Clinical trials toolkit

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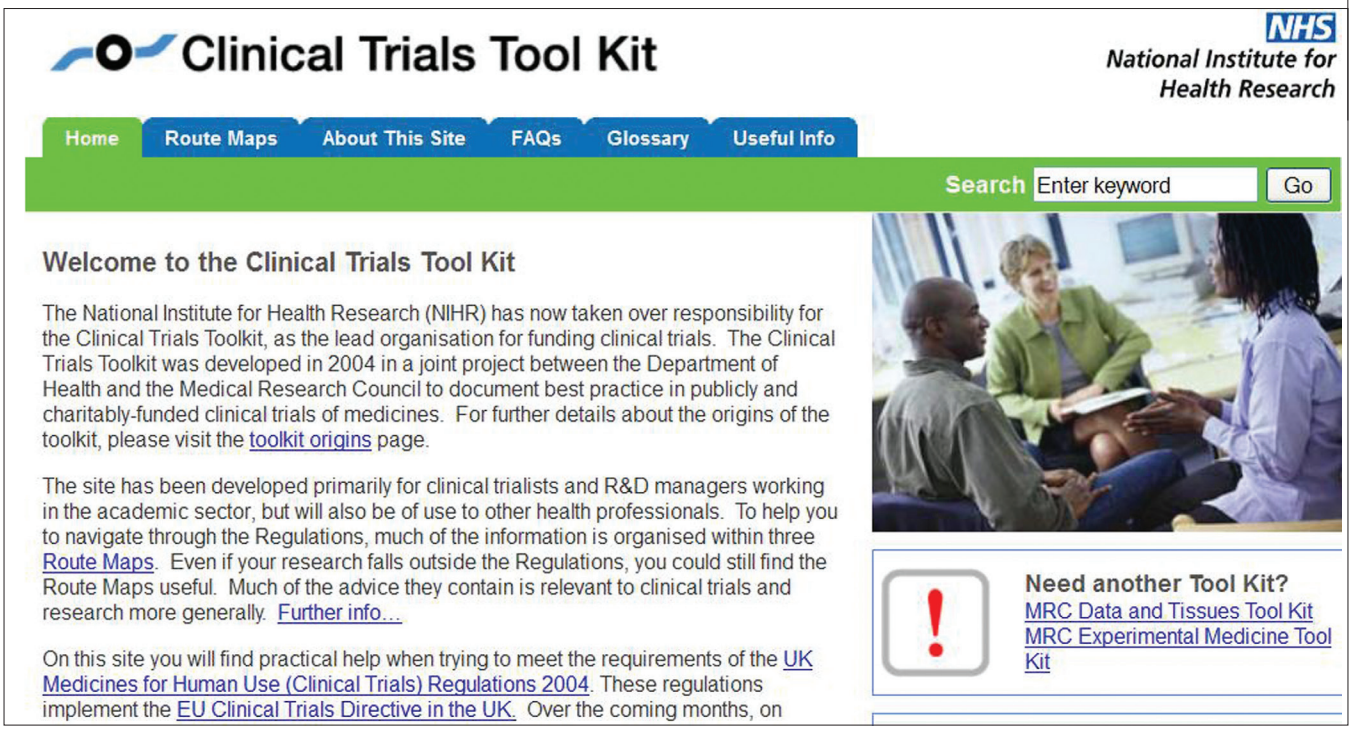

Clinical research aims to address the uncertainties that exist about treatments and interventions that are in use for a variety of diseases. This results in better choices for patients and more responsible decisions by physicians. Clinical research can also help in critical rediscovery of the causes of human disease and its prevention.

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During a clinical trial, newer treatments are tested from laboratory till therapeutic use with patients. In addition, the benefits and harms of existing treatments and interventions are also adequately relooked at. Prospectively randomized controlled clinical trials that reduce known and unknown biases, are the best way to reduce uncertainties about the relative merits and disadvantages of both new and existing treatments and interventions in order to provide better choices for patients.

Clinical trials have been the focus of a number of controversies in the past. They have emerged from the dark shadows of World War II and the infamous US Tuskegee study with a firm commitment from the medical profession to always uphold the interests of the patient, above commercial and scientific gains. The spirit of the Helsinki Declaration framed and updated by

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the World Medical Association is expressed in the regulations governing and guiding the conduct of clinical trials, and has yielded best practice guidelines called Good Clinical Practice (GCP) guidelines. GCP specifies the desirable process of conducting clinical trials, spelling out in great detail the steps to ensure the ethical conduct, and to safeguard the interests of the patient or volunteers participating in the trial. However, in common parlance, the clinical trials still conjure up a picture of unethical experimentation especially when powerful pharmaceutical companies try to conduct them in countries with lax regulatory mechanisms.

The European Parliament passed the landmark Clinical Trials Directive in 2001 that aimed to simplify and harmonize the administrative provisions governing the clinical trials by establishing a clear, transparent procedure. Despite criticism of unnecessary bureaucratic control and being interpreted differently in different countries the directive has helped in bringing about an awareness regarding GCP and Good Manufacturing Practice (GMP) guidelines. In the United Kingdom, the Clinical Trials Toolkit was developed in 2004 in a joint project between the Department of Health and the Medical Research Council to document best practice funded clinical trials of medicines to understand the regulations of the Clinical Trials Directive.

The Clinical Trials Toolkit website (http://www.ct-toolkit.ac.uk/) is presently hosted by The National Institute for Health Research (NIHR) which is the lead organization for funding clinical trials in the UK. The site primarily caters to the needs of clinical trialists and RandD managers working in the academic sector.

The information is organized within three Route Maps which are useful learning tools. These depict as to where the processes and good practice have wider relevance. The maps are divided into sections and "stations". These stations are further hyperlinked to resources and take the user through various documents and checklists depending on the stage that the trial is in. Three types of Route Maps are accessible: for trials that began before 2004, for planning a new trial and for trial management and closure.

For new trials, the Route Map begins with the framing of the research question. It then goes on to resources for regulatory requirements, sponsorship, and protocol development with inputs from peer review, GCP guidelines, pharamacovigilance. This further links to a checklist for RandD, ethical and Clinical Trial Authorization, before the final submission. The Route maps allow the trial to proceed in a regulated way and the checklists ensure that the scope for error or missing documents is minimized at all stages. Symbols for various processes signify the importance of every station in terms of whether it is a standard process, a legal requirement, falls under good practices or is simply important. The Trial Management Map starts with consent and recruitment and covers other areas including reporting, monitoring, audit, and inspections. The end of trial, data analysis, and dissemination of results form a part of this map.

The Route Maps are easy to navigate and are relevant to clinical trials under any settings. Minor modifications in the process flow could lead to their adoptability in any situation regardless of the country.

The Glossary section expands various cryptic terms used in clinical trials; however, it does not give details of these terms.

The Useful Links section has links to virtually all the documents and websites related to clinical research in the UK. These resources address everything starting from simple guidance, regulations, ethics, clinical trials, research, and funding issues.

The website is an excellent resource for framing guidelines in the conduct of clinical trials. By minimizing transgressions and ensuring transparency, the algorithms ensure that the trialist, research funders, and patients are involved in an ethically and logically sound experience that can help improve design and delivery of a trial for maximum benefit of the society.

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