

# Clinical Trials

## Nursing roles during the approval process and pharmacovigilance of biosimilars

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**BACKGROUND:** The development of biosimilars is occurring more rapidly as patents on biologics expire. Oncology nurses will have an integral role in the new era of biosimilars regarding administration and education.

**OBJECTIVES:** The purpose of this article is to review the role of the oncology nurse during biosimilar clinical trials, including regulatory guidelines, comparability exercise, clinical trial designs, and extrapolation of clinical trial data. This article also reviews pharmacovigilance.

**METHODS:** A literature search was performed using various databases, and U.S. regulatory agency websites were searched for guidelines.

**FINDINGS:** The role of the oncology nurse during biosimilar clinical trials includes assessment, monitoring, and reporting of adverse drug reactions associated with a biosimilar. Oncology nurses have key roles in pharmacovigilance of biosimilars, particularly in tracing, monitoring, and accurate reporting of adverse events associated with a specific biosimilar. Oncology nurses and patients must be educated on the proper reporting of adverse events.

### KEYWORDS

biosimilar; oncology nurse; pharmacovigilance; adverse drug reactions

### DIGITAL OBJECT IDENTIFIER

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**BIOSIMILARS ARE USED FOR THE SAME PURPOSE** and at the same dose as the reference biologic (Weise et al., 2012). As patents for biologic drugs expire, biosimilars in development are integrated into clinical practice (Kim, Ogura, Kwon, & Choi, 2017; Nabhan & Feinberg, 2017). The purpose of this article is to review biosimilar clinical trials, including regulatory guidelines, comparability exercise, clinical trial designs, and extrapolation of clinical trial data for biosimilar indications. In addition, this article provides a comprehensive review of biosimilar pharmacovigilance, including patient safety monitoring, traceability, counterfeit monitoring, and interchangeability. Lastly, this article explores the role of the oncology nurse during clinical trials, the pharmacovigilance process, and patient education.

### Clinical Trials

To obtain regulatory approval, a biosimilar in development requires evidence of high similarity. This evidence is more extensive than evidence required for a small molecule in a generic drug but less extensive than evidence required for a biologic agent. Because of the inability to control manufacturing conditions of the pharmaceutical companies, a biosimilar cannot be a perfect replication of the reference biologic (Bui & Taylor, 2014). For a biosimilar to be approved, there must be evidence that it is highly similar to and have absence of significant clinical differences in safety, purity, and potency to the reference biologic. Regulatory guidelines put forth by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and World Health Organization (WHO) compare the analytical and clinical evidence of the biosimilar manufacturer (Camacho, Frost, Abella, Morrow, & Whittaker, 2014; Schellekens, Smolen, Dicato, & Rifkin, 2016). Preclinical activities to demonstrate biosimilarity include analytical comparisons of the biologic and biosimilar evaluated through comparability of physiochemical characterization and in vitro/in vivo studies of pharmacodynamic bioactivity. Once biosimilarity is established, clinical trials are designed to determine the safety, efficacy, pharmacokinetics, and pharmacodynamics of the product (Bui & Taylor, 2014; Jarrett & Dingermann, 2015; Schellekens et al., 2016). Data from clinical trials are then extrapolated to indications for use in practice.

### Regulatory Guidelines for Biosimilar Evaluation

Guidance for the assessment of biosimilarity has been published by the FDA and EMA for the United States and Europe, respectively. Both sets of guidelines include a stepwise approach beginning with comprehensive in vitro