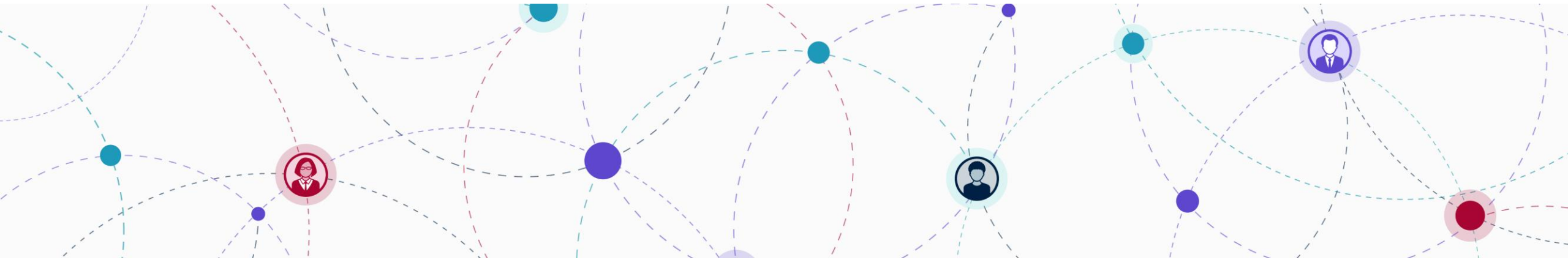


Proportionate Oversight in Decentralized Clinical Trials (DCTs)

Launch Webinar | MRCT Center & Medable



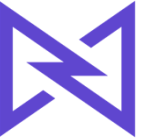
Barbara Bierer, MD
Hayat Ahmed, MS
Emina Berbic, MPH

Pamela Tenaerts, MD, MBA
Melissa Dunn, BA

24 September 2026

Learn more at www.mrctcenter.org

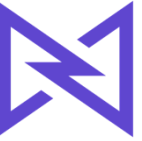
Disclaimer



- This material and opinions expressed here are those of the task force discussants and are not intended to represent the position of Brigham and Women's Hospital, Mass General Brigham, Harvard University, Medable, HHS, FDA, or any organization, institution, or entity. Participants serve and served in their individual capacities.
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Agenda



1. Collaborative work on Decentralized Clinical Trials (DCTs)
2. Ethical review of DCTs
3. ICH E6(R2) → ICH E6(R3)
4. Tools for Monitoring and Oversight of Clinical Trials with Decentralized Elements
5. Open discussion
6. Please enter questions or comments in the Q&A bottom button.

*This presentation is being recorded.
The webinar and slides will be publicly posted next week.*

The Journey



IRB review of trials with DCT elements

Ethics committees carried an uneven and growing review burden as decentralized elements entered protocols.

IRB / EC review of trials with DCT elements are challenging

- Variability in process, requirements, expectations, and time to approval.
- Which ethical issues, if any, differ in the review or approval of a trial with DCT elements versus a traditional trial?
- Which technology changes need an amendment or IRB re-review?

A multi-stakeholder group addressed

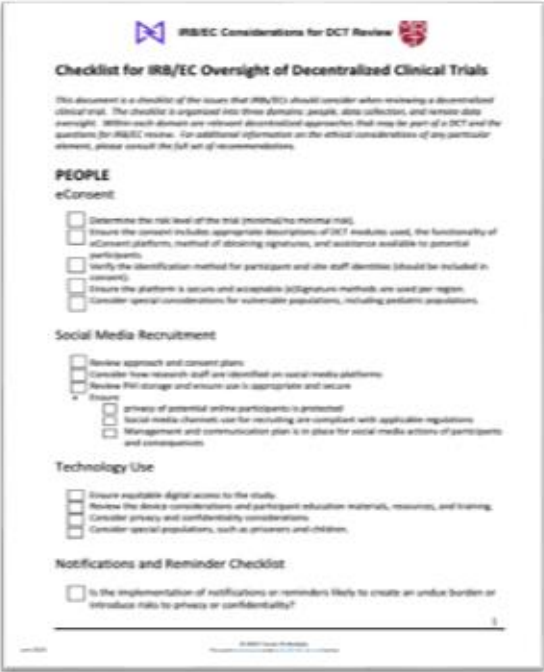
- Participant burden
- Minimum necessary data
- Connectivity, cost
- Access, complexity
- Security of data and device
- Safety monitoring
- Changes in relationships and culture

MRCT Center and Medable DCT resources

Published June and November 2023, as open access



Full document · June 2023



Checklist - November 2023



Figure 1: IRB/EC Considerations for DCTs

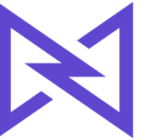
Checklist · November 2023

mrctcenter.org/wp-content/uploads/2023/06/Revised-Full-Documents-CompiledDCT-14-June-23-final-2.pdf

mrctcenter.org/wp-content/uploads/2023/11/Check-List-61423-EDITED.pdf

Investigator Oversight: Background

Decentralization widened who touches a trial while the investigator's obligation stayed where E6(R2) left it.



