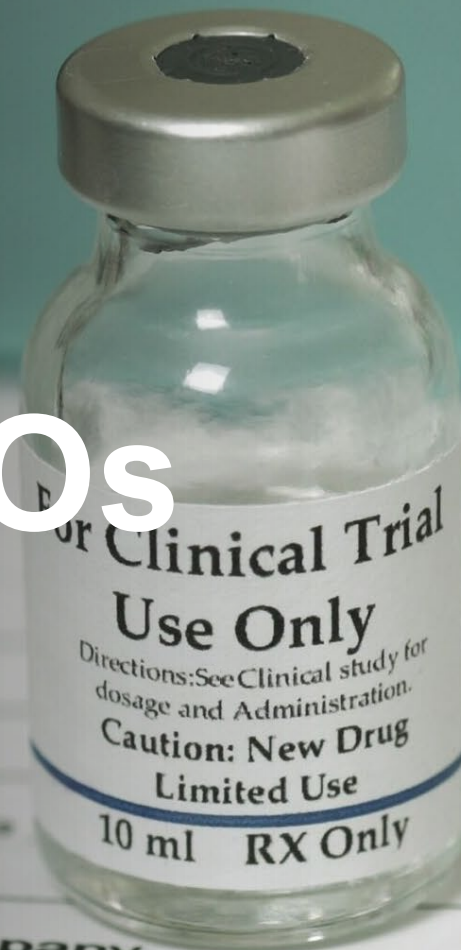


# Future-Fit CROs

Capitalizing on emerging pharma trends to outperform the market

April 2024



# Pharma is resetting expectations and CROs must adapt

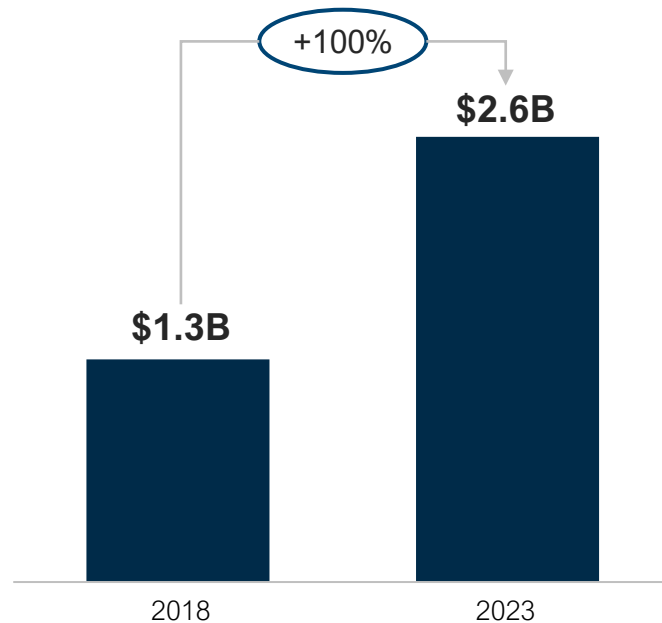
The landscape of drug development is poised for a paradigm shift. The services that propel these discoveries will undergo a metamorphosis so profound that the very fabric of pharma support will become irrevocably altered, leaving behind the models of the past



