Author’s response to reviews

Title: A guide to applying the Good Publication Practice 3 Guidelines in the Asia-Pacific Region

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Author’s response to reviews:

Responses to reviewer’s comments: Manuscript RIPR-D-19-00014R1

Dear Dr Kowalczuk,

Thank you for the additional feedback provided on this manuscript and requesting that we submit a revised manuscript for consideration for publication in Research Integrity and Peer Review.

We have reviewed the feedback provided by the Reviewers and have revised the manuscript to the greatest extent that is reasonably feasible in response to the Reviewers’ comments, as detailed in the marked-up copy of the manuscript submitted alongside this response.

We have addressed each of the comments specifically as detailed below.

Yours sincerely,
Blair Hesp
Reviewer #1:

Prior to responding to the comments of Reviewer #1, the Authors wish to provide an overarching comment.

This manuscript is targeted to the Asia-Pacific region, but is not intended to be “specific”. By definition, specific recommendations would only have utility in the Asia-Pacific region. The Authors hope that some of the recommendations offered here may be considered from broader application outside of the region and/or used to assist in the interpretation of guidelines internationally. As an analogy, when a statute is passed into law (the GPP3 guidelines), it must be interpreted by judges who generate case law (academic discussion, application and interpretation of the GPP3 guidelines by authors, journal editors and other stakeholders). That case law may then be accepted as fixed and codified in later statutes (the future GPP4 guidelines).

Furthermore, while the Authors have responded to each comment individually, we believe that it is important to provide an overarching view demonstrating the challenges faced by the Authors in addressing conflicting comments. For example:

• Comment #1.1 requests the Authors to make a point about poor publications practices and how they need to be addressed, while Comment #1.13 asks the Authors to highlight the good work being done in the region.

• Comment #1.12 challenges the Authors regarding the use of ‘grey literature’, while Comment #1.5 asks the Authors to publish content from this manuscript in a blog format rather than in the peer-reviewed literature.

• Comment #1.4 suggests that cross-border US and UK anti-corruption laws that are not relevant to the Asia-Pacific region, while Comment #1.14 suggests the EU regulations that have no relevance to the Asia-Pacific region should be incorporated into our suggestions.

• Comment #1.9 assails the Authors for refusing to incorporate key references, but fails to respond to our prior invitation to provide examples of key references that have been omitted.

• In the first round of review Reviewer #1 admonished the Authors for using this manuscript as a trojan horse for launching an organisation in competition with ISMPP, but now asks for us to use this manuscript to highlight the need for leadership in the Asia-Pacific region in Comment #1.28.

We provide specific responses to each comment below:
General

Comment #1.1:

I really agree with the authors that some leadership is needed for biomedical publication collaborations with industry in the AP region, but this paper is not doing that job well enough. I feel like the paper needs to start out with the idea that these authors see a need for leadership in the region and then specifically map out what that would mean.

I can see the work that went into the revision, but I am sad to say that the paper still does not seem publishable. In fact, the writing in the responses to the comments does a much better job explaining the purpose of the paper than the paper does—so the authors clearly have an important point to make, but it is not coming through in the paper. So, once again, while it seems like a good idea to have AP-specific guidance, this paper does not provide that guidance clearly enough for a reader who does not already know the area very well. It seems like a matter of experts talking to experts and not quite understanding how to address people who are naive to the area.

Response #1.1:

This is correct. The intended audience will be professionals involved in the publication of industry-sponsored research who are tasked with ensuring that the GPP3 and other relevant guidelines are met when preparing medical publications for submission to peer reviewed journals. The same criticism could be levelled at all guidelines relating to medical publications. Furthermore, it can be reasonably expected that Authors should be familiar with the requirements that they are expected to meet, especially if they are collaborating with industry. Likewise, we provide advice for medical communications professionals on how to educate authors.

This manuscript does not aim to “make a point”. The manuscript aims to strike a positive, supporting tone to assist stakeholders in the Asia-Pacific region in interpreting and applying guidelines. Therefore, we decline the request to amend the tone of this manuscript to be confrontational, which is inconsistent with accepted cultural practices in the Asia-Pacific region. This approach has been routinely applied in the literature and has been proven to be ineffective.

Comment #1.2:

As a peer reviewer, I am confused by the new material included as a response to my comments. If the goal of the paper is to define how GPP3 works in the AP region, why is there an ICMJE authorship table?

