JAPAN CRO ASSOCIATION

Remote Access Monitoring
(Ver.1.4e)

January 2026

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About This Document

- This document may not cover all methods, and new methods may be developed.
- Remote monitoring of clinical trial–related documents not involving subject-level (case) monitoring, such as the review of archived or stored materials, is not included.

Introduction

- Following the inclusion of remote source data verification (SDV) in the "*Five-Year Plan for Activating Clinical Research and Clinical Trials 2012*," the Japan CRO Association (JCROA) has actively promoted its implementation. Key initiatives include the establishment of a Remote Review Room at the Tokyo office in 2015, the expansion to Osaka in 2022, and collaboration agreements with 11 medical institutions to date.

- The Remote Review Room is a purpose-built, secure facility designed to support remote access monitoring, including clinical data review and source document verification. These facilities are available to all eligible users, irrespective of JCROA membership.

- During the COVID-19 pandemic, the absence of clearly defined terminology resulted in the interchangeable use of "remote SDV" and "remote monitoring." This ambiguity was compounded by the broad scope of remote monitoring, which comprises both activities conducted without source document review (e.g., via telephone or e-mail) and those involving remote access to source documents.

- In response to the growing importance of remote approaches for enhancing clinical trial efficiency, JCROA has defined monitoring that involves remote review of source documents as **Remote Access Monitoring**. This framework clearly delineates the concepts of **Remote Monitoring**, **Remote Access Monitoring**, and **Remote SDV**, and outlines associated challenges and considerations.

Changes in Monitoring Methods and Definitions of Remote Monitoring, etc.

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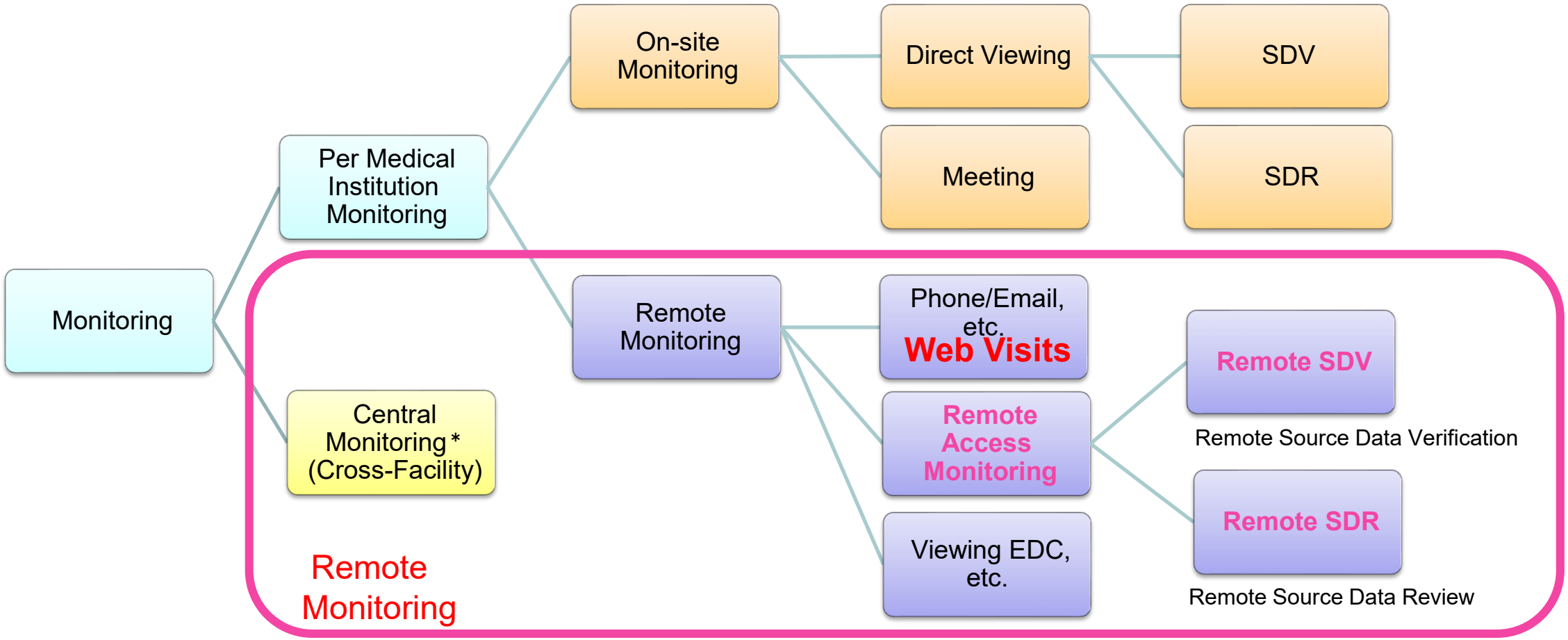
Changes in Monitoring Methods