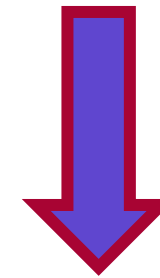
The Opportunity

Decentralized trial elements improve participant access and protocol performance.

Our Response

A cross-functional team built four resources, published September 2026.

ICH E6(R2)

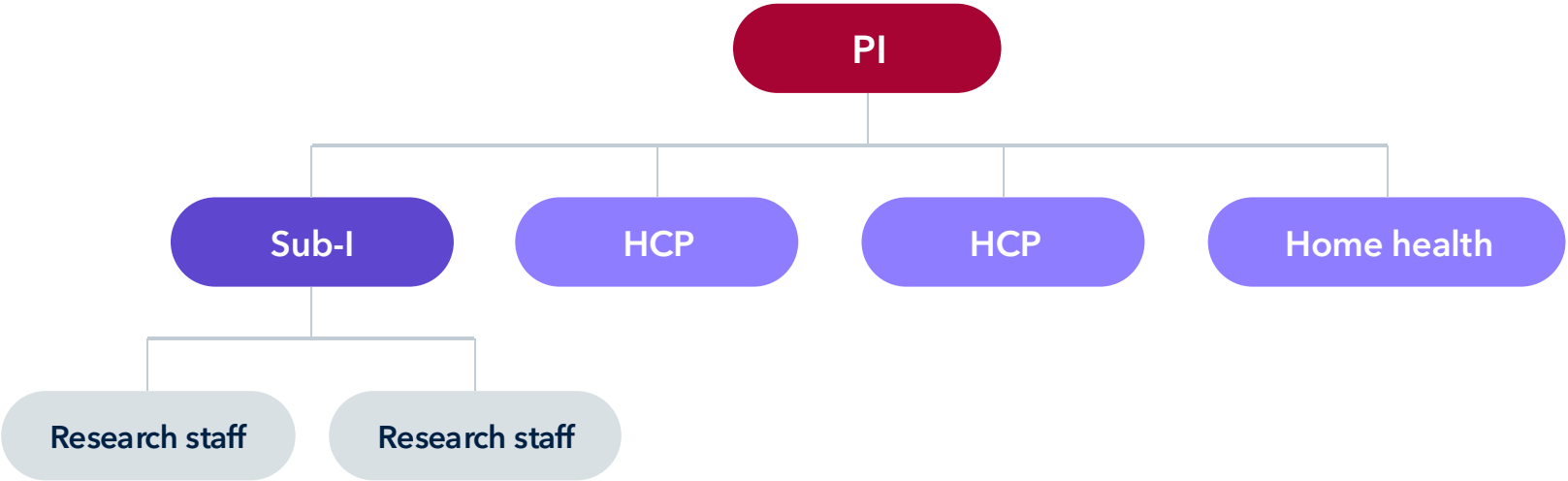
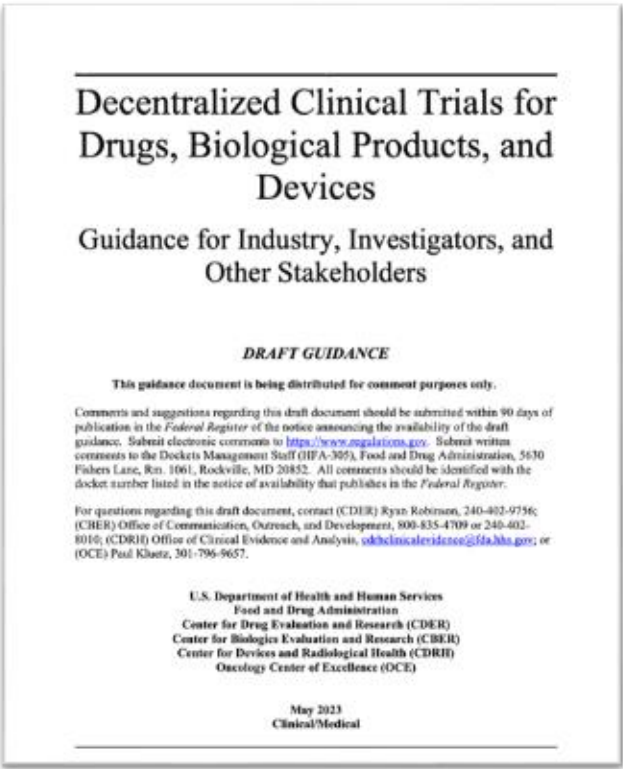


ICH E6(R3)

FDA Guidance on Decentralized Elements



FDA regulatory requirements for DCTs are **the same** as those for traditional site-based clinical trials.



Delegation reaches further in a decentralized trial and, with it, investigator responsibilities for supervision (ICH E6(R2)) and Investigator responsibilities for oversight (ICH E6(R3))

Draft cover, May 2023. Finalized 18 September 2024. [fda.gov/media/167696/download](https://www.fda.gov/media/167696/download)

Key Conceptual Shifts in Investigator Oversight

Principles and Annex 1 in effect as of 23 July 2025. Annex 2 adopted 3 June 2026, in effect 15 January 2027.



