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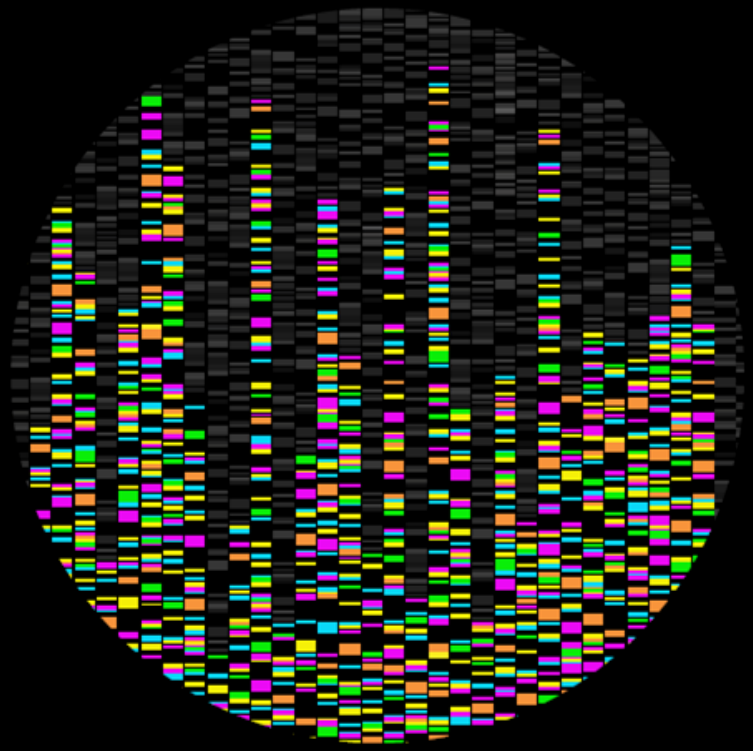


Pharma R&D - growth, investment and returns

AHPPI Annual Meeting 2022
Naveed Panjwani
Lead for R&D operations consulting, Deloitte UK

Twelve years of publishing *Measuring the return from pharmaceutical innovation* have generated a wealth of data on R&D productivity

12 year's data measuring the financial return from pharmaceutical innovation

Top 20 R&D Companies

Combined cohort

Original cohort

12 largest companies by Pharma R&D spend 2009

AMGEN, Lilly, MERCK, Roche, AstraZeneca, gsk, NOVARTIS, SANOFI, Bristol-Myers Squibb, Janssen, Pfizer, Takeda

Extension cohort

Four additional mid to large-cap companies in top 25 companies by Pharma R&D spend 2012 to 2014

abbvie, Biogen, Celgene, GILEAD

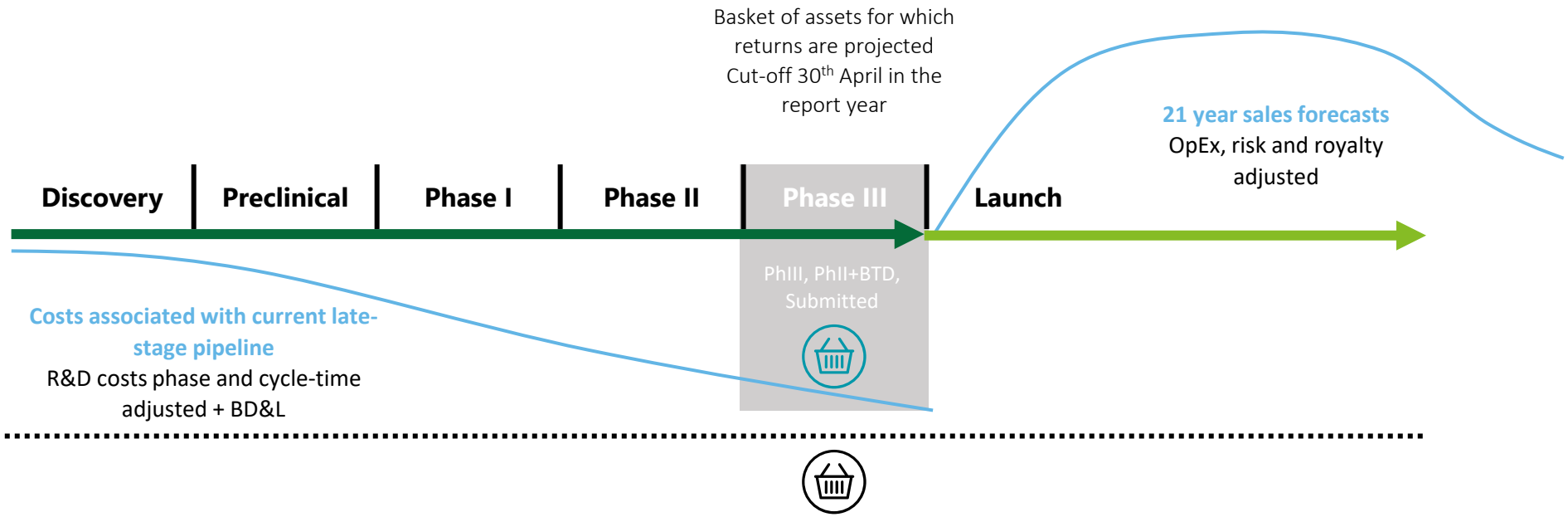
Additional five

Five additional companies to expand analysis to top 20 companies by Pharma R&D spend 2020

astellas, Boehringer Ingelheim, BAYER, novo nordisk, REGENERON

The Deloitte returns figure is a static snapshot in time of projected future returns for the late-stage pipeline taking into account R&D costs and projected returns

Static IRR:
Snapshot calculation based on investment costs and expected returns



Dynamic IRR:
Illustrates the impact of underlying levers on changes in IRR over time

Transition of new assets
(earlier phases of development, external sources)

