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-19-00014

Dear Dr Kowalczuk,

Thank you for the 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 accordingly, 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:

Thank you for the opportunity to review this important work. I wish you luck with the process of revision.

General:

Comment #1.1:

Despite my very strong bias in favor of a paper of this type, the current draft is not publishable yet. It contains promising ideas; however, the authors must give themselves permission to come out and state their opinions clearly. In fact, the paper reads as though the authors are almost fearful of making a clear, strong point. This is a shame because guidance for the AP region is probably needed—the problem for me as a reader is that I feel unconvinced that this claim has been adequately supported.

Response #1.1:

The Authors thank the Reviewer for noting the benefits that may be provided by this manuscript. However, the Authors’ intent is to provide neutral guidance on how to apply guidelines on good publication practices in the Asia-Pacific region. The principles outlined in the Good Publication Practice 3 (GPP3) contain some ambiguous phrasing, which introduces difficulties for interpretation, particularly for speakers of English as a second language attempting to apply these guidelines in the cultural context of the Asia-Pacific region.

The Authors have intentionally avoided judgment or criticism of stakeholders both within and outside of the region because we believe this to be counterproductive to the aim of improving publication practices within the Asia-Pacific region and increasing alignment with other regions.

Given the current lack of written guidance tailored to the Asia-Pacific region we believe that a collaborative rather than confrontational tone is most appropriate for this manuscript. We have now provided more specific examples and suggestions on how to effectively and appropriately meet the GPP3 guidelines throughout the revised manuscript.

Comments #1.2 and #1.5:

The authors appear to be affiliated with organizations that, on the whole, are unlikely to be experiencing specialized problems over and above those of other global employees working with multilingual and multicultural authoring teams. For example, English is a primary language in Australia, New Zealand, and Singapore. And it is worthy of note here that the specific study of the English language actually began in India, which may confer an advantage.
AND

A more serious problem is the way the authors seem to claim that problems of writing English as a foreign language are unique to the Asia Pacific region. Many authors in the EU, LatAm, Middle East and North America are also in this situation. The mention also makes the focus of the paper unclear. If the main point is that the specialized problems of publication in the Asia Pacific region are not addressed in existing guidelines, then it would be clearer to say this outright and focus the paper on this problem.

Responses to #1.2 and #1.5:

We acknowledge the concerns of the Reviewer, and while the challenges faced in the Asia-Pacific region may not be unique, the approach that may need to be taken to address those challenges most certainly is. As medical publication professionals actively practicing in the countries within which they reside, including countries where English is less common, such as Japan and China, we are appropriately positioned to make informed comment on the topic.

Likewise, the literature cited in the Introduction of the manuscript largely directs criticism towards the Asia-Pacific region, despite investigating practices in other regions where English is not a dominant language and lower income countries, which also suggests that challenges in adopting ethical publication practices are, to a large extent, unique to the Asia-Pacific region.

Furthermore, the Authors wish to reiterate that the purpose of this manuscript is to assist stakeholders in applying and adhering to ethical publication practices by providing practical guidance rather than attempting to set an alternative standard.

Comment #1.3:

The authors really, in my opinion, need to do the following:

a. Define existing good practice guidelines

Response #1.3a:

Please note that the intention of this manuscript is not to redefine or develop novel guidance on already established practices. Accordingly, the 10 principles of GPP3 guideline are offered here with an interpretation in the context of the cultural norms of the Asia-Pacific region and suggestions provided with the aim of encouraging compliance with already established practices.

We have now included Table 1 to clearly define the International Committee of Medical Journal Editors guidelines on authorship criteria.
b. Support the claim that these guidelines do not address the AP region enough—OR—simply state that the AP region has special concerns that make further clarification needed

Response #1.3b:

The Authors believe that the guidelines are applicable for the Asia-Pacific region. However, the ambiguity incorporated into the phraseology of the 10 principles of GPP3 mean that additional explanation is required to assist stakeholders in the Asia-Pacific region in interpreting these principles, particularly for speakers of English as a second language. For example, “Journal and congress requirements should be followed, especially ethical guidelines on originality and avoiding redundancy (that is, duplicate publication)” potentially raises questions about whether or not encore presentations in the Asia-Pacific region are consistent with GPP3 when the congress may explicitly says yes, but an encore could be considered to be duplicate publication.

The introduction to the section “Applying the Good Publication Practice 3 Guidelines in the Asia-Pacific Region” has been significantly expanded to clarify some of the specific challenges faced by stakeholders in the Asia-Pacific region regarding ambiguities in the language used in the guidelines.

c. Explain what the special concerns of the AP region are and then show how to address these special concerns within existing guidelines

Response #1.3c:

The Authors believe that poor publication practices in the Asia-Pacific region have been the subject of a number of studies published in the peer-reviewed literature, and this literature has been extensively cited in the Introduction as the rationale for the manuscript being developed.

