

For Whose Benefit?

Transparency [redacted] in the development
[redacted] and procurement of [redacted] COVID-19 vaccines

This document summarises the findings from our **For Whose Benefit?** report, it provides an overview of the key risks of a lack of transparency in COVID-19 vaccine clinical trials and procurement contracts, and suggests recommendations for reform.

Our findings carry important implications, not only for the development of COVID-19 medical technology, but also for future health emergencies and the wider governance of pharmaceutical development and public procurement. The elements highlighted in our analysis are important in bringing COVID-19 vaccines to market whilst offering important opportunities to move the dial in wider conversations on transparency beyond the pandemic.

Key Findings

The report reveals a disturbing trend of poor transparency in clinical trials as well as in contracting for the supply of vaccines. This is highlighted by:

- The incoherent global clinical trial transparency policy landscape.
- Poor sharing of vaccine clinical trial protocols.
- The frequent use of media to announce clinical trial results without the accompanying publication of the associated data analysis, facilitating misinformation and misunderstanding.
- Extremely low publication of contracts worldwide.
- Significant redactions in the published contracts which hide key details of public interest.
- The variable pricing of vaccines and extensive indemnification clauses, underlining the need for more transparency in these areas.

20 COVID-19 vaccine candidates
included in analysis¹

Name of vaccine developer	Name of vaccine
Moderna	mRNA-1273
Pfizer/BioNTech	Comirnaty (BNT162b2)
Medicago (w/GSK adjuvant)	CoVLP
Anhui Zhifei Longcom	ZF2001
Bharat Biotech	Covaxin (BBV152)
CureVac	CVnCoV
Clover Biopharmaceuticals (w/GSK adjuvant)	SCB-2019
Sinopharm (Beijing)	BBIBP-CorV
AstraZeneca	AZD1222 / Covishield (ChAdOx1 nCoV-19)
CanSino Biologics	Convidicea (Ad5-nCoV)
Johnson & Johnson	Ad26.COVS.2.S
Novavax	NVX-CoV2373
Sinovac Biotech	CoronaVac
Gamaleya Research Institute	Sputnik V
AnGes	AG0302-COVID19
Zydus Cadila	ZyCoV-D
Vector Institute	EpiVacCorona
Chinese Academy of Medical Sciences	Unnamed Inactive Vaccine - Yunnan
Research Institute for Biological Safety Problems	QazCovid-in
Sinopharm (Wuhan)	Unnamed Inactive Vaccine - Wuhan

Disjointed clinical trial transparency policies

Six vaccines – or 30 per cent of the total - are being made by developers based in countries that do not align with best practice and require the reporting of clinical trial summary results within 12 months of trial completion. Due to varying national clinical trial policies, we can expect that clinical study reports will only be made available for vaccines which have been applied for approval to be distributed in Canada and the EU².

During public health emergencies, the World Health Organisation (WHO) recommends that quality-controlled interim results be shared prior to trial completion³. However, no explicit guidance has been given as to how and what information should be shared, nor has this recommendation been implemented into national legislation in the countries analysed.

RECOMMENDATIONS

1. The WHO should update its guidance on sharing clinical trial results to include an expanded amendment on public health emergencies, to be implemented by national governments.
2. National governments should adopt, fully implement, and enforce broadened legislation which requires all clinical trials to be pre-registered, and make summary results public within 12 months of their completion on a trial registry.
3. Drug regulatory agencies should make complete clinical study reports available, after excluding individual participant identifiers if unavoidable, within 60 days of regulatory approval for all medical products, including COVID-19 vaccines.

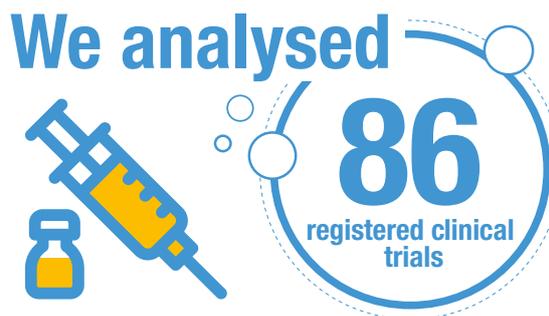
Clinical study reports are only made available in

two of the nine countries

where developers are based

Poor sharing of COVID-19 vaccine clinical trial protocols

We identified 86 registered clinical trials across the 20 vaccines we examined. Of these, clinical trial protocols were only shared for just 12 per cent (10) of the trials in our analysis⁴. The early sharing of clinical trial protocols is important, as it enables external expert scrutiny of methodology and design integrity to highlight potential bias and can also deter the selective reporting of results^{5 6}.



across 20 different COVID-19 vaccines

RECOMMENDATIONS

4. COVID-19 vaccine developers that have not yet published their clinical trial protocols should do so on a publicly accessible clinical trial registry. In future they should publish them when the trial is approved, prior to participant recruitment. Any protocol amendments should be published at the time of results sharing.
5. All governments should revise clinical trial legislation to require the public sharing of clinical trial protocols when the trial is approved, on a publicly accessible platform which meets WHO standards, then updated with any amendments at the time of results sharing.



