

Research on the Effects of the Global Static Management Policy against COVID-19 in 2022 on Clinical Trials in Shanghai

Zhaodan Tan¹, Zengguang Xu¹, and Yan Shi¹

¹Shanghai East Hospital

March 1, 2023

Abstract

Aims: To improve the countermeasures of clinical trial institutions against major public health events such as COVID-19. **Methods:** A questionnaire was created to investigate the effects of the global static management policy against COVID-19 on clinical trials in Shanghai in 2022. And the convenience sampling combined with snowball sampling were adopted to interview clinical research coordinators (CRC) and clinical research associates(CRA) on the platform of SOJUMP as well as WeChat. **Results:** 156 valid questionnaires were collected, with an effective recovery rate of 93.98%. 98.07% of the respondents believed that the effects was severe. The extent of effects on different links of clinical trials was different (rank sum test $P < 0.01$), being great on medication/follow-up (76.28% of significant effects), monitoring/audit (74.36%) and screening/admission (71.79%).The protocol deviations associated with out of visit window (experienced by 94.23% of respondents, during the static management policy), inspection (78.85%), medication (67.95%) and withdrawal (62.82%). And the interviewees reported 49.66% of the exclusion should blame the epidemic situation. The development of online-office or remote-ethics meetings alleviated the impact of lockdown policy on approval/ethics/contract and data cleaning/site closing. 90.98% of oral drugs could be sent by express delivery, but only 1.28% had the experience of online informed consent and remote inspection. **Conclusions:** We shall speed up the application of the intelligent clinical trial system and remote monitoring system, realize the transformation to a new model of patient-centered clinical trial, and improve the ability to cope with major public health events such as COVID-19.

Hosted file

20230228-Research on the Effects of the Global Static Management Policy against COVID-19 in 2022 on Clinical Trials in Shanghai available at <https://authorea.com/users/591263/articles/627289-research-on-the-effects-of-the-global-static-management-policy-against-covid-19-in-2022-on-clinical-trials-in-shanghai>