



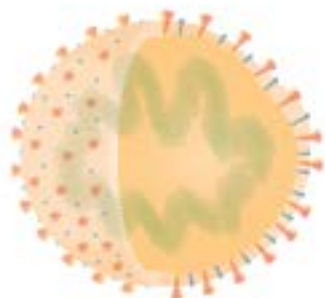
Data Transparency in COVID Times

Ida Sim, MD, PhD

Co-Founder, Vivli

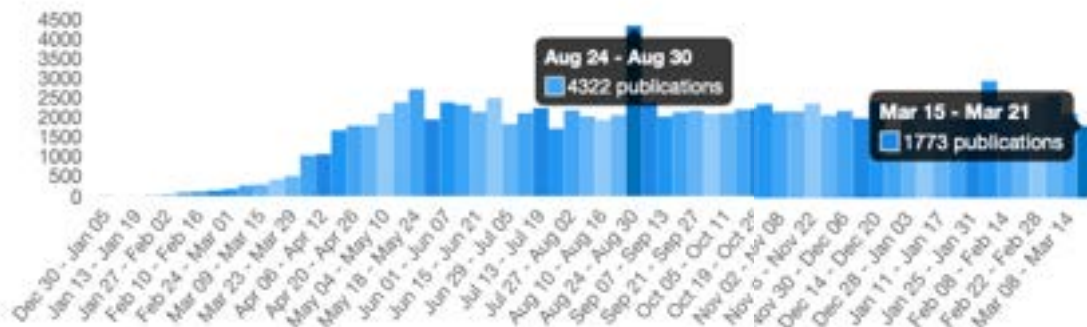
Professor, University of California San Francisco

March 26, 2021



LitCovid is a curated literature hub for tracking up-to-date scientific information about the 2019 novel Coronavirus. It is the most comprehensive resource on the subject, providing a central access to [110934](#) (and [growing](#)) relevant articles in PubMed. The articles are updated daily and are further categorized by different research topics and geographic locations for improved access. You can learn more at [Chen et al. Nature](#) (2020) or our [FAQ](#), and download our data [here](#).

Weekly Publications



Latest Publications

DIAGNOSIS • TREATMENT

Status epilepticus and COVID-19: A systematic review.

Dono, Fedele et al. • *Epilepsy Behav*

CASE REPORT

Reinfection, recurrence, or delayed presentation of COVID-19? Case series and review of the literature.

Elzein, Fatehi et al. • *J Infect Public Health*

medRxiv is receiving many new papers on coronavirus SARS-CoV-2. A reminder: these are preliminary reports that have not been peer-reviewed. They should not be regarded as conclusive, guide clinical practice/health-related behavior, or be reported in news media as established information.

COVID-19 SARS-CoV-2 preprints from medRxiv and bioRxiv

14,308 Articles (11,072 medRxiv, 3,236 bioRxiv)

Most recent first

Page 1: Articles 1-10 | Next ↗

TMPRSS2 inhibitor discovery facilitated through an in silico and biochemical screening platform

Peiffer, A. L., Garlick, J. M., Wu, Y., Soellner, M. B., Brooks, C. L., Mapp, A. K.

10.1101/2021.03.22.436465 — Posted: 2021-03-22

Structural modeling of the SARS-CoV-2 Spike/human ACE2 complex interface can identify high-affinity variants associated with increased transmissibility

Subject Areas

All Articles

Addiction Medicine

Allergy and Immunology

Anesthesia

Cardiovascular Medicine

Dentistry and Oral Medicine

Dermatology

COVID-19 Vaccine Clinical Trials

JAMA FULL TEXT

Original Investigation
January 21, 2021

Effect of Bamlanivimab as Monotherapy or in Combination With Etesevimab on Viral Load in Patients With Mild to Moderate COVID-19: A Randomized Clinical Trial

Robert L. Gottlieb, MD, PhD¹; Ajay Nirula, MD, PhD²; Peter Chen, MD³; et al

[Author Affiliations](#) | [Article Information](#)
JAMA. 2021;325(7):632-644. doi:10.1001/jama.2021.0202

MEETING DATE: 10 December 2020

NEJM SUBSCRIBE OR RENEW

EDITOR STEP 1 & Control

PERSPECTIVE Addressing Workforce Diversity — A Quality-Improvement Framework

REVIEW ARTICLE Extrahepatic Manifestations of Chronic HCV Infection

Published on July 17, 2020, at NEJM.org

...patients with Covid-19

...the RECOVERY Collaborative Group⁸

Evolution of Clinical Trial Data Sharing

Clinical trials registration

ICMJE requirement for publication (2004)
FDAAA requirement for applicable trials (2007)

Summary data shared

FDAAA Final Rule (published 2016, effective Jan. 2017)
EU no. 536/2014 requires lay summaries (effective late 2020)

Clinical Study reports - CSRs & Individual Participant Data (IPD) shared

EMA Policy 0070 (2014), Policy 0043 (2010)
Health Canada Regulations (2019) (IPD not included)
PhRMA/EFPIA principles for data sharing (2014)
IOM Sharing Clinical Trial Data report (2015)
FDA Clinical Data Summary Pilot (Jan. 2018)
ICMJE IPD sharing statement (July 2018)

Introducing Vivli

THE ENTITY

- Non-profit organization
- Convenes stakeholders in neutral space
 - Industry, academia, funders, govt, etc
- Community-based governance and policy
 - Harmonizing language & agreements
- Advocating for culture of data sharing
- Oversight of Implementation

THE PLATFORM

- State-of-the art platform for listing, requesting, accessing and computing on individual participant-level clinical trials data (IPD)
- Serving the international community
- Trials from any disease, country, sponsor, funder, or investigator

Vivli by the numbers ...today



Vivli's COVID-19 Portal

- Provides a dedicated search function
- Availability of fast-tracked review and sharing
- Waiver of all fees to share, archive, access, and analyze COVID-19 trials
- Waiver of anonymization fees through key Vivli partners



“d-wise is proud to play its part to accelerate the sharing ecosystem in the fight against COVID-19.”

