

# BALANCING RELIABILITY ASSURANCE AND OPTIMIZATION GCP INSPECTION BASED ON TRENDS OF CONDUCTING GLOBAL CLINICAL TRIAL

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# Today's Topics

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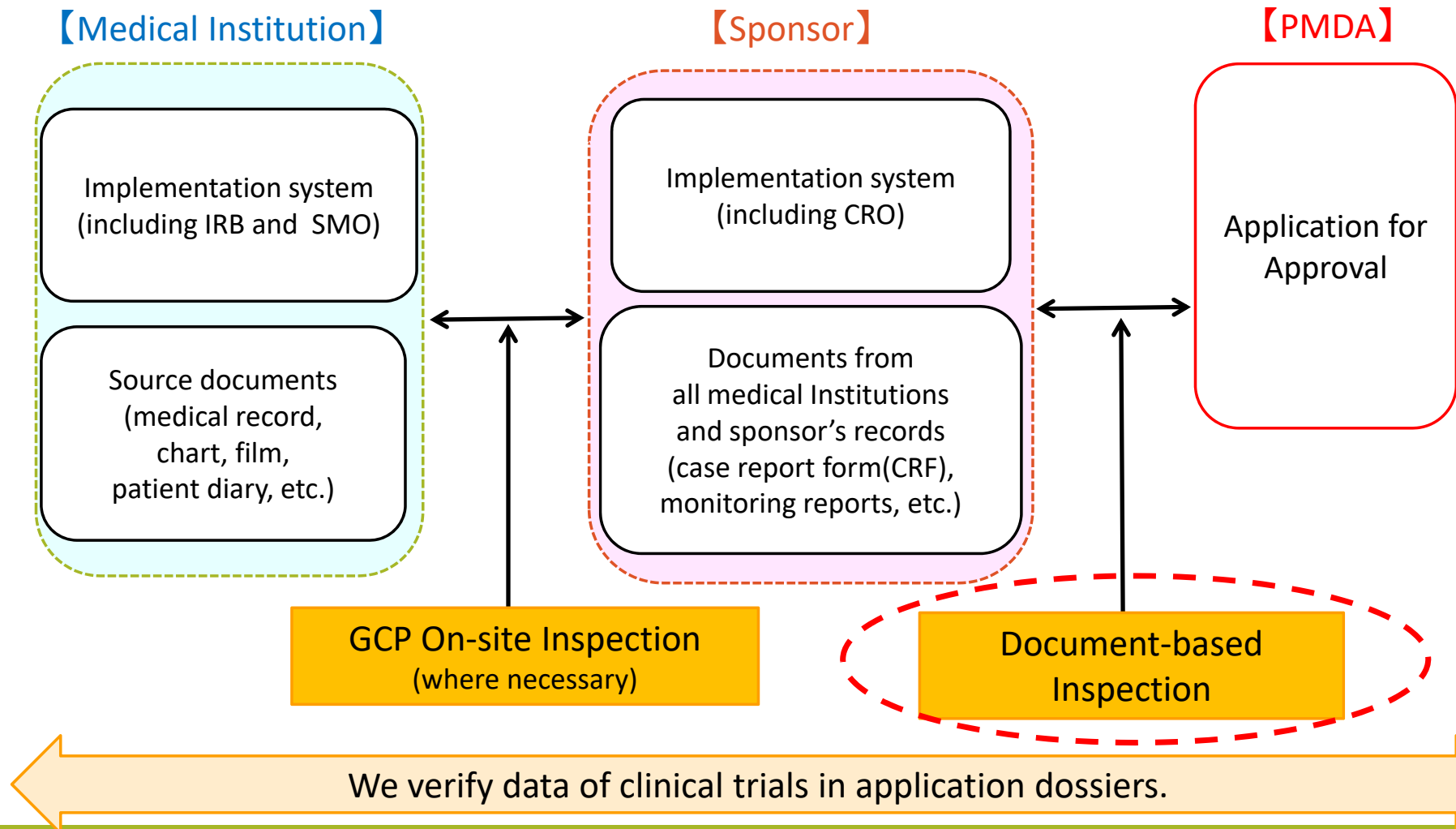
1. Compliance Inspection by PMDA
2. Trial method (Remote Inspection)
3. Conducting a remote inspection

# Today's Topics

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1. Compliance Inspection by PMDA
2. Trial method (Remote Inspection)
3. Conducting a remote inspection

# Inspection for Clinical Data



# Schedule (Compliance Inspection by PMDA)

## Inspection Schedule (as usual compliance inspection)

Applicant



- *Submission Documentation for Inspection*



*Applicant brings documents in PMDA*



**Main-Inspection**

*Face-to-face meeting*



**close**

Pmda

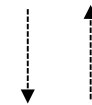
*Prepare for inspection*



*Check*

- *Protocol*
- *Clinical Study Report*
- *Case Report Forms*
- *Deviation list*
- *etc*

*Inquiry (as necessary)*



# Today's Topics

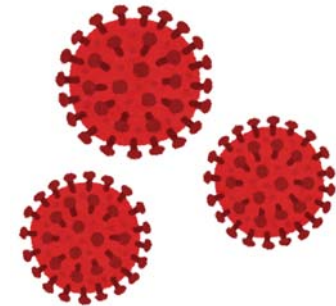
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1. Compliance Inspection by PMDA
2. Trial method (Remote Inspection)
3. Conducting a remote inspection

# Trial Method (Remote Inspection)

## Pandemic outbreak

- ✓ A state of emergency has been declared nationwide on 16th April 2020 due to COVID-19 pandemic.
- ✓ MHLW issued notification on GCP and document-based inspections during the COVID-19 pandemic on 12th May 2020.



