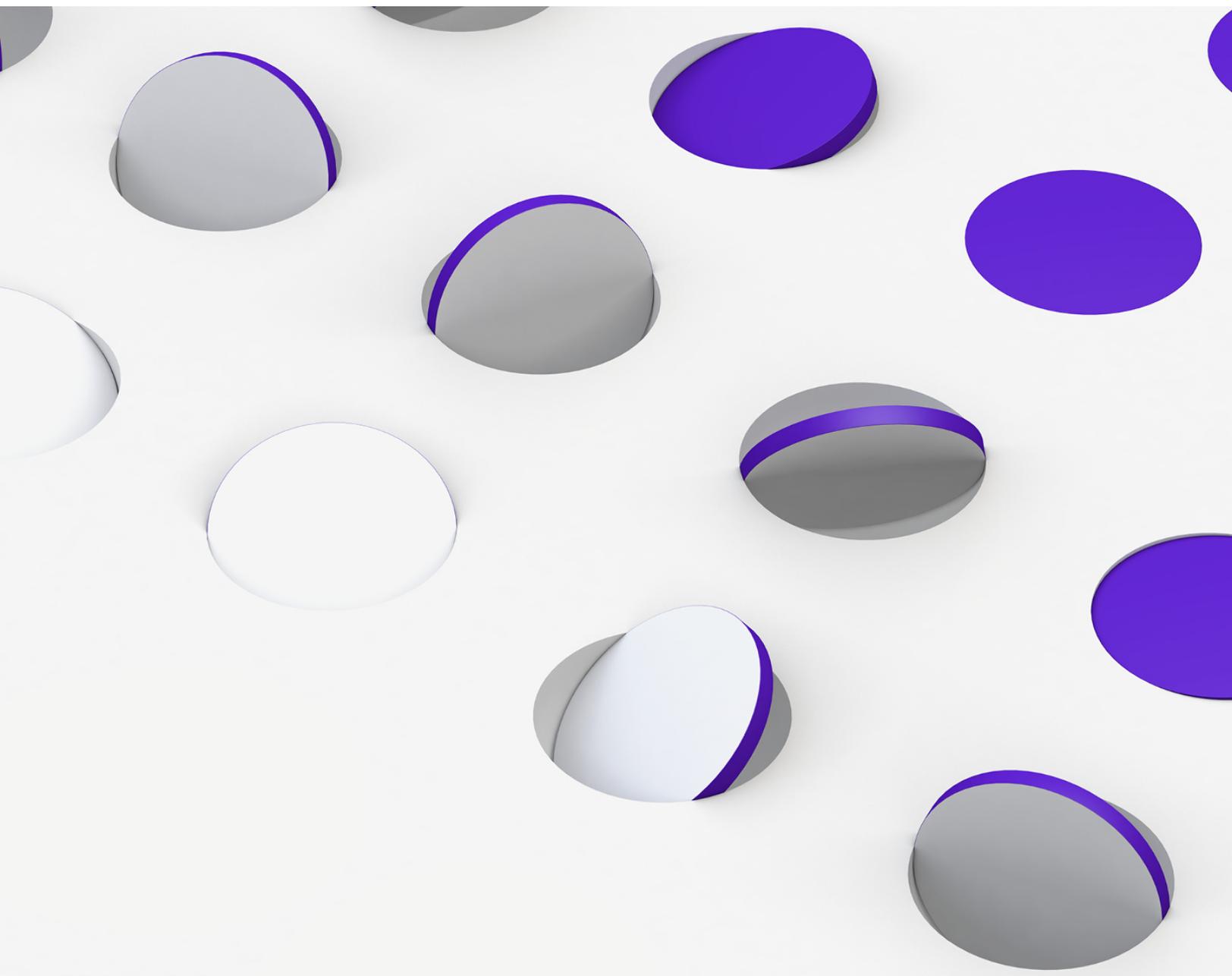


CMR International

2019 Pharmaceutical R&D Factbook



Pharma innovation in 2019: Staying ahead of the competition

Quickly see who's innovating, and in what areas, across pharma with the CMR International 2019 Pharmaceutical R&D Factbook – the objective and reliable source for pharmaceutical benchmarks and trends. Whether you're assessing performance of your own program, the competition, your clients, or an investment opportunity, you need reliable, accurate benchmarks and industry data.

