

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

I need a preprint server that assigns a DOI to material and performs author checks



I need a platform to share my data and figures, in addition to my article



I want to post my article to a platform that exposes all or part of the peer review process



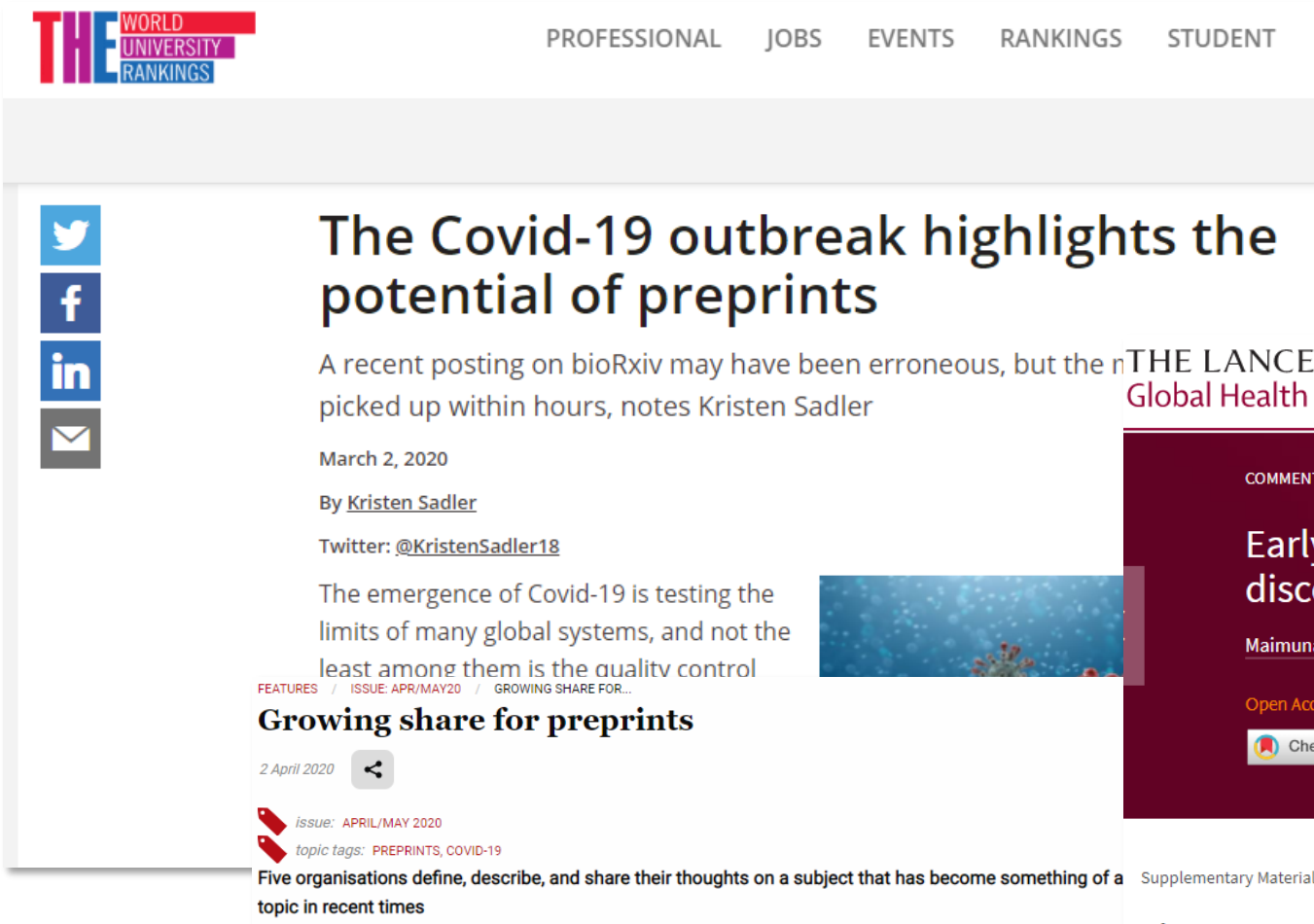
Benefits of sharing research as a preprint include ...

