Category: Clinical Trial Operations – Work in Progress

Transformative Lessons for Clinical Trials From the COVID-19 Pandemic: Remote Monitoring, Virtual Research Visits, and Added Flexibility for Patients

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1. Background

The onset of the COVID-19 global pandemic required creative strategy in clinical trial operations while keeping staff and patients safe. Virtual clinical trials operations were adjusted based on trial characteristics: visit frequency, inpatient vs. outpatient therapies, infusions vs. oral medications, etc. The FDA Guidance published in March 2020 served as an excellent resource. From the beginning, it was clear that flexibility would be essential. Lessons learned from the pandemic will change the way we conduct clinical trials for years to come.

2. Goals

1. Explore opportunities to transition research appointments to fully virtual visits
2. Virtual visits for site qualification (SQVs), study initiation (SIVs), audit/monitoring, and closeouts
3. Pharmacy virtual visits for SQVs, SIVs, monitoring/auditing, and closeouts
4. Staffing plans to minimize COVID-19 exposure risk

3. Solutions and Methods

1. Patients
    a. Phone/virtual visits: received approval from sponsors for virtual visits and use of external laboratory results. Study teams regularly discussed which patients could transition to virtual visits.
    b. Communication: implemented secure messaging through Epic and the Doximity app for virtual calls.
2. Sponsor/Study Teams
    a. Remote monitoring: implemented an institutional mandate for permanent remote monitoring visits through EpicCare Link/SimpleShare.
    b. Deviation management: developed a COVID-19 specific EPIC SmartForm for deviation documentation, necessary for identification and reporting. The IRB allowed for cumulative submission of COVID-19 related deviations during annual continuing review.
3. Pharmacy
    a. Drug shipment: assessed options for drug shipment and commercially available agents that could be dispensed locally. Developed a standardized SmartPhrase within EPIC for communications with pharmacy.
    b. Pharmacy audits/monitoring visits: implemented virtual tours of the pharmacy using iPads with a secured Zoom account. Electronic temperature logs were made available for monitor review and a video of our facility was created for SQVs and SIVs.
4. Staff

a. Teleworking: early in the pandemic, all data clinical research coordinators (CRCs) were moved to full telework and 75 percent of clinical CRCs worked remotely. Currently, 25 percent of clinical CRCs rotate working remotely.
b. Adverse event (AE) capture and paper source: implemented an electronic AE documentation process through EPIC. Paper documents were mailed to patients or sent electronically.
c. New staff: initially remained on site. Implemented a hybrid (remote/onsite) 8-week training program.

4. Outcomes

1. Patients: increase in the use of virtual visits observed.
2. Sponsor/study team: from September to December 2020, we released 12,392 individual patient charts for 858 remote monitoring visits. These charts spanned 107 unique CRCs and 469 studies across the cancer center inclusive of all Mayo Clinic sites.
3. Pharmacy: during 2020, we conducted 360 virtual pharmacy monitoring visits, seven virtual audits, and mailed out 499 research prescriptions.
4. Staff: we transitioned from 100 percent onsite work to 53.5 percent onsite and 46.5 percent offsite. As of November 2020, on quarter of clinical CRCs continue to work remotely using a patient load dependent weekly rotation. Additionally, we trained 34 new CRC hires using the new training program.

5. Lessons Learned

- Provided flexibility for research participants via virtual visits
- Significantly increased efficiency through remote monitoring/audits
- Completed transition to long-term remote monitoring
- Implemented long-term teleworking strategy for all CRC staff
- Developed hybrid remote/onsite new hire training and onboarding program
- Continue exploring transition options from paper to electronic source, including e-consenting for cancer center research participants

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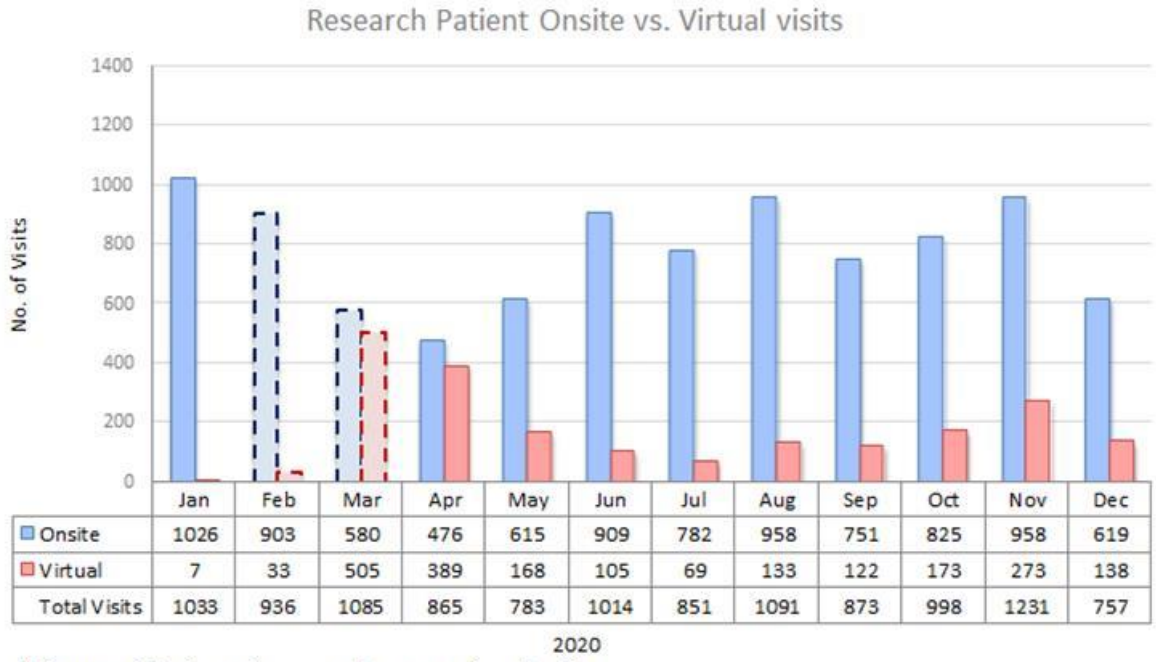
Figure:



	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Onsite	1026	903	580	476	615	909	782	958	751	825	958	619
Virtual	7	33	505	389	168	105	69	133	122	173	273	138
Total Visits	1033	936	1085	865	783	1014	851	1091	873	998	1231	757

2020

*February and March are estimates as we have one week worth of data.