Answer questions you need for effective planning:

- How much is the industry forecasted to spend on R&D over the next 3 years?
- How much annual revenue is the industry reinvesting into R&D?
- How many blockbusters are set to lose patent exclusivity over the next 3 years?
- Which therapeutic areas have experienced positive-growth in pipeline volume over recent years?
- Which therapeutic area has the highest investment?
- How is patient recruitment shifting across the industry?

CMR International, a Clarivate Analytics business, gathers and analyzes data from multiple proprietary data sets to provide authoritative and robust industry metrics for every stage of pharmaceutical development.

Use the authoritative source for pharma and biotech metrics to better inform your strategy and planning:

- Gain an in-depth understanding of industry dynamics and trends
- Determine how your organization performs against the market and gauge your productivity versus the competition
- Identify the key differences between therapy areas and how to apply to your R&D strategies
- Set performance targets that will motivate and challenge your businesses
- Share the report across the organization – access data within the 75+ interactive charts and data or adapt report slides for your own presentation

Start using the most trusted benchmarks in the industry today. **Order your 2019 Factbook now!**

List of figures

Chapter 1. Overview

1. Summary of R&D Statistics for 2018
2. Global R&D expenditure, development times, global pharmaceutical sales and new molecular entity output 2008-2018
3. Global pharmaceutical R&D expenditure and annual changes in R&D expenditure 2008-2022p
4. Global pharmaceutical sales and annual changes in pharmaceutical sales 2008-2022p
5. Total R&D expenditure: sales ratio in 2018 by company size (max/median/min)
6. Number of new molecular entities and new active substances first launched onto the world market 2009-2018
7. Number of new molecular entities first launched onto the world market 2009-2018 by company size
8. Breakdown of total sales in 2018 by top 3 products and products launched in the previous 5 years

Chapter 2. R&D Resources

1. Proportion of total R&D expenditure in 2018 by function
2. Proportion of total FTEs in 2018 by function
3. Proportion of total R&D expenditure on alliances or joint ventures by stage of R&D in 2018
4. Number of drug commercialization / licensing deals between 2014-2018
5. Proportion of total R&D expenditure in 2018 by phase of R&D
6. Proportion of total FTEs in 2018 allocated to each phase of R&D
7. Allocation of R&D expenditure between new development and line extension projects in 2017 and 2018
8. Allocation of R&D expenditure between internal and external spend by company size in 2018

Chapter 3. R&D Pipeline Volume

1. Summary of R&D pipeline volume statistics for 2018
2. Trend in mean number of active substances developed for first launch between 2014-2018
3. Indexed trend in number of active substances entering each phase of development 2013-2018
4. Number of projects achieving key milestones between 2014-2018 by project type

5. Number of lead, parallel and line extension projects entering each phase of development between 2014-2018
6. Changes in the number of lead projects in each development phase between 2014 and 2018 by active substance origin
7. Number of projects terminated in Phase III between 2013-2018

Chapter 4. Success Rates

1. Probability of success to market for active substances
2. Probability of success to market from key milestones: changes over time
3. Probability of success to market by origin
4. Predicted number of active substances required at each stage to achieve one marketed active substance

Chapter 5. Cycle Times

1. R&D key milestones
2. Development time for new molecular entities first launched onto the world market 2009-2018
3. Trend in actual clinical development time for lead projects submitted 2009-2017
4. Composite median interval duration for lead projects 2013-2017
5. Indexed trend in median interval durations for lead projects between 2009-2017

