

RTI *(h)(s)*<sup>™</sup>

Health Solutions

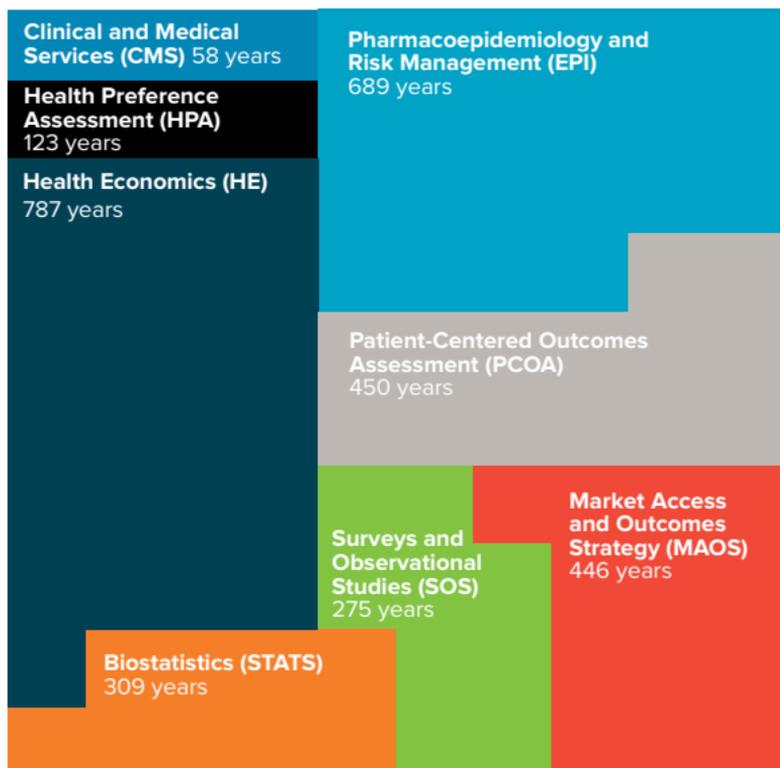


The power of **knowledge.**  
The value of **understanding.**

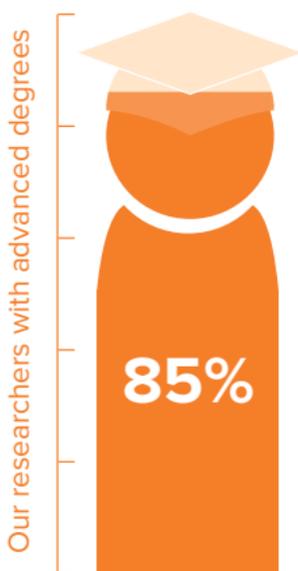
# 3,100

## Years of Experience

With a team that has over 3,100 combined years of research experience, we provide robust scientific knowledge and the highest ethical standards to help ensure your results will hold up to scrutiny.



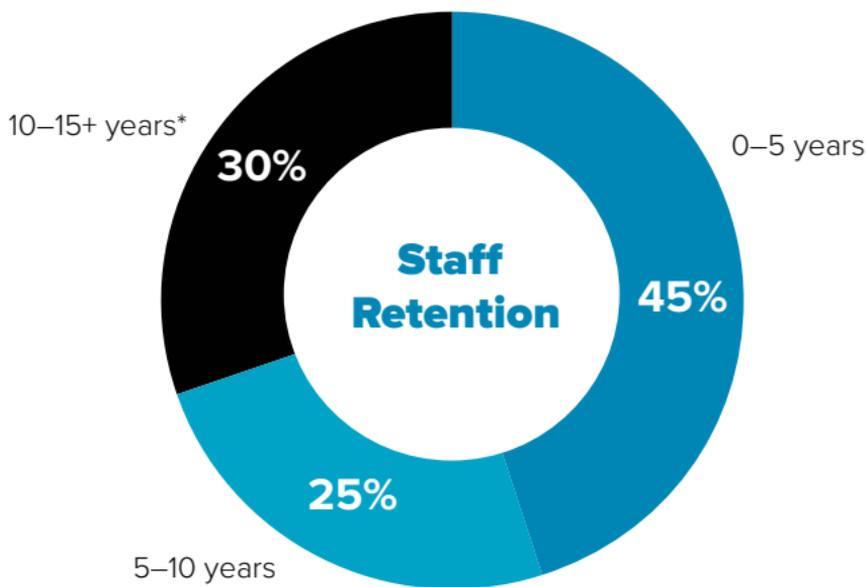
169 of our 200 researchers hold advanced degrees, so you can trust that your projects will be staffed by well-educated professionals who use state-of-the-art approaches and proven methods.