We have now inserted additional specific suggestions throughout the manuscript to address particular circumstances faced in the region.

d. Given that GPP4 is underway, perhaps make some recommendations for how that guideline could better address global audiences

Response #1.3d:

The Authors agree that input from the Asia-Pacific region will be required during the development of GPP4 and would welcome the Authors of GPP4 to consider some of the challenges identified and solutions offered in this manuscript.
The Authors believe that the most appropriate method of contributing to the development of GPP4 will be through direct communication with the GPP4 steering committee and Authors via formal mechanisms that we expect to be implemented going forward, e.g., public consultation.

Abstract:

Comment #1.4:

This (like the full paper) is quite wordy. For example, the authors could open by saying that the ICMJE, GPP and other powerful guidelines (like COPE) for biomedical publications focus on problems in Western countries. A strong argument/support for this claim needs to be made because (with the possible exception of COPE), existing guidelines work hard to address global audiences.

Response #1.4:

The authors do not believe that international guidelines are exclusively directed at Western audiences or designed to address Western problems. In fact, the literature cited in the manuscript suggests that the opposite is true, in that the guidelines are relevant to practices that have been reported to be more prevalent in the Asia-Pacific region than elsewhere (Rohwer et al. BMJ 2017). Therefore, the intention of this manuscript is to help stakeholders in the Asia-Pacific region to navigate and adhere to the recommendations made in GPP3, in line with the expectations of their international peers.

The Authors have also thoroughly reviewed the Abstract and body of the manuscript and edited the content to remove as much potentially superfluous content as possible.

The following amendments have been made to the Abstract (lines 2–5) to define the need for this manuscript as described below:

“However, these guidelines have largely focused on practices and expectations in North America and Europe are composed of language that incorporates a level of ambiguity that can be challenging to interpret, particularly for speakers of English as a second language and in the context differing cultural expectations that are prevalent in the Asia-Pacific region.”

Introduction

Comment #1.6:
The paper starts out with a telling mistake (likely the result of collaborative authoring or cut and paste error): the ICMJE Recommendations provide guidance on the design, conduct, and authorship of studies to be published in biomedical journals as well as advice to editors.

Response #1.6:

The first paragraph of the introduction has been amended to address this comment as follows:

“The most well-known are the authorship guidelines issued by the International Committee of Medical Journal Editors (ICMJE), which provide guidance on all aspects of medical research that is intended to be published in peer-reviewed journals, including authorship. Accordingly, the ICMJE guidelines are commonly referred to in ‘Instructions to Authors’ issued by peer-reviewed medical and scientific journals”

This amendment broadens the reference to the ICMJE guidelines beyond authorship alone to cover the broader concept of research beyond publishing, as requested by the Reviewer.

Comment #1.7:

Page 3, lines 14-20: It would be helpful to see more information about the other guidelines (like their names), aside from ICMJE. For example, an explanation of GPP would be helpful here.

Response #1.7:

Thank you for this suggestion. Given the large number of potential guidelines and recommendations that could be referred to, we have included a list of useful resources in the new Supplementary Appendix and refer the reader to this resource in the text.

Comment #1.8:

Page 3, lines 30-35: this is not helpful information for the current argument. I'd delete.

Response #1.8:

Please note that we have received conflicting recommendations from the Reviewers relating to this point.

As Reviewer #2 has requested that this point be expanded to refer to the publication volume originating in China versus the US, we have retained this statement.

Comment #1.9:
Page 4, lines 1-12: I know from experience and exposure that it's fairly common for publications professionals to complain about poor awareness of "publication ethics" in the AP region. My question is how much of this material is published, by whom, and what the authors think is unfair about these characterizations. For example, people in some cultures may feel that it is unethical not to list the funder in the author list, even though ICMJE guidelines say otherwise. It's important here for the authors to come out and make a claim: what is your opinion and why? What problems exist? How does this specific paper present a solution?

Response #1.9:

The Authors believe that it is important to cite relevant literature that has suggested poor publications practices in the Asia-Pacific region to support the rationale for this manuscript, but also believe that it is necessary to provide a balanced discussion by acknowledging contrary claims that have also been made in the literature. These statements are referenced to multiple peer-reviewed sources accordingly, and are not independent assertions made, or opinions expressed, by the Authors of this manuscript.

However, despite abundant debate regarding adherence to publication practices, there is a distinct lack of practical solutions suggested in the literature. Hence, the current manuscript aims to provide practical guidance, tailored to the needs of stakeholders in the Asia-Pacific region.

Furthermore, sometimes there is ambiguity in GPP3 and other times there is not. Accordingly, some practices are clearly considered unethical, irrespective of cultural expectations, and in such cases it is appropriate to reiterate this. However, in cases of ambiguity, where further clarification would be beneficial, the manuscript attempts to address this and offer possible solutions.

