

## VIEWPOINT

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# Building transparency and trust in industry-sponsored clinical research through open access publishing

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### Abstract

A desire for both transparency in research and widespread access to the results of research has led to activism in support of open access publishing. Open access publishing, particularly publishing industry-sponsored research, can be complex. The overarching benefits of, and challenges to, open access are described, illustrated with the initiatives related to Medical Publishing Insights and Practices to help promote a better understanding of open access and its importance in ensuring transparency in industry-sponsored research.

**Keywords:** Transparency, industry-sponsored research, open access, MPIP

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The growing advocacy for access to results of clinical trials has generated interest and debate around open access (OA) publication of these results. The results of clinical trials are interpreted and disseminated primarily through publishing in peer-reviewed journals.<sup>1</sup> Traditionally, access to these articles was limited to subscribers – mostly institutions – to the journal in question or to anyone willing and able to purchase a given article.<sup>2</sup> The move towards OA publishing was based on the belief that the findings of publicly funded research should, upon publication, be accessible immediately and freely with reuse rights.<sup>3-5</sup> Broad access to, and visibility of, scientific research through OA publications should increase the transparency of research findings<sup>6</sup> and public awareness of the latest developments in research.<sup>2</sup>

Variations in the definitions, policies, and available options for OA can be challenging while navigating the field of OA. The gold standard of OA (Gold OA), namely immediate and free access to an article from the journal's website upon publication, is typically available only on paying article processing charges (APCs), which vary with the journal.<sup>2,6</sup> This level of OA is usually offered by journals that are exclusively OA (the full OA model) but can also be available as an option from journals that follow the hybrid publishing model. In the hybrid model, if authors – or those who funded the research being published – wish to make their article OA, or freely available to all, they can pay for Gold OA or wait for the article to be made available after an embargo period; alternatively, the authors can simply follow the traditional publishing route, in which articles are available only to those who subscribe to the journal in which the article is published or to those who pay for the article in question. Many journals with high impact factors impose substantial APCs, which may

be too expensive for researchers beginning their careers unless the journal is willing to waive the APCs.<sup>2</sup> Alternatively, a journal or a publisher may allow self-archiving of articles for which no APCs have been paid (Green OA) but may stipulate an embargo period before allowing such public access.<sup>2</sup> Reuse policies and copyright licences also vary. Licensing options may be relatively restricted in journals that follow the hybrid model, including some prestigious journals, and the choice of a copyright licence may also be restricted depending on the source of funding.<sup>6</sup> Many agencies that fund academic research stipulate publication policies: for example, the US National Institutes of Health require that final, peer-reviewed, manuscripts be submitted to the National Library of Medicine's PubMed Central<sup>7</sup> upon acceptance (before publication) and be made publicly available no later than 12 months after the official date of publication,<sup>7</sup> and the Wellcome Trust stipulates that articles be made available through PubMed Central and Europe PubMed Central as soon as possible and in any event within 6 months of the journal publisher's official date of final publication.<sup>8</sup>

The above discussion applies to academic publishing in general; however, researchers working for pharma companies have limited opportunities to publish their work through Gold OA. An analysis of OA policies of 21 medical journals with high impact factors (>15) indicated that most journals did not offer commercial organizations the option to use a CC BY Creative Commons licence, which allows free reuse and sharing of the work.<sup>6</sup> Restricted licence options in addition to high APCs probably make commercial organizations wary of mandating OA publishing, although two pharma companies, Shire, which was later acquired by Takeda, and Ipsen, announced that they would follow the lead of governmental and not-for-profit

research funders in making OA publishing mandatory for researchers they fund.<sup>9,10</sup>

