

Mastering Patient Recruitment for Rare Disease Clinical Trials

Innovative Strategies
for Finding the Few
Among the Many



Breaking the Patient Recruitment Barrier for Rare Diseases

Rare disease clinical trials have evolved dramatically over the past decade, with advances in gene therapy, precision medicine, and novel therapeutics offering new hope for patients. However, these groundbreaking trials face a persistent challenge: patient recruitment. Despite technological and methodological advances, approximately 30% of rare disease trials are terminated due to insufficient enrollment, with participant identification and engagement remaining one of the most significant barriers to completion.

The complexity of rare disease clinical trials creates substantial recruitment challenges. Small patient populations, often geographically dispersed across multiple countries, dramatically narrow the eligible patient pool. Combined with complex diagnostic pathways, delayed diagnoses, and competing trials, these factors threaten the timely completion of critical rare disease research. The impact extends beyond missed deadlines – delayed trials postpone access to life-changing treatments, increase development costs, and can lead to promising research being abandoned.

For pharmaceutical companies and research institutions, recruitment delays can extend timelines by 2–3 years, while patients and families awaiting new treatment options face profound personal consequences as their conditions progress without intervention.

This white paper presents a comprehensive framework for optimizing patient recruitment in rare disease clinical trials, offering practical, implementable strategies for all stakeholders in the clinical trial ecosystem. Our analysis encompasses technological innovations, patient-centric approaches, and systematic process improvements, with special attention given to creative and digital outreach approaches that can revolutionize how we identify, engage, and enroll qualified participants. By addressing these challenges, this white paper aims to help clinical trial professionals accelerate the development of new rare disease treatments and improve patient outcomes.



MATTHEW STUMM
PRESIDENT AND FOUNDER
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“The statistics around rare disease trial recruitment tell a clear story: traditional approaches are no longer sufficient.

When 30% of trials fail due to enrollment challenges, we’re not just facing a business problem – we’re facing a human crisis. Our mission at Stark / Raving Health is to pioneer new approaches that bring trials to patients, rather than expecting patients to find their way to trials.”

Mapping the Maze: The Complex Landscape of Rare Disease Clinical Trials

Rare disease clinical trials represents one of the most complex and challenging areas in medical research today. With approximately 7,000 identified rare diseases affecting 400 million people worldwide, the scale of unmet medical need is staggering. Yet despite this large collective patient population, the development of treatments for rare diseases faces unique obstacles that distinguish it from traditional clinical research.

Current Landscape

The rare disease therapeutic market stands at a pivotal moment of opportunity and challenge. Scientific advances in gene therapy and precision medicine, coupled with favorable regulatory frameworks, have sparked interest from pharmaceutical companies and researchers. The global orphan drug market, projected to reach \$250 billion by 2025, reflects this growing focus on rare disease treatment development.

Recent years have witnessed remarkable growth in rare disease research investment and activity:

- + Trial initiations have increased 56% between 2019 and 2024, with more than 800 companies now actively developing orphan drugs
- + Development timelines have improved, with orphan drugs moving through the pipeline an average of 18 months faster than traditional therapeutics
- + Regulatory agencies worldwide have implemented specialized pathways and incentives for rare disease drug development

This surge in activity, however, exists against a backdrop of persistent challenges in patient identification and engagement. The geographic distribution of rare disease patients creates particular complexity for trial recruitment. Unlike common conditions that can reliably be studied at major medical centers, rare disease trials must often cast a global net to find sufficient participants. This dispersal of potential participants intersects with varying healthcare systems, cultural contexts, and access to specialized care.

The Challenge of Identification and Recruitment

The journey from symptom onset to clinical trial participation in rare diseases often resembles a complex maze rather than a straight path. Patients typically consult an average of 7.3 specialists and wait 4.8 years before receiving an accurate diagnosis.

This odyssey stems from several interrelated factors:

- + Limited awareness among healthcare providers about specific rare conditions
- + Variable access to specialized diagnostic testing
- + Overlapping symptoms with more common conditions
- + Lack of established diagnostic criteria for many rare diseases

Once diagnosed, patients face additional hurdles in connecting with appropriate clinical trials. The traditional model of site-based recruitment shows particular strain in the rare disease context, where eligible patients may live hundreds or thousands of miles from the nearest study site. This geographic challenge interacts with financial and logistical barriers that can make trial participation prohibitively difficult for many families.

