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RESEARCH ARTICLE

Individual participant data sharing intentions and practices during the coronavirus disease-2019 pandemic: A rapid review

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Abstract

The coronavirus disease-2019 (COVID-19) pandemic has led to the irrational use of drugs in the absence of clinical management guidelines. Access to individual participant data (IPD) from clinical trials aids the evidence synthesis approaches. We undertook a rapid review to infer IPD sharing intentions based on data availability statements by the principal investigators (PIs) of drug and vaccine trials in the context of COVID-19.

Searches were conducted on PubMed (NCBI). We considered randomized controlled trial (RCT) publications from January 1, 2020, to October 31, 2021. IPD sharing intentions were inferred based on the data availability statements in the full-text manuscript publications. We included 180 articles. Of these, 81.7% (147/180) of the publications have arrived from the findings of the RCTs alone, 12.8% (23/180) of the publications were protocol publications alone, and 5.6% (10/180) of the RCTs had both published protocol and publication from the trial findings. We have reported IPD sharing intentions separately in RCT protocol publications (n = 23 + 10) and publications from RCT findings (n = 147 + 10). Among RCT protocol publications, one-third (11/33) of the PIs intended to share IPD. In fact, over half of the PIs (52.2%, 82/157) in their published RCT findings intended to share IPD. However, information to share about IPD was missing for 57.6% (19/33) of RCT protocols and 38.2% (60/157) of published RCT findings.

Stakeholders must work together to ensure that overarching factors, such as legislation that governs clinical trial practices, are streamlined to bolster IPD sharing mechanisms.

Policy Significance Statement

This research aimed to analyze the individual participant data (IPD) sharing intentions during coronavirus disease-2019 (COVID-19) using a rapid review approach. We assessed the practice and influence of the trial sponsor. The practice of sharing IPD does not just get influenced by the researcher's intention but stakeholders such as pharmaceutical companies, clinical research organizations, country policies, and many more. Thus, this

paper can serve as a basis for stimulating policy debates on the mechanisms and processes to share IPD in a manner that is safe for all the stakeholders involved.

1. Introduction

1.1. Background

When the novel coronavirus disease-2019 (COVID-19) emerged in December 2019, there were no drugs or vaccines available. The irrational use of drugs was observed in many quarters (World Health Organization, 2020a). To manage the pandemic, researchers investigated drugs and vaccines; various clinical trials were initiated. As the COVID-19 pandemic unfolded, the rapid synthesis of evidence on clinical management guidelines was prioritized due to sparse existing evidence (World Health Organization, 2020b).

Meta-analyses based on clinical trial data provide a precise estimate of the treatment effect as compared to individual clinical trials. Individual participant data (IPD) meta-analysis *vis a vis* aggregate meta-analysis is preferable due to its reliability in assessing risk and effect of treatment in clinical care. IPD is the original participant-level data while aggregate data are derived from IPD. IPD meta-analysis is based on the trial participant data recorded for each individual in a clinical trial and includes participant characteristics (age, sex, height), clinical parameters (e.g., blood pressure, serum cholesterol), medical history, and follow-up details (e.g., history of hypertension, medications received), laboratory results (e.g, blood sugar level, serum sodium level), interventions received (type of drug received in the clinical trial) and details on adverse events and clinical outcome (e.g., improved health condition or death) (Riley et al., 2021). The results of clinical trials remained indecisive for most randomized controlled trials (RCTs) during the initial phase of the pandemic, buttressing the need for rapid evidence synthesis approaches (Lim et al., 2021). This approach has had positive effects: in the first year of the pandemic, IPD meta-analyses including convalescent plasma therapy (Goldfeld et al., 2021), and hydroxychloroquine treatment (Fiolet et al., 2021) helped to estimate the efficacy of interventions and reform treatment guidelines.

The potential benefits of IPD data sharing are well known: it encourages the optimal use of a valuable resource, encourages reproducible scientific research, and new insights can be gained from existing data sets (Institute of Medicine (US), 2015). IPD sharing promotes transparency in clinical trials. Rapid and wide sharing of clinical trial data, as well as epidemiological data during health emergencies makes a difference by enhancing response efforts (Abramowitz et al., 2018; Lucas-Dominguez et al., 2021). The recent Ebola epidemic (2014–2016), and the Yellow fever epidemic (2016) have shown that the lack of timely access to the epidemiological and clinical trial data slow down research efforts and thereby the pandemic response (Abramowitz et al., 2018; Lucas-Dominguez et al., 2021). Not surprisingly, there are ongoing calls from researchers, funders, and the scientific community for the rapid sharing of clinical trial data (McBride et al., 2018). The accelerated use of pre-prints enabled the release of pre-peer-reviewed research results (Fraser et al., 2021) and this increase in collaborations (Guillou, 2020) has been credited with the speedy development of vaccines. This has fuelled calls for data sharing including clinical trial data and IPD sharing to be part of the international pandemic treaty (Nature, 2021). Most importantly, the ethical imperative to share IPD for the common good is clear (Prainsack and Buyx, 2011).

1.2. A complicated issue

Given these benefits, it is not surprising that sharing de-identified IPD is encouraged by the International Committee of Medical Journal Editors (ICMJE) (Taichman et al., 2017), clinical trial agencies such as Pragmatic Clinical Trials Unit (PCTU) (Woukeu, 2020), Medical Research Council (MRC) (Medical Research Council, 2020), UK Clinical Research Collaboration (UKCRC) (UKCRC | UK Clinical Research Collaboration, n.d.)-registered clinical trials units, Cancer Research UK (Cancer Research UK, n.d.), and Welcome Trust (Home, n.d.). Clause 164.514 of the HIPAA Privacy Rule defines

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de-identification as "health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information (TrialData C on S for RS of C, Policy B on HS, Medicine I, 2015)." The MRC, UKCRC, Cancer Research UK, and Welcome Trust have endorsed good practice principles for sharing IPD from publicly funded clinical trials (Smith et al., 2015). However, these are only recommendations and are not obligatory. Evidence suggests that IPD data sharing does not regularly occur (Banzi et al., 2019). Numerous barriers to this data sharing exist: for the PI, there may be concerns about the impact of IPD data sharing on intellectual property rights (IPR), commercial interests, and commercial confidentiality. The reluctance to share data may also be fuelled by exploitative practices (van Panhuis et al., 2014; Maxmen, 2021). Also, since data-sharing policies have primarily been developed by high-income countries to serve their interests, there are practices that often do not credit the data collector or even those who help to generate the data (Maxmen, 2021). For example, Colombo et al. (2019) found that the majority of the patients and citizen group perceived that the reidentification of trial data and privacy were possible risks. For the participant, the sharing of IPD poses a privacy risk: Zarin and Tse (2016) detailed the different types of IPD being shared (uncoded, abstracted, coded, computerized, edited, analyzable, and analyzed) and the granularity of information available. If the IPD is uncoded, then the risk of compromising privacy is highest for the participant; it is lowest if it is in the form of a summary (that is, the data has been already analyzed).