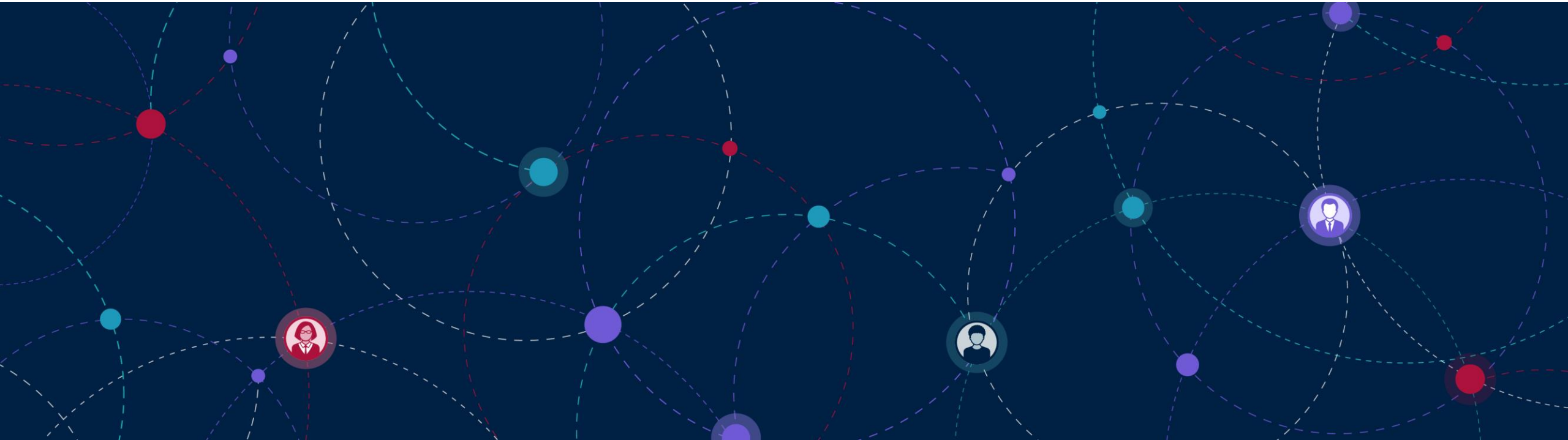
Dimension	E6(R3) changes
Language	"Oversight" indicates broader, more strategic accountability than supervision
Scope	R3 defines the investigator site as the location(s) where trial activities are conducted or coordinated under the investigator's oversight, which includes participants' homes
Delegation	Principle 10 and Section 2.3 codify delegation and require proportionality
Service providers	Investigator must maintain oversight of sponsor-identified service providers
Data governance	Investigator and sponsor share it under the new Section 4
Proportionality	Level of oversight must be proportionate to risk; threaded throughout the guideline
Documentation	Proportionate documentation; clinical practice activities may not require delegation logs

ANNEX 2

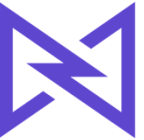
Annex 2 carries the decentralized-trial provisions. ICH adopted it 3 June 2026 and it comes into effect 15 January 2027, which gives study teams about 16 weeks to align site oversight practice.

Resources & Tools

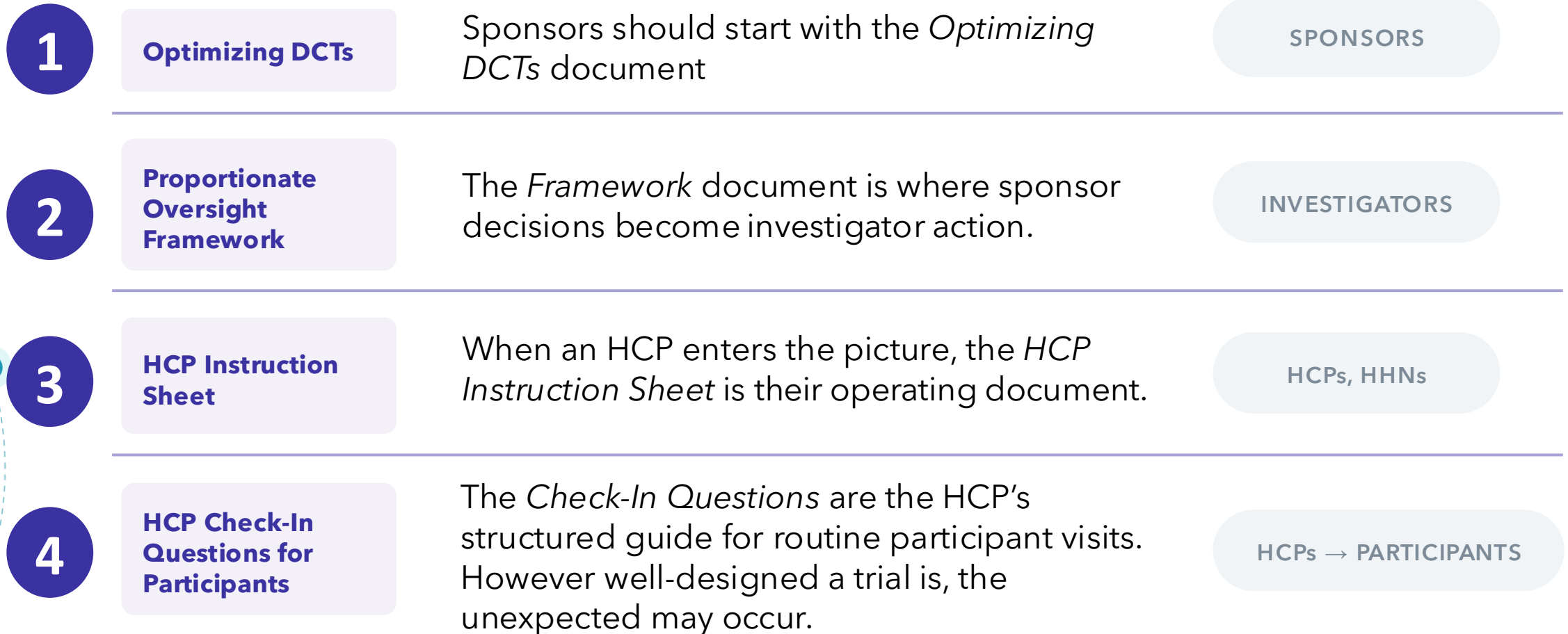
Together, the four documents become a coherent, integrated system for DCT conduct – sponsor-driven design, investigator-calibrated oversight, HCP-executed delivery, and a clear escalation structure when reality diverges from plan.



