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Remote Monitoring in Clinical Trials

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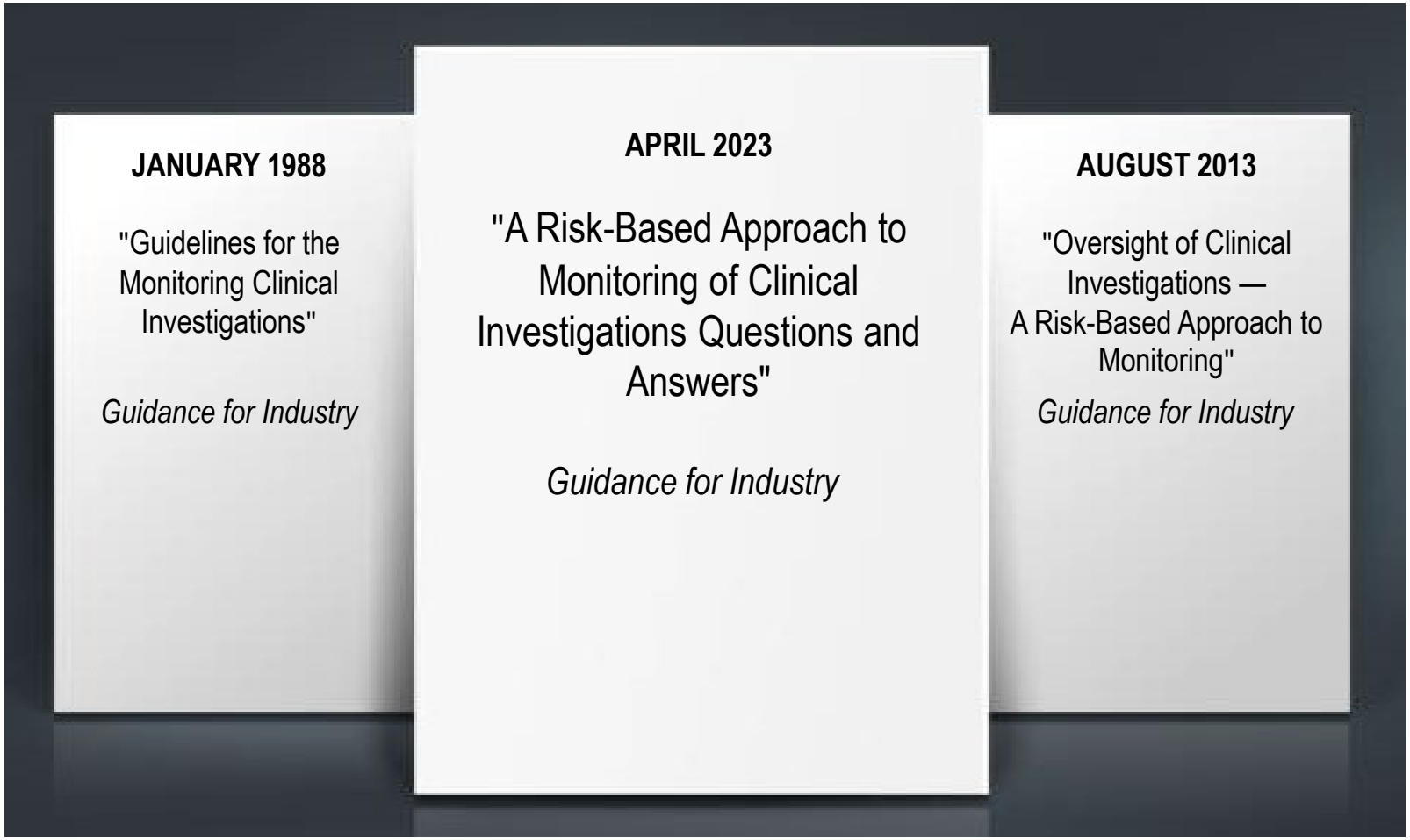
Introduction and Agenda

Although the Food and Drug Administration (FDA) suggesting shifted to remote monitoring in 2013, the industry has been slow to adopt remote monitoring technology until the COVID-19 pandemic made traditional monitoring impossible.

