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The book will be
useful will be

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useful for biopharma

Biostatistics
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statisticians at

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Features:

Describes a system of principles for pragmatic problem solving in clinical drug development.

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small pharma and
big pharma.

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useful statistical
background that
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enterprise.

Explains some
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philosophy in a
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transfusion field

where many

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through a population,
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interpret and
incorporate the

latest biomedical

research into their

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author draws from

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developing and

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biostatistics courses

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nurses, offering a

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presentation that is non-technical and accessible. The book begins with a basic introduction to the relationship between biostatistics and medical research, asking the question "why study statistics?," while

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also exploring the significance of statistical methods in medical literature and clinical trials research.

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regression, and
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methods Survival
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Throughout the
book, statistical
methods that are
often utilized in
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research are
outlined, including
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analysis of

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variance, hazard ratios, contingency tables, log rank tests,

bioequivalence, cross-over designs, selection bias, and group sequential methods. Exercise sets at the end of each chapter allow readers to test their

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comprehension of
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clinicians in the
fields of medicine,
public health,
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life sciences who
need to understand
and apply
statistical methods
in their everyday
work. It also serves
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involved in the
design and conduct
of clinical trials.

This will be the
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encountered by
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drug development.

The primary

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purpose of the book is to encourage and facilitate discussion between statisticians and their colleagues of the many complex statistical issues that arise in drug development. The book will be suitable as a course

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of self-instruction
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who are new to the
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statistical methods used in today's biomedical research and provides insight on their appropriate application. Rather than provide detailed mathematics for each of these methods, the book emphasizes what healthcare practitioners need to know to interpret and incorporate the latest

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biomedical research
into their practices.

The author draws
from his own
experience
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courses for
physicians and
nurses, offering a
presentation that is
non-technical and
accessible. The book
begins with a basic

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the book, statistical
methods that are
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for doctors, nurses,
and other practicing
clinicians in the fields
of medicine, public
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who need to
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Study design and
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methodology are two
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The presentation of
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event, and event-count methods.

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expressions and formulae. Explores the main types of clinical research studies, such as, descriptive, analytical and experimental studies. Addresses advanced modeling techniques such as interaction analysis and encoding by reference and polynomial

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Understanding

Biostatistics looks at the fundamentals of biostatistics, using elementary statistics to explore the nature of statistical tests.

This book is intended to complement first-year statistics and biostatistics textbooks. The main focus here is on

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ideas, rather than on methodological details. Basic concepts are illustrated with representations from history, followed by technical discussions on what different statistical methods really mean. Graphics are used extensively throughout the book in order to introduce

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mathematical formulae in an accessible way. Key features: Discusses confidence intervals and p-values in terms of confidence functions. Explains basic statistical methodology represented in terms of graphics rather than mathematical formulae, whilst

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highlighting the mathematical basis of biostatistics. Looks at problems of estimating parameters in statistical models and looks at the similarities between different models. Provides an extensive discussion on the position of statistics within the medical

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Discusses distribution functions, including the Gaussian distribution and its importance in biostatistics. This book will be useful for biostatisticians with little mathematical background as well as those who want to understand the connections in

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branch of
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science, has
as its main
focus the
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sciences, and
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confluence of
statistics and
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fields. The
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demands, the
advancements
in computer
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growth of life
science data
(e.g.,
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data) have promoted the formation of modern biostatistics. There are at least three characteristics of modern biostatistics: (1) in-depth engagement in

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has to match
the fast
growth of data
with a
constantly
changing face.
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**and scientists
who are
interested in
quantitative
analyses. The
goal is to
introduce
modern
methods in
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and help
researchers**

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dependent. Over
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developed into a
highly active field
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students,
researchers or the
non-specialists. By
briefly tracing the
paths traveled by

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the pioneers of different national backgrounds, the interviews attempt to put a cultural face to an intellectual endeavor that is often perceived as dry and austere by the uninitiated. They should also

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interest those who are intrigued by the influence of the environment on the creative spirit, and, in particular, those who are interested in the psychology and history of ideas. Statistical methods that are commonly

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used in the review and approval process of regulatory submissions are usually referred to as statistics in regulatory science or regulatory statistics. In a broader sense, statistics in

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regulatory science
can be defined as
valid statistics that
are employed in
the review and
approval process
of regulatory
submissions of
pharmaceutical
products. In
addition, statistics
in regulatory

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science are involved with the development of regulatory policy, guidance, and regulatory critical clinical initiatives related research.

This book is devoted to the discussion of statistics in

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regulatory science
for pharmaceutical

development. It

covers practical

issues that are

commonly

encountered in

regulatory science

of pharmaceutical

research and

development

including topics

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related to research activities, review of regulatory submissions, recent critical clinical initiatives, and policy/guidance development in regulatory science. Devoted entirely to discussing

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statistics in
regulatory science
for pharmaceutical
development.

Reviews critical
issues (e.g.,
endpoint/margin
selection and
complex innovative
design such as
adaptive trial
design) in the

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pharmaceutical
development and
regulatory

approval process.

Clarifies

controversial

statistical issues

(e.g., hypothesis

testing versus

confidence interval

approach, missing

data/estimands,

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multiplicity, and Bayesian design and approach) in review/approval of regulatory submissions.

Proposes innovative thinking regarding study designs and statistical methods (e.g., n-of-1 trial

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design, adaptive
trial design, and
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procedure for

sample size) for

rare disease drug
development.

Provides insight

regarding current

regulatory clinical

initiatives (e.g., pre

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cision/personalized
medicine,

biomarker-driven
target clinical trials,
model informed
drug development,
big data analytics,
and real world
data/evidence).

This book provides
key statistical
concepts,

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innovative designs, and analysis methods that are useful in regulatory science. Also included are some practical, challenging, and controversial issues that are commonly seen in the review and

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approval process
of regulatory
submissions.

About the author

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has also held
various positions in

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author or co-
author of over 300
methodology

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and discusses the

results and

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statisticians involved

in the industry as

research scientists,

regulators,

academics, and/or

consultants who

want to know more

about how to use S-

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