Contract Research Organizations & Contract Development and Manufacturing Organizations

CROs & CDMOs play essential roles in the healthcare industry.

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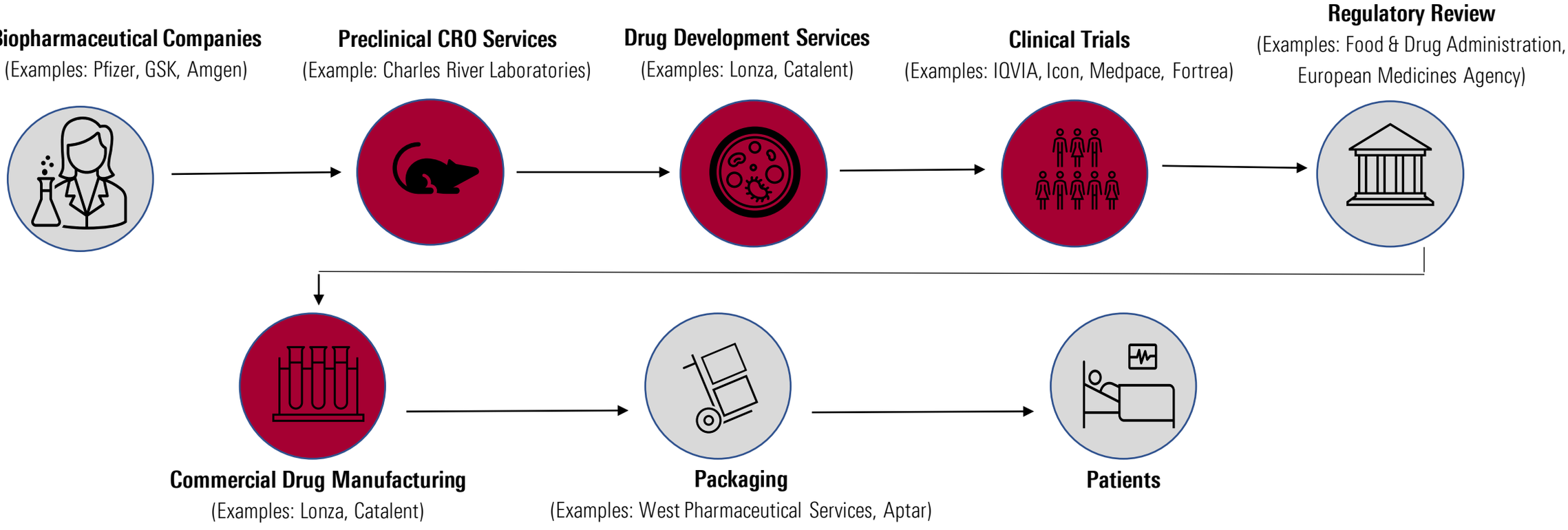
Industry Map

Contract research organizations, or CROs, and contract development and manufacturing organizations, or CDMOs, have played an increasingly important role in drug development over the past few decades as pharmaceutical and biotechnology customers have realized the benefits of being able to outsource clinical trials and drug manufacturing to third parties. A CRO's role can begin at the start of a drug's life with preclinical testing in animals and extend to the end of a drug's life, including commercialization efforts and additional studies after regulatory approval. CDMOs offer drug product development services and then manufacturing services once prospects for commercial approval are relatively high.

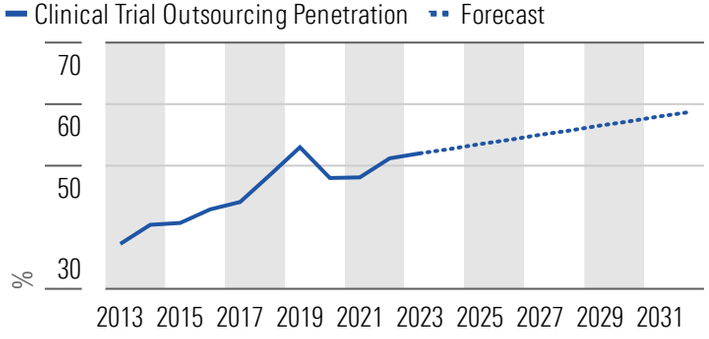
The CRO and CDMO Supply Chain



Source: Morningstar.

Key Industry Themes

Increased Outsourcing Demand



Source: Morningstar, IQVIA.

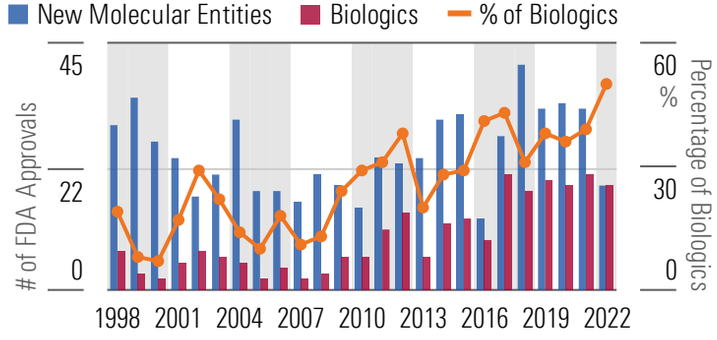
Demand for outsourced clinical trials and drug manufacturing has steadily increased as pharmaceutical and biotechnology companies have realized the benefits of outsourcing these services to CROs and CDMOs. Additionally, there has been a lot of consolidation among CROs and CDMOs, which has allowed them to expand their therapeutic areas of expertise and increase their manufacturing capabilities, allowing them to take on new business.

Decentralized Clinical Trials

Source: Morningstar.

The COVID-19 pandemic has significantly accelerated the adoption of decentralized clinical trials, or DCTs. These trials deliver measurable benefits for biopharma customers by reducing time and costs. The FDA acknowledges that DCTs can reduce patient and sponsor burden while increasing accrual and retention of a more diverse trial population, and we think this will support the adoption of more DCTs in the future.

Biologics Are Very Complex and Gaining Share



Source: Nature Biotechnology, January 2023.

In 2022, biologics gained share and accounted for 50% of FDA approvals during the year. Pharmaceutical and biotechnology companies have increased their investments in these drugs for several reasons, including biologics' greater efficacy at targeting diseases and the high selling price they can command compared with other drugs. These drugs are very complex to produce and require specialized manufacturing capabilities, which create tailwinds for the CRO and CDMO industry.

Industry Value Drivers

Simplified Financial Statement: Medpace 2022

Pro forma income statement ($ Mn).

Pro Forma Income Statement ($ Mn.)	2022
Revenue (1)	1,460
Cost of Goods Sold (2)	1,028
Gross Profit	**432**
Selling, General, and Admin. Expenses (3)	131
Research & Development (4)	0
Other Operating Expense (Income)	0
Depreciation & Amortization	22
Operating Income (Exc. Charges)	**279**
Restructuring & Other Cash Charges	0
Impairment Charges	0
Other Non-Cash (Income) / Charges	(7)
Operating Income (Inc. Charges)	**286**
Interest Expense	3
Interest Income	0
Pre-Tax Income	**283**
Income Tax Expense (5)	37
Other After-Tax Cash Gains (Losses)	0
Other After-Tax Non-Cash Gains (Losses)	0
(Minority Interest)	0
(Preferred Dividends)	0
Net Income	**245**

DCF Build Up ($ Mn.)	2022
Operating Income (6)	**279**
Amortization	3
Other Non-Cash Charges	23
Restructuring & Other Cash Charges	0
After-Tax Operating Adjustments	0
Cash Taxes	(61)
Pension Adjustment	0
Earnings Before Interest	**244**
Depreciation	19
(Capital Expenditure)	(37)
(Net Investment In Working Capital)	106
(Net Change In Operating Assets/Liabilities)	(2)
(Net Acquisitions)/Sales (7)	0
Net New Investment (NNI)	**86**
Free Cash Flow to the Firm (FCFF)	**330**

Source: Company reports, Morningstar.

Key Income Statement Metrics (CRO & CDMO Industry Median in Italics):

[1] Revenue: CROs and CDMOs earn revenue through contracts with pharmaceutical and biotechnology firms to run their clinical trials.

[2] Cost of goods sold *(median: 66% of sales)*: The cost to run clinical trials and manufacture drugs largely comprises direct labor costs, fees paid to site investigators, and laboratory services.

[3] Selling, general and administrative *(median: 12% of sales)*: SG&A is relatively low for the CRO and CDMO industry. SG&A primarily comprises compensation, recruitment expenditures, and costs related to facilities and information systems.

[4] Research and development: CROs and CDMOs typically don't have an R&D expense line item since their investments are largely included within capital expenditure.

[5] Tax rate *(median: 16%)*: The typical tax rate benefits from revenue earned in low-tax-rate countries.

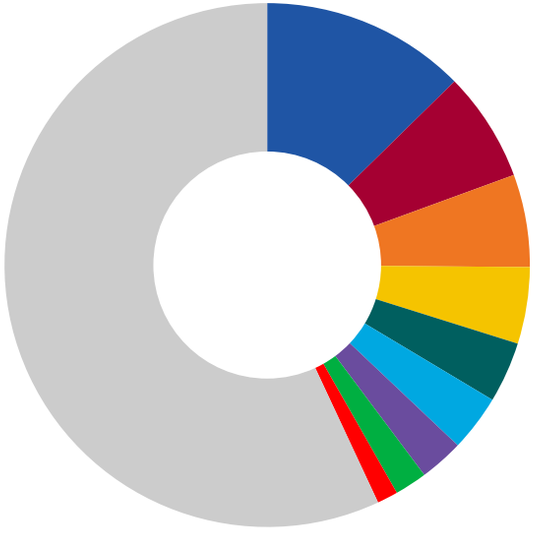
[6] Operating income: Most firms exclude restructuring costs, impairment charges, and legal expenses to reach operating income.

[7] Acquisitions: While Medpace is focused on organic growth, most CROs and CDMOs make tuck-in acquisitions to expand their capabilities and global footprint.

Market Share and Concentration

In the CRO and CDMO industry, the top nine companies represented about 43% of the total market share based on revenue in 2022. IQVIA had the highest sales at 13%, followed by Icon at 7%. Overall, the industry is lightly concentrated, with a Herfindahl-Hirschman Index Score of 625, below the threshold of 1,500, the level considered to be moderately concentrated by the U.S. Department of Justice.

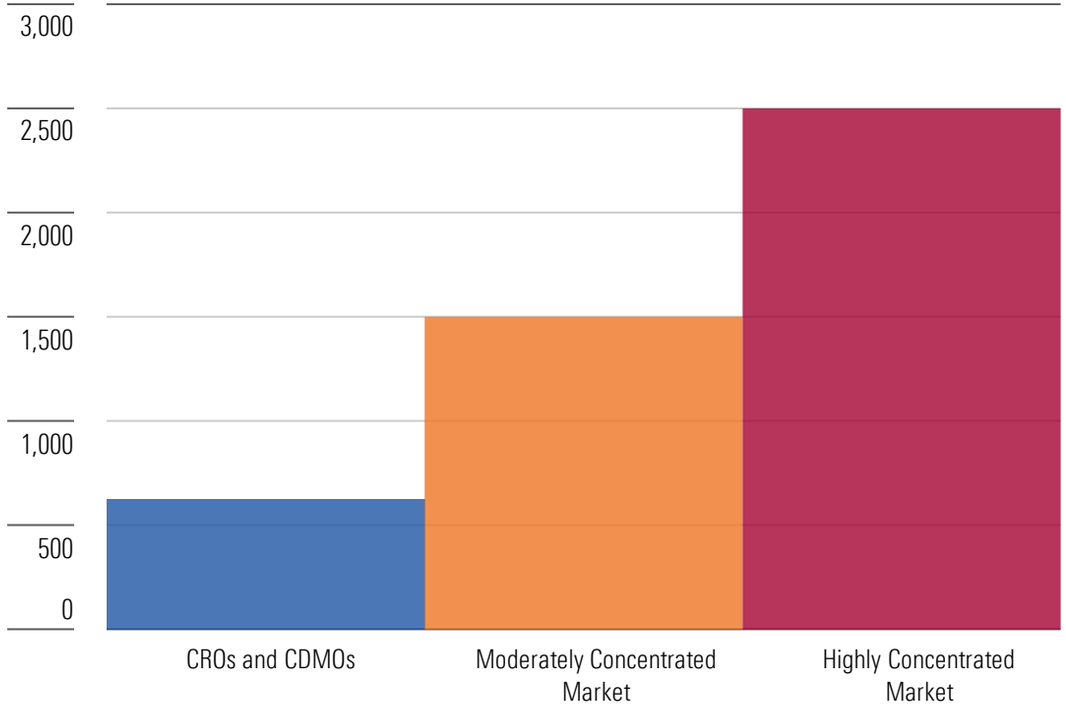
Key Industry Players and Revenue Market Share



Companies	%
IQVIA	12.63
Icon	6.78
Lonza	5.71
Syneos Health	4.73
Catalent	3.75
Charles River	3.48
Fortrea	2.71
WuXi Biologics	1.99
Medpace	1.28
Other	56.94

Source: Morningstar and PitchBook. Revenue data as of fiscal year-end 2022.

Herfindahl-Hirschman Index vs. U.S. DOJ Concentration Thresholds (2022)



Source: PitchBook, Morningstar. Data as of fiscal year-end 2022.

Coverage List and Ratings

Morningstar covers eight companies in the CRO and CDMO industry across mid and large market capitalizations.

CRO and CDMO Companies Under Our Coverage

Company (Ticker)	Market Cap (Billions, Local)	Moat Rating	Uncertainty Rating	Last Close (Local)	Fair Value Estimate	Star Rating	P/FVE	P/E	EV/EBITDA	Yield	1-Year Return
Catalent (CTLT)	7 USD	Narrow	High	39.87 USD	65 USD	★★★★★	0.61	336.6x	19.3x	0.0%	(5%)
Charles River Laboratories International (CRL)	10 USD	Narrow	Medium	189.04 USD	260 USD	★★★★★	0.73	20.5x	11.8x	0.0%	(22%)
Fortrea Holdings (FTRE)	3 USD	Narrow	High	31.89 USD	35.5 USD	★★★	0.90	-41.1x	26.4x	0.0%	6%
Icon (ICLR)	22 USD	Narrow	Medium	269.95 USD	243 USD	★★★	1.11	43.4x	17.9x	0.0%	25%
IQVIA (IQV)	37 USD	Narrow	Medium	204.79 USD	250 USD	★★★★	0.82	34.4x	16.0x	0.0%	(5%)
Lonza Group (LONN)	26 CHF	Narrow	Medium	355 CHF	530 CHF	★★★★★	0.58	22.0x	19.5x	1.0%	(33%)
Medpace (MEDP)	9 USD	Narrow	Medium	274.01 USD	239 USD	★★	1.15	32.2x	25.0x	0.0%	25%
WuXi Biologics (HKG: 02269)	201 HKD	Narrow	Very High	47.25 HKD	76.8 HKD	★★★★	0.63	44.1x	28.7x	0.0%	(7%)

Source: Morningstar and PitchBook. Data as of Nov. 20, 2023.

