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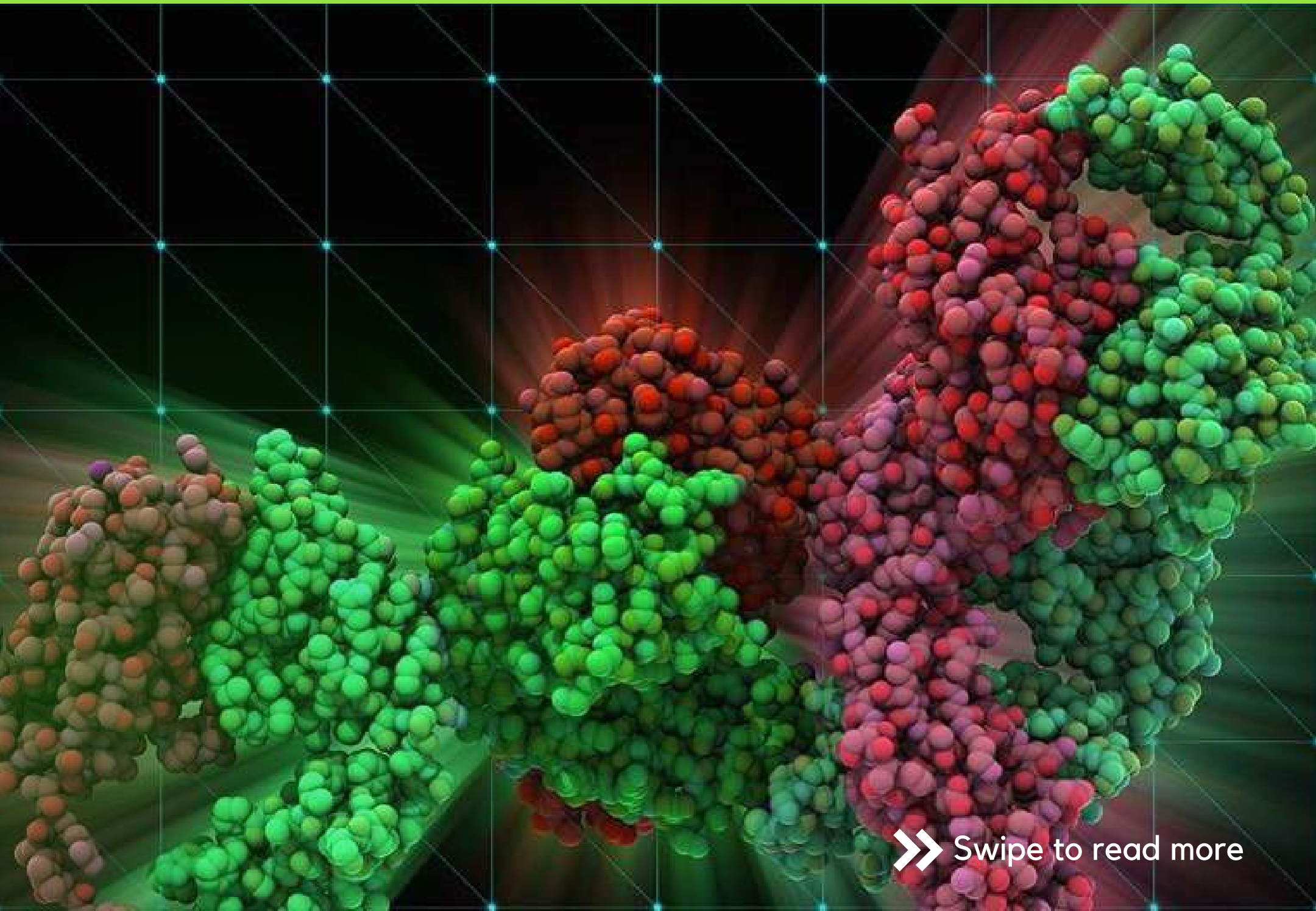
Rise of Biosimilars: The Next Frontier in Affordable Drugs



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To date, Biosimilars have been used in over 364 Mn days of patient care but do we really know them that well?

