

Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY



IMPACT REPORT

ANALYSIS & INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

A growing proportion of clinical trials are conducted in AMC- and network-affiliated sites

Nearly half of site networks received private equity and venture capital funding

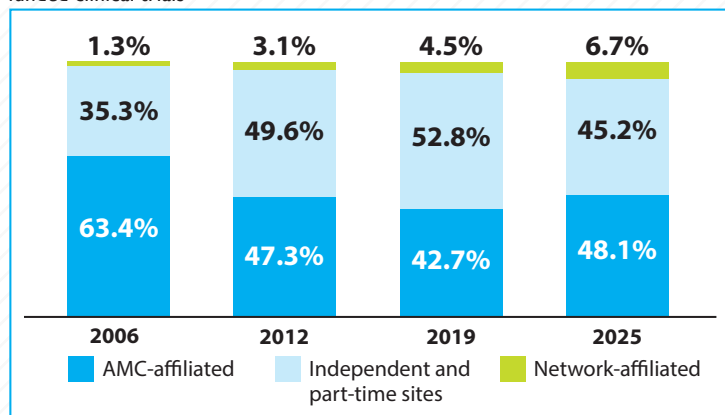
- Investigative sites affiliated with academic medical centers (AMCs) currently make up 48.1% of active global sites, reversing a multi-decade proportional decline.
- The proportion of sites that are AMC-affiliated, independent and part-time, or network-affiliated varies by global region.
- Almost 40% of network-affiliated sites report receiving investment capital from venture capital and private equity firms.
- AMC-affiliated sites attract the highest percentage of study participants living more than 50 miles away and are the most likely to offer local laboratory and pharmacy visits, while network-affiliated sites are the most likely to offer mobile and pop-up locations.
- Protocol complexity is among the top operating challenges reported by all types of investigative sites; profit pressure is a top operating challenge among network-affiliated sites.

Investigative sites conducting clinical trials face unprecedented operating challenges, including complex and demanding protocols, stringent regulatory requirements, novel executional models (e.g., virtual and remote sites), participant enrollment difficulties, economic pressures, workforce shortages and turnover, shifting grant opportunities, and intensifying competition, particularly from private equity and venture-backed networks.

This *Tufts CSDD Impact Report* presents the results of recent research conducted by the Tufts Center for the Study of Drug Development (CSDD) to assess how these challenges have impacted the structure, capacity, and performance of the global investigative site landscape.

The proportion of AMC- and network-affiliated investigative sites has grown

Percent of total global investigative sites actively conducting one or more industry-funded clinical trials

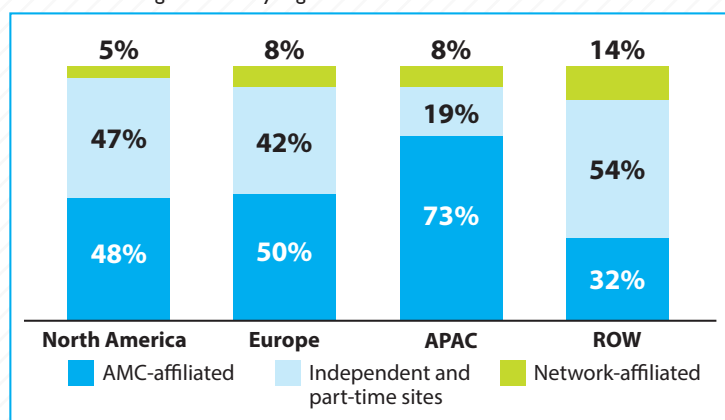


Source: Tufts Center for the Study of Drug Development

- Network-affiliated investigative sites (also referred to as site networks) currently represent 6.7% of the total landscape, up from 1.3% in 2006.
- Capturing 48.1% of total active global sites in 2025, the academic medical center (AMC)-affiliated site segment reversed its multi-decade proportional decline.
- The proportion of sites in the independent and part-time segment decreased in 2025 due to divestitures, consolidation, and difficulty competing with the infrastructure and capabilities of AMCs and site networks.

Site networks as a proportion of total active sites are higher outside of North America

Percent of investigative sites by region



Source: Tufts Center for the Study of Drug Development

- North America had a smaller proportion of sites operating within site networks than did other global regions.
- The Asia-Pacific (APAC) region, which includes East Asia, Southeast Asia, South Asia, and Oceania, had a disproportionately high percentage of AMC-affiliated sites and a relatively low proportion of independent and part-time sites.
- In the Rest of World (ROW), which includes regions outside of North America, Europe, and APAC, less than one-third of active investigative sites were AMC-affiliated and more than half were independent and part-time sites.

Forty percent of network-affiliated sites received investment capital

Capacity, trial volume, and source of investment reported by sites

Site capacity and trial volume*	AMC-affiliated	Independent and part-time sites	Network-affiliated
Number of PIs conducting at least one industry-funded clinical trial	187.3	6.6	144.9
PIs with 6+ years of experience	57.1%	54.8%	54.0%
Annual number of industry-funded clinical trials per PI	1.8	3.5	5.2
Source of site investment			
Capital received from VC/PE firms	18.0%	22.2%	39.0%
Capital received from CROs	19.7%	15.4%	6.5%

* Values given as means

Source: Tufts Center for the Study of Drug Development

- A large number of principal investigators (PIs) in AMC-affiliated sites individually conducted less than two industry-funded clinical trials annually.
- About 20% of AMC-affiliated sites received investment funding from contract research organizations (CROs) and the capital markets.
- On average, independent and part-time sites had seven PIs conducting 3.5 industry-funded clinical trials annually, with one-out-of-five reporting that they received investment funding.
- Nearly 40% of network-affiliated sites reported receiving venture capital (VC) and private equity (PE) funding to support their PIs and annual clinical trial volume.