Changes in monitoring methods due to the emergence of COVID-19

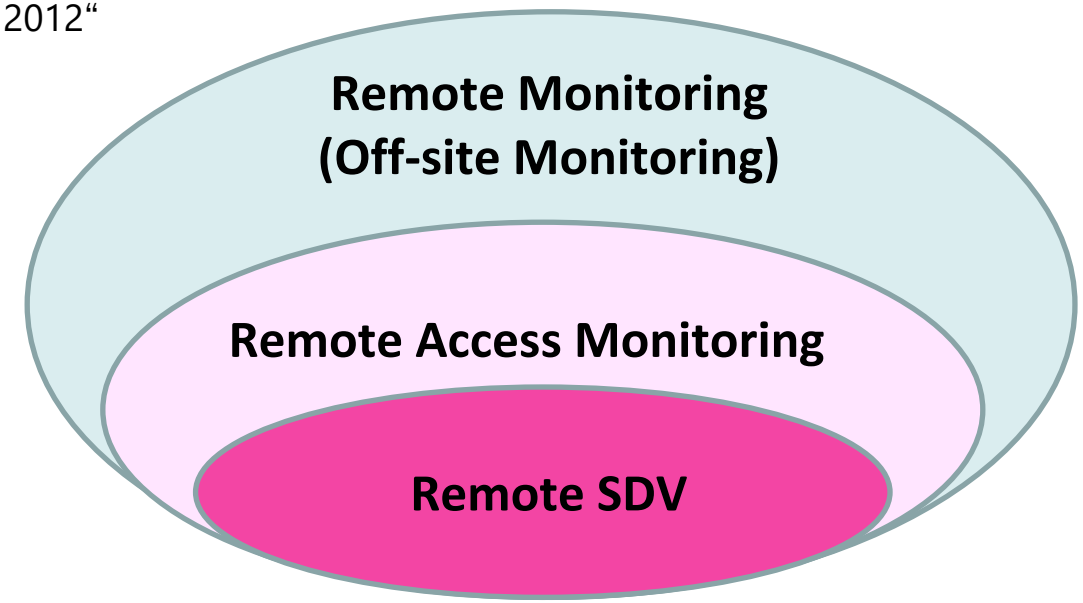


*: Pharmaceutical and Medical Devices Agency Notice No. 0705-7, July 5, 2019: Basic Approach to Risk-Based Monitoring
**: Offsite verification of EDC/laboratory values (e.g., CRAD in the testing company's system)/registration center information

Definitions

- Remote monitoring refers to monitoring that does not require visits to the implementing medical institution and is synonymous with off-site monitoring. (Japan Pharmaceutical Manufacturers Association http://www.jpma.or.jp/medicine/shinyaku/tiken/tiken119/416.html)
- Remote Access Monitoring refers to the act of performing monitoring by accessing source documents, etc., using a system, within the scope of Remote Monitoring.
- Remote SDV refers to the act of viewing source documents from outside the implementing medical institution and performing "SDV: verification of source documents against case report forms" within remote access monitoring. * (Source documents: include copies or transcriptions verified as accurate reproductions)

＊ "Five-Year Plan for Activating Clinical Research and Clinical Trials 2012“
https://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/120403_3.pdf
(modified in part)



