



# AP ISMPP U - Applying GPP 2022 in the Asia Pacific

June 28, 2023



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• Application deadline for the September CMPP exam is August 1





### **ISMPP** Announcements



#### **NEW ISMPP Academy**

Save the date: September 28-29, 2023

Where: Convene, Philadelphia

ISMPP Academy is a new meeting that will deliver best practices education to professionals:

- Who work at biotechnology, small pharma, and medical device companies
  - Who are newer to the field •
  - Who want to build their expertise •

#### More details to come!



### **How To Ask Questions**

Feel free to ask a question at any time, however all questions will be held until the end the of the presentation.

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

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

We will make every effort to respond to all questions live (out loud)





 Information presented reflects the personal knowledge and opinions of the faculty and does not necessarily represent the position of their current or past employers





- Summarize the overarching principles of GPP 2022 and the key changes versus GPP3
- Understand how to adapt and implement GPP 2022 to the APAC publication landscape
- Recognize key challenges and opportunities in the APAC context and potential best practices







Dikran Toroser Senior Director, Publications Group Lead Merck



Blair Hesp Principal Consultant First In Human



Shobana Ganesan Senior Manager, Quality and Training Cactus Life Sciences





### GPP 2022

Application in the Asia Pacific Region

- Diversity, Equity & Inclusion
- Plain Language Summaries
- Enhanced Content

Dikran Toroser, PhD CMPP Merck & Co, Inc. Rahway, NJ, USA

*ISMPP-U June 27<sup>th</sup>, 2023* 



#### DISCLAIMER

#### All opinions are the author's and do not necessarily reflect the opinions of their present or past employers or any professional organization







- GPP 2022: 4<sup>th</sup> iteration of GPP...free to access
- New content includes:
  - Diversity, Equity & Inclusion [DE&I]
  - Plain Language Summaries [PLS-Ps]
  - Enhanced content [EC]
- CHANGING TRENDS:
  - APAC, Demographics, Post-pandemic publication landscape
- ENTRY POINTS TO MEDICAL DATA
  - Democratization of information
- CONCLUSIONS and Future State

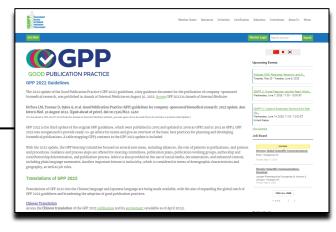


#### GPP 2022...what are the updates General description, and resources

- Great summary from ISMPP pub planning workshop
- 5.5-pages in 2003 → 32-page guideline in GPP 2022

Strengthen core values; more publication/ study types; roles of patients as authors; DE&I, PLS-Ps; author limits out; alliances; social media; enhanced content





#### **ISMPP WEB PORTAL**

https://www.ismpp.org/gpp-2022



GPP 2022: https://www.acpjournals.org/doi/10.7326/M22-1460

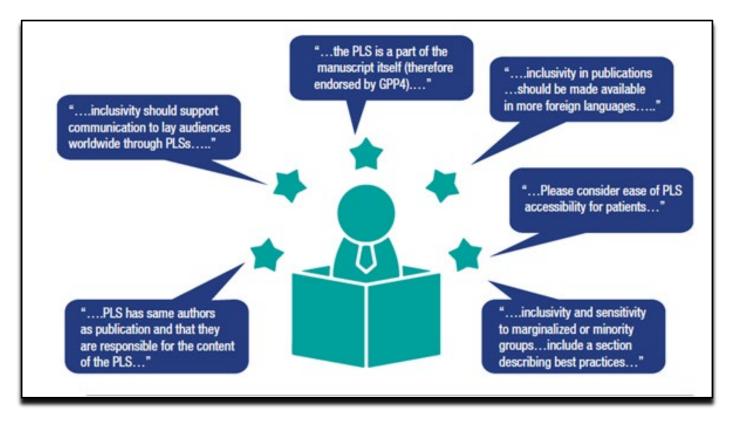


- Staggering Growth in Publications and AUDIENCE
  - (Doubling of information every 9 years since WWII<sup>1</sup>)
- Largest growth: APAC/Emerging markets (India, China, South Korea)<sup>2</sup>
  - Unique and rapidly evolving environment<sup>3</sup>
- Hyper-competitive environment

