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Evolution of drug development: What has changed in the last 10 years?

ITIF FORUM

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These slides were presented at a closed-door discussion hosted by the Information Technology and Innovation Foundation on October 10, 2024. They are based mostly on content from our report titled *Global Trends in R&D 2024: Activity, Productivity and Enablers* published by the IQVIA Institute for Human Data Science in February 2024. Some exhibits have been modified from their original format for the purposes of this presentation. Please refer to the report for additional detail and explanation of the content including methodologies used.

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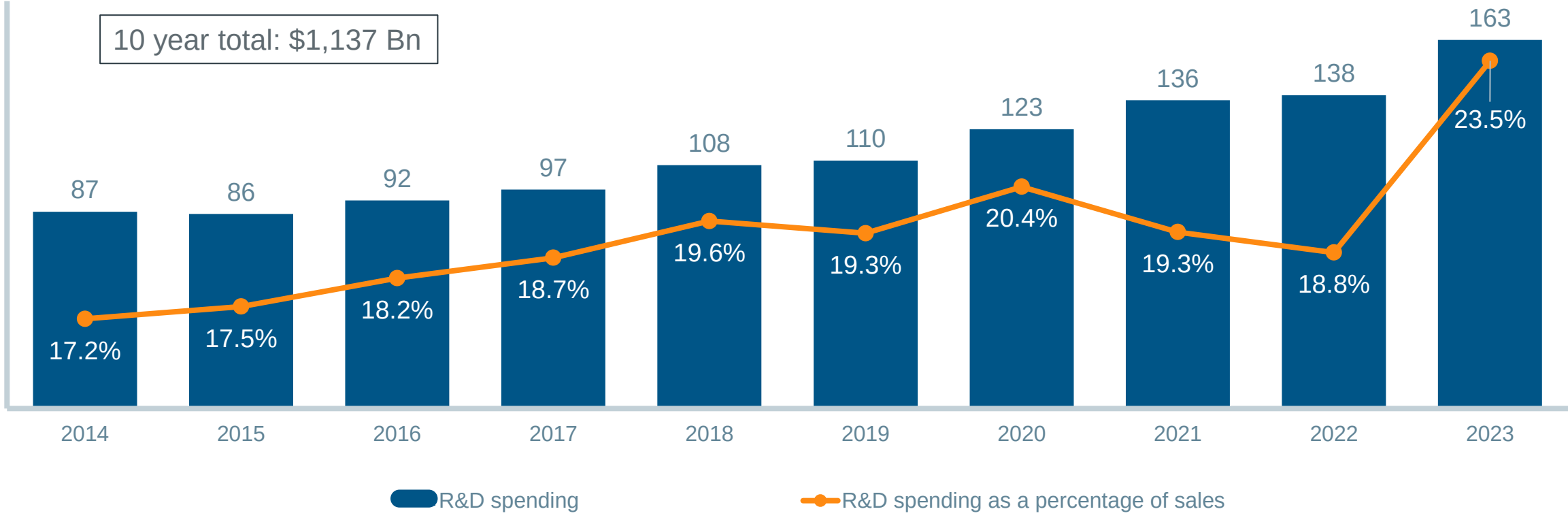
A Decade of Drug Development: What's changed?

- Investment in life sciences and drug development - both venture capital flows and large pharma expenditure - has expanded, and more trials are being started — especially during the pandemic
- "Emerging biopharma" companies have increased their role as sponsors of clinical trials through regulatory submission, and corresponding decline in "large pharma" share of activity
- The geographic mix of companies sponsoring clinical trials has shifted towards China and away from Europe and Japan
- Much greater focus is being placed on oncology, some increase in rare disease treatments, significant movement toward novel modalities
- More drugs are being approved globally with exceptional levels in 2020 and 2021, and new drugs trending toward specialty, biologics, orphan drugs and first-in-class
- Clinical development success rates have trended down during the decade at the same time greater scientific risk was taken, with some uptick in 2023
- Complexity of trials – a proxy for cost - has increased due to more eligibility criteria, subjects and endpoints
- Timelines for clinical development have remained long, with slower trial enrolment, more "white space" between phases, and overall time from first patent filing or human subject to launch fluctuating between 11 and 16 years – and longer when expedited regulatory pathways are not used
- These changes are notwithstanding multiple areas that have advanced over the past decade to bring greater operational efficiency to clinical development, including regulatory, policy and incentive alignment; clinical trial pathway strengthening and partnerships; mobilization of representative patients; use of real-world data in research settings; and adoption of technology in trial planning and execution

R&D expenditure by large pharma companies has increased steadily as companies have increased their strategic focus on innovation

Large pharma R&D spending (US$Bn) and percentage of sales, 2014–2023



AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, Eli Lilly, Gilead, GlaxoSmithKline, Johnson & Johnson, Merck, Novartis, Novo Nordisk, Pfizer, Roche, Sanofi, and Takeda

Source: Company financial statements; IQVIA Institute, Aug, 2024.
Global Trends in R&D 2024: Activity, Productivity, and Enablers, Feb 2024. Report by the IQVIA Institute for Human Data Science.(updated analysis)

