CHAPTER 1

What Is Evidence-Based Healthcare?

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OVERVIEW

- Evidence is the available information or facts which indicate whether a belief or proposition is true.
- Evidence in healthcare is linked to quality, patient safety and improved clinical outcomes.
- The concept of justifying practice through the use of evidence can be found from the earliest times.
- Modern evidence-based practice has its roots in the development of critical appraisal and modern research methods.
- The ethical dimension is essential in determining the quality and application of evidence.

Introduction

On explaining to a fellow new student on another university course that I was studying evidence-based healthcare and how to bring evidence into our clinical practice, the alarmed response I received was, 'You mean healthcare isn't already evidence-based?' It seems obvious that something as important as healthcare should proceed only on the basis of the evidence, given the possible consequences of poor practice. The answer to my colleague's concern is, of course, both 'Yes, it is' and 'No, it isn't or rather 'There is evidence, but it could be better, both in terms of the knowledge and how the knowledge is applied to patient care'. It is always this tension between where practice is now and where it could be in the future, which should motivate both scientists and clinicians to always develop the scope of evidence further in our practice.

Evidence is not only static but also dynamic in the sense our depth of understanding should always be evolving. An example is finger clubbing, first described by Hippocrates in a patient with empyema in the sixth century BCE. Our understanding of clubbing is different from 2500 years ago (Box 1.1).

Therefore, observation is crucial in healthcare because it raises curiosity about the origin of the data, and in this case a physical sign clinicians see in their patients. Hippocrates' initial observation of a patient's fingers and his curiosity about a relationship (coincidence, association or causation?) with their empyema has evolved into an evidence-based physical sign which remains important in physical diagnosis. These clinical questions are vital in clinical reasoning and decision-making about a patient's management. They divide into questions about general knowledge of a condition, disease or process (background questions) and specific questions to facilitate clinical decision about the patient in front of us (foreground questions) (Chapter 2) (Box 1.2).

The volume of medical knowledge and belief has evolved immensely. Currently, Medline is adding over a million new records to its database every year. Hippocrates alone wrote around 60 treatises (the *Hippocratic Corpus*) describing theories of disease, ethical dimensions and approaches to observation and physical examination. Now every busy clinician appreciates the need to access high-quality information quickly and efficiently for the immediate benefit of patients. The need to summarise evidence and manage changing medical knowledge has been recognised since the seventeenth century with the publication of an abstracting journal in 1682 and the first medical journal in England, *Medicina Curiosa,* in 1684 (1). The development of indexing, databases and computerisation in the twentieth century has provided the automated databases and evidence retrieval we enjoy now, particularly in the last 30 years. These have facilitated an explosion in the opportunities for a more systematic and rigorous consideration of scientific evidence, which informs clinical practice today (Chapter 3). Many of us will remember the previous challenges of retrieving references for our student essays from the hefty volumes of the *Index Medicus*, followed by a search of the dusty shelves of a medical library stack room.

Comparing similar groups whose baseline characteristics are similar is particularly important in evaluating a new intervention and is the basis of the randomised controlled trial (RCT). Again, the concept has a long history, with the poet Francisco Petrarch proposing in the fourteenth century that the effects of then-current treatments for conditions in one group be compared with a similar group of patients in which the natural history of the condition was allowed to proceed unchecked. A famous example is James Lind's intervention in sailors with scurvy in 1747 (Box 1.3). The first recognised RCT is of the use of streptomycin in the treatment of pulmonary tuberculosis (2). Given the inherent variability of biological systems both individually and in populations, the precise comparison of groups required in accurately evaluating the effectiveness of interventions

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Box 1.1 **Understanding the clinical significance of finger clubbing 'Hippocratic fingers'**

Clubbing is characterised by a bulbous swelling of the terminal phalanges of the fingers. It was described first by Hippocrates, who observed it in a patient with empyema. Later it was found to be associated with many conditions, including bronchiectasis, lung cancer, liver cirrhosis, cyanotic congenital heart disease and infective endocarditis. In 1976, South African cardiologist Leo Shamroth observed in his own clubbed fingers an obliteration of the diamond-shaped spaced normally seen when the dorsal surface of the nails are brought into contact with one another (Shamroth's sign). A study in *JAMA* in 2010 found inter-examiner agreement using Shamroth's sign on the presence of clubbing to give *kappa* values of 0.3–0.9 and concluded its use reasonable in the identification of clubbing. Clubbing is present in 1% of patients admitted acutely to acute medical wards and is associated with serious disease in 40% of these patients.

