

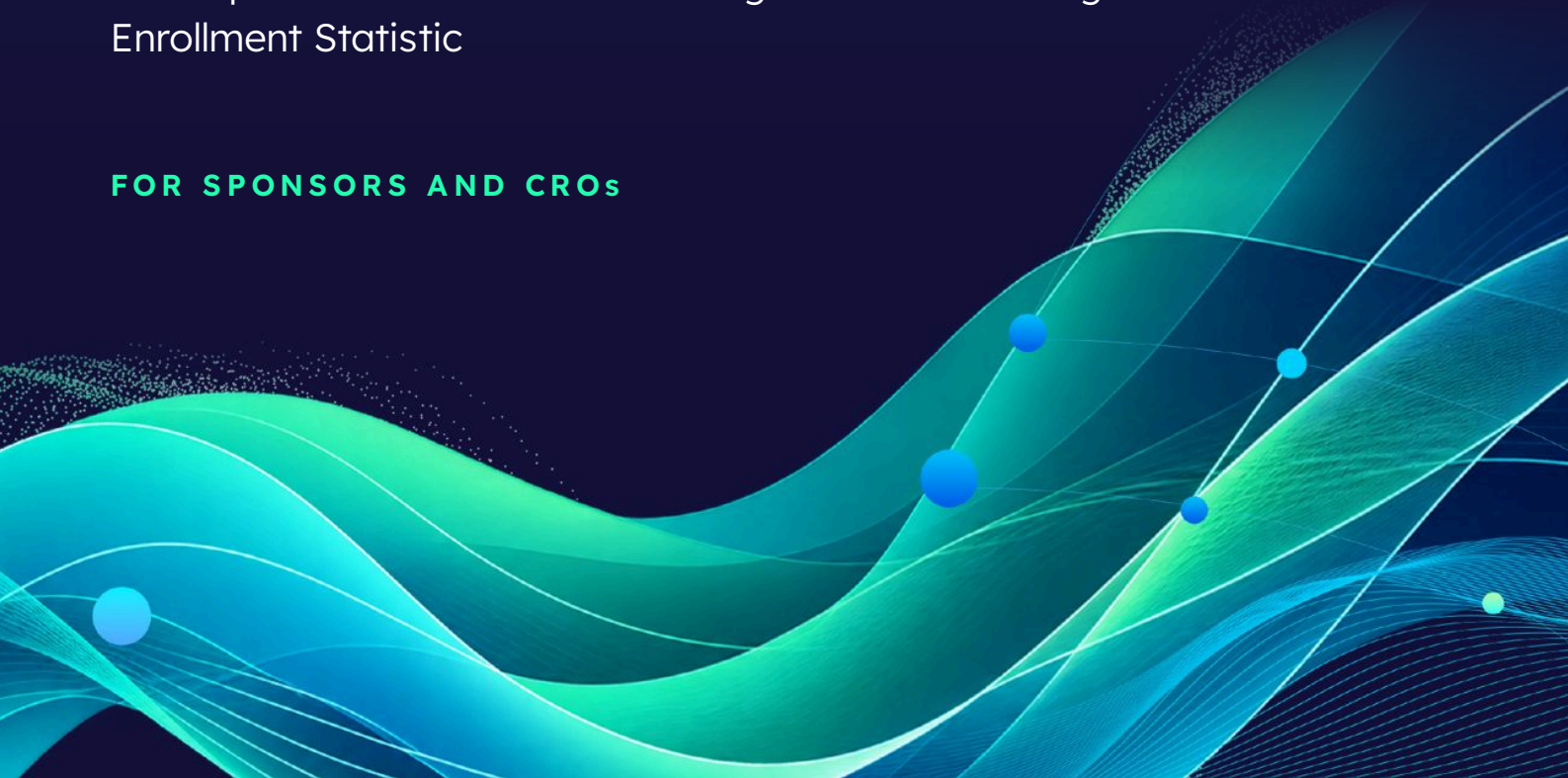
12

insights
from Citeline SMEs

Parsing the 2026 Patient Recruitment Roundup:

How Sponsors Can Avoid Becoming Just Another Negative Enrollment Statistic

FOR SPONSORS AND CROs





Our 2026 Patient Recruitment Roundup, a comprehensive analysis of clinical trial recruitment rates between 2022 and 2025, paints a less than rosy picture for trial enrollment. The overall median enrollment rate (MER) declined to a four-year low in 2024, and enrollment duration has risen sharply since 2010 across all phases, more than doubling for Phase I trials.

So how can the industry course correct? We asked SMEs from Citeline and its parent company, Norstellla, for advice on how sponsors and CROs can take findings from this report and, with the help of Citeline solutions, turn them into opportunities to move the needle on patient recruitment numbers. Here are their actionable insights.