Competition and Resource Constraints

The increased focus on rare disease research has created an unexpected challenge: competition for a limited patient population. Multiple trials often seek participants from the same small patient groups, particularly in rare diseases that have attracted significant research interest. This competition plays out against a backdrop of:

- + Fragmented patient registries and databases
- + Limited natural history data to inform trial design
- + Resource constraints at clinical sites
- + Complex inclusion/exclusion criteria that further narrow the eligible population

For pharmaceutical companies and research organizations, these challenges translate into significant operational and financial implications. Nearly 30% of rare disease trials terminate due to insufficient enrollment, and recruitment periods typically extend 30% longer than planned. These delays increase development costs and, more critically, postpone patient access to potentially beneficial treatments.

The Site Selection Paradox

The distribution and capabilities of research sites and investigators present another critical dimension of the rare disease trial landscape. Unlike trials in common conditions where established site networks can reliably support recruitment, the rare disease environment requires a more nuanced understanding of site and investigator capabilities.

Research centers of excellence have emerged as crucial hubs in the rare disease landscape, but their distribution creates both opportunities and challenges. These centers typically combine robust research infrastructure with disease-specific expertise, yet they serve large geographic regions with dispersed patient populations. The concentration of expertise at these centers has significant implications:

Regional distribution patterns:

- + 70% of rare disease research sites are located in major metropolitan areas
- + Significant gaps across rural and suburban regions
- + Clustering of expertise in specific geographic corridors
- + Limited access points in many developing markets

Beyond geography, the investigator landscape presents its own complexities. The pool of investigators with rare disease expertise is often limited, leading to:

- + High competition for experienced investigators
- + Growing workload pressure on research teams
- + Limited bandwidth for new trial activation
- + Need for intensive training and support for less experienced sites

This landscape analysis reveals the importance of strategic site selection and support. Success in rare disease trials increasingly depends on building flexible site networks that can:

- + Combine established centers of excellence with community-based research sites
- + Leverage remote trial capabilities to extend reach
- + Provide enhanced training and support
- + Create collaborative networks that share resources

The future of rare disease clinical trials will depend on our ability to develop recruitment strategies that address both the practical and systemic challenges while leveraging emerging technologies and methodologies. By understanding these fundamental landscape challenges, organizations can better position themselves to design and implement successful rare disease clinical trials that accelerate the development of much-needed treatments.

The Rare Disease Journey: Understanding the Barriers to Participation

Understanding the rare disease patient journey is fundamental to developing effective patient recruitment strategies that work in the real world. While clinical trials often focus on scientific protocols and regulatory requirements, success depends on aligning these requirements with the complex reality of patients’ lives. By examining the path patients take from first symptoms to potential trial participation, we can design patient recruitment strategies that address both practical and emotional needs, transforming recruitment into a patient-centered journey.

A Diagnostic Odyssey

The path taken from initial symptoms to participation in a clinical trial often represents one of the most challenging aspects of rare disease research. This journey, marked by uncertainty, frustration, and hope, fundamentally shapes both the success of clinical trials and the lives of patients and their families. Understanding this complex journey is crucial for developing recruitment strategies that address real human needs rather than theoretical solutions.

For most rare disease patients, the journey begins with what medical professionals often call the “diagnostic odyssey” – a prolonged and often frustrating search for answers that averages 4.8 years from first symptoms to accurate diagnosis. During this period, patients typically consult eight or more physicians and receive multiple misdiagnoses.

The impact of this delay extends far beyond medical uncertainty:

- + Families deplete savings pursuing medical opinions
- + Disease progression continues without appropriate intervention
- + Psychological toll mounts as answers remain elusive
- + Trust in the healthcare system erodes through repeated disappointments
- + Family relationships strain under the weight of uncertainty

When patients finally receive a correct diagnosis, they often find this moment of clarity quickly overshadowed by new challenges. Many discover their local healthcare providers have limited experience with their condition, forcing them to travel long distances for specialist care. Insurance coverage frequently becomes a complex battle, with many treatments and tests requiring extensive documentation and appeals. Meanwhile, patients and families must rapidly educate themselves about a condition that many of their doctors may never have encountered before.