Source: Pallarés-Sanmartín et al. (20), Vandemergel and Renneboog (21).

Box 1.2 **Examples of background and foreground questions**

Background questions identify knowledge and understanding of disease processes or clinical conditions. They are often broad in scope and may be answerable from textbooks, general online sources and review articles. They may help information decision-making about a foreground question and a particular patient but are not the answers in themselves about what is appropriate for a particular patient.

Example – What is the pathophysiology and prognosis of acute otitis media in children under two years?

Foreground questions require knowledge to assist decision-making. They may involve a comparison of treatment options, including intervention. Answers to foreground questions require synthesis of primary studies and a comprehensive literature search. These may be used to produce an evidence summary or systematic review.

Example – Will prescribing oral antibiotics to my 18-month-old patient with acute otitis media improve or have any effect on their long-term prognosis?

has led to the development of medical statistics to describe these effects accurately (Chapter 6).

Healthcare before evidence-based healthcare

Evidence existed before the 1990s, and anyone practising in that era knows clinicians both aspired to and did practise scientifically for the benefit of patients. What happened in 1992 and afterwards happened because of what came before, as well as the development of innovative technology and the inspirational leadership of individuals and academic departments in articulating a new vision for the evaluation and application of evidence in healthcare. First is the improvement in the evaluation of interventions and treatments. This has been

Box 1.3 **James Lind and comparison of similar groups in the treatment of scurvy**

Scurvy results from a lack of vitamin D. It was particularly prevalent in the Royal Navy in the eighteenth century. Provision of citrus fruits to Dutch sailors suggested a reduction in the disease. In 1747, James Lind, a Royal Navy surgeon, selected 12 sailors with scurvy 'as similar as I could have them'. All sailors received the same diet. The sailors were divided into groups of two. Two were given a quart of cider each day, two took vitriol three times daily, two took two spoonfuls of vinegar daily, two were given seawater and two were given dietary supplements. The remaining two were each given two oranges and one lemon every day. 'The most sudden and visible effects were perceived from the use of oranges and lemons one being at the end of six days fit for duty and the other appointed to attend the rest of the sick'.

(Dr James Lind's Treatise on Scurvy, 1753)

Source: Adapted from Bhatt (19).

Table 1.1 A light-hearted perspective on alternatives to evidence-based medicine.

- Evidence-based medicine – relies on the randomised controlled trial and the systematic review
- Eminence-based medicine – the precedence of seniority of years in making the correct decision
- Vehemence-based medicine – the stridency with which one makes one's own beliefs known
- Eloquence-based medicine – the ability of ensuring one's views prevail given an ability to explain them beautifully
- Diffidence-based medicine – accepting the inevitability of the natural history of the patient's disease
- Nervousness-based medicine – practising with the aim of avoiding complaint or litigation

Source: Adapted from Straus et al. (3).

achieved through better study design, including registration of trials, protocols and promotion of reporting standards (Chapter 4). In addition, the promotion of critical appraisal skills, including in healthcare training programmes, has enabled practitioners to exercise greater reflection and discernment in how to apply evidence to their own patients (Chapters 7 and 8). Even though light-hearted in tone and certainly not advocated as viable alternatives, Isaacs and Fitzgerald's perspectives on evidence-based healthcare were written as a necessary counterpoint to the evidence-based approach and the issues raised by it. It is worth reflecting on Isaacs and Fitzgerald's thoughts on alternative methods of clinical decision-making (Table 1.1). In all things, there should always be a healthy scepticism, if only to encourage necessary questioning and debate to flourish.