Sustainalytics ESG Exposure Ratings

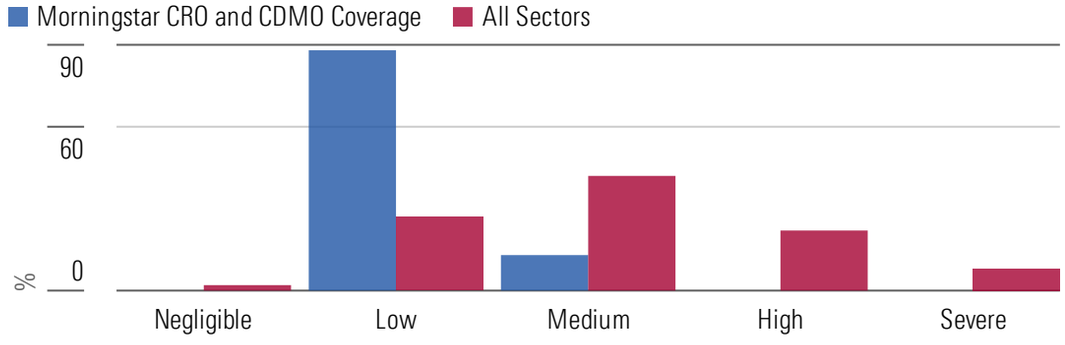
Sustainalytics assigns a greater proportion of laboratory equipment and services firms ESG Risk Ratings that fall into the Low bucket compared with all other sectors, which causes the entire CRO and CDMO industry to lean less risky than the overall market. Product governance is the biggest area of increased risk relative to all sectors.

Product Governance

The CRO and CDMO industry has significant exposure to this material environmental, social, and governance issue. CROs and CDMOs must ensure that their clinical trials, safety assessment tests, and drug manufacturing services meet strict quality and safety standards from a variety of regulatory entities.

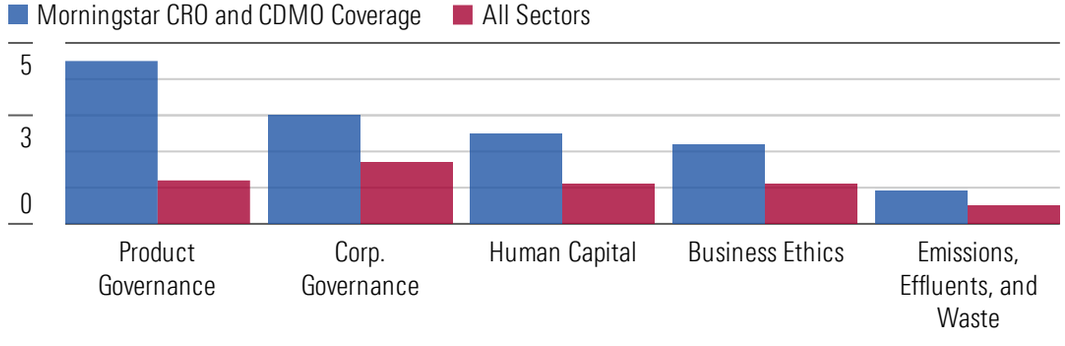
Failure to adhere to these extensive regulations and quality management standards can lead to expensive recalls, increased regulatory scrutiny, compliance costs, lawsuits, and loss of customer trust. A firm's overall risk level is generally driven by its history of quality and safety issues, portfolio (by therapeutic focus), and the regulatory agency for its geographic focus.

Distribution of ESG Risk Ratings for CROs and CDMOs and All Industries



Source: Sustainalytics, Morningstar. Data as of October 2023. Note: Excludes Fortrea.

Top ESG Risk Rating Scores by Material ESG Issue



Source: Sustainalytics, Morningstar. Data as of October 2023. Note: Excludes Fortrea.

Economic Moat

Intangible assets and switching costs support moat ratings.

Summary of Moat Ratings and Sources

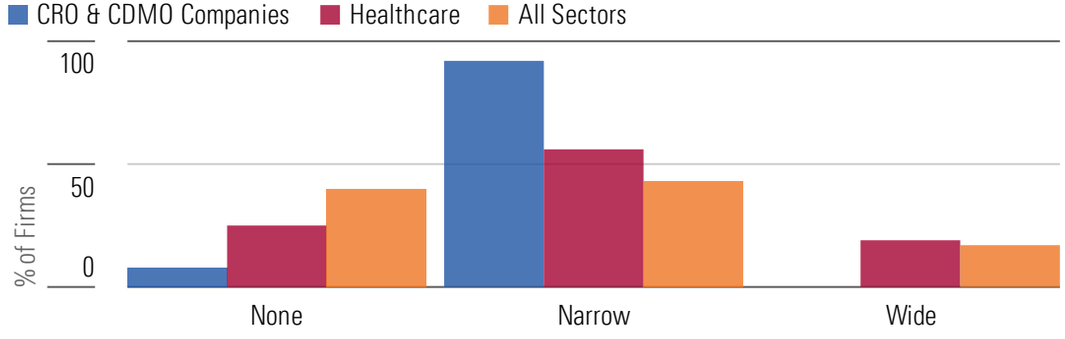
CRO and CDMO Moat Ratings

Moats are largely concentrated in the narrow moat category within our coverage of the CRO and CDMO industry. Lengthy customer relationships that can extend throughout the lifecycle of a drug and significant late-stage clinical trial exposure support a narrow moat rating. Many smaller CROs and CDMOs that we do not cover would likely skew the distribution of the industry toward no moat, as these firms have smaller geographic footprints, fewer areas of therapeutic expertise, and smaller customer bases. The CROs and CDMOs under our coverage are in the top tier of the industry thanks to their extensive therapeutic and manufacturing expertise, which allows them to secure lengthy global contracts with biopharma companies. The CRO and CDMO industry carries a high percentage of narrow moat ratings relative to the rest of the healthcare sector and other sectors. We remain hesitant to assign a wide moat rating to the CROs and CDMOs under our coverage since customer contracts are generally for 5-10 years.

CRO and CDMO Moat Sources

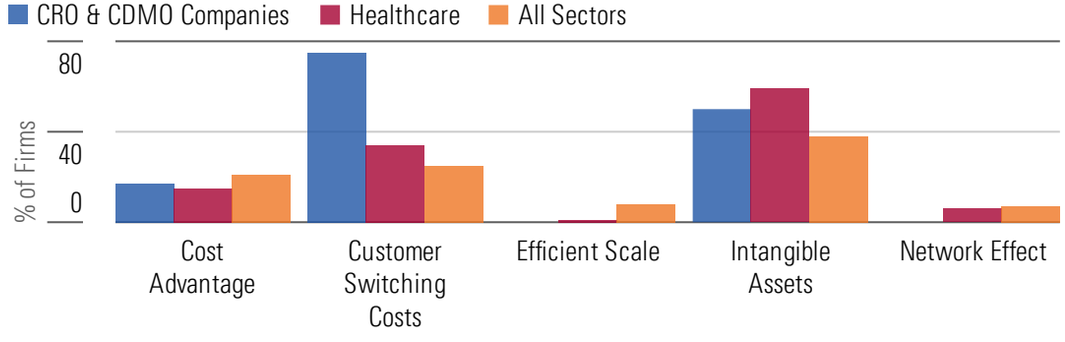
CROs and CDMOs source their moat protection almost entirely from high customer switching costs and intangible assets in the form of therapeutic and manufacturing expertise, client and regulatory agency relationships, and technology. The challenges and compliance risks associated with changing a drug's manufacturing process creates a sticky relationship for CDMO customers, which makes them unlikely to switch to a different firm. For CROs, late-stage trials are complex and have a high risk of failure, so companies typically stay with their selected CRO throughout the drug's lifetime.

Distribution of Moat Ratings Compared With Cross-Sector Average



Source: Morningstar. Data as of Nov. 17, 2023.

Distribution of Moat Sources Compared With Cross-Sector Average



Source: Morningstar. Data as of Nov. 17, 2023.

Many Steps Involved in the Regulatory Approval of a CDMO Line

The process for getting a drug manufacturing line at a CDMO approved by the FDA or other regulatory agency typically involves several steps over one to two years, which underscores the narrow economic moats for Catalent, Lonza, and WuXi Biologics. Customers would face significant delays if they were to switch their manufacturing to a different CDMO due to the high switching costs moat source. We outline below the steps involved in the regulatory approval of a CDMO line.

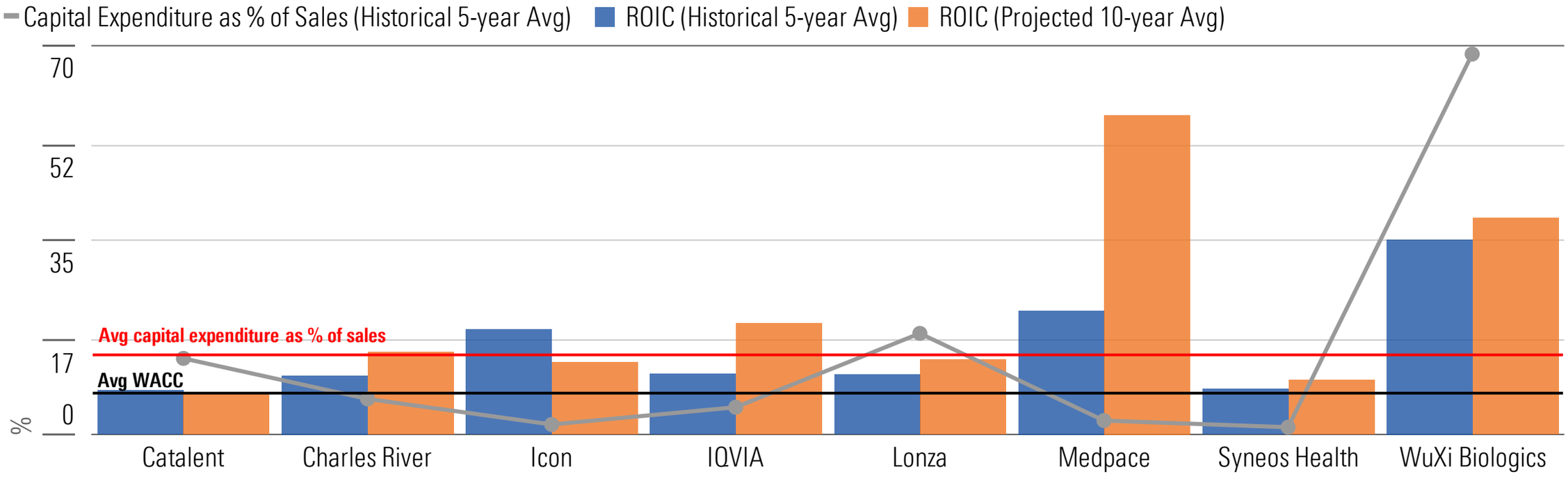
Each Step of the Regulatory Approval Process Must Meet Extensive Requirements

Source: Morningstar.

CROs and CDMOs Must Balance Generating Excess Returns and Investing in New Capabilities to Have a Moat

To ensure long-term excess returns, CROs and CDMOs need to generate returns on invested capital above their weighted average cost of capital while also investing in new capabilities to run clinical trials and manufacture novel therapeutics. The CRO and CDMO industry's WACC hurdle of 8% is lower than many industries, since it is generally less sensitive to macroeconomic movements. The industry's historical level of capital expenditure has averaged around 14.7% of sales, which has enabled investments in new clinical trial and manufacturing capabilities to support long-term returns. WuXi Biologics has been in a phase of rapid expansion, which skews the average capital expenditure as a percentage of sales from 7% (excluding WuXi Biologics) to roughly 15%.

Large-Cap Biopharma Firms Invest in Research and Development to Support Long-Term Returns

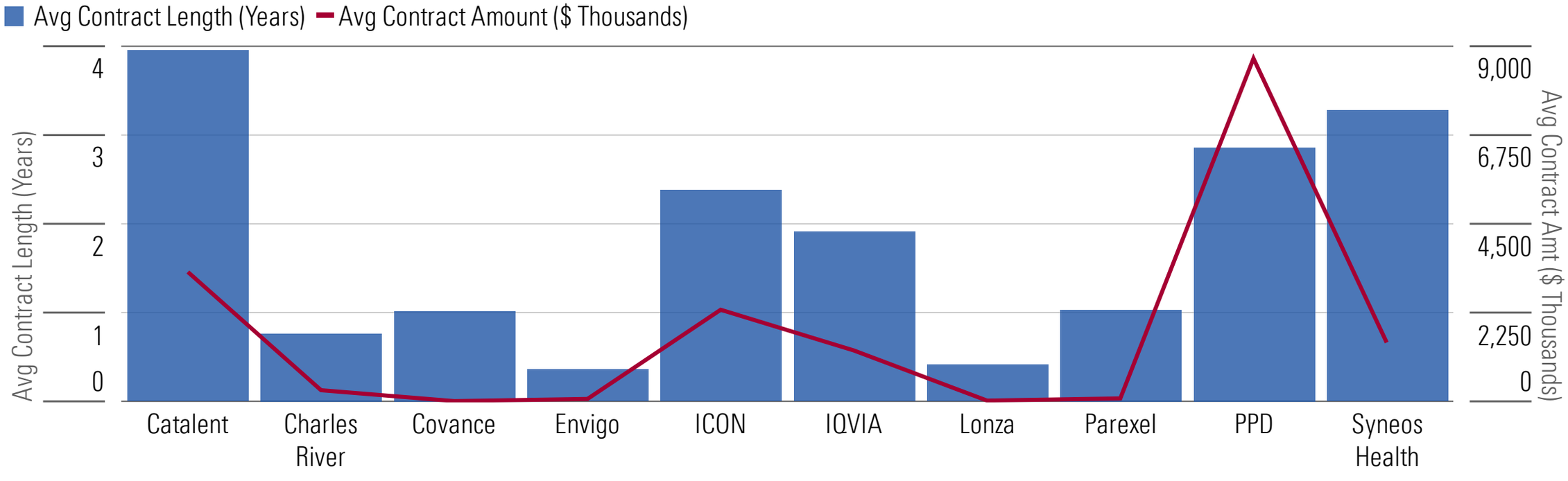


Source: Company reports, Morningstar. Note: Syneos projections are as of Aug. 9, 2023, before the firm was taken private on Sept. 28, 2023.

