

# Shorten discussion time for Clinical Trial Agreement !

~First step towards creating the National Template~

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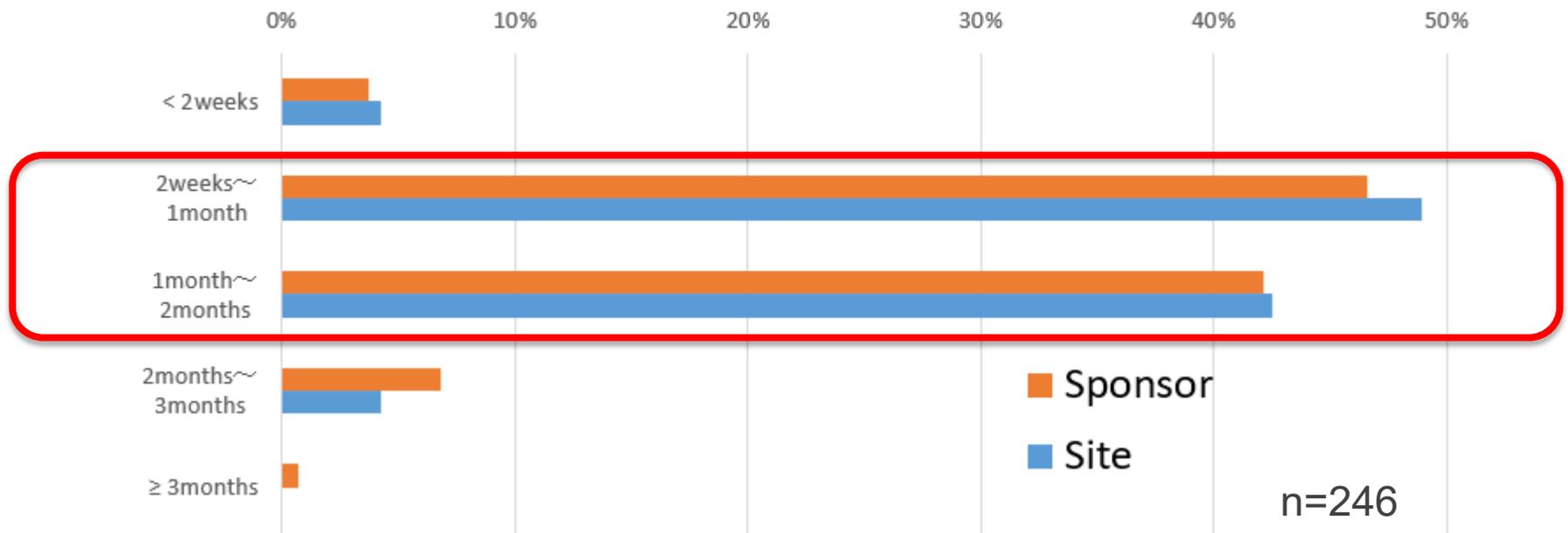
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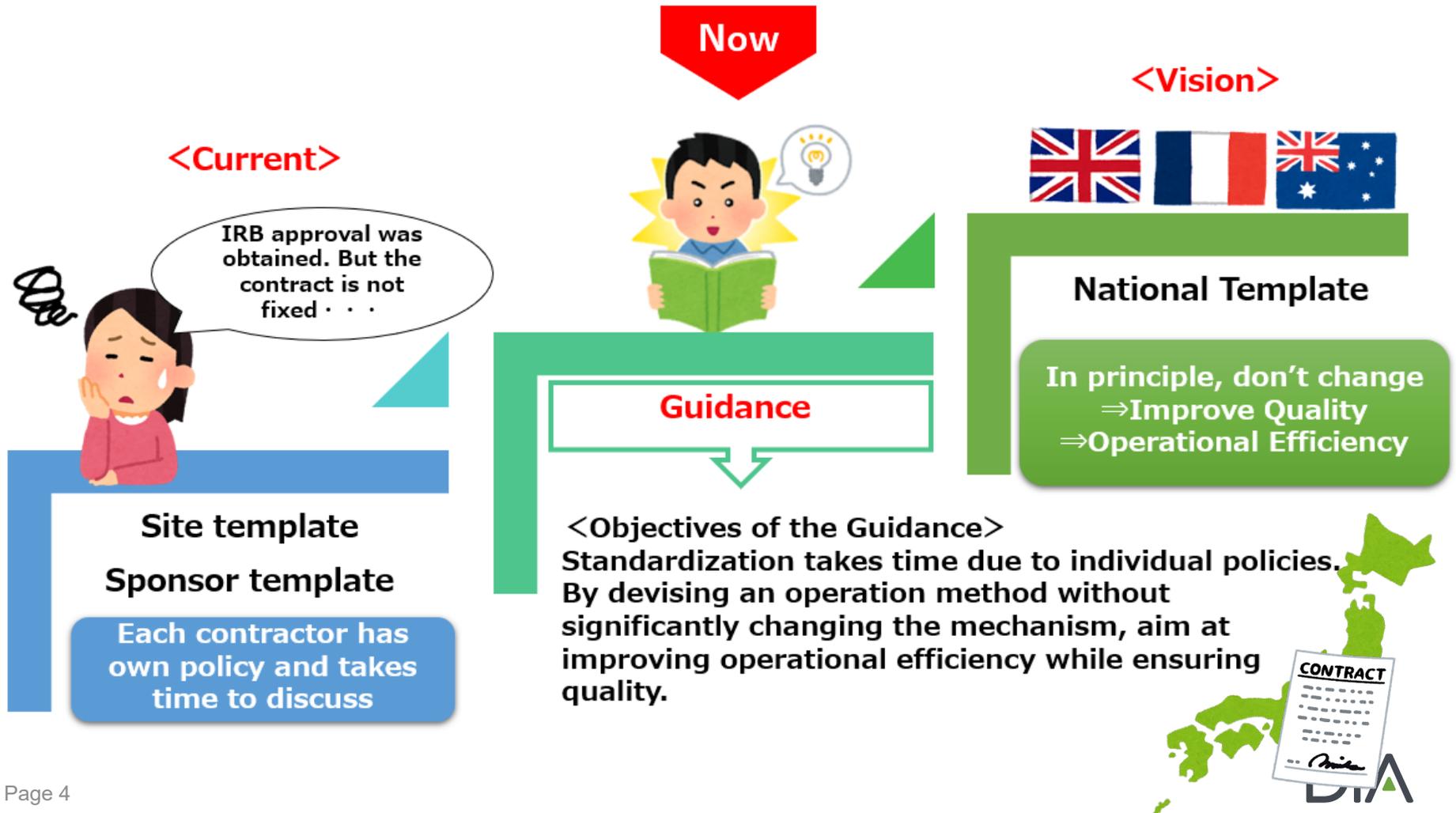
# Issues to be resolved in contracts