Existing assets
Sales forecast changes

Approved assets
Forecasts progress to commercial portfolio

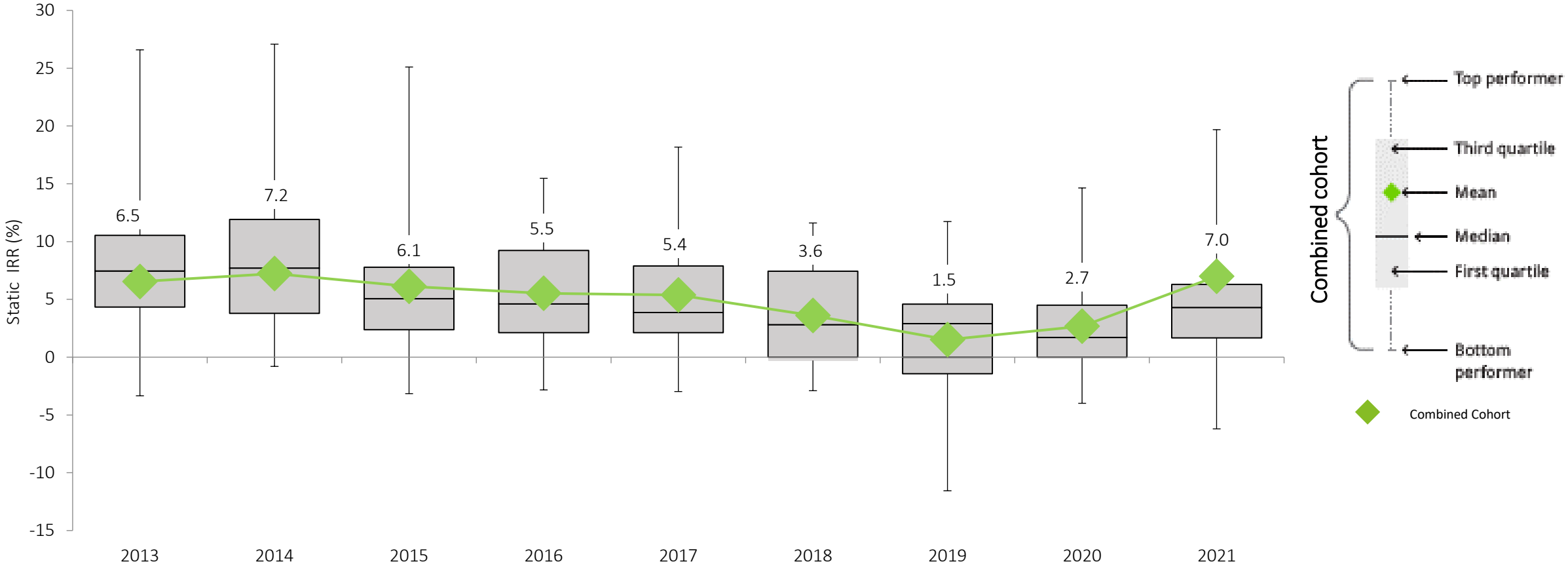
Terminated assets
Forecasts fall out of the equation

Full methodology can be found here

Source: Analysis based on Deloitte measuring returns from pharmaceutical innovation data set

The combined cohort has seen a large uptick in its IRR in 2021

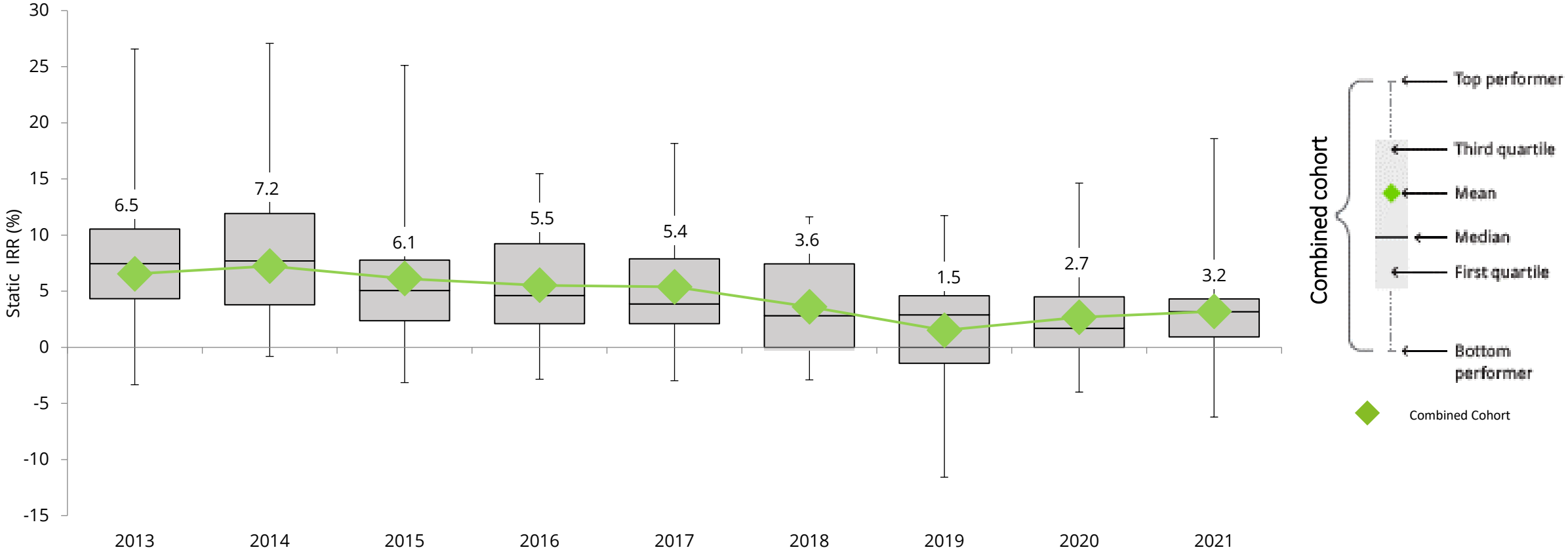
Return on late-stage pipeline, combined cohort - 2013-21



Source: Analysis based on the Measuring returns from pharmaceutical innovation dataset

The IRR is still higher than the 2020 value when COVID-19 emergency approval assets are excluded

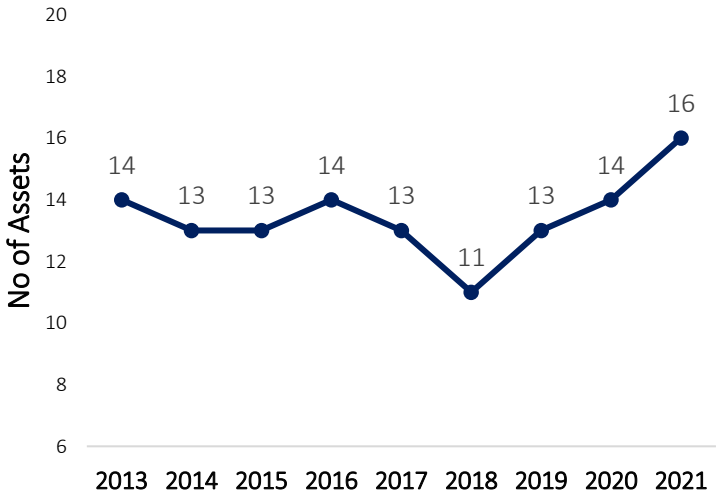
Return on late-stage pipeline, combined cohort - 2013-21, without emergency approval COVID-19 assets



Source: Analysis based on the Measuring returns from pharmaceutical innovation dataset

The average number of assets in development has increased steadily, average peak sales have had sustained uptick and R&D costs have decreased

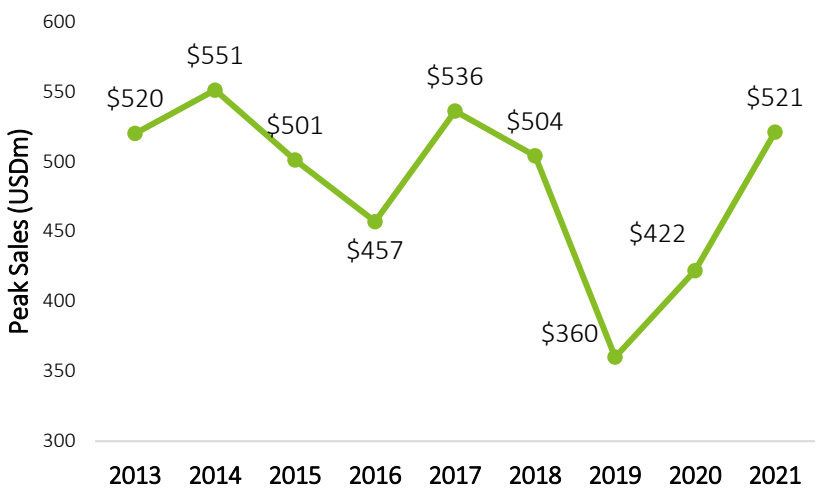
No of late-stage assets, combined cohort - 2013-2021



