Elevating the Patient Voice in Generic Drug and Biosimilars Development:

Biosimilar Developer's Perspective in brief

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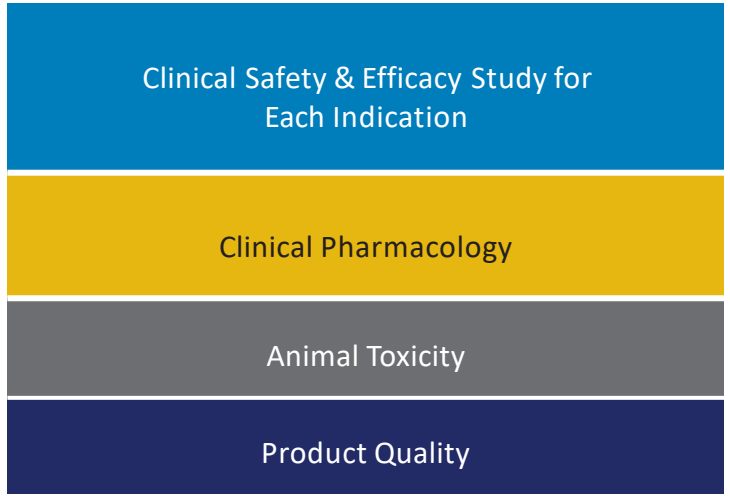
Streamlined Biosimilar Development

Increased efficiency with the same benefits and risks as RP

New Biologic / Reference Product

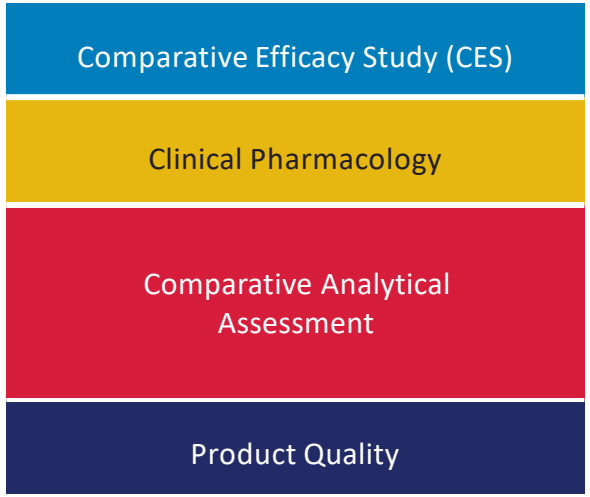
Goal: Establish safety & efficacy of a new product
Experience: ~ post marketing data



Biosimilar

Goal: To demonstrate biosimilarity to a reference product based on comparative assessments

