

Comparison of COVID-19 studies registered in the clinical trial platforms: A research ethics analysis perspective

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Abstract

Background: The coronavirus disease (COVID-19) treatment must be based on scientific methods such as clinical trials. Trials involving human subjects and those requiring a risk-benefit analysis may occasionally face challenges owing to the time limitations in the pandemic.

Methodology: This study analyses the WHO's International Clinical Trials Registry Platform and clinicaltrials.gov, where most COVID-19 clinical trials are registered, according to ethical criteria including study design, conflicts of interest, enrollment of healthcare workers, study locations, site-, design-, and participant-related issues. The discussion is based on three aspects: the quality of the information to be produced, the relevance to significant health problems, and the creation or evaluation of interventions, policies, or practices that promote individual or public health.

Results: There were significant differences between the two platforms regarding the investigational medicinal product (IMP), the comparator, ethics committee/institutional review board approval, plan to share individual participant data, study phase, site, IMP, and design-related issues. Conflict of interest, sponsor information, and management of vulnerable groups were the main areas wherein both platforms lacked sufficient information.

Conclusion: With this analysis, we aimed to define a minimum set of ethical criteria for clinical trial platforms to obtain standardization between these two platforms.

KEYWORDS

clinical trials, COVID-19, ethics, platform, research, standardization

1 | INTRODUCTION

The combination of the outbreak of the coronavirus disease (COVID-19) in Wuhan, China in December 2019, followed by the World Health Organization's (WHO) declaration recognising COVID-19 as a pandemic on March 11, 2020, resulted in an urgent race to find a permanent solution to the disease and an end to the pandemic. Clinical trials evaluating not only the investigational pharmaceutical products but also devices, supplements, etc., were explored during the conduct of this analysis and

writing the manuscript. Although the extent of the coronavirus disease (COVID-19) and the urgency to find a permanent solution, whether through an effective treatment or protection by a vaccine, are forcing investigators and regulatory authorities to work quickly, there are essential ethical rules that cannot be bypassed, or underestimated in light of this urgency.

Both the WHO International Clinical Trials Registry Platform (ICTRP) and ClinicalTrials.gov (CTG) were created in the early 2000s to "establish a voluntary platform to link clinical trials registers to ensure a single point of access and the unambiguous

identification of trials to enhance access to information by patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions."^{1,2}

The main aim of these platforms is not only to facilitate the prospective registration of all clinical trials but the public accessibility of that information as well. This study focuses on analyzing the discrepancies in clinical trial platforms and the lack of available essential information regarding the ethics and integrity of registered studies, which can be overlooked easily owing to the pandemic rush. The objective of this analysis is to identify the current standards of clinical trial platforms and to set a minimum of ethical criteria for them. Amending the clinical trial platforms per these standardized ethical criteria will better shape platforms for future clinical trials.

2 | METHODOLOGY

We analyzed 400 COVID-19 clinical trials from the ICTRP and CTG according to 19 criteria (Table 1). At the time the analysis was initiated on May 20, 2020, 808 studies were registered on the ICTRP. We considered that including 50% of the registered clinical trials would elucidate the ethical parameters selected for the analysis. Thus, we randomly selected 400 studies registered on the ICTRP and another 400 registered on CTG. Our research team included four researchers, and each researcher analyzed 100 randomly distributed studies from each platform. The random numbers were generated via www.random.org. After each investigator's analysis, one researcher reviewed all the reports to correct any inconsistencies and ensure standardization of the evaluation process.

The 19 criteria evaluated were selected from the minimum requirements set by the ICTRP and CTG and are listed below. The first 15 criteria were included in both platforms. The presence of criteria items 16 to 19 differed between platforms but was included in the analysis as they are ethically important.

The criteria in Table 1 were selected for evaluation based on brainstorming in the above-mentioned methodological process. We focused on criteria referenced in the platforms that were compatible with each other. We only searched the platforms for the presence of information addressing these criteria, instead of evaluating the quality of the information provided under each criterion.

The limitations of the criteria we chose were as follows: There was not enough or no data on some criteria. The analysis was completed considering this situation and we noted the limitations followed by a critical analysis and made suggestions for improvement.

Per our aim, we made a correlation between our results and the ethical principles outlined in the Council for International Organizations of Medical Sciences' (CIOMS) International Ethical Guidelines for Health-related Research Involving Humans. This ethical framework was selected because the CIOMS guidelines align the codes of human research ethics with the social value and necessity of scientific research. Our ethical analysis is based on the correlation of the scientific and social value of COVID-19 research and respect for patients' rights. The scientific and social value of research depends on three aspects: first, the quality of the information to be produced; second, the relevance to significant health problems; and third, its contribution to the creation or evaluation of interventions, policies, or practices that promote individual or public health.³

2.1 | Statistical analysis

Data were presented as numbers, percentages, and range (age), and the duration of the studies as median and range. The results of the two platforms were compared using a Fisher exact test, and 95% confidence intervals (CI) were calculated. Statistical significance was indicated by $p < 0.05$. SPSS statistics software was used for the data analysis.

3 | RESULTS

The number of volunteers to be recruited to clinical trials, and the range and median number of volunteers for each clinical trial phase are presented in Table 2. It also summarizes the phase categorization of each study. All three studies defined as a "new treatment measure clinical study" for phase categorization were from China. They were designed to evaluate the integration of traditional Chinese and Western medicine, the efficacy and safety of high dose intravenous vitamin C, and the efficacy of mesenchymal stem cells. Significantly more studies in CTG than in ICTRP indicated they were phase I ($p = 0.0033$, 95% CI: 1.26–6.51) or phase II ($p < 0.0001$; 95% CI: 8.59–20.29), or the phase was not applicable ($p = 0.0094$; 95% CI: 1.91–13.53). The ICTRP included significantly more studies with no phase information ($p = 0.0042$; 95% CI: 0.88–5.01).

