RADAR-PGx Registry defining Adverse Drug Reaction (ADR) improvement measures with medication optimization for therapeutic effectiveness and safety. Medication Management utilizing Pharmacogenomic Testing

The way individuals metabolize medicine is often influenced by their genes. There is a known genetic variance from one individual to another. The study of the role genetics plays in the body’s ability to process medicine is called pharmacogenomics.

We are enrolling physicians to assist in gathering data for pharmacogenomic testing (PGx) to help manage subjects medication regimens and assess if testing can have a positive impact in avoiding adverse drug events, hospitalization and emergency department visits.

**Primary Objective**

To evaluate the use of PG Testing as medical necessity in the management of patients who are under treatment with several drugs with any of the sequences of biochemical reactions, catalyzed by enzymes, known to be influenced by genetic variations in a patient population.

**Secondary Objective**

To determine if the frequency of adverse drug events is reduced with PGx testing, and evaluate the therapeutic effects of PGx testing on the requirements for emergency department visits and hospitalizations for drug-related adverse events.

**Eligible Drug Classes**

- Analgesics
- Anti-infectives
- Antidepressants
- Anticonvulsants
- Antipsychotics
- Benzodiazepines
- CNS stimulants
- Methadone
- NSAIDs
- Proton inhibitors
- Statins
- Vasodilators
- Antiallergens
- Antiarythmics
- Anticoagulants
- Antiepileptics
- Antihypertensives
- Barbiturates
- Clopidogrel
- Diuretics
- Muscle relaxers
- Opioids
- SSRIs
- Steroids

**Inclusion Criteria**

1. Patient is a male or female over 25 years of age.
2. Patient was receiving at least one medication known to be associated with allelic variation at the time of the index PGx test, including over-the-counter medications;
3. Patient has a history of at least one Target Adverse Event (TDAE) over the 24 month period preceding receipt of PGx test results, or has experienced inadequate therapeutic efficacy from a target drug;
4. Patient underwent PGx testing for alleles appropriate to the target drugs within the prior 120 days (“index PGx test”);
5. Patient is able and willing to provide written informed consent;

**Exclusion Criteria**

Patients will be excluded if any of the following criteria apply:

1. Patient is unable to provide an accurate history due to mental incapacity;
2. Patient is currently hospitalized;
3. Patient’s medical and medication history is unavailable over the 120-day period preceding the receipt of PGx test results;
4. Subject is known to have undergone prior PGx testing for genes specific to the target drug(s), exclusive of the PGx test relating to this Registry.

**Genomic Assessments**

The Registry will assess genes associated with a patient’s target medications or with substitute medications considered as replacements for target drugs.

Additional genes and variants maybe included in the protocol as the body of knowledge in PGx testing expands.

This is intended as a general overview of the protocol and benefits. If you have questions pertaining to the clinical study, honorarium or administration of testing, please contact your local account manager.

Honorarium

An honorarium is available to physicians upon completion of the trial survey for patients enrolled in the study.