Inflammatory Bowel Diseases, 2021, **XX**, 1–2
DOI: 10.1093/ibd/izab111
Advance access publication 14 May 2021
Letter to the Editor

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Impact of COVID-19 on Inflammatory Bowel Disease Clinical Trial Recruitment: A Global Survey of Principal Investigators

Vipul Jairath, MBChB, DPhil,[*,†,‡] Leonardo Guizzetti, PhD,[*] K. Adam Baker, PhD,[*] Lee Anne Williamson,[*] Rocio Sedano, MD,[*,†] Hershell Thompson, MSc, MBA,[*] and Christopher Ma, MD, MPH[*,§]

From the *Alimentiv Inc. (formerly Robarts Clinical Trials, Inc.), London, Ontario, Canada
[†]Department of Medicine, Division of Gastroenterology, Western University, London, Ontario, Canada
[‡]Department of Epidemiology and Biostatistics, Western University, London, Ontario, Canada
[§]Division of Gastroenterology and Hepatology, Departments of Medicine and Community Health Sciences, Cumming School of Medicine, University of Calgary, Calgary, Alberta, Canada
Conflicts of interest: VJ has received has received consulting fees from AbbVie, Eli Lilly, GlaxoSmithKline, Arena Pharmaceuticals, Genentech, Pendopharm, Pfizer, Fresenius Kabi, Bristol Myers Squibb, Roche, Ferring, Sandoz, Merck, Takeda, Janssen, Alimentiv Inc. (formerly Robarts Clinical Trials Inc.), Topivert, Celltrion, Mylan, and Gilead and speaker's fees from Takeda, Janssen, Shire, Ferring, AbbVie, and Pfizer. LG, KAB, LAW, and HT are employees of Alimentiv Inc. (formerly Robarts Clinical Trials, Inc.). RS reports no conflicts of interest. CM has received consulting fees from AbbVie, Amgen, AVIR Pharma Inc, Ferring, Fresenius Kabi, Janssen, Mylan, Takeda, Pfizer, Roche, Alimentiv (formerly Robarts Clinical Trials Inc.); speaker's fees from AbbVie, Janssen, Takeda, and Pfizer; and research support from Pfizer.

Address correspondence to: Vipul Jairath, MBChB, DPhil, Western University, London, Ontario, Canada (vipul.jairath@alimentiv.com).

Key Words: COVID-19, inflammatory bowel disease, clinical trials

To the Editors,

COVID-19 has posed unprecedented challenges to the design, conduct, and implementation of clinical trials.[1,2] Clinical trials in inflammatory bowel disease (IBD) have specific nuances, such as the need for colonoscopy for enrollment and rerandomization and as a component of the primary efficacy endpoint. However, access to endoscopy during the initial wave of the pandemic in 2020 was often limited to urgent clinical care. We conducted a global survey of IBD clinical investigators to explore the impact of the initial wave of COVID-19 on IBD clinical trial conduct.

A total of 339 investigators completed a 24-question survey related to IBD clinical trial activities between March 16 and June 1, 2020. Full survey results are presented in the Supplementary Data Content. Most respondents were from Europe (161/339; 47%) or North America (113/339; 33%) and were from an academic center (126/339; 37%) or private clinical practice (124/339; 37%). Further, 136/331 (41%) investigators indicated that patient recruitment had halted. Recruitment was reduced by >50% in one-third of respondents (104/330; 31%). Overall, 214/330 (65%) respondents were enrolling new patients, of whom 178/214 (83%) were considering all potentially eligible patients and the remainder were only considering patients with IBD with no commercially available alternative.

For ongoing IBD trials, 199/328 investigators (61%) reported that follow-up visits were still being conducted in-person, and 71/328 (22%) investigators were conducting a hybrid of in-person and virtual follow-up visits. Endoscopy units were reported to be performing IBD clinical trial–related procedures by most investigators (272/326; 83%), although 112 of these 272 (41%) investigators reported reduced capacity. Most respondents (251/275; 91%) reported that follow-up endoscopies were still being conducted; 134/247 (54%) investigators were not prioritizing the trial timepoint, whereas 87/247 (35%) investigators prioritized endoscopy that was part of the trial primary endpoint or informed a rerandomization process.

In summary, this global survey showed that >40% of investigators had halted IBD trial recruitment because of COVID-19. Given the already poor recruitment rates to IBD trials, this stoppage is likely to cause additional delays

and costs to development programs. However, the pandemic has also served as a potential catalyst for change in clinical trial conduct. To protect against further closures and subsequent waves of the pandemic, IBD trials should become more patient-centric and embrace remote consent procedures, telemedicine to minimize health care exposures and minimize the risk of missing data during follow-up visits, and alternative strategies for investigational drug administration with observation closer to the patient's home.

Supplementary Data

Supplementary data are available at *Inflammatory Bowel Diseases* online.

References

1. North CM, Dougan ML, Sacks CA. Improving clinical trial enrollment—in the COVID-19 era and beyond. *N Engl J Med.* 2020;383:1406–1408.
2. Upadhaya S, Yu JX, Oliva C, *et al.* Impact of COVID-19 on oncology clinical trials. *Nat Rev Drug Discov.* 2020;19:376–377.