The philosophy of evidence-based healthcare (4)

Healthcare is about diagnosis but at least as importantly about management including treatment and intervention. Historically, three approaches have been taken. Firstly, the impact of expertise

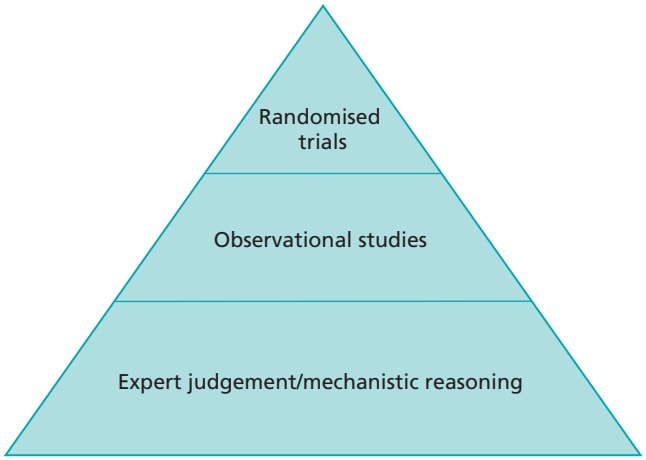

Figure 1.1 Simplified hierarchy of evidence (systematic review of all study types is assumed to be superior to single studies). *Source:* Howick (4)/John Wiley & Sons.

and experience allied to mechanistic reasoning ('In my experience, from the patients I have seen…'). There is also the approach that any treatment can only be deemed curative if the precise mechanism is known and understood. The final approach, advocated in evidence-based healthcare, is that the effects of a medical intervention are best evaluated by direct observation of the effects by comparing groups as similar as they can be – one which has received the intervention and one which has not. All the aforementioned constitute evidence, but a hierarchy of evidence exists (Figure 1.1) (4):

- Randomised trials (RCTs) or systematic reviews of many randomised trials offer stronger evidential support than observational studies.
- Comparative clinical studies in general (including both RCTs and observational studies) offer stronger evidential support than mechanistic reasoning from more basic sciences.
- Comparative clinical studies in general (including both RCTs and observational studies) offer stronger evidential support than expert clinical judgement.

The first decades of evidence-based healthcare have seen this approach become well established across clinical practice. At the same time, other themes have also emerged which were not initially considered (Chapter 9). For example, the perspectives of the patient and practitioner are both important in translating evidence into practice, and qualitative evaluation of these perspectives is also required. Moreover, clinical experience and expertise remain important, particularly in the realm of integrating policy, resources and shared decision-making with patients. Finally, though the robustness of study design and reporting has improved, historically marginalised and underserved populations remain underrepresented in research participation. This limits the wider application of evidence into practice.

The origins of the evidence-based healthcare movement

The 'Evidence-Based Medicine' movement was launched in the early 1990s by a group of epidemiologists at McMaster University, Hamilton, Canada. The aim was a new paradigm of medical practice. Proponents advocated greater reliance on published data with evidence from clinical trials considered superior to mechanistic reasoning and clinical judgement (5). The concept of hierarchies of evidence developed during the 1970s (6). This culminated in 1981 with the publication of a series of articles in the *Canadian Medical Association Journal* on how to appraise the medical literature (7). While the principles of evidence-based medicine were quickly accepted into practice, nonetheless there was concern about restriction of clinical judgement, 'cookbook medicine' and use of evidence-based medicine by policymakers to implement cost-cutting measures. These concerns were rebutted by the authors in an excellent *BMJ* article published in 1996, which stated (8):

> 'Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making care about the care of individual patients'.

Furthermore, the authors were clear that this meant integrating the best available evidence from systematic research with individual clinical expertise and that this increased expertise arises from effective and efficient diagnosis in combination with thoughtful identification and compassionate use of individual patients' predicaments, rights and preferences in decisions about their care. In the opinion of the authors, clinically relevant research may be from the basic sciences but especially from patient-centred research, including diagnostic accuracy, prognostic markers and the efficacy and safety of therapeutic, rehabilitative and preventive management (8). While well-conducted clinical trials and systematic reviews represent particularly high-quality research, this does not invalidate other well-designed studies if they are relevant and appropriate to the patient's presenting problem. This correlates all the areas from which clinical questions from both patients and practitioners are likely to arise and which reflect the domains of evidence-based healthcare:

- Aetiology/harm (causation)
- Prevention
- Diagnosis
- Therapy (treatment)
- Prognosis
- Meaning (patient's experiences)