- ▶ Due to non-standardized templates of contract among many investigational sites and sponsors, contract discussions might delay trial starts in Japan.



# Our Goal

To create a common template for Clinical Trial Agreement (National template)



# National Template from Partial Optimization to Total Optimization

## Site/Sponsor template

→ Individualization of contract  
(Partial Optimization)



- **Quality:** Prepare according to the requirements/background of sites/sponsors
- **Efficiency:** Simplified review within the organization



## National Template

→ Standardization of contract  
(Total Optimization)



- **Quality:** Prevents errors and omissions, and reflect Japan-specific regulatory requirements without omissions
- **Efficiency:** Start clinical trials quickly by aligning of contracts

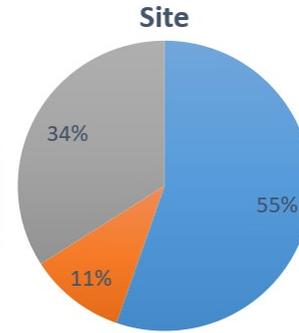
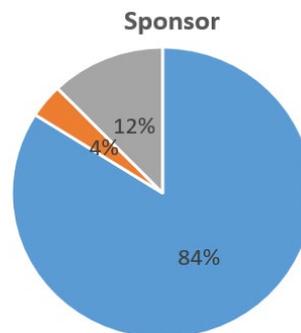
Challenge

Since there are specific requirements for sites / sponsors, adjustment is required.

**Results of  
Questionnaire on the  
Introduction  
of National Template**

80% (274/341)  
agreed to a  
National Template

■ Agree ■ Disagree ■ Neither agree nor disagree



# Guidance Summary

## Preparation method:

- ✓ A web-based survey "Monitoring 2.0 WG14 Survey on the clinical trial contract " was conducted from Dec. 2023 to Jan. 2024 among sites, SMOs, sponsors, CROs, etc..
- ✓ The responses to the survey were reviewed and discussed within WG14 to prepare this guidelines.
- ✓ Interviews were conducted with medical professional regarding the contents of this guidelines. We reflected the results of the discussions in the guidelines.