Biosimilars have been created to **mimic an already approved biologic drug** called the reference product

These are intended to play a role parallel to the role generic drugs play wrt innovator small molecules. Entering the market after the monopoly period, they are **intended to drive down prices through competition**

Globally 475 organizations are actively developing **1,015 biosimilars** for various therapeutic areas such as cancer, rheumatoid arthritis and neutropenia

Sources: FDA, HealthAffair, Optum

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Biosimilars are comparable yet very different from Generics. Here's how

Biosimilars	Generics
Similar to and not identical to reference product	Bioequivalent and identical to reference product
20-30% discount over reference product	80-90% discount over reference product
$100 - $200 Mn in development cost	$1 - $5 Mn in development cost
8-10 yrs development timeline	3-5 yrs development timeline
No interchangeability or automatic substitution	Interchangeability with reference product
Extremely sensitive to storage and handling	Extremely stable compounds that are simple to store
May elicit immunogenic response	Almost no immunogenic potential

Source: GaBI Journal

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Biosimilar market size is expected to surpass $100 Bn mark by 2028

CAGR of ~35% (2022-2028)

- Increase in disease prevalence and need for cost-effective care are the key drivers of biosimilars market
- Rising approvals of biosimilar products are also fuelling their market growth

Sources: Vantage Market Research, Cardinal Health

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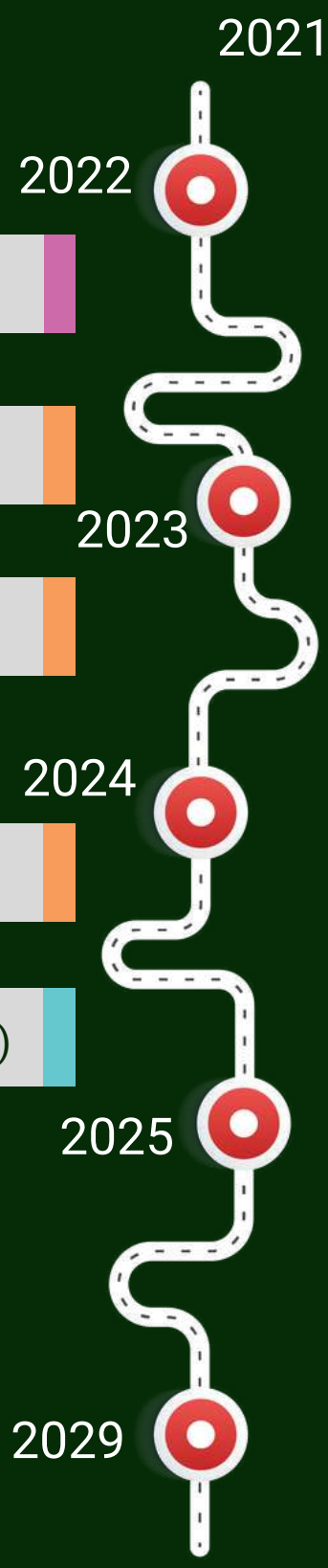
Timeline of new and upcoming biosimilar launches in the US

Reference Biologic (Molecule)	#

Number of biosimilars either in phase III trials, pending FDA approval or FDA approved

Diabetes · Bone health · Immunology · Ophthalmology · Supportive Care



2021	**Lantus** (insulin glargine)	4
2021	**NovoLog** (insulin aspart)	2
2021	**Neulasta onpro** (pegfilgrastim)	3
2022	4 **Lucentis** (ranibizumab)	
2022	2 **Actemra** (tocilizumab)	
2022	5 **Stelara** (ustekinumab)	
2023	**Humira** (adalimumab)	10
2023	**Eylea** (aflibercept)	7
2024	1 **Simponi** (golimumab)	
2024	5 **Prolia/Xgeva** (denosumab)	
2025	**Soliris** (eculizumab)	1
2029	**Enbrel** (etanercept)	3

