Compliance in Market Research

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Developed by: Japan Medical Marketing Research Group

Approved by: Japan Pharma Meeting

The purpose of creating a guideline for conducting market research

- Various problems have been pointed out and examined with regard to physician targeted market research. However, every time, those problems were bypassed via ambiguous interpretation and by avoiding the problem during operation.
- With the revision in Protection of Personal Information law, stricter Promotion Code, and adverse event reporting issues etc. a strict compliance is now being required for market research, and pharmaceutical companies are conducting market research by creating their own individual rules.
- Even within the market research industry, the views and methods of operation vary by company, resulting in a situation where market research is being conducted without a unified understanding.
- With this situation, the market research industry has now devised a general guideline for conducting healthcare market research, so that all parties involved will have a unified understanding.

Premise of the guideline upon conducting market research

- Market research agencies affiliated with the Japan Medical Marketing Research Group shall conduct research in accordance with this guideline.
- The idea of the guideline is to permeate the recognition that "Market research is not (sales) promotion".
  - Please check the guideline if you perceive the market research to be different from standard research.
- Conducting research in accordance with this guideline will not impede the primary purpose of market research.
- The purpose of the guideline is to clearly distinguish between market research and promotion in order to avoid any doubts, and all laws and regulations, including Protection of Personal Information law will be strictly followed.
  - In particular, protection of personally identifiable information will be strictly enforced
- The foundation of the guideline is to avoid research content that is offensive, defamatory or excessive
  - The guideline is to support both pharmaceutical companies and market research agencies to maintain and develop pharmaceutical market research without any misunderstanding by society.

Agenda

- Considerations on research sample size
- How to present target products/competitor products
- Considerations upon data presentation
- Considerations on when to conduct the research
- Considerations regarding personally identifiable information (possibility of identification)
- Considerations upon observation (qualitative studies)
- Considerations regarding recorded media deliverables

➢ Considerations on research sample size (quantitative studies)

A rough indication of the standard number of samples to be collected = n=100 ~ 400 in total or n=100 ~ 200 per department

- In consideration of statistical significance and standard error, the final sample size should be decided upon consultation/discussion amongst the pharmaceutical company and the market research agency.
- For common diseases, a rough indication is n=100 ~ 200.
  - e.g. n=100 (50 x hospital-based / 50x office-based), n=200 samples (100 x hospital-based / 100 x office-based), n=200 (100 x 2 departments), etc.
- For more specialized diseases, a rough indication is n=200 ~ 400.
  - e.g. n=200 (100 x hospital-based / 100 x office-based), n=400 samples (200 x hospital-based / 200 x office-based), n=400 (100 x 4 departments), etc.
  - From the perspective of being misunderstood for promotion, it is recommended not doing research with an unnecessarily large sample size
- For rare diseases, since only n=30 or so can be recruited for research, the idea of qualitative/quantitative may not apply

⇒ In case of large sample studies, such as a segmentation study, or if there is a disagreement in the proposed sample size between the pharmaceutical company and market research agency, it should be addressed through discussions

➢ How to present target products/competitor products

Before marketing approval	Product X, Product Y, etc.
After marketing approval	Usage of brand names is allowed
After approval of expanded indication(s)	Usage of brand names is allowed

- Basically, if the product is at a stage where advertisements are allowed in Japan (i.e. post-approval), the brand name can be shown.
- The positioning of expanded indication is the same as marketing approval, therefore, it needs to be handled in the same way (i.e. cannot show the brand name before approval).
- In the case of additional formulation(s), the brand name can be shown regardless of approval.
- After approval, the brand name can be shown regardless of whether the product has actually launched or not. The decision to show the brand name or to use “Product X” can be decided by the pharmaceutical company.
- When showing products that are available overseas but not yet approved in Japan, the oversea brand name and/or the generic name should be used (planned Japanese brand name cannot be used)

➢ Considerations upon data presentation

Major premise: DO NOT slander / libel, exaggerate, or distort the facts

<MUST DO>

- Clearly state that the presented data is for market research purposes only
- When presenting data of competitor products, the source should be confirmed

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- It should clearly state that the data is hypothetical (for market research purposes), therefore it's not a matter of whether the presented data are facts or not.
- Competitor data could be taken as defamation, thus only data with a clear source should be used.
  - It should be clear that the data is not something that has been created by the competitor company or by the market research agency.
- If the source cannot be disclosed or if the data has not yet been published, the product should be presented as a hypothetical product, such as Product X.
  - Whether or not to (and how to) present the source should be determined though discussions.
- For data that have been made public, the idea of a product being "superior" or "inferior" does not apply (i.e. there are no issues relating to defamation).

