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# Best Practice Model

## for the Disclosure of Results and Transparent Information on Clinical Trials

**April 2007**
**Revised June 2008**

# ABPI Best Practice Model for the Disclosure of Results and Transparent Information on Clinical Trials

## Explanatory Memorandum

Open access to clinical trial information is becoming increasingly important to policy-makers, healthcare professionals, patients and the general public. The pharmaceutical industry actively wishes to change the general public's negative perception of clinical research and their lack of trust in science which is directly related to the lack of clear information freely available to them.

Answering the call for greater transparency of information on clinical trials, on 6th January 2005 the world's major pharmaceutical industry trade associations from Europe, Japan and the USA announced their commitment to increase the transparency of the clinical trials sponsored by their member companies[1]. This Joint Position established industry's commitment to contribute to repositories for information on on-going clinical trials. This was later consolidated by the development of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Portal which is searchable for a number of internet-based databases & registries.

The announcement also established Industry's commitment to publish the results of all confirmatory clinical trials (as defined in the document[1]) on a free, publicly accessible, clinical trial results database, regardless of outcome. Where a link to a free journal publication is unavailable, or the results are not published in a journal, the results should be presented in the standard ICH E3 summary format, along with the unique identifier used to register the trial from inception to completion.

In June 2005, aware of their responsibilities to patients and society the Standing Committee of European Doctors (CPME) and the European Federation of Pharmaceutical Industries & Associations (EFPIA) jointly declared their commitment to transparency [2]. Amongst the principles to be adhered to in conducting clinical trials is the open availability of efficacy and safety results on marketed products, irrespective of the outcome. The results are to be published on the internet, at least in summary form, within one year of the trial product receiving its marketing authorisation; with other trial results of clinical importance similarly published.

The World Health Organisation (WHO) has also asked all sponsors of clinical trials to register their trials in a centralised database – the International Clinical Trials Registry Platform. They are engaged in continued dialogue about trial registration and results reporting as they move forward with the Registry Platform.

Industry has responded to all these developments by registering their trials, as agreed, and reporting the results of those trials, whether through journal publications or summary reports, available for free on the internet. The Clinical Study Results database (www.clinicalstudyresults.org) is a widely accessible web-based results repository set up by the Pharmaceutical Research & Manufacturers of America (PhRMA). It is primarily designed for US-marketed pharmaceuticals and can be searched via the IFPMA portal. Many companies have also developed their own websites for publishing clinical trial results.

This is a working document that will be will be subject to regular review.

## 1. Introduction

These recommendations for best practice have been developed by the ABPI with the intention of setting a "gold standard" for the presentation of clinical trial results in a format which is clear, concise and easily understood by patients and the general public (the main stakeholders in the end-point of clinical trials – a medicinal product). It is of utmost importance for the United Kingdom's pharmaceutical industry to be the forerunner in setting high standards for the presentation of clinical trial results, which will clearly demonstrate the industry's ability to recognise the public's needs and to administer transparency in a self-regulatory manner.

Several end-users of clinical trial results can be identified; patients, who may wish to learn more about their prescribed medicines or may be exploring future treatment options; study subjects, who want to know the outcomes of trials in which they participated; healthcare professionals, browsers and information seekers. Regardless of intent, the clinical trial information should meet all these needs and should be presented using a "user-centric" approach, going beyond the prescribed ICH E3 format for the summary of clinical trial results.

This model of best practice is designed for ABPI members and all industry sponsors of clinical trials who are required to publish their trial results on a publicly accessible clinical trial results database or web site. The model is to be followed to the best of that sponsor's ability, to the extent that their corporate branding and global head quarters will allow, without breaching the ABPI Code of Practice [3] or any previous joint positions / declarations. We would hope that academic sponsors of clinical trials follow a similar practice to similarly demonstrate their commitment to transparency and to patients and study subjects.

In following this model, the sponsor gains reputational advantage in demonstrating their commitment to transparency, and benefits the reputation of the pharmaceutical industry as a whole, while providing clear concise background information about marketed products, over and beyond the package information.

Voluntarily following the recommendations of this model will serve to enhance the transparency of published clinical trial results.

## 2. Issues & considerations[4]

The prescribed ICH E3 format for the summary of clinical trial results does not address the issues of clarity of content or presentation of information This is primarily because the potential end-user, be it a patient or member of the public, has not been taken into consideration in its design. It is an "easy to use" template for presenting clinical trial results, but this does not take into consideration the need to make it "easy to understand".

Key issues have been identified which act as barriers to end-users being able to find clear, concise information on clinical trial results. These issues have to be taken into consideration when finding a way to present information that is easily accessible both in location, content, presentation and functionality.

### 2.1 Access to clinical trial result information on the internet is poor.

Clinical trial information is not generally returned as part of a search on the internet – the user has to specify 'clinical trial' within the search term. If entering a product name on an Internet search engine, none of the results databases or portals (PhRMA, IFPMA) or company websites return with clinical trial results for that product. This reflects on the way the clinical trial results websites are constructed – they are not optimised for search engines, e.g. Google, which would be most commonly used by the general public. (Google's refined search returns trial results under the "for health professionals" banner.)