Source: Cardinal Health

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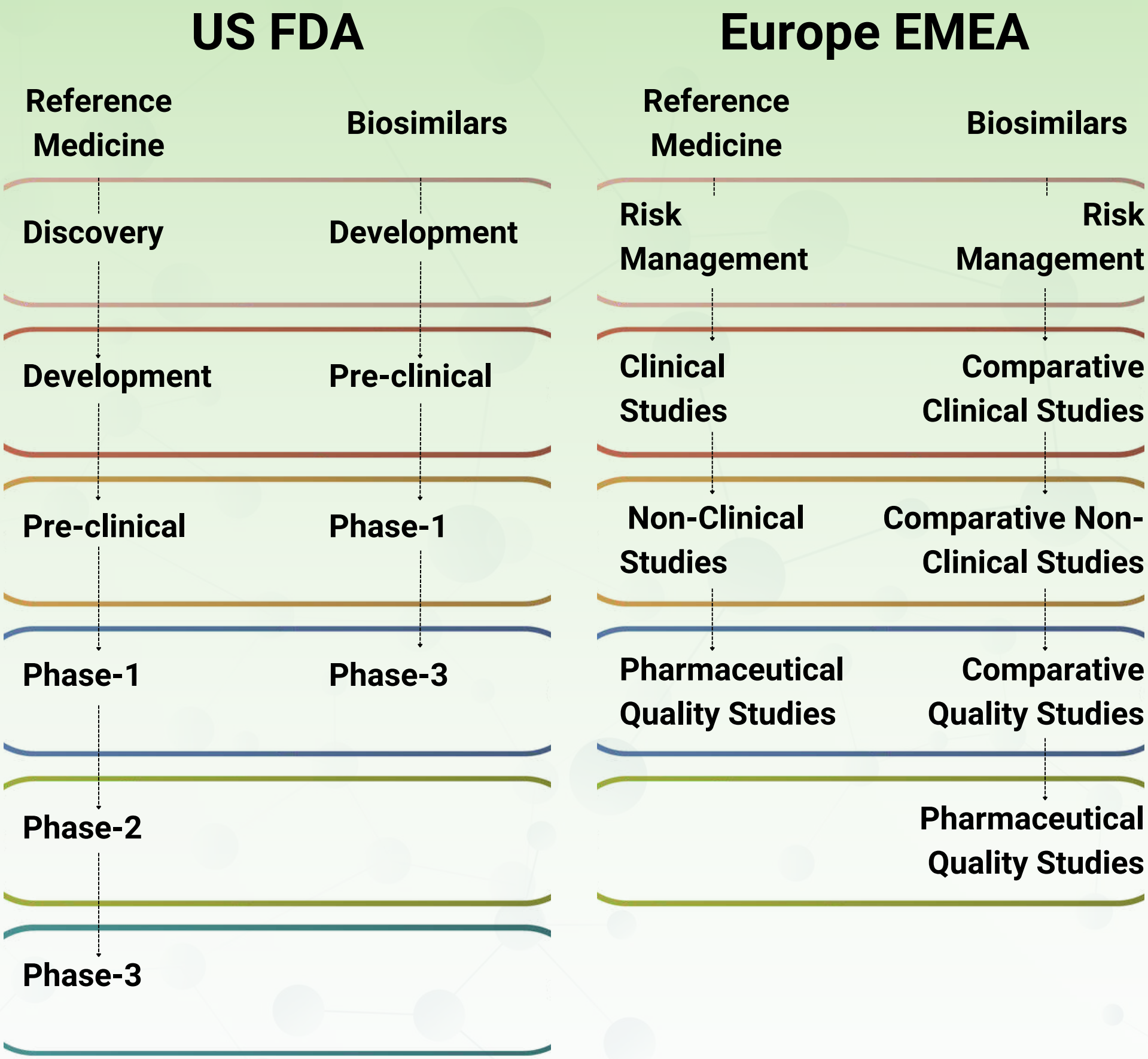
Regulatory Angle: Biosimilar approval process differs in both US and Europe