# 55%

## >5 Years at RTI-HS

Low employee turnover creates stable project teams—even on multi-year studies. We can provide research continuity on your studies and as your product goes through its development lifecycle.

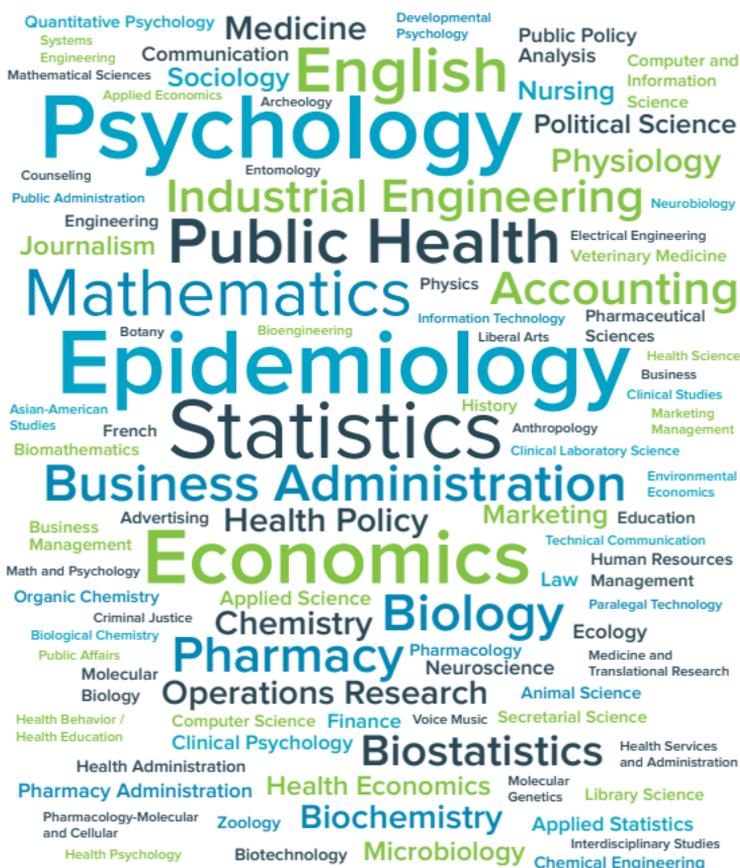


\* Includes staff who started with parent company, RTI International, prior to 2000.

# 156+

## Academic Specialties\*

From medicine to industrial engineering, we look at problems from diverse points of view, which brings fresh thinking to your research questions.



\* For research staff, including bachelor's degrees and higher.

# (6,250+) Publications

Our research holds up to the standards of scientific publishing—over the past 5 years, we've published an average of 226 peer-reviewed research articles and another 236 research posters and presentations per year.

In the past **5 years...**



...by **RTI-HS** researchers

# 6,000+

 Projects

With every new project, we build upon our 16 years of company experience across nearly all therapeutic areas. The most studied therapeutic areas are below:



**1,049**

Oncology



**449**

CNS/Neurology



**359**

Infectious Disease



**325**

Psychiatry



**303**

Gastroenterology



**297**

Dermatology



**294**

Cardiovascular



**270**

Respiratory



**240**

Diabetes & Endocrine  
Disorders



**194**

Pain



**178**

Women's Health



**171**

Rheumatology



**164**

Hematology



**109**

Vaccines



**102**

Hepatic



**96**

Men's Health

With rigorous scientific practices and deep industry experience, we help reveal the benefits, risks, value, and potential of your products.

Let our experts help you generate knowledge and greater understanding so that you—and those who regulate, pay for, prescribe, and use your products—can make better decisions.

“Research is to see what everybody else has seen and think what nobody has thought.”

– Albert Szent-Györgyi, MD, PhD  
Nobel Prize Recipient



## Patient-Centered Outcomes Assessment

Assess disease and treatment outcomes from the perspective of your patients, caregivers, and health care professionals.

Measurement Strategies

Instrument Development

Psychometric Evaluation

Utility Assessment

Market Research

Regulatory Guidance & Support

### **Case Study**

To develop novel PRO measures for use in future clinical trials for irritable bowel syndrome, we collaborated with the Critical Path Institute's (C-Path) PRO Consortium, three pharmaceutical sponsors, clinical experts, and the FDA. We also collaborated with another client to support the revision and qualification of an existing measure.

