

Clinical Trials for COVID-19: Speed vs. Efficiency

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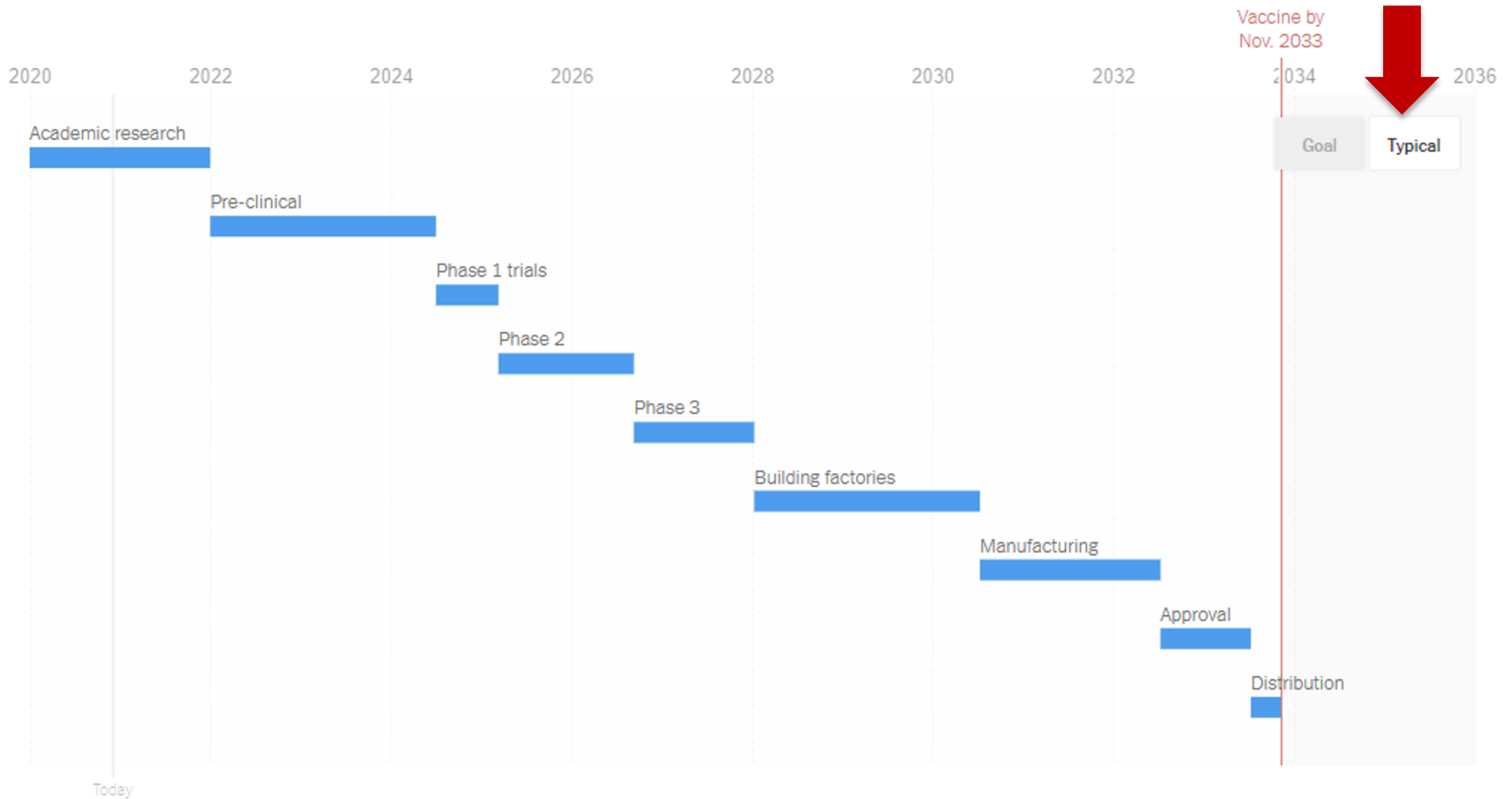
Link: https://www.youtube.com/watch?v=WF8iaqRqI60&ab_channel=Cocomelon-NurseryRhymes



How Long Will a Vaccine Really Take?

