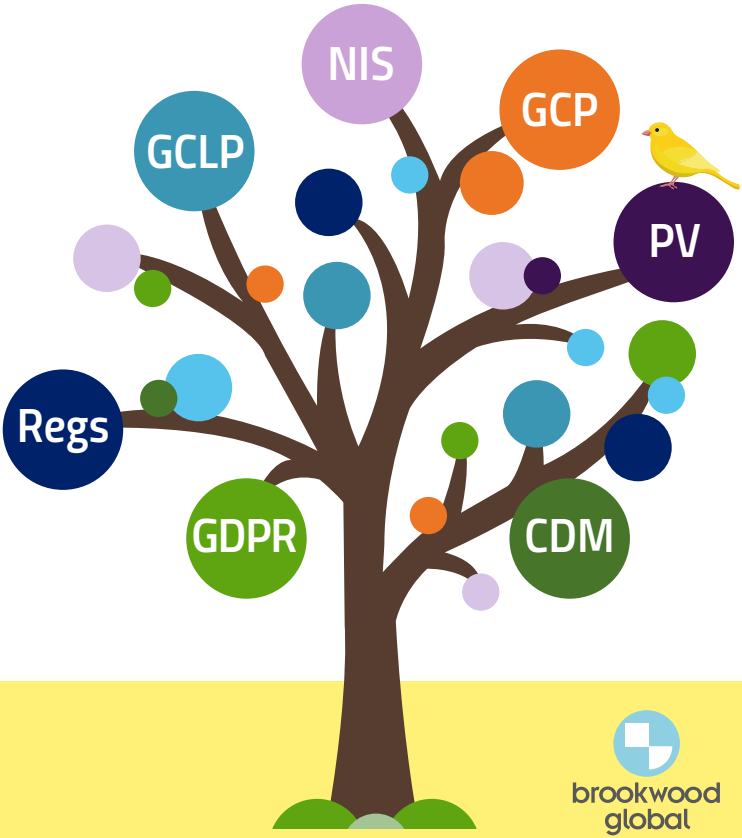
# Brookwood Global's on demand online clinical research training and publications




brookwood global

**Brookwood has provided clinical research training since 1985. Tens of thousands of people from over 60 countries in the world have either attended Brookwood face to face courses or undertaken our online courses.**

We have trained professionals from pharmaceutical and biotech companies, investigators and study site personnel, academics, regulatory authority inspectors and members of ethics committees.

We provide high quality up-to-date products at a reasonable cost.

What are the benefits of Brookwood's global training?

- Online, on demand. Do it anywhere! All that is needed is a strong continuous internet signal
- Globally log in at any time 24/7, 365 days a year
- Personalized using the participant's first name
- Can be done using PC, laptop, iPad, iPhone and other mobile devices
- Most courses have narrated or read-only choices
- Tracking of individual user activity
- Progress reporting by user and group
- Certification for satisfactory completion
- Costs dependent on the number of participants
- Excellent packages for multiple users
- Option to fix costs with a 2-year agreement or longer
- Help in the event of problems
- Valuable e-resources

**Visit www.brookwood-global.com for further details and to order online**

**Take a look at our product range. We have courses and publications in good clinical practice (GCP), pharmacovigilance (PV), non-interventional studies (NIS), clinical data management (CDM), data protection (GDPR), GCP for clinical laboratories (GCLP), and the UK Clinical Trial Regulations (UK-Regs).**

## Customization

All courses and publications can be fully customized. We can fully manage the training for you using our learning management system (LMS) or you can run the courses on your own LMS.

## Contact

For more details visit our website www.brookwood-global.com or contact us by email **info@brookwood-global.com**

## Other contacts

For training: **info@brookwoodacademy.org**

For publications: **info@canarybooks.com**

Brookwood Global is the new trading name for Brookwood International Academy and Canary Ltd. It better represents the successful and global nature of our business.


GCP
GDPR
PV
CDM
NIS
UK-Regs
GCLP
Books

@ **To evaluate the training, contact us by email info@brookwood-global.com**

## ▪ ONLINE TRAINING ▪

# GCP online training – specifically for sponsors

*Can be done on PCs, Macs, iPhones, iPads and android devices*

**Essential GCP for Sponsors** – narrated and read-only tracks, suitable for both inexperienced and experienced staff

**GCP Refresher for Sponsors** – ideal for those who have had GCP training and need an update/refresher

## ▪ BOOKS ▪

### Essential Good Clinical Practice


Professor David Hutchinson's popular book describing the basics of good clinical practice. This book is based on the GCP guidelines developed from the ICH GCP E6(R2) guidelines. It is suitable for anyone needing a basic understanding of GCP. 70+ pages, perfect-bound paperback.