# Pharma is under pressure to drive efficiencies in R&D

## R&D costs are doubling...

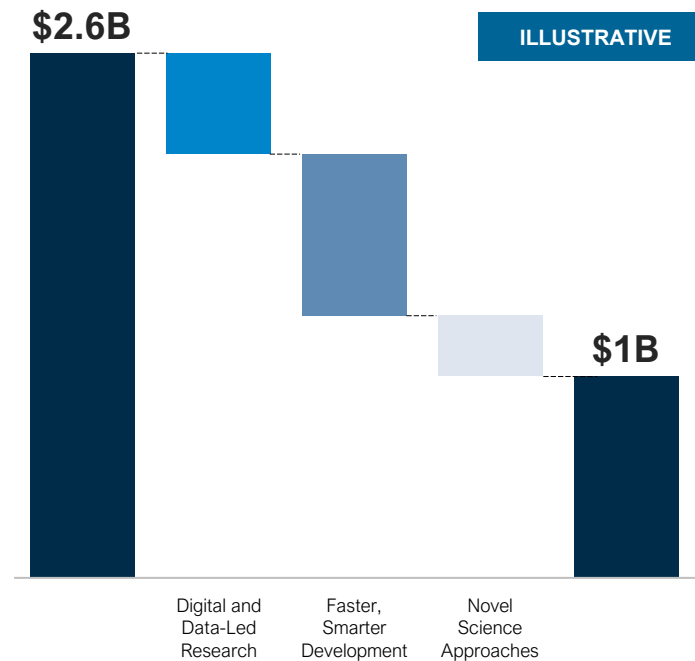
The staggering costs to successfully bring a drug to market have doubled over the last 5 years<sup>1</sup>



\*Includes the cost of capital and cost of failure

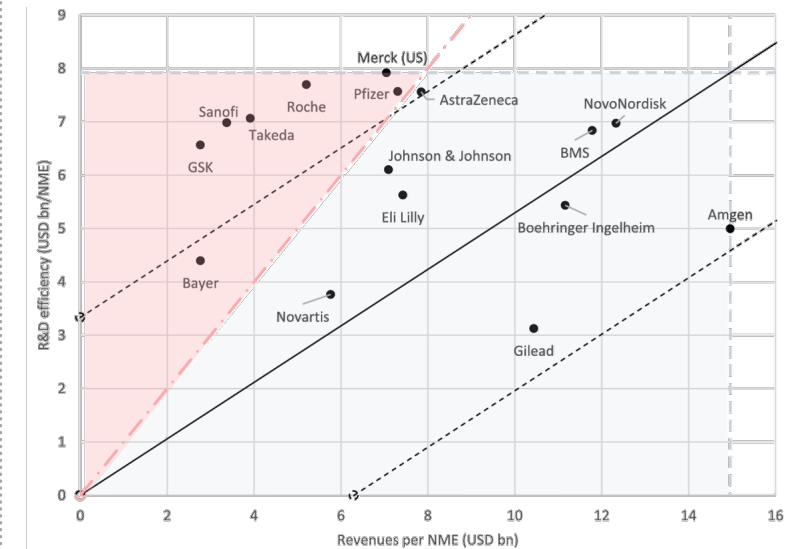
## ...creating new efforts to drive productivity...

Research suggests a few key levers will help reduce the cost of developing new treatments from billions to millions<sup>3</sup>



## ...to improve Pharma's ROI on R&D spend

R&D spend as a % of revenue continues to rise over the last decade<sup>4</sup>



Source: <sup>[1]</sup> London School of Economics Estimated Research and Development Investment Needed to Bring a New Medicine to Market (March 2020) Olivier Wouters; <sup>[2]</sup> Tufts Center for the Study of Drug Development (2014): DiMasi JA, Grabowski HG, Hansen RA. Innovation in the pharmaceutical industry: new estimates of R&D costs. Journal of Health Economics 2016;47:20-33; <sup>[3]</sup> Accenture From Billions to Millions: Improving R&D Productivity (October 2021); <sup>[4]</sup> Schuhmacher et al., Drug Discovery Today, Vol. 28, No. 10, p. 5 (October 2023)

# Three trends, coupled with the need to improve R&D productivity, shape the pharma services landscape



## New Places

Evolving science prompts Pharma to shift its portfolio towards novel modalities and unmet needs



## New Faces

Small, midsize and virtual pharma continue to be a growing force in the industry and are driving R&D



## New Races

Pharma seeks to leverage cutting-edge tech and embrace agile practices to innovate faster

