific validity of any translations should also be confirmed.

5. *Open-access or free-to-access options for publications should be used whenever possible, and funds for this purpose should be factored into publication budget planning.*

Open-access publication is encouraged to remove barriers to accessing biomedical research. However, caution must be exercised to ensure that open-access publication occurs in a reputable format, and not in a predatory journal.

Open-access fees may be a barrier to publication, but authors based in APAC should check to see if they qualify for reduced open-access fees via their country of residence. Potential fees associated with publication should be identified during the journal selection process and budgeted for accordingly. Ideally, journal selection should not be influenced by relative cost of publication and study sponsors should be prepared to support the authors' journal choice on merit.

Principles to Support Inclusivity

1. *Attention should be paid to inclusivity and addressing the needs of marginalized or minority groups worldwide. Cultural differences must also be recognized and respected. Regional publication planning may address some inclusivity issues; AND*
2. *Inclusivity should be considered in publication steering committees and working groups by including colleagues from different geographic regions and job roles and with varied demographic characteristics (for example, sex or gender, race, and national origin); AND*
3. *Inclusivity also applies to author bylines; ICMJE encourages inclusion of co-authors and collaborators from the region(s) where research is conducted.*

GPP 2022 has removed the previously suggested limit of 10 authors in favor of ensuring greater inclusiveness. An artificial limit on numbers may conflict with the requirement for all individuals who qualify for authorship being attributed authorship. The prevalence of honorary authorship and ghost authorship in APAC is not significantly different from other regions, although this was reported amongst a self-selected population of individuals with substantial familiarity with the ICMJE authorship criteria (74% "very familiar"; 18% "had heard of them but were not familiar with their content") [11], but 'gift or honorary authorship' for individuals who do not meet all four ICMJE authorship should still be avoided. Likewise, equality should be exercised when attributing authorship on publications, with lead/senior authorship being allocated based on merit and relative contribution to a publication.

For publications directed at an APAC audience, such as regional subgroup analyses or regional conference presentations, senior authorship may need to be granted to an author resident in the region to meet conference and/or language requirements, and to recognize the contextual expertise that authors based in APAC may bring to data analysis and interpretation. However, it may still be

difficult for each author in an oversized author group to legitimately claim authorship, so care should be taken to ensure proper documentation is collated to demonstrate individual authorship of a publication.

Diverse viewpoints can improve outcomes, often because individuals become aware of the limitations of their understanding and perspective. However, different cultural expectations and practices in APAC can give the appearance of free and frank discussion between authors not occurring to the extent that may be expected in a Western context [55]. Therefore, publication professionals should consider how to facilitate discussion without violating cultural norms. For example, feedback may be sought via one-on-one interactions between a publication professional and individual authors, with comments anonymized and collated into a single document for further consideration.

Cultural differences can be accounted for by applying differing practices without compromising ethical publication standards, such as the ICMJE authorship criteria [40]. Cultural practices should not be cited as a justification for lowering ethical standards. However, cultural differences may need to be considered when demonstrating how ethical publication practices are met, for example, if an author provides comment but does not appear to expand beyond the comments of a colleague [10].

Where scientific or medical data have been generated within a community, or are intended to be utilized by a community, members of that community should be fairly represented. Generalizations should be avoided, where possible. For example, regional subgroup analyses are commonly referred to as 'Asian' subgroup analyses, but it is important to recognize the diversity and complexity of populations within the world's largest continent. Furthermore, referring to 'Asian patients' may also fail to properly recognize the differing outcomes observed in patients of Asian ethnicity in Western versus APAC settings, and the differing definition of descriptors such as 'Asian' can have different connotations in Western countries (i.e., of South Asian [e.g., Pakistani, Indian, Sri Lankan, or Bangladeshi] descent in the United Kingdom versus of East Asian descent [e.g., Chinese, Japanese, Korean, Thai, Vietnamese, or Indonesian] in the US, Australia, and New Zealand). Therefore, care should be taken in selecting terminology and descriptions that accurately reflect a population or community, particularly when referencing studies performed in APAC. This may be achieved by clearly defining the scope/populations included in any regional analysis (e.g., listing countries in the abstract as well as the full Methods section), recognizing the cultural and genetic differences across populations in APAC, as well as differing healthcare settings.