Number of late-stage pipeline assets

$$= \Sigma(unique\ late\text{-}stage\ molecules)$$

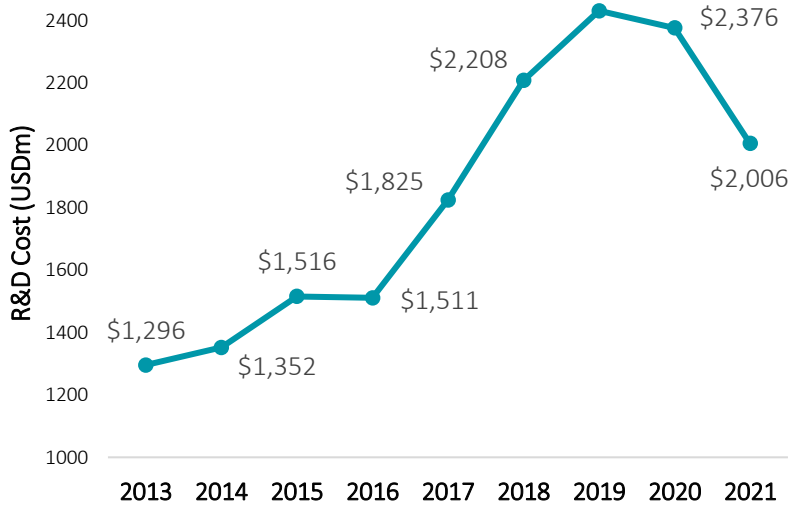
Average forecast peak sales, combined cohort - 2013-2021



Forecast average peak sales per asset

$$= \frac{(Total\ risk\ adjusted\ peak\ sales\ for\ all\ assets)}{N^o\ assets}$$

Average R&D cost, combined cohort - 2013-2021



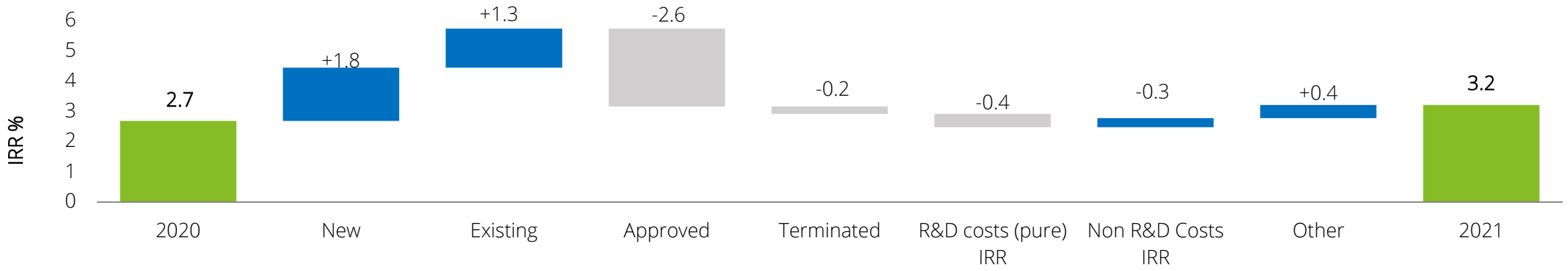
R&D cost to bring an asset to market

$$= \frac{(Total\ phase\ adjusted\ R\&D\ cost + deal\ costs)}{N^o\ assets\ * PTRS}$$

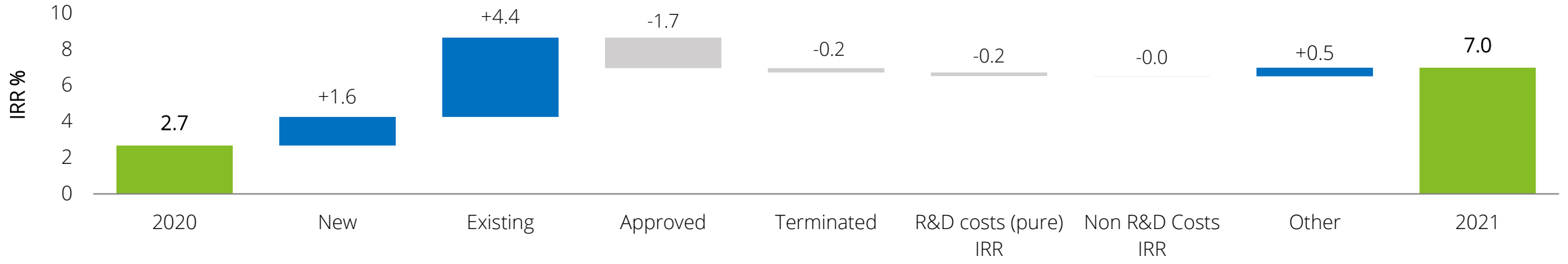
Source: Analysis based on the Measuring returns from pharmaceutical innovation dataset

When emergency approval COVID-19 assets are removed from the pipeline

Drivers of change in IRR, combined cohort without COVID EUA assets - 2020-21



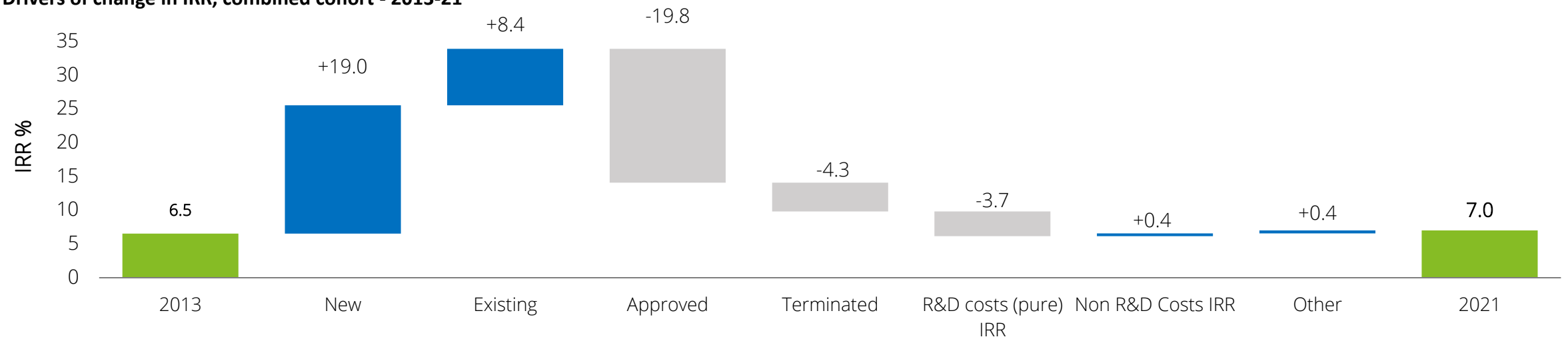
Drivers of change in IRR, combined cohort - 2020-21