Enable feedback before publication in a peer-reviewed journal

As a form of discussion rather than a form of dissemination



Preprints have the potential to accelerate research



THE WORLD UNIVERSITY RANKINGS PROFESSIONAL JOBS EVENTS RANKINGS STUDENT

The Covid-19 outbreak highlights the potential of preprints

A recent posting on bioRxiv may have been erroneous, but the n picked up within hours, notes Kristen Sadler

March 2, 2020
By [Kristen Sadler](#)
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

Growing share for preprints

2 April 2020

Issue: APRIL/MAY 2020
topic tags: PREPRINTS, COVID-19

Five organisations define, describe, and share their thoughts on a subject that has become something of a topic in recent times



FIRST OPINION

Covid-19 is reshaping the world of bioscience publishing

By JEFFREY S. FLIER / MARCH 23, 2020



COMMENT | ONLINE FIRST

PDF [192 KB]

Early in the epidemic: impact of preprints on global discourse about COVID-19 transmissibility

Maimuna S Majumder • Kenneth D Mandl

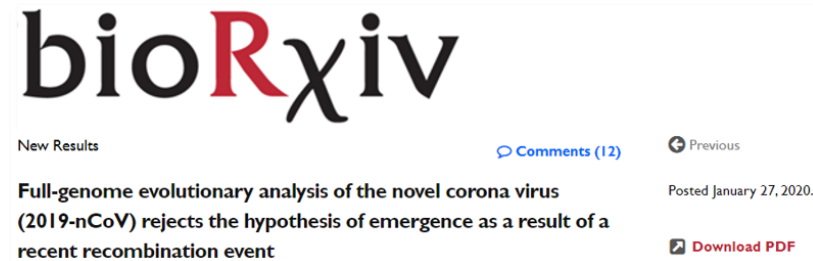
Open Access • Published: March 24, 2020 • DOI: [https://doi.org/10.1016/S2214-109X\(20\)30113-3](https://doi.org/10.1016/S2214-109X(20)30113-3)

Check for updates

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



bioRxiv

New Results

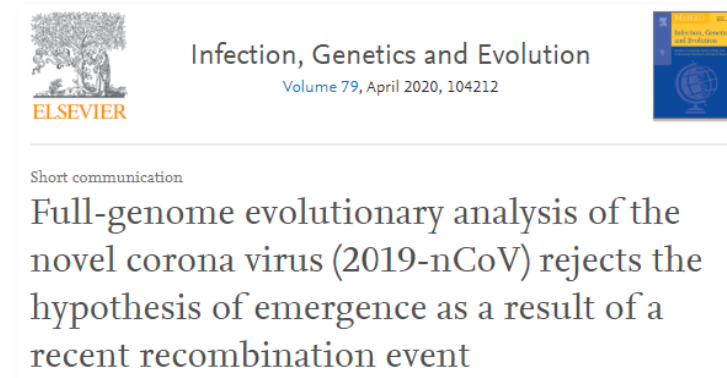
Full-genome evolutionary analysis of the novel corona virus (2019-nCoV) rejects the hypothesis of emergence as a result of a recent recombination event

Comments (12)

Previous

Posted January 27, 2020.

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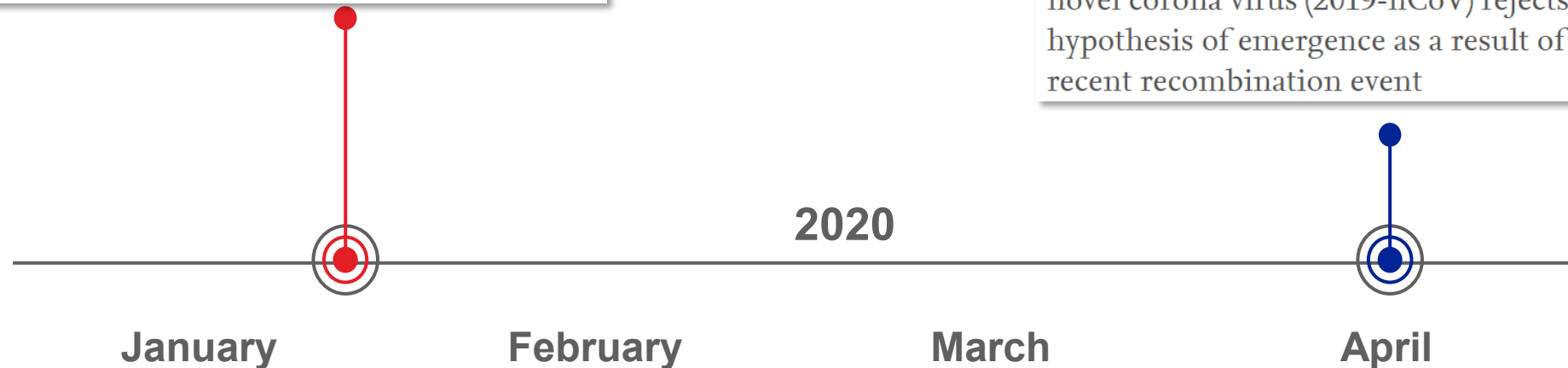
Infection, Genetics and Evolution