Response #1.2:
The introduction of a table explaining the ICMJE criteria is not in response to any comment from Reviewer #1. The table has been incorporated as a specific request from Reviewer #2. Therefore, we believe that no amendment is required to address this comment.

Comment #1.3:

And if the goal of the paper is to explain both ICJME and GPP3, then why is ICMJE not discussed more specifically? I still think it would be clearer to organize the text around unique situations in the AP region rather than repeating the GPP3 text (especially since GPP4 is already underway). In my opinion, it should be relatively easy to concentrate on the areas needing specific attention in the AP region instead of duplicating material already published elsewhere. In other words, the paper should have been fundamentally reorganized around specific areas of interest in the AP region and should not serve as basically a repetition of GPP3 with a few added notes.

Response #1.3:

We disagree. The aim of this manuscript is to provide positive, affirmative guidance on how to adhere to the current iteration of the GPP guidelines (GPP3), as stated in the title. References to the ICMJE authorship guidelines are incidental and inherently interwoven with the GPP3 guidelines.

As discussed above, we believe that a confrontational approach that focuses on finding fault is counterproductive. Likewise, identifying major issues in the region, identifying their root cause and proposing solutions to specific problems is not within the scope of this manuscript and will most likely be of interest to an overlapping, but different audience.

Comment #1.4:

While I still generally like the idea of providing specific advice for the AP region, this paper does a somewhat poor job at building a case for the need for such guidance and also in giving the specific guidance needed. (Again, the response to reviewers does a better job than the paper itself.) In fact, the local laws mentioned are from the US and UK, which undercuts the value of this publication as a document by and for AP colleagues.

Response #1.4:

There is a simple case for this manuscript – guidance tailored to the Asia-Pacific region does not currently exist. No additional justification is required.
The Reviewer is also incorrect to assert that we refer to US and UK laws as “local laws”. The passage on page 6, lines 20–24 reads:

“Stakeholders based in the Asia-Pacific region should be conscious of, and respect, laws that extend beyond national borders, such as the US Foreign Corrupt Practices Act of 1997, US Sunshine Act of 2013 (when working with healthcare professionals based in the US), General Data Protection Regulations (when handling personal data from citizens of the European Union) and the UK Antibribery Act 2010.”

Likewise, in Table 3, we stated:

“All authors should be aware of any relevant local laws that apply to their research, as well as any laws that may apply to their co-authors and other stakeholders, such as study sponsors.”

This is an extremely important element of this manuscript because stakeholders in the Asia-Pacific region may not be aware that the laws of other countries may cover their actions, and those of their employer, in their own country. No one expects to be subject to another country’s laws when operating in their home country.

Comment #1.5:

Furthermore, the advice given is rather bland and could have been presented on a member website in a series of blog posts or some other format that would be more easily accessible. In other words, this paper (as written) provides no new or useful information for an AP audience that warrants peer-reviewed publication in this format.

Response #1.5:

Firstly, articles discussing guidelines as a genre will always be procedural in nature.

Secondly, the Reviewer’s proposal carries many of the same pitfalls as publishing in a predatory journal, which is a practice that we are trying to discourage in the region, namely:

• The absence of robust peer review would undermine the validity of any discussion offered by the Authors.

• Any blog post cannot be guaranteed to be available in perpetuity.

• A blog post may not be readily discoverable, especially using common search engines, such as PubMed.

• The voice of Asia-Pac will be ignored because it is not considered to be presented in a globally acceptable format.
The extent of the novel and useful information in this manuscript that has been overlooked during review is outlined in detail in response to Comments #1.11–1.26.

Comment #1.6:
In addition, the information presented is distributed across text and the long table in such a way as to prevent readers from finding it easily.

Response #1.6:
The text is currently separated into several individual sections by topic for quick reference. Likewise, the tables offer concise, quick-reference sources.

In accordance with the required format for submitting for peer review, the tables are of course difficult to find as they are required to be submitted in a manner that is appended to the text.

Comment #1.7:
The case studies are only tangentially related to the rest of the text and would be better placed elsewhere so that they can function in the way the authors explain in their response to reviewers.

Response #1.7:
Reviewer #2 has expressly requested that the case studies remain and has asked that more examples are given. Therefore, in light of the conflicting comments, and the Authors previous action to move the case studies into the Supplementary Appendix at the request of the Reviewers, we believe that no further action is required.