CRO and CDMO Contracts with the U.S. Government

The details of contracts between CROs, CDMOs, and their biopharmaceutical customers are confidential. However, the U.S. government has publicly available contracts with several CROs and CDMOs. We analyzed the contracts to determine the average contract length and dollar amount. Generally, the contract length for government work is shorter than the typical length between private biopharma companies since the government usually does research in the beginning of a drug's lifecycle or follow-up studies evaluating a drug's side effects, both of which would not be for the entire lifecycle of a drug. Nevertheless, the U.S. government has fairly lengthy relationships with the CROs and CDMOs listed below.

All CROs and CDMOs with U.S. Government Contracts



Source: U.S. government (USAspending.gov), Morningstar.

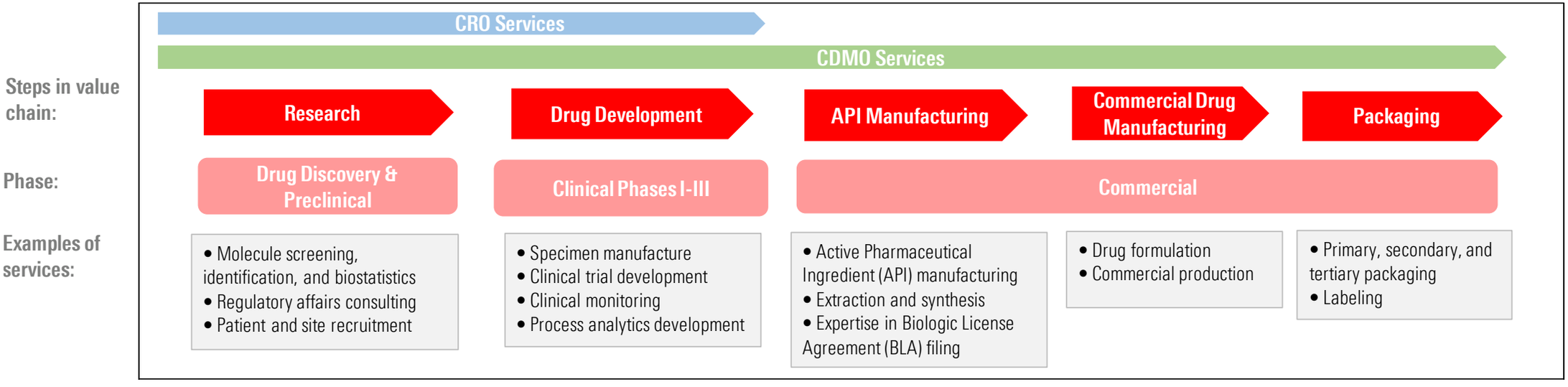
Industry Basics

Key dynamics and metrics of the CRO and CDMO industry.

The Services Provided by CROs and CDMOs Are Interconnected and Support the Biopharma Industry

CROs largely focus on assisting biopharma firms with preclinical and clinical development services. CDMOs partner with biopharma firms to offer drug product development services and later manufacturing services, once prospects for commercial approval are relatively high. Biopharma firms can choose to partner with CDMOs if they lack the expertise to efficiently produce a given drug at scale, or if the anticipated demand for the drug is high enough to require multiple production lines.

CROs and CDMOs Assist Biopharma Firms Across Development and Commercialization



Source: Morningstar.

Drug Development Process Is Lengthy With a Low Average Probability of Success

Biopharmaceutical firms seek to shorten the drug development timeline while maintaining the precision and accuracy necessary for regulatory approval. This is the driving force in the CRO business model, in which CROs leverage their assets and expertise to design a trial tailored to regulatory technicalities, quickly identify target patients at sites around the world for rapid enrollment, and then advise on data collection and analysis for regulatory approvals as efficiently as possible. According to Research and Markets, clinical trials conducted by CROs are completed up to 30% more quickly than those conducted in-house by pharmaceutical companies.

Typical Clinical Drug Development Process and Average Probabilities of Success

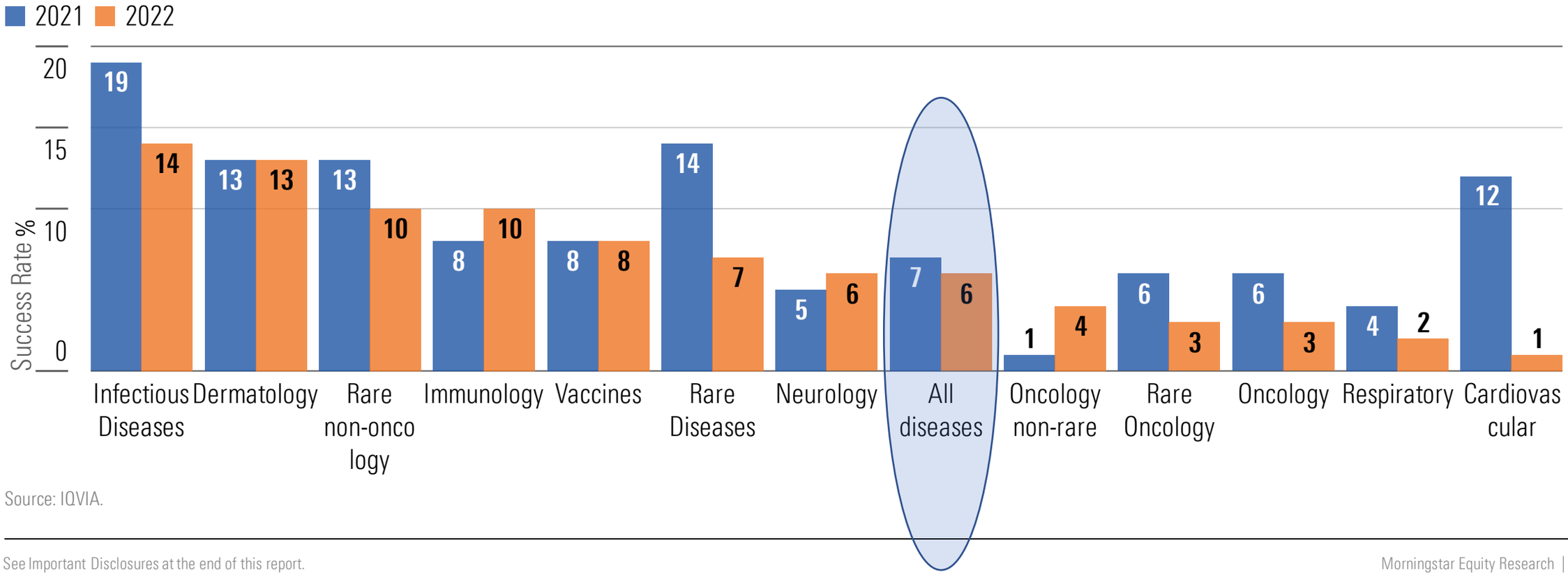
Source: FDA, BIO Industry Analysis, Research & Markets. Morningstar.

Development Prospects Vary by Therapeutic Area

While recent overall approval rates from phase 1 to market have averaged around 8%, there is a wide band around this rate. One of the biggest factors in success rates is therapeutic area, as the biology of some diseases is better understood than others. For example, there are several mechanisms for vaccines and antivirals that can be used across multiple viruses, and rare non-oncology drugs often replace an enzyme that is known to be missing. On the other hand, our understanding of cancer and the brain is still at an earlier stage.

Success Rates by Therapeutic Area

Infectious disease and immunology have higher success rates than oncology drug candidates.

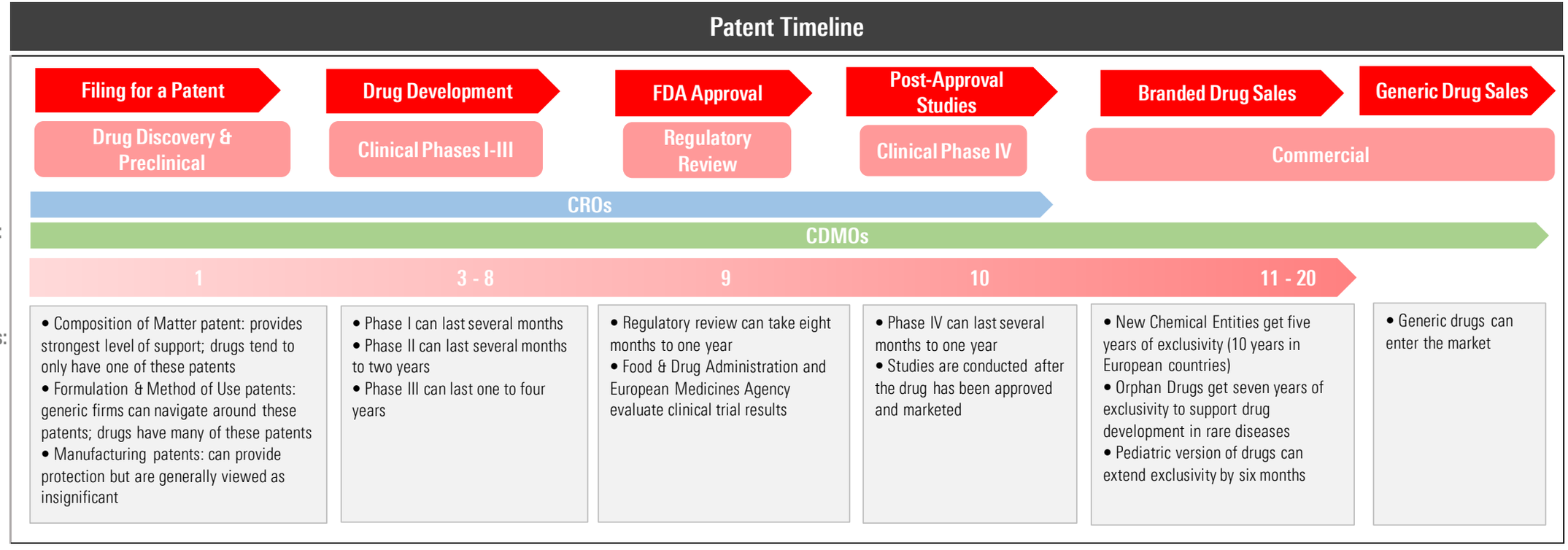


Source: IQVIA.

CROs and CDMOs Assist Biopharma Firms to Efficiently Bring Drugs to Market to Preserve Patent-Protected Time

CROs and CDMOs leverage their scientific and regulatory expertise to assist biopharmaceutical firms in the drug development process. The objective is to shorten the time frame from drug discovery to commercialization to efficiently bring drugs to market, which helps preserve valuable patent-protected time before generic drugs reach the market. We have outlined below the patent timeline related to drug development and commercialization.

CROs and CDMOs Assist Biopharmaceutical Firms Across Development and Commercialization



Source: Morningstar.

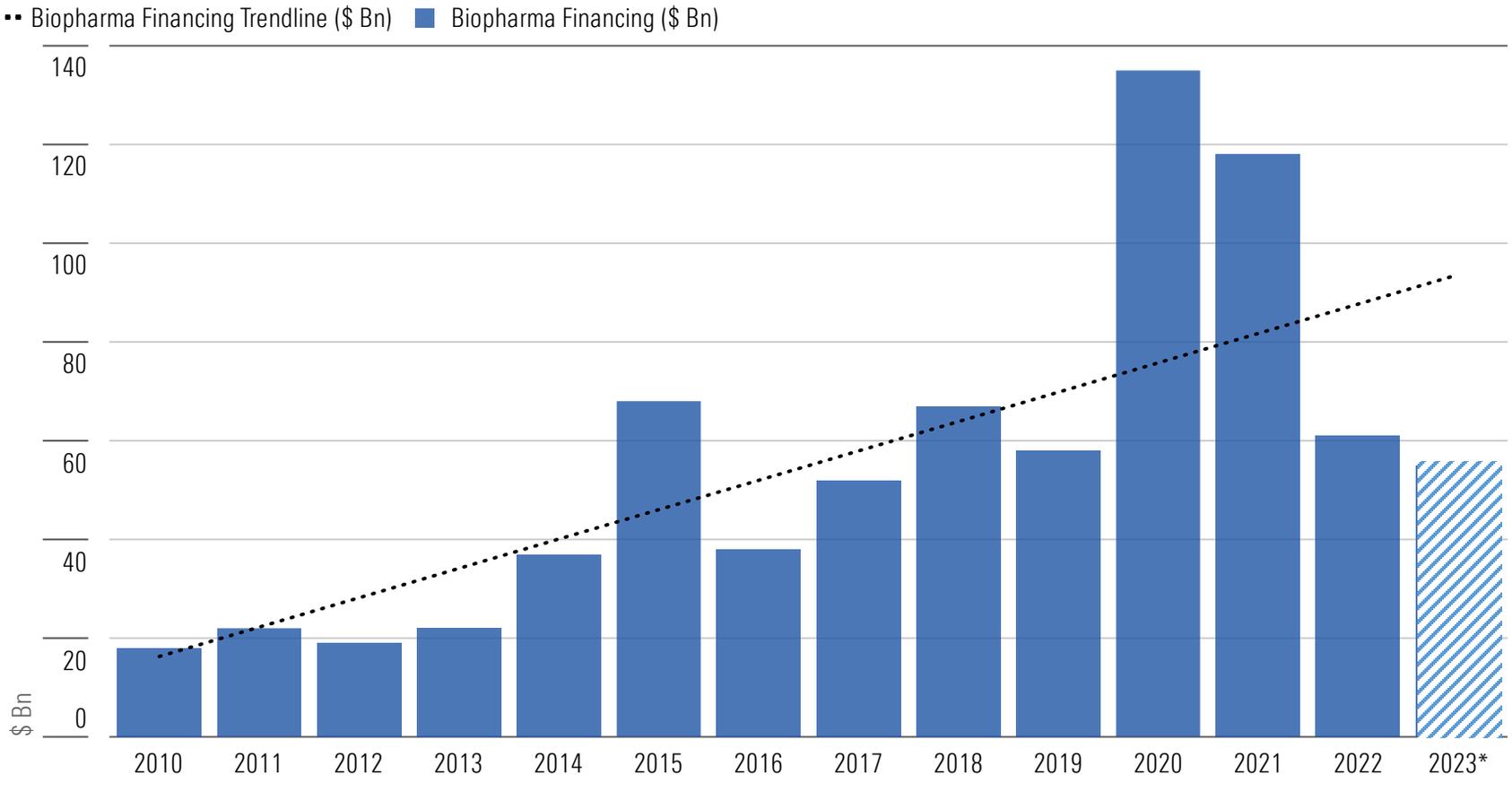
Biopharma Financing Has Trended Upward

Total biopharma funding has trended upward over the last several years. Some investors have been concerned about the recent drop in biopharma financing compared to the levels reached in 2020 and 2021—however, we note that the COVID-19 pandemic contributed to record-high levels of biopharma financing.

