CIOMS' mission is to advance public health through guidance – principally targeted at health professionals and health policy-makers, but also of relevance to many other stakeholder groups and the public – on health research including ethics, medical product development and safety.

Through its guidance, CIOMS seeks to promote how health research is conducted – be it this at local, national, regional or international level – that is scientifically valid, ethical, and can contribute to improved, safer and more effective options for treatment, and a strengthened health care system overall.

CIOMS' core values

- ***Scientific Integrity:*** *CIOMS encourages the promotion of honest, unbiased, and transparent research practices. It advocates for the highest scientific standards in both clinical and biomedical research.*
- ***Ethical research practices:*** *CIOMS advocates adherence to ethical principles in the conduct of medical and clinical research, to ensure that studies benefit society while avoiding or minimizing harm to participants.*
- ***Accountability and transparency:*** *CIOMS supports transparent decision-making processes and accountability in all aspects of medical and health research, with clear documentation of ethical considerations and outcomes.*
- ***Respect for human dignity:*** *CIOMS emphasizes the importance of safeguarding human rights and promoting respect for individuals in scientific and medical research.*
- ***Protection of vulnerable populations:*** *CIOMS works to protect vulnerable groups, including children, the elderly and individuals in low-resource settings, and to ensure they are not exploited or subjected to harmful research practices.*
- ***Global health equity:*** *CIOMS seeks to alleviate global health disparities by fostering international collaboration and advocating for equitable access to healthcare.*

These values guide CIOMS' work in fulfilling its mission.

1. Purpose and scope

CIOMS' editorial policy seeks to ensure the integrity, quality and consistency of its guidance and its alignment with the organization's core values.

CIOMS guidance is primarily in the form of CIOMS working group (WG) reports. These reports are the organization's most important outputs.

This editorial policy also encompasses articles for publication, content for inclusion in CIOMS presentations at conferences and professional meetings, and content for CIOMS webinars and its website.

2. Content creation

Topics selected for CIOMS WG reports are often complex topics, for which existing guidance is insufficient, scattered or out of date.

Each WG report is a consensus document, developed by a specially constituted WG. WG members are selected based on their expertise, their representation of a relevant organization or stakeholder group, and with a view to ensuring different perspectives (e.g. academic, plus regulatory, plus industry, plus patient perspectives). The length of WG reports ranges from 60 pages to almost 300 pages.

Other outputs – for example, for presentations at conferences or for the CIOMS website – are often a distillation of content created by a WG. CIOMS webinars are generally organized around a WG report.

The CIOMS quarterly newsletter is written and produced by an in-house team. Before online publishing, it is reviewed by at least two CIOMS staff who have not been involved in producing the draft.

3. Development of WG reports / consensus documents

Each WG may take up to three years (sometimes longer) to finalize its consensus document and recommendations. Most groups hold one or two in-person meetings per year, with several virtual meetings in between. The groups work collaboratively. This includes capitalizing on existing initiatives, to provide output that is comprehensive, does not duplicate other efforts and brings added value.

4. Approval process

Each consensus document undergoes extensive review by WG members. This involves review of initial draft chapters before they are compiled into a draft consensus document. Each WG member will have been requested to draft or contribute to drafting of a specific chapter or chapters. Thereafter WG members review the chapters to which they have not contributed. Following this round of view, a draft consensus document is created. After it has been agreed to by all WG members, it is made available for a public consultation period of generally no less than six weeks. This is to provide CIOMS key stakeholder groups – regulators, academia, industry and patient organizations – with sufficient time to review and comment on the document. WG members themselves encourage review by those whom they consider can provide useful input.

Comments must be submitted in the prescribed format, otherwise they are discarded. Organizations are requested to submit a single set of comments.

For each report, the CIOMS Secretariat creates a single, consolidated file of comments. To facilitate systematic review, it discards any irrelevant comments and, where needed, clarifies the language of comments.

The comments are reviewed by an editorial group, which is a subgroup of the WG. The editorial group is responsible for reviewing and deciding which comments should be incorporated in the report. If the editorial board is unable to reach agreement on a comment, it will consult the relevant report section lead. The Secretariat incorporates accepted comments into the draft report.

If any query is received regarding a comment(s) that was/were rejected, CIOMS will respond that all comments have been reviewed by the editorial board and accepted or rejected as it considered appropriate, and that the report is a consensus report of the WG.

Following review of comments received, and production of a revised draft of the report by the editorial board and a CIOMS medical writer, the WG is invited to review and endorse the report before it undergoes final editing and layout.

5. Editorial standards and principles

Accuracy: The external expert members of the WG – together with CIOMS staff (internal or contracted) ensure the accuracy of technical content, language and references of WG reports. All other material produced by CIOMS is likewise reviewed.

