R&D Head Club
Snapshot Survey in 2020
- Actions for ‘COVID-19’ in member companies -

October 2020 (version1)

- **This report is the results report to a R&D Head Club member company for a research discussion.**
- **This report is the first version, and should be updated if corrections are made**
- **Expenses for this report were borne by member companies of R&D Head Club.**
- **For the secondary use of this document, see p. 40.**

Working Group Members

The 2020 Snapshot Survey was designed, conducted, and analyzed, and this report was authored, by a working group made up of representatives from the following 5 companies who were appointed by the R&D Head Club.

When collecting the questionnaire, a third-party vendor was assigned for masking the company name in the questionnaire before submitted to Working Group Member.

Confirmations were made via a third-party vendor when queries occurred to the questionnaire.

Performance Working Group members　(abc order)

• Astellas Pharma Inc.	Development,	Kazuaki Gamo,
• Eli Lilly Japan K.K.	Clinical Development,	Shino Fujimoto,
• Janssen Pharmaceutical K.K.	Japan Clinical Operations Div,R&D,	Shiho Jokoji,
• Pfizer R&D Japan G.K.	Portfolio & Project Management,	Kei Yamashita,
• Shionogi & Co., Ltd.	Clinical Research Department,	Ai Nakamura,

Contents

1. Outline of Surveillance (1)

[Purpose]

1. To investigate response results related to PMDA Q&A*
   *: Q&A on conducting clinical trials of drugs, medical devices, and Human Cell Therapy and Gene Therapy Products under the circumstances of the COVID-19 pandemic
2. To confirm ideas and issues leading to the improvement of future clinical trial environment based on how studies have been handled under the COVID-19 pandemic

[Participating companies]

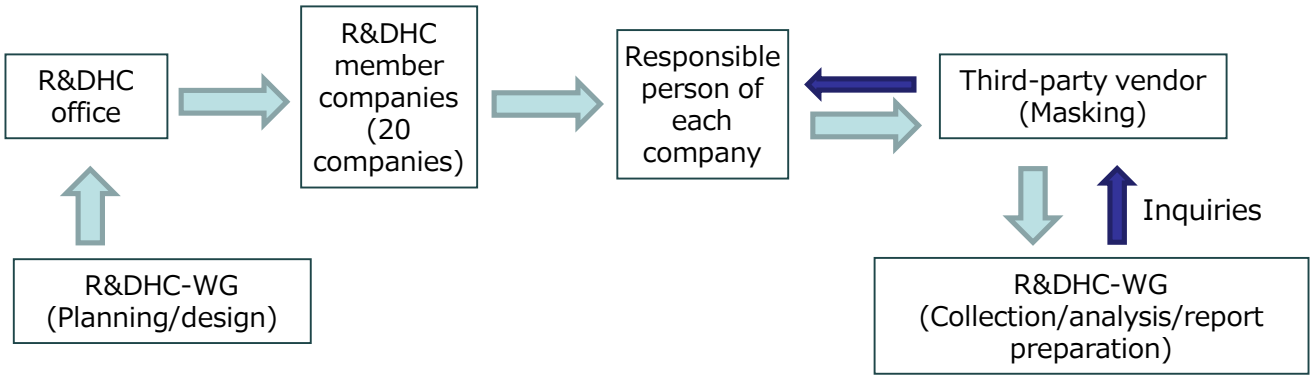
20 member companies of R&D Head Club

[Surveillance period]

August 27 to September 7, 2020 (Survey form collection completed on September 15)

[Methods]

Flow of questionnaire



1. Outline of surveillance（2）

【Participating Companies】

The following 20 member companies of the R&D Head Club participated in the 2020 survey.

	Company Name		Company Name
1	AbbVie GK	11	Janssen Pharmaceutical K.K.
2	Amgen K.K.	12	Japan Tobacco Inc.
3	Astellas Pharma Inc.	13	MSD K.K.
4	AstraZeneca K.K.	14	Nippon Boehringer Ingelheim Co., Ltd.
5	Bristol-Myers Squibb K.K.	15	Novartis Pharma K.K.
6	Chugai Pharmaceutical Co., Ltd.	16	Otsuka Pharmaceutical Co., Ltd.
7	Daiichi Sankyo Co., Ltd..	17	Pfizer R&D Japan G.K.
8	Eisai Co., Ltd.	18	Sanofi K.K.
9	Eli Lilly Japan K.K.	19	Shionogi & Co., Ltd.
10	GlaxoSmithKline K.K.	20	Takeda Pharmaceutical Co., Ltd.

(abc order)

1. Outline of Surveillance (3)

Survey Items
Q1 : On-site monitoring alternatives in ongoing clinical studies
Q2 : Selection of GCPs for investigators and study sites: status of remote implementation
Q3 : Study Initiation Meeting: status of remote implementation
Q4 : Delivery status of investigational drug, investigational device or investigational product (hereinafter referred to as "investigational products") to subject home
Q5 : Implementation status of telemedicine in Clinical Trials (Medical acts by investigators)
Q6 : Implementation status of the home visits by investigators or nurses
Q7 : Procedures for affixing the seal: Use of electronic signatures
Q8 : Approach for site IRB
Q9 : Response to patients during the clinical study (e.g. Visits to other study sites)
Q10 : Investigation of the benefits and issues gained from various measures and considerations implemented under the COVID-19 pandemic

2. Surveillance results

[Points to note for this material]

- The last subquestions under Q1 to Q9 and the subquestions under Q10 are answered by free descriptions regarding benefits and issues. The Working Group classified and grouped the elements for each comment and totalizes the number of cases. If a comment contains 3 elements, the case is counted as 1 for each of the 3 groups.
- Some of the comments in each subquestion under Q1 to Q9 are summarized.

2. Surveillance results

[Term/abbreviation] Terms/abbreviations used in comment of this surveillance

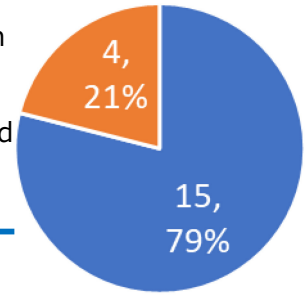
Abbreviations	Original language/Japanese translation
Under the circumstances of the COVID-19 pandemic	Under the circumstances of the COVID-19 pandemic: Duration around the State of Emergency declaration <Reference> 'State of Emergency' declared by the government "April 7 to May 25, 2020", extended to all prefectures based on 'the Act on Special Measures' on April 16
CRO	Contract Research Organization
CTMS	Clinical Trial Management System
DBL	Data Base Lock
EHR / EMR	Electronic Health Record / Electronic Medical Record
ICF, IC	Informed Consent Form
IRB	Institutional Review Board
OS	Overall Survival
OJT	On the Job Training
PMDA	Pharmaceuticals and Medical Devices Agency
SDR	Source Data Review
SDV	Source Data Verification
SIP	Shared Investigator Platform
SMO	Site Management Organization
SOP	Standard Operating Procedures

2. Surveillance results

Q1: On-site monitoring alternatives (1)

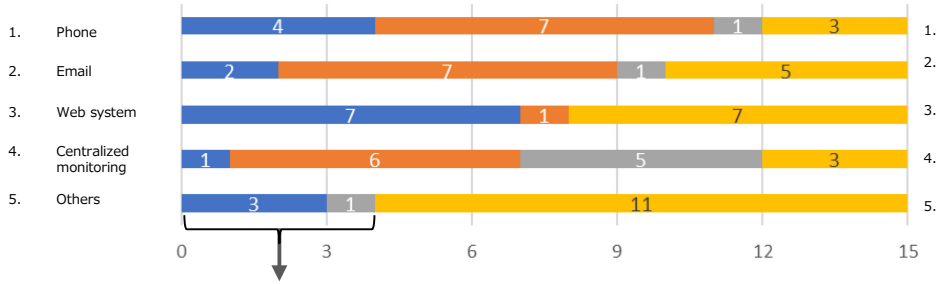
[Subquestion 1]
In ongoing trials under the COVID-19 pandemic, if on-site monitoring (SDR/SDV) cannot be carried out, what alternative measures were taken?

(1) Whether an alternative SDR was implemented



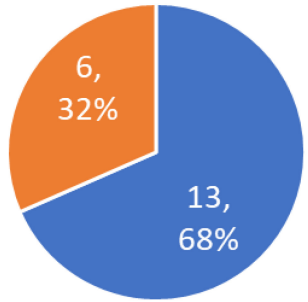
[1 company: Unable to answer because there was no applicable study to be considered]

Implemented
Not implemented



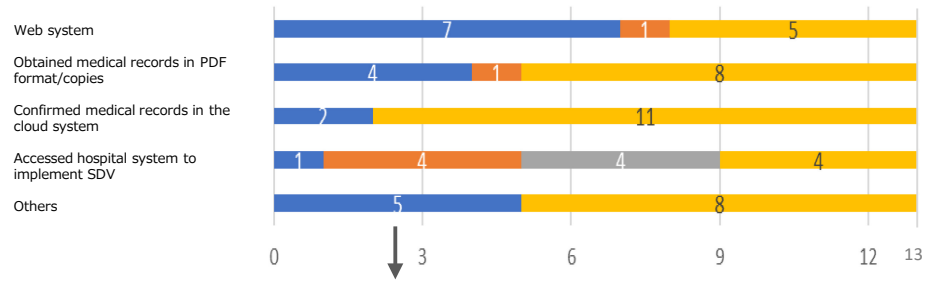
Others: Comment (4 companies)		Number of cases
Started preparation for remote access to electronic medical records		1
De-anonymized paper source documents and converted them into PDF format to implement SDR		1
Digitized source documents on the cloud system to confirm the contents		1
Obtained a copy of worksheet, if used		1

(2) Whether an alternative SDV was implemented



[1 company: Unable to answer because there was no applicable study to be considered]

Implemented
Not implemented



Others: Comment (5 companies)		Number of cases
CRC read source documents and CRA verified data (One company limited to studies prior to DBL)		2
Started preparation for remote access to electronic medical records		1
Established a policy to permanently and completely discontinue SDV for all studies, and determined to discontinue SDV for some studies in advance		1
For the studies which were under pre-DBL phase only: CRA issued queries, and CRC compared source data with CRF and answered to the queries		1

It has been newly implemented since COVID-19 pandemic

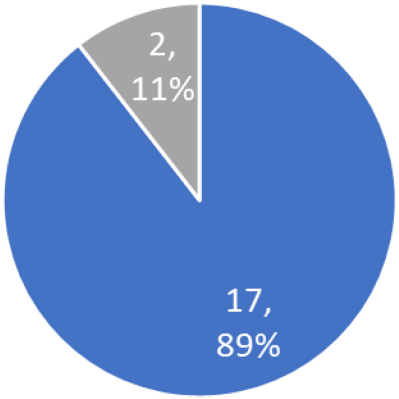
It was already utilized before COVID-19 pandemic, and its usage opportunities remained unchanged or decreased

It was already utilized before COVID-19 pandemic, and its usage opportunities have increased

It is not implemented under the COVID-19 pandemic and was not implemented before either/not applicable ('5. Others' only)

Q1: On-site monitoring alternatives (2)

[Subquestion 2]
Looking back on the alternative measures taken this time, what measures are considered (should be considered) for future clinical trials (for non-emergencies)?



[1 company: Unable to answer because there was no applicable study to be considered]

- Non-on-site monitoring should be promoted
- Non-on-site monitoring should not be promoted
- Others

Others: Comment (2 companies)
If remote SDR/SDV can be implemented, they should be promoted. However, it is necessary resolving issues faced by clinical study sites (e.g., remote access to source documents) and to clarify the standards to be complied by sponsor/CRO from the viewpoint of protecting personal information
Both on-site and remote monitoring should be effectively utilized instead of promoting one of them

2. Surveillance results

Q1: On-site monitoring alternatives (3)

[Subquestion 3]
Are there any benefits or issues gained while non-on-site monitoring was implemented and reviewed?