Using evidence at the bedside

Healthcare is a high-pressure, time-limited activity which relies on the interaction and co-operation of all team members for the safety of the patient. This is facilitated by the availability of evidence. A feasibility study in 1995 at the University of Oxford, UK, concluded that making evidence available quickly to busy clinicians increased evidence-seeking and the incorporation of evidence into patient care decisions (9). An 'evidence cart' was taken on clinical rounds (Figure 1.2). On average, two to three questions arose for each patient. It took between 15 and 90 seconds to find relevant evidence (9). Evidence was found most quickly using a resource of pre-appraised topics, followed by use of *Best Evidence* with a Medline search taking the longest. Evidence changed management in one-third of patients (Table 1.2).

The development of tablets and handheld devices has overcome the practical challenges of a 'cart'. Clinicians are now used to retrieving

Figure 1.2 David Sacket demonstrating the evidence cart. *Source:* Straus et al. (10)/with permission of Sage Publications.

Table 1.2 Impact of the evidence cart.

- 81% – affected diagnosis and/or treatment
- 52% – confirmed current or tentative diagnostic or treatment plans
- 25% – led to new diagnostic skills, additional tests and new management decision
- 23% – corrected previous clinical skill, diagnostic test or treatment
- The perceived need for evidence was high, but search was done in only 12% of patients

Source: Adapted from Sackett and Straus (9).

evidence from their devices, even in front of patients. It is considered in the interests of patient safety and presents a cultural change from the perception the doctor must already know everything and be seen to already know everything. The development of pre-appraised sources and guidelines facilitates this, though time is still a limiting factor. Even so, evidence-based healthcare is not simply looking up evidence and what to do. Evidence must be assimilated and reasoned through even within the few seconds it takes to make a clinical decision. This approach needs to be embedded in training curricula – both undergraduate and postgraduate (Chapter 10). Use of evidence should permeate the whole of the clinical assessment and management pathways, including the history and examination. Teaching and learning evidence-based healthcare is not simply critical appraisal. It needs to be taught imaginatively to engage learners, and it should relate to their current experience. The content of healthcare courses should reflect the best evidence and how to apply it rather than simply where to find it. Learners should have the opportunity to apply evidence to patients they have encountered under supervision and receive feedback on their progress.

The achievements of evidence-based healthcare

Evidence-based healthcare has been forefront in the development of healthcare over the past 30 years. Its launch coincided with the growth of clinical guidelines. Guidelines have become influential in disseminating research evidence to frontline practitioners. The rigorous application of study design and reporting standards to medical research is essential in bringing structure and quality to the explosion of information and knowledge available via the internet. Ensuring treatments and interventions are applied only once they are rigorously and scientifically evaluated is essential in reducing patient harm and the overuse of technologies. The promotion of RCTs and systematic literature reviews (SLRs) has been both instrumental in focusing medical progress in interventions, treatments and devices firmly on an evidence base.

A particular achievement is the Cochrane Collaboration (Box 1.4). Founded in the United Kingdom and sponsored by the UK Department of Health, it has grown to an organisation of over 40 000 volunteers from over 190 countries responsible for producing over 400 systematic reviews each year on a wide range of medical treatments. Cochrane's members and supporters include researchers, health professionals, patients and carers. Worldwide 3.66 billion people have point-of-use access to the library (11). Over 7500 systematic reviews have been published by the Cochrane Library, where they are downloaded over 12.5 million times each year (Tables 1.3 and 1.4) (11).

Medical knowledge is more readily available to patients and non-clinicians. Healthcare practitioners are expected to share their knowledge in collaboration with patients in management. These conversations need to be evidence-based. Integrating evidence with clinical communication to share decision-making with patients is a recognised domain of clinical reasoning applicable in many areas of practice (12–14). Evidence-based practices consistently improve patient outcomes and returns on investment for healthcare providers (15).

Box 1.4 **The Cochrane database of systematic reviews**

The Cochrane Library is an international research network made up of several databases relating to biomedical research and associated economic analyses. The Cochrane Database of Systematic Reviews (CDSR) is an online repository of high-quality systematic reviews covering a wide range of topics. Cochrane reviews all follow guidelines for research methods relating to research question scope, systematically collecting evidence, assessing bias, statistical analysis and performing meta-analyses of amalgamated datasets. These guidelines are free to view online at https://training.cochrane.org/handbooks. The full texts of completed systematic reviews are freely available on the CDSR due to the Cochrane Library's commitment to open-access research. Protocols of completed and ongoing systematic reviews are also freely available and are a useful source for those wanting to better understand research methods for literature reviews.