Objectivity and fairness: CIOMS seeks to ensure that WG report content is balanced, impartial, and unbiased. WG members are selected not only based on their expertise and experience, and representation of relevant organizations, but also with consideration of the role they have played in developing other consensus documents. Great care is also taken to ensure that key stakeholder groups are represented equitably within any WG.

Ethical Considerations*:* CIOMS does not tolerate plagiarism, respects privacy, and handles sensitive information with appropriate care. All efforts are made to implement these principles.

Clarity and Readability: Most of the content developed by CIOMS covers complex, technical topics. To facilitate understanding of the topics covered, CIOMS actively encourages all WG members to ensure that any text they draft is accessible and comprehensible. (See Appendix 1.)

See also the CIOMS Code of Conduct and Standards.

6. Overall responsibility for editorial management

The CIOMS Secretary-General has overall responsibility for ensuring that content aligns with the organization's standards, goals, and audience expectations.

Appendix 1

CIOMS Guidance for authors and editors

General guidance on writing

The following is extracted from the Plain English Campaign website.

- **Keep your sentences short.** Aim for 15 to 20 words per sentence; each sentence should ideally deal with just one idea. Mixing short sentences with longer ones works well. Short punchy sentences can be very effective for pushing home a strong point.
- **Prefer active verbs.** Active verbs give strength to a message and the writing feels less bureaucratic. Here's an example:

A study was conducted by Huber et al. (2016) to understand how different stakeholders, including patients, view and define what 'health' is.	Huber and colleagues[1] conducted a study to understand how different stakeholders, including patients, view and define 'health'.

  Passive voice is appropriate in some circumstances e.g. when we want to give prominence to the object rather than the subject or when it sounds better.

- **Use 'you' and 'we'.** Personal pronouns connect the writer with the reader. They make our writing more conversational and, therefore, more engaging. In this report, instead of expressions such as 'the authors', consider saying 'we'.
- **Use words that are appropriate for the reader.** We should avoid jargon and choose shorter, familiar words. Our readership will feel at ease with technical reports but given the report's subject, it should serve as a model for good communication with the public.

When determining goals, consideration should be given for how each patient engagement activity will ultimately improve patient health or outcomes and benefit the larger patient population as a whole.	To determine goals, consider how each patient-engagement activity improves health outcomes for all patients.

- **Don't be afraid to give instructions.** Imperatives get to the point quickly and are readily understood. They also reduce the time and effort of constructing fully formed, grammatically correct sentences. Consider:

A discussion about compensation should take place with the patients who are to be engaged to understand their desires and concerns ...	Discuss compensation with patients who are to be engaged to understand their expectations and concerns...

- **Avoid nominalization.** This involves turning a verb into a noun. The verb's energy is diminished when it is nominalized. In the following example, the verbs *to analyse* and *to choose* have been used as nouns: analysis and choice.

Thorough analysis of the patient engagement activity should precede the choice for a specific type of input...	The patient-engagement activity should be thoroughly analysed to choose a specific type of input...

- **Use lists where appropriate.** In our work, lists will usually be in the form of bullet points. Bullets can be complete sentences, in which case, the sentence should start with an upper-case letter

and end with a full stop. Alternatively, the bullet points may form part of a sentence, in which case the bullet point starts with a lower-case letter. If a bullet point or points will consist of more than two sentences, the text should rather be presented in paragraphs. More on bullet points later.

Guidance for Working Group XI report

Chapter structure

A typical chapter will have the following structure:

- Chapter heading
    - Short introductory text to lay out the scope of the chapter
    - Key take-home message heading
        - Chapter summary or bullet point list (cross-referred to section headings)
- Level 1 section headings
    - What the sections are about
        - Level 2 subsection headings
            - One or two key points or recommendations for each subsection
            - Body text
- References

Headings

- Use up to 3 numbered levels of main headings. Laying out the headings in a hierarchical tree can help to arrange the structure and sequence of the information. One or two levels of (unnumbered) side headings may be used.
- Headings start with an upper-case letter with all other words in lower case (except for proper nouns or abbreviations, such as CIOMS).
- Make headings short and pithy. Headings should generally be just 4 or 5 words and rarely take up more than a line. Short headings work better for scanning a document or for navigation. Also bear in mind that readers often don't read headings at all and read round them.

Chapter prose

- **Spellings.** The *WHO Editorial Style Manual* advises, 'British rather than American spelling is normally used'. But the original spelling must be preserved in proper nouns, quotes or references.