### Indexed ICH GCP Guidelines with Integrated Addendum E6(R2)


A 'carry-around' pocketbook or A5 desk version of the ICH GCP E6(R2) guidelines together with our unique index that allows the user to search for the appropriate sections using subject index and key words.

**Visit www.brookwood-global.com for further details and to order online**

# ▪ KEY FACTS ▪

## Essential GCP for Sponsors

- Based on the sponsor responsibilities laid down in Section 5 of the ICH GCP E6(R2) guidelines as well as some of the investigator responsibilities that sponsors need to monitor
- Users can choose between a narrated or read-only (no sound) track
- The training is divided into key sections, each with interactions
- Quick 50-question test at the end of the training confirms knowledge
- Those who attain the 80% pass mark will receive certification
- Test answers can be reviewed and the test retaken
- Takes around 1 hour

## GCP Refresher for Sponsors

- An interactive quiz game to scale the highest buildings of the world – it adds fun and interest to GCP training
- Sponsor-specific questions cover a wide range of GCP topics based on ICH E6(R2)
- It is an ideal refresher
- 11 levels of slightly increasing difficulty – complete them all to pass
- 5 questions at each level – must get 4 correct to proceed (80%)
- Feedback given for incorrect answers, with opportunity to review and repeat the level
- Compulsory 'Did you know?' sections to enhance learning
- Takes around 45 minutes

**To evaluate the training, contact us by email**
**info@brookwood-global.com**

## ▪ ONLINE TRAINING ▪

# On demand online GCP training for investigators and site staff

**Essential GCP for Investigators** – narrated and read-only tracks, suitable for both inexperienced and experienced staff

**GCP Refresher for Investigators** – ideal for those who have had GCP training and need an update/refresher

This ICH GCP E6(R2) Investigator Site Training meets the minimum criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

- **Online training available in 14 languages: English, French, German, Italian, Polish, LatAm Spanish, Brazilian Portuguese, Chinese, Japanese, Russian, Turkish, Serbian, Czech and Hungarian**

## ▪ BOOK ▪

## 12 Golden GCP Rules for Investigators


- This quick and easy to read, illustrated, 'bullet point' guide to ICH GCP is ideal for investigators and other members of the study team.
- Helps investigators comply with ICH GCP investigator responsibilities and items on the monitor's wish list. It contains relevant extracts from the GCP guidelines.
- Books available in 11 languages: English, French, German, Spanish, Czech, Polish, Bulgarian, Chinese, Japanese, Russian and Turkish. *15 Rule US version also available.*

**Visit www.brookwood-global.com for further details and to order online**

# ▪ KEY FACTS ▪

## Essential GCP for Investigators

- Based on the investigator responsibilities laid down in Section 4 of the ICH GCP E6(R2) guidelines
- Users can choose between a narrated or read-only (no sound) track
- The training is divided into key sections, each with interactions
- Integral quizzes and an online multi-choice test at the end of the training confirms knowledge
- Those who attain the 80% pass mark receive certification
- Test answers can be reviewed and the test retaken
- Takes around 1 hour

## GCP Refresher for Investigators

- An interactive quiz game to scale the highest buildings of the world – it adds fun and interest to GCP training
- Investigator-specific questions cover a wide range of GCP topics based on ICH E6(R2)
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- Compulsory 'Did you know?' sections to enhance learning
- Takes around 45 minutes

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## A Guide to European Data Protection

This book by Dr Lisbeth Tofte Hemmingsen with contributions by Professor David Hutchinson focuses on European data protection rules based on the latest General Data Protection Regulation.

The book breaks down the regulation into bite-sized chunks to make the complex topic easier to understand. It is suitable for anyone who processes or transfers personal data.

## General Data Protection Regulation 2016/679 – with unique index


This book is a reproduction of the EU General Data Protection Regulation 2016/679.