Volume 79, April 2020, 104212

ELSEVIER

Short communication

Full-genome evolutionary analysis of the novel corona virus (2019-nCoV) rejects the hypothesis of emergence as a result of a recent recombination event



Published 68 days earlier on bioRxiv

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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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

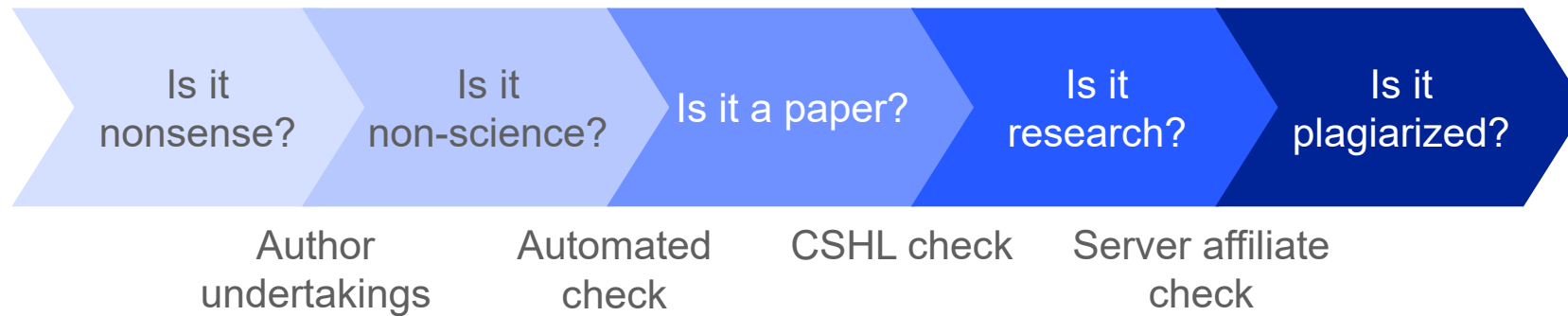
Of the five leading medical journals, three accept articles shared as preprints

	✓
	Posting as a preprint will necessitate the decision as to whether publication will bring new/meaningful insight
	✓
	No mention of preprints
	✓

^aPublication policies correct as of 21 December 2020

Preprint servers *employ checks* to ensure research quality

Risk mitigation at bioRxiv



Preprint servers *employ checks* to ensure research quality

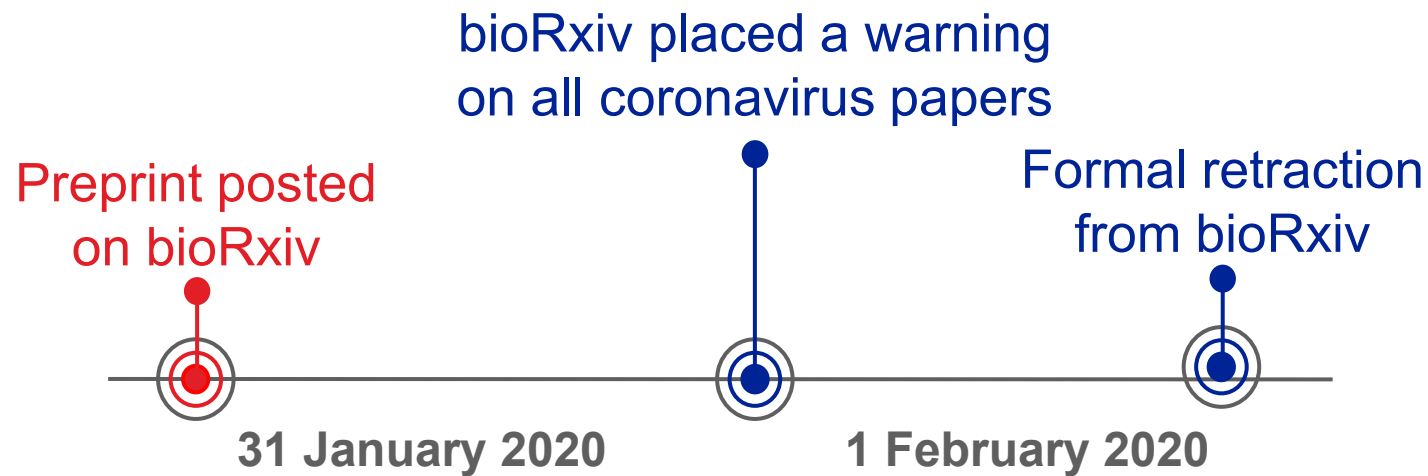
medRxiv builds upon the checks performed at **bioRxiv**



