

Researcher perspectives on bureaucratic obstacles to the conduct of COVID-19 clinical research in low- and middle-income countries:

Summary report of a short survey

Introduction

Excessive bureaucracy has been identified as an obstacle to the conduct of clinical research in many settings. Complex requirements, including administrative authorization, ethical clearance, medicine regulatory agency approval, importation licenses, and lengthy processes, often delay and sometimes prevent the initiation of research work. This slows progress and may demotivate researchers from further efforts. The COVID-19 pandemic has demonstrated how advances in medical science can translate rapidly into innovations and tools for prevention, containment, and treatment. However, there are still many knowledge gaps for which research is required, particularly in resource-limited settings, to inform current and future pandemic strategies.

In this ever-changing environment, it is crucial that the systems, processes, and mechanisms that are in place to obtain funding, guide and protect participants, import study materials, and inform institutions do not serve as a deterrent to knowledge advancement. This survey sought to gain insights into how researchers and health professionals regard the effects of bureaucratic processes on the conduct of COVID-19 clinical research.

Methods

An online survey was developed by members of the Steering Committee of the COVID-19 Clinical Research Coalition. The survey was distributed by email to the coalition membership (via eBulletin) and to non-member stakeholders who subscribe to Coalition updates (via eNews) on 27 August 2021, as well as being posted on the Coalition's website and shared on social media. Recipients of the survey were asked to share it within their networks. The target group of respondents was researchers, scientists, health workers involved in clinical research, and relevant policy makers. The survey was closed to responses on 30 September 2021.

Results

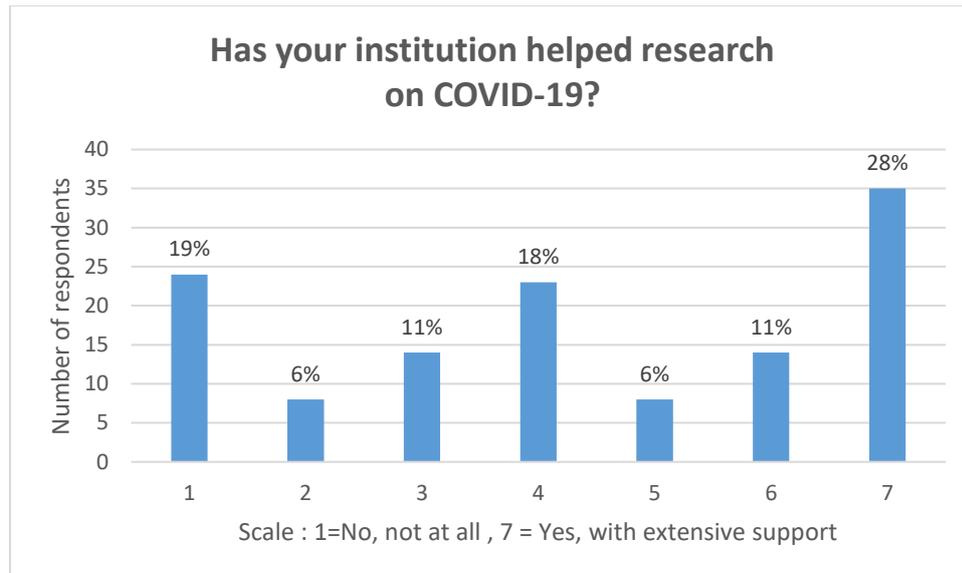
Respondents

A total of 126 respondents from 54 countries participated in the survey. Entries for only 11 data points were missed. Over 80% (102/126) of respondents were from institutions currently involved in COVID-19 research. Most institutions (84%) were from low- and middle-income countries and the same proportion (84%) conducted research in low- and middle-income countries. Because the survey was open to anyone and circulated widely, it was not possible to determine a non-response rate.

The predominant institution types were academia (54/126, 43%) and non-governmental organizations (31/126, 25%). The fewest respondents were from 'Other' institution types (8/126, 6%) and public health/governmental institutions (16/126, 13%).

