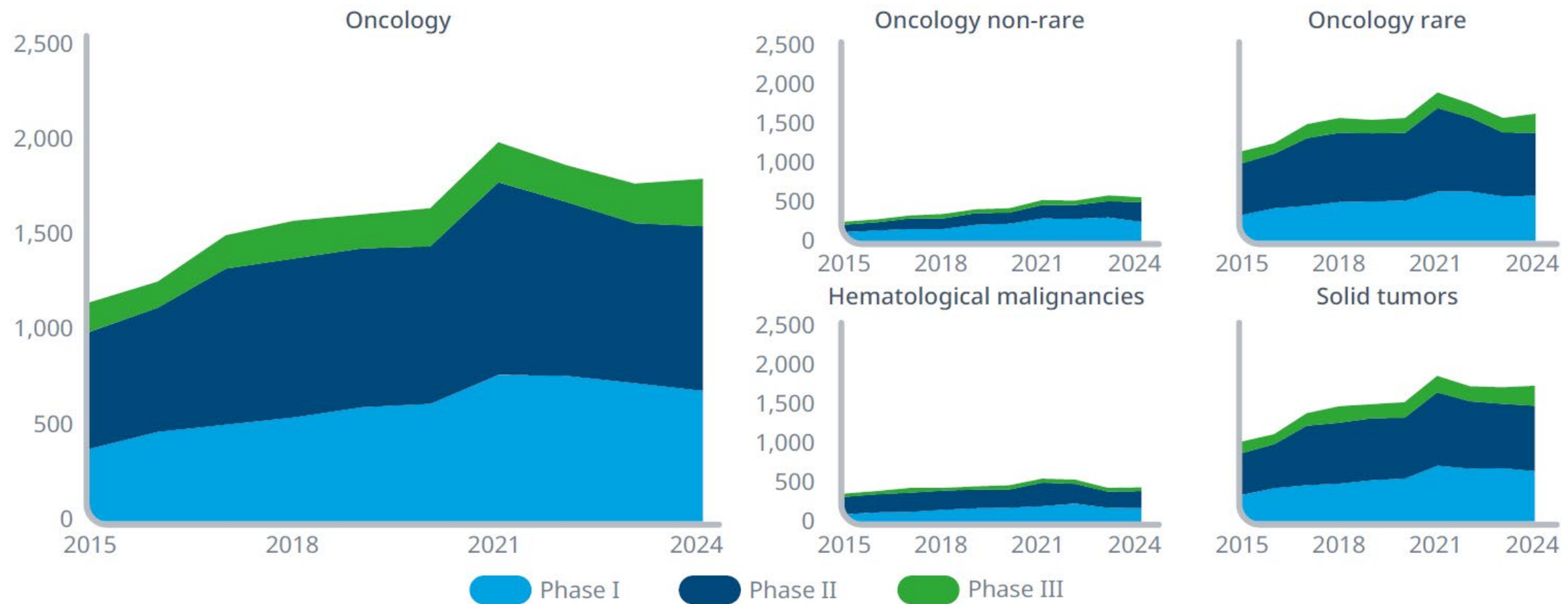


Early phase oncology clinical trials

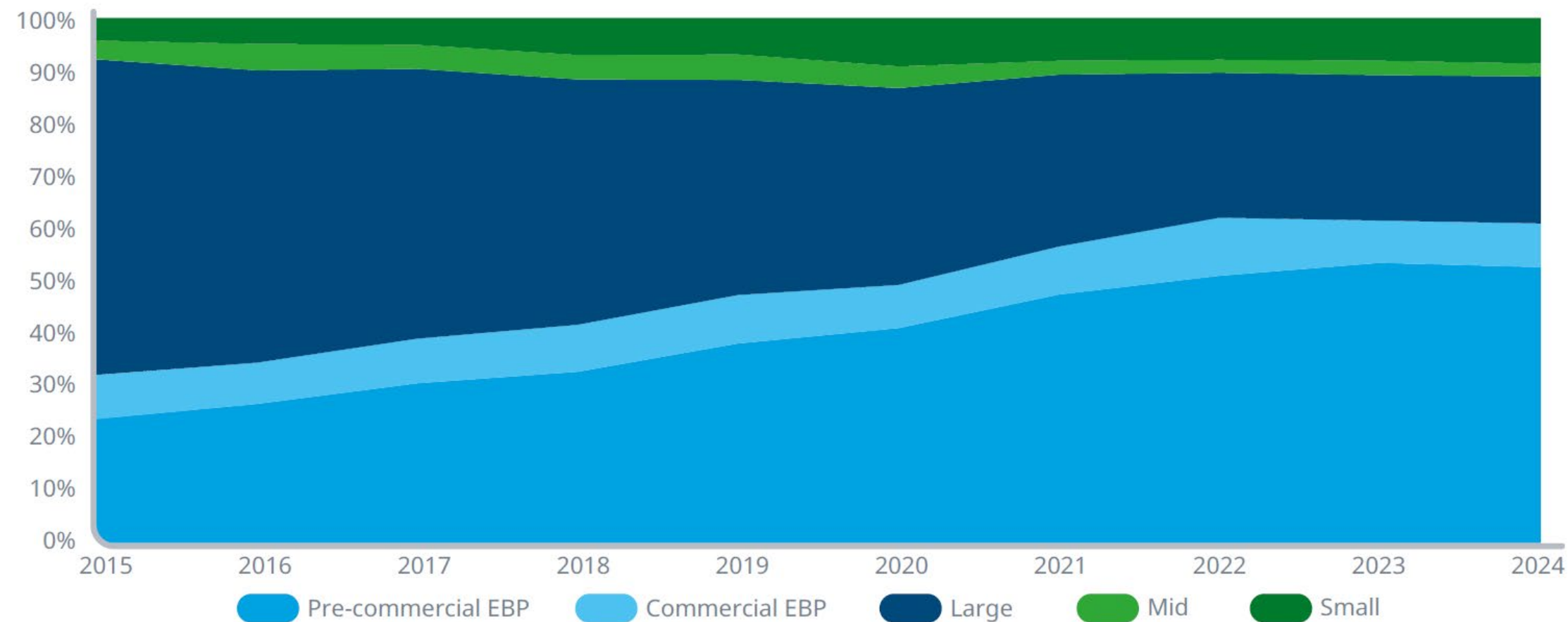
Global & US landscape

National Cancer Advisory Board

Oncology trial starts have increased globally focused on early phase trials for rare cancers & solid tumors