<sup>1</sup>Bornmann and Mutz (2015) Growth rates of Modern Science
 <sup>2</sup>AJE Scholarly Publishing Report (2016) *Current Publication Trends* <sup>3</sup>Hesp, Arai, Bose *et al.*, 2023 [*CMRO*] <u>https://pubmed.ncbi.nlm.nih.gov/37184123/</u>



#### **GPP 2022: Direct Quotes from Volunteer Reviewers**



#### **Reviewer locations\***



- Diversity, Equity & Inclusion
- Plain Language Summaries
   [Enhanced Content]
- [Enhanced Content]

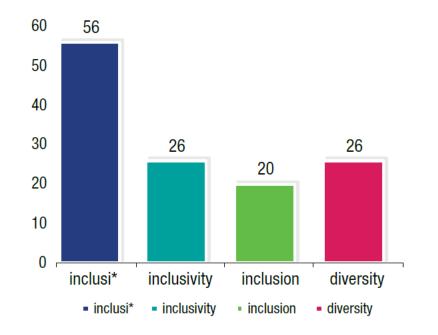
\*Some submitting reviewers selected multiple locations for multiple contributing reviewers; Locations were provided for 137 reviewers contributing to a total of 118 comment sets.



Volunteer Reviewer Feedback [GPP 2022]

# **DE&** Incidence of keywords around DE&I in the raw comments





- Diversity in trial design
- FDA requirement...diversity plan for clinical trials
- UREGS in protocols



#### **GPP 2022: Enhanced content and PLS**

- GPP endorses the use of enhanced content if it is developed following the same ethical and quality principles as the main publication
- This includes the use of plain language summaries (PLS) to support the communication of scientific information to lay audiences
- Formats might include text, video, audio, podcast, or infographic
- Enhanced content must be consistent with that of the underlying publication and must not be promotional in language, tone, or style







 New FORMATS for DIVERSE consumer populations PLS-Ps, Enhanced Content, Preprints, Other New formats often PubMed indexed [formal citations]
 MULTIPLE ENTRY POINTS

Apps, Virtual sessions, Other

3. A paperless highly connected experience



#### UNINTENDED CONSEQUENCES ...to increasing speed & volume

#### Concerns...retractions and bias

- peer-review speed/quality
- publication bias....(cherry picking?)
- cost of OA publishing/inequality

AMWA-EMWA-ISMPP joint position statement on med pubs, preprints & peer review <a href="https://www.tandfonline.com/doi/full/10.1080/03007995.2021.1900365">https://www.tandfonline.com/doi/full/10.1080/03007995.2021.1900365</a>

https://theacse.com/2021/slides/18.%20Dikran%20Toroser\_.pptx

OUALITY

Potential harm of inadequate vetting

**Risk of losing public** 

trust in science

**Publication Dilemma** 

JOINT POSITION STATEMENT + CHECKLIST

SPEED Necessity to

communicate

relevant scientific findings rapidly

#### **NEW NORMAL**



- RISK reduction for our "new normal"
  - GUIDELINES: (eg. GPP 2022 and EQUATOR)
  - EDUCATION: ISMPP-U, ISMPP workshops, ACSE, AMWA, EMWA etc.

- DECENTRALIZATION and regions
  - REGIONAL Nuance...Cultural sensitivity
  - Increased Access to REGIONAL Healthcare information





- Increased ACCESS to publications
- Publications will have to incorporate DE&I concepts
  - additional formats; eg, PLS-Ps, Enhanced Content
- Changing GLOBAL DEMOGRAPHIC of pubs consumers
- SPEED to the public domain is increasing
- UNPRECEDENTED times in publications!