Comment #1.10:

Page 4, paragraph 2: it says "studies" but I see only one citation in that sentence and only 2 in the paragraph.

Response #1.10:

The word “Studies” has been replaced with “An investigation”.

Comment #1.11:

Another problem here is the lack of explanation as to how authorship, retraction, and ICMJE are connected. I agree that a claim like that could be made, but it would need to be written out for the reader. I also see no reference to GPP3, which is in the title of the paper.
Response #1.11:

The Authors believe that it is important to discuss ethical publication practices, in general, of which authorship is only one issue, but is somewhat more difficult to detect than other forms of unethical publishing practices. The following statement is included in the amended manuscript:

“A lack of consistency in how authorship guidelines are applied, as well as imbalances between the expectations and practices of junior versus senior researchers, are common barriers to applying recommended publication practices, and are commonly cited as reasons for publication retraction in the Asia-Pacific region. Similarly, while low in number, a higher incidence of retractions due to other issues surrounding publication ethics, such as plagiarism, duplicate publication, fake peer review and breach of copyright, have also been reported in Asia compared with other regions”

We believe that on the face of it, these behaviours can all be classified as unethical publications practices and it should not be necessary to link these particular behaviours to specific guidance, especially as several of these behaviours would be considered to be unlawful.

Likewise, the authors believe that the most appropriate tone for this manuscript is a positive one, providing support and guidance to the Asia-Pacific region on how to improve.

Furthermore, reference [2] is the GPP3 guideline (mentioned in the first and final paragraphs of the introduction). An expanded introduction has also been included to the main body of the guidance.

Comment #1.12:

Following paragraphs: As a reader who has actually read the source materials (and is very much in favor of the idea behind this paper) I find the text almost impenetrably wordy. The authors need to come out with a clean, specific argument that makes particular claims and connects GPP, ICMJE and the points to be made later in the paper.

Response #1.12:

The Authors have made amendments to the manuscript, including removing the Case Studies and placing them in a new Supplementary Appendix to reduce the length of the manuscript. Additional amendments have also been made to the content of the manuscript following a thorough review in response to the peer review process.

Applying GPP3 to AP Region
Comment #1.13:

I find this section of the paper (and the long table) very confusing because it is unclear how the authors see:

• The main purpose of GPP3
• How GPP3 is focused on regions other than AP (a claim that I would need to see better support for, because I personally do not believe that GPP3 ignores the AP region)
• Special considerations for the AP region by specific stakeholders. What should authors do? Editors? Publication professionals?

I also find the cases to be distracting and unconvincing as part of the overall argument of this paper… a better placement for these could possibly be the main ISMPP members page. But my impression is that the cases distract from the argument rather than support it.

Response #1.13:

The purpose of the GPP3 recommendations has now been incorporated into the brief introductory statements in the first paragraph of this section.

We also wish to offer the following additional comments:

• We do not believe that a claim is made that the GPP3 neglected the Asia-Pacific region and focused too heavily on other regions. We highlight that compliance to ethical publication practices is lower in the Asia-Pacific region, so providing practical suggestions in the form of an open-access manuscript is one measure for assisting stakeholders in the region in applying appropriate practices that has not yet been explored to our knowledge.

• The Authors believe that the case studies offered here, based on personal experience, provide examples that could be emulated by readers, or provide inspiration for novel approaches, and should be freely available to the general public in the form of an open-access manuscript. We believe that it would be counterproductive to place the case studies behind a paywall that requires paid ISMPP membership to access, especially as ISMPP have already acknowledged the barrier that costs represent in the Asia-Pacific region by offering reduced membership fees.

Additional Considerations

Comment #1.14:

This section is also confusing. It feels as though the authors are trying to assemble a stand-alone section that is not connected to the rest of the paper. Reorganizing the paper around special considerations for the AP region would be helpful in addressing this problem.
Response #1.14:

The Additional Considerations section aims to introduce and familiarise stakeholders in the region to additional tools and methods that are either useful in the publication development process or areas of concern that are not currently addressed by GPP3. This section is intended to complement the Asia-Pacific–specific commentary on GPP3, which forms the backbone of the manuscript.

Need for leadership

Comment #1.15:

Unfortunately, this section reads as though the purpose of the paper is to establish a separate professional organization for the AP region. I would suggest that this seems to suggest that there should be separate leadership for every region—which seems cumbersome to me as a member of the profession. It would be more helpful to the global community to have more of a sense of who in the AP region is doing which work and why. For example, journals and authors in India and Pakistan have done a lot of work to address specific publication ethical problems (like ghostwriting and plagiarism), suggesting (to me at least) that there is already some academic leadership in the area that already has a global impact.

Response #1.15:

Firstly, it is important to note that as part of their involvement in the 2019 ISMPP Asia-Pacific Meeting Organising Committee, several of the Authors have signed non-compete agreements with ISMPP. Accordingly, the Authors extended the courtesy of allowing ISMPP to review this manuscript prior to submission and no objection to its content was offered. Likewise, all relevant potential or perceived conflicts of interests have been disclosed by the Authors.

