Satisfy stakeholder evidence demands
with a proactive approach

Real-world and late phase research is becoming critical to product success as stakeholders seek additional evidence to support regulatory, reimbursement and prescribing decisions. New studies must meet emerging scientific standards for design, operations, analysis and quality assurance.

An experienced strategic research and technology partner, Quintiles can help guide the design and implementation of a high-quality program tailored specifically to meet your needs.

Achieve research objectives with a dynamic combination
Determining the right approach to achieve research objectives requires expertise and experience in real-world and late phase research. Quintiles, a leader in interventional IIIb/IV studies and observational research, is the world’s largest provider of biopharmaceutical development and commercial outsourcing services. Whether monitoring safety and evaluating benefit-risk or demonstrating effectiveness and gaining market access or proving efficacy in new indications and new formulations, Quintiles offers you a comprehensive approach to evidence development.

Establish the appropriate steps to accomplish your goals
- Generate knowledge and evidence
- Demonstrate effectiveness or comparative effectiveness in different populations
- Establish efficacy
- Meet post-marketing commitments
- Generate evidentiary requirements for coverage
- Monitor long-term safety and safety in different populations
- Manage risks and benefits
- Generate data for new indications or label extensions
- Obtain or expand market access
- 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
- Understand the natural history of disease and treatment
- Generate evidence for product differentiation and positioning

We can offer you the right approach for the right question to meet your research objectives.
Develop lifecycle solutions that facilitate marketplace success
Planning for real-world and late phase research earlier in the product lifecycle can help ensure the success of your product once it reaches the market. You can rely on Quintiles’ extensive clinical development experience from end-to-end lifecycle solutions and the assurance of an effective plan to transition evidence development efforts from early phase research into Phase IIIb and post-approval.

These innovative strategies and tools can help bring commercial insights to clinical development, resulting in more efficient studies that can meet different stakeholder needs and provide higher quality data to help improve a product's success in the marketplace.

Through these offerings, we can help you reduce complexities, mitigate risks and decrease costs of overall product development. As a research partner, we give our customers a continuity of knowledge on company procedures, extensive knowledge on the compound and the ability to facilitate internal stakeholder interaction. Quintiles helps to provide the development of a more complete picture of the product, to help you improve your probability of reimbursability.

Access therapeutic and medical practice expertise for improved outcomes
The ability to understand the nuances that make every therapeutic and medical practice area unique combined with a deep scientific and clinical knowledge in that area can lead to better study outcomes for your product. We can put together a Quintiles team that has experience in all major therapeutic and medical practice areas, including 14 Therapeutic Centers of Excellence, to help you achieve your research goals. The end result is valuable insight and support, from protocol design to site recruitment and retention to analyzing and publishing results.

Employ comprehensive data analytics to gain reliable insight
The systematic growth of real-world clinical data from health information systems may provide more timely and accurate information to help answer questions on effectiveness, safety and quality of healthcare. Through a series of partnerships and networks Quintiles offers, you will be able to work with new clinical data sources for rapidly and cost effectively answering key clinical and research questions on practice patterns, treatment effectiveness, complex diagnosis and care plans, disease prevalence and more with access to clinical, claims and electronic health record (EHR) data representing the leading aggregate and most rapidly growing set of patient records. These networks can be leveraged to enable studies with data from multiple geographies and care settings, including inpatient and outpatient and integrated data from other sources, including claims, pharmacies and labs.

Quintiles has access to ~21 million patient lives with ~8M active records through the COMPASS network
PROGRAM TYPES

• Registries: Patient, Disease, Product, Pregnancy
• Post-Approval and Phase IV Studies
• Observational Studies
• Phase IIIb/Expanded Access
• Market Access
• Quality Measurement and Improvement Initiatives
• Benefit Risk Management/RiskMAPS/REMS
• Safety, Surveillance, PASS, PAES
• Health Outcomes/Health Economics
• Quality of Life
• Patient Reported Outcomes (PRO)
• Patient Retention
• Performance Tracking Systems
• Instrument Validation Studies
• Controlled Distribution Programs
• Post-Marketing/Regulatory Commitment
• Health Interventions
• Performance-Linked Access Systems
• Comparative Effectiveness Research

APPROACHES
(Primary and secondary data capture)

• Interventional Trials
• Observational Research and Registries (prospective and retrospective)
• EHR and Database Studies
• Chart Reviews

RESEARCH QUESTIONS

• Safety
• Benefit-Risk
• Cost Effectiveness
• Comparative Effectiveness
• Efficacy
• Quality
• Value

FOCUS

• Products (Drug, Biologic, or Medical Device)
• Healthcare Services (including Procedures)
• Diseases or Conditions
• Exposure
Plug into worldwide reach with unmatched local expertise

There are many considerations and challenges when designing and implementing global and regional studies, and certain nuances that can make a big difference in achieving successful outcomes. Since Quintiles has experience with studies that cumulatively include thousands of sites and millions of patients across the globe with participants in more than 100 countries, we can assist you as you begin to build and plan for trials by drawing on similar experiences as well as regional and local know-how.