[1 company: Unable to answer because there was no applicable study to be considered]

(1) Benefits for sponsor/CRO:
Yes, 19 companies; No, 0 company

Benefits	Number of cases
Reducing resources such as travel time/transportation costs	17
Utilizing the resources [of monitor] effectively	3
Implementing monitoring promptly including for emergencies	3
Adjusting schedule flexibly for monitoring	3
Implementing efficient monitoring (e.g., oversight/back-up systems, holding continuous explanatory meetings)	2
Reducing infection risks during travel	2
Relevant parties other than monitors were able to attend web meeting	2
Utilizing remote monitoring for in-house monitor education	1
Establishing remote SDR/SDV procedures that were utilized by CROs to comply with deadlines	1
Contributing to promoting RBM	1

(2) Issues of sponsor/CRO:
Yes, 18 companies; No, 1 company

Issues	Number of cases
Arranging and optimizing SOPs/procedures for remote monitoring	7
Arranging IT environment (e.g., stable connection, security)	5
Securing remote monitoring sites	5
Concern about increase in burden/work for clinical study sites (especially CRCs)	4
Handling risks associated with personal information leakage	3
Improving off-site monitoring skills of monitors (including communication with clinical study sites)	3
Need to make preliminary arrangements within the range that can be handled over the web without losing the purpose of monitoring. The definition has not been established.	3
How to confirm non-EHR source documents	3
Establishing process for direct access to EHR	2
Concern about impact on quality due to limited range that can be handled over the Web	2
Establishing trustful relationships with clinical study sites	1
Considering support for clinical study sites	1

(3) Issues of the clinical study sites :
Yes, 19 companies; No, 0 company

Issues	Number of cases
Increase in burden on study sites due to remote response, need to secure resources	13
Establishing infrastructure/process and arranging procedures for remote access to EHR	8
Considering how to handle non-electronic documents (paper documents)	4
Arranging IT environment (e.g., stable connection, security)	3
Considering how to handle remote monitoring	2
Obtaining understanding and cooperation from investigators and clinical study sites who cannot respond remotely.	2
Establishing trustful relationships with [sponsor]	1
Need to make preliminary arrangements within the range that can be handled over the web without losing the purpose of monitoring	1
Limitation in the range that can be handled over the web	1
Cost burden related to system introduction/maintenance	1
Training staffs in clinical study sites to be proficient	1

Q1: On-site monitoring alternatives (4)

[Subquestion 3]
Are there any benefits or issues gained while non-on-site monitoring was implemented and reviewed?

(4) Others:
Yes, 3 companies; No, 16 companies

[1 company: Unable to answer because there was no applicable study to be considered]

Others: Comment (3 companies)
*Need to consider risks associated with the monitoring only with records that are remotely available in fragments *In Japan, since there are no guidelines from authorities, we, as an industry organization, need to provide guidelines, such as standardization of terms and minimal handling procedures.
Changing to the Focused SDV Approach from 100% SDV, or to the approach to ensure reliability in accordance with the importance of data
*Remote SDV will increase the burden on clinical study sites (especially CRCs) and is considered to return to on-site SDV after COVID-19 pandemic. *It is desirable that medical record access system and e-Source studies, etc. are widely used

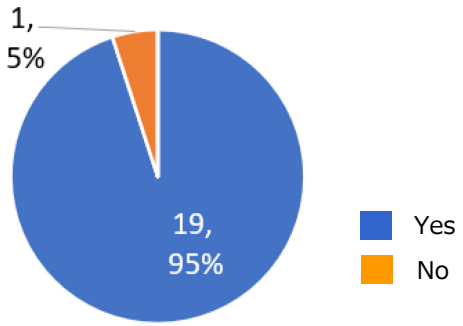
[Subquestion 4]
If a new approach to ensure the quality of data that are not dependent on SDV was (or has been) considered due to the corona influence, describe a case example.

Yes, 10 companies; No, 10 companies

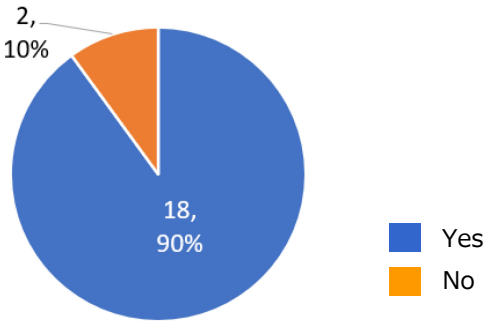
New approach	Number of cases
Implementing/considering SDV with limited range or SDV/SDR with focuses on important data and process	3
Using sampling SDV and promoting RBM are under consideration	2
Implementing effective off-site monitoring (with no access to source documents)	1
Increasing frequency of remote data check to ensure data quality	1
SDV: Establishing a policy to permanently discontinue. SDR: Implementing the sampling SDR based on risk assessment	1
Considering to ensure data quality by implementing off-site monitoring or SDR, not SDV, with the assessment by central monitoring as the major method	1
Considering to expand the range to take risk for RBM	1

Q2: Selection of GCPs for investigators and clinical study sites : status of remote implementation (1)

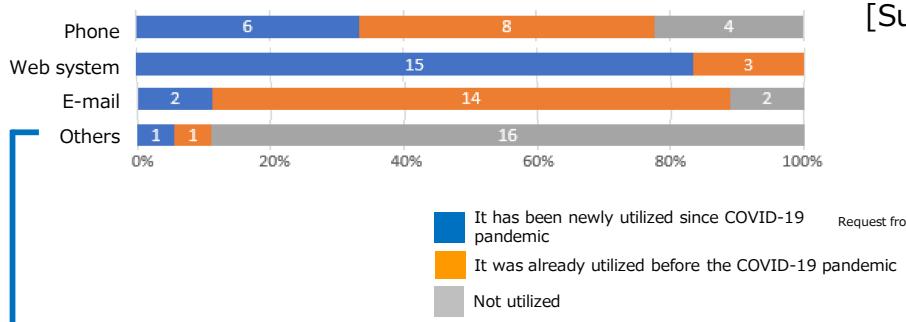
[Subquestion 1] Have you selected GCP sites under the COVID-19 pandemic?



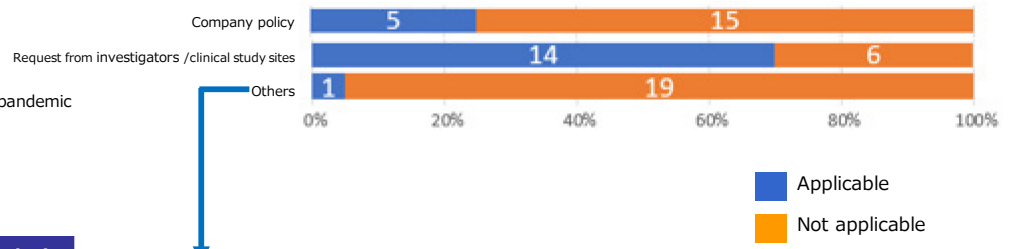
[Subquestion 2] Are there any sites where selection of principal investigators and study sites were completed without visit?



[Subquestion 3] If you selected "Yes" for the Subquestion 2, which method was used?



[Subquestion 4] If there were sites where "partially" or "complete" visits were required in selecting the principal investigator and study sites, tell us the reason. [Select all that apply]



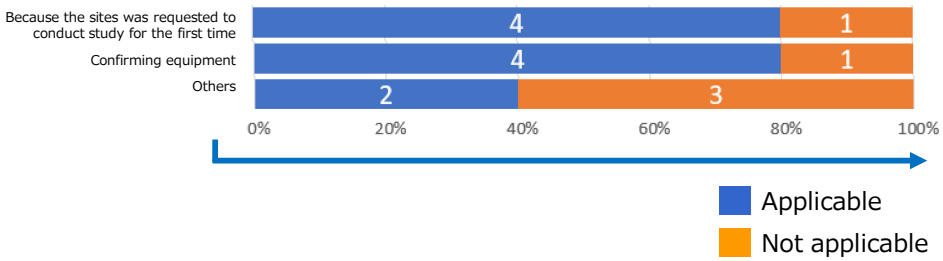
[Subquestion 3] Others "newly utilize" or "previously utilized": Comment (2 companies)	
Selection based on experience and existing information	
Have been using CTMS, etc.	

[Subquestion 4] Other "Applicable": Comment (1 company)

The sponsor was unable to use the web conference system that can be used by the clinical study sites due to security issues, and visits were required. In addition, although the policy of clinical study sites enabled remote implementation, visits were required because there was no room with remote access and there was no room to accommodate the number of people attending meetings.

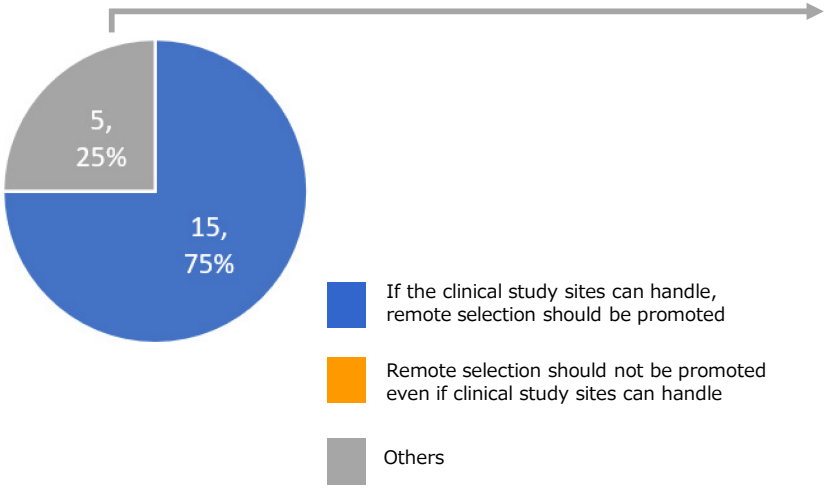
Q2: Selection of GCPs for investigators and clinical study sites : status of remote implementation (2)

[Subquestion 5] If you selected "Company policy" in Subquestion 4, tell us the reason. [Select all that apply]



[Subquestion 5] Others "Applicable": Comment (2 companies)
The company's procedures have enabled remote selection of sites to the greatest possible extent, but if clinical study sites meets certain conditions, visits to confirm equipment, etc. were required before the conclusion of the contract (if conditions are not met, it is selected remotely).
The procedures require to visit the sites at least once before study initiation

[Subquestion 6] Looking back on the selection measures taken this time, what measures are considered for future clinical trials (for non-emergencies)?



[Subquestion 6] Others: Comment (5 companies)
Although remote selection itself continues to be recommended in the future, it is desirable to visit study sites depending on the study contents and situations. Complicated negotiation and explanation are difficult to be handled remotely and, in some cases, can be done smoothly through visits and face-to-face meetings
Remote selection may be promoted for sites where past studies were conducted. However, visits to new sites should be considered for investigation
clinical study sites where our past studies were conducted are selected remotely. Sites with no experience of conducting studies should be handled on site as much as possible to ensure quality
In principle, we consider to promote remote selection. However, study-related systems and facility equipment need to be checked for some sites, such as new facilities or those where studies were not conducted for a certain period.
Remote and on-site selections should be effectively combined in handing matters that can only be confirmed on-site (e.g., on-site implementation for sites where no study was conducted before)

Q2: Selection of GCPs for investigators and clinical study sites : status of remote implementation (3)

[Subquestion 7] Are there any benefits or issues gained while remote selection was implemented and reviewed?