Four Tools and a Guide to the documents



How These Four Documents Work Together: A Practical Guide for Sponsors, Investigators, and HCPs



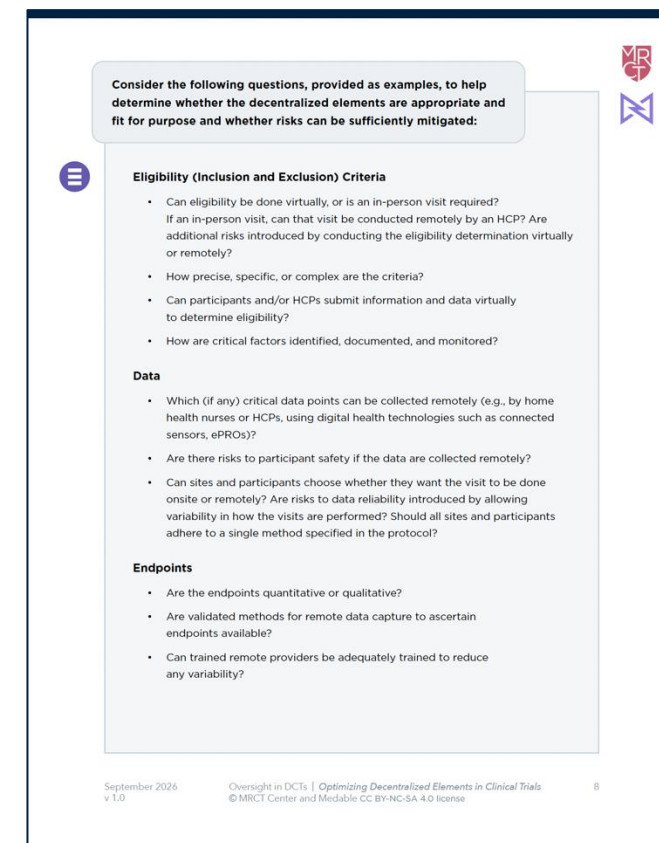
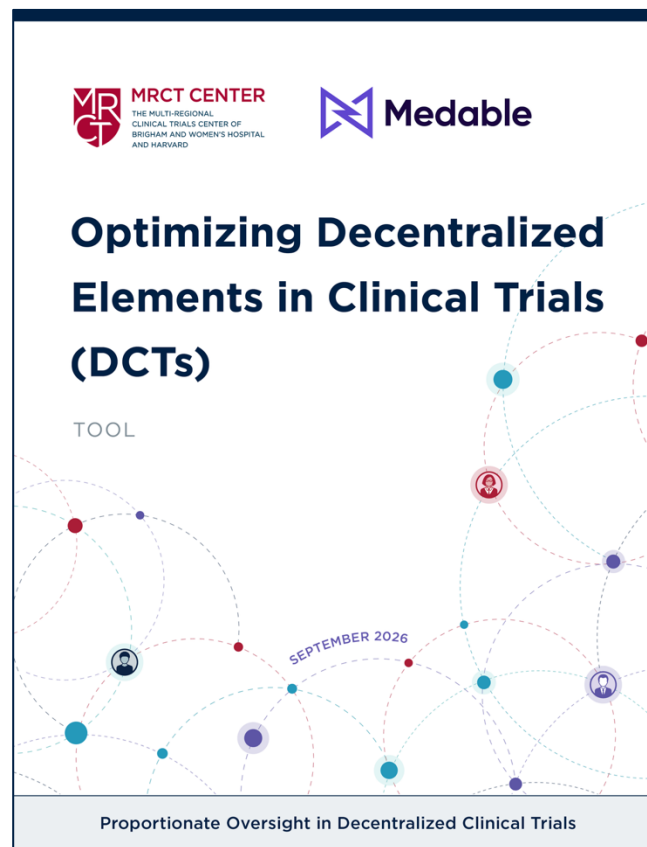
Optimizing Decentralized Elements in Clinical Trials



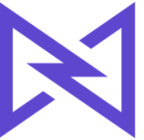
This is the first document in a two-part series.

