



CHAPTER 1

Overview and Purpose of this Guide to Clinical Trials in the NHS

Clinical trials are a form of medical research involving patients. They are carried out to try to find new and better ways to diagnose and treat disease. *Clinical Trials Explained* has been written as a guide for healthcare professionals seeking an introduction to clinical trials in the NHS. It aims to provide comprehensive information on why, how and what clinical trials are run in the UK. It is based on what research and discussions with patients reveal as the most critical issues that adults should understand when considering clinical trial participation. It is hoped that this guide will assist healthcare professionals when discussing care options with their patients. This chapter provides an overview of the information in this guide.

Overview and purpose of this guide

Overview

Clinical Trials Explained is a guide to clinical trials in the NHS (National Health Service). It offers carefully researched, objective information about the study of medical interventions in adult humans, and the process by which patient care is improved by comparing available and new interventions in clinical trials. Medical interventions in the context of this guide mean the:

- Diagnosis of disease, for example by using medical equipment to produce images of the diseased part of the body; and
- Treatment of disease, for example by using drugs, surgical procedures and/or medical devices such as heart pacemakers.

Please note that this guide does not address issues concerning clinical trials for preventing disease, nor does it cover clinical trials involving healthy volunteers, trials for children or trials for patients who are unconscious or not mentally able to make a decision about entering a trial.

2 Chapter 1

This guide is divided into sections providing comprehensive facts about clinical trials and addressing common questions. It provides:

- An overview of clinical trials, what they are and why they are needed (Chapter 2). This chapter provides a detailed description of how clinical trials are designed and conducted, and who is involved. Chapter 2 also includes an explanation of the different trial phases, including an analysis of what each phase might mean for patients;
- A description of the process of clinical trial approval and regulation (Chapter 3). This chapter describes the organisations involved in approval and regulation, including those that pay for clinical trials and those that manage them once they are running. Chapter 3 also lists the laws and guidance used in the UK to ensure that trials are safe and of the highest quality;
- An explanation of the important concepts in clinical trials that describe design elements and research results (Chapter 4). This chapter also explains the terminology of clinical trial design and results; and
- Answers to the questions most commonly asked by patients and their carers (Chapter 5). This chapter includes information on patient rights, why patients do or do not choose to participate in clinical trials and how patients can be empowered during a clinical trial. Chapter 5 also answers important questions about the practical impact clinical trials have on their lives, e.g. costs.

This guide also provides:

- A list of additional resources providing information on how to find out about clinical trials that are available;
- A *Glossary* defining the terms used in this guide and others relating to clinical trials; and
- The ECRI Evidence Report outlining research into patients' reasons for participation in clinical trials and effect of trial participation on patient outcomes.

Purpose

The format of this guide has been developed to help the reader:

- Develop a broad understanding of clinical trials and the clinical trial process at his or her own pace;
- Find specific information of immediate importance to the reader by recognising that not all the information provided may be of interest; and
- Refer to relevant sections during discussions between patients, carers and healthcare professionals on the benefits and risks of entering a clinical trial.

Who should use this guide to clinical trials in the NHS?

This guide is for healthcare professionals, such as general practitioners and hospital doctors, research nurses and medical students, seeking an introduction to clinical trials and/or a framework for discussion with their patients about clinical trials.

Overview and Purpose 3

Clinical Trials Explained is designed to sit alongside the patient information and decision-making tool *Clinical Trials: The Basics*. *Clinical Trials: The Basics* aims to provide patients with easy-to-understand information on clinical trials, as well as with simple tools to help them make a decision about whether or not to enter a clinical trial. Healthcare professionals using this guide are encouraged to make *Clinical Trials: The Basics* available to their patients to help them make informed decisions about their care. The patient guide is available via www.ecri.org.uk.