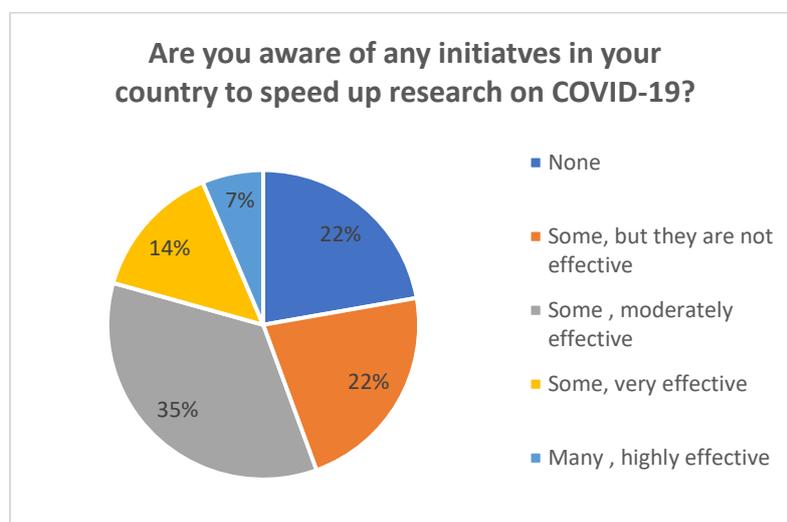
Institutional involvement towards furthering COVID-19 research

Perceived institutional support, or lack of support, was distributed across a seven-point scale, from no support to extensive support. Overall, 45.2% (57/126) of respondents perceived their institutions as providing some or extensive support for furthering COVID-19 research, while 36.5% (44/126) perceived their institutions as having provided no or little support for COVID-19 research. 18.3% (23/126) of respondents responded neutrally on this question.



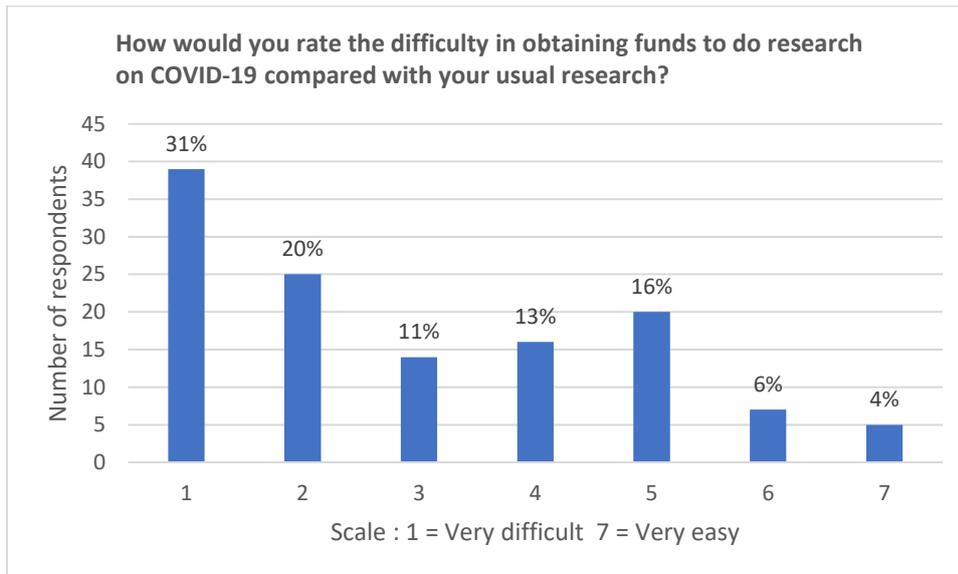
Awareness of COVID-19 research-enabling initiatives

44% of respondents reported either not being aware of any initiatives or being aware of only some, not very effective initiatives supporting COVID-19 research in their countries. 35% of respondents reported being aware of some moderately effective initiatives to speed up COVID-19 research in their countries. Only 6% were aware of many highly effective initiatives to speed up COVID-19 research in their countries.



