Early stage development of biosimilars determines structural, functional and pharmacokinetic similarity, which are critical attributes of the process.

**BIOSIMILARS**

**PRE-PHASE I**  
**STRUCTURAL AND FUNCTIONAL ANALYSIS**  
The protein structure of the reference product is determined through sophisticated analytical techniques and in-vitro biological tests. Reverse engineering is used to enable production of a similar product.

**NONCLINICAL ASSESSMENTS**  
Demonstrating that any potential small differences in the molecules will not produce biologically meaningful differences in responses.

**PHASE I**  
**CLINICAL PHARMACOLOGY**  
Pharmacokinetics (PK) analyzes how a medication is processed. Pharmacodynamics (PD) demonstrates the medication’s effects on the body.

**COMPARATIVE CLINICAL TRIALS**  
Clinical trials compare the safety and efficacy profile of the biosimilar to the reference product.

**NOVEL BIOLOGICS**  
In the development of novel biologics, the most critical step is clinical trials.

**SMALL MOLECULE GENERICS**  
In the development of small molecule generics, comparative clinical trials are not required.

For more information on Pfizer Biosimilars go to: [www.pfizerbiosimilars.com](http://www.pfizerbiosimilars.com)