AGENDA

- Evolution of Monitoring
- Source Documentation
- Remote Monitoring

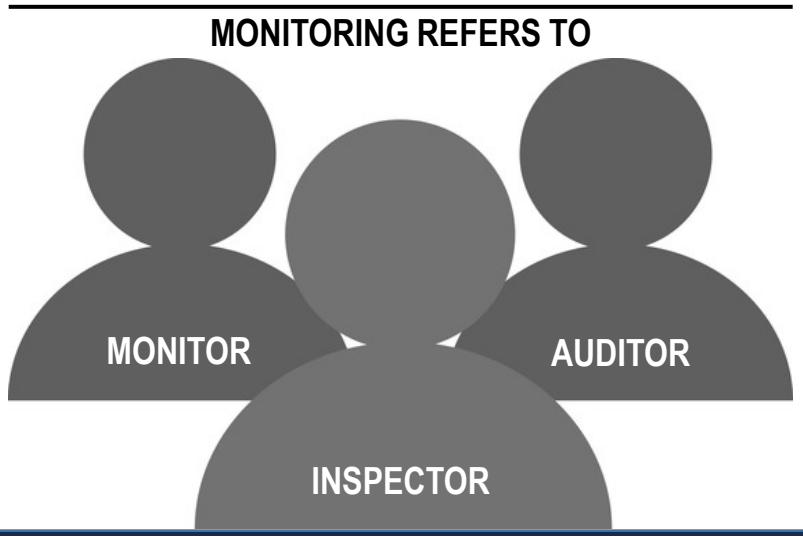
FDA Guidance



Quick Refresher: Monitoring

In the context of clinical trials monitoring refers to:

- Monitor where the study sponsor actively oversees the conduct of a clinical trial by regularly checking on study sites
- Auditor to conduct an independent reviews of data and procedure to ensure compliance
- Inspector from a regulatory agency to assess study practices



Evolution of Monitoring

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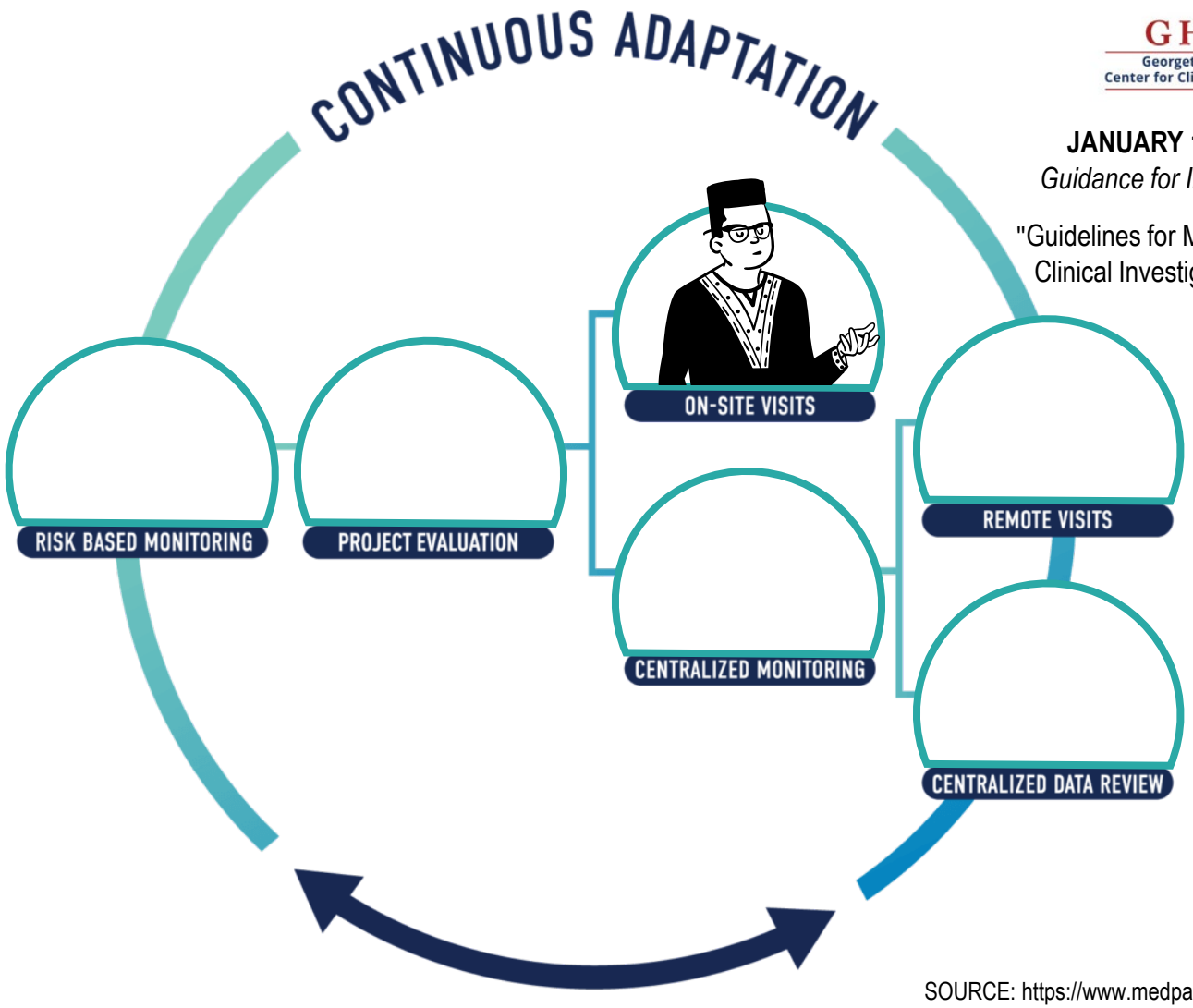
JANUARY 1988
Guidance for Industry