(1) Benefits for sponsor/CRO:
Yes: 20 companies No: 0 company

Benefits	Number of cases
In addition to the responsible person, people playing various roles, such as managers and in-house physicians, can participate	16
Reducing resources such as travel time/transportation costs	16
Contributing to efficient operations for the responsible person	5
Able to respond promptly to inquiries from the clinical study sites	5
Easy to adjust schedule	5
Multiple sites can be selected in one day	3
Contributing to reducing period in selecting the clinical study sites	3
Easy to communicate and make appointments	2
Possible implementation of investigation for selection without delay	2
Investigation for selection can be implemented for the clinical study sites where visits are restricted	2
Convenience	1
Diversified evaluation is possible	1
Conversation can be carried out efficiently due to limited time	1
All site selection procedures, including receipt of confidentiality agreements, can be completed remotely	1
Reducing infection risks and psychological burden of CRA	1
Based on the experience, remote site selection in Japan has low risk	1

(2) Issues of sponsor/CRO:
Yes: 18 companies No: 2 companies

Issues	Number of cases
Difficulties in communication due to invisible facial expression of the sites staff	7
IT/Web environment	7
Confirming system at the clinical study sites (e.g., equipment, sample storage)	4
Handling documents that cannot be fully digitized	2
Accuracy of remotely exchanged information	2
Communication skills to implement remote site selection	2
Handling cases where selection by visits is effective (e.g., complicated negotiation, explanation) or where remote selection is difficult (e.g., lack of past studies)	1
IT literacy	1
Introducing Shared Investigator Platform (SIP)	1
Eliminating stereotypes	1
Preparing procedures	1
In advance preparation and role-sharing for efficient/effective inquiries	1
Burdens arising from CRA requesting sites staff to implement duties that should be done by CRA	1

(3) Issues of the clinical study sites :
Yes: 15 companies No: 5 companies

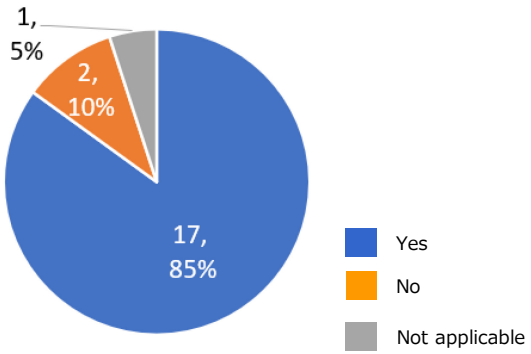
Issues	Number of cases
IT/Web environment, infrastructure development	9
Supporting CRCs by the clinical study sites staff, leading to increase in burden	7
IT literacy	6
Cannot be handled over the Web	4
Communication within the clinical study sites [Difficult to assess situations]	2
Location of remote implementation	2
Eliminating stereotypes	2
Difficult to coordinate within the clinical study sites	1
Delay in the study schedule due to issued that cannot be handled over the web	1
Phone confirmation to multiple staff	1
Disclosing information on site infrastructure	1

(4) Others:
Yes, 2 companies; No, 18 companies

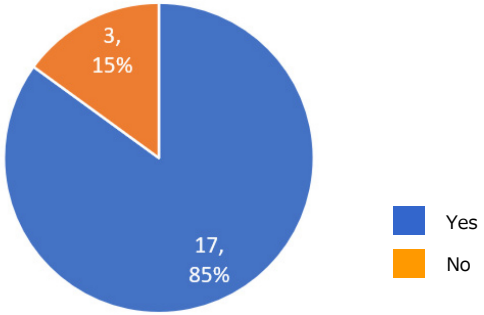
Others
Standardizing the site infrastructures to be confirmed upon visit among companies
Since the initial selection is essential in terms of quality, selection should be implemented through visits as much as possible, and remote selection, using past study experience, should also be available as an option

Q3: Study Initiation Meeting: status of remote implementation (1)

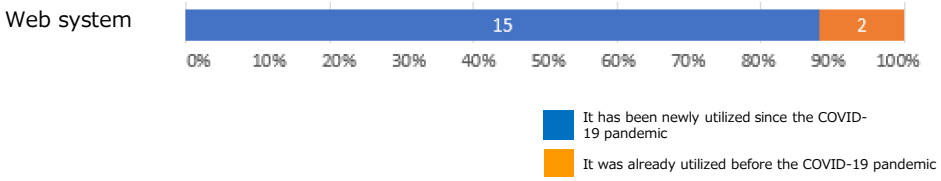
[Subquestion 1] Did you hold the study initiation meeting under the COVID-19 pandemic?



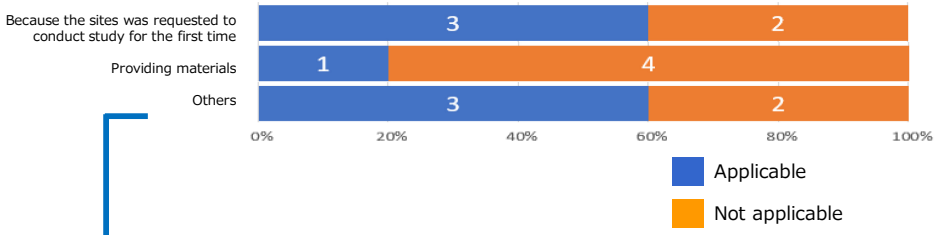
[Subquestion 2] Are there sites where study initiation meeting was held remotely without visit?



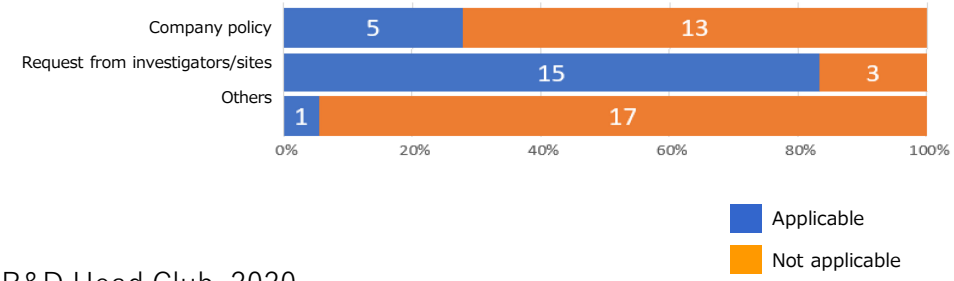
[Subquestion 3] If you selected "Yes" for the Subquestion 2, which method was used?



[Subquestion 5] If you selected "Applicable" for “Company policy” in the Subquestion 4, tell us the reason. [Select all that apply]



[Subquestion 4] If there were sites where you had to visit to hold a study initiation meeting, tell us the reason. [Select all that apply]

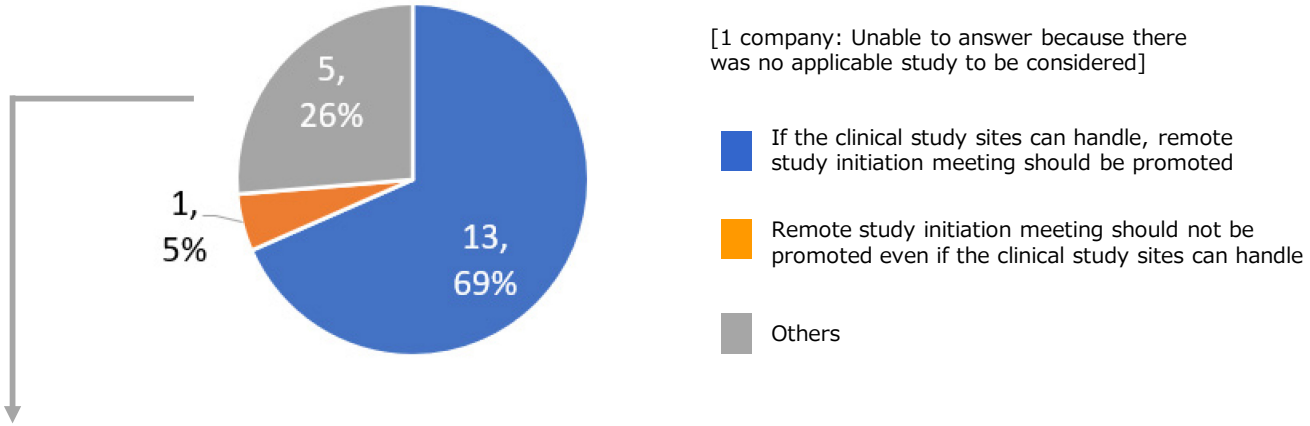


[Subquestion 5] Others "Applicable": Comment (3 companies)

Whether to hold the study initiation meeting remotely is determined by the manager for each study
Because the in-house guidance includes the following regulations for the prevention of corona infection spread: Web meetings should be prioritized for meetings with external parties, and the number of staff attending face-to-face meetings is limited to 10.
On site SIV was required in accordance with the in-house regulations, but it was reconsidered after the COVID-19 pandemic. Remote study initiation meeting is now allowed if the conditions are met.

Q3: Study Initiation Meeting: status of remote implementation (2)

[Subquestion 6] Looking back on the handling of remote study initiation meeting, what measures are considered for future clinical trials?



[Subquestion 6] Others: Comment (5 companies)
While the remote implementation is the first choice for sites where remote conduct is possible, both remote and face-to-face meetings should be combined flexibly according to the features, degree of understanding, etc. of the clinical study sites
Remote implementation (web conference system) should be promoted. However, remote and face-to-face meetings should be combined flexibly according to the features/conditions of each study or the clinical study sites , and not all meetings should be held remotely.
In principle, a remote study initiation meeting should be promoted but should be determined on a case-by-case basis, depending on the nature of the study, difficulty (e.g., simple study, complex study), and the features of clinical study sites (e.g., university hospital, clinic) the
Remote meetings should be promoted if the following issues can be solved: clinical study sites staff attend meetings individually using PC, and training logs are obtained digitally.
clinical study sites where our past studies were conducted are selected remotely. Sites with no experience of conducting studies should be handled on site as much as possible to ensure quality

Q3: Study Initiation Meeting: status of remote implementation (3)

[Subquestion 7] Are there any benefits or issues gained while remote study initiation meeting was implemented and reviewed?

[1 company: Unable to answer because there was no applicable study to be considered]

(1) Benefits for sponsor/CRO:
Yes: 19 companies No: 0 company

Benefits	Number of cases
In addition to the responsible person, people playing various roles, such as managers and in-house physicians, can participate	18
Reducing resources such as travel time/transportation costs	16
Able to respond promptly to inquiries from the clinical study sites	10
Utilizing web functions	8
Study initiation meetings can be held at multiple sites in one day	3
Optimizing resource utilization	2
Holding study initiation meeting at the clinical study sites where visits are restricted	2
Easy to adjust schedule	1
Utilizing for in-house monitor education	1
Diversified evaluation is possible	1
Easy to adjust participants and the number of attendees	1
Able to hold a joint meeting involving multiple sites	1
Reducing infection risks and psychological burden of CRA	1

(2) Issues of sponsor/CRO:
Yes: 17 companies No: 2 companies

Issues	Number of cases
IT/Web environment	12
Difficulty in communication	7
Assessing the understanding of study contents	5
Handling documents that cannot be fully digitized	4
Identifying individuals when there are multiple participants	3
Enhancing motivation management/commitment of staff in conducting clinical trials	3
IT literacy	2
Handling cases where implementation through visits is effective (e.g., explanation of setup method in using device available at sites) or cases where remote implementation is difficult (e.g., confirmation of equipment at sites)	2
Training Log preparation process	1
Communication skills to hold study initiation meeting remotely	1
Assessing structural issues	1
Eliminating stereotypes	1
Difficulty in discussing with the clinical study sites staff in a timely manner	1
Communication skills to implement study initiation remotely	1
Whether video recordings are allowed	1

(3) Issues of the clinical study sites :
Yes: 15 companies No: 4 companies

Issues	Number of cases
IT/Web environment, infrastructure development	9
Supporting CRCs by the clinical study sites staff, leading to increase in burden	5
Cannot be handled over the Web	4
Location of remote implementation	4
IT literacy	3
Difficulty in asking questions	1
Identifying individuals when there are multiple participants	1
Fulfilling responsibilities as the clinical study sites without depending on sponsor	1
Difficulty in coordinating within the clinical study sites when there are multiple participants	1

(4) Others:
Yes, 1 company; No, 18 companies

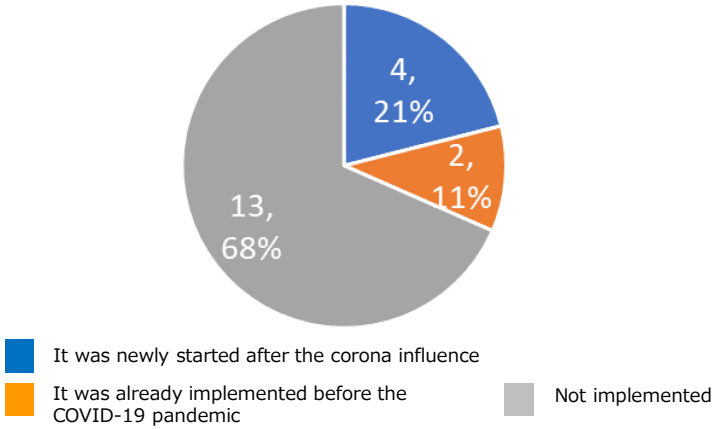
Others
The clinical study sites have the following opinions: *Since sites staff can attend individually using PC, they can practice social distancing *Meaningful study initiation meeting can be held because multiple participants from the sponsor can attend

2. Surveillance results

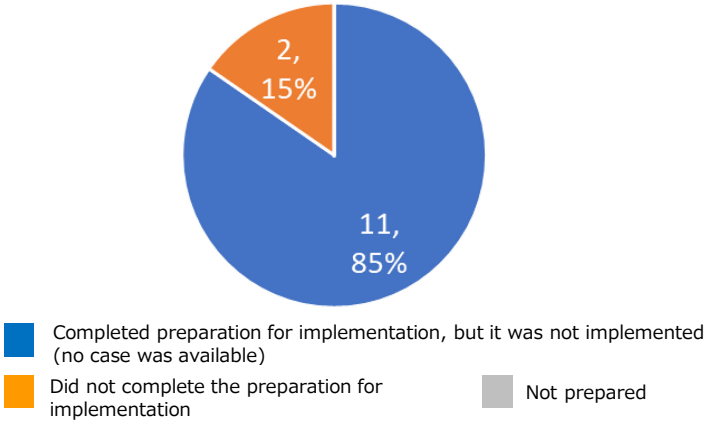
Q4: Delivery status of investigational drug, investigational device or investigational product (hereinafter referred to as "investigational products") to subject home (1)

*1 company: Unable to answer because there is no applicable study to be surveyed

[Subquestion 1]
Were the investigational products delivered to subject home under the COVID-19 pandemic?



