Project TEACH Online Education Course

Key Takeaways Module by Module

As a new Engaged Patient Partner, or EPP, you'll be progressing through the course and learning various key takeaways to help you become an effective advocate for yourself and others. To help you prepare for each module, or have a handy guide to review during the course, below are each module's key takeaways and lessons learned.

Module 1 – *Why This Matters: A Primer on Health and Empowerment*

- While cancer takes a heavy toll on all Americans, research shows that Black women are at greater risk than white women of developing or dying from certain cancers.
- By looking back at our history, we can better understand the impact and significance of racial injustices in the medical field. With that knowledge, we can work to correct those inequities for ourselves and future generations.
- Trials and treatments won't reflect you unless you get involved. It is critical Black women become partners in research.
- Through broad participation in clinical trials, you have the opportunity to impact potentially life-saving treatments by adding your experience to medical advancements.

Module 2 – *FDA 101: The Food and Drug Administration*

- The FDA is a Consumer Protection Agency that is responsible for reviewing new medical products before they can be marketed.
- The FDA regulates a wide spectrum of products, including all prescription drugs and medical devices.
- When a drug is approved by the FDA it is deemed to be "safe and effective." This does not mean that the drug is free of risk, instead it means that, in the FDA's view, the drug's benefits outweigh its risks for the patients it is intended to treat.

Module 3 – *Bench to Bedside: Medical Research and Drug Development*

- Drug discovery and the basic science that supports it require a vast amount of time and resources.
- When a new drug is approved, there is still much we don't know about it, particularly related to long-term effects, rare adverse events, and impacts in subgroups of patients.
- FDA Review is just one small part of a years-long process from discovery to market.

Module 4 – *Regulatory Flexibility: Paths to FDA Approval*

- FDA does not have a one-size-fits-all" approach to drug approval; instead it has a host of programs to expedite therapies for rare and serious life-threatening diseases.
- FDA's expedite programs reflect Regulatory Flexibility – the act of balancing competing interests such as Speed vs. Safety in the name of advancing and protecting the public health.

Module 5 – *Advocacy in Action: Make Your Voice Heard*

- When Patient Advocates get involved and are armed with the knowledge of the FDA regulatory environment, the clinical trial process, and an understanding of how the system impacts them, they can have a profound impact on the way treatments are developed.
- At various points in the drug development process, you can work to make sure patients are getting the best treatments possible by serving on an IRB, an FDA Advisory Committee, or advocating for improvements in clinical trials.