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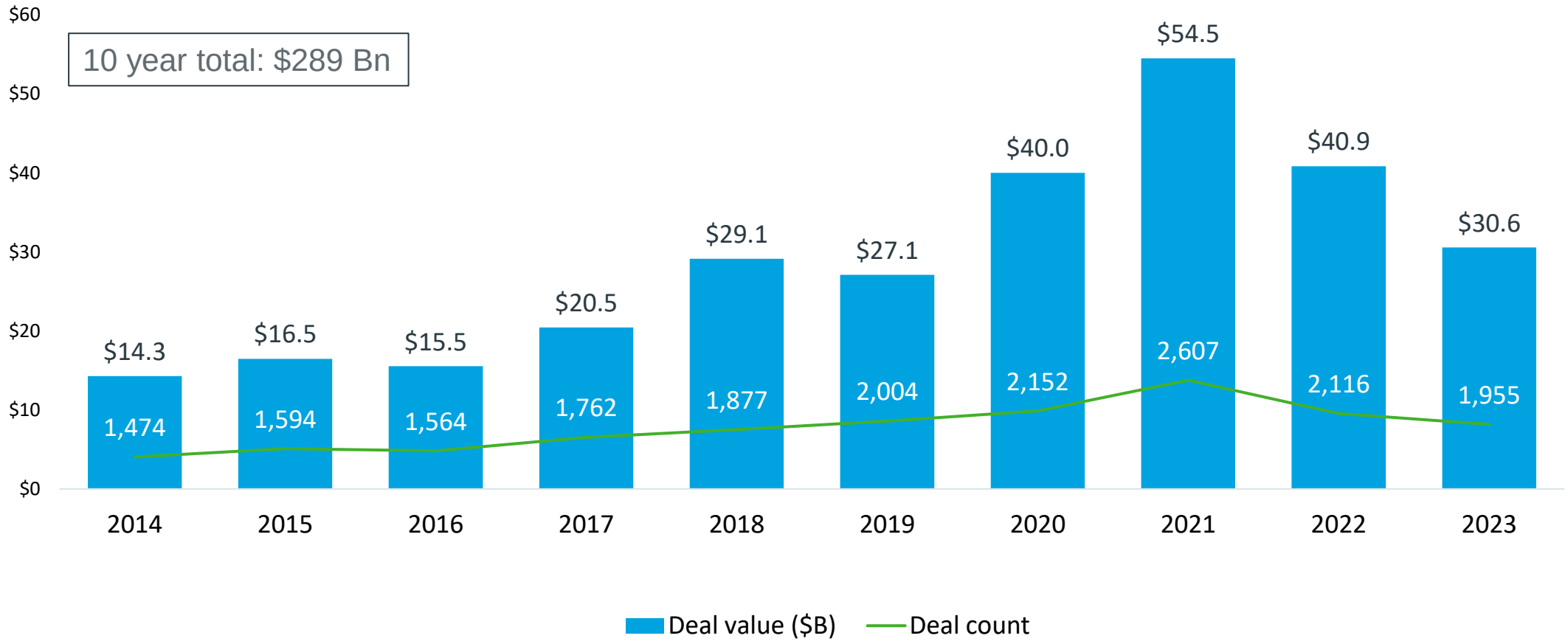
Venture capital flows into the U.S. life sciences sector have been more cyclical with a significant peak during the pandemic years

US Life Sciences Venture Capital Deal Value (US$Bn) and Deal Count, 2014-2023



Source: PitchBook-NVCA Venture Monitor Q2, 2024, accessed October 2024. Available from: https://nvca.org/document/q2-2024-pitchbook-nvca-venture-monitor-data-pack/

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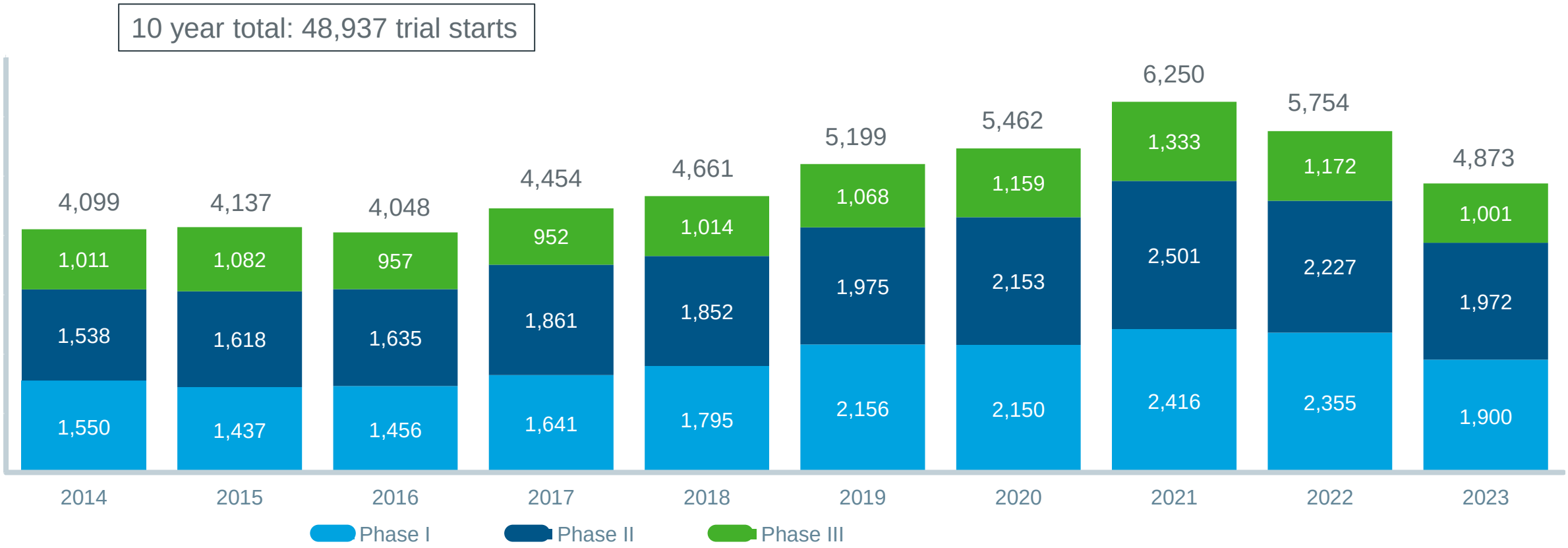
Industry-sponsored interventional Phase I – III trial starts peaked during the pandemic and totaled almost 49,000 over the decade

Total number of industry-sponsored interventional Phase I – III clinical trial starts, 2014–2023



Source: Citeline Trialtrove, Jan 2024.
Global Trends in R&D 2024: Activity, Productivity, and Enablers, Feb 2024. Report by the IQVIA Institute for Human Data Science

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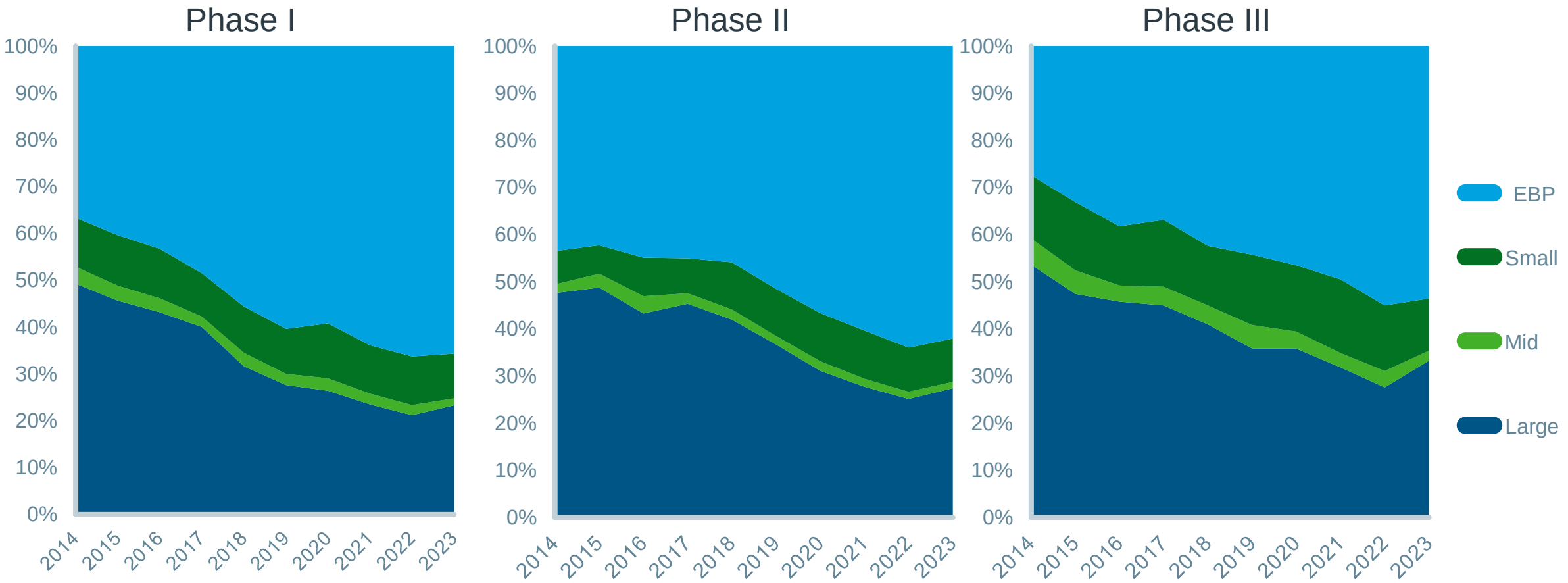
Emerging biopharma companies have steadily increased their share of clinical trial starts over the decade

