Approach to Market Research

October 2022

Japan Medical Marketing Research Group

Partially revised on May 1, 2023

Introduction

The landscape of medical research is changing with the revision of the Act on the Protection of Personal Information (APPI) and the Promotion Code for Prescription Drugs, along with changes to adverse events reporting. Under these circumstances, the Japan Medical Marketing Research Group (JMMRG) revised the medical research guidelines so that all parties can continue to have a shared understanding when conducting research.

Research conducted by market research agencies affiliated with the JMMRG shall be done in accordance with these guidelines.

- Conducting research in accordance with these guidelines does not impede the primary purpose of market research.
- These guidelines are intended to inculcate the idea that “Market research is not sales promotion.”
- Laws such as the APPI, the Copyright Act, and the Unfair Competition Prevention Act, as well as the rules and regulations of the pharmaceutical and marketing research industry organizations, shall be strictly observed.
- Market research shall be conducted based on the public’s trust and the respondent’s willingness to cooperate. It shall not be misleading or coercive.

Research

- "Research" is one approach on how to effectively provide/promote a supply of quality goods and services in order to maximize meeting consumer demand.
- It **functions to connect** the consumer/client/public with **the marketer** by using information.
- If the method used is "research," then the act **must be considered as research** and **recognized as pertaining to sociology** (e.g., social development, public health), even when it does not address matters directly related to marketing.
- Research **strictly maintains the complete anonymity of research respondents**. It cannot be considered marketing research if the name, address, or affiliation of someone involved is used for anything other than the objective of research.

Agenda

- ✓ Sample size
- ✓ Recruiting samples
- ✓ How to present products in stimuli
- ✓ Considerations when scheduling research
- ✓ Handling personal information
- ✓ Conducting qualitative research
- ✓ Qualitative research incentives
- ✓ Considerations regarding qualitative research participation
- ✓ Considerations regarding qualitative research
- ✓ Observation of recorded qualitative research
- ✓ Delivery and secondary use of recorded media

Sample size

▪ Quantitative research

Typically, the total sample size is around 100-400:

- The sample size should be determined through consultation/discussions between the client and the research agency, taking into account factors such as statistical significance and standard errors.
- They should discuss/consider avoiding research with an unnecessarily large sample size as it might be considered promotional activity.

For research on diseases requiring specialty care (including rare diseases), the sample size should be determined considering the research content:

- The target population may be small in some specialties.
- For rare diseases, the research content must be carefully examined since the target population is likely to be small and sufficient samples may not be found.
  While this kind of research is less likely to be misinterpreted as promotional activity targeting a large audience, care must be taken as it might be perceived as promotional activity to a limited audience.

▪ Qualitative research

Typically, the total sample size is around 30:

- Unlike quantitative research, qualitative research will not be misinterpreted as promotional activities targeting a large audience. However, the research content and sample size must be examined carefully because depending on the content and respondent criteria, it might be regarded as promotional activity to a limited audience.

Recruiting research samples

▪ Quantitative research

It is possible to select and invite respondents based on:

- basic attributes (e.g., medical department, number of beds)
- answers to questions (e.g., number of patients, type of treatments used)
- DCF codes (doctor/facility codes)

(Note: Only applicable when the client and the research agency are both MDB members.)

Data provided by the client must be handled carefully under the amended APPI.

- Each research agency should handle the received data according to the law (Explanation should also be given to the client according to the research agency's policies).
- Since DCF codes are considered personal information, they should be handled in accordance with the APPI.
  → When sharing DCF with external parties, the client is required to follow the application procedures specified by Nihon Ultmarc Inc.

- Since the data cleansing service is no longer available, it is generally not possible to use DCF codes in mail and telephone surveys (where the name of the client is not revealed). It is only possible if the consent of the participants has been obtained.

Recruiting samples

- ✓ Sample size
- ✓ Recruiting samples
- ✓ How to present products in stimuli
- ✓ Considerations when scheduling research
- ✓ Handling personal information
- ✓ Conducting qualitative research
- ✓ Qualitative research incentives
- ✓ Considerations regarding qualitative research participation
- ✓ Considerations regarding qualitative research
- ✓ Observation of recorded qualitative research
- ✓ Delivery and secondary use of recorded media

▪ Qualitative research

Recruiting respondents using a list that shows the names of facilities/doctors is not permitted:

- Requesting a specific KOL or a doctor at a certain facility (i.e., *"Recruit Dr.___ from ___Hospital"*) violates anonymity and thus does not meet research requirements.
- Extra care must be taken when recruiting well-known doctors such as KOLs.
  If the client requests a certain doctor referring to his/her name, it means that the client knows that doctor; although it is acceptable to recruit the doctor, the client is not allowed to observe the interview.
- Giving or receiving a list containing the names of doctors is generally not permitted, since it is regarded as a transfer of personal information.

