Recording and reporting clinical trial results

Introduction

After each clinical trial, the trial sponsor will compile a detailed clinical study report (CSR), which follows a format laid down by the regulatory authorities. Every CSR is usually several hundred pages long. Access to the complete CSR is usually limited to the sponsor and the regulatory authorities that are assessing the marketing authorisation application (MAA).

Information that has been summarised from the CSR is, however, likely to come into the public domain via a number of routes. These are described in the following sections.

European Public Assessment Reports (EPARs)

When authorisation for a new medicine is sought via the Centralised Procedure (CP), an assessment report (EPAR) is written by the European Medicines Agency (EMA). This report is published on EMA website after a decision has been made either to approve or reject the authorisation application. The EPAR provides public information on a medicine, including how it was assessed by the EMA committees. Any information handled during the scientific assessment that is considered confidential is removed before the EPAR is published. The EPAR is intended for a professional audience and uses technical language. It is, however, accompanied by a summary, normally two or three pages long, which presents the key facts in non-technical language.

Clinical trial registries

In Europe, the European Clinical Trials Database (EudraCT, www.clinicaltrialsregister.eu) of the European Medical Agency collects information on all clinical trials of medicines performed in Europe. As of July 2014, this database also makes trial summary results available to the public. For trials taking place in the EU starting after 1st January, 2015, all such results must be published, regardless of their positive or negative implications. The World Health Organisation (WHO), through its International Clinical Trials Registry Platform (ICTRP), is setting international standards for registering and reporting on all clinical trials. In the United States (US), the ClinicalTrials.gov registry (www.clinicaltrials.gov) is doing similarly.

Marketing authorisation product information

Although specific results of individual clinical trials are rarely presented in this way, an overall summary of the information available on a particular medicine is available from its summary of product characteristics (SmPC). This is a document aimed at healthcare professionals; however, it also forms the basis of the package leaflet (PL) (previously known as the patient information leaflet (PIL)). The PL is aimed at the user or patient. Depending on national regulations, these documents may be available on the internet, from regulatory authorities, from individual manufacturer’s websites, or from websites run by independent organisations. The product information contained in the EPAR is published in all EU languages.

Journal papers

The classic route for publication of clinical trial results is a research paper in a specialist medical journal. The appearance of a clinical trial report in one journal rather than another is more likely to be a reflection of how common the disease is and thus how many doctors are likely to be interested in the results. Virtually all modern journals subject potential articles to a peer-review process under which independent experts in the field review the manuscript and challenge any weak aspects of it before publication.

Conferences

Many international medical conferences are held every year, some with a fairly general theme, but many focussing on narrow, specialist areas. Clinical trial results are often presented at these conferences, either as oral presentations or as posters displayed in public areas of the conference venue. Access to this information is often restricted to those who are attending the conference and it is not easily available to those who are not. In many cases, however, the same trial will also be the subject of a journal paper. Patient organisations also organise conferences at which information from the international medical conferences is reported back to their communities.

Patient organisation websites

Many specialist support organisations provide help to patients with specific illnesses, and many also have websites that publish reports of relevant clinical trials. Interpretation by experts working with the organisation and the use of patient-friendly language tend to make these reports particularly useful to patients.

Popular news media

The accuracy and understanding with which television, radio, and newspaper reports present the results of clinical trials varies a great deal. As a general rule, it is wise to approach such reports with the understanding that a sensational story is more likely to sell newspapers than a sober account of results.

Attachments

- Presentation: Recording and Reporting Clinical Trial Results

  Size: 372,913 bytes, Format: .pptx

  A presentation describing the recording and reporting of clinical trial results, which can be adapted for own use.

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