AI/ML Medical Device Clinical Trials: 2025 Investment Landscape

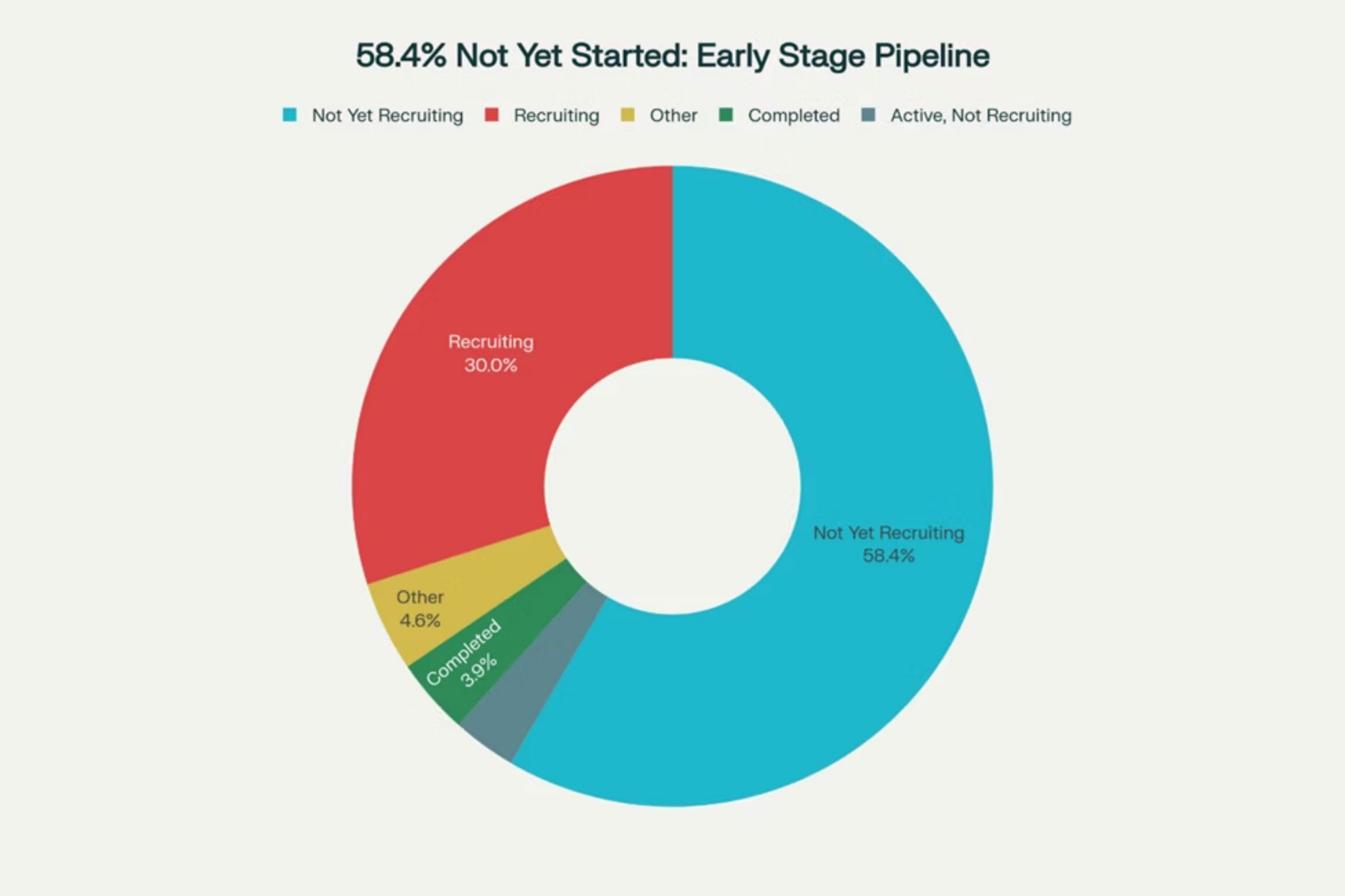
We analyzed 1,272 clinical trials initiated in 2025 to surface investor-relevant trends across AI/ML medical devices. The dataset covers device type, geography, AI function, and therapeutic area—over 95% remain in progress. The following pages distill the key signals shaping the near-term AI/ML device landscape.