Remote Access Monitoring - Basic Principles

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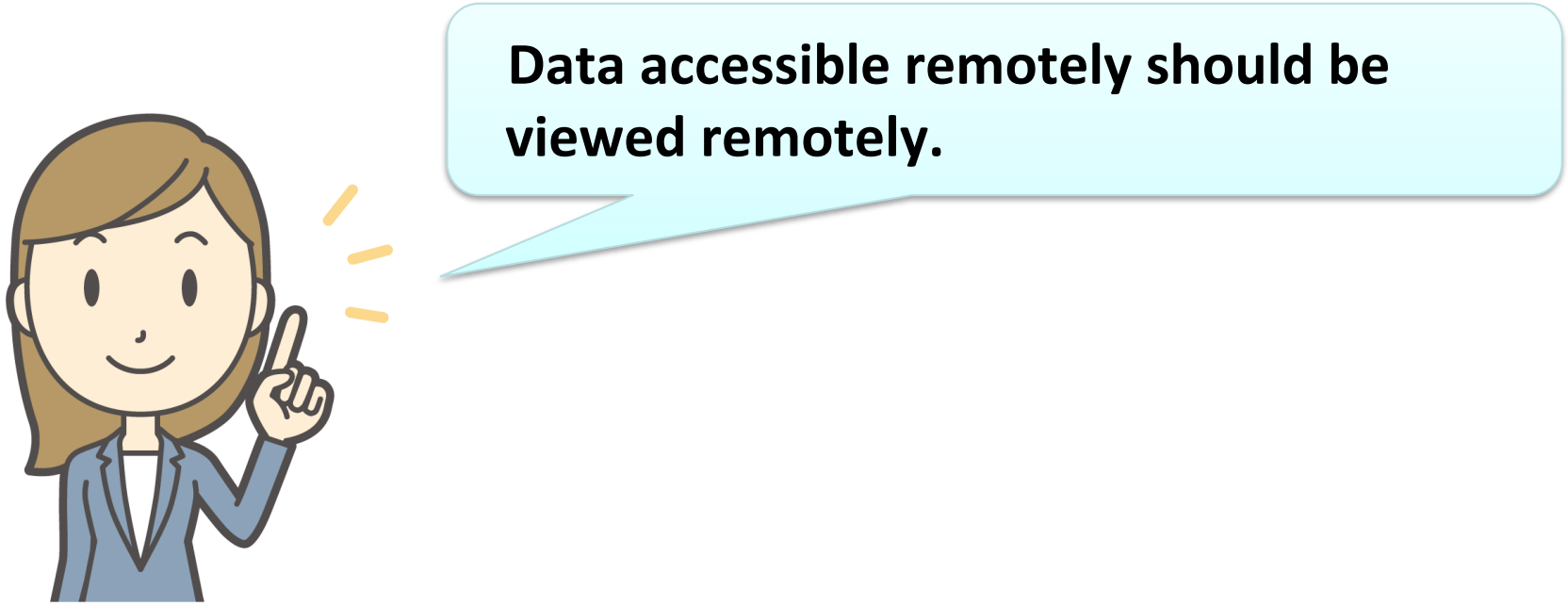
JCROA's Basic Approach to Remote Access Monitoring (1)

- In current monitoring practices, a **Risk-Based** Approach has been initiated as part of quality management. This approach focuses on monitoring critical data based on the visualization of Site Performance.
- For Remote Access Monitoring, monitoring should focus on **critical data and data deemed necessary for each trial**.



JCROA's Basic Approach to Remote Access Monitoring (2)

Remote access monitoring is a method that utilizes information technology to conduct monitoring more effectively and efficiently.

Key Considerations for Selecting Monitoring Methods

- Define the scope of materials to be reviewed for each monitoring approach, considering data authenticity, readability, archiving, and information security
- Select monitoring methods (on-site or remote) according to the monitoring objectives, and apply them appropriately, either individually or in combination
- Ensure collaboration between medical institutions and trial sponsors on:
  - Establishment and compliance with procedures for Remote Access Monitoring
  - Education and training of all relevant personnel

Reference: Explanation of ER/ES Guidelines for General Users

Authenticity

- The "authenticity" of an electronic record refers to its reliable nature and the ability to confirm that the original information has not been tampered with.

Readability

- The "readability" of an electronic record refers to the characteristic that allows the stored electronic information to be displayed or printed in a human-readable format.