3.1 | Investigational medicinal products and comparators

Table 3 shows the investigational medicinal products (IMPs) and comparators used in each study. Comparing the two platforms, CTG included significantly more studies investigating pharmaceuticals,

¹World Health Organization International Clinical Trials Registry Platform. (2020). About the WHO ICTRP. Retrieved August 10, 2020, from <https://www.who.int/ictip/about/en/>
²clinicaltrials.gov. (2020). *clinicaltrials.gov Background*. Retrieved August 10, 2020, from <https://clinicaltrials.gov/ct2/about-site/background>

³CIOMS. (2016a). International ethical guidelines for health-related research involving humans. Retrieved August 17, 2020, from <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>

TABLE 1 Criteria evaluated in the ICTRP and CTG

1. IMP	6. Conflict of interest	11. Study arms	16. Country of origin
2. Comparator (tried against)	7. Sponsored by	12. Eligibility criteria	17. Site-related issues
3. Ethics Committee/Institutional Review Board approval	8. Participants are healthcare workers (only)	13. Gender	18. IMP -related issues
4. Plan to share individual participant data	9. Study design	14. Age range (years)	19. Design-related issues
5. Informed consent procedure	10. Study phase	15. Addressing inclusion of vulnerable groups and plan on how to approach these groups	

Abbreviations: IMP, investigational medicinal product; CTG, clinicaltrials.gov; ICTRP, WHO's International Clinical Trials Registry Platform.

laboratory tests, and convalescent plasma than those in ICTRP. Contrarily, supplements, traditional medicinal products, and vitamins were evaluated in more studies in ICTRP than in CTG.

A placebo or an active comparator was used significantly more in CTG registered studies than ICTRP. Contrarily, the standard of care was used as a comparator significantly more in studies registered in the ICTRP than in CTG.

In Table 4, the numbers and percentages of several criteria are presented and significant differences between CTG and ICTRP indicated with p values.

Of the studies that declared conflict of interest (COI), nine (11.39%) were commercially sponsored studies (CSS) and 14 (4.36%) were non-CSS (NCSS), which was significantly different ($p = 0.0163$; 95% CI: 1.04%–16.06%).

The research registered in the two platforms did not differ in terms of the study design (Table 4). Among the ICTRP registered studies, the one that defined the design as not applicable tested the effects of having schools open or closed (which probably should not be classified as a clinical trial at all), and three studies provided no information on the design.

3.2 | Eligibility criteria, gender, and age

Of the studies registered in CTG, only two (0.5%) had no eligibility criteria (evaluating the diagnostic test/swab efficacy). Of the remaining 398 (99.5%) studies, six (1.51%) stated that all patients with a positive COVID-19 test are eligible. No other criteria were mentioned. Similarly, 398 (99.5%) studies registered in the ICTRP had eligibility criteria, one study did not, while another study stated it was not applicable as it aimed to evaluate the effectiveness of teaching how to apply a ventilator for non-anesthesiology residents.

All genders are included in the 393 (98.25%) studies in the CTG and 394 (98.5%) in the ICTRP. Of the studies registered in CTG, six (1.5%) and one (0.25%) included only women and men as participants respectively. Of the studies registered in the ICTRP, one (0.25%) planned to include only women, and two (0.5%), only men. Three (0.75%) ICTRP-registered studies provided no information on gender. We confirmed that the gender distribution in the studies is proportional and that only patients of a particular

gender are included for disorders related to COVID-19 that may be gender specific.

3.3 | Addressing the inclusion of vulnerable groups and plan on how to approach these groups

One study registered in the CTG (with children aged 3–10 years), and three in the ICTRP (with children aged 0–18 years, 1–15 years, and 10–16 years, respectively) included only children. Of the 28 (7.0%) studies registered in CTG and 47 (11.75%) in ICTRP that planned to recruit both children and adults, none declared specific arrangements for these participants. Three of the studies registered in CTG somewhat addressed the involvement of children with the following phrases: “Consent signed by at least one parent/holder of parental authority and assent of the child (if applicable); IC prior to initiation of any study procedures from subject (or legally authorized representative); refusal to participate from the parents or the child.” Similarly, studies recruiting only elderly people (> 65 years old; four in CTG and three in ICTRP) did not include details on handling age-specific issues ethically. The five studies with no age information and one study with age information indicated as “not applicable” evaluated the mental health and psychological status of doctors, nurses, and patients (the target of healthcare workers (HCWs) suggests an adult age group), and provided recommendations for the diagnosis and treatment of influenza patients in the COVID-19 pandemic, telemedicine, convalescent plasma, and remote rehabilitation using a wearable biological monitoring device.

The inclusion of information on vulnerable populations was also evaluated. Significantly fewer studies in CTG provided this information as part of their exclusion criteria than those in ICTRP ($n = 44$, 11.0% vs. $n = 79$, 19.75%, respectively; $p = 0.0006$; 95% CI: 3.76–13.73). Furthermore, 286 (71.5%) studies in CTG reported that no members of the vulnerable population would be included, while 197 (49.25%) studies in the ICTRP stated the same, significantly fewer than those in CTG ($p < 0.0001$; 95% CI: 15.53–28.68). Significantly more studies in ICTRP than in CTG did not specify anything to address vulnerability ($n = 66$, 16.5% vs. $n = 41$, 10.25%; $p = 0.0095$; 95% CI: 1.53–10.98) or indicated that the vulnerable population would be included but provided no mitigation plan ($n = 58$, 14.5% vs. $n = 29$, 7.25%; $P = 0.0010$; 95% CI: 2.95–11.61).