Limiting the recruitment criteria should be discussed/examined:

- Limiting the recruitment criteria may enable individuals to be identified, so precautionary measures must be taken.

How to present products in stimuli

▪ How to present products/competitor products in stimuli

Before manufacturing approval	'Product X' or 'Product Y' ＊Generic name cannot be used
After manufacturing approval	Brand name
Before indication expansion approval	'Product X' or 'Product Y' ＊Generic name cannot be used
After indication expansion approval	Brand name
When a new dosage form is to be added	Brand name

- Generally, the brand name can be displayed once a product enters the stage where advertising is allowed in Japan. (Promotional activities can be commenced once manufacturing approval is given)
- A product can be referred to by its brand name or as 'Product X' if it has not yet been launched but has received manufacturing approval. (Whether to use the brand name or 'Product X' should be determined in consultation with the client)
- As for pre-approved products under development, showing participants information that has been made publicly available on a website (i.e., accessible to anyone) by providing a link to the site and navigating them to the site is permitted. (This is only allowed for in-house products.)
- A product should be referred to as 'Product X' or 'Product Y' if its indication expansion has not yet approved; it should be treated just like a product under development.
- The brand name can be displayed when a new dosage form is to be added.
- If a product is available overseas but not yet approved/launched in Japan, it should be referred to by its overseas brand name and/or generic name; the planned Japanese brand name cannot be displayed.
- Both in-house and external products can be referred to as 'Product X' or 'Product Y.'

How to present products in stimuli

▪ Stimuli

➡ The stimuli should be marked as "research material."

- └ Clearly state that it does not matter whether the data presented is true or not and that the data is hypothetical for research purposes.
- └ The volume of the material to be presented should be determined by mutual consultation within reasonable bounds. (The number of slides is increasing recently, but having more slides than necessary, may mislead the respondent.)
  The amount of information to be presented should be kept to a minimum (3 to 5 pages).

➡ The stimuli content must not be exaggerated, defamatory, or distorted.

- └ Do not intentionally emphasize or exaggerate data that has been published (by using large text or larger numerical values).
- └ Do not show data or messages that may be favorable to the product.
- └ Avoid potentially misleading expressions that may lead to direct comparisons.
  (Avoid expressions that imply superiority more than necessary)
- └ Including data from other companies may be considered slanderous; use data with clear sources.
- └ Modifying the values of published data is not allowed for both in-house and third-party products.

How to present products in stimuli

▪ Stimuli

When the stimuli are reviewed by the client (when there are compliance requirements):

- Generally, the client's decision should be prioritized. However, if the research agency makes a more stringent decision, whether to adopt the agency's decision should be decided upon mutual consultation.
- If research involves multiple clients and they have different rules for stimuli, they should discuss and decide what to do.
- Some clients have stricter rules (i.e., not allowing to display brand names even after product launch); in that case, follow these clients' rules.

The source of any external information (e.g., data created by other companies, product information of other companies) must be confirmed.

- When using publicly available data, such as information published at conferences or in academic papers, make sure to confirm the source and other relevant information (list the sources if necessary).
- When not stating the source in the stimuli, be prepared to answer if asked by the respondents (e.g., doctors).
- If permission is required to use the data, the client should obtain permission.
- It is necessary to confirm whether or not reproduction is allowed; some data cannot be reproduced even if it is accessible to anyone. If unauthorized copying or replication is not allowed, be sure to obtain permission.
- Adding a link in an online survey to a website is not considered copying or replication.