It addresses the sponsor's role: designing DCT elements into the protocol, identifying critical-to-quality (CTQ) factors, and implementing a proportionate and risk-based approach to quality management into the trial plan.

Sponsor focuses on trial design and quality management



Optimizing Decentralized Elements in Clinical Trials



Apply Quality by Design (QbD) approach during study planning. Protocols should be fit-for-purpose and clear.

Identify critical-to-quality factors (CTQs) and identify risks to the CTQs

Mitigate or eliminate risks with attention to participant safety and impact on data reliability

CTQs -and the ability to mitigate risks to those CTQs--should guide sponsor quality assessment and management.

Introduction of flexibilities and design methods for the conduct of each

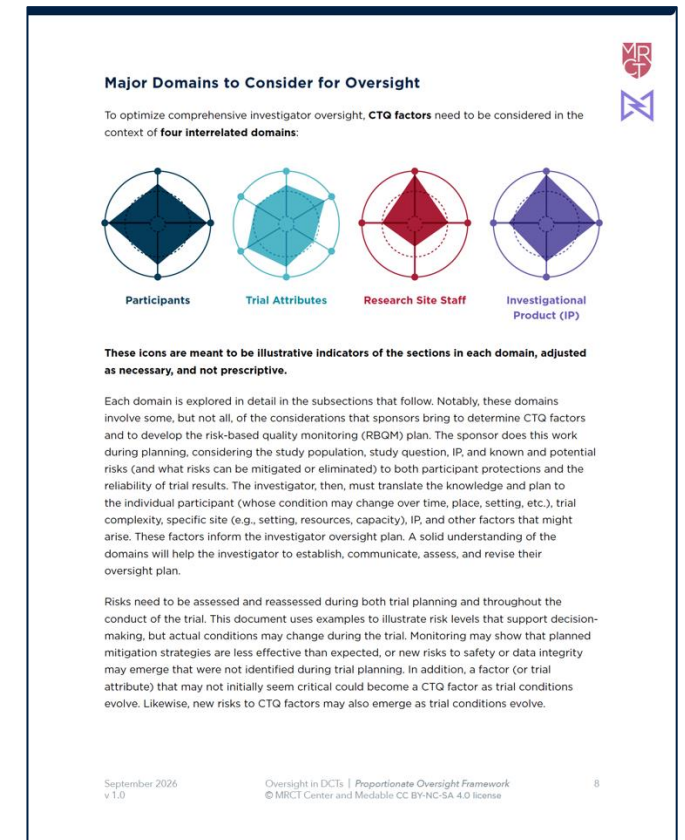
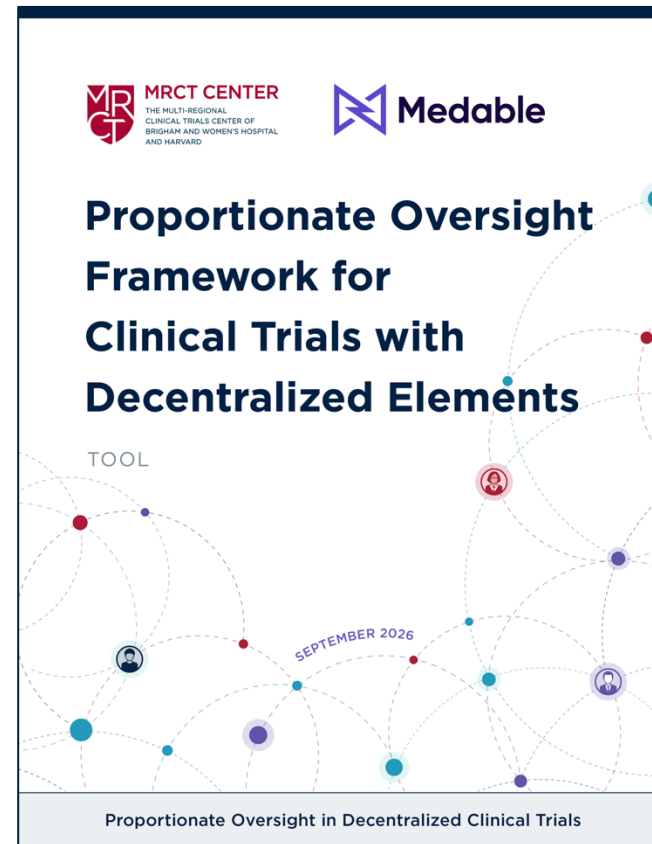
Communicate oversight plan to investigators.