TABLE 2 Total number of volunteers and studies according to the phase of the study

Study Phase	n volunteers (%)	New treatment measure clinical study	0	I	II	III	IV	I and II	II and III	III and IV	Not applicable	No information	Total
CTG	n volunteers (%)	0	0	1071 (0.44)	25531 (10.37)	76164 (30.95)	12973 (5.27)	2789 (1.13)	25893 (10.52)	0	101218 (41.13)	336 (0.14)	246,093
	Median (range)	-	-	40 (9-1090)	120 (10-12000)	310 (10-15000)	300 (10-2414)	35 (4-1090)	256 (12-12000)	-	120 (10-40000)	168 (50-286)	
	n studies (%)	0	0	21 (5.25)	116 (29.0)	68 (17.0)	31 (7.75)	20 (5.0)	34 (8.5)	0	108 (27.0)	2 (0.5)	400
ICTRP	n volunteers (%)	260 (0.06)	13353 (2.89)	100 (0.02)	4301 (0.93)	142650 (30.90)	211005 (45.70)	801 (0.17)	19025 (4.12)	1324 (0.29)	56601 (12.26)	12290 (2.66)	461,710
	Median (range)	80 (10-3808)	80 (10-3808)	20 (5-24)	60 (10-140)	124 (10-100000)	240 (40-100000)	72.5 (30-160)	230 (150-10560)	-	100 (8-20000)	160 (24-6400)	
	n studies (%)	3 (0.75)	73 (18.25)	6 (1.5)	66 (16.5)	87 (21.75)	37 (9.25)	10 (2.5)	27 (6.75)	1 (0.25)	77 (19.25)	13 (3.25)	400

Abbreviations: CTG, clinicaltrials.gov; ICTRP, WHO's International Clinical Trials Registry Platform.

TABLE 3 Investigational medicinal products and comparators of each study registered in the CTG and ICTRP

	CTG (n, %)	ICTRP (n, %)	p value (95% CI)
Investigational medicinal products			
Pharmaceutical	238 (59.5)	209 (52.25)	0.0391 (0.37–14.03)
Oxygen	7 (1.75)	7 (1.75)	
Device	22 (5.5)	13 (3.25)	
Test	24 (6)	1 (0.25)	0.0001 (3.50–8.53)
Plasma	37 (9.25)	16 (4)	0.0029 (1.81–8.83)
Stem cell/cell	22 (5.5)	18 (4.5)	
Physiological intervention (exercise, prone position, etc.)	12 (3)	21 (5.25)	
Radio therapy	4 (1)	1 (0.25)	
Psychological intervention	22 (5.5)	23 (5.75)	
Vaccine	10 (2.5)	11 (2.75)	
Supplement, traditional medicinal herb	7 (1.75)	77 (19.25)	<0.0001 (13.50–21.75)
Vitamin	6 (1.5)	15 (3.75)	0.0467 (0.02–4.73)
The comparator			
Active	69 (17.25)	46 (11.5)	0.0205 (0.88–10.62)
Placebo	123 (30.75)	85 (21.25)	0.0022 (3.42–15.49)
Standard of care	110 (27.5)	164 (41.0)	0.0001 (6.93–19.91)
No comparator was used or was not applicable	104 (26.0)	105 (26.25)	

Abbreviations: CTG, clinicaltrials.gov; ICTRP, WHO's International Clinical Trials Registry Platform.

Table 5 shows the number and percentage of each vulnerability criterion included either as exclusion criteria or in the statement of including members of the vulnerable population.

3.4 | Country of origin

The 400 studies we evaluated registered in the CTG were from 47 countries. The highest number of studies was in the USA ($n = 123$; 30.75%), followed by France ($n = 45$, 11.25%), China ($n = 37$, 9.25%), Spain ($n = 21$, 5.25%), and Italy ($n = 20$, 5.0%). The 400 studies we evaluated registered in the ICTRP were from 27 countries, and 15 (3.75%) were multinational. China had the highest number of studies ($n = 140$; 35.0%), followed by Iran ($n = 98$; 24.5%), Spain ($n = 25$; 6.25%), France ($n = 20$; 5.0%), and India ($n = 20$; 5.0%).

3.5 | Site-, investigational medicinal product-, and design-related issues

No detailed information was shared regarding all four items of site-related issues (Table 6). However, some studies provided contact information for healthcare providers and research staff, and is evaluated within the scope of the information that has to be provided.

Regarding IMP-related issues, studies registered in CTG significantly more often shared the number of doses available than those in ICTRP. Contrastingly, CTG-registered studies had significantly less information regarding the number of doses likely to be available/scaling up issues/continued access than those in ICTRP. Information on the risk of IMP to health was significantly more often included in CTG-registered studies than in ICTRP ones.

While information on the duration of the study was shared in all CTG-registered studies ($n = 400$, 100%), only 296 (74%) of those in ICTRP shared this information ($p < 0.0001$; 95% CI: 21.83–30.51). For studies in CTG, the median duration was 7 months with a range of 1–44 months, and 5 months for those in ICTRP with a range of 1–60 months.

Information provided regarding bias-internal consistency and ability to maintain privacy and confidentiality in ICTRP-registered studies was greater than in those in CTG registered studies. Significantly more studies in ICTRP included information on the ability to maintain privacy and confidentiality (see Table 6).

4 | DISCUSSION

The results of the analysis in the CTG and the ICTRP revealed both the strengths and weaknesses of these platforms. The summary of the main findings is as follows: **the phase categorization** of studies in two databases is quite different; the ICTRP included significantly

