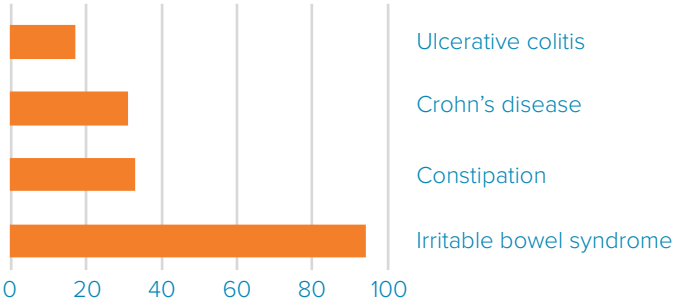
RTI (h)(s)
Health Solutions

Gastroenterology Experience

Position your product for market access

We have collaborated with our clients on more than 280 projects researching gastrointestinal disorders, treatments, and the burden and complications of gastrointestinal disease. As a result of our research, we have published numerous journal articles and presented our work at many scientific conferences.

330+
published journal articles, posters, and presentations



280+
projects

45+
staff with experience in gastroenterology projects

Types of Projects

Our researchers have experience in a wide range of study types and can help you determine what you need to position your drug for market access. Recent projects have included:

- Clinical trial design, implementation, and analyses
- Consulting on drug development from preclinical through postmarketing
- Patient reported outcomes (PRO) instrument development, evaluation, and validation
- Development of PRO measurement strategies
- Statistical analyses of PRO measures
- Development of PRO dossiers to support label claims
- Exploratory analyses of clinical trial data
- Qualitative physician and patient research
- Health economic models
- Economic burden of illness studies
- Health care resource utilization studies
- Cohort and case-control studies
- Benefit-risk preference studies
- Risk management programs including development, implementation, and evaluation
- Systematic literature reviews
- Retrospective analyses using longitudinal databases
- Research gap analysis and publication planning
- Development of reimbursement and value communication strategies

Development of novel PRO measures for use in clinical trials for IBS.

Case Study

We collaborated with the Critical Path Institute's (C-Path) PRO Consortium, three pharmaceutical sponsors, clinical experts, and the FDA to develop novel PRO measures for each of the three irritable bowel syndrome subtypes to be used in future clinical trials. Results of the qualitative research that provided the foundation for the new measures support the content validity of the IBS patient-reported outcome measures. A pilot study was recently initiated to inform item reduction, develop scoring algorithms, and provide preliminary psychometric information. These results were published in the April 2017 issue of *Value In Health*.

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RTI Health Solutions®

Patient compliance on cost-effectiveness of H. pylori tests

Case Study

We conducted a study to evaluate the cost-effectiveness of urea breath tests (UBT), fecal antigen tests (FAT), and serologic tests (SAT) for initial diagnosis of H. pylori infection in a population with a relatively high prevalence of H. pylori infection. Although the costeffectiveness of various H. pylori test options has been published, none of the previous models incorporated patient preference and compliance in the analysis. The study concluded that UBT is the most cost-effective test after adjusting for patient compliance. Study results were presented as a poster at the 79th Annual Scientific Meeting of the American College of Gastroenterology, Oct 17, 2014.

Estimates for incomplete information in drug safety study

Case Study

A study to evaluate the risk of sudden cardiac death related to oral domperidone (DOM) required a detailed assessment of the daily dose and duration of exposure to DOM. Using all available data in the Clinical Practice Research Datalink (CPRD) prescription records, freetext field, and a questionnaire sent to CPRD physicians, we were able to estimate dose in CPRD GOLD when the recorded information was not complete. Results were published in Pharmacoepidemiology and Drug Safety, 2014;23(S1):329.

Observational study to determine key driver of decreased costs

Case Study

We conducted an observational cohort study to assess the association between adherence to oral 5-aminosalicylates (5-ASAs) and allcause costs and health care utilization among patients with active ulcerative colitis (UC) in the United States. We concluded the key driver of decreased costs among adherent patients was inpatient hospitalizations, which more than offset these patients' expected higher pharmacy costs. Study results were published in BMC Gastroenterology, 2012 Sep 1;12(Sept):132.

Phase II trial to demonstrate efficacy of asimadoline for adequate relief of IBS

Case Study

We conducted a study to evaluate the effects of three doses of asimadoline and placebo in subjects with IBS through a Phase II double-blind, randomized, placebo-controlled trial. In diarrhoea-predominant IBS patients with at least baseline moderate pain, asimadoline (0.5 mg) produced significant improvement on total number of months with adequate relief of IBS pain or discomfort, adequate relief of IBS symptoms, pain scores, pain free days, urgency and stool frequency. In patients with alternating IBS, significant improvement was seen on adequate relief endpoints. Asimadoline was also shown to be well-tolerated. The results of the study were published in *Alimentary Pharmacology & Therapeutics* 2008 Jul 1;28(2):239-49.