

TRANSPARENCY IN CLINICAL RESEARCH



Andy Powrie-Smith, Director, ABPI

INTRODUCTION

Transparency, in the context of openness, communication and accountability, is an important subject for the pharmaceutical industry, both in clinical research and in its relationships with patients, clinicians, the research community and government. It is something we are continually striving to improve.

Transparency in clinical research and reporting of research results is highly important to the industry, to other researchers and academics, and to patients and the public. It contributes to medical education, to the collective knowledge of the research community, to public health and ultimately benefits patients. For example, it can help in the understanding of disease mechanisms, improved protocol design and help avoid duplication of research studies. This is particularly important when reporting on research of significant medical importance, even when the research has failed to produce a viable healthcare product.

WHAT WE ARE DOING ALREADY

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) is the global non-profit Non-Governmental Organisation (NGO) representing the

research-based pharmaceutical, biotech and vaccine sectors. The IFPMA Clinical Trials Portal is one example of a number of global resources set up to help stakeholders access clinical research information and results, both positive and negative, from around the world. It is accessible to all – healthcare professionals and the public – and is easily searchable, providing accurate, non-promotional information. The advantage of this Portal is that information on negative research results – where results show that research was not continued as it would not lead to a viable safe healthcare product – is also published. Journals are often reluctant to publish negative research data as it is not as interesting as positive research information and results. This means it can be very difficult to get negative trial data published in peer reviewed journals and so it often goes unpublished. The Portal provides an avenue through which information on both negative and positive research results is publicly available.

The pharmaceutical industry, as a sponsor of clinical research, is proactive in ensuring transparency in clinical research and has signed up to guidelines and principles of reporting set out in the IFPMA Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases, agreed in 2005. Companies committed to a number of principles regarding the disclosure of information relating to clinical research, such as the timeline for reporting and the nature of the information to be disclosed. The Joint Position was referred to in the 2006 ABPI Code of Practice for the Pharmaceutical Industry, and since 2008 the Code has required companies to disclose details of clinical trials in line with the IFPMA Joint Position. The Joint Position itself was

updated in 2008, then 2009¹, with a subsequent Joint Position on the Publication of Clinical Trial Results in the Scientific Literature agreed in 2010².

In addition to this, there is a legal requirement in the UK for industry and others in the research community to disclose information on clinical trials involving investigational medicinal products. The European Union Drug Regulating Authorities Clinical Trials (EudraCT) database established by the European Medicines Agency (EMA) is a database of all clinical trials commencing in the EU from 1 May 2004 onwards. Prospective registration of trial details on EudraCT is required in order to apply to the UK Medicines and Healthcare Products Regulatory Agency (MHRA) for authorisation to conduct a clinical trial in the UK, and to apply for Research Ethics Committee (REC) approval for a study. Data extracted directly from EudraCT was made available to the public in March 2011 as the fully searchable EU Clinical Trials Register.

Guidelines issued by the European Commission cover not only which data are stored in the EudraCT database, but also which of these data should be made available to view by the public. As a result, comprehensive information about trials conducted in the UK is collected, including descriptive data about the study. Plans for the future include the publication of summaries of results, planned for late 2012.

WHAT ELSE ARE WE DOING?

As already noted, this is an important area not just for pharmaceutical companies, but for the wider research community (including devices and diagnostics companies) and patients. All stakeholders need to work together to improve

openness, communication and accountability.

ABPI is a partner in a multi-stakeholder group which includes the medical Royal Colleges, regulatory and professional bodies of the medical community, and trade bodies representing other healthcare industries such as diagnostics and devices. This group is working to improve awareness of best practice in the reporting of clinical research information across the entire research community, both commercial and academic. It aims to ensure that the relationship between healthcare professionals and industry benefits patients and meets the expectations of stakeholders.

Part of the group's work is looking at clinical research transparency. The group is seeking to increase best practice across all trials, be they commercial, non-commercial, surgical, academic or devices. The group is working on a set of mutually agreed principles to apply across the research community. These principles will be aligned to the IFPMA Joint Position already established by the pharmaceutical industry and will be published shortly.

The pharmaceutical industry is committed to clear and open communication and we believe the solution is to work together as a whole research community. Consequently, we are committed to working with all the stakeholders to increase transparency to the benefit of patients.

Footnotes

1 http://clinicaltrials.ifpma.org/clinicaltrials/fileadmin/files/pdfs/EN/November_10_2009_Updated_Joint_Position_on_the_Disclosure_of_Clinical_Trial_Information_via_Clinical_Trial_Registries_and_Databases.pdf

2 http://clinicaltrials.ifpma.org/clinicaltrials/fileadmin/files/pdfs/20100610_Joint_Position_Publication_10Jun2010.pdf