FDA Updates Clinical Trial Guidance, Addressing Adverse Event Reporting (June 8)
Sponsors and sites conducting non-COVID-19 research should use an independent data
monitoring committee to determine whether serious adverse events (SAE) are caused by
the COVID-19 virus or by the investigational drug before submitting a safety report to the
FDA, according to an update to the agency’s guidance on conducting clinical trials during the
COVID-19 crisis. The guidance acknowledges that trial participants may become infected for
reasons unrelated to the investigational drug and says only those SAEs that can be
attributed to the drug itself need to be reported. Sponsors of already-approved drugs being
tested for use against COVID-19 also must report SAEs if they determine the drug caused
the event, according to this third update to the guidance the FDA first issued in March.

Full IRB Review Not Required for Expanded Access Requests, FDA Says (June 8)
Citing a substantially increased volume of requests for expanded access to investigational
drugs to treat COVID-19, the FDA has issued a final guidance that clarifies the conditions
under which it will consider sponsor and investigator requests for waivers from full IRB
review. The guidance, which will be in effect only for the duration of the public health
emergency, says the agency will grant a waiver if an IRB chairperson or other designated
IRB member approves the individual use before treatment begins. The guidance
recommends that IRBs establish procedures for single-member review that focus on
assessing the risks and benefits for the patient involved. A new protocol is not necessary for
expanded access, the agency says, if the patient’s history and treatment plan provide
enough information for the assessment.

ISO 14155 Update to Focus on Risk Management in Medical Device Trials (June 8)
Sponsors and sites conducting medical device trials will need to include risk-based
monitoring and clinical quality management plans in their clinical trial development plans
under the upcoming revision of ISO 14155, the international standard on good clinical
practices for devices. The revised standard, ISO 14155:2020, will be published later this
year, adding a number of new requirements for device trials, including a focus on risk
management throughout the clinical investigation process, a process for escalating
unanticipated serious adverse device effects, registration of the trial in a publicly available
database and increased attention to statistical considerations.

Remote GCP Inspections May Be More Demanding Than On-Site Inspections, Says
EMA Guidance (6/15)
Remote good clinical practice (GCP) inspections of a trial site and/or sponsor may be
necessary during the COVID-19 health crisis, according to new guidance from the European
Medicines Agency (EMA), but inspection teams should recognize that preparation of remote
GCP inspections will be more demanding than on-site inspections as it will require early
communication with the sponsor to determine whether a remote inspection is feasible.
Sites/sponsors will also need to meet requirements for providing remote access to electronic
systems while maintaining communication and support to inspectors, according to the
guidance. Inspectors as well as the sponsor and/or site should be granted remote access to
electronic case report form (eCRF) systems and should be able to review electronic trial
master file (eTMF) audit trails, activity logs and metadata during inspections.

Patient Experience Data Should Influence Trial Design, FDA Guidance Says (6/22)
New recommendations for the collection, reporting, management and analysis of patient
experience data to be used in trial design are outlined in a final guidance the FDA released last week. An eight-step process for collecting and using patient experience data set out in the guidance includes determining the population from which to collect data, considering the research setting and data collection instruments, and deciding what analyses of the data will be needed to achieve research objectives. In this process, trials should examine previous studies and relevant research literature, and consult subject matter experts to help determine the most appropriate questions to ask patients. The guidance outlines how to identify target patient populations and provides recommended methods of collecting data.

These headlines are excerpted from the CenterWatch Weekly (CWW), FDAnews Drug Daily Bulletin, and FDAnews Device Daily Bulletin. CenterWatch Weekly is one of several newsletters published by CenterWatch, the global source for clinical trials information, timely news, in-depth analysis, study grant and career opportunities, and the largest listing of industry-funded clinical trials on the Internet. For more information, visit www.centerwatch.com. FDAnews Drug Daily Bulletin and FDAnews Device Daily Bulletin are published by FDAnews, which provides regulatory and quality executives the most thorough, up-to-date understanding of inner workings at the FDA and EMA and how they’re likely to alter your development and manufacturing strategies. For more information, visit www.fdanews.com.