Barriers to Trial Participation

The transition from diagnosis to potential trial participation presents its own set of complex barriers. Many patients remain unaware of clinical trial opportunities, while others struggle to navigate the complicated landscape of trial eligibility and participation.

Healthcare providers, often focused on immediate care needs, may not discuss clinical trial options with their patients. When they do, the information can be difficult to understand and overwhelming. Common challenges at this stage include:

- + Limited understanding of the clinical trial process
- + Misconceptions about risks and benefits
- + Difficulty finding trials through public databases
- + Language and cultural barriers in trial information
- + Uncertainty about insurance coverage and costs

For those who do identify potential trials, practical obstacles often prevent participation. Geographic distance to trial sites represents one of the most significant barriers, particularly for rare disease patients who may find only a handful of trial locations across the country or even globally. This geographic challenge interacts with a complex web of personal and practical considerations.

Logistical challenges:

- + Extended travel requirements
- + Work and family obligations
- + Care giving responsibilities
- + Transportation limitations
- + Housing needs for site visits

Impact on Patients and Families

The financial impact of study participation can be equally daunting. While trial sponsors typically cover direct medical costs, many other expenses fall to the patient and family. Lost work time, travel expenses, childcare costs, and other indirect expenses can quickly become overwhelming, particularly for families already strained by the costs of rare disease care.

The emotional and psychological aspects of participation weigh heavily on patients and families. Deciding whether to participate in a trial involves complex considerations about hope, risk, and quality of life. Patients must weigh the potential benefits of new treatments against known risks, all while managing their current symptoms and care needs. For families with children affected by rare diseases, these decisions become even more complex, as parents struggle to balance hope for new treatments with concerns about their child's comfort and well-being.

The increasing incorporation of technology in clinical trials, while offering potential solutions to some barriers, has introduced new challenges. Remote participation options can reduce travel burden but require reliable internet access, technical proficiency, and comfort with digital platforms. Many patients, particularly in rural or underserved areas, face significant barriers in meeting these technical requirements:

Technology-related challenges:

- + Access to required devices and internet connectivity
- + Comfort with digital platforms and interfaces
- + Privacy concerns about health data sharing
- + Need for technical support and training
- + Reliability of remote monitoring systems

Understanding these interconnected challenges is essential for developing effective recruitment strategies. Success requires addressing not just the practical barriers to participation but also the emotional, financial, and family impacts of the trial journey. Only by acknowledging and actively working to mitigate these challenges can we hope to improve trial accessibility and participation rates for rare disease patients. The solution lies not in addressing each barrier in isolation, but in developing comprehensive support systems that recognize the complex reality of the rare disease patient journey.

Strategic Solutions: The Power of Advocacy Group Partnerships

Success in rare disease clinical trials depends not just on scientific innovation but on our ability to meaningfully connect with patient communities. This connection relies on patient advocacy organizations – groups that have evolved from support networks into sophisticated research partners. These organizations hold the key to understanding patient needs and accelerating new treatments, making advocacy partnerships fundamental to trial success.

Building Meaningful Advocacy Partnerships

At the heart of successful rare disease patient recruitment lies the relationship between pharmaceutical companies and patient advocacy groups. These organizations serve as the backbone of rare disease communities, providing essential support, education, and connection for isolated patients and families. Their role extends beyond patient support – they are vital bridges between the scientific community and patient populations.

The Evolution of Advocacy Leadership

Modern patient advocacy organizations have evolved into sophisticated research partners, employing scientific advisors and maintaining disease registries while driving research priorities. They serve multiple crucial functions in the rare disease ecosystem:

- + Building and maintaining patient communities
- + Funding critical research initiatives
- + Creating educational resources and programs
- + Facilitating physician education and awareness
- + Driving policy changes and research funding

These organizations often represent the only source of reliable, comprehensive information about rare conditions, making them invaluable partners in trial awareness and recruitment. Their deep connection with patient communities allows them to:

- + Identify and reach potential trial participants
- + Understand real-world patient needs and concerns
- + Provide trusted validation of trial opportunities
- + Support patients throughout the trial journey
- + Share trial results and outcomes with the community

Creating Strategic Partnerships

Effective advocacy partnerships must evolve beyond traditional transactional interactions into true strategic collaborations. Companies that excel in rare disease research engage advocacy groups early in the development process, involving them in key decisions about:

- + Protocol design and endpoint selection
- + Patient education materials development
- + Recruitment strategy planning
- + Communication approaches

Engaging Patient Advocacy Groups for Clinical Trial Awareness

The relationship between pharmaceutical companies and patient advocacy groups is critical when generating awareness about new clinical trials. These organizations serve as trusted voices within their communities and can provide invaluable guidance on how to communicate opportunities to potential participants.