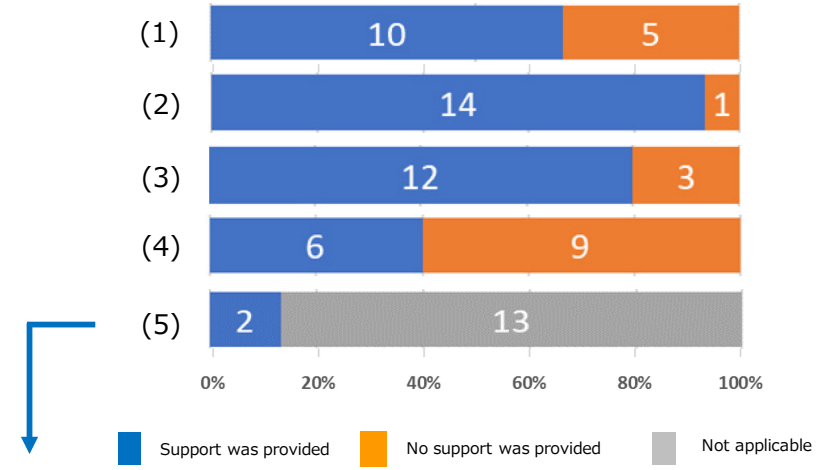
[Subquestion 2]
If you selected "Not implemented" in the Subquestion 1, tell us the reason.



[Subquestion 3]

If you selected "Implemented: It was newly started after the COVID-19 pandemic" in the Subquestion 1, or "Completed preparation for implementation, but it was not implemented" in the Subquestion 2, what supports were provided by the sponsor (including CRO)?

(1) Assisting preparation of procedures for clinical study sites
(2) Introducing delivery company to clinical study sites
(3) Supporting new contract between clinical study sites and delivery company
(4) Handling emergencies based on the agreement between clinical study sites and sponsor
(5) Others



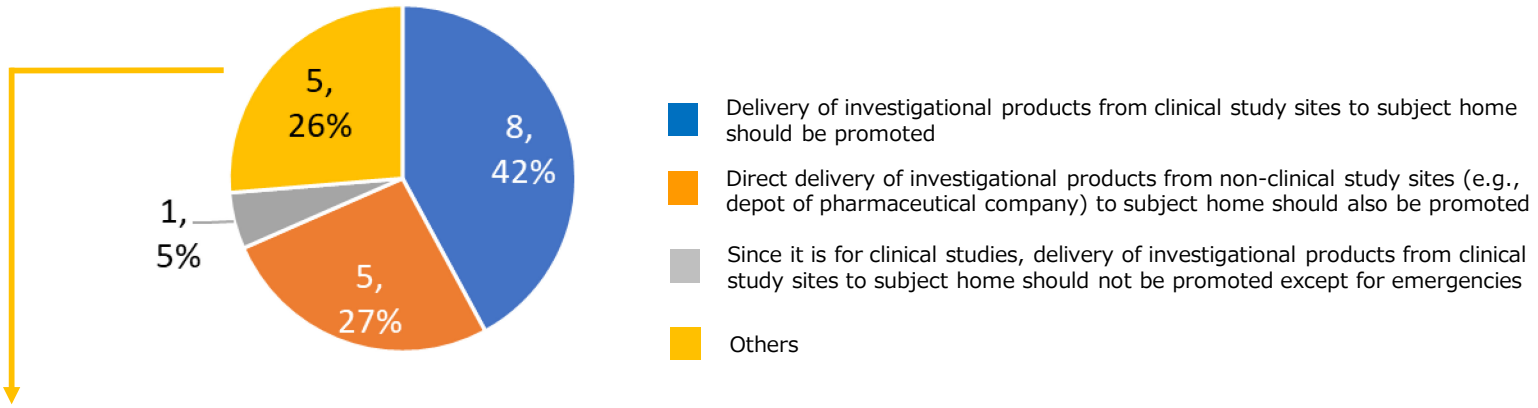
[Subquestion 3] Others "Support was provided": Comment (2 companies)
Preparing procedures, agreement template, contract template, etc. on the premise of "products delivered by the company that was selected/contracted by the sponsor"
Assisting preparation of consent form, including provision of personal information to delivery company

Q4: Delivery status of investigational drug, investigational device or investigational product (hereinafter referred to as "investigational products") to subject home (2)

*1 company: Unable to answer because there is no applicable study to be surveyed

[Subquestion 4]

Looking back on the handled case this time, what measures are considered (should be considered) for future clinical studies (for non-emergencies)?



[Subquestion 4] Others: Comment (5 companies)
Rather than promoting it, delivery should be arranged as an option
On the basis of the features of the study, drug, and target disease, careful consideration is required for whether to deliver products from clinical study sites to subject home or from depot of pharmaceutical company to subject home Ideally, flexible selection should be available, rather than "promoting" in all cases
If there is a need, it is better to prepare as an option In many cases, medical examination/test and prescription are done on the same day; therefore, the needs for delivery alone are limited
Rather than implementing in all cases, target patient population, study design, etc., should be considered in an as-needed basis
Depending on study design and target disease, the option for delivery should be prepared to reduce the burden on clinical study sites

2. Surveillance results

Q4: Delivery status of investigational drug, investigational device or investigational product (hereinafter referred to as "investigational products") to subject home (3)

*1 company: Unable to answer because there is no applicable study to be surveyed

[Subquestion 5] Are there any benefits or issues gained while the delivery of new investigational products to subject home was implemented and reviewed?

(1) Benefits for sponsor/CRO:
Yes, 15 companies; No, 4 companies

Benefits	Number of cases
Able to continue clinical study without depending on the visit	15
Improving the clinical study quality (prevention of withdrawal due to non-compliance, improvement of compliance rate, thorough temperature control of the investigational drug)	5
Reducing burden on subjects	4
Assessing feasibility of [delivery of investigational drug to subject home]	1
By reducing investigational drug storage space at clinical study sites , attention to storage control is no longer required	1
Lending a refrigerator from sponsor to clinical study sites and checking requirements are no longer needed	1
Developing infrastructure in advance enables smooth handling of emergencies	1

(2) Issues of sponsor/CRO:
Yes, 17 companies; No, 2 companies

Issues	Number of cases
Discussion on delivery cost/cost burden	6
Selection of delivery company and contract	6
Procedure preparation	4
Issues on test/examination, including remote medical care accompanying prescription	2
Cooperation with clinical study sites /system establishment	2
Considering protocol/ICF amendment	1
Considering preparation and storage of records	1
Applicable studies are limited to those of drug formulations that can be administered by subjects themselves	1
Long-term continuing application is difficult for safety reasons	1
Issues due to lack of experience of delivery company	1
Global differences in views on temperature control	1
Collection of remaining drugs is up to the subject's next visit	1
Lack of acceptance/needs by clinical study sites	1
If it is introduced in the middle of a study, it takes time for IRB review, etc.	1
If the payment to delivery company is made by sponsor, disclosure is required by the Transparency Guidelines	1
Difficulty in establishing temperature control system and adjusting delivery schedule	1
Reviewing GCP interpretations	1

(3) Issues of the clinical study sites :
Yes, 17 companies; No, 2 companies

Issues	Number of cases
Selection of delivery company and contract (complicated procedures, delivery company selected/contracted by clinical study sites)	8
Lack of acceptance/needs	5
Issues on troublesome tasks/experiences and resources	5
Procedure preparation	3
Handling temperature excursions on weekends	1
Considering follow-up actions such as dosing instructions	1
Risks associated with the use of old investigational drug	1
Safety assurance of subjects	1
Handling ICF, etc. individually	1
Need to consider as an option for clinical study sites	1

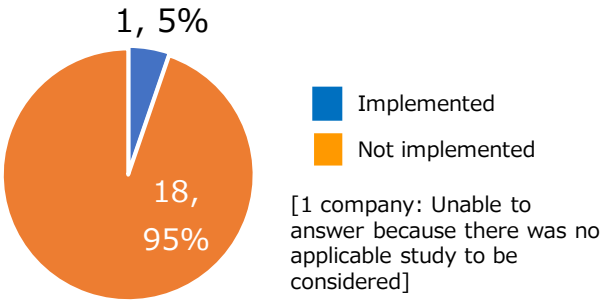
(4) Others:
Yes, 5 companies; No, 14 companies

Others: Comment details	
Delivery should be promoted in response to emergencies and subject requests Since the sponsor specifies visiting intervals to ensure safety, visits should be promoted as much as possible in accordance with the protocol	It is desirable to determine whether to adopt delivery at the time of study initiation for the IRB to review guide for patients
Options should be available for emergencies	Vendors do not allow changes from the contract template
It may be introduced in advance Dosing adherence can be maintained if subjects cannot visit study site for reasons other than infection	Issues, etc. should also be clarified for the deliveries from depot of pharmaceutical companies

Q5: Implementation status of telemedicine in Clinical Trials (Medical acts by investigators) (1)

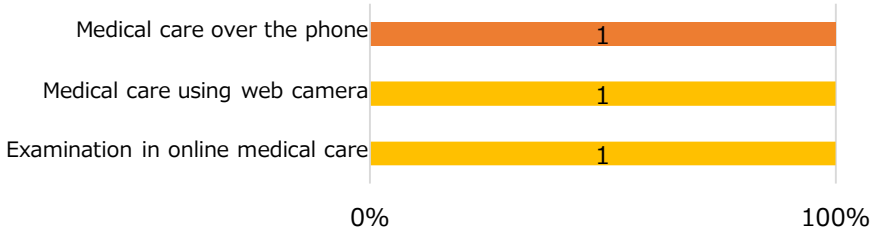
[Subquestion 1]
Did you implement telemedicine in clinical trials (medical acts by investigators) under the COVID-19 pandemic? If "Implemented" is selected, how was it provided?

(1) Status of telemedicine in clinical trials



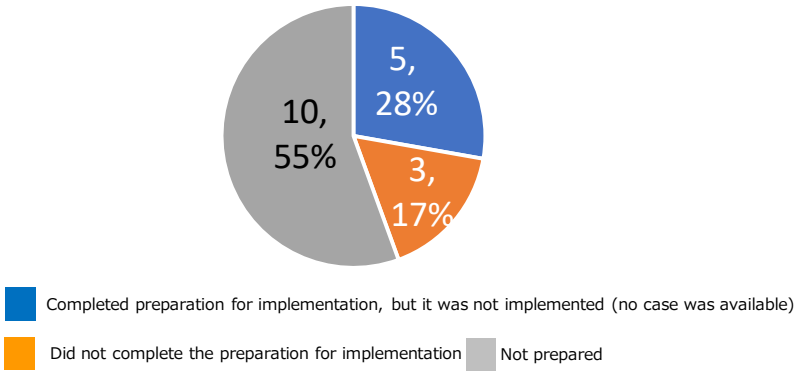
[1 company: Unable to answer because there was no applicable study to be considered]

(2) Implemented telemedicine

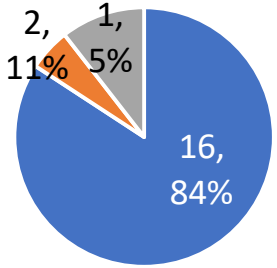


- It has been newly implemented under the COVID-19 pandemic
- It was already utilized before COVID-19 pandemic, and its usage opportunities have increased
- It was already utilized before COVID-19 pandemic, and its usage opportunities remained unchanged or decreased
- It is not implemented under the COVID-19 pandemic and was not implemented before either

[Subquestion 2]
If you selected **"Not implemented"** in Subquestion 1, tell us the reason



[Subquestion 3]
Looking back on the handled case this time, what measures are considered (should be considered) for future clinical trials (for non-emergencies)?