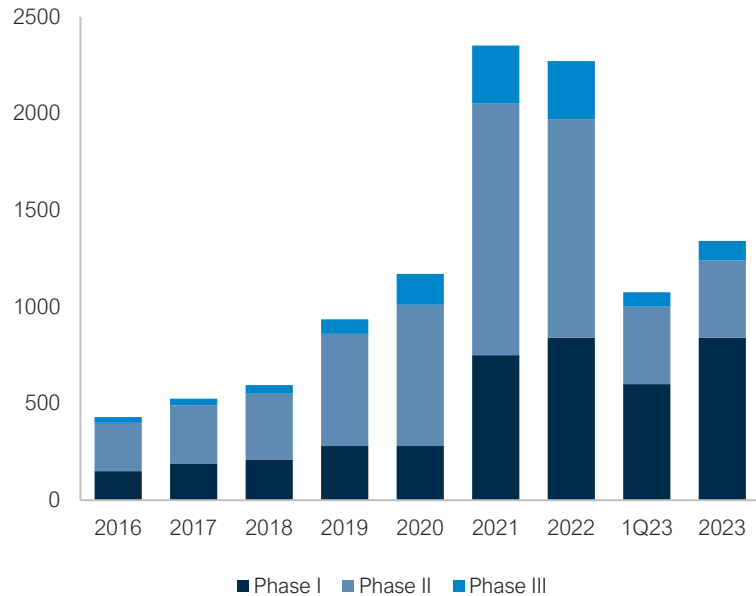
# New Places: The science is evolving

As treatments become more targeted and complex the types of trials CROs will need to support will look different

## Targeted treatments like cell and gene therapies are on the rise...

CGT trials peaked during COVID-19 and have returned to growth. Nearly one third of all clinical trials in 2023 were cell and gene therapies<sup>1</sup>

Cell & Gene Therapy Clinical Trials



## ...Non-oncology trials garner significant attention...

**68% increase**



Obesity clinical trials in 2023 were up by 68% from 2022, and nearly doubled when compared to 5 years ago<sup>2</sup>

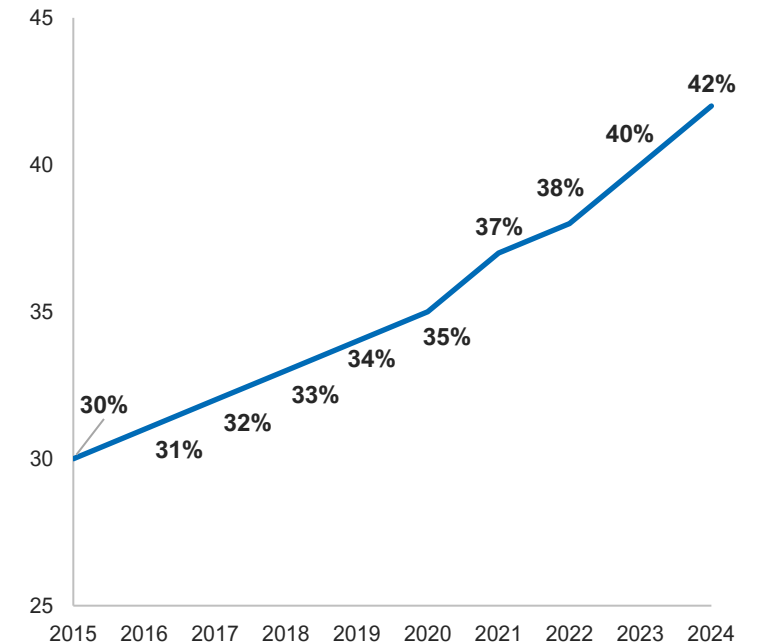
**84% growth**



NASH (the most severe form of Non-alcoholic fatty liver disease) trial starts grew 84% from 2019 to 2023<sup>2</sup>

