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Measuring What Matters

The Strategic Role of Health Outcomes and Clinical Assessment in Pharma Today

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Agenda

1. Why outcomes matter
2. What is HEOR?
3. What are COAs?
4. Cross-functional impact of outcomes
5. How to choose the right COA
6. Trends & innovations in COAs
7. Challenges & gaps
8. Strategic recommendations
9. Bringing it all together
10. Q&A

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Abbreviations: COA: Clinical Outcome Assessment; HEOR: Health Economics and Outcomes Research

Why Outcomes Matter in Pharma Today

It is no longer enough to show a drug works – we must show it matters

Regulators

Expect evidence that reflects patient experience

- Look for outcomes that show meaningful benefit beyond clinical measures
- Prioritize COAs that capture symptoms, functioning, and daily life impact
- Increasingly expect patient-centered evidence in submissions and labeling

Payers

Evaluate real-world value to guide coverage decisions

- Assess whether outcomes translate into meaningful improvements for patients
- Rely on credible COA and PRO data to understand value and differentiation
- Use outcomes to inform access, reimbursement, and formulary decisions

Patients

Care about improvements that matter in daily life

- Define what "meaningful benefit" truly looks like in practice
- Focus on relief of symptoms, improved functioning, and HRQoL
- Want treatments that help them participate more fully in daily activities

Examples

Kybella label includes PRO measures	COPD therapies using SGRQ	Wearables for itching or gait speed

Outcomes-focused thinking is now a strategic necessity across the drug development lifecycle.

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Abbreviations: COA: Clinical Outcome Assessment; COPD = Chronic Obstructive Pulmonary Disease; HRQoL: Health-Related Quality of Life; PRO = Patient-Reported Outcome; SGRQ: St. George's Respiratory Questionnaire

Poll Question

Which stakeholder do you think cares MOST about outcomes?

A Regulators

B Payers

C Clinicians

D Patients

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Health Economics and Outcomes Research

What is HEOR?

Clinical Measures (e.g., HbA1c, FEV1)

Understanding how treatments affect people's lives

Patient-Centered Outcomes (e.g., pain, functioning, HRQoL)

Health outcomes research evaluates how a treatment impacts symptoms, functioning, HRQoL, and the lived experience of patients.

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Abbreviations: FEV1: Forced Expiratory Volume in 1 Second; HbA1c: Hemoglobin A1c; HEOR: Health Economics and Outcomes Research; HRQoL: Health-Related Quality of Life

Why Health Outcomes Research Matters

- Focuses on how treatments affect symptoms, functioning, and HRQoL
- Helps us understand what “meaningful benefit” looks like from the patient’s perspective
- Complements clinical measures by capturing real-world impact
- Supports decisions across development, regulatory, access, and commercial

Examples

- **Migraine:** FDA requires patient-reported endpoints like pain freedom and most bothersome symptom
- **Oncology:** HRQoL measures (e.g., EORTC QLQ-C30) contextualize benefit–risk
- **Psoriasis:** DLQI shows how skin clearance translates into daily-life improvement

These examples reinforce that outcomes research is already embedded in real approvals and value assessments

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Abbreviations: DLQI: Dermatology Life Quality Index; EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Core 30; FDA: Food and Drug Administration; HRQoL: Health-Related Quality of Life

Poll Question

Which of these are outcomes?

1. Pain score
2. Ability to climb stairs
3. MRI machine model
4. Blood pressure
5. Dose of study drug

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Abbreviations: MRI: Magnetic Resonance Imaging

Clinical Outcome Assessment

How We Measure Outcomes: The Four Types of COAs

A measure that describes or reflects how a patient feels, functions, or survives

ClinRO: Disease severity, neurological functioning, motor function scores

A measure based on a clinician's observation and professional judgement

PRO: Pain severity, fatigue level, ability to perform daily activities

A measure based on what patients report directly about their symptoms or functioning, without interpretation by clinicians or others

ObsRO: Pediatric sleep diaries, behavior checklists, seizure frequency

A measure based on observations made by a caregiver or other observer when the patient cannot reliably report

PerfO: Walking distance, physical task performance, cognitive tasks

A measure based on how well a patient performs a standardized task

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Abbreviations: ClinRO: Clinician-Reported Outcome; COA: Clinical Outcome Assessment; ObsRO: Observer-Reported Outcome; PerfO: Performance Outcome; PRO: Patient-Reported Outcome