Comment #1.8:
Personally think they should be incorporated into the ISMPP main site because they are valuable for that membership.

Response #1.8:
The Authors refuse to entertain any request to transfer the value contained in this manuscript to an organisation that the Reviewer has a clear affiliation with, which would prima facie be of personal benefit to the Reviewer.
Comment #1.9:
In addition, I am somewhat taken aback that the authors refused to look at the long list of ISMPP-sponsored publications on more granular practices for authors. It seems somewhat irresponsible in a paper by ISMPP members that mentions regional work by ISMPP to neither consult nor cite this work. For example, A Stocks and colleagues recently published an ISMPP-sponsored paper on the very authorship questions these authors find confusing—this paper should be cited instead of trying to reinvent the material.

AND

GPP Principle 7:
Stocks and colleagues just published a paper about the specific nature of authorship criteria and many (many) publications exist that give this type of general advice, much of which seems to parallel GPP3. Some of that literature should be cited.

Response #1.9:
This comment appears to be identical to a previous broad request for additional unspecified references to be included in this manuscript. In the absence of specific references being suggested by the Reviewer for inclusion in this manuscript, we asked the Reviewer to identify the specific references that the Reviewer believed should be referenced in this manuscript for consideration by the Authors.

We have incorporated Stocks et al. in the current draft on page 12, lines 15–16:

“The scope of ‘drafting the work or revising it critically for important intellectual content’ has not been clearly defined, but proposed definitions of what constitutes a substantial contribution to the development of a manuscript have been published [22].”

and on page 13, lines 16–19:

“Likewise, it has been suggested that performing technical editing, language editing or proofreading, collating author comments, and making minor corrections for grammar, language, formatting or layout does not constitute a substantial contribution to the manuscript [22].”

The AMWA-EMWA-ISMPP joint position statement on predatory publishing that was published after the first round of revisions has also been incorporated into the manuscript as reference 28 on page 17, between lines 2 and 12.

In addition, the Authors have conducted a search of the PubMed database for publications authored by the Reviewer. No publications uncovered as a result of that search were considered by the Authors to be of sufficient relevance to be included in this manuscript given the focus on the subject of ghostwriting, which is not covered in this manuscript.
Accordingly, the Authors have made every effort to address this comment to the fullest extent possible.

Comment #1.10:

This brings me to another problem, which is that the reference citations seem wrong. The very first citation is incorrect, which affects the entire paper, and makes me think the authors have not really taken enough time to carefully review their article before resubmission. Or perhaps the submission program picked up a penultimate version in error?

Response #1.10:

This editorial error has been corrected in the references section. A full data check has also been performed and no further amendments are considered necessary.

Specific:

Comment #1.11:

Introduction:

The authors need to make one clear claim to support the need for this paper. So, either there is some problem with the existing guidelines (as stated in the introduction and abstract) or people in the AP region are unfamiliar with the global guidelines and having trouble implementing them based on local practices (as stated in the conclusion). I believe the latter is true, given the comments the authors made in their peer review responses.

Response #1.11:

The Reviewer’s comments appear to erroneously separate a single problem into two mutually exclusive problems, namely, ambiguous wording in the GPP3 guidelines makes it difficult to effectively meet those guidelines when operating in accordance with local practices in the Asia-Pacific region.

Therefore, this manuscript does have a unified theme and no amendment is required to address this comment.

Comment #1.12:
The references supporting claims about the AP region seem to conflate all scientific publishing with publishing in biomedicine. For example, the Science paper is not specifically about biomedicine. Also, a heavy proportion of this work is grey literature, including opinion pieces, or specifically about China. So, if the authors want to make a claim about the whole AP region in the context of GPP3 (which is a guidance for biomedical publication collaborations with industry), I would want to see some citations that specifically address problematic collaborations with industry in the region -OR- some interesting information about local regulatory or other practices that present challenges in the AP region in this setting.

Response #1.12:

The Authors have used the most appropriate references that are available. Most are readily discoverable on search engines, such as PubMed. Alternatively, Medical Writing is the official journal of the European Medical Writers Association. This approach is consistent with other manuscripts covering similar ground in the field.

Likewise, with a population of over 1 billion people and being an emerging global scientific powerhouse, a higher proportion of the citations relating to China, which receives extended coverage, is appropriate. The same approach is often taken in the West by taking a US = worldwide approach.