## ...which will lead to more outsourcing to drive efficiency

A higher % of R&D spending is being outsourced to CROs and CDMOs

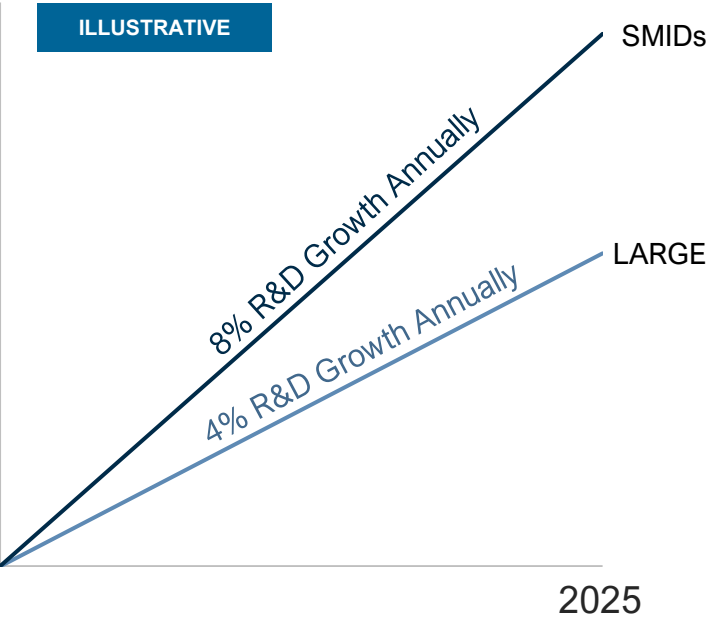


# New Faces: Customers are changing

Small and midsize pharma (SMIDs) have record numbers of clinical trials started and FDA approvals and require CROs to adapt new ways of working

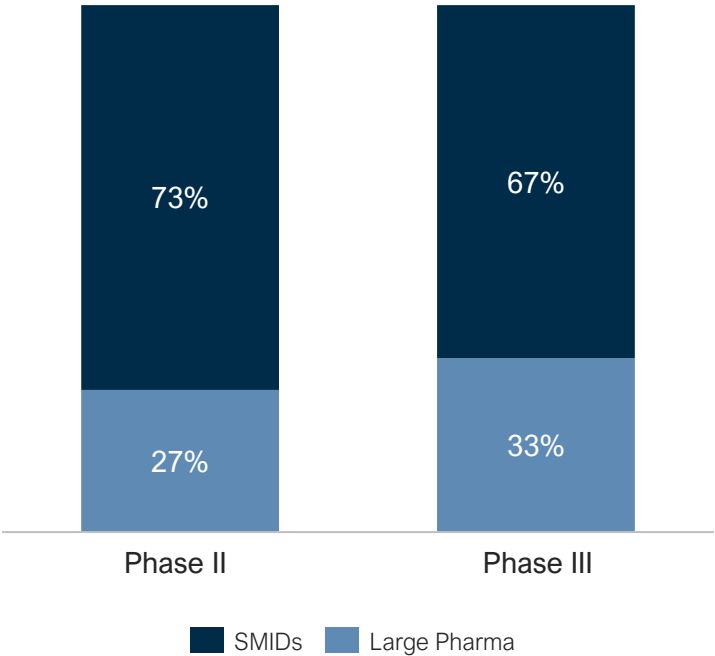
## SMIDs are outspending large pharma on R&D...

SMIDs are expected to grow R&D spending twice as fast as large pharma<sup>1</sup>