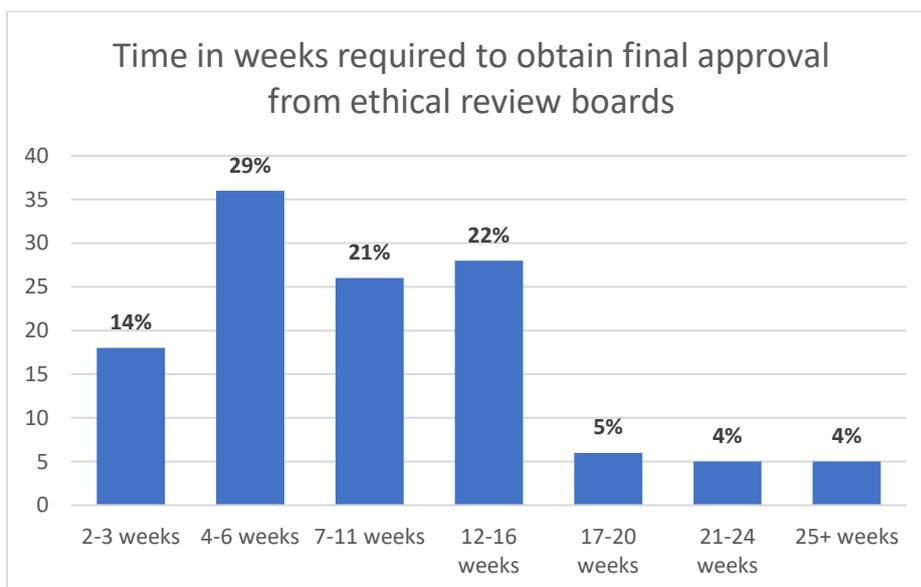
Funding for COVID-19 research

The majority of respondents (62%, 78/126) reported that it was difficult to obtain funding for COVID-19 research compared with their usual research. Nearly all respondents (72/78 or 92%) who reported difficulty in obtaining funds were from low- or middle-income countries, the majority of whom (44/78 or 56%) were from institutions in the African region. Overall, 50/78 or 64% of respondents reporting difficulty in obtaining funds were from either universities/academia or non-governmental organizations. Only 4% reported obtaining of funds to be very easy.

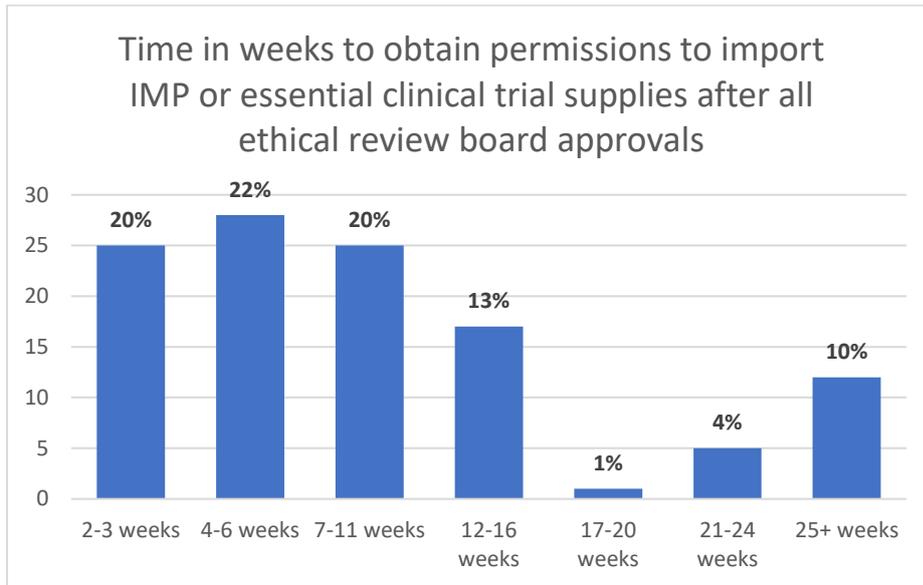


Time required for ethical review and import permits

Respondents reported a range of time required to obtain final approval from ethical review boards, from 2-3 weeks to more than 25 weeks (excluding one outlier response of 500 weeks). The median duration was eight weeks to obtain final ethical approval, with 21% reporting 7-11 weeks and 22% reporting 12-16 weeks.