How to present products in stimuli

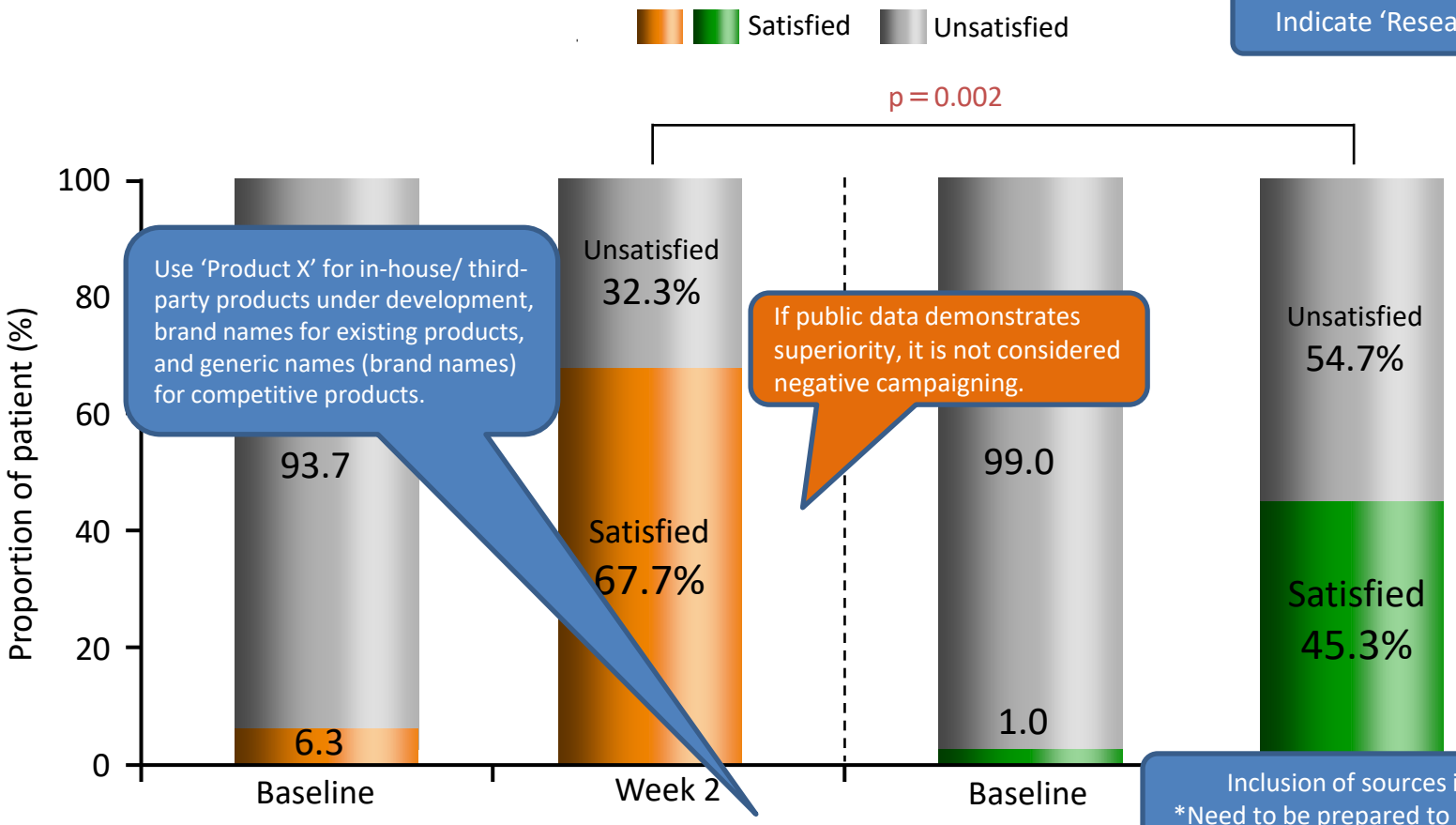
Other

- The stimuli should be prepared reasonably even if they are marked as “research material.” (Even if the information contained is hypothetical, it does not mean that you can put anything in the stimuli)
- Do not assume that what’s not allowed in advertisements is allowed in research stimuli.
- Be prepared to answer if doctors ask about publicly available information (guidelines, data, etc.) in stimuli. (This does not apply to information that has not been publicly disclosed)

- The research agency must confirm all necessary information with the pharmaceutical company.
- Generally, the client (pharmaceutical company) is responsible for handling any problems that may arise from the data presented, even if the data has been reviewed and approved by the client (pharmaceutical company). Both the client and the agency should consult with each other and deal with the problems in good faith.
  Depending on the circumstances, the research agency may waive its obligation of confidentiality as required by law.

Research material

Example: Patient Satisfaction after Switching from Brand Name to Product X



Target/method:

International multicenter, double-blind, randomized study involving 201 patients who had received 4 or 6 mg/day of Brand Name for least 4 weeks and were deemed to have had an inadequate response. Patients were allocated to either the Product X arm, in which they received 6-12 mg/day of Product X for 6 weeks, or the Brand Name arm, in which they continued to take 4 or 6 mg/day of Brand Name for 2 weeks, and then received 6-12 mg/day of Product X (starting dose of 6 mg/day) for 4 weeks, and the Medication Satisfaction Questionnaire (MSQ) was assessed.

