

What medical residents should know about clinical trials

JAN 11, 2021

Marc Zarefsky

Contributing News Writer

Medical science is a never-ending process of ideas and evolutions, making it an industry ripe for innovation. Whether it's a vaccine to protect against SARS-CoV-2, a pharmaceutical treatment or a new kind of medical device, in order for the innovation to see the public, it needs to go through clinical trials. That, of course, extends to trials of vaccine candidates, such as the ones that are generating so much hope.

Though not all residents will be involved in clinical trials throughout their medical career, most will have some sort of involvement in human subject research. An online AMA module helps residents better understand the ethics behind these types of studies.

“Understanding Clinical Trials” is one of more than 30 online courses available to medical and surgical residents at residency institutions that have subscribed to the AMA GME Competency Education Program.

Among the program's experts are several who contributed to the AMA's Health Systems Science textbook, which draws insights from faculty at medical schools that are part of the Association's Accelerating Change in Medical Education consortium.

Modules cover five of the six topics—patient care, practice-based learning and improvement, interpersonal and communication skills, professionalism, and system-based practice—within the Accreditation Council for Graduate Medical Education's core competency requirements. The sixth requirement, medical knowledge, is one that is typically addressed during clinical education.

In-depth look at clinical trials

To best prepare residents for the potential of participating in clinical trials, the AMA module outlines

the terms associated with clinical trials, the phases of drug testing, and traces the evolution of guidelines for ethical conduct of clinical trials. Residents are also given information about the organizations responsible for monitoring clinical trials and an explanation of what to know before beginning a clinical trial.

It is important to understand that innovation takes time, and there are four key phases in the development of a new product or procedure. Those phases focus on:

- | Safety and dosage ranges.
- | Short-term efficacy and side effects in the target population.
- | Effectiveness and adverse effects.
- | Post-approval studies.

Ethical conduct is incredibly important when it comes to clinical trials. There have been a number of policies and reports issued to outline and protect this conduct:

- | The Nuremburg Code established the concept of voluntary, informed consent.
- | The Declaration of Helsinki expanded on The Nuremburg Code.
- | The Belmont Report identified the principals that should inform any clinical research conducted on people.

Many residents will not get the opportunity to take part in clinical trials, but if you are one who will participate, it is important to know best practices and the types of questions you should be asking before joining a clinical research project.

Visit the AMA GME Competency Education Program for more information on this and other offerings or to request a demo.