The nature of some of the references does not invalidate their relevance.

Furthermore, we have provided numerous examples, particularly in the case studies, or local practices that present challenges in the Asia-Pacific region, such as junior authors often requesting no amendments to manuscripts.

Comment #1.13:

I still fail to believe that working in Australia, New Zealand, or Japan (a founding ICH region) presents huge barriers to biomedical publishing. It might help to explain what those barriers are, exactly. For example, there seems to me to be a space for debunking vague generalities about "poor practice" in the AP region by being more specific about the high-quality work already being done there.

Response #1.13:

The Authors have decades of combined in-market experience and we stand by our statements about our experience.

As noted in our previous response, and responses in this document. We aim to take a positive approach to encourage adherence. Dwelling on past failures and admonishing the reader
regarding practices that they may not be a party to, and are interested in changing, would be counterproductive.

Comment #1.14:

Requirements for reporting research

GPP Principle 1:

The authors note that information and guidelines are not available in AP-regional languages (although I am unclear as to where Persian is spoken in the AP region, given that most of its native speakers reside in Iran and Afghanistan?) and then recommend that all local data be published in English. I'm not sure this makes sense, and it seems to counter to the idea that local physicians need access to this data. It's also inconsistent with recent EU requirements for Lay Summaries…. companies that market products in the EU will already need to have data in local languages.

Response #1.14:

Firstly, Persian is mentioned as Iran is an Asian country and a Persian translation of some of the EQUATOR Network and the ICMJE guidelines is available. There is no legitimate reason to arbitrarily exclude its mention when listing guidelines in Asian languages.

Secondly, data needs to be published in English for global accessibility. Additional opportunities may then exist to publish translations in local journals, as discussed in the manuscript (see page 8, lines 11–13).

Discussion of local requirements in the EU is irrelevant to the discussion of practices in Asia-Pacific.

Comment #1.15:

I do not think, given the problems in the Science article the authors cite, that the authors should be recommending editing services instead of noting the value of professional medical writers with specific experience in the AP region. It also might be more helpful to address the idea of translation (with back translation), and how to go about doing that for local and global audiences.

Response #1.15:

Many journals recommend English-language editing services to Authors in the region to improve outcomes. The Authors also have a clear conflict of interest in recommending the services of a
medical writer, so have refrained from overt statements that would bring into question our neutrality.

Discussion relating to methods of translation are beyond the scope of this manuscript.

Comment #1.16:

I don't understand what kind of data are not suitable for peer-reviewed publication. Can the authors give an example that is specific to the AP region? And explain why can't such data be added to a review?

Response #1.16:

Firstly, a review is a summary of the literature and is not generally a forum for presenting new data, especially given the increasing expectation that non-commissioned reviews should be systematic in nature.

Suitability for publication is a subjective matter and must be determined by the relevant stakeholders. Providing examples will provide an anchoring reference, resulting in an unnecessary and unjustifiable limitation of this definition to specific circumstances.

Regardless, in light of comments from the Editor suggesting that this manuscript be placed on a preprint server while undergoing peer review, we have amended the relevant section of text on page 5, lines 13–21 to read:

“Data that are not considered suitable for peer-reviewed publication should can be made available to the public prior to peer-reviewed publication via appropriate non–peer-reviewed methods, such as publication via a trial registry, preprint server such as bioRxiv or PeerJ preprints, or a publicly accessible database. This can minimise delays in public data dissemination, provide transparency by demonstrating the evolution of a manuscript as author comments are incorporated and improve the quality of the manuscript by soliciting broad feedback from the scientific community prior to, or in parallel, with formal peer review at a journal. This approach should not compromise the ability to submit to a peer-reviewed journal, but the publication policy of any target journal should be checked in advance.

Principle 1 in Table 3 has also been amended accordingly to read:

“Data that are not considered suitable for peer-reviewed publication should be made To minimise delays in data dissemination, authors should consider making draft manuscripts available via appropriate non–peer-viewed methods, such as publication via a trial registry, preprint server such as bioRxiv, or a publicly accessible database prior to peer-reviewed publication prior to peer-reviewed publication.”
Comment #1.17:

Why are publications delayed for subgroup analyses in this region but not others? And how might one address this problem? An ISMPP group, for example, published on using publication planning as a means of guiding study design and data analysis planning. That could be a helpful reference that will put this paper in conversation with ongoing ISMPP work.