Secondly, the Authors believe that there is a need for leadership in publication practices in the Asia-Pacific region and a call to action is an appropriate component of this manuscript. One of the driving factors behind this manuscript is the extensive criticism of practices in the Asia-Pacific region in the literature without practical solutions being offered, so we believe that ongoing debate, collaboration and innovation, as is an inherent expectation of the scientific community, should be encouraged. Furthermore, given that organisations such as the American, European and Australasian Medical Writers Associations all operate in parallel to the International Society of Medical Publications Professionals (ISMPP), as well as the ICMJE, Committee on Publication Ethics (COPE), World Association of Medical Editors (WAME) etc., if this manuscript contributed to an Asia-Pacific regional organisation coming into existence, then surely this would be a positive outcome.
Conclusions:

Comment #1.16:

The conclusions, for me, are not supported by the contents of the paper. It really feels as though the paper was authored in sections and the colleagues were too polite to edit each others' work enough to create a clear and cohesive argument. This is a shame because this paper addresses a vitally important topic but the reader who doesn't already understand the problems of the region will not be able to understand the text as written.

Response #1.16:

The Conclusions have been revised to clarify the Authors aims with this manuscript. In particular, the Authors aim to provide guidance and solutions for Authors in the Asia-Pacific region in the absence of other tailored resources.

References

Comment #1.17:

Given the authors' affiliations, I do not see adequate references to recent publications by ISMPP members and groups. The Foster paper on poster presentations is interesting (but perhaps unsustainable), and other papers have been appearing on a fairly regular basis.

Response #1.17:

The Authors believe that references should be included on the basis of merit and relevance to the content of the manuscript. Several references cited in the manuscript have been sponsored by ISMPP or have authors with a well-known affiliation to ISMPP.

Furthermore, given that this manuscript aims to apply ethical practices, we believe that the Authors’ declared affiliations should have no role in influencing reference selection.

However, we would be happy to consider specific references suggested by the Reviewer that are believed to be relevant to this manuscript for incorporation on their merits.

Please also note that the Foster reference has been updated following its recent publication in Research Integrity and Peer Review.

Comment #1.18:
It would be helpful to have a better understanding of how the authors chose these specific papers from the vast array of publications available.

Response #1.18:

Please note that this manuscript has been submitted as a ‘Commentary’, not a systematic review. As with any scientific publication the Authors have used their expertise to search the literature and identify references they believe to be most relevant to the background and rationale for this manuscript (i.e., research and commentary relevant to publication practices in the Asia-Pacific region).

The Authors have aimed to maintain a concise and highly relevant reference list, but have added a list of ethical guidelines to the Supplementary Appendix.

However, we would be happy to consider any suggestions of highly relevant references for inclusion from the Reviewer.

Table

Comment #1.19:

This table is confusing and, for me, unhelpful. For instance, it's not useful to say that AP region colleagues should follow local laws. It would be more helpful to have some better information about what those laws are, which countries in the region have compatible (and incompatible) requirements and regulations and how different stakeholders should comply. It would also be more helpful to organize these tables around specific special circumstances for the AP region rather than GPP3 headings.

Response #1.19:

We thank the Reviewer for their comment, but we note that the wording of GPP3 is reflected in this manuscript with regard to local laws. While the intended scale of this manuscript is more restricted than GPP3 itself, there are still 48 countries in the Asian continent, without considering Australia and the Pacific and laws regularly evolve with time. Therefore, providing individual examples will have limited applicability to individual circumstances and risk being superseded.

Furthermore, the purpose of the table (now Table 3) is to provide a quick reference guide to the main suggestions from the manuscript. We believe that its utility will be increased once it is typeset within the manuscript rather than its current presentation as an orphan at the end of the manuscript.
Reviewer #2:

ABSTRACT

Comment #2.1:

Suggest qualifying that the primary focus of this article is on pharmaceutical company-sponsored research (as is GPP3). Add (GPP3) as an abbreviation, similar to your using (ICMJE).

Response #2.1:

This editorial amendment has been incorporated.

INTRODUCTION

PAGE 3

Comment #2.2:

If you start by saying there are numerous recommendations and guidelines you should cite some of them, eg, those from EQUATOR, CONSORT, WAME, COPE, CSE, AMWA, EMWA, MPIP, etc. Also, as above, recommend qualifying that you are focusing on pharmaceutical company-sponsored research when you talk about scientific and medical publications and the application and interpretation of GPP3.

Response #2.2:

Thank you for this suggestion. Given the extensive list of possible guidelines and recommendations that could be cited, we have opted to include a list of relevant materials in the new Supplementary Appendix and referred the reader to this document.

