

EXECUTIVE SUMMARY

Genetic testing can provide additional insight for pharmacists and physicians seeking to find the right treatments for their patients. This science—pharmacogenomics (PGx)—is well studied, included on US FDA drug labels, and is supported by reliable testing technologies. The big challenge has been how to employ these new insights, at population scale, and in the context of the health delivery models that exist today.

Coriell Life Sciences (CLS) has developed a modular delivery framework and supporting tools that supplement and enhance the pharmacy services companies and payers rely on now. Key to this is the elevation of the Pharmacist as the medication specialist and case manager in the patient care continuum. Trained Pharmacists are empowered with dynamic clinical decision support tools that draw together genetic and non-genetic risk factors and allow for real-time modeling of alternatives. Pharmacists become the lynchpin experts delivering comprehensive treatment recommendations to the patient's own clinicians.

Equally important is knowing who is appropriate to test and review in the first place, and accurately measuring the results of the program as it progresses. CLS wraps the core implementation with population analytics of claims data to ensure that the right people are targeted for engagement and the ROI achieved is visible and predictable.

CLS is uniquely suited to partner with healthcare companies to provide medication clinical decision support by incorporating genetic and non-genetic information to personalize clinical recommendations for every patient. We have been recognized as a research thought leader and commercial solution provider for pharmacogenomics, and more broadly, medication safety management.

CLS's Solution

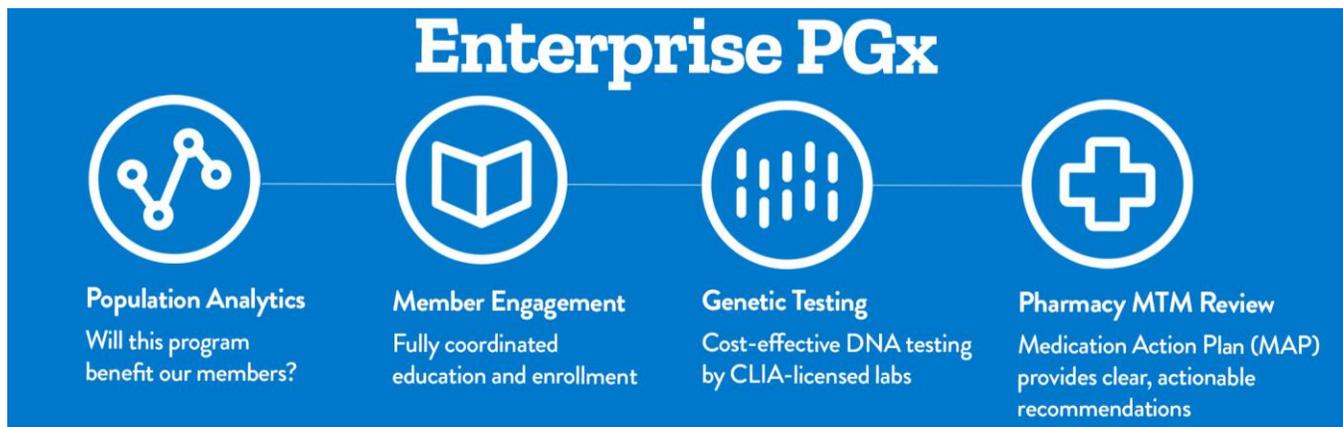
We know the science of pharmacogenomics to be important and exciting when prescribing medications. Genetic variation can cause significant differences between individuals using the same treatments. Coriell Life Sciences has developed an ever-expanding knowledge base, along with an interpretation and reporting engine for Pharmacogenomics that combines the best available guidance with evidence-driven evaluation to produce a truly clinical grade result. However, pharmacogenomic testing is just one aspect of medication risk and should not be relied upon as the only tool for treatment guidance. Used in conjunction with risk factors considered during a more traditional comprehensive Medication Therapy Management (MTM) review, physicians and pharmacists can achieve a far greater level of insight. The relative importance of individualized genetic risks needs to be weighed on a common scale with factors like drug-drug interactions, age-related risks, anticholinergic burden, pregnancy risks, lifestyle/food risks, and more.

