January 30, 2026

Clinical Operations
Pharmaceutical Company

<u>Request for Your Cooperation in Promoting Remote Access Monitoring</u>

The Japan CRO Association (JCROA) has been promoting the use of remote access monitoring with the aim of improving the efficiency and quality of clinical trials. This initiative now represents an important step toward strengthening Japan's clinical trial ecosystem, and we are advancing related frameworks in collaboration with clinical trial sites.

To realize these benefits in practice, we kindly ask for your understanding of the significance of remote access monitoring (R-SDR+R-SDV) and for your cooperation in appropriately incorporating it into the monitoring strategies of your studies, including through collaboration with your contracted CROs.

The introduction of remote access monitoring is expected to yield the following benefits:
- Greater flexibility and efficiency in monitoring operations
- Enhanced collaboration with clinical trial sites and reduced burden on site staff
- Improved visibility into trial quality and strengthened real-time responsiveness

The acceptance of remote monitoring by clinical trial sites has been increasing year by year. Through surveys and educational activities, JCROA is also developing practical guidelines that reflect the perspectives of those engaged in clinical trial operations.

However, we have observed that in some studies, remote access has not been included in monitoring plans and on-site monitoring continues to be the default. We would appreciate your consideration of making remote access a higher priority in collaboration with your outsourced CROs.

For your reference, we have enclosed the following materials:
- Exhibit: Model Cases for Assessing the Effectiveness of Remote Access Implementation
- Attachment: Remote Access Monitoring (Ver. 1.4e) — JCROA Overview and Initiatives

We would be grateful for your continued support and collaboration in our activities.

Sincerely yours,

Toru Fujieda
Chairman
Japan CRO Association

Exhibit: Model Cases for Assessing the Effectiveness of Remote Access Implementation

This exhibit summarizes situations in which remote access monitoring can be effective, as well as measures to increase its effectiveness. The discussion is based on comparing (1) the extent to which source documents can be accessed remotely and (2) the relative costs of implementing monitoring remotely versus on-site.

Remote access may be dismissed in practice due to concerns such as "some source documents cannot be accessed remotely" or "remote access costs more than on-site monitoring." As shown below, however, remote access can still be beneficial in many such cases—particularly when combined appropriately with on-site activities (e.g., SDV/SDR performed on-site). We hope this will serve as a useful reference when designing monitoring approaches that balance quality, efficiency, and cost.

Remote access to source data	Relative monitoring cost	Strategies and example use cases
100% of source documents accessible remotely	Remote < On-site	Proactively update monitoring plans/SOPs to enable R-SDV/R-SDR when implementation is hindered by procedures. Conduct other on-site tasks as needed (e.g., IP/PI accountability, schedule coordination). When travel is required for other nearby sites, consider using remote access to reduce total travel time and maximize productivity.
	Remote > On-site	Remote access is highly effective for urgent data review regardless of cost. A hybrid approach (remote + on-site) can reduce overall man-hours, for example when: (i) visit scheduling is difficult (no slots available); (ii) visit intervals are short; or (iii) large volumes of data require frequent review that cannot be completed in a single on-site visit.
Some source documents not accessible remotely	Remote < On-site	When a large amount of reviewable data is available remotely, combining remote and on-site monitoring is highly effective even if some documents require on-site access.
	Remote > On-site	Even with higher costs, remote access can be effective by reducing CRA travel time and lowering the burden on site staff for the portion of data that can be reviewed remotely.
	Remote > On-site	For urgent safety or efficacy information, partial remote access can provide timely visibility and support rapid decision-making.
	Remote > On-site	If remote access is not practically usable (e.g., most source documents are not viewable remotely or procedures are overly complex), request improvements to the site's system and/or processes to enable more effective use.

Terms:
SDV = Source Data Verification; SDR = Source Data Review; R = Remote; R-SDV + R-SDR = Remote Access Monitoring.
Remote < On-site: Remote monitoring is less expensive than on-site monitoring.
Remote > On-site: Remote monitoring is more expensive than on-site monitoring due to remote usage fees, etc.