We believe the reference to GPP3 is made in the context of industry-sponsored research in several places in the Introduction, but have further clarified this in the brief introductory statement preceding the practical guidance.

Comment #2.3:

Rephrase the description of ICMJE guidelines - they are used by major journals as a basis for much more than just authorship criteria - perhaps note their broad scope then say that they are probably the leading source of determining authorship criteria.

Response #2.3:
The first paragraph of the introduction has been amended to address this comment as follows:

“The most well-known are the authorship guidelines issued by the International Committee of Medical Journal Editors (ICMJE), which provide guidance on all aspects of medical research that is intended to be published in peer-reviewed journals, including authorship. Accordingly, the ICMJE guidelines are commonly referred to in ‘Instructions to Authors’ issued by peer-reviewed medical and scientific journals”

This amendment broadens the reference to the ICMJE guidelines beyond authorship alone to cover the broader concept of research beyond publishing, as requested by the Reviewer.

Comment #2.4:

Line 17/18 reads "as well as and" - please fix.

Response #2.4:

This editorial amendment has been incorporated.

Comment #2.5:

For the last line of this para, again suggest expanding the citations as noted above.

Response #2.5:

Please see the response to Comment #2.2.

A reference to the Supplementary Appendix has been incorporated at the end of this paragraph.

Comment #2.6:

re: expanding pharma in AP region and Japan, I believe there are data now that the number of clinical trials and publications in China has eclipsed that of North America - an important point here.

Response #2.6:

Thank you for raising this point. An additional sentence and supporting reference have been added at the end of paragraph 2 on page 3 introducing this point.
Comment #2.7:
re: "executing regional publication plans" - suggest providing an explanation of what this is, otherwise you are assuming all readers are familiar with this concept.

Response #2.7:
A new Table 2 has been inserted that defines key jargon. “Publication plan” has been included as one of these terms.

Comment #2.8:
re: first mention of GPP3, I think you need to introduce to the reader what this is, what it covers, why it was developed, and that it contains specific ethical best practices for pharma-sponsored publications.

Response #2.8:
This sentence has been amended to read:

“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…”

Comment #2.9:
re: "lower income countries", I don't think income is necessarily the reason that some countries are not aware of Western guidelines/best practices. Japan, China, Australia/NZ, for example, are not low income countries, but ethical and cultural differences are considerable.

Response #2.9:
We agree with the Reviewer in that Japan, Australia and New Zealand should not be classified as “lower income countries”, but this is the terminology used in the reference cited in this sentence. Therefore, we have attempted to clarify this statement by amending the relevant content to read:

“…in lower income countries, including some countries in the Asia-Pacific region”.

PAGE 4
Comment #2.10:
re: "adherence to ethical publication practices in the Asia-Pacific region" - you mean adherence to Western ethical publication practices - I think you need to say somewhere in the Intro that Western regions have gone to some lengths to set best practice guidelines, which is why you are proposing interpreting them for application in the AP region.

Response #2.10:

The Authors believe that ethical publication practices should not be defined by region and there should be a consistent international standard, which we believe that stakeholders in the Asia-Pacific are striving to achieve. As outlined in paragraph that follows this statement, there are a number of challenges and barriers that may need to be overcome to achieve this.

Of note, the problems encountered in applying good publication practice in the Asia-Pacific region are not unique, hence the broad reference to ethical publication practices, but the approach need to address these problems in the region is likely to be unique.

Comment #2.11:

re: authorship practices, it would be helpful here to explain some cultural differences with regard to authorship in different regions. I don't think it's just lack of consistency in applying (Western) guidelines, but there are strong cultural expectations in some regions that are very different.

Response #2.11:

The Authors are aware that there are distinct cultural expectations regarding authorship, but these are not unique to the Asia-Pacific region. Many of the same expectations can be encountered in Europe and North America, but are perhaps more strongly held in the Asia-Pacific region.

Accordingly, this manuscript aims to provide guidance on how to apply the authorship practices that have been internationally promulgated, while maintaining ethical standards where cultural practices may result in differing processes. For example, as discussed in the manuscript, some authors may have thoroughly reviewed a manuscript, but decline to offer substantial comment on a manuscript. Therefore, relevant stakeholders may be unsure if an author qualifies for authorship according to Western perceptions, which should not be confused with Western standards.

Comment #2.12:

re: same comment about "globally recognised ethical publication practices" - I don't think the guidelines you focus on are globally recognized (yet).
Response #2.12:

The Reviewers acknowledge the Reviewer’s comment and have amended the terminology in this sentence to read “internationally recommended” instead of “globally recognised” to improve the accuracy of the wording used here.

PAGE 5

Comment #2.13:

"Data should also ultimately be published in a peer-reviewed journal following any conference or informal presentation" - this isn't clear to me. Do you mean every abstract/poster/oral should be published in a peer-reviewed journal? Is this really possible? Perhaps qualify by saying that publication or presentation at international congresses is encouraged for abstracts/posters/orals at regional or country-specific congresses to broaden their accessibility.

