

Biosimilars Overview

Quick Start Guide

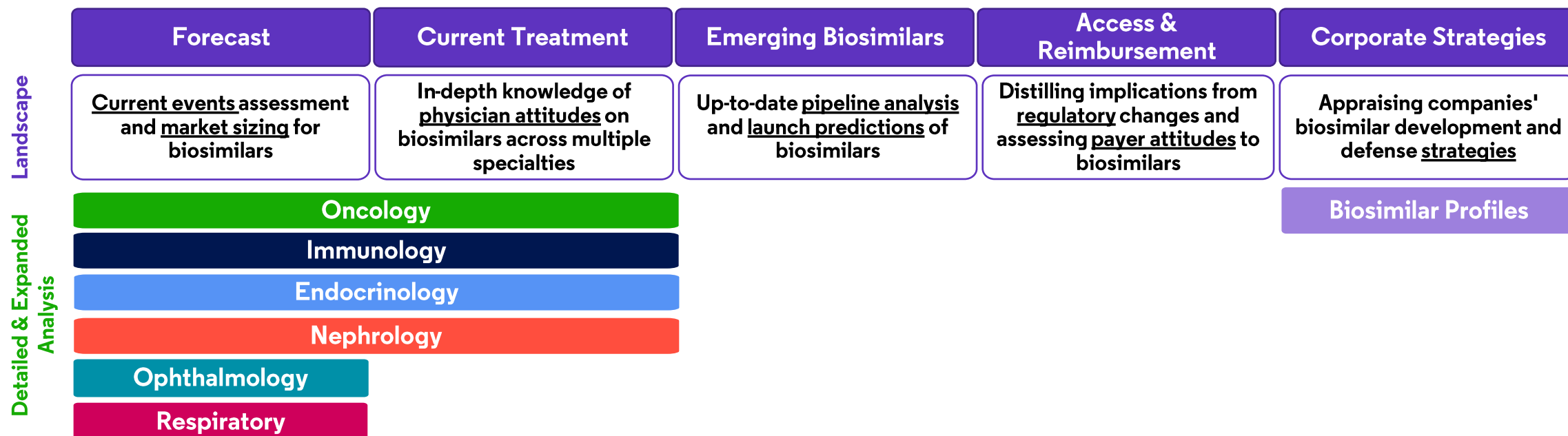
July 2022



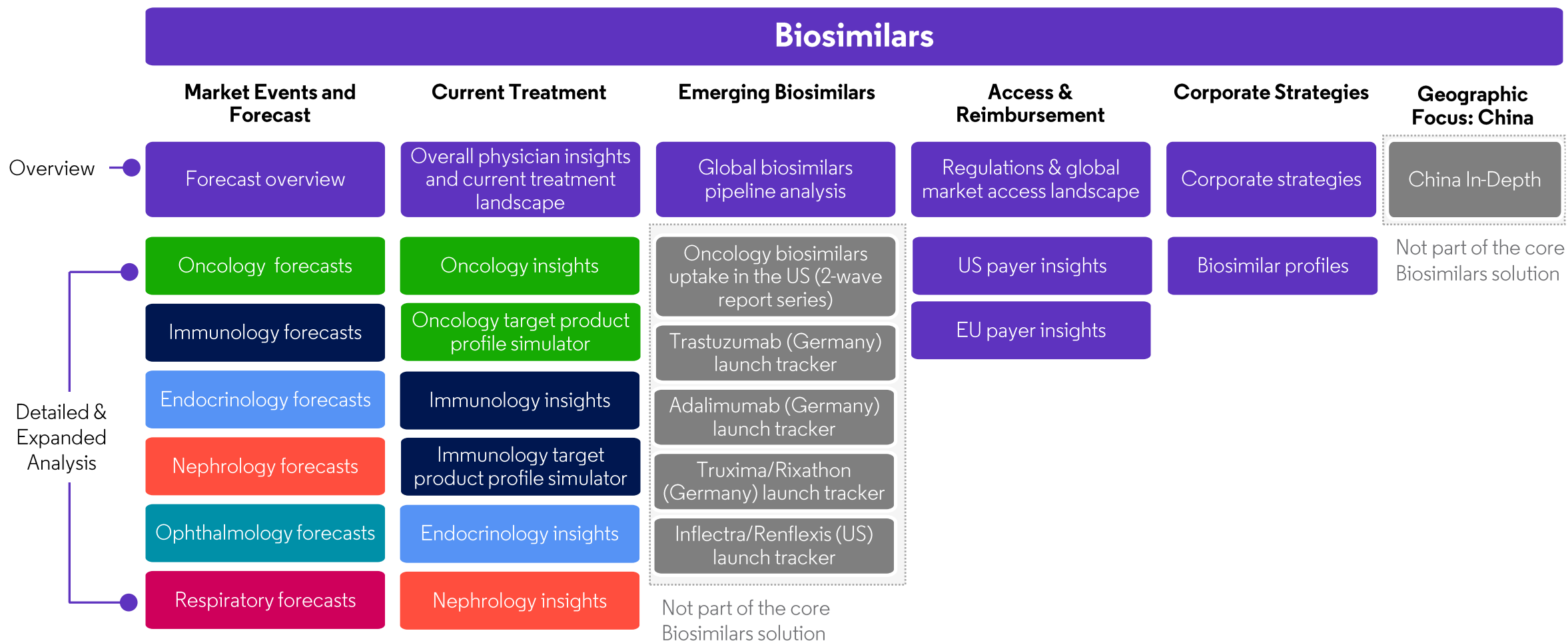
What is Biosimilars?

