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Decentralized Clinical Trials for Drugs, Biological Products, and Devices

药物、生物制品和器械的去中心化临床试验

Guidance for Industry, Investigators, and Other Stakeholders

行业、研究者和其他利益相关者指南

DRAFT GUIDANCE

指南草案

This guidance document is being distributed for comment purposes only.

本指南文件仅供征求意见之用。

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

关于本文件草案的意见和建议应在《联邦公报》发布指南草案通知后 90 天内提交。将电子意见提交至 https://www.regulations.gov。将书面意见提交至美国食品药品监督管理局卷宗管理人员（HFA-305），地址：5630 Fishers Lane,rm. 1061,Rockville,MD 20852。所有意见均应注明发布于《联邦公报》中的可用性通知所列出的档案编号。

For questions regarding this draft document, contact (CDER) Ryan Robinson, 240-402-9756; (CBER) Office of Communication, Outreach, and Development, 800-835-4709 or 240-4028010; (CDRH) Office of Clinical Evidence and Analysis, cdrhclinicalevidence@fda.hhs.gov; or (OCE) Paul Kluetz, 301-796-9657.

关于本文件草案的问题，请联系（CDER）Ryan Robinson，240-402-9756；（CBER）沟通、推广和发展办公室，800-835-4709 或 240-4028010；（CDRH）临床证据和分析办公室，CDRHClinicalEvidence@fda.hhs.gov；或（OCE）Paul Kluetz，电话：301-796-9657。

U.S. Department of Health and Human Services

美国卫生与公众服务部

Food and Drug Administration

美国食品药品监督管理局

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药品评价和研究中心（CDER）

Center for Biologics Evaluation and Research (CBER)

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器械与放射卫生中心（CDRH）

Oncology Center of Excellence (OCE)

肿瘤卓越中心（OCE）

May 2023

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包含不具有约束力的建议

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行业、研究者和其他利益相关者指南 [Footnoteref:1][1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

本指南草案定稿后，将代表美国食品药品监督管理局（FDA 或机构）对该主题的当前看法。它不为任何人建立任何权利，也不对 FDA 或公众具有约束力。如果满足适用法令和法规的要求，您可以使用替代方法。如需讨论替代方法，请联系标题页上列出的负责本指南的 FDA 工作人员。

I. INTRODUCTION

I. 引言

This draft guidance provides recommendations for sponsors, investigators, and other stakeholders regarding the implementation of decentralized clinical trials (DCTs) for drugs, biological products, and devices.,, In this guidance, a DCT refers to a clinical trial where some or all of the trial-related activities occur at locations other than traditional clinical trial sites.

本指南草案为申办者、研究者和其他利益相关者提供了关于实施药物、生物制品和器械的去中心化临床试验（DCT）[FootnoteRef:2]的建议。

[FootnoteRef:3],[FootnoteRef:4],[FootnoteRef:5]在本指南中，DCT 是指部分或全部试验相关活动在传统临床试验中心以外的地点进行的临床试验。[2345]

In fully decentralized clinical trials, all activities take place at locations other than traditional trial sites. These trial-related activities may take place at the homes of trial participants or in local health care facilities that are convenient for trial participants. In hybrid DCTs, some trial activities involve in-person visits by trial participants to traditional clinical trial sites, and other activities are conducted at locations other than traditional clinical trial sites, such as participants' homes.

在完全去中心化的临床试验中，所有活动均在传统的研究中心以外的地点进行。 这些试验相关活动可在受试者家中或受试者就近的当地医疗保健机构进行。 在混合 DCT 中，一些试验活动需要受试者到传统的临床试验中心访视，而其他的活动则在传统临床试验研究中心以外的地点进行，如受试者家中。

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[1] This guidance has been prepared by the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), and the Oncology Center of Excellence (OCE) at the Food and Drug Administration.
本指南由药品评价和研究中心（CDER）与生物制品评价和研究中心（CBER）、器械和放射卫生中心（CDRH）以及美国食品药品监督管理局肿瘤卓越中心（OCE）合作编写。

[2] Words and phrases in bold are defined in the Glossary.
粗体字和短语在词汇表中定义。

[3] See section 201(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(g)) for the definition of a drug. In this guidance, all references to drugs include both human drugs and biological products, unless otherwise specified.
有关药物的定义，请参见《联邦食品、药品和化妆品法案》（FD&C 法案）（21 U.S.C.321（g））第 201（g）节。 在本指南中，除非另有说明，否则所有药物均包括人用药物和生物制品。

[4] See section 351(i) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(i)) for the definition of a biological product.
关于生物制品的定义，请参见《公共卫生服务法》（PHS 法案）（42 U.S.C.262（i））第 351（i）条。

[5] See section 201(h) of the FD&C Act (21 U.S.C. 321(h)) for the definition of a device.
有关器械的定义，请参见 FD&C 法案第 201（h）条（21 U.S.C.321（h））。

FDA's regulatory requirements for investigations of medical products are the same for DCTs and traditional site-based clinical trials. Section 3606(a) of the Food and Drug Omnibus Reform Act (FDORA) directs FDA to "issue or revise draft guidance that includes recommendations to clarify and advance the use of decentralized clinical studies to support the development of drugs and devices," not later than December 29, 2023. This guidance provides recommendations related to FDA's requirements for investigations of medical products when applied to DCTs and fulfills the requirement set forth in section 3606(a)(1) of FDORA. The content described in section 3606(b) of FDORA is further addressed through this guidance's reference to the draft guidance for industry, investigators, and other stakeholders entitled Digital Health Technologies for Remote Data Acquisition in Clinical Investigations (December 2021).

美国食品药品监督管理局对医疗产品研究的监管要求对 DCT 和传统的以研究中心为主的临床试验相同。[FootnoteRef:6]《食品药品综合改革法案》（FDORA）第 3606（a）节指导 FDA 在 2023 年 12 月 29 日之前"发布或修订指南草案，其中包括澄清和推进使用去中心化临床研究以支持药物和器械开发的建议"。本指南提供了应用 DCT 时 FDA 对医疗产品研究要求相关的建议，并需符合 FDORA 第 3606（a）（1）条规定的要求。《FDORA》第 3606(b)节中描述的内容将进一步于对行业、研究者和其他利益相关者的草案指南阐述，通过本指南标题为"临床研究中远程数据采集的数字健康技术"（2021 年 12 月）的参考文献。[FootnoteRef:7][67]

In general, FDA's guidance documents 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 guidances means that something is suggested or recommended, but not required.

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[6] See 21 CFR parts 312 and 812.

参见 21 CFR 第 312 和 812 部分。

[7] When final, this guidance will represent FDA's current thinking on this topic. We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatoryinformation/search-fda-guidance-documents.

最终定稿后，本指南将代表 FDA 当前对该主题的看法。我们定期更新指南。有关指南的最新版本，请访问 FDA 指南网页 https://www.fda.gov/RegulatoryInformation/search-fda-guidance-documents。

总体而言，FDA 的指南文件未确立法律上可强制执行的责任。相反，指南描述了 FDA 当前对某一主题的看法，应仅视为建议，除非引用了具体的法规或法定要求。FDA 指南中使用的“应该”一词是指建议或推荐，但不是强制要求。

II. BACKGROUND

II. 背景

Many clinical trials already include decentralized elements such that not all trial-related activities involving participants take place at traditional clinical trial sites. For example, laboratory tests are often conducted by clinical laboratory facilities at locations remote from traditional trial sites. DCTs have the potential to expand access to more diverse patient populations and improve trial efficiencies. Advances in clinical care using electronic communications and information technology to interact with trial participants in different locations (i.e., telehealth) allow for fewer in-person visits to clinical trial sites. Digital health technologies (DHTs), for example, have expanded the types of trial-related data that can be obtained remotely from trial participants. By enabling remote participation, DCTs may enhance convenience for trial participants, reduce the burden on caregivers, and facilitate research on rare diseases and diseases affecting populations with limited mobility or access to traditional trial sites. This may help improve trial participant engagement, recruitment, enrollment, and retention of a meaningfully diverse clinical population.