Chapter 6. Regional Comparisons

1. Regional distribution of total R&D expenditure in 2018
2. Region of first launch for new molecular entities 2009-2018
3. Proportional change of enrolled patients in each geographical region between 2011 and 2017
4. Median approval times for new active substances approved for three major regulatory agencies between 2008-2018
5. Regulatory approval times from date of submission to approval for new active substances approved between 2012-2016
6. Time between first world approval and submission in emerging market countries for new active substances approved between 2012-2016
7. Number of expedited and standard new active substance approvals 2007-2012 compared with 2013-2018
8. Median time in roll out to emerging market countries for new active substances approved between 2012-2016

Chapter 7. Therapeutic Area Focus

1. Total R&D expenditure in 2018 by therapeutic area

2. Total R&D expenditure in 2018 by therapeutic area by phase
3. Proportion of first new molecular entity launches in 2018 by therapeutic area
4. Change in number of lead projects in development for first launch between 2016-2018 by therapeutic area
5. Therapeutic area diversification between 2016-2018 by company size
6. Probability of success to market by therapeutic area (1) CMR success rates methodology
7. Probability of success to market by therapeutic area (2) CMR success rates methodology
8. Composite median interval durations for lead and parallel projects between 2013-2017 by therapeutic area
9. Median approval times for new active substances between 2013-2018 by therapeutic area

Chapter 8. Biopharmaceutical Focus

1. Proportion of R&D expenditure in 2017 and 2018 by active substance type
2. Proportion of ethical pharmaceutical sales in 2018 by active substance type
3. Number of first NME launches between 2008-2018 by active substance type
4. Proportion of NBE active substances in development between 2014-2018 by company size
5. Proportion of licensed-in or acquired active substances in development in 2014 and 2018 by active substance type
6. Probability of success to market by active substance type
7. Composite median interval durations for lead projects between 2013-2017 by active substance type

Chapter 9. Clinical Functions

1. Median total study duration in 2017
2. Clinical study median interval durations by study phase in 2017
3. Comparisons of the change in clinical study median interval durations between 2013 and 2017 by study phase

Chapter 10. Patents

1. Number of pharmaceutical patent applications and granted patents for 5 major patent issuing authorities 2008-2018
2. Total and new compound WO, EP or US patent document filings 2010-2018
3. Most popular targets by number of 'new entrants' since 2016 for the industry
4. Most popular targets by number of 'new entrants' since 2016 for the 30 most innovative companies
5. Therapy area focus of the most popular emerging targets since 2016

Chapter 11. Global Generics Market

1. Number of ANDA final approvals in each year between 2016-2018 by country of origin
2. Number of ANDA approvals for Indian generic companies between 2009-2018
3. Exposure of products to Paragraph IV challenges in US between 2012-2018
4. Total Paragraph IV challenges by country (count of single filing per group)
5. Number of products predicted to lose exclusivity in US between 2019-2025
6. Current experience of generic API manufacturers with regard to supplying the regulated markets
7. Number of European Certificates of Suitability (COS) granted between 2009-2018 by location of company headquarters
8. Number of US DMF granted each year between 2009-2018 by location of company headquarters
9. API Plants inspected by FDA in each year between 2010-2018 by location of company headquarters

Stop using old benchmarks! Get the authoritative source for pharma metrics and trends – all in one convenient report. **Purchase your copy now!**

About CMR International

CMR International, a leader in global pharmaceutical R&D performance measures, brings together data sets from prominent sources to provide objective information and insights into global pharmaceutical R&D performance. For over 20 years, CMR International has worked with the leading global pharmaceutical companies to assess R&D productivity and provide insights into industry trends which are used to strengthen the planning and effectiveness of R&D.

Since 2003, CMR International has published the Pharmaceutical R&D Factbook, an annual report designed to equip the Pharmaceutical R&D sector with a reliable quotable source of key reference metrics and an insight into current industry trends.

The CMR International performance metrics programs on which this report is based cover every aspect of pharmaceutical R&D and are broken into three key areas – Global R&D, Global Clinical, and Asia Pacific. CMR programs are ongoing and focused on key issues, with datasets built on over 20 years of rigorous development. The datasets have the unique depth and historical context to uncover reliable industry trends, set in context against the changing marketplace.

To find out more about CMR International, visit:

<https://clarivate.com/cortellis/solutions/benchmarking-services/>