^aVersus after peer review

Preprint servers are equipped to deal with possible misinformation

A COVID-19 case study



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

THE WATCHDOGS

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

By IVAN ORANSKY and ADAM MARCUS / FEBRUARY 3, 2020



Withdrawn

This article has been withdrawn. [Click here for details](#)

Previous

Uncanny similarity of unique inserts in the 2019-nCoV spike protein to HIV-1 gp120 and Gag

126 comments

Posted January 31, 2020.

Prashant Pradhan, Ashutosh Kumar Pandey, Akhilesh Mishra, Parul Gupta, Praveen Kumar Tripathi, Manoj Balakrishnan Menon, James Gomes, Perumal Vivekanandan, Bishwajit Kundu

doi: <https://doi.org/10.1101/2020.01.30.927871>

This article is a preprint and has not been certified by peer review [what does this mean?].

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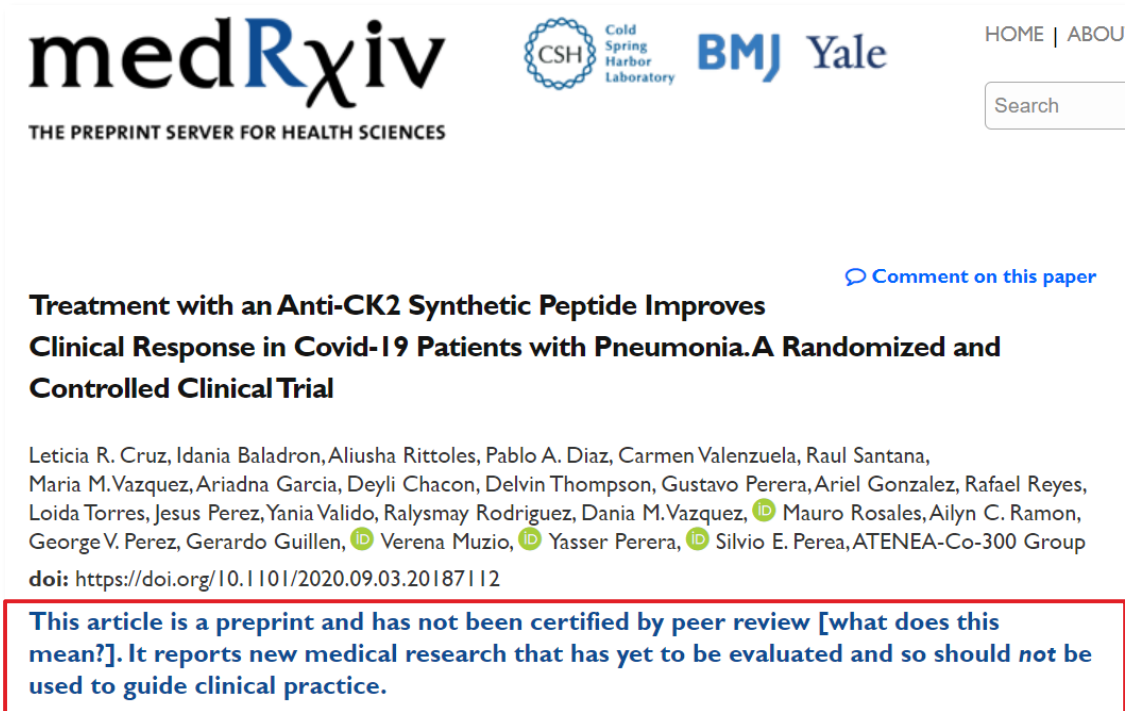
Supplementary Material