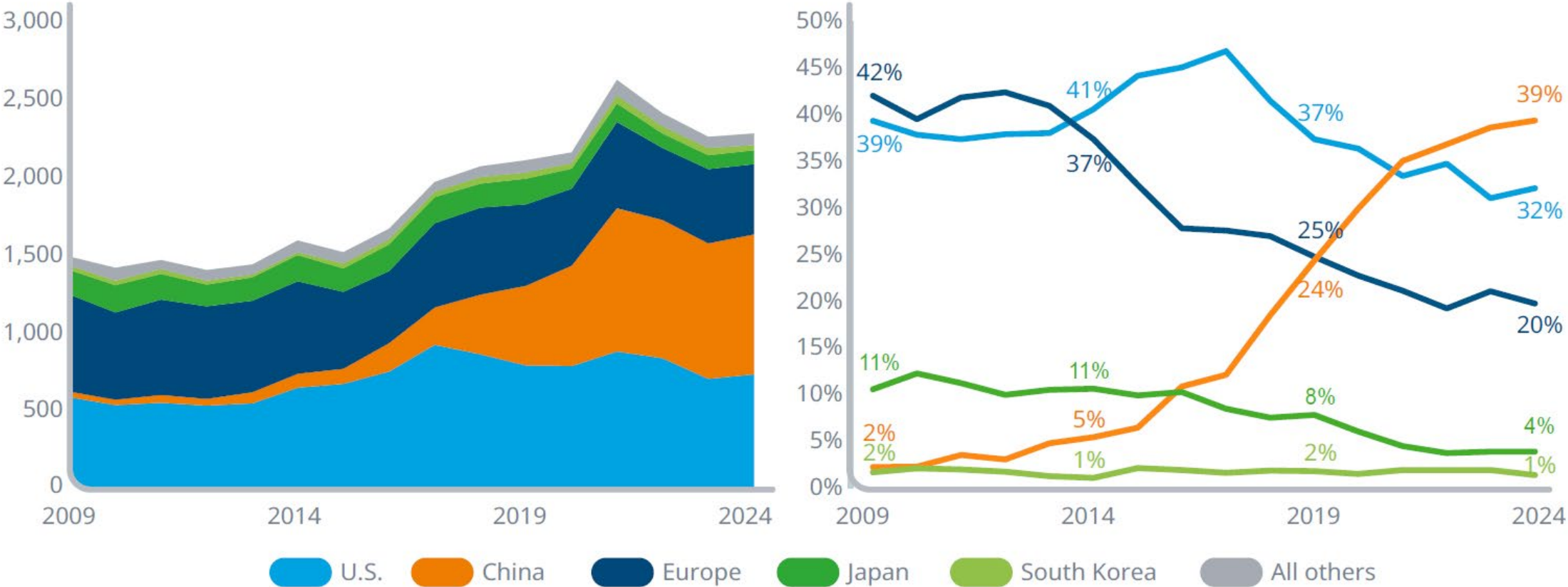


Oncology trials are increasingly supported by pre-commercial emerging biopharma sponsors