Response #2.13:

This paragraph has been amended to clarify how data can be effectively disseminated. We also believe that discussion of local presentations is also adequately, and appropriately, covered in relation to Point 3 (redundant publication).

PAGE 6

Comment #2.14:

"Data relevant to the Asia-Pacific region is often delayed" - the reason for this delay is not clear to me as written. Do you mean that subanalyses by region/ethnicity of international studies are undertaken and published later because they are subanalyses? It is recommended that the primary analysis of any trial is published first anyway, regardless of any planned subanalyses. And what about studies that are only, for example, conducted in Asian or Japanese patients? These aren't mentioned here. This section seems to be focusing on large international trials only, so I think this needs more explanation.

Response #2.14:

This paragraph has been amended to clarify that data “generated as part of multinational studies that is relevant to the Asia-Pacific region”.

Comment #2.15:
re: "evidence gaps", again I don't think all readers will be familiar with this concept so it needs explanation and/or the text/statement rewording. Overall, this whole para is confusing - it's not clear how this para relates to ethical best practices statement that "The design and results of all clinical trials should be reported in a complete, accurate, balanced, transparent, and timely manner." For example: "there is a need to drive awareness of potential differences in clinical study design" - who should be driving this awareness, what are these differences, and how might they be resolved?

Response #2.15:

Thank you for highlighting the need for clarity in this paragraph. We have rewritten this paragraph to improve clarity and focus.

Comment #2.16:

re: "stakeholders" - again I think you need to explain what you mean here - these terms/jargon are familiar to people in the West working in industry or agencies, but I am not sure they are generally understood.

Response #2.16:

A new Table 2 has been inserted that defines key jargon. “Stakeholder” has been included as one of these terms.

Comment #2.17:

Can you provide any examples in this past para of p6 of key laws in AP regions that may also have to be applied by? As you are talking about applying GPP3 in AP regions, might there be laws or regulations that are contrary to what GPP3 proposes? How should this be handled?

Response #2.17:

The wording used here is also consistent with GPP3 and is intended to be a catch all in that complying with local laws will obviously take precedence over guidelines. Likewise, laws evolve over time and are specific to every nation, so the Authors believe that the onus is on the reader to be aware of, and to apply, any relevant laws.
Is it true that ICMJE and GPP3 are "readily accessible" in the AP region? Do all researchers/authors in these countries have access to these websites, for example? If not, what are some ways that these guidelines and resources could be accessed or disseminated?

Response #2.18:

The Reviewer raises an interesting question, and we have confirmed with our Chinese co-author that these guidelines are freely accessible via the internet in China.

Comment #2.19:

Case Study 1 needs a bit more explanation – was this a diagnostic test developed in or for the AP region and/or by an AP company, and/or written for an AP audience? It isn’t clear as written.

Response #2.19:

Yes. This was developed by a company in the Asia-Pacific region that performed clinical studies in the region. The first sentence of this case study in the Supplementary Appendix has been amended accordingly.

PAGE 8

Comment #2.20:

Again there is reference to "overall publication planning process" - I think this kind of industry-specific language should either be avoided or clearly defined.

Response #2.20:

We have opted to delete this mention of “overall publication planning processes” to avoid confusion. We believe the relevant sentence can stand alone without this mention.

Comment #2.21:

“While originality is always preferable” – not sure what this means in this sentence. Overall I think this para needs rewriting as the focus is not clear. Are you trying to say that access to international or overseas congress data is limited in the AP region, so encore presentations at AP regional events should be considered? If so, I think that would be a simpler way to say it.

Response #2.21:
This section has been reworded following the feedback offered here and should now offer greater clarity.

Comment #2.22:
"data that is of high interest and has not been presented" - data ARE plural - so "data that are of high interest and have not..." (also elsewhere in the manuscript).

Response #2.22:
The Authors have corrected the grammar relating to the use of ‘data’ in this instance and have reviewed and corrected other relevant instances where this word has been used throughout the manuscript.

Comment #2.23:
"local audiences" - presume you mean researchers in AP countries.

Response #2.23:
We have opted to delete this mention of “local audiences” after editing this section.

Comment #2.24:
"universal authorship agreement" - I'm not sure this document would be well known outside the pharma/agency field.

Response #2.24:
We have replaced the word “universal” with “single” and further edited and adapted this sentence for simplicity.

PAGE 9

Comment #2.25:
"Opportunities may exist to republish articles initially published in English in other languages" - this is confusing as written and should be revised, eg, "Opportunities may exist to republish in other languages articles initially published in English."
Response #2.25:
This editorial amendment has been incorporated.

Comment #2.26:
"If republishing a translated version of a manuscript" - here I think you mean publication, not manuscript?
Response #2.26:
The Reviewer is correct. “Manuscript” has been replaced with “publication” accordingly.