Apsis Consulting Group, LLC

Ery Anguiano

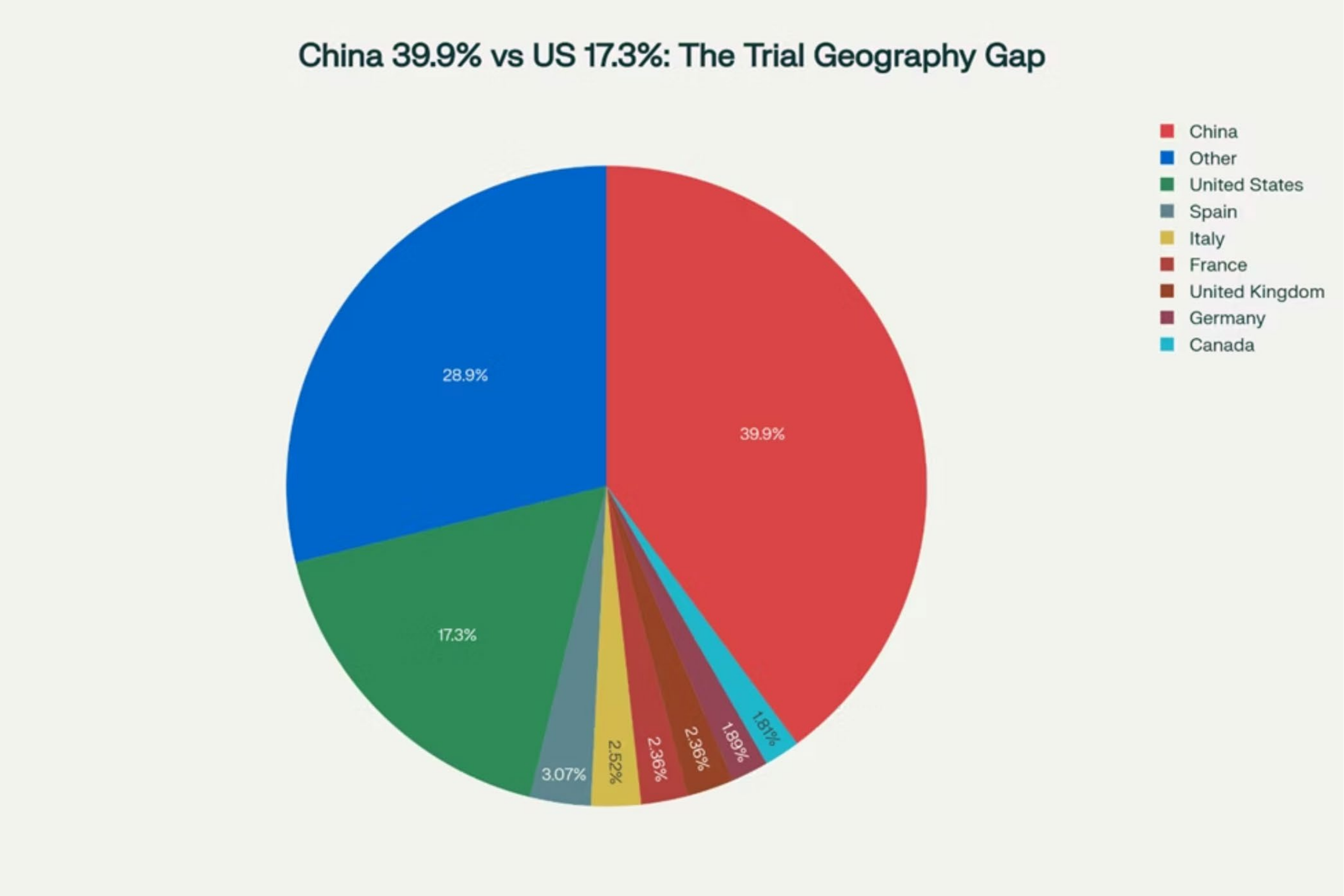
Dataset - Active In-Progress Trials

The overall status distribution reveals that most trials are still in early stages, with nearly 60% not yet recruiting participants.



The remaining 8.1% includes Active Not Recruiting (41 trials), Enrolling by Invitation (39 trials), and Other statuses (19 trials).

China Leads New Trials by Wide Margin



Chinese institutions account for 39.9% of new AI/ML device trials (507), approximately 2.3× the United States (220). This leadership position extends across all AI modalities including decision support, robotics/surgical automation, and therapy optimization.

