Biomarkers of Anti-TNF Treatment Efficacy in Rheumatoid Arthritis–Unresponsive Populations (BATTER-UP)

Research Areas

- Biomarker Research
  - Diagnostic, Genomic Biomarker
- Basic Research

At a Glance

- Status: Completed Consortium
- Year Launched: 2006
- Initiating Organization: Feinstein Institute for Medical Research
- Initiator Type: Academia
- Location: North America

Abstract

In a collaborative effort between the pharmaceutical industry, academia, and community rheumatologists, researchers are evaluating a new biomarker screening test that might help identify patients with rheumatoid arthritis (RA) who are unlikely to benefit from anti-tumor necrosis factor-α (TNFα) medications. Titled the “Biomarkers of Anti-TNF Treatment Efficacy in Rheumatoid Arthritis–Unresponsive Populations (BATTER-UP),” the consortium is enrolling 1,000 patients with moderate to severe disease who have had an unsatisfactory response to conventional disease-modifying antirheumatic drugs and are about to start treatment with an anti-TNF agent, or who have had an inadequate response to an initial anti-TNF drug and are about to switch to a different one.

Mission

The consortium seeks to validate biomarkers that predict patient response to anti-TNF therapy in an effort to advance personalized medicine for RA. The BATTER-UP trial will enroll approximately 1,000 patients being treated by one of several marketed anti-TNF RA drugs: Enbrel, Remicade, Humira, Simponi, or Cimzia. Through data analyses and predictive response modeling, the consortium aims to
better understand which patients with RA will derive the greatest benefit from TNF inhibitors.

The investigators in this observational study will attempt to validate an eight-gene biomarker set based on work by Biogen Idec researchers as likely to predict anti-TNF responsiveness in patients with RA. In preliminary results, the eight-gene biomarker set predicted with 89 percent accuracy individuals who did not reach EULAR DAS-28 “good” response after 14 weeks of treatment. The eight genes included in the screen are CLTB, MXRA7, CXorf52, COL4A3BP, YIPF6, FAM44A, SFRS2, and PGK1.

**Consortium History**

The consortium’s story begins in Dr. Peter K. Gregersen’s lab at the Feinstein Institute for Medical Research in Manhasset, New York. In 2004, Gregersen and his colleagues in the Auto-immune Biomarkers Collaborative Network (ABCoN) profiled gene expression in a prospective trial of 116 RA patients who were beginning anti-TNF therapies. In 2009, Carulli, Gregersen, and colleagues at Biogen and Feinstein streamlined these candidates to an eight-gene panel. In a Genomics paper, the team shows that the panel is 89 percent accurate in predicting anti-TNF response. Aware that validating the predictive power of these transcripts would require a large, prospective clinical trial, Carulli, Gregersen, and the others began recruiting collaborators from across academia and industry, and BATTER-UP was born.

**Structure & Governance**

The consortium is focused on improving care for people living with rheumatoid arthritis and is structured as an academia-industry collaboration. Leadership for this innovative approach to personalized medicine is provided by Dr. Peter K. Gregersen of the Feinstein Institute and Dr. Michael Weinblatt from Brigham and Women’s Hospital, Harvard University. The academic investigators direct consortium scientific activities through a Scientific Advisory Board and publication team to ensure rapid dissemination of research.

**Financing**

Joining forces to provide funding and operational support for the consortium are several companies
including Biogen Idec, Bristol-Myers Squibb, Centocor Research & Development, Crescendo Bioscience, Genentech, Medco Health Solutions, Regeneron Pharmaceuticals, and Sanofi-Aventis.

**Patent Engagement**

The BATTER-UP study, a multi-center, cross-sectional investigation of response to anti-TNF agents in RA, will enroll a cohort of approximately 1,000 patients who have been diagnosed with moderate to severe RA and who have been recently prescribed or have been receiving TNF inhibitor therapy. Additional study protocol details can be found at www.clinicaltrials.gov (reference #NCT01211678). Biological samples and clinical outcome information from the study will be used to confirm and extend the utility of previously published biomarkers that can predict response to anti-TNF agents. These data may also generate new hypotheses for further testing. The BATTER-UP samples and data will be established as a reference set for investigation of personalized medicine in RA.

**Impact/Accomplishment**

The study will be a resource of deoxyribonucleic acid (DNA) and other biological materials that can be investigated for biomarkers in the future as new technologies arise.

**Links/Social Media Feed**

Other website  www.clinicaltrials.gov

**Points of Contact**

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