

Healthcare market research examined. Relevant, rigorous and highly regulated

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Market research vs. marketing

Market research is invariably confused with marketing – but, in fact, the two disciplines are very different. Put in its simplest terms, marketing is about **promotion** whilst market research is about **understanding**. Accordingly, data collected for market research purposes are used in a completely different way to that gathered for marketing, with research practices heavily regulated to ensure high ethical standards.

Let's begin with a definition of what, exactly, market research is. According to the ICC/ESOMAR International Code 2007 (a definition also adopted by the European Pharmaceutical Market Research Association), it is: «the systematic gathering and interpretation of information about individuals or organisations using the statistical and analytical methods and techniques of the applied social sciences to gain insight or support decision-making. The identity of respondents will not be revealed to the user of the information without explicit consent and no sales approach will be made to them as a direct result of their having provided information».

In other words, market research is carried out by independent agencies, commissioned by pharmaceutical companies, who gather information that is consolidated into aggregated reports with no references to individual doctors. Extensive regulations safeguard respondents' rights and ensure privacy of information.

Whilst some doctors may be unclear as to how their information will be used – and feel cautious about participating in market research as a result – they need not fear. It will never find its way into a database that is subsequently used for sales and marketing.

What's more, market research has significant benefits for doctors and the wider industry.

What are the benefits to doctors?

Primarily, market research helps companies to develop new drugs that actually **meet the needs of marketplace** – i.e. drugs of interest from a clinical perspective as well as a scientific one. On a more pragmatic level, it also makes the contact between doctors and the industry more relevant to doctors' needs (after all, sales representatives will waste less of doctors' limited time if they know what, overall, they are interested in). Fundamentally, it helps the industry to be more efficient overall and more focused on the things that are really needed.

There are, of course, incentives for doctors taking part in market research studies; these too are regulated to make sure they're entirely commensurate with the task involved.

How is market research regulated?

We've talked about regulation, but who holds this important responsibility? Certain aspects, primarily around data protection, are of course covered by law – but the setting of high ethical and professional standards is the job of the European Pharmaceutical Market Research Association (EphMRA).

As the representative body for the healthcare market research industry, EphMRA exists to drive excellence in professional standards, to champion members' interests and to harness and cascade knowledge – all with a view to fulfilling its vision of empowering healthcare market researchers to become highly valued business partners. EphMRA's ever-expanding membership includes practically all major pharmaceutical companies worldwide, and a significant proportion of its market research suppliers.

Prior to 2009, healthcare market research was governed by the Joint Code of Conduct with ESOMAR – but, as healthcare market researchers were increasingly discovering, there was a clear need for specific guidance on legal, ethical and data protection issues unique to **this** industry. In order to meet this demand, EphMRA commissioned a dedicated in-house team, along with consultancy support, to create a Code of Conduct that would provide vital guidance on defining and safeguarding respondents' rights and protecting data integrity when conducting primary healthcare market research in international markets. The subsequent introduction of the EphMRA Code of Conduct in 2009 was undoubtedly one of the biggest and most important initiatives of the Association's 50-year history.

Today, the EphMRA Code covers everything from respondents' rights to regulation of incentives to adverse event reporting – as well as all legal requirements. It regulates interviews with patients as well as doctors, and covers how we deal with sensitive subjects and patient groups. It also includes clear rules around product-testing, so it is not confused with clinical studies. And, having been informed by extensive dialogue with market research organisations worldwide, EphMRA's Code is very much intended for international use. As such, it is a comprehensive guide for today's healthcare market researcher.

Perhaps the most important thing to say about the Code, however, is that it is a living, breathing entity. One that is, and always will be, regularly updated in order to keep apace with the industry.

Although compliance with the Code is not currently compulsory (excepting those aspects of data protection required by law), EphMRA works hard to optimise its uptake and value. So far, it has established a Code Query Service for Members, offers Code training in multiple formats, and has established competency certification for members who wish to demonstrate their knowledge and commitment.

A snapshot of the Code

But back to actual **content** of the Code of Conduct. To give a flavour of the type of regulations by which healthcare market researchers are governed, below is a snapshot of the Code's three main areas.

There are many country-specific variances within these – all covered by the Code – but below are the common principles.

On respondents' rights

Fundamentally, safeguarding respondents' rights and detailing researchers' responsibilities towards them is what the Code of Conduct is all about.

Specifically, the Code states that respondents' participation in MR *must* be voluntary and the respondent must be made aware of a number of points. These are: what exactly is involved; the confidentiality and anonymity of the process; the fact that the research is not in any way promotional; how the information will be used; the need for adverse event reporting; and their right to withdraw at any time. Additionally, re-contacting respondents on the same study is only permitted if agreed during recruitment or interview.

On protection of privacy & personal data

This element of the Code is in fact a legal requirement, based on a Data Protection directive from the European Union. The EU enforces strict controls on the processing of personal data (i.e. any information that can identify an individual – their initials, pieces of information that can single out a specialist in a small study and, in Germany, even an IP address). Also, the transfer of personal data to a non-EU country is forbidden unless privacy protection is in place.

So, what specific protocols exist to support us in complying with data protection law? Firstly, the mandate to store personal data securely. Secondly, there are a number of protocols for the **transfer** of data – within the EU, between the EU and US, and even within a single multinational company. And the absolute rule: MR data cannot be used to build databases used for non-market research purposes, in particular for sales and marketing activities.

... Adverse Event (AE) reporting

The Code also covers adverse event reporting, which has become a big issue for the industry.

Whilst there is no universal agreement on how this should operate within the context of MR, EphMRA advises members to establish in advance with the client (or local association) the specific AE reporting requirements for each study. However, EphMRA's Code does offer recommendations on AE reporting: the interviewer must remind the respondent to report when an adverse event is mentioned in the course of an interview. Patients would then be responsible for informing their doctor, and doctors for informing the pharmaceutical company and/or the authorities.

... Incentives

The Code of Conduct recommends that incentives are kept to a minimum – always appropriate to the respondent type and commensurate with the time and task involved. What kinds of incentives are **not** allowed? In short, anything that influences opinion or behaviour, requires the respondent to spend money (e.g. to claim a discount), is subject to use of the company's goods or services, or is a covert means of collecting personal data.

What's next for the EphMRA Code of Conduct?

Currently the Code of Conduct covers ten markets (G5 Europe, USA, Denmark, Finland, Norway and Sweden) with extensions to China, Japan and India underway. Russia, Turkey and Poland will follow shortly afterwards. Collaboration with relevant local and international associations is ongoing, and

training has become even more accessible due to a new free online module. There is also in the pipeline a potential member consultation on making the Code mandatory.

In sum, the Code of Conduct is one of the most important EphMRA initiatives of recent times, and it continues to evolve. Over the last 18 months it has become established as the industry standard for our business. The geographical expansion to new countries, especially emerging markets, makes it set to become the healthcare gold standard for our business globally. Above all it gives you the reassurance that participation in market research studies is completely anonymous, highly regulated and ultimately making the pharmaceutical industry more relevant to your needs.