Response #1.17:

Page 6, lines 1–2 have been amended as follows:

“Therefore, it is recommended, subgroup analyses, including those in Asian populations, should be planned in advance to help expedite publication”

We presume that the Reviewer is alluding to the following publication that she authored:


This manuscript was reviewed and considered by the Authors during the development of the initial drafts of this manuscript and was not considered to be of sufficient relevance to justify inclusion.

Furthermore, discussion of study design and data analysis that delays publication is an internal matter for study sponsors to consider that is beyond the scope of this manuscript as it precedes the publication development process.

Comment #1.18:

The authors could address where to publish local subgroup analyses and how to find journals or conferences that meet needs across a subgroup.

Response #1.18:

We do not believe that this topic requires specific discussion in this manuscript as methods of journal selection have minimal relevance to ethical publication practices. If anything, we are encouraging stakeholders to incorporate ethical practices into publication development to increase opportunities to publish in high-impact global journals.

Furthermore, to suggest that an Asia-Pacific–specific approach to journal selection is required would be counterproductive and risks driving authors to predatory journals if it is suggested that authors in the region should actively seek alternate publication options.
Comment #1.19:

GPP2 Principle 2:

None of the laws mentioned are pertinent to the AP region specifically. Please list some local laws that impact publications.

Response #1.19:

The laws mentioned in this manuscript cross borders and that is specifically why they are relevant to the Asia-Pacific region. Stakeholders may be unaware that their actions in their home country may be subject to the laws of another country. This is unlikely to be well understood.

However, to satisfy this comment, the Authors have made the following amendment to the manuscript on page 6, lines 14–20:

“All stakeholders should be aware of any relevant local laws that apply to clinical studies and the dissemination of research findings, such as the “Korean Sunshine Act” (Article 47-2 of the Pharmaceutical Affairs Act and Article 13-2 of the Medical Devices Act of Korea), The Philippines Department of Health’s guidelines on pharmaceutical marketing and promotions (Administrative Order N.2015—0053) and Indonesian Sponsorship for Healthcare Professionals: Regulation 58. Relevant local self-regulatory activities, such as the Medicines Australia Code of Conduct and the Japan Pharmaceutical Manufacturers Association’s Transparency Guideline for the Relation between Corporate Activities and Medical Institutions should also be considered.”

Comment #1.20:

Recommending the use of EQUATOR guidelines is not new, and the comments on translations do not make very much sense in the context of the recommendation in the previous section that all publishing be in English. I feel like these sections were handled by different authors and that the last read-through wasn't quite finished. (Maybe the submission program picked up the wrong version?)

Response #1.20:

The language in which the EQUATOR Network guidelines are translated into is irrelevant to the language of publication.

Accessibility of guidelines in a local language increases the possibility of the guidelines being understood and followed. If this investment was not justified to improve adherence then organisations such as the EQUATOR Network, ISMPP and the ICMJE would not be concerned
with publishing translated versions of their guidelines. In fact, the ICMJE is actively soliciting volunteer and independent support to facilitate translations into additional Asian languages.

Comment #1.21:

GPP Principle 3:
Nothing in this section looks that different compared with the recent paper by Foster and colleagues. What is specific to the AP region? What is new?

Response #1.21:
The Authors believe that there are clear recommendations in this section that are both novel and specific to the Asia-Pacific region, namely:

- “Original presentation of regionally relevant data should ideally occur within the Asia-Pacific region” – novel and Asia-Pacific–specific.
- “The possibility of an encore presentation at a later date should be raised with all authors at the time of preparing the primary publication.” – novel.
- “Providing a single authorship agreement that relates to the primary publication and any encore publications.” – novel.
- “This may include an agreement that additional authors may be added to encore presentations, for example, if the encore must be delivered by an author who is a speaker of a language other than English.” – novel and Asia-Pacific–specific.
- “Furthermore, any prior presentation should always be acknowledged and a study identifier included as a link between data generated from a common study” – novel expansion beyond Foster et al.

Comment #1.22:

GPP Principle 4:
Nothing in this section seems original or targeted to the AP region. What is new? What is specific to the AP region?

