RTI(h)(s) RTI HEALTH SOLUTIONS®

Dermatology Experience

More than 30 staff with experience in dermatology projects including

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A Wealth of Experience

At RTI Health Solutions, we have collaborated with our clients on more than 150 projects researching cutaneous diseases, cutaneous treatments, and complications and comorbidities of cutaneous diseases. Our experience includes:

- Acne
- Alopecia
- Atopic dermatitis
- Dry skin
- Eczema
- Herpes
- Psoriasis
- Skin cancer
  - Basal cell carcinoma
  - Squamous cell carcinoma
  - Melanoma
- Stevens-Johnson syndrome
- Systemic lupus erythematosus
- Toxic epidermal necrolysis
- Warts

Types of Projects

We have implemented studies to help our clients develop strategies in the dermatology market and develop and gain market access for products to treat cutaneous diseases and complications arising from treatment of cutaneous illnesses. Recent projects have included:

- Epidemiology of disease
- Retrospective analyses using longitudinal databases
- Patient-reported outcomes (PRO) instrument development, psychometric evaluation, and validation
- Decision-analytic modeling to examine
  - Cost-effectiveness
  - Budget impact
- Meta-analyses
- Gap analyses for HEOR strategy planning
- Measurement of patients' benefit-risk preferences and willingness to pay for treatment
- Economic burden of illness studies
- Systematic literature reviews
- Global value dossiers
- Value communication and reimbursement strategies
- Q-TWiST analyses (quality-adjusted time without symptoms or toxicities)
- Exploratory analyses of clinical trial data
- Abstract and manuscript development

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Dermatology Experience

See How We've Helped Others

Conjoint Analysis to Assess Patients' Preferences and Willingness to Pay for Treatment

We implemented a conjoint analysis study to estimate how the severity and size of psoriasis lesions affect patients' preferences and willingness to pay for treatments. The study asked patients about lesion severity, percentage of body surface area (BSA) covered by lesions, type of treatment, discomfort or pain from injection treatments, risk of serious lung infection, and monthly out-of-pocket cost. The study found that patients are willing to pay substantial amounts (up to $487 per month) to reduce lesion severity and percentage of BSA covered by lesions. Study results were published in *Journal of Dermatological Treatment*, 2011;22(5):266-75.

Economic Threshold Model for a Treatment for Atopic Dermatitis

We developed an economic threshold model to explore the potential clinical and economic value of a new product in development for the treatment of atopic dermatitis. The model was designed to evaluate the effects of using the new product in a variety of populations to demonstrate safety advantages compared to existing treatments. Additionally, the model allowed us to evaluate the effects of using the new product on sensitive parts of the body and on a larger percentage of body surface area compared with existing treatments. Our client was able to use the model to support early decisions about relevant comparators, pricing, and the design of phase 3 clinical trials for the new product.

Burden of Chronic Idiopathic Urticaria

We conducted an observational, non-interventional, multinational, multicenter study to identify and quantify the humanistic and economic burden of illness of chronic idiopathic urticaria (CIU) patients. The study yielded key data on the HRQOL and financial burden experienced by patients with CIU; providing real-world data to support the value proposition for treatment of CIU. Study results were published in *Allergy*, 2014 Jan;69(Suppl 99):122.

Daily Diary to Assess Psoriasis-Related Symptoms

We collaborated with a major pharmaceutical company to conduct a psychometric evaluation of phase 3 clinical trial data in support of a daily diary designed to measure symptoms related to psoriasis. In addition, we developed a PRO dossier to support FDA review of the diary. In January 2015, the FDA approved a label claim based on the diary. The psychometric evaluation was presented at the ISPOR 19th Annual International Meeting in November 2014.

Selected Publications and Presentations By Our Staff

Kauf TL, Yang JC, Kimball AB, Sundaram M, Bao Y, Okun M, Mulani P, **Hauber AB**, Johnson FR. Psoriasis patients' willingness to accept side-effect risks for improved treatment efficacy. J Dermatolog Trea. 2015 May 6. [Epub ahead of print]

Stull DE, **McBride DW**, **Houghton KF**, Balp MM. Correlation between changes in urticaria symptoms and sleep experience in patients with chronicspontaneous/idiopathic urticaria (CSU/CIU): a post-hoc analysis from 2 randomized, double-blind, placebo-controlled phase 3 trials of omalizumab. Poster presented at American Academy of Dermatology (AAD); 2015 Mar 20-24; San Francisco, CA.

Mitchell S, Balp MM, **Samuel M**, **McBride D**, Maurer M. Systematic review of treatments for chronic spontaneous urticaria with inadequate response to licensed first-line treatments. Int J Dermatol. 2014 Dec 16. [Epub ahead of print]

Hawe E, **Vickers AD**, Mallya UG, **McBride DW**, Capkun-Niggli G, Olson M, Thorlund K. Secukinumab 300mg demonstrates highest probability of efficacy than other biologics in psoriasis: indirect comparison. Poster presented at the 23rd European Academy of Dermatology and Venerology Congress; 2014 Oct 8; Amsterdam, The Netherlands.

Eastman WJ, Malahias S, Delconte J, **DiBenedetti D**. Assessing attributes of topical vehicles for the treatment of acne, atopic dermatitis, and plaque psoriasis. Cutis. 2014 Jul;94(1):46-53.

Mauskopf J, **Samuel M**, **McBride D**, Mallya UG, Feldman SR. Treatment sequencing after failure of the first biologic in cost-effectiveness models of psoriasis: a systematic review of published models and clinical practice guidelines. Pharmacoeconomics. 2014 Apr;32(4):395-409.

Sherrill B, **Wang J**, Kotapati S, Chin K. Q-TWiST analysis comparing ipilimumab/dacarbazine vs placebo/dacarbazine for patients with stage III/IV melanoma. Br J Cancer. 2013 Jul 9;109(1):8-13.

Norquist JM, Girman C, **Fehnel S**, **Demuro-Mercon C**, Santanello N. Choice of recall period for patient-reported outcome (PRO) measures: criteria for consideration. Qual Life Res. 2012 Aug 1;21(6):1016-20.

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