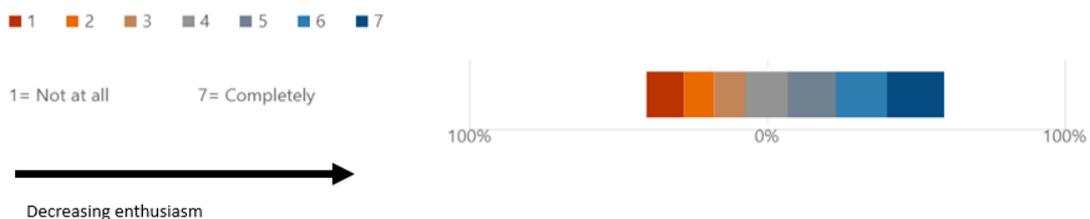
The time taken to obtain necessary permissions to import investigational medicinal products (IMP) or essential clinical trial supplies for research projects after all ethical review board approval had been obtained also ranged from 2-3 weeks to more than 25 weeks (excluding two outlier responses of 120 and 500 weeks, respectively). The median duration was six weeks to obtain the necessary permissions, with 20% reporting 7-11 weeks, 13% reporting 12-16 weeks, and 10% of respondents reporting more than 24 weeks.



Impact of bureaucracy on research enthusiasm

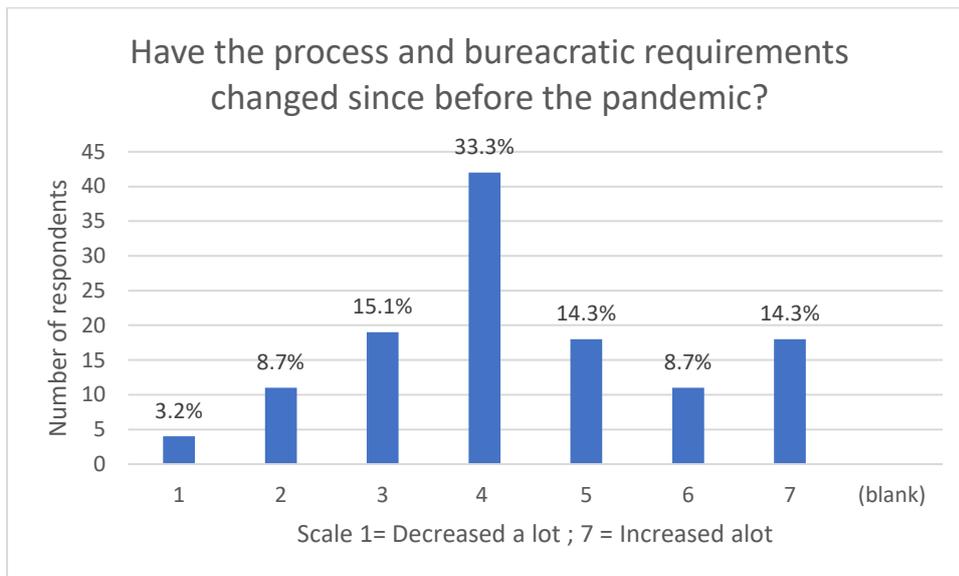
There was a broad spread of responses to the question about the impact of bureaucracy on research enthusiasm, with 52.4% reporting a marked reduction in enthusiasm (scores 5-7) and 14.3% reporting a neutral position.