International organizations have reiterated the right to privacy as a fundamental right as well as an ethical obligation in research. The World Health Organization (WHO) (Solidarity Call to Action, 2020), United Nations (UN) (United Nations, 2020), the Organisation for Economic Co-operation and Development (OECD) (OECD, 2020), the European Data Protection Board Supervisor (EDPS) (EDPS Homepage | European Data Protection Supervisor, n.d.), the Council of Europe (Data Protection, 2021), and the Access to COVID-19 Tools (ACT) Accelerator (Staunton et al., 2021) have all emphasized the importance of using personal data in accordance with the right to privacy, and with appropriate data protection during the COVID-19 pandemic. Therefore, IPD sharing necessarily must be in accordance with the principles of data protection.

Data protection regulations across the world such as the General Data Protection Regulation (GDPR) (GDPR.Eu, 2018; Staunton et al., 2019) in Europe, the Protection of Personal Information Act (POPIA) (Mahomed and Staunton, 2021) 2013 in South Africa, and the General Personal Data Protection Law 13,709/2018 in Brazil (LGPD Brazil, 2018) have strengthened the protection of personal information. These are general data protection regulations that apply to the use of personal information in all sectors, including research. In the United States, the Health Insurance Portability and Accountability Act (HIPPA) protects personally identifiable information (CDC, 2019). Such regulations and laws directly affect the collection, use, and sharing of IPD. While they seek to safeguard the privacy of the individual, there are differing standards and protections. Indeed, within Europe, there has been a fragmented approach to the application of the GDPR at a national level. This is a challenge for research collaboration and the sharing of IPD (Staunton et al., 2019) and becomes even more problematic for the cross-border sharing of data. Further, jurisdictional differences in standards and protections not only hamper, but can prevent, the sharing of data (Bovenberg et al., 2020). Gratifyingly, such high levels of protection do not apply to anonymous data—data that cannot be reasonably re-identified. However, questions have been raised as to whether certain kinds of data can ever be truly anonymous, and anonymizing data limits its utility as other data cannot be linked to it in future. As such, the sharing of coded, or (in GDPR terms) pseudonymized data is preferred, but such data is considered personal data (GDPR.Eu, 2018). The USA's Federal Data Protection Act (1990) defines anonymization as "changing of personal information so that the individual information about personal or material relationships can no longer be assigned to a certain person or determinable natural person or only with an unreasonably great expense of time, costs and effort" or, simply put, deletion of identifying characteristics (Johner Institute, 2019).

Therefore, sharing of IPD must be rooted in human rights respecting the right to privacy, data protection, and other fundamental rights, and, furthermore, the preferences of participants as stated by the terms of informed consent, as appropriate (Guillou, 2020; Nature, 2021). Due to jurisdictional

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differences, there is a lack of standards on data sharing across the world. The current COVID-19 pandemic has witnessed a large number of clinical trials globally (ClinicalTrials.gov, 2020). Despite the importance of data sharing in an emergency, data-sharing agreements, legislative frameworks, and policies in data sharing in the context of a public health emergency vary considerably (Callaghan, 2020; Staunton and Mascalzoni, 2021). Our previous review highlighted the need to build a feasible data-sharing mechanism for clinical trial investigators including IPD sharing (Gudi et al., 2021). The COVID-19 Clinical Research Coalition (COVID-19 CRC) established a data-sharing working group, which identified IPD sharing as an important thematic area for policy research. This review was a component of the Strengthening Health Data Access for Health Systems Resilience and Evidence-informed policy for the COVID-19 response (SHARE) program of the COVID-19 CRC (Home|COVID-19 Clinical Research Coalition, 2020). While IPD sharing was and continues to be expected for COVID-19-related clinical trials, it is currently unclear how it has operated in reality thus far. Therefore, the objective of this review was to analyze the IPD-sharing intentions made by principal investigators (PIs) of drug and vaccine trials, in the context of the COVID-19 pandemic, as revealed in the appropriate data availability statements.

2. Methods

2.1. Review design

We received a request from the data-sharing working group of COVID-19 Clinical Research Coalition (COVID-19 CRC) since one of the authors (OJ) is a member of data sharing working group. The COVID-19 CRC is a consortium of researchers whose vision is to provide "a global research response to COVID-19 driven by the needs of people in low-resource settings" through advocacy and collaboration for the development of COVID-19 research, and "to strive for equitable access to solutions in the global response to the pandemic" (Home|COVID-19 Clinical Research Coalition, n.d.). In discussion with the data-sharing working group, we decided to analyze the IPD sharing intention in the data availability statement by PIs of the drug and vaccine trial investigators in the context of the COVID-19 pandemic. A rapid review approach was followed to address the objectives as a part of a priority-setting exercise. We conducted a rapid review as these approaches are often used when policy makers are required to make critical decisions in conditions such as the ongoing pandemic within a limited time frame (Tricco et al., 2017). Here, the traditional systematic or scoping review approaches are streamlined by limiting parameters such as the search date and language to provide timely evidence (Tricco et al., 2017).

2.2. Eligibility criteria

Inclusion criteria: Therapeutic drug and vaccine trials that were focused on the clinical management of COVID-19 or prophylactic use against COVID-19 have been included in this review.
Population: Human trials.
Intervention: Drug or vaccine trials aimed at either clinical management or prophylactic use against COVID-19.
Comparator: Type of comparator was not assessed as the team believed this is not significant given the scope of our review was to analyze data availability statements.
Study designs and type of publication: non-RCT study designs such as observational studies and non-randomized controlled studies were excluded. In addition to these, review-based publications such as scoping review, systematic review, and meta-analysis publications were also excluded.
Language: Full-text publication published in English language.
Timeline considered: January 1, 2020 to October 31, 2021. (The recent full-text publications for all the respective trial registrations were tracked until November 07, 2021).
Outcome: IPD sharing intentions as mentioned or documented in the data availability statement of full-text publication in RCT protocol or publication of RCT findings.

