THIRD ROUND OF UPDATES TO THE FDA GUIDANCE FOR CLINICAL TRIAL RESEARCHERS AMID COVID-19 PANDEMIC

July 7, 2020

THE U.S. FOOD AND DRUG ADMINISTRATION ("FDA") AGAIN SUPPLEMENTS ITS MARCH 18 GUIDANCE ENTITLED "CONDUCT OF CLINICAL TRIALS OF MEDICAL PRODUCTS DURING COVID-19 PUBLIC HEALTH EMERGENCY"

The FDA is again seeking to further address the challenges raised by COVID-19 changes in isolation practices, site closures, travel limitations, and supply chain interruptions by updating its research guidance. Balancing concerns for trial participant safety with the need to maintain good clinical practices and trial integrity, the new guidance provisions further refine permissible methods for obtaining informed consent and documenting trial visits conducted via telehealth modalities. The updated guidance is posted here, and a brief summary of key provisions follows.

OBTAINING INFORMED CONSENT FROM A HOSPITALIZED PATIENT WHO IS IN ISOLATION

The FDA provides clarity on two alternate informed consent procedures that will satisfy FDA's informed consent documentation requirements when it is not feasible to utilize a paper copy or an electronic version of the consent form. These procedures may become necessary when a hospital's COVID-19 infection control policy prevents research staff from entering a patient's room to collect a signature. Under the first method, a telephone or video conference may be held between the patient and study staff to discuss a consent form delivered to the patient by someone permitted to be in the patient's room. After following a standardized process for that conference, a photograph of the signed form may be entered into the trial record along with the required attestation. Where a photograph of the signed consent form cannot be obtained in that scenario, the telephone or video conference may be attended by a witness, or may be recorded in lieu of the participation of a witness and entered into the record along with certain other attestations. For either method, certain additional recordkeeping and documentation requirements are also provided.

OBTAINING INFORMED CONSENT WHERE OBTAINING THE SIGNATURE IS NOT FEASIBLE

The FDA recognizes that COVID-19 challenges may prevent a prospective trial participant (or his/her legally authorized representative) from printing and signing a paper copy of the consent form even where successfully delivered through electronically means. Additionally, those same challenges may prevent the individual from electronically signing the form. Tight study conduct timeframes may likewise make it impossible for the signed consent form to be effectively mailed or otherwise delivered in hard copy back to the clinical trial staff. The FDA has provided an alternative process for obtaining and documenting informed consent under these circumstances that involves the use of a telephone or video conference and verbal confirmation by the participant (or legally authorized representative) that they signed and dated a blank piece

of paper with a written statement that they voluntarily agree to participate in the protocol, noting both the Protocol 'NUMBER' and brief protocol title after the consent form is received electronically by the participant. An image of the newly created document must be sent to the study staff by facsimile, text message, or email or, alternatively, the document itself may be mailed or brought to a subsequent in-person study visit. Once received through any of these routes, the document must be appended to a copy of the consent document and retained in the trial records with certain other required notations. Although this approach would appear to lend great flexibility, before being implemented, the approach itself must first be reviewed and approved by the IRB overseeing the trial.

DOCUMENTATION BEST PRACTICES FOR REMOTE TRIAL VISITS

Drawing from learnings from the recent increased use of telemedicine in clinical practice, the FDA clarified that the same information that would be documented during a face-to-face visit should be included in the record when those visits are conducted remotely, including the date of a real-time video conference visit and the time of the visit. Additionally, investigators should consider asking for the trial participant's location during a video conference visit in case a medical emergency arises.

CONCLUSION

The COVID-19 public health emergency continues to impact the conduct of clinical trials of medical products, including drugs, devices, and biological products in unprecedented ways. The FDA is acting quickly to consider how challenges posed by quarantines, site closures, travel limitations, interruptions to the supply chain for the investigational product, and other considerations can be addressed.

If you have any questions about these pharmacy measures, please contact a member of the Life Sciences team. For any other concerns arising from the pandemic, please contact a member of our COVID-19 Task Force.