## Eligible person :

- ✓ Sponsor/Site /CRO/SMO involved with Clinical Trial Agreement

## Public location :

- ✓ Monitoring 2.0 Review Committee Website (available for download)

## Disclaimer:

- ✓ No attorneys participated in the members of WG14.
- ✓ While we have some suggestions for this Guideline, we would like you to interpret it as an option and consider adopting it between the parties hereto.

# Background of the Guidance

## Classification of items described in the contract

As shown in the table below, Article 17 of J-GCP specifies necessary items in the contract. We classified them into “Items that need to be changed per Protocol ” and “ Items that unnecessary be changed per Protocol.”

### Items that need to be changed per Protocol

Date of contract  
 Name and address, scope of work of relevant CRO  
 Name of Principal Investigator  
 Term of the agreement  
 Costs for the clinical trial

Some items need to be modified depending on the study. (e.g. Human cell therapy and gene therapy products, Post-marketing clinical trial etc.)

### Items that unnecessary be changed per Protocol

Name and address of Sponsor  
 Name and address of Institution  
 Name and Title of contractor  
 Accountability for trial drugs  
 Recordkeeping  
 Matters related to notification  
 The trial subject confidentiality  
 Protocol Compliance  
 Cooperation in Monitoring  
 Cancellation of the agreement  
 Compensation for health damage to the trial subjects  
 Other matters necessary to ensure that the clinical trial is conducted properly and smoothly

More than a half of the items are "items that unnecessary be changed per protocol"

# Guidance Suggestion ①

## ~ Avoiding Repeated Discussions ~

When the contents of the contract are fixed, identify and agree the parts that do not need to be re-discussed, and keep the record.

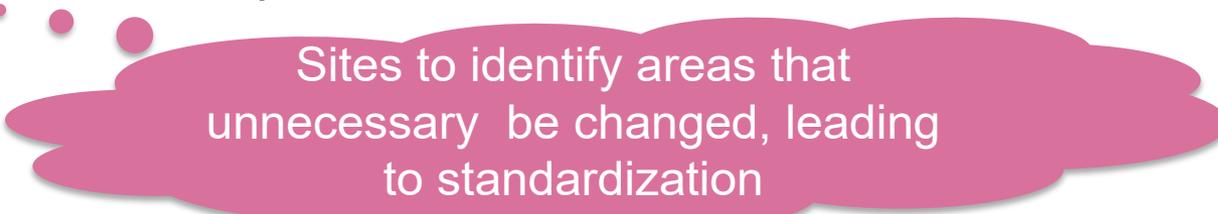


# Guidance Suggestion ①

## What is different from the current operation?

At the time of finalization of the contract, record the mutual agreement for the next trial.

- ▶ The counter person for the next study does not know the background of the discussion. So keep records at the time of agreement and align perceptions among the contact person.



Sites to identify areas that unnecessary be changed, leading to standardization

What information will be included in the agreed document?

- ▶ Date of agreement, the items that do not need to be re-discussed, point of contact for the study, masked\* descriptions. Agreed contents and masked \* contract template should be shared with the next study's person in charge.

\*When outsourcing to CRO, it is assumed that study-specific information be masked for confidentiality.

# Guidance Suggestion ①

## Results of Discussion and Interview

### 【Benefits】

- ✓ Can reduce negotiate time.
- ✓ It is possible to share with CRO by masking study-specific information.
- ✓ By disclosing the initiatives as suggestion① on the site's website, it may be possible to appeal the shortening of contract consultation period.

### 【Anticipated issues】

When outsourcing to multiple CROs, the sponsor needs to manage the masked contracts for each study site.

If CRO to be outsourced is different for each study, there will be more contracts to be managed.



In the case of a three-party contract including a CRO, how to discuss the parts that do not need to be discussed ?

Option1

Identify the parts that do not need to be discussed between the site and the sponsor, then reflect the information on CRO for each study.

