

Progress in Quality Management of Clinical Trials

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Source

Johnson J., Gupta N.V., "Recent Advances in Quality Management of Clinical Trials"
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Introduction

The article "Recent Advances in Quality Management of Clinical Trials" by Gupa et al, 2013 is published in the International Journal of Pharmacy and Pharmaceutical Science in May 16, 2013. The article explores the recent developments and advances in quality management in Clinical Trials. It is a very current article on Quality Management of Clinical Research. This review critically reviews the article's structure, authority, currency, stability, objectivity and its relevance to Clinical Researchers and Clinical Research organizations. The review will first summarize the article and then critique the article on the basis of its authority, accuracy, currency, relevance, objectivity, stability and the data analysis. The review will analyze all the relevant data and information provided by the article before commenting on the credibility and the reliability of the article. Overall, the article is well written and relevant to Clinical Researchers, Clinical Research Organizations and the Academia.

Article Summary

The article is a current article on Quality management of Clinical Trial. The aim of the article is to discuss recent adopted quality methods in Clinical trial. The quality methods are the Quality by design (QbD) and Quality risk management methods, of ensuring effective quality control, assurance and audit in Clinical trial. It also emphasis the incorporation of quality design from the on set of the Clinical trial design to the end of the trial and beyond. The article provides information on various quality management strategies in Clinical trial. It then centers the discussion on the current methods adopted by Food and Drug Administration. The article ends on quite long conclusion and provides future directions. The article is relevant to Clinical Researchers, Contract Research Organizations and academia and it is also well written.

Article Structure

The article start an abstract which provides a brief background of the article. The abstract summaries and state the purpose of the article. It is structured into four Sections; Abstract, Introduction, Discussion and Conclusion. The discussion section makes up 80% of the main article. This section is the main body of the articles. It is logically organized into eighteen sub-headings of at least one short paragraph. Each sub-heading thoroughly discusses the current quality management methods in Clinical trial. The article is written in a clear language, this makes it easy for readers to clearly understand it. It is in PDF format making it easily accessible and manageable. The references are well cited, both in-text and outside text. It also provides all the necessary information about the article. Overall the article is well written and structured.

Article Critique

Authority

“Recent Advances in Quality Management of Clinical Trials” is an article written by Gupta et al, 2013. It is published in the International Journal of Pharmacy and Pharmaceutical Science. The article provides the affiliation, credentials of the authors and the address and contact e-mail of the corresponding author. These information attest to the credibility of the article and its source. The article provides references which are authentic and true. Hence the article is credible and reliable.

Accuracy

The article provides information from known and reliable sources. It provides information on the authors, affiliation and credentials of authors, the date, volume and the journal in which it is published. The sources of the information in the article are accurate and both the in-text citation and the reference list at the reference section are accurate. Each in-text cited number corresponds accurately to the list. The International Journal of Pharmacy and Pharmaceutical Science is a recognized scientific journal in India. The highly esteemed status of the editorial and the reviewing processes that the article was taken through contribute to its accuracy and credibility.

Currency

The article is published in the International Journal of Pharmacy and Pharmaceutical Science, Volume 5, issue 3, in 2013. The article was received in March 23, 2013 and accepted in May 16, 2013. The article provides references from current articles upon verification shows that the information provided by the article is current. The article is written from 41 referenced papers published between 2002 to 2012. This indicates that the article is current.

Relevance

The article is of relevance in the field of Clinical research and academia. The article explores the topic extensively supported by the necessary data and illustrations. This makes it easy for the reader to clearly understand the article. Every part of this article provides so much relevant information to the reader. The information is very practicable and applicable. The article is of very great importance and relevance to Clinical Researchers, Contract Research Organizations and Academia.

Objectivity

The article objectively discusses the recent advances in quality management of Clinical trial. The data and information discussions are very clear to understand. The article is also firm, scientifically sound. This shows that the article is objective and unbiased. Therefore the article is objective and not biased.

Stability

The article is a stable article. International Journal of Pharmacy and Pharmaceutical Science is well known and is a stable journal. The source of the article and the sources of the information it provides also confirm it. The article is in the PDF format which also makes it easily accessible. Therefore, the article is stable.

Analysis of Graph and Tables

Not applicable

Recent Advance Related to the topic

Not applicable.

Conclusion

The review has critically reviewed the article: “Recent Advances in Quality Management of Clinical Trials” by Gupta et al., 2013. The review first summarized and reviewed the article's structure. The review also analyzed and critiques the article. The article is well-structured; it is credible, current, accurate, stable and objective. The article provides the relevant information supported by facts and figures which enhances the readers’ understanding. The article is very resourceful to Clinical researchers, Contract Research Organizations and the Academia. The article is objective and stable. Overall the article is well written, clear and well structured.