The Investigator Training Program (ITP) is an educational program designed by Pfizer to support clinical trial investigators. It aims to improve the many skills required for the planning, conduct, and reporting of clinical trials. The ITP provides a forum in which all personnel involved in clinical trials can share their experiences and receive practical advice on trial organization and execution. The program examines the entire trial process, from the planning stages through to trial close-out activities, and provides practical recommendations for increasing the efficiency of clinical trial conduct at investigative sites.

The ITP is divided into a comprehensive series of five modules focusing on all of the essential topics for running a successful clinical trial, including patient recruitment, data management, and overall planning. Two additional modules may be presented focusing on drug development and additional regulations.

Led by experienced professionals, each module comprises presentations, discussions and group tasks, as well as complementary handouts and workbooks. Other components of the course include a DVD presentation and an interactive CD-ROM quiz designed to test the participant's knowledge.

ITP Modules:

- Module 1:
  Planning and preparation
- Module 2:
  Recruitment and enrollment
- Module 3:
  In-trial procedures
- Module 4
  Safety in clinical trials
- Module 5
  Monitoring, audits, inspections, and publication

Additional Modules:

- Drug Development Process
- Additional Regulations

Key learning objectives have been established for each module with the expectation that each participant should be able to meet the following objectives after attending the course.

Module 1: Planning and preparation
1. Explain their responsibilities and those of their team
2. Identify the resources required to conduct a clinical trial
3. Name all of the parties they will need to interact with prior to and during a clinical trial
4. Initiate all processes that must be in place prior to the first subject visit

Module 2: Recruitment and enrollment
1. Plan effective recruitment and enrollment activities
2. Identify when these activities can occur
3. Initiate all those activities required during recruitment and enrollment
4. Conduct the informed consent process in compliance with applicable regulations

Module 3: In-trial procedures
1. Identify required documents and explain how and where they need to be retained
2. Explain the steps involved in data management
3. Implement the processes required for investigational product and specimen handling
4. Set up strategies to maximize subject retention and compliance

Module 4: Safety in clinical trials
1. Recognize and define essential safety terms
2. Describe the processes involved in AE reporting
3. Identify the roles and responsibilities of all those involved in the AE reporting process
4. Explain the importance of and comply with safety reporting requirements

Module 5: Monitoring, audits, inspections, and publication
1. Recognize the importance of quality in clinical trials
2. Describe the role of the monitor
3. Manage audits and inspections effectively
4. Explain the key issues surrounding ownership of data and publication

The drug development process
1. Describe the steps involved in clinical development
2. Explain the scope and intent of guidelines and regulations that govern clinical research, particularly the ICH–GCP
3. Differentiate between the investigator's and the sponsor's responsibilities in clinical research

Additional regulations governing clinical trials
Key learning objectives
By the end of this module the participant should be able to:
1. Recognize how local regulations in addition to ICH–GCP govern the conduct of clinical trials
2. Determine which regulations apply to the participating global multi-center registration trials
3. Explain and apply applicable privacy regulations pertaining to clinical research