TABLE 4 Comparison of presence of several criteria between CTG and ICTRP

	CTG (n, %)	ICTRP (n, %)	p value (95% CI)
Ethics Committee/Institutional Review Board approval status			
No Information	380 (95.0)	18 (4.5)	<0.0001 (86.90–92.89)
NA	11 (2.75)	14 (3.5)	
Plan to Share Individual Participant Data			
No information	81 (20.25)	126 (31.5)	0.0003 (5.19–17.21)
Will not be shared	193 (48.25)	16 (4.0)	0.0001 (38.83–49.37)
Planning to share it	51 (12.75)	207 (51.75)	<0.0001; (32.91–44.67)
Will be shared after de-identification	11 (2.75)	12 (3.0)	
Undecided	59 (14.75)	37 (9.25)	
NA	5 (1.25)	2 (0.5)	
Informed Consent Procedure			
Present	265 (66.25)	285 (71.25)	
No information	121 (30.25)	99 (24.75)	
Verbal	8 (2.0)	–	
NA	6 (1.5)	4 (1.0)	
Conflict of Interest Information Present	23 (5.75)	0	
Sponsor			
Commercial	79 (19.75)	45 (11.25)	0.0009 (3.49–13.50)
Noncommercial	321 (80.25)	355 (88.75)	
Healthcare Worker Participants	36 (9.0)	23 (5.75)	
Study Design			
Not applicable	0	1 (0.25)	
No information	0	3 (0.75)	
Case series	0	12 (3.0)	
Interventional	0	5 (1.25)	
Non-randomized	63 (15.75)	40 (10.0)	
Randomized clinical trials	302 (75.5)	312 (78.0)	
Single-arm trials	35 (8.75)	27 (6.75)	

Abbreviations: CTG, clinicaltrials.gov; ICTRP, WHO's International Clinical Trials Registry Platform; NA, Not applicable.

more studies with no phase information. When comparing the two databases, in terms of **IMPs and comparators**, CTG included significantly more studies investigating pharmaceuticals, laboratory tests, and convalescent plasma than those in ICTRP. On the contrary, traditional medicinal products were evaluated more in ICTRP than in CTG. The research registered in the two databases did not differ in terms of **study design** and 99.5% of the studies registered both in CTG and ICTRP had **eligibility criteria**. Checking the **COI declaration**, 11.39% were commercially sponsored studies (CSS) and 4.36% were non-CSS (NCSS). The inclusion of information on **vulnerable populations** was significantly fewer in studies in CTG (information provided as part of their exclusion criteria) than those in ICTRP. In terms

of **site-, IMP-, and design-related issues**, a few studies provided contact information for healthcare providers and research staff in both the databases. Studies registered in CTG significantly more often shared the number of doses available than did those in ICTRP. And information about **privacy and confidentiality** issues were significantly greater in ICTRP-registered studies.

Although the minimum WHO data set requirements do not include some criteria such as “COI, site-, IMP-, and design-related issues,” we conducted our analysis considering these criteria because the criteria beyond the minimum requirements were items that we thought were necessary to both provide ethical standards and guide researchers who might want to conduct similar research or make an

TABLE 5 Number and percentage of each vulnerability criterion included either as exclusion criteria or in a statement of inclusion of vulnerable population for each study in the CTG and ICTRP

Exclusion criteria	CTG (n; %)	ICTRP (n; %)	p value (95% CI)
Pregnancy	26 (59.09)	72 (91.14)	0.0002 (16.31-44.32)
Lactating	14 (31.82)	43 (54.43)	0.0145 (4.49-39.18)
Childbearing potential	0	2 (2.53)	NA
Mental/intellectual inability	4 (9.09)	9 (11.39)	–
Language difficulties	0	2 (2.53)	NA
Psychological	1 (2.27)	3 (3.80)	–
Lack of ability to provide informed consent	6 (13.63)	2 (2.53)	0.0467 (–0.22-20.59)
Legal protection/guardianship	3 (6.82)	3 (3.80)	–
Police/military	0	2 (2.53)	NA
Prisoner	5 (11.36)	1 (1.27)	0.0457 (–0.30-19.02)
Elderly	1 (2.27)	0	NA
Emergency	0	0	NA
Cancer or chronic illness	7 (15.91)	0	NA
Minors	1 (2.27)	0	NA
Yes to inclusion of vulnerable groups			
No specification	5 (17.24)	49 (84.48)	<0.0001 (46.51-79.24)
Severe disease	13 (44.83)	3 (5.17)	<0.0001 (21.0-57.61)
Cancer	2 (6.90)	0	NA
Minors	2 (6.90)	0	NA
Elderly	3 (10.35)	8 (13.79)	–
Comorbidity	6 (20.69)	4 (6.90)	–
Healthcare workers	1 (3.45)	0	NA

Abbreviations: CTG, clinicaltrials.gov; ICTRP, WHO's International Clinical Trials Registry Platform.

accurate and sufficiently informed decision for those considering participating in the study

Considering the results, answers to some questions such as “what did WHO take into account when determining the minimum requirement?”, “how much have ethical values have been taken into account?” and “what should be the minimum for both scientific quality and volunteer well-being under pandemic conditions?” have been discussed.

4.1 | Phase and number of subject discrepancies

Phase 0 trials are conducted to gather preliminary data on the agent's pharmacokinetics on a small group of volunteers (10–15).⁴ The median number of volunteers for phase 0 studies in ICTRP does not seem to fit its “small number of subjects” definition. From an ethical viewpoint, volunteers do not have an advantage of therapeutic utility

from the small doses given in phase 0 studies. Moreover, patients are not allowed to enroll in a trial with therapeutic intent, which is unethical considering the detrimental effects of enrolling a COVID-19 patient without any possible treatment.⁵

Phase I studies are performed on a small group of (20–100) healthy volunteers, and phase II trials on groups of 100–300 people with a specific disease and are designed to assess how well the drug works. However, in some studies, the recruitment goal did not correlate with the definition of the phase of the study; for example, a study recruited 580 patients and it was recorded as phase I.⁶ Considering the urgent need to decrease the detrimental effects of COVID-19, particularly the number of deaths and long-term hospitalizations, including more than the defined number of subjects in phase I or II vaccine studies may be

⁴Coloma, P. M. (2013). Phase 0 clinical trials: theoretical and practical implications in oncologic drug development. *Open Access Journal of Clinical Trials*, 5, 119–126.