Preservability

- The "preservability" of an electromagnetic record refers to its characteristic of being securely stored for the required period, maintaining a state where it can be verified and utilized later.

https://www.jcroa.or.jp/wp-content/uploads/2024/06/ER-ES_supporting_document.pdf

Types of Remote Access Monitoring

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Classification of Remote Access Monitoring

Types Proposed to Date

- Type A:

  A method for viewing medical institutions' **electronic medical** records via a dedicated security system

- Type B:

  A method viewedwhere paper medical records or printed copies of electronic medical records are converted to PDF and via a dedicated security system

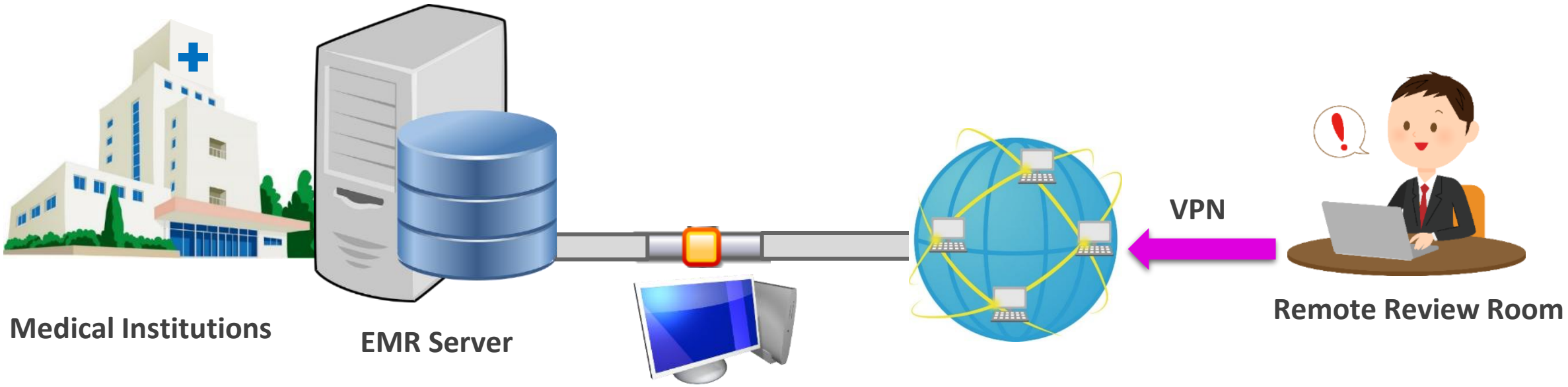
- Web conferencing system:

  A method where participants connect via platforms like Zoom or Teams and view original records using a webcam

Source: Japan Pharmaceutical Manufacturers Association, Remote SDV Deliverables 2013 (partially modified)