Response #1.22:
Every sentence in this section makes specific reference to publication planning activities in the Asia-Pacific region, with a specific focus on integration with publication planning occurring
outside of the region. In addition, the Authors have provided two Asia-Pacific–specific case studies relating to this topic.

Comment #1.23:

GPP Principles 5-7:

This paper opens by criticizing the very guidelines you cite here (unless the problem is just that the abstract needs updating), but this section just says to follow the guidelines and offers little to no specific advice about working in the AP region.

Response #1.23:

The Authors note that the Abstract states:

“Numerous recommendations and guidelines aim to improve the quality, timeliness and transparency of medical publications. However, these guidelines use ambiguous language that can be challenging to interpret, particularly for speakers of English as a second language.”

The Abstract makes no reference to the issues associated with the GPP3 and ICMJE guidelines or specific reference to the sections of these guidelines that relate to authorship.

Furthermore, the Authors make numerous Asia-Pacific–specific recommendations, above and beyond what would be readily understandable as useful advice by an audience in the region, including the following:

• “Likewise, there should be a clear differentiation between the roles of an editor, professional medical writer and a translator, as each provides a different service. “

• “Alternatively, the agreement should be written in ‘plain English’ that would be readily understandable for authors who speak English as a second language.”

• “For example, in situations where following up with senior authors may not be culturally acceptable, a desire to avoid delays in submitting a manuscript for publication should not override the need for input and approval to submit from every author.”

• “A case study on effective multinational collaboration in publication development in the Asia-Pacific region is provided in Case Study 4 in the Supplementary Appendix.”

• “However, consideration is needed as to what may be reasonably expected of authors in the Asia-Pacific region”

• “Alternatively, senior authors in the Asia-Pacific region may prefer to only be asked for comment after their junior collaborators have first provided their input. “
• “Whenever possible, authors’ should be supported through the publication process by a speaker of their native language to ensure understanding of roles and responsibilities and accurate recording of comments.”

• “For speakers of English as a second language, care should be taken to ensure that any translation or English-language editing service maintains the integrity of the publication.”

• “While such authorship is commonly offered to Heads of Department and other senior researchers within the Asia-Pacific region…”

• “Instances of authorship being offered for sale, which have been reported in the Asia-Pacific region, are not acceptable under any circumstances."

Comment #1.24:

GPP Principle 8:

Relies too heavily on US guidance and does not explain the unique situation in the AP region.

Response #1.24:

No guidance in this section is derived from US sources.

At least half of this short section is dedicated to advice that is targeted at an Asia-Pacific audience using suggestions independently generated by the Authors, as detailed below:

• The US National Institutes of Health has provided a useful pictorial guide of demonstrating what contributions may support a claim to authorship and the strength of such claims [21]. This may be provided to authors to explain the expectations of surrounding authorship, particularly if it is adapted and translated to meet local needs.

• Authors may also be offered a list of potential contributions in their native language to provide a record of their contribution and help draft contributorship statements for publications. The author list should only be revised during the peer review process under exceptional circumstances.

Comment #1.26:

GPP Principles 9-10:

Also feel heavily derivative of the GPP3 guidelines

Response #1.26:
Yes, this section is heavily derived from the GPP3 guidelines. However, this section is also heavily annotated with practical suggestions that build above and beyond any previously published content.

Comment #1.27:

…. The next sections on ORCID ID's and predatory journals would also benefit from information specific to the AP region. None of this information feels new.

Response #1.27:

This section provides additional advice and specific details about why this is important for Authors in the Asia-Pacific region, eg, the difficulty regarding the consistent use of naming conventions.

We believe that this section has clear utility for Authors in the Asia-Pacific region and previously amended this section in response to comments from Reviewer #2, which appear to have been resolved.

Comment #1.28:

Leadership on Publication Ethics in the AP Region

This is really the most interesting section of the paper, but it does not go far enough. The authors need to define the AP region and its concerns for the reader and then and explain how to balance the concerns of different constituencies across the region. The idea is to explain this information to naive (but intelligent) readers. Personally, I would really welcome such a paper because it could highlight some of the really important work already being done by the authors.

Response #1.28:

We note the Reviewer previously criticised the Authors for calling for leadership in the region as this was deemed to be a call for organisation coming into existence that would be in competition with ISMPP.