⁵Editorial. (2009). Phase 0 trials: A platform for drug development? *Lancet*, 374(9685), 176. [https://doi.org/10.1016/S0140-6736\(09\)61309-X](https://doi.org/10.1016/S0140-6736(09)61309-X)

⁶clinicaltrials.gov. (2020). The Impact of Camostat Mesilate on COVID-19 Infection (CamoCO-19) Identifier: NCT04321096. Retrieved September 6, 2020, from <https://clinicaltrials.gov/ct2/show/NCT04321096>

TABLE 6 Site-, IMP- and design-related issues of each study in the CTG and ICTRP

	CTG (n; %)	ICTRP (n; %)	p value (95% CI)
Site-related issues			
Healthcare provider availability	68 (17)	279 (69.75)	<0.0001 (46.61-58.21)
Research staff availability	268 (67)	375 (93.75)	<0.0001 (1.51-31.90)
Infrastructure	1 (0.25)	7 (1.75)	<0.0331 (0.04-3.33)
Capacity for ethics review	1 (0.25)	114 (28.5)	<0.0001 (23.89-32.87)
IMP-related issues			
Prior knowledge about safety/ effectiveness			
Not applicable	105 (26.25)	96 (24.0)	
No	232 (58.0)	253 (63.25)	
Yes	63 (15.75)	51 (12.75)	
Number of doses available			
Not applicable	105 (26.25)	87 (21.75)	<0.0001 (8.02-18.91)
No	52 (13.0)	106 (26.5)	0.0103 (2.12-15.76)
Yes	243 (60.75)	207 (51.75)	
Number of doses likely to be available/ scaling up issues/continued access			
Not applicable	110 (27.5)	132 (33.0)	<0.0001 (9.09-22.70)
No	238 (59.5)	174 (43.5)	0.0001 (5.17-15.79)
Yes	52 (13.0)	94 (23.5)	
Risk to health			
Not applicable	104 (26.0)	128 (32.0)	<0.0001 (6.51-14.18)
No	242 (60.5)	259 (64.75)	
Yes	54 (13.5)	13 (3.25)	
Design-related issue			
Bias-internal consistency			
Not applicable	121 (30.25)	0	<0.0001 (24.92-34.22)
No information	278 (69.5)	396 (99.0)	
Information present	1 (0.25)	4 (1.0)	
Ability to maintain privacy and confidentiality			
Not applicable	101 (25.25)	6 (1.5)	<0.0001 (19.38-28.30)
No information	278 (69.5)	345 (86.25)	<0.0001 (11.06-22.33)
Information present	21 (5.25)	49 (12.25)	0.0005 (3.11-11.0)

Abbreviations: IMP, Investigational Medicinal Product; CTG, clinicaltrials.gov; ICTRP, WHO's International Clinical Trials Registry Platform.

understandable. However, at the time of our analysis, a total of 22 vaccine trials were registered on both platforms and one vaccine trial from each platform aimed to recruit >10000 volunteers.

This situation raises three different research ethics problems:

1. Risk mitigation and avoiding unnecessary harm: Including more than the necessary number of patients in the study implies exposing them to more risk than they should be, in such a case the principle of "do no harm" is ignored.

2. Protecting research integrity: Determining the sample size incompatible with the research protocol and standard rules of phase studies is one of the essential issues to breach research integrity.
3. Justice and unfair distribution of resources: For COVID-19 clinical trials and treatment attempts, time, number of researchers, protective materials, research/treatment resources, and scientific knowledge are limited. The question regarding how to decide on the allocation of limited resources is both medical and ethical. Wasting resources and the simultaneous performance of similar comprehensive studies creates duplication, which affects the principle of justice through the unfair distribution of research resources. This approach reduces the capacity to contribute to the creation of new interventions or practices when they are needed, and therefore, results in the scientific and social inferiority of every study conducted thus far.

Several similar studies evaluating the same IMP such as hyperbaric oxygen treatment choose various phases for their studies. Of the studies evaluating pharmaceuticals that declare the phase was “not applicable,” some are likely to be classified as phase III or phase IV, as they evaluate the efficacy and safety of drugs, most of which already have marketing authorization for other indications and are being evaluated for a new indication, namely the treatment of COVID-19. A discrepancy in design criteria was evident for one study defined as interventional, but that claims to be retrospective. The inconsistency of phases suggests a lack of sufficient knowledge and/or overlooking basic issues of research integrity during research planning or entering data into the platform.

4.2 | Investigational medicinal product discrepancies

If the research is being conducted to show or prove the clinical importance or value of the product, and to confirm safety or efficacy, then it must follow standardized pharmacokinetic and pharmacodynamic rules. Today, while there is proven technology to show the active compound profile in each plant in the finest detail and to investigate its efficacy and safety profile, avoiding this is ignoring the accumulated scientific literature. What we witnessed was that while CTG included more studies investigating pharmaceuticals, ICTRP included more studies investigating supplements, traditional medicinal products, and vitamins. The excessive concentration and accumulation of information in the literature on such traditional approaches, whose scientific validity seems controversial, creates complexity and difficulties for scientists in accessing the necessary scientific information.

4.3 | Ethics committee/institutional review board approval and informed consent procedure discrepancies

The main purpose of both platforms is not to provide ethical information about the clinical trials but to announce the initiation and results of the conducted studies to the public, primarily patients, on web pages.

Therefore, the platforms' approach is considered in terms of presenting information to the patient. However, if the reliability and reproducibility of a clinical study are to be validated through these platforms, it is inevitable to be able to prove its ethical acceptability, that is, to share the Ethics Committee/Institutional Review Board (EC/IRB) approval status and information. The users of these platforms may think that any protocol registered on the platform has an EC/IRB approval by default, but our research proved that this assumption is incorrect. For example, one study declares that recruitment was initiated, but also states that ethical approval has not yet been received, which is an obvious ethical breach.