> **Tip.** Set your document language in MS Word to British English so that the spellchecker picks up non-British variants. Here's how to do this:
>
> 1. Select the whole document (CTRL + A)
> 2. In the Review tab: Language > Set Proofing Language … > *select* English (United Kingdom)

- **Short paragraphs.** To help readers grasp ideas readily, organize them into short paragraphs. This also improves the appearance of the page and renders it less intimidating. Aim for 4 or 5 sentences in each paragraph.
- **Emphasis.** Sparing use of bold and italic can be effective. Use these devices in a consistent way. Do not set blocks of text either in italic or bold; they interfere with easy reading and can end up de-emphasizing surrounding text.
- **National bodies.** Inevitably, chapters refer to information issued by national bodies. A couple of things to bear in mind when referring to such bodies:

- to make the report truly international, check for similar bodies in other jurisdictions and mention them where you can
- readers from one region may not know much about the work of national bodies in other regions; consider if the function, make-up and authority of the national bodies are worth covering
- spell out the full name of the body at its first appearance in the chapter.

- **Brackets.** Use brackets to enclose a few words of supplementary information. But any more than five words will interrupt the smooth flow of the sentence, and the reader may lose their thread. When this supplementary information extends to more than a few words, put the information into a new sentence; or show it after a semicolon. An example:

Various sources have published eligibility criteria for patient organisations (e.g. EMA framework, EUPATI guidance docs, NHC standards of excellence) in order to provide transparency on grounds for selection.	Various sources have published eligibility criteria for patient organisations that make the grounds for selection transparent; such sources include EMA framework, EUPATI guidance docs and NHC standards of excellence.

- **Abbreviations.** Use abbreviations sparingly; the reader might not recognize abbreviations you are very familiar with. The first mention should spell out the full term, followed by the abbreviation in brackets. Some abbreviations have entered common parlance and can be used without explanation: examples include AIDS, FDA, USA, and, now, COVID-19. Do not use full stops within abbreviations, so USA, not U.S.A.

  Keep working lists of abbreviations for each chapter. A single list of abbreviations will be created when the report is finalized.

- **Text boxes.** A single-cell table is appropriate for a text box because the format is retained on conversion from word-processor file to portable document format (PDF).

- **Footnotes.** Use symbols to identify footnotes (numbers are used for citations).

- **Index terms.** Highlight any terms that should be indexed (highlight all important occurrences of each term). These will be used to create an end-of-book index.

- **Lists and bullets.**
  - Where several elements make up an idea, it's best to list these elements as bullet points rather than trying to cram them into a sentence; with the right introductory wording, this can work even when the list is not complete.
  - Reading the introductory text with any bullet point should work as a complete sentence.
  - Each bullet point should stand on its own and not have to rely on preceding ones to make sense.

- **Padding.** Look out for padding — words that can be omitted without loss of meaning. Here are some examples that have cropped up in the draft chapters:

as appropriate	as far as possible
where relevant	but not limited to
within reasonable limits	

Such padding clouds the main point and gives our writing an off-putting legalistic air. If a qualification is important, then add it as a supplementary sentence or after a semi-colon. An example:

Within reasonable limits, based on local laws and regulations as applicable to a patient engagement, relationship and partnership should be publicly disclosed to support transparency.	For full transparency, relationships and partnerships should be publicly disclosed and comply with relevant regulations.

- **Upper and lower case**. All too often upper-case letters are inappropriately used for common nouns. Sometimes, upper case is used simply because a phrase or collection of words has found an abbreviation; there is no need to use upper case letters in 'patient-focused medicines development', just because it is abbreviated to PFMD. Use upper case only for proper nouns.

Miscellaneous style points

advice (noun)
advise (verb)
appendix (plural: appendixes)
drug: avoid where possible because of the term's negative connotation; when describing a formulated product, use *medicine*
e.g. (not e.g.,)
formulas (not formulae)
healthcare (not health care)
i.e. (not i.e.,)
index (plural: indexes)
practice (noun)
practise (verb)
quotation marks: by preference, use single quotation marks. When quoting passages of text, omit quotation marks but indent the quoted text.

References

- **Citations.** Use superscripted numerals in the body of the chapter to cite references.
- **Vancouver style.** Use the Vancouver referencing style. Many helpful guides on this style of referencing are available; Imperial College has published comprehensive guidance on citation and referencing.
    - To help the reader, show the URL where the reference can be found and add the date you last used the URL: '[Accessed 2 December 2020]'.
    - Include hyperlinks to the full paper/PDF/web page (if open-access without login), or else PubMed entries, as shown below. In this way readers can see straight away whether the full paper is available.
        - Maxmen A. Busting the billion-dollar myth: how to slash the cost of drug development. Nature. 2016;536(7617):388–390. (Journal full text)
        - Maïga D, Akanmori BD, Chocarro L. Regulatory oversight of clinical trials in Africa: progress over the past 5 years. Vaccine. 2009;27(52):7249-7252. (PubMed) https://doi.org/10.1016/j.vaccine.2009.08.113
- **Full reference**. Give the full reference information and be consistent.