Proportionate Oversight Framework

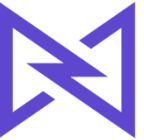
This is the second document in a two-part series.

This document is a practical decision-support tool intended to support implementation of existing regulatory requirements, expectations, and standards, and is not intended to go beyond current regulatory requirements.

The investigator focuses on the oversight of delegated activities wherever they occur, reviewing safety signals, ensuring protocol compliance, and escalating issues to the sponsor, including when the investigator is not sure whether controls are working.



Proportionate Oversight Framework



Focused on CTQ factors and their risks

Proportionate to the trial related activities, importance of the data being collected, and the risks to participant rights, safety, and well being, and data reliability.

Consider:



DCT activities can be organized along three dimensions:

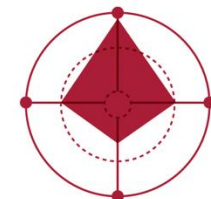
- **Who** performs the activity
- **Where** it occurs
- **What** enabling technology is used



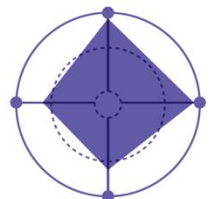
Participants



Trial Attributes

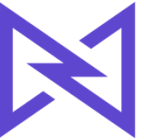


Research Site Staff



Investigational Product (IP)

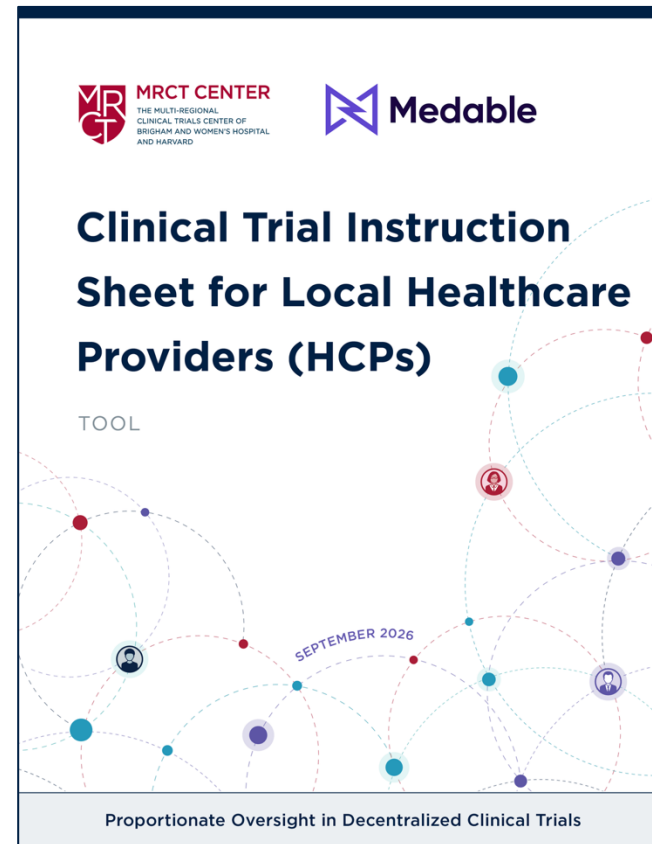
Instruction Sheet for Local HCPs



This document is designed to be completed collaboratively by the sponsor and the research site before it reaches local HCPs

Colored-text placeholders mark every field requiring site or sponsor input prior to delivery to the HCP. The HCP reads it, performs the visit, documents the findings, and transmits them to the research site.

The document consolidates the expected management, communications, logistics, documentation, and reporting for local HCPs.



Who is this For?

PART 1: ♦ Sponsors and ♦ Investigators/Sites

This instruction sheet is intended to help **sponsors (♦)** and **investigators/sites (♦)** prepare clear, practical instructions for healthcare providers (HCPs) who will conduct a protocol-specified participant visit away from the clinical trial site. Sponsors and investigator/sites should complete all applicable fields before the sheet is provided to the HCP, using the color-coded prompts to identify which party is responsible for each section. ♦ **The sponsor should provide study-level requirements, procedural specifications, documentation expectations, and any special handling or reporting instructions.** ♦ **The investigators/site should add participant-specific information, site contacts, visit details, and escalation pathways.** Before sharing the final, completed sheet with the HCP, confirm that all sponsor and site placeholders have been completed or removed and that the instructions are accurate, complete, and appropriate for the HCP's role and scope of practice.

-----! (after the completion of the form, delete Part 1: pg i-iii) !-----

PART 2: HCP Instruction for Trial Participant Visit

The **HCP Instructions for Trial Participant Visit** sheet is the HCP-facing instruction sheet that will be provided to the healthcare provider conducting the protocol-specified participant visit. Sponsors and investigators/sites should use this section to give the HCP only the information needed to complete the assigned visit activities safely, consistently, and within their clinical scope of practice. The HCP should expect (1) readily available and current contact information for the investigator and study team, (2) participant and visit details, (3) step-by-step procedure instructions, (4) documentation requirements, and (5) any specimen handling or transfer instructions. Avoid adding unnecessary protocol background, study rationale, or duplicative detail that could overburden the HCP; instead, keep instructions concise, practical, and limited to what the HCP needs to do, document, and escalate during or after the visit.