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Table 1.3 Types of review published by the Cochrane Library.

Intervention review	Assess the effectiveness/safety of a treatment, vaccine, device, preventative measure, procedure or policy
Diagnostic test accuracy review	Assess the accuracy of a test, device or scale to aid diagnosis
Prognosis review	Describe and predict the course of individuals with a disease or health condition
Qualitative evidence syntheses	Investigate perspectives and experiences of an intervention or health condition
Methodology reviews	Explore or validate how research is designed, conducted, reported or used
Overviews of reviews	Synthesise information from multiple systematic reviews on related research
Rapid reviews	Are systematic reviews accelerated through streamlining or omitting specific methods
Prototype reviews	Include other types of systematic review that do not yet have established standard methodology in Cochrane, such as scoping reviews, mixed-methods reviews, reviews of prevalence studies and realist reviews

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Table 1.4 Themes and examples of Cochrane library systematic reviews.

Themes	Published reviews	Example topics
Allergy and intolerance	63	Eczema Vaccinations Asthma
Cancer	833	Bone loss prevention Gene therapy Chemotherapy and biologic therapy Surgical management
Diagnosis	173	Triage/screening tools for spine injuries Measuring drug therapy adherence Imaging methods for diagnosis Novel tests for sepsis
Mental health	693	Antipsychotic effectiveness comparisons Risk assessments for schizophrenia Cognitive rehabilitation
Ear, nose and throat	218	Vestibular migraine management Virtual reality training for surgeons Management of acute otitis media
Gynaecology	382	Pain management in dysmenorrhoea Urinary incontinence management Surgical methods in hysterectomy
Public health	117	Implementing policies for diet, physical activity and tobacco use in schools Interventions for reducing social isolation in older people Fortification of foods to target malnutrition in the general population
Rheumatology	344	Nonmedical management of systemic lupus erythematosus Management of osteoporosis Pain management in rheumatoid arthritis

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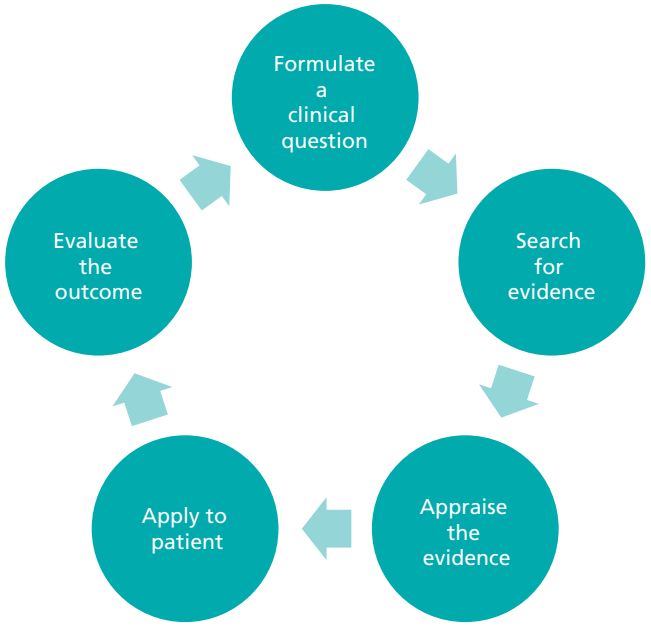

Figure 1.3 The five key steps of evidence-based healthcare.

The key steps of evidence-based healthcare

Whether researcher, frontline clinician, patient or policymaker, all end users of evidence-based healthcare need to execute efficiently and confidently the five key steps of evidence retrieval and application (Figure 1.3). In the chapters which follow, we will look at each of these in more detail and point the reader towards further resources and tools before considering the teaching and learning of evidence-based healthcare.

So what is evidence-based healthcare?