许多临床试验已经包括去中心化的要素，因此并非所有涉及受试者的试验相关活动都在传统临床试验研究中心进行。例如，实验室检查通常由远离传统研究中心的临床实验室机构进行。DCT 有可能扩大获得更多样化患者人群的机会，并提高试验效率。[Footnoteref:8]临床护理方面的进展,使用电子通信和信息技术与不同地点的试验受试者进行互动（即远程医疗），从而减少了到临床试验中心的现场访视。例如，数字健康技术(DHT)扩大了可以从试验受试者那里远程获取试验相关数据的类型。通过实现远程参与，DCT 可提高试验受试者参与临床试验的便利性，减轻护理者的负担，并促进对罕见疾病

和患者活动受限或无法前往传统研究中心的疾病的研究。 这可能有助于改善有意义的多样化临床人群的参与、招募、入组和保留。[8]

Fully decentralized trials may be appropriate for investigational products (IPs) that are simple to administer or use, have well-characterized safety profiles (see section III.F), and do not require complex medical assessments. Alternatively, hybrid decentralized trials may be more appropriate in cases where the administration of an IP or a complex medical assessment needs to be performed at a clinical trial site and some follow-up assessments could be performed remotely through online patient-reported outcome measures, via telehealth or in-home visits, or by local health care providers (HCPs), as appropriate (see section III.B).

完全去中心化的试验可能适用于易于给药或使用、具有充分的安全性特征（见第 III.F 节）且不需要复杂医学评估的试验用药品（IP）。 或者，如果需要在临床研究中心进行给药(IP)或进行复杂的医学评估，而一些随访评估可以通过在线患者报告结局指标、远程医疗或家庭访视远程进行或由当地医疗保健提供者（HCP）完成（视情况而定），则混合去中心化试验可能更合适（见第 III.B 节）。

Challenges related to DCTs may include coordination of trial activities with individuals and facilities in multiple locations that are not traditional clinical trial sites. DCTs generally include specific plans to facilitate the decentralization of the trial. These plans should include, as appropriate, the use of local health care facilities, local HCPs, and local clinical laboratory facilities; visits to trial participants' homes; and direct distribution of the IP to trial participants at their locations. Specific issues related to the feasibility, design, implementation, or analysis of a DCT should be discussed early with the relevant FDA review divisions. Appropriate training, oversight, and up-front risk assessment and management will be key to implementing a DCT successfully.

与 DCT 相关的挑战可能包括与非传统临床研究中心的多个地点的个人和机构的试验活动的协调。 DCT 通常包括促进分散化操作的具体计划。 这些计划应包括（如适用）使用当地医疗保健机构、当地医疗保健提供者（HCP）和当地临床实验室机构；到试验受试者的家中访视； 并将试验用药品（IP）直接发送给各地的

[8] See the guidance for industry Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs (November 2020).
参见行业指南“增强临床试验人群的多样性-合格性标准、入组实践和试验设计”（2020 年 11 月）。

118 试验参与者。应尽早与相关的 FDA 审查部门讨论 DCT 的可行性、设计、实施或分析有关的具体问题。适当
119 的培训、监督以及前期风险评估和管理将是成功实施 DCT 的关键。[9][10]

120

121 ## III. RECOMMENDATIONS FOR IMPLEMENTING DCTS

122 ## III. 实施 DCT 的建议

123

124 The sections below provide guidance on specific topics for DCT implementation.
125 以下各节提供了关于 DCT 实现的特定主题的指导。

126

[9] See 21 CFR 312.57(a), 312.62(a), 812.140(a)(2), and 812.140(b)(2) (describing requirements for disposition of the investigational product).
参见 21 CFR 312.57（a)、312.62（a)、812.140（a）（2）和 812.140（b）（2）（描述试验用药品的处置要求)。

[10] See the draft guidance for industry Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products (December 2017) and the draft guidance for industry Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products (June 2018). When final, these guidances will represent FDA's current thinking on these topics. See also the guidance for industry and FDA staff Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program (January 2021). For applicants preparing abbreviated new drug applications (ANDAs), the Office of Generic Drugs in CDER encourages submission of controlled correspondence or a pre-ANDA meeting request to discuss the design, analysis, and implementation of a DCT before conducting the trial. See the draft guidance for industry Controlled Correspondence Related to Generic Drug Development (December 2022) (when final, this guidance will represent FDA's current thinking on this topic). For submitting a pre-ANDA meeting request, see the revised guidance for industry Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA (October 2022).
参见行业指南草案 FDA 与 PDUFA 申办者或申请人之间的正式会议 产品（2017 年 12 月）和行业指南草案 FDA 与 BSUFA 产品申办者或申请人之间的正式会议（2018 年 6 月)。 最终定稿后，这些指南将代表 FDA 当前对这些主题的看法。 另请参见行业和 FDA 工作人员指南《医疗器械申报反馈和会议请求：Q 申报项目》（2021 年 1 月)。 对于准备简化新药申请（ANDA）的申请人，CDER 仿制药办公室鼓励提交受控通信或 ANDA 前会议请求，以在进行试验前讨论 DCT 的设计、分析和实施。 参见行业指南草案《仿制药开发相关受控通信》（2022 年 12 月）（定稿后，本指南将代表 FDA 当前对该主题的看法)。关于提交 ANDA 前会议请求，请参见经修订的行业指南《GDUFA 下复杂产品的 FDA 与 ANDA 申请人正式会议》（2022 年 10 月)。

A. DCT Design

A. DCT 设计

In a DCT, some or all trial-related activities will occur at locations other than traditional clinical trial sites (e.g., the participant's home or local health care facilities). DCTs may involve a network of locations where trial personnel and local HCPs work and where trial-related services (e.g., imaging and laboratory services) are provided, all under the oversight of the investigator.
在 DCT 中，部分或所有试验相关活动将在传统临床研究中心以外的地点进行（例如，受试者家中或当地医疗保健机构）。 DCT 可能涉及试验人员和当地 HCP 工作以及提供试验相关服务（例如成像和实验室服务）的地点网络，所有这些地点均在研究者的监督下进行。

For inspectional purposes, there should be a physical location where all clinical trial-related records for participants under the investigator's care are accessible and where trial personnel can be interviewed. This location should be listed on Form FDA 1572 or for investigational device exemption (IDE) applications must be included in the IDE application.
出于核查目的，应该有一个物理位置，可以访问研究中的受试者的所有临床试验相关记录，并可以与试验人员面谈。 该位置应列于 FDA 1572 表[FootnoteRef:11]中，或者试验用器械豁免（IDE）申请必须包含在 IDE 申请中。[FootnoteRef:12][11][12]

The variability and precision of the data obtained in a DCT may differ from the data in a traditional site-based clinical trial. This would not affect the validity of a finding of superiority in a trial using such data (although it could reduce the effect size), but it could affect the validity of a finding of non-inferiority. Remote assessments may differ from on-site assessments, particularly when trial participants are responsible for performing their own physiological tests

[11] This information should be entered under Sections 1 and 3 on Form FDA 1572.
该信息应输入 FDA 1572 表的第 1 节和第 3 节。

[12] See 21 CFR 812.20(b). The investigator's address is often the same as the location or institution where the trial is being conducted. However, if the addresses are different, both locations must be included in the IDE application.
参见 21 CFR 812.20（b）。 研究者的地址通常与开展试验的地点或机构相同。 但是，如果地址不同，则 IDE 申请中必须包含这两个位置。

(e.g., home spirometry). Assessments performed by local HCPs as part of routine clinical practice (e.g., evaluation of symptoms) may also be more variable and less precise than assessments conducted by dedicated trial personnel. In non-inferiority trials, when the effect size of an active control drug, for example, has only been determined in a traditional site-based clinical trial, it may not be reasonable to assume that the same effect size would be seen for the active control drug in a DCT. This may present challenges in calculating a non-inferiority margin. FDA review divisions should be consulted when planning a non-inferiority trial in a DCT setting.

在 DCT 中获得的数据的变异性和精确度可能与传统的基于研究中心的临床试验中的数据不同。 这不会影响 使用此类数据的试验中优效性结果的有效性（尽管可能会降低效应值），但可能会影响非劣效性结果的有效性。[FootnoteRef:13]远程评估可能与现场评估不同，尤其是当试验受试者负责进行自己的生理检查（例如家庭肺活量测定）时。由当地 HCP 进行临床评估时（例如，症状评价），即使是常规临床操作，也可能比由专门的试验人员进行的评估变异性更大，更不精确。 例如，在非劣效性试验中，当活性对照药物的效应值仅在研究中心进行传统临床试验中确定时，假设在 DCT 中观察到活性对照药物的相同效应值可能是不合理的。 这可能会给计算非劣效性界值带来挑战。 在 DCT 背景下计划非劣效性试验时，应咨询 FDA 审查部门。[13]

B. **Remote Clinical Trial Visits and Clinical Trial-Related Activities**

B. 远程临床试验访视和临床试验相关活动

Remote clinical trial visits and clinical trial-related activities are important strategies to make trials more convenient and more accessible to trial participants. The following should be considered when planning remote clinical trial visits or clinical trial-related activities:

远程临床试验访视和临床试验相关活动是使试验更方便、更容易为受试者参与用的重要策略。 计划远程临床试验访视或临床试验相关活动时，应考虑以下内容：

[13] See the guidance for industry Non-Inferiority Clinical Trials to Establish Effectiveness (November 2016).
参见行业指南《确定有效性的非劣效性临床试验》（2016 年 11 月）。

- In general, investigators can consider telehealth visits instead of in-person visits with trial participants if no in-person interaction is needed. The protocol should specify when a telehealth visit with a trial participant is appropriate and when a participant should be seen in person.