Early engagement is essential. Advocacy groups should be approached well before trial initiation to:

- + Provide input on protocol design and patient burden
- + Review recruitment materials for clarity and relevance
- + Share insights about community needs and concerns
- + Help identify potential barriers to participation

Effective collaboration requires a transparent, bi-directional partnership approach:

- + Share comprehensive information about the clinical trial's objectives and design
- + Provide clear education about the investigational drug
- + Offer regular updates on trial progress and milestones
- + Support advocacy groups' broader mission beyond clinical trial recruitment
- + Create materials that advocacy groups can easily share with their communities

Most importantly, companies must recognize that advocacy groups' primary loyalty is to their patient communities. Building trust means demonstrating a genuine commitment to patient needs and being responsive to community feedback. This might include:

- + Adjusting trial designs based on patient input
- + Creating patient-friendly educational resources
- + Providing support for community initiatives
- + Maintaining open communication channels
- + Being transparent about trial outcomes and next steps

By fostering genuine partnerships with advocacy groups, companies can create more effective awareness campaigns that resonate with rare disease communities while respecting their unique needs and concerns.

Awareness and Education Initiatives

Patient and Family Education:

- + Creating accessible disease information
- + Explaining treatment and research options
- + Providing decision support tools
- + Offering guidance on navigating healthcare systems
- + Supporting insurance and access challenges

Healthcare Provider Education:

- + Developing physician education programs
- + Creating diagnostic resources
- + Facilitating expert networking
- + Sharing patient experience insights
- + Distributing clinical care guidelines

Research Community Education:

- + Sharing patient preference data
- + Providing natural history insights
- + Identifying unmet medical needs
- + Suggesting meaningful endpoints
- + Offering trial design feedback

These early partnerships yield multiple benefits. Advocacy groups can identify potential barriers to participation before they become obstacles, suggest practical solutions based on real patient experiences, and help companies understand the true impact of protocol requirements on patients and families. Moreover, they can provide invaluable guidance on patient communication, helping companies frame their outreach in ways that resonate with the rare disease community.

Strategic Solutions: Creativity and Its Impact on Engagement

In the quiet corners of medicine, where diagnoses are uncommon and treatment options limited, patients with rare diseases often navigate an isolating journey. For these communities, learning about clinical trials isn't just about awareness – it's about hope. This is where thoughtful creative approaches become essential bridges between science and human experience.

Finding Your Voice in the Wilderness

A patient diagnosed with a rare metabolic disorder after years of unexplained symptoms found that medical terminology was overwhelming, but was ultimately reached through a brochure featuring stories from fellow patients.

This illustrates why effective brand building for rare disease clinical trials matters:

- + Patient communities recognize authenticity immediately
- + Visual identities that reflect real experiences foster trust
- + Consistent messaging reduces cognitive burden
- + Language choices signal whether organizations truly understand the disease journey

When a national rare disease network revamped their materials with patient artwork and testimonials, enrollment increased by 34%.

Translating Complexity Without Losing Meaning

Parents often become experts in their children's conditions out of necessity, yet many find that clinical trial information remains difficult to decipher.

Effective health literacy approaches include:

- + Layered information architecture allowing patients to dive as deep as they choose
- + Visual explanations for complex trial designs
- + Plain language summaries paired with necessary medical terminology
- + Materials tested with patient advocacy groups
- + Multiple formats addressing diverse learning styles

Meeting Patients Where They Are

For the Newly Diagnosed:

- + Build foundational understanding
- + Emphasize hope without over promising
- + Provide clear next steps

For Experienced Patients:

- + Offer deeper scientific rationales
- + Address treatment fatigue

For Long-term Community Members:

- + Recognize their expertise
- + Address skepticism from past disappointing trials

Digital Spaces as Community Centers

Successful digital engagement strategies:

- + Develop interactive tools explaining complex processes
- + Use data visualization for statistical information
- + Ensure accessibility across devices
- + Incorporate video with site staff and patient advocates

Collaborative Wisdom: The Power of Advocacy

A physician leading clinical trials discovered after recruitment struggles that their visually appealing materials missed the mark because they hadn't engaged the community first.