#### Acknowledgements

### **GPP 2022 Authoring Team**

- Dan Bridges
- Lise Baltzer
- Leslie Citrome
- Lisa DeTora
- Faith Di Biasi
- Laura Dormer

- Eline Hanekamp
- Trevor Lane
- Fiona Plunkett
- Angela Sykes
- Dikran Toroser
- Christine Vanderlinden





# **GPP2022 in Asia-Pacific**

Blair Hesp PhD NZDipBus CMPP

**First In Human** 



# **Disclosures**

- Managing Director and Owner, Kainic Medical Communications
- Principal Consultant, First In Human (a division of Kainic Medical Communications)



# **Publication ethics: Challenges of the past**<sup>a</sup>

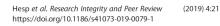
- Limited participation of experts and community representatives from the Asia-Pacific region in guideline development
- Arbitrary choice of publication ethics research projects with little coordination or engagement with people in the Asia-Pacific region
- Assumption that European and North American experts are better placed to generate insight than local representatives
- Resources based in high-income countries

<sup>a</sup>Note: These challenges were broadly identified as ways in which global health organisations based in high-income countries can perpetuate inequities in healthcare, in general, not specifically medical writing-related topics. Khan M. et al. *BMJ Global Health* 2021;6:e005604.



# **Moving forward in Asia-Pacific**

- Inclusion of an Asia-Pacific representatives in the GPP development process
- Organic local initiatives
  - Asia-Pacific adaptations of GPP3 and GPP 2022
  - Localised research into publication ethics
  - Regional societies promoting publication ethics



Research Integrity and Peer Review

#### COMMENTARY

#### **Open Access**

Check for

#### A guide to applying the Good Publication Practice 3 guidelines in the Asia-Pacific region

Blair R. Hesp<sup>1\*</sup>, Katsuhisa Arai<sup>2</sup>, Magdalene Y. S. Chu<sup>3</sup>, Stefanie Chuah<sup>4</sup>, Jose Miguel B. Curameng<sup>3</sup>, Sandeep Kamat<sup>5</sup>, Zhigang Ma<sup>6</sup>, Andrew Sakko<sup>7</sup> and Hazel Fernandez<sup>8</sup>

CURRENT MEDICAL RESEARCH AND OPINION https://doi.org/10.1080/03007995.2023.2214433 Article ST-0163.R1/2214433 All rights reserved: reproduction in whole or part not permitted

Taylor & Francis Taylor & Francis Group

Check for upd

REVIEW ARTICLE

#### Applying the good publication practice 2022 guidelines in the Asia-Pacific region: a practical guide

Blair R. Hesp<sup>a</sup> (b), Katsuhisa Arai<sup>b</sup>, Namita Bose<sup>c</sup>, Rachael Profit<sup>d</sup>, Malvika Katarya<sup>e</sup> (b), Jonathan Lee<sup>f</sup> (b), Ronnie Lin<sup>g</sup> (b), Magdalene Chu<sup>h</sup>, Andrew Sakko<sup>i</sup> (b) and Hazel Fernandez<sup>i</sup> (b)

<sup>a</sup>Kainic Medical Communications Ltd, Dunedin, New Zealand; <sup>b</sup>Wiley Publishers, Tokyo, Japan; <sup>c</sup>Cactus Communications Pvt Ltd, Mumbai, India; <sup>d</sup>MIMS Pte Ltd (Taiwan Branch), Taipei, Taiwan; <sup>e</sup>AMICULUM Asia Pte Ltd, Singapore, Singapore; <sup>f</sup>Takeda Pharmaceuticals International AG–Singapore Branch, Singapore, Singapore; <sup>g</sup>Hasten Biopharmaceutic Co, Ltd, Shanghai, China; <sup>h</sup>MIMS (Hong Kong) Ltd, Causeway Bay, Hong Kong; <sup>i</sup>Syneos Health, Gordon, NSW, Australia; <sup>j</sup>Janssen Asia Pacific, A Division of Johnson & Johnson Pte Ltd, Singapore, Singapore



# **Diversity, equity and inclusion**

Term	Definition	
Diversity	Who is represented, e.g., gender, sex, age, ethnicity, disability etc.	
Equity	Fair treatment of all – identity is not predictive of opportunities	
Inclusion	The experience of individuals – the ability of individuals to make meaningful contributions	

# **Real-world challenges in applying DEI**

### "....many people in Asia regard diversity and inclusion as a Western concept, shaped by Western experiences and Western values..."

# **Real-world challenges in applying DEI**

### "....There's also a view that the focus on "individuals" and "difference" inherent in diversity is at odds with Asian cultural and social values..."



