Increased Utilization of Virtual Visits and Electronic Approaches in Clinical Research During the COVID-19 Pandemic and Thereafter

Adil E. Bharucha, MBBS, MD, Cathi T. Rhodes, PMP, Christine M. Boos, BS, Daniel A. Keller, MS, Angela Dispenzieri, MD, Ryan P. Oldenburg, MBA,

Mayo Clinic, Rochester, MN

Abstract

• Objectives: To assess the impact of the COVID-19 pandemic on clinical research and the use of electronic approaches to mitigate this impact.
• Methods: We compared the utilization of electronic consenting and remote visits in all research studies conducted at Mayo Clinic sites (Arizona, Florida, and Minnesota) before and during the COVID-19 pandemic. Participants are consented through a participant tracking system (PTrax) linked to the electronic health record.
• Results: Between May 2019 and December 2020, there were 130,800 new consents across every modality (electronic and paper) to participate in non-trial (107,176 [82%]) or a clinical trial (23,624 [18%]). New consents declined from 5,741 in February 2020 to 913 in April 2020 but increased to 11,864 in November 2020. The mean (SD) proportion of virtual visits increased from 22 (2)% before to 45 (20)% during the pandemic (P<.001). Mean (SD) remote electronic consenting increased from 0.3 (0.5)% to 29 (21)% (P<.001). The mean (SD) number of patients with virtual visits increased from 3.5 (2.4) to 172 (135) (P=.003) per month between pre-COVID (July 2019-February 2020) and post-COVID (March-December 2020) periods. Virtual visits used telemedicine (68%) or video (32%).
• Conclusions: After a sharp early decline, enrollment of new participants and ongoing study visits recovered during the COVID-19 pandemic. This recovery was accompanied by the increased utilization of electronic tools.

Methods and Data Analysis

• At Mayo Clinic, participants are consented by the Participant Tracking System (PTrax) application (Mayo Clinic). Participant status is tracked in real time and interfaced to the EHR.
• By default, the Mayo Clinic IRB approves hard copy consenting for all studies. When specifically requested and if approved, electronic consent (eg, with a tablet) also requires a conversation - either in-person or remotely (ie, through video or telephone) between the study team member and the potential participant.
• Introduced in December 2013, the electronic option has evolved over time. Between December 2013 and August 2019, it was only used for on-site consent. In August 2019, the remote electronic consent option, accomplished with an email link and facilitated by DocuSign (DocuSign) was added. An enhancement introduced in April 2021 allows both the participant and the person obtaining consent to electronically sign the consent form. PTrax keeps track of whether participants were consented onsite or remotely.
• Data were summarized as the number of consents rather than the number of participants because a few participants participated in 2 or more studies.
• Where feasible, in-person visits were replaced with telemedicine or video visits. These metrics were available and analyzed from 7/1/2019 and 2/28/2020 (PreCOVID) and 3/1/2020 and 12/31/2020 (COVID).

Background and Aims

• Most clinical research studies entail in-person visits to evaluate participants and collect data. Such visits increase participant burden and increase the duration and expense of conducting clinical trials. This burden is arguably greater for rural residents, who travel further to access clinical trials. At Mayo Clinic, approximately one in three clinical trial participants are rural residents versus one in five in the population.
• The COVID-19 pandemic markedly hindered the conduct of these studies.
• Gradually activities resumed, prompted by the need to meet the ethical obligations to patients and the research process, while adapting to stay-at-home orders.
• Where feasible, face-to-face visits were replaced with virtual visits. The US Food and Drug Administration and other agencies provided guidance on measures to mitigate the risk while ensuring compliance with Good Clinical Practice. Institutions and study sponsors implemented several modifications to overcome these challenges.
• At Mayo Clinic, prior to the pandemic, most research studies documented informed consent in person and via hard copy. A majority of study visits were conducted in person.
• Our aims were to compare the utilization of electronic consent and virtual (telemedicine and video) visits in every clinical research study conducted at 3 Mayo Clinic sites (Arizona, Florida, and Minnesota) before vs during the COVID-19 pandemic.

Conclusions

• After a sharp early decline, the enrollment of new participants and ongoing study visits recovered during the COVID-19 pandemic.
• This recovery was accompanied by the increased utilization of electronic tools in research studies at Mayo Clinic.
• Sustained over time, the remote electronic consent option and virtual visits will reduce the expense of participating in studies and encourage participation, especially among minority communities.


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Figure 1: Temporal trends in clinical research studies and enrollment of new participants

Between May 2019 and February 2020, the number of new consents signed for all studies, which includes clinical trials and non-trials, was relatively stable, averaging 5,878 ± 618 consents per month. Coincident with the pandemic, the number of consents declined precipitously to 3,483 and 719 per month in March and April 2020. Thereafter, these numbers steadily increased to 11,572 consents per month in November 2020.

Figure 2: Temporal trends in electronic consenting

In February 2020, 1,300 of 5,248 consents (25%) were completed electronically. In December 2020, this proportion had increased to 6,463 of 9,446 consents (68%). Between the pre- (May 2019 to February 2020) and during-COVID (March to December 2020) epochs (P<.003), 68% of these virtual visits used telemedicine capabilities; the remainder were video-enabled visits.

Figure 3: Temporal trends in virtual research visits

In July 2019, only 3 patients had virtual research visits. In April and December 2020, respectively 541 and 194 patients had a virtual visit. The number of patients who had virtual visits increased from 3.5 ± 2.4/month to 172 ± 135/month between pre-COVID (July 2019-February 2020) and during-COVID (March to December 2020) epochs (P<.003). 68% of these virtual visits used telemedicine capability; the remainder were video-enabled visits.