Biosimilars is part of a suite of Clarivate applications on our Disease Insights platform. It sizes the potential opportunity and evaluates the disruptive effects of biosimilars could have on the pharma industry. Biosimilars is based on surveys of over 500 physician specialists, 60 US payers, and country-specific interviews with 10 EU5 payers.

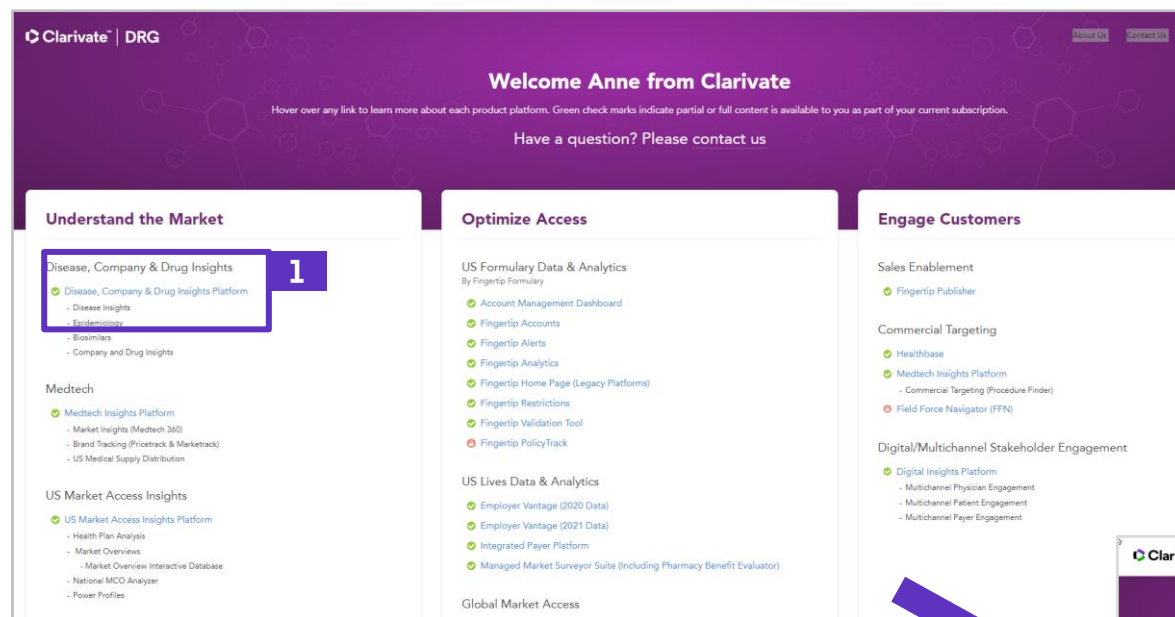
- **Landscape** provides insights that are critical to understanding the biosimilars landscape for all therapeutic areas.
- **Detailed & expanded analysis** provides in-depth analysis within select core research modules for the four leading therapeutic areas for biosimilars.



Summary of Biosimilars on Insights Platform

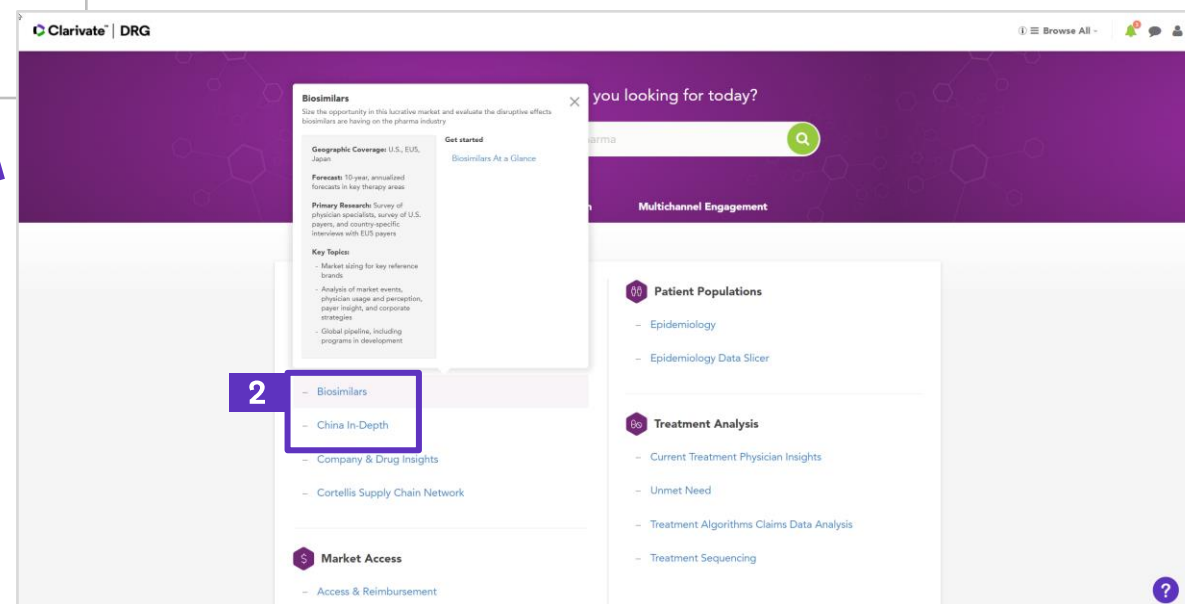


Get started using Biosimilars



1.
Click on the “Disease, Company & Drug Insights” link to launch the Disease, Company & Insights platform.

2.
Click Biosimilars link and then select Biosimilars At a Glance link.



Biosimilars Report At a Glance

Clarivate™ | DRG Biopharma Search within Biopharma

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At a Glance Market Events and Forecast Current Treatment Emerging Biosimilars Access & Reimbursement Corporate Strategies Geographic Focus: China Meet The Team

