Data Transparency in COVID Times

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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 (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.

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

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

TMPRSS2 inhibitor discovery facilitated through an in silico and biochemical screening platform
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
COVID-19 Vaccine Clinical Trials

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, PhD; Ajay Nirula, MD, PhD; Peter Chen, MD; et al.

Evolution of Clinical Trial Data Sharing

Clinical trials registration
- ICMJE requirement for publication (2004)
- FDAAA requirement for applicable trials (2007)

Clinical trials registration
- EU no. 536/2014 requires lay summaries (effective late 2020)

Summary data shared
- 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)

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

- 5,900+ Trials
- 3.6M Participants from 119 countries
- 31 Members
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
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

<table>
<thead>
<tr>
<th>Intend to share?</th>
<th>Number (Percentage)</th>
</tr>
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<tbody>
<tr>
<td>Yes</td>
<td>145 (16%)</td>
</tr>
<tr>
<td>Undecided</td>
<td>131 (14%)</td>
</tr>
<tr>
<td>No</td>
<td>440 (48%)</td>
</tr>
<tr>
<td>No response</td>
<td>208 (22%)</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td><strong>924</strong></td>
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<table>
<thead>
<tr>
<th>Timing of intended sharing</th>
<th>Number (Percentage)</th>
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<tbody>
<tr>
<td>Immediately</td>
<td>56 (39%)</td>
</tr>
<tr>
<td>1 to &lt; 6 months</td>
<td>14 (10%)</td>
</tr>
<tr>
<td>6-12 months</td>
<td>22 (15%)</td>
</tr>
<tr>
<td>12-24 months</td>
<td>16 (11%)</td>
</tr>
<tr>
<td>No timing given</td>
<td>37 (25%)</td>
</tr>
<tr>
<td><strong>TOTAL NUMBER</strong></td>
<td><strong>145</strong></td>
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COVID-19 Trial Publications: Data Sharing Intent

<table>
<thead>
<tr>
<th>Intend to share? (Publication)</th>
<th>Intent at Registration</th>
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</thead>
<tbody>
<tr>
<td>Yes</td>
<td>6 (21.4%)</td>
</tr>
<tr>
<td>Undecided</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>No</td>
<td>1 (3.5%)</td>
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<tr>
<td>No response</td>
<td>21 (75%)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>28</td>
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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
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

Abstract

Traditional screening for COVID-19 typically includes survey questions about symptoms and travel history, as well as temperature measurements. Here, we explored the potential of using wearable sensor data, specifically heart rate variability, alongside self-reported symptoms to improve early detection of mild-to-moderate COVID-19 cases. After analyzing data from 30,529 participants over a study period from 25 March to 7 June 2020, we found that incorporating sensor data into the detection model increased the area under the curve (AUC) to 0.80 (IQR 0.73-0.86), compared to symptoms alone which had an AUC of 0.71 (IQR 0.63-0.79) (*P < 0.01). With the current data set at >36,000 participants, we are confident in the robustness of our findings.
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

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...with other qualified researchers without your name or other identifiers (so your data can be used to help people everywhere)
Data Transparency: “Before” and “After” Times

Dismaying 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 "deidentified data" to any “qualified” researcher
  ◦ many patients are willing and want to share their data to accelerate findings

Code availability is still rare