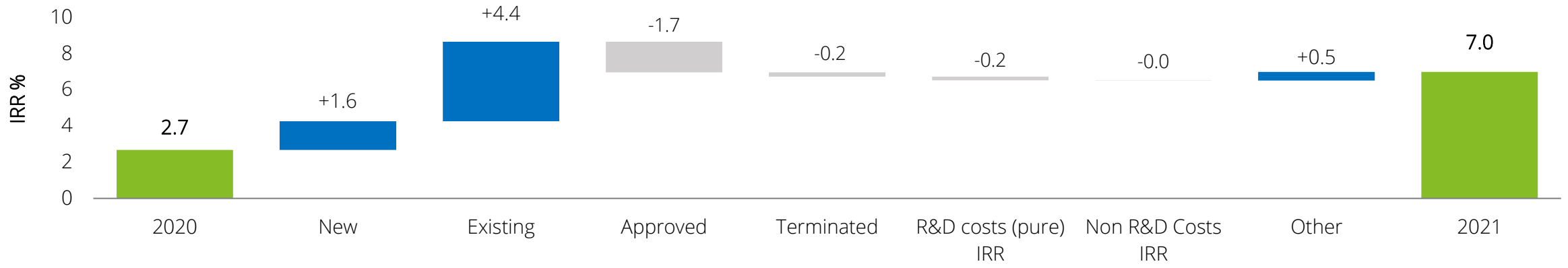
Source: Analysis based on the Measuring returns from pharmaceutical innovation dataset

2021 has been another good year for portfolio replenishment for the combined cohort, which together with the increase in value of existing assets compensated for approvals and terminations

Drivers of change in IRR, combined cohort - 2013-21



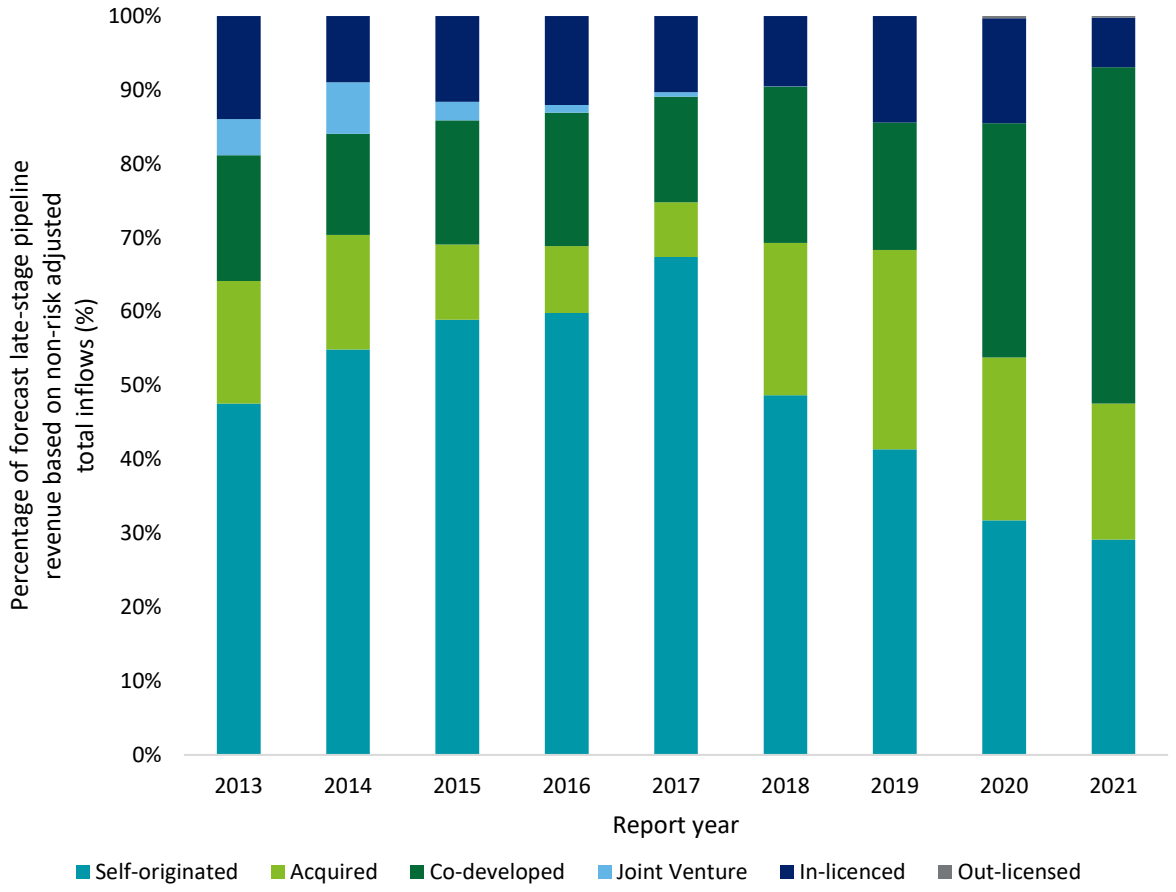
Drivers of change in IRR, combined cohort - 2020-21



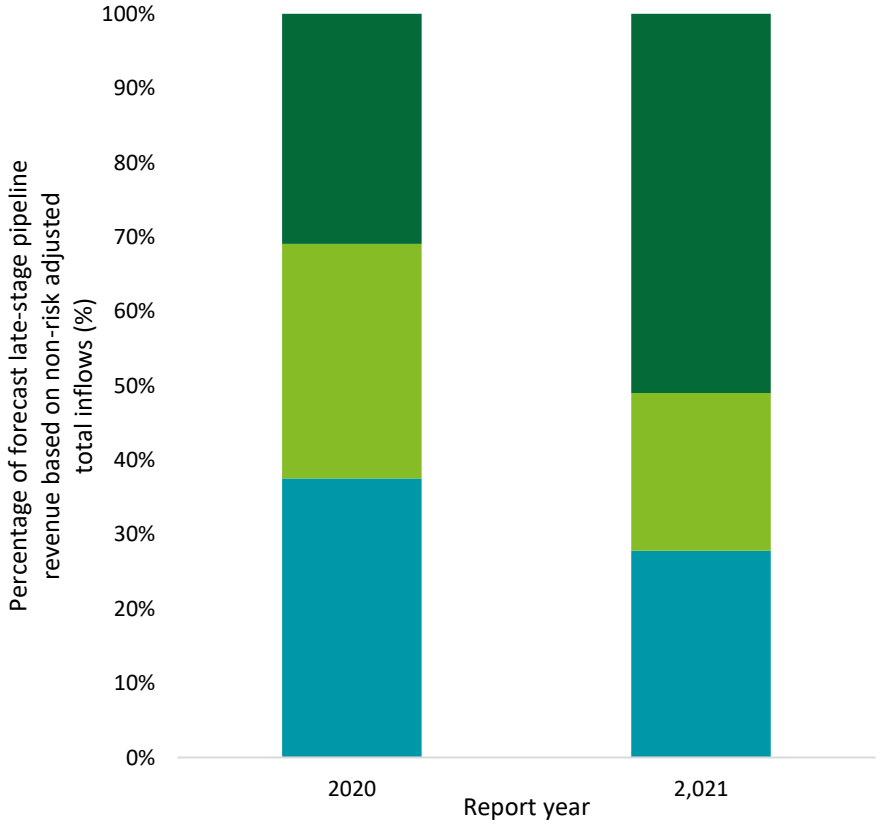
Source: Analysis based on the Measuring returns from pharmaceutical innovation dataset

