2024/2025 edition released!

# Barnett's Good Clinical Practice

## *A Question & Answer Reference Guide*

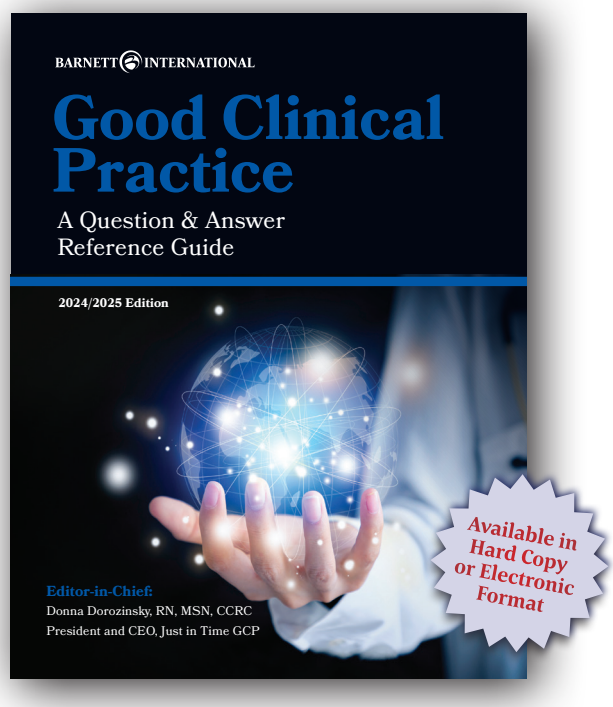
**Use Promo Code GCP25 at Checkout for a 25% Discount**

In the past several years we have seen the release of many new regulations and guidance throughout the world. We are coming out of a pandemic which has changed how we conduct and manage clinical trials, and we are dealing with an unstable world where research subjects are living in war torn regions. The 2024/2025 edition of Barnett's Good Clinical Practice: A Question & Answer Reference Guide has been reorganized with added topics to address this new era of clinical research.

This industry-leading GCP reference guide answers over 1,500 of the most common and difficult questions regarding the interpretation and implementation of U.S. and international GCP standards for drugs, biologics, and medical device clinical trials.

**Some highlights of the completely updated and expanded guide include:**

- An all-new section on risk-based quality management (RBQM) and Quality by Design, which are receiving ever more emphasis from global regulators
- Emphasis on Quality Tolerance Limits (QTLs), Key Risk Indicators (KRIs) and approaches to outsourcing RBQM
- Updates specific to ICH E6 and E8 including the ICH E6 (R3) Draft
- Public comments from regulators and references to other industry guidance/sources
- Impact of the new Clinical Trial Regulations in the EU and how Clinical Trial Information System (CTIS) are used for SUSAR reporting in Europe
- Content covering Decentralized Clinical Trials (DCTs) and what evidence regulators require for data quality
- Questions and answers regarding the balancing of equity and equality in trials (including study design, patient recruitment, compensation structures)
- Details around the use of real-time data monitoring and participant engagement technologies and their ethical implications
- A new section on conducting a clinical trial during a pandemic and/or war including trial management, risk assessments, monitoring activities, investigational product management, informed consent, and site change considerations
- And much more...!




**Designed for the clinical researcher, it covers commonly asked questions and answers regarding Good Clinical Practice standards categorized into 21 different areas, including:**

- Clinical monitoring
- Investigators/site compliance
- Source data and documentation
- Quality assurance activities
- Study auditing
- Inspections
- Decentralized trial management
- Diversity
- Equity and inclusion
- Informed consent
- Managing the trial master file
- And many other important areas

**TO ORDER:**

**Call Barnett International:** +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
**Or Order Online:** www.barnettinternational.com

**Publication Code: GCP24** ..... Price: $139.00
**Electronic Version: GCP24E** ..... Price $129.00