Available Content

MARKET EVENTS AND FORECAST

- Overview
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- Overview of Biosimilars Forecasts
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CURRENT TREATMENT

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- Biosimilar Target Product Profiles (Oncology)
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EMERGING BIOSIMILARS

- Overview
- Emerging Biosimilars Landscape
- Special Topics: Oncology Biosimilars in the United States - Wave 2

Market Summary

Key Industry Events

2022

JAN

- Samsung Bioepi's regulatory submission for higher concentration (100 mg/mL) version of previously approved adalimumab biosimilar, Hadlima (50 mg/mL), accepted in the United States.
- EirGenix / Sandoz's regulatory submission of their trastuzumab biosimilar, EG12014, accepted in Europe.
- Safety review of Lannet / HEC's insulin glargine biosimilar IND application completed in the United States.

FEB

- Regulatory submission for Nichi-Iko Pharmaceutical / mAbxience's bevacizumab BS intravenous infusion 100 mg/400 mg approved in Japan.
- Regulatory submissions for interchangeable adalimumab biosimilars developed by Pfizer (Abrilada) and Alvotech (ATV02) accepted in the United States.

MARCH

- Regulatory submission for Amneal's filgrastim biosimilar, RELEUKO, accepted in the United States.

Emerging Biosimilars

Global Biosimilars Pipeline by Class

631

Legend: Oncology MAb, Ophthalmology MAb, Parathyroid hormone, TNF-α inhibitor, Immune biologic (non TNF-α inhibitor), Others, G-CSF, Insulin, Unspecified, ESA

Performance of Biosimilars

Biosimilars Sales by Class in Major Markets in 2020

Access & Reimbursement

U.S. Payer Discount Expectations for Biosimilars in 2021

What's new? All Updates

UPDATED CONTENT

Market Events and Forecast - Clarivate publishes new findings on the biosimilars ophthalmology market in the United States, EU5, and Japan. 31 Mar 2022

UPDATED CONTENT

Market Events and Forecast - Clarivate publishes new findings on the biosimilars respiratory market in the United States, EU5, and Japan. 31 Mar 2022

UPDATED CONTENT

Market Events and Forecast - Clarivate publishes new findings on the biosimilars endocrinology market in the United States, EU5, and Japan. 31 Mar 2022

UPDATED CONTENT

Market Events and Forecast - Clarivate publishes new findings on the biosimilars nephrology market in the United States, EU5, and Japan. 31 Mar 2022

UPDATED CONTENT

Market Events and Forecast - Clarivate publishes new findings on the biosimilar immunology market in the United States, EU5, and Japan. 31 Mar 2022

1. The At a Glance page displays all of the modules available within Biosimilars:

- Market Events and Forecasts
- Current Treatment
- Emerging Biosimilars
- Access & Reimbursement
- Corporate Strategies

These modules can be accessed via the tabs in the report banner or via the Available Content directory.

Biosimilars Market Events & Forecast Module

Clarivate™ DRG Biopharma Search within Biopharma

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Overview of Biosimilar Forecasts

Last updated 30 March 2022

This section provides a top-level overview of biosimilar erosion in the seven major pharmaceutical markets under study (United States, France, Germany, Italy, Spain, United Kingdom, and Japan) for all biologics included in the biosimilars forecasts over the 2020-2030 forecast period.

Key Drivers and Barriers to Biosimilars in the Major Markets

Key Drivers of Biosimilars in the Major Markets	Key Barriers to Biosimilars in the Major Markets
<ul style="list-style-type: none"> Looming biologics' patent cliff (a term that refers to the abrupt drop in an originator product's sales upon patent expiry). Pressure on healthcare systems to contain healthcare costs. Technological advances in biologics analytics and manufacturing, including lower-cost production. 	<ul style="list-style-type: none"> Complexity of development and changing regulatory requirements. Physician caution adopting biosimilars, particularly for patients already receiving the reference brand. Relatively small savings compared with small-molecule generics. A current lack of pharmacy-level substitution for biologics. Limited presence of cohesive payer strategies to drive uptake of biosimilars at a national level (notably in the United States).

Last updated: March 2022
Source: Clarivate

Total Major-Market Reference Brand and Biosimilar Market Shares: 2030

100

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Meet the Team

Hamzah Aideed, M.Sc.
Manager

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1. This module provides market events and biosimilars forecasts overall and in key therapy areas of oncology, immunology, nephrology, endocrinology, respiratory, and ophthalmology. Chapters include:
 - Market event analysis
 - Overview of biosimilars forecasts – size current market and assess historical sales performance. Includes forecasts at the geographic and drug class level.
 - Therapy area forecasts– includes quantitative market forecasts for over 40 brands and their biosimilars with sales, market share, patient share across US, EU5, and Japan markets.