"Guidelines for Monitoring
Clinical Investigations"

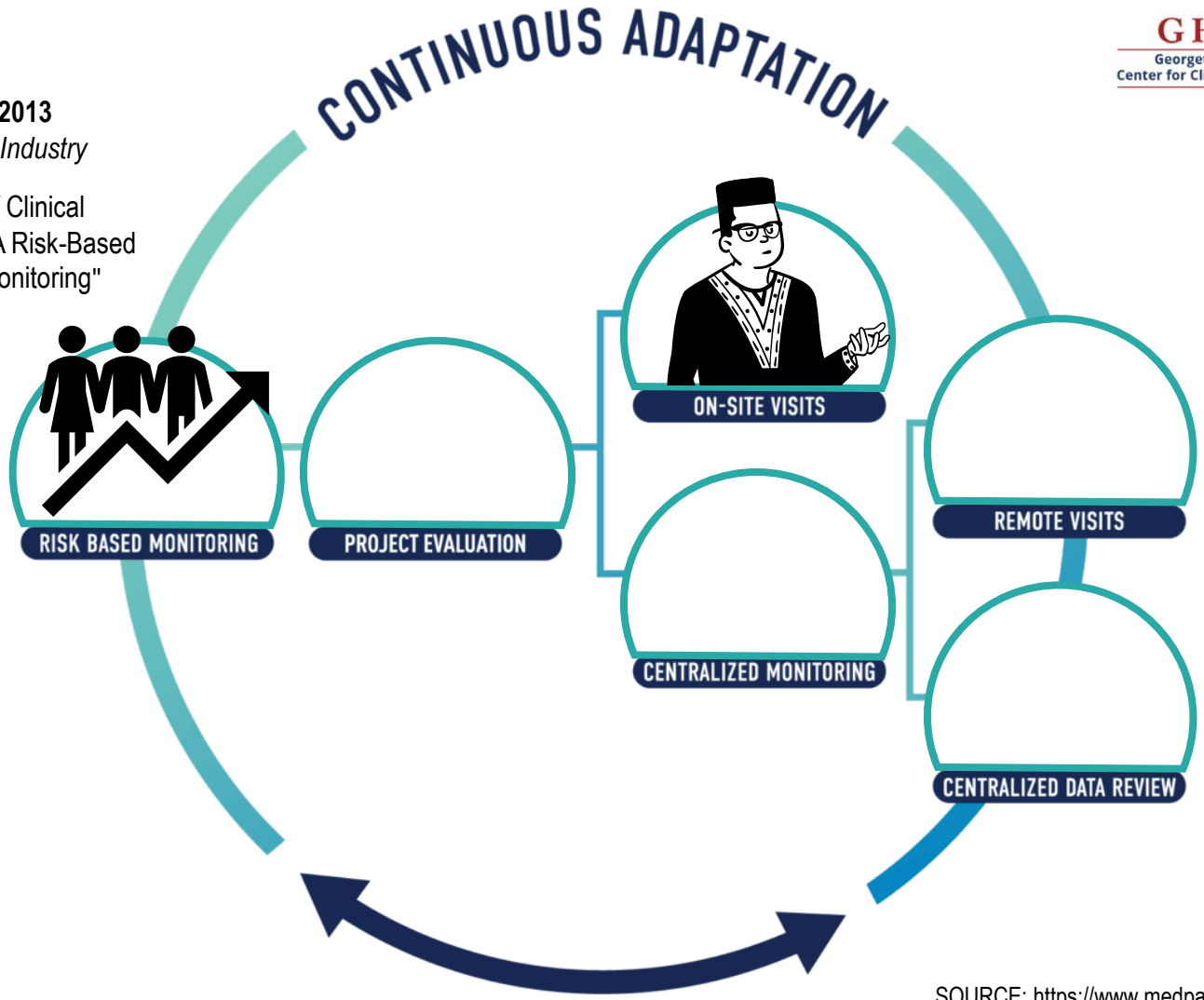


SOURCE: https://www.medpace.com/cro/clinical-monitoring/

Evolution of Monitoring

AUGUST 2013
Guidance for Industry

"Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring"