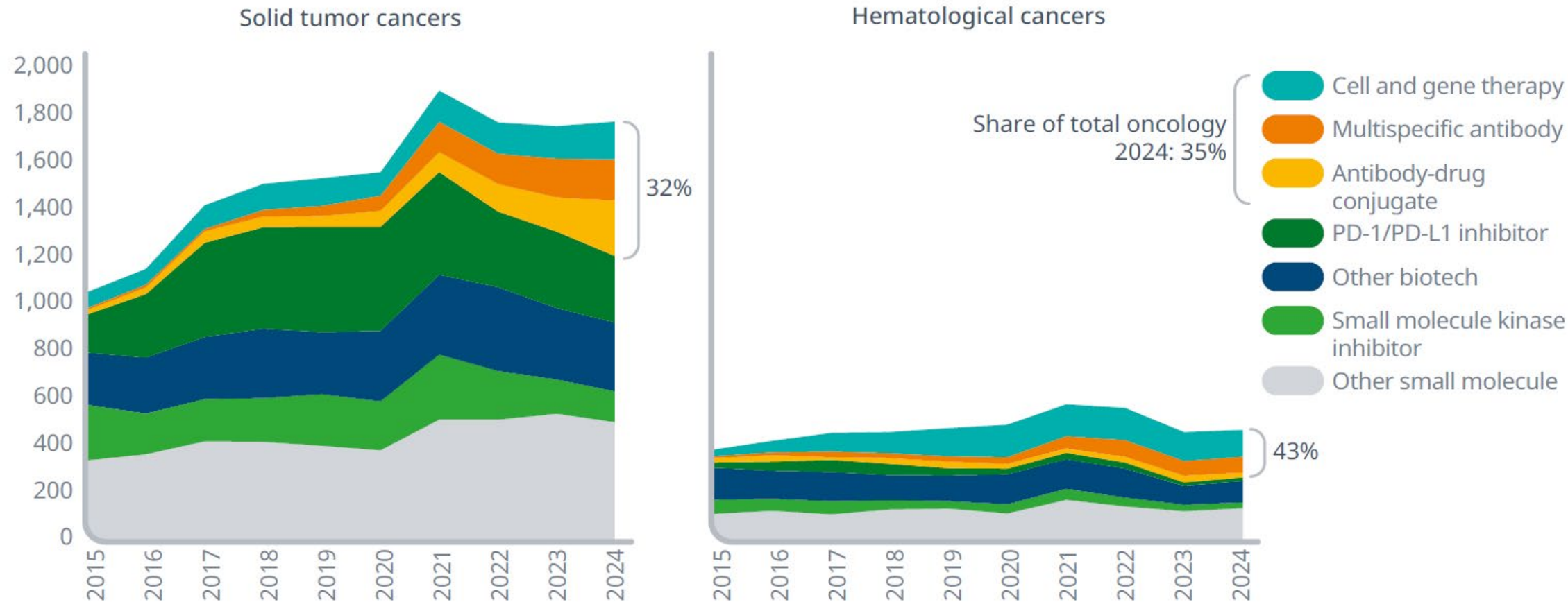


<https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-oncology-trends-2025>

The geographic distribution of oncology trial sponsors has changed with continued US centrality alongside shift toward China