- Telemedicine in clinical trials should be promoted as an option, whether it is for emergencies or non-emergencies
- Since it is for clinical trials, telemedicine should not be promoted except for emergencies
- Others
  - If the safety of subjects can be assured and assessed remotely, it should be considered as an option
  - Depending on study design and target disease, telemedicine should be considered as an option

Q5: Implementation status of telemedicine in Clinical Trials (Medical acts by investigators) (2)

[Subquestion 4] Are there any benefits or issues gained while telemedicine in clinical trials was considered and implemented?

(1) Benefits for sponsor/CRO:
Yes, 15 companies; No, 4 companies

Benefits	Number of cases
Able to continue study without depending on the visit of subjects	10
Reducing burden on subjects, providing opportunities to participate in clinical trials, and improving enrollment of subjects	7
Saving cost for visit financial assistance for patients	2
Combined home nursing with delivery of investigational drug enables further reduced burden on subjects to visit study sites	2
If patients receive medical care at places where they reside, such as home, it may be possible to examine and diagnose their actual conditions	1
Reducing missed measurements	1
Possible provision of information for OS follow-up subjects in a timely manner (written consent)	1
Introducing and promoting Decentralized Trial in Japan	1

(2) Issues of sponsor/CRO:
Yes, 14 companies; No, 5 companies

Issues	Number of cases	Issues	Number of cases
Procedure preparation, protocol revision, etc. are required (resulting in increased workload)	5	Unable to administer drug and draw blood	1
Establishment/optimization of procedures (e.g., scope and method of medical care, test method, monitoring) are required	5	Activities for easing restrictions for blood draws, sample collection, etc. by vender are required	1
Evaluating and selecting appropriate online system	4	[Risks of] switching subjects by mistake	1
Need to evaluate and consider protocols to be applied/applicable protocols (disease/item). Limitation in application	4	If deviated from the current rules in clinical practice, it is difficult to determine	1
Ensuring data quality and equivalence	3	Need to discuss how to share expenses	1
Safety assurance and management	2	Developing test system	1

(3) Issues of the clinical study sites:
Yes, 14 companies; No, 5 companies

Issues	Number of cases
Arranging online medical care structures (e.g., system, process)	9
Increase in resources such as manpower and cost	5
Whether the data obtained over online medical care are appropriate in assessing and ensuring the safety	4
Lack of acceptance system and needs	3
Patient environment (infrastructure arrangement)	2
Adjusting to various digital tools	1
Limited number of investigators are trained for telemedicine	1
[Risks of] switching subjects by mistake	1
[Quality assurance in] investigational drug management	1

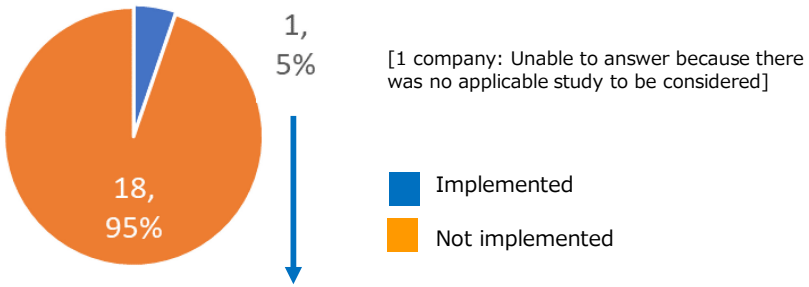
(4) Yes, 4 companies; No, 15 companies

Comment
Use of online medical care at clinical study sites is much less than that published by the Ministry of Health, Labour and Welfare. In practice, telemedicine is rarely introduced at study sites
On the basis of the fact that online medical care is far less common than the published rate, it may be realistic to provide medical care using video in clinical trials, without considering the “online medical care" an option
Key point is whether the restriction of online medical care that is currently accepted under the corona influence will stay lifted
Need to confirm the recognition by authorities: (1) Pharmaceutical and Medical Devices Act on telemedicine /GCP interpretations, (2) evaluation of different assessment environment
Need to develop guidance and law in implementing online medical care in clinical trials
Online medical care is not strictly for clinical trials and is not established within the frame of clinical trials (e.g., cost, prescription)

Q6: Implementation status of the home visits by investigators or nurses (1)

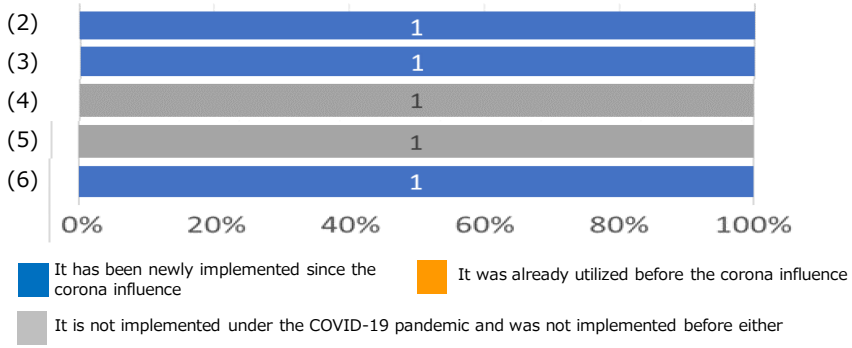
[Subquestion 1]
Were the **home visits by investigators or nurses implemented** under the COVID-19 pandemic? If "Implemented" is selected, how was it provided?

(1) Whether the home visits by investigators or nurses were implemented

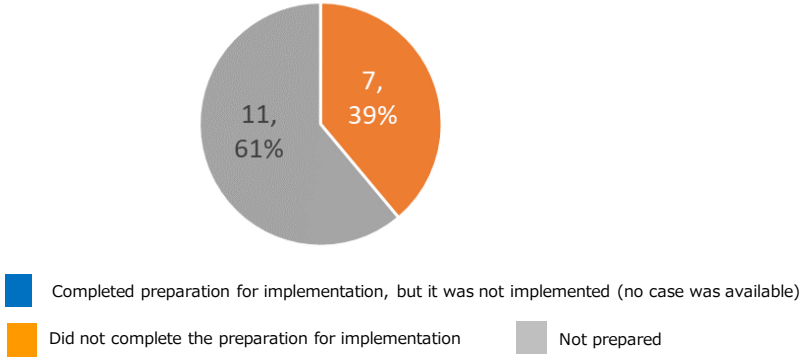


[1 company: Unable to answer because there was no applicable study to be considered]

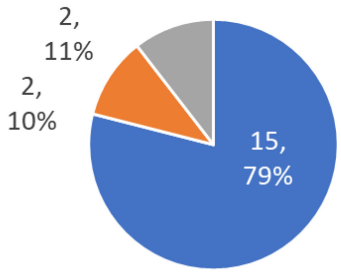
(2) Dispatch investigators (from study sites)
(3) Dispatch nurses (from study sites)
(4) Dispatch investigators (from non-study sites)
(5) Dispatch nurses (from non-study sites)
(6) Others [Consideration to establish network for visits by investigators or nurses]



[Subquestion 2]
If you selected **"Not implemented"** in Subquestion 1, tell us the reason



[Subquestion 3]
Looking back on the handled case this time, what measures are considered (should be considered) for future clinical trials (for non-emergencies)?



Home visits by investigators or nurses should be promoted as an option, whether it is for emergencies or non-emergencies

Since it is for clinical trials, home visits by investigators or nurses should not be promoted except for emergencies

Others

As a measure to continue the clinical trial in an emergency, it is necessary to start preparation for system development in advance so that it can be introduced at any time

Depending on study design and target disease, home visit should be considered as an option

Q6: Implementation status of the home visits by investigators or nurses (2)

[Subquestion 4] Are there any benefits or issues gained while the home visits by investigators or nurses were implemented and reviewed?

(1) Benefits for sponsor/CRO:
Yes, 15 companies; No, 4 companies

Benefits	Number of cases
Able to continue study without depending on the visit of subjects (test and sample collection are also possible)	8
Study can be continued even if subjects have issues (e.g., physical condition, difficult to visit study site due to disease characteristics)	4
Improving opportunities to participate in clinical trials and case accumulation	4
Reducing withdrawal risk	2
Reducing burden on subjects and families	2
Alternative procedure when direct delivery to subject home is not possible	1
Financial assistance for patients is not required	1
Increase in compliance	1
Study can be continued even under spread of infectious diseases, such as COVID-19	1

(2) Issues of sponsor/CRO:
Yes, 16 companies; No, 3 companies

Issues	Number of cases
Expenses [associated with sending personnel]	7
Descriptions and changes of contract/plan/IC	7
Legal issues on temporary personnel business (including scope of operation)	7
Arranging processes, procedures and systems, and workload associated with such operations	5
Not many clinical study sites can utilize	3
Regulatory consultation and discussion time, easing restrictions	3
Assessments/tests to be implemented are limited	2
Handling study data and ensuring reliability	2
Expanding vendors supporting clinical study sites	2
Concern about increased workload for investigators	1
Compensation for accidents during traveling	1
Limitations by disease characteristics	1
Lack of knowledge of home care in companies	1
Low needs by subjects	1
Responsible parties for the management and supervision of investigators/nurses to be dispatch are unclear	1
Difficulty in adjusting schedule for Home Nursing Visit	1

(3) Issues of the clinical study sites :
Yes, 16 companies; No, 3 companies

Issues	Number of cases
Concern about increased workload for investigators nurses, and CRCs (resource)	12
Operation and acceptance system of clinical study sites	6
Concern about legal issues on temporary personnel business	5
No procedures are available for home care	4
Limitation in the scope of operation in home nursing services	2
Lack of understanding in home care	1
Acceptance/needs by clinical study sites	1
Expenses [associated with sending personnel]	1
Liabilities	1
Selecting vendors supporting clinical study sites	1
Responsible parties for the management and supervision of investigators/nurses to be dispatch are unclear	1
Verifying cost/benefit of travel/visit by investigators	1
Limited to patients living nearby	1

(4) Others:
Yes, 4 companies; No, 15 companies

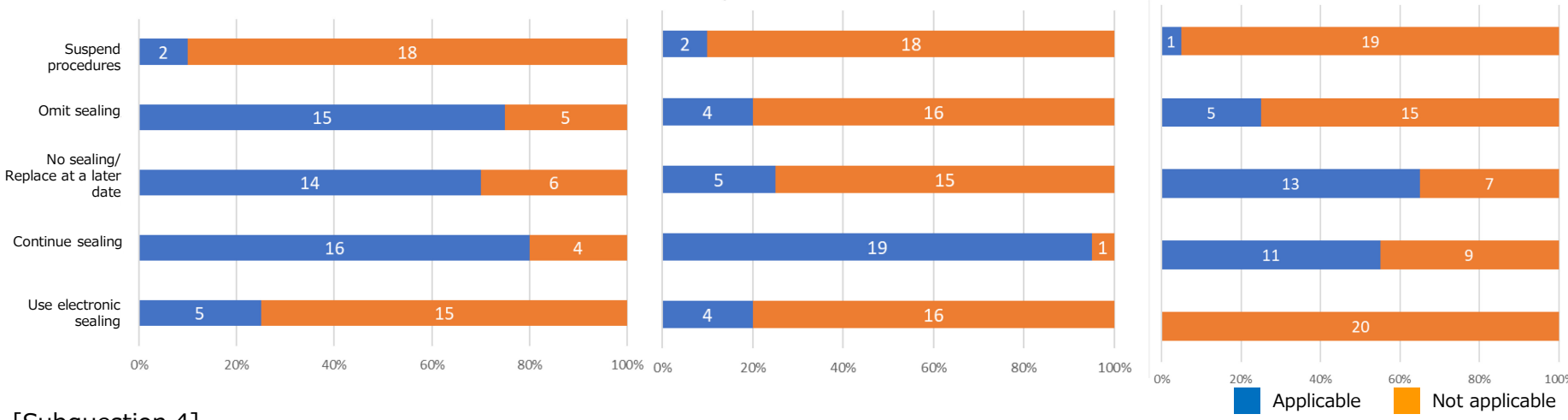
Comment details
The issue is if there are any vendors providing nationwide home medical care that be used for clinical trials
The issue is to secure resources and develop environment for clinical study sites and home nursing to be used in clinical trials
The issue is to confirm the recognition by authorities: (1) Pharmaceuticals and Medical Devices Law and GCP interpretations on the home visits by investigators and nurses, (2) evaluation of different assessment environment, and (3) reliability of assessment at home
The study should be conducted under the similar environment as ordinary medical care except in emergencies

