Clinical Development 401: Phase IV

50-MINUTE ONLINE COURSE | LEVEL 3

SUGGESTED PREREQUISITES: CLINICAL DEVELOPMENT 101, CLINICAL DEVELOPMENT 201, CLINICAL DEVELOPMENT 301: PHASE II/III

OVERVIEW

Clinical Development 401: Phase IV surveys the ongoing post-approval clinical assessments required by regulatory agencies. Learn how drug risk management is accomplished through detecting, assessing and reporting adverse effects using real-world data.

Five Takeaways:

1. Purpose of Phase IV studies.
2. Key limitations of pre-market studies and why post-market studies are an important complement to Phase I-III studies.
3. Role of regulatory safety information reporting programs including MedWatch in US and EudraVigilance in Europe.
4. In-depth look at Real-World Data (RWD) and Real-World Evidence (RWE) and their impact on safety.
5. Identification of important real-world data sources.

AGENDA

- **Phase IV Studies** explains the purpose of Phase IV studies and takes an in-depth look at numerous study examples including long-term safety and pharmacoeconomic studies.
- **Pharmacovigilance and Post-Marketing Safety Follow-Up** explains important regulatory terms such as pharmacovigilance, safety signal, signal detection and signal analysis. The purpose of regulatory safety information reporting programs such as MedWatch in US and EudraVigilance in Europe is thoroughly reviewed. The section ends by describing the post-marketing regulatory actions that may be taken in response to emerging knowledge of safety risks.
- **Real-World Evidence** discusses how regulatory authorities, such as FDA, are increasingly using real-world evidence to improve regulatory decisions. Important sources of real-world data are identified.