Option2

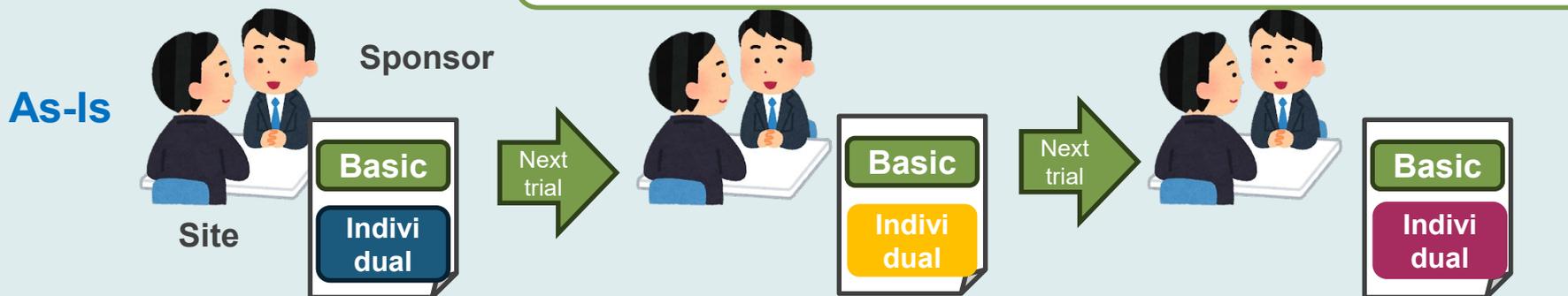
Identify and agree on parts that do not need to be discussed by the three parties.  
e.g. Case that the sponsor outsources to a specific CRO

# Guidance Suggestion ②

## ~Sign of Basic contract~

Allows to sign the agreement once, and have multiple clinical trials , without having to re-negotiate the common terms every time.

Common contents across trials are also discussed at each study start up.



Only individual contract specific to the trial will be discussed.

# Guidance Suggestion ②

## Results of Discussion and Interview

It is **physically** possible to avoid re-negotiate the parts not requiring discussion.

- ▶ The agreed contents may be accidentally modified when a file is editable. However, it would not be changed when the basic agreement is signed off.



What is the timing of discussing the basic agreement ?

It is assumed that, at the decision of the sponsor, consultation will be sought with sites that continuously request new trials or are planning to conduct multiple trials with the same compound. It is necessary to understand between contractors that the basic agreement will not be revised in a minor manner.



Is it better to include CRO as a contractor of the Basic contract ?

Basically, it is recommended to conclude the Basic contract between the site and the sponsor, then add the CRO to the Individual contract.

# Guidance Suggestion ②

## Results of Discussion and Interview (continued)

### 【Benefits】

- ✓ Can physically prevent re-negotiation of common part across trials.
- ✓ Providing the Basic agreement template by the site may also standardize language across sponsors.
- ✓ By disclosing the initiatives as suggestion② on the site's website, it may be possible to appeal the shortening of contract consultation period.

