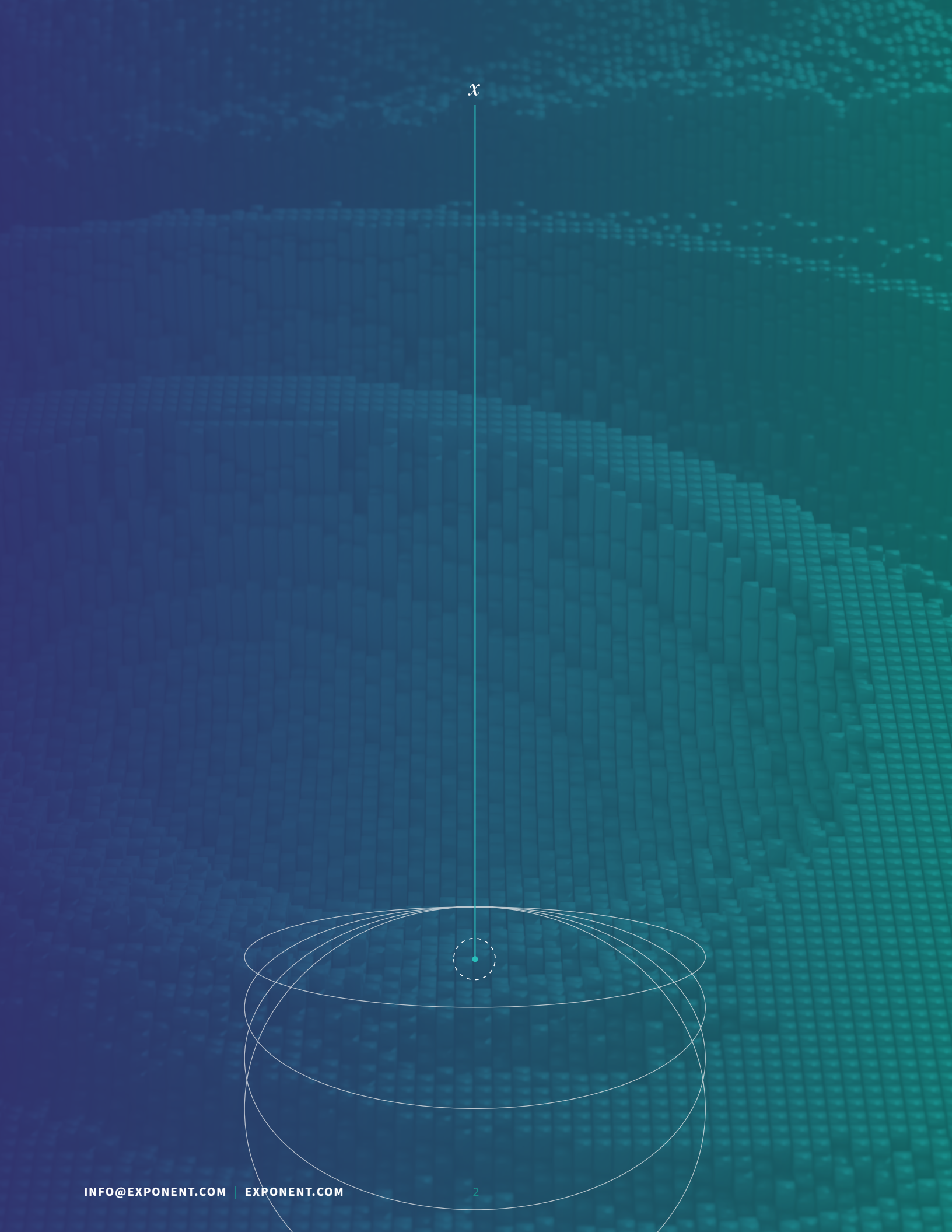
Exponent®

Multidisciplinary Expertise for Pharmaceuticals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Next-Generation Wellbeing

In an era of radically-accelerating change, Exponent is the only premium engineering and scientific consulting firm with the depth and breadth of expertise to solve your most profoundly unique, unprecedented, and urgent challenges.

Our multidisciplinary teams of epidemiologists, physicians, toxicologists, chemists, industrial hygienists, exposure scientists, biostatisticians, and regulatory experts work together to provide answers regarding the health risks of the wide variety of substances encountered in our daily life.