Cross-functional Impact of Outcomes

Outcomes shape decisions from early research through commercialization

R&D/Clinical Development

Identify meaningful concepts; select endpoints early

Regulatory Affairs

Demonstrate meaningful benefit; defend context of use

Statistics

Ensure measurable, sensitive, analyzable endpoints

Commercial

Differentiate product value; support claims and messaging

HEOR and Market Access

Support payer value frameworks; align with reimbursement needs

Medical Affairs

Communicate evidence; build scientific credibility

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Disclaimer: Key functions shown; outcomes impact extends beyond this list.

Abbreviations: HEOR: Health Economics and Outcomes Research; R&D: Research and Development

Choosing the Right COA

Selecting a COA depends on the concept you want to measure and who can report it reliably

Decision Path

Concept of interest
What matters to patients?

Who can best report it?
Patient / Clinician / Caregiver / Task-oriented

Fit-for-purpose?
Valid, reliable, interpretable

Feasibility
Burden, frequency, mode

COA Types

PRO
Patient reports

ClinRO
Clinician rates

ObsRO
Caregiver reports

PerfO
Task based

Regulatory expectation: COA must measure meaningful patient benefit

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Abbreviations: ClinRO: Clinician-Reported Outcome; COA: Clinical Outcome Assessment; ObsRO: Observer-Reported Outcome; PerfO: Performance Outcome; PRO: Patient-Reported Outcome

Trends and Innovations in COAs

New technologies and methods are reshaping how we measure what matters

DHTs & eCOA Evolution

- Wearables, sensors, and mobile apps capturing continuous RWD
- Passive monitoring
- More ecologically valid assessments with lower patient burden

Examples

- Actigraphy-based sleep and activity monitoring (e.g., wrist-worn accelerometers)
- Digital mobility measures (e.g., step count, gait speed, turning metrics)

Novel & Composite Endpoints

- Hybrid endpoints combining multiple domains
- Symptom clusters and multi-attribute outcomes
- Greater alignment with patient-prioritized concepts

Examples

- Composite symptom scores (e.g., combining pain + fatigue + physical function)
- Hybrid endpoints mixing PRO + PerfO (e.g., dyspnea PRO measure + 6MWT)

Decentralized & Remote Assessments

- Remote PRO collection and virtual clinician assessments
- Video-based performance tests
- Increased inclusivity and reduced site burden

Examples

- Remote PRO collection via mobile apps
- At-home PerfO tests (e.g., remote 6MWT with GPS)

RWD Integration

- Linking COA data with EHRs, claims, registries
- Real-world validation and longitudinal follow-up
- Strengthening external control arms and post-market evidence

Examples

- Registry-based PRO data collection (e.g., disease foundations collecting longitudinal PROs)
- External control arms incorporating COA data

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Abbreviations: 6MWT: 6-Minute Walk Test; COA: Clinical Outcome Assessment; DHT: Digital Health Technology; eCOA: Electronic COA; EHR: Electronic Health Record; GPS: Global Positioning System; PerfO: Performance Outcome; PRO: Patient-Reported Outcome; RWD: Real-World Data

Challenges and Gaps in COA Science

Innovation brings opportunity — and new complexities we must navigate

1. Validation & Regulatory Expectations	2. Data Quality & Measurement Consistency	3. Operational & Site Burden	4. Equity, Access & Representativeness
• Ensuring digital measures are clinically meaningful • Establishing context of use for novel endpoints • Limited precedents for DHT-based COAs	• Variability in sensor accuracy and device calibration • Missing data from remote or passive capture • Ensuring equivalence across modes (paper → ePRO → digital)	• Training sites and patients on new technologies • Managing device logistics, updates, and troubleshooting • Increased complexity in decentralized trial workflow	• Digital divide affecting older adults, low-resource settings • Language, literacy, and cultural adaptation gaps • Risk of excluding populations who cannot use certain technologies

Innovation expands what is possible, but it also raises the bar for scientific and operational rigor.