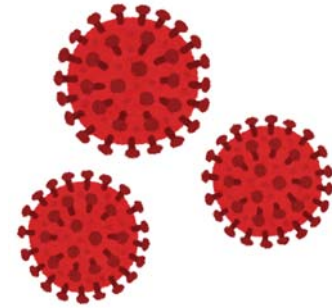
### (Summary of the notification)

- Inspectors remotely review documents shared in the cloud and video conferencing systems for inspection.
- GCP inspections for clinical sites are conducted by focusing on the sponsors' management of medical institutions without visiting them.
- If serious concerns are identified, GCP inspection will be conducted on medical institution after COVID-19 pandemic.

# Trial Method (Remote Inspection)

## Inspection during COVID-19 pandemic

- ✓ A meeting type compliance inspection is **difficult between PMDA and applicant.**
- ✓ But **a compliance inspection is required by law.**



## Trial Method (Remote Inspection)

- ✓ PMDA's inspectors (hereinafter referred to as "inspectors") may examine records/documents which form the basis of the inspected trials and studies (hereinafter referred to as "documentation") from PMDA office remotely through the cloud system or video conferencing system (hereinafter referred to as "Remote Inspection").



# Remote Inspection by PMDA

## A Remote Inspection by PMDA

- ✓ The applicant, etc. present **documentation** in advance
  - (a) Uploading documentation through the cloud system or
  - (b) Storing documentation in CD or DVD and sending them to PMDA



- ✓ Inspectors examine the documentation, and interview the applicant, etc. in main-inspection.



# Schedule (Remote Inspection by PMDA)

## Inspection Schedule (Remote Inspection)

Electronic records

Applicant

- Submission Documentation for Inspection
- Uploading documentation through the cloud system, or
- Storing documentation in CD or DVD and sending them to PMDA



Prepare for inspection

Inspection

- Inspectors shall inform the applicant, etc. of concerns to be examined at the main-inspection

Main-Inspection



close

Inquiry (as necessary)

PMDA



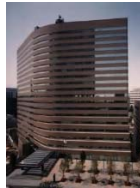
# Today's Topics

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1. Compliance Inspection by PMDA
2. Trial method (Remote Inspection)
3. **Conducting a remote inspection**

# Conducting a remote inspection

## PMDA inspection



### ● GCP clinical study

- ✓ Inspected clinical study; **domestic, overseas and global clinical trial**
- ✓ Inspection; Data management, Statistical analysis, Medical Writing, Case report form, etc.

### ● Inspection term

- ✓ PMDA is proceeding with the GCP inspection while considering the reduction of the risk of COVID-19 infection, but the inspection period did not change much between the remote and the face-to-face meeting inspection.

# Conducting a remote inspection

## Example of comment for remote inspection



- **Required time**

(for preparing documentation) **no change**

(for main-inspection) **short**

(for coorespondence after main-inspection) **short**



- **Many Comments**

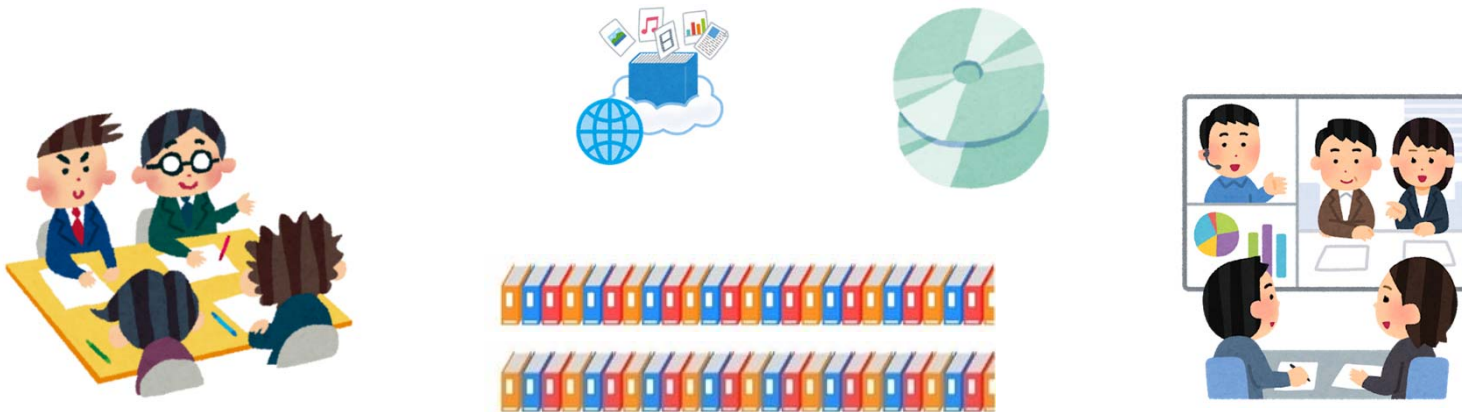
Possibility to continue remote inspection after the COVID-19 pandemic



# Conducting a remote inspection

## Future expectation

- ✓ After the COVID-19 pandemic, PMDA will consider implementation a remote inspection method, taking advantage of remote and face-to-face meeting inspection.





**Thank you for your attention!**