Share of clinical trial starts by phase and company segment, 2014–2023



Source: Citeline Trialtrove, Jan 2024; IQVIA Institute, Jan 2024.
Global Trends in R&D 2024: Activity, Productivity, and Enablers, Feb 2024. Report by the IQVIA Institute for Human Data Science (adapted format).

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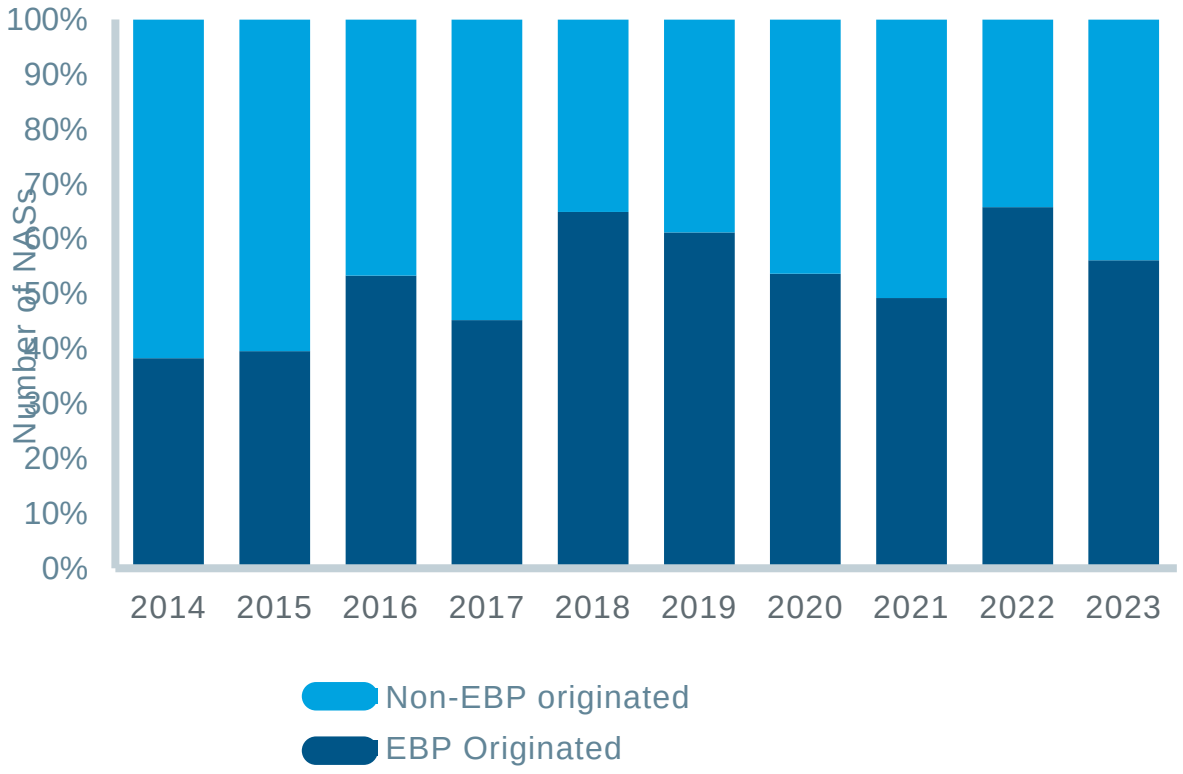
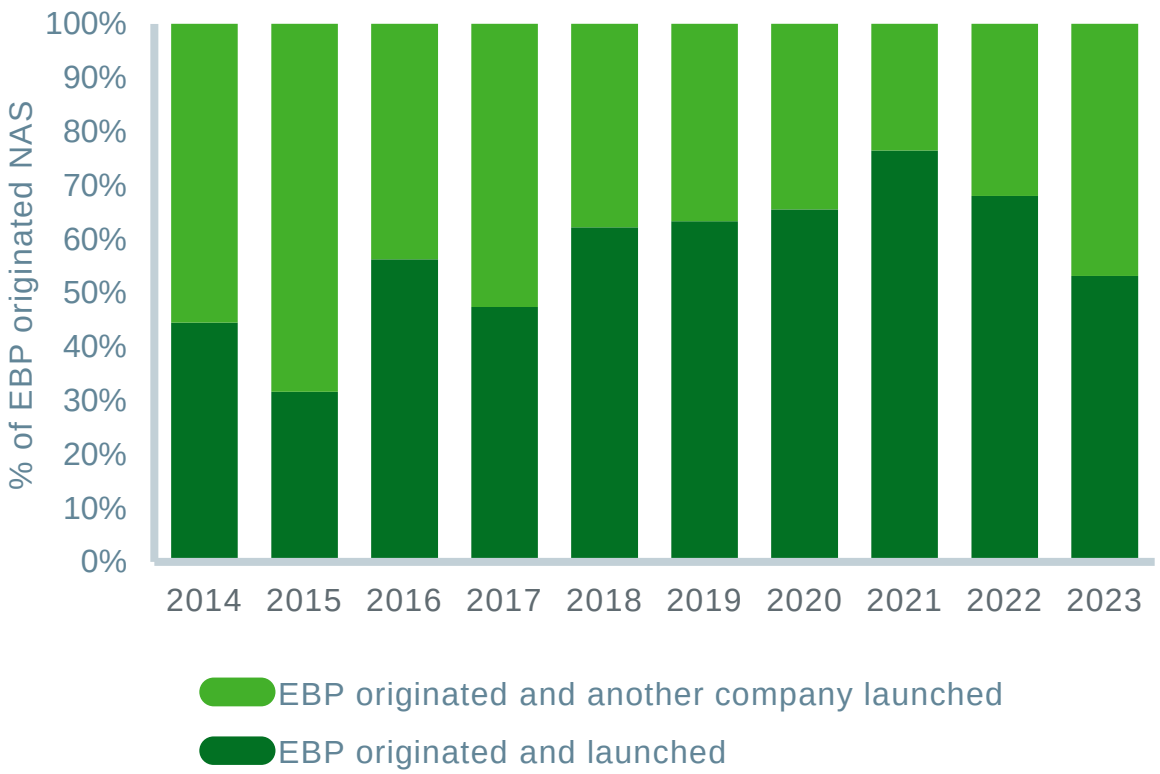
Emerging biopharma companies originate a growing share of NASs and are holding them through commercialization