Stephen Baker, d-wise

Privacy Analytics will waive fees to anonymize COVID-19 vaccine and pivotal drug trials for a limited time to accelerate COVID-19 response*

*Data to be provided in specified SDTM format, waivers may be granted in exceptional cases

Intent to Share IPD in a Pandemic

What is the “upper bound” of COVID trialist interest in sharing their IPD?

Methods:

- Data sharing declarations in ClinicalTrials.gov
 - interventional trials on COVID-19 (and related terms) before 6/30/20: **924 COVID interventional trials**
 - reviewed data sharing fields
- Data sharing statements in publications
 - Searched PubMed in May 2020 for COVID-related interventional trials in humans: **28 COVID publications**
 - reviewed data sharing statements

COVID-19 Trial Registrations: Data Sharing Intent

Intend to share?	
Yes	145 (16%)
Undecided	131 (14%)
No	440 (48%)
No response	208 (22%)
TOTAL	924

Timing of intended sharing	
Immediately	56 (39%)
1 to < 6 months	14 (10%)
6-12 months	22 (15%)
12-24 months	16 (11%)
No timing given	37 (25%)
TOTAL NUMBER	145

COVID-19 Trial Publications: Data Sharing Intent

Intend to share? (Publication)		Intent at Registration	
Yes	6 (21.4%)	4	
Undecided	0 (0%)		
No	1 (3.5%)	1	
No response	21 (75%)		1 2
TOTAL	28		

Li, R., et al. *Trials* **22**, 153 (2021). <https://doi.org/10.1186/s13063-021-05104-z>


Summary of COVID-19 Data Sharing Intent

- Before the pandemic, intent to share IPD was in the 5-10% range
- 15% willingness to share is an improvement
- **Overall only 7.6% of registered trials agreed to share their data (70/924) within the first 6 months**



Can a Wearable Detect COVID-19 Before Symptoms Appear?

A health study conducted by

 Scripps Research



nature > nature medicine > letters > article

Letter | Published: 29 October 2020

Wearable sensor data and self-reported symptoms for COVID-19 detection

Giorgio Quer , Jennifer M. Radin, Matteo Gadaleta, Katie Baca-Motes, Lauren Ariniello, Edward Ramos, Vik Kheterpal, Eric J. Topol & Steven R. Steinhubl

Nature Medicine 27, 73–77(2021) | [Cite this article](#)

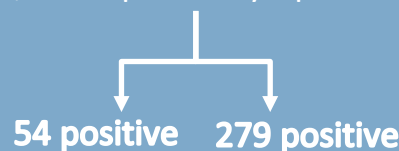
41k Accesses | 10 Citations | 706 Altmetric | [Metrics](#)

Abstract

Traditional screening for COVID-19 typically includes survey questions about symptoms and travel history, as well as temperature measurements. Here, we

N = 30,529* participants
Study Period: 25 March and 7 June 2020

3,811 reported symptoms



```
graph TD; A[3,811 reported symptoms] --> B[54 positive]; A --> C[279 positive];
```

54 positive 279 positive

Symptom & sensor data **AUC = 0.80**
(IQR 0.73–0.86)

vs.

Symptoms alone **AUC = 0.71** (IQR 0.63–0.79) ($P < 0.01$)

*now at >36,000 participants

DETECT



HEALTH STUDY

Broad access to the data under basic Data Use Agreement.

Relies on de-identification to protect patient privacy.

Data availability

All interested investigators will be allowed access to the analysis dataset following registration and pledging to not re-identify individuals or share the data with a third party. All data inquiries should be addressed to the corresponding author.

Fight COVID-19 in 5 minutes a day!

- ▶ Identify symptoms
- ▶ Help prevent infection
- ▶ Track the impact

Use Study Key [COVID19](#) on Mobile.



Participate

Brought to you by



Powered by



57,877

PARTICIPANTS

and counting.

Everyone 18+ years old with an internet connection can participate, whether or not you have been tested for COVID-19!



Default is that de-identified data will be made available to other researchers

You decide how to share your data

We'll ask if you want to share the data you donate with other research studies that you're participating in (so you don't have to share your name or other identifiers) ...with other qualified researchers without your name or other identifiers (so your data can be used to help people everywhere) or not at all. The default is to share your data with other researchers.

Data Transparency: “Before” and “After” Times

Dismayingly low level of intention to share clinical trial IPD (15%)

Desire to hold onto the data during a pandemic (only 7.6% willing to share within 6 months of publication)

Different culture of sharing in digital cohort studies: default is sharing “de-identified data” to any “qualified” researcher

- many patients are willing and want to share their data to accelerate findings

Code availability is still rare