2005



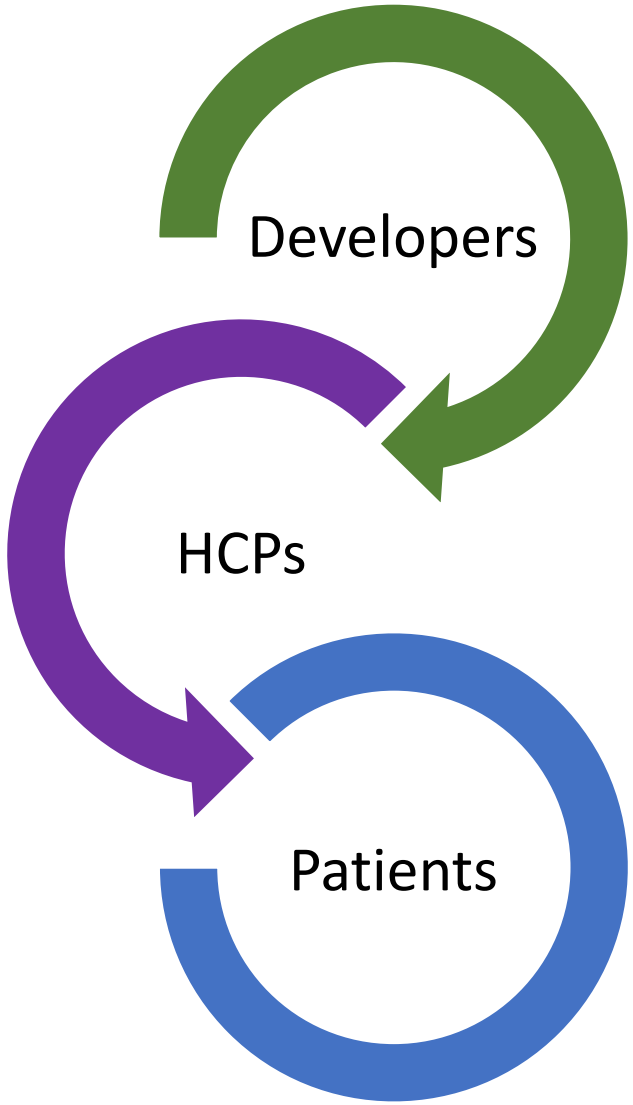
Goal for Today

Accumulation of **two decades** of global development experience

Source: Figure modified from FDA BsUFA III Research Roadmap, January 2025; accessed June 2025 - ***BsUFA III Regulatory Research Pilot Program: Revised Research Priorities***

Goal of Biosimilar Pathway is Patient Access:

Where is the patient voice in development?



What ***can*** biosimilar developers do?

- Education
- Storage and Handling
- Device

Where are the entry points for the patient voice?

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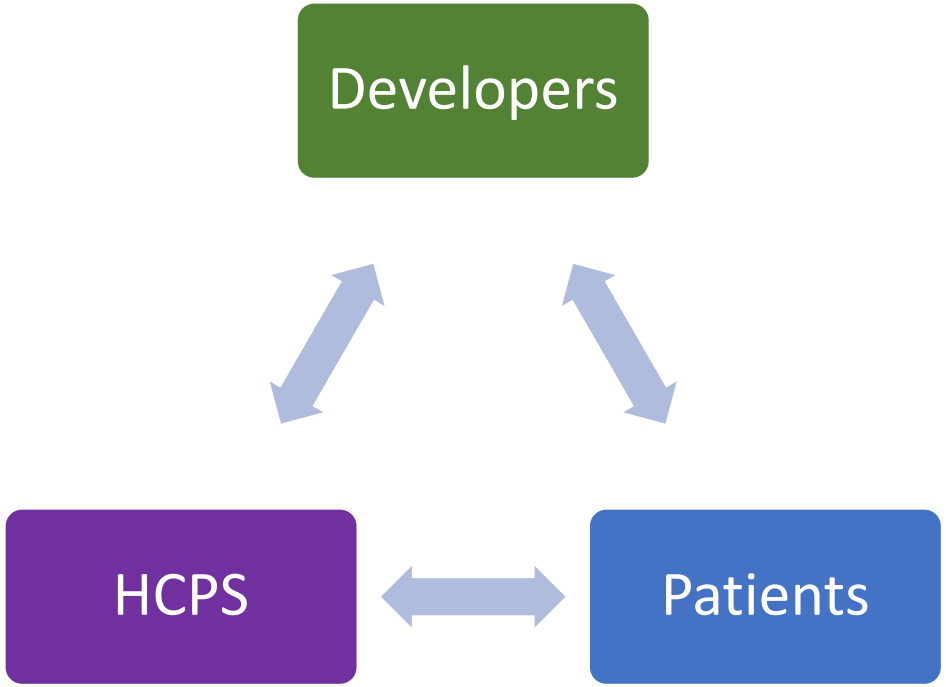
- Faster patient access via competition following HA acknowledgement lack of scientific basis for using a CES
- Biosimilar sustainability through policy change to incentivize filling the ‘biosimilar void’
- Patient-focused changes to biosimilars through 505(b)(2)-like pathway



Thank you!

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