  一般而言，如果不需要面对面互动，研究者可以考虑远程医疗访视，而不需要受试者到现场进行访视。[FootnoteRef:14]方案应规定何时适合与试验受试者进行远程医疗访视以及何时应亲自见到受试者。[14]

- In-person visits and trial-related activities can be conducted by trial personnel who are sent to participants' homes or preferred locations.

  现场访视和试验相关活动可由试验人员前往受试者家中或受试者选择的地点进行。

- Depending on the trial protocol, in-person visits and trial-related activities may also be conducted by HCPs who are located close to trial participants' homes but are not part of the trial personnel. These local HCPs (such as doctors or nurses) may be used by sponsors or investigators to perform certain trial-related activities; for example, on a fee-for-service basis. The trial-related services that they provide should not differ from those that they are qualified to perform in clinical practice (e.g., performing physical examinations, reading radiographs, obtaining vital signs). These services should not require a detailed knowledge of the protocol or the IP.

  根据试验方案，现场访视和试验相关活动也可由位于试验受试者家中附近但不属于试验人员的 HCP 进行。申办方或研究者可使用这些当地 HCP（如医生或护士）进行某些试验相关活动；例如，按服务收费。他们提供的试验相关服务不应与他们在常规医疗中提供的服务不同（例如，进行体格检查、读取 X 线片、获取生命体征）。这些服务不需要详细了解试验方案或研究药物。

[14] See 21 CFR parts 312 and 812.

参见 21 CFR 第 312 和 812 部分。

- Trial-related activities that are unique to research and/or require a detailed knowledge of the protocol or the IP should be performed by qualified trial personnel who have been appropriately trained. When applicable, both trial personnel and trial participants should be trained on how to conduct or participate in a telehealth visit.
  研究特有和/或需要详细了解方案或 IP 的试验相关活动应由经过适当培训的合格试验人员进行。 如适用，试验人员和试验受试者均应接受如何进行或参与远程医疗访视的培训。

- During each remote trial visit, investigators should confirm the trial participant's identity. FDA does not endorse any specific identification method. Sponsors and/or investigators can consider referring to existing digital identity guidelines.
  在每次远程试验访视期间，研究者应确认试验受试者的身份。 FDA 不对任何特定的识别方法给出认定。 申办者和/或研究者可考虑参考现有的数字化身份指南。[FootnoteRef:15][15]

- Case report forms and other documentation should be completed for telehealth visits, including the date and time of the visit.
  远程医疗访视应填写病例报告表和其他文件，包括访视的日期和时间。

- The trial protocol should specify how adverse events identified remotely will be evaluated and managed. The protocol should describe how care will be provided for adverse events that require urgent or in-person attention. It is the sponsor and investigator's responsibility to ensure that remote clinical trial visits conducted via telehealth comply with laws governing telehealth in the relevant U.S. States or territories and other countries, as applicable.
  试验方案应规定如何评判和管理远程发现的不良事件。对需要紧急或现场关注的不良事件，方案应描述如何提供照护。 申办方和研究者有责任确保通过远程医疗进行的远程临床试验访视符合美国相关州或地区以及其他国家（如适用）关于远程医疗的法律。

[15] See, for example, National Institute of Standards and Technology (NIST) Digital Identity Guidelines, NIST Special Publication 800-63A: Enrollment and Identity Proofing Requirements when developing an identity verification plan (https://pages.nist.gov/800-63-3/sp800-63a.html).
例如，参见国家标准与技术研究所（NIST）数字身份指南，NIST 特别出版物 800-63A：制定身份验证计划时的入组和身份验证要求（https://pages.nist.gov/800-63-3/SP800-63A.html）。

C. **Digital Health Technologies**

C. 数字健康技术

DHTs may allow transmission of data remotely from trial participants wherever they are located. The sponsor should consider the following information regarding the use of DHTs in a DCT:
DHT 可允许远程传输来自试验受试者的数据，无论其位于何处。申办者应考虑以下关于在 DCT 中使用 DHT 的信息：

- The draft guidance for industry, investigators, and other stakeholders Digital Health Technologies for Remote Data Acquisition in Clinical Investigations provides recommendations to sponsors, clinical investigators, and other parties for measuring clinical events and characteristics of interest using DHTs to acquire data remotely from participants in clinical trials for drugs, biological products, and devices. The guidance discusses selection of DHTs for clinical trials; verification, validation, and usability testing; use of DHTs to collect data for clinical trial endpoints; training on the use of DHTs; and management of risks related to the use of DHTs in clinical trials. Other issues regarding the use of DHTs in clinical investigations are discussed in other FDA guidances.
  行业、研究者和其他利益相关者指南草案《临床研究中远程数据采集的数字健康技术》[FootnoteRef:16]向申办方、临床研究者和其他各方提供了使用 DHT 测量临床事件和关注特征的建议，以远程获取药物、生物制品和器械临床试验受试者的数据。本指南讨论了临床试验中 DHT 的选择；验证、确效和可用性测试；使用 DHT 收集临床试验终点的数据；关于 DHT 使用的培训；以及与临床试验中使用 DHT 相关的风险管理。其他 FDA 指南中讨论了关于在临床研究中使用 DHT 的其他问题。[FootnoteRef:17][16][17]

[16] When final, this guidance will represent FDA's current thinking on this topic.
最终定稿后，本指南将代表 FDA 当前对该主题的看法。

[17] See the revised draft guidance for industry Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers (March 2023). When final, this guidance will represent FDA's current thinking on this topic. For considerations on FDA's oversight of clinical decision support software, see the

- Sponsors should ensure that DHTs used in a DCT are available and suitable for use by all trial participants. When a trial permits participants to use their own DHTs, sponsor provided DHTs should be available as an option to ensure that participants who do not have a protocol-specified DHT are not excluded from the DCT for that reason (e.g., lower socioeconomic groups who cannot afford the DHT).
  申办者应确保 DCT 中使用的 DHT 可用且适合所有试验受试者使用。当试验允许受试者使用自己的 DHT 时，申办者提供的 DHT 应作为一种选择提供，以确保受试者不会因没有使用方案规定的 DHT 而被排除在 DCT 之外（例如，无法负担 DHT 的较低社会经济群体）。

D. **Roles and Responsibilities**

D. 职务和职责

The roles and responsibilities of sponsors and investigators are described below.
申办者和研究者的角色和职责如下所述。

1. The Sponsor

申办方

- Sponsor responsibilities are the same for DCTs and traditional site-based clinical trials. Because DCTs may involve many contracted services, sponsors should ensure proper coordination of the decentralized activities (e.g., use of mobile nurses for at-home visits, use of local HCPs, direct shipping of IP to participants) (see sections III.B and III.G).

guidance for industry and FDA staff Clinical Decision Support Software (September 2022). For information on patient-reported outcomes and other clinical outcome assessments, see BEST (Biomarkers, EndpointS, and other Tools) Resource Glossary, 2016, available at https://www.ncbi.nlm.nih.gov/books/NBK326791.
参见修订后的行业指南草案《临床研究中的电子系统、电子记录和电子签名：问答》（2023 年 3 月）。最终定稿后，本指南将代表 FDA 当前对该主题的看法。关于 FDA 监督临床决策支持软件的注意事项，请参见行业和 FDA 工作人员指南临床决策支持软件（2022 年 9 月）。有关患者报告结局和其他临床结局评估的信息，请参见 BEST（生物标志物、终点和其他工具）资源术语表，2016 年，网址为 https://www.ncbi.nlm.nih.gov/books/NBK326791。