Canuso CM, et al.: ・・○○・・・・・○○. ○○ ・・・・・・・・・

Considerations when scheduling research

Be careful not to conduct research near the approval date or launch date.

- Research should not be conducted two weeks before or after approval/launch, including the day of approval/launch.
  - Generally, an online survey should not be conducted during this period; reaching out to a wide audience simultaneously might be perceived as a promotional announcement.
  - Surveys on both in-house and external products should not be conducted during this period.
- Qualitative research may be conducted upon consultation.
  - Generally, qualitative research may be conducted during this period since the sample size is small and limited.
- Research may be conducted if the product to be approved/launched only appears as one of answer options.
  - Research that mainly focuses on a product to be approved/launched should not be conducted near the approval, launch, or indication expansion approval date. However, research may be conducted if the product to be approved/launched only appears as one of answer options to questions asked during the research (e.g., The product appears as an answer to questions like, “Please tell us all the treatments you prescribe” or ”What medication would you switch to?”)

Handling personal information

- **Deliverables that could reveal personal information are not allowed.**

Deliverables are not allowed to include **Names, Facility Names, DCF Doctor Codes, or DCF Facility Codes**.

Example:

Medical Specialty × Type of Facility × Prefecture × Position / Age = *"Oh, that's Dr.__."*

If multiple flags could be combined to reveal or infer a respondent's identity, those flags are not allowed to be submitted.

Example:

Flag 1 × Flag 2 × Flag 3 × Position / Age = *"Oh, that's Dr.__."*

└ Answers from university hospital/advanced treatment hospital physicians that include data on their **Location, Job Title, or Age** may not be included in the deliverable data.

Handling personal information

- **KOL surveys should be conducted:**

According to the research agency's policies
(Contact respective agencies for details)

- Presenting deliverables that contain the names of doctors to the client is considered a transfer of personal information to a third party.
  - Providing personal data that was collected indirectly through a questionnaire to the client without obtaining consent from the data subject is generally considered a transfer of personal data to a third party.
  - Agencies that submitted the "opt-out" application* to the Personal Information Protection Commission (PPC) may use the "opt-out" exception for third-party transfers.
    *Application for disclosure of personal data to a third party set forth in the opt-out clause

Note:
The amended APPI imposes more stringent rules for the handling of personal information than before.
Be sure to check what can and cannot be done under the new APPI.

- A doctor is not considered to be a public figure; their information should not be made public.
- Doctors' personal information is published on academic papers and websites because they personally gave consent and/or wanted it there.
- Note that searching and listing abstracts and other information may also violate the APPI.

Handling personal information

- **Patients**

  Information acquired in patient research (targeting patients with diseases) is considered "special care-required personal information" under the APPI.

  - Research using patients' social media is emerging, but their posts on social media may be considered personal information.

  - Depending on the question, asking patients their medical history during research can also be regarded as obtaining personal information.

Conducting qualitative research

- **When conducting qualitative research:**

Online interviews are recommended.

- Online interviews are recommended to prevent the spread of COVID-19.
- Whether to conduct a face-to-face interview should be determined according to the research agency's policies, in consultation with the client.
- Online interviews should be conducted using a system specified by the research agency.

Conducting a face-to-face interview should be decided upon consultation between the research agency and the client.

- In some cases, face-to-face interviews are preferred depending on the theme and content of research; when conducting a face-to-face interview, make sure that infection prevention measures are in place.
- The Interim Guidelines for Prevention of COVID-19 Infections in Face-to-face Interviews set by the Japan Marketing Research Association (JMRA) should be observed to reduce the risk of infection.

Interim Guidelines for Prevention of COVID-19 Infections (excerpt)

Interim Guidelines for Prevention of COVID-19 Infections in Face-to-face Interviews (October 2020)

- The following persons should be excluded at the time of recruitment: those with fever, cold, and other symptoms; those who have traveled abroad or have had contact with someone who has traveled abroad in the past month; those who have been infected with COVID-19 in the past month or those whose family members living together have been infected with COVID-19 in the past month; and those who have had contact with an infected person in the past month.
- Desks, chairs, writing utensils, and other items touched by a research participant should be wiped with a disinfectant solution to remove the virus each time the participant is replaced.
- Any material to be used during an interview should be distributed without being directly touched, such as by wearing rubber gloves.
- Material that cannot be disinfected, such as paper handouts, may not be used repeatedly, and new ones should be prepared each time.
- Regardless of whether or not prior approval has been given, the participants should be asked to wear masks on the day of the interview.
- In general, masks should be worn during the interview; in addition, face shields and other protective equipment may be used as necessary.