SOURCE: https://www.medpace.com/cro/clinical-monitoring/

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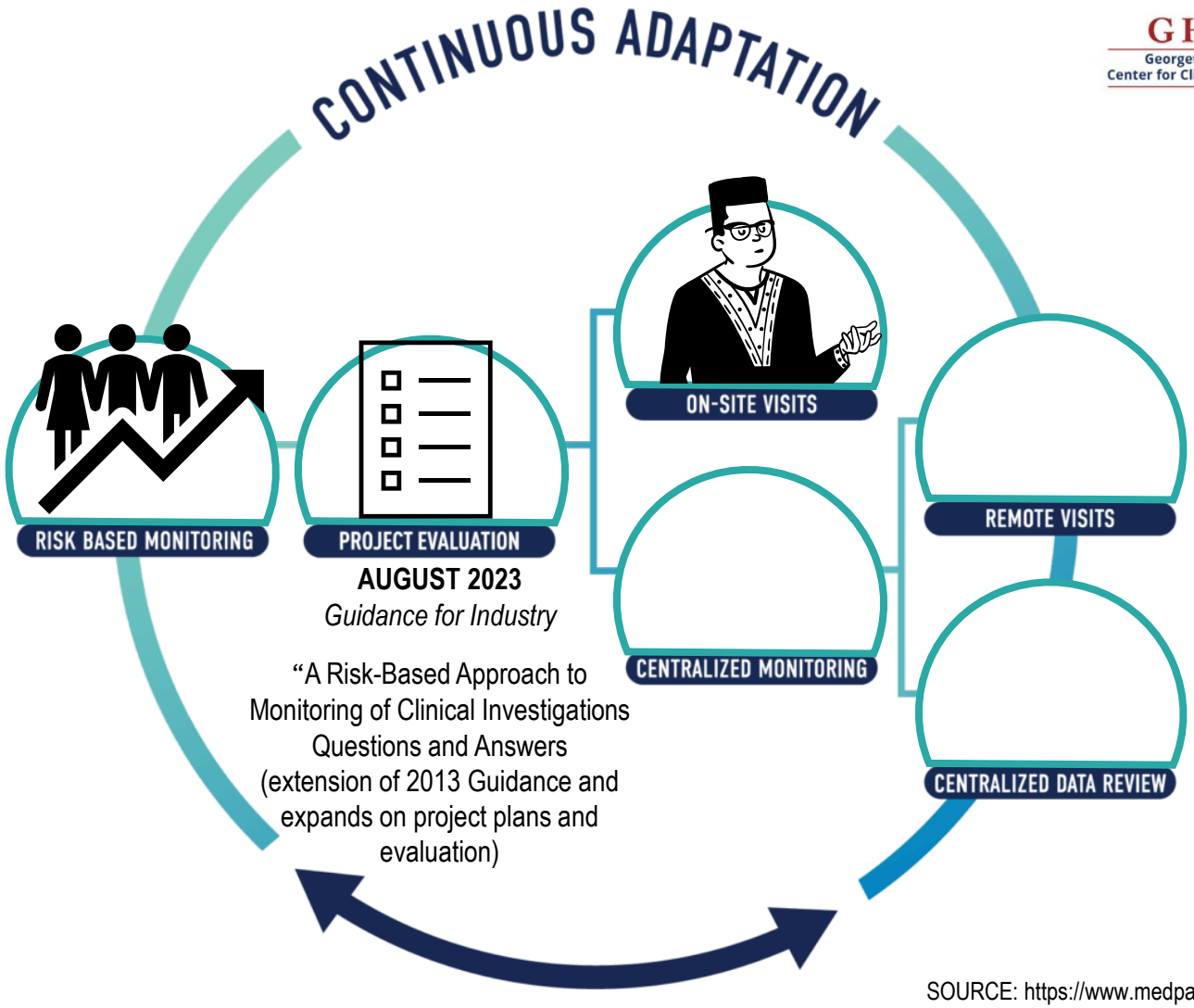

AUGUST 2023

Guidance for Industry

"A Risk-Based Approach to Monitoring of Clinical Investigations Questions and Answers (extension of 2013 Guidance and expands on project plans and evaluation)