对于 DCT 和传统的基于研究中心的临床试验，申办方的责任是相同的。[FootnoteRef:18]由于 DCT 可能涉及许多合同服务，申办方应确保适当协调去中心化活动（例如，使用流动护士进行家庭访视、使用当地 HCP、直接向受试者运输 IP）（见第 III.B 节和第 III.G 节）。[18]

- Sponsors should strive for diversity and inclusiveness in trial populations. Outreach through local health care institutions (e.g., pharmacies, clinics) may facilitate recruitment of diverse participants in areas where there are limited or no traditional clinical trial sites.
申办者应努力实现试验人群的多样性和广泛包容性。[Footnoteref:19]通过当地医疗保健机构（例如药房、诊所）进行外联活动可能有助于在没有传统临床试验中心或者数量有限的地区招募不同的受试者。[19]

Bringing trial-related activities to participants' homes, including through the use of DHTs, may reduce the need for travel and improve engagement, recruitment, and retention amongst potential participants with challenges accessing traditional clinical trial sites. The use of local HCPs close to potential participants' homes may improve engagement, recruitment, and retention of diverse participants (e.g., race, ethnicity, age, sex, and geographic location). Further, the use of local HCPs may reduce cultural or linguistic barriers to participation in clinical trials.
将试验相关活动带到受试者家中（包括通过使用 DHT），可能会减少差旅需求，并改善原本难以前往传统临床研究中心的潜在受试者的参与、招募和保留。利用潜在受试者家附近的当地 HCP，可能会改善多样化受试者（例如人种、种族、年龄、性别和地理位置）的参与、招募和保留。此外，利用当地 HCP 可减少参与临床试验的文化或语言障碍。

[18] See 21 CFR parts 312 and 812.
参见 21 CFR 第 312 和 812 部分。

[19] See the draft guidance for industry Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials (April 2022). When final, this guidance will represent FDA's current thinking on this topic.
参见行业指南草案《改善临床试验中代表性不足人种和种族人群受试者入组的多样性计划》（2022 年 4 月）。最终定稿后，本指南将代表 FDA 当前对该主题的看法。

- To account for multiple sources of data collection in a DCT, the sponsor should include at least the following in a data management plan (DMP):
  考虑到 DCT 中的多个数据收集来源，申办者应在数据管理计划（DMP）中至少包括以下内容：

  - Data origin and data flow from all sources to the sponsor (see section III.I) (e.g., a diagram that depicts the flow of data from creation to final storage)
    数据来源和从所有来源至申办方的数据流（见第 III.I 节）（例如，描述从创建到最终存储的数据流的图表）

  - Methods used for remote data acquisition from trial participants, trial personnel, and contracted service providers (e.g., local clinical laboratory facilities and local HCPs who perform trial-related activities)
    从试验受试者、试验人员和合同服务提供商处（例如，进行试验相关活动的当地临床实验室设施和当地 HCP）远程采集数据的方法[FootnoteRef:20][20]

  - A list identifying vendors for data collection, handling, and management
    用于识别数据收集、处理和管理的供应商的列表

- Sponsors should describe in the trial protocol how operational aspects of the DCT will be implemented. This description should cover, but may not be limited to, the following:
  申办者应在试验方案中描述 DCT 的操作方面将如何实施。 该描述应涵盖但不限于以下内容：

[20] See the revised draft guidance for industry Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers and the draft guidance for industry, investigators, and other stakeholders Digital Health Technologies for Remote Data Acquisition in Clinical Investigations for recommendations related to storage and handling of data. When final, these guidances will represent FDA's current thinking on these topics.
参见修订后的行业指南草案《临床研究中的电子系统、电子记录和电子签名：问答》和行业、研究者和其他利益相关者指南草案《临床研究中远程数据采集的数字健康技术》与数据存储和处理相关的建议。 最终定稿后，这些指南将代表 FDA 当前对这些主题的看法。

- Scheduled and unscheduled clinical trial visits (remote and in-person, as applicable)
  计划内和计划外临床试验访视（远程和现场，如适用）

- Transmission of reports on activities performed at different locations (e.g., medical imaging; clinical laboratory tests; and procedures performed at trial participants' home, work, or other local facility)
  传输在不同地点进行的活动的报告（例如，医学影像；临床实验室检查；以及在试验受试者家中、工作场所或其他当地机构进行的程序）

- Delivery of IPs to trial participants, if applicable, and accountability for IPs
  向试验受试者运送研究产品（如适用）和研究产品的清点

- Safety monitoring and management of adverse events
  安全性监测和不良事件管理

- Case report forms should identify when and where data were collected and by whom.
  病例报告表应确定收集数据的时间、地点以及由谁收集。

- Sponsors must comply with relevant local laws, regulations, and licensing requirements governing medical practice and IP administration when conducting a DCT. This may involve addressing laws in multiple U.S. States, territories, and other countries.
  在进行 DCT 时，申办方必须遵守管理医疗实践和研究产品的相关当地法律、法规和许可要求。这可能涉及美国多州、地区和其他国家的法律。

- Sponsors must ensure proper monitoring of an investigation. As with any trial, sponsors may use a variety of approaches to monitor DCTs, and the monitoring plan for a trial should be based on the sponsor's risk assessment. A trial monitoring plan should (1) describe how monitoring will be implemented to assess protocol compliance and data quality and integrity, (2) specify the frequency with which trial records and source documents will be reviewed, and (3) note any unique aspects related to the DCT

procedures. FDA encourages risk-based monitoring approaches and use of centralized monitoring to identify and proactively follow up on missing data, inconsistent data, data outliers, and potential protocol deviations that may be indicative of systemic or significant errors.

申办方必须确保对研究进行适当监查。[FootnoteRef:21]与任何试验一样，申办方可使用多种方法监查 DCT，试验的监查计划应基于申办方的风险评估。[FootnoteRef:22]试验监查计划应（1）描述如何实施监查，以评估方案依从性以及数据质量和完整性，（2）规定监查试验记录和源文件的频率，以及（3）注明与 DCT 程序相关的任何独特方面。 FDA 鼓励采用基于风险的监查方法和使用中心化监查，以识别和主动跟进被缺失数据、不一致的数据、数据离群值和可能提示系统性或重大错误的潜在方案偏离。[2122]

2. The Investigator and Delegation of Trial-Related Activities

研究者和试验相关活动的授权

Investigators are responsible for the conduct of the DCT and the oversight of individuals delegated to perform trial-related activities, including ensuring that these delegated activities and/or tasks are conducted according to the investigational plan, applicable regulations, and relevant laws. A key difference between DCTs and traditional site-based clinical trials is the extent to which the investigator uses telehealth, trial personnel working remotely, local HCPs, and/or DHTs in the conduct of the trial. Whether the trial can be conducted entirely using remote visits or a hybrid trial design is appropriate depends on the types of assessments and procedures needed to collect endpoints and monitor safety. The decentralized features of the trial may necessitate additional training, coordination, and standard operating procedures to ensure consistent implementation.

研究者负责开展 DCT 并监督被授权履行试验相关活动的人员，包括确保这些被授权的活动和/或任务

[21] See 21 CFR 312.50 and 812.40.
参见 21 CFR 312.50 和 812.40。

[22] For detailed information on risk-based approaches to monitor clinical trials, see the guidance for industry A RiskBased Approach to Monitoring of Clinical Investigations: Questions and Answers (April 2023).
有关基于风险的临床试验监测方法的详细信息，请参见行业指南《基于风险的临床研究监测方法：问答》（2023 年 4 月）。

按照研究计划、适用法规和相关法律进行。[FootnoteRef:23]，[FootnoteRef:24]DCT 与传统基于研究中心的临床试验之间的主要区别在于研究者在试验开展过程中使用远程医疗、远程工作的试验人员、当地 HCP 和/或使用 DHT 的程度。 试验是否适合完全使用远程访视或以混合试验设计进行，取决于收集终点和监测安全性所需的评估类型和程序。试验的去中心化特点可能需要额外的培训、[Footnoteref:25]协调和标准作业程序，以确保执行的一致性。[232425]

- When permitted by the trial protocol, investigators may delegate trial-related activities to local HCPs to perform trial-related procedures that require in-person interactions with trial participants (e.g., physical examinations and other medical procedures). These procedures may take place at participants' locations or other local health care facilities as specified by the trial protocol.
  如果试验方案允许，研究者可将需要与试验受试者现场访视和互动的试验相关活动授权给当地 HCP 来进行（例如体格检查和其他医疗程序）。[FootnoteRef:26]这些程序可在试验方案规定的受试者所在地或其他当地医疗机构进行。[26]

- Videoconferencing and other technologies may be useful to allow investigators to oversee trial personnel performing activities described in the trial protocol (e.g., photographing lesions, fitting wearable sensors) at participants' locations.