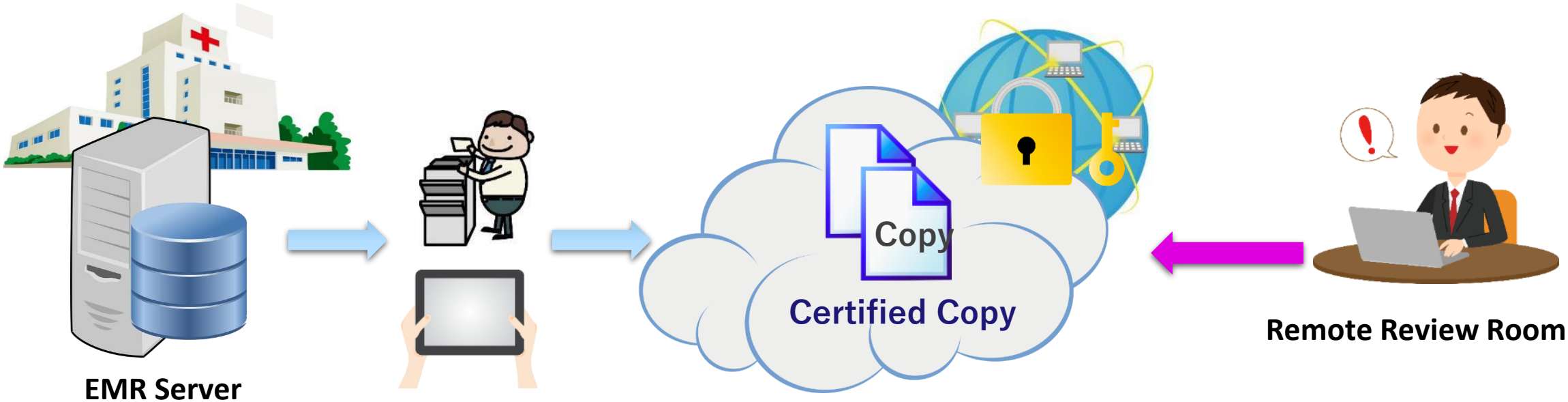
Type A

Viewing electronic medical records via a dedicated security system



Type B

Viewing copies of paper medical records or electronic medical records at medical institutions

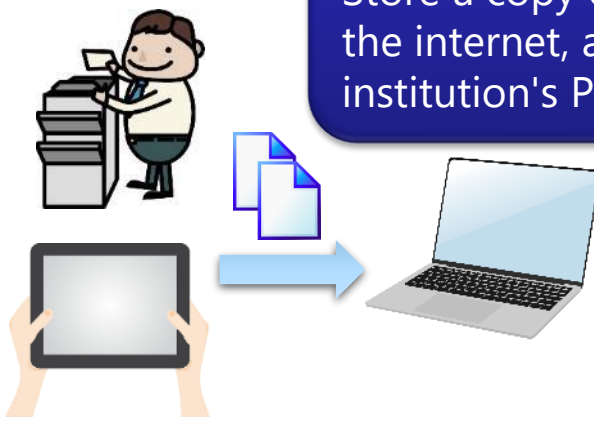


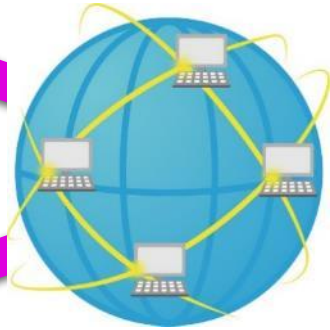
Web Conference System Type

Web Conference System 1

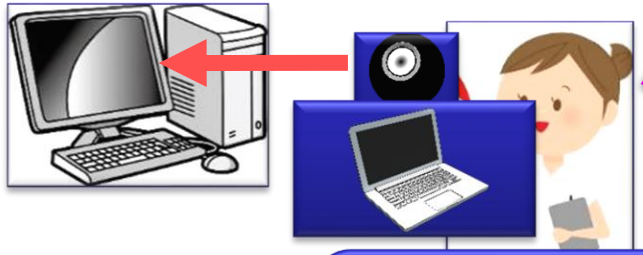
Store a copy of the original record on a PC connected to the internet, and CRA remotely operates the medical institution's PC.

Medical Institution





Remote Review Room



Web Conference System 2

Medical institution personnel display original records using webcams, etc.

JCROA's Basic Considerations for Remote Access Monitoring

While the advantages and challenges of remote access monitoring differ by system type, its purpose and timing must be carefully considered.

Appropriate implementation can improve operational efficiency, protect trial participants, and enhance trial reliability.

The Japan CRO Association aims to continue and deepen discussions on this topic.

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Common Considerations for Remote Access Monitoring

Procedures

- Medical institutions and sponsors/CROs shall establish and comply with procedures for Remote Access Monitoring.
- Procedures should be developed in consultation with the sponsor and applied consistently during implementation.

Implementation of Remote Access Monitoring

- Determine in advance, with the CRA and healthcare institution, which data may be accessed remotely.
- Define verification methods based on data criticality and trial requirements.
- For data not available via remote access, assess the need for timely verification and define alternative approaches.
- When paper source documents exist alongside electronic copies, on-site verification shall be performed as needed.

Operational Considerations

- Loan conditions for institution-provided viewing PCs shall be confirmed in advance.
- Viewing IDs and passwords must be handled strictly in accordance with institutional security policies.

Reference: <https://www.jcroa.or.jp/wp-content/uploads/2025/09/remote_access_monitoring_20250930.pdf>