Biosimilars Market Events & Forecast Module (cont.)

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Last updated: March 2022

Source: Clarivate

Total Major-Market Reference Brand and Biosimilar Market Shares: 2030

100

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Manager

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1. Select Table of contents sections or enter word search term in search field to locate topic of interest. Word matches will be highlighted in yellow.

2. Reports can be downloaded by selecting the reports of interest. The accompanying PowerPoint diagrams and Excel tables can be downloaded as separate documents.

Biosimilars Current Treatment Module

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Current Treatment: Biosimilars Landscape Report 2021

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Biosimilar Target Product Profiles (Oncology)

Biosimilar Target Product Profiles (Immunology)

Current Treatment: Biosimilars Landscape Report 2021

Last updated 24 November 2021

DISPLAY All 0 0 1

Current Treatment: Landscape Biosimilars

Analyst: Anushree Dhar, M.Sc.
Published: December 2021

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Anushree Dhar

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Our analytic experts harness the

1. The Current Treatment Landscape provides overarching physician perspectives on biosimilars from ~540 physicians across 6 specialties in the US and EU

2. Therapy area-specific analysis of physician-reported current and anticipated use of biosimilars, drivers and barriers to biosimilar use, and how physicians are choosing between biosimilars.

Biosimilars Target Product Profiles

1. Select Target Product Profiles (TPP) for Oncology and Immunology. TPP uses conjoint analysis methodology to determine trade-offs across key biosimilar attributes that surveyed oncologists are willing to make when considering which biosimilar to prescribe.

2. Download the Target Product Profile (TPP) Simulator tool to run market simulations

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Biosimilar Target Product Profiles (Oncology)

Target Product Profiles

Assessing Biosimilar Development Opportunities

Target Product Profile Methodology

Attribute Importance and Part-Worth Utilities

Conjoint Analysis-Based Simulation of a Market Scenario

Biosimilar Target Product Profiles (Immunology)

1

Assessing Biosimilar Development Opportunities

Target Product Profiles

Assessing Biosimilar Development Opportunities

Target Product Profile Methodology

Attribute Importance and Part-Worth Utilities

Conjoint Analysis-Based Simulation of a Market Scenario

Target Product Profiles

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Last updated 23 October 2021

Assessing Biosimilar Development Opportunities

To determine the trade-offs across key biosimilar attributes that surveyed medical oncologists are willing to make when considering which biosimilar to prescribe, we included an adaptive choice-based conjoint (ACBC) module in the survey. Following appropriate analysis, ACBC data allow for the simulation of physician preference share and likelihood to prescribe of user-defined target product profiles (TPPs). Conjoint analysis is based on the idea that any product or service is seen by consumers as a combination of attributes or features, each of which contributes to their overall interest in the product or service.

We report on key ACBC analysis findings and one market simulation performed on three hypothetical TPPs (see the "Conjoint Analysis-Based Simulation of a Market Scenario"). The Excel-based Target Product Profile Simulator allows for the creation of up to seven user-defined TPPs with varying performance across the attributes included in the survey. To access the Excel-based Target Product Profile Simulator, see the "Downloads" section of the report.

Through research conducted by Clarivate, we identified six attributes relevant to the assessment of biosimilar development opportunities in the oncology space to be included in our analysis. We included attributes known to be key differentiators of biosimilars in the oncology space, including price:

Availability of clinical data in the indication I am prescribing for.

Inclusion in treatment guidelines.

Type of manufacturer.

Reimbursement restrictions.

Postmarketing data (time on market).

List price.

Downloads

MAIN CONTENT

Biosimilar Target Product Profiles (Oncology)

Full Report

TPP Simulator - Oncology Biosimilars

Attachment

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Biosimilar Target Product Profiles (Oncology)

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Hamzah Aideed, M.Sc.

Manager

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Interactive target product profiles: oncology & immunology

Quantify how physicians choose between multiple biosimilars of a given reference product based on specific attributes (including price). Understand the preference share and likelihood to prescribe each biosimilar product based on modelling different clinical and non-clinical attributes.

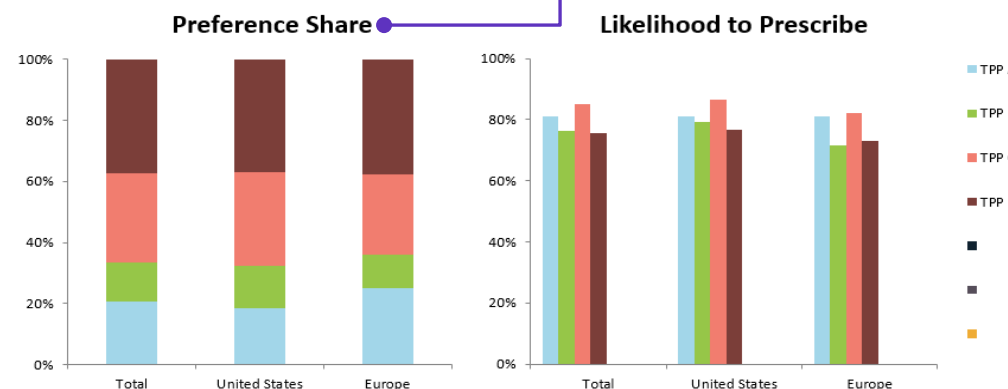
Choose attribute levels for each biosimilar TPP

Compare up to 7 TPPs across 6 attributes

Learn preference share and likelihood to prescribe custom biosimilar TPPs versus others