- A5 size, spiral-bound and contains 150+ pages.
- It contains our unique subject index to help the reader find relevant sections in the Regulation more easily.

# The Principles of the General Data Protection Regulation (GDPR)

*All of our online training can be done on PCs, Macs, iPhones, iPads and android devices*

This online on demand training with a quiz and certification is an ideal way for those processing personal data to learn about the latest requirements for data protection.

**Content includes:**

- Key roles
- Definitions of personal data
- Applicability of the GDPR and exemptions
- Consent and rights of Data Subjects
- Legal basis for processing
- Obligations towards Data Subjects
- Risk assessment
- Data transfer outside EEA
- Record keeping
- Data security and storage
- The Data Protection Officer
- Data protection 'by design and default'
- Audits
- Managing breaches, compensation and penalties
- Data protection checklist
- Specific content on the impact of GDPR on pharmacovigilance and clinical trials.

Both books and online course cover the principles of data protection covered by the EU General Data Protection Regulation 2016/679.

**To evaluate the training, contact us by email**
**info@brookwood-global.com**

# PV for ALL

This 15 min* 'Step 1' online pharmacovigilance (PV) training is for an entire organization's staff. It can be fully customized. Run it on your own server or let us manage it for you.

**Content includes:**

- Types of product safety information that may be encountered
- Who might report safety information
- How and when to report to the Local Safety Contact
- Key information to be obtained

# Know PV

This 60 min* 'Step 2' online training covers essential PV in more depth. It is ideal for those who need a more detailed knowledge of PV.

**Content includes:**

- What is and what governs PV
- Roles and responsibilities
- Key PV process steps; safety information and its capture
- Product safety oversight
- ADRs – basic facts, solicited v unsolicited reports
- Expedited individual case safety reporting
- MedDRA coding
- Periodic safety reporting, PSURs, PBRERs, DSURs
- Risk management planning
- Safety signals
- Reference safety information
- PV system master file
- Inspections

**Visit www.brookwood-global.com for further details and to order online**

# PV for the Local Safety Contact and L-QPPV

This 40 min* 'Step 3' online training covers the responsibilities of the company's Local Safety Contact and the additional obligations of a Local QPPV (L-QPPV). Suitable for those involved as Local Safety Contacts and those who work with them.

**Content includes:**

- Regulatory requirements and main responsibilities
- L-QPPV's role in capturing, recording and reporting local safety information and PV activities
- Managing local challenges

# PV Refresher

An interactive Q&A game to update and refresh PV knowledge. Face five inspectors (see below) and answer 8/10 questions correctly each time to 'pass the inspection'!

Questions include a wide range of PV topics, as covered in our other courses.


Antonio


Brian


Janell


Laura


Sam

* Average time taken. Individual timings will vary.



To evaluate the training, contact us by email info@brookwood-global.com


## Essential Pharmacovigilance

This book is written by Dr Lisbeth Tofte Hemmingsen, a highly experienced specialist in quality assurance and pharmacovigilance (PV), with contributions by Professor David Hutchinson.

It focuses on the principles of PV and is relevant to everyone involved in PV, both directly and indirectly through their role.

## PV for ALL – a guide to recognizing and reporting product safety information


A short, easy to read booklet for all staff who might encounter a product safety issue. From telephone receptionist to CEO, regulators expect that someone who is told of a product safety issue knows how to report it to their Local Safety Contact.

This booklet is a useful aide-memoire and helps the reader to recognize product safety issues when they are told of them, and know what information to collect and how and when to report this to the Local Safety Contact.

Can be customized to meet your specific processes.

## ▪ ONLINE TRAINING ▪

# GCP for Clinical Data Management

This online on demand training with a quiz and certification is a fun interactive way for data management personnel to learn about their GCP responsibilities.

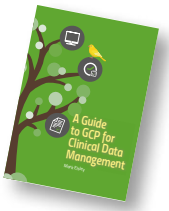
**Content includes:**

- Qualifications, training, SOPs
- Computerized systems
- Data flow and source data quality
- Data collection, quality and management
- Documentation
- Using CROs
- Risk register and risk-based approaches
- GCP checklist for clinical data management

CDM

## ▪ BOOK ▪

# A Guide to GCP for Clinical Data Management




The book is written by experienced Head of Data Management Mark Elsley, in conjunction with Professor David Hutchinson.