Q7: Procedures for affixing the seal: Use of electronic signatures (1)

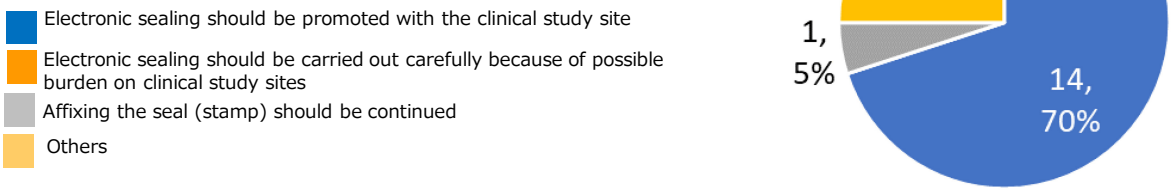
[Subquestion 1]
Regarding the procedure for affixing the seal under the corona influence, please answer the company's policy on the clinical trial application form for clinical study sites .

[Subquestion 2]
Regarding the procedure for affixing the seal under the corona influence, please answer the company's policy on the clinical trial contract (including memorandum) with the clinical study sites .

[Subquestion 3]
Regarding the procedure for affixing the seal under the corona influence, please answer the company's policy on materials to be submitted to the authorities.



[Subquestion 4]
Looking back on the handling of sealing this time, what measures are considered (should be considered) for future clinical trials (for non-emergencies)?



Others: Comment (5 companies)	Number of cases
Omission of sealing should be promoted for GCP-related documents except for contracts	3
Electronic sealing should be promoted for contracts	1
In accordance with the policy of the regulatory authorities, in general, affixing the name and seal, or signature	1
Considering the global situation, abolition of the sealing should be promoted	1

Q7: Procedures for affixing the seal: Use of electronic signatures (2)

[Subquestion 5] Are there any benefits or issues gained while the switch to electronic sealing was implemented and reviewed?

(1) Benefits for sponsor/CRO:
Yes, 18 companies; No, 2 companies

Benefits	Number of cases
Simplifying and expediting procedures/reducing workload	13
Able to operate remotely	11
Practicing paperless (need no storage space, reduce mailing cost)	4
Reducing risk of losing documents	2
Possible to clarify the approver/responsible person	1
Possible to implement risk management for document counterfeiting	1

(2) Issues of sponsor/CRO:
Yes, 15 companies; No, 5 companies

Issues	Number of cases
Acceptance/understanding/time required to adopt electronic sealing by clinical study sites	8
Introducing electronic sealing/signature system	6
Undeveloped or not proficient procedures	3
Handling multiple systems/acceptance/compatibility	3
Understanding and solving regulations/regulatory requirements	2
Expenses for electronic sealing	2
Risk of mistransmission	1
In-house arrangements	1
Electronic signature is not recommended for contracts with clinical study sites	1

(3) Issues of the clinical study sites :
Yes, 17 companies; No, 3 companies

Issues	Number of cases
Introducing electronic sealing/signature system, preparing for acceptance	8
Introducing electronic document storage system	5
Handling multiple systems/acceptance/compatibility	4
Psychological resistance due to unfamiliarity with IT systems	3
Expenses for electronic sealing	3
Undeveloped procedures	3
Conventional sealing (stamp)	2
Understanding to omit sealing	1
No experience in using electronic sealing/signature	1

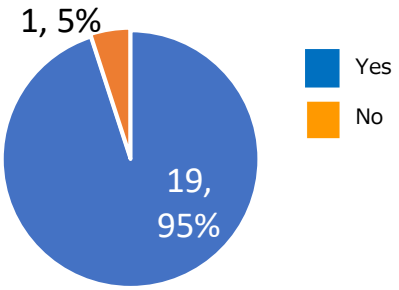
(4) Others:
Yes, 2 companies; No, 18 companies

Others: Comment	Number of cases
Standardizing the "No need to affix sealing" as the [pharmaceutical] industry	2
Obtaining understanding from clinical study site that the sealing itself is unnecessary	1
Not many facilities that can fully adopt digitization	1

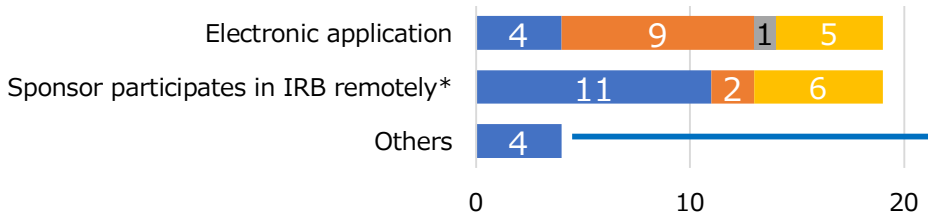
Q8: Approach for site IRB (1)

[Subquestion 1]
What is the remote approach for site IRB under the COVID-19 pandemic?

(1) IRB held



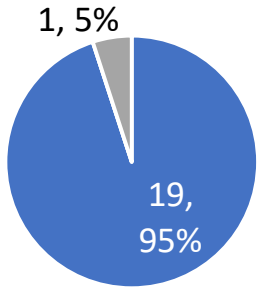
(2) Implemented remote approach for IRB



- It has been newly implemented since COVID-19 pandemic
- It was already utilized before COVID-19 pandemic, and its usage opportunities have increased
- It was already utilized before COVID-19 pandemic, and its usage opportunities remained unchanged or decreased
- It is not implemented under the COVID-19 pandemic and was not implemented before either

(*Sponsor or CRO participated in site IRB online)

[Subquestion 2]
Looking back on the handled case this time, what measures are considered (should be considered) for future clinical trials (for non-emergencies)?



- Remote response for IRB should be promoted, whether it is emergencies or non-emergencies
- Since it is for clinical trials, remote response for IRB should not be promoted except for emergencies
- Others

It is better to develop an environment where response for IRB can made remotely, to shift to remote response promptly in emergencies, and even in non-emergencies, to select or combine remote and conventional methods as appropriate based on the experiences gained from emergencies

Others: Comment (3 companies, 1 company with no comment)

Transmit review documents online, and send materials by mail
Although we accepted the digital transmissions, we ended up accepting only paper documents as before because several facilities need to comply with the facility policy and SOP
There are case examples where external members participated in IRB remotely

Q8: Response for site IRB (2)

[Subquestion 4] Are there any benefits or issues gained from the experiences of CRA in participating in site IRB to provide explanations online?

(1) Benefits for sponsor/CRO:
Yes, 14 companies; No, 6 companies

Benefits	Number of cases
Reducing resources such as travel time/transportation costs	11
Participation of multiple members allows them to respond to Q&A on the spot and to improve reply quality	11
[In electronic application], (preparation and delivery of) printed documents can be omitted	3
Possible to participate in IRB under visit restriction	2
Reducing infection risks/psychological burden	2
Easier to respond to Q&A because all materials can be prepared at hand	1
Possible to implement efficient and timely monitoring	1
Able to participate calmly without tension	1
Creating an environment for easy participation	1

(2) Issues of sponsor/CRO:
Yes, 5 companies; No, 15 companies

Issues	Number of cases
Securing stable connection	2
In advance confirmation, adjustment and practice of web system/requirements	2
Establishing/ensuring system security	2
Increase in burden on clinical study sites due to differences in systems available for each sponsor	1
A backup system is required in consideration for unexpected situations	1
Submission of printed materials [to clinical study sites] is still required regardless of remote implementation	1

(3) Issues of the clinical study sites:
Yes, 10 companies; No, 10 companies

Issues	Number of cases
Arranging procedures (e.g., remote holding, electronic transmissions, electronic archive)	4
Inadequately arranged IT environment/ensured security	4
Stability of remote connection	2
Need to consider holding an IRB meeting itself remotely (IRB members were in the conference room as before)	1
IT support for IRB members attending from home	1
Sound concentrating microphone is needed	1
Need to use a strategic approach to obtain opinions from IRB members even in remote meetings. Or in advance hearing of opinions is needed	1
Need to communicate with sponsor efficiently regarding the entry/exit information [while IRB is held]	1
Lack of understanding in remote response	1

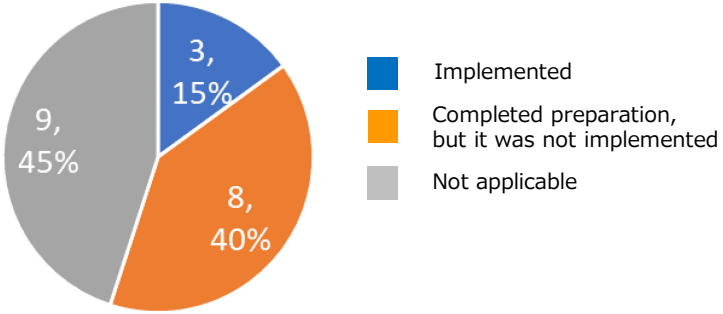
(4) Yes, 3 companies; No, 17 companies

Comment	Number of cases
Need to establish a system to provide explanations at IRB without depending on sponsor	2
In addition to simply promoting remote IRB meetings, efficient review of clinical trials, including centralization and digitalization, should be considered in multiple aspects	1

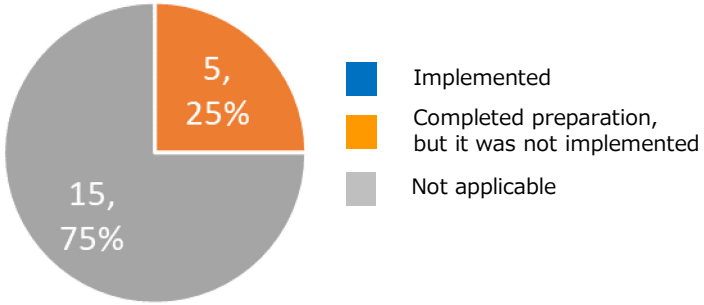
Q9: Response to patients during the clinical study (1)

[Subquestion 1]
Have the following measures been taken for the subjects under the COVID-19 pandemic

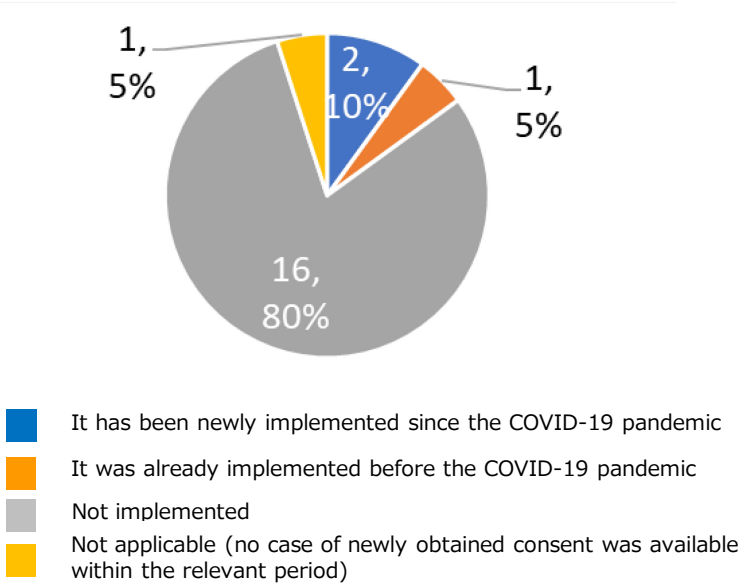
(1) When a subject cannot visit clinical study Site A and instead visits a nearby sites or clinical study Site B where the study is conducted, the subject receives tests required under protocol, or investigator at clinical study Site A assesses safety and efficacy based on the data obtained from clinical study Site B to determine whether to continue the treatment with the investigational product



(2) When a subject cannot visit clinical study Site A and instead visits clinical study Site B where the study is conducted, the subject receives investigational product or assessments required under protocol



[Subquestion 2]
Was the initial informed consent explained remotely under the COVID-19 pandemic (not including signatures)?