SOURCE: https://www.medpace.com/cro/clinical-monitoring/

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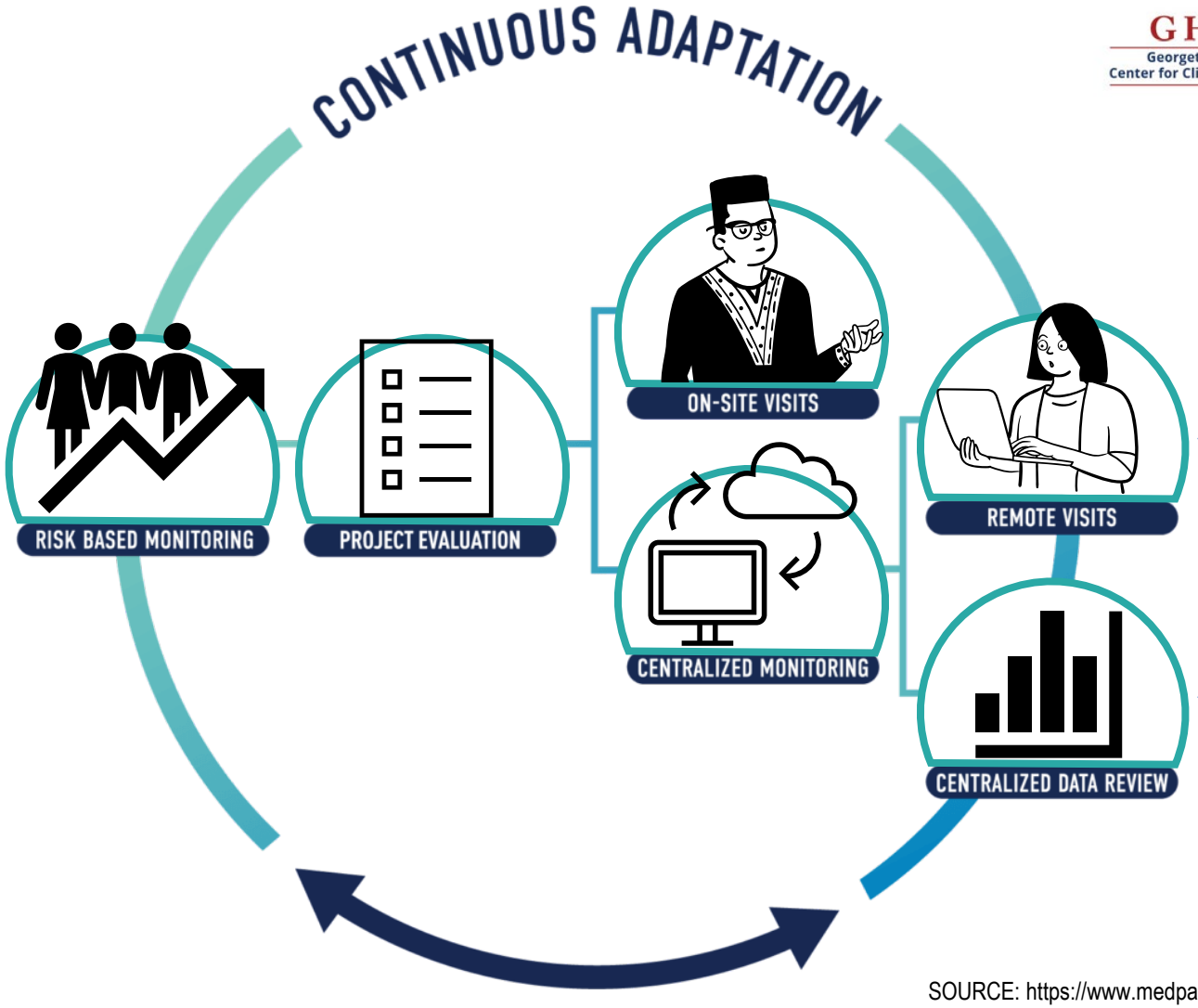

Centralized Monitoring and Remote Visits started around 2013 and gained significant traction during the pandemic.

SOURCE: https://www.medpace.com/cro/clinical-monitoring/

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RISK-BASED MONITORING

Focus	Proactive approach to ensuring the quality and integrity of a clinical trial by identifying and mitigating risks that could impact patient safety or data quality.
Process	• Risk Assessment: Identify potential risks throughout the study such as data errors, protocol deviations, or safety concerns. • Resource Allocation: Resources and monitoring activities are allocated based on assessed risks and "not one-size-fits all" approach. • Focus Area: Focuses on high-risk areas, such as critical endpoints, safety data, and processes affect data quality and patient safety.
Goal	Ensures that monitoring activities are efficient and focused on the areas where they are most needed.