Oncology trials are increasingly focused on new treatment modalities



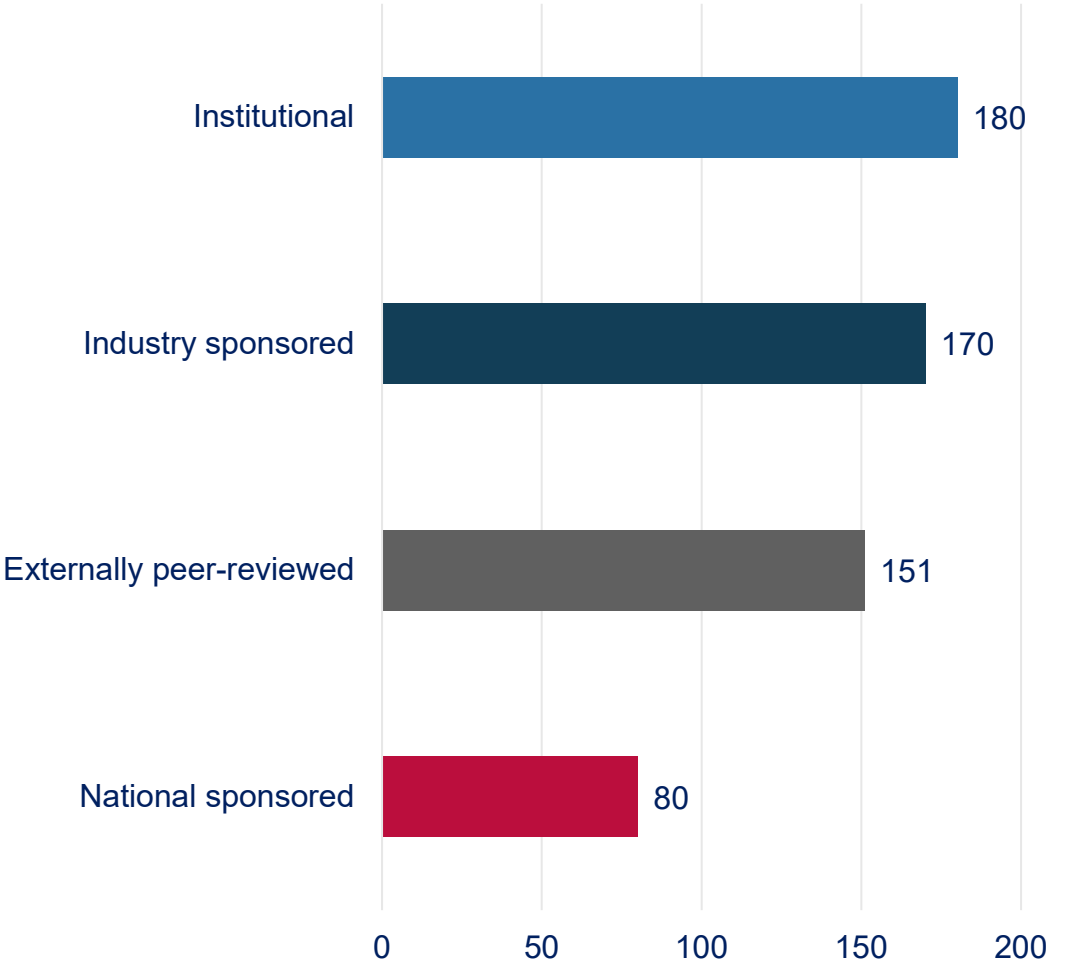
<https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-oncology-trends-2025>