➢ Considerations upon data presentation

<MUST NOT DO>

- You CANNOT alter/change numerical values in data that have already been published (company's own products or competitor products).
- You CANNOT present data from different clinical trials without clearly stating that they are from different clinical trials.

- If the pharmaceutical company has their own review systems and/or regulations for data handling, these need to be strictly followed.
  - [Whether to use actual data or test/dummy data (converted/rounded values) should be determined based on the intention of the pharmaceutical company.]
- Even if data is for research purposes, over exaggeration should be avoided.
- Deliberately exaggerating the data (using large fonts, different color, highlights etc.) or numerical values (excessive emphasis) of published data should be avoided (it will become a problem within the pharmaceutical company in terms of compliance).
- The use of expressions that may be misunderstood as a direct comparison should be avoided since it could be taken as excessively communicating the superiority of the sponsoring company.
- If you state that the "materials are for research purposes", the (hypothetical) content will not become an issue/problematic.
  - However, if the content is too extreme, it should be determined through discussions.

➢ Considerations upon data presentation

- Is anything possible as long as the materials are for research purposes?
  - The premise is; if the physician (respondent) asks “is this true?”, “where is the data?” etc. you need to answer them (e.g., “The contents are hypothetical, but please assume that they are true.”)
  - Use expressions such as “potential product”, “hypothetical data” “potential introduction” etc.
- There is a tendency of people to believe that, what’s not possible in advertisement is possible in market research (especially those in pharmaceutical companies, advertisement agencies and consulting firms).
- When using overseas data, you need to pay attention to the credibility.
- Citing a source may require permission of the author, thus you need to be cautious.
- If you will not be specifying the source, you should be prepared to answer to inquiries from the respondents (physicians) about it.
  - E.g., Be prepared to answer to inquiries, such as “I would like to know the source because I want to see the details of the data which I saw in the study.”

Recommended questioning method

< Data/materials presentation >

★ Notes

- Whether to use actual data or test/dummy data should be determined through discussions
- State that the materials are for “research purposes only”
- The handling of evidence/sources should be determined through discussions
- Obtaining the permission to use the source is the role of the pharmaceutical company
- Etc.

If not done, it may be seen as promotion

< Questioning method >

★ Ask for opinions

- Do you agree/disagree?
- What are your thoughts?
- What do you like about it?
- Would you consider it in the first line?
- Etc.

Better to ask questions where the respondent makes their own judgments about the presented materials (no leading questions)

<Considering that most pharmaceutical companies have their review systems/regulations>

✓ Only data/materials that have been approved by the internal review board of the pharmaceutical company should be presented.

✓ The market research agency should confirm the requirements of the data/materials with the pharmaceutical company.

*As the presented materials have been approved by the internal review board of the pharmaceutical company as not problematic, if any problem arises as a result of presenting such materials, the pharmaceutical company is held fully responsible.

(Depending on the situation, the market research agency may breach confidentiality obligations based on legal provisions.)

➢ Considerations on when to conduct the research

Need to avoid market research near the approval / launch / expanded indication approval dates.

- You cannot conduct quantitative studies on the same day as approval / launch / expanded indication approval dates.
  - Since an online survey can reach tens of thousands of people at once, it could be taken as promotion by ways of mass announcement.
- You have to be cautious when conducting quantitative studies near (before and after) the day of approval / launch / expanded indication approval dates.
  - It is a gentleman's agreement between the pharmaceutical company and the market research agency.
  - Market research study should not be conducted within 1~2 weeks before and after the approval/launch dates.
  - As an unwritten rule, market research agencies may refuse.
- For qualitative studies, the timing of the study is not a problem since the number of respondents is limited.

- **Protection of personally identifiable information**

Having access to personally identifiable information can lead directly to promotional activities. In order to avoid this situation, it is extremely important that personally identifiable information be strictly protected during market research.

