

Module 2 – Understanding the Research Process and R&D Decision Making

Post-market Research

The last type of research that is important for research advocates to understand is called post-market research. These are clinical studies of drugs and medical devices that are already approved.

Post-market research helps improve our understanding of how to use medical products in the real world. Some post-market research may be required by regulators as a way to better understand risks or to confirm efficacy for drugs or devices that receive expedited approvals.

Other post-market research supplements the data from clinical development with new information. For example, post-market studies might evaluate whether a treatment can reduce the need for other expensive healthcare, which can help sponsors get payers like insurance companies and national health systems to pay for the treatment. Post-market studies also can provide additional information about whether and how a treatment improves quality of life for the people who use it, and how it can be used in combination with other therapies that were not tested in the original development program.

Post-market research can also help answer important questions about the best ways to avoid or manage side effects caused by a treatment.

Post-market research is usually conducted by drug and medical device sponsors when regulators require it, or when new information can help gain acceptance of the treatment with doctors or payers.

When there is no requirement or business reason for sponsors to conduct post-market research, it might be done by government research agencies, academic investigators, and other physicians who do clinical research.

Research advocates speaking on behalf of their communities can help identify what questions need to be answered about new treatments during post-market research. Advocates also can improve post-market research in many of the same ways they help during clinical development, for instance by improving clinical trial design to increase participation.

This concludes Module 2: Understanding the Research Process and R&D Decision-Makers. Before you take the quiz, let's review some key points in the next video.