The combined cohort is increasingly relying on codeveloping assets to replenish pipelines and the additional five companies replicate the trends

Late-stage pipeline revenue sourced from internal and external sources, combined cohort - 2013-21



Late-stage pipeline revenue sourced from internal and external sources, additional five companies - 2020-21



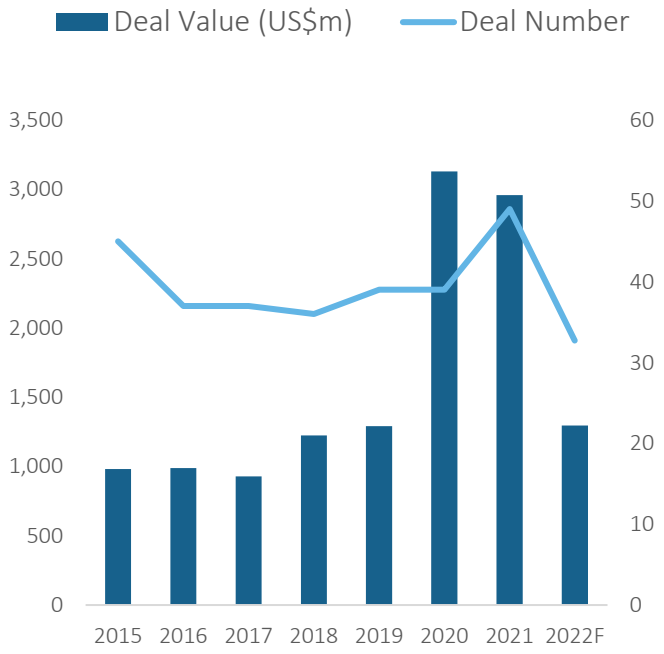
Source: Analysis based on the Measuring returns from pharmaceutical innovation dataset

Percentage of forecast late-stage pipeline revenue is based on non-risk adjusted total inflows (%)
For purpose of analysis GNE assets considered self-originated

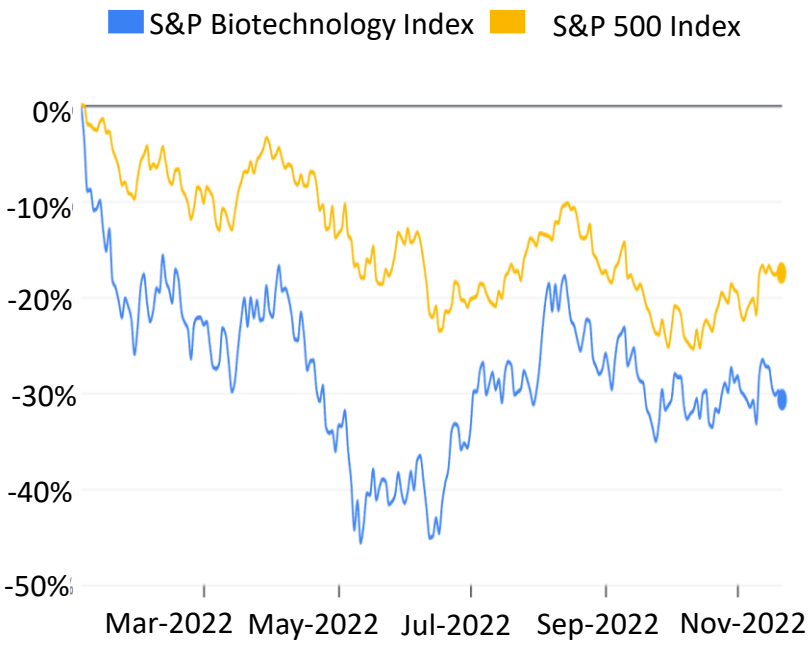
Venture investment and licensing deals

We expect continued focus on bolt-on acquisitions aimed at bulking up R&D pipelines. With smaller firms, talent, tools, and intellectual property may be ported into the parent, adding value in many ways.

