Guidance on Approval Requirements for Market Research in the UK

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The purpose of this document is to help those planning to conduct a market research project in the UK

- **To be clear on the requirements**
- **To prepare for the steps that are needed**

So that the project can progress through UK approval in a way which will fit in with the overall, multi-country, project timeline.

Background

Market Research projects are regularly conducted at a multi-country level by global teams in pharmaceutical companies. These projects are usually executed via a market research agency on behalf of their client. However, in order to run the project in each of the desired countries, the project must meet the requirements of the regulations, for running market research, in that country. This obligation is usually addressed by asking the local pharmaceutical company affiliate to approve the project for their market.

Many multi-country projects will include the UK as one of the target markets. The UK has specific conditions covering the approval of market research materials. These conditions are regulated by the Association of the British Pharmaceutical Industry (ABPI), the trade association for over 120 pharmaceutical companies in the UK. Their Code of Practice sets standards for the promotion of medicines, for prescribing, to health professionals and other relevant decision makers in the UK. The Code of Practice also specifically covers the approval of market research materials.

The UK Approvals Process

As mentioned above the Association of the British Pharmaceutical Industry (ABPI) is the trade association for over 120 pharmaceutical companies in the UK. The majority of pharmaceutical companies are members of the ABPI.

The ABPI requires market research materials to be examined by a signatory or an Appropriately Qualified Person from the pharmaceutical company.

Below is the relevant excerpt from the ABPI Code of Practice.

Clause 8.3 (14.3) Examination of Other Material
Material issued by companies which is not required to be certified under the Code should be examined by a signatory or an AQP, who needs not be a signatory, to ensure that it does not contravene the Code or the relevant statutory requirements. Such material might include corporate advertising, press releases, market research material, financial information to inform shareholders, the Stock Exchange and the like, and written responses from medical information departments or similar to unsolicited enquiries from the public etc.

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The approval process takes time and this needs to be built into the overall project timeline. The timings will vary from company to company, liaising with the local team responsible for market research approvals will be helpful as

- It makes them aware that the project is coming
- They can talk to the local PV/approvals team to understand where this project might fit into their workload
- They can schedule the project locally if appropriate

Adverse Event Reporting, Product Complaints, Special Reporting Situations

Dependent on the type of market research you are conducting it is possible that you may become aware of Adverse Events (AEs), Product Complaints (PCs) or Special Reporting Situations (SRSs).

The MAH/Conformity Certificate Holder has primary responsibility for compliance with pharmacovigilance legislation and for assessing whether market research activities may generate AEs, PCs or SRSs.

Each company will have their own procedures, this may involve training for agency staff, and/or reviewing/inputting into the materials.

There may also be a requirement for a specific AE reporting clause to be included in the contract with the supplier for specific types of data collection that may include market research. Again engaging with the local affiliate early will ensure that any local contract requirements are in place.

Fair Market Value

Local FMV will also need to be agreed.

Third Party Agreements

Early onboarding of the UK will also allow time for Third party agreements to be arranged with CRM list providers, if required, in parallel with the preparation of any requirement for the usage of target lists for fieldwork

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