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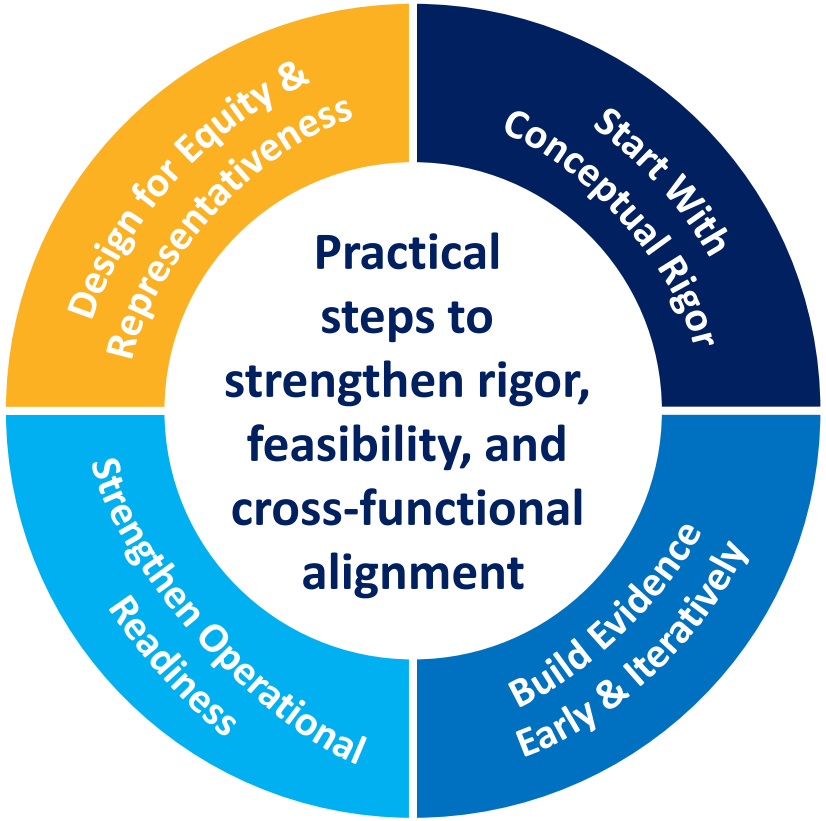
Abbreviations: COA: Clinical Outcome Assessment; DHT: Digital Health Technology; ePRO: Electronic Patient-Reported Outcome

Strategic Recommendations

- Ensure accessibility across literacy, language, and technology comfort levels
- Include diverse patient populations in validation and feasibility work
- Monitor differential missingness or performance across subgroup

- Anchor every COA decision in a clear concept of interest and context of use
- Prioritize early patient input to ensure relevance and meaningfulness
- Map concepts to endpoints before selecting instruments



- Invest in site and patient training for new technologies
- Simplify device logistics and reduce burden wherever possible
- Establish clear data-flow pathways for decentralized and digital assessment

- Conduct early feasibility and usability testing for digital measures
- Generate validation evidence aligned with regulatory expectations
- Use pilot data to refine scoring, thresholds, and interpretation

Well-selected COAs turn patient experience into credible, decision-ready evidence.

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Abbreviations: COA: Clinical Outcome Assessment

