A Conversation with Emerald Clinical Trials, Global Head, Early Phase

Tamara Murdock, Head Global, Early Phase

Tamara has over 25 years of clinical research experience in pharmacology and therapeutic areas including oncology, metabolic disorders, cardiology, and dermatology. A distinguished leader in Early Phase, she has worked in a Phase I unit in Australia and with Australian-based CROs. Her expertise and deep passion guide clients to accelerate their early-phase research and transform promising ideas into groundbreaking medical advancements. As Global Head of Early Phase Research, she is dedicated to ensuring that studies are conducted with precision, efficiency, and the highest scientific and ethical standards. Her commitment to excellence and strategic vision make her a trusted partner in bringing new therapies to life.

Describe the collaborative nature of an Emerald Clinical Early Phase Oncology study and team.

Early Phase Oncology sponsors are guided through the complexities of studies by a specialized team with deep scientific, operational, and regulatory expertise who work in close coordination with our later-phase experts to stay informed of downstream regulatory and commercial needs. Our Early Phase Oncology team work closely with our Oncology Therapeutic Area Leads to provide strategic insight and hands-on support throughout the study lifecycle, ensuring that scientific objectives are operationally feasible and aligned with executional plans. Sponsors have a single point of contact with direct visibility into progress, risks, and milestones. Regular cross-team meetings and decision checkpoints resolve issues rapidly and accelerate timelines. Long-term relationships with sites and labs expedite operations, create smooth logistics, and assure alignment of all stakeholders. This collaborative communication network results in smoother, faster, and more efficient trials.

How does Emerald Clinical ensure that Early Phase sponsors are more prepared for downstream studies (Phase II / III) and for commercialization purposes?

Our Early Phase Oncology team collaborates with sponsors to define clinical pathways positioned effectively for market success from the beginning. We work closely with our

late-phase teams to ensure seamless transition into Phase II/III trials and through to commercialization. Our close relationship with Oncology KOLs ensures endpoint alignment, optimal clinical pathways, and scientific integrity. Expert advisory boards guide development strategy, utilizing adaptive trial designs and rapid start-up capabilities.

We also provide robust data management and regulatory support, including medical writing, statistical analysis, and regulatory affairs, ensuring that trial data is accurately captured and compliant with regulatory requirements. This facilitates the preparation of regulatory submissions and supports the transition from clinical trials through the lifecycle to market approval.

What advantage to getting the right patients into the study does Emerald Clinical offer?

Emerald Clinical offers a distinct advantage in recruiting the right patients into early phase oncology clinical studies through:

- Tailored strategies and a deeply patient-centric approach that aligns recruitment efforts with patient needs and trial complexity
- Sites that have direct access to the target patient population
- Strong relationships with KOLs to enhance protocol designs, optimize site selection, and create culturally and regionally appropriate patient targeting strategies
- Use of pre-screening tools, site training, and localized outreach
- Integration of feasibility data and predictive analytics to select high-performing sites
- A focus on speed without compromising quality, enabling sponsors to meet aggressive timelines and critical first-in-human milestones
- Diversity-conscious recruitment planning, ensuring broader representation and compliance with regulatory expectations

This model ensures that Emerald Clinical has the right patients enrolled efficiently, and we typically have high recruitment and retention rates with fewer protocol deviations. The result is more robust safety and efficacy signals, stronger overall trial outcomes, and faster paths to proof of concept.

How does Emerald Clinical's "one team of Early Phase Oncology experts" streamline the lifecycle of a study?

Our "one team of Early Phase Oncology experts" streamlines the lifecycle of a study through an integrated, end-to-end model, minimizing handovers and maximizing efficiency. Many of our cross-functional team members have hands-on experience in early phase studies, providing a deep understanding of Early Phase operational and regulatory nuances. This expertise:

- Enables rapid site activation
- Optimizes protocol design
- Ensures proactive risk management and faster decisions
- Accelerates timelines
- Improves data quality

The result? A smoother and more efficient trial that is ready for transition to pivotal phases, regulatory approvals and commercialization success.

What advantages do Emerald Clinical's years of relationship building with KOLs, sites, teams, and vendors offer sponsors?

With more than two decades of global experience, Emerald Clinical's long-term relationships with Oncology- specific KOLS, sites, teams and vendors offers sponsors a significant advantage for faster, smoother, and more reliable trials. The trust, strong collaboration and established communication networks we have developed lead to:

- ***Best site selections***
- ***Faster start-up***
- ***Higher protocol adherence***
- ***Faster, more consistent patient recruitment and retention***

Longstanding vendor relationships ensure quality, reliability, and agility in logistics, labs, and data management. Close relationships with global clinician/ researcher Oncology KOLs ensures study design is aligned with real-world clinical practice and patient needs.

Is the Australian tax rebate good for smaller companies?

If managed correctly, the Australia R&D tax rebate of up to 43.5% can make a substantial difference for smaller biotech companies, particularly those in early development stages with limited funding. The rebate is refundable for eligible small companies (typically those with less than AUD $20 million in annual turnover and not controlled by a larger corporate group) who can receive a cash refund, not just a tax offset.

