

Can preprints accelerate pharma publishing?

Educational material





A preprint is a version of a scientific manuscript posted to a public server before formal peer review and publication

Popular preprint servers for the health sciences





Benefits of sharing research as a preprint include ...





Enable feedback before publication in a peer-reviewed journal

Preprints have the potential to accelerate research



WORLD UNIVERSITY RANKINGS	PROFESSIONAL JOBS EVENTS RANKINGS	STUDENT	Covid-19 is reshaping the world of bioscience publishing
Ƴ f	The Covid-19 outbreak highlights the potential of preprints		
in	A recent posting on bioRxiv may have been erroneous, but the r picked up within hours, notes Kristen Sadler	THE LANCET Global Health	
	March 2, 2020 By <u>Kristen Sadler</u> Twitter: @KristenSadler18 The emergence of Covid-19 is testing the limits of many global systems, and not the least among them is the quality control FEATURES / ISSUE: APR/MAY20 / GROWING SHARE FOR Crowing share for preprints 2 April 2020	COMMENT ONLIN Early in t discours Maimuna S Majur Open Access • Pu () Check for up	EFIRST PDF [192 K8] the epidemic: impact of preprints on global about COVID-19 transmissibility mder ♥ • Kenneth D Mandl ublished: March 24, 2020 • DOI: https://doi.org/10.1016/S2214-109X(20)30113-3 •
	<i>issue:</i> APRIL/MAY 2020 <i>topic tags:</i> PREPRINTS, COVID-19 Five organisations define, describe, and share their thoughts on a subject that has become something of a topic in recent times	a Supplementary Material	Since it was first reported by WHO in Jan 5, 2020, over 80 000 cases of a novel coronavirus disease (COVID-19) have been diagnosed in China, with exportation events to nearly 90 countries, as of March 6,

Research is made available months earlier than the peer-reviewed publication





Risks and mitigations for pharma preprints



Industry must be even more careful than publicly funded institutions

1. Some medical journals consider preprints a form of prior publication	 Authors, not sponsors, choose target journals If a journal objected to a preprint, would the sponsor or the journal be held responsible for restricting author choice?
2. Preprints might sacrifice research quality for speed	 Pharma publications have more quality control than non-industry research, resulting in better reporting quality Companies are not likely to risk substandard reporting quality Would allowing proper time for peer review improve the Version of Record compared with expedited publication processes?
3. Preprints may not count as the 'safe harbour' of 'scientific exchange' as do peer-reviewed publications by convention	 Informal guidance from regulators, academics and patients is that the intent is key: is this bona fide scientific exchange? Posters are not peer reviewed (although abstracts are to a lesser degree than papers) and are increasingly accessible online; however, this is not perceived as promotion
4. Comments on preprints can make scientific disagreements public	Monitoring and moderation may be needed, in particular for adverse event reporting

Discoverable but not citable?



What, if any, citation of pharma preprints would be appropriate?

1. EFPIA, PCMPA, PhRMA and other regulations require peer-reviewed references for promotional claims	 Preprints will not be used to support claims Pharma is well set with compliance processes to ensure that preprints are not used improperly
2. Preprints can be cited in grant applications to institutions such as the Wellcome Trust	• Would preprints be citable in place of 'data on file' in pharma documentation such as health technology assessments and marketing authorization submissions, improving transparency?
3. Journalists, members of the public or other scientists may misuse or misinterpret the preprint and cite it as if it were a peer-reviewed source	 Prominent labelling of non-pharma preprints has not prevented their occasional misuse in this way Would pharma be held accountable?
4. Preprints are public and discoverable by simple, direct Internet search	 Public sharing of academic preprints is common, but pharma rarely even shares links to peer-reviewed papers to avoid any perceived promotion Is it realistic to expect preprints not to be cited by third parties? Is pharma responsible for third-party sharing and citation?