As of the end of October 2023, biopharmaceutical financing was $55 billion, which appears on pace to exceed 2022's $61 billion.

We think investments in novel therapeutics will continue to drive growth in biopharma financing.

Total Biopharma Financing

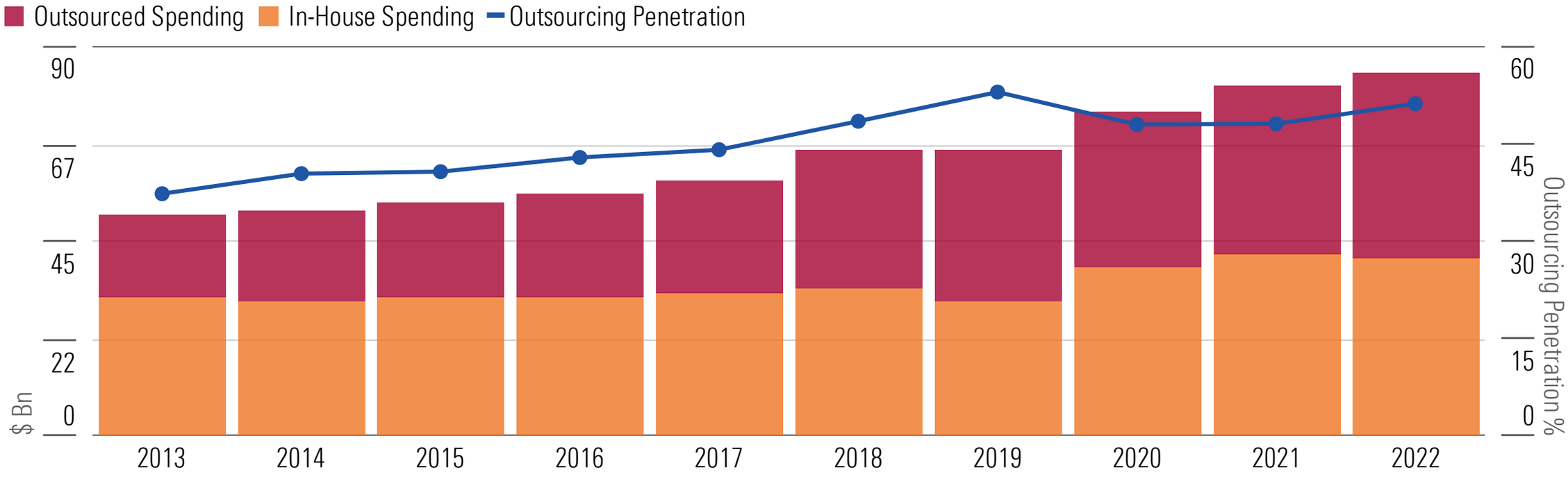


Source: BioWorld. Note: Biopharma financing includes from private, public, IPOs, follow-ons, and other types of financing.
Note: *2023 represents a partial year with financing data through Oct. 29, 2023.

Contract Research Organizations Poised to Benefit From Continued Growth in Outsourced Clinical Trials

Biopharma firms run their own clinical trials or hire contract research organizations. CROs have been steadily gaining share of clinical spending and accounted for more than half of spending in 2022, according to IQVIA. These specialized firms help biopharma companies enroll and run trials more efficiently, which can be particularly important for global, phase 3 trials. For smaller biopharma firms with less clinical trial experience, or large firms running at capacity or branching into new fields, CROs can help shorten development timelines.

Biopharma Clinical Spending and Percentage Outsourced to CROs



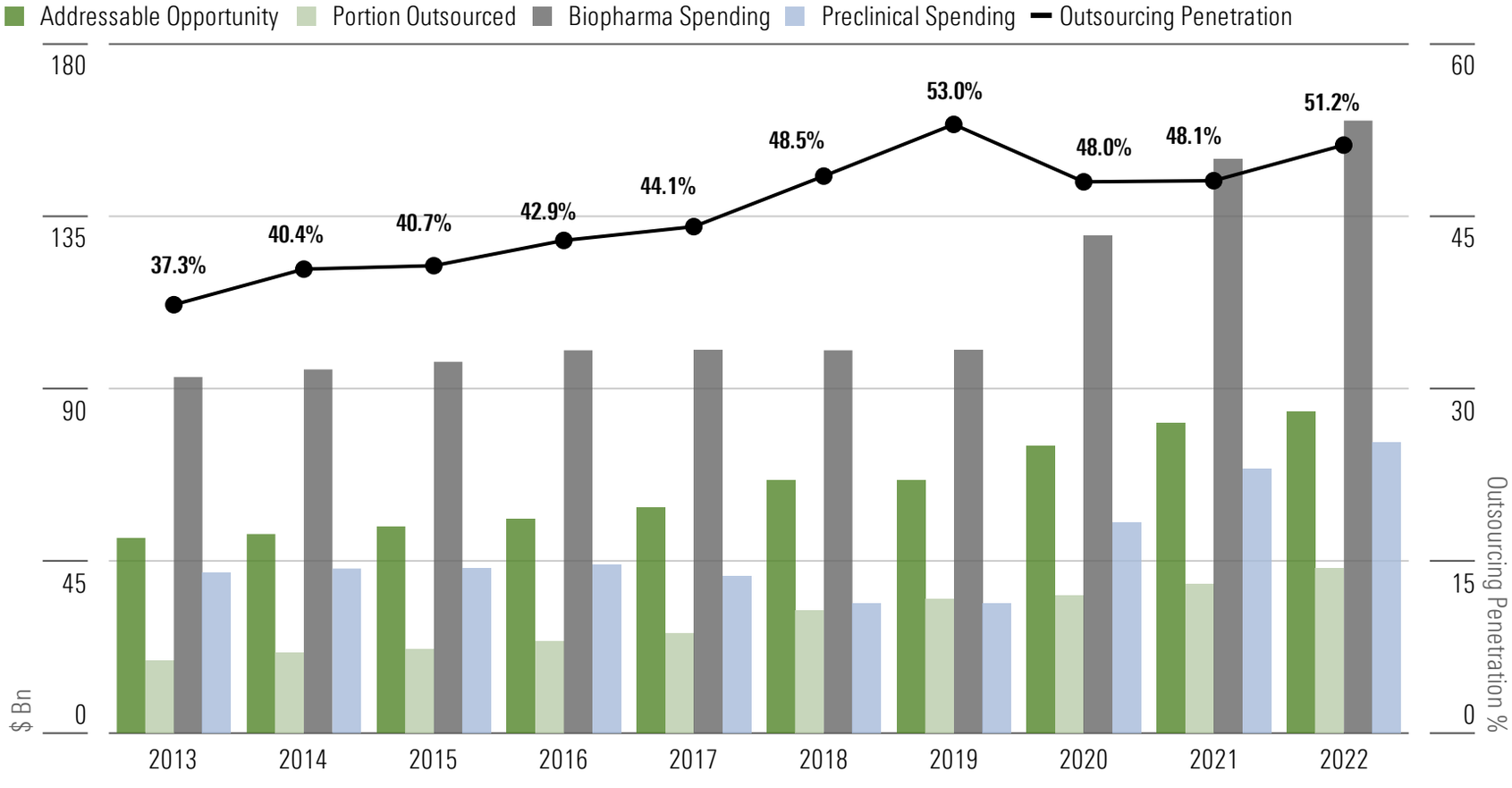
Source: IQVIA SEC Filings.

Outsourcing Is Increasing Despite Pandemic Deceleration

The deceleration in outsourcing penetration in 2020 and 2021 was due to the pandemic, and it has proven to not be long-lasting given the increase of about 300 basis points between 2021 and 2022. The pandemic skewed clinical-stage outsourcing penetration figures because it led to an increase in preclinical spending—as companies initiated early-stage development work for COVID-19 vaccines and treatments.

The increase in the addressable opportunity for late-stage CROs, which rose from $66 billion in 2019 to $81 billion in 2021, represented growth of 23%. The portion outsourced has also grown over 11% between 2019 and 2021 to $39 billion. Both figures continued to increase even during the COVID-19 pandemic, which provides support that outsourcing levels to CROs should continue to rise.

Outsourcing Penetration Relative to Biopharma Spending on Drug Development, in USD Billions



Source: IQVIA and Morningstar. Note: Addressable opportunity = clinical development spending excluding preclinical spending; Outsourcing penetration represents outsourcing from clinical development; and biopharma spending = total biopharmaceutical spending on drug development.

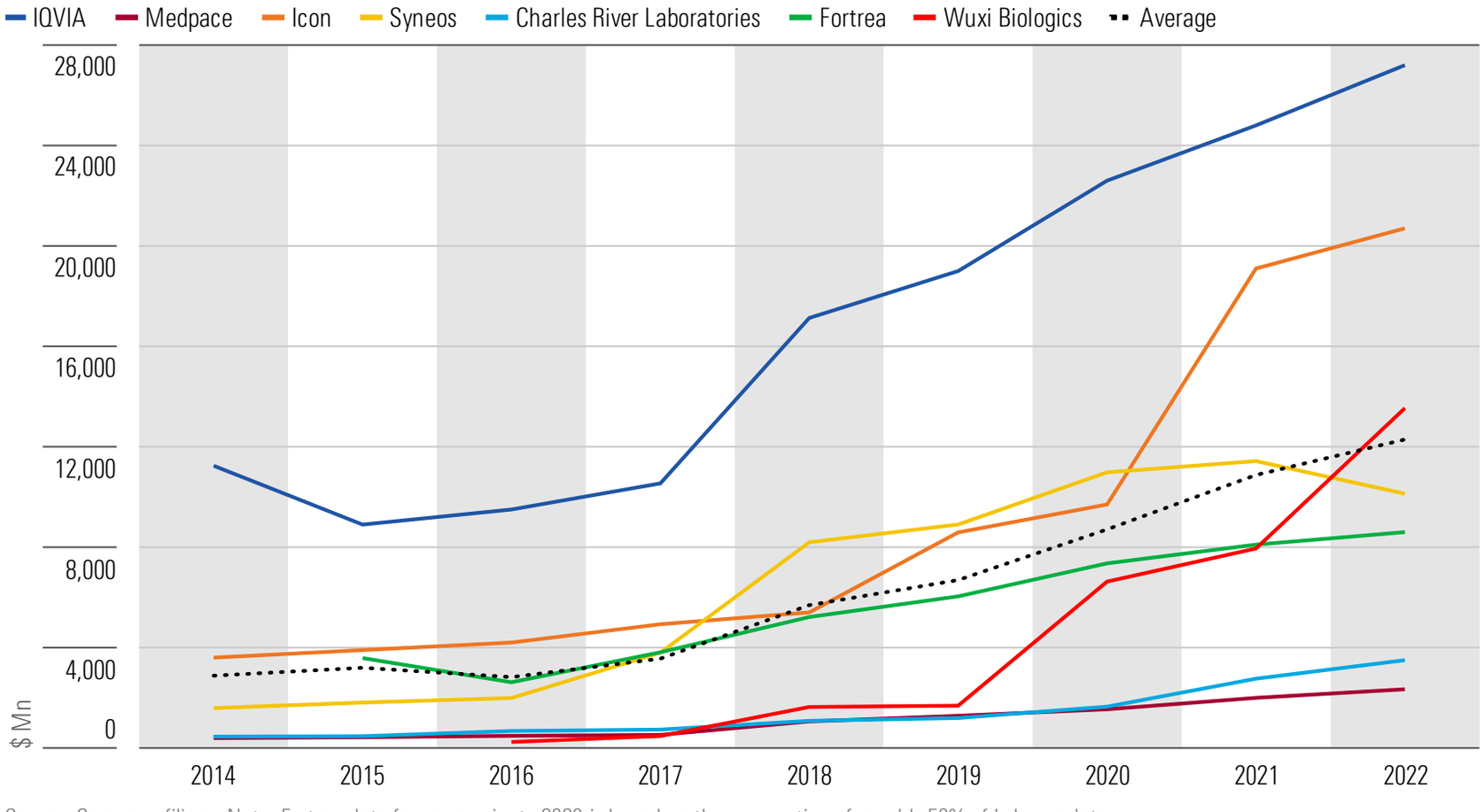
CRO Historical Backlog Levels Have Steadily Increased Thanks to Greater Outsourcing Levels

A CRO's backlog represents anticipated net service revenue from contracts that either have not started but are expected to begin soon, or are in process and have not been completed.

Historical backlog levels have trended upward across nearly all the companies under our coverage from 2014 to 2022, thanks to strong demand for outsourced clinical trial services.

The average year-over-year growth rate in backlog levels for these firms has been 21% between 2015 and 2022.

Historical Backlog for CROs Under Our Coverage



Source: Company filings. Note: Fortrea data for years prior to 2020 is based on the assumption of roughly 50% of Labcorp data.