➢ Considerations regarding personally identifiable information (possibility of identification)

Study results/data that could lead to the identification of individuals cannot be included in the deliverables (qualitative or quantitative study)

- Information that could lead to the identification of individuals, including personal names, facility names, and DCF codes, cannot be included in the deliverable data. (It can be used within the study, but it will not be included in the deliverable data).
- For physicians practicing in university hospitals or specialized hospitals, the location, job title, and age cannot be included in the deliverable data. (It can be used within the study, but it will not be included in the deliverable data).
- If an individual could be identified by combining multiple flags, then flags which can lead to the identification cannot be included in the deliverable data. (It can be used within the study, but it will not be included in the deliverable data).
- A tabulated data can be delivered.
- The basic policy is to NOT conduct quantitative KOL identification studies.
  - However, whether to ask questions relating to KOLs should be determined through discussions with the market research agency.
  - In principle, individual names, even physician names, cannot be disclosed legally without permission unless they are public figures.
  - Members of management (chairperson, board members, administrators, hospital director, etc.) are public figures whereas department heads are private figures.

➢ Considerations upon observation (qualitative studies)

- Before the start of the interview/focus groups, an observer's agreement needs to be signed by the observers (from the pharmaceutical company)
- Be very cautious about the respondent and the observer coming in contact

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- Everyone within the pharmaceutical company needs to be well-informed about the issues associated with observations.
  - In principle, an observer's agreement form needs to be signed even for participation via Focus Vision.
- If the participant (observer) accidentally comes into contact with the respondent (physician, etc.) at the venue, the participant cannot observe the interview.
- During the interview, participants are prohibited from searching the physician or the facility via internet and such. If the participant discloses the search results to other participants, s/he will need to leave the venue immediately.
- A participant who knows the respondent (physician, etc.) can still participate in the research as long as s/he does not disclose the fact that "s/he knows the respondent."
- Market research agencies are considering posters and notifications at the venue, and/or creating a jointly signed document by the market research agencies (JMMRG) etc., in order to enforce this.
  - The pharmaceutical companies are also advised to conduct activities to raise internal awareness about this guideline (especially to staffs outside the research department).

➢ Considerations regarding recorded media deliverables

- Audios/videos should not be delivered.
- If they are to be delivered, videos/audios need to be anonymized.
- If the anonymized audios/videos are to be delivered, a consent form specifying the means of use needs be prepared.

- Basically, audios/videos should not be delivered.
  - If they need to be delivered, they need to be anonymized (mosaic, voice changer etc.).
- If a deliverable is not necessary, but the pharmaceutical company wants to listen to/view them, this is allowed as long as they are viewed/listened at a place specified by the market research agency.
  - The audios/videos cannot be lent out.
- If the pharmaceutical company wants to view/share the anonymized audio/video within their company, it should be used in a restricted manner (closed environment).
- If the anonymized audios/videos are to be used externally, a consent will be necessary from the respondent(s), thus it needs to be confirmed by the market research agency.
  - The market research agency may ask in advance who will ultimately view/listen to the audios/videos.

➢ Considerations regarding recorded media deliverables

- There was an incident in the past when a person other than a research participant thanked a respondent (physician, etc.) for having participated in an interview. Thus, sufficient care needs be taken to prevent such an incident from occurring.
- If pictures need to be delivered as part of the research, anything in the background that shows the hospital/clinic name and/or the physician name(s) has to be edited out/anonymized.
- In the case of research originating from overseas (pharmaceutical companies and research agencies, and particularly foreign-affiliated companies), a written consent is necessary guaranteeing that the recording media will not be delivered/provided to its Japanese subsidiary/office.
  - Confirmation is also necessary that the physician information in any form will not be provided to the sales representatives of the Japanese subsidiary/office.
- In research that is intermediated by an ad agency or a consulting firm, the request for audio/video deliverable is quite common, and some will say “I’ve received it before” “a different market research agency will provide it” etc.
  - Therefore, when conducting research that is intermediated by an ad agency or a consulting firm, the pharmaceutical company also needs to be very cautious.
- When developing a Q&A (for sales reps etc.) using the actual interview contents, the contents need be edited, and thus the actual contents itself (respondents’ comments) cannot be used.

To conclude;

- **Notes from the market research (MR) agencies**

  - **If any questions or concerns, the MR agency will always confirm this with the pharmaceutical company.**
  - **Excessive use of hypothetical contents can lead to misunderstandings, thus please be cautious.**
  - **If rights-related permission (usage of source etc.) is necessary, the pharmaceutical company is responsible for obtaining this.**
  - **If problems arise during the study, the MR agency needs to address this initially. Therefore, the pharmaceutical company should provide all necessary information for the MR agency to address the problem.**
  - **In the event that a problem arises, the situation should be addressed via cooperation between the MR agency and the pharmaceutical company.**