

REAL-WORLD *results*

CORPORATE PROFILE

Safety • Effectiveness • Value • Quality

Outcome, the real-world and late phase research company of Quintiles, is the global market leader in patient registries, peri and post-approval studies, data, and integrated technologies for evaluating real-world outcomes. We provide services and technologies focused on evaluating the safety, effectiveness, value, and quality of healthcare products, therapies, and services. Our teams have designed, developed, and managed an industry-leading number of real-world studies including many of the largest and most well-recognized programs for disease outcomes, safety, and risk management. Backed by expertise and experience in more than 40 therapeutic and medical practice areas, Outcome has been focused on post-approval and quality improvement programs since its inception.

Unique Strategies and Solutions

Real-world studies are not one size fits all. Each program must be designed and managed in a way that meets its specific purpose(s). We have assembled an outstanding group of experts in program design and management, epidemiology, statistics, health economics, technology, integrated services, and related regulatory (safety, coverage, privacy) aspects of registries, peri, and post-approval programs to assist you with all aspects of your study, using a proven, integrated step-by-step process:

1. Establish goals and scientific objectives
2. Design an effective program
3. Develop study plans and materials
4. Build a community (recruit and manage sites)
5. Manage and support data collection, cleaning, and reporting
6. Analyze data, interpret results, and publish

Scientific Leadership

Our Scientific Affairs team of epidemiologists, biostatisticians, pharmacists, and clinicians leads or assists in the development of scientific concepts and study protocols and guides study execution, analysis, and interpretation. They also provide guidance, as needed, through study start-up and conduct to overcome practical obstacles, lead or support study analysis and reporting, and disseminate information through publishing articles and making presentations to clinical and business audiences.

Patented Technology

Technology plays a critical role in a successful real-world program and building the solution around the most appropriate technologies improves efficiency, ROI, site satisfaction, and decreases the time to results. Our patented* system is unique because it is specifically designed for evaluating real-world outcomes.

BUILT FOR BUSY CLINICAL PRACTICE: Our client platform is easy to learn and simple to use, providing flexibility in data capture (web, telephone, offline, fax, and existing office systems).

ROBUST, UP-TO-DATE STUDY METRICS: Monitor the progress of the study and review key project and safety metrics in real time throughout the entirety of the study.

DELIVERING VALUE: For sites, access to real-time data, reports, patient education, treatment guidelines, and recommendations. For the sponsor, access to real-time metrics, data and unique analytic tools.

GLOBAL CAPABILITIES: Designed for international use and localization (currently used in more than 90 countries).

An Integrated Solution

What We Do

An Integrated Solution

- Unique Strategies, Solutions, Implementation, and Management
- Scientific Leadership
- Clinical Program Design
- Best-in-class Technology
- Superior Customer Service
- Proven Robust Methodology
- Global Reach
- Strategic Partnerships

What We Do

- Generate knowledge and evidence (scientific presentations and publications)
- Demonstrate effectiveness

- or comparative effectiveness in different populations
- Meet post-marketing commitments
- Generate evidence for coverage
- Monitor safety
- Manage risks and benefits
- Generate data for new indications or label extensions
- Change behavior
- Improve quality of care
- Prove product value through economic or quality of life benefits
- Bring scientific information to stakeholders sooner
- Enhance the practice of personalized medicine

Programs

- Patient Registries
- Post-Approval and Phase IV Studies
- Observational Studies
- Phase IIIb/Expanded Access
- Quality Measurement and Improvement Initiatives
- Benefit Risk Management/ RiskMAPS/REMS
- Safety & Surveillance
- Health Outcomes/Health Economics
- Quality of Life/PROs
- Patient Retention
- Performance Tracking Systems
- Instrument Validation Studies
- Controlled Distribution

Programs

- Health Interventions
- Performance-Linked Access Systems

Focus

- Products (Drug, Biologic, or Medical Device)
- Healthcare Services (Including Procedures)
- Diseases or Conditions
- Exposure

*The Outcome System® service is covered by one or more of the following Patents: U.S. Patent No(s): 7,353,238.
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CORPORATE PROFILE

Operational Excellence

We provide a full-service offering for real-world studies, ranging from small regional programs to large global studies. No matter the size of your study, we focus on operational excellence in every step of the process. Our project teams provide:

- Scientific Guidance
- Project Strategy
- Project Management
- Protocol Design
- Adverse Event Management
- Medical Monitoring
- Risk Minimization
- Statistical Analysis
- Data Management
- Site Recruitment and Qualification
- Site Support and Retention
- Education and Communication
- Abstract and Publication Support

Superior Customer Service

Outcome's focus on the customer extends into every aspect of your program. Our focus on customer service begins with viewing ourselves as your strategic partner, designing the best possible program, and integrating the right technologies. It continues with being responsive to your needs, recommending solutions, and managing change. And, it exceeds your expectations by providing site management (help desk) support described as best-in-class.

