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Reimagining Renal Drug Development: Through Strategic Design

Renal drug development is going through a renaissance of sorts as the pace of innovation has accelerated rapidly in the past few years. Competitive pipelines are reshaping standards of care. Emerging biomarkers promise more precise endpoints. Yet for all this scientific momentum, the development pathway remains fraught with clinical, regulatory, and commercial risk.

That's why we've launched a new Renal Clinical Development Advisory Board to address a critical gap we see in the ecosystem: the lack of integrated, domain-specific strategic design support for sponsors developing renal therapeutics.

Why Renal Needs Its Own Strategic Design Engine

In other therapeutic areas like oncology, strategic development capabilities are often built in. Large pharmaceutical companies and venture-backed biotechs alike maintain internal due diligence teams. These are cross-functional groups of drug development experts who assess feasibility, inform trial design, and shape the long arc of clinical strategy.

Renal, however, has lagged behind. Despite being home to complex diseases with long timelines, heterogeneous populations, and evolving endpoints, many sponsors still approach renal trials without the benefit of specialized strategic input. In renal, you rarely see the kind of longitudinal, integrated design support that's common elsewhere. And that's a missed opportunity.

Our new advisory board aims to change that. By bringing together seasoned drug developers and practicing nephrologists, we're creating a collaborative forum where scientific, clinical, and regulatory insights intersect early, often, and with purpose across geographies.

The Right Expertise at the Right Time

The advisory board is composed of numerous KOLs. Some examples of our distinct pillars of expertise are:

- **Dr. Colin Orford**, a veteran of pharmaceutical R&D with decades of experience in global drug development strategy, brings deep operational insight and a sharp commercial lens to trial design and lifecycle planning. Multiple experts that specialize in biostatistics, regulatory engagement, and clinical development round out the team.
- **Dr. Jon Barratt**, **Professor David Wheeler**, **Dr. Richard Lafayette, and Dr. Adrian Liew**, internationally recognized nephrologists and active clinical researchers, offer real-world clinical insight grounded in day-to-day patient care, with a particular focus on IgA nephropathy, chronic kidney disease, and glomerular diseases.
- Multiple other renal experts (90+) in the US, Europe, APAC, and LATAM are available to help sponsors design smarter studies, from preclinical through pivotal phases, by focusing on what truly matters: endpoint selection, biomarker validation, trial feasibility, and clinical differentiation. This allows for the consideration of different standards of care across geographies that impact design.

Strategic Enablement Matters

To be clear: Emerald's advisory offering is not about running trials. It's about designing them with the right evidence, the right assumptions, and the right input from the start.

Endpoint selection is not just a scientific decision. It's regulatory, it's clinical, and it's commercial. You need to be able to defend the endpoint, and that requires you to be deeply in tune with what regulators will accept, what clinicians care about, and what's feasible in practice.

That's where our team excels: helping clients walk the tightrope between innovation and practicality. An exciting new biomarker might look promising in theory, but will it hold up to regulatory scrutiny? Can it be consistently measured in real-world trial settings? Does it translate into a meaningful benefit for patients and prescribers?

These questions are the heart of strategic design.

Why This Matters Now

The renal development landscape is more dynamic than ever. Competitive pipelines are pushing the boundaries of care. New mechanisms are entering the clinic. Clinical endpoints are evolving. And most importantly, the patient population is changing, growing, diversifying, and demanding more personalized approaches.

In this environment, early strategic choices carry exponential weight. Sponsors can't afford to wait until Phase 3 to start thinking about clinical differentiation or commercial planning. Those conversations need to happen in Phase 1, or even earlier.

Dr. Orford's involvement is especially valuable here. With his pharmaceutical background, he helps sponsors design development programs that align with long-term commercial strategy instead of just regulatory endpoints. It's not enough for a drug to be safe and effective. It needs to be differentiated. And that starts at the design phase.

From Tactical Decisions to Paradigm Shifts

One of the most powerful aspects of this model is its continuity. Rather than offering point-in-time advice, our advisory board supports sponsors throughout the lifecycle of a program, from preclinical design through Phase III and beyond.

There's tremendous value in having the same group of experts guide development across all phases. They understand the science but also the strategy, the evolution, and the nuances. This type of consistency and insights leads to smarter programs.

When sponsors aggregate insights across clinical, regulatory, operational, and commercial, they have the ability to make far better decisions.

Seeing the Patient, Not Just the Protocol

It's easy to get lost in models, endpoints, and statistical plans. But at the core of this offering is something simpler and more human: a commitment to patient-centered design.

Because our nephrology experts are active clinicians, they bring a level of insight that goes beyond the literature. They see what patients are going through. They understand what's realistic in clinical settings. They know what trial burdens are sustainable and what endpoints matter in the real world.

That perspective is essential. Because we see renal trial patients at scale, it changes the conversation. It takes us beyond what's theoretically interesting to talking about what's feasible and meaningful.

Competitive Intelligence That Fuels Strategy

Another cornerstone of the advisory service is its competitive landscape analysis. Understanding how a candidate therapy fits into the broader treatment ecosystem is key to designing trials that don't just succeed technically but also stand out commercially.

Our team evaluates competitor pipelines, standard-of-care trends, and unmet medical needs to help sponsors define and articulate their clinical value proposition. This strategic positioning informs everything from protocol design to endpoint selection to eventual commercialization.

Bringing It All Together

The vision behind Emerald's renal consulting service is simple but ambitious: to elevate the quality and impact of renal drug development by embedding the right expertise early and throughout the lifecycle.

This is not a bolt-on consulting service. It's a strategic co-pilot.

It's a way for sponsors to tap into the collective wisdom of developers, clinicians, and commercial strategists who know renal inside and out. And who are committed to designing programs that work not just in theory, but in practice.

As the renal development landscape continues to evolve, sponsors who invest in strategic design will have a powerful advantage. They'll be better prepared for regulatory review. Better aligned with clinical practice. And better positioned to bring life-changing therapies to patients who need them.

That's the future we're building one trial design at a time.

To learn more about our offering, please contact us.