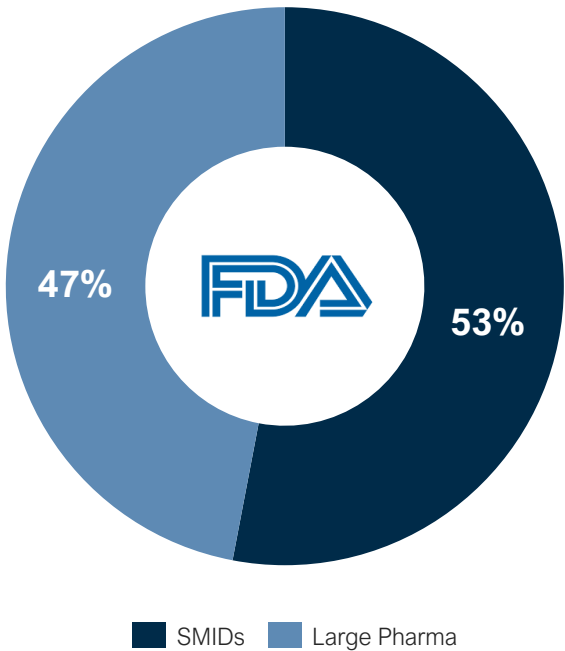
## ...And account for nearly two-thirds of trial starts...

SMIDs account for nearly two-thirds of Phase II and Phase III clinical trials<sup>2</sup>



## ...and lead the way for FDA approvals

SMIDs launched 53% of drugs in 2023<sup>2</sup>



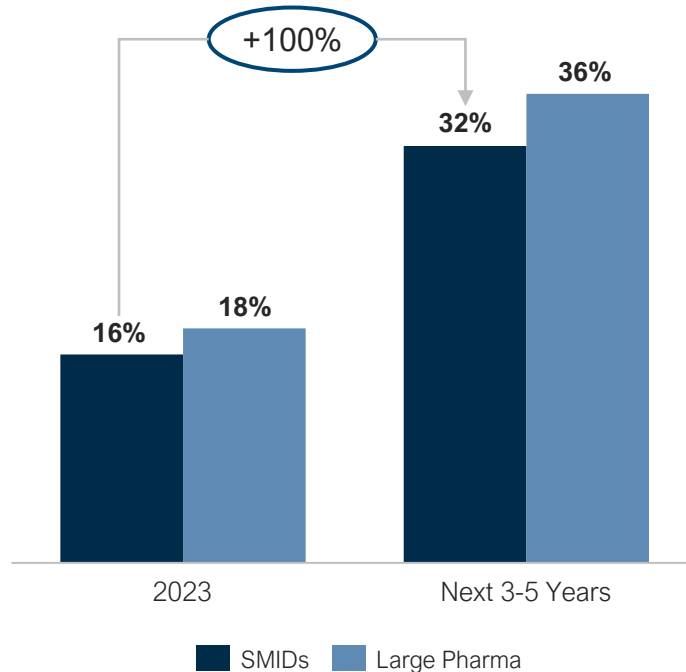
Source: <sup>[1]</sup> Evaluate Pharma and McKinsey Research CROs and Biotech companies: fine-tuning the partnership (June 2022); <sup>[2]</sup> IQVIA Institute for Human Data Science: Global Trends in R&D 2024 (February 2024)

# New Races: Digital and data capabilities will win

Pharma knows the future of accelerated drug discovery is by leveraging cutting-edge technologies and agile practices and it will look to CROs to bring both

## The use of AI tools is prevalent...

The % of pharma companies using AI in drug discovery will double over the next 3-5 years



## ...as is using technology to change how trials are run...

**22x**

Growth in the number of trial starts that were either remote, virtual or decentralized from 2019 to 2023<sup>2</sup>