Qualitative research incentives

- **Incentives should be decided based on the agency's policies.**

An incentive shall be given in return for providing information.

- The research agency should decide the amount of an incentive.
  (Currently, there is no significant difference among agencies)
  The incentive amount should not differ significantly among agencies to protect industry integrity.
- Incentives should be paid in the name of the agency or the panel management company.
  (It is difficult to secure respondents if the incentive amount is low)

- Generally, the client cannot specify the incentive amount
  (should be determined in consultation with the client)
  It is recommended that interviews be conducted by an agency that agrees to conduct them at the specified amount.

- If necessary, how research incentives differ from monetary payments from pharmaceutical companies should be explained.
  (e.g., permission cannot be obtained without disclosing the client's name to the respondent)

Considerations regarding qualitative research participation

▪ Respondents (e.g., doctors, patients)

Have them sign the participation consent form
(AE reporting, confidentiality agreement)

- Obtain their consent in writing or on a website (e.g., by using a checkbox).
- Verbally confirm/obtain consent again before the interview begins.
- Remind the participant to refrain from mentioning their name, the name of their facility, and the county or city they are in.
- Inform them that the content of the interview will not be disclosed to third parties and that their personal information will be kept strictly confidential.
- Obtain consent for recording and videotaping (to be used by the research agency).
- Videos showing the respondent's face or audios will be treated as personal information.

Participating location

- Confirm where the respondent will participate in the online interview from:
  The respondent should participate from a location where information cannot be leaked (e.g., their room, conference room, outpatient clinic, or a less crowded place in a doctor's office).
- Do not conduct the interview while the respondent is traveling (e.g., on a bullet train, driving a car, etc.) or in the presence of unspecified third parties.
- If there is any change in circumstances, respond to the change such as by adjusting the schedule.
- Make sure the name of the hospital/doctor is not shown in the background during the interview.

Considerations regarding qualitative research participation

■ Observers (e.g., clients, participants)

Have them sign the consent form (confidentiality agreement)

- Participants' written consent is required for both face-to-face and online interviews.
- In the case of an online interview, have them sign the remote viewing agreement form.

Interview Confidentiality and Personal Information Protection Agreement

On behalf of [INSERT COMPANY NAME]

When we observe the interview (interview participant) conducted for the research, we agree to adhere to the following:

1. Any information obtained through remote viewing for the interview will be used while protecting the anonymity of the respondent, and shall not be used, under any circumstances, for any purpose other than market research. No information will be provided or disclosed to third parties.
2. No record of the respondent's personal information will be kept. No photographs, recordings, or any other act to record information will be conducted.
3. In regard to the respondent, Internet searches or other conduct that could identify the individual or their workplace will not be conducted. If not upheld, the viewer must stop viewing the interview.
4. In the case that a viewer knows the respondent, the personal information of said respondent must not be disclosed to third parties, including other viewers. If disclosed, the viewer must stop viewing the interview.
5. No contact will be made with the respondent without the written consent of the institution conducting research.
6. Whosever signs this document will be viewing the interview described below and shall adhere with the terms and conditions stated in this document.

Project Title:

Date of Fieldwork:

Location:

Name of Agency/Viewer:

Agency	Name	Agency	Name

Written Consent regarding the Remote Viewing of Interviews

On behalf of [INSERT COMMISSIONING AGENCY],

I agree with the terms and conditions written in the above confirmation letter regarding the telephone and online remote viewing of interviews.
All of the Information obtained through remote viewing of the interview (indicated below) shall not be used, under any circumstances, for any purpose other than market research.

Project Name:

Duration of fieldwork: yyyy/mm/dd - yyyy/mm/dd

Company Project Number:

Location:

Project Manager:

Date:

Name of Agency:

Name:

Signature:

Note:
- → You may list multiple venues.
- → Each viewer must sign this written consent on the day of the interview

Considerations regarding qualitative research participation

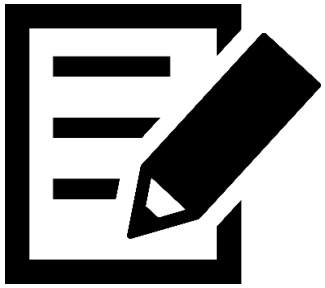
A participant who knows the respondent (such as a doctor or a pharmacist) is not allowed to observe the interview.