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Exclusion criteria: Clinical trials conducted under the principles of traditional systems of medicine alone or in combination with evidence-based medicine (often referred to as allopathic or modern medicine). Nutritional trials and non-drug or vaccine trials that evaluated alternative interventions such as physical activities, and cognitive therapies. Supportive therapies such as convalescent plasma and oxygen therapies were excluded. We excluded studies on convalescent plasma as we anticipated that most of these trials could halt mid-way if the WHO revise its Clinical Practice Guidelines (CPG). The WHO revised its CPG on the use of convalescent plasma on December 7, 2021 and recommended against its use for the management of COVID-19 (WHO, 2021). We excluded studies on oxygen therapies owing to the rapid nature of this review. We contacted corresponding authors seeking access to the full-text publications, as appropriate. If the author did not revert to us within 15 days, we excluded those studies as the full text was not available.

2.3. Searches

A literature search was conducted by NG on PubMed Central (NCBI) using the PubMed Advanced Search Builder (PubMed, 1996) since most of the COVID-19 studies were freely available, and there was a commitment from various publishers to make the evidence openly available to support ongoing public health emergency response efforts (Wellcome, n.d.; Tricco et al., 2017; Arrizabalaga et al., 2020; Lazarus et al., 2020). Common search terms were identified and combined to locate studies. We also searched for references of systematic reviews to collate a comprehensive list of RCTs. The search strategy is presented in Supplementary file 1: Search strategy.

2.4. Data extraction, analysis, and reporting

Screening and data extraction was conducted using MS Excel by the PK. This has been a recognized practice in the rapid review approach (Hartling et al., 2015; Polisena et al., 2015; Abou-Setta et al., 2016; Tricco et al., 2017). Trial details were extracted from the respective primary clinical trial registry. Data extraction was performed by PK for the following variables: registration details, country of trial implementation, trial start, and end date, and current trial status. The data availability statement was analyzed to determine whether the PI intended to share IPD: if so, when could IPD be expected to be shared? Who would provide access to IPD? If not, were reasons stated for not sharing IPD?

We summarized our review findings using a narrative approach with the aid of heat maps and descriptive statistics. We report the characteristics of the RCTs, the geographical distribution of single-country and multicountry RCTs, and WHO region-wise representations (World Health Organization, 2021). The status of the trial was identified as per the recruitment status classification on the ClinicalTrials.gov website. The status was classified as "Recruiting" if the trial was still recruiting participants; or "Not yet recruiting", if the trial had not begun recruitment; or "Active but not recruiting" if potential participants were not currently recruited or enrolled but the trial was ongoing with participants receiving the intervention or under examination. We classified trial status as "Suspended" if the trial was stopped early but could recommence; or "Terminated" if the trial stopped early, and participants were no longer being examined or treated; or "Completed" if the trial ended normally; or "Withdrawn" if the trial stopped before enrolling its first participant; or, finally, "Unknown" if the trial status had not been verified, or updated in primary clinical trial registry recently (ClinicalTrials.gov, l "B56" 2021).

The PI's intention to share IPD was coded as "Yes", "No", or "Undisclosed". We coded the following responses as "Undisclosed" if the PI failed to provide the description of IPD sharing intentions or an explicit mention of IPD sharing was absent. The time frame to share IPD was coded based on the investigators' description in relation to the trial completion and trial publication. We categorized the source of funding according to the type of funding agencies. Funding support by the government, or the ministry of health, or federal agencies were categorized as "public funding"; funding support from the independent entrepreneurs and non-profit organizations were categorized as "non-governmental organization"; finally, profit-based industrial agencies covering pharmaceutical, or vaccine manufacturers were categorized as "commercial

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funders". Independent research funding agencies or those associated with the academic organization were classified as "academic funders". If the PIs did not fully disclose the source of funding, we categorized them as "unclear". Any combination of various funding sources was categorized under "consortia of funders".

2.5. Reporting of the study

In the absence of specific reporting guidelines for a rapid review (EQUATOR Network, 2008; Tricco et al., 2017), we have adapted Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA- ScR) to report this rapid review (Annals of Internal Medicine, 2018).

3. Results

3.1. Search results

The initial search resulted in 768 records in PubMed (NCBI) and 28 records with a manual search. After removing duplicates, 653 (from our PubMed search) and 19 reports (from our manual search) were assessed for eligibility. Based on predefined eligibility criteria, we excluded studies if the following reasons applied: the study was not an RCT, not relevant to COVID-19 or a structured summary of protocol ($n = 235 + 9 = 244$), the study was a review-based publication ($n = 140 + 2 = 142$), the study concerned an alternative system of medicine or concerned nutritional or supportive therapy ($n = 92$), the study concerned animal trials ($n = 4$), was not in English ($n = 5$), or the full text of the study was not available ($n = 5$). We had written to one of the authors seeking the full-text publication edition; the author did not share the full text. Corresponding author details were missing for the other four publications. Since the full text was not available, we had to exclude these five publications (Figure 1: PRISMA chart). A detailed list of references utilized for this study is provided in Supplementary file 2.