RESULTS			
Preference Share	Total	United States	Europe
TPP A	20.6%	18.4%	24.9%
TPP B	12.9%	13.8%	11.2%
TPP C	29.2%	30.9%	26.0%
TPP D	37.3%	36.9%	37.9%

Likelihood to Prescribe	Total	United States	Europe
TPP A	81.0%	81.0%	81.1%
TPP B	76.5%	79.1%	71.5%
TPP C	85.1%	86.7%	82.0%
TPP D	75.5%	76.8%	73.1%



ATTRIBUTE	TPP A	TPP B	TPP C	TPP D	TPP E	TPP F	TPP G
Attribute 1	32	36	36	40			
Attribute 2	10	12	12	14			
Attribute 3	40%	60%	60%	60%			
Attribute 4	15%	15%	5%	5%			
Attribute 5	11%	11%	1%	1%			
Attribute 6	Intravenous	Intravenous	Intravenous	Oral			
Price	\$6,500.00	\$8,500.00	\$8,500.00	\$10,000.00	\$2,000.00	\$2,000.00	\$2,000.00
Include Product?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Emerging Biosimilars Module

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Emerging Biosimilars Landscape

Biosimilars Pipeline Analysis

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2 **Special Topics: Oncology Biosimilars in the United States - Wave 2**

Special Topics: Oncology Biosimilars in the United States - Wave 1

Oncology: Trastuzumab Biosimilars Launch Tracking (Germany) Wave 3

Immunology: Adalimumab Biosimilars Launch Tracking (Germany) Wave 3

Oncology & Immunology: Truxima/Rixathon Launch Tracking (Germany) Wave 3

Immunology: Inflectra/Renflexis Launch Tracking (US) Wave 3

Emerging Biosimilars Landscape

Last updated 23 June 2022

Biosimilars Pipeline Analysis

Biosimilars Development Pipeline by Phase of Development

Of all biosimilars globally, 33% are in preclinical development; 9% are in Phase I trials, 14% are in Phase III trials, 2% are filed, 4% are approved, and 35% are marketed.

Phase	Percentage
Launched	35%
Preclinical	33%
Phase III	14%
Phase I	9%
Approved	4%
Filed	2%
Clinical (unspecified phase)	2%

Downloads

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Emerging Biosimilars Landscape Full Report

Global Biosimilars Pipeline Attachment

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Yashu Malhotra Analyst

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1. The Emerging Biosimilars module contains the global pipeline analysis curated by our experts to provide insights into the evolving marketplace. Analyses are updated quarterly to reflect major market events and changes in biosimilar launch dates.

2. There are additional supporting biosimilars launch tracking reports, however these are not part of the core Biosimilars suite.

Biosimilars Access & Reimbursement Module

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Overview

🕒 Last updated 16 December 2021

- Biosimilar regulations and guidance have been defined, at least in draft form, in the majority of the world's leading pharmaceutical markets.
 - In many cases, biosimilar guidance is based on that of the EMA, but the degree of similarity and granularity varies by country.
- Biosimilars and their reference brands are subject to a diverse array of pricing mechanisms, ranging from automatic price cuts in Japan and South Korea to reference pricing in Germany and Spain.
- Clarivate's primary market research with payers in the EU5 and United States indicates that a number of factors are considered when deciding whether to reimburse biosimilars, including the following:
 - The net price of the biosimilar in relation to the reference biologic.
 - Statistically insignificant differences in efficacy.
 - The robustness and number of clinical trials the biosimilar has undertaken.
 - The reliability of the biosimilar company's supply chain.
- Automatic substitution has yet to gain traction, although our research suggests that payers are receptive to it.
 - Countries with defined biosimilar guidelines, including some in the EU, Japan, and South Korea, either do not permit or heavily restrict automatic substitution due to safety and efficacy concerns.
 - Other markets, such as Australia, France, and the United States, have passed legislation to allow automatic substitution.

Downloads

[Access & Reimbursement Brochure](#)

Customize Your Insights

Our analytic experts harness the potential of Real World Data to reveal customized insights for our clients. See how our robust claims and EHR database can be applied to provide tailored insight on clinical practice, patient journey, competing therapies, and more.

[Request a consult](#)

Next section [Payer Insights Landscape \(US-EU5\)](#)

1. The Payer Landscape is based on surveys of 60 US payers and interviews with 10 EU5 payers and provides insights into drivers and barriers to uptake of biosimilars, pricing expectations, and factors influencing choice among biosimilars.

2. The global landscape provides a primer on biosimilars policy, regulations, pricing, reimbursement in US Europe Japan and rest of world.

Biosimilars Corporate Strategies Module

1. Corporate strategies provides critical competitive intelligence and actionable recommendations on how to maximize market share.

A. Strategic secondary research highlights how the leading players are seeking to defend their innovator biologics portfolios.