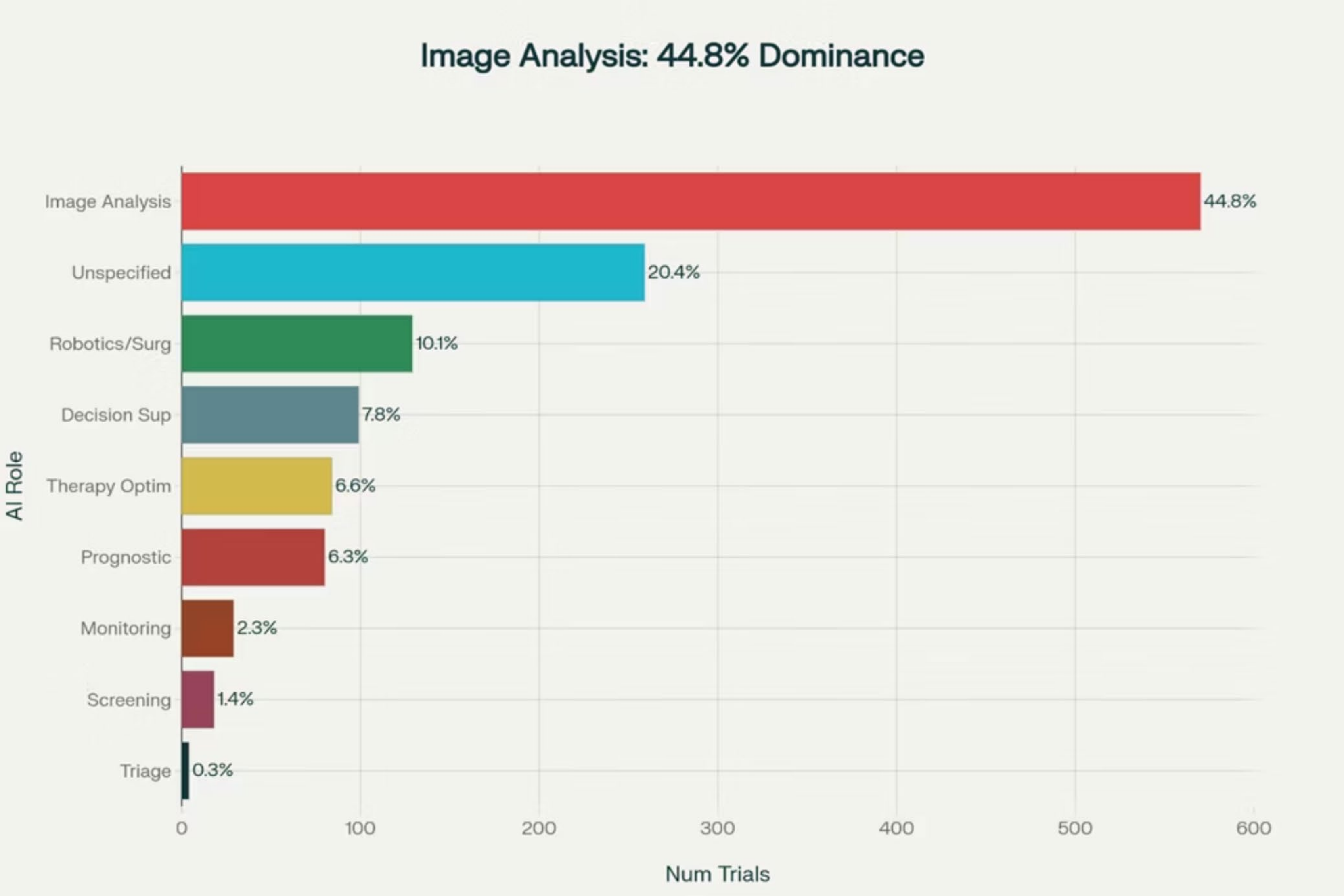
Investor Insight: Expect increased flow of clinically validated AI/ML devices from China. For U.S. market entry, assess data fitness for FDA including study design, endpoints, GCP compliance, and need for bridging studies.

China's Academic-Driven Growth Trajectory

China's 44.3% market share in 2025 holds steady without pharma trials (77 trials out of 174 global), proving China's trial surge isn't pharma-driven but reflects academic/tech/device focus.

Strategic Implication: China's clinical trial leadership reflects government-funded academic research and tech company investment in validation—not Western pharma partnerships. This makes China's evidence base more strategically autonomous.

