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Personal Narrative About COVID-19 Research

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Personal Narratives From Investigators

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Personal Narrative About COVID-19 Research

Gary Schiller

I direct a clinical research program in Hematological Malignancies and Hematopoietic Cell Transplantation. On a practical level, this means that I direct a team of nine, soon to be ten people, who perform regulatory, data management, research nursing, and research coordination for about 25 active clinical trials, and about 20 more trials awaiting activation, or closed to accrual. We work with patients with diseases as diverse as myelodysplasia, acute leukemia, multiple myeloma, and bone marrow and stem cell transplantation. Our group also includes several younger faculty members and is self-contained, by which I mean that I developed the funding model that supports the personnel. We do not receive funds from the university to run the program. In a normal year, we accrue about 50 or sometimes 60 patients per year into these trials.

At the start of the safer-at-home orders, it was challenging to conduct clinical research, but it was essential. The worst scenario that we had to confront was the closure of studies for some of our

most vulnerable patients. This might have been done because meeting certain endpoints, such as study visits, became difficult, although doable with telemedicine. But the major reason that studies were shut down, in my opinion, did not have to do with study-related visits, which continued since our hospitals and clinics were open, but due to monitoring problems. Closing studies due to regulatory challenges was, in my opinion, the wrong thing to do, and I said so at the time, not just now, in the sunlight of looking retrospectively at the situation. The reason it was wrong is that diseases don't disappear by virtue of a pandemic. Even during a crisis, cancer does not take a break, so sponsors who closed studies did so at the risk of ever achieving accrual targets and did a disservice to our patients. I sure hope that, when these studies are completed and results published, editors of journals require a statement in the methods section of the paper documenting whether there was a hold period for the study. I bet that this recommendation will be met with resistance, even if behind closed doors! Also, monitoring was hit hard by the crisis, as I described above. Ultimately, the institution determined that monitoring could be done electronically, with safeguards in place to protect confidentiality and to restrict access to personal information, but

this took a few months, and mechanisms for safe monitoring to continue to be developed.

When the initial lockdown came, around March 12, 2020, we were confronted with safer-at-home orders but no guidance regarding research studies. Because our patients do not have the luxury of scheduling their diseases outside a pandemic epoch, we had to work around restrictions imposed by the County and the University. We somehow did that, and maintained many of our trials, and have accrued about 50 patients to our studies as of November 1, 2020. I was offered participation in several multi-center studies from industry for COVID-19 therapy based on drugs that we had used for patients with hematological malignancies and transplantation. Although these drugs were developed in a cancer setting, their mechanisms of action offered potential efficacy outside neoplasia. I turned these over to my colleagues in Infectious Diseases who are coordinating the research strategies of this academic institution. I did attend several conference calls prior to initiation of the studies, feeling some responsibility for bringing them here.

The challenges to our research initially consisted of the safer-at-home orders that did not define research personnel on clinical trials as essential workers. Fortunately, I was able to come to my office daily, and since I run a large clinical research program, I was able to supervise those studies still accruing patients. My team of physicians and I also consented many subjects, and my team of two research nurse practitioners and one study coordinator screened them. Many have gone on research protocols at this time. However, not having the regulatory staff on-site proved very difficult. Although they worked from home, many things were not done in a timely manner, documents were not signed, and amazingly, there were no easy electronic options. For example, FDA 1572 forms could not be signed electronically. Data management was doable from home, but interfacing with regulatory bodies in the academic structure was not easy and we could not furlough employees, so I, and the few of us on-site, did the bulk of the secretarial work—printing out forms, signing them, sending them electronically, etc. I have no idea whether any of these documents are being filed, and I know that we did not receive anything through the mail for months. Presently,

we get mail about once a week, but the backlog is immense. Finally, after 3 months of confusion, we developed a rotation system by which all personnel were assigned days to come into an office, without other personnel present, in order to complete their work, answer phone calls from patients or trial subjects, provide support to the research nurses, and electronically meet with monitors.

IRBs and researchers will need to develop different standard operations based on what was learned during this critical period. Either we have to develop a system of electronic signatures, or a delivery system for hard-copy signatures. The research infrastructure will need to assess the value added by scientific peer review, by coverage analysis, and by contracts, by reviewing the large number of outside serious adverse events sent, pro forma to investigators, and the overhead costs of all those personnel who may be working from home. Zoom or other electronic platforms provided some help, but in the end, they merely added to the work of people on-site who ran multiple functions. Even today, I am writing this essay while intermittently checking email and while attending an on-line international academic meeting! The logistics of all the juggling of multiple responsibilities actually required more staff on-site, not fewer, and left many of us wondering whether our staffing models were correct prior to the pandemic.

Not What Anyone Signed up for: Unnecessary and Insurmountable Barriers Encountered in Conducting Clinical Trials in COVID-19

Westyn Branch-Elliman & Paul A. Monach

WBE's perspective

My 2020 started with an email entitled, "Happy New Year! Have You Read about this Virus that's Coming to Kill Us All?"

I remember the last day my life was "normal." It was the end of February, 2020 and I was on the phone with my father, and he was asking me my