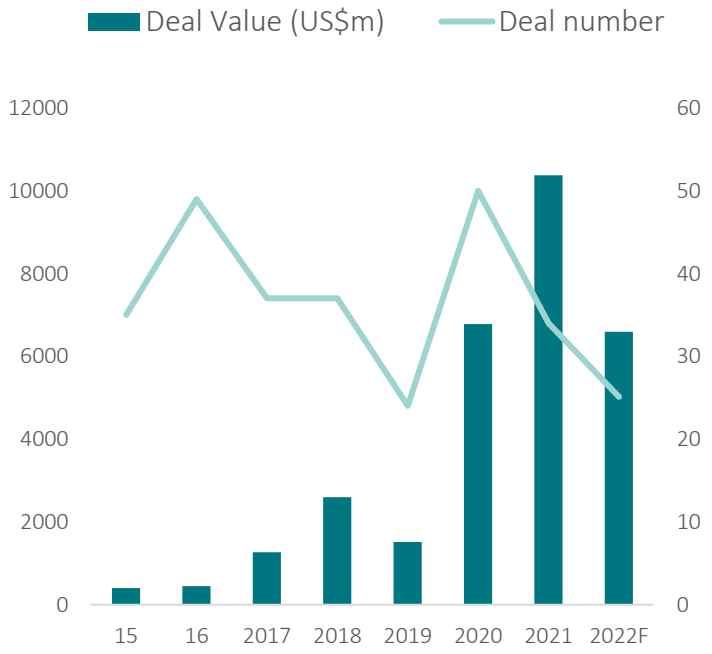
Venture investment is falling



Public biotechs are trading below IPO valuations



Licensing deal value has increased



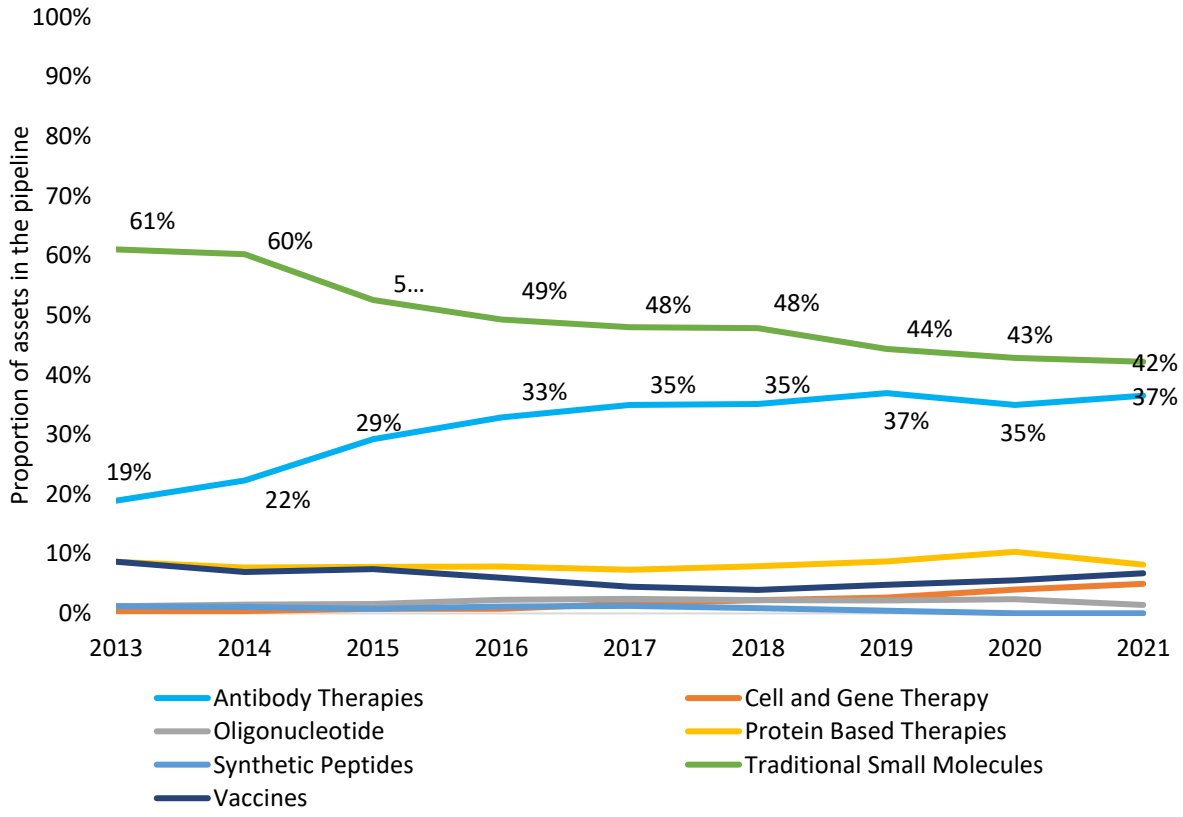
As smaller biotechnology firms and larger pharmaceutical companies position themselves for opportunities to acquire assets, we expect to see many more types of collaborative relationships maximizing new technologies.

Source: Deloitte Analysis

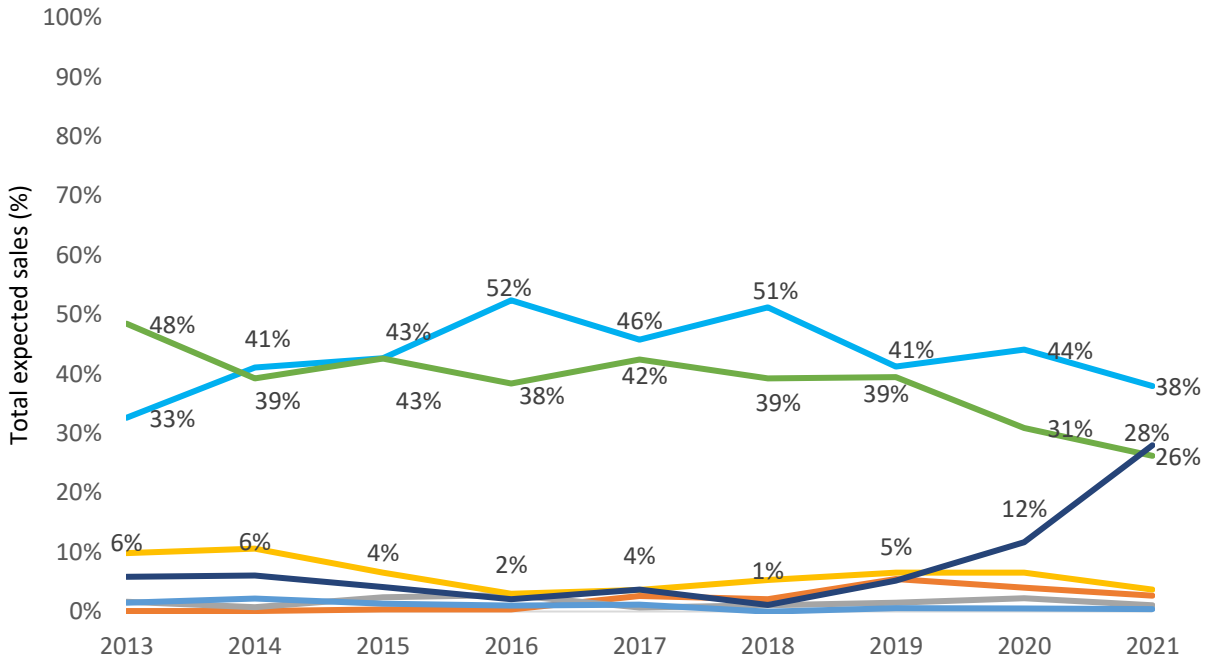
Traditional small molecules still lead based on asset volume, but the difference with other modalities is narrowing

Forecast sales data suggests antibody therapies are the most valuable drug modality for the combined cohort with vaccines increasing