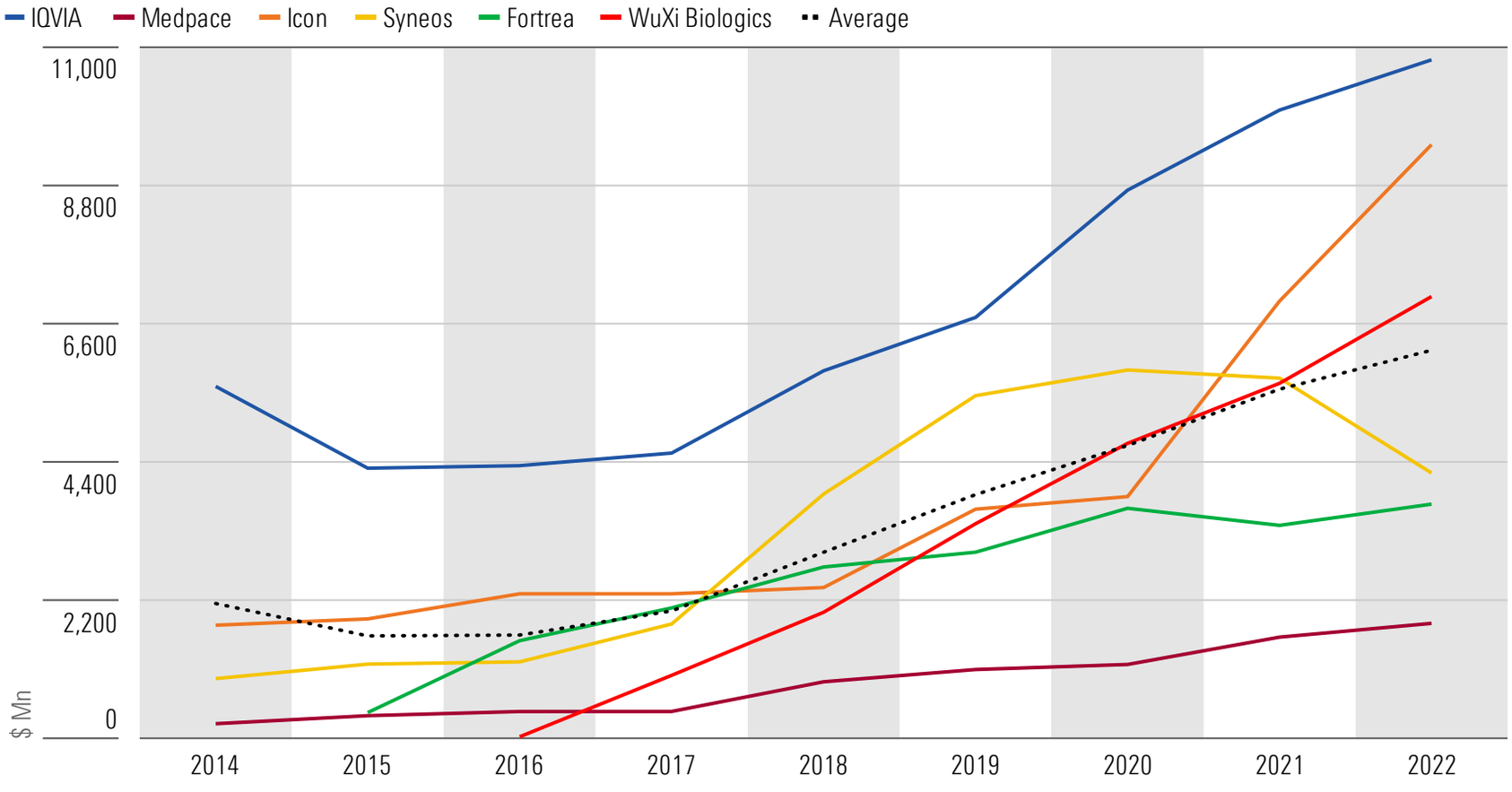
CRO Historical Net New Business Awards Have Trended Upward

Similar to the growth observed in the historical backlog levels, the CROs have seen strong net new business awards thanks to healthy demand for outsourced clinical trials.

Historical net new business awards have trended upward across nearly all the companies under our coverage from 2014 to 2022, except Syneos, which experienced company-specific challenges and was acquired by a consortium of private equity firms in 2023.

The average year-over-year growth rate in net new business awards for these firms has been 25% between 2017 and 2022.

Historical Net New Business Awards



Source: Company filings. Note: Fortrea data for years prior to 2020 is based on the assumption of roughly 50% of Labcorp data.

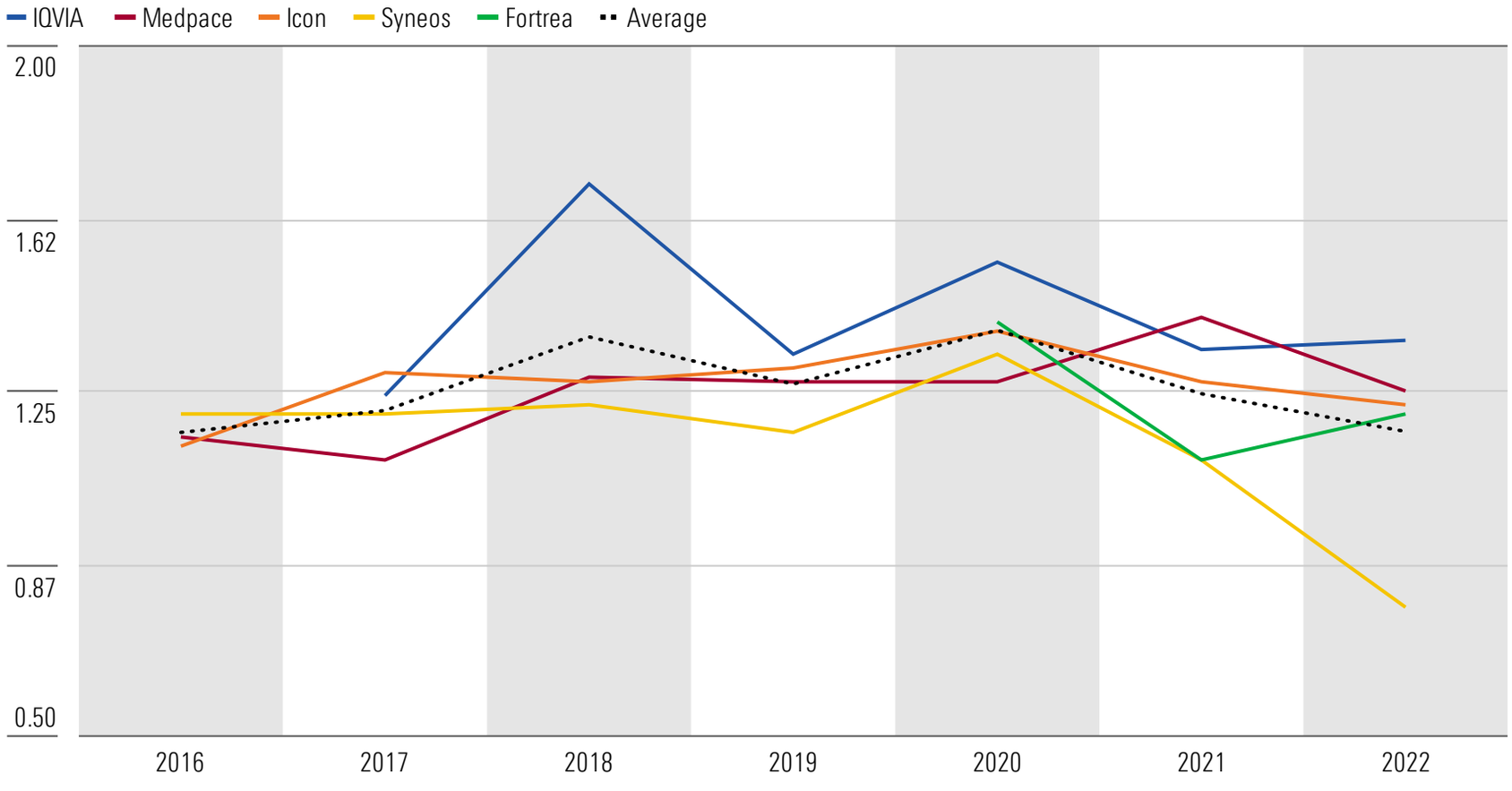
CRO Historical Net Book/Bill Ratios Have Largely Remained Above 1.0, Signally Healthy Growth

A CRO's book/bill ratio represents the ability of the CRO to replenish its backlog with new business by comparing net new business generated in the period to revenue recognized in the period.

A ratio greater than 1.0 signifies backlog growth and a ratio below 1.0 signifies contraction.

The average book/bill ratio for these firms has been 1.26 between 2016 and 2022, representing a healthy figure for this growing industry.

Historical Net Book/Bill Ratios



Source: Company filings. Note: Fortrea only reports data from 2020; IQVIA reports from 2017; all other companies report from 2016.

Glossary of Terms Used in the CRO and CDMO Industry

Commonly Used Terms in the CRO and CDMO Industry

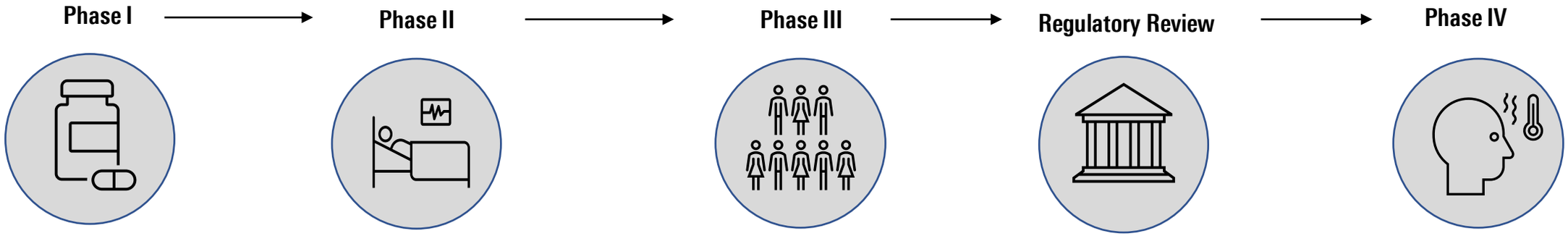
Term	Definition
Backlog	Anticipated future net service revenue from contracts, letters of intent, and other written forms of commitments that either have not started but are anticipated to begin in the near future, or are in process and have not been completed.
Book/Bill ratio	Evaluates the ability of the CRO to replenish its backlog with new business by comparing net new business generated in the period to revenue recognized in the period. A ratio greater than 1.0 signifies backlog growth and a ratio below 1.0 signifies contraction.
First patient in (FPI)	The date and time when the first patient that meets the trial's inclusion criteria is enrolled and randomized into a study.
Last patient in (LPI)	The date and time when the last patient to participate in a clinical trial is enrolled.
Screen failure	A screen failure occurs when a potential patient undergoes screening but never gets enrolled into the trial, which results in significant costs for the sponsor without contributing valuable data to the study.

Source: Syneos Health 2015 annual report; Deloitte, "Understanding and evaluating deal considerations in the contract research organization sector: An update for private equity investors, 2016"; Medical Dictionary by Farlex; NIA Glossary of Clinical Research Terms, National Institute on Aging.

Clinical Trials Phases I-IV

The length of clinical studies spans many years, and it is difficult for biopharma companies to change CROs once studies are underway since this would lead to delays in the development timeline. This creates high switching costs for the biopharma customers and supports the narrow economic moat ratings for CROs. We define the key phases of clinical development below.

Overview of Phases I-IV



Phase I trials test a new biomedical intervention in 20-100 people to determine a safe dosage range and to identify side effects. Phase I trials can include healthy participants.

Phase II trials study the biomedical intervention in several hundred people with the disease to determine efficacy and further evaluate its safety and short-term side effects.

Phase III trials investigate the efficacy of the biomedical intervention in several hundred to several thousand people by comparing it to other standard or experimental interventions and monitoring side effects.

Regulatory agencies, such as the Food & Drug Administration and European Medicines Agency evaluate the results of the trial to determine whether to approve the new biomedical intervention.

Phase IV studies are conducted after the biomedical intervention has been approved and marketed. These studies monitor the effectiveness of the intervention in the general population and collect information about side effects associated with widespread, long-term use.

Source: Syneos Health 2015 annual report; Deloitte, "Understanding and evaluating deal considerations in the contract research organization sector: An update for private equity investors, 2016"; Medical Dictionary; NIA Glossary of Clinical Research Terms, National Institute on Aging.

Industry Basics

Evolution of the CRO and CDMO industry.

Private Equity Investments Accelerate Consolidation in the CRO Industry

Major strategic shifts across the pharmaceutical and biotechnology industries have occurred over the past 40 years, which have resulted in the current CRO industry being dominated by a handful of top-tier, global CROs. In the 1980s, it was typical for pharmaceutical companies to run everything themselves, including the drug discovery process, clinical trials, and ultimately manufacturing and commercializing drugs. However, pharmaceutical companies occasionally encountered capacity issues, which restricted their growth potential. This led to the formation of CROs. Since then, there has been significant consolidation in the CRO and CDMO industry as private equity firms have entered the space.

Private Equity Investments in CROs

Target CROs	Private Equity Firms	Year Acquired	Purchase Price (USD)
Premier Research	ECI Partners; Indigo Capital; HarbourVest	2008	$118.18 million
PPD	Hellman & Friedman; Carlyle Group	2011	$3.6 billion
inVentiv Health	Thomas H. Lee Partners	2011	$1.1 billion
PRA International	KKR	2013	$1.3 billion
Medpace	Cinven	2014	$915 million
Parexel	Pamplona Capital Management	2017	$5 billion
Parexel	EQT Private Equity; Goldman Sachs	2021	$8.5 billion
Syneos	Elliott Investment Management; Patient Square Capital; Veritas Capital	2023	$7.1 billion

Source: PitchBook, company press releases.

Consolidation Across the CRO Industry Has Expanded Geographic Footprints and Capabilities

Publicly traded firms across the healthcare industry have made many sizable acquisitions, in addition to tuck-in acquisitions, which have led to significant consolidation across the CRO industry. These acquisitions have expanded geographic footprints, capabilities, and created global, top-tier CROs. Notably, Labcorp and Thermo Fisher Scientific entered the CRO space through their hefty acquisitions of Covance for $5.6 billion and PPD for $17.4 billion, respectively.

Notable Acquisitions Across the CRO Industry

Target CROs	Publicly Traded Acquirers	Year Acquired	Purchase Price (USD)
Covance	Labcorp	2015	$5.6 billion
Quintiles	IQVIA	2016	$9 billion
Covance	Eurofins Scientific	2018	$670 million
MPI Research	Charles River Laboratories	2018	$800 million
Citoxlab	Charles River Laboratories	2019	$510 million
Hemacare	Charles River Laboratories	2020	$380 million
Envigo	Inotiv	2021	$657.78 million
PPD	Thermo Fisher Scientific	2021	$17.4 billion
PRA Health Sciences	Icon	2021	$12 billion
Q2 Solutions	IQVIA	2021	$760 million

Source: PitchBook, company press releases. Note: some acquisitions listed are for specific service units, not full company.

Private Equity Investments in CDMOs Have Increased Over the Last Several Years

Since 2017, mergers and acquisitions in the CDMO industry have been increasing, with around 50 transactions completed annually across public and private equity buyers. Private equity firms have found CDMOs to be attractive investment opportunities thanks to the long-term growth prospects, the increasing complexity of drug development and manufacturing, and the potential for less risky healthcare exposure compared with investing directly in biotechnology or pharmaceutical companies.

Private Equity Investments in CDMOs

Target CDMOs	Private Equity Firms	Year Acquired	Purchase Price (USD)
Catalent	Blackstone; Aisling Capital; Genstar Capital	2007	$3.3 billion
Unither Pharmaceuticals	Equistone Partners; Ardian; Parquest Capital; Picardie Investissement; CM-CIC Investissement	2011	$284.68 million
Unither Pharmaceuticals	Ardian	2016	$715 million
Unither Pharmaceuticals	Ardian; IdInvest Partners; Keensight Capital; Parquest Capital	2017	$717.68 million
Albany Molecular Research, Inc	The Carlyle Group; GTCR; HarbourVest	2017	$1.96 billion
Ritedose	AGIC Group; Humanwell Healthcare; China Investment Corp	2017	$700 million
Vibalogics	Ampersand Capital Partners	2019	Not disclosed
Cambrex	Permira	2019	$2.4 billion
Biofarma Group	White-Bridge Capital Management	2019	Not disclosed
Performance Cell Manufacturing	Great Point Partners; OrbiMed	2021	Not disclosed
Recipharm	EQT Partners; Ardian	2021	$2.1 billion
UDG Healthcare	Inizio; Clayton, Dubilier, & Rice	2021	$3.87 billion
Ritedose	Novo Holdings	2022	$915 million
Biofarma Group	Ardian; Synergetic	2022	$1.22 billion
Vibalogics	Recipharm; EQT; Ardian	2022	Not disclosed
CordenPharma	Astorg	2022	$2.6 billion
Unither Pharmaceuticals	Parquest Capital; Keensight Capital; IK Partners; NiXEN Partners; GIC	2023	$535.64 million

Source: PitchBook, company press releases. Note: excludes acquisitions under $100 million.