By **Stuart A. Thompson**

April 30, 2020



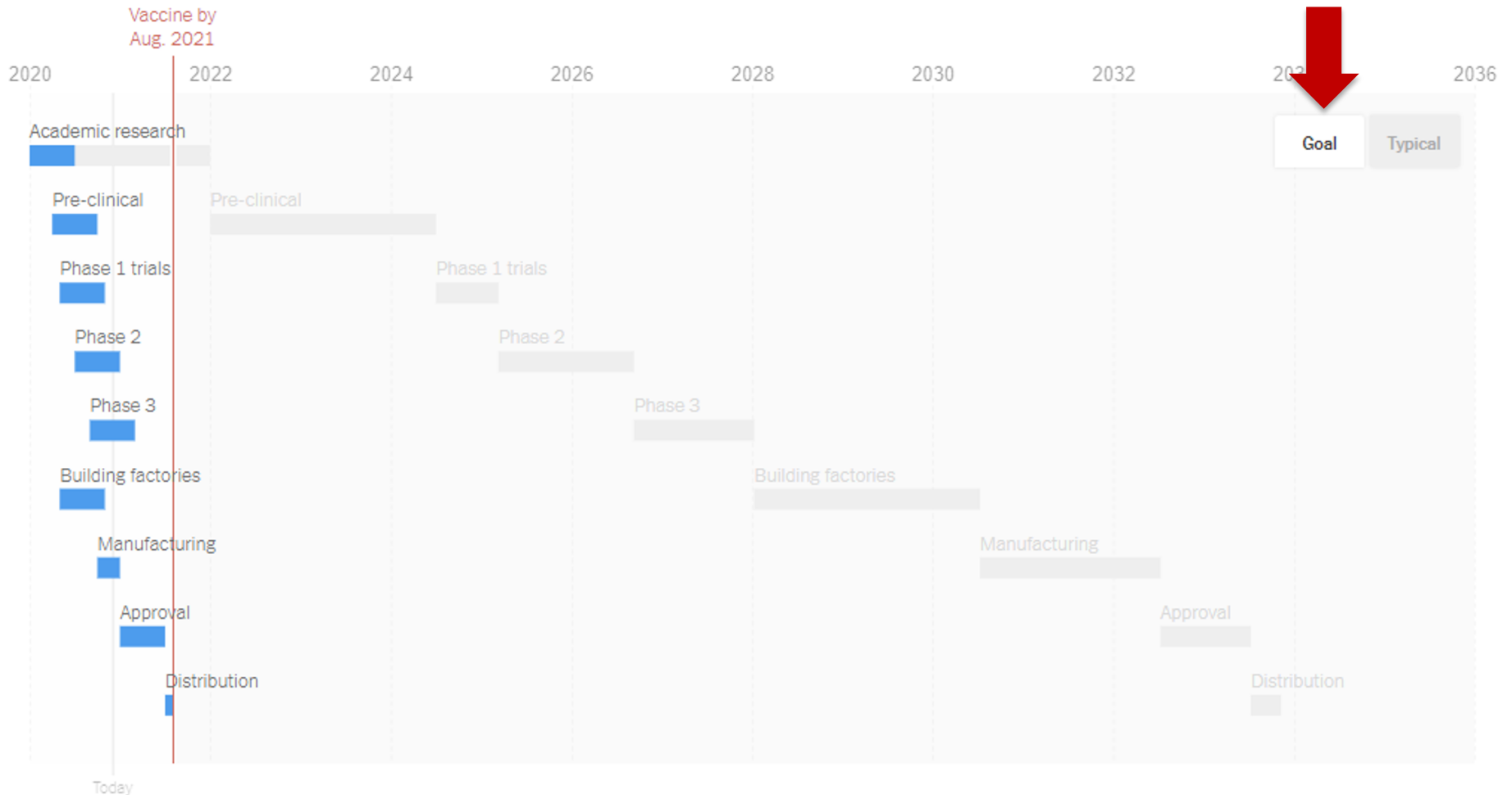
Link: <https://www.nytimes.com/interactive/2020/04/30/opinion/coronavirus-covid-vaccine.html>



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Coronavirus Treatment Acceleration Program (CTAP)



Coronavirus (COVID-19) | Drugs

CDER's Work to Protect Public Health During the COVID-19 Public Health Emergency

Coronavirus Treatment Acceleration Program (CTAP)

Bioequivalence Studies for Submission in ANDAs during the COVID-19 Pandemic

Clinical Trial Conduct During the COVID-19 Pandemic

Drug Shortages Response | COVID-19

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- [For Researchers and Developers of Therapeutics](#)
- [Contact Information for Sponsors](#)
- [For Patients and Consumers](#)
- [Accelerating COVID-19 Therapeutic Interventions and Vaccines \(ACTIV\) Partnership](#)

Content current as of: 09/30/2020

Regulated Product(s)
Drugs

Health Topic(s)
Infectious Disease
Coronavirus

What is CTAP?