Companies originating and filing FDA regulatory submissions for NASs and percent of launches by NAS launch year, 2014-2023





Source: IQVIA Institute, Jan 2024.
Global Trends in R&D 2024: Activity, Productivity, and Enablers, Feb 2024. Report by the IQVIA Institute for Human Data Science

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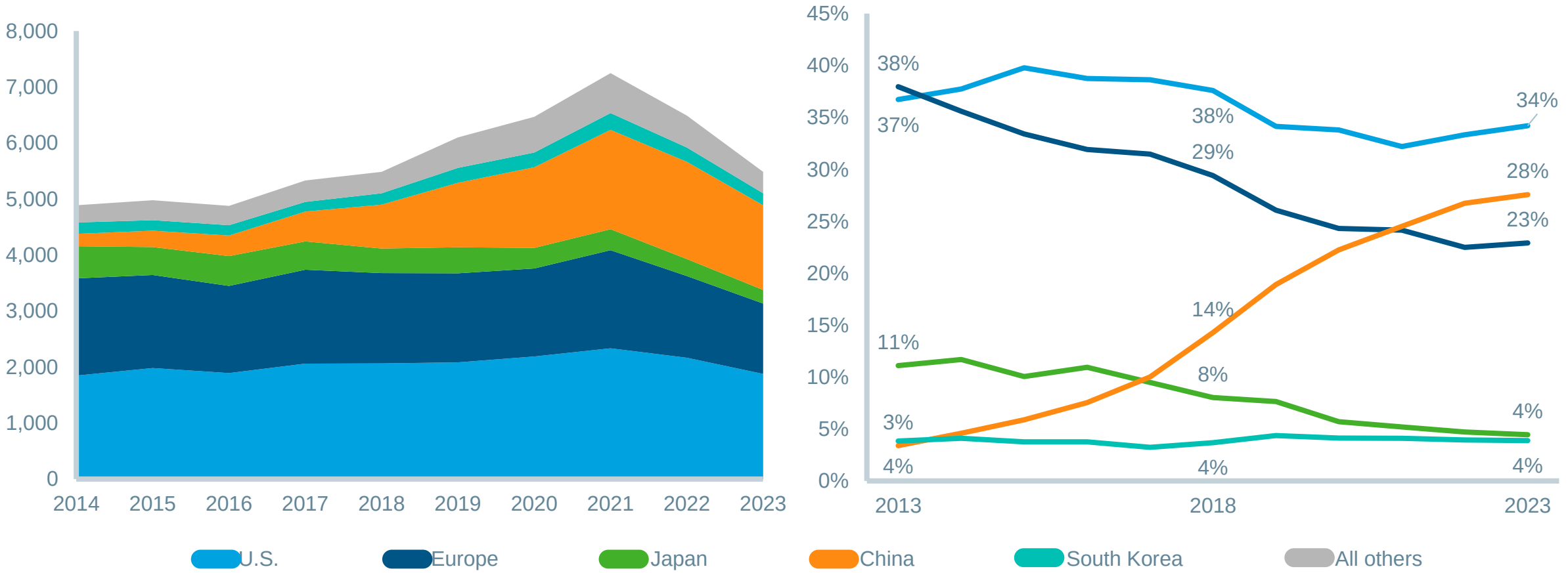
The geographic mix of companies sponsoring trials has shifted as China-headquartered companies have expanded their presence

Number of Phase I to III trial starts based on company headquarters location, 2014–2023



Source: Citeline Trialtrove, Jan 2024; IQVIA Institute, Jan 2024.
Global Trends in R&D 2024: Activity, Productivity, and Enablers, Feb 2024. Report by the IQVIA Institute for Human Data Science

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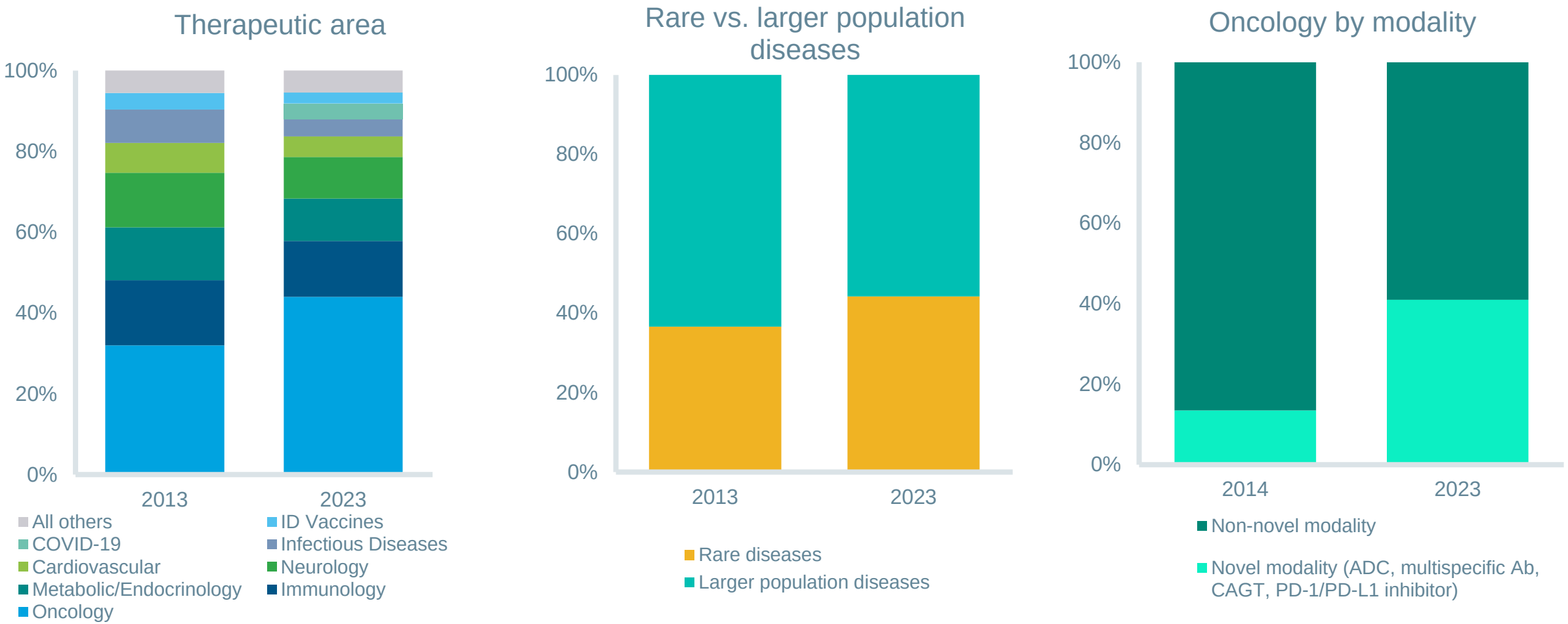
Clinical development focus has shifted toward oncology, rare diseases and novel modalities over the past decade