As previously detailed, we have included a call to action because the form of any action is beyond the scope of this manuscript. Likewise, and as noted by the Reviewer, such discussion should be the subject of a separate manuscript.
Reviewer #2:

Comment #2.1:

I appreciate that you have made significant changes to the manuscript to try to address the reviewers' comments and your efforts have certainly improved the manuscript. The appendix with links to other organizations and guidances is a useful addition, as are the new Tables 1 and 2. However, in my opinion, the manuscript still does not provide "a practical guide" as stated in the manuscript title. You also state "we provide practical guidance for applying these guidelines in the context of situations that are relevant to authors in the Asia-Pacific region" but the cases and interpretations in the text do not meet this goal as currently written. This is unfortunate, as a publication that provides practical guidance on the application of GPP3, ICMJE, and other biomedical publication guidelines in the Asia-Pacific region would be a valuable contribution to the literature for those of us who work in this field.

Response #2.1:

Given the Reviewer’s specific concern regarding the use of the term “practical” in the title and description of the manuscript and whether adequate ‘practical’ assistance is provided to the reader, we have amended the title to read:


The word “practical” has also been deleted throughout the Abstract and Introduction.

We believe that the manuscript provides extensive guidance on how to interpret the recommendations offered in GPP3 in the context of the Asia-Pac region, specifically when ambiguity exists that may require clarification. Therefore, this title continues to be accurate and appropriate.

Comment #2.2:

As noted previously, your own experiences and practical examples would be very useful throughout the manuscript. I understand that every situation is unique but as a reader I would value hearing about specific situations you have encountered in the AP region, and how you addressed/resolved them. These experiences would be so valuable to the reader.

Response #2.2:

The Authors are very interested in sharing their personal experiences, but this is limited by a number of factors:
• Manuscript length – During review we have already been asked to move the case studies to supplementary material to reduce manuscript length.

• Confidentiality – Unfortunately, confidentiality limits free discussion in many cases. Accordingly, anonymising the unique details of individual cases, as has been done here, also removes some of the key details that distinguish case studies on similar topics.

• Repetition – Case studies on similar topics risk repeating details that we have aimed to distil into specific guidance within the main body of the manuscript.

Comment #2.3:

I have also noted some specific points below as examples of where I think more work needs to be done, although this is not a comprehensive list.

In the Introduction, you state: "This manuscript aims to provide a practical guide for authors and publications professionals in the Asia-Pacific region on applying the GPP3 and ICMJE guidelines when developing medical publications." However, you still do not explicitly state that your paper is specific to pharma industry-supported research, which is evident from their use of pharma/agency language and the cases presented. I think it is essential to clarify for readers the scope/limitations of this paper from the very beginning for the readers - who is it for and what does it cover.

Response #2.3:

We have amended this sentence of page 4, lines 16–18 to read:

“This manuscript aims to provide a practical guide for authors and publications professionals in the Asia-Pacific region on applying the GPP3 and ICMJE guidelines when developing medical publications, particularly publications derived from industry-sponsored research.”

As noted, the main target for this manuscript will be the publication of industry-sponsored research, but we do not wish to unnecessarily limit the scope of its relevance to industry-sponsored research alone.

Comment #2.4:

There are specific statements throughout that need clarification. For example, you state: "These include... the Good Publication Practice 3 (GPP3) guidelines on industry-sponsored research." GPP3 provides guidance on COMMUNICATING industry-sponsored medical research - an important clarification, in my view.
Response #2.4:

We agree that this distinction is important and have amended the manuscript accordingly on page 3, line 7.

Comment #2.5:

Regarding "steps necessary to achieve authorship" in the text and in Table 3, I suggest rewording to say "steps necessary to meet ICMJE authorship criteria".

Response #2.5:

We agree that this amendment would increase clarity and have amended the manuscript accordingly on page 10, lines 22–23 and in Table 3 (principle 5).

Comment #2.6:

I found that your responses to comments did not always explain what had been done in the manuscript to address the comment. For example, in response to my query about whether these guidelines are readily accessible, you stated as a response that you confirmed with your Chinese co-author that "these guidelines are freely accessible via the internet in China", however, this response does not reflect the actual changes made to the text of the manuscript, which made reviewing the responses and text revisions quite time-consuming.

Response #2.6:

We apologise for the difficulty in interpreting the changes in the revised manuscript. The extensive, and often overlapping, amendments required to address both reviewers’ comments made it difficult to effectively illustrate how and where some of the amendments had been addressed.

