COSMOS
Navigate the Compliance Universe

Compliance Today - April 2023

Darri L. Scalzo (darri.scalzo@ankura.com, linkedin.com/in/darri-scalzo-768947180/) is Senior Director at Ankura Consulting, Chicago, IL

Jane Hohn (jane.hohn@ankura.com, linkedin.com/in/jane-hohn-11320a19/) is Managing Director at Ankura Consulting, Chicago, IL.

Carla Starks (Carla.starks@ankura.com, linkedin.com/in/carla-starks-79ba5825/) is Senior Director at Ankura Consulting, Chicago, IL.

Implications of therapeutic misconception in clinical research

by Darri L. Scalzo, Jane Hohn, and Carla Starks

Clinical research is one of the most valuable efforts in advancing healthcare. Most healthcare professionals understand the importance of clinical research. Additionally, most healthcare providers involved in clinical research are aware of potential clinical risks in research involving human subjects. However, many may not recognize one of the most significant ethical concerns and risks inherent in clinical research, which occurs when patients also participate in research studies. Therapeutic misconception occurs when principal investigators, healthcare providers, and research participants cannot distinguish the differences between medical care and research. When a person agrees to participate in a clinical research study, their status changes from patient to research subject or participant. The care provided to research participants differs in some ways due to the research protocol requirements. Certain services required by the protocol are intended to further the clinical investigation aims. Because of the differences in the care and services provided, a patient's risks of participating in research may be higher than the risks of clinical care received outside a clinical trial. All parties involved in research—from the investigators to the research staff to the participants—must understand that the goals of medical care and research are different, as are the roles of a clinician and an investigator.

How does therapeutic misconception happen?

According to Anne Wisgalla and Joerg Hasford, "While standard medical care focuses solely on the benefit for the individual patient, the primary goal of clinical research is to obtain generalisable knowledge on a specific scientific question, for example, which treatment is superior for a given disease. Thus, clinical trials are primarily oriented towards the benefit for future patients."[1] However, due to limited available treatments, the line between standard medical care and clinical research may be blurred for certain diseases. For instance, many cancer and rare disease studies also offer routine clinical care services or provide procedures with therapeutic intent to the enrolled participants in the absence of conventional care. While these research studies primarily focus on discovering new and better treatment options, they also provide clinical care for the participants. This can lead to confusion and, ultimately, therapeutic misconception.