Finding meaningful information within the PhRMA database and IFPMA portal (if the user is already aware of their existence and function) is difficult unless the user really knows what they are looking for. The clinical trial result summaries that a search returns contain a lot of information, but not in language and format that a lay person would understand.

### 2.2 Content of clinical trial result information is not user-friendly.

While technically fulfilling the requirements of the Joint Position, the aim to be transparent and improve the public perception of the industry is failing. Where results of trials can be found reported on a company website or one of the databases, some simple omissions include; statements such as "this is a report of results from x trial"; date of last update of the results information (not to be confused with date of last update of the web page); the current status of the product – has it successfully gone on to be approved?

The inclusion of links to publications is helpful, but should not constitute the entirety of clinical trial result information provided. Often, the link is to the abstract of the publication, and membership / registration is required to access the full publication. Whichever the case, a journal publication does not provide clear, understandable information for the average member of the public.

The current clinical trial result information found in the ICH E3 format is highly complex, containing technical jargon and would be challenging for many healthcare professionals to comprehend, let alone members of the public. In addition, links to labelling and SmPCs (where the product has been licensed), are not always present. Where present on www.clinicalstudyresults.org the links to labelling is entirely inappropriate to any country other than the US. If the product is marketed in more than one country, including the UK, there is no link to all the country-specific product information.

### 2.3 Presentation of clinical trial result information is not visually inviting.

The visual format that has been used to present clinical trial results needs considerable improvement. Little or no design consideration has been applied in the presentation of trial results. Text appears to have just been cut and pasted into the relevant boxes in the ICH E3 format. No effort has been made to make information, which can be quite technical, easier to understand by the use of colour, formatting or user-friendly illustrations. There is no evidence of the use of web-designers to present clinical trial results in a user-friendly format.

### 2.4 Functionality of clinical trial result information has been ignored.

The functional aspect of the presentation of clinical trial results is restricted to links to journal abstracts / publications and other inappropriate or unhelpful information. There is no facility to provide patients or members of the public with other types of information or to engage the user with additional resources. There is no provision for contacting the market authorisation holder of marketed products, e.g. contact details for medical information resources; or to submit feedback.

## 3. Best practice recommendations[4]

These recommendations are designed to make clinical trial result information more transparent. Whether published on a dedicated website or database, or on a pharmaceutical company website, there are certain steps which can be taken to make this information, though inevitably technical, more accessible to patients, healthcare professionals and the general public.

### 3.1 Access

A company's clinical trial results & summaries should be easy to find. The organisation and tagging of existing clinical trial result information should be reassessed so as to ensure it rates higher in search engine searches, increasing its visibility to the public. The trial results should be linked to other information on a site that has higher ranking in the search engines such as eMC (for products authorised in the UK), the sponsor company's websites in each country and other medicine information sources. This would have the advantage of providing support information (such as the country-specific label, leaflet & SmPC). Work with IT experts to ensure high visibility and link with search engines e.g. Google Coop.

### 3.2 Content

Provide a clear indication that the report is on a completed trial (with relevant dates), the date of the last update of the results (separate from last update of the web page), whether the product went on to be licensed – if so, it's marketed name(s).

Provide clinical trial result information that is user-friendly and written in plain English. Above and beyond all agreements and the ICH E3 formatting, there is nothing to deter companies from providing a user-friendly summary for all postings of clinical trial results, regardless of status of journal publication, written by a consumer writer, as the user's first level of information. Leading on from this, drill-down to ICH E3 formatted results and/or journal publications would be available for those with more knowledge / interest.

Consider the use of the Plain English Campaign[5], which is widely recognised, incorporating the Crystal Mark and Honesty Mark on documents.

### 3.3 Presentation

Clinical trial results are a subset of wider information about medicines and healthcare and as such should be presented in a consumer-friendly format where design considerations have been applied. Web pages containing clinical trial result information should be user-friendly, easy to navigate, with visually inviting

design. Transparency and comprehension would be greatly enhanced by the use of web designers to implement colour, formatting and illustrations

### 3.4 Functionality

Provide users with the appropriate tools which allow them to become involved in the process of accumulating information. Supply links to contextual and related information (appropriate to the country of the user) such as the label, leaflet, SmPC, (UK specific; X-PIL, eMC), company website(s); and possibly to facilities for users to provide feedback or request further information.

## 4. Conclusion

For the UK's pharmaceutical industry to take the lead in clinical trial transparency, open access to clinical trial results information which is freely available, clear, concise and useful will be a positive step. Adhering to these recommendations will serve to strengthen the industry's reputation for providing good quality information to patients, healthcare professionals and members of the public.

## 5. References


1. Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases. IFPMA, Announced 6th January 2005

2. Joint Declaration of CPME and EFPIA on the Cooperation between the Medical Profession and the Pharmaceutical Industry, CPME-EFPIA June 2005

3. ABPI Code of Practice for the Pharmaceutical Industry 2006

4. Clinical Trials Publication: A Review, Datapharm Communication Ltd, September 2006

5. Plain English Campaign, www.plainenglish.co.uk