**80%**

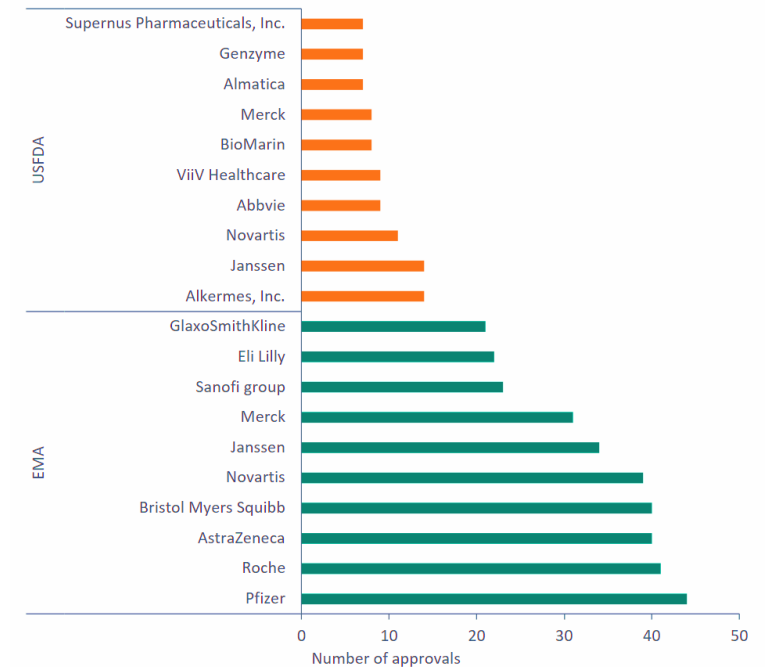
Percent of trials by ICON, a leading CRO, that incorporated a decentralized clinical trial component in 2022<sup>3</sup>

**28%**

Percent of all trials R&D experts estimate were conducted as decentralized clinical trials) in 2023<sup>4</sup>

## ...and using analytics to use RWE to support regulatory filings

Pharma companies using RWE in regulatory filings to the FDA and EMA is on the rise<sup>5</sup>



**Sources:** <sup>[1]</sup> Cowen Equity Research: AI in Drug Development: From Hype to the Clinic & Beyond (June 2023); <sup>[2]</sup> IQVIA Institute for Human Data Science: Global Trends in R&D 2024 (February 2024); <sup>[3]</sup> Truist Securities – Momentum is Real for a Well Positioned Industry Leader (December 2023); <sup>[4]</sup> Truist Securities – A Well Positioned CRO Despite broader Market Uncertainties (March 2024); <sup>[5]</sup> AXTRIA Insights: Real-World Evidence Usage in Regulatory Approvals from USFDA and EMA; Shaikh J, Samnaliev M (ISPOR May 2023)

# Consider the ways CROs can raise their game and grow faster than the market

1

## Sharpen the partnership with SMIDs

Small and midsize pharma (SMIDs) need CROs, perhaps more than large pharma, but studies suggest they report feeling less satisfied.<sup>1</sup> CROs should consider how to be better strategic partners for SMIDs

- Design flexible support models to fill the gaps of individual SMIDs as opposed to “one-size-fits-all” offerings
- Hire and retain higher-caliber talent that can be strategic advisors to SMID C-Suite
- Eliminate internal incentives that prioritize the larger pipelines associated with large pharma

2

## Adapt new ways of working to bring services to pharma

As pharma races to innovate, CROs can enhance their effectiveness and become valuable, long-term partners with pharma and other industry players. CROs should consider how to bring differentiated services to pharma

- Retain top-notch talent and develop capabilities that showcase expertise in disease areas and novel modalities, such as a Cell and Gene Center of Excellence
- Develop relationships that are more than transactional; have the strategic input necessary to help bring the drugs to market

3

## Align business models with the shift to outcomes

CROs can continue to position themselves as a true strategic partner of choice and improve margins by adapting to the industry-wide shift to outcomes. CROs should consider how to take bolder steps with business models to commit to their pharma partners

- Assess alternative ways to get paid (e.g., eliminate the “cost per patient” model) as services evolve beyond recruitment
- Tie fees to the success of the clinical programs CROs are managing (e.g., less upfront, more milestones with a premium) as a business model, not one-off agreements

4

## Build capabilities rapidly to move faster than new entrants

New entrants are blurring the lines between CROs and other pharma services providers as they are all looking to pivot to higher-margin services. As a result, competition for the same share is increasing, and CROs are at risk if they move too slowly. CROs should consider how to launch services before the market matures

- Expand capabilities in specialized skills with rising importance in clinical development, such as decentralized or RWE trials, as well as market access and pricing support

# Thank you