Q9: Response to patients during the clinical study (2)

[Subquestion 3] Are there any benefits or issues gained while the response to patients during clinical study (Subquestions 1 and 2) was implemented and reviewed?

(1) Benefits for sponsor/CRO:
Yes, 12 companies; No, 8 companies

Benefits	Number of cases
Increase in options for subjects to be in the clinical study continuously	6
Reducing burden on subjects	5
Reducing missing data (reducing impacts on effect)	3
Increase in the number of subjects who can participate, and promoting enrollment	2
Thorough safety assurance of study participants	1

(2) Issues of sponsor/CRO:
Yes, 13 companies; No, 7 companies

Issues	Number of cases
Arranging the system at contracted clinical study sites and ensuring the quality of the clinical trial	15
Contract procedures	5
Arranging a system (including thorough explanations to clinical study sites)	2
Expenses (payment to nearby clinics, acceptance or rejection of payment of financial assistance for patients)	2
Handling difficult subjects (elderly people)	1
Sponsor's opinions, including confirmation with PMDA on the appropriateness of oral consent	1

(3) Issues of the clinical study sites:
Yes, 13 companies; No, 7 companies

Issues	Number of cases
Acceptance/system establishment	11
Procedures for contract/burden on handling preparation	5
Establishing procedures	3
Responsible parties for performing tests at other sites	2
Written consent was required even though PMDA approved study participation with an oral consent (written consent obtained at a later date)	1
How to keep records of which appropriateness can be assessed even by third party	1
Preparing informed consent form	1
Data storage and management at other sites	1
Anxiety about accepting and evaluating patients with unknown background	1

(4) Others:
Yes, 5 companies;
No, 15 companies

Others: Comment details	
Investigator recommended visiting a nearby sites considering the infection risks during travel, but the patient requested to visit the investigator. Difficult to handle different ideas between investigators and patients	Regulatory Q&A update was delayed, and preparation took time. Despite the burden of ongoing studies, regulatory guidance required new measures and procedures, and the use of other clinical study sites and nearby clinics was no longer practical
Visiting nearby clinical study sites is beneficial for subjects	Establishing systems by SMOs, etc. which support partial assessments at other clinical study sites
Although clinical study sites may have used a strategic approach on how to explain the initial informed consent as specified in the Subquestion 2, the sponsor does not know about it	It is too early to discuss these benefits or issues at this time when there is no system available for telemedicine

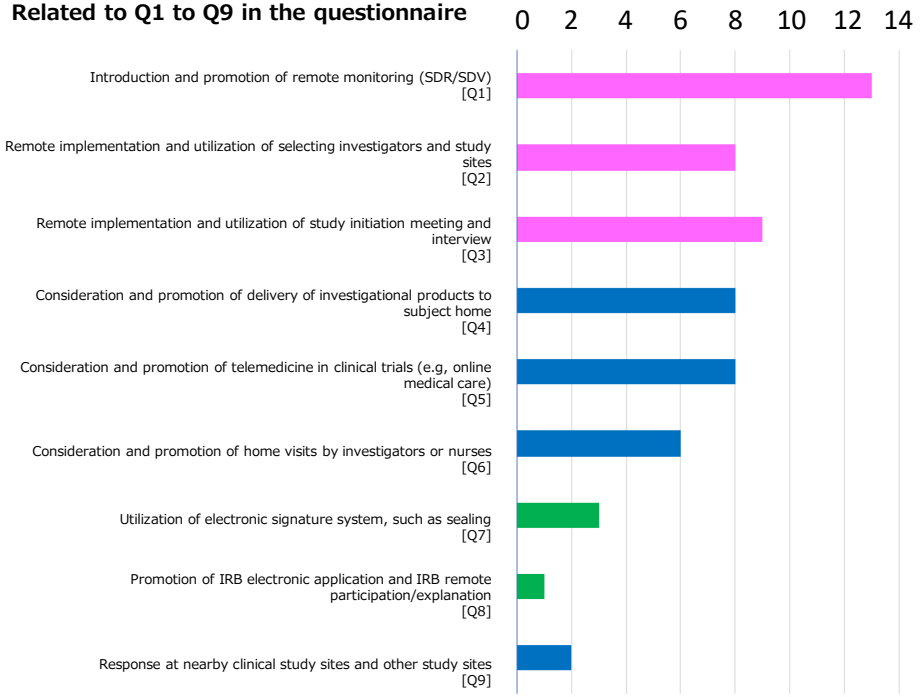
Q 10: Investigation of the benefits and issues gained from various measures and considerations implemented under the COVID-19 pandemic (1)

[Subquestion 1] Based on the experience gained under the COVID-19 pandemic , what are **the important case examples that may affect clinical trial operation in the future**?

◆Please select **important items from Q1 to Q9 in the questionnaire**.

◆Please describe **items other than** Q1 to Q9 in the questionnaire.

Related to Q1 to Q9 in the questionnaire



Other descriptions

[Note]

- For Q10, replies were obtained in free writing regarding benefits and issues
- For each comment, elements were classified and grouped by "Related to Q1 to Q9" and "Others", and the number of cases was displayed
- After grouping, "Items to be arranged in the future" were displayed by color coding
- Major comments are described as "Comment case examples" (described later)

[Items to be arranged]

- Establishing and utilizing remote procedures for monitoring operations
- Developing a system not requiring subjects to visit study sites
- Promoting utilization of digital technologies
- Promoting RBM, etc.

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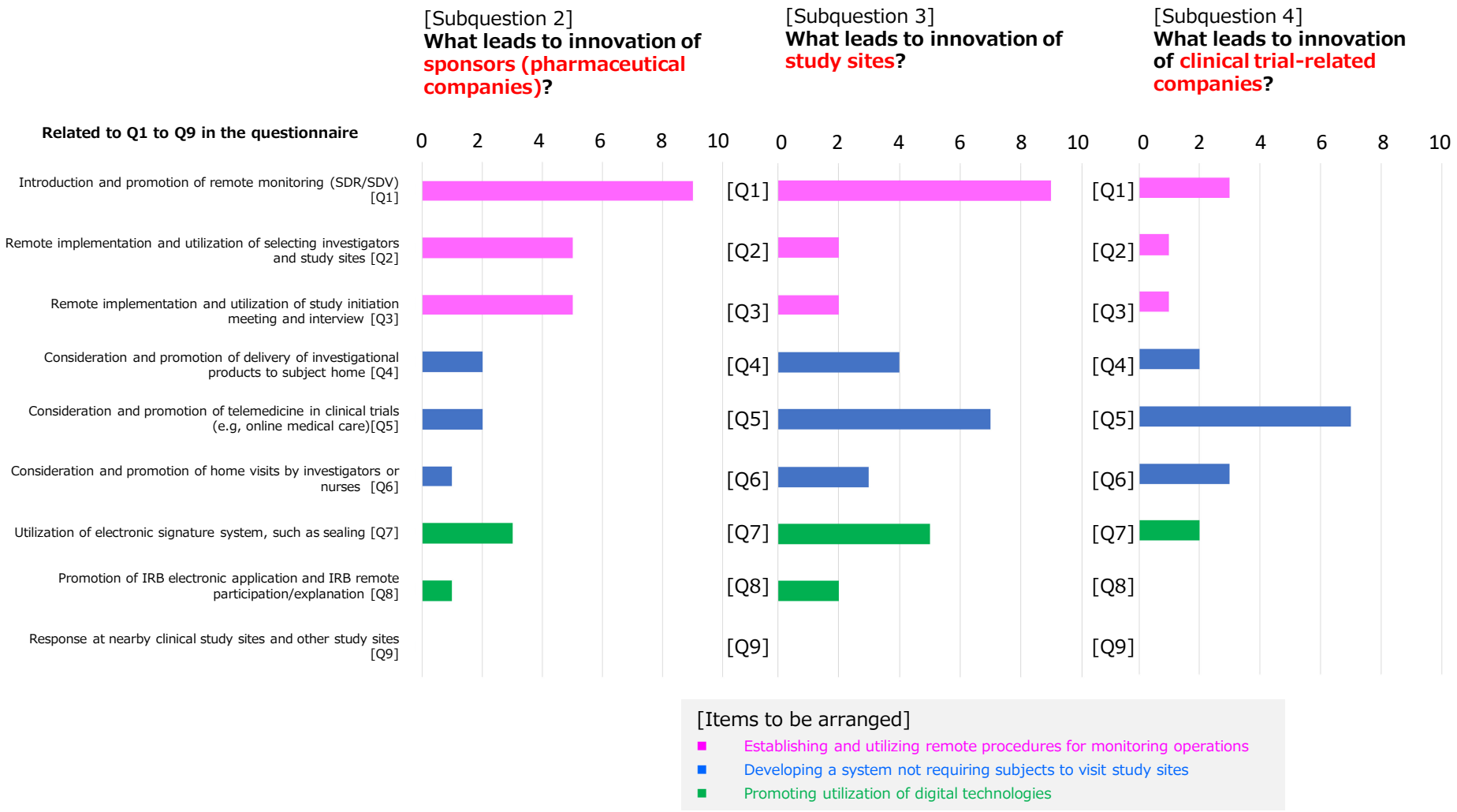
Q10: Investigation of the benefits and issues gained from various measures and considerations implemented under the COVID-19 pandemic (2)

◆Please select important items from **Q1 to Q9** in the questionnaire.



*: CRO, SMO, companies handling digital devices such as electronic medical records, online medical care-related companies, etc.
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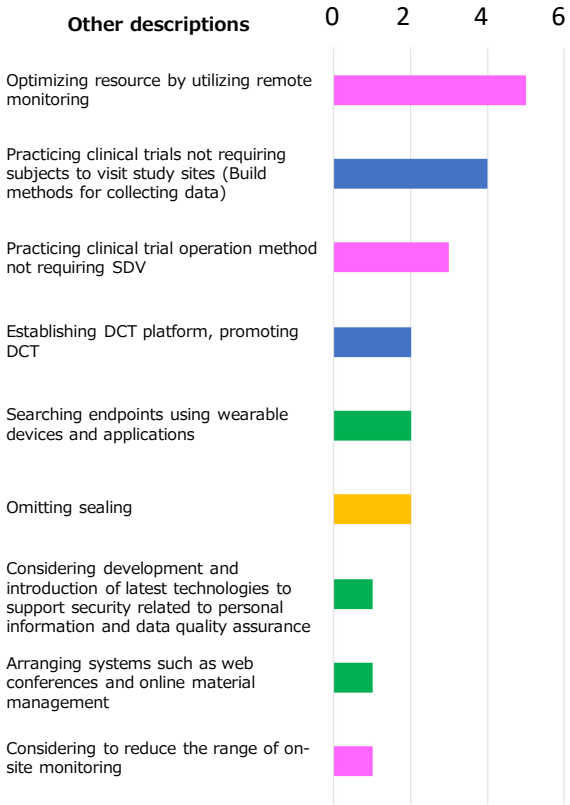
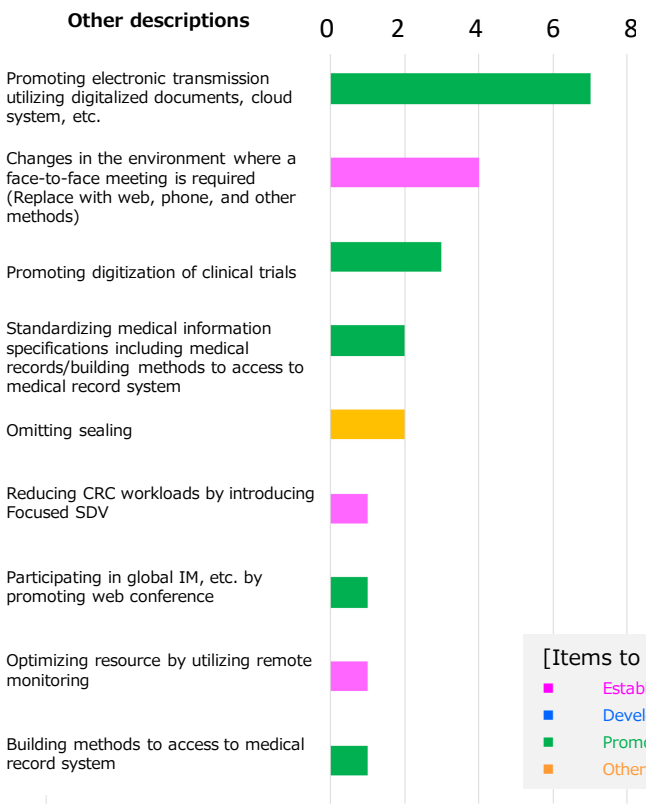
Q10: Investigation of the benefits and issues gained from various measures and considerations implemented under the COVID-19 pandemic (3)