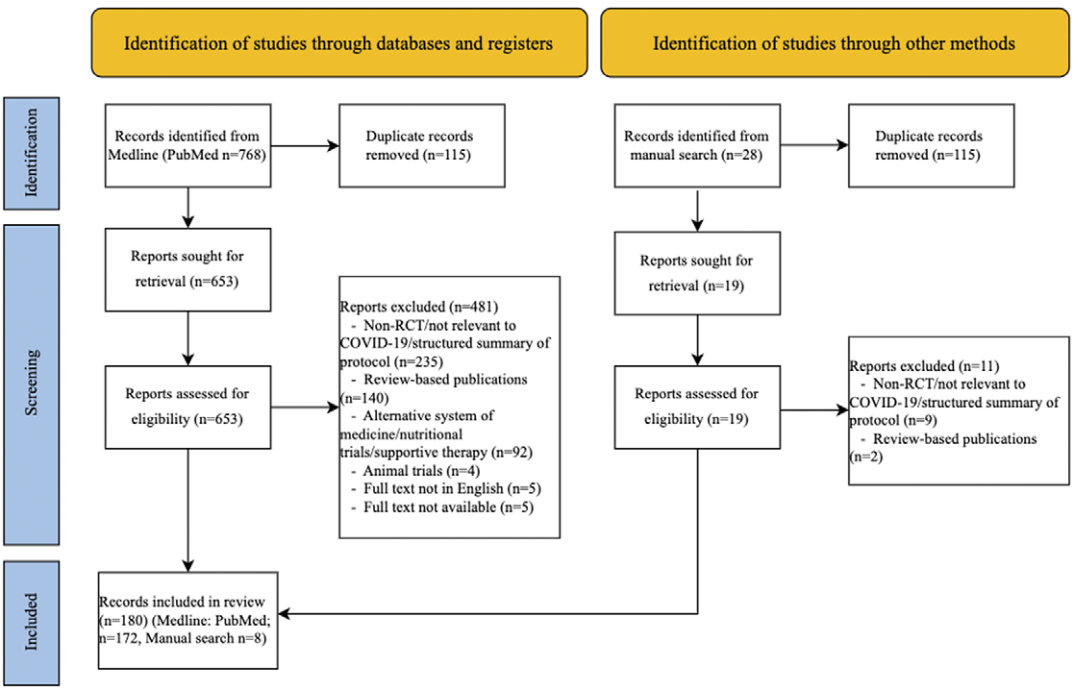

Figure 1. *PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) 2020 chart.*

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3.1.1. Characteristics of published RCTs (N = 180)

The important characteristics of published RCTs are reported in Table 1. A majority of the RCTs were drug trials (78.3%, 141/180). These drug and vaccine trials (21.7%, 39/180) were either completely new or repurposed for therapeutic and prophylactic use for COVID-19. Less than half of the RCTs were completed: 41.7% (75/180), while 17.2% (31/180) were recruiting participants. Trial status was unknown for 9.4% (17/180) of the RCTs. More than half (60%, 108/180) of the RCTs were registered on

Table 1. *Characteristics of published RCTs*

Trial characteristics	Categories	N (%)
Type of trial		
	Drug trials	141 (78.3%)
	Vaccine trials	39 (21.7%)
Trial status		
	Completed	75 (41.7%)
	Active, not recruiting	32 (17.8%)
	Recruiting	31 (17.2%)
	Status unknown	17 (9.4%)
	Terminated	11 (6.1%)
	Not yet recruiting	10 (5.6%)
	Ongoing	2 (1.1%)
	No longer recruiting	2 (1.1%)
Primary clinical trial registry		
	ClinicalTrials.gov	108 (60%)
	Iranian registry of clinical trials	18 (10%)
	Chinese clinical trial registry	17 (9.4%)
	EU clinical trials register	11 (6.1%)
	ISRCTN registry	7 (3.9%)
	Not known	6 (3.3%)
	Brazilian clinical trial registry	6 (3.3%)
	Clinical trial registry of India	5 (2.8%)
	Japanese primary registries network	1 (0.6%)
	Pan African registry	1 (0.6%)
Funding		
	Yes	154 (85.6%)
	No sufficient information	26 (14.4%)
Type of funder (n = 154)		
	Public funding	36 (23.4%)
	Consortia of funders	35 (22.7%)
	Academia	33 (21.4%)
	Commercial	19 (12.3%)
	Private funding	17 (11.1%)
	Non-profit organisation	10 (6.5%)
	Unclear	4 (2.6%)
Type of RCT publications		
	Publication of trial findings alone	147 (81.7%)
	Protocol publications alone	23 (12.8%)
	Both protocol, and publication of trial findings	10 (5.6%)

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ClinicalTrial.gov. The Japanese primary registries network (0.6%, 1/180) and the Pan African registry (0.6%, 1/180) registered fewer RCTs.

Funding information was available for most of the RCTs (85.6%, 154/180). Most (23.4%, 36/154) of the RCTs were publicly funded, followed by consortia of funders (22.7%, 35/154). The list of consortia of funders is given in Supplementary file 3 (Supplementary file 3: List of consortia of funders). A majority (81.7%, 147/180) of the publications are from the findings of the RCTs, 12.8% (23/180) of the publications were protocol publications, and 5.6% (10/180) of the RCTs had both published protocol and publication from the trial findings (Table 1). We have reported IPD sharing intentions in RCT protocol publications (n = 23 + 10) and publications from RCT findings (n = 147 + 10) separately.

3.1.2. Geographical distribution of RCTs (N = 180)

Out of 180 RCTs included, 85% (153/180) were single-country studies, and 15% (27/180) were multi-country studies. Among single-country studies (n = 153), China (n = 27), followed by Iran (n = 23), and the United States (N = 19) have reported a higher number of RCTs.

Multicountry studies (n = 27) were conducted across 44 countries. Among the multicountry studies (n = 27), the United States (n = 18) and the United Kingdom (n = 10) had the most frequently conducted RCTs (Figure 2). Data supporting analysis of single and multicountry studies is given in Supplementary File 4 (Supplementary File 4: Data supporting analysis of geographical distribution of single and multicountry RCTs).

3.1.3. WHO-region-wise distribution of RCTs

The WHO region-wise distribution (World Health Organization, 2021) of 180 RCTs showed that the European Region accounted for 34.4% of the RCTs, followed by the Region of the Americas (30.8%). The African Region (2%) and South-East Asia Region (4.3%) accounted for fewer RCTs (Supplementary file 5: WHO-region-wise distribution of RCTs).

3.1.4. Analysis of data availability statements in RCT protocol publications (N = 33)

*Intention to share IPD (*N = *33).* Among the RCT protocol publications (n = 33), 11 PIs intended to share IPD while three were not willing to share IPD. More than half (n = 19) of PIs did not disclose their intention to share IPD (Table 2).

*Time frame to share IPD (*N = *11).* Of the 11 PIs who intended to share IPD, only three had mentioned the anticipated time frame to share IPD. These time frames varied from each other as follows: after the study recruitment (n = 1), and after study completion (n = 1). One of the investigators described an ambiguous time point: "when IPD is ready to share" (Gyselinck et al., 2021) (Table 3).

*Reasons stated for not sharing IPD (*N = *3).* The reasons stated for not intending to share IPD are listed in Table 4. However, one of the PIs did not provide any reason (Table 4).

3.1.5. Analysis of data availability statement in publication of RCT findings (N = 157)

*Intention to share IPD (*N = *157).* In the publications reporting RCT findings, a majority (52.2%, 82/157) of the PIs indicated their willingness to share IPD, but 9.6% (15/157) explicitly stated that they have no plans to share IPD. However, 38.2% (60/157) of the PIs did not disclose any intent to share IPD (Table 5).