Sources: European Medicines Agency, Clinical Options

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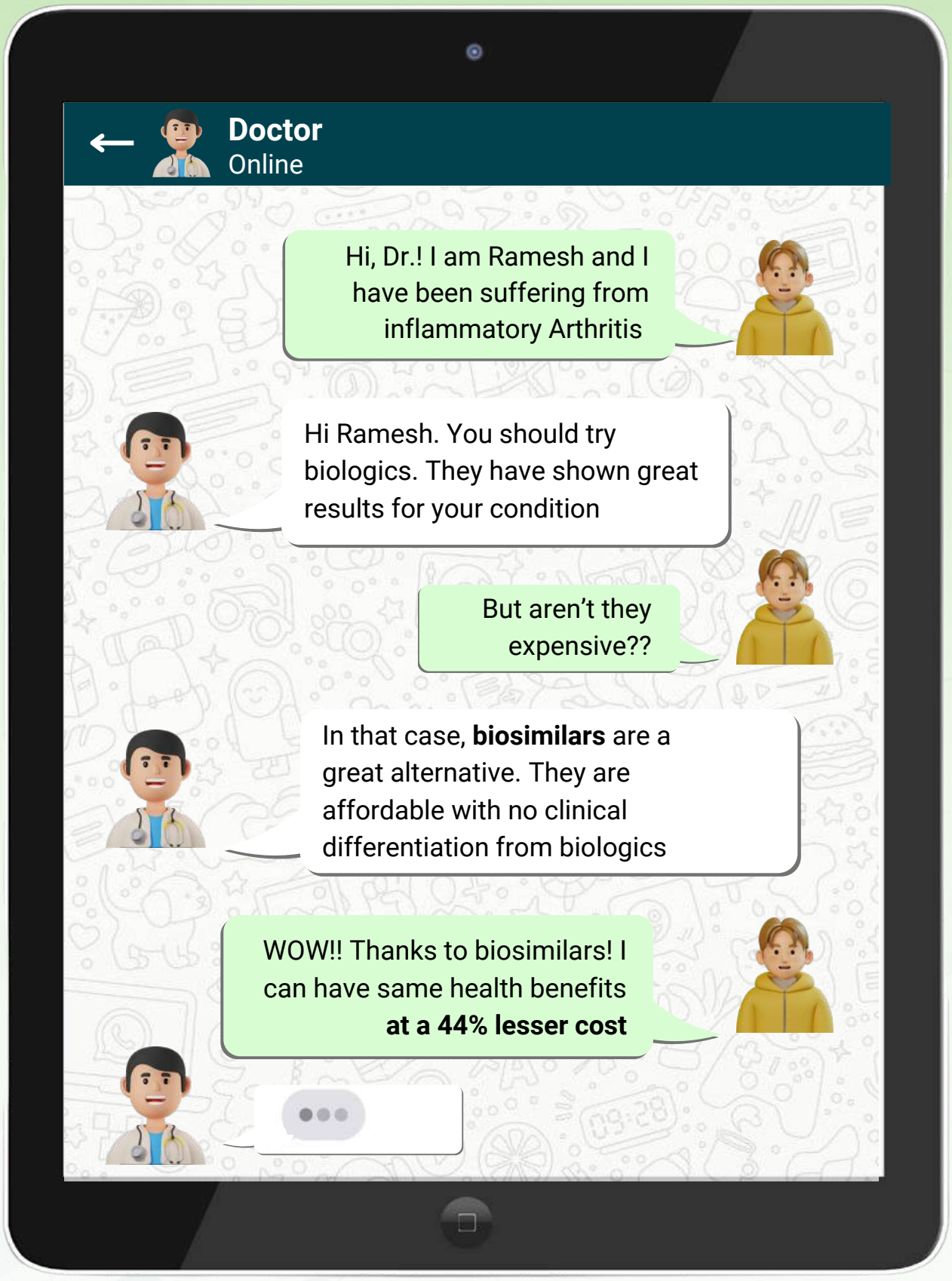
Biosimilars to generate $383 Bn in savings over the next 4 years!