This direct cash injection can be used to fund ongoing operations or extend runway which is critical for early- stage biotechs. Eligible R&D spends include clinical trial costs, CRO fees, lab work, etc.

With faster start-up timelines in Australia and reduced costs, biotechs can reach key go/no-go decisions earlier, based on solid data, without exhausting their capital. The substantial savings can be used to extend the range of a Phase I study or saved for the next development phase. Investors often view the rebate as a form of built-in cost mitigation as it helps lower the financial risk of early trials, making companies more attractive to venture capital and strategic partners.

Emerald Clinical actively support biotechs looking to leverage this advantage by connecting them with experienced R&D tax incentive (RDTI) specialist accountants. These professionals help ensure accurate, compliant claims and maximize the financial return. By combining this financial benefit with faster study start-up and high-quality, FDA-accepted data, Australia, supported by Emerald Clinical's infrastructure and network, becomes a strategic choice for early clinical development.

Emerald Clinical's valued relationships, and collaborative networks extend to our sponsor / partners to reduce delays, lower risk, and improve the overall quality and efficiency of each study.

How are Emerald Clinical's Oncology KOLs advantageous to Early Phase studies?

Our Oncology KOL partners ensure a scientifically rigorous, clinically relevant protocol aligned with current standards of care and patient needs. Ethics review is expedited by protocols designed with patient-centricity and operational logistics in mind.

KOL input also helps shape revisions when protocol changes are needed – providing critical insight into the scientific justification and real-world impacts including patient burden, safety implications, and operational feasibility.

By involving both internal experts and trusted site- based KOLs, Emerald Clinical ensures that studies are designed and adapted to reduce protocol deviations, improve recruitment and retention, and ultimately lead to smoother, more successful trial execution.

How does Emerald Clinical Early Phase team handle protocol changes?

Emerald's Early Phase team handles protocol changes with a proactive, collaborative, and patient-focused approach. We assess proposed changes quickly and comprehensively and engage the site early to evaluate the scientific rationale and operational implications of any modification, ensuring changes are both feasible and meaningful.

Our team works cross-functionally to adjust timelines and re-train site staff if needed, along with updating patient-facing materials promptly and accurately. Changes are implemented with minimal disruption. This agile, integrated response helps ensure ongoing protocol compliance and data integrity, while prioritising patient safety and comfort.

What is Emerald Clinical's relationship with vendors and how does that ensure safer and more efficient trials?

Our strong, long-term relationships with a trusted network of specialized vendors reduce operational risks, errors, and miscommunication. Patient safety and data integrity are safeguarded. Proactive vendor oversight enables early identification and resolution of potential issues, streamlining trial execution, and maintaining compliance.

Longstanding vendor relationships safeguard patient safety, study quality, and overall trial success.

Does Emerald Clinical have a proven Retention Strategy for Early Phase studies?

Yes, Emerald Clinical has a proven retention strategy specifically tailored for Early Phase studies combining participant support, clear communication, and site engagement to minimize dropouts. Our approach includes:

- ***Patient-centered communication*** - providing patients with clear, understandable information – often using multilingual and accessible materials — to reduce anxiety and build trust.
- ***Regular engagement*** - maintaining consistent contact through scheduled check-ins and reminders, ensuring patients

feel supported throughout the study.

- ***Site team training*** - equipping site staff with best practices in patient interaction, emphasizing empathy and responsiveness to patient needs or concerns.
- ***Flexible scheduling*** - wherever possible, accommodating patient availability to reduce the burden of visits.
- ***Proactive risk monitoring*** - identifying potential retention risks early through data monitoring and patient feedback, allowing timely interventions.

How has Emerald Clinical responded to new FDA guidance such as Project Optimus?

Emerald Clinical fully embraces the FDA's Project Optimus guidance by integrating flexible, adaptive trial designs and comprehensive dose optimization strategies into Early Phase Oncology studies. The shift to determining the optimal biological dose requires more complex trials with multiple dosing cohorts, detailed PK/PD assessments, and exposure-response analyses -- challenges we are uniquely equipped to manage thanks to our experience and strong collaborations with KOLS.

Our patient-centric, scientifically rigorous approach emphasizes proactive risk management and seamless communication between sponsors, sites, and scientific advisors. By adopting Optimus principles early, we help sponsors generate better safety and efficacy data while minimizing delays and protocol deviations. Our expertise also includes providing strategic regulatory guidance such as supporting key FDA interactions like End of Phase 1 (EOP1) meetings to ensure study designs meet regulatory expectations and avoid costly setbacks.

To help clients understand when and how best to implement the Optimus approach, we offer early scientific and regulatory consultation tailored to each molecule's characteristics and development goals and leverage our network of KOLs and regulatory experts to advise on study design choices. We equip sponsors and sites with the knowledge needed to confidently apply dose optimization strategies at the right stage, maximising patient safety and trial efficiency. This comprehensive, consultative approach makes us an ideal partner for sponsors aiming to comply with Project Optimus while accelerating development and improving outcomes in Early Phase Oncology trials.

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Contact us to explore how we can leverage our scientific leadership, responsive service and results-focused clinical research solutions for your organization today.

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