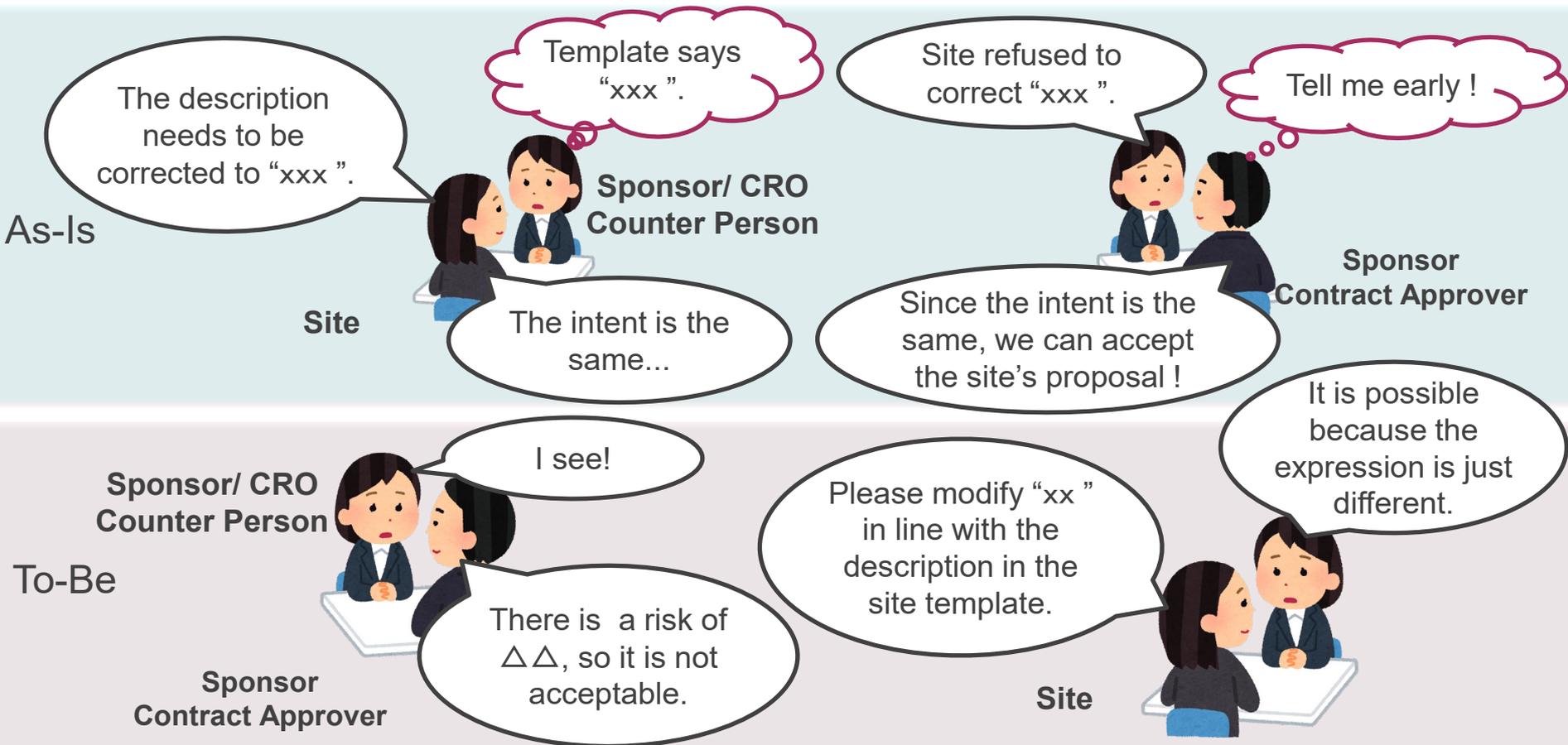
### 【 Anticipated issues 】

- ✓ It is necessary to take time to discuss the contents of the basic contract.
- ✓ In order to confirm the contents of the contract, it is necessary to confirm both the Basic content and individual content.
- ✓ It is necessary to link and manage Basic contracts and Individual contracts.
- ✓ It is difficult to outsource Basic contract discussions to CRO.

# Guidance Suggestion ③

## ~Visualize acceptable content~

Establish a system that enables the person in charge of contracts to make a decision. Do not ask for modifications other than essential terms.



Describe the unacceptable description along with the reason

# Guidance Suggestion ③

## Specific methods

- ▶ Do not require modifications to non-essential sections.
- ▶ The contract approver shall share visualization and examples of acceptable ranges of the contracts.
- ▶ The contract approver shall share the unacceptable background, reason, and risk with the counter person.
- ▶ Conduct training to enhance understanding of contract for the counter person.



Expand the scope of judgment by the counter person.



# Guidance Suggestion ③

## Results of Discussion and Interview

### 【 Benefits 】

- ✓ Cut the number of negotiation and time required for consultations.
- ✓ Able to have appropriate negotiation after accurately understanding the contents of the contract.

### 【 Anticipated issues 】

- ✓ Risks due to misunderstanding and over-interpretation of the contents of the contract.
- ✓ Since the frequency of contract negotiations is not high, it is difficult to improve the level of proficiency.



Isn't it faster to have direct discussions between the contract approver between the sites and the sponsor rather than repeating negotiation through the counter person ?

For the contents for which discussion is difficult, it is considered useful to use web conference, etc. between contract approvers.



# Conclusion and Future Plan

- ▶ We had planned to suggest an example of the provisions of the Clinical Trial Agreement based on J-GCP, but could not present them in this presentation. This is an issue to be discussed in the future.
- ▶ We need to improve the situation where barren debate are repeated every time. For this purpose, it is ideal to adopt the National Template. Before that, it is considered that the methods suggested in this guideline can improve efficiency.
- ▶ By identifying the parts that need not be discussed or promoting the Basic Contract, it may become a foothold for the standardization of the clinical trial contract in Japan.
- ▶ It is important to have a mindset that the essential contents of the contract are discussed and minor descriptions are allowed
- ▶ It is considered necessary to prepare the English National Template and consider its dissemination within the industry.

# One Last thing

Toward the implementation of National  
Template,  
we will increase the number of  
participants and wave !



Thank you to all the medical institutions, sponsors, CROs, SMOs, etc.  
that collaborated in the web-based survey and interviews.  
The guidance provided can be viewed and downloaded from the  
following website.



Thank you for your continued cooperation.

DIA