Up-to-date EC/IRB approval information is very important for researchers who examine the platform to review studies similar to the ones they are planning. For example, at the beginning of the COVID-19 pandemic, there were discussions about whether the studies related to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) were included in a full review or whether they were first passed through an expedited review or, if necessary, a full review. After the research was initiated, if there was a problem, a full review was made. Therefore, entering full review information into the platform reduces the concerns of researchers about this issue. Moreover, if EC/IRB decides to modify, suspend or cancel the study, researchers should record these changes to the respective research registries as soon as possible including those that are part of ICTRP. In the case of the suspension or cancellation of the study, investigators should communicate this decision to the scientific community and the public.⁷

4.4 | Informed consent procedure

The CIOMS guidelines state that “*the individual IC of participants is obtained even in a situation of duress unless the conditions for a waiver of IC are met.*” The urgency caused by the COVID-19 pandemic creates a situation of duress; however, there were studies raising concern regarding the most indispensable procedure of clinical trials guaranteeing patient autonomy and rights. For example, one study registered on CTG stated that it included volunteers who provided written or verbal consent, or without consent.⁸ Eight studies stated that consent will be obtained, indicating the exclusion criterion “*refusal to participate in the research,*” but not indicating whether it will be written or verbal.⁹ Correlatively, eleven of

⁷Pan American Health Organization (PAHO). (2020). Guidance for ethics oversight of COVID-19 research in response to emerging evidence. Retrieved November 30, 2020, from <https://iris.paho.org/handle/10665.2/53021>

⁸clinicaltrials.gov Identifier: NCT04346589. Retrieved September 6, 2020, from <https://clinicaltrials.gov/show/NCT04346589>

⁹clinicaltrials.gov Identifier: NCT04357028. Retrieved September 6, 2020, from <https://clinicaltrials.gov/ct2/show/NCT04357028>; clinicaltrials.gov Identifier: NCT04354441. Retrieved September 6, 2020, from <https://clinicaltrials.gov/ct2/show/NCT04354441>; clinicaltrials.gov Identifier: NCT04255017. Retrieved September 6, 2020, from <https://clinicaltrials.gov/ct2/show/NCT04255017>; clinicaltrials.gov Identifier: NCT04254874. Retrieved September 6, 2020, from <https://clinicaltrials.gov/ct2/show/NCT04254874>; clinicaltrials.gov Identifier: NCT04390152. Retrieved September 6, 2020, from <https://clinicaltrials.gov/ct2/show/NCT04390152>; clinicaltrials.gov Identifier: NCT04366817. Retrieved September 6, 2020, from <https://clinicaltrials.gov/ct2/show/NCT04366817>; clinicaltrials.gov Identifier: NCT04325867. Retrieved September 6, 2020, from <https://clinicaltrials.gov/ct2/show/NCT04325867>; clinicaltrials.gov Identifier: NCT04355234. Retrieved September 6, 2020, from <https://clinicaltrials.gov/ct2/show/NCT04355234>

the ICTRP- registered studies stated they are undecided about obtaining IC, and one study stated that it will register the patients and obtain consent later.

4.5 | Individual participant data share discrepancy

Clinical trial data should be shared and treated as a public good, that is, whether they are publicly funded or commercial.¹⁰ Ethically, if access to health and healthcare is a basic human right, access to clinical trial data that can improve health is similarly a fundamental right, and those patients involved in research have an obligation to their fellow citizens to respect and promote it.¹¹ This is the only way to properly recognize the value of the data and the generosity of the patients who provided them. Although the researchers who generate the data may have the greatest stake in their use, they should not perceive it as their “private property”. So, any data sharing model should be based on the concept of data “stewardship” rather than data “ownership”.¹² The presence of the consent to collect and use personal data draws the boundaries between the definitions of data stewardship and ownership. The EU clinical trial regulation 536/2014 also refers to the reuse of data from clinical trials for future scientific research, underlining the importance of the consent to use data outside the protocol of the clinical trial, the right to withdraw that consent at any time, and mechanisms to review that secondary analyses are appropriate and ethical.¹³ However, some studies planning to share individual participant data (IPD) provide no information on how to maintain the privacy and confidentiality of the subjects. For example, regarding the IPD share plan, one study merely states that the “*medical history and biographical and clinical data of each patient will be recorded and shared.*” We consider this issue an inconsistency caused by a tendency for “sloppy” research. There may be two reasons for its conceptualization. First, the researchers may be doing it just to enter data into the platform without questioning the consistency or accuracy thereof. Second, researchers supported by funding organizations that adopt an open science strategy may be accepting the IPD share plan without questioning the ethics because of this strategy requirement. If identifiable personal information is included among the IPD to be shared, this data should be anonymized to protect subjects’ privacy and confidentiality. If disclosed to third parties, the collection of health data could cause harm, stigma, or distress. Access to IPD and trial documents should be as open as

possible and as closed as necessary to protect participant privacy and reduce the risk of data misuse. IPD related concerns for the sponsors who are the data controllers include the inability to protect participant privacy, and for the investigators who are the data generators, include the possible misinterpretation of the data.¹⁴ To us, the fact that no explanation or precaution was taken regarding this matter implies that the researchers did not sufficiently know the scope of open science.^{15,16} What is more, before open access to clinical trial data is authorized, some further considerations should be taken into account such as safeguarding the rights of patients who enter trials, protecting the intellectual property rights of the researchers who designed the trial and collected the data, and providing a barrier against unnecessary duplication.¹⁷ Determining the minimum data entry requirement regarding ethical aspects of the protocol would enhance the scientific quality and volunteer well-being; both concern the researchers and potential trial subjects. For example, the requirement to enter an IPD plan raises awareness for researchers. Standardizations for “publicly available” research data are especially important in the context of the COVID-19 pandemic, as new scientific evidence is being produced rapidly. This rapid and crucial production of knowledge can impact the social and scientific value of COVID-19 studies, their risk/benefit balance, and other aspects of their ethical acceptability.¹⁸

4.6 | Conflict of interest discrepancy

According to our results, there is no information regarding any COI of investigators in most studies registered in CTG and none of the studies registered in ICTRP. COI information is especially important not only for CSS but also for NCSS.¹⁹ Open science strategies at the national and international levels are being adopted expeditiously.^{20,21} Funding decisions comprise an earlier step of the research process. In terms of conducting and publishing the research, funding should also be transparent in an open science approach. Research funding and policy-making organizations are responsible for the transparency

¹⁴Ohmann, et al., op.cit, note 12.