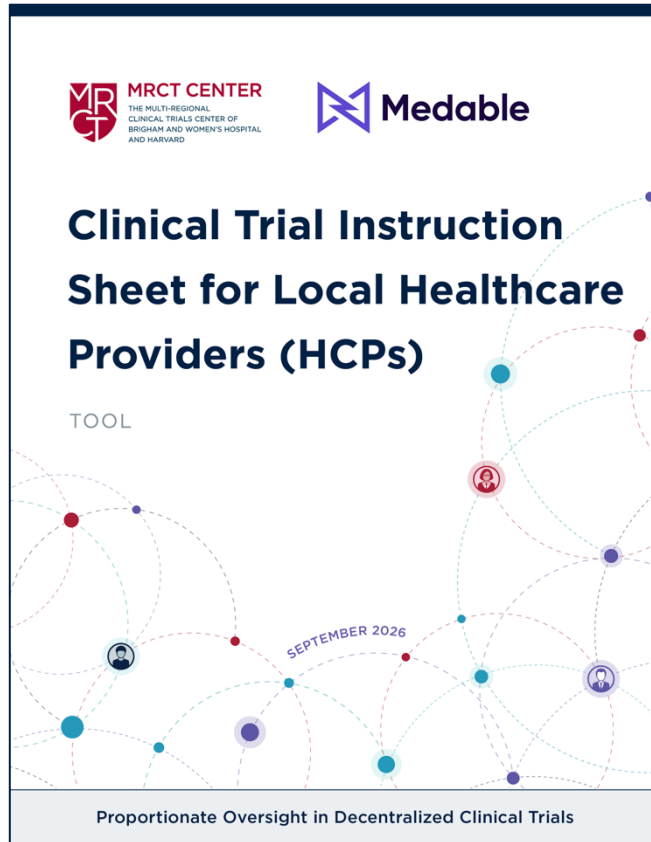
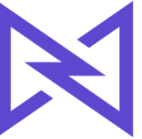
CONFIDENTIALITY NOTICE: This document contains confidential clinical trial information intended solely for the named HCP and the study team. Do not distribute, copy, or disclose to unauthorized parties. All participant information is protected under applicable privacy regulations (e.g., HIPAA, GDPR).

September 2026
v1.0

Oversight in DCTs | HCP Instruction Sheet
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Instruction Sheet for Local HCPs



The document consolidates the expected management, communications, logistics, documentation, and reporting for local HCPs.

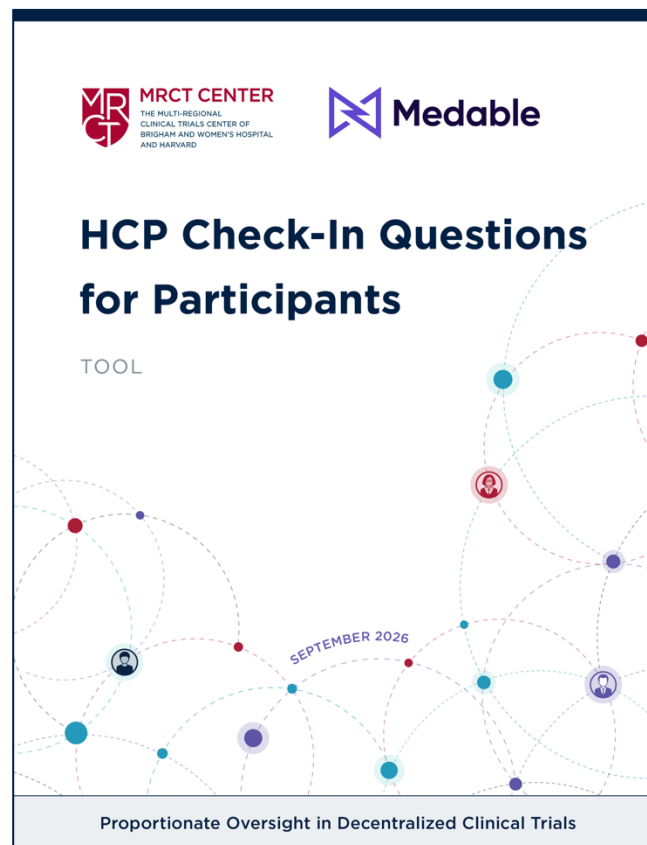
This Form has 6 sections:

- [Section 1: Contact Information](#)
- [Section 2: General Study Information](#)
- [Section 3: Participant information](#)
- [Section 4: Instructions for Participant Visit, Data, and Specimens](#)
- [Section 5: Procedures and Data Capture](#)
- [Section 6: HCP Acknowledgment](#)

HCP Check-In Questions for Participants



The document helps the HCP consistently ask key questions, record the participant's response, and identify the appropriate immediate action.