- **Despite accounting for only about 2% of all prescriptions in US, biologics account for about 40% ($120 Bn) of all prescription drug spending**
- **Biosimilars are typically launched with initial list prices that are 15-35% lower than list prices of their reference products**

Sources: Rand, Seminars in Arthritis and Rheumatism

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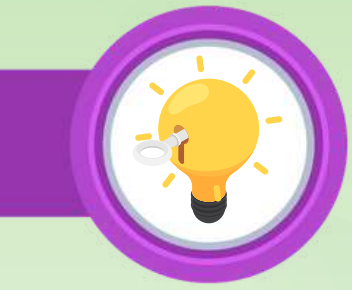
What challenges are inhibiting biosimilars from achieving their full potential?

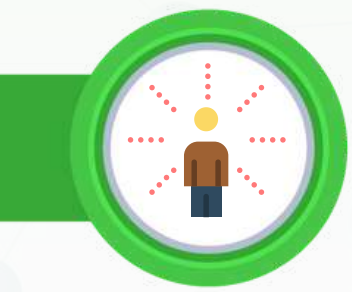


Intellectual property and patent issues: Original drug manufacturers give a strong competition to biosimilar manufacturers to enter the market

Regulatory hurdles: Regulatory process for approving biosimilars is often more complex and time-consuming than for traditional small-molecule drugs

Difficulty in pricing: Complexity and variety of pricing and reimbursement models across different markets make it difficult for biosimilar manufacturers to accurately price their drug

Interchangeability between biosimilars and reference products: Switching patients repeatedly between reference drugs and biosimilars can create significant issues and confusions



Perceptions and awareness: Lack of awareness around the safety & efficacy of biosimilars leads to a reluctance among patients and healthcare providers to switch to biosimilars

Source: Drug Patent Watch

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India might gain up to 30% share of global biopharma production market by next decade

Large-scale Involvement

100+ Indian biopharmaceutical companies are engaged in manufacturing and marketing of biosimilars. Biosimilar is called as “similar biologics” by Indian regulatory agencies

1st Biosimilar in 2000

First biosimilar in India was approved in the year 2000, a vaccine for hepatitis B, 10 years ahead of FDA’s first biosimilar approval

Economic Impact

Association of Biotechnology Led Enterprises (ABLE) in India estimates that economic impact of biologics will expand at a 22 % CAGR to $12 Bn by 2025

Worldwide Market Leaders

In the pharmaceutical sector, India has ranked tenth globally in terms of value and ranked third in terms of volumes

Sizeable Opportunity

The huge volume of biosimilars approved in India in last 5 years represents a significant scope for these drugs

Source: AbleIndia

Key players India vs Global

Indian Players

Wockhardt
Reliance
INTAS
LUPIN
Dr. Reddy's
Emcure
SUCCESS THROUGH INNOVATION
ipca
A dose of life
Cipla
Glenmark
A new way for a new world
zydus
Dedicated To Life
Lilly
Biocon

Global Players

FRESENIUS KABI
Boehringer Ingelheim
NOVARTIS
GEDEON RICHTER LTD.
APOTEX
ADVANCING GENERICS
mabion
HEALTHCARE CELLTRION
MERCK
Coherus
BIOSCIENCES
Pfizer
Biogen
AMGEN
FUJIFILM

Sources: Economic Times, Clinical Trials Arena