

# Your trusted partner for clinical outcome assessment and regulatory-grade evidence

We offer bespoke, one-to-one support, with every engagement led by senior-level experts.

**Bottomley Consulting Group**  
*An EMA-registered SME providing  
regulatory-aligned COA and PRO strategy*



## Comprehensive Clinical Outcome Assessment Solutions for Every Stage

We provide comprehensive clinical outcome assessment (COA) solutions across every stage of drug development, from early study design through to regulatory submission and post-approval evidence generation. Our work ensures that clinical endpoints, instruments, and analysis strategies are scientifically robust, clinically meaningful, and aligned with the expectations of regulators and health technology assessment bodies.

Our team supports the full COA lifecycle, including endpoint strategy, patient-reported outcome (PRO) selection, instrument validation, data collection, statistical analysis, and interpretation. We focus on ensuring that what is measured in a trial truly reflects how patients feel, function, and survive, allowing study results to translate into credible, decision-ready evidence.

By integrating regulatory insight, methodological expertise, and deep therapeutic-area knowledge, we help sponsors maximise the value of their COA data. Whether supporting early development, pivotal trials, or real-world evidence generation, we enable organisations to produce patient-centred outcomes that withstand regulatory scrutiny and support clinical and commercial success.

## Why Choose Us?

Bottomley Consulting Group brings unrivalled expertise in clinical outcome assessments, built on decades of leadership in patient-reported outcomes, regulatory science, and oncology research. Our team combines deep methodological knowledge with hands-on experience in global clinical development, ensuring that every COA strategy is grounded in both scientific excellence and real-world regulatory expectations.

We work on a highly personalised, one-to-one basis, with every engagement led by senior experts rather than junior teams. This means our clients benefit directly from strategic insight, practical problem-solving, and continuity across the life of their programmes — from early development through regulatory review and beyond.

As an EMA-registered SME with strong links to international regulators, academic networks, and industry partners, we are uniquely positioned to bridge science, patients, and regulation. We help organisations turn high-quality COA data into credible, decision-ready evidence that supports regulatory success, payer acceptance, and meaningful impact for patients.

## Our Services

All our services are fully personalised, with every engagement led directly by a senior expert.



### EMA/FDA Regulatory-Aligned COA & PRO Strategy

An integrated service aligning your COA and PRO strategy with EMA and FDA expectations. We support protocol and endpoint design, instrument selection, implementation of estimand framework, missing-data strategy, regulatory interactions, and label positioning to ensure your evidence is robust and regulator-ready.



### Modular and bespoke COA & PRO Services

Flexible, pick-and-choose support covering PRO readiness audits, regulatory advice preparation, endpoint and instrument selection, statistical and estimand support, missing-data strategy, and label feasibility – giving you senior expertise exactly where you need it.



### Global COA & PRO Alignment

Support for programmes operating across multiple regions, aligning COA and PRO strategies across EMA, FDA, and key international regulators. We help ensure consistency in endpoints, instruments, and analyses so that evidence generated in one region can support approvals, labelling, and HTA submissions worldwide.

## Invest with Confidence

Strong regulatory and reimbursement decisions depend on the credibility of your clinical outcome data. Investing in a robust COA and PRO strategy early reduces the risk of costly redesigns, regulatory setbacks, and lost opportunities.

We help you build confidence in your endpoints, instruments, analyses, and regulatory positioning, so your data are clear, credible, and ready to support decision-making when it matters most.

## Planning for Tomorrow

The clinical and regulatory landscape is evolving rapidly, with increasing expectations for patient-centred, data-driven evidence. Investing in a forward-looking COA and PRO strategy today helps ensure your development programmes remain relevant, competitive, and aligned with future regulatory and payer requirements.

We work with you to build evidence frameworks that are designed not only for today's submissions, but for tomorrow's approvals, labelling opportunities, and real-world value.

## How We Work

We work in close partnership with our clients, providing highly personalised, one-to-one support led exclusively by senior experts. Every engagement is tailored to your programme's scientific, clinical, and regulatory needs, ensuring focused attention, continuity, and strategic clarity from start to finish.

Our approach combines rigorous methodology with practical regulatory insight. We collaborate seamlessly with your internal teams and external partners, translating complex COA and PRO science into clear, actionable guidance that supports confident decision-making and regulatory success.

## Understanding Your Goals

We begin every engagement by taking the time to fully understand your scientific, clinical, and commercial objectives. By aligning our COA and PRO strategy with what truly matters for your programme – whether regulatory approval, label differentiation, or patient impact – we ensure that our work is focused, relevant, and value-driven.

This deep understanding allows us to design outcome strategies that support your broader development goals, helping you generate evidence that is not only methodologically sound, but also meaningful for regulators, payers, clinicians, and patients.



## Start Your Journey Today

Begin your journey with a team that helps you invest wisely in your clinical outcome strategy — building evidence today that supports tomorrow's approvals, labels, and market access.

## Get in touch

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