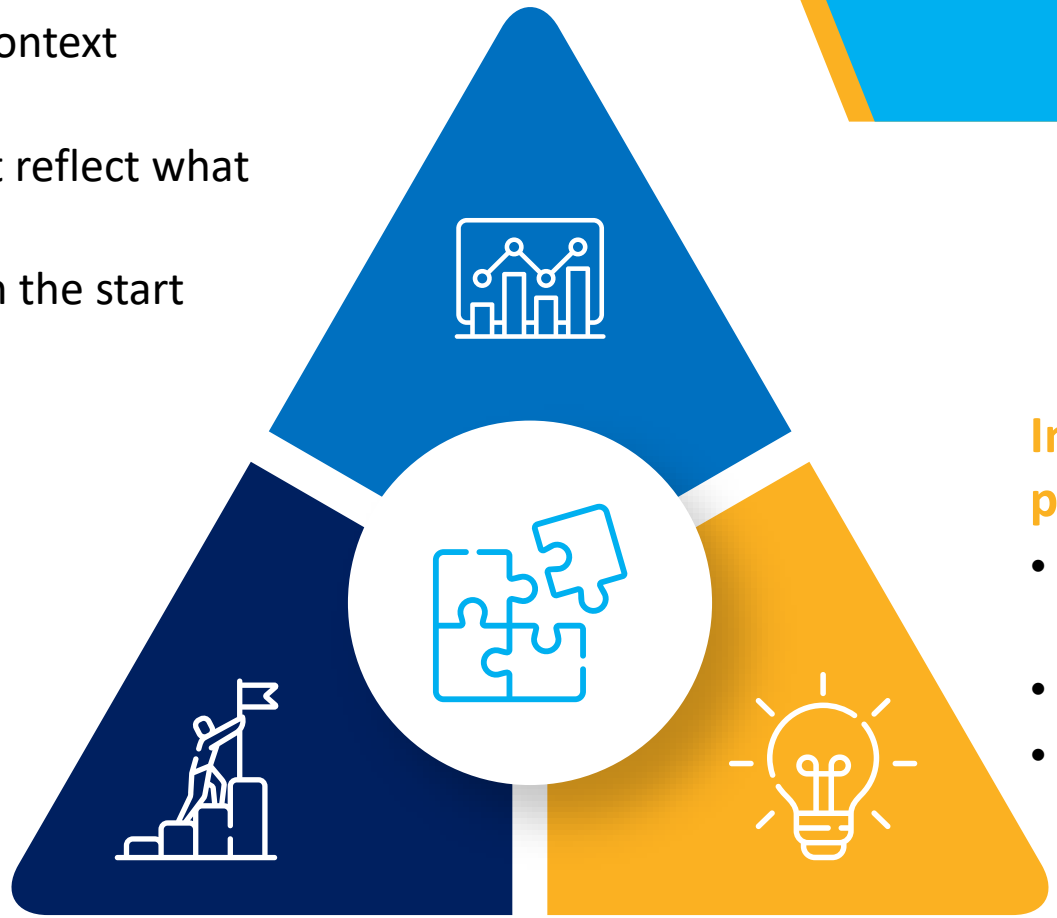
Bringing it all together

Outcomes anchor meaningful measurement

- Clear concepts of interest and context of use
- Patient-centered endpoints that reflect what matters
- Cross-functional alignment from the start

Rigor and readiness determine success

- Strong validation and regulatory alignment
- Operational feasibility and data quality
- Equity and representativeness across populations



Innovation expands what is possible

- DHTs and decentralized assessments
- Novel and composite endpoints
- RWD integration

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Abbreviations: DHT: Digital Health Technology; RWD: Real-World Data

Q&A

Bio and Contact Information

Somali Misra Burgess, PhD
is the **CEO and Research Director of Sunlight Outcomes Research**, a boutique consultancy specializing in clinical outcome assessment (COA) and patient-centered research strategy. With 28 years of experience across the consulting and pharmaceutical industries, she delivers tailored COA solutions that support strategy development, global regulatory success, patient-focused drug development (PFDD), and real-world evidence generation.

This is not Somali's first entrepreneurial venture. She previously founded Strategic Outcomes Services, a successful COA-focused consultancy, which led to her recruitment by Xcenda (now Cencora) to build and lead their Outsourcing Solutions team, where she also served as Senior Director and Patient-Reported Outcome (PRO) Thought Leader.

Before launching Sunlight Outcomes Research, Somali was a Senior Principal in IQVIA's Patient-Centered Solutions team, leading research across North America and serving as Scientific Lead for the Asia-Pacific (APAC) region. Her prior executive and leadership roles include Vice President (VP), Patient-Centered Outcomes at Endpoint Outcomes (now Lumanity); VP, Endpoint Development and Outcomes Assessment at Adelphi Values; Senior Research Scientist, Patient-Centered Research at Evidera; and Director, Global Health Outcomes Strategy and Research at Allergan (now AbbVie), where she led COA and outcomes research efforts across multiple therapeutic areas.

Somali's expertise spans COA strategy development, measure validation, regulatory submissions, and value demonstration across a broad range of therapeutic areas, including aesthetics, dermatology, gastrointestinal and respiratory conditions, immunology, neuroscience, oncology, ophthalmology, rare diseases, and urology. She has also played a pivotal role in advancing COA strategies in the APAC region, tailoring approaches to meet regulatory requirements.

Committed to advancing patient-centered research and regulatory success, Somali continues to collaborate with biotech and pharmaceutical partners to optimize COA strategies, elevate PFDD, and support market access.

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