In this book, we will use the term 'evidence-based healthcare'. Is this the same as 'evidence-based medicine'? What about evidence-based practice? Is 'evidence-based' the same as 'evidence-informed'? What is the evidence?

A search on PubMed for articles published in the *Journal of Clinical Epidemiology* reveals 'evidence-based medicine' to be the most popular term closely followed by evidence-based practice (Table 1.5) (16). David Sackett et al. used these two terms interchangeably without ascribing a particular meaning to either term (8). Evidence-based medicine has been attributed to decisions about individuals, while some authors use evidence-based healthcare to describe populations. Another justification for using 'evidence-based healthcare' is that healthcare is not delivered only by doctors. The term 'healthcare' rather than 'medicine' is more inclusive of professionals in nursing and allied health professionals who contribute to research and implementation in healthcare. Many authors acknowledge that all these terms may be used interchangeably (17). A more recent term is 'evidence-informed' (-medicine, -practice and -healthcare). This is intended to acknowledge challenges around implementing evidence and whether it is more realistic to consider evidence informing practice rather than

Table 1.5 Use of 'evidence-based' terms in the titles of articles published in the *Journal of Clinical Epidemiology* (search performed on October 31 2021).

Term	PubMed	*Journal of Clinical Epidemiology*
Evidence-based medicine	4489	16
Evidence-based practice	3693	5
Evidence-based clinical practice	541	1
Evidence-based healthcare (or healthcare)	230	1
'Evidence-based clinical practice' without the word guideline(s)	73	0

Source: Puljak (16)/with permission of Elsevier.

being entirely based on the best available evidence. This has relevance in medical education and how these concepts are framed for healthcare students (18).

The ethical dimension

The aftermath of the Second World War saw several advances to protect the rights of individuals and populations. This extended to medical experimentation and research and will be discussed in Chapter 9. These included the Nuremberg Code, the Declaration of Helsinki, the Belmont Report and the publication in 1996 of Good Clinical Practice, now accepted as the universal standard for the ethical conduct of clinical trials (Table 1.6) (19). No study design should expect to receive approval or findings without ethical consideration. Yet, there remain issues of representation in research which continue to leave historically minoritised and underserved individuals and communities outside the benefits of the best available evidence, and this affects their healthcare. Ethical practice is not a fixed endpoint or destination but one, similar to liberty, self-determination and democracy, where vigilance is imperative. It is not enough to have ethical approval for research but also to ensure that plan is implemented and that the lives of all research participants and the populations whom they represent are all improved by it.

Table 1.6 Thirteen principles of the good clinical practice ethical, scientific and practical standards for research.

- Ethics – clinical trials should be conducted in accordance with the principles of the Declaration of Helsinki
- Trial risk versus trial benefit – risks and inconveniences of a proposed clinical trial should be weighed against the benefits for both participants and wider society. Anticipated benefits should justify the risks
- Trial participants – the rights, safety and well-being of trial participants are the most important considerations and take precedence over the interests of science and wider society
- Information on proposed medicine or intervention – the available information, clinical and nonclinical, about a proposed use of medicine or intervention should be sufficient to justify the proposed trial
- Good-quality trials – should be scientifically robust and explained in a clear, detailed protocol
- Compliance with the study protocol – the study protocol should be reviewed by an independent ethics committee prior to commencement of the study and should then be followed as described
- Medical decisions – all medical care, and all medical decision-making, for study participants should be made by a suitably qualified clinician
- Trial staff – all staff involved in the conduct of a clinical trial should be educated, trained and experienced in their required role. Where necessary, appropriate supervision should be provided
- Informed consent – participants should be given full information to make free and informed consent prior to commencement of the trial
- Clinical trial data – all data related to the trial should be recorded and stored to facilitate accurate reporting, interpretation and verification
- Confidentiality – any information which could identify participants should be protected, including their privacy
- Good manufacturing practice – products used in the investigation and/or intervention should be manufactured, handled and stored in compliance with good practice. They should be stored in accordance with the approved study protocol
- Quality assurance – systems should be implemented in the study design to ensure the quality of all aspects of the trial

Source: Adapted from Biddle K, Blundell A, Sofat N. Understanding clinical research: an introduction. Banbury: Scion Publishing Ltd, 2023 and https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-clinical-practice (accessed August 19 2024).

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