

After the green light: Evaluating drugs in Phase IV studies

Bikash Ranjan Meher, Archana Mishra

Abstract:

The drug development process is lengthy and complex and Phase IV is a crucial phase within it. Phase IV studies are conducted after a drug has been approved by regulatory agencies to further evaluate its safety, efficacy, usefulness in special populations, new indications, and new formulations. There are many examples of Phase IV studies; not all Phase IV studies are postmarketing surveillance (PMS) studies, but every PMS study is an example of a Phase IV study. Phase IV studies are imperative as they evaluate the drug's effectiveness and performance in real-world clinical practice and premarketing trials have some inherent limitations. Phase IV studies can be observational or interventional studies, depending on the objectives of such studies. A drug utilization study is a Phase IV study; similarly, a registry is also an example of a Phase IV study.

Keywords:

Effectiveness, generalizability, Post-marketing safety surveillance, real-world study