*Time frame to share IPD (*N = *82).* Of the PIs intending to share IPD (n = 82), 56.1% (46/82) outlined a time frame to share IPD, while 43.9% (36/82) did not specify a time frame at which IPD would be shared. The time points identified by the PIs were as follows: at 6 months (n = 1), at 12 months (n = 2), and at 18 months (n = 1) from trial completion. PIs also referred to time points from the trial publication as follows: within or at 1 month (n = 3), within or at 3 months (n = 4), and at 18 months (n = 1) from the

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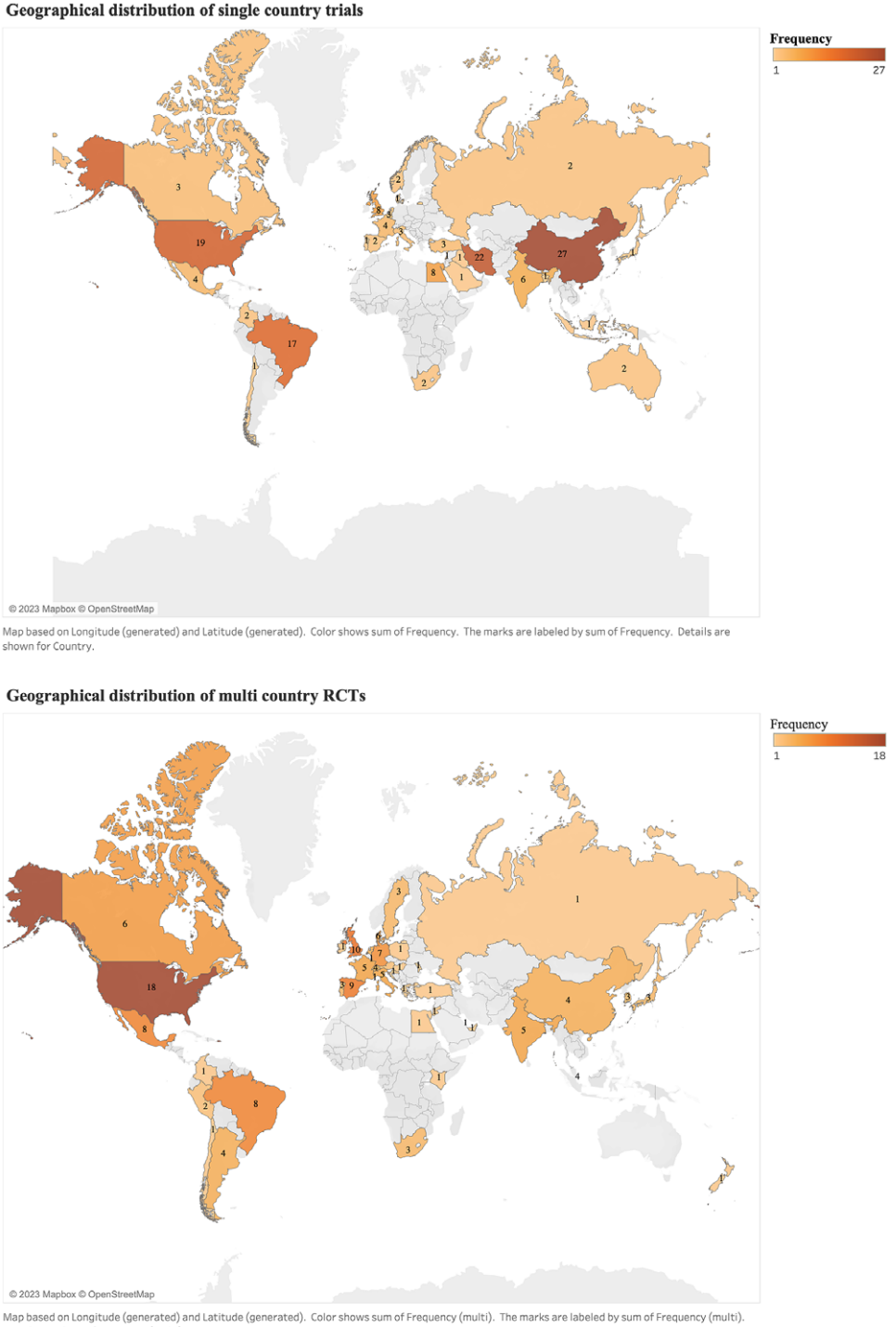

Figure 2. *Geographical distribution of single and multicountry RCTs.*
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Table 2. *IPD sharing intention in protocol publications*

IPD sharing intention	N (%)
Yes	11 (33.3%)
No	3 (9.1%)
Undisclosed	19 (57.6%)

Table 3. *Time frame to share IPD in protocol publications*

Time frame	*N* (%)
After the study recruitment	1 (33.3%)
After study completion	1 (33.3%)
When IPD is ready to share	1 (33.3%)

Table 4. *Reasons stated for not sharing IPD in protocol publications*

Reasons stated	N (%)
Study was ongoing	1 (33.3%)
Protocol publication	1 (33.3%)
No reason mentioned	1 (33.3%)

Table 5. *IPD sharing intention in publications of RCT findings*

IPD sharing intention	*N* (%)
Yes	82 (52.2%)
No	15 (9.6%)
Undisclosed	60 (38.2%)

publication of trial findings. PIs also made general reference to time frames without being specific on time points such as during or following trial completion ($n = 12$) and along with the publication of trial findings ($n = 22$) (Figure 3).

*Reasons stated for not sharing IPD (*N = *15).* Of the 15 PIs who were unwilling to share IPD, 11 failed to provide a reason for not doing so. PIs did not indicate their intention to share IPD in the foreseeable future either (Table 6).

3.1.6. IPD sharing intentions vs type of publications from RCT findings (N = 157)

Out of 157 publications from RCT findings, 18.5% (29/157) were based on interim or preliminary analysis and 4.5% (7/157) were based on the final results of trials. These specifications were missing for 77.1% (121/157) of RCTs. Figure 4 shows IPD sharing intentions based on the type of publications from RCT findings. Of the seven RCT publications with final results, 71% ($n = 5$) of PIs intended to share IPD and of the 29 interim or preliminary analyses, 52% ($n = 15$) of PIs intended to share IPD (Figure 4).