Association of American Cancer Institutes benchmarking surveys reflect real-world operational burdens of these shifts

Cancer Center Clinical Trial Office metrics, 2018 vs 2023

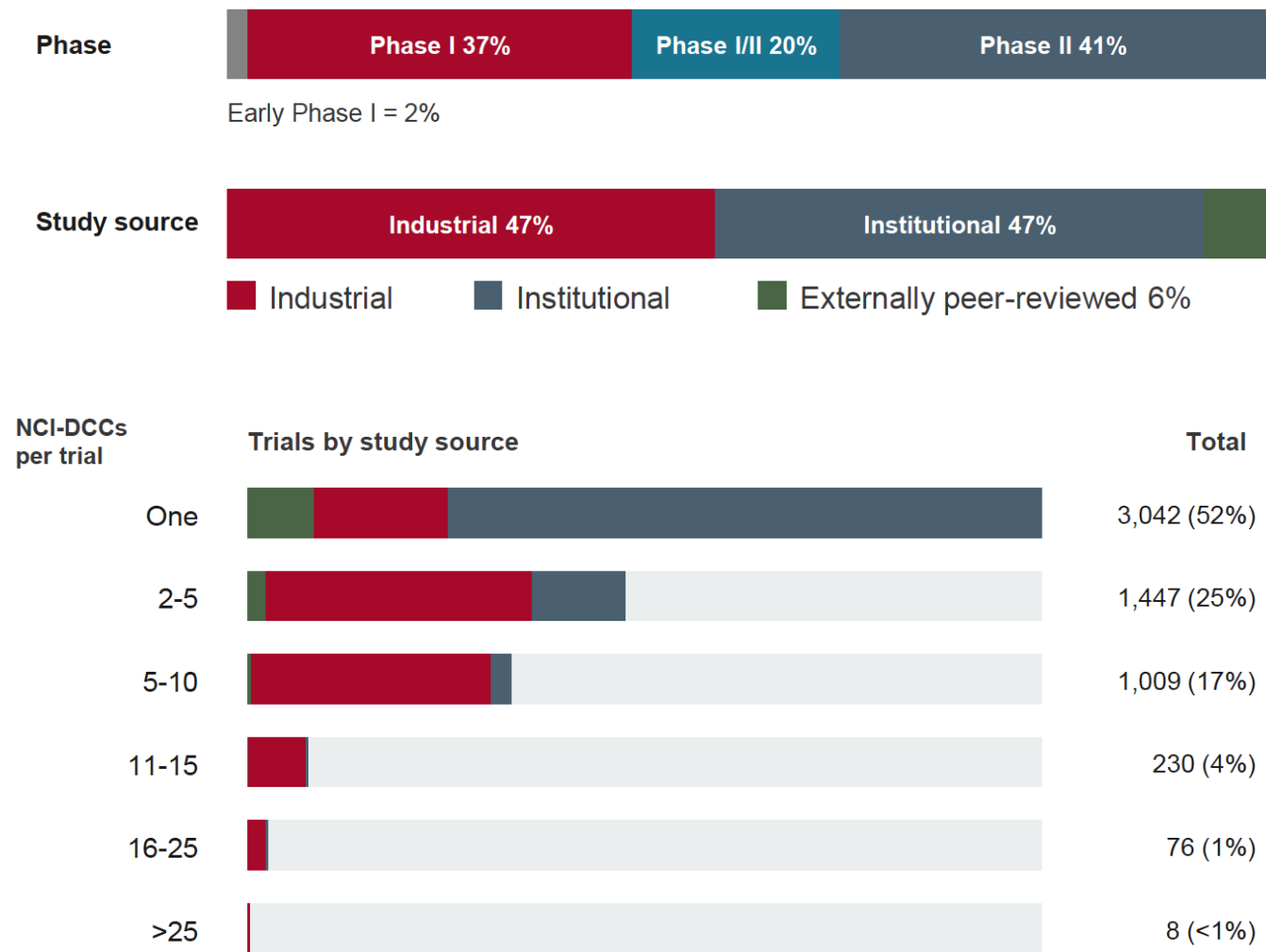
Median metric	2018	2023	Change
Annual budget	\$8.2M	\$11.5M	+40%
Full-time equivalents	104	150	+44%
Active treatment trials	280	384	+37%
Treatment accruals	531	479	-10%