## Health Economics

Demonstrate your products' global economic value and impact in the context of health outcomes.

Decision Analytic Modeling

Retrospective Health Care Data Analyses

Medical Chart Abstraction

HEOR Evidence Generation &  
Section 114 Consulting

Interactive Communication Tools

Literature Reviews & Meta-Analyses

Heterogeneity of Treatment Effect Analyses

### **Case Study**

We worked with a manufacturer on a novel drug that has been shown to reduce the consumption of alcohol by alcohol-dependent patients. In close collaboration with the manufacturer, we conducted the cost-effectiveness and budget impact analyses needed to support the drug's launch across a large number of European markets. This collaborative approach allowed for efficient knowledge transfer between markets and ultimately facilitated earlier treatment access.



## Health Preference Assessment

Quantify the effects of health care outcomes and interventions on the satisfaction, utility, and behavior of patients, physicians, and other decision makers using stated-preference studies.

Discrete Choice Experiments & Conjoint Analysis  
Benefit-Risk Assessments  
Willingness-to-Pay Studies  
Multi-Criteria Decision Analysis

### **Case Study**

We conducted a preference study that allowed for systematically quantifying the tradeoffs patients are willing to make among benefits, harms, and other features of weight loss devices. Designed to provide scientific data on patient preferences to inform clinical trial design for obesity devices, the study resulted in sufficient data to inform FDA regulatory decision-making on a new device.

## Market Access and Outcomes Strategy

Develop and implement value-driven strategies and outcomes research plans throughout all stages of drug development to help you differentiate your product, gain market access, and achieve commercial success.

Global Value Dossiers & Other Value Communication Materials

Market Access Strategies

Payer Research

Systematic & Other Literature Reviews

Reimbursement Dossiers & HTA Submissions

### **Case Study**

We collaborated with a client to create a global value dossier for an advanced non-small cell lung cancer treatment that assisted country affiliates in formulating local submission documents and preparing for market access and reimbursement activities. The dossier included a robust value story with evidence-driven messages and key information that effectively communicated the clinical, humanistic, and economic value of the product.



## Surveys and Observational Studies

Execute customized real-world observational studies and survey research using robust methodologies to support regulatory commitments, product development, and market access.

Patient, Caregiver, & Provider Surveys

Prospective Studies

Multi-Site & Multi-National  
Observational Studies

Medical Record Abstractions

Natural History & Registry Studies

### **Case Study**

We conducted an observational study to understand real-world treatment patterns, health care resource use, health-related quality of life, and indirect costs associated with a dermatological condition. Data collection occurred via medical record abstractions, surveys, and diaries from approximately 700 patients across seven countries.

## Biostatistics

Benefit from our impartial interpretation of your data—from clinical trials to post-marketing studies—so you can trust the results and your stakeholders can confidently act upon them.

Clinical Trial Analyses

Observational Study Analyses

Outcomes Research Analyses

Meta-Analyses

### **Case Study**

Based on our experience with patient registries and advanced technical capabilities, we were chosen as a statistical coordinating center for a multi-year patient cancer registry. We developed the statistical analysis plan, provided routine reports, participated on the external advisory board, and helped present data at scientific meetings.

## Pharmacoepidemiology and Risk Management



Reduce the uncertainty of risks to patients by investigating disease epidemiology, drug outcome associations, and usage in routine clinical practice and by designing and evaluating the effectiveness of risk management strategies.

### Consulting

Database Studies, including Multi-Database  
Research Programs

Non-Interventional Field-Based  
Studies & Surveys

Literature Reviews

### **Case Study**

In response to a signal in animal studies of a potential association between a medication to treat osteoporosis and osteosarcoma, we are leading a 15-year surveillance study. As part of the surveillance program and to meet a regulatory commitment, we are also conducting a long-term registry linking patient information with cancer registries.

## Clinical and Medical Services

Rely on our therapeutic experts—including Dr. Allen Mangel (gastroenterology)—and our experienced CMS team to design and implement clinical studies for your products in any therapeutic area.

Strategic Planning

Study Design

Study Implementation

Analysis & Reporting

### **Case Study**

Following the successful completion of a phase 2b study, we designed and implemented a phase 3, 215-center study for the same irritable bowel syndrome drug. We led the FDA negotiations, wrote the study protocol, developed the specifications for the interactive voice and web response system, and designed the CRF. We were responsible for site recruitment; site monitoring; and overall project management, including oversight of the data management and central laboratory vendors. Our biostatistics team wrote the SAP and analyzed the data, and we wrote the clinical study report.