10. Do the process and bureaucratic requirements reduce your enthusiasm for conducting clinical research on COVID-19?

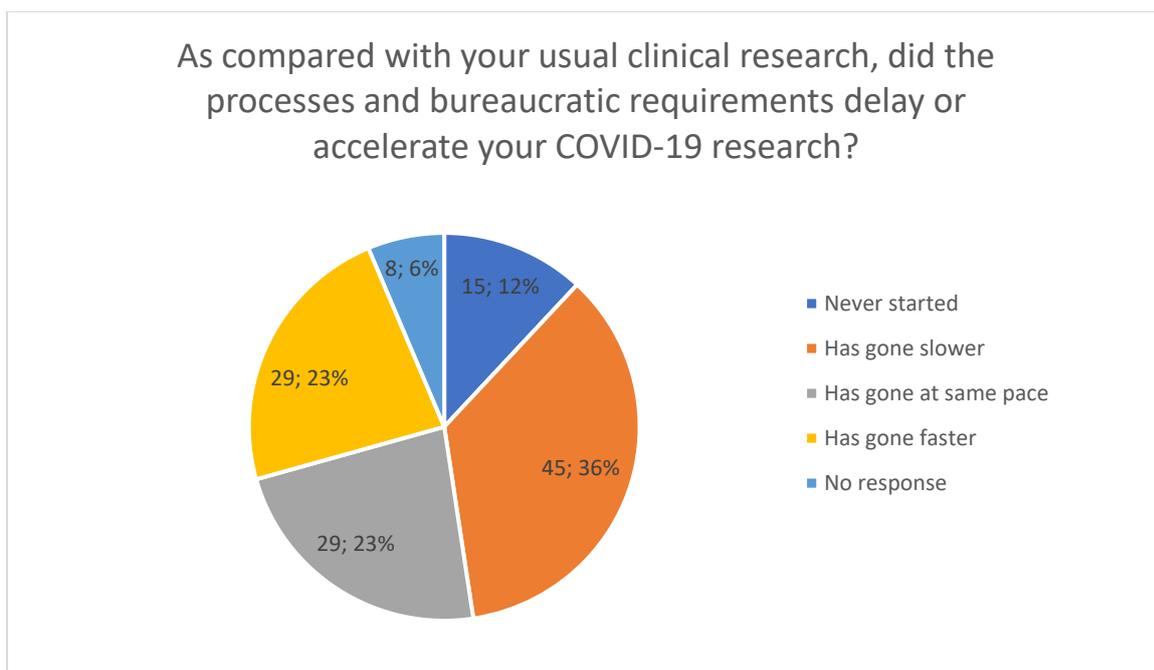


Have the bureaucratic requirements for clinical research conduct increased or decreased during COVID-19?

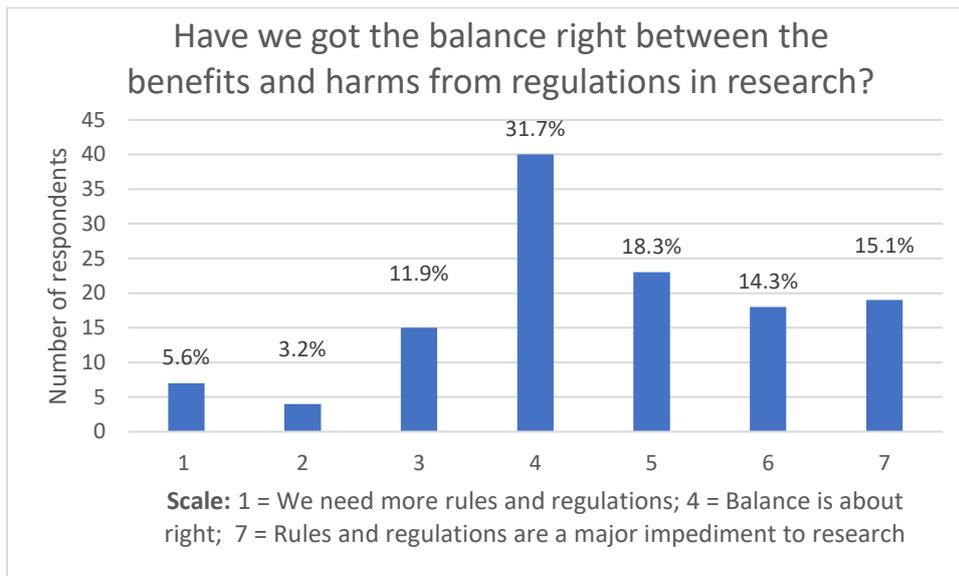
About one third of respondents (33%) reported neither a decrease nor increase in requirements compared to before the pandemic. 3 (2.4%) of 126 respondents did not provide a response.