Comment #2.27:
Use of "stakeholders" here and throughout - I think this terms should either be avoided or defined - to me it seems like pharma/agency jargon.
Response #2.27:
A new Table 2 has been inserted that defines key jargon. “Stakeholder” has been included as one of these terms.

PAGE 10
Comment #2.28:
Case 3 - add that this was an AP regional affiliate.
Response #2.28:
This editorial amendment has been incorporated in Case Study 3, which is now in the Supplementary Appendix.

PAGE 11
Comment #2.29:
Could the 4 ICMJE criteria be listed here for those not familiar with them?
Response #2.29:
A new Table 1 has been inserted that includes the four criteria for authorship, as recommended by the ICMJE.

PAGE 12

Comment #2.30:
"authors must agree to the writer's involvement" - I think what you mean is that all authors must be asked if they agree to the involvement of a medical writer.

Response #2.30:
This editorial amendment has been incorporated.

Comment #2.31:
This section discussed what should be done on a practical/process level when implementing ICMJE authorship criteria, but doesn't address how to explain these requirements to investigators/authors who are used to a very different cultural norm with regard to authorship and the roles and responsibilities. Similarly for authorship seniority and order. Can the authors provide some guidance about this here? What approaches have been successful in their experience?

Response #2.31:
We note that this comment reflects comment #2.41. We have now incorporated a link to a pictorial decision aid that lists a number of potential intellectual contributions to the development of a manuscript, and the strength of each of those contributions in terms of supporting a claim for authorship. We believe that this could be readily adapted and translated to meet the need of stakeholders in the Asia-Pacific region.

We note that how to attribute authorship seniority in publications has been a matter of debate for a number of years, and guidance is frequently requested, yet major guideline issuing bodies from around the world have yet to tackle this subject because of its complexity. In this instance, we believe that the priority is to first determine qualification for authorship, while seniority is a secondary consideration. However, the pictogram that we have now included does provide some guidance on attributing levels of seniority, although direct discussion of this topic lies outside the scope of this manuscript.

Comment #2.32:
Instead of talking about an author needing to be "removed from a manuscript", this implies that someone else is making this decision. May be better to just stop at "proposed author does not meet the ICMJE criteria". Can you give that author the opportunity to meet these criteria before any discussions about removing them? Perhaps mention also the option to have such an individual listed in an Acknowledgment?

Response #2.32:

Thank you for this insightful suggestion. “Removed from a manuscript” has been deleted from both the main text and Table.

An additional practical suggestion has been included regarding providing prospective authors the opportunity to fulfil authorship criteria or accept an acknowledgement as an alternative.

PAGE 13

Comment #2.33:

This case is written as a mixture of statements and a case, ie, not a problem and a solution. Recommend rewriting to present as a case, eg, "Employees of a multinational pharmaceutical company were trained on the ICMJE and GPP3 recommendations. However, when working Japanese investigators of a clinical trial, cultural norms made it difficult for study sponsors to explain to the authors why the ICMJE authorship criteria should be followed. This was compounded by professional medical writing support provided in English by an overseas-based agency. To address this problem, local medical writers who were familiar with both cultural norms and ethical publications practices were brought in to..."

Response #2.33:

Upon review, the Reviewer is correct in this assertion. Case Study 4 in the Supplementary Appendix has been reformatted into a full case study format accordingly.

PAGE 14

Comment #2.34:

This is a bit better as it provides suggestions re: how to implement 'Western' guidelines when working with people in the AP region who are either not familiar with them, or who have different cultural norms re: authorship and seniority. The authors' experiences and practical examples would be very useful here and elsewhere in the manuscript.

Response #2.34:
We wish to thank the reviewer for their feedback on this element of the manuscript.

Comment #2.35:
"However, the scope of 'drafting the work..." - explain for the readers that this is one of the 4 ICMJE authorship criteria, as not everyone will be familiar with this.

Response #2.35:
This statement has been amended for clarity to read:

“However, the scope of ‘drafting the work or revising it critically for important intellectual content’ is subjective and not clearly defined by in the ICMJE criteria for authorship.”

PAGE 15

Comment #2.36:
"may need to develop new methods of engaging authors" - can you give some examples that have worked for you? If the intent of this paper is to be a "practical guide", there should be practical examples that the readers can try.

Response #2.36:
Every situation is likely to be unique and can require a novel approach, so we have aimed to encourage a level of flexibility and innovation. In this instance, we have now inserted the suggestion of scheduling a face-to-face meeting at which the author would dictate their comments, as this may offer several advantages, including fixed timing for a response, increased engagement with the author and an opportunity to maximise the input from an author by asking questions or gaining insight into their reasoning for amendments.

Comment #2.37:
"If an author does not agree with a study's findings, as presented in a manuscript, they may wish to politely decline authorship." - is this their only option? Shouldn't discussions be set up to evaluate everyone's interpretation of the data before this stage is reached?