AMC-affiliated sites report offering strong access and convenience to participants

Participant proximity and convenience capabilities reported by sites

Percent of study participants based on proximity to site	AMC-affiliated	Independent and part-time sites	Network-affiliated
Study participants living <10 miles from site	31.5%	37.9%	39.1%
Study participants living 11-50 miles from site	33.5%	38.5%	31.9%
Study participants reporting close access to public transportation	50.5%	38.4%	57.2%
Conveniences offered by sites			
Local laboratory visits	74.5%	59.9%	71.9%
Protocol visits at a local pharmacy	30.5%	18.3%	19.5%
Home visits	12.7%	11.5%	14.3%
Mobile research units	2.2%	11.5%	19.9%
Pop-up locations	5.8%	5.6%	6.1%

Source: Tufts Center for the Study of Drug Development

- AMC-affiliated sites attracted the highest percentage of study participants living more than 50 miles away, were the most likely to offer local laboratory and pharmacy visits, and were the least likely to offer mobile and pop-up locations.
- The highest relative percentage of sites offering home visits, mobile units, and pop-up locations operated as part of a site network.
- A much lower percentage of independent and part-time sites were close to public transportation.

Site networks have lower randomization and higher completion rates

Site enrollment performance reported by sponsor

Site enrollment performance*	AMC-affiliated	Independent and part-time sites	Network-affiliated
Screen failure rate	38.0%	46.4%	79.1%
Randomization rate	62.0%	53.6%	20.9%
Completion rate	21.5%	31.3%	70.6%
Actual months from first patient to last patient visit as a percent of planned months	52%	53%	46%

* Based on 12 global, multi-therapeutic Phase II/III studies involving 524 sites

Source: Tufts Center for the Study of Drug Development

- Compared to other site segments, network-affiliated sites had the lowest randomization rates, but the highest participant completion rates.
- AMC-affiliated and independent and part-time investigative sites reported comparable screen failure and randomization rates, but AMC completion rates were lower.
- Actual average enrollment time in months between first and last patient in, for all site segments, was approximately half the planned time.

Patient recruitment and profit pressures are top challenges for independent sites and site networks

Operating areas rated by sites as among top three challenges

Reported operating challenges	AMC-affiliated	Independent and part-time sites	Network-affiliated
Protocol complexity	20.5%	25.3%	18.2%
Participant recruitment	18.2%	24.7%	24.7%
Staff turnover	17.8%	16.7%	15.6%
CRO communication and relationship	14.4%	17.2%	19.5%
Patient recruitment of diverse backgrounds	12.8%	18.8%	13.0%
Increased pressure to make profit	12.4%	15.9%	22.1%
Technical issues	8.5%	14.8%	14.3%

Source: Tufts Center for the Study of Drug Development

- Network-affiliated sites reported that participant recruitment and profit pressures are among their top three operating challenges.
- All site segments reported that protocol complexity was among their top three operating challenges.
- Nearly one-out-of-five independent and part-time sites rated recruitment of diverse study participants as a top three operating challenge.

About this study

The Tufts CSDD collaborated with nine sponsors and contract research organizations (CROs) that are actively conducting industry-funded clinical trials, to assess the global investigative site landscape. The study consisted of a global survey distributed between late February to early April 2025, with a data collection effort among participating companies. There were a total of 1,154 responses from 555 AMC-affiliated sites, 522 independent and part-time investigative sites, and 77 for-profit investigative site networks. Participating companies provided enrollment performance data for 12 multi-therapeutic studies for 857 investigative sites. Average number of principal investigators and annual trial volume by site segment are based on estimates drawn from publicly available government databases.

This study was conducted by Abigail Dirks, MS, senior data scientist; Joan Chambers, consultant; and Kenneth Getz, MBA, research professor and executive director, all of Tufts CSDD.

Definition of terms

AMC-affiliated sites — A clinical trial site that is affiliated with, and operates within, an academic medical center or government health system.

Completion rate — The percent of patients that are randomized and complete the study.

Home visits — Clinical trial visits conducted at the patient's home by a healthcare professional.

Independent network-affiliated sites — An investigative site that is part of a larger system or network of sites. The site may be owned and operated independently, but it is affiliated with a network, or the site operation and personnel are owned and employed respectively by a corporation.

Independent and part-time sites — An investigative site that is not part of or affiliated with a network. This segment includes both sites that derive most of their income from study grants and those that derive most of their income from clinical care services.

Local laboratories — Laboratories near the investigative site that gather blood, urine, stool, and tissue samples.

Mobile research unit — A portable healthcare facility, often housed in a vehicle, that delivers medical services to communities.

Planned to actual time from FPI to LPI — The ratio of actual months from date of first patient in (FPI) to date of last patient in (LPI) compared to the planned timeline in months. A ratio of less than one indicates that the actual number of months was less than planned.

Pop-up location — Temporary short-term locations, usually located in targeted patient communities.

Randomization rate — The percent of patients that are screened and randomized.

Screen failure rate — The percent of patients that are screened but are not randomized.

Venture capital/private equity (VC/PE) firms — Investment firms that provide funding in return for equity.

About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development at Tufts University School of Medicine is a multidisciplinary research center dedicated to optimizing drug development performance, efficiency, and economics through robust, data-driven assessments, analysis, and insight.

Tufts Center for the Study of Drug Development

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