¹⁵Martinez, C. I., & Poveda, A. C. (2018). Knowledge and perceptions of open science among researchers—A Case Study for Colombia. *Information*, 9, 292. <https://doi.org/10.3390/info9110292>

¹⁶Kaba, A., & Said, R. (2015). Open access awareness, use, and perception: A case study of AAU faculty members. *New Library World*, 116(1/2), 94–103. <https://doi.org/10.1108/NLW-05-2014-0053>

¹⁷Sydes, M. R., Johnson, A. L., Meredith, S. K., et al. (2015). Sharing data from clinical trials: the rationale for a controlled access approach. *Trials*, 16, 104. [10.1186/s13063-015-0604-6](https://doi.org/10.1186/s13063-015-0604-6)

¹⁸Pan American Health Organization (PAHO). (2020). Guidance for ethics oversight of COVID-19 research in response to emerging evidence. Retrieved November 30, 2020, from <https://iris.paho.org/handle/10665.2/53021>

¹⁹CIOMS. (2016b). Conflict of interest. international ethical guidelines for health-related research involving humans. Retrieved September 7, 2020, from <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>

²⁰European Commission (EC). (2018). *Open Science Policy Platform*. Retrieved August 11, 2020, from <https://ec.europa.eu/research/openscience/index.cfm?pg=open-science-policy-platform>

²¹TUBITAK. (2019). Open Science Policy. Retrieved August 11, 2020, from <https://ulakbim.tubitak.gov.tr/en/haber/tubitak-open-science-policy-accepted>

¹⁰Reichman, J. H. (2009). Rethinking the role of clinical trial data in international intellectual property law: the case for a public goods approach. *Marquette Intellect Prop Law Rev*, 13, 1–68.

¹¹Lemmens, T., & Telfer, C. (2012). Access to information and the right to health: the human rights case for clinical trials transparency. *Am J Law Med*, 38, 63–112.

¹²Ohmann, C., Banzi, R., Canham, S., et al. (2017). Sharing and reuse of individual participant data from clinical trials: principles and recommendations. *BMJ Open*, 7, e018647. <https://doi.org/10.1136/bmjopen-2017-018647>

¹³European Union (EU). (2014). Official Journal of the European Union. 50 Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use. Retrieved December 30, 2020, from https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

of publicly funded research. Today, this is important in terms of knowing the ratio of the public research budget allocated to COVID-19. Moreover, providing information on COI would enhance the transparency and reliability of a study. The primary aim of funding organizations or researchers should always be to generate the scientific knowledge needed to promote human health, not scientific recognition or financial gain. Transparency is crucial in maintaining the public's trust in the scientific process, and COI documentation warrants the ethical conduct of research and the absence of any kind of COI. Therefore, researchers must address COI during the grant application process.^{22,23}

4.7 | Subject issue discrepancies and ethical implications about vulnerability

Protection of subjects included in studies conducted in hierarchical environments such as the military or police force must be considered and the necessity of inclusion of these subjects must be well defined. Two studies in ICTRP performed on naval personnel or police lack this information.²⁴ HCWs are exposed to the risk of infection during long work hours, rendering them one of the most vulnerable groups of people in the COVID-19 pandemic, because of the hypothetical social contract between them and society. When subjects are likely to be vulnerable to coercion or undue influence, additional safeguards should be included in the study to protect their rights and welfare.²⁵ Understanding the scope of vulnerability depends on recognizing the power differential; vulnerable populations are influenced by individuals with the power in the relationship. HCWs are employees in this type of power differential.

According to the CIOMS guidelines, the ethical implication of recruiting employees as research subjects is the over-representation of humans that are already disadvantaged and it may cause serious ethical problems. First, HCWs or people working in a hierarchical environment already experience increased risks from social and economic disadvantage, meaning the risk posed by COVID-19 research may be too excessive to endure. Second, if these disadvantaged groups are already at risk of research, it should be ensured that they will not be excluded from or they do not have difficulty in accessing the benefits of the study. Rather, they should

be the first to benefit from the research results.²⁶ Therefore, these public databases should include information about the justification for recruiting only from these vulnerable populations and risk mitigation strategies to avoid exploitation of these subjects.

It is also important to discuss age in terms of vulnerability.²⁷ Studies planning to recruit children did not declare specific arrangements for these participants. The need for specific arrangements underlines the fact that children and adolescents must be included in health-related research unless a good scientific reason justifies their exclusion.²⁸ In CTG, we found phrases such as “*consent signed by at least one parent/holder of parental authority and assent of the child (if applicable); IC prior to initiation of any study procedures from the subject (or legally authorized representative); refusal to participate from the parents or child.*”²⁹ Similarly, studies in both CTG and ICTRP recruiting only elderly people did not address ethical issues regarding age. We also observed that no precautions were noted for subjects in studies with the potential to include patients who are pregnant or lactating.

In the case of COVID-19 trials, the capacity to consent to research participation is the main criterion of vulnerability.³⁰ Two reasons why people may not be able to decline to consent may be due to therapeutic misconception, as mentioned above, and second, as an individual who has been infected and quarantined, the patient may think he or she has nothing to do but participate in the research.

The discrepancies regarding inclusion-exclusion information criteria are another important issue for discussion. Several studies had only one inclusion criterion, namely “*testing positive for COVID-19,*” and one exclusion criterion, “*not consenting to participate in the study.*” A scientifically sound and ethically appropriate research protocol should provide eligibility criteria coherent with the content of the ICP. Although there is no standard for the number of inclusion/exclusion criteria in terms of explaining the basic elements of IC such as the aim of the research and benefits or risks to the subjects, IC remains the cornerstone of participating in a study. Subjects should be certain about their decision to enroll in “scientifically designed research.”