Share of clinical trial starts Phase I to III by therapeutic area, population, and oncology modality



Source: Global Trends in R&D 2024: Activity, Productivity, and Enablers, Feb 2024. Report by the IQVIA Institute for Human Data Science (adapted format).

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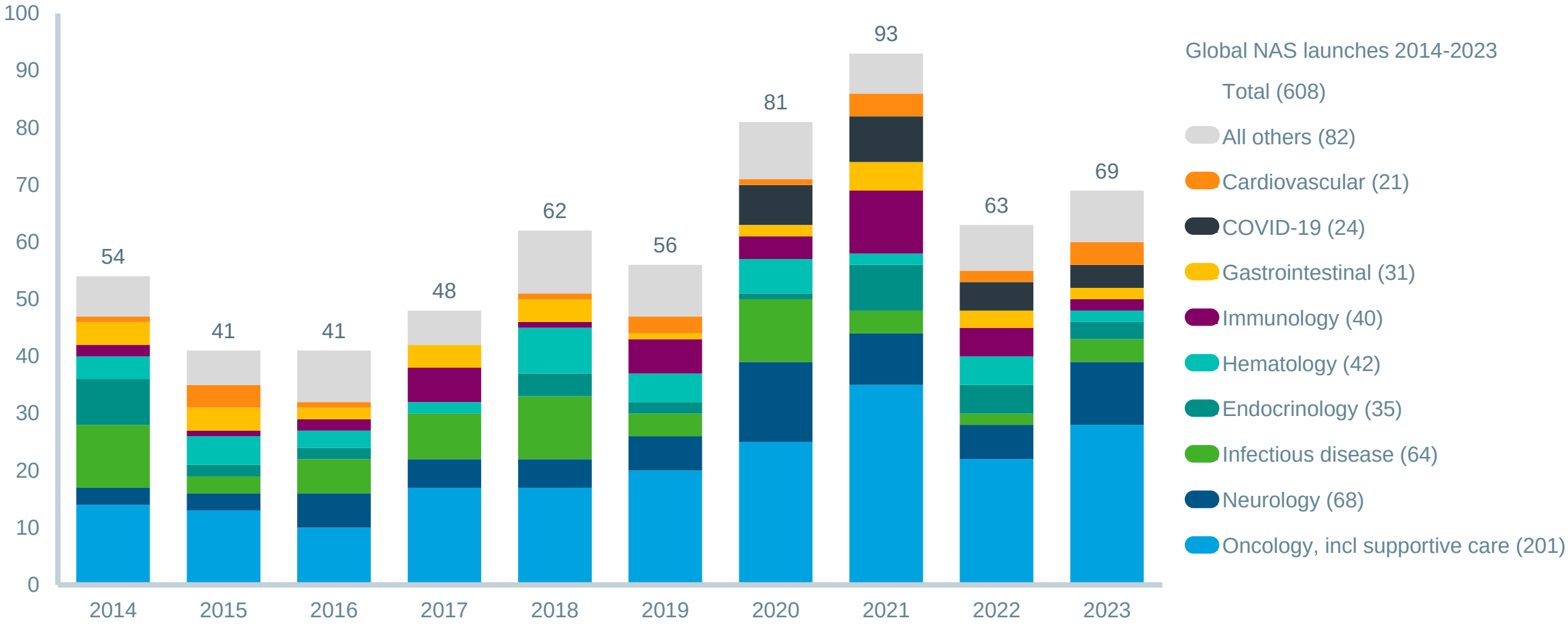
Over 600 novel active substances (NASs) were launched globally over the past decade

Global launches of novel active substances (NAS) by therapy area, 2014−2023



Source: IQVIA Institute, Jan 2024
Global Trends in R&D 2024: Activity, Productivity, and Enablers, Feb 2024. Report by the IQVIA Institute for Human Data Science.

