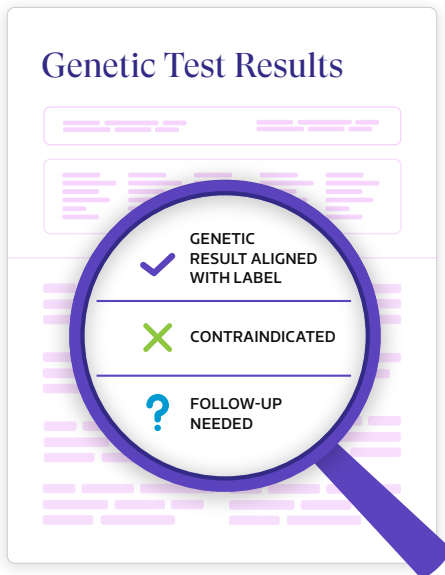


Biopharma Company Ensures Optimal Patient Inclusion with Genetic Eligibility Verification Program

Confirming Patient Genotype Match for On-Label Therapy Usage



Before the launch of a first-to-market rare disease therapy, a global pharmaceutical company (Company) decided to implement a genetic test result review program to ensure that patients whose healthcare provider submitted a product enrollment form had a genetic report consistent with the genetic indication and contraindication in the prescribing information.

Because of the high complexity of the eligibility requirements, the Company recognized the need for external genetics expertise to build and support a fully operationalized genetic eligibility verification program. Additionally, the company's compliance team advised an external eligibility review program to reduce any perceived bias in the review process.

Advisory Services Partnership Accelerates Path Forward

A COLLABORATIVE PARTNERSHIP

The Company partnered with Genome Medical, the leading telegenetics care delivery company, to design and implement a genetic eligibility verification program in support of its commercial launch.

Leveraging Genome Medical's expertise in genetics program development, the Company's internal teams were able to focus on other facets of the commercial launch. In addition, Genome Medical's certified genetic counselors were engaged to staff the program once it launched.

PROGRAM GOALS

The goal of the program is to allow the Company to accurately, efficiently, and consistently verify that a patient's genetic results are aligned with the label as part of the enrollment submission process. The program also augments efforts to educate physicians about the genetic contraindications detailed in the prescribing information.

After collecting and reviewing all of a patient's genetic test results, Genome Medical provided one of three recommendations to the Company:

- Confirmation that the prescribed patient met the genetic result label requirements
- Determination that the patient was contraindicated based on their genetic variant
- Determination that additional data or testing is needed before proceeding with dosing

BENEFITS OF ELIGIBILITY VERIFICATION FOR COMPANY

- Consistently apply genetic eligibility requirements across clinical trial sites/populations
- Reduce exclusion of eligible patients due to genetic test result misinterpretation
- Reduce patient risks (e.g. patients with exclusionary criteria or contraindications)
- Maximize genomic research opportunities through systematic data collection

Genetics Expertise Streamlines Program Development

Genome Medical's Advisory Services team worked with the Company's Medical, Commercial, and Patient Services teams to develop and launch the new genetic eligibility verification program by applying evidence-based guidance for genetics program development.



DESIGN

- Identified data sources needed to determine eligibility
- Determined data collection requirements
- Developed workflows and KPI metrics
- Recruited and onboarded external scientific advisory board



BUILD

- Built data sharing infrastructure and partner integration
- Developed standard operating procedures and policies



TESTING/TRAINING

- Onboarded Genome Medical genetic counselors
- Completed launch readiness testing
- Developed quality audit plan



LAUNCH

- Initiated program
- Staffed program with certified genetic counselors and program support staff



IMPROVEMENT

- Ongoing project management: weekly meetings and KPI assessments
- Coordinated scientific expert committee as needed for advice on the program

Verification Program Strengthens Commercialization Efforts

Through the partnership with Genome Medical, the Company successfully built and implemented the genetic eligibility verification program to support its commercial goals. The program enabled the Company to ensure that every patient prescribed the new medication appropriately aligns with the genetic indication on the FDA label.

The program has met all target key performance indicators including:

- **Timeline:** Completed comprehensive end-to-end testing and program readiness assessments in advance of FDA approval.
- **Capacity:** Program has capacity to support 250 case reviews per month.
- **Turnaround:** Each case review is completed within 2 business days. Genome Medical often exceeds expected case review turnaround times.
- **Coverage:** Company has consistent access to certified genetic counselors across the U.S. every business day.

HOW THE PROGRAM WORKS

Therapy Ordered

Prescribing physician submits an enrollment form including a copy of the genetic test.

Referral to Program

The Company sends information to Genome Medical, indicating standard or STAT turnaround.

Genetics Review

Two Genome Medical genetic counselors review each patient case, align on a result outcome, and submit key data to the Company.

Fulfill Order or Discuss

Based on verification of aligned genetic result the case proceeds through the process or if follow-up is needed, facilitates discussion with the ordering provider.

Learn more about our Advisory Services at GenomeMedical.com/Advisory
Contact us at info@genomemedical.com