4. *Patients and patient advocates may be included in publication planning and development, including as authors or contributors to publications, as appropriate to the topic or therapeutic area.*

Patient authorship is becoming more accepted with nearly 70% of medical journal Editors-in-Chief being willing to consider patients or patient advocates as authors of publications, yet less than 15% confirm patient authorship within their journal [56]. However, it can be difficult for patients and patient advocates to meet the ICMJE authorship criteria and less than 5% of journals provide specific guidance on patient authors [56]. There are tools available [57] that can help demonstrate how a patient's contribution to clinical research meets criterion 1 of the ICMJE criteria (substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work), thereby justifying authorship.

The lack of experience of journal Editors-in-Chief in managing patients and patient advocates as authors should be considered in publication planning. If intending to include a patient or patient advocate as an author, journals should be carefully selected with the aim of selecting a journal that is open to patient authorship, while providing a structured approach to their expectations of patient authors. Given the heterogeneous approaches of journal Editors-in-Chief to patient authorship and relative rarity of patient authorship [56], a pre-submission enquiry and/or request for guidance should be made prior to submitting a publication with a patient or patient advocate as an author.

Consideration should be given to cultural aspects of including patient authors in APAC [9], and the study sponsor's compliance policies consulted before engaging with patients and patient advocacy groups. Likewise, it may be necessary to explain some of the cultural challenges associated

with engaging patients in the region to journal editors who may not be resident or experienced in APAC.

If engaging patients or patient advocates from APAC, care should be taken to ensure appropriate cultural protocols are adhered to. Cultural norms regarding appropriate methods of communicating medical and scientific data should also be considered and patient confidentiality maintained. Local guidelines, such as those issued by the Japan Agency for Medical Research and Development [58], should be consulted. For example, many cultures in APAC may expect senior healthcare professionals to be the conduit of advances in clinical practice. Agreement from a patient's extended family may also need to be sought in some cases [9].

Principles for Authorship, Contributorship, and Accountability

1. *Publication planning and development should reflect the collaborative nature of biomedical research and the full range of skills required to conduct, analyze, interpret, and report research findings. Authorship criteria should be considered at the start of research; AND*
2. *Authors must be enabled to make informed decisions and should therefore have access to adequate study data and other relevant information to enable them to be accountable for publication contents and take public accountability for accuracy and integrity of the work; AND*
3. *Author bylines and acknowledgments should follow relevant authorship criteria, using ICMJE as a default, to accurately reflect all contributions; AND*
4. *Before publication preparation begins, the rights, roles, requirements, and responsibilities of contributors and authors should be confirmed in writing.*

Any plans for publications derived from regional or national analyses of international studies performed in APAC will ideally be prepared while initiating biomedical research in the region. However, post-hoc analyses continue to have an important role in ensuring that data generated from patient populations in APAC are adequately reported and in a format that allows that data to be effectively considered and implemented in the region. Likewise, local experts may need to be engaged to assist with data interpretation in an APAC context, qualifying them for authorship and resulting in authorship bylines for APAC analyses that differ from related analyses from multinational populations.

Authors should be proactively notified of the update to GPP 2022 that extends authors' 'responsibility' for the accuracy and integrity of publications beyond that defined in the ICMJE authorship criteria to being willing to 'take public accountability'. This requirement moves beyond the authors agreeing to help resolve questions about the accuracy and integrity of a publication and may be culturally challenging for authors in APAC in terms of balancing cultural conceptions of honour, respect, and responsibility with open scientific debate. The willingness to be held publicly accountable should also extend to study sponsors because of the co-dependent relationship and shared responsibility for data accuracy between study sponsors and authors of publications. Therefore, as discussed in the Principles to Support Inclusivity section, culturally appropriate avenues should be provided to all authors in APAC to facilitate feedback and allow any issues identified by individuals to be addressed.