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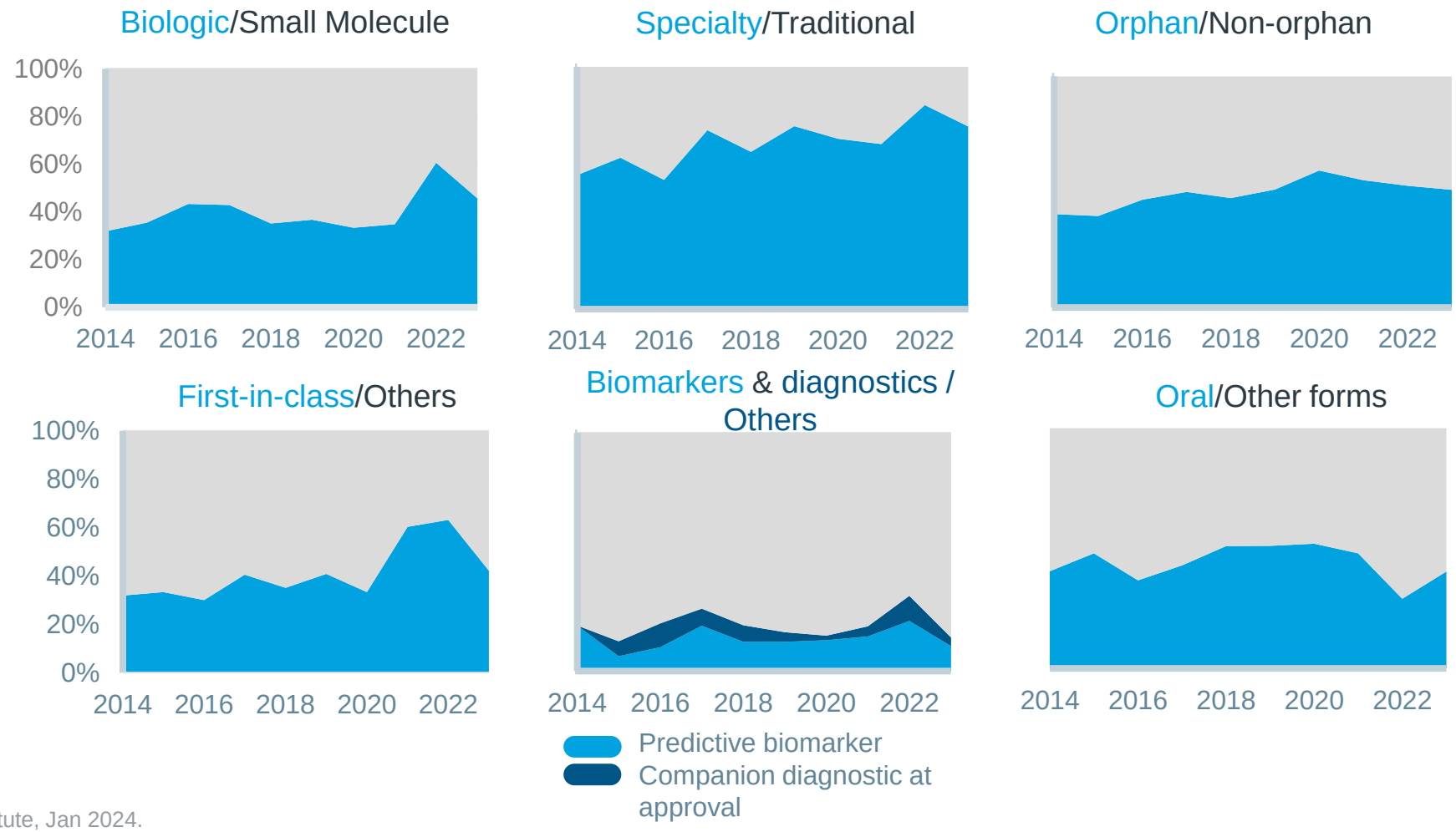
Characteristics of the NASs launched in the U.S. have trended toward specialty, biologics, orphan drugs and first-in-class

U.S. novel active substances (NASs) by product attributes, 2014–2023



Source: IQVIA Institute, Jan 2024.
Global Trends in R&D 2024: Activity, Productivity, and Enablers, Feb 2024. Report by the IQVIA Institute for Human Data Science (revised version).

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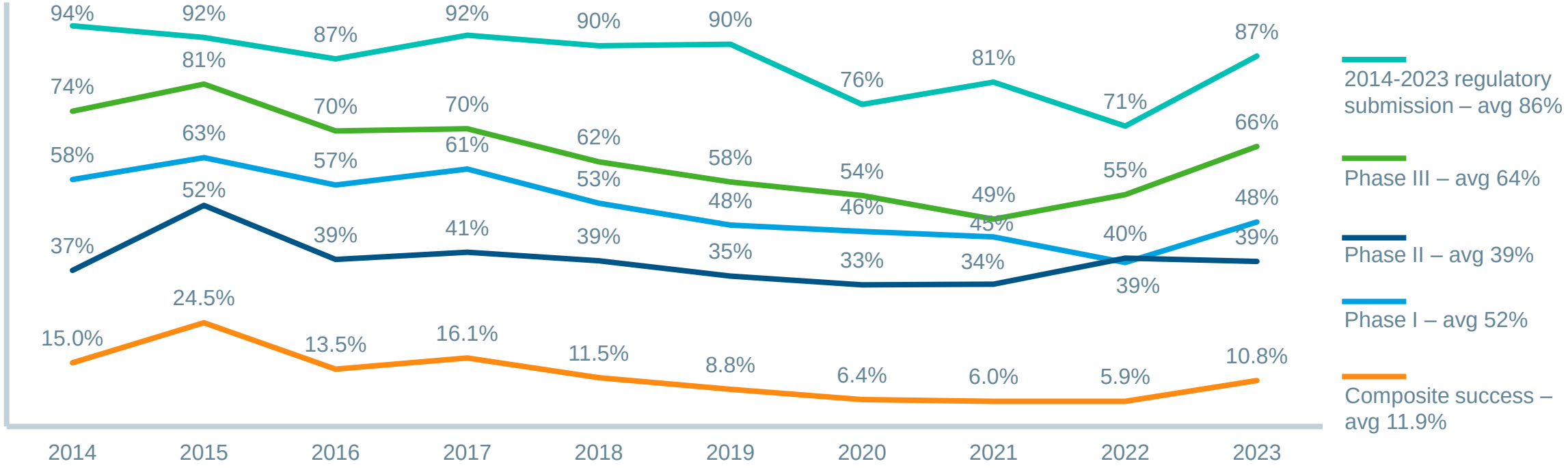
Phase and composite success rates have generally trended down over the decade, with some uptick in 2023

R&D composite success rate and average phase success rates Phase I to filing, 2014−2023



$$\text{Phase success\%} = \frac{\text{Success (drug reaches any higher phase)}}{\text{Total of success and failure}}$$

Composite success % = Phase I x Phase II x Phase III x Regulatory submissions

Source: IQVIA Pipeline Intelligence, Dec 2023; IQVIA Institute, Jan 2024
Global Trends in R&D 2024: Activity, Productivity, and Enablers, Feb 2024. Report by the IQVIA Institute for Human Data Science. .