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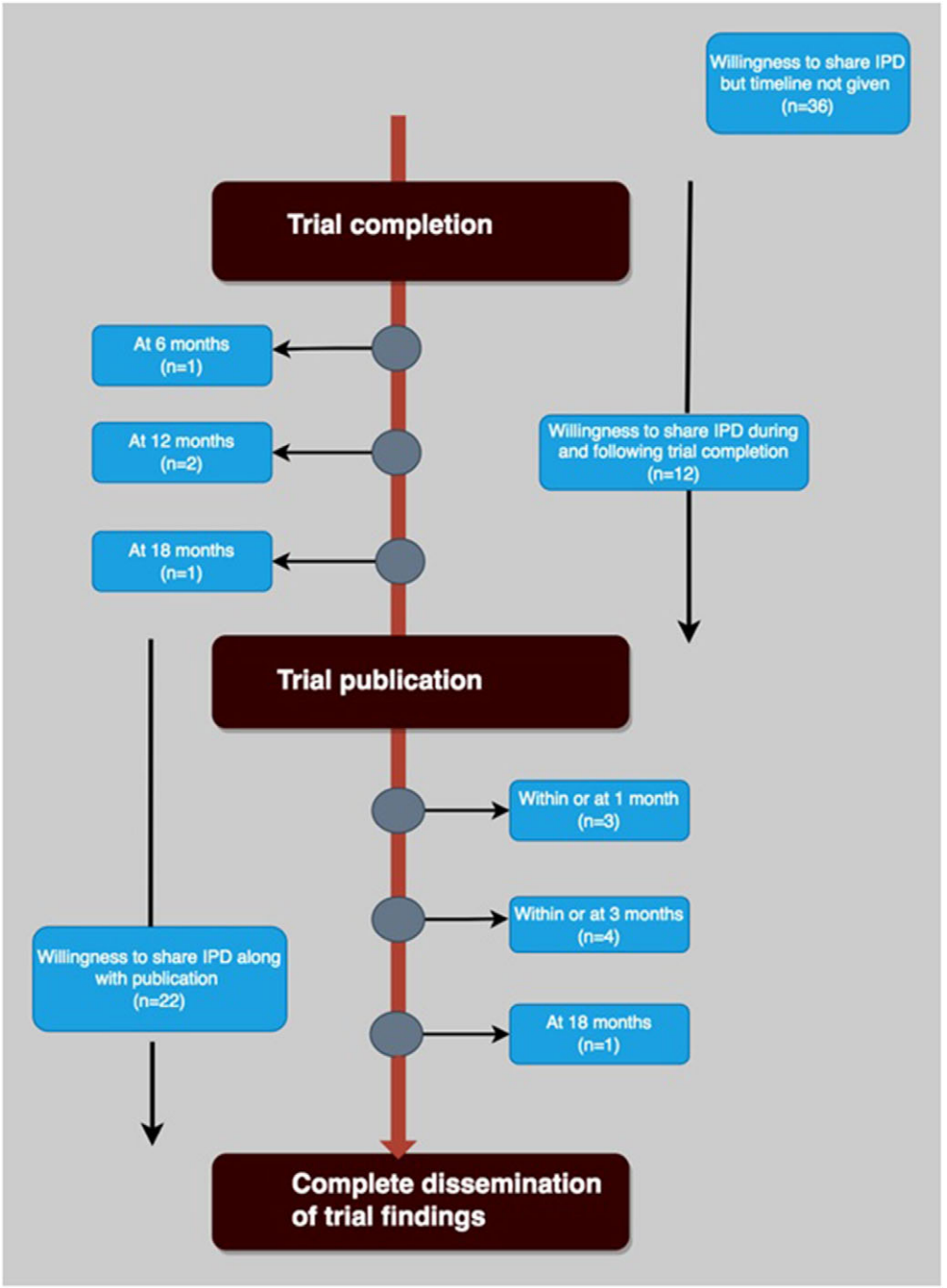

Figure 3. *Time frame to share IPD in publications of RCT findings.*

3.1.7. Type of funder vs IPD sharing intentions (N = 154)

Figure 5 presents our analysis of IPD sharing intentions across different types of funders. Among publicly funded RCTs, the majority (61%, 22/36) of PIs intended to share IPD. Similarly, 58% (11/19) of commercial funders and 57% (20/35) of consortia of funders intended to share IPD.

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Table 6. *Reasons stated for not sharing IPD in RCT findings*

Reasons stated	N (%)
No reason mentioned	11 (73.3%)
Interim analysis or preliminary analysis	4 (26.7%)

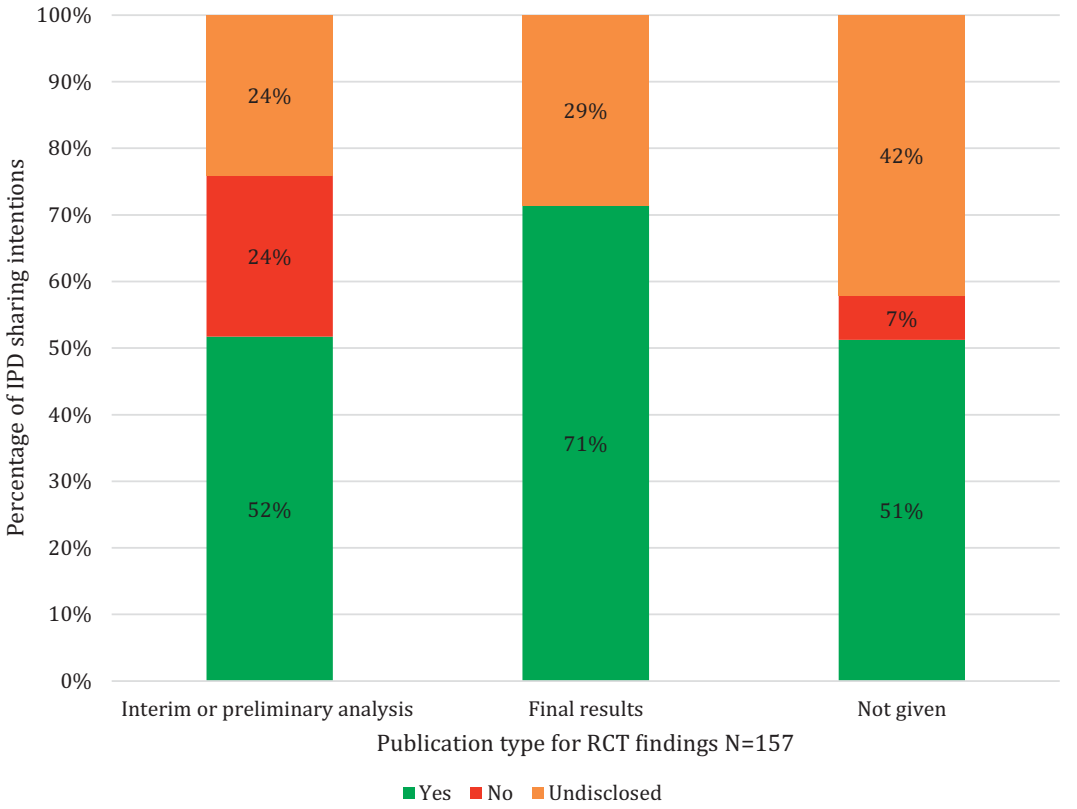

Figure 4. *IPD sharing intentions as based on type of publications from RCT findings.*

The ICMJE declaration on data sharing requires PIs to declare who would provide access to data in the data availability statement. When we analyzed this sub-question from the data availability statement, we found that only 2.2% (4/180) of the PIs declared that the funder would provide access to IPD. On examination of these four publications (Goldman et al., 2020; Mulligan et al., 2020; Caricchio et al., 2021; Salama et al., 2021) for the type of funder, we noticed that all of these were commercial pharmaceutical funders.

