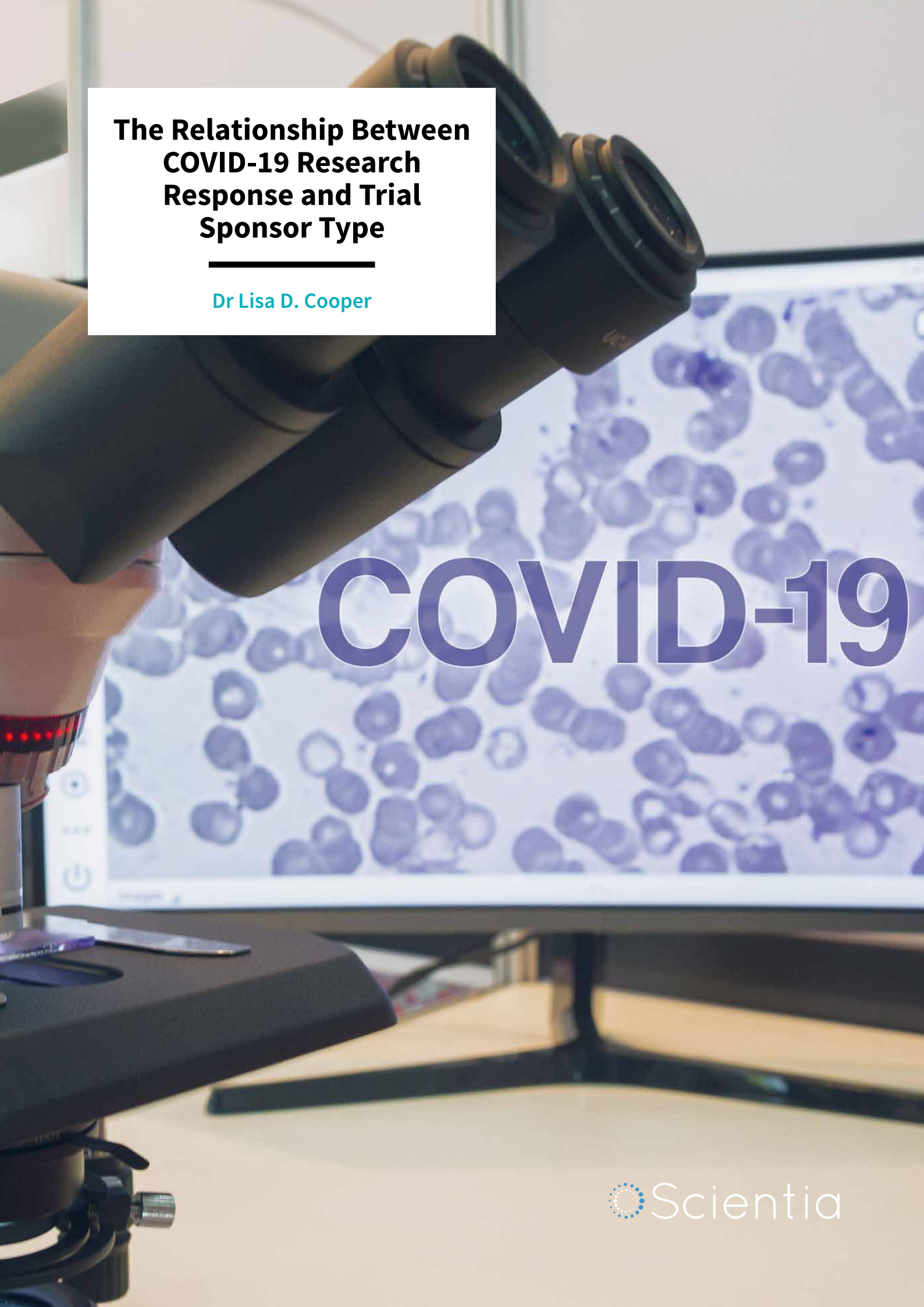
The Relationship Between COVID-19 Research Response and Trial Sponsor Type

Dr Lisa D. Cooper



Scientia

THE RELATIONSHIP BETWEEN COVID-19 RESEARCH RESPONSE AND TRIAL SPONSOR TYPE

The COVID-19 pandemic prompted an explosion of clinical trials into preventative, therapeutic and diagnostic products. **Dr Lisa Cooper** and her colleagues at The State University of New Jersey in the USA recently investigated the relationship between the type of clinical trial sponsor (i.e., industry, academic or other) and research response time to the COVID-19 pandemic.