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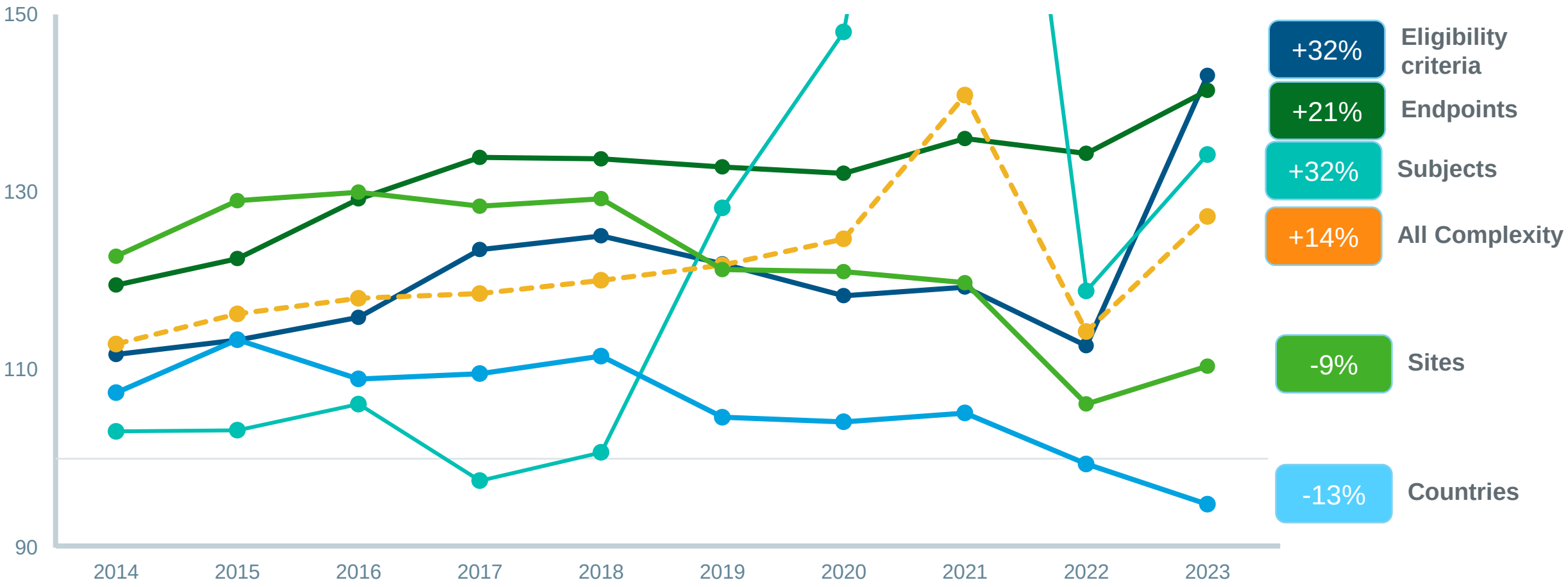
Clinical trial complexity has increased with more eligibility criteria, subjects and endpoints

Elements of complexity, all phases 2014−2023, indexed to 2010 = 100



Note: Number of subjects not shown
Source: Citeline Trialtrove, IQVIA Institute, Jan 2024
Global Trends in R&D 2024: Activity, Productivity, and Enablers, Feb 2024. Report by the IQVIA Institute for Human Data Science (adapted format). .

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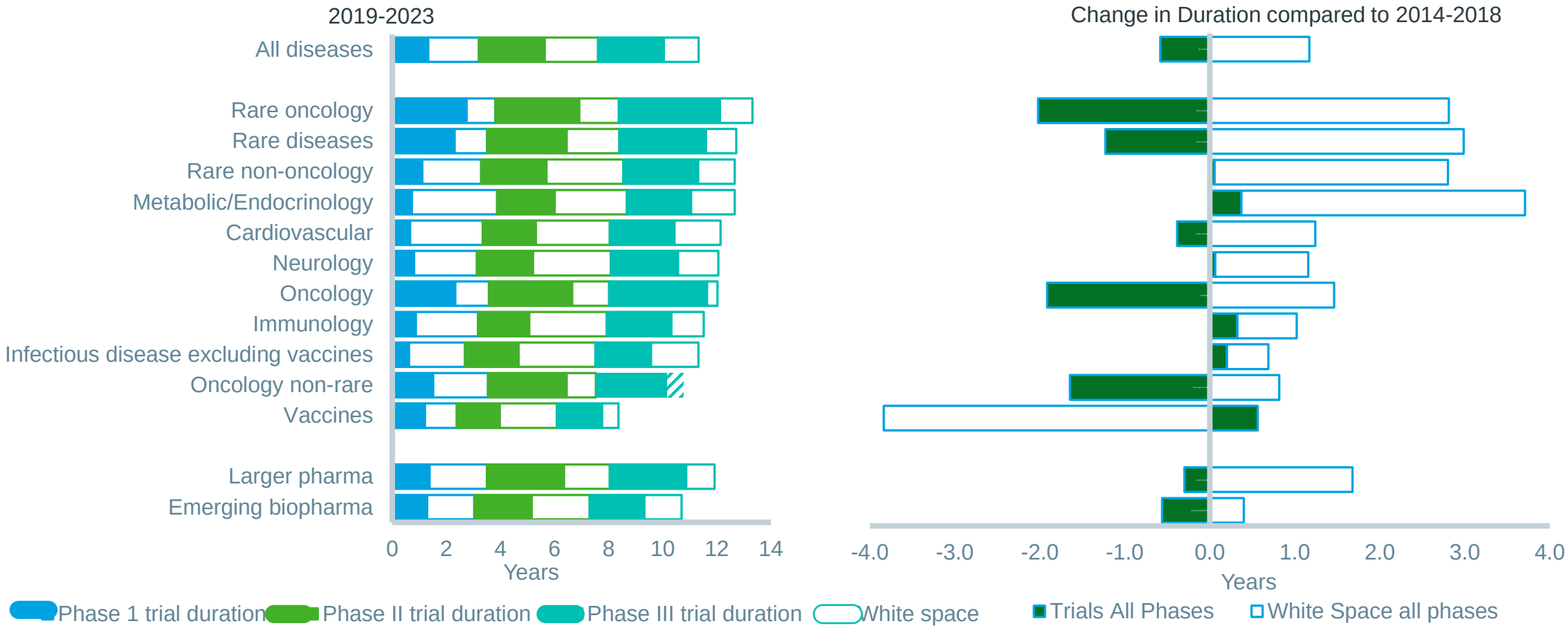
Trial durations have declined while the ‘white space’ before starting a subsequent research phase has increased

Comparison of trial duration to phase-change duration (years) in key disease areas, 2014–2023



Source: IQVIA Pipeline Intelligence, Dec 2023; Citeline Trialtrove, IQVIA Institute, Jan 2024.
Global Trends in R&D 2024: Activity, Productivity, and Enablers, Feb 2024. Report by the IQVIA Institute for Human Data Science.