Key findings

OVERALL MER

0.37

Median patients per site per month in 2022–25, down from 0.76 in 2010

PHASE II DURATION

19.2–20.4 months

Phase II enrollment duration, up from 12.2 months in 2010

ONCOLOGY MER

0.16

In 2025, down from 0.20 in 2022, a further 20% drop

PHASE II MER

0.27

In 2025, down from 0.66 in 2010 as median site counts rose from 10 to 14

PHASE IV MER

0.70

In 2025, down from 1.04 in 2023

ASIA ADVANTAGE

62–69%

Asian sites outperform North American sites on overall MER, and European sites by 89–120%

INSIGHT 1

Build enrollment forecasts around comparable studies

From the report: The overall median enrollment rate (MER) decreased, from 0.76 in 2010 to 0.37 in 2022–25. Meanwhile, Phase II enrollment duration increased from 12.2 months to 19.2–20.4 months.

Sponsors should revisit enrollment timelines using recent studies with similar indications, phases, eligibility requirements, and modalities. They should develop base and conservative scenarios that account for site activation and recruitment ramp-up. Feasibility is a complex discipline, landscapes are forever changing (clinical, commercial, standard of care, regulatory, etc.). The more data/reference points that can be used to give a clearer risk profile, the more realistic baselines will be and the right adaptive planning can be put in place.

Citeline's Feasibility as a Service (FaaS) can provide a comprehensive risk assessment of your trial; using clinical data, we can benchmark comparable trials and assess protocol, country, and site feasibility, providing evidence to support revised planning assumptions. We can provide standard-of-



care pathways and locate where the desired patient population is seen in the clinic. Commercial insights give line of sight into existing and future treatment pathways that could stall recruitment.

INSIGHT 2

Implement a data-driven strategy for trial design

From the report: Phase I enrollment now takes 17–20 months versus 8 months in 2010. Phase II enrollment has grown from 12 to 19–20 months. This extended exposure period does not compensate for lower per-site rates; it primarily reflects broader trial complexity and regulatory requirements.

ICH E6(R3) is the rewritten [good clinical practice](#) (GCP) standard, and it puts quality by design and proportionate, risk-based decision-making front and center. Being able to demonstrate evidence for design decisions, such as through profiling how protocols translate to patients in the real world (via Citeline's [Cohort SmartBuilder](#)), or showing that sites are selected based on performance and patient access (Citeline's [Sitetrove⁺](#)), alongside evidence of standard-of-care guidelines justifying trial designs or country selection (Citeline's [Patient Intelligence](#) and [Trialtrove⁺](#)), ensures decisions are defensible and grounded in data.

Greater trial and regulatory complexity necessitates advanced analytics to proactively identify and manage risks. From being able to identify trial analogs via [Trialtrove⁺ Trial Similarity](#), to calculating probability of technical and regulatory success (PTRS), or forecasting enrollment rates that are 33% more accurate than relying on historic benchmarks, the ability to deploy Citeline's clinical intelligence solutions drives greater certainty every step of the way as you plan your trial.

INSIGHT 3

Know what sets apart successful protocols

From the report: Oncology MER has declined from an already low 0.20 (2022) to 0.16 (2025), a further 20% drop in an already challenging environment. Rare disease closely follows at 0.17 in 2025. These two areas account for a disproportionate share of the industry pipeline, making their low recruitment performance a critical operational challenge.

The increasingly complex pharmaceutical landscape requires sponsors and CROs to understand what sets apart operationally successful protocols. To do so, they must drill down into how protocols translate to real-world patients and then the best-fit countries, sites, and investigators to deliver. This allows teams to build out scenarios that better identify and manage risk. This is what [Citeline SmartSolutions](#), spanning [Protocol SmartDesign](#), [Cohort SmartBuilder](#), and [Investigator SmartSelect](#), was designed to do. An extension of the [Trialtrove/Sitetrove](#) data trusted by the industry, this suite of tools is purpose-built to bring greater predictability in day-to-day decisions.

INSIGHT 4

Make complex eligibility criteria actionable

From the report: In 2025, oncology MER was 0.16 and non-oncology rare disease MER was 0.17.

For successful recruitment, sponsors should build a patient funnel showing how desired diagnosis, biomarkers, prior treatment, and other measurable inclusion/exclusion criteria narrow the population. Using [Cohort SmartBuilder](#), sponsors can identify the criteria that most affect recruitment and either challenge the need to have them in place or relax them while still retaining endpoint rigor. Protocol adaptation prior to finalization will save costly amendments when a study is in flight. Sponsors also can establish when patients should be approached based on patient journeys via [Patient Intelligence](#) and whether a desired comparator arm is indeed standard of care.