We believe that the specific comment referred to here related to the accessibility of certain publications in China. In this case, we merely aimed to confirm their accessibility. No amendment appeared to be required, nor was an amendment made, to the manuscript in response to that comment.

Comment #2.7:

Similarly, some of the revised text/statements that you list as responses were not in the tracked changes manuscript pdf. For example, for comments #2.8, you state that you revised the
manuscript to say "As a result, awareness of the Good Publication Practice 3 (GPP3) recommendations on the transparent and ethical publication of industry-sponsored research and other relevant guidelines in lower income countries...". However, I could not find this revised language in the manuscript. The closest text in the document that I reviewed states "However, awareness of the GPP3 recommendations in lower income countries..." This was an issue with other responses to comments - the revised text in the manuscript was not the same as the revised text you stated in the response letter.

Response #2.7:

As above, we apologise for the complexity in attempting to explain how the more than 70, often overlapping and competing comments were addressed. However, we note that no suggestion has been raised regarding any of the abovementioned comments failing to be addressed.

Comment #2.8:

Table 2 should provide a better explanation of gift, guest, or honorary authorship - there are plenty of publications that provide examples. Also add 'regional publication plans', 'evidence gaps', 'knowledge gaps', and 'authorship agreements' to this table.

Response #2.8:

Definitions for the terms “authorship agreement” and “regional publication plan” have been added to Table 2 on pages 27 and 28. Gift, guest and honorary authorship has also been split into individual rows and broader definitions provided.

We note that the terms “knowledge gap” is not used in the main body of the manuscript, but have now been defined in text in the supplementary material rather than this table.

The term “evidence gap” is not used in the manuscript.

Comment #2.9:

As commented previously, I don't think the case studies as written provide much practical help to the reader. In my experience of developing cases, the goal is to present the case (ie, the situation) and then what was done and the outcome, ie, how the situation was addressed/resolved. For example, case 1 sets out the situation but does not state how it was resolved. In this case, the reviewer asked for the STARD checklist to be submitted. Were the authors able to do this? If not, what happened to the manuscript - was it submitted elsewhere as is, or revised to follow the STARD checklist? By presenting what happened, you can provide practical advice to the reader - if developing a manuscript of a certain type (eg, observational study, systematic review,
diagnostic study), check EQUATOR for relevant guidelines and follow them. For case 2, you could rewrite to present the situation as the new publication professional joined and found that there were <5 publications from the region. He/she developed a publication plan for their local situation that was aligned with the global plan, facilitating increased resource allocation from the global sponsor and increasing the publications output considerably. If this format was applied to the other cases too, I think this would provide more practical guidance for the reader, which is the intent of the paper.

Response #2.9:

The following text has been added to Case Study #1 to clarify the outcome:

“As the medical writer had applied the STARD guidelines when developing the manuscript, no changes were required to the manuscript to meet the STARD requirements and the manuscript was immediately accepted upon presentation of a completed checklist.”

While additional amendments have been made to the case studies to improve their flow as suggested, the proposed style is not necessarily appropriate for the case studies presented here.

One of the challenges in providing case studies for this manuscript is that demonstrating how processes run smoothly when applying our suggestions does not offer utility. Likewise, when suggesting preventative measures, there is little utility in demonstrating a ‘rescue’ situation. Therefore, these case studies are ‘negative’ case studies, offering examples of what can happen if the suggestions provided are not applied, and illustrating how these situations could have been avoided by applying our suggestions.

Comment #2.10:

The link provided to the NIH pictorial decision guide for authorship did not work for me - it took me to a "Page moved" message, so this needs to be updated.

Response #2.10:

We have reviewed the link to the pictorial guide (reference 23 [previously reference 21]) and it appears to be correct. We did not experience any issues in accessing the page.

However, we have noted that if copying and pasting the link, the error reported by the Reviewer may occur if the full stop at the end of the reference is included.

Comment #2.11:
re: "a tick-box list of commonly disclosed conflicts", this would be better worded as "a tick-box list of common disclosures of potential conflicts of interest". A disclosure as such does not mean a conflict. A reference and link to the ICMJE COI form would also be helpful here.

Response #2.11:

The requested amendment has been applied on page 15, lines 24–page 16, line 1.

A link to the ICMJE conflict of interest form has also been inserted on page 15, line 21.