[23] See 21 CFR 312.60, 312.61, and 812.100.
参见 21 CFR 312.60、312.61 和 812.100。

[24] See the guidance for industry Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects (October 2009).
参见行业指南《研究者职责-保护研究受试者的权利、安全和福利》（2009 年 10 月）。

[25] See 21 CFR 11.10(i).
参见 21 CFR 11.10（i）。

[26] See 21 CFR 312.3 and 812.3.
参见 21 CFR 312.3 和 812.3。

视频会议和其他技术可能有助于研究者监督试验人员在受试者所在地进行试验方案中描述的活动（例如，拍摄病变、安装可穿戴传感器）。

- Investigators should enroll only as many trial participants as they can appropriately manage to ensure adequate supervision of DCT-related activities.
研究者应仅入组他们能够适当管理的试验受试者数量，以确保充分监督 DCT 相关活动。

- As for any drug trial subject to 21 CFR 312.53, Form FDA 1572 must be completed by all investigators. The decision to include individuals as subinvestigators in a DCT should be based on their assigned responsibilities.
对于受 21 CFR 312.53 约束的任何药物试验，所有研究者必须填写 FDA 1572 表。 在 DCT 中增加助理研究者（Sub-I）的决定应基于其分配的职责。

  - When trial personnel contribute directly and significantly to the trial data, they should be included on Form FDA 1572 as subinvestigators.
  当试验人员对试验数据的产生有直接和重要作用时，应将其作为助理研究者（Sub-I）纳入 FDA 1572 表中。[FootnoteRef:27][27]

  - Local HCPs contracted to provide trial-related services that are part of routine clinical practice (e.g., performing physical examinations, reading radiographs, obtaining vital signs) and where a detailed knowledge of the protocol, IP, and the investigator's brochure is not necessary should not be listed on Form FDA 1572 as subinvestigators. However, local HCPs should be included in a task log (as described below in this section).
  当聘用当地 HCP 提供常规临床工作的试验相关服务（例如，进行体格检查、读取 X 线片、获取生命体征），并且不需要详细了解方案、IP 和研究者手册的情况下，当地

[27] See 21 CFR 312.3 and 312.53. For more information on subinvestigators, see questions 31 and 32 in the information sheet guidance for sponsors, clinical investigators, and IRBs Frequently Asked Questions – Statement of Investigator (Form FDA 1572) (May 2010) and the guidance for industry Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Trial Subjects.
参见 21 CFR 312.3 和 312.53。 有关助理研究者的更多信息，请参见申办者、临床研究者和 IRB 须知页指南中的问题 31 和 32，常见问题-研究者声明（表 FDA 1572）（2010 年 5 月）和行业指南-研究者职责-保护试验受试者的权利、安全和福利。

HCP 不应在 FDA 1572 表中列为助理研究者（Sub-I）。但是，本地 HCP 应包含在任务日志中（如本节下文所述）。

- For device investigations, investigator responsibilities under 21 CFR part 812 include the requirement that there be a signed agreement between the investigator and sponsor (see 21 CFR 812.43(c)(4) and 812.100). A list of all investigators in the study is also required as part of an IDE application (see 21 CFR 812.20 and 812.150(b)(4)). Local HCPs contracted to provide trial-related services that are part of routine clinical practice and where a detailed knowledge of the protocol or the IP is not required are generally not considered investigators and should not be included in the IDE list of investigators. However, these local HCPs should be included in a task log (as described below in this section).

  对于器械研究，21 CFR 第 812 部分规定的研究者职责包括了要求研究者和申办方之间必须签署协议（参见 21 CFR 812.43（c）（4）和 812.100）。作研究中所有研究者的名单，也是 IDE 申请的一部分（参见 21 CFR 812.20 和 812.150（b）（4））。聘用当地 HCP 提供常规临床工作的试验相关服务并且不需要详细了解方案或 IP 的当地 HCP，通常不视为研究者而不应纳入研究者 IDE 列表中。但是，这些当地 HCP 应包含在任务日志中（如本节下文所述）。

- A critical consideration in a DCT when delegating trial-related activities to local HCPs is the potential for variability in the approach across different practices (e.g., documenting vital signs, physical examinations, and evaluation of adverse events). Quality control measures should be in place to help reduce variability, including regular review by investigators of participant data entered by local HCPs, to assess consistency and completeness of the required procedures. The type and scope of quality control measures should be tailored to the criticality of the data and the complexity of procedures done by the local HCPs.

  DCT 中一个关键考量，就是当试验相关活动授权给当地 HCP 时，由于不同操作方法（例如，记录生命体征、体格检查和不良事件评价）带来的可能的差异。应制定质量控制措施，以帮助减少差异性，包括研究者定期审查当地 HCP 输入的受试者数据，以评估所需程序的一致性和完整性。质量控制措施的类型和范围应根据数据的重要性和当地 HCP 执行程序的复杂性进行调整。

- As part of preparing and maintaining adequate case histories, investigators must maintain a task log of local HCPs who perform trial-related activities.
  研究者必须维护执行试验相关活动的当地 HCP 的任务日志，作为准备和维护充分病历的一部分 [FootnoteRef:28]。[28]

  - The task log should include (1) the names and affiliations of the local HCPs, (2) a description of their roles and assigned tasks, (3) the dates these local HCPs are added to the log, and (4) the locations where these activities are conducted.
    任务日志应包括（1）当地 HCP 的姓名和隶属关系，（2）其角色和分配任务的描述，（3）当地 HCP 被添加到日志中的日期，以及（4）开展这些活动的地点。

  - The task log should be dated and signed by the investigator when initially created and updated when new local HCPs are added. The task log should be available to FDA during inspections.
    任务日志最初创建时应由研究者注明日期并签名，并在添加新的当地 HCP 时进行更新。 在检查期间，应向 FDA 提供任务日志。

  - Other health care professionals not involved in the clinical trial who deliver care to trial participants but not as part of the trial should not be listed on Form FDA 1572, the task log, or a medical device sponsor's current list of investigators. These professionals may include emergency room personnel, hospital personnel, family physicians, and nurses providing routine care for trial participants with emergent or existing conditions.
    未参与临床试验、向试验受试者提供照护但不作为试验一部分的其他医疗保健专业人员不应列于 FDA 表中。1572、任务日志或医疗器械申办者的当前研究者名单。 这些专业人员可能包括急诊室

[28] See 21 CFR 312.62 and 812.140.
参见 21 CFR 312.62 和 812.140。

工作人员、医院工作人员、家庭医生和为患有紧急或现有疾病的试验受试者提供常规护理的护士。

- Some trial protocols will include designated clinical laboratory facilities to perform activities required by the protocol (e.g., phlebotomy, x-rays). Other trial protocols may permit the use of a variety of clinical laboratory facilities close to the trial participant to perform these activities. Generally, designated clinical laboratory facilities are preferable to minimize variability, particularly for critical data such as those used to evaluate outcomes, and to perform investigations and tests that are specialized. If appropriate, specimens from trial participants (e.g., blood, sputum) may be collected by remote trial personnel, local HCPs, or clinical laboratory facilities and sent to designated facilities for processing. Local clinical laboratory facilities may be adequate for routine clinical tests that are well-standardized.
一些试验方案将包括指定的临床实验室设施[FootnoteRef:29]，以进行方案要求的活动（例如，静脉切开术、X 线检查）。其他试验方案可能允许使用受试者就近的各种临床实验室设施进行这些活动。通常，最好使用指定的临床实验室设施，以尽量减少差异，尤其是对于关键数据，例如用于评价结局的数据，以及进行专门研究和检测的数据。如适用，可由远程试验人员、当地 HCP 或临床实验室机构采集试验受试者的标本（例如血液、痰液），并送至指定机构进行处理。当地临床实验室设施可能足以进行标准化的常规临床检查。[29]

- All clinical laboratory facilities should be listed on Form FDA 1572 or in the investigational plan for device studies under an IDE.
所有临床实验室设施均应列于 FDA 1572 表或 IDE 器械研究的研究计划中。

- Technicians and other personnel working for clinical laboratory facilities should not be recorded on the task log or Form FDA 1572. However, for certain device studies (e.g., in vitro diagnostic devices), it may be necessary to identify the responsible individual at the laboratory facility where device testing is done in the task log or IDE application.