We also noted several studies' mandates as “*having medical insurance*” or to “*be included in the insurance systems of x country*” as inclusion criteria. This is ethically problematic because this situation, unfortunately, sets the stage for therapeutic misconception. If the research methodology were presented to the subjects as a treatment

²²CIOMS. (2016b). Conflict of interest. international ethical guidelines for health-related research involving humans. Retrieved September 7, 2020, from <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>

²³National Institute of Health (NIH). (2016). Being Transparent About Conflict of Interest. Retrieved September 7, 2020, from <https://www.nih.gov/about-nih/what-we-do/science-health-public-trust/perspectives/being-transparent-about-conflicts-interest>

²⁴Sri Lanka Clinical Trials Registry. (2020). Hydroxychloroquine for Post-Exposure Prophylaxis of COVID-19 among naval personnel: a placebo-controlled, randomized, clinical trial. Trial Number: U1111-1251-3613. Retrieved September 13, 2020, from <https://slctr.lk/trials/slctr-2020-011>

²⁵Electronic Code of Federal Regulations. (2018). Code of Federal Regulations for criteria for IRB approval of research. Retrieved August 11, 2020, from https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pid=20180719&n=part45.1.46&r=PART&ty=HTML#se45.1.46_1111

²⁶CIOMS. (2016a). International ethical guidelines for health-related research involving humans. Retrieved August 17, 2020, from <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>

²⁷Evans, N. (2020). COVID-19: The ethics of clinical research in quarantine. *BMJ*, 369, m2060. <https://doi.org/10.1136/bmj.m2060>

²⁸CIOMS. (2016c). Research involving children and adolescents. Retrieved September 7, 2020, from <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>

²⁹clinicaltrials.gov. (2020). Identifier: NCT04376476. Retrieved August 19, 2020, from <https://clinicaltrials.gov/ct2/show/NCT04376476>; clinicaltrials.gov. (2020). Identifier: NCT04328129. Retrieved August 19, 2020, from <https://clinicaltrials.gov/ct2/show/NCT04328129>; clinicaltrials.gov. (2020). Identifier: NCT04377737. Retrieved August 19, 2020, from <https://clinicaltrials.gov/ct2/show/NCT04377737>

³⁰Beauchamp, T. L., & Childress, J. F. (2001). Respect for Autonomy. *Principles of Biomedical Ethics*. 5th Edition. Oxford University Press. p. 112–115.

in China, it is not possible to see the information in such detail on Chinese platforms. Since publicly available scientific knowledge, shared from a single source by an authority such as WHO, must be comparable, it is appropriate to have a single standard.

3. Data should not be entered as though those in the vulnerable groups such as children, elderly people, or patients without health insurance are outside the vulnerable group.
4. To determine that the confidentiality of patients is maintained, trials indicating “yes” in terms of the “plan to share IPD” criteria must explain the measures they have taken to ensure the “ability to maintain privacy and confidentiality”. Incomplete or inaccurate data should be avoided, while increasing researchers’ knowledge and awareness about the IPD plan is crucial and, to achieve this, the design of the platforms that guide these researchers should be highlighted.

5 | CONCLUSION

Our starting point was that there should be no ethical violations in clinical trials carried out during the COVID-19 pandemic. The main concern was that the need for urgent results may hinder the ethical and scientific integrity of research conducted during clinical trials. Registry platforms are important resources for the public and for researchers to follow the emergence of scientifically proven medical interventions. The standardization of data entry on ethical aspects of the protocol in platforms is necessary to avoid compromising the quality of clinical research conducted in a hurry even in the environment of time restrictions created by the COVID-19 pandemic and inform the public and scientists about the ethical appropriateness of their protocols.

The minimum requirement under pandemic conditions should let researchers, EC/IRBs, and the public determine and justify how to proceed with the research results when new evidence from a different study could affect the process of ongoing research. Another important concluding remark is to question how WHO finds the difference in the content of platform links of different countries compatible with its minimum data requirement standards.

The important findings in terms of the responsible conduct of research were the need for a standardized definition of clinical trials and phases and the maximum number of patients that can be enrolled in a specific phase stage, the need for a properly completed ICP, the need to address issues pertaining to vulnerability, and the need to improve attempts to maintain privacy and confidentiality in terms of COI strategies. These findings are considered to be the minimum set of ethical criteria that must be present in clinical trial platforms, which should be designed to guide researchers in inputting correct and reliable information.

The standardization of data for ethical aspects of the protocols would contribute to scientific and ethical integrity of research and improve public trust and compliance, only if this standardization is accompanied by a comprehensive understanding to promote ethical principles and values for research integrity during public health

emergencies. Table 7 summarizes the main standardization problems of databases with the suggestions made. Research integrity is even more important for research during the COVID-19 pandemic, because while fast results are required in this situation, poorly designed and poorly peer-reviewed studies are no excuse for bad research practices.^{35,36} This comprehensive understanding should embrace a wide spectrum of activities such as EC/IRB member training to cope with a limited amount of time without ignoring the conditions of expedited review and ethical standards, maintaining, and supporting the ethical awareness of the researchers, the sponsors, and promoting community engagement.

CONFLICT OF INTEREST

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³⁵The European Network of Research Integrity Offices (ENRIO). (2020). ENRIO statement: Research integrity even more important for research during a pandemic. Retrieved from <http://www.enrio.eu/enrio-statement-research-integrity-even-more-important-for-research-during-a-pandemic/>. Accessed 7 September 2020.

³⁶The European Network of Research Ethics Committees (EUREC). (2020). Position of EUREC on the responsibility of research ethics committees during the COVID-19 Pandemic. Retrieved from http://www.eurecnet.org/documents/Position_EUREC_COVID_19.pdf. Accessed 7 September 2020.

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