Further Consolidation Across the Fragmented CDMO Space Expands Manufacturing Capabilities

Similar to the consolidation seen among CRO firms, publicly traded firms across the healthcare industry have made many sizable acquisitions, in addition to tuck-in acquisitions, which has led to significant consolidation across the CDMO industry. These acquisitions have expanded geographic footprints, capabilities, and created global, top-tier CDMOs.

Notable Acquisitions Across the CDMO Industry

Target CDMOs	Publicly Traded Acquirers	Year Acquired	Purchase Price (USD)
Epic Pharma	Humanwell Healthcare; PuraCap Pharmaceutical (private)	2016	$550 million
DPT Laboratories (Owned by Renaissance Pharma in 2016)	Mylan (Now owned by Pfizer)	2016	$972.7 million
CMC Biologics	AGC (Tokyo) (Owned by Owens Corning)	2016	$511 million
Capsugel	Lonza	2017	$5.5 billion
Cook Pharmica	Catalent	2017	$950 million
Generis Farmaceutica	Aurobindo Pharma	2017	$144.51 million
Patheon	Thermo Fisher Scientific	2017	$7.36 billion
Gland Pharma	Fosun Pharma	2017	$1.09 billion
Brammer Bio	Thermo Fisher Scientific	2019	$1.67 billion
Paragon Bioservices	Catalent	2019	$1.19 billion
Oxgene	WuXi AppTec	2021	$135 million
Cognate BioServices	Charles River Laboratories	2021	$875 million
Aldevron	Danaher	2021	$9.6 billion
Vectura Group	Philip Morris International	2021	$1.51 billion
Quay Pharma	SGS	2021	$120.26 million

Source: PitchBook, company press releases.

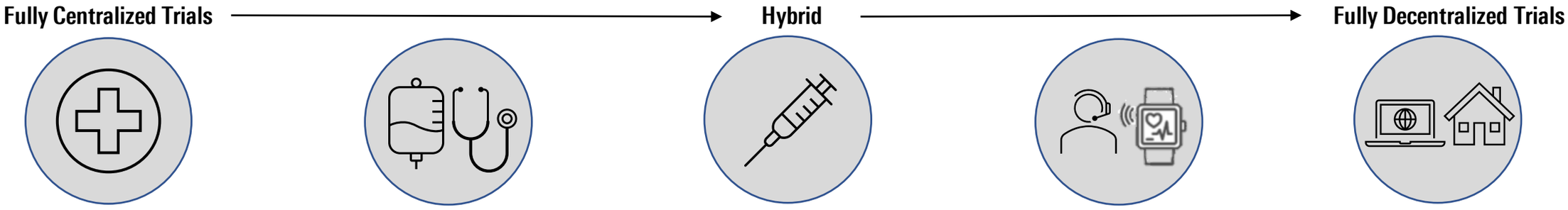
Outlook: Decentralized Trials

Decentralized clinical trials deliver measurable benefits for CRO customers.

There Are a Variety of Clinical Trial Designs, Spanning Fully Centralized to Fully Decentralized Trials

Decentralized clinical trials, or DCTs, are the modernization of the traditional, in-person trials conducted at clinical trial sites. DCTs are defined as studies "executed through telemedicine and mobile/local healthcare providers, using processes and technologies differing from the traditional clinical trial model." The term "decentralization" refers to activities that previously occurred in a centralized location at a CRO site, traditional academic medical center, or hospital. Some of these activities can now be conducted remotely either in a participant's home via telehealth or at a local lab or pharmacy. The foundation of DCTs is technology, which enables patient participation and convenience.

Clinical Trials Can Take a Variety of Forms From Fully Centralized Trials to Hybrid to Fully Decentralized Trials

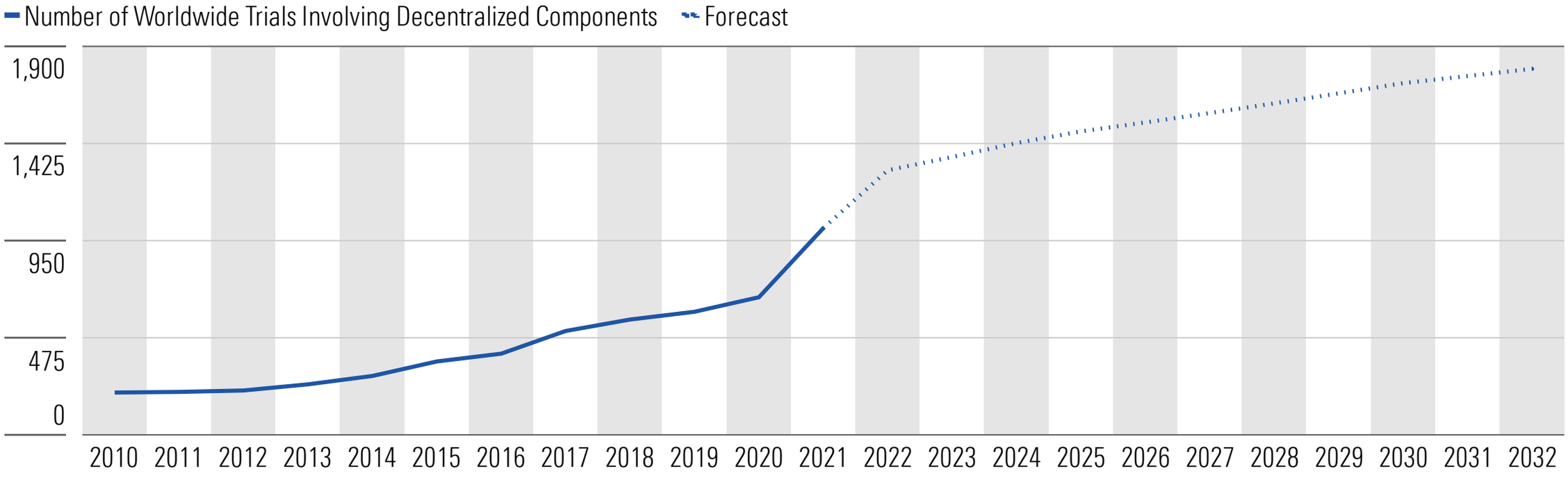


Source: Clinical Trials Transformation Initiative, Morningstar.

The COVID-19 Pandemic Necessitated Decentralized Clinical Trials

The COVID-19 pandemic significantly accelerated the adoption of DCTs. Prior to the pandemic, some trials were conducted in a hybrid format in combination with traditional, in-person trials. However, many clinical trial investigators were hesitant to use DCTs due to regulatory uncertainty. The public health emergency from the pandemic accelerated the Food and Drug Administration's efforts to provide guidance for running DCTs. There has been a significant increase in worldwide trials involving decentralized components, which increased from 207 trials in 2010 to 1,011 trials in 2021. We anticipate demand for DCTs will continue to steadily increase as regulatory agencies establish more guidelines for their broader adoption.

The Number of Worldwide Trials Involving Decentralized Components Has Accelerated Thanks to the COVID-19 Pandemic



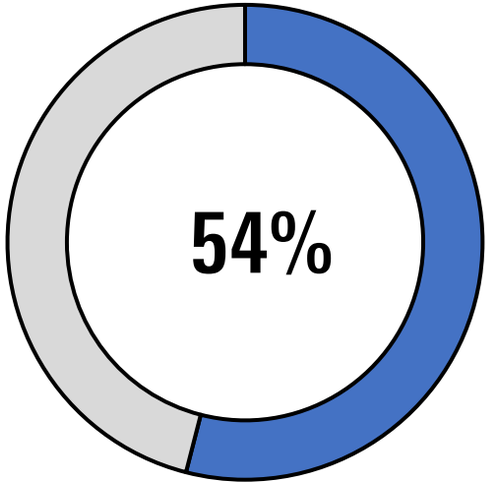
Source: GlobalData, Morningstar.

Decentralized Clinical Trials Deliver Measurable Benefits by Reducing Time and Costs

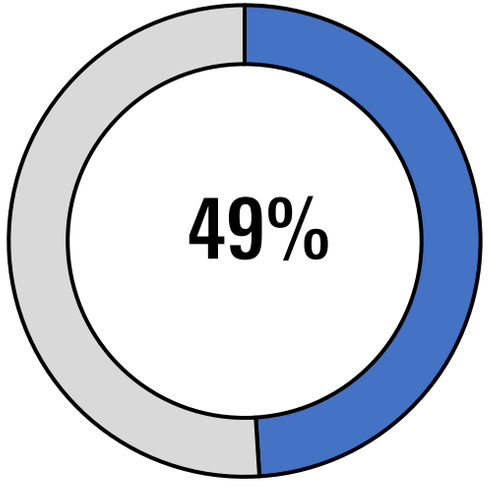
Biotechnology and pharmaceutical firms seek to shorten the drug development timeline while maintaining the precision and accuracy necessary for regulatory approval. IQVIA published an in-depth analysis of decentralized clinical trials in July 2022, which compared IQVIA's DCTs with traditional clinical trials across 12 studies and three therapeutic areas (neurology, infectious disease, and dermatology). The analysis revealed that DCTs delivered time and cost efficiencies, reduced risks, improved trial quality, and enhanced the patient experience throughout the clinical trial journey.

Decentralized Clinical Trials Deliver Measurable Benefits

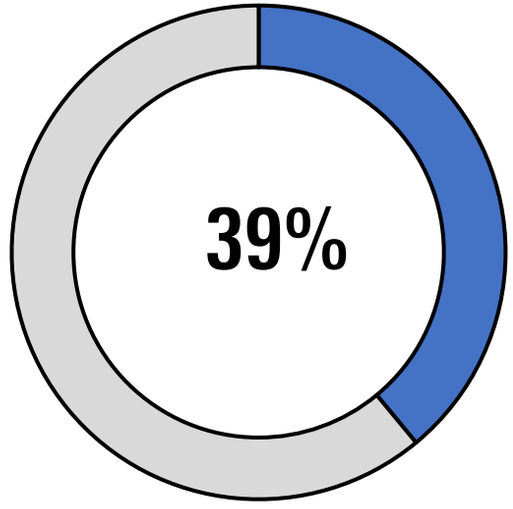
Clinical trial protocol deviations dropped an average of 54% for DCTs compared with traditional trials.



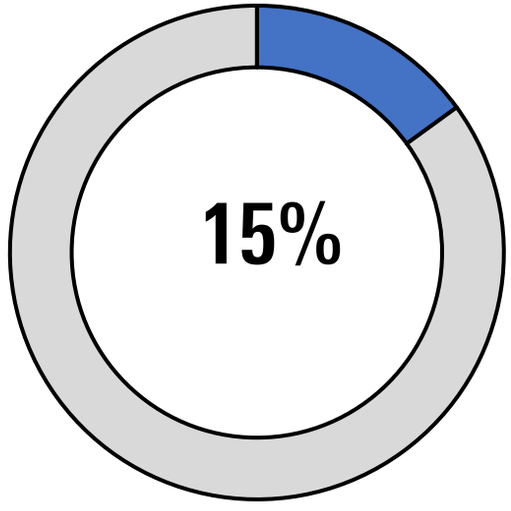
DCTs reduced the time to first patient in, or FPI, by an average of 49%.



Screen failure rates dropped by 39%, which leads to time and cost savings for sponsors.



DCTs experienced a 15% reduction in participant dropout rates.



Source: IQVIA.

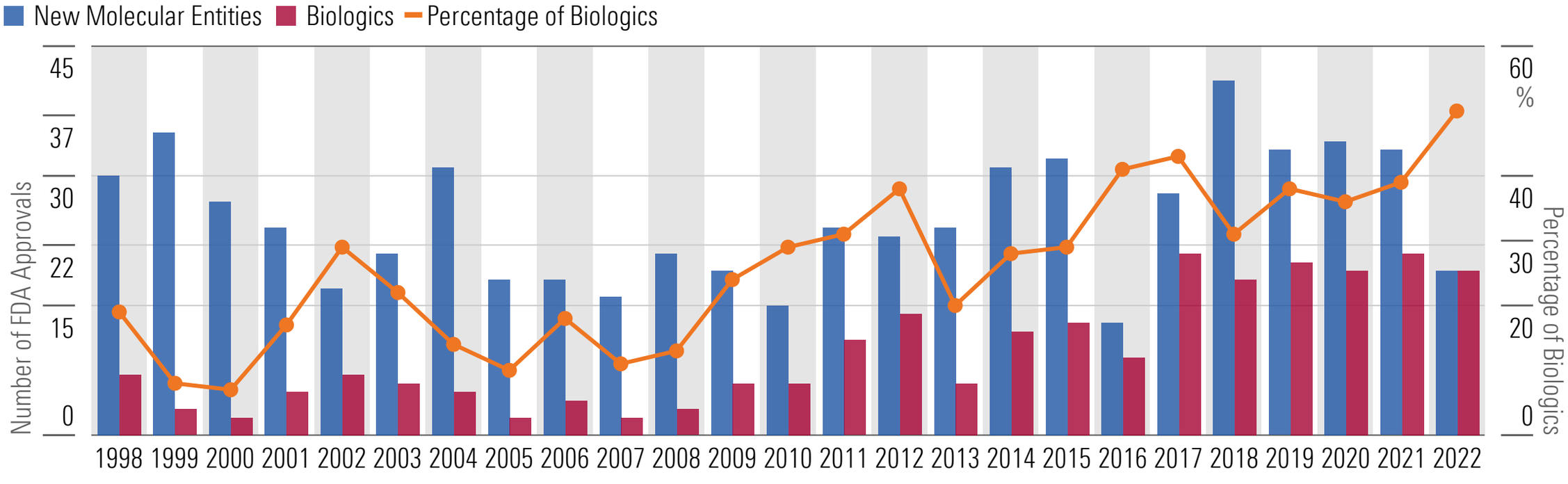
Outlook: CROs/CDMOs and Biopharma

Biopharma growth creates tailwinds for CROs and CDMOs.