	Centralized Monitoring	Remote Monitoring	On-Site Monitoring
Focus	Data-driven approach that involves remote review of aggregated electronic data, including data analysis, to identify potential issues and trends.	Involves evaluation activities, such as review and verify study data and assess protocol adherence remotely, using technology instead of physical site visits.	Monitoring where the sponsor monitor visits the clinical site to review and verify study date and assess protocol adherence.
Activities	Analytical evaluation of study conduct across multiple clinical sites, carried out by personal at a central location.	Sponsor monitor reviews source documents remotely to ensure data accuracy, adherence to protocol, regulatory documents and GCPs.	Sponsor monitor reviews source documents on-site to ensure data accuracy, adherence to protocol, regulatory documents and GCPs.
Benefits	• Real –Time Data Analysis • Efficiency • Holistic View	• Cost-Effectiveness • Efficiency	• Personalized Evaluation • Direct Interaction
Approach	Integrated into a Risk-Based Monitoring strategy to improve data quality and patient safety.	Can be combined with other monitoring forms, such as centralized monitoring, to create a comprehensive monitoring plan.	Can be combined with other monitoring forms, such as centralized monitoring, to create a comprehensive monitoring plan.

Source Documentation

Before we take an in-depth look at remote monitoring...

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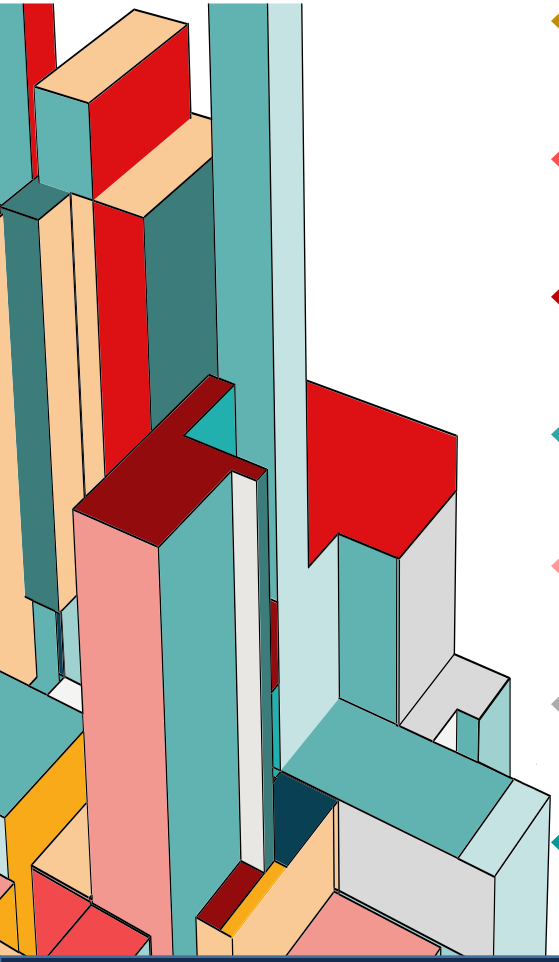

DEFINITION

Source Documentation is the first documentation of the primary data point(s) for a study participant. For example, where the blood pressure measured during a particular study visit was first recorded.

PURPOSE

The primary purpose of Source Documentation is to ensure the accuracy, validity, and reliability of data and to allow for the reconstruction of how a study or activity unfolded.

CONTENT

Source Documents can include various types of records, such as hospital records, clinic charts, lab results, subject diaries, pharmacy dispensing records, assessment measures, and informed consent forms.

IMPORTANCE

Source Documentation ensure 1) accuracy and integrity of data, 2) reconstruction of events, 3) protection of research participants, and 4) transparency and accountability.

DISTINCTION FROM CASE REPORT FORMS (CRFs)

Source Documents are the original records, while CRFs are standardized forms used to collect and summarize data from the Source Documents.

TYPES OF SOURCE DOCUMENTS

Source Documents include patient records, medication logs, stipend payments, study protocols, observation records and interview notes.

GOOD CLINICAL PRACTICE (GCP)

ICH GCP emphasize the importance of proper source documentation in clinical trials, and provide specific requirements for content, organization, and maintenance of Source Documents.