Image Analysis Dominates—Market Saturation Risk

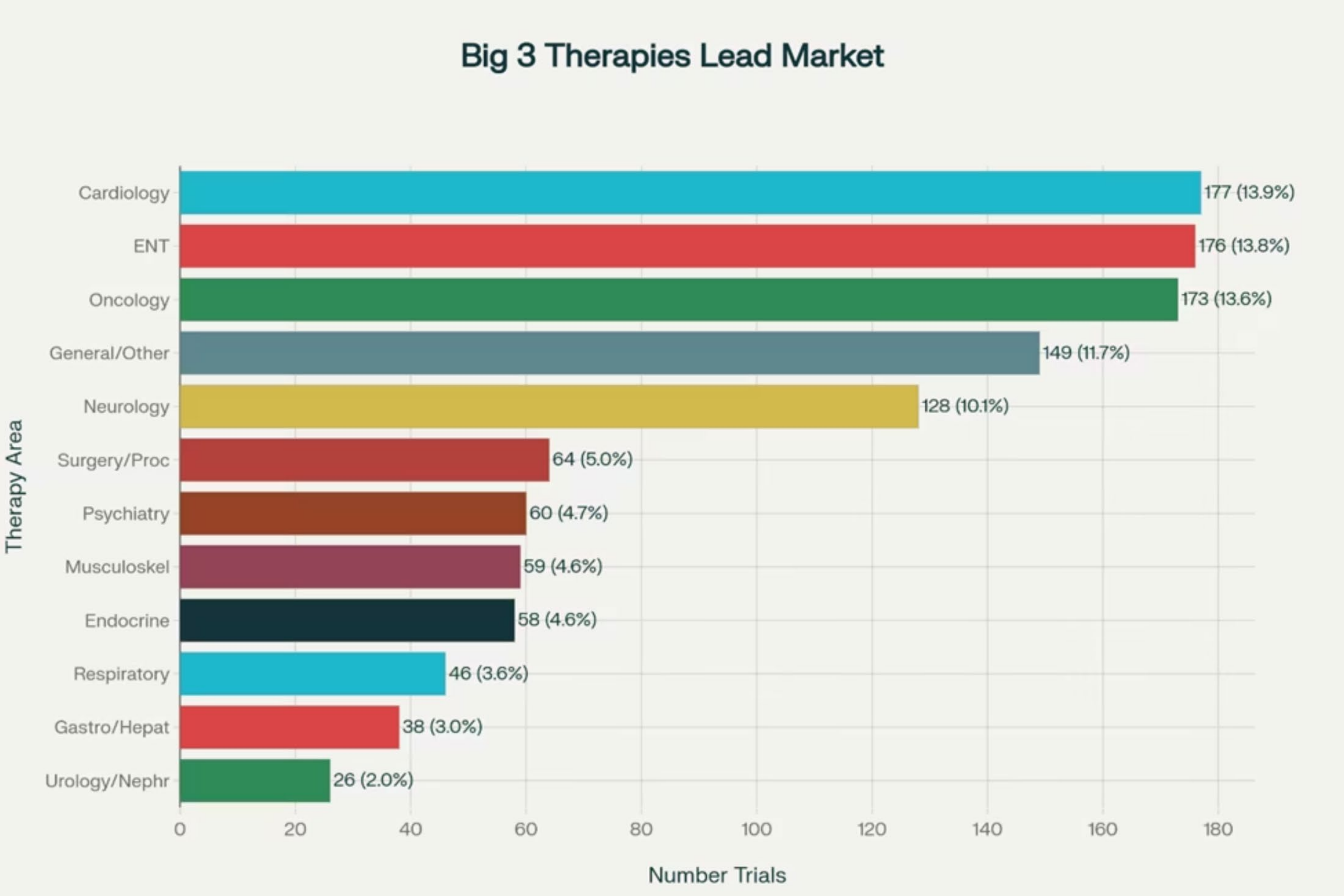


> "Market concentration risk is extreme. Image Analysis at 44.8% indicates saturation similar to radiology's 75% FDA clearance dominance."

Investor Insight: Companies in Image Analysis need exceptional differentiation or investors should pass. Look for

Therapeutic Areas Show Balanced Distribution

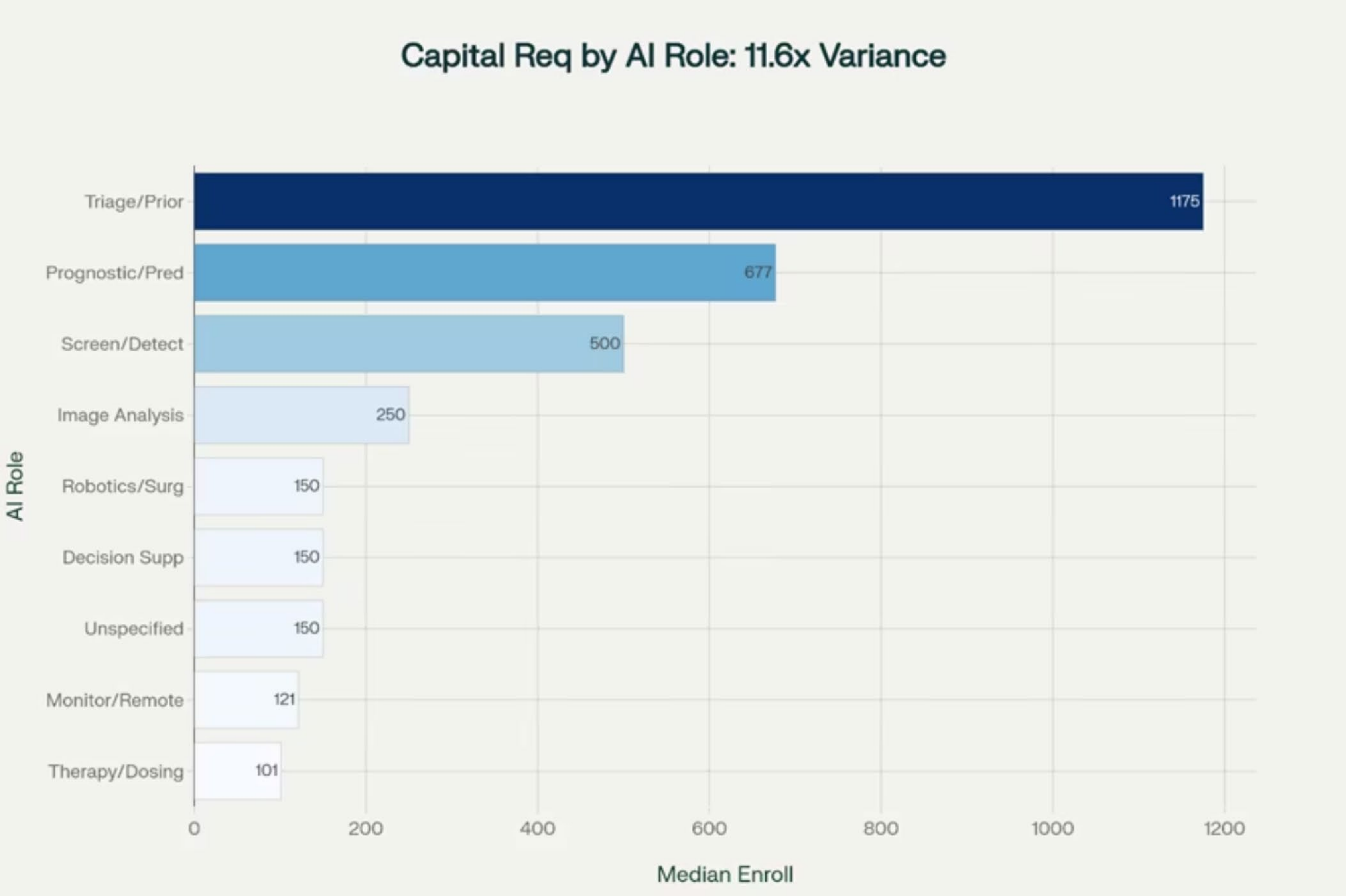
The therapeutic mix is evenly distributed at the top, with Cardiology (13.9%), ENT (13.8%), and Oncology (13.6%) showing virtually identical trial counts. Adding General/Multiple (11.7%) brings the top four to approximately 53% of all trials.



