NOMINATED SIGNATORY

Market Research and Non-interventional studies Summary

1 Definitions

Market Research
Systematic gathering and interpretation of quantitative or qualitative data on the market environement. It may be conducted with health professionals or patients.

Non-interventional studies
Falling under the umbrella of 'Real World Studies' these utilize data collected through observation of 'current clinical practice' and/or patient reported experience. They do not involve any intervention (experimental or otherwise) on the part of the investigator.

2 Market Research Principles

It must be non promotional

This applies whether a product has a marketing authorization or not at the time of the research. Research materials must appear non promotional. Branding and excessive use of brand names should be avoided (except for the purposes of specifically testing branding concepts which is allowable).

There must be a genuine business need

The results should assist with a particular business decision to be made - this need should be formally documented. Market research should never be conducted to build advocacy or raise awareness of a product or a disease.The number of participants must ensure sufficient statistical rigour while not exceeding what is required to achieve the objectives.

Considerations with respect to blinding

If unblinded AZ knows the names of the participants. In this case the same principles apply as to blinded market research, however the process for engaging health professionals needs to be followed. You also need to consider transparency and disclosure requirements. For research with patients, only aggregated patient data should be used (>10, minimum 5).

The rights of participants

As a nominated signatory you must consider confidentiality, privacy (handling of data and local privacy laws), consent, adverse event reporting and fees (fair market value according to AZ policies and no cash or vouchers etc).

3 Non Interventional Studies Principles

A non-interventional study is observational in nature. The product is prescribed in the usual manner, in accordance with the terms of the marketing authorization, without any additional investigations, monitoring or interventions. The decision to treat is taken separately from the decision to include the patient in the study.

Collected data should undergo formal analysis.
Non-Interventional studies are never conducted to influence prescribing practice.

All the principles of the Good Clinical Practice IGH guideline apply, including the need for informed consent and collection of adverse event data if the study involves use of an AZ product.

Selection of investigators must be based on their relevant expertise and never based on prescribing practices or used to train HCPs on use of a particular therapy.

Treatment must be lawful, on label and in accordance with established local medical practice. Patients must not be given or switched to the product for the purpose of taking part in the study.

A formal written agreement must be in place. The agreement must describe the scope, duration and payment for all applicable procedures.