Biologics Provide Additional Tailwinds for CDMOs Due to Their Complex Manufacturing Requirements

In 2022, biologics gained share and accounted for 50% of FDA approvals during the year. Biopharma companies have increased their investments in these drugs for several reasons, including biologics' strong efficacy at targeting diseases and the high selling price they can command compared with other drugs, such as small molecules. It's estimated that biologics account for only 2% of all drugs on the market, but they are responsible for 37% of all drug spending in the United States. We anticipate the substantial investments in biologics made by biopharma firms will create a tailwind for the CRO and CDMO industry as these drugs are more complex to evaluate in clinical trials and difficult to produce. We appreciate that Lonza, Catalent, and WuXi Biologics have been investing in biologics and gene editing manufacturing services to keep up with strong demand for these novel therapeutics.

Historical FDA Approvals and Percentage of Biologics

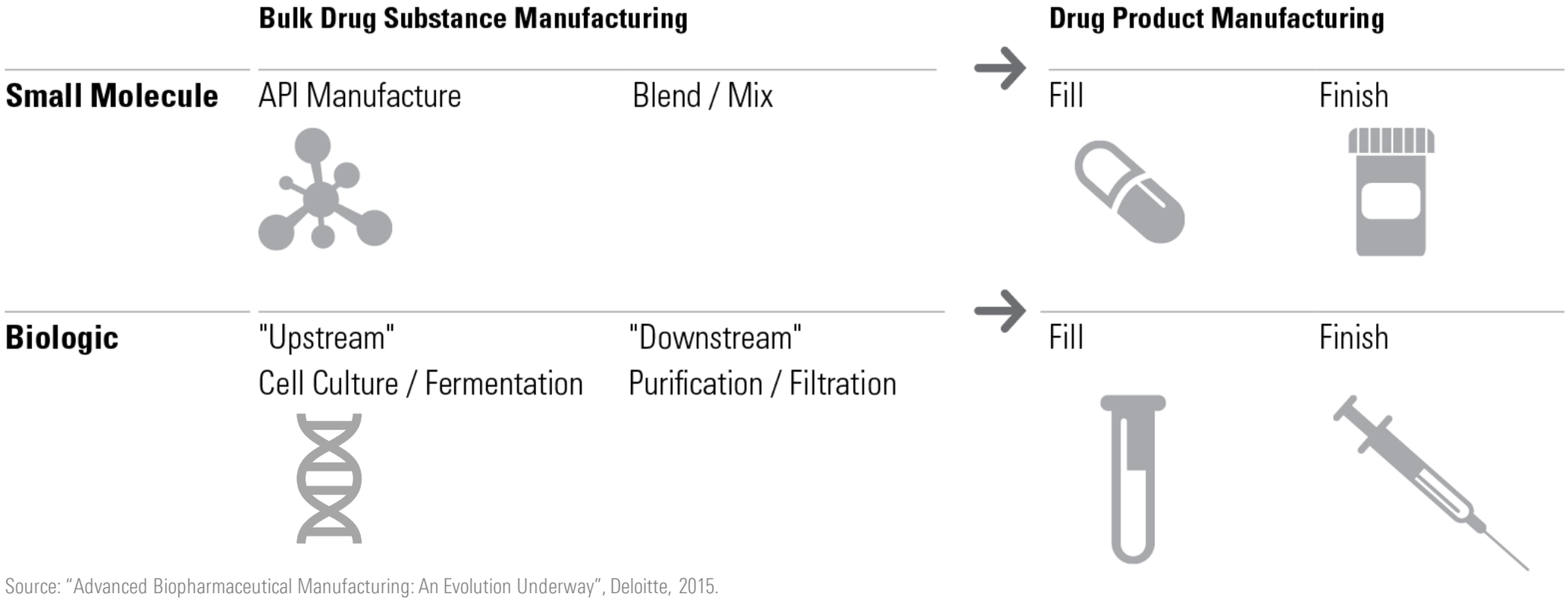


Source: Nature Biotechnology, January 2023.

Top-Tier CDMOs Possess Drug Manufacturing Expertise Across Various Drug Types

Large CDMOs like Lonza, Catalent, and WuXi Biologics possess drug manufacturing expertise across small molecules and biologics, which allows them to take on a variety of customers' orders across different drug types and therapeutic areas. Most drugs are either small molecule drugs (typically oral) or biologics (typically injected), but new gene and cell-based therapies are reaching the market. Small molecule manufacturing involves chemical synthesis to make the active pharmaceutical ingredient and creating a pill. Biologics are larger enzymes or proteins created in living cells.

Manufacturing Small Molecules Versus Biologics



Source: "Advanced Biopharmaceutical Manufacturing: An Evolution Underway", Deloitte, 2015.
Note: API stands for active pharmaceutical ingredient.

CDMOs Have Invested Heavily in Next-Generation Drug Manufacturing Capabilities

Lonza and Catalent have been investing heavily in novel drug manufacturing capabilities to meet the current demand, and anticipated demand, as their biopharma customers are researching next-generation drugs using cell therapies, gene therapies, GLP-1s, and mRNA technologies. We appreciate that Lonza and Catalent have been expanding their manufacturing capabilities and expertise for these novel therapeutics. Even if some of the novel drugs currently in development do not have successful clinical data or do not receive approval, the CDMOs will have developed the manufacturing capabilities to produce other drugs using the same technology, which will set them up for long-term growth opportunities.

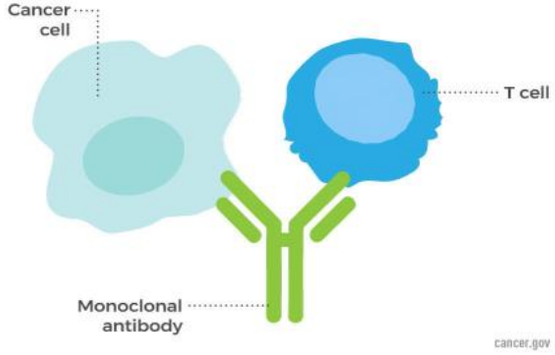
CDMO Partnerships to Produce Novel Drug Types

CDMO	Biopharmaceutical Firm	Drug Type	Therapeutic Area (Drug Name)
Lonza	Vertex	Cell Therapy	Type 1 diabetes
Catalent	AavantiBio	Gene Therapy	Friedreich's ataxia
Catalent	Sarepta Therapeutics	Gene Therapy	Duchenne muscular dystrophy (Elevidys)
Lonza	Bluebird Bio	Gene Therapy	Beta thalassemia (Zynteglo); Cerebral adrenoleukodystrophy (Skysona)
Catalent	Novo Nordisk	GLP-1	Obesity (Wegovy)
Catalent	Moderna, Pfizer, AstraZeneca	mRNA	COVID-19
Lonza	Moderna, Pfizer, AstraZeneca	mRNA	COVID-19
Catalent	AstraZeneca	AAV Vector Vaccine	COVID-19
Lonza	AstraZeneca	AAV Vector Vaccine	COVID-19

Source: Company press releases.

CDMOs Increasingly Manufacture Complex Biologics

Monoclonal Antibodies



Source: National Cancer Institute, 2019.

- Monoclonal antibodies are similar to antibodies that humans naturally make to fight illness, but they are designed in a lab to attach to a specific target in the body.
  - Lonza extended its collaboration with a major biopharma partner for the large-scale supply of monoclonal antibodies.

Bispecific Antibodies in the Pipeline

BCMA Targeting	CD20 Targeting
J&J's Tecvayli	Regeneron's odronextamab
Regeneron's linvoseltamab	Roche's Lunsumio, glofitamab
Pfizer's elranatamab	AbbVie's epcoritamab

Source: Company reports. Note: BCMA stands for B-cell maturation antigen; CD20 is a B cell-specific membrane protein.

- Bispecific antibodies contain two targets in one molecule. Rather than both arms of the antibody focusing on a single target, the arms have different targets and are often used to bring two different cells together.
  - Lonza has an agreement with ABL Bio, a Korean biologics company, to develop and manufacture ABL Bio's new bispecific antibodies for immuno-oncology and neurodegenerative diseases.

Antibody Drug Conjugates: Key Players

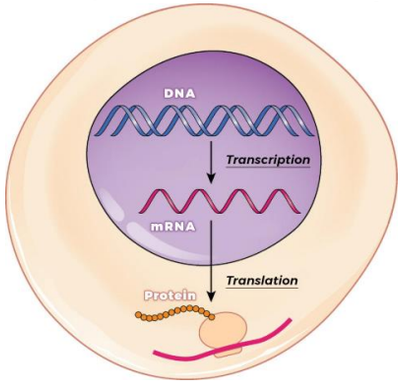
AstraZeneca/ Daiichi Sankyo	Seagen	Roche	Gilead
Enhertu	Adcetris	Kadcyla	Trodelvy
datopotamab deruxtecan	Padcev	Polivy	
patritumab deruxtecan	Tivdak		

Source: Company reports.

- Antibody-drug conjugates, or ADCs, are composed of a monoclonal antibody attached to a potent chemotherapy agent that is released once the ADC reaches the target in order to treat cancer.
  - Lonza extended its collaboration with a major biopharma partner for the commercial-scale filling of ADCs.

CDMOs Invest in Manufacturing Capabilities for New Drug Classes to Support Long-Term Growth

Messenger RNA (mRNA) Codes For Key Proteins



Source: National Cancer Institute, 2020.

Leading Antisense and RNAi Therapies

RNAi
Alnylam's Onpattro/Amvuttra
Alnylam's Givlaari
Antisense
Ionis/Biogen's Spinraza
Ionis/Astra's Eplontersen (2023E Approval)

Source: Company reports.

Leading Gene Editing and Gene Therapy Programs

Gene Editing Firm	Disease	Launch
Intellia/Regeneron	Amyloidosis	2025E
Intellia/Regeneron	Hereditary Angioedema	2026E

Gene Therapy Firm	Disease	Launch
Novartis	SMA	2019
BioMarin	Hemophilia A	2023E
Roche	Hemophilia A	2025E

Source: Company reports. Note: SMA stands for spinal muscular atrophy.

- Messenger RNA, or mRNA, occurs naturally in the body and serves as an intermediary in the creation of proteins from an individual's DNA.
    - Catalent extended its manufacturing partnership with Moderna to support the manufacturing of multiple mRNA pipeline candidates including flu and respiratory syncytial virus, or RSV, vaccines, in addition to its COVID-19 products.

RNA interference, or RNAi, is a gene silencing technology that inhibits protein synthesis in target cells using double-stranded RNA. A similar result is achieved by Antisense technology through single-stranded RNA.

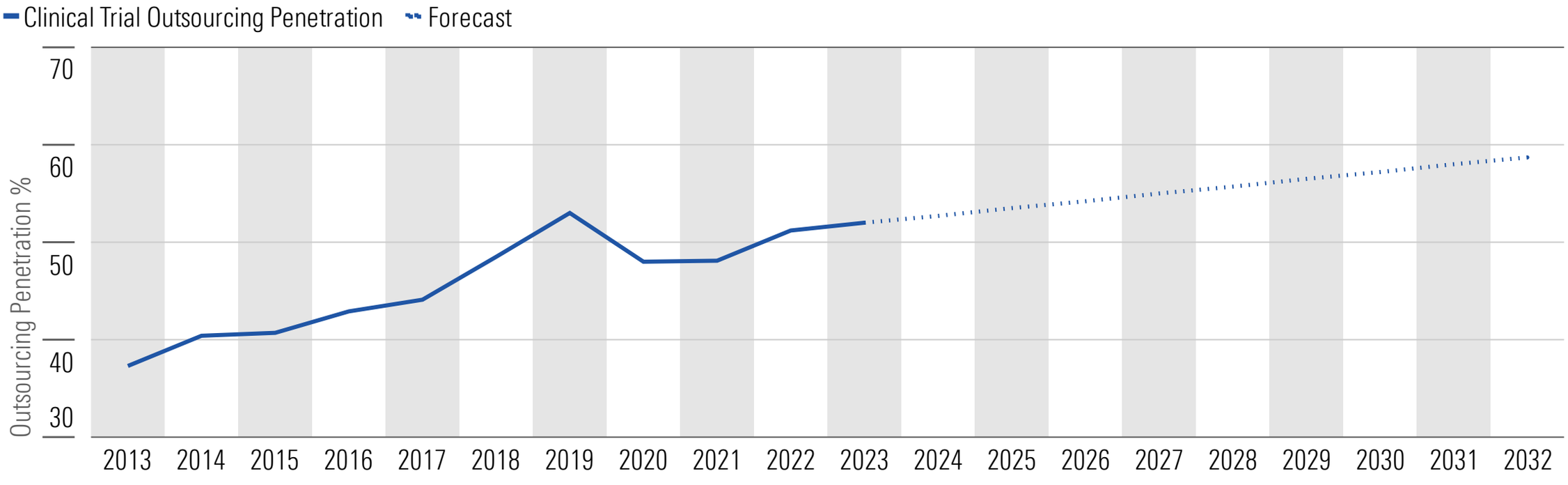
- Lonza's facility in Visp, Switzerland is equipped with small- and large-scale automated synthesizers for the production of oligonucleotides, such as siRNA and Antisense therapies.

- While mRNA, Antisense, and RNAi work at a level just before protein production, gene editing and gene therapy focus on the underlying DNA sequence, with the objective of making the DNA changes permanent.
    - Catalent opened a new commercial-scale plasmid DNA manufacturing facility to support the development of cell and gene therapies.

Tailwinds Support Healthy Outsourcing Outlook

Clinical trial outsourcing penetration has been increasing over the last ten years–growing from 37.3% in 2013 to 51.2% in 2022 as biopharmaceutical companies have realized the benefits of outsourcing to CROs. We anticipate this trend will continue, with steady outsourcing growth over the next 10 years and reaching nearly 60% outsourcing by 2032.