FDA has created a special emergency program for possible coronavirus therapies, the Coronavirus Treatment Acceleration Program (CTAP). The program uses every available method to move new treatments to patients as quickly as possible, while at the same time



We are moving fast, and
we should.

But does that mean we
compromise quality?



BMJ Open Characteristics of registered clinical trials assessing treatments for COVID-19: a cross-sectional analysis

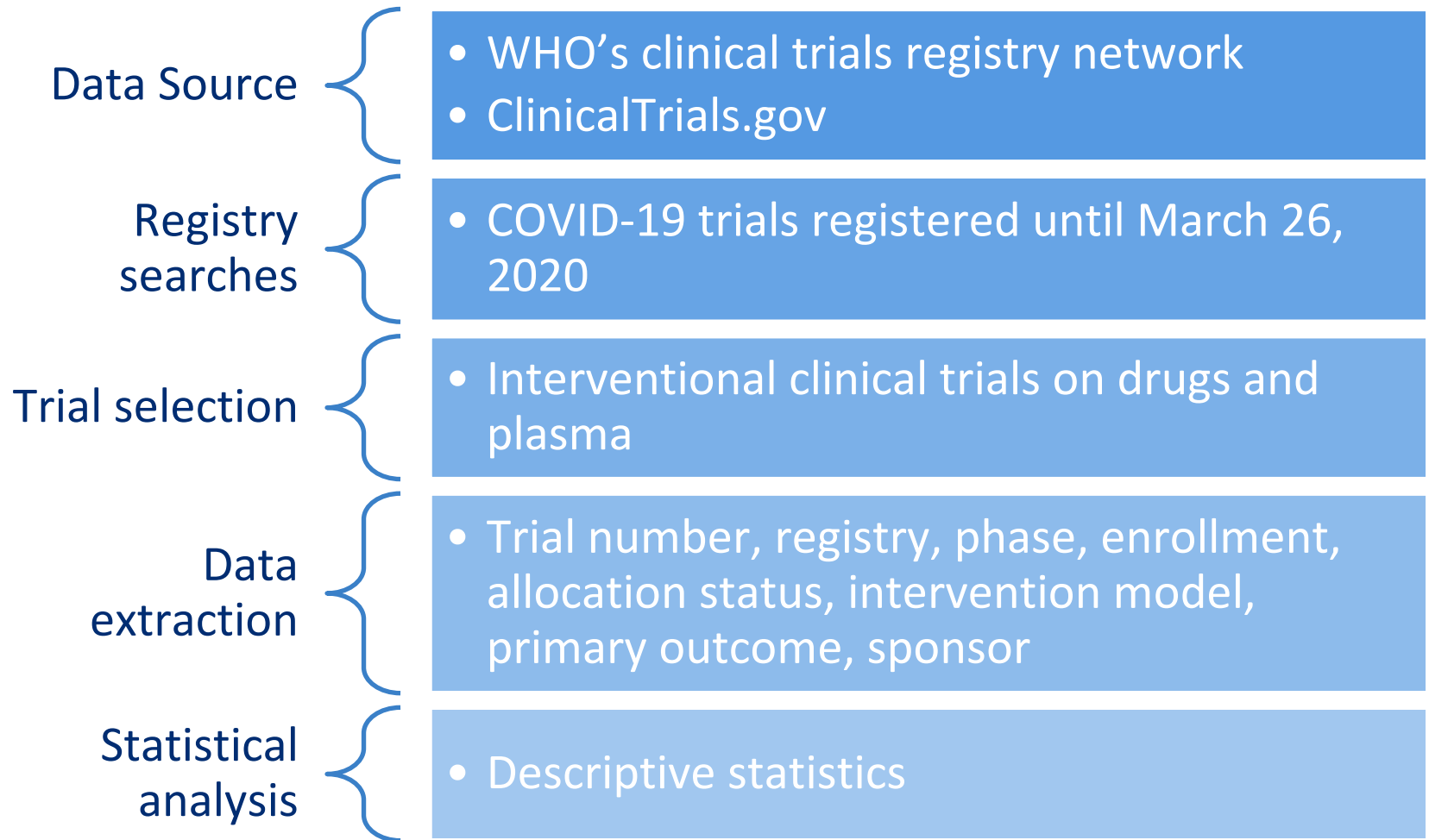
Hemalkumar B Mehta ^{1,2} Stephan Ehrhardt,¹ Thomas J Moore ³,
Jodi B Segal,^{1,2,4} G Caleb Alexander^{1,2}