Whether or not adequate access to data and other relevant information has been provided may be a source of contention between authors and study sponsors because the outputs of the authors are ultimately dependent on the quality, accuracy, and integrity of the data set provided to the authors. Therefore, study sponsors should be prepared to assist authors in addressing their reasonable requests for additional information to support publication development. Professional medical writers may have a role in mediating discussions about data availability, but should not have a role in, or responsibility for, preparing new data sets or analyses in response to requests from authors.

It should be noted that three of the four authorship criteria defined by the ICMJE relate to participating in publication development (study performance and/or data interpretation, participating in publication preparation, and publication approval), while two criteria involve a right

to refuse authorship (final approval and agreeing to accept responsibility) [40]. Consistent, objective definitions of substantial contributions to industry-sponsored biomedical research that meet the first criterion of the ICMJE criteria for authorship (study performance and/or data interpretation) have been published elsewhere [59]. ISMPP has also released an Authorship Algorithm Tool, which is exclusively available to its members, to help both determine whether the first ICMJE criterion has been met and to weigh the relative contributions of individual authors [60]. The Contributor Roles Taxonomy (CRediT) system is increasingly being applied by journals with statements included in manuscripts to demonstrate the contributions of individual authors [61].

If authors do not approve of content and/or are not willing to be held responsible for the accuracy and integrity of a publication, they can opt to withdraw their authorship. However, the requirement for approval to submit and taking responsibility for content should not be used as a method of excluding individuals who would otherwise qualify for authorship. For example, the opportunity to approve the final draft of a publication should not be withheld from individuals who were involved in performing a study and the drafting of a publication.

Likewise, all authors should be actively and regularly engaged in the publication development process. Publications should not be disproportionately prepared in isolation by a lead author(s) and presented to co-authors as a final version for comment and approval for submission without further review. Authors should consult with each other, share their scientific knowledge and perspective, regardless of seniority, with the aim of improving the overall quality of a publication by reaching a consensus amongst all authors.

Study sponsors, including representatives of the study sponsor who qualify for authorship, should not unreasonably interfere in the development of a publication and incorporation of author comments. If representatives of the study sponsor intend to provide substantial input into the preparation of a publication, to the extent that they qualify for authorship, then the representative should be prepared to accept authorship and the corresponding public accountability for the publication as an individual rather than as a representative of the sponsor.

As discussed previously [10], written authorship agreements should be developed and presented to each proposed author prior to developing a publication. Guidance on how to develop these agreements has been provided elsewhere [62].

Practical planning principles

1. *Steering committees and publication working groups should convene before study data are available; member responsibilities should be described in writing; AND*
2. *Publication plans should be developed with the input of appropriate contributors; AND*
3. *Best practices for publication planning will anticipate problems; therefore, policies and procedures should provide built-in arbitration, escalation, and mediation processes that are clearly articulated and communicated to teams before work begins on relevant publications; AND*
4. *Policies, standard operating procedures, and working instructions should guide the work of biomedical publication planning and development and should be consistent with the current iteration of GPP; AND*
5. *The publication development process, publication plans, and data sharing should be documented following auditable methods. Regular self-audits are recommended.*

Study sponsors having an authorship policy and disseminating this as part of clinical research proposals can improve adherence to the practical planning principles described in GPP 2022 [11,63]. Early discussion of publication authorship may be facilitated by having an authorship policy, ensuring author familiarity with the ICMJE authorship criteria, and the routine application of those authorship criteria [11]. The use of explicit authorship criteria may also support perceived fairness amongst study investigators and other individuals who may consider themselves eligible for authorship [11].

Anecdotally, collaboration between study sponsors and external publication professionals in APAC does not occur to the same extent as in North America and Europe. Accordingly, if intending

to engage external publication professionals, study sponsors in APAC should consider seeking input from these external contributors in advance to improve planning processes and adherence to ethical practices.