Effective communications leverage collaboration:

- + Early creative reviews with advocacy organizations catch blind spots
- + Patient advisory boards provide ongoing guidance
- + KOL input ensures scientific accuracy while maintaining accessibility
- + Advocacy partnerships extend reach within tight-knit communities

Materials co-developed with advocacy partners achieved 67% higher engagement than those developed internally.

The collaborative approach transforms workflows:

Traditional Development:

- Step 1: Internal briefing
- Step 2: Agency creative
- Step 3: Regulatory review
- Step 4: Advocacy review
- Step 5: Launch

Collaborative Development:

- Step 1: Joint briefing with advocates
- Step 2: Co-creation workshops
- Step 3: Parallel development
- Step 4: Regulatory review with advocacy context
- Step 5: Collaborative launch

Effective collaborations:

- + Credit advocacy input transparently
- + Compensate appropriately for expertise
- + Create flexible materials advocates can customize
- + Build long-term relationships beyond single campaigns

Balancing Science with Soul

Many participants report that while scientific merit matters, the deciding factor in joining a trial is often seeing that the research team truly understands their lived experience.

- + Effective approaches balance scientific accuracy with emotional resonance by:
- + Framing trials as collaborative journeys rather than experiments
- + Acknowledging the emotional weight of treatment decisions
- + Showcasing incremental research progress

The journey to meaningful rare disease trial engagement begins with approaches that honor the complexity of patient experience while making science accessible, building communities of hope around scientific advances.

Strategic Solutions: Digital Engagement and Global Patient Outreach

Digital engagement in rare disease clinical trials offers unprecedented potential to connect with geographically dispersed patient populations while presenting unique complexities. Success demands more than basic digital campaigns—it requires a sophisticated balance of regulatory awareness, cultural sensitivity, and technological infrastructure. Organizations that master this multidimensional approach not only improve recruitment metrics but build meaningful relationships with the rare disease communities they serve.

Balancing Global Reach with Local Requirements

Creating effective digital engagement for rare disease trials demands balancing consistent messaging with adaptation to local requirements and cultural contexts. This challenge becomes particularly acute with multi-region trials spanning different healthcare systems, languages, and regulatory environments.

Navigating Complex Regulatory Landscapes

The regulatory landscape varies significantly across regions. Some countries require extensive pre-approval of materials and limit patient outreach, while others offer flexibility but demand attention to privacy regulations. Companies must navigate these variations while maintaining their recruitment message integrity. Considerations include:

- + Country-specific restrictions on clinical trial advertising
- + Requirements for ethics committee approvals
- + Social media usage guidelines that vary by region
- + Patient privacy regulations, including GDPR compliance
- + Local requirements for content review and approval

Technology and Cultural Considerations

Beyond compliance, successful digital engagement requires understanding how different populations interact with technology. Internet access, device preferences, and social media platform usage vary dramatically across regions. Companies must consider local technology infrastructure, cultural preferences, and healthcare system structures when developing digital strategies.

Content Development and Localization

Content development presents challenges in the global context. Creating materials that resonate across cultures while meeting local requirements demands more than simple translation. Educational content must be culturally appropriate, locally relevant, and accessible across different technology platforms, requiring flexible content frameworks that maintain consistent core messaging about the trial.

Building Global Infrastructure

The infrastructure required to support global digital engagement is substantial, including robust systems for managing multi-language content, tracking regional compliance, and measuring performance across markets:

Technical capabilities:

- + Content management systems supporting multiple languages and regions
- + Analytics platforms tracking engagement across different markets
- + Tools for managing translations and local adaptations
- + Systems for maintaining regulatory documentation

Human Expertise and Local Knowledge

Beyond technology, successful global digital engagement requires significant human expertise and local knowledge in each market, including understanding of:

- + Healthcare system structures and patient journeys
- + Cultural nuances and communication preferences
- + Regional regulatory requirements
- + Local digital platform preferences
- + Healthcare provider relationships and referral patterns

Measuring Success and Optimization

Measuring success requires sophisticated analytics that account for regional variations while providing meaningful insights. Companies need to track not just basic engagement metrics but understand how different approaches perform across regions and translate into actual trial recruitment.