HCP Participant Check-in Questions:

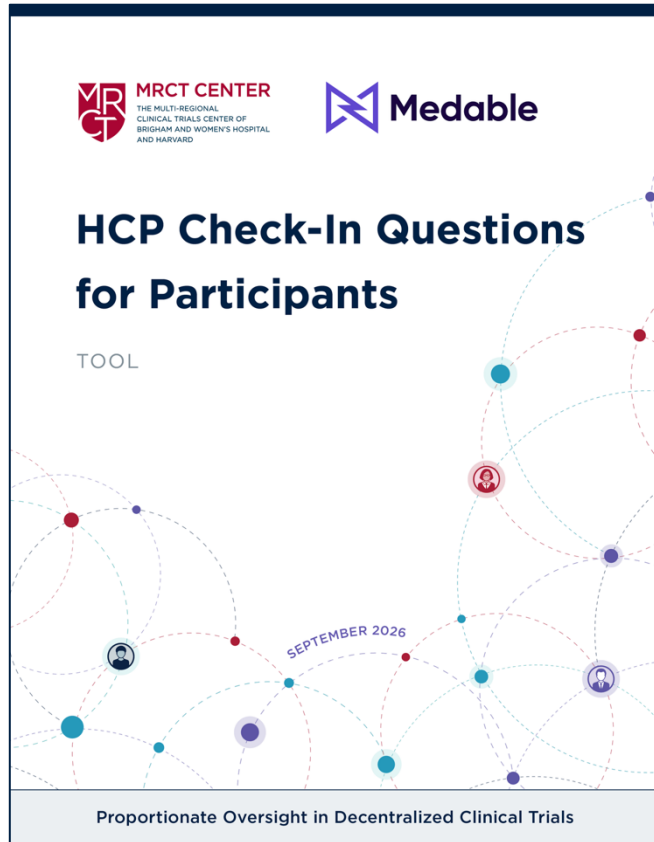
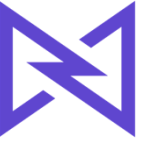
The HCP Participant Check-in Questions are intended to structure each visit and ensure key safety, adherence, and protocol-relevant issues are consistently assessed. Use these questions to guide the conversation, document findings, and promptly engage the research site when clinical or study-related concerns arise.

ASK THE PARTICIPANT: | RESPONSE: | ACTION TO TAKE:

- Study Participation**
Are you willing to continue the study?
☐ NO ☐ YES
If NO: Notify site; do not act independently
If YES: Continue study per protocol
- Decision Making Capacity**
Have you noticed any changes in your memory, thinking, or your ability to understand and make decisions?
☐ YES ☐ NO
If YES: Notify site ASAP; site determines re-consent
If NO: Document; continue visit
- Adverse Events/SAEs**
Have you had any new symptoms, side effects, or received any abnormal test results since your last visit?
☐ YES ☐ NO
If YES: Clinical care first; notify site ASAP
If NO: Document; continue visit
- Unscheduled Procedure/Hospitalization**
Have you had any unplanned procedures, surgeries, ER visits, or hospital stays since your last visit?
☐ YES ☐ NO
If YES: Document details; notify site ASAP
If NO: Document; continue visit

September 2026, v 1.0 | Oversight in DCTs | HCP Check-In Questions for Participants | © MRCT Center and Medable CC BY-NC-SA 4.0 license | 4

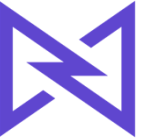
HCP Check-In Questions for Participants



The questions structure each visit and ensure key safety, adherence, and protocol-relevant issues are consistently assessed.

- Study Participation
- Decision-Making Capacity
- Averse Events/SAEs/UPs
- Unscheduled procedure and hospitalizations
- Medication Adherence
- Lost/Damaged Study Medication
- New Concomitant Medicines
- Pregnancy/Suspected pregnancy

DCT Task Force Members



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Denise Snyder

Duke University

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Novartis (currently European Industrial Pharmacist Group (EIPG))

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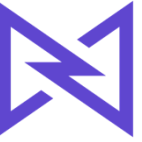
Colleen Tenan

Javara

Ramya Thota

Intermountain Healthcare

Panelists and Discussion



Cheryl Grandinetti

*Associate Director for Clinical Policy
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Office of Scientific Investigations
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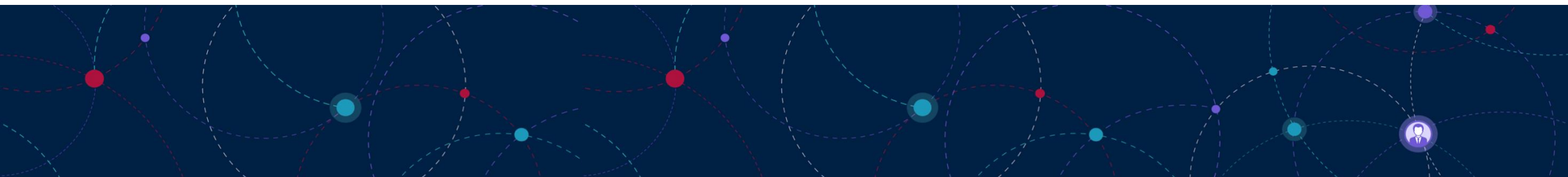
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Discussion