45/126 (36%) respondents reported that the process and bureaucratic requirements had delayed their COVID-19 research. By comparison, 29/126 (23%) respondents reported that the requirements had accelerated their COVID-19 research.



Lastly, 31.7% felt that the balance between the risks and benefits of bureaucratic requirements was about right. A larger proportion of respondents, 47.7%, perceive that the existing rules and regulations in their contexts are an impediment to research, versus 20.7% who favoured having more rules and regulations.



Conclusion

This is a relatively small survey of opinions and experiences, mainly from our membership and their networks, but it has a broad geographical reach. The majority (81%) of respondents were involved in COVID-19 research when they filled out the survey and the majority (84%) were working in low- or middle-income settings. There is a mixed picture in terms of support from institutions and initiatives to accelerate or support research, but a broad perception that research funding was difficult to obtain. Nearly half of the respondents also reported not being aware of initiatives to foster COVID-19 research in their settings. From this small number of respondents, about one third felt that the balance between benefit and risk with the regulations in clinical research was ideal. There is value in carrying out additional research to better understand the impact that existing systems and processes have had on COVID-19 research, in order to better identify bottlenecks and their possible solutions.

Annex 1 – Survey Questions

Obstacles to the conduct of COVID-19 clinical research in low-resource settings

In this brief, anonymous survey, which should not take more than 5 minutes, we would like to learn your views on the procedural, organizational and/or bureaucratic hurdles to conducting COVID-19 clinical research in your setting.

Thank you in advance for your feedback and for sharing this survey with others in your network!

Your institution

1. Are you or your institution currently involved in COVID-19 research?
2. In which country is your organisation/institution located?
3. In which country or countries is your COVID research being conducted?
4. Your organization/institution type
 - University/academic
 - Independent research/health institute
 - Public health institute/governmental institution
 - NGO

5. Has your institution helped research on COVID-19?

"Help" can be anything that accelerates research or makes it easier, e.g., expedited review processes, extra funding or resources, and/or other incentives.

General

6. Are you aware of any initiatives in your country to speed up research on COVID-19?
7. How would you rate the difficulty in obtaining funds to do research on COVID-19 compared with your usual research?
8. Approximately how long in WEEKS from first submission do you think it would take you to get final approval from your ethical review boards for an internationally funded COVID-19 clinical research project? If you need two or more approvals (e.g., institutional and National Ethics Review boards) please give the total time.
9. After you obtained all the ethics review board approvals, on average, how many WEEKS would it take you to get the necessary permissions to import investigational medical products or essential clinical trial supplies for your research projects?

Impact of Bureaucracy

10. Do the process and bureaucratic requirements reduce your enthusiasm for conducting clinical research on COVID-19?
11. In your opinion, have the process and bureaucratic requirements for clinical research been decreased or increased since before the pandemic?
12. As compared with the usual clinical research, did the process and bureaucratic requirements delay or accelerate your COVID-19 research?
13. There is a balance between benefit and harm from all the rules, regulations and requirements around clinical research. The benefits are to protect the participants, ensure

standards, protect the integrity of the research, provide important information to organisations etc. The harm is in slowing down, increasing the cost and sometimes preventing research. In this COVID-19 pandemic have we got it right?

14. Do you have any comments or advice for us?