BOBI Compliance Challenge 2020

Overview

The BOBI Compliance Challenge is based on a hypothetical RfP and proposal for a UK primary market research (MR) project. It throws up real compliance issues and questions, the sort of issues that will test your understanding of compliance requirements and ability to resolve them.

It includes four challenges which focus on different issues and the different perspectives of key parties in the MR chain. Your task will be to respond to the compliance challenges, providing solutions and explain why they are the right way to go. You should quote or reference the guidelines, regulations or laws that support your responses.

Whilst the RfP and proposal may not be as detailed as a typical project, it does contain all the information required to address the challenges. The organising team cannot answer questions or enter into any correspondence. If you think something is missing from the RfP or proposal or needs to be clarified, please mention this within your submission and explain any assumptions you have made.

In your responses to the challenges we are looking for you to demonstrate the ability to apply compliance know-how in a pragmatic and business-friendly way.

Deliverables

Entries must be submitted in PowerPoint and there is a limit of 13 slides, including one slide that lists any references. Using a range of sources and citing references is encouraged and will earn marks.

- In terms of format, concise bulleted points are encouraged.
- References should be listed on one slide but key detail drawn from legislation, regulation or guidelines should be quoted in the main body of the submission

Judging criteria

1. **Breadth and depth of compliance knowledge**

- Thoroughness of the responses
  - Have all the potential issues been identified?
  - Have the issues been examined from more than one angle?
- Accuracy of knowledge
  - Is the guidance correct?
  - Have the sources for the responses and guidance been correctly identified?

2. **Interpretation of the rules in a business-friendly way**

- Has the guidance offered applied compliance know-how in a pragmatic and business-friendly way i.e. has it tried to take into account and balance compliance needs with the needs of the business?
- Has any additional value been added i.e. has anything been offered that is helpful but that wasn't prompted?

3. **Presentation**

- Style is clear and concise and there is no unnecessary jargon
- Easy to read and easy to understand
- Provide an answer(s), justification(s) for this answer and supporting references

The Case Study

The RfP

Background

The commissioning client company (i.e. the end client) is an international pharmaceutical manufacturer headquartered in the UK and an established player in the depression market. The manufacturer has developed a new drug for the treatment of depressive illnesses; it is currently in phase 3 development. The market research team commissioning this work are based in the UK.

Business Decision

The MR is needed to assess reactions to the product. In addition, the marketing team must prepare a sales forecast and require an indication of likely uptake of the drug.

Objectives

- To understand reactions to the new drug – a product profile will be provided
- To measure likely uptake of the drug and the impact on competitor treatments

The perspective of patients as well as psychiatrists and GPs is required.

The work will be undertaken in the UK only.

Research Approach

Recommendations as to the most appropriate research approach are required. The proposal should take into account the fact that the company:

- Wants to listen in to and view some of the fieldwork
- Will provide a list of potential psychiatrist respondents

Timings

Full results and presentation needed 14 weeks from the date of commissioning.

Project deliverables

Presentation at the UK offices in PowerPoint plus a PowerPoint report.

Market Research Proposal

Methodology

The MR agency recommends a 2 stage approach to meet the objectives.

Stage 1 – Qualitative Phase

- Face to face individual 60 minute depth Interviews with 12 psychiatrists and 12 patients.
- 3 central location days at different geographic locations, viewing facilities (via a one-way mirror) will be available at all locations. The interviews will all be video-recorded and available to view via an online streaming service FocusVision.
- A UK-based MR agency will design the screener and guide but sub-contract recruitment and moderating of all the interviews to a small team of experienced freelance researchers who are expert interviewers. The work will be overseen by the MR agency who will conduct the analysis from transcripts and recordings and prepare the report and deliver its presentation.

Stage 2 – Quantitative Phase – Online patient record study

- 50 psychiatrists and 150 GPs will each complete 5 patient records providing a total patient sample of 1000.
- The MR agency will design the screener and patient record form. Recruitment will be sub-contracted to a fieldwork agency with its own online access panels. The end client will provide a list of potential psychiatrists for matching with panel members. The fieldwork agency will also programme and host the patient record form survey (to be completed online) and provide tabulations of results. The MR agency will design the questionnaires, carry out the analysis, prepare the report and deliver the presentation.

The patient record form would include the following fields: age, sex, date of diagnosis, current medication, previous medication used, the reasons for switching and the likelihood to use the new product following review of the drug profile.

Social media monitoring

In addition we would like to offer a search of public folders such as blogs, Facebook, Twitter, etc. to see what people are saying about depression, its treatment and new therapeutic options. We would not charge any extra for this service as it is something we are already doing for a number of our clients and we hope will add value to both parties' understanding of this disease area.

Respondent reimbursement

- Psychiatrists (qualitative phase) - £150 per interview (60 min)
- Psychiatrists (quantitative phase) - £150 to complete 5 online patient records.
- GPs (quantitative phase) - £100 to complete 5 online patient records.
- Patients (qualitative phase) - £50 for the IDIs (60 min)

The Challenges

Challenge 1

You are a UK based freelance researcher and are recruiting respondents for the face to face interviews with UK based doctors, the MR agency has provided the following recruitment text (to be used for telephone recruitment). How would you respond to the MR agency in terms of changes that could be made to the text and any associated compliance issues that you would recommend they address?

> My name is *name* and I'm contacting you on behalf of *MR agency name*. We are conducting market research on behalf of a major pharmaceutical manufacturer and would really value your opinion.
>
> We invite you to an interview on *start time* at *location,* it will last *one hour.* We will provide a payment of *amount* paid by *method of payment* at *time/place.*
>
> The purpose of the research is to help the pharmaceutical company to shape the development of a new drug and your participation would be greatly appreciated.
>
> The research will comply with UK Data Protection law and with the British Healthcare Business Intelligence Association's Legal & Ethical Guidelines.
>
> Any information you provide us with will be treated as confidential, it will be combined with feedback from others like yourself. You will remain anonymous unless you give permission to be identified. Your information will only be used for market research purposes and will not be passed to any other organisation without your permission. You have the right to refuse to answer questions or withdraw at any time.
>
> We need your consent in order for us to collect and use any information about you. We won't keep any personal data you give us for longer than 6 months.
>
> The interview will be video recorded for analysis purposes and also watched by some pharmaceutical company personnel from the team supporting the development of the drug so that they can hear for themselves what you have to say.
>
> We are required by law to pass on to the pharmaceutical manufacturer details of adverse events that may be related to their products mentioned during the interview. If this happens, we will need to collect details and report the event, even if you have already done so. In order to use your personal data for adverse event reporting we must have a lawful basis for doing so, our lawful basis is that it is necessary for the "performance of a task carried out in the public interest".
>
> If you have any questions, please contact me by email *email address and/*or call this number *telephone number*.

This text is accompanied by the BHBIA's Recruitment Agreement.

Challenge 2

As the MR agency managing and designing this MR, explain what steps you could take to mitigate the compliance risks inherent in this project?

Challenge 3

For the quantitative phase of fieldwork, you - the fieldwork agency - would prefer to forward completed AE/PC/SRS report forms directly to the end client's drug safety team. Assume that the lawful basis for processing personal data for AE/PC/SRS reporting purposes is consent. What are the compliance pros and cons of this position?

Challenge 4

You are the pharmaceutical company's in-house MR Lead for this project and your colleagues in the medical department are insisting that the patient case record survey is not market research but is non-interventional research and therefore requires Research Ethics Committee (REC) approval. How would you counter this?