Both the book and online training cover the key ICH GCP E6(R2) requirements relevant to members of the data management team. They also provide valuable practical advice gained from the author's extensive experience in this field.

**To evaluate the training, contact us by email**
**info@brookwood-global.com**

## ONLINE TRAINING

# Principles and practical aspects of non-interventional studies

**Non-interventional Studies, General Principles (Module 1)** – interactive, personalized, narrated and read-only tracks, suitable for both inexperienced and experienced staff. Provides a generic core basic training (takes approx. 35 mins).

**Non-interventional Studies, Practical Aspects (Module 2)** – interactive, personalized, narrated and read-only tracks ideal for those who need a generic but more in-depth knowledge of running non-interventional studies (NIS) (takes approx. 45 mins).

## KEY FACTS

### NIS, General Principles (Module 1)

**Content includes:**

- What are NIS?
- Why perform NIS?
- Definition of NIS
- Declaration of Helsinki
- Rules governing NIS
- Data protection
- Requests by regulators
- PAS, PASS, PAES explained
- NIS in pharmacovigilance
- Pharmacovigilance inspections
- Abbreviations explained
- Glossary of terms
- Short quiz

**Visit www.brookwood-global.com for further details and to order online**

## NIS, Practical Aspects (Module 2)

Designed around an air journey to different parts of the real world to learn about key elements of running NIS.

**Content includes:**

- Setting up and running NIS
- Planning
- Impact of EU and US requirements
- Choosing a design
- Role of SCOPE; GRACE principles
- Cross-sectional, case-control and cohort studies
- Protocol content and development
- Declaration of Helsinki and NIS
- ENCePP guidance
- Study milestones
- Consent in NIS
- Study conduct
- Analysis of data
- Codes of conduct and agreements
- Scientific independence
- Monitoring
- MAH oversight obligations
- NIS and safety reports; risk management plans
- Data privacy
- Study report
- Publication of results
- Training
- Documentation and archives
- Glossary of terms
- Short quiz



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## ▪ ONLINE TRAINING ▪

# NIS for investigators and members of the study site on the requirements for performing non-interventional studies

**NIS Essentials for Investigators** – narrated and read-only tracks, suitable for both inexperienced and experienced investigators and their teams (takes approx. 25 mins).

This course can be fully customized to meet your requirements.

We can provide full registration, tracking, reporting and certification services, or run it under licence on your own learning management system.

## ▪ BOOK ▪

# Essential Guide to Non-interventional Studies


This short book outlines both the general principles and practical aspects of running a non-interventional study.

Topics are similar to those covered in our NIS online training courses.

**Visit www.brookwood-global.com for further details and to order online**

## NIS Essentials for Investigators

This training provides an understanding of the general obligations of researchers when undertaking non-interventional studies.

- Personalized – the participant is addressed by their first name.
- Users can choose between a narrated or read-only (no sound) track.
- The training is divided into key sections, each with interactions.
- A short test at the end of the training consolidates knowledge.
- The course can be set up to have a pass or simply certification for completion.
- Content is based on Good Pharmacoepidemiology Practice requirements, the Declaration of Helsinki and data protection principles.

**Topics include:**

- Definition of non-interventional
- Types of study
- Key factors affecting NIS
- Ethics and consent
- Health authority approval
- Data privacy
- Protocol and its content
- Current medical practice
- Safety data collection
- Study contracts
- Data access
- Study reports
- Publication of results
- Glossary of terms and abbreviations
- Short quiz



**To evaluate the training, contact us by email info@brookwood-global.com**

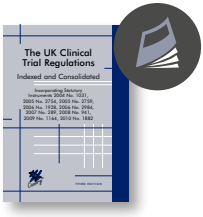
# Learn & Refresh UK Clinical Trial Regulations

*Can be done on PCs, Macs, iPhones, iPads and android devices*

Designed for those who need to learn about and demonstrate their UK Clinical Trial Regulations knowledge.

- Can be used as either initial or refresher training.
- Take a journey through the regions of the UK and visit famous landmarks whilst you answer questions on the UK Clinical Trial Regulations.
- Several 'Did you know?' interactions enhance knowledge.
- Visit nine locations and answer 8/10 questions correctly in each section to move on.
- If you finish your tour satisfactorily you will be awarded certification.