B. Assessment of the leading biopharma companies establishes those most at risk from biosimilar competition.

C. Profiles on the leading biosimilars companies provide insights into how market success has been achieved.

2. Report can be downloaded as PDF.

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A Biosimilar Developer Strategies

B Reference Brand Developer Strategies

C Biosimilar Profiles

Appendix

Overview

Last updated 22 December 2021

- Both reference brand and biosimilars developers use a range of strategies to maximize their respective market share.
- Strategic partnerships are common practice between biosimilars developers to complement manufacturing capabilities and bridge knowledge gaps in the regulatory and marketing landscape.
- Key factors helping biosimilars developers differentiate their agent from the competition include the following:
 - Drug price.
 - Manufacturer's trustworthiness.
 - Robustness of the clinical data.
- In addition to offering a lower-priced biosimilar, companies can differentiate their product by offering valuable attributes such as patient support programs.
- (Co-)Development of next-generation biologics has become a common defense strategy adopted by reference brand developers to protect their sales from biosimilar erosion.
- Reference brand developers seeking to extend the term of market exclusivity need to build their patent estates ahead of time and seek strong legal advice.
- Strategies adopted by reference brand developers include the following:
 - Price hikes ahead of a biosimilar launch.
 - Exclusionary agreements with payers in the form of rebates and price discounts.
 - Innovation of delivery devices or systems.
 - Development of next-generation biologics.

2 Downloads

Corporate Strategies Brochure

Meet the Team

Hamzah Aideed, M.Sc.
Manager

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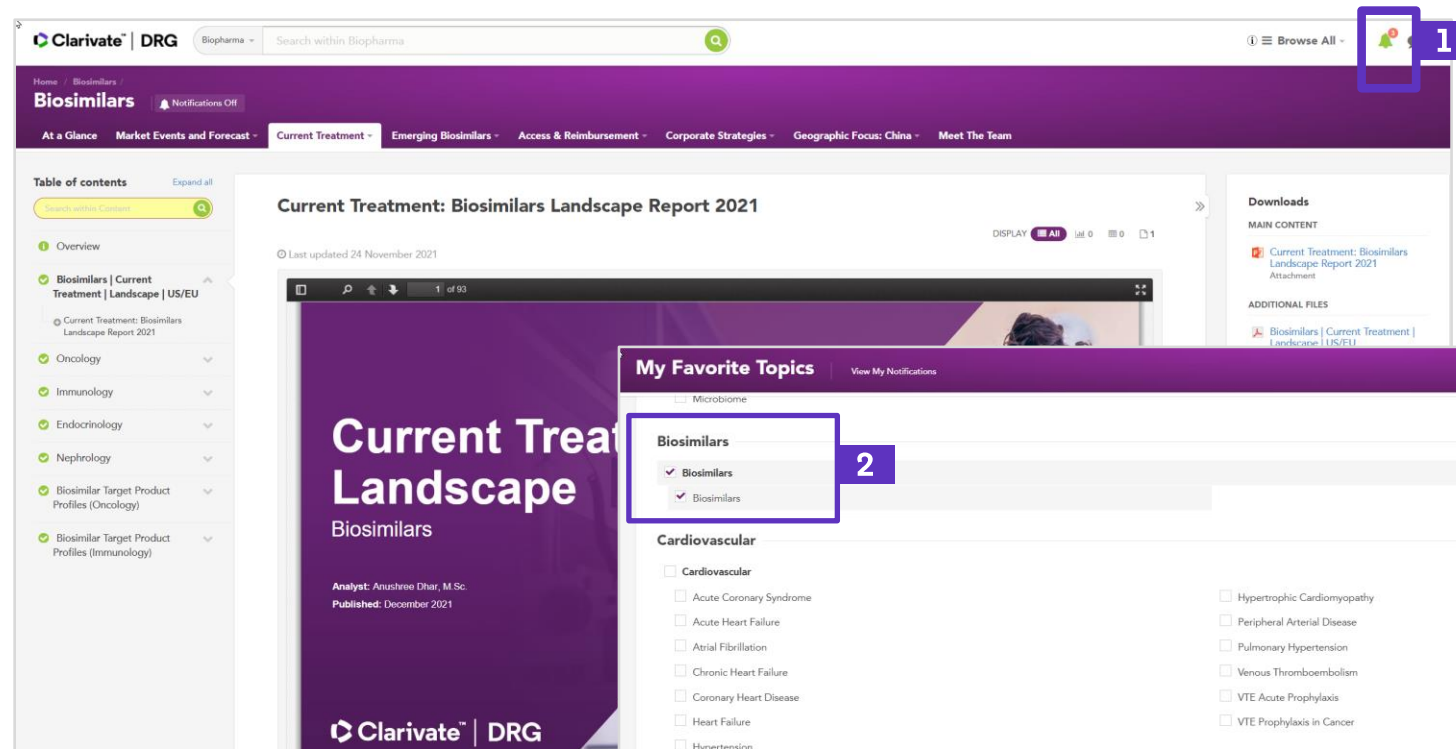
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Our analytic experts harness the potential of Real World Data to reveal customized insights for our clients. See how our robust claims and EHR database can be applied to provide tailored insight on clinical practice, patient journey, competing therapies, and more.

