

The **MOMENTUS** Readiness Platform supports assets from proof of concept to regulatory approval, providing strategic insights, targeted recommendations, and evidence-generation platforms and plans designed to meet the dynamic needs of prescribers, payers, and patients.

### ASSET DEVELOPMENT

Today's innovators must develop their science with the commercial end in mind. We ensure a well-informed clinical development and regulatory strategy that incorporates the needs of prescribers, payers, and patients. Via our team of clinical trial experts, we optimize the value of your asset and the path from proof of concept to regulatory approval.

### STRATEGIC ACCELERATION WITH MOMENTUS AI

**MOMENTUS AI** is a strategic approach that blends deep consulting expertise with advanced AI to drive smarter, faster decisions in healthcare. It empowers our experts to proactively shape strategies, accelerate new technology adoption, and deliver high-impact outcomes across clinical development, regulatory, commercial and market access.



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### THOUGHT LEADERSHIP

**MOMENTUS Perspective** is our thought leadership platform exploring the forces shaping biopharma and healthcare. Through expert insights across policy, market access, value and pricing, and emerging applications of AI, we examine, and offer our opinions how strategy, evidence, and innovation converge to support smarter decisions across the product lifecycle.

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### COMMERCIAL LAUNCH READINESS

Our consultants are industry-experienced brand leaders and new product planners who seamlessly bridge clients from early asset development to commercial launch. Offering proven strategic guidance for portfolio strategy, lifecycle indication planning, brand planning, and pricing & reimbursement, we ensure a patient-centric commercial strategy to optimize launch and marketplace success.

### EVIDENCE GENERATION

Pivotal trials, no matter how well designed for market realities, do not mark the end of the readiness journey. Continued success requires proactive real world data generation and economic analyses that matter to key stakeholders. Our holistic and integrated evidence planning platform enables the prioritization and execution of the right evidence for the right audience - prescriber, organized provider and payer.

## CONTACT US

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## PROJECTS SUPPORTED FROM EARLY DEVELOPMENT TO LAUNCH

### Regulatory & Clinical Development

<p><b>Portfolio Planning &amp; Indication Sequencing</b></p> <p><b>Program Gap Analysis</b> (Pre IND and Ph1)</p> <p><b>Workshopping / cross-functional alignment</b> of Clinical Development Plans (CDP) and Target Product Profiles (TPP)</p>	<p>Advise on <b>Clinical Trial Design</b> (Ph2 &amp; Registrational)</p> <ul style="list-style-type: none"> <li>• Primary insights with KOLs and Payers</li> <li>• Benchmarking analogue programs and designs</li> <li>• Optimize populations, endpoints and comparators (PICO)</li> </ul> <p>Strategies to gain agency acceptance of <b>novel endpoints</b></p>	<p><b>Regulatory Engagement Readiness</b> (FDA, EMA, Health Canada)</p> <ul style="list-style-type: none"> <li>• Strategic planning with internal cross functional teams</li> <li>• Development of meeting objectives, questions, briefing dossiers</li> <li>• Representation at meetings</li> </ul> <p><b>FDA Advisory Committee Readiness</b></p> <p>Facilitate and run <b>Advisory Panels</b> with Investigators &amp; KOLs</p>
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### Value, Access & Pricing (VAP)

<p><b>US Landscape Analysis</b></p> <ul style="list-style-type: none"> <li>• Coverage-payment-coding; trade and distribution strategy, policy forecasting</li> </ul> <p><b>Global and US Price/Access Attainability Studies</b></p> <ul style="list-style-type: none"> <li>• Primary insights in US, Europe, &amp; Japan</li> </ul> <p><b>Europe HTA Readiness</b></p> <ul style="list-style-type: none"> <li>• PICO, JCA, P&amp;R</li> </ul>	<p><b>US Contracting and GTN Planning</b></p> <p><b>Payer insights informing Ph2 and Registrational trial designs</b></p> <p><b>Holistic/integrated evidence generation plans</b></p> <p><b>Pragmatic/targeted literature reviews, burden and cost of illness assessments</b></p>	<p><b>Retrospective claims/EHR data analysis &amp; Real World study execution</b></p> <p><b>Develop budget impact and total cost of care models</b></p> <p><b>Facilitate and run Payer Advisory Panels in US &amp; Europe</b></p> <p><b>Negotiation Readiness</b></p>
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### Investment Guidance

<p><b>Expert Partner Network - Strategic Guidance &amp; Counsel</b></p> <ul style="list-style-type: none"> <li>• Feasibility of regulatory agency approval</li> <li>• Labeling scenarios, market and landscape scenarios including regulatory, payer, P&amp;R policy</li> </ul>	<p><b>Gap analysis and hypothesis generation sessions with VC/PE teams</b></p> <p><b>Primary insights interviews with KOL and Payers to inform due diligence and deal valuation</b></p>	<p><b>Advise on US and Global price, access and GTN for valuation models</b></p>
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## OPTIMIZING YOUR ASSET'S VALUE

**Why?**  
Industry transformation and regulatory complexity require a need for targeted insights and strategies.

**What?**  
Strategic expertise and operational support across business, clinical, and commercial functions.

**Together.**  
We can accelerate the approval and adoption of life-changing therapies for patients.

All in Support of Commercial Readiness