[FaaS](#) can pressure-test eligibility requirements. [Citeline PatientMatch](#) uses protocol-based algorithms across lab, biomarker, EMR, and longitudinal data, with timed alerts that help sites assess candidates during relevant treatment windows.

INSIGHT 5

Establish a course-correction plan before launch

From the report: Phase IV MER fell from 1.04 in 2023 to 0.70 in 2025, showing that historically stronger enrollment categories also need reassessment.

To optimize recruitment, sponsors should compare actual enrollment with the study-specific forecast and investigate where the recruitment funnel is losing patients.

Rolling feasibility is always good practice with ever-changing landscapes. [FaaS](#) can support renewed feasibility assessments, both clinical and commercial, as well as mid-trial rescue decisions. For [Citeline PatientMatch](#) custom alerts, sponsors should review follow-up as well as downstream screening and enrollment outcomes with sites.

INSIGHT 6

Validate patient access before adding sites

From the report: We see that Phase II median site counts increased from 10 in 2010 to 14 in 2025, while MER fell from 0.66 to 0.27.

ICH GCP E6(R3) now requires sites to be selected based on evidence of required patient populations. Do your existing sites have access to the required patient population and where those patients receive care? Use your answers to decide which sites need recruitment support and where additional sites could add value.

The extensive real-world data (RWD) that sits behind [Patient Intelligence](#) shows where patients go for treatment and how they are treated, allowing trial and patient to meet at the optimal time and location. [FaaS](#) combines patient availability, investigator experience, and competing trial activity to inform site



prioritization. [Citeline PatientMatch](#) can then support patient identification around suitable sites within its covered US footprint.

INSIGHT 7

Assess competition alongside investigator experience

From the report: Non-industry trials enrolled 1.59 million patients in 2024, compared with approximately 783,000 in industry trials.

To fully vet study sites, sponsors and CROs should examine current studies competing for similar patients at proposed sites. Ask sites about staffing, referral capacity, and overlapping recruitment commitments. These totals justify investigating competition, but do not establish a particular site's workload.

[FaaS](#) can assess the competitive landscape and identify alternative sites. Where patient identification is the bottleneck, [Citeline PatientMatch](#) offers an additional recruitment pathway.

INSIGHT 8

Find more patients per site, not just more sites

From the report: Combined median enrollment was 0.37 patients/site/month, roughly half the 2010 rate. Oncology and rare disease sit at just 0.16–0.22. Phase II site counts grew 30–40% while enrollment rates fell more than 50%.

Based on these metrics, merely adding sites will not solve the problem.

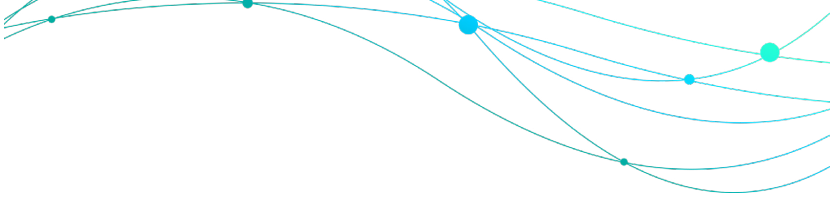
[Citeline PatientMatch](#) takes a different angle: It alerts investigators, site staff, and patients directly when patients who match sponsor trial protocols qualify for a trial based on comprehensive lab, biomarker, EHR, and claims results. This helps identify protocol-matched patients earlier and reduce screening burden.

INSIGHT 9

Put the patient at the center of enrollment

From the report: As stated above, the analysis reveals that overall industry-sponsored patient trial enrollment has remained low and relatively stable, with a combined MER of 0.37 patients/site/month. Enrollment rate is one of the most consequential performance metrics in clinical operations. Delays in patient recruitment are consistently cited as the leading cause of trial timeline overruns, accounting for an estimated 80% of study delays.^{1,2} Low enrollment rates translate directly into extended development timelines, increased costs, and delayed patient access to novel therapies.

With industry-sponsored enrollment holding steady at just 0.37 patients per site per month, it's clear that incremental improvements to traditional recruitment approaches aren't enough. Meeting enrollment goals requires a more proactive approach, starting earlier in the process and putting



the patient at the center.

At Citeline, we take a pipeline-to-patient approach, placing patients at the center of every decision. By applying our comprehensive, multi-source RWD to patient-driven recruitment, Citeline helps sponsors identify the right patients and sites from the outset, rather than discovering enrollment challenges once a study is already underway. Citeline brings together trial, site, and investigator intelligence with RWD to provide a more complete picture of both the patient population and the clinical trial landscape.

