

Integrated Health Systems Outcomes Coalition

AmerisourceBergen

Biosimilar Comparison to Reference Product Tool

Parameter	Reference Product	Biosimilar for Comparison
Domain 1: Regulatory Status		
What are the FDA-labeled indications for the reference product and biosimilar product?		
Domain 2: Clinical Data		
For which disease states have the reference product and biosimilar product been studied?		
What is the FDA approved dosing, by indication, for each product?		
Domain 3: Safety Data		
What are the most commonly reported adverse effects and associated frequencies?		
What are the most severe reported adverse effects and associated frequencies?		
How common are serious immunogenic reactions or anti-drug antibody development during use of the biosimilar or reference product?		
Domain 4: Pharmaceutics		
Are there any differences in commercially available dosage sizes or strengths between the biosimilar and reference product? If so, include.		
Are there any clinically significant differences in formulation or excipients of the biosimilar versus the reference product? If so, include.		