OP16

The Importance of Contract Research Organizations (CROs) in Clinical Research and Impact of COVID-19

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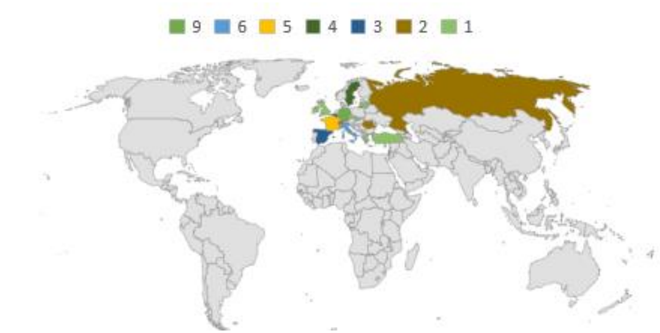
Background

CROs play a major role in ensuring clinical trials (CTs) are executed in line with ethical and regulatory requirements, ultimately to support the development of new drugs that benefit patients worldwide. To meet the evolving needs of pharmaceutical and biotech companies, CROs have expanded the services they provide. Innovations in the areas of decentralized trials, artificial intelligence and patient recruitment strategies, among others, enhance efficiency and help bring new life-saving drugs, therapies and medical devices to the market faster. As a result of how they adapted during the pandemic, the value CROs deliver has increased significantly, thereby strengthening the role they play in the industry overall.

Patients and methods

An online survey was distributed to EUCROF affiliated CROs between July and September 2022. Topics covered included the impact of COVID-19 on clinical trials and on in-field activities, and how CROs have adapted to this reality. 52 CROs completed the survey (Fig.1.).

Figure 1 . Geographic distribution of CROs surveyed



References:

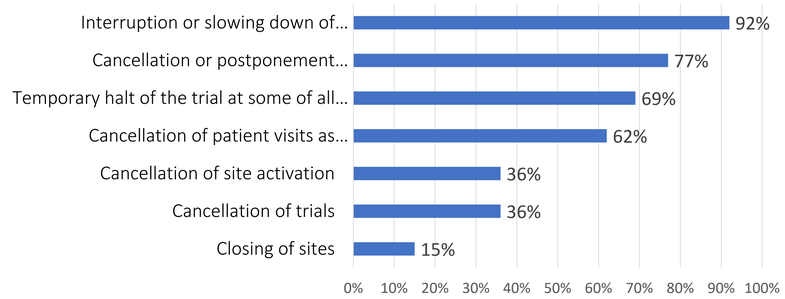
1. European Medicines Agency. Guidance on the management of clinical trials during the COVID-19 (coronavirus) pandemic. Version 5 10/02/2022. https://health.ec.europa.eu/system/files/2022-02/guidanceclinicaltrials_covid19_en_1.pdf.

Results

- *Impact of pandemic on clinical research*

A total of 77% of respondents from the participating CROs stated that the COVID-19 pandemic caused changes in their internal organization and 75% reported that this pandemic induced negative impacts on their ongoing trials (Fig.2).

Figure 2. Negative impacts on clinical research encountered in CROs during the COVID-19 pandemic.



The main measures taken to reduce the negative impacts of the COVID-19 pandemic were the conversion of on-site visits into remote visits (82%) and extension of the duration of the trial (82%).

The European Medicines Agency published guidelines on “Guidance on the management of clinical trials during the COVID-19 (coronavirus) pandemic” [1]; 83% of the respondents were aware of these guidelines and 77% implemented them. A total of 93% of respondents thought that these guidelines were useful to improve their business in this context (Table 1).

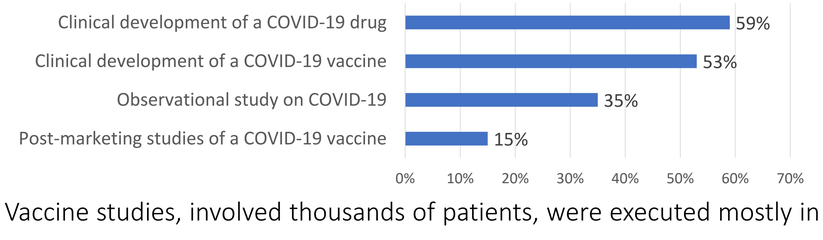
Table 1. Use of EMA guidelines by CROs

Were these guidelines, or some of them, implemented at your CRO?	Do you think these guidelines useful to improve your business in this context?		
	No	Yes	Total
No	0	3 (7%)	3 (7%)
Yes	3 (7%)	37 (86%)	40 (93%)
Total	3 (7%)	40 (93%)	43 (100%)

- *Development of COVID-19 vaccines and treatments*

A majority of CROs (65%) reported participating in COVID-19 trials between 2020–2022. 41% participated in at least two studies, 21% participated in 5–10 studies, and 29% participated in more than 10 studies. Most of these studies were large studies, involving thousands of participants and were essentially on drugs development (59%) or vaccines (53%) - (Fig.3).

Figure 3. Types of studies on COVID-19 performed by CROs in 2020–2022 (multiple answers possible).



Vaccine studies, involved thousands of patients, were executed mostly in Europe and North America .

- *New technologies*

New digital tools (e.g., telemedicine, remote monitoring) have been implemented by 69% of the CROs in the context of the COVID-19 pandemic. They all will continue to use these tools despite the reduction of the effects of the pandemic.

Conclusion

The obstacles encountered by clinical research during the COVID-19 pandemic have revealed the ability of CROs to adapt quickly to a new environment. They have been a key contributor in the development of new drugs and vaccines by demonstrating their agility and ability to implement solutions to overcome a changing and challenging operating environment in a shortened timeframe to meet an urgent public health demand.

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