From there, **Citeline PatientMatch** helps turn these insights into action. By identifying the right patients for enrollment, alerting motivated sites, and facilitating direct-to-patient outreach, **Citeline PatientMatch** helps connect patients with opportunities to participate in clinical research and gives them a more active role in their care journey. Throughout the process, patient data remains de-identified, helping protect privacy while supporting more efficient recruitment.

The result: smarter site selection, faster enrollment, shorter timelines, and earlier access to novel therapies for the patients who need them.

INSIGHT 10

Capitalize on stronger recruitment trends through precise targeting

From the report: On specific therapies and conditions, peptide therapy MER improved from 0.73 in 2022 to 0.90 in 2025; metabolic disease MER reached 0.78 in 2025.

Determine whether a favorable benchmark applies to the exact study population. Focus outreach on patients matching treatment history, laboratory requirements, and other eligibility criteria.

FaaS can validate a study's recruitable population. For appropriate US cohorts, **Citeline PatientMatch** and its **Patient Outreach** component can support targeted outreach.

INSIGHT 11

Look at the longitudinal patient journey

From the report: With MER at 0.16–0.20 for oncology and 0.17–0.22 for rare disease, and declining trends in both areas, these therapy areas require the most robust site networks and patient identification strategies.

Develop a more granular understanding of the longitudinal patient journey via Citeline's **Patient Intelligence**, understanding not only a patient's disease progression but also what care they receive and where, profiling treating and referring healthcare practitioners, allowing sponsors to activate broader referral networks and increase site capture.

FaaS seamlessly analyzes the longitudinal patient journey, selecting sites based on protocol-matched patients or their connectivity to referral networks. **Citeline PatientMatch** alerts sites to when eligible patients are present, providing the precision needed to reach every patient and enabling sites to be more productive, starting with where the patients are.



Through custom NLP algorithms, **Citeline PatientMatch** dissects different patient cohorts, from undiagnosed patients presenting with symptoms or patients with a high probability of mutations that should be tested again, to predicting events such as flares in Crohn's disease. Citeline's industry-leading RWD asset not only finds the best-fit patients for your protocol but also understands how your protocol translates to patients in the real world and whether you should consider a protocol amendment to increase eligible patients at your sites.

INSIGHT 12

Location, location, location

From the report: Asian sites outperform North American sites by 62–69% on overall MER and outperform European sites by 89–120%. This advantage holds across Phase II, III, and IV (though is compressing in Phase I and IV in 2024–25). For sponsors with geographic flexibility, increasing Asian site allocation can reduce recruitment timelines.

Geographic diversification brings risk, but the ability to understand patient availability via epidemiology, local standard of care, how countries have performed with respect to speed of activation, time to first patient in (FPI), enrollment, and screen failure (via Citeline's [Trialtrove+](#) and [Patient Intelligence](#)), allows sponsors to make those decisions confidently.

As site productivity decreases, the ability to select sites or investigators based on their ability to support the successful execution of your trial becomes critical. [Investigator SmartSelect](#) combines proprietary Citeline data sources regarding site-level performance, patient availability, past experience, and ongoing activity. Sponsors can obtain country-site recommendations and best-fit pools of investigators, not just those that have demonstrated consistent delivery over the past 10 years and are a good fit for this trial, but also the up-and-coming sites that become crucial as sponsors navigate white space and target sites/investigators more likely to be productive.

Check out the full report, with clinical planning recommendations and strategic recommendations.

[Read the full report](#)

Meet the Experts



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Resources

- 1 Conduct Research (2026) The 5 Most Common Trial Delays, and How to Prevent Them. Available from <https://conductresearch.ca/the-5-most-common-clinical-trial-delays-and-how-to-prevent-them/> [Accessed Sept. 21, 2026]
- 2 MED Institute (2020) 5 Reasons your Clinical Trial has Poor Patient Enrollment and Retention. Available from <https://medinstitute.com/blog/5-reasons-your-clinical-trial-has-poor-patient-enrollment-and-retention/> [Accessed Sept. 21, 2026]



Citeline, a Norstella company, powers a full suite of complementary business intelligence offerings to meet the evolving needs of life science professionals to accelerate the connection of treatments to patients and patients to treatments. These patient-focused solutions and services deliver and analyze data used to drive clinical-, commercial-, and regulatory-related decisions and create real-world opportunities for growth.

Our global teams of analysts, journalists, and consultants keep their fingers on the pulse of the pharmaceutical, biomedical, and medtech industries, covering it all with expert insights: key diseases, clinical trials, drug R&D and approvals, market forecasts, and more. For more information on one of the world's most trusted life science partners, visit [Citeline.com](https://citeline.com)

