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tivity in RA patients on methotrexate. The investigators found that patients carrying the minor allele of an ATIC single nucleotide polymorphism (SNP) were more likely to have lower disease activity after adjustment for other confounders (Rheumatology [Oxford] 2009;48:613-7). Similarly, in a multicohort study which included BRASS samples, those individuals with the protein tyrosinde phosphatase receptor type C (also known as the CD45 gene) had a better response to anti–tumor necrosis factor therapy than did those without the CD45 gene (Mol. Med. 2009;15:136-43).

RN: How have the genetic data been used in research to date?

Dr. Shadick: Our genetic researchers have analyzed the cohort using genome-wide association studies (GWAS) analyses which allow screening of a large number of genes, or SNPs, that are potentially associated with a number of RA outcomes. Pooling the results with other cohorts as well as controls without RA, the BRASS cohort data have helped determine new susceptibility genes for RA, genes that predict disease severity, nonerosive disease in RA, and earlier onset of RA.

RN: What are some of the clinical or genetic questions that the BRASS registry might help answer down the line?

Dr. Shadick: We would like to look more closely at gene/environment interactions that result in some RA comorbidities such as infection, certain cancers, RA that never erodes bone despite disease activity, and genetic predictors for RA-induced interstitial lung disease.

RN: What have been some of the challenges in the development, maintenance, and application of BRASS registry data?

Dr. Shadick: Maintaining a large patient database takes a well-organized team of researchers, physicians who contribute patient information, and RA patients who tirelessly remain in the study and fill out forms. However, many of the participants and the rheumatologists find participating in the BRASS registry rewarding, particularly when new scientific discovery occurs from the data. There are a few limitations in using registry data. For example, registry data (unlike randomized controlled trials) often lack the ability to evaluate drug efficacy. On the other hand, observational registries are more representative of the real-world population, and as such we are observing instead "real world effectiveness."

–Interview by Diana Mahoney

DR. SHADICK *is a rheumatologist at Brigham and Women's Hospital and on the faculty of Harvard Medical School in Boston. She has received research grant support from Biogen Idec, Crescendo Biosciences, and Amgen.*

Safety Reporting Rules Align FDA With the WHO

Investigational new drugs, including biologic drugs, will face new safety reporting requirements designed to increase timeliness as well as decrease unnecessary reporting of events not likely to be causal.

The changes bring the Food and Drug Administration's reporting policies in line with international agencies, including the World Health Organization (WHO).

The changes focus on the reporting of adverse events clearly linked to the drug that occur during animal or human testing of the agent.

Read our expanded coverage of this topic in upcoming issues.

Adherence to the former rule often resulted in reporting of events not likely to be associated with the drug, slowing recognition of truly causal effects, according to the draft guidance.

Under the new rule, applicants may submit only "suspected adverse reactions," defined as events for which there is "evidence to suggest a causal relationship between the drug and the adverse event," according to a FDA draft guidance for investigators.

Other reportable findings include data concerning bioequivalence of generic biologic drugs, compared with their name-brand counterparts – for example, differing rates of absorption into the bloodstream.

–Denise Napoli

To see the full text of the final rule, visit http://tinyurl.com/36fld9u.