Investment Thesis: The virtually identical trial counts indicate market consensus on these specialties, clinical need parity, and comparable commercial opportunity. No single specialty saturation exists (unlike Image Analysis in AI roles).

AI Role Determines Capital Efficiency

Enrollment is a first-order proxy for capital and time. AI role determines capital efficiency more than therapeutic area, with an 11.6× variance in capital needs.



Due Diligence Question: "What's your AI role and median enrollment?"

Investment Strategy by Fund Size

Under $5M Funds

Limit to Therapy Optimization, Monitoring, Decision Support (≤150 patients)

- Therapy Optimization: $808K
- Monitoring: $968K
- Decision Support: $1.2M

$5-15M Funds

Can support Image Analysis, Screening (150-500 patients)

- Image Analysis: $2.0M
- Screening: $4.0M

$15M+ Funds

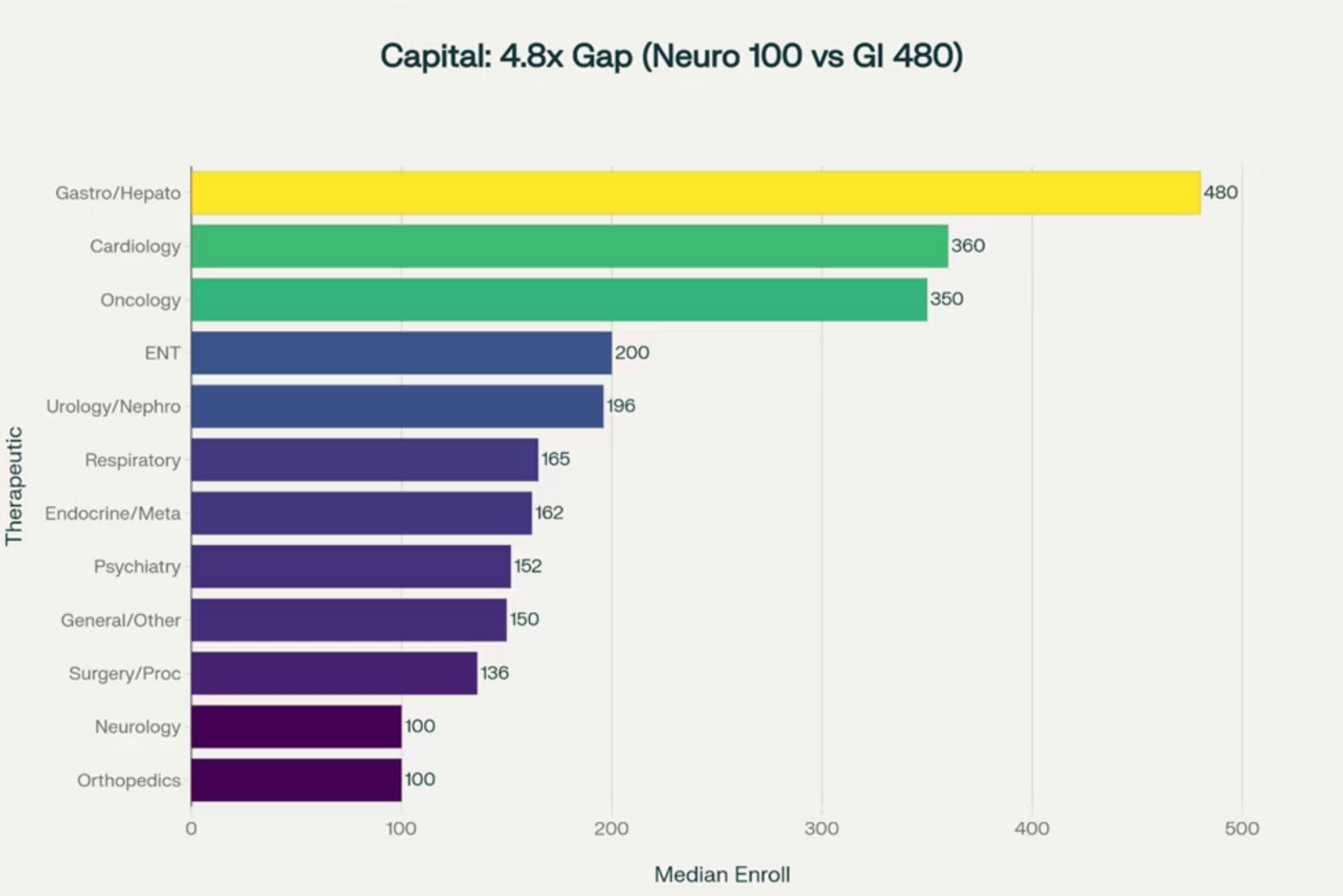
Required for Prognostic/Predictive, Triage (>500 patients)