Incoherent sharing of COVID-19 clinical trial results

At least some clinical trial results had been announced for 18 of the 20 vaccines we examined, however vaccines developed by AnGes and Zydus Cadila have yet to announce any results.

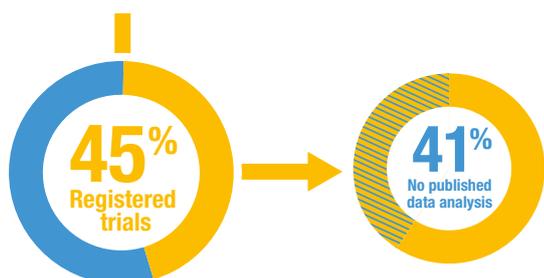
Of the total registered clinical trials in our analysis (86 trials across the 20 vaccines), just 45 per cent have seen results announced. Of these with trials with announced results, 41 per cent have no published data analysis, meaning that only top-level results were provided through a press release, press conference or media report, with minimal data. Sinovac Biotech and the Vector Institute shared no clinical trial data analysis for their vaccines at all, despite both vaccines having been administered to populations since July 2020 and October 2020, respectively.

This trend of ‘science by press release’ led to the selective sharing of results and a failure to explain methodological details that are key to interpreting the results. Furthermore, press releases and press conferences enable companies to sequence information releases alongside stock movements, gaining a potential opportunity for private profit.

RECOMMENDATIONS

6. COVID-19 vaccine developers must publish all missing clinical trial data analysis.
7. Use of the media should only be used to announce clinical trial results in tandem with data analysis published in a peer-reviewed medical journal, trial registry or as a pre-print article.
8. Further research is required to explore potential manipulation of key clinical trial information and trading activities of pharmaceutical developers.

Results have been announced for 45% of the total registered clinical trials in our analysis



Of these **41 per cent** have no published data analysis, meaning that **only top-level results were provided through a press release, press conference or media report, with minimal data**

Low publication rate of COVID-19 vaccine contracts

Of the 20 vaccine candidates we analysed, we found a total of 183 agreements for the purchase of 12 different COVID-19 vaccines which have been concluded between 75 buyers and 13 suppliers globally⁷. We found that only six per cent (13) of these contracts are publicly available. Out of these 13 contracts, 11 were published through official channels⁸, while the remaining two were unofficially leaked.

The 11 formally published contracts were provided by four countries and one bloc: The United Kingdom, Brazil, Dominican Republic, the USA and the European Union. All five entered into multiple agreements with vaccine developers and did not formally publish every contract. They formally published an average of 23 per cent of their concluded agreements. The USA is the only exception and has formally published all six of the contracts it signed.

RECOMMENDATIONS

9. All buyers have an obligation to be transparent and accountable and should follow the lead of the USA and publish their remaining contracts. Brazil, the UK, and the European Commission should champion this given their relative wealth and number of doses already secured. The COVAX facility should reaffirm its commitment to equity by publishing all vaccine contracts, and if necessary, use redacted versions that are clearly and specifically justified.
10. International NGOs should advocate for transparency and provide resources that assist with obtaining justifications for contractual secrecy by buyers. Where possible, these INGOs should combine efforts to also target regional and international decision-making bodies such as the African Union and COVAX.
11. Governments and the WHO should provide guidance on public health emergency procurement which contains robust transparency rules, including when and how to publish contracts in a pandemic, in order to guarantee that transparency is not a casualty in future crises.

Widespread redactions in COVID-19 vaccine contracts

Out of the 11 formally published contracts, 10 were published with a high number of redactions and cannot be described as adhering to the Center for Global Development’s (CGD) Principle of “Full Contract Publication”. The contract redactions often cover entire pages and sections, as well as information of key public interest, such as the total cost paid, the price per dose, and delivery timetables. The remaining one contract was published by the Dominican Republic and included no redactions.

Analysis shows that 24 per cent of the contract between the European Commission and CureVac was obscured by redactions⁹, whilst a comparison of the unredacted and redacted versions of the European Commission – AstraZeneca contract showed that 12 per cent of the words were redacted¹⁰. Additionally, most contracts obscured information that is of heightened public interest.

RECOMMENDATIONS

12. Buyers with already published and redacted contracts that are not marked with a justification - the UK, the European Commission and Brazil - should immediately republish with such details. Future publication of contracts should follow the CGD principle “All redactions should be clearly marked with the reason for redaction”.
13. Justification of redactions should detail the decision-making process that led the buyer to conclude that it is of a higher public interest to redact, or not redact at all. These should be specific to discrete sections of the contract rather than blanket explanations.

Just one contract, or 0.5% of the total, was published by buyers without redaction. The vast majority redact large sections that are of critical public interest, price per dose and delivery timetables



For AstraZeneca’s vaccine, upper-middle income countries like South Africa are paying an average of 25% more per contract than high income countries like the USA.