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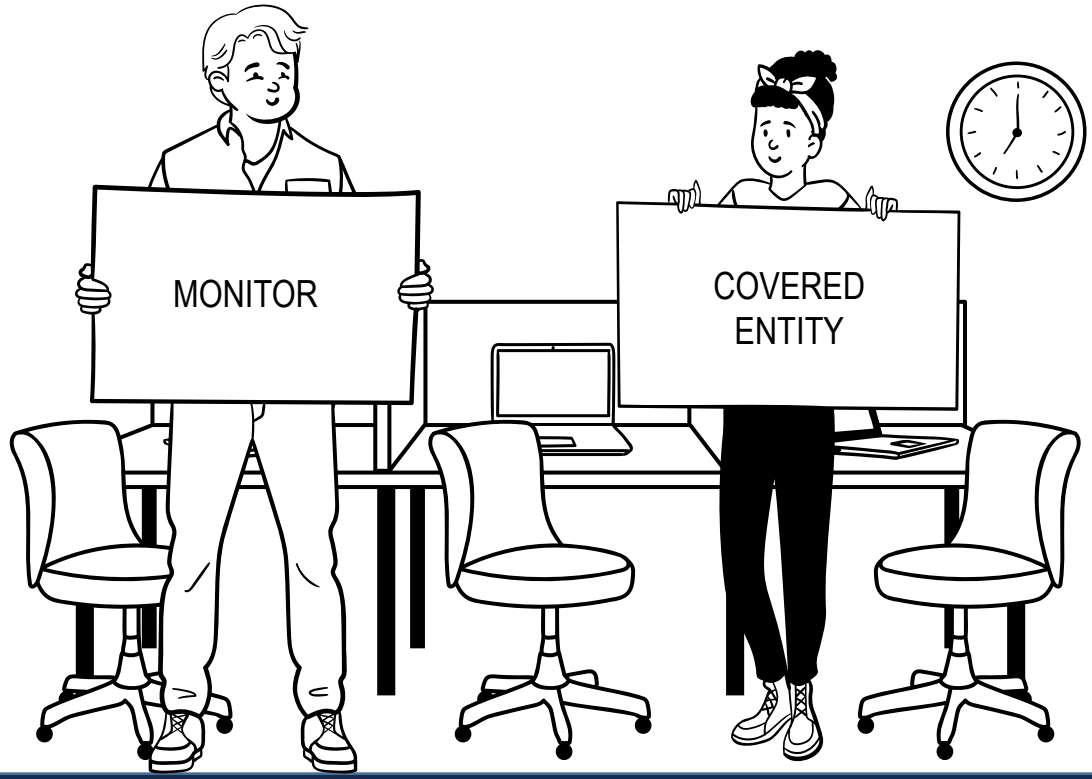
To ensure confidentiality, monitor/auditor/inspector must identify a private location or room in which sponsor representative will complete remote monitoring. Remote monitoring/auditing/inspection should never take place in a public space or open-plan office setting. Do you agree?

Remote Monitoring

Monitors/auditors/inspectors have a right and obligation to review source documents, including paper and electronic records (21 CFR 312.56 and 814.46). As a covered entity, like MedStar Health, has a right and obligation to control access to the records. Is this true?



Remote Monitoring

In prep for a remote monitoring visit, the research coordinator is printing paper versions of the EHR and will upload the documents to a HIPAA compliant cloud-based file storage platform, such as BOX, with read access only for the sponsor monitor to review. Is something missing?