Pipeline focus by modality, combined cohort - 2013-21



Percentage of total forecast sales per modality, combined cohort - 2013-21

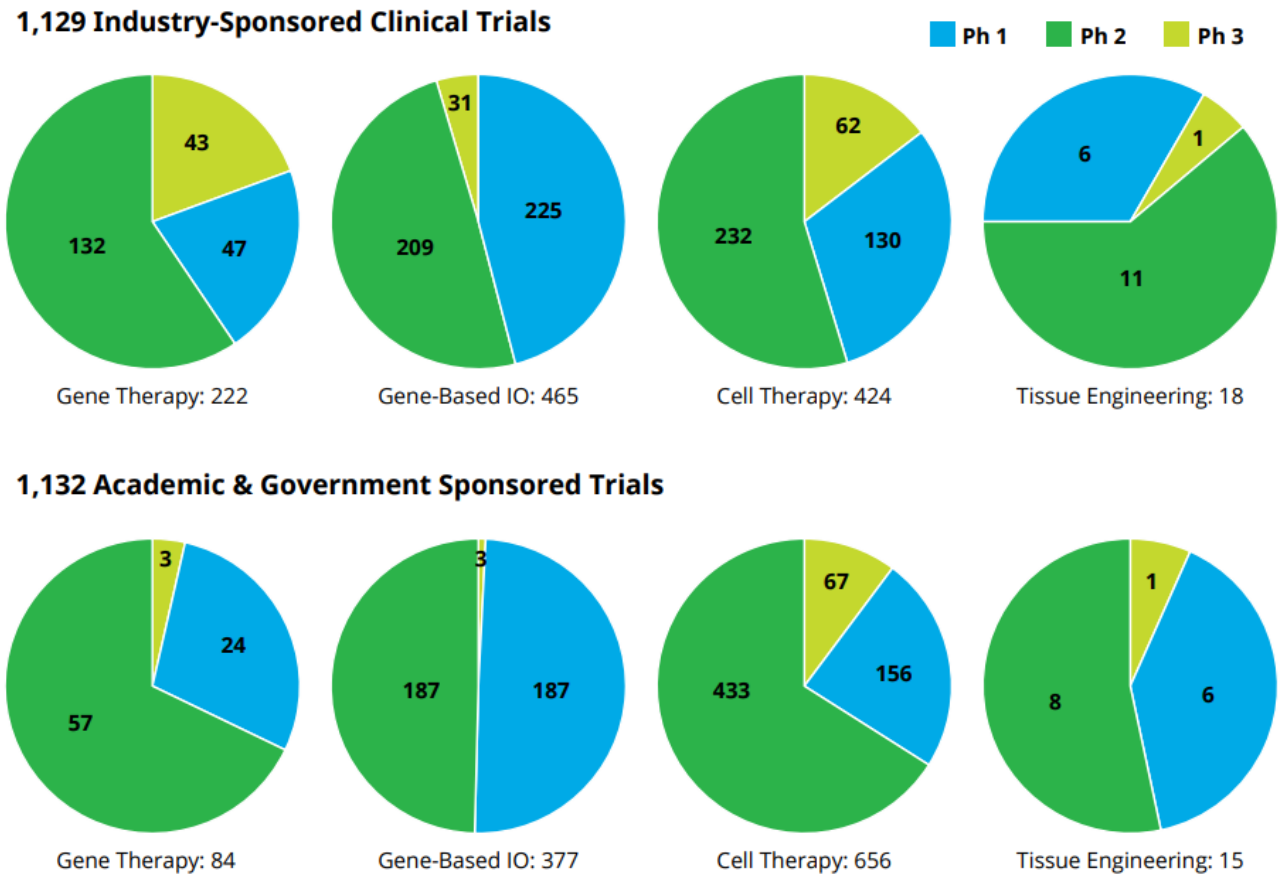


Source: Analysis based on the Measuring returns from pharmaceutical innovation dataset

New Therapeutic Modalities

The science of therapeutics is maturing with new and compelling modalities, with greater than ever focus on diseases that were once thought intractable

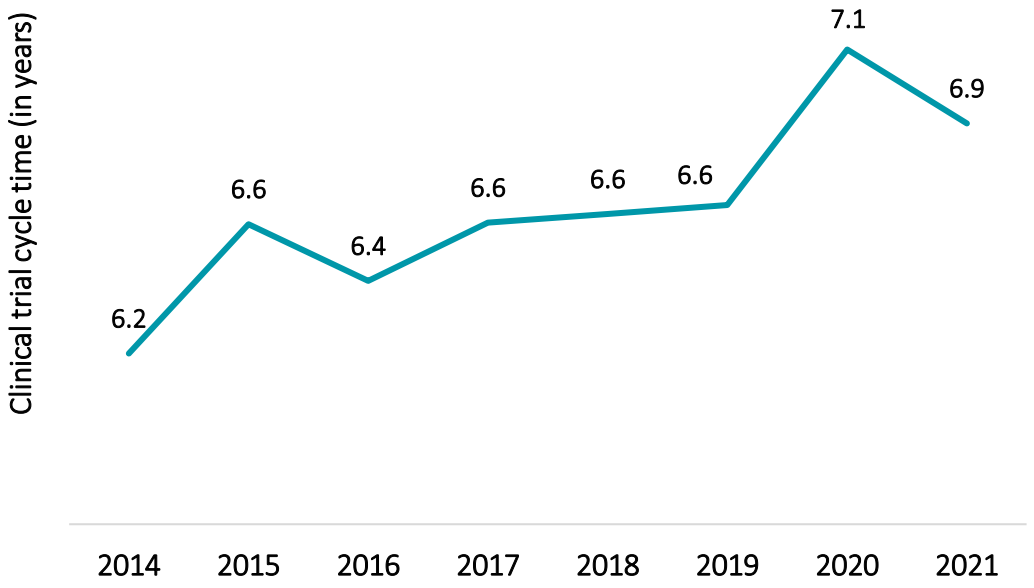
Cell and Gene clinical trials in development, March 2021



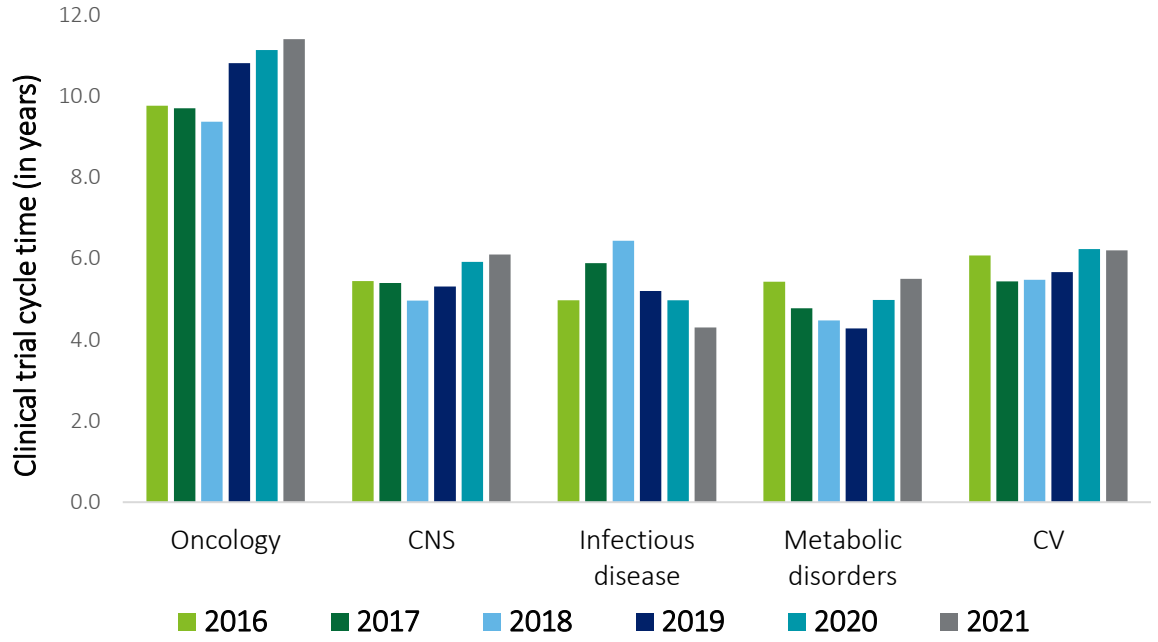
Source: ARM, 2022

Clinical trial cycle time for the cohort has improved slightly, but remains above pre-pandemic levels

Average cycle time, combined cohort - 2014-2021



Clinical trial cycle time by TA, combined cohort - 2016-2021



Case Study: Expediting study start-up to test the world's first oral COVID-19 therapy

To accelerate Phase 1 trials of its oral COVID-19 drug, Merck undertook several study start-up activities in parallel. Clinical trial applications and study protocol submissions, review and approval were completed in both US and UK within 16 days. In parallel , pharmacy set-up activities were completed within two weeks from project initiation while recruitment teams pre-screened volunteers even before clinical trial applications were approved. Such parallelisation enabled the first patient to be dosed on day 23 as compared to standard timelines of 4 months

