Managing interventional clinical trials in the setting of COVID-19: Experience in an autoimmune skin disease unit

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The impact of the novel COVID-19 has diverted research efforts to COVID-19, leaving other research without clear plans of how to continue safely and effectively. This was the case in interventional clinical trials unrelated to COVID-19, a vital component in bringing much needed new medications to patients. These trials should be continued if they can be completed safely, not only for good data and potential approval of needed treatments but because enrolled patients may have a worsening disease without access to care. With COVID-19 case numbers increasing in many areas worldwide, it is more important than ever to analyze our response to improve policies and procedures. By describing our experiences in the Autoimmune Skin Disease Unit at the University of Pennsylvania, we hope to provide a framework for other clinical research units in how to maintain essential research through a pandemic or similar crisis. This experience is limited to a single academic center; thus, the feasibility of continuing any research should be assessed against local restrictions and current disease burden.

Our approach throughout the COVID-19 pandemic focused on frequent and open communication between research staff, patients, our local institutional review board, and industry sponsors. As guidelines frequently changed based on new data, it was important to communicate to adjust procedures to the current best practice. When possible, safety visits and laboratory collection were conducted remotely to avoid unnecessary in-person exposure. In situations where investigational medicinal product (IMP) distribution was required, abbreviated visits were offered where subjects could pick up the IMP in their car. Standard visits were conducted when on-site study procedures, such as IMP administration or biopsies, were required. Procedures such as photography, which required prolonged mucosal exposure, and spirometry, which could facilitate COVID-19 transmission, were discontinued and recorded as protocol deviations. In total, 26 of our 29 current interventional clinical trial patients elected to continue in-person visits during the pandemic shutdown to receive IMP, while 3 opted for abbreviated visits, picking up the IMP from their cars.

Abbreviation used:

IMP: investigational medicinal product

We followed current personal protective equipment recommendations, adhered to room-cleaning protocols, and spaced visits to allow adequate time for disinfection. Communication from patients was encouraged for updates regarding COVID-19

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exposure or infection. After 5 months and 103 research patient visits, none of our patients have tested positive for COVID-19.

Other specialties, such as oncology, also continued in-person visits for essential study procedures, although these opted for telemedicine when possible.[1] Although the use of teledermatology in clinical trials could be favorable during a pandemic, this approach needs further investigation. Berg et al[2] found that the remote use of cutaneous assessment tools is inferior to an on-site expert evaluation. On-site visits provide superior efficacy and safety data and could still be carried out provided that the highest level of safety measures are set in place. The continued participation of patients should be reviewed regularly by the investigator and/or the medical monitors of the trial.

Clinical trials are critical in diseases where patients have poor quality of life and limited therapeutic options such as in cutaneous lupus erythematosus and dermatomyositis.[3] With such large investments of resources and effort in attaining better therapies, careful planning and execution is required to prevent the derailing of important studies.

Conflicts of interest

Dr Werth has received honoraria from Biogen, Celgene, Eli Lilly, GlaxoSmithKline, Resolve, Abbvie, AstraZeneca, Kyowa Kirin, Cugene, and Medimmune and has received grants form Biogen, Celgene, and Viela. Authors Borucki, Concha, Burroughs, and Okawa have no conflicts of interest to declare.

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