### All people being treated the same (equality)

#### Accounting for a person's unique circumstances

### Adjusting treatment accordingly



McKinsey and Company. What is What is diversity, equity, and inclusion? Available at: <a href="https://www.mckinsey.com/featured-insights/mckinsey-explainers/what-is-diversity-equity-and-inclusion">https://www.mckinsey.com/featured-insights/mckinsey-explainers/what-is-diversity-equity-and-inclusion</a>. Accessed May 2023.

# **Case study: ESMO Asia Congress**

E)

Feature	Application	Impact
Presenters	Leading global and Asian thought leaders co-presenting	Recognising the value of the audience
Location	Major Asian hub of Singapore with fewer visa barriers for regional travel	<ul> <li>A diverse audience</li> <li>Representation from throughout Asia and the Pacific</li> </ul>
Topics	Targeted to regional issues	<ul> <li>Lung cancer – China</li> <li>Stomach cancer – Korea/Japan</li> <li>Melanoma – Australia/NZ</li> </ul>
Guidelines	Pan-Asia guideline adaptations	<ul><li>Increased relevance</li><li>Greater accessibility</li></ul>



# **Improving accessibility in Asia-Pacific**



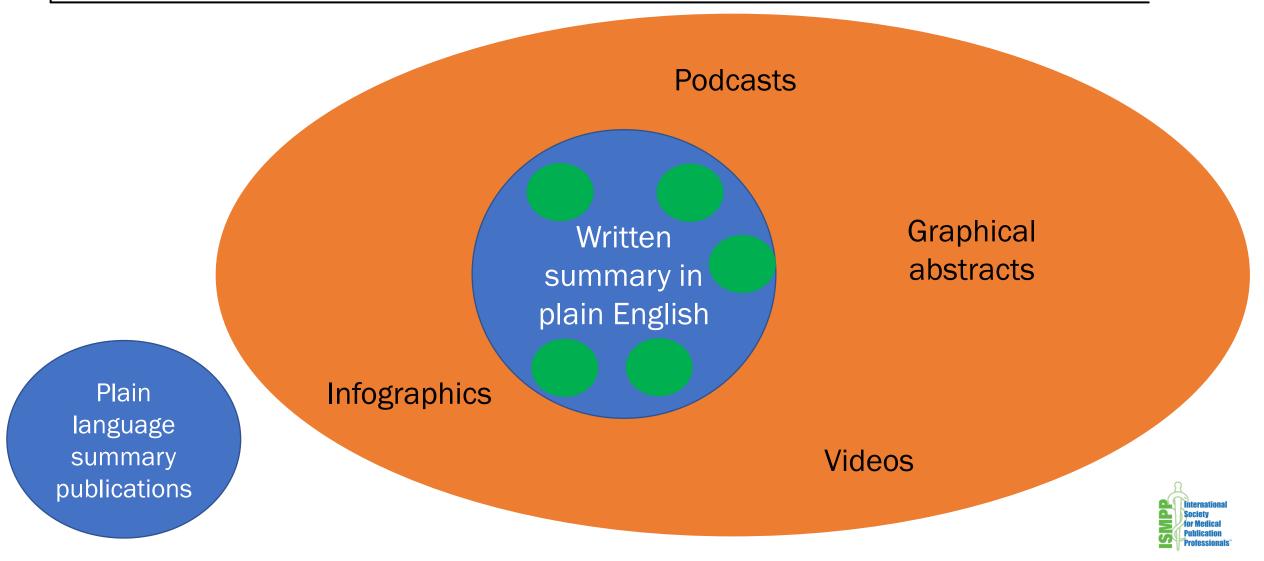
**Good:** Reduced fees and transformation open access agreements for the Asia-Pacific region

**Bad:** Predatory journals (and predatory journal checkers!) remain active and prevalent in the region

**Ugly:** Blurred lines – recognised publishers acting in a similar manner to predatory journals, fake reviewer scams, etc.