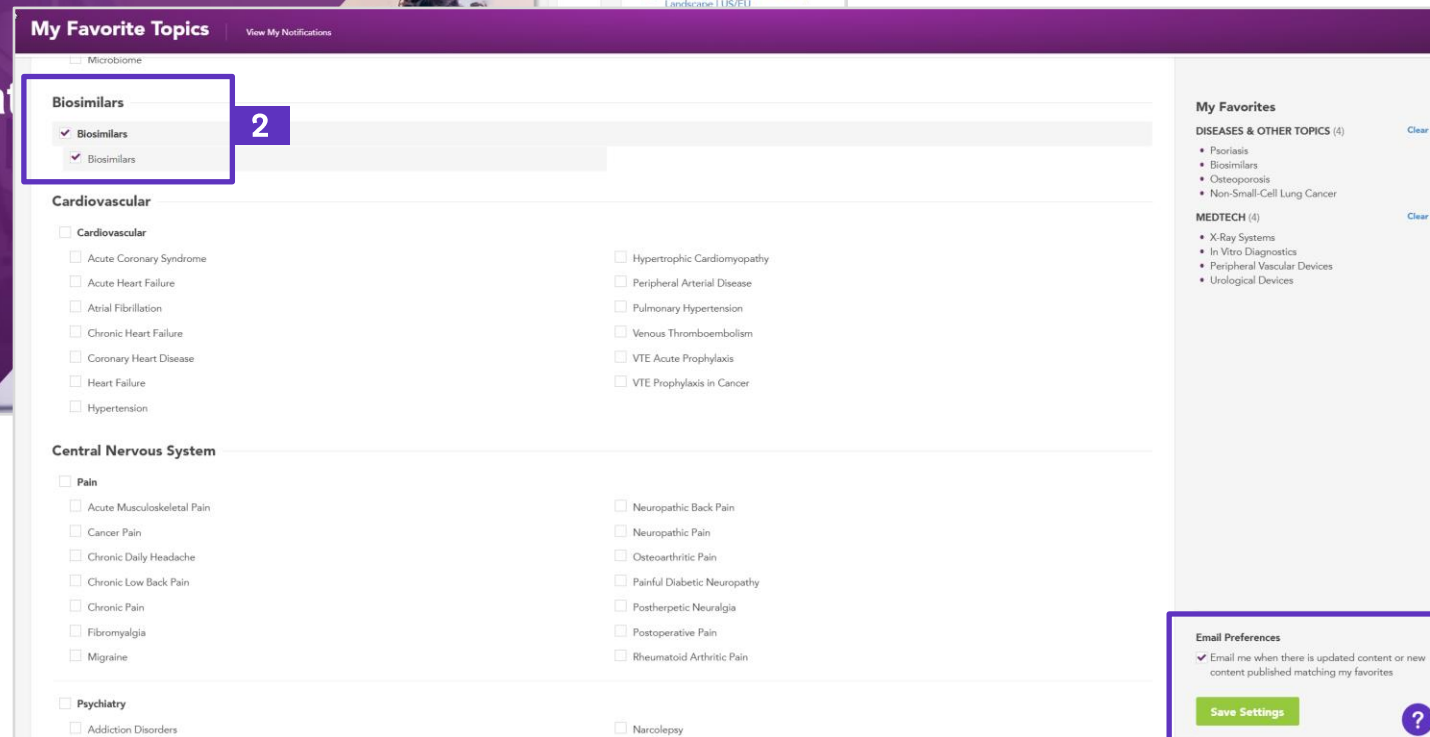
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Key Findings

Alerts Request



The screenshot shows the Clarivate DRG Biosimilars website. The top navigation bar includes the Clarivate logo, 'DRG', a search bar, and a 'Browse All' link. A red box labeled '1' highlights the bell icon in the top right corner of the navigation bar. Below the navigation bar, the main content area displays the 'Current Treatment: Biosimilars Landscape Report 2021'. A sidebar on the left contains a 'Table of contents' and a list of categories. A 'My Favorite Topics' overlay is visible, showing a list of topics with checkboxes. A red box labeled '2' highlights the 'Biosimilars' checkbox in the 'My Favorite Topics' overlay.

1.
To request email alerts of Biosimilars report key updates, select the bell icon.



The screenshot shows the 'My Favorite Topics' overlay. It features a list of topics with checkboxes. A red box labeled '2' highlights the 'Biosimilars' checkbox. Below the list, there is an 'Email Preferences' section with a checkbox labeled 'Email me when there is updated content or new content published matching my favorites'. A red box labeled '2' highlights the 'Save Settings' button in the 'Email Preferences' section.

2.
Select the disease markets that you are subscribed to, then select the “Email Preferences” checkbox, then select the “Save Settings” button.

Support Requests

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Bottom-Up Forecast Overview: All Drug Classes Excluding G-CSFs

Drug Classes Covered in the Bottom-Up Forecast

Top-Down Forecast Overview: G-CSFs Only

Sources of Information for Biosimilars Forecast

Brands Included in Market Forecast

General Market Assumptions

Overview of Biosimilars Forecasts

Oncology

Immunology

Nephrology

Endocrinology

Methodology

Last updated 30 March 2022

Bottom-Up Forecast Overview: All Drug Classes Excluding G-CSFs

Clarivate creates 10-year annualized forecasts for biosimilars and reference brands from the bottom up, an approach also known as a patient-based or epidemiology-based methodology. Using this approach, we build our reference-brand baseline forecasts based on our assumptions of the number of patients receiving prescription drug treatment in each year and add additional assumptions of patient share per drug, drug price per treated day (the drug regimen per cycle for oncology drugs), the number of treated days per patient (the number of cycles per patient for oncology drugs), and the compliance rate to estimate total sales.

We validate our reference-brand baseline model and assumptions using a top-down, or sales-based, methodology in which we compare our base-year sales projections with available sales data provided by company annual reports, SEC filings, government health authorities, and other publicly available sources. Company-reported sales may include various markups and discounts that affect the price of drugs as they progress through the pharmaceutical supply chain. Our model estimates ex-manufacturer sales exclusive of rebates (for more details on Clarivate's bottom-up forecast methodology, please refer to our *Disease Landscape & Forecast* reports).