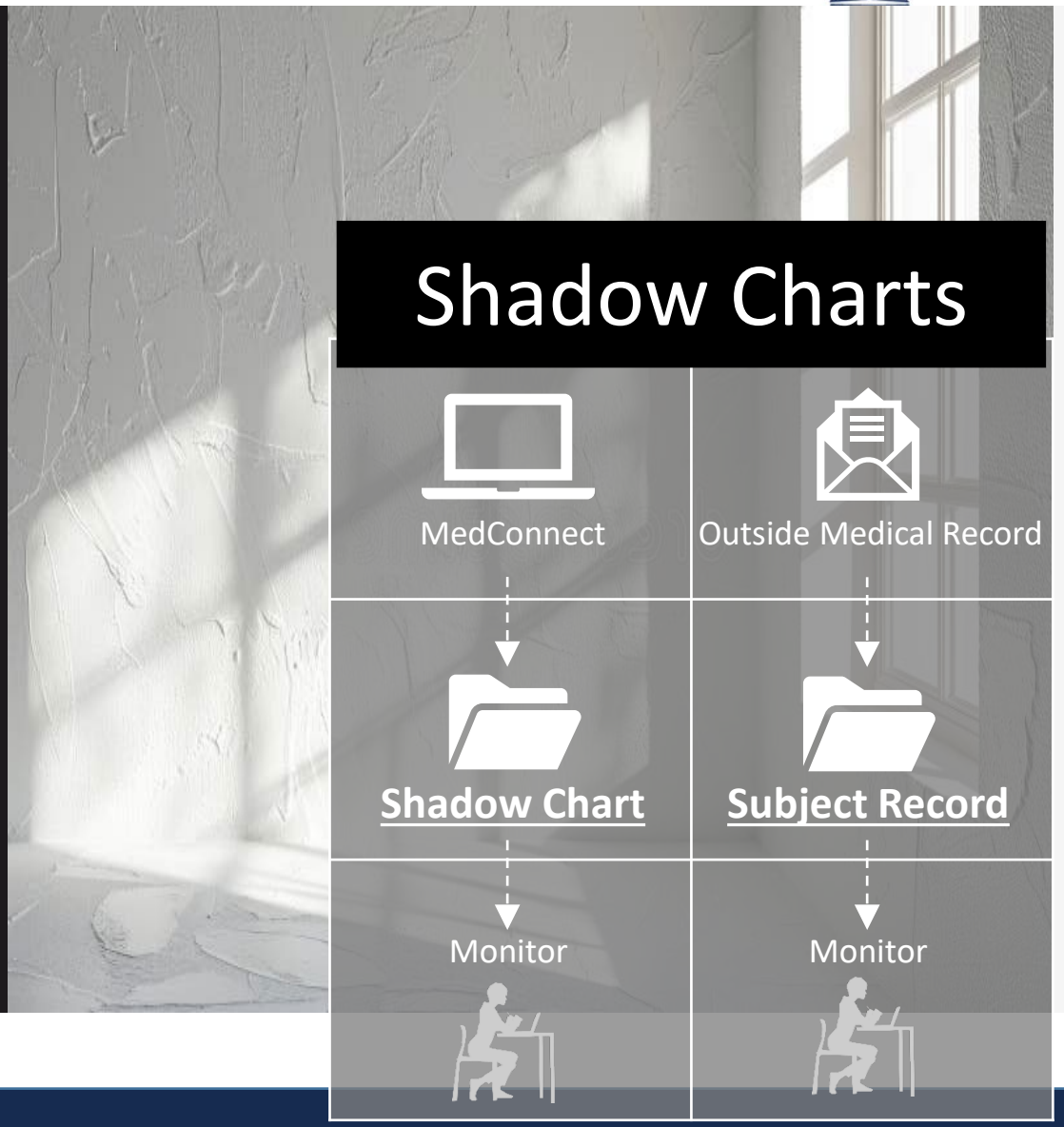
Remote Monitoring

A paper record print out of print screen of electronic data in the electronic health record is considered a shadow chart that is kept separately from the primary custodial record and should not be used as original source documentation. If a print out or print screen is used, copies must be certified as identical to original source documents following intuitional policy.

Remote Monitoring

"Shadow Charts" are printed versions of EHR records, emails, faxes and act to assemble a record that is fragmented and retained separately from the primary custodial record and

SHOULD NOT BE USED



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What is the FDA accepted definition of certified copies?

A certified copy is a copy of original information that has been verified, as indicated by a dated signature, as an exact copy having all of the same attributes and information as the original *(from 2013).*

What are the current regulations regarding the "verified process" of certified copies?

You can define your own process of certifying copies by defining clear SOPs. By having clear SOPs, you can use a certified copy instead of an original. Certification should be done by the person who made the copy, by signing or initialing and dating the copy to show that it meets the requirements of a certified copy (*from 2016).*

What is our Process?

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MedStar and Georgetown have shared polices and procedures

- MG.O-004.08 Sponsor Monitoring Visit
- MG.O-004.09 Requesting Restricted Access to MedStar Health Network for Research Monitoring
- MG.O-004.10 Source Documentation

What is our Process?

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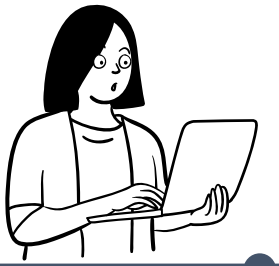

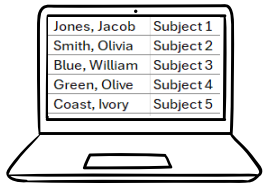

Coordinator works with monitor, auditor, inspector to schedule mutually convenient date and time to conduct remote monitoring

1 SCHEDULE

Sponsor and Coordinator signs the "Confidentiality and Security Acknowledgement for Sponsor Monitor to access MedStar Health EHR" agreement executed and good one year from date signed and updated yearly

1. Monitor according to applicable protocol
2. Do not share or misuse credentials such as passwords
3. No screen shots, screen capture, or posting PHI
4. Access is temporary

2 SECURITY

Coordinator completes form in REDCap

1. MedStar Georgetown Requesting Access
2. Non-Employee Request
3. Sponsor Registration Request
4. Network Access
5. Upload Subject List

3 REDCap FORM

Sponsor Monitor prepares device and log in to access MedStar Health applications

4 ACCESS

MedStar Health IS creates subject chart queues in EHR (limited to 25 subjects) and responsible for governance

5 SUBJECT QUEUE

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Implemented March 23, 2020
and as of
March 17, 2025

5,270 Requests to Monitor

Average of 20 Subjects Per Request

5,270 (20) = 105,400 Records Reviewed

QUESTIONS

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