# Why are plain language summaries difficult to develop?



### **Plain language summaries: Symbolism matters**

#### Western culture: Owl = wisdom









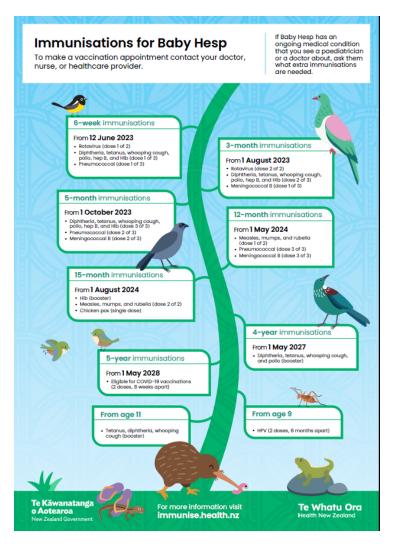


#### Māori culture: Ruru = death





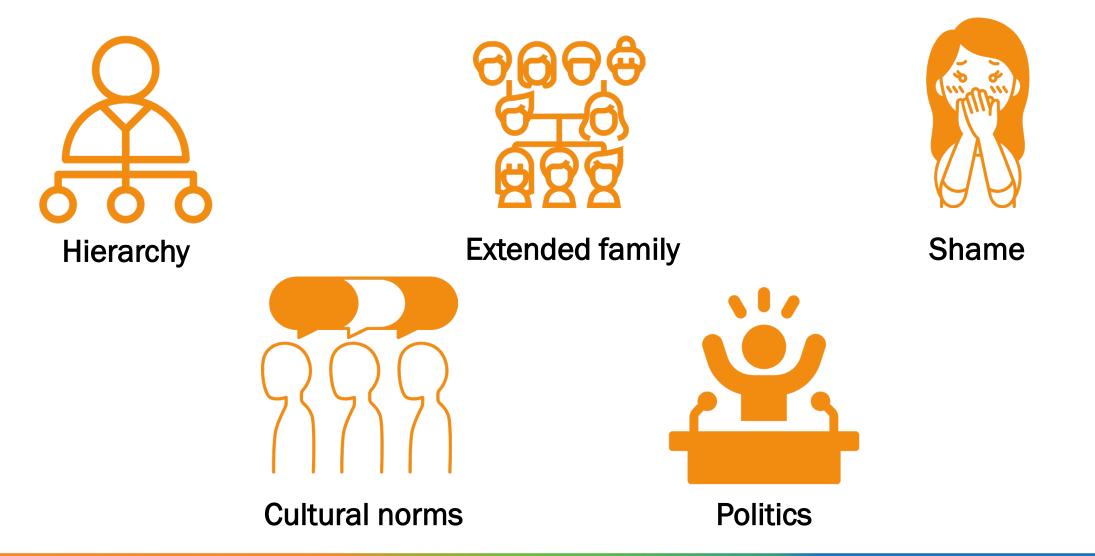
# **Infographics in practice**



- Use of inclusive imagery
  - Lots of native birds and animals, but no ruru!
  - Pasifika patterns
  - Merging Western imagery early bird gets the worm/Jack and the Beanstalk
- Use of inclusive language on website
  - Te Whatu Ora = Health New Zealand
  - Pēpi = baby
  - Whānau = family
  - Tamariki = children

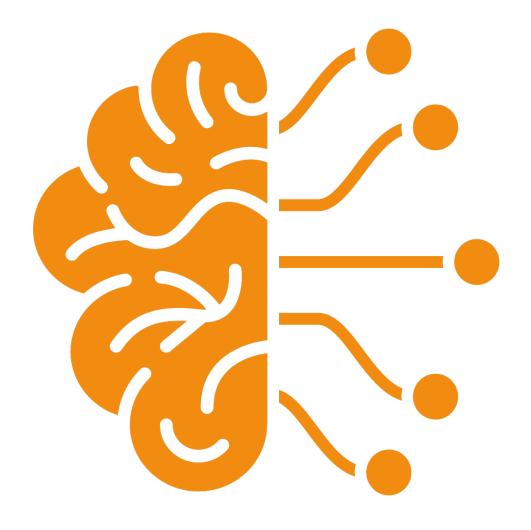


#### Is Asia-Pacific ready for patient authorship?





### The future – generative artificial intelligence in medical writing



- Rapidly evolving, but not yet mature
- Need to keep up-to-date with guidance
- Beware of pitfalls:
  - 'Hallucinations' (content that appears real and supported, but has been made up by AI)
  - Anything used as a prompt becomes publicly accessible



