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Comments or questions are welcome: contact the author at www.umbachpartner.com

TO THE READER

Dear Reader,

This book has a power that will not be experienced if it is merely read.

It will take you only a few minutes to read each of the sections. Choose the tips, suggestions and recommendations that seem appropriate to you and action them.

What may seem a simple idea when first read, could prove to be a gateway to personal success once started.

Let this book inspire you.

Kind regards,

Günter Umbach

Dr. Günter Umbach

CODES OF PRACTICE

Transparency

Full transparency and accountability requires that the complete trial results be made available to the public without any bias or selectivity in reporting. Not reporting the results of negative trials is ethically and scientifically unacceptable.

Pharmaceutical companies should endorse good publication practice guidelines.

The industry should promote adherence to these guidelines.

Standards

The process from publishing of a protocol for a planned study to reporting the results of study must be done to exacting standards. All ethical and legal standards need to be applied in all communications – whatever the medium. All communications must ensure a fair balance and must adhere to the relevant Codes of Practice in company, industry and country. For examples please see those put forth by the following organizations.

Selected relevant organizations

- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA): www.ifpma.org
- European Federation of Pharmaceutical Industries and Associations (EFPIA): www.efpia.org
- Japanese Pharmaceutical Manufacturers Association (JPMA): www.jpma.or.jp/english
- Pharmaceutical Research and Manufacturers of America (PhRMA): www.phrma.org
- Association of the British Pharmaceutical Industry (ABPI): www.abpi.org.uk
- Verband Forschender Arzneimittelhersteller

(VFA): www.vfa.de

- US Food and Drug Administration (FDA): www.fda.gov
- Medical Research Council (MRC): www.mrc.ac.uk
- World Health Organization (WHO): www.who.int

Please check their websites for details.

Benefits

This book explains the do's and don'ts of communicating clinical trial results so that everybody can win: patients, physicians, payors, pharmaceutical companies and other parties involved such as hospitals and professional organizations.