Clinical Trial Outsourcing Penetration Forecast

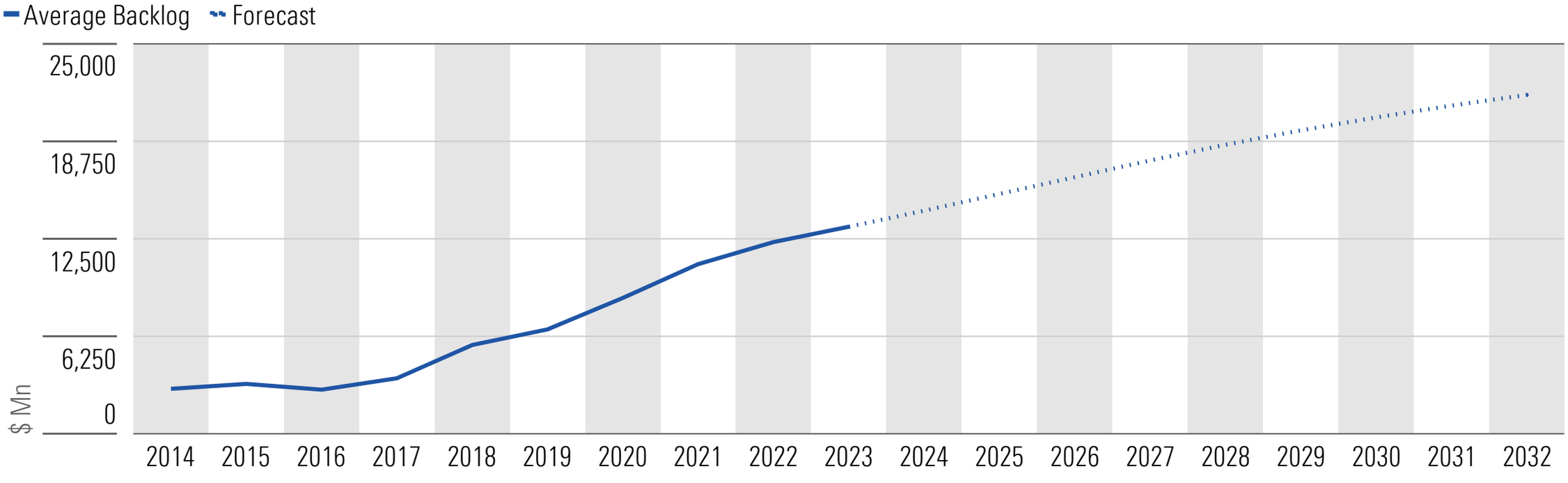


Source: IQVIA, Morningstar.

Tailwinds Support Healthy Backlog Outlook

Historical backlog levels in the CRO industry have trended upward across nearly all the companies under our coverage from 2014 to 2022, thanks to strong demand for outsourced clinical trial services. The average year-over-year growth rate in backlog levels for these firms has been 21% between 2015 and 2022. We anticipate the combined average backlog level for the CRO industry to remain healthy over the next 10 years and reach nearly $22 billion.

CRO Backlog Forecast



Source: Company filings, Morningstar.

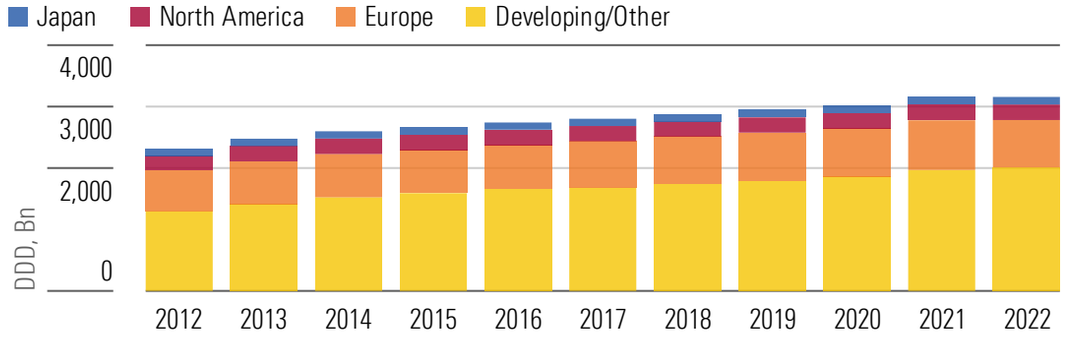
Greater Demand for Medicine Globally Supports Continued Growth for CROs and CDMOs

The demand for medicine has expanded globally, and this benefits the CRO and CDMO industry. Greater demand for medicines, especially from developing countries, leads to an expanded patient population and more revenue opportunities for CROs and CDMOs as the drug development process continues to steadily become more outsourced.

According to IQVIA's estimates of defined daily doses of medicine globally, use of medicine has increased at roughly a 3% average annual rate over the past 10 years, slowing to a 2% average annual rate over the past three years. Most of this growth has taken place in markets beyond major developed countries due to improving healthcare access and population growth in developing markets.

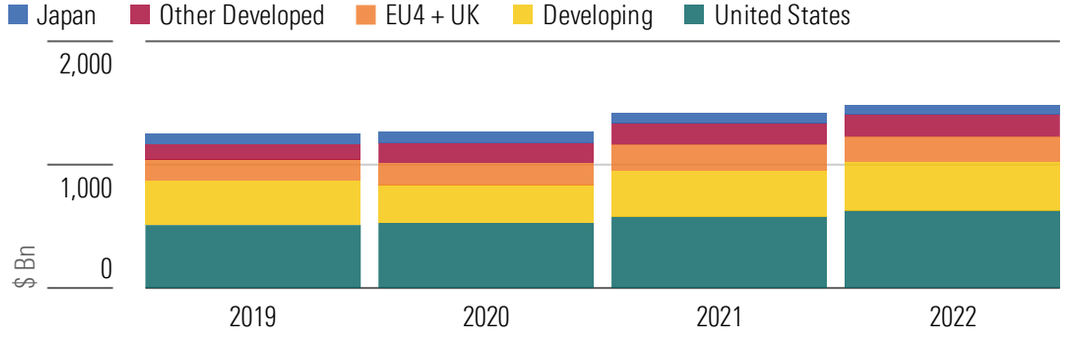
Global invoice-level drug spending (excluding insurer rebates) in 2022 was roughly $1.5 trillion, with $900 billion from branded drugs. Although the U.S. represents less than 5% of the global population, it accounts for more than 40% of the global prescription drug market (more than $600 billion). Global spending has increased at an average annual rate of 6% since 2019, differing from volume growth (based on defined daily doses) over this period likely because of price increases and new drugs launching at higher-than-average prices, particularly in the U.S. market.

Global Use of Medicine Has Increased at a 3% Average Annual Rate, 2012-22



Source: IQVIA. Note: DDD stands for defined daily doses.

Global Drug Spending by Region Rose 6% Annually, 2019-22



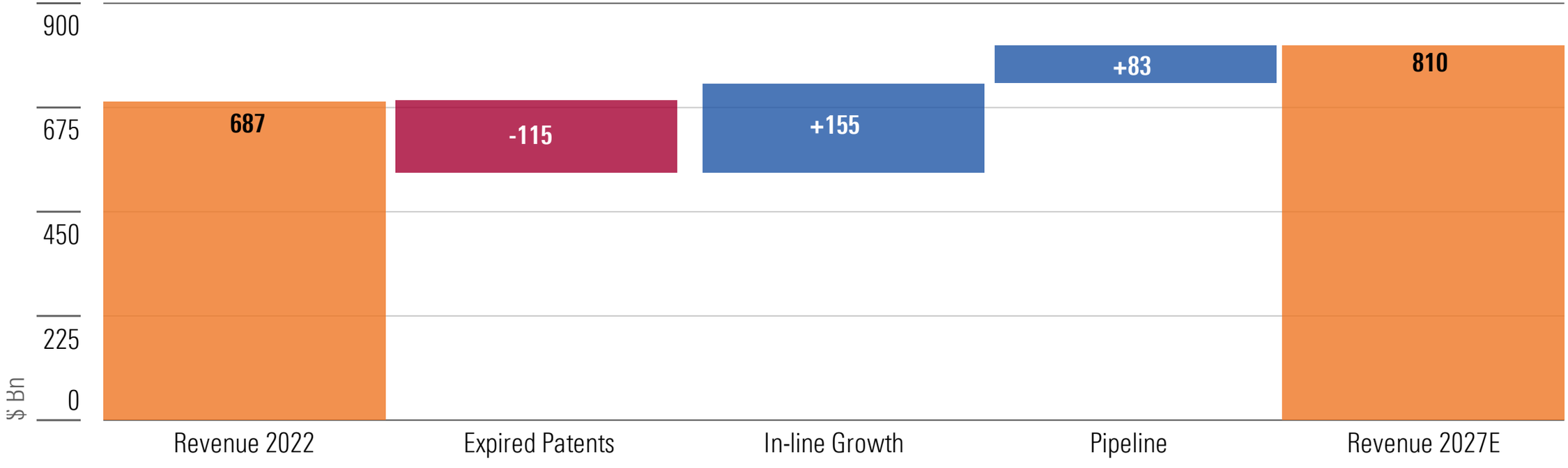
Source: IQVIA. Based on invoice-based pricing (includes supply chain concessions, but not insurer rebates).

Catalent and Lonza Benefit From Growth Within Branded Drugs

We estimate branded drug sales from the top 18 biopharma firms under our coverage will have a 3.3% CAGR through 2027. Catalent and Lonza primarily manufacture branded drugs, as opposed to generics. In fiscal 2022, 55% of Catalent's net revenue was derived from branded protein-based biologics and cell and gene therapies, 28% from branded small-molecule drugs, 3% from generics, 6% from over-the-counter drugs, and 8% from consumer health. Catalent's high percentage of revenue from branded drugs further supports the switching costs argument for a narrow economic moat. Switching costs are high for branded drugs due to their complex manufacturing requirements and limited patent life before generic entry.

Branded Drug Sales at Top Biopharma Firms Poised to Grow at 3.3% CAGR Through 2027

Excluding Pfizer's COVID-19 vaccine and Paxlovid sales, we forecast a 4.5% CAGR.



Source: Morningstar, company reports. Note: Projections include drug sales and exclude consumer health, device, crop science and diagnostics divisions. The large-cap biopharma list includes AbbVie, Amgen, AstraZeneca, Bayer, Biogen, BioMarin, Bristol-Myers, Gilead, GSK, Johnson & Johnson, Eli Lilly, Merck, Novartis, Novo Nordisk, Pfizer, Regeneron, Roche, and Sanofi.

Note: In-line growth refers to sales from already approved drugs that do not face patent expirations over the forecast period.

CROs and CDMOs With Expertise in Oncology, Neurology, and Obesity to Experience the Largest Tailwinds

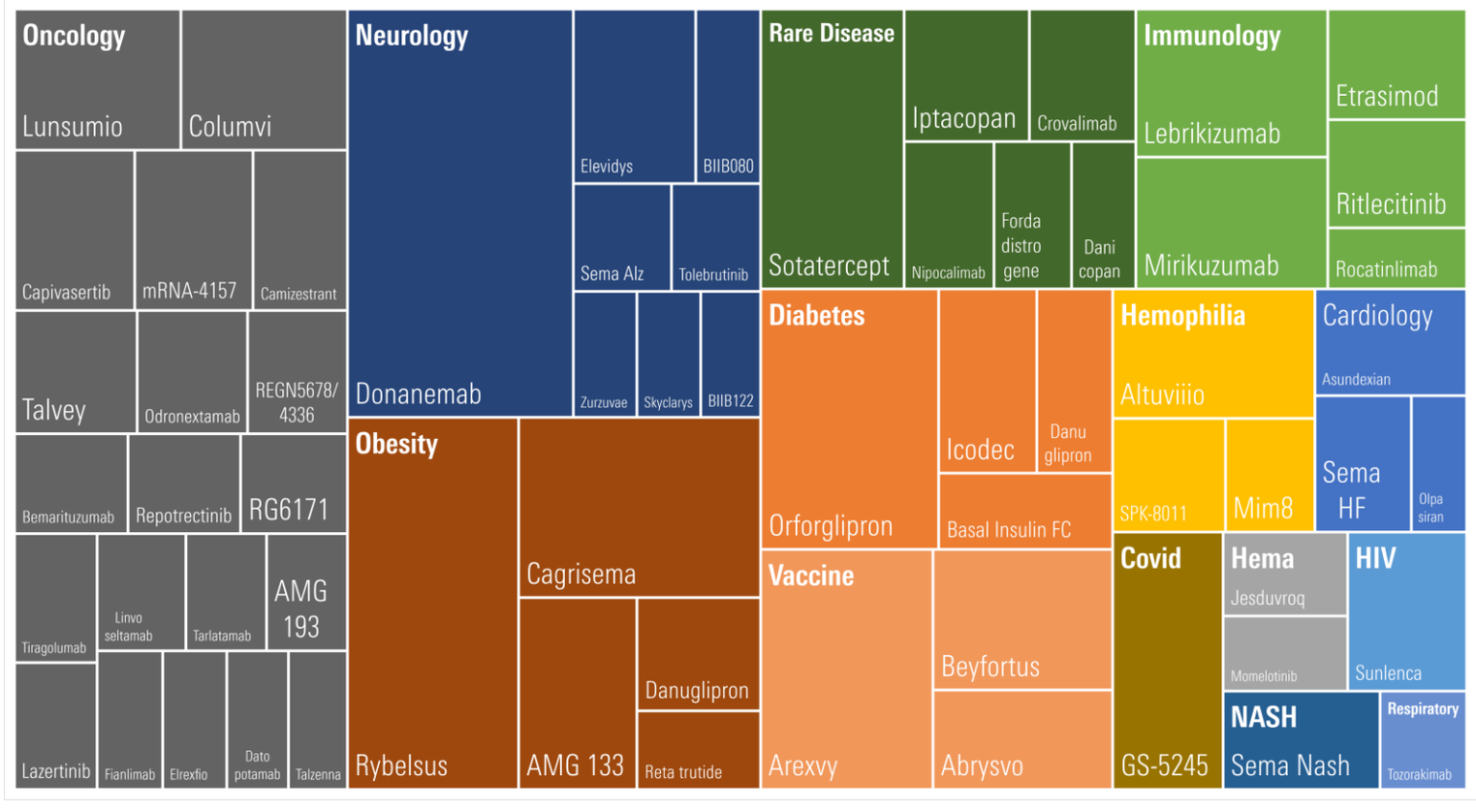
The top-tier, global CROs under our coverage have extensive expertise across a range of therapeutic areas, which allows them to take on new clinical trials for customers developing drugs across various diseases. In comparison, niche CROs have particular areas of expertise and are not able to serve as many customers across a variety of therapeutic areas.

Oncology is the biggest growth driver of our estimated $83 billion in global branded drug sales by 2027 from the pipelines of the 18 largest biopharma firms. We see neurology and obesity as the next largest growth drivers.

With the exception of Eli Lilly's Alzheimer's disease candidate, donanemab, most of this pipeline growth is spread across multiple candidates. The CROs and CDMOs under our coverage possess the scientific expertise and manufacturing capabilities across oncology, neurology, and obesity to benefit from these tailwinds.

Estimated Pipeline Contribution by 2027, by Therapeutic Area

Projections only include pipeline (approvals 2023 or later) with the largest sales gains in our large-cap biopharma list.



Source: Morningstar, company reports. Note: Includes AbbVie, Amgen, AstraZeneca, Bayer, Biogen, BioMarin, Bristol-Myers, Gilead, GSK, Johnson & Johnson, Eli Lilly, Merck, Novartis, Novo Nordisk, Pfizer, Regeneron, Roche, and Sanofi. Listed Drugs account for 75% of our total pipeline growth forecast at these firms through 2027.

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