[29] See the information sheet guidance for sponsors, clinical investigators, and IRBs Frequently Asked Questions – Statement of Investigator (Form FDA 1572).
参见申办者、临床研究者和 IRB 的信息表指南-研究者声明（表 FDA 1572）。

在临床实验室机构工作的技术人员和其他人员不应记录在任务日志或 FDA 1572 表中。但是，对于某些器械研究（例如体外诊断器械），可能有必要在任务日志或 IDE 申请中确定进行器械试验的实验室机构的负责人。[FootnoteRef:30][FootnoteRef:31][30][31]

- As in any trial, trial participants experiencing any health emergency (e.g., hypoglycemia or abnormal cardiac rhythm) should seek medical attention at local health care facilities (such as an emergency room), as appropriate. With the permission of trial participants, investigators should attempt to obtain reports from these local health care facilities, and investigators should also attempt to obtain reports from primary providers of routine health care when activities take place that are relevant to the trial (e.g., change in concomitant medications).

  与任何试验一样，发生任何健康紧急情况（例如低血糖或心律异常）的试验受试者应酌情在当地医疗机构（如急诊室）就医。经试验受试者许可，研究者应尝试获取这些当地医疗保健机构的报告，当发生与试验相关的活动（例如，合并用药的变化）时，研究者还应尝试从常规医疗保健的主要提供者处获得报告。

E. Informed Consent and Institutional Review Board Oversight

E. 知情同意和机构审查委员会监督

Obtaining informed consent remotely may be considered as part of a DCT. Institutional review board (IRB) oversight is required to ensure the process is adequate and appropriate.31

[30] For certain device studies, the laboratory facility is a clinical trial site under 21 CFR part 812, and complete information on the site, including the investigator (i.e., responsible individual), is required in the IDE application and study records.

对于某些器械研究，实验室机构是 21 CFR 第 812 部分规定的临床试验中心，并且在 IDE 申请和研究记录中需要提供关于该中心的完整信息，包括研究者（即负责人）。

[31] CFR 56.103, 56.104, and 56.105.

CFR 56.103、56.104 和 56.105。

远程获得知情同意可视为 DCT 的一部分。需要机构审查委员会（IRB）监督，以确保该过程充分且适当。31

- Investigators may obtain electronic informed consent from trial participants at their remote locations provided that all applicable regulatory requirements regarding informed consent are met. The process of obtaining electronic informed consent remotely may include a remote visit if needed.
  研究者可在其远程地点获得试验受试者的电子知情同意，前提是符合关于知情同意的所有适用监管要求。[FootnoteRef:32]远程获得电子知情同意的过程，如需要，可能包括远程访视。[32]

- With a DCT, the informed consent process must include notifying participants of whom to contact for answers to pertinent questions about the research and research subjects' rights and whom to contact in the event of a research-related injury to the subject.
  对于 DCT，知情同意过程必须包括通知受试者关于研究和研究对象权利的相关问题，以及如果受试者受到与研究相关的伤害，应与谁联系。[Footnoteref:33][33]

- The informed consent should describe who will have access to the trial participant's personal health information obtained during the DCT.
  知情同意书应描述 DCT 期间谁有权获得的试验受试者个人健康信息。

[32] For FDA regulations about informed consent, see 21 CFR part 50 (including the elements of informed consent under 21 CFR 50.25 and the documentation of informed consent under 21 CFR 50.27). For additional information, see the guidance for IRBs, investigators, and sponsors Use of Electronic Informed Consent: Questions and Answers (December 2016).
关于知情同意的 FDA 法规，请参见 21 CFR 第 50 部分（包括 21 CFR 50.25 规定的知情同意要素和 21 CFR 50.27 规定的知情同意文件）。更多信息请参见 IRB、研究者和申办者使用电子知情同意书的指南：问答（2016 年 12 月）。

[33] See 21 CFR 50.25(a)(7).
参见 21 CFR 50.25（a）（7）。

- FDA recommends the use of a central IRB in DCTs to facilitate efficient review of the protocol, the informed consent documents, and other relevant trial-related information.
  FDA 建议在 DCT 中使用中心 IRB，以促进对方案、知情同意文件和其他相关试验相关信息的有效审查。[FootnoteRef:34][FootnoteRef:35][34][35]

F. Investigational Products in a DCT
DCT 中的试验用研究产品

1. Drugs and Biological Products
药品和生物制品

An investigator must administer an IP only to participants under the investigator's personal supervision or under the supervision of a subinvestigator responsible to the investigator.[35] The nature of the IP should be considered when determining whether administration outside of a clinical trial site in a DCT is appropriate. IPs that involve complex administration procedures; have a high-risk safety profile, especially in the immediate post-administration period; or are in early stages of development such that the safety profile is not well defined may need in-person supervision by the investigator at a trial site.
研究者必须亲自或者由对研究者负责的助理研究者（Sub-I）监督研究产品仅发放给了受试者.[35] 决定 DCT 中是否合适在临床试验中心以外的地点给药时，应考虑 IP 的性质。涉及复杂给药程序的 IP；具有高风险安全性特征，尤其是在给药后立即有高安全风险有；或处于早期开发阶段，安全性特征尚不明确，可能需要研究者在试验中心进行亲自监督。

[34] See 21 CFR 56.114 (for a description of arrangements related to use of a central IRB). For additional information, see the guidance for industry Using a Centralized IRB Review Process in Multicenter Clinical Trials (March 2006).
参见 21 CFR 56.114（有关使用中心 IRB 的安排描述）。更多信息请参见行业指南《在多中心临床试验中使用集中 IRB 审查流程》（2006 年 3 月）。

[35] CFR 312.61.
CFR 312.61。

572

573 For IPs for which the safety profile is well-characterized and that do not involve specialized
574 monitoring during the immediate period following administration, it may be appropriate for local
575 HCPs or trial personnel working remotely to administer the IP at local health care facilities or
576 participants' homes. Hybrid DCTs may be designed for drugs that require supervised but
577 infrequent (e.g., monthly) administration when administration can be done at trial sites with
578 follow-up done remotely.
579 对于具有良好安全性特征且在给药后较短的一段时间内不需要专门监测的 IP，当地 HCP 或远程工作
580 的试验人员在当地医疗机构或受试者家中进行 IP 给药，可能是适合的。 混合 DCT 可设计用于需要监
581 督但不频繁（例如每月一次）给药的药物，可在试验中心进行给药，并使用远程随访。

582

583 Depending on the safety profile of the IP (e.g., a class of drug with a risk of hypersensitivity,
584 abuse potential) and the type of trial (e.g., dose escalation trial), sponsors should estimate the
585 urgency and complexity of care that may be needed based upon risks related to the IP and the
586 participant's underlying condition. Investigators should take steps to help ensure that participants
587 have access to an appropriate level of local care.
588 根据 IP 的安全性特征（例如，具有超敏反应风险、滥用可能性的一类药物）和试验类型（例如，剂量
589 递增试验），申办者应根据与 IP 相关的风险和受试者的基础疾病估计可能需要照护的紧迫性和复杂
590 性。 研究者应采取措施帮助确保受试者能够获得适当水平的当地治疗。

591

592 Drugs best suited for direct shipment to the participant's home include those with long shelf lives
593 and those with good stability profiles. Drugs that involve specialized handling, shipping, and
594 storage conditions may not be suited for direct shipment to locations outside the trial site.
595 最适合直接运输至受试者家中的药物包括有效期较长的药物和稳定性良好的药物。 涉及特殊处理、运
596 输和储存条件的药物可能不适合直接运输至试验中心以外的地点。

597

598 2. Medical Devices
599 医疗器械

600

601 When determining the appropriate use or administration of an investigational device in a DCT,
602 sponsors should consider the type of medical device, its intended use, its instructions for use, and

whether it is a significant risk or nonsignificant risk device.
当在 DCT 中决定试验用器械是否适当或使用试验器械时，申办者应考虑医疗器械的类型、预期用途、使用说明，以及是重大风险器械还是非重大风险器械。[FootnoteRef:36][36]