Randomized Clinical Trials for COVID-19 Treatments

- The impact of the pandemic has unleashed a wave of biomedical research to identify safe and effective treatments for COVID-19
- While new molecular entities are under investigation, many therapies previously approved by regulators for the treatment of other diseases are also being evaluated for repurposing for viral suppression or for lessening the inflammatory consequences of infection
- We aimed to characterize registered clinical trials assessing drugs or plasma treatments for COVID-19.



Methods



3826 Studies found for: COVID-19

Also searched for COVID and SARS-CoV-2. [See Search Details](#)

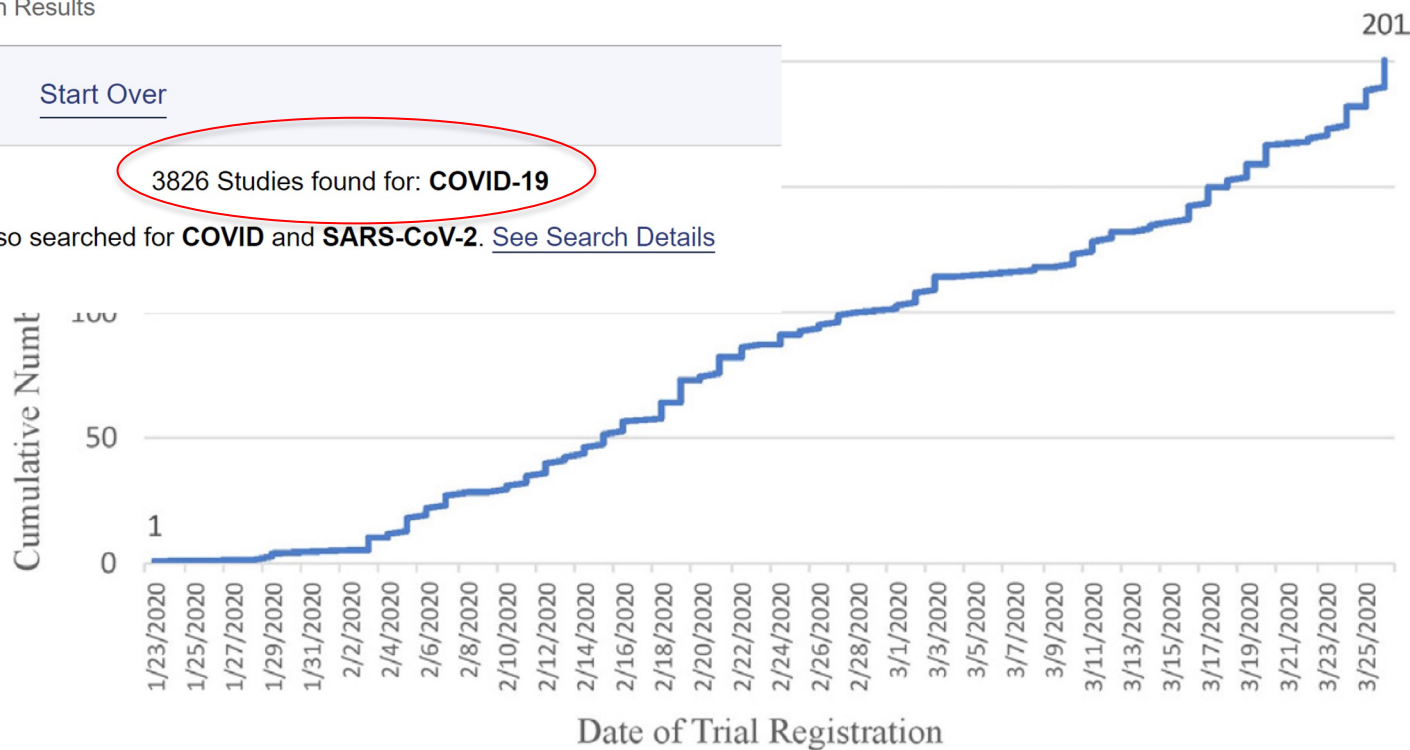


Figure 1 Cumulative number of registered clinical trials of products for SARS-CoV-2 infection. Sources: WHO and ClinicalTrials.gov (as of 26 March 2020). SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

