

# RETHINKING HOW WE COMMUNICATE CLINICAL TRIAL RESULTS: WHAT ISN'T WORKING AND HOW CAN WE CHANGE IT?



It's clear that people are continually adapting and evolving how they consume information, and businesses need to continually evolve to reflect this—just look at how social media and websites such as craigslist have changed the newspaper business. But is scientific publishing keeping up with this change? And if not, what are the other options that can be used in parallel to communicate data?

Results from clinical trials are shared for two fundamental reasons—to enable clinicians to use the knowledge gained to advance clinical care and because patients take part in clinical trials with the expectation that the results will be used to improve treatments for themselves and others.

Clinical data, therefore, need to be communicated quickly and openly. Publishing them in scientific journals will continue to play a key part in this process, but it is important to consider any limitations and how these might be overcome.

## Challenges with the current model

**Frustrating delays:** Authors often comment that the communication of trial data, based on publication in conventional peer-reviewed scientific journals, can be slow. The time taken from submission to publication of a manuscript, typically 6 to 12 months, means that important scientific research is not shared quickly enough in today's era of rapid communication.

**Can't see the forest for the trees:** The publication of results in one of many thousands of journals that readers often have to pay to access also means that data are difficult to find and may not reach the relevant audience.

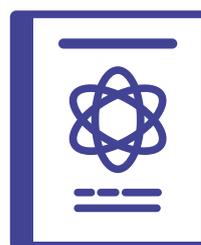
**Lack of innovation:** The limited format of standard journal articles, often restricted to a certain number of pages and figures, makes it difficult for readers to gain a complete picture of the trial's findings, while the static nature of these publications discourages iterations, creativity, and interactivity. Crucially, this also means that journals may not reflect how readers prefer to consume information in an increasingly connected and socially integrated world.

**Bias:** As humans, we naturally prioritize exciting, positive, or surprising findings over the negative or mundane, and it's no surprise that this results in bias, unconscious or conscious, in the study data that are selected for publication. Everyone contributes toward this bias: authors, reviewers, journals, and even readers. Although vehicles do exist to publish less "exciting" data, it's almost impossible to eliminate bias completely, so we need alternative ways of sharing the totality of data.

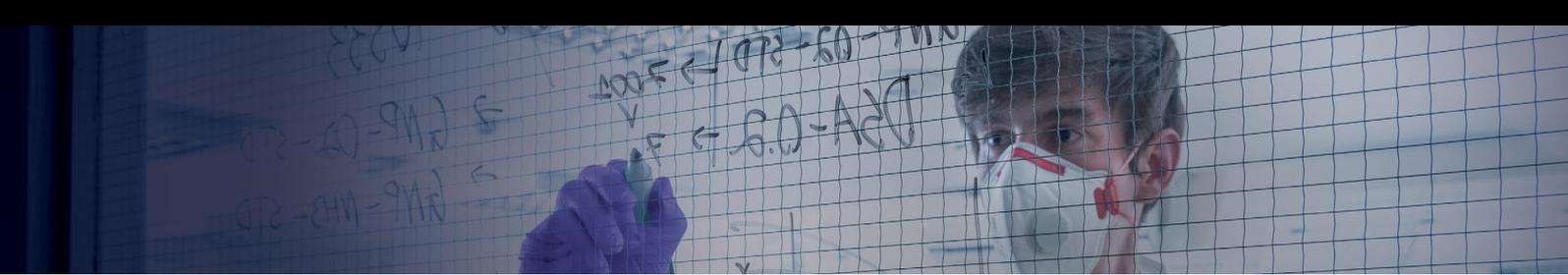
## How can the model change?

The International Committee of Medical Journal Editors (ICMJE) published the following requirements last year, showing that there may be light at the end of the tunnel:

- Since July 1, 2018, clinical trial manuscripts submitted to ICMJE journals have had to contain a data-sharing statement that explains what patient data will be shared (e.g., patient-level data), what additional documents will be made available (e.g., clinical study reports or protocols), how these can be accessed, and when this will happen.
- Clinical trials that start enrolling patients on or after January 1, 2019 need to include a data-sharing plan in the trial's registration.



*“Although the publication of clinical trial data in scientific journals will remain the gold standard, it is important to consider how this can be improved to ensure all audiences have quick, easy, and open access”*



Of course, the ClinicalTrials.gov website mandates interventional trials registered there to report results on the site within 1 year of completion. However, an audit in 2012 established that a remarkable 88% of studies registered on ClinicalTrials.gov had failed to do so.

Some journals have developed digital platforms in the hope of overcoming the challenges of traditional scientific publications. They offer features such as fast publication, no length restrictions, links to social media, open peer review, and pre-peer-review publication. These are gaining some recognition, as shown by Wellcome Trust's launch of an in-house journal to ensure rapid publication of data from their funded research to encourage transparency and reproducibility. There is also the option of using a pre-print server such as bioRxiv to share publications and get comments before submission to peer-reviewed journals, but while these are being more widely used, they have yet to gain wide acceptance for sharing clinical trial manuscripts.

Platforms such as these are starting to improve the sharing of clinical data but have clearly still to make a significant change to the behavior of most investigators and authors.

### What should the future for communicating clinical trial data look like?

Groups such as AllTrials ([www.alltrials.net](http://www.alltrials.net)) have been working to ensure that results from clinical trials are fully reported, which is obviously a great aim. The downside is that the pharmaceutical industry has sometimes been portrayed as being reluctant, overcautious, and opaque when it comes to communicating clinical data.



*“Advances toward more transparent and effective data sharing include proposals by the ICMJE and new digital publishing platforms, but more needs to be done”*



#### About the author

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