COVID-19 vaccine pricing transparency

Despite the advantages of pricing transparency for vaccine distribution, price per dose - the contractual information perhaps most highly valued by the global community - has also been systematically unpublished. Whilst there have been reports from parties involved in agreements, information on pricing is incomplete in all formally published contracts other than those of the Dominican Republic and USA.

Analysis of prices sourced from UNICEF’s Market analysis dashboard, indicates concerning price variation both as a whole and when assessing specific vaccines. For example, for the AstraZeneca developed vaccine, the dashboard showed that on average High-Income Economies are paying the least at USD 6.26 per dose, second are the Lower-Middle Income Economies at USD 6.72, and the most spent on vaccines is by Upper-Middle Economies at USD 7.81.

RECOMMENDATIONS

14. All vaccine developers, and particularly AstraZeneca, should justify their commitment to broad and equitable access by releasing their price per dose of all their agreements, preferably within a contract.
15. The EU, the USA, the UK, Japan, Canada and Australia should champion pricing transparency, by releasing contracts without redaction of prices.
16. A pricing database should be established by the WHO with the general principle that all countries report their prices anonymously.

Indemnification clauses in COVID-19 vaccine contracts

As is generally accepted in pandemic situations, those countries that do not have laws covering liability included indemnity clauses in contracts. These clauses ensure that the supplier is protected from legal repercussions should there be any adverse reaction to a vaccine.

However, as the Pfizer contracts with the Dominican Republic and Albania show, some contracts cover additional liabilities. The clauses in these contracts go much further and seeks to push the risk onto national governments, and away from the developer, even if missteps are made by the developer or supply chain partners.

Our analysis, supported by media and NGO reports^{11 12}, indicates a “pandemic norm” where a priority aspect of negotiation for suppliers has been limiting the level of financial risk should something go wrong in the development and distribution of vaccines. In turn, such aspects of a contract become more commercially sensitive, creating a higher incentive on behalf of the supplier to redact or not publish such information. This situation is compounded, particularly in lower-middle income economies, as many do not have the administrative or legal capacity to adapt quickly, and procurement systems may already be overstretched due to the pandemic.



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RECOMMENDATIONS

17. In the absence of full publications of contracts by buyers, suppliers should release the full extent of its agreed upon indemnification clauses.
18. The WHO should develop toolkit to promote good practice in pandemic vaccine agreements complete with template clauses and guidance.

REFERENCES

- 1 All vaccines were in, or had completed, phase III clinical trials as of January 11th 2021.
- 2 The policies regarding CSR sharing in EU and Canada only applies to medicines which have been applied for approval to be distributed in the jurisdiction.
- 3 'WHO | Developing Global Norms for Sharing Data and Results during Public Health Emergencies' (WHO) http://www.who.int/medicines/ebola-treatment/blueprint_phe_data-share-results/en/ accessed 24 February 2021.
- 4 Full dataset can be found in Annex 3 of the full report.
- 5 An-Wen Chan and Asbjørn Hróbjartsson, 'Promoting Public Access to Clinical Trial Protocols: Challenges and Recommendations' (2018) 19 *Trials* 116.
- 6 Morgan Lucey, Jocalyn Clark and Paul Glasziou, 'Public Availability of Trial Protocols' (2017) 390 *The Lancet* e54.
- 7 This is of 5th March 2021 and based on UNICEF'S Market Analysis Dashboard: <https://www.unicef.org/supply/covid-19-vaccine-market-dashboard>.
- 8 Formally published is defined as the hosting of the contract on an institutional web platform. This can either be published proactively or through Freedom of Information requests.
- 9 Esther Snippe, Natasha Foote and Vlagyiszlav Makszimov, 'COVID Vaccine Contract: Nearly a Quarter Obscured' (www.euractiv.com, 22 January 2021) <https://www.euractiv.com/section/coronavirus/news/covid-vaccine-contract-nearly-a-quarter-obscured/> accessed 10 May 2021.
- 10 'COVID-19 Vaccine Contract Data – Transparency International Global Health' <http://ti-health.org/covid-19-vaccine-contract-data/> accessed 10 May 2021.
- 11 Madlen Davies and others, "'Held to Ransom": Pfizer Plays Hardball in Covid-19 Vaccine Negotiations with Latin American Countries' *Stat News* (23 February 2021) <https://www.statnews.com/2021/02/23/pfizer-plays-hardball-in-covid19-vaccine-negotiations-in-latin-america/> accessed 9 April 2021.
- 12 Ivan Ruiz and others, 'GOVERNMENTS OF LATIN AMERICA GRANTED LEGAL AND TAX BENEFITS TO PHARMACEUTICAL COMPANIES IN THE PURCHASE OF VACCINES' <https://www.redpalta.org/post/los-beneficios-a-farmaceticas-en-compra-de-vacunas/> accessed 15 April 2021.