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The statistical issues in drug development are explained in this book, enabling non-statisticians to work more easily alongside their statistical colleagues in planning, analysing and interpreting clinical trials. The author aims to make the book of particular benefit to the physician who might have little access to

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Commercial pressures mean that the stakes are high in drug development and regulatory standards mean that much that is done is examined very closely. As a consequence the non-statistician working in drug development has to have a considerable appreciation of statistical issues, which this book can provide. About the second edition.

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This book is an attempt to present many of the statistical issues in drug development in a way which is comprehensible to life scientists working in drug development whilst avoiding false consensus. The emphasis will be on the intuition which Polya, although himself a distinguished mathematician, valued so highly.

Statistical Issues in Drug Development

1.1 drug development Drug development is the process not only of finding and producing

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therapeutically useful pharmaceuticals and of turning them into high-quality formulations of usable, effective and safe medicines, but also of delivering valuable, reliable and trustworthy information about appropriate doses and dosing intervals and about likely effects and side-effects of these treatments.

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The statistical challenges in drug development are ever-changing as new clinical technologies and new statistical methods are developed. 1 These often go hand in hand as a new clinical technology may go into a new patient population, which may then require novel statistical methods to be developed.

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