The COVID-19 Pandemic

According to the World Health Organization, there have been over 700 million cases of COVID-19 globally and almost 7 million deaths since the identification of the virus in 2019. First appearing in Wuhan, China, the infection quickly spread, leading to the declaration of a global pandemic in March 2020.

COVID-19 is spread by respiratory droplets, particularly when a carrier coughs or sneezes. Whilst some people are lucky enough to experience no symptoms, it has proved fatal for many, particularly older people and those with medical comorbidities. COVID-19 treatment initially focused on providing supportive care and reducing symptoms, but as case numbers grew, governments worldwide imposed restrictions on travel, businesses and communities to try to minimise the spread. It also became apparent that new treatments, as well as diagnostic products, were needed to help fight the virus.

Before the approval of any drug, intervention or diagnostic for human use, investigations known as clinical trials are required to determine its safety and efficacy. Sponsors in clinical trials are defined as the individual, company, institution or organisation responsible for initiating and managing that trial.

Three dedicated individuals at The State University of New Jersey collaborated to learn more about how sponsor types may impact research response time to COVID-19. Dr Lisa Cooper and Dr Doreen Waldron Lechner work in the Department of Health Informatics, and Irene Lee is a pharmacy student at the Ernest Mario School of Pharmacy.

Expediting the Research Process

Dr Cooper explains that the development process for preventative, therapeutic and diagnostic products to fight COVID-19 had to be facilitated to mitigate the looming healthcare crisis. In the USA, the Food and Drug Administration (FDA) encouraged the use of established statutory programmes such as Emergency Use Authorisations, Expanded Access and Accelerated and Priority Approvals to facilitate quick product approvals. The repurposing of already approved treatments is also commonly used to help reduce the amount of time required for the initiation of clinical investigations.

The novelty of the virus, speed of spread and severity of disease resulted in a flurry of much-needed new diagnostic tests, vaccines and therapeutic approaches. To address this concern, the healthcare community initiated a vast number of COVID-19-related clinical trials, but little research has specifically explored how this response varied by different types of trial sponsors. Response time analysis may provide valuable insight for treating clinicians by predicting the types of trials, and when they may be available to patients should a future pandemic were to occur. Thus, Dr Cooper and her colleagues used the Clinicaltrials.gov website to determine if and how the trial sponsor type was linked to the 'time to COVID-19 response'. They defined this outcome as the date from the disease discovery in Wuhan to the ClinicalTrials.gov study 'first posted' date for each registered interventional clinical trial.

Exploring the Registry of Clinical Trials

ClinicalTrials.gov is an online registry of clinical trials. This continually updated database holds information about publicly and privately funded clinical studies conducted worldwide and is provided by the US National Library of Medicine at the National Institutes for Health. The registry was created to increase access to clinical trial data. In the USA, there are various legal requirements that trial sponsors must uphold when it comes to posting trials, such as the requirement to post the study prior to enrolling the first participant.

Dr Cooper and her colleagues used this valuable database to gather information specifically about COVID-19 studies. They searched using the terms 'COVID-19' and 'SARS-Cov-2' and looked for trials for which the primary sponsor was located in the USA (or had at least a single trial site in the USA). They discounted studies posted before 31st December 2019, as these preceded the discovery of COVID-19, and removed behavioural studies.

Then, the researchers categorised the study sponsors based on the information provided within each study listing as 'Industry', 'Academic' or 'Other' (this included government and non-profit organisations, for example). The Academic sponsors were further split into Clinical and Translational Science Awards (CTSA) hubs or affiliates, or non-CTSA hubs. Dr Cooper explains that the CTSA program provides funding for the development of innovative, collaborative and streamlined research processes, and various institutions receive CTSA support across the USA. Finally, the researchers noted the response time for each trial listing by calculating the number of days from 31st December 2019 to the date the listing was first posted on the ClinicalTrial.gov website by the study sponsor.