CLS's suite of personalized medicine decision support tools does exactly that. The tools integrate over a dozen medication risks factors and provide an easy-to-understand, clinically-actionable report. They are designed to quickly show physicians and pharmacists which medications present risks for that individual and which ones are likely to be effective. The tools present alternative options in the context of the patient's illnesses, drug regimen, and cost concerns, and can be limited to specific in-patient and out-patient formularies, as necessary. This increases the chances of achieving the desired therapeutic effect, reduces risk to the patient, lowers the cost of healthcare, and increases patient satisfaction.

Coriell Life Sciences offers a comprehensive solution to integrate a medication clinical decision platform based on pharmacogenomic testing. Our extensive experience working with large healthcare organizations and our collection of cutting-edge products allows CLS to quickly and seamlessly introduce this new service with a zero-disruption implementation.

SUMMARY OF CORIELL LIFE SCIENCES' PRODUCTS AND SERVICES

Coriell Life Sciences has developed an easy-to-use suite of medication safety products that bridge the gap between genetic science and clinical utility. For the Teachers' Retirement System of Kentucky (TRS-KY), we provided a turnkey solution that included population analysis, member outreach and enrollment, DNA testing, and medication therapy management with communication to each participating member's primary care physician.



Population Analytics

CLS's risk analysis system can be used in advance of patient implementation to surface the "high risk/likely-to-benefit" members of a healthcare system answering quickly and definitively, "Who should we test?"

To answer this question, Coriell Life Sciences goes beyond looking at just polypharmacy or disease conditions as rough filter testing criteria. CLS's analysis provides a holistic picture of both known and possible risks in a visual and measurable form. This assessment is "tune-able" by the healthcare customer to reflect differences in payer models. Since CLS's risk assessment system provides a quantitative risk score, it is straightforward to set a threshold for risk that includes both genetic and non-genetic factors.

The CLS Testing Appropriateness Algorithm incorporates a risk score based on potential genetic risk, drug-drug interaction risk, anticholinergic burden risk, age-related toxicity risk, adverse drug reaction (ADR), and black box warnings, together with medical history of ADRs, slip-and-falls, conditions with known PGx implications, cost to the healthcare system, member age, as well as de-prioritizing factors. The resulting analysis produces a rank-ordered list of all members showing who would be appropriate for testing and who should be discouraged from participating.

Through the process, one can be assured that only those members who stand to benefit will be targeted for testing and MTM review.

MEMBER ENGAGEMENT

Our experience shows that approximately 30% of invited members choose to enroll in the Coriell Life Sciences (CLS) Enterprise PGx program. We achieve and build on enrollment through a robust combination of education, outreach, and direct communication. CLS works with each partner to build a custom engagement strategy and suite of materials uniquely aligned to their employees. Tone, privacy concerns, and health-related questions are addressed early in the conversation to ensure a comfort level and sustain an ongoing relationship. Members consistently report high satisfaction, become advocates for their own health care, and act as program ambassadors

amongst their peers.

GENETIC TESTING

DNA testing begins with the member submitting a DNA sample to our laboratory network. A collection kit with simple instructions, a consent form, and a tube/swab for the collection of a small amount of DNA is sent to the member. After collecting the sample, the member returns the kit to the laboratory for testing in the same postage pre-paid box in which it arrived. The assays used to detect clinically-relevant changes take less than 48 hours to complete and do not uncover health concerns outside of the pertinent pharmacogenomic information. A comprehensive panel, co-developed by CLS and Thermo Fisher Scientific, is run on all samples to provide the best available guidance for medication response today and in the future. The panel is inclusive of:

- All drugs with PGx guidance on FDA drug labels
- All drugs with high or emerging evidence noted by CPIC
- All drugs with high or emerging evidence noted by the Dutch PGx Working Group
- All drugs approved for clinical release by the Coriell Pharmacogenomic Advisory Group

DNA collection can be done in several ways. Cheek swabs (buccal) and saliva collection kits are the most common and non-invasive methods. CLS provides either Coriell Life Sciences-branded collection kits or custom branded kits as required. Saliva kits are generally recommended for in-home collection due to the durability and longevity of the samples collected.