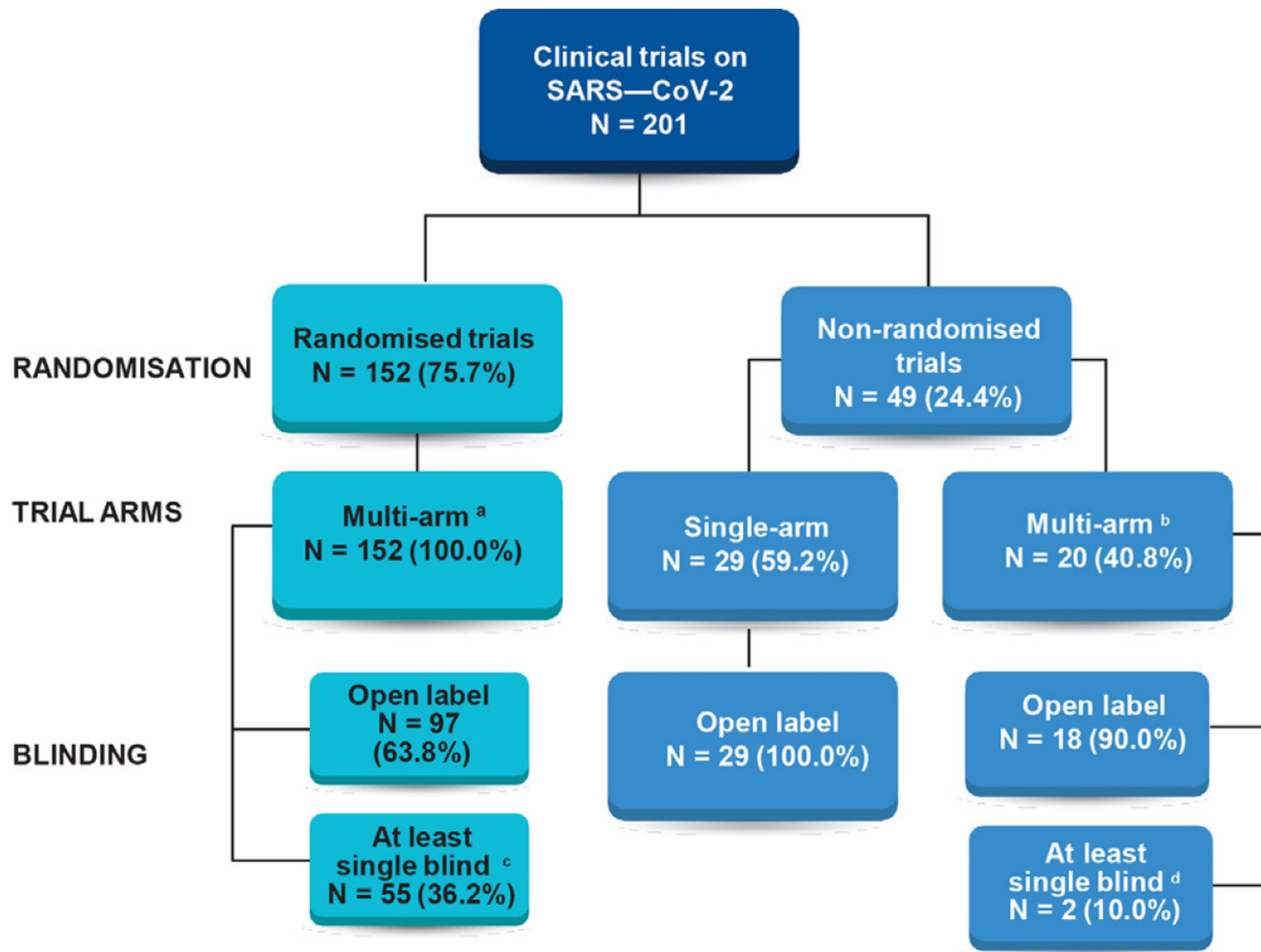


Figure 2 Study designs of registered clinical trials of products for SARS-CoV-2 infection (n=201 trials). ^aIncludes



Table 1 Characteristics of registered clinical trials for SARS-CoV-2 infection (n=201 trials)