Our dedication to superior customer service stems from our recognizing that our sites are often your customers. In fact, we survey our sites at key points in every project, and we are proud to share our results with you.

Best Practice Leader

AHRQ Registry Handbook

Outcome led the development of the Agency for Healthcare Research and Quality (AHRQ) handbook, "Registries for Evaluating Patient Outcomes: A User's Guide," released May 2007 and updated with a second edition in September 2010. The handbook provides key information on developing, operating and evaluating patient registries and provides tools intended to help evaluate the quality of a patient registry. In 2010, Outcome was awarded the task of creating a 3rd edition of the handbook, scheduled to be released in 2013.

RoPR

In 2010, AHRQ awarded Outcome a task order to design and develop a Registry of Patient Registries (RoPR) database. The main objectives of RoPR are to: Provide a searchable central listing of patient registries in the United States to enable interested parties to identify registries in a particular area; Encourage and facilitate the use of common data elements and definitions in similar conditions—to improve opportunities for sharing, comparing, and linkage—through the listing and searching of such elements; Provide a central repository of searchable summary results, including results for registries that have not published their findings in peer-reviewed literature; Offer researchers a search tool to locate existing data, from either ongoing studies or closed studies, to request for use in new studies; and Serve as a recruitment tool for researchers and patients interested in participating in patient registries.

Visit www.outcome.com/ropr.htm to learn more.

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Strategic Partnerships

At Outcome, we believe to achieve success we must sometimes work outside the traditional paradigm. Our partnerships and clients include key relationships with providers and healthcare organizations, specialty associations, hospital associations, pharmacist associations, managed care organizations, state departments of public health, QIOs, and government agencies. Through our strategic relationships, we have designed and managed some of the world's largest and most recognized real-world studies.

Global Capabilities

Outcome-powered studies include thousands of sites and millions of patients across the globe. Outcome has program participants in more than 90 countries on 6 continents, with more than 2,500 U.S. hospitals participating in at least one Outcome registry.

Outcome regularly works with thought leaders, regulators, and government agencies from many regions of the world, including the European Medicines Agency, the Agency for Healthcare Research and Quality, the U.S. Food and Drug Administration, the UK National Institute for Health and Clinical Excellence, and many more.

Our headquarters are in Cambridge, MA and St-Prex, Switzerland, and as a Quintiles company, we have regional staff and resources in 60 countries.

DEcIDE Research Center

Outcome is an AHRQ DEcIDE (Developing Evidence to Inform Decisions about Effectiveness) Research Center. As a DEcIDE research center, Outcome conducts accelerated practiced studies about the outcomes, comparative clinical effectiveness, safety, and appropriateness of healthcare items and services.

Visit www.effectivehealthcare.ahrq.gov to learn more.

GRACE Principles

Selected by the National Pharmaceutical Council (NPC), Outcome leads the development of good practice principles for observational comparative effectiveness research.

Learn more at www.graceprinciples.org.

ENCePP & PROTECT-EU

Outcome is a European Medicine Agency PROTECT-EU partner and EN-CePP research center. The PROTECT-EU project (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium) is a multi-national consortium of public, private and academic organizations across Europe that have come together to develop innovative methods in pharmacoepidemiology (PE) and pharmacovigilance (PV). PROTECT-EU looks at the limitations of current methods used in PV and PE in order to strengthen the monitoring of the benefit/risk balance of medicines marketed in Europe. The ENCePP (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance) project is aimed at strengthening the monitoring of post-marketed medical products in Europe. The project's goals include facilitating multi-center, independent, PASS studies focusing on a lack of efficacy.

Visit www.encepp.eu and www.imi-protect.eu to learn more.