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Clinical Trials Handbook is invaluable for practicing clinicians and trialists who would like to learn more about or improve their understanding of the design and execution of clinical trials. The book is also an excellent supplement for courses on clinical trials at the graduate level. Acknowledgments xi. Preface xiii. On planning xv

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1. Introduction Clinical trials, compared to observational studies, are considered by many to be the gold standard method for evaluation of healthcare interventions. They contribute significantly to relevant research evidence developed by the National Institute for Health Research (NIHR) to support the NHS in England and other care providers.

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Clinical trials involving therapeutic goods are generally undertaken

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to assess the effects, efficacy, performance and/or safety of the product. It is therefore necessary that clinical trials are conducted using appropriate experimental designs to obtain valid data without exposing participants to unnecessary risks.

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and fundraising to publishing the results.

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