Median days protocol submission to open, 2023



NCI-designated cancer centers are a key national asset & engine of early phase oncology trials in US

- 5812 early phase treatment trials opened at NCI-designated cancer centers 2020-2025
 - 969 mean new openings per year
 - 263 national network trials excluded
 - Most are industrial or institutional trials conducted at a single center or 1-10 centers



Multiple opportunities to lose time prior to activation

Budget and coverage analysis

Rate cards, coverage analysis, calendars, pharmacy and imaging fees

Contracting

CTA terms, indemnity, publication, data rights, repeated redlines

Local review and IRB

Reliance decisions, consent language, ancillary reviews, sequencing with local processes

Protocol amendments

Changes during startup can force sites to rebuild work they just completed

Sponsor/CRO handoffs

Incomplete startup packages, staff turnover, slow clarification cycles

Australia is an instructive quality & efficiency case study

Success factor	Australia experience
Regulatory & ethics	▪ Model relies on sponsor, ethics committee, & institutional authorization rather than routine pre-trial agency review ▪ Ethics & site governance proceed in parallel
Cost & incentives	▪ Tax incentive materially reduces net costs for eligible sponsors ▪ Early phase startup costs are predictable and visible to investors
Quality	▪ Reputation for high quality ▪ Experienced investigators, strong medical infrastructure ▪ Data accepted by major regulators
Strategic positioning	▪ Concerted effort to be first-in-human or first-activation partner for sponsors ▪ Not a replacement for US development activities

Conclusions

- US remains a leader in global oncology trials but operational inefficiencies threaten innovation, scientific leadership, & progress for patients
- NCI is working with cancer centers & other partners to optimize & leverage capabilities as a truly national asset & ecosystem
- NCI is working with FDA & other federal partners to optimize & leverage a whole-of-government approach
- Dr. Doroshow to discuss recent & ongoing efforts within NCI-supported clinical trial networks

An official website of the United States government [Here's how you know](#) ▾

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HHS LAUNCHES UNPRECEDENTED DEPARTMENT-WIDE EFFORT TO RESTORE AMERICAN LEADERSHIP IN CLINICAL TRIALS

NIH's National Cancer Institute (NCI) is working with cancer centers, researchers, and other stakeholders to streamline clinical trial activation and improve enrollment in cancer studies that have contributed to major advances in patient care.

<https://www.hhs.gov/press-room/hhs-launches-clinical-trials-reform-initiative.html>

U.S. Department of Health and Human Services (HHS) + Follow ...

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This week, HHS held a Clinical Trials Roundtable to announce a coordinated department-wide effort to strengthen America's leadership in clinical research, accelerate the development of lifesaving treatments, and ensure that patients have access to the most innovative therapies in the world.

The Department's actions reflect a broader commitment to advancing American scientific leadership, expanding patient access to cutting-edge treatments, and ensuring that the United States remains the world leader in medical innovation.



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