Clinical trial characteristics	Total trials (n=201)
Trial intervention, n (%)	
Drug	188 (93.5)
Plasma	13 (6.5)
Trial registry source, n (%)	
China	100 (49.8)
USA	76 (37.8)
Europe Union	9 (4.5)
Iran	10 (5.0)
Japan	4 (2.0)
ISRCTN	2 (1.0)
Status, n (%)	
Recruiting	120 (59.7)
Not yet recruiting	75 (37.3)
Withdrawn	6 (3.0)
Anticipated enrolment, n (%)	
Median (IQR)	100 (50–240)
≤50	54 (26.9)
51–100	53 (26.4)
≥100	94 (46.8)
Outcome,* n (%)	
Surrogate/biomarker	85 (42.3)
Clinical scale	33 (16.4)
Clinical outcome	134 (66.7)



July 27, 2020

Characteristics and Strength of Evidence of COVID-19 Studies Registered on ClinicalTrials.gov

Krishna Pundi, MD¹; Alexander C. Perino, MD¹; Robert A. Harrington, MD¹; Harlan M. Krumholz, MD, SM²; Mintu P. Turakhia, MD, MAS¹

» Author Affiliations | Article Information

JAMA Intern Med. 2020;180(10):1398-1400. doi:10.1001

Allergy EUROPEAN JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY



REVIEW ARTICLE | Free Access

COVID-19 Clinical trials: Quality matters more than quantity

Sergio Bonini , Giuseppe Maltese

[Eur J Intern Med.](#) 2020 Jul 7

doi: [10.1016/j.ejim.2020.07.002](https://doi.org/10.1016/j.ejim.2020.07.002) [Epub ahead of print]

PMCID: PMC7340035

PMID: [32653152](https://pubmed.ncbi.nlm.nih.gov/32653152/)

Waste in COVID-19 clinical trials conducted in western Europe

[Rafael Dal-Ré](#)^{1,*} and [Ignacio Mahillo-Fernández](#)²

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Volume 123, July 2020, Pages 120-126



COVID-19 Articles

COVID-19 coronavirus research has overall low methodological quality thus far: case in point for chloroquine/hydroxychloroquine

Paul Elias Alexander ^{a, b} , Victoria Borg Debono ^{a, c}, Manoj J. Mammen ^d, Alfonso Iorio ^{a, e}, Komal Aryal ^a, Dianna Deng ^f, Eva Brocard ^g, Waleed Alhazzani ^{a, b, e}



Correspondence | Published: 22 September 2020

COVID-19 clinical trials: learning from exceptions in the research chaos

Kari A. O. Tikkinen, Reza Malekzadeh, Martin Schlegel, Jarno Rutanen & Paul Glasziou 

Nature Medicine (2020) | [Cite this article](#)

5780 Accesses | 286 Altmetric | [Metrics](#)

To the Editor – Jeremy Farrar, Director of Wellcome and Chair of the World Health Organization R&D Blueprint Scientific Advisory Group, has said “It’s critical that the global research effort is rapid, robust and is conducted at scale and co-ordinated across multiple countries.”



Of the >2,000 planned drug studies examining COVID-19 treatments (<https://www.covid-trials.org>), most have delivered little or no directly useful information¹. Exceptions include two large, adaptive, pragmatic trials, RECOVERY and SOLIDARITY, which combined have randomized >20,000 patients to assess the effects of several treatments on mortality², and the US National Institutes of Health ACTT trial, which randomized 1,059 patients to assess the effect of remdesivir on time to disease resolution³.



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2



Doctors are desperate for treatments for coronavirus patients. Three experts discuss how to identify what can help. TIM DIRVEN/PANOS PICTURES/REDUX

'We've got to be able to move more quickly.' The pandemic reality of COVID-19 clinical trials

<https://www.sciencemag.org/news/2020/06/we-ve-got-be-able-move-more-quickly-pandemic-reality-covid-19-clinical-trials>



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EDITORIAL



Underpromise, overdeliver

H. Holden Thorp[+ See all authors and affiliations](#)

Science 27 Mar 2020:
Vol. 367, Issue 6485, pp. 1405
DOI: 10.1126/science.abb8492

[Article](#)[Info & Metrics](#)[eLetters](#)[PDF](#)

“The scientific method is a very deliberate process that has been honed over time: Basic research, which describes the problem, is followed by applied research that builds on that understanding. Now, scientists are trying to do both at the same time. This is not just fixing a plane while it’s flying—it’s fixing a plane that’s flying while its blueprints are still being drawn”



WHAT IS PUBLIC HEALTH?

Protecting Health
Saving Lives—
Millions at a Time