Medical devices suitable for home use (i.e., over-the-counter devices) that do not pose significant risks to trial participants may be appropriate for use by trial participants without the investigator's direct oversight. The use of medical devices that are not intended for self-use (i.e., devices used in hospital or ambulatory care settings) or that pose significant risks to trial participants should be used or administered by qualified trial personnel with investigator oversight. An investigator shall not supply an investigational device to any person not authorized under 21 CFR part 812 to receive it. Certain follow-up procedures needed after using the medical device or after surgical implantation of the device in trial participants may be performed by appropriately qualified and trained local HCPs or trial personnel via telehealth visits, at the homes of trial participants, or in local health care facilities. A telehealth visit may be appropriate if an assessment in that setting does not pose significant risk to trial participants and, in such settings, adverse events can be (and are) properly assessed and documented.
不对试验受试者造成重大风险的家用医疗器械（即非处方器械）可能适合试验受试者在没有研究者的直接监督的情况下使用。 非自用医疗器械（即在医院或门诊护理环境中使用的器械）或对试验受试者构成重大风险的医疗器械应由合格的试验人员在研究者监督下使用或管理。 研究者不得向未根据 21 CFR 第 812 部分授权接收试验用器械的任何人提供试验用器械。[FootnoteRef:37]使用医疗器械后或试验受试者手术植入器械后所需的某些随访程序可由具有适当资质且经过培训的当地 HCP 或试验人员通过远程医疗访视、在试验受试者家中或在当地医疗保健机构进行。 如果在这种情况下的评估不会对试验受试者造成重大风险，并且在这种情况下，可以（并正在）适当地评估和记录不良事件，则远程医疗访视可能是合适的。[37]

[36] See the information sheet guidance for IRBs, clinical investigators, and sponsors Significant Risk and Nonsignificant Risk Medical Device Studies (January 2006).
参见 IRB、临床研究者和申办者重大风险和非重大风险医疗器械研究的信息表指南（2006 年 1 月）。

[37] See 21 CFR 812.110.
参见 21 CFR 812.110。

G. Packaging and Shipping of Investigational Products

G. 试验用药品的包装和运输

Generally, DCTs may allow for the direct distribution of investigational products to trial participants at their locations. The sponsor should consider the following recommendations regarding packaging, shipping, and storage of IPs in a DCT:

通常，DCT 可允许将试验用药品直接分发至试验受试者所在地点。[FootnoteRef:38]申办者应考虑以下关于 DCT 中 IP 包装、运输和储存的建议：[38]

- The protocol should describe how the physical integrity and stability of the IP will be maintained during shipment to trial participants, including appropriate packaging materials and methods (e.g., temperature control). Shipping containers should include clear instructions for handling and storing the IPs and instructions for returning unused

  方案应描述在运输给试验受试者期间如何保持 IP 的物理完整性和稳定性，包括适当的包装材料和方法（例如温度控制）。运输容器应包括处理和储存 IP 的明确说明以及返还未使用的 IP 的说明

- When relevant, DCT personnel should be trained on procedures and appropriate documentation for handling, packaging, shipping, and tracking IPs.

  如相关，DCT 人员应接受处理、包装、运输和跟踪 IP 的程序和适当文件的培训。

- A central distribution service could be used to ship the IP directly to trial participants. The investigator or delegated trial personnel must control the release of the IP by the distributor; monitor receipt and use by trial participants (or participants' legally

[38] See 21 CFR 312.61.

参见 21 CFR 312.61。

authorized representatives), according to procedures described in the protocol; and monitor the return or disposal of any unused product as directed by the sponsor.
可使用中心分发服务将 IP 直接运送给试验受试者。研究者或指定的试验人员必须控制配送者对 IP 的放行；根据方案中描述的程序，监查试验受试者（或受试者的法定授权代表）的接收和使用情况；并按照申办者的指示监测任何未使用产品的返还或处置情况。[FootnoteRef:41][39]

- The protocol should describe how investigators will track and document that trial participants (or participants' legally authorized representatives) receive IPs.
方案应描述研究者将如何跟踪和记录试验受试者（或受试者的法定授权代表）接受 IP。

- The protocol should describe procedures that investigators or participants (or participants' legally authorized representatives) should use to return or dispose of unused IPs and how this will be documented.
方案应描述研究者或受试者（或受试者的法定授权代表）返还或处置未使用 IP 的程序，以及如何记录。[FootnoteRef:42][FootnoteRef:43][40][41]

- Sponsors and investigators must comply with applicable Federal, State, and international laws and regulations that address shipping IPs in their respective jurisdictions.
申办者和研究者必须遵守其各自管辖范围内涉及 IP 运输的适用联邦、州和国际法律法规。

[39] See 21 CFR 312.61, 312.62(a), and 812.110.
参见 21 CFR 312.61、312.62（a）和 812.110。

[40] See 21 CFR 312.62(a) and 812.110(e) (for requirements related to disposition of the IP).
参见 21 CFR 312.62（a）和 812.110（e）（有关 IP 处置的要求）。

[41] CFR 312.50 and 812.40. See also the guidance for industry Oversight of Clinical Investigations — A RiskBased Approach to Monitoring (August 2013).
CFR 312.50 和 812.40。另请参见行业指南《临床研究监督-基于风险的监查方法》（2013 年 8 月）。

H. Safety Monitoring Plan
安全性监查计划

The sponsor is required to ensure proper monitoring of the investigations and to ensure that the investigations are conducted in accordance with the general investigational plan and protocols contained in the IND or IDE applications.[43] Sponsors should implement a safety monitoring plan to ensure the safety and welfare of trial participants in a DCT.

要求申办者确保对研究进行适当监查，并确保研究按照 IND 或 IDE 申请中包含的总体研究计划和方案进行 [43]。申办者应实施安全性监查计划，以确保 DCT 中试验受试者的安全性和福利。

- The safety monitoring plan should take the decentralized nature of the clinical trial into account and ensure that adverse events are appropriately captured and adequately addressed. The monitoring plan should prespecify if and when telehealth visits or inperson visits (e.g., physical examinations) will be scheduled with trial personnel or local HCPs to collect safety data by (see section III.B).

  安全性监查计划应考虑临床试验的去中心化性质，并确保适当采集和充分解决不良事件。[FootnoteRef:44]监查计划应预先规定是否以及何时安排试验人员或当地 HCP 进行远程医疗访视或亲自访视（例如体格检查），以收集安全性数据（见第 III.B 节）。[42]

- As in any site-based clinical trial, the safety monitoring plan should describe how participants are expected to respond to and report adverse events, including where to seek medical assistance locally when necessary and where to receive follow-up care.

[42] Certain late-stage pre-approval or post-approval clinical trials could be able to use selective safety data collection. See the ICH guidance for industry E19 A Selective Approach to Safety Data Collection in Specific Late-Stage PreApproval or Post-Approval Clinical Trials (December 2022).
某些后期批准前或批准后临床试验可以使用选择性安全性数据收集。 参见 ICH 行业指南 E19 特定后期批准前或批准后临床试验中安全性数据收集的选择性方法（2022 年 12 月）。

与任何基于研究中心的临床试验一样，安全性监查计划应描述预期受试者如何应对和报告不良事件，包括必要时在哪里寻求当地医疗援助以及在哪里接受随访治疗。[FootnoteRef:45][43]

- Trial participants must be able to contact trial personnel to report adverse events and to have pertinent questions answered.
  试验参与者必须能够联系试验人员报告不良事件并回答相关问题。[Footnoteref:46][44]

- Trial participants should be able to arrange for an unscheduled visit using telehealth or an in-person visit, as appropriate (see section III.B).
  试验受试者应能够酌情通过远程医疗或面对面访视安排计划外访视（见第 III.B 节）。

- The safety monitoring plan should describe the type of information that will be collected by a DHT (when used to collect data in a DCT), how that information will be used and monitored, and what action trial participants or personnel should take in response to abnormal findings or electronic alerts.
  安全性监查计划应描述 DHT 将收集的信息类型（当用于在 DCT 中收集数据时）、如何使用和监查该信息以及试验受试者或工作人员应对异常结果或电子警报应采取的措施。

- If significant safety risks emerge because of the remote administration or use of an IP, sponsors must discontinue remote administration or use; notify FDA, the IRB, and all investigators who have participated in the trial; and determine if the trial should continue.