4. Discussion

4.1. Principal findings

This rapid review identified RCT drug and vaccine publications by clinical trial investigators in the context of COVID-19. Most RCTs were drug trials. China, Iran, and the United States reported a large number of RCTs. Of the 180 publications included, 33 were protocols while 157 were findings from RCTs. Among 33 RCT protocol publications, 33.3% of PIs intended to share IPD. On the other hand,

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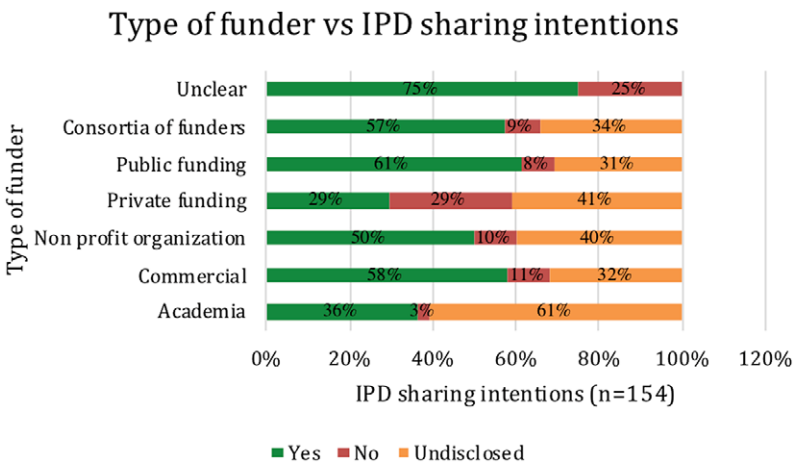

Figure 5. *IPD sharing intentions among different types of funders.*

based on the published RCT findings, more than half (52.2%) of the PIs stated that they intended to share IPD. However, varying time frames to share IPD were given by the PIs.

According to the WHO, timely sharing of clinical, epidemiological, and genetic research data are of paramount importance for a rapid pandemic response (World Health Organization and Organisation mondiale de la Santé, 2016; Pisani et al., 2018). In our review of publicly available and published RCT findings, the intention to share IPD (52.2%) is almost double compared to the recent review (21.4%) of publications during COVID-19 (Li et al., 2021). However, 57.6% of PIs among RCT protocol publications and 38.2% of PIs in publications of RCT findings did not disclose when they would share IPD with no reference to future intentions. Similar findings were reported in the previously conducted review on data sharing practices from infectious disease epidemics of WHO priority pathogens: 65% of PIs provided no information to discover or access data underlying research including IPD (Pisani et al., 2018). While clinical trial data is scientifically rich, limited access to such data potentially affects opportunities for evidence synthesis (Dron et al., 2021). It may well be that new RCTs may be focusing unnecessarily on the same drug or vaccines that may not prove treatment efficacy resulting in inefficiencies and duplication of research.

Unfortunately, arguments on whether to share, or not to share, interim or preliminary data still persist. On the side of standards, the ICMJE guides PIs to disclose what, where, when and how clinical data ideally ought to be shared with a special mention of whether, and when, IPD will be made available (Taichman et al., 2017). In our review, we found that 56.1% of PIs (among published RCT findings) described varying time frames in relation to trial completion and publication of trial findings. On reviewing the protocol publications, one study mentioned that IPD would be shared "when IPD is ready to share" (Gyselinck et al., 2021). This raises a veritable Pandora's Box of a range of equally valid questions concerning who would adjudicate this "readiness" to share IPD when multiple stakeholders are involved.

Funders can play a pivotal role in promoting data-sharing practices, and encourage IPD sharing for their grant recipients (Coetzee et al., 2021). During the pandemic, most of the funding agencies were concerned about sharing trial data, and these funders were guided by their own data-sharing policies (Gaba et al., 2020). In our review, 61% of publicly funded and 58% of commercially funded trials intended to share IPD. Among clinical trials funded by academic organizations, only 36% of PIs intended to share IPD. This proportion is lesser compared to other funding agencies. Such a practice might be a reflection of non-binding data-sharing policies. A recent survey showed that 41% (41/100) of commercial funders had a data-sharing policy in place, compared to 38% (30/78) of non-commercial funders (Gaba et al., 2020). Another study shows that out of 18 non-commercial funder policies, only two data-sharing policies

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required IPD sharing (JAMA Network, 2018). In our review, we found that follow-up questions concerning the data availability statement regarding who would provide access to IPD were rarely answered by PIs. Of the 180 publications, only four of the PIs had stated that the funder would provide access to IPD. These declarations were made by PIs on behalf of trial funders. On examining the funders of these four publications, we found that these four were commercial funders. We believe that, in reality, a larger proportion of funders could have played a significant role in making IPD available upon requests by researchers. A survey of commercial funders' data-sharing policies from a list of pharmaceutical association members, and the top 100 pharmaceutical companies in terms of sales showed that 80% (n = 33/41) of the funders mentioned that they have made IPD available upon request by researchers (Gaba et al., 2020). Such intentions of whether a funder intends to share IPD or is not declared by the PIs for the majority of publications. In our review, we have very little information on the degree and extent to which different types of funders play a role in IPD sharing.

Many registered clinical trials often do not get published, especially when sponsored by pharmaceutical firms (Xuemei et al., 2010; John et al., 2018). This further hampers IPD sharing. When a consortium of commercial funders sponsors trials, there are non-disclosure agreements. Such factors raise questions about the integrity and transparency of research. The EDPS recognizes this as corporate secrecy where commercial pharmaceutical firms are reluctant to share personal data and thereby have control over the use and re-use of IPD or any other forms of clinical trial data. To minimize this, the EDPS recommends stronger dialogue between data protection authorities and ethical review boards, thereby beginning the debate on the access to research data that is held by private companies in the light of larger public health interests (EDPS Homepage | European Data Protection Supervisor, n.d.).