Tweet

Like 25K

Preprints come with a bold disclaimer

Preprints provide an opportunity for scientific discussion

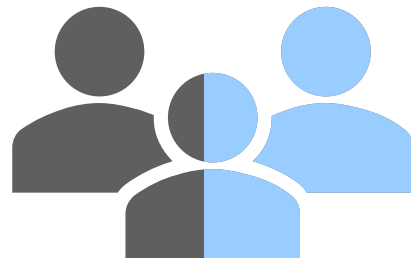


The screenshot shows the medRxiv preprint server interface. At the top left is the medRxiv logo with the tagline 'THE PREPRINT SERVER FOR HEALTH SCIENCES'. To its right are logos for CSH Cold Spring Harbor Laboratory, BMJ, and Yale. A search bar is located in the top right corner. The main content area features a preprint title: 'Treatment with an Anti-CK2 Synthetic Peptide Improves Clinical Response in Covid-19 Patients with Pneumonia. A Randomized and Controlled Clinical Trial'. Below the title is a list of authors: 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, Mauro Rosales, Ailyn C. Ramon, George V. Perez, Gerardo Guillen, Verena Muzio, Yasser Perera, Silvio E. Perea, and the ATENEA-Co-300 Group. A DOI link is provided: <https://doi.org/10.1101/2020.09.03.20187112>. A red-bordered box at the bottom of the screenshot contains the following disclaimer: '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

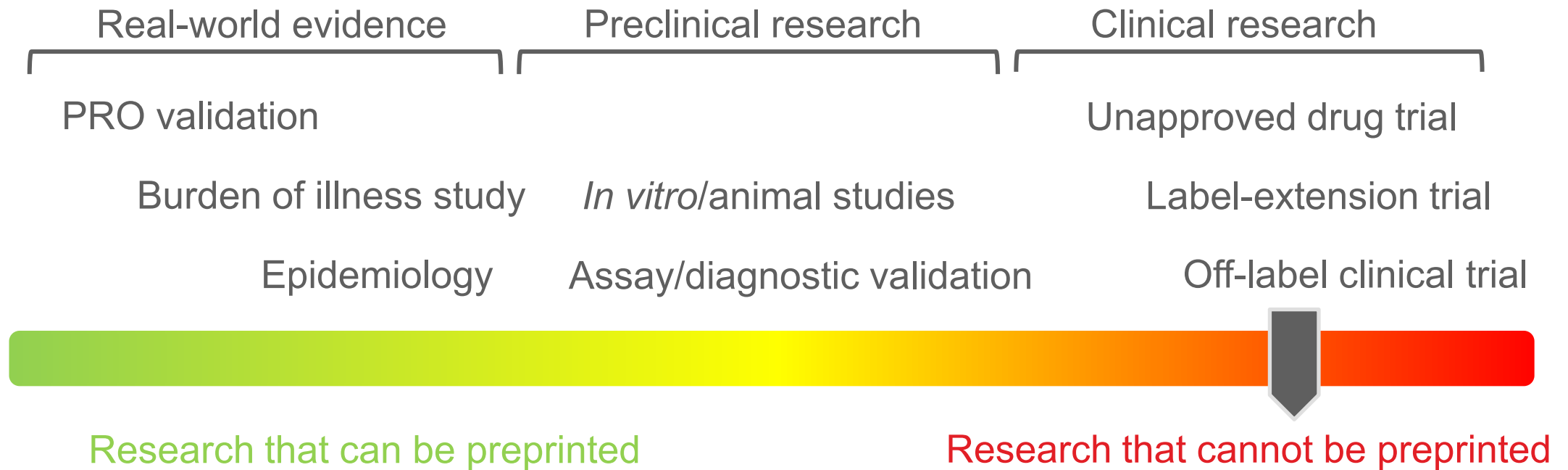
Of these **26** articles

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

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

Research

- Anderson KR. bioRxiv [Preprint]. 2020. <https://doi:10.1002/leap.1265> (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. <https://doi.org/10.1101/2020.05.22.111294> (Accessed 11 January 2021)
- Majumder, Maimuna S *et al.* *Lancet Glob Health* 2020; 8:627–30
- <https://www.nature.com/articles/d41586-020-01394-6>

An industry viewpoint

- AMWA-EMWA-ISMP joint position statement on medical publications, preprints, and peer review. *Current Medical Research and Opinion* 2021;37(5):861–866 <https://doi.org/10.1080/03007995.2021.1900365>