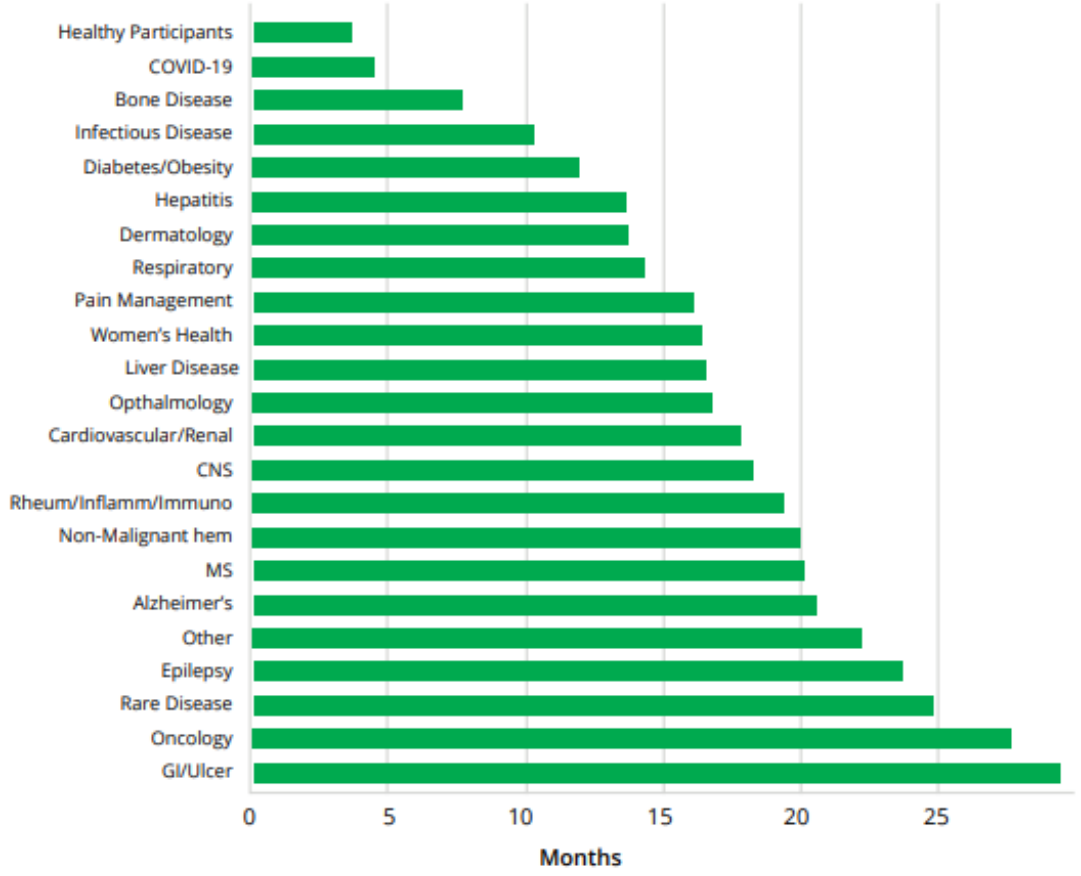
Note: Cycle time includes time from start of phase 1 trials to completion of phase 3 trials
CNS = central nervous system and CV = cardiovascular

Source: Analysis based on the Measuring returns from pharmaceutical innovation dataset

Driving Productivity – A Need For Speed

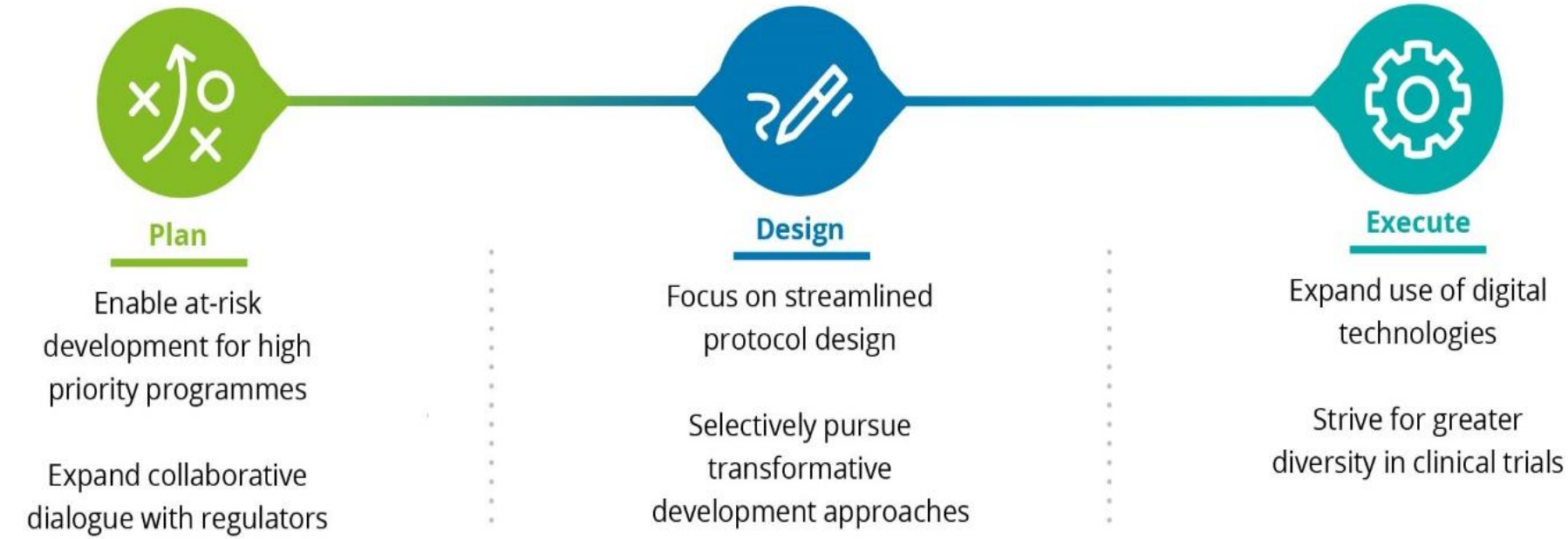
New processes adopted to expedite vaccines to tackle COVID-19 are now being applied to other drugs. In 2022, pressures are expected to be on optimizing processes to fundamentally change the drug development paradigm

Weighted average enrolment time in months by company (left) and by therapeutic area (right)



Source: Deloitte Analysis, "R&D Pentathlon: Which Pharma's R&D is faster, higher, stronger —ahead of the curve," Cowen, 26 July 2021.

Incorporating the lessons from the R&D approaches adopted for COVID-19 into routine clinical development



Source: Deloitte LLP, 2021

Case Study: Enhancing participant diversity in a COVID-19 phase III study

Genentech's EMPACTA Phase III study focused on enrolling underserved and minority patients to demonstrate its efficacy in treating COVID-19 associated pneumonia. Approximately 85 percent of the 389 patients were from minority racial and ethnic groups and included Hispanics, Native American and Black populations.

To achieve this Genentech first identified COVID "hotspots" and then analysed epidemiology data to find communities and hospitals where underrepresented patients were being treated. This included areas in New Orleans, New Mexico, and Arizona as well as hospitals in the Bronx where the disease burden was high for underserved populations. After the study sites were identified, enrolment was the fastest among all studies in the history of Genentech, disproving the notion that it takes more time to recruit diverse study populations.

Source: Analysis based on the Measuring returns from pharmaceutical innovation dataset

Deloitte.