Developing transparent standards will help. For this, further research is warranted in strengthening IPD sharing mechanisms and understanding the role of stakeholders in discussing the readiness and time frame to share IPD. PIs may lack clarity on IPD sharing. Moreover, clinical trial agreements are likely to serve as deterrents to IPD sharing. In particular, we strongly suggest that IPD sharing mechanisms address how to provide access to IPD and include guidance parameters for PIs regarding the timelines by which they ought to share IPD (given how long the actual evaluation of safety and treatment efficacy measures in an RCT take). It is evident from our review that the poor planning for IPD sharing right from the beginning of the trial is clearly a pattern, if not merely an inference. We recommend incorporating IPD sharing plans from the very beginning of clinical trials. Although the ICMJE (Taichman et al., 2017) requires authors to include data-sharing plans within published manuscripts, adherence to this remains suboptimal. We infer that the planning process for IPD sharing may not be well considered during the protocol design phase or thereafter. In addition to this, we found that none of the publications described a consenting process specific to IPD sharing in the public domain. Moreover, funders particularly those in the public sector could mandate that clinical trial agreements include IPD sharing as a key deliverable, and incentivizing the same is likely to enhance IPD sharing.

Data sharing mechanisms for IPD sharing need a consensus from many specialists. Our previous work has highlighted the importance of feasible data-sharing mechanisms for clinical trial data including IPD (Gudi et al., 2021). It is crucial to consider feasible data-sharing mechanisms that incorporate principles of data sharing. While both de-identification and anonymization processes potentially remove key identifiers from data, they take different approaches resulting in differing outcomes. Novel approaches such as the k-ANONYMITY models have been a boon to data-sharing efforts (Sweeney, 2002). Pseudo-anonymization of identifiable variables is another approach often used to share data. This approach uses a separate key where identifiers are classified using a code and these codes can only be accessed if the key is available (Johner Institute, 2019). Planning IPD sharing in the beginning must empower trial investigators to adhere to data-sharing principles, protect participant confidentiality, and overcome barriers such as participant consent for IPD sharing. From a pragmatic standpoint, ethical concerns associated with IPD sharing will continue to emerge. It follows that promoting science considering such concerns at various levels of the research process is vital. A good oversight mechanism should be in place to address such concerns a priori. IPD sharing should not be limited even in the context of the realities of data ownership and potential threats to data security. Towards this end, regulatory or oversight bodies must be empowered to balance the interests

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of researchers and trial participants. This will promote transparency and help foster IPD sharing in the scientific community. Tucker et al. (2016) emphasize the utility of clinical trial datasets which pave the ways for meaningful research while excessive application of legislation may pose a public health risk if misleading results are produced. Thus, capacity building and sensitization within the scientific community could be useful. In addition to capacity building around data sharing, a coordinated effort by trial funders, trial investigators, and technical agencies are crucial to foster IPD sharing in clinical research. The need for systematic evaluation of the factors that hinder IPD sharing and the design of effective interventions to incentivize IPD sharing requires research, implementation as well as ongoing encouragement.

Adherence to the research practice of publishing protocols and sharing the findings from trials has been poor during the contemporary COVID-19 pandemic. A recent paper reported a large number of investigators conducted COVID-19 trials without disseminating results in the form of scientific publications. Only 3.38% (n = 85) of PIs published trial results against a total of 2516 registered COVID-19-related clinical trials which implies that 97% of the PIs did not publish their trial results (Gaba et al., 2020). Similar observations have been noted in our review where the number of drug and vaccine RCT protocols that were published in academic journals were few. Solid ethical justifications for not sharing data do exist and must be respected. However, with the appropriate engagement and efforts of varied entities involved in research, our belief is that IPD deserves to be a common resource well positioned to be accessible as part of a global scientific commons in a manner that is legally and ethically acceptable.

4.2. Limitations

We have focused on COVID-19 therapeutic and prophylactic trials that limit the scope of our work to published drug and vaccine trials rather than nutritional and supportive trials such as oxygen therapy and plasma convalescent therapies. We would like to highlight that our interpretations are based on the author's descriptions in the data availability statement. However, we did not reach out to the authors of incomplete data availability statements. Further, we did not investigate why authors did not intend to share IPD and what had influenced PIs, and funders to agree to share IPD. We would like to acknowledge these factors as limitations of our review.

5. Conclusion

Our review scrutinized RCT publications to understand and describe IPD-sharing practices in the context of the COVID-19 pandemic. We found that IPD sharing from clinical trials during COVID-19 was suboptimal, lacking comparability if not uniformity. Based on our review, while PIs demonstrated their commitment to share IPD, this varied greatly. Data-sharing statements by PIs could be influenced by professional incentives to publish findings in high-impact journals as per ICMJE guidelines. However, improving IPD sharing practices is not easy as there are valid ethical concerns attached to it. For effective IPD sharing, key issues must be addressed: participant privacy, consent issues, data ownership, and data security. Collaborative efforts to promote IPD sharing in a legal and ethical manner involving various stakeholders thereby ensuring transparency in the funders' role in IPD sharing can augment collective efforts to build on existing foundations of solid data. As governments are working on proposals for an international instrument for pandemic prevention, preparedness, and response, the critical role of IPD sharing is being prioritized. In this context, the COVID-19 CRC through its data-sharing working group has initiated engaging various stakeholders at the global level. The acceleration of such efforts toward building a consensus and mainstreaming best practices around data sharing and policy guidance would be invaluably helpful to build preparedness for public health emergencies in the future.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/dap.2023.26.
Supplementary file 1. Search strategy.
Supplementary file 2. List of studies used for the analysis of this study.
Supplementary file 3. List of consortia of funders.
Supplementary file 4. Data supporting analysis of the geographical distribution of single and multicountry RCTs.

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Supplementary file 5. WHO-region-wise distribution of RCTs.

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Authors' contribution. O.J. and N.G. were responsible for the conceptualization of this study. N.G. and O.J. were responsible for methodology. P.K. was responsible for data curation and data analysis. This study was supervised by N.G. and O.J. The original draft was written by P.K., N.G., and O.J. P.K., N.G., O.J., C.S., and A.J. were responsible for writing, reviewing, and editing the manuscript. N.G., A.J., and O.J. were involved in making critical revisions. O.J. was involved in funding acquisition.

Data availability statement. All the data related to the review are presented in the supplementary file.

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