JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 14, No. 7, July 2018 "Happy Trials to You"

"A Comprehensive and Practical Guide to Clinical Trials"

Delva Shamley and Brenda Wright, editors, 2017, 196 pages, Academic Press, $89.95

Review by Norman M. Goldfarb

"A Comprehensive and Practical Guide to Clinical Trials" might be the slimmest book to make the claim of being comprehensive, but it can fairly be called practical. For example, the chapter on Investigational Medicinal Product (IMP) Management includes the following section:

Storage

1. Consideration needs to be given to requirements for temperature, humidity and light control, which will dictate storage conditions during transit and once at the site. This information is available on the Certificate of Analysis (COA), prescribing information, investigators brochure (IB), or package insert for registered medicine.
2. Appropriate storage conditions need to be maintained throughout the study period, from source to destruction/disposal.
3. During transport to the site, validated boxes may be used to ensure that appropriate temperatures are maintained, ranging from ambient to freezing temperatures. Data loggers are commonly used for continuous monitoring during transit, and a process should be in place to review the data from the logger and ensure no temperature excursions have occurred.
4. Post-IMP receipt, daily temperature monitoring of the storage area is essential. Best practice is to have two temperature monitoring systems, ensuring a backup if the primary system fails. This could include manual temperature recording and continuous monitoring via temperature recording probes or data loggers. Ensure that all recording devices are regularly checked and calibrated. Automated alarms need to be set up to ensure that any temperature deviations or power failures are immediately notified to the appropriate personnel. Pharmacists are advised to regularly check, download and acknowledge the automated temperature data (e.g., signing the print-out).
5. A written procedure for backup storage is essential and will dictate where and how to move IMP if an appropriate pharmacy environment is unable to be controlled.
6. Attempt to store each study's IMP in a unique storage area, which could be a cupboard or labeled baskets if storage is limited.
7. The sponsor may issue an extended expiry date for IMPs, which requires the relabeling of IMP with the updated expiry date. The sponsor may require IMP to be returned to extend the dates, or the site may be instructed to execute the relabeling process. If relabeling is to be done at the site, ensure that the original label is not obscured by the new one and record the procedures performed during this process.
8. Accountability records for storage of IMP may include temperature logs, calibration certificates, SOPs, COAs and IBs.

The book includes 17 chapters by five contributors:

- Introduction to Clinical Trials
- Clinical Trial Phases
- Setting Up of Site, Site Assessment Visits, and Selection
- Regulatory Requirements

- Contracts and Agreements
- Protocol, Informed Consent Documents, and Investigator Brochure
- Planning
- Recruitment and Retention
- Training
- Data Management
- Investigational Medicinal Product (IMP) Management
- Collecting, Processing and Shipment of Blood and Urine Samples
- Source Document
- Screening, Treatment and Safety Follow-Up Visit
- Quality Management
- Monitoring, Close-Out Visits, and Archiving
- Audits and Inspections

The authors are at the University of Cape Town in South Africa, so set aside time for a visit to learn more about points of interest.

Reviewer

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