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By Elizabeth Wager



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Published February 2008

ISBN-13 978-1-905676-20-0

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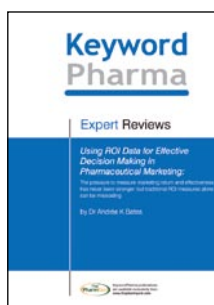
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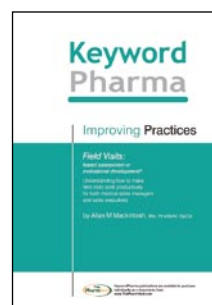
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FDAAA Legislation: Global Implications for Clinical Trial Reporting and Publication Planning

First published November 2008 by NetworkPharma Ltd

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A CIP catalogue record for this title is available from the British Library.

ISBN-13 978-1-905676-23-1

Managing Director: Peter Llewellyn; Editor: Chris Ross; Production/editorial: Gill Gummer; Typesetting and artwork: Blenheim Colour

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FDAAA Legislation: Global Implications for Clinical Trial Reporting and Publication Planning

by Elizabeth Wager

Executive summary

The Food and Drug Administration Amendments Act (or FDAAA), which was passed in 2007, has major implications for drug companies that plan to market their products in the USA. Section 801 of the Act outlines the ways in which clinical trials need to be reported. Most notably, it makes registration and the public reporting of results mandatory for certain clinical studies, through the www.ClinicalTrials.gov website.

The legislation applies to all FDA-approved medical products licensed for use in the USA and for products that are due to be submitted for marketing approval to the FDA. All controlled clinical investigations other than phase I studies are covered by the Act.

Although FDAAA is US legislation, it is likely to have consequences far beyond the USA and may profoundly affect the ways in which clinical trials are reported and made public. The legislation has implications for the publication of clinical trial findings in peer-reviewed journals, as well as for the clinical trial registers recognised by the International Committee of Medical Journal Editors.

This report, *FDAAA Legislation: Global Implications for Clinical Trial Reporting and Publication Planning*, describes the requirements for trial registration and the reporting of results, and explains what companies need to do now. Since the legislation is open-ended, and several aspects will not come into force for the next couple of years, the report also analyses future implications and highlights currently unanswered questions.

The first phase of FDAAA implementation, with elements governing clinical trial reporting, was due to come into force in late September 2008. Despite its US focus, it is clear that, globally, companies need to have systems in place to ensure they comply with this new legislation.

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About the author



Elizabeth (Liz) Wager is a member of the World Health Organization (WHO) Scientific Advisory Group on trial registration, the CONSORT statement group, the *BMJ*'s Ethics Committee, and the World Association of Medical Editors Ethics Committee. She is Secretary of the Committee on Publication Ethics and a Visiting Fellow of the UK Cochrane Centre. She is a regular peer-reviewer for several journals including the *BMJ*, the *Journal of Medical Ethics*, *PLoS Medicine* and *JAMA*.

After obtaining a First Class zoology degree from Oxford in 1983 she worked for Blackwell Scientific Publications, Janssen-Cilag then Glaxo-Wellcome. In 2001, she set up her own company, Sideview, which provides training, writing, editing and publication consultancy services. She has advised numerous drug companies and communication agencies about trial registration and publication policies, and has run workshops on five continents.

Liz has written books on '*Getting Research Published: an A to Z of Publication Strategy*' and '*How to Survive Peer Review*'. She is a co-author of '*Good Publication Practice for Pharmaceutical Companies*' and the European Medical Writers Association guidelines on the role of medical writers.

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