Most journals *do not* consider preprints as prior publications^a



Of the five leading medical journals, three accept articles shared as preprints

The NEW ENGLAND JOURNAL of MEDICINE	
JAMA Network [™]	Posting as a preprint will necessitate the decision as to whether publication will bring new/meaningful insight
Journal of Clinical Oncology® An American Society of Clinical Oncology Journal	
Annals of Internal Medicine [®]	No mention of preprints
THE LANCET	

Preprint servers *employ checks* to ensure research quality



Risk mitigation at bioRxiv



Preprint servers *employ checks* to ensure research quality



medRxiv builds upon the checks performed at bioRxiv



Preprint servers are equipped to deal with possible misinformation



A COVID-19 case study



Withdrawn

THE WATCHDOGS

Quick retraction of a faulty coronavirus paper was a good moment for science

By IVAN ORANSKY and ADAM MARCUS / FEBRUARY 3, 2020



The retraction occurred before the paper was covered by a single news outlet with any reach

Preprints come with a bold disclaimer



Preprints provide an opportunity for scientific discussion



Controlled Clinical Trial

Leticia R. Cruz, Idania Baladron, Aliusha Rittoles, Pablo A. Diaz, Carmen Valenzuela, Raul Santana, Maria M.Vazquez, Ariadna Garcia, Deyli Chacon, Delvin Thompson, Gustavo Perera, Ariel Gonzalez, Rafael Reyes, Loida Torres, Jesus Perez, Yania Valido, Ralysmay Rodriguez, Dania M.Vazquez, (D) Mauro Rosales, Ailyn C. Ramon, George V. Perez, Gerardo Guillen, (D) Verena Muzio, (D) Yasser Perera, (D) Silvio E. Perea, ATENEA-Co-300 Group doi: https://doi.org/10.1101/2020.09.03.20187112

This article is a preprint and has not been certified by peer review [what does this mean?]. It reports new medical research that has yet to be evaluated and so should *not* be used to guide clinical practice.

"Readers should therefore be aware that articles on medRxiv have not been finalized by authors, might contain errors, and report information that has not yet been accepted or endorsed in any way by the scientific or medical community"

"We also **urge journalists** and other individuals who report on medical research to the general public to consider this when discussing work that appears on medRxiv preprints and **emphasize that it has yet to be evaluated by the medical community** and the information presented may be erroneous"

Use of medRxiv by pharma was low in the 6-months after launch¹









Of the **335** preprints screened, only **26** (7%) stated funding from pharma

Of these **26** articles

13 (50%) had a pharma-affiliated author
6 (23%) described trials registered on ClinicalTrials.gov, including one phase 4 RCT

What research should be shared as a preprint?



Has COVID-19 changed this?



Could over 90% of research be made available as a preprint?

Useful links for preprints



Educational resources

- <u>https://www.annaclemens.com/blog/downsides-publishing-preprint</u>
- <u>https://asapbio.org/preprint-info</u>
- <u>https://publicationethics.org/resources/discussion-documents/preprints</u>
- <u>https://www.slideshare.net/BaltimoreNISO/inglis-preprints-in-biology-and-medicine</u>

Research

- Anderson KR. bioRxiv [Preprint]. 2020. <u>https://doi:10.1002/leap.1265</u> (Accessed 11 January 2021)
- Carneiro C, Queiroz V et al. bioRxiv [Preprint]. 2020. https://doi.org/10.1101/581892 (Accessed 11 January 2021)
- Fraser N, Momeni F et al. Quantitative Science Studies 2020;1:618–38
- Karalian A, Jolly L and Booth M. Curr Med Res Opin 2020;36 Suppl 1:S11

Preprints and COVID-19

- Fraser N, Brierley L *et al.* bioRxiv [Preprint]. 2020. <u>https://doi.org/10.1101/2020.05.22.111294</u> (Accessed 11 January 2021)
- Majumder, Maimuna S *et al. Lancet Glob Health* 2020; 8:627–30
- <u>https://www.nature.com/articles/d41586-020-01394-6</u>