The efficacy of auditing is dependent on a framework of remedies and penalties [64,65]. Study sponsors and their collaborators, such as medical communications agencies, will need to develop processes for reconciling gaps in record-keeping for publications, particularly surrounding how each author meets authorship criteria. Similar protocols may be necessary for acknowledgements, while deeper auditing processes may also need to be developed to uncover and identify other forms of poor or unethical publication practices, such as authorship being denied to individuals who qualify or an individual acting in a capacity similar to that of an author.

Automated filing processes may be used to centrally record all correspondence between stakeholders in a publication for the purpose of auditing. Likewise, written notes should be collated following oral discussions and forwarded to all parties to confirm their accuracy. All correspondence in languages other than English should also be retained.

Additional considerations

Encore conference presentations in APAC

Many conferences indicate that the presenter must be listed as an author of any abstract submitted for presentation, but physical attendance may not be possible for international authors. International authors may also lack adequate local-language skills. However, this should not be a barrier to relevant data being presented in APAC or in a language other than English.

Publication plans that include presentations in APAC should plan to incorporate novel local or regional data to justify expanded authorship that includes a suitably qualified local or regional author. If novel data is not available, stakeholders may consider arranging for a non-author presenter to attend the conference, if permitted, or if it is mandatory for the presenter to be named in the author byline, to include the presenter with a listed affiliation of 'non-author presenter' alongside the authors of the primary conference presentation. Any non-author presenter should have a relationship to the study, such as being a local investigator who has not qualified for authorship on any prior presentation. Appropriate acknowledgement of prior presentation should also be included in any APAC encore presentation, and permission to present the encore sought from the prior conference, where applicable (e.g., if the prior conference claims copyright ownership over abstracts and/or presentations).

Improving knowledge of ethical publication practices in APAC

An ongoing barrier to ethical publication practices is the lack of bilingual English–local language publication professionals, particularly professional medical writers who can navigate both the international and local biomedical publications and cultural environments. When authoring English-language publications, non-native English speakers can benefit from the support of publication professionals with experience from predominantly English-speaking environments, to mitigate challenges in communicating technical information that may inadvertently contribute to plagiarism of published work.

Furthermore, general knowledge of ethical publication practices in APAC is likely to correlate with study sponsors' investment in dedicated publications support in the region. The increasing complexity of the environment within which dedicated publication professionals must now gain substantial expertise beyond publication planning and development to data sharing, PLSs, open access, copyright, and other matters of publication ethics is likely to justify the investment.

Industry-related social media in APAC

Social media posts relating to industry-sponsored research in APAC should be limited to company-sponsored accounts. Employees of study sponsors and other industry stakeholders should not independently comment on industry-sponsored research.

Consensus statements

Consensus (or position) statements are commonly used in APAC to adapt international guidelines and recommendations to local settings. The primary purpose of such statements should be to fill gaps in knowledge or to provide useful advice on adapting guidance to specific APAC circumstances, not as a method of suggesting endorsement of particular treatments. When developing consensus statements, appropriate guidelines and EQUATOR Network checklists should be applied [17,66]. Where possible, the Delphi method, which utilizes anonymous voting, should be used to avoid making participants from APAC uncomfortable by forcing open disagreement. Despite unanimous agreement not being necessary to form a consensus statement [24], authors may feel that they remain responsible for the content in accordance with the ICMJE authorship criteria. Publication professionals may have a role in facilitating collaboration between authors with the aim of attempting to reach a unanimous consensus and ensuring that appropriate methodology is adhered to and reported.

Leadership on publication ethics in APAC

The need for institutional leadership on publication ethics continues to be highlighted as a foundational principle of improving adherence to ethical publication practices [34]. Educational activities within APAC continue to expand. For example, the Australasian Medical Writers Association has increasingly expanded its remit to communicate ethical matters relating to company-sponsored research, despite its traditional focus on non-promotional medical writing.

Conclusions

Awareness and implementation of ethical publication practices is increasing in APAC. The GPP 2022 guidelines represent the latest iteration of global standards for publishing industry-sponsored biomedical research, but practical guidance on how to apply these guidelines in the APAC context is necessary. Publication practices are expected to continue to evolve as new innovations in biomedical publishing are implemented and best practice is advanced.

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