◆Items **other than Q1 to Q9** in the questionnaire

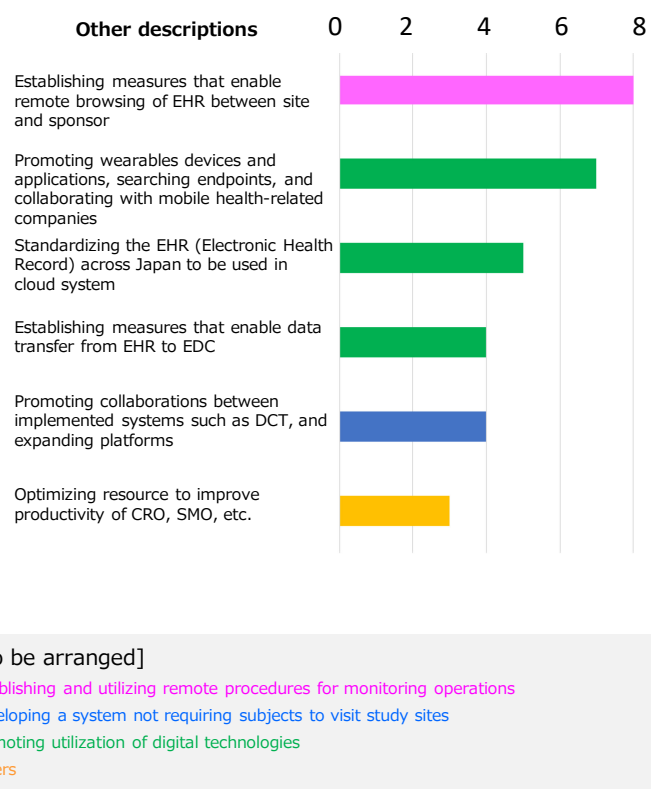
[Subquestion 2]
What leads to innovation of sponsors (pharmaceutical companies)?



[Subquestion 3]
What leads to innovation of study sites?



[Subquestion 4]
What leads to innovation of clinical trial-related companies?



[Items to be arranged]
- Establishing and utilizing remote procedures for monitoring operations
- Developing a system not requiring subjects to visit study sites
- Promoting utilization of digital technologies
- Others

*: CRO, SMO, companies handling digital devices such as electronic medical records, online medical care-related companies, etc.
**:Decentralized Clinical Trial

Q10: Investigation of the benefits and issues gained from various measures and considerations implemented under the COVID-19 pandemic (4)

◆Comment case examples (major replies to Subquestions 1 to 4)

[Subquestion 1]
What are the important case examples that may affect clinical trial operation in the future?

- We were able to carry out interviews with investigators over web/phone and explanatory meetings/initiation meetings, although these external factors were previously considered difficult to implement. It is necessary to make such efficient efforts continuously, knowing that they were possible to be carried out just because we were under the COVID-19 pandemic
- Again we acknowledged the importance of handling non-emergencies based on what we learned from emergencies. In order to prepare environment where subjects can participate in clinical trials more easily, it is necessary to develop non-emergency measures for telemedicine and direct delivery of the investigational drug

[Subquestion 2]
What leads to innovation of sponsors (pharmaceutical companies)?

- Remote communication with clinical study sites and SDV/SDR are new monitoring methods, which are expected to change how CRAs work greatly and to lead to more efficient productivity improvement
- In addition to DtP* and home nursing, there will be an environment in the future where the clinical trial can be conducted safely while subjects are not required to visit sites [*: Direct to Patient]
- Until now, each company has determined whether to adopt RBM. However, this is an opportunity to review the need/significance for the entire industry and to consider reducing range of on-site monitoring

[Subquestion 3]
What leads to innovation of study sites?

- This is an opportunity to change the culture where face-to-face meeting was considered as a matter of course. Some operations can be completed by phone or web conference
- Digitize clinical trial-related documents and complete the procedures by electronic transmissions
- Building methods to access to medical record system
- It is necessary to establish a system for online medical care in routine practice. However, if the opinions of the authorities/GCP interpretations are clarified to enable remote medical care and home care in clinical trials, the burden on patients and the functions by clinical study sites will change
- Developing systems such as electronic sealing, web conferences and online material management

[Subquestion 4]
What leads to innovation of clinical trial-related companies?

- Responsible persons at CROs, as well as at sponsors, can expand their operations because remote monitoring (Q1) and remote site selection (Q2) can reduce worktime previously spent for travel and work
- The IT infrastructure business may expand in storing electronic medical records in the cloud and developing secured portal that can be shared between sites and sponsor
- Promoting collaborations among various systems to implement Decentralized Trial
- Common use of platform for remote SDV and virtual clinical trial

*: CRO, SMO, companies handling digital devices such as electronic medical records, online medical care-related companies, etc.

Q10: Investigation of the benefits and issues gained from various measures and considerations implemented under the COVID-19 pandemic (5)

[Subquestion 5]

If there are **any issues in sponsor's operations** **under the COVID-19 pandemic** other than specified in the subquestions (of this surveillance), please describe them

◆Comment case examples (major replies to the Subquestion 5)

- There were several sites providing safety information which had to be in paper form with sealing It is possible to fully shift to providing safety information electronically, if accepted by all clinical study sites
- Because paper invoices from sites need to be stored by the sponsor, tax and related laws need to be changed
- It is necessary to upgrade from sending/receiving documents, FAX, etc. in paper form
- Mindset needs to be changed by employees who are somewhat anxious about remote operations

[Items to be arranged]

- Establishing and utilizing remote procedures for monitoring operations
- Developing a system not requiring subjects to visit study sites
- Promoting utilization of digital technologies
- Items related to paper documents
- Others

3. Summary

1. To investigate response results related to PMDA Q&A*

   *: Q&A on conducting clinical trials of drugs, medical devices, and Human Cell Therapy and Gene Therapy Products under the circumstances of the COVID-19 pandemic

2. To confirm ideas and issues leading to the improvement of future clinical trial environment based on how studies have been handled under the COVID-19 pandemic

1. Response results related to PMDA Q&A* (outline)

*: Q&A on conducting clinical trials of drugs, medical devices, and regenerative medical products under the circumstances of the COVID-19 pandemic

Q&A on the conduct of clinical trials under the circumstances of the COVID-19 pandemic		Applicable items in this surveillance		Implementation status [The value indicates the number of companies]	Method when implemented, or response when not implemented [The value indicates the number of companies]
Q&A_1	Delivering investigational products to subject home	Q4	Delivery status of investigational product to subject home	It was already implemented: 2 It has been newly implemented: 4 Not implemented: 13	Completed preparation for implementation, but not implemented: 11 Started preparation for implementation but have not completed: 2 Did not prepare for implementation: 0
Q&A_3	Handling cases where on-site monitoring cannot be implemented	Q1	Whether an alternative SDR was implemented	Implemented: 15 Not implemented: 4	[Method]Phone, e-mail", web system
			Whether an alternative SDV was implemented	Implemented: 13 Not implemented: 6	[Method]Web system, obtained medical records in PDF format or in copies, accessed hospital system to conduct SDV
		Q2	Whether GCP site selection was completed only by remote method	Yes: 18 No: 2	Example: Implemented through web system Newly implemented, 15; Have previously implemented, 3
		Q3	Whether study initiation meeting was held only by remote method	Yes: 17 No: 3	Example: Implemented through web system Newly implemented, 15; Have previously implemented, 2
Q&A_6	When a subject cannot visit study Site A, he or she visits a nearby clinical study site or Site B to receive tests, and whether to continue the treatment is determined based on the test results	Q9	Tests are performed at nearby clinical study site or other sites, and whether to continue the treatment is determined based on the test results	Implemented: 3 Completed preparation, but it was not implemented:8 Not applicable: 9	
Q&A_7	When a subject cannot visit study Site A, he or she visits Site B where whether to administer investigational product and to perform assessment are determined	Q9	Whether to administer investigational product and to perform assessment are determined at nearby clinical study site or other study sites	Implemented: 0 Completed preparation, but it was not implemented: 5 Not applicable: 15	
Q&A_8	If a subject cannot visit study site, nurses at study site visit the subject home to administer investigational drug	Q6	Whether the home visits by investigators or nurses were implemented	Implemented: 1 Not implemented: 18	Completed preparation for implementation, but not implemented: 0 Started preparation for implementation but have not completed: 7 Did not prepare for implementation: 11
Q&A_9	Clinical trials conducted in online medical care	Q5	Telemedicine in clinical trials (Medical acts by investigators)	Implemented: 1 Increase in medical care opportunities by phone Not implemented: 18	Completed preparation for implementation, but not implemented: 5 Started preparation for implementation but have not completed: 3 Did not prepare for implementation: 10

2. To confirm ideas and issues leading to the improvement of future clinical trial environment based on how studies have been handled under the COVID-19 pandemic

Findings from experiences/surveillance obtained under the COVID-19 pandemic

[Experiences in implementation/preparation]

- Remote monitoring
  - SDR / SDV
  - Selection/study initiation meeting
- Delivering investigational products to subject home
- Utilizing on-line medical care, etc.
- Home visits by investigators or nurses
- Utilizing electronic signature system, such as sealing

[Unsolved issues]

- Increase in burden on clinical study sites (especially CRCs)
- Issues on paperless and digitalization

[Obtained knowledge]

- Insufficient experiences of the above and inadequate recognition of problems/issues
- Since the burden on CRC, etc. has increased in handling various matters, it is assumed that if the problem/issue are not reasonably solved (in technologies and resources) by the time COVID-19 subsides, the procedures will promptly return to the conventional ways

[Ideas from this surveillance (items to be arranged promptly)]

1. Establishing and utilizing remote procedures for monitoring operations
2. Developing a system not requiring subjects to visit study sites
3. Promoting utilization of digital technologies

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Issue (1): Continue to gain experiences

- Items to be newly implemented
  - ➡ Continue to identify and share issues early
- Items for which preparation for implementation was completed
  - ➡ Implement and accumulate experiences and issues
- Started preparation for implementation. Incomplete items
  - ➡ Promptly complete preparations for implementation

Issue (2) Share and solve problems

- Collaboration among clinical study sites, regulatory authorities, and companies

4. Secondary use of this result

This report has been prepared by R&D Head Club member companies by bringing together data in order to understand current clinical trial environment in Japan. Please note the following instruction when you use this material for the secondary use.

Preliminary actions for secondary use

- Please let the R&D Head Club secretariat know below contents by contact form in the R&D Head Club home page（https://rdhead-club.com/contact/）
  - User (name, affiliation, opportunity to use)
  - Where used (applicable pages and purpose of use*）

Ex.）
Name：Ichiro Suzuki
Affiliation：ABC Pharma K.K.
Purpose for ues：Oral presentation in OOO annual meeting, MMM/DD/YYYY
Data of use：Slide #18
Introduction on current clinical cost in Japan

How to describe Source Data

- Source of reference：R&D Head Club Snapshot Survey in 2020 https://rdhead-club.com/

*：It is to confirm that there is no discrepancy with the perception of R&D Head Club, and does not restrict secondary use.

End of File