Response #2.37:
This has now been clarified to indicate that academic discussion, led by the lead author or a professional medical writer, should be used to resolve any disagreements and that an author should only consider declining authorship when an impasse is reached.

Comment #2.38:
"Guest or gift authorship" - these terms should be explained/defined. Honorary authorship is another term that could be used/defined here.

Response #2.38:
A new Table 2 has been inserted that defines key jargon. “Gift, guest or honorary authorship” has been included as one of these terms.

PAGE 16
Comment #2.39:
Again, can you provide practical guidance on how to implement these authorship guidelines where culture or language is a barrier?

Response #2.39:
We have inserted additional guidance at the beginning of this section recommending that an informal approach is made to authors, ideally by a speakers of authors’ native language, to ensure understanding of the author’s role and responsibilities in advance of any formal initiation of manuscript development.

Comment #2.40:
Case study 5 does not seem specific to an AP region situation. Given the title of this paper and its goals, it would be better to provide a case that reflects an AP authorship situation.

Response #2.40:
This case study is derived from a situation faced by one of the Authors in the Asia-Pacific region. While a scenario such as this may not be isolated to this region, we believe that it remains relevant. We have updated the case study to specifically state that this occurred within the region accordingly.
Comment #2.41:

There isn't really a recommendation here about capturing "intellectual contribution" as it relates to working with AP authors. What suggestions/recommendations can you make, eg, authors should be provided with a list of potential contributions (in their native language if necessary) from which to indicate their specific contributions to the research and the reporting of it. And/or work with a local affiliate (familiar with culture, customs, and language) to discuss these requirements with AP authors.

Response #2.41:

Thank you for this suggestion. We have now incorporated a link to a pictorial decision aid that lists a number of potential intellectual contributions to the development of a manuscript, and the strength of each of those contributions in terms of supporting a claim for authorship. We believe that this could be readily adapted and translated to meet the need of stakeholders in the Asia-Pacific region.

Comment #2.42:

As above, what recommendations do you have with respect to working with AP authors? Perhaps, as above, provide a list of potential COIs (in their native language if needed) from which they can indicate their specific COIs. And/or work with a local affiliate (familiar with culture, customs, and language) to discuss these COI requirements with AP authors.

Response #2.42:

Thank you for this suggestion. A recommendation to provide authors with a tick-box list of commonly disclosed potential or perceived conflicts of interest has been inserted into the manuscript.

Comment #2.43:

Case study 6 - as previously, can you make this more relevant to an AP situation?

Response #2.43:

As noted in Response #2.40, this case study is derived from a situation faced by one of the Authors in the Asia-Pacific region. While scenarios such as this may not be isolated to this
region, we believe that it remains relevant. We have updated the case study to specifically state that this occurred within the region accordingly.

PAGE 19

Comment #2.44:

"All authors in the Asia-Pacific are encouraged" - suggest rewording to "All authors in the Asia-Pacific should be encouraged"

Response #2.44:

This editorial amendment has been incorporated.

Comment #2.45:

"Awareness of data-sharing requirements in the Asia-Pacific is low." - if so, what do the authors recommend to address this situation?

Response #2.45:

We have noted that reviews on the subject of data sharing have been published in local Polish and Portuguese medical journals and have suggested a similar approach in the Asia-Pacific region, in addition to more general methods of communicating data-sharing policies, such as journal instructions to authors and the ICMJE website.

PAGE 20

Comment #2.46:

What suggestions or recommendations can the authors provide to address some of these issues?

Response #2.46:

Additional recommendations have been inserted throughout this section, in addition to the selection of tools and recommended sources that were already included within this section.

Comment #2.47:
"a majority of the audience" - there can only be one majority so "the majority of the audience" or "most attendees"

Response #2.47:
This editorial amendment has been incorporated.

Comment #2.48:
"audience is comprised of" - should be "audience comprises". Better to simplify/reword, eg, "Most attendees at such meetings are industry stakeholders"

Response #2.48:
This editorial amendment has been incorporated.

PAGE 21

Comment #2.49:
Suggest a separate section earlier in the manuscript on predatory journals/congresses if they are particularly prevalent in the AP region, including a better definition of these.

Response #2.49:
The section on predatory journals and conferences has been moved forward and called out. Unfortunately, there is no generally accepted definition of ‘predatory’ practices, so we have inserted a description of common characteristics of predatory journals according to a recent systematic review of the literature on the subject.

TABLE 1

Comment #2.50:
Some of the suggestions/recommendations noted above should be included in this table to provide practical advice for people working within or across the AP region. Many of these recommendations state what "should" be done without providing guidance on "how" to do so, given the cultural, financial, language, and other barriers.

Response #2.50:
The table (now Table 3) has been updated to reflect the amendments made in response to the comments from the Reviewers throughout the manuscript.