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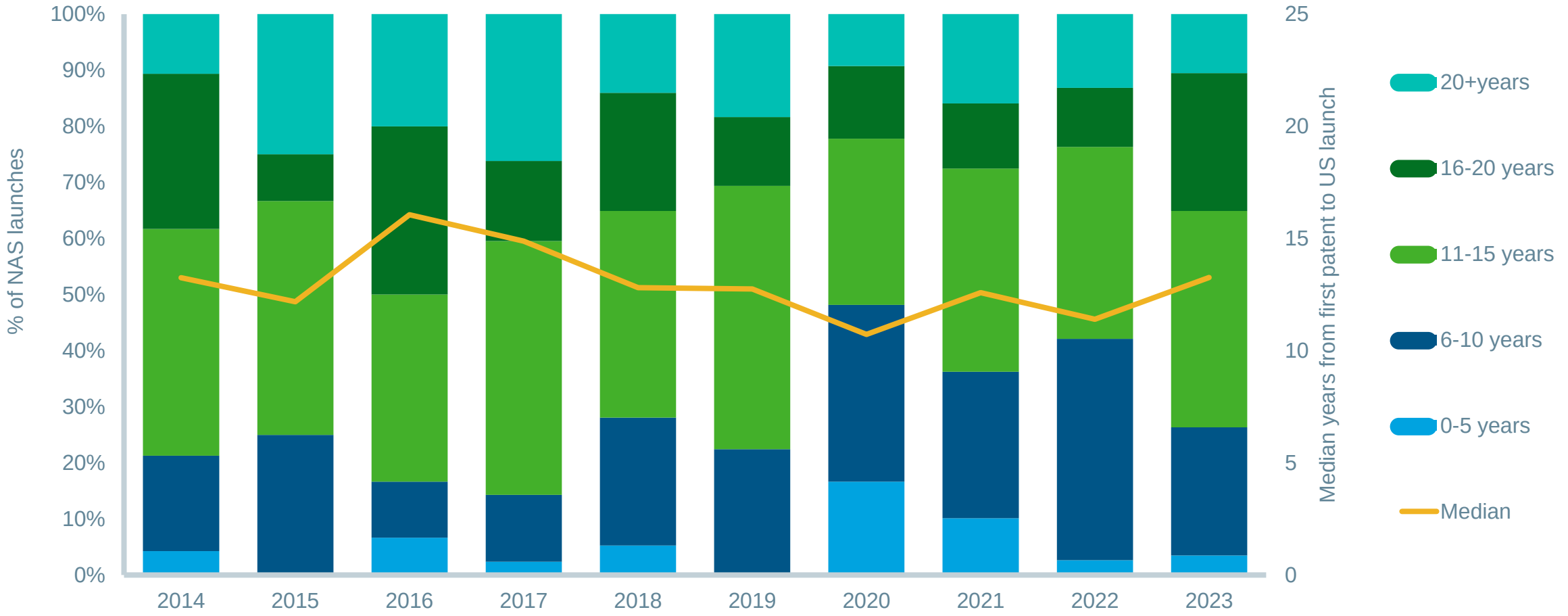
Median total development time has fluctuated between 11 and 16 years over the decade, trending up since 2020

Time from first patent filing or human trial and U.S. launch for novel active substances, 2014–2023



Source: IQVIA ARK Patent Intelligence, Citeline TrialTrove, IQVIA Institute, Jan 2024.
Global Trends in R&D 2024: Activity, Productivity, and Enablers, Feb 2024. Report by the IQVIA Institute for Human Data Science.

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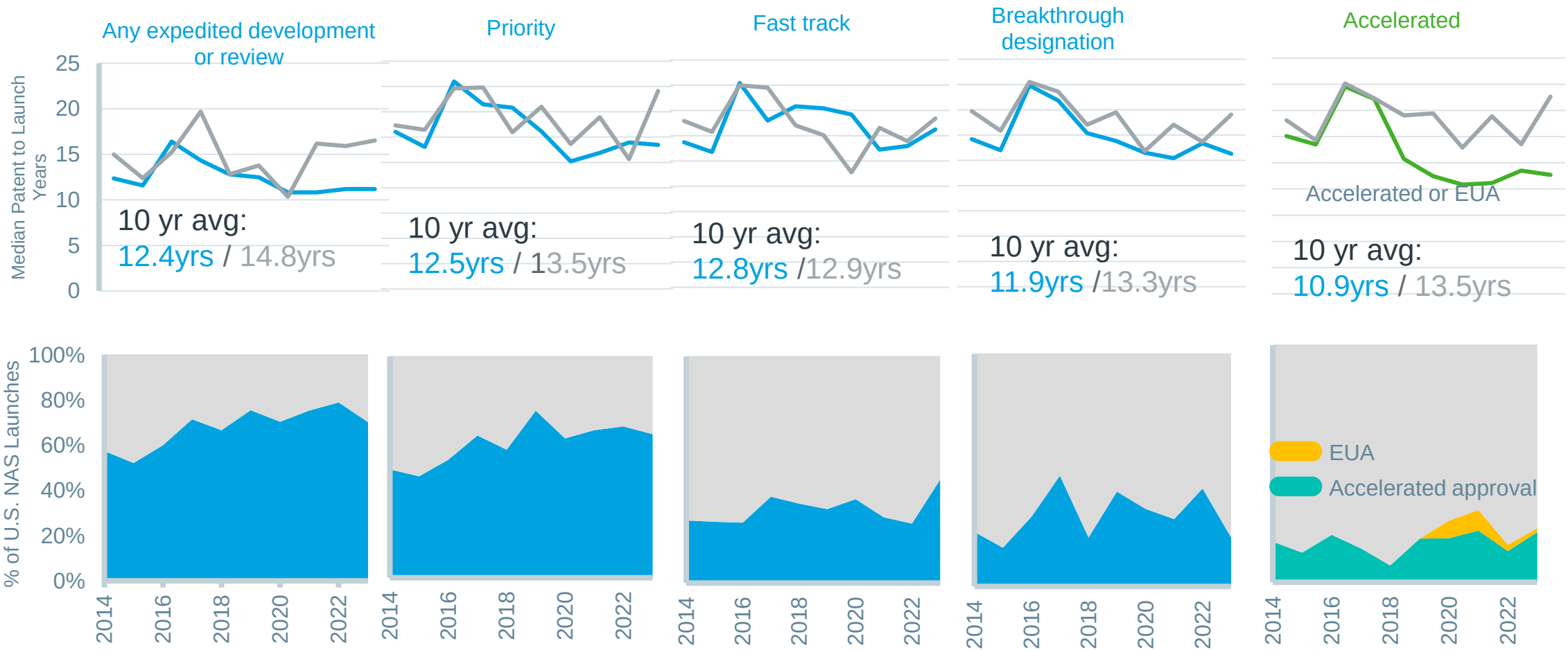
Most approvals are on an expedited regulatory pathway with median overall development duration 1-2 years faster when used

U.S. NAS launches and time from first patent filing or human trial to approval, 2014-2023



Source: IQVIA Institute, Jan 2024.
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Areas of advancement over past decade

Regulatory, policy and incentive alignment
Including impact of multiple FDA, EMA, ICH initiatives, Project Warp Speed, etc.

Clinical trial pathway strengthening and partnerships
Including diagnostics, referrals, multi-center collaboration

Mobilization of representative patients
Including use of registries and pre-screened pools of patients, patient organization roles, clinical research as a care option

Use of real-world data in clinical research settings
Including use for comparator arms, site identification, patient screening and matching

Adoption of technology in trial planning and execution
Including novel trial design, trials with decentralized elements, use of connected devices, AI applications

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