Patient-Centered Digital Design

Putting patients at the center of digital engagement strategy has emerged as a critical differentiator. Successful patient-centered approaches include:

- + Personalized digital journeys that recognize where patients are in their diagnostic odyssey
- + Adaptive content that evolves based on patient interaction and feedback
- + Digital tools that empower patients to understand their condition and trial options
- + Accessibility features that accommodate specific physical limitations associated with certain conditions

Case studies show that digital platforms designed with direct patient input achieve higher engagement rates and more successful trial conversions.

The Role of AI and Machine Learning

AI and machine learning are transforming rare disease digital engagement through more sophisticated patient identification, personalization, and optimization:

- + Natural language processing to better understand patient needs
- + Predictive algorithms that help identify potential trial candidates
- + Automated content personalization delivering the right information at the right time
- + Enhanced analytics providing deeper insights into patient behavior
- + Real-time optimization of digital strategies based on performance data

Ethical Considerations in Digital Engagement

The vulnerabilities of rare disease populations demand careful ethical consideration:

- + Avoiding exploitative or emotionally manipulative messaging
- + Ensuring digital content accurately represents trial benefits and risks
- + Providing appropriate resources for informed decision-making
- + Respecting patient privacy while maintaining digital connectivity
- + Creating inclusive digital experiences that don't disadvantage certain patient populations

Organizations that address these ethical considerations build deeper trust with rare disease communities.

Rare Connections: Reimagining Patient Recruitment for Rare Disease Clinical Trials

Rare disease clinical trials stands at a critical juncture. While scientific advances have created unprecedented opportunities for developing breakthrough treatments, the challenge of patient recruitment continues to pose a significant barrier to research progress. The solution lies not in incremental improvements to traditional recruitment methods, but in fundamental transformation of how we approach patient engagement and trial participation.

Success in rare disease patient recruitment demands a comprehensive strategy that acknowledges both the complexity of the challenge and the humanity at its core. This requires:

- + Deep partnership with patient advocacy organizations that extends beyond traditional relationships
- + Sophisticated global digital engagement that navigates complex regulatory environments
- + Clear, accessible communication that addresses varying levels of health literacy
- + Robust support systems that remove practical barriers to participation
- + Long-term commitment to rare disease communities

The future of rare disease research depends on our ability to bridge the gap between scientific capability and patient participation. As we look ahead, we must continue to evolve our understanding of patient needs, leverage technology thoughtfully, and maintain focus on removing practical barriers to participation – all while remembering that behind every recruitment metric are real patients and families hoping for breakthroughs.

By implementing the strategies outlined in this white paper, companies can create recruitment programs that not only meet their research objectives but truly serve the needs of rare disease patients and their families. The time for transformation is now. Success depends on our willingness to embrace new approaches and maintain an unwavering focus on the patients we serve.



ANDRÉ BRIOLA
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“What makes rare disease recruitment unique is the incredible knowledge and engagement of the patient communities.

These aren't just potential trial participants – they're experts in their own conditions who often know more about their diseases than many healthcare providers. Our role is to build systems and strategies that honor this expertise while making trial participation as accessible as possible.”



Stark / Raving Health is a specialized clinical trial marketing agency that delivers breakthrough creative and sophisticated media solutions to connect groundbreaking medical research with the patients who need it most. Our creative approach transforms complex scientific opportunities into compelling, actionable communications, while our advanced global media strategies ensure precise, HIPAA-compliant targeting across traditional and emerging channels to drive patient recruitment and accelerate clinical research.

As strategic partners to sponsors and CROs, we combine powerful storytelling with data-driven media optimization to achieve measurable results in patient recruitment. Our commitment to creative excellence and media innovation, supported by advanced analytics and deep patient understanding, ensures we deliver campaigns that not only meet enrollment goals but advance the development of life-changing therapies through meaningful patient connections.

Contact us to explore how we can support your mission with data-driven strategies and authentic patient engagement approaches. Together, we can advance medical discovery while ensuring every potential participant has the information they need to make informed decisions about clinical research opportunities.

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