- Research is founded upon maintaining anonymity; once the identity of the respondent is revealed, the research would no longer be considered research.
  If a participant and a respondent accidentally see each other at the face-to-face interview facility, the participant should remain quiet and participate without mentioning that information.
- Participants are forbidden from looking up the names or facilities of respondents (e.g., doctor) on the Internet during an interview. If a participant looks them up and makes it known to other participants (e.g., *"That's Dr.___ from ____Hospital"),* that participant will be asked to promptly leave the room. (They will be unable to observe for the remainder of that interview.)

Remote viewing of an interview (live observation)

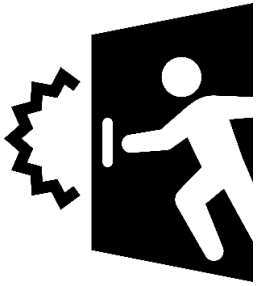
- Participants are forbidden from sharing any information about the respondent using chat and other functions during an online interview.
- Visual/audio recordings are not allowed.
- Systems that allow recording and processing on the viewing side (i.e., client) cannot be used even if requested to do so.
- Participants are not permitted to observe the interview in a place where it is visible to anyone other than participants (those who have consented to participate in the interview).

インタビュー視聴時のお願い / Rule of Interview Viewing



観察同意書に
必ずご署名ください

Please sign the observation agreement form



入出・退出際は、
対象者と出会わないよう
ご注意ください

Please avoid to meet the respondents when you come in or go out of the room

インタビューの
録音・録画・撮影禁止

No recording,
No photo, No video

対象者個人をご存知の方は
インタビューの視聴禁止

No viewing if you know the respondents personally

対象者及び施設特定の
検索禁止

No searching for respondents or institute on the Internet

対象者の個人情報は
口外禁止

No speaking out the personal information of the respondents

ご視聴の際、守っていただけない場合は、ご退出をお願いすることがございます
You may be asked to leave if you do not follow the above

Considerations regarding qualitative research

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▪ Observers (e.g., clients, participants)

Be careful when handling information obtained in research.

└ Ask the client (pharmaceutical company) to be careful not to share information with anyone other than those involved in the research.

In addition to the client (pharmaceutical company), ensure that other observers also follow the rules.

└ Consulting firms and advertising agencies tend to be less aware of research rules. If they participate, the research agency and the client (pharmaceutical company) must ensure that these companies understand the rules.

Be careful when having research commissioned by an overseas company (overseas pharmaceutical company).

└ If research is commissioned by an overseas company that has a Japanese subsidiary, be wary of mistakenly sending information or deliverables to the Japanese subsidiary.

Observation of recorded qualitative research

- A consent form should also be signed for later observation.
- Observing the recorded interview at a facility specified by the research agency:
  - Visual/audio recordings that have not been altered or edited may be viewed.
- Observing the recorded interview using the Online Interview system:
  - The cloud-based video streaming should be viewed under the supervision of the research agency (on a specified date or during a specified period).
    Visual/audio recordings that have not been altered or edited may be viewed.
  - The same rules shall apply as for live observation.
    (e.g., Do not record the interview, search the participant's information on the Internet, or disclose that the participant knows the respondent)
  - Ensure that recorded media is viewed in a closed environment.
    (In the past, there was an incident where recorded media was viewed on a train, so please use extreme caution.)

Delivery and secondary use of recorded media

Recorded media can be delivered:

- Visual recordings must be blurred before being delivered.
- Audio recordings must be edited before being delivered (consult the research agency).
- A consent form specifying the method/purpose of use must be made when visual/audio recordings are delivered.

When using visual/audio recordings internally before delivering them:

- Make sure they are used in a closed environment.
- If the respondent mentions the name or location of the facility they work at or the name of another physician (e.g., KOL) during the interview, make sure to mask it before submitting the recorded media.

▪ Considerations for secondary use of visual/audio recordings

When internally using recordings such as for training:

- The user (client) must tell the respondent the purpose of use and obtain permission from the respondent.
  How and where it will be used (e.g., number of users)
- Generally, recordings must be blurred and edited.
- If the respondent requests to check the recordings that will be used, respond accordingly.

When using the interview content for creating material (such as Q&As):

- The original content must be altered and not be used as is.