- Prognostic/Predictive: $5.4M
- Triage: $6.4M

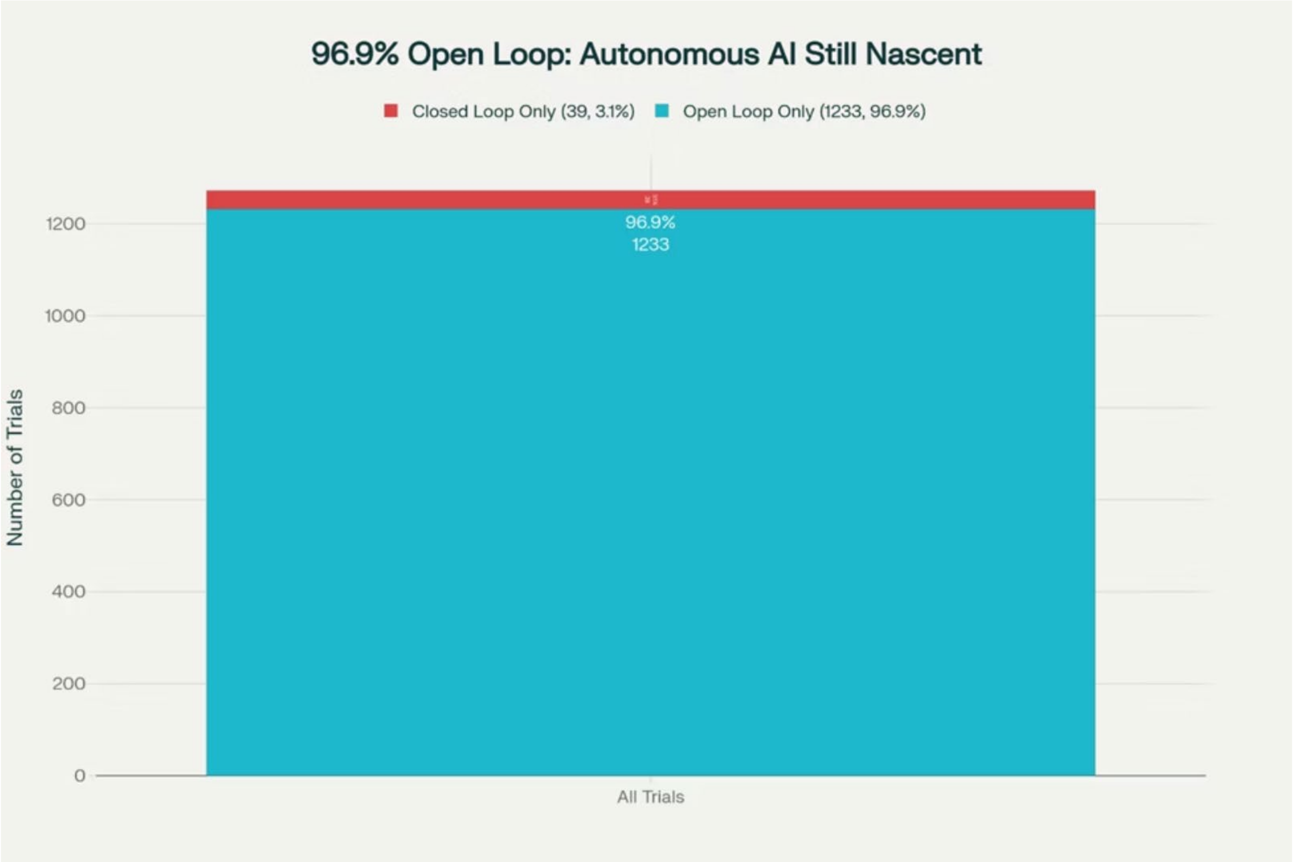
Investor Insight: Validate that a startup's target enrollment matches AI role benchmarks. Budgets and runway should scale with enrollment; mismatched or underpowered designs are red flags.