For each molecule, we model the following forecasts:

- Total biosimilar patient share (%).
- Biosimilar patient share split by biosimilar products expected to launch during the forecast period, listed by companies marketing the biosimilar (%).
 - Of note, if there is no marketer yet for a biosimilar product, then the company developing the biosimilar is listed instead.
- Pricing expectations for biosimilars and reference brands, relative to reference brand's baseline ex-manufacturer price (%).
- Total biosimilar sales, also split by each biosimilar product (in millions of U.S. dollars).
- Total sales of the reference brand following the launch of new biosimilars after the first year of the forecast period (in millions of U.S. dollars).

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Appendix – Module details

Market events & forecast details

Module details and scope

- **Overview of biosimilars forecasts**

- Annualized sales, patient shares, and market shares from 2020-2030, segmented by region
- Forecasted biosimilar- and brand-treated patient numbers
- Interactive forecasts with graphical visualizations
- Forecasts for individual biosimilar products
- Updated biannually

- **Detailed & expanded analysis by therapy area**

- Download interactive, quantitative market forecasts for over 40 brands and their biosimilars, updated biannually.
- Access in-depth, transparent assumptions behind the market forecasts.

Key questions answered

- What is the future MARKET SIZE for biosimilars at a regional level, class and molecule level?
- When will different biosimilars ENTER the Major Markets (i.e., U.S., EU5, and Japan) markets and how will they behave?
- How will PRICING dynamics evolve between brands and biosimilars throughout the forecast period?
- Which biosimilar marketers are anticipated to win the greatest market share when competing with multiple biosimilars referencing the same brand molecule?

Current treatment details

Module details and scope

- **Landscape**

- Gauge how current use of biosimilars compares across 540 physicians from 6 specialties in the United States and Europe (France and Germany).
- Assess how perceptions of the drivers and barriers to biosimilar uptake vary by specialty and region.
- Compare physicians' expected future uptake of biosimilars by specialty and region.

- **Detailed & expanded analysis by therapy area**

- Track physician-reported use of currently available biosimilars
- Understand how physicians are currently choosing between biosimilars of the same reference product.
- Understand the barriers and drivers of biosimilar use, including clinical, commercial, patient, and market access factors.
- Quantify physicians' expectations for future use of biosimilars.
- Test which biosimilar attributes will have the greatest influence on physician selection of specific biosimilars in oncology and immunology using our interactive Target Product Profiles.

Key questions answered

- What are PHYSICIANS' CONCERNS about biosimilars are how have they changed over time?
- Will physicians SWITCH currently treated patients to a biosimilar or restrict use to new starts?
- Which factors will have the greatest INFLUENCE ON CHOICE of biosimilars

Emerging biosimilars details

Module details and scope

- **Landscape**

- Global pipeline analysis curated by biosimilars experts provides a clear view of the evolving competitive landscape.
- Quarterly updates highlight major pipeline changes and biosimilar launch dates for the major markets, by company.



Key questions answered

- When will competitors launch biosimilars in the MAJOR MARKETS?
- How AWARE are physicians of a biosimilar at LAUNCH and over its first year?
- Which patients are physicians selecting to treat with the NEW BIOSIMILAR?

Access & reimbursement details

Module details and scope

- **Landscape**

- Primer on biosimilars policies, regulations, pricing and reimbursement in the United States, Europe, Japan, and ROW.
- Understand the strategies in place to encourage use of biosimilars at a national / regional level.

- **Detailed & expanded analysis**

- Surveys with 60 U.S. payers and interviews with 10 EU5 payers address:
- The drivers and barriers to uptake of biosimilars.
 - Factors influencing payers' choice between multiple biosimilars.
 - Pricing expectations for biosimilars and innovator brands in a biosimilars market.
- Current and future strategies used by U.S. and EU5 payers to drive uptake of specific biosimilars.
- US and EU5 payer attitudes towards specific biosimilars and novel biologics.

Key questions answered

- How are PRICING, REIMBURSEMENT AND SUBSTITUTION policies evolving for biosimilars?
- How do biosimilars REGULATIONS differ across regions?
- How will PAYERS INFLUENCE uptake of biosimilars?

Corporate strategies details

Module details and scope

- Addresses observed and potential strategies of biosimilar developers from target selection through to product launch, providing critical competitive intelligence, as well as actionable recommendations about how to maximize market share.
- Profiles on the leading biosimilars companies provide insights into how market success has been achieved.
- Assessment of the leading biopharma companies establishes those most at risk from biosimilar competition.
- Strategic secondary research highlights how the leading players are seeking to defend their innovator biologics portfolios.

Key questions answered

- How have companies **ACHIEVED SUCCESS** in the biosimilars market?
- What strategies are being developed to **DEFEND AGAINST** biosimilars?



Have a Question?

healthcare.support@clarivate.com
clarivate.com

About Clarivate

Clarivate™ is a global leader in providing solutions to accelerate the lifecycle of innovation. Our bold mission is to help customers solve some of the world's most complex problems by providing actionable information and insights that reduce the time from new ideas to life-changing inventions in the areas of science and intellectual property. We help customers discover, protect and commercialize their inventions using our trusted subscription and technology-based solutions coupled with deep domain expertise. For more information, please visit clarivate.com.

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