We provide robust, industry-leading support rooted in sound science to evaluate the benefit, risks, and value of pharmaceuticals, medical devices, and diagnostics. Through rigorous research and investigations, we provide insights into complex health challenges and help our clients succeed in bringing advanced medical technologies to market.

Pharmaceutical Industry Services

Our Health Sciences practice applies an unparalleled combination of industry-specific knowledge, specialized expertise, and an interdisciplinary approach to a broad range of scientific, regulatory, and business issues facing the pharmaceutical industry. Our scientists leverage decades of experience in pharmacoepidemiology, toxicology, industrial hygiene, health services research, health economics and outcomes research, regulatory sciences, statistics and data sciences, biomedical engineering, and other technical fields.

Selected Capabilities

Pharmacoepidemiology & Real-World Evidence

Our pharmacoepidemiology and RWE services include the following capabilities:

- Designing and conducting pre- and postmarketing safety and effectiveness studies
- Novel epidemiological designs and analytic methodologies
- Selection, quality assessment, and analysis of electronic health records (EHR) and healthcare claims data
- Scientific and regulatory consulting on emergent safety issues
- Evaluation and support of regulatory strategies across the full life cycle
- Signal detection, enhanced pharmacovigilance, and risk evaluation and mitigation strategies (REMS)
- Comparative effectiveness research (CER)
- Prescription to over-the-counter (Rx-to-OTC) switches
- Evaluating and implementing RWE strategies
- Estimating healthcare access, costs, and value
- Systematic review and meta-analysis
- Litigation support

Health Economics & Outcomes Research

Our team designs and implements a variety of health economics & outcomes research (HEOR) engagements across the life sciences sector. Our HEOR work is often applied to market access strategies such as value-based pricing, health technology assessment (HTA) submissions, and value dossier input. HEOR provides the evidence framework for valuebased healthcare (VBHC) collaborations between pharma and other healthcare stakeholders including but not limited to value-based agreements such as pay-for-performance and warranty constructs.

Representative project types include strategy, modeling, and research studies:

Strategy:	Systematic Literature Reviews and Meta-analysis; Protocol Design; Therapeutic Area Reviews, and Asset HEOR Plans
Modeling:	Burden-of-Illness Assessment; Cost-Effectiveness Analysis; Budget Impact Analysis
Research:	Early- and Late-Phase Trial HEOR Input; Retrospective and Prospective HEOR Research; Scientific Conference Abstracts, Presentations, and Journal Manuscripts

Selected Capabilities *(continued)*

Market Access & Value-Based Healthcare

Representative project types include strategy, modeling, and research studies:

Strategy:	Value Dossiers; Therapeutic Area Reviews, Asset Market Access Plans; Value-Based Agreement Scenario Planning; Digital Health Strategy
Modeling:	Value-Based Pricing; Value Framework & Health Technology Assessment Simulations; Value/Risk/Outcomes-Based Agreement Analysis
Research:	Value-Based Healthcare Collaborations between Pharma, Payers, Providers, Medical Associations and Technology Partners

Regulatory Sciences & Support

Exponent offers regulatory advising and strategic consulting across the product life cycle.

- **Pre-Approval:** Even before a product is approved, Exponent can assist with the development of pre-approval study designs, preparation for regulatory advisory meetings, and creation of postapproval safety strategies.
- **Peri-Approval:** Exponent scientists work with sponsors to respond to regulatory queries, negotiate post-marketing requirements, and design protocols for enhanced pharmacovigilance, registries, REMS, and epidemiological studies.
- **Post-Approval:** Exponent supports regulatory milestones, including safety reports, enhanced pharmacovigilance, re-evaluation of regulatory requirements, and Rx-to-OTC switches.

Toxicology

Our toxicologists assess potential health risks of reagents, excipients, degradants, and impurities in drug products and extractables in combination products through the following activities:

- Designing and performing chemical characterization studies
- Conducting toxicological assessments to derive permissible daily exposure levels
- Developing exposure limits for extractables for specific products that pertain to product quality and safety.

Industrial Hygiene

Our broad experience in conducting workplace evaluations and occupational risk assessments includes the following areas of expertise:

- Characterizing reproductive, developmental, and other hazards
- Evaluating inhalation and dermal exposures to active pharmaceutical ingredients
- Assisting in deriving occupational exposure limits, occupational exposure banding, and surrogate (containment) verification for various manufacturing.