In Asia Pacific, the Middle East, Africa and other emerging markets, dedicated teams understand the unique regulatory and operational challenges and are experts at translating your research needs into solutions that meet your stakeholder requirements.

Recognizing the importance of developing relationships with your key stakeholders, Quintiles 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.

With a team of more than 36,000 professionals in more than 100 countries, you can trust that Quintiles has the dedicated and knowledgeable resources needed to support your project regionally or globally.
Integrated partner services

Sponsors have access to an integrated research solution through specialized scientific, strategic and operational expertise with innovative technology.

Science
A Scientific Affairs team, comprised of epidemiologists, biostatisticians, pharmacists, health economists and clinicians, works closely with you to lead or assist in the development of scientific concepts and study protocols. When it’s time to guide study execution and analyze and interpret data, the experience of the team will pay dividends. They provide guidance as needed through study start-up and conduct to overcome practical obstacles, support study analysis and reporting, and disseminate information through articles and presentations.

Strategy
Ensuring the Right Approach to the Right Question requires a comprehensive understanding of healthcare stakeholder needs. Deep therapeutic knowledge and understanding of the key issues combined with clinical experience from a global team of physicians drives more effective and efficient research. Quintiles offers HTA Watch, a web-based global repository of published HTA reports from 100 agencies in 32 countries. It is designed to provide instant and complete data to help companies determine strategic direction for their products, based on previous assessments from agencies around the world. Reflecting the importance of the patient voice, Quintiles offers more than 3.5 million patient relationships across 6 online communities in 7 countries as of October 1, 2014. Strategic insights such as these ensure that research can be designed to capture the right clinical and economic endpoints and patient-reported outcomes.

Operations
Large or small, every study is different and calls for its own operational strategy to fulfill the unique objectives of your programs. Quintiles’ offering for real-world and late phase research includes a full suite of services designed to complement a range of programs, from small regional studies to large global trials. With a focus on operational excellence throughout every step of the process, dedicated project teams provide services ranging from project strategy and management to site recruitment and support to risk minimization and medical monitoring.

Technology
Technology plays a critical role in a successful real-world or late phase program and building the solution around the most appropriate technologies improves efficiency, return on investment (ROI), site satisfaction and decreases the time to results. Quintiles leverages specialized electronic data capture (EDC) technologies to evaluate real-world outcomes through observational research and registries and select market-leading platforms for interventional trials that are designed for international use and localization. Through these technologies, you receive added value through access to robust project and safety metrics, real-time data and analytic tools.
Best practices & collaborations

**AHRQ Handbook**
www.effectivehealthcare.ahrq.gov

Quintiles leads the development of the Agency for Healthcare Research and Quality handbook, “Registries for Evaluating Patient Outcomes: A User’s Guide,” which provides key information on developing, operating and evaluating patient registries. This guide has been translated into Chinese and adapted in Korean.

**ROPR**
https://patientregistry.ahrq.gov
(Registry of Patient Registries)

Under an AHRQ task order, Quintiles leads the effort to design and develop a Registry of Patient Registries database, which will enable the registration of registries similar to how clinical trials are registered in clinicaltrials.gov.

**AHRQ OCER Guide**
www.effectivehealthcare.ahrq.gov

Quintiles leads the development of the Agency for Healthcare Research and Quality’s “Developing a Protocol for Observational Comparative Effectiveness Research (OCER): A User’s Guide,” which aims to identify both minimal standards and best practices for designing observational comparative effectiveness research (CER) studies.

**ENCePP®**
www.encepp.eu
(European Network of Centres for Pharmacoepidemiology and Pharmacovigilance)

Quintiles is an ENCePP® research center, a project aimed at strengthening the monitoring of post-marketed medical products in Europe.

**PROTECT-EU**
www.imi-protect.eu
(Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium)

Quintiles is a European Medicine Agency PROTECT-EU partner, a multi-national consortium of European organizations joined to develop innovative methods in pharmacoepidemiology and pharmacovigilance.

**ASTER-D**
(Adverse Event Spontaneous Triggered Electronic Reports for Devices)

Quintiles is participating in the ASTER-D project, a pilot focused on demonstrating the use of a spontaneous trigger approach to collecting adverse event data through electronic health records (EHR) and/or Incident Reporting Systems (IRS) and transmitting it electronically to the U.S. FDA.

**GRACE Principles and Checklist**
www.graceprinciples.org
(Good Research for Comparative Effectiveness)

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