PRA Health Sciences

SLIP SHEET

Pharmacogenomics in Pain Management: Navigating the Path to Personalized Pain Therapy

Our Expertise

PRA Health Sciences provides a range of pharmacogenomics services across the product life cycle,led by a multi-disciplinary group with members from Pharmacovigilance & Patient Safety, Scientific Affairs, Medical Affairs, Real World Solutions, Early Development Services, and Marketing. Services include:

- Protocol consultation and development
- Informed consent consultation and development
- Patient screening
- Laboratory services (in partnership with a laboratory with expertise in sample collection, DNA extraction, and biomarker identification)
- Consulting on summary of product characteristics (SmPC) pharmacogenomics-related sections
- Developing pharmacogenomic information for product labeling
- Sample repository with a biobank in Germany
- Risk management, including pharmacogenomics-related signal management and risk minimization strategy and measurement
- Effectiveness measurement

Members of our Pharmacogenomics group are also board members of the European Society of Pharmacogenomics and Personalised Therapy, an organization committed to transcending boundaries of geography and industry and developing the field of pharmacogenomics and personalized medicine.

"To encourage genetic testing as a widespread part of clinical research, we use genome-associated studies to unlock the genetic puzzle and identify full genetic signatures for pain and pain treatment."

LYNN R WEBSTER, MD
Vice President, Scientific Affairs

The Landscape

In the US, an estimated 100 million adults suffer with chronic pain. Approximately 80% of people undergoing surgery report some degree of post-operative pain; of these, less than 50% feel they received adequate pain relief and 10-50% develop chronic pain. The estimated annual national cost of pain management is $560-635 million.

The Challenge

More than 12 million Americans receive some form of opioid therapy to manage pain. Recent high-profile deaths have called attention to the potential dangers of opioid use, and have stimulated a global cultural movement to decrease reliance on opioid therapy for pain management and increase research into alternatives.

The Solution

Scientists are beginning to examine the genetic variations that may influence pain processing. If a genetic factor determines the expression and perception of pain—including the varying mechanisms of nociceptive, neuropathic, and visceral pain—the potential exists for new analgesic targets affecting those genes.

Pharmacogenomics (studying the entire genome) and pharmacogenetics (studying specific candidate genes) have emerged as important disciplines in assessing the safety and efficacy of treatments. Their goal in clinical trials is to develop effective, safe medications and dosing that can be tailored to individual genetic profiles.

Pharmacogenetic assessments can benefit clinical trials in 3 ways:

1. Optimizing pharmacovigilance by identifying individuals at risk for adverse drug reactions
2. Recommending therapeutic dose regimens of specific drugs for specific populations, both during clinical trials and in the post-marketing setting
3. Improving clinical research and post-marketing treatment by stratifying populations based on genetic differences and susceptibility to drug activity