Therapeutic Specialty Drives Budget Impact

Therapeutic specialty drives capital requirements independent of AI role. The 4.8× difference between Neurology (100 patients) and Gastroenterology (480 patients) means specialty choice impacts budget more than most founders realize.



Human-In-the-Loop Remains Standard

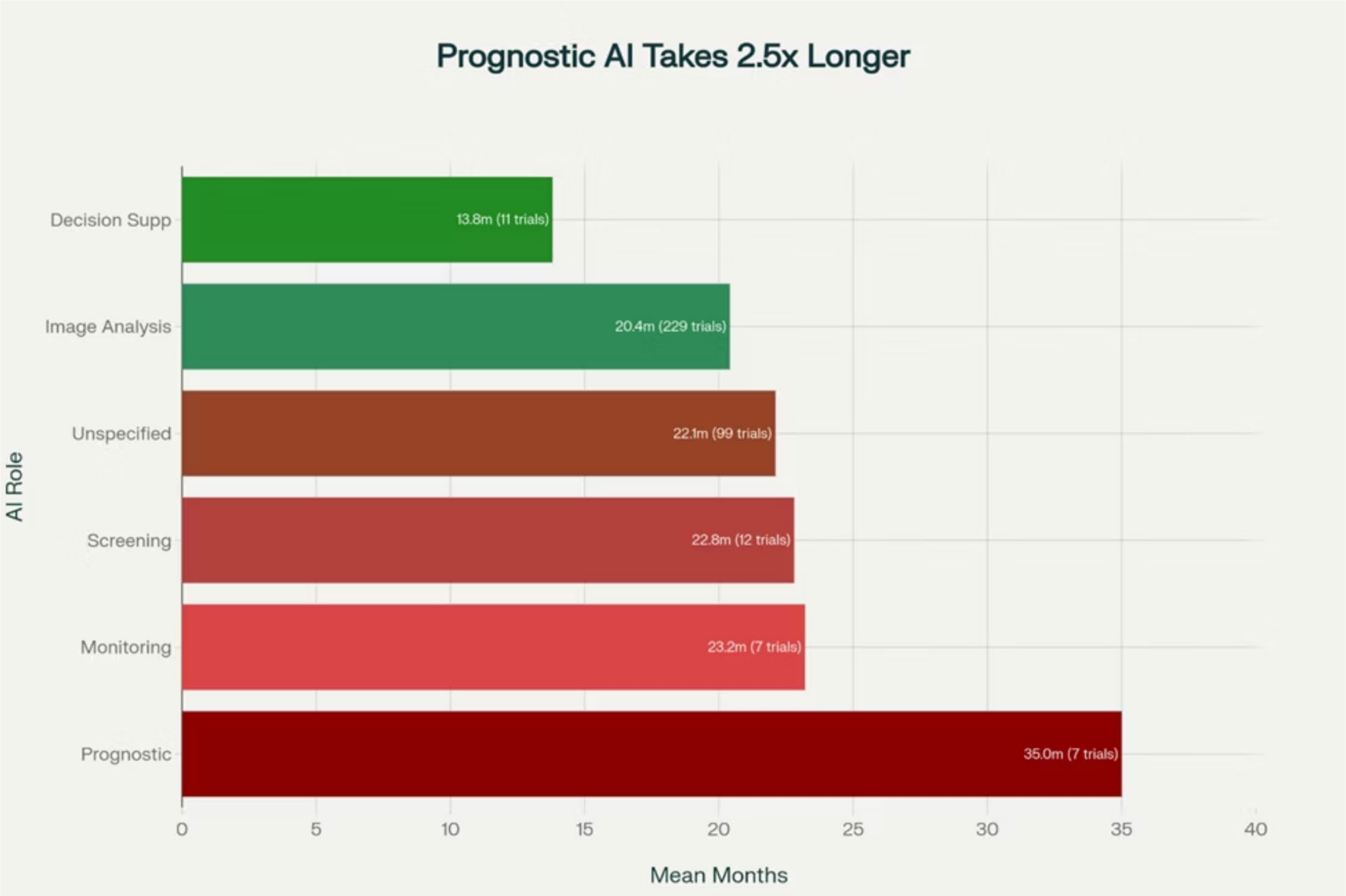


Open-loop trials still account for 96.9% versus 3.1% closed-loop/autonomous, consistent with current regulatory risk posture and evidence demands.

Investor Insight: Treat autonomous claim timelines skeptically. Look for a staged plan (semi-auto → auto), Q-Sub feedback, safety-critical endpoints, and a budget/runway sized for higher evidence burdens and post-market commitments.