The CC BY licence, which makes all published articles available to all regardless of funding source, would provide more opportunities for others to access and reuse published works. Making the results of clinical research more transparent by publishing the results through OA facilitates the engagement of a wider community. Healthcare professionals and patients, particularly those in countries with more modest finances, use publicly available information to keep abreast of recent advances and to ensure better-informed patient care.<sup>6</sup> Physicians also use review articles in teaching and policy papers in advocating for patients.<sup>11</sup> At present, local communities that partner with academic medical centres and community members who participate in academic research find that journals are difficult to access;<sup>12</sup> such adverse perceptions can be overcome through OA publishing, which makes communities aware of the positive impact of research. Overall, greater and equal access to scientific literature can strengthen public interest and awareness of current advances in science. Therefore, OA publishing has the potential to influence public policy positively and to increase public interest in funding research.<sup>2</sup> Open access publishing also makes it easier for researchers to avoid duplication of experimental studies and to build on existing research, thereby accelerating clinical development and advancing patient care. Equally important is to make supplementary materials also OA, as manuscripts often include data, study designs, and, more recently, enhanced publication content as supplementary material—access to these deepens the reader's understanding of the work. The landscape of OA is evolving, with many groups advocating wider adoption of OA, including Open Pharma<sup>13</sup> (<https://openpharma.blog/position-statement-on-open-access/>) and cOAlition S<sup>14</sup> (<https://www.coalition-s.org/>), and the proportion of OA publications from the private sector continues to rise.<sup>15</sup>

The COVID-19 pandemic has made the need for wider access to research even more acute and has had a direct bearing on OA publishing. Publishers, journals, and government agencies are making all research relevant to COVID-19 freely available to promote rapid data sharing.<sup>16,17</sup> The current global health crisis has the potential to demonstrate the value of OA to scientific research.

Policies on OA can also affect the perceptions of transparency in research. Industry-sponsored research in particular has struggled with establishing credibility, mainly because of the restrictions on such research and its reporting.<sup>18</sup> To win trust and to ensure greater transparency in industry-sponsored research, a group of pharmaceutical companies partnered with the International Society for Medical Publication Professionals (ISMPP) in 2008 to form MPIP, or Medical Publishing Insights and Practices (<https://www.mpip-initiative.org/>).<sup>18,19</sup> The organization collaborates actively with such societies as AMWA, the American Medical Writers Association, and with editors of journals to attain the shared goal of raising standards of medical publishing and expanding access to research, and conducted a survey of medical journal editors to assess their perceptions of changes in the transparency and credibility of industry-sponsored research over a 5-year period (2010 to 2015).<sup>19</sup> The results showed that most editors believed that transparency had increased over that time, with the largest impacts being that those of disclosing the sponsor of the study, making

registration mandatory, and posting the results of clinical trials to ClinicalTrials.gov.<sup>19</sup> The participating editors also stated that making all data publicly available contributes greatly to making the work more transparent and credible—but also noted that the practice is yet to be widely adopted, and more work is yet needed. Over the past decade, industry professionals and journal editors have been meeting more regularly to share perspectives and develop approaches to make industry-sponsored research more transparent. One outcome of these gatherings was the establishment of *Transparency Matters*, an online hub and education platform for efforts related to promoting transparency. *Transparency Matters* seeks to make the research and publishing community more aware of the importance of transparent reporting of research and encourages practices to attain this goal. As part of this initiative, MPIP not only identified OA publishing as a topic that needs to be understood better and known more widely but also created resources to meet those needs, including a reference site, a pocket guide to different models of OA and of the licences governing it, and a series of insightful blogs contributed by leading names within the OA movement. Most recently, MPIP launched a tool that provides information on journals that offer OA for industry-funded research.<sup>20</sup>

Transparency is crucial to winning and fostering public trust, ensuring the reproducibility of research, and advancing science. We believe that providing greater access to the results of research increases public trust in the integrity of research regardless of its source of funding. By partnering with journal editors and interested parties to promote greater and wider understanding of OA and its impact on transparency, MPIP has been promoting the common goal of improving access to the results of clinical research as a service to humankind.

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