# The UK Clinical Trial Regulations



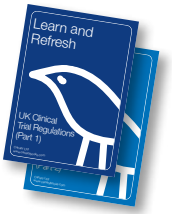

This indexed book consolidates, as a single text, the original Statutory Instrument 2004 No. 1031 and the eight amendments made up to August 2019. This third edition incorporates 2005 No. 2754, 2005 No. 2759, 2006 No. 1928, 2006 No. 2984, 2007 No. 289, 2008 No. 941, 2009 No. 1164 and 2010 No. 1882.

The book is wire-bound, to allow flat opening, and contains 180+ pages.

The book has a useful subject index to help the reader find the appropriate sections.

In addition, this book comes with a CD containing the official Statutory Instruments as PDFs.

# Learn & Refresh by Q&A




See the website for our range of new pocket-size Q&A booklets on a variety of topics including

- ICH GCP (for sponsors and investigators)
- UK Clinical Trial Regulations
- pharmacovigilance and GDPR

.... and more to come on FDA Regs, Phase I studies and non-interventional studies.



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# GCP for Clinical Laboratories – online training in GCLP

*Can be done on PCs, Macs, iPhones, iPads and android devices*

This 30-min narrated course is ideal for laboratory staff needing an insight into GCLP requirements, as well as sponsors' monitors, medical experts and auditors who utilize laboratory services in clinical trials.

It is based on the guidance given in the European Medicines Agency: "Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples", adopted by the GCP Inspectors Working Group in 2012.

It covers the most important aspects in the Reflection Paper and offers practical advice on how and when a laboratory should comply.

The program also covers some GCP basics to fulfil the requirement that laboratory staff have relevant GCP knowledge.

## Good Clinical Practice for Laboratories


This guide is ideal for laboratory staff needing an insight into GCP requirements, as well as sponsors' monitors, medical experts and auditors who utilize laboratory services in clinical trials.

The guide covers the most important aspects in the Reflection Paper and offers practical advice on how and when a laboratory should comply.

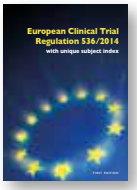
## OECD Principles of GLP – with unique index

This pocketbook contains the OECD Principles of Good Laboratory Practice (GLP) together with a unique cross-referenced subject index to facilitate finding the key requirements more easily.

This publication, the first in the OECD series on Principles of Good Laboratory Practice and Compliance Monitoring, contains the Principles of GLP as revised in 1997 [C(97)186/Final].

# EU Clinical Trial Regulation 2014 No. 536 – with index

A reproduction of the EU Clinical Trial Regulation as published in the *Official Journal* on 27 May 2014. In addition, this A5 wire-bound book (pocketbook version also available) contains a unique index of subject headings and key words to help users find the appropriate sections quickly and easily.




The index cross-references content to the Clinical Trials Directive 2001/20/EC and ICH GCP. This book can be customized with your company details – please ask us for details.

# Key Requirements Affecting Clinical Trials in Europe – with index

This wire-bound A5 size book opens flat for easy reading. Its 174 pages contain copies of the following guidelines/requirements, all cross-referenced by a unique index:

- ICH GCP E6(R2) guidelines
- Directive 2001/20/EC (including amendments since 2001)
- GCP Directive 2005/28/EC
- GMP Directive 2003/94/EC
- Annex 13 of GMP (2010)
- Declaration of Helsinki 1996 and 2013.

**Visit www.brookwood-global.com for further details and to order online**

# The Essentials of How to be a Great Manager


Managers in the workplace have a huge impact on the well-being and lives of their staff. However, many managers are not creating environments in which employees feel motivated or even comfortable.

This book provides guidance for managers new to the role, and shows them how to develop a team that is happy, innovative and productive.

The author, Mark Elsley, has over 28 years of experience working for major pharmaceutical companies, academic institutions and contract research organizations, including 18 years at managerial level.

## ▪ ADVISOR NEWSLETTER ▪


*Clinical Research and Clinical Quality Assurance Advisor* is a quick and easy to read newsletter, usually consisting of 8 pages, published 20 times per annum.

- Helps busy clinical research and QA professionals to keep up to date with the latest news and information.
- More than 445 issues published since 1997.
- Single-reader and a variety of multiple-reader and bespoke electronic subscription options. Paper version still published!

For our full range of online courses, publications and face to face training visit

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