Trial Completion Timelines: AI Role Impact

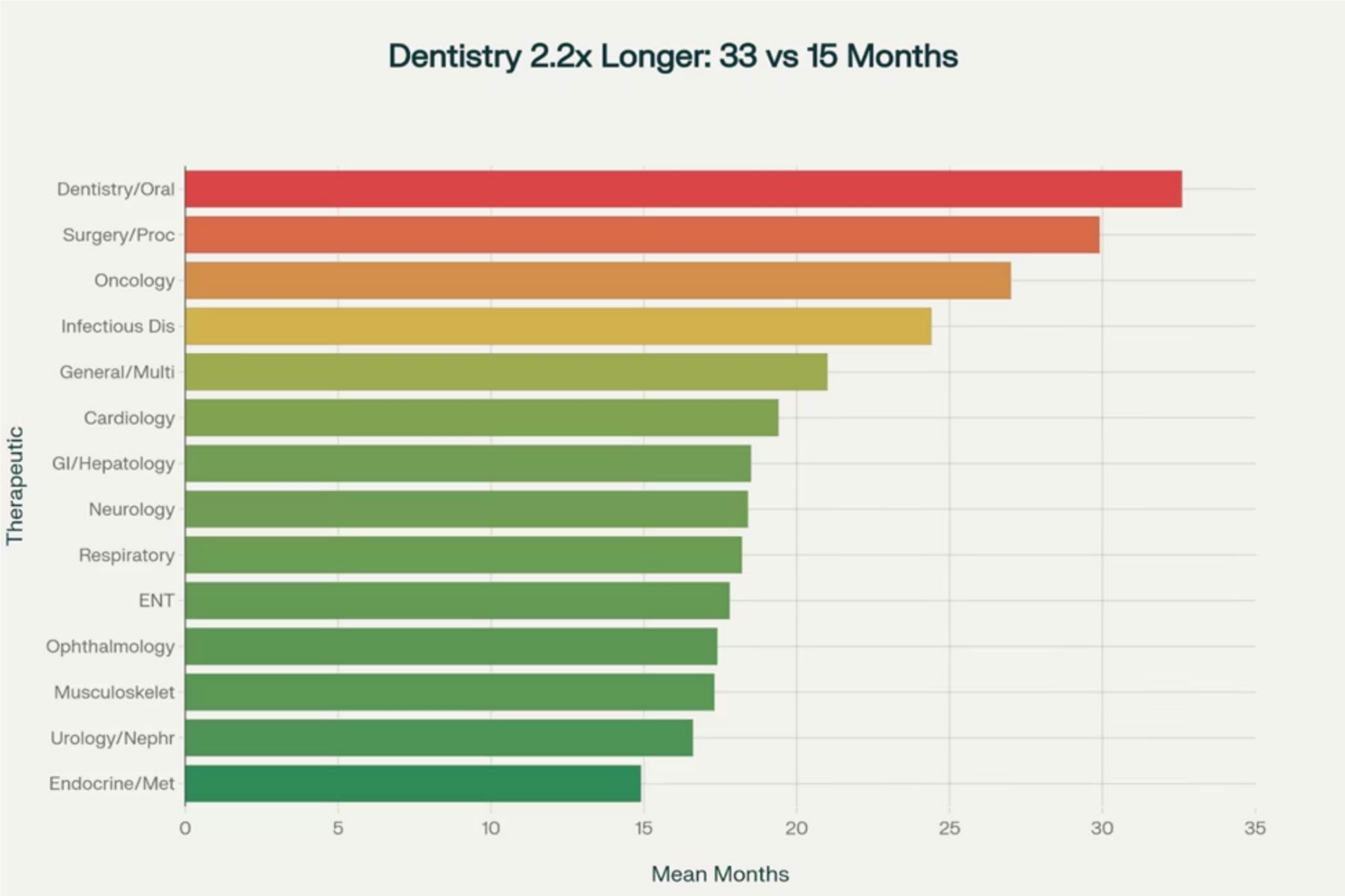
Based on 381 completed AI medical device trials in 2024/2025, median completion is 16.9 months, with AI role driving 2.5× variance (13.8-35.0 months).



> Prognostic models must wait for clinical events to occur—predicting heart attack risk requires waiting for actual heart attacks, extending timelines by 2.5× versus decision support.

Specialty Choice Drives Timeline Variance

Therapeutic area drives 2.2× variance in completion time (14.9-32.6 months). Dentistry takes longest at 32.6 months despite similar procedural complexity to faster specialties.



Key Investment Takeaways

Geographic Strategy

China leads with 39.9% of trials—assess FDA data fitness for U.S. entry. Academic-driven growth creates strategically autonomous evidence base.

Market Positioning

Image Analysis saturated at 44.8%.

Prioritize Decision Support (7.8%) and Prognostic/Predictive (6.3%) for less crowded opportunities.

Capital Efficiency

AI role drives 11.6× variance in capital needs. Match fund size to AI role: <$5M for Therapy Optimization, $15M+ for Prognostic.

Timeline Planning

Prognostic AI takes 2.5× longer (35 months). Mid-size trials (201-500 patients) slowest due to coordination overhead without scale economies.

Leverage forward-looking trial data to pinpoint head-to-head competitive zones, identify overcrowded therapeutic areas, and prioritize programs with credible, decision-grade endpoints and defensible data moats.