MEDICATION SAFETY MANAGEMENT REVIEW & MEDICATION ACTION PLANNING

With each GeneDose report, a record is provisioned into Coriell's GeneDose LIVE system for use by our pharmacists in the care of that patient. GeneDose LIVE is a cloud-hosted medication safety modeling system that provides real-time access to genetic and non-genetic risk information and immediate recommendation and modeling of alternative medications that meet the same therapeutic intent as the targeted change. GeneDose LIVE serves to empower practitioners by placing the genetic results in apple-to-apples context with the risk vectors they already evaluate.

A comprehensive Medication Action Plan (MAP) is delivered to the member's prescribing physician guiding the PGx and risk assessment into action. The combinatorial effects of risk, genetic and otherwise, are simplified into report that presents medications to add, remove, change dosing, and keep the same.

Proven Results

Last year the Teachers' Retirement System of Kentucky began offering pharmacogenomic testing and medication review through Coriell Life Sciences with its 35,000 members. After the first year, with more than 8,000 members enrolled, the benefits to the members and the pension fund were clearly demonstrated.

In an analysis of healthcare claims data of those individuals who had undergone testing and review, the following were found:

- **Incidents of medication related medical events dropped by 29%**
- **Total healthcare costs for those tested vs. a risk-normalized control group dropped by 12%**
- **Hospitalizations were reduced by 29%**

- **Overall pharmacy spend reduced by 11%**
- **Patients reported 4.8 stars out of 5 in satisfaction surveys**

Benefit

Coriell Life Sciences is a leader in the field of pharmacogenomics and medication risk management. Our unique and innovative technological solutions are coupled with rigorous and vigilant focus on the science of genetics. Coriell has published dozens of papers with findings from our research activities in pharmacogenomics and personalized medicine. The pioneering Coriell methodology used to curate other research for inclusion in our products has likewise been published and peer reviewed.

As a collaborator, CLS:

- Is your trusted advisor with a foundation of decades of research
- Brings real world implementation experience in large scale populations
- Has proven tools and technologies making a difference in patients' lives today
- Is agnostic to laboratory technologies allowing a seamless transition from outsourced testing to in-house fulfillment when the time is right
- Maintains ongoing scientific vigilance to ensure up to date gene-drug interpretations
- Provides healthcare practitioners with what they actually need: **Immediate Recommendations in Plain Language**

Why do we think that our organization deserves to win the PBMI Excellence Award?

Coriell Life Sciences Enterprise PGx program was implemented by TRS-KY to address medication management issues in their population. The goal was to realize a reduction in healthcare spending as well as improved care for their members. This program combines cutting edge genomic medicine with individualized medication review by pharmacists. It is a novel approach to the skyrocketing epidemic of wasted pharmacy spend on ineffective, and often dangerous, medications. The results have been overwhelmingly well received by the members and their physicians. We believe that what we have done with TRS-KY is innovative and will have a real impact across both the public and private sectors. Recognition by the PBMI Excellence Award would help to raise awareness among other organizations so that these same results could be replicated elsewhere.

Conclusion

Coriell Life Sciences brings a depth of scientific and clinical expertise to positively impact public health. We demonstrate a unique ability to execute commercially and can ensure success for state-run retirement systems like TRS-KY and responsible companies in charge of employee and member health and well-being. We have crafted our model to address what is right for the patient and the payer. CLS's network of laboratories, software tools, and customer-focused resources stand at the ready.