- Organic, local publication ethics initiatives are becoming more common
- The Asia-Pacific region may be engaged with the best of intentions, but expect cultural misunderstandings
- Navigating open-access publishing options continues to be challenging
- If plain-language summaries were simple, everyone would already be generating them
- Be cautious in using artificial intelligence



# How do I access the Asia-Pacific adaptation of GPP 2022?

#### Journal

Hesp BR et al. *Curr Med Res Opin* 2023. doi: 10.1080/03007995.2023.2214433



Openaccess preprint

https://www.preprints.org/manuscript/ 202304.0092/v2





## **Audience Q&A**

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



#### **Upcoming ISMPP U Webinars**

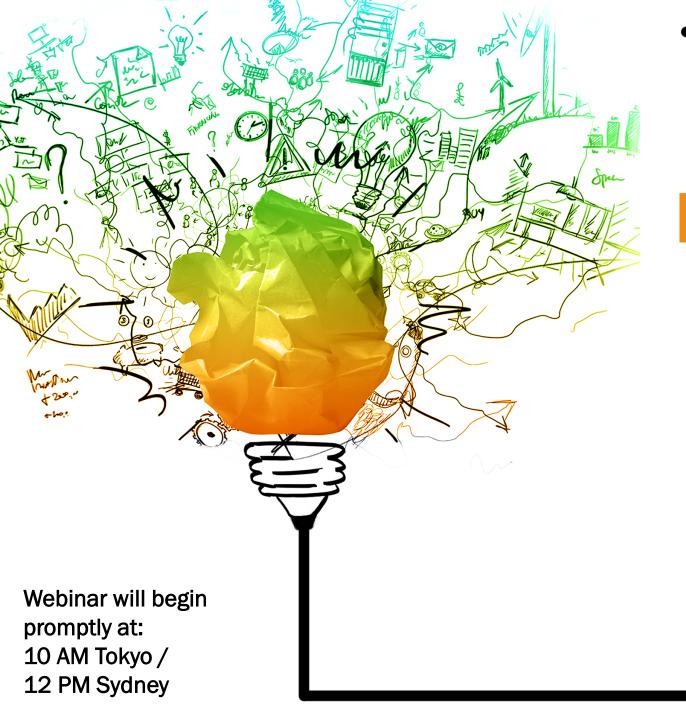
July 19, 2023:

ISMPP U: Member Research Spotlight: 19th Annual Meeting of ISMPP Oral Presentations

The Chinese translation of GPP 2022 is available and can be accessed through this link: <u>GPP 2022 (ismpp.org)</u>

Japanese translation is planned to be available in Q3 2023







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June 28, 2023



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#### Thank you for attending the Webinar. Please click Continue to participate in a short survey.

you will be leaving zoom.us to access the external URL below https:// www.surveymonkey.com/r/ISMPPU

Are you sure you want to continue?







## **Faculty Bios**



#### Blair Hesp, PhD, NZDipBus, CMPP



- Principal Consultant at First in Human
   Communications and Managing Director at Kainic
   Medical Communications, a multi-award—winning
   medical communications agency
- Lead author of APAC adaptations of GPP3 and GPP2022
- An active contributor to ISMPP, the Australasian Medical Writers' Association and the Asia-Pacific MedComms Network who has previously been named the most innovative person in marketing and communications in New Zealand



#### Dikran Toroser, PhD, AMWC, CMPP



- Publications Group Lead at Merck (ID/Vaccines) and has an extensive background in publication planning and medical writing
- Active in publications-related professional organizations (ISMPP, AMWA and ACSE) and most recently has worked in compiling guidelines for the publications profession (eg, AMWA/EMWA/ISMPP Joint Position Statement and GPP-2022)



#### Shobana Ganesan, MSc, ELS



- Senior Manager, Quality & Training, at Cactus Life Sciences and member of the ISMPP Asia Pacific Education Task Force
- Over 10 years of experience in scientific communications with expertise in operations, training, and mentoring
- Currently trains new/aspiring medical writers and equips them with the key technical skills required to succeed in this profession

