

Entering medical communications as a non-native English speaker

The third EMWA Internship Forum will be held on May 3, 2018 at the forthcoming spring conference in Barcelona. As the language of international medical communications is almost exclusively English, have you ever wondered what it takes for a non-native English speaker to break into the field?

Forum attendees will have the opportunity to

meet with companies offering internships. We are also pleased to announce that Sara Rubio will be giving a presentation on her experiences on finding employment in medical communications as a non-native English speaker. Born and raised in Barcelona, Sara speaks Spanish and Catalan as native languages. She participated in the first EMWA Internship Forum in 2016 and

completed an internship at Costello Medical. She is currently a medical writer at XPE Pharma & Science.

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Updated ICMJE recommendations:

Changes to clinical trial registration and data sharing practices

The recommendations set by the International Committee of Medical Journal Editors (ICMJE) are designed to guide authors, editors, and others through all stages of creating and distributing accurate, clear, reproducible, unbiased medical journal articles. As such, they are a go-to resource for answering questions and solving issues that arise when preparing scientific manuscripts.

At the end of 2017, the ICMJE updated the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals.¹ The most substantive updates to the recommendations are in their policy for clinical trial registration.

To start, authors are now asked to ensure they have met the requirements of their funding and regulatory agencies for reporting aggregate clinical trial results in clinical trial registries. Even when this is not required, reporting results in registries is strongly encouraged. The updated recommendations emphasise making clinical trial results publicly accessible for all clinical trials. They also now state that it is the responsibility of authors, and not the journal editors, to explain any discrepancies between results reported in registries and journal publications.

The ICMJE's guidelines for clinical trial registration now also include a new data sharing policy:²

1. *As of July 1, 2018, manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement (see below).*

2. *Clinical trials that begin enrolling participants on or after January 1, 2019, must include a data sharing plan in the trial's registration. If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript and updated in the registry record.*

The data sharing statements must indicate:

- whether individual de-identified participant data (including data dictionaries) will be shared;
- whether additional related documents will be available (e.g., study protocol, statistical analysis plan, etc.);
- when the data will become available and for how long;
- by what access criteria data will be shared (i.e., with whom, for what analyses, and how).

Usefully, the updated recommendations provide a table with examples of data sharing statements that fulfil the new requirements.

Authors of secondary analyses using shared data must now attest that their use was in accordance with the terms (if any) agreed to upon their receipt and must reference the dataset identifier. They must also explain completely how their analyses differ from previous analyses and are encouraged to collaborate with, or at least fully acknowledge, those who collected the data.

The updated recommendations also include a revised section on predatory and pseudo-journals – journals that claim to be scholarly medical journals yet do not perform peer review and charge (often hidden) fees for article processing and publication.³ The revisions give

details on how these entities operate and provide guidance and resources for identifying and avoiding them.

Finally, the ICMJE recommendations now set in stone that *all* investigators are responsible for ensuring the planning, conduct, and reporting of human research are in accordance with the revised 2013 Helsinki Declaration and that all authors seek approval to conduct research from an independent local, regional, or national review body (e.g., ethics committee, institutional review board). These commitments to protecting research participants must be stated in the manuscript's Methods section.

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References

1. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. December 2017. International Committee of Medical Journal Editors. Available from: <http://www.icmje.org/recommendations/>.
2. Taichman DB, Sahni P, Pinborg A, et al. Data sharing statements for clinical trials: a requirement of the International Committee of Medical Journal Editors. *Ann Intern Med.* 2017;167:63–65.
3. Identifying predatory or pseudo-journals. 18 February 2017. World Association of Medical Editors. Available from: <http://www.wame.org/identifying-predatory-or-pseudo-journals>.