

临

中

与

(FDA)

与 中 (CDER)

与 中 (CBER)

中 (CDRH)

临

(OGCP)

The Food and Drug Administration (FDA or Agency) plays a critical role in protecting the United States from threats including emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support continuity and response efforts to this pandemic.

FDA ( COVID-19 )  
。 FDA ,  
。

FDA is issuing this guidance to provide general considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity during the COVID-19 pandemic.

FDA — (sponsors) 、  
临 (GCP) COVID-19  
。

Given this public health emergency, this guidance is being implemented without prior public comment because the FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

临 与 (FD&C) 、  
21 , FDA  
。

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidance means that something is suggested or recommended, but not required.

， FDA ( ) □ 上 。 ，  
了 FDA 个主 ， 了  
为 。 FDA 中 “ ”—  
。

There is currently an outbreak of respiratory disease caused by a novel coronavirus that was first detected in Wuhan City, Hubei Province, China, and that has now been detected in many locations internationally, including cases in the United States. The virus has been named “SARS- CoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.1 In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.

， 中 一 为“SARS CoV-2”，  
， 为 2019（COVID-19）。2020 1 31 ，  
与 （HHS） 了一 与 COVID-19  
为 COVID-19， 2020 3 13 。

FDA recognizes that the COVID-19 pandemic may impact the conduct of clinical trials of medical products. Challenges may arise, for example, from quarantines, site closures, travel limitations, interruptions to the supply chain for the investigational product, or other considerations if site personnel or trial subjects become infected with COVID-19. These challenges may lead to difficulties in meeting protocol-specified procedures, including administering or using the investigational product (For the purposes of this guidance, the term investigational product refers to human drugs and biological products, and medical devices.) or adhering to protocol-mandated visits and laboratory/diagnostic testing. FDA recognizes that protocol modifications may be required, and that there may be unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 control measures. Although the necessity for, and impact of, COVID-19 control measures on trials will vary depending on many factors, including the nature of disease under study, the trial design, and in what region(s) the study is being conducted, FDA outlines the following general considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity.

FDA COVID-19 临 。  
COVID-19, 临 、 、 、 )  
(investigational product, 中 )  
中 。

FDA ， 且 COVID-19 / COVID-19  
不 。 COVID-19  
了 下一 ， 个 ， FDA  
临 (sponsors)  
(GCP) 。

临



• Ensuring the safety of trial participants is paramount. Sponsors should consider each circumstance, focusing on the potential impact on the safety of trial participants, and modify study conduct accordingly. Study decisions may include those regarding continuing trial recruitment, continuing use of the investigational product for patients already participating in the trial, and the need to change patient monitoring during the trial. In all cases, it is critical that trial participants are kept informed of changes to the study and monitoring plans that could impact them.

。 ， 下 :  
、 为 与  
。 下， 了  
。

• Sponsors, in consultation with clinical investigators and Institutional Review Boards (IRBs)/Independent Ethics Committees (IECs), may determine that the protection of a participant's safety, welfare, and rights is best served by continuing a study participant in the trial as per the protocol or by discontinuing the administration or use of the investigational product or even participation in the trial. Such decisions will depend on specific circumstances, including the nature of the investigational product, the ability to conduct appropriate safety monitoring, the potential impact on the investigational product supply chain, and the nature of the disease under study in the trial.

与临 (IRB) / (IEC) ,  
与 中  
, 中 与 , , 。  
, , ,  
中 。

• Since trial participants may not be able to come to the investigational site for protocol-specified visits, sponsors should evaluate whether alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) could be implemented when necessary and feasible, and would be sufficient to assure the safety of trial participants. Sponsors should determine if in-person visits are necessary to fully assure the safety of trial participants (for example to carry out procedures necessary to assess safety or the safe use of the investigational product appropriately); in making the decision to continue use or administration of the investigational product, the sponsor should consider whether the safety of trial participants can be assured with the implementation of the altered monitoring approach.

，  
( , , )

(virtual visit)、

, ,  
。

中 ), 且  
□ ,

之 , ,  IRB 下 IND IDE

specific specimens, if feasible. For individual instances where efficacy endpoints are not collected, the reasons for failing to obtain the efficacy assessment should be documented (e.g., identifying the specific limitation imposed by COVID-19 leading to the inability to perform the protocol-specified assessment).

, FDA  与  
 , 下,   
 。  个 ,   
 ( , COVID-19 ,  
 )。

- If changes in the protocol will lead to amending data management and/or statistical analysis plans, the sponsor should consider doing so in consultation with the applicable FDA review division. Prior to locking the database, sponsors should address in the statistical analysis plan how protocol deviations related to COVID-19 will be handled for the prespecified analyses.

中 / , 与  
FDA 。 之 ,  
与 COVID-19 。

- If planned on-site monitoring visits are no longer possible, sponsors should consider optimizing use of central and remote monitoring programs to maintain oversight of clinical sites.

不  中  
 , 临 。

、 一 , :

- Sponsors, clinical investigators, and IRBs should consider establishing and implementing policy and procedures, or revise existing policy and procedures, to describe approaches to be used to protect trial participants and manage study conduct during possible disruption of the study as a result of COVID-19 control measures at study sites. Changes to policy and procedures could address, but not be limited to, impact on the informed consent process, study visits and procedures, data collection, study monitoring, adverse event reporting, and changes in investigator(s), site staff, and/or monitor(s) secondary to travel restrictions, quarantine measures, or COVID-19 illness itself. Policy and procedures should be compliant with applicable (regional or national) policy for the management and control of COVID-19. Depending upon the nature of the changes described above, a protocol amendment may be required under the applicable regulations (see 21 CFR 312.30(b) and 21 CFR 812.35(a)).

、临 IRB ,   
 , COVID-19 中  
 。 不  
 、 不  、  
 / 、 COVID-19  
 。 COVID-19 ( )

。 上 ， ( 21  
CFR 312.30(b) and 21 CFR 812.35(a))。

、  :  
Sponsors should describe in appropriate sections of the clinical study report (or in a separate study-specific document):

临 ( 中 ) :

1. Contingency measures implemented to manage study conduct during disruption of the study as a result of COVID-19 control measures.

1. COVID-19 中 ， 为  
。

2. A listing of all participants affected by the COVID-19 related study disruption by unique subject number identifier and by investigational site, and a description of how the individual's participation was altered.

2. 中 COVID-19 中  ( 一  
)， 个 与 。

3. Analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., trial participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the study.

3. ( ， / 与 、  
/  )

Robust efforts by sponsors, investigators, and IRBs/IECs to maintain the safety of trial participants and study data integrity are expected, and such efforts should be documented. As stated above, FDA recognizes that protocol modifications may be required, including unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 control measures. Efforts to minimize impacts on trial integrity, and to document the reasons for protocol deviations, will be important.

、 IRB/IEC 为  
 ， 上 ， FDA  
， COVID-19 / COVID-19 不  
。  
。



For further questions on clinical trial conduct during the COVID 19 pandemic, please email:

□ 临 :

[Clinicaltrialconduct-COVID19@fda.hhs.gov](mailto:Clinicaltrialconduct-COVID19@fda.hhs.gov).

Contact information for FDA's review divisions is as follows:

FDA :

CDER:

<https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-new-drugs>

CBER:

<https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/contactcenter-biologics-evaluation-research-cber#indcont>

CDRH:

<https://www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization>

, 丹 中 与

丹

( )

□

~~某~~ CEO

中

专业、

专业

主