[43] For information about the medical care of trial subjects, see section 4.3 in the guidance for industry E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) (March 2018).
有关试验受试者医疗护理的信息，请参见行业指南 E6（R2）药物临床试验质量管理规范：ICH E6（R1）综合附录（2018 年 3 月）第 4.3 节。

[44] See 21 CFR 50.25(a)(7).
参见 21 CFR 50.25（a）（7）。

如果因 IP 的远程给药或使用而出现重大安全性风险，申办者必须停止远程给药或使用；通知 FDA、IRB 和所有参与试验的研究者；并决定试验是否应继续。[Footnoteref:47][45]

- If authorized in the protocol, routine safety monitoring involving laboratory testing and imaging may be performed using local clinical laboratory facilities close to trial participants (see section III.D.2). Investigators should ensure they promptly receive reports of these services and review them in a timely manner.
  如果方案授权，可使用靠近试验受试者的当地临床实验室设施进行涉及实验室检查和影像学检查的常规安全性监测（见第 III.D.2 节）。 研究者应确保及时收到这些服务的报告，并及时对其进行审查。

I. Software Used in Conducting DCTs
I. 用于进行 DCT 的软件

Sponsors should consider the following regarding software used in a DCT:
关于 DCT 中使用的软件，申办者应考虑以下内容：

- Software to support the conduct of DCTs can be run through a variety of platforms (e.g., tablets, cell phones, personal computers). Software can be used to perform multiple functions to manage DCT operations, including:
  支持进行 DCT 的软件可通过各种平台（例如平板电脑、手机、个人计算机）运行。 软件可用于执行管理 DCT 操作的多种功能，包括：
  - Managing electronic informed consent (e.g., maintaining approved versions of informed consent, documenting IRB approval, archiving signed forms)

[45] See 21 CFR 312.56(d) and 812.46.
参见 21 CFR 312.56（d）和 812.46。

管理电子知情同意书（例如，维护知情同意书的批准版本、记录 IRB 批准、存档签署的表格）

- Capturing and storing reports from remote trial personnel, local HCPs, and local clinical laboratory facilities
  采集和存储来自远程试验人员、当地 HCP 和当地临床实验室机构的报告

- Managing electronic case report forms (eCRFs)
  管理电子病例个案报告表（eCRF）

- Scheduling trial visits and other DCT-related activities
  安排试验访视和其他 DCT 相关活动

- Tracking IPs that are shipped directly to trial participants
  跟踪直接运送给试验受试者的 IP

- Syncing information recorded by DHTs
  同步 DHT 记录的信息

- Serving as communication tools between DCT personnel and trial participants
  作为 DCT 人员和试验受试者之间的沟通工具

- Training should be provided to all parties (e.g., trial personnel, local HCPs, and trial participants) using software to support the conduct of DCTs.
  应向所有使用软件的各方（例如，试验人员、当地 HCP 和试验参与者）提供培训，以支持 DCT 的实施。

- There are several ways local HCPs can submit trial-related data for inclusion in clinical trial records, including but not limited to the following:
  当地 HCP 可通过以下几种方式提交试验相关数据以纳入临床试验记录，包括但不限于：

772

773 – If the local HCPs have access to the eCRF, they can enter trial-related data
774 directly into the eCRFs.
775 如果当地 HCP 可以访问 eCRF，则可将试验相关数据直接输入 eCRF。
776 [FootnoteRef:48][46]

777

778 – Alternatively, local HCPs can upload forms or documents by using methods of
779 secure data transfer to investigators. Investigators or other trial personnel are then
780 responsible for entering these trial-related data into the eCRF.
781 或者，当地 HCP 可以使用安全数据传输的方法向研究者上传表格或文件。然后，研究
782 者或其他试验人员负责将这些试验相关数据录入 eCRF。[FootnoteRef:49][47]

783

784 • Remote trial personnel or local HCPs submitting trial data directly into the eCRF should
785 be included in the sponsor's list of authorized data originators.
786 将试验数据直接提交至 eCRF 的远程试验人员或当地 HCP 应纳入申办者的授权数据发起人列
787 表中。[FootnoteRef:50][48]

788

[46] See the guidance for industry Electronic Source Data in Clinical Investigations (September 2013).
参见行业指南《临床研究中的电子源数据》（2013 年 9 月）。

[47] See 21 CFR 312.62 and 812.140.
参见 21 CFR 312.62 和 812.140。

[48] See the guidance for industry Electronic Source Data in Clinical Investigations. As recommended in that guidance, "[a] list of all authorized data originators (i.e., persons, systems, devices, and instruments) should be developed and maintained by the sponsor and made available at each clinical site."
参见行业指南《临床研究中的电子源数据》。根据该指南的建议，"申办者应制定并维护所有授权数据发起人（即人员、系统、器械和仪器）的列表，并在每个临床研究中心提供。"

- Software programs that are used to produce and process trial records required by the FD&C Act and FDA regulations are subject to 21 CFR part 11. These programs must ensure data reliability, security, privacy, and confidentiality.
用于产生和处理 FD&C 法案和 FDA 法规要求的试验记录的软件程序受 21 CFR 第 11 部分的约束。这些程序必须确保数据的可靠性、安全性、隐私性和机密性。[Footnoteref:51][49]

- FDA considers real-time video interactions, including telehealth, as a live exchange of information between trial personnel and trial participants. These live interactions are not considered electronic records and, therefore, are not subject to 21 CFR part 11, but local laws governing telehealth may apply. Privacy and security of these real-time visits should be ensured, and the visits must be documented. If this documentation is captured in electronic form, such documentation is subject to 21 CFR part 11.
FDA 将实时视频互动（包括远程医疗）视为试验人员和试验参与者之间的实时信息交换。这些实时互动不被视为电子记录，因此不受 21 CFR 第 11 部分的约束，但管理远程医疗的当地法律可能适用。应确保这些实时访问的隐私和安全，必须记录访问情况。[Footnoteref:52]如果这些文件是以电子形式记录的，则这些文件应遵守《联邦法规》第 21 篇第 11 部分的规定。[50]

[49] See 21 CFR part 11. See also the guidance for industry Electronic Source Data in Clinical Investigations and the revised draft guidance for industry Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers (when final, this guidance will represent FDA's current thinking on this topic).
参见 21 CFR 第 11 部分。另请参见行业指南《临床研究中的电子源数据》和行业指南修订草案《临床研究中的电子系统、电子记录和电子签名：问答》（定稿后，本指南将代表 FDA 当前对该主题的看法）。

[50] See 21 CFR 312.62(b) and 812.140(a)(3).
参见 21 CFR 312.62（b）和 812.140（a）（3）。

GLOSSARY
术语表

The following terms are defined for the purposes of this guidance:
本指南定义了以下术语：

clinical laboratory facilities: Clinical laboratories or testing facilities that contribute to or support the clinical study, such as diagnostic labs performing blood work, imaging centers, or cardiology labs. As appropriate, these clinical laboratory facilities may be located close to trial participants' homes.
临床实验室机构：有助于或支持临床研究的临床实验室或检测机构，例如进行血液检查的诊断实验室、影像中心或心脏病学实验室。 如适用，这些临床实验室设施可能位于试验受试者家附近。

data management plan (DMP): A written document that describes the data a sponsor expects to acquire or generate during the course of a research study; how the sponsor intends to manage, describe, analyze, and store said data; and what mechanisms will be used at the end of the study to preserve and share the research data.
数据管理计划（DMP）：描述申办者预期在研究过程中获得或生成的数据的书面文件； 申办者计划如何管理、描述、分析和存储上述数据； 以及在研究结束时将使用哪些机制来保存和共享研究数据。

decentralized clinical trial (DCT): A clinical trial where some or all of the trial-related activities occur at locations other than traditional clinical trial sites.
去中心化临床试验（DCT）：部分或全部试验相关活动在传统临床试验中心以外的地点进行的临床试验。

digital health technology (DHT): A system that uses computing platforms, connectivity, software, and/or sensors for health care and related uses. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, or as an adjunct to other medical products (devices, drugs, and biologics). They may also be used to develop or study medical products.
数字健康技术（DHT）：将计算平台、连接、软件和/或传感器用于医疗保健和相关用途的系统。 这些技术的用途广泛，从一般健康应用到作为医疗器械的应用。 这些技术包括预期用作医疗产品、医疗产品中或作为其他医疗产品（器械、药品和生物制剂）的辅助器械的技术。 它们也可用于开发或研究医疗产品。

investigational product (IP): Human drugs, biological products, or devices that are being investigated in a clinical trial.„

试验用药品（**IP**）：正在临床试验中研究的人用药品、生物制品或器械。[FootnoteRef:53]、

[FootnoteRef:54]、**[FootnoteRef:55]**[515253]

telehealth: The use of electronic information and telecommunications technologies to support and promote long-distance clinical health care.

远程保健：使用电子信息和电信技术支持和促进远程临床保健。

[51] See footnote 3.

见脚注 3。

[52] See footnote 4.

见脚注 4。

[53] See footnote 5.

见脚注 5。