An In-Depth Examination of Influencing Factors

Dr Cooper and her colleagues found a total of 673 USA-sponsored COVID-19 trials, the majority of which were small, early-stage studies. Of these, 293 (43.5%) were Industry-sponsored, 349 (51.9%) were Academic-sponsored, and 31 (4.6%) had Other sponsors. Furthermore, 181 (51.9%) of the Academic-sponsored studies were CTSA hubs. The team found the average response time was 189 days, with Academic sponsors having the shortest average response time of 172.6 days and CTSA hubs having a significantly shorter average response time of 168.1 days compared to all the other sponsor types.

Dr Cooper and her colleagues had predicted that Academic sponsors would sponsor more research-focused studies, as opposed to studies designed to achieve market approval, as well as have a quicker response time to the COVID-19 pandemic when compared to Industry and Other sponsor types – and their hypothesis was confirmed.

Interestingly, the number of postings for Academic-sponsored studies peaked early in the course of the pandemic (i.e., April) and consisted primarily of repurposed approved and investigational drugs for the treatment of COVID-19, followed by a general pattern of decline until August, when a short peak was observed. Industry sponsored trials peaked later (i.e., June 2020), followed by a more gradual decline and then a second peak in October, which mainly comprised repurposed novel therapy investigations (rather than repurposed marketed drugs).

Implications and Recommendations for Future Research

While the quality and integrity of the data available on ClinicalTrials.gov depend upon the accuracy of information provided by the sponsor, and instances of missing or inaccurate data were rare but did occur, the researchers are confident the records they analysed were sufficient to allow robust findings and conclusions.

On the basis of their detailed findings, Dr Cooper suggests that the type of IND (investigational new drug) application (part of the FDA approval process for trials), whether commercial or research, should be assessed for its impact on response time in analyses carried out in the future. Indeed, it is unsurprising that Academic-sponsored studies were set up most quickly, given the nature of the research being conducted. She also argues that controlling for sponsor collaborators should be considered since some Academic sponsors conduct industry-driven studies.

Meet the researcher

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Dr Lisa Cooper gained her BSc in Biology from York College, Pennsylvania, in 2000, her MSc in Biology from Fairleigh Dickinson University in 2005, and finally, her PhD in Leadership from Alvernia University in 2015. She is currently an Assistant Professor at Rutgers School of Health Profession's Master of Science Clinical Research Management programme, which is a part of the Health Informatics department. In addition to her own research, she teaches multiple courses within the Clinical Research Management master's programme and oversees the Capstone programme (an independent, multifaceted research component in the American higher education system). She has held several roles in regulatory affairs and quality assurance within the pharmaceutical industry over the years, and is currently a Regulatory Affairs Consultant for the Bracken Group, an organisation which provides consulting services in the development of drugs, biologics and medical devices. In recognition of her work, she has received the Ikaria Research and Development Big Six On the Spot Award multiple times since 2010, and she won the PhD Director's Award from the School of Graduate and Adult Education at Alvernia University in 2014.

About the Clinical Research Management programme:
The Master of Science in Clinical Research Management is a 36-credit multi-disciplinary curriculum offered in a hybrid model by the Rutgers School of Health Professions. It builds a broad and well-rounded foundation for the clinical research professional through a synchronous and asynchronous curriculum that has been carefully designed to ensure students graduate with the core competencies outlined by the Joint Task Force for Clinical Competency. Students can take one of three discipline tracks: Clinical Research Management, Drug Safety and Pharmacovigilance, or Academic Clinical Research Management.

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FURTHER READING

L Cooper, I Lee, D Waldron Lechner, COVID-19 pandemic response varies by clinical trial sponsor type, Journal of Clinical and Translational Science, 2021, 5(1), e111. DOI: https://doi.org/10.1017/cts.2021.25

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