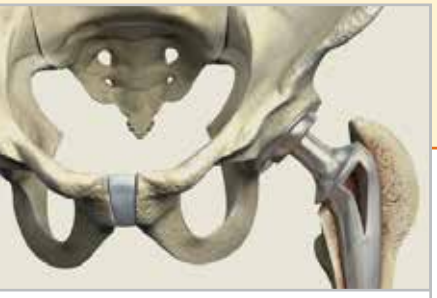
RTI(h)(s) RTI HEALTH SOLUTIONS®



Diagnostics and Medical Device Experience

A Wealth of Experience

At RTI Health Solutions (RTI-HS), we understand the medical device and diagnostics development and commercialization process, and appreciate the differences compared to pharmaceutical development. We help our clients develop and present evidence to demonstrate the value of their devices and tests. We provide guidance on health economic and outcomes measures that will be critical in payers reimbursement decisions. Our experience includes:

- Cardiovascular devices
- Cellular therapies that require device delivery systems
- Contrast media and dye
- Diabetes monitoring and therapeutic devices
- Imaging technologies
- Implantable and laparoscopic devices
- Injection devices
- Lap-band devices
- Molecular diagnostics and personalized medicine products
- Novel drug delivery systems
- Orthopedic devices
- Pain management devices

Types of Projects

We have implemented numerous projects that have helped our clients develop and gain market access for medical device and diagnostics products. Recent projects have included:

- Qualitative and quantitative market access research with payers and physicians
- Commercialization and reimbursement strategies that include:
  - Coding, coverage, and payment analysis
  - Competitor analysis
  - Health policy implications
  - Evaluation of payer and health technology assessment (HTA) agency requirements
  - Limited intellectual property (IP) protection for some products
  - Regulatory pathway implications
- Payer and physician engagement and communication
  - Payer advisory boards, interviews, and surveys
  - Global value and reimbursement dossiers
  - Product value message development and communications support
  - Development of reimbursement submissions for global payers and HTA agencies
- Health outcomes and economics evidence development strategy and implementation
  - Protocol development and review for clinical trials and observational studies
  - HTA and coverage policy analysis of proxy products
  - Clinical trials, observational studies, and registries
  - Patient-reported outcomes
  - Health preference assessment
- Decision-analytic modeling to support product reimbursement
- Reimbursement due diligence, portfolio analysis, and investment valuation

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Our experts in diagnostics and medical device include

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Diagnostics and Medical Device Experience

See How We've Helped Others

Reimbursement Strategy for an Allogeneic Stem Cell Therapy

RTI-HS assisted a cellular therapy manufacturer in developing a US reimbursement strategy for a novel allogeneic therapy. We assessed coding, analyzed coverage limitations, identified payment levels associated with relevant procedural steps, and conducted payer research to characterize the reimbursement environment.

Decision Tool to Inform Portfolio Reimbursement Planning

RTI-HS developed a decision support tool to assist a global medical device and diagnostics manufacturer in identifying core technologies that face significant reimbursement hurdles. The tool enabled the client to identify and prioritize portfolio technologies for the following reimbursement support: development of product value dossiers, direct payer engagement, outcomes research, and new pricing and contracting strategies to improve reimbursement and market access.

Reimbursement Strategy Support for a Molecular Diagnostic

We helped a molecular diagnostic manufacturer create a strategy for evidence development and outcomes and payer communication. Their goal was to improve uptake of a cardiovascular test that had reached the market but faced reimbursement challenges. Project deliverables included input on clinical study design, health economic modeling, payer research, and reimbursement strategy.

Value Dossier to Demonstrate the Value of Imaging

We developed a reimbursement dossier to characterize the clinical and economic value of a cardiovascular imaging modality that faced coverage and patient access challenges in the US. This dossier served as the basis for consistent communication with commercial payers. We also assisted in implementing payer engagement and communication strategies.

Patient-Reported Outcomes, Regulatory, and Reimbursement Strategy for a Knee Repair Product

We assisted a leading global medical device manufacturer in establishing a patient-reported outcomes (PRO) strategy for a therapy for knee cartilage repair. Deliverables included perspectives on the likelihood of achieving a PRO label claim, payer interviews to identify pain and functional PRO endpoints, and patient outcomes required for US commercial payer reimbursement.

Payer Research to Inform a Device Investment Decision

Our client was considering investing in a new orthopedic device. We interviewed payers to help the client better understand the reimbursement landscape. Findings characterized the likelihood of product reimbursement success, identified clinical and economic outcomes relevant to payers, and helped the client make an informed investment decision.

Selected Publications and Presentations By Our Staff

Clark M, Hofmann A, Tabberer M, **Martin S.** Development and Content Validity of the COPD Device Preference Questionnaire. Poster Presented at: ISPOR 14th Annual European Congress, Madrid, Spain, November 5-8, 2011.

Earnshaw, S.R., **C. McDade**, A.M. Chapman, D. Jackson, and L. Schwamm. Economic impact of using additional diagnostic tests to better select patients with stroke for intravenous thrombolysis in the United Kingdom. Clinical Therapeutics. 2012;34(7):1544-1558.

Earnshaw SR, Jackson D, Farkouh R, Schwamm L. Cost-effectiveness of patient selection using penumbral-based MRI for intravenous thrombolysis. Stroke. 2009; 40(5):1710-20.

Faulkner E, **Khan S**. Key considerations for development of evidence dossiers for pharmaceuticals vs. diagnostics or medical devices. Poster presented at: Academy of Managed Care Pharmacy Annual Meeting; 2010 Apr 7; San Diego, CA.

Faulkner E, **Khan S**, Watkins J, Polkus V. Making a case for value: differences in dossier development and value communication for pharmaceuticals versus diagnostics and medical devices. Workshop conducted at: ISPOR 15th Annual International Meeting; 2010 May 15-19; Atlanta, GA.

Jackson D, **Earnshaw SR**, Farkouh R, Schwamm L. Cost-effectiveness of CT perfusion for selecting patients for intravenous thrombolysis: a US hospital perspective. Am J Neuroradiol. 2010;31(9):1669-74.

Kauf TL, Farkouh RA, **Earnshaw SR**, Watson ME, Maroudas P, Chambers MG. Economic efficiency of genetic screening to inform the use of abacavir sulfate in the treatment of HIV. Pharmacoeconomics. 2010;28(11):1025-39.

Knight SJ, Mohamed A, **Johnson FR**, Marshall DA, Ladabaum U, Phillips KA, Walsh J. Preferences for Genetic Testing to Assess Colon Cancer Risks. Poster presented at: ISPOR 16th Annual International Meeting, Baltimore, Maryland, May 21-25, 2011.

Mladsi DM, Redekop K, Goettsch, **Earnshaw SE**. Challenges and insights in establishing and communicating the economic value of companion diagnostics. Workshop conducted at: ISPOR 13th Annual European Congress; 2010 Nov 6-9; Prague, Czech Republic.

EXPDiagnostics&MedDev.1013