InformedDNA®
Genetics, Decoded.

Strategies for Genetic Data Use and Compliance in Clinical Trials

As the number of personalized medicine therapeutics in clinical trials grows, sponsors face an increased need for genetic data from clinical trial candidates AND a plan for adhering to guidelines regarding the collection, use, and storage of that data.

InformedDNA helps sponsors develop and implement genetic screening programs that meet national guidelines, and obtain impactful data.

Key ways clinical genetics experts can help your trials:

- ✔ **Test result adjudication**
- ✔ **VUS (variants of uncertain significance) resolution support and family outreach**
- ✔ **Genotype/phenotype data analysis and review**
- ✔ **Collection of patient-reported outcomes and real-world evidence data for FDA submission**

Sponsors want...	Our solution
Direct to patient outreach	Creates IRB-approved, compliant programs that utilize telemedicine support and ship test kits to patients' homes
Maximum genetic data	Obtains consent from patients and facilitates data transfer from lab to sponsor
Clinical data for genotype/phenotype analysis	Reviews medical records and obtains additional medical and family history from patients, and provides reports to sponsor

National guidelines state...	Our solution
Genetic testing should be applicable for study population	Partners with any lab to create custom genetic screening tests to reduce clinical uncertainty for patients and optimize genetic data for research
Informed consent must be obtained for ALL testing performed	Develops informed consent protocols that enable research beyond screening for current study
Study documents must be communicated at an appropriate reading level, including process for children	Delivers deep genetics content library with reports written at minimum reading level, across diseases
Genetic test results should be returned by a knowledgeable genetics provider	Implements genetic counseling program to ensure that all screened patients consistently receive results at their level of understanding
Ordering clinicians must have a plan for disclosure of updated genetic test results	Reviews and contacts patients and providers with updated genetic test results, with interpretation of medical management impact

Maximizing Data, Minimizing Risk: A Case Study

InformedDNA partnered with an emerging biotechnology company, in support of its CRISPR-based clinical trial, to:

Collaborated with the genetic testing lab to create a more targeted test with less clinical uncertainty. **This resulted in a more targeted test with improved clinical utility and a 55% reduction in the number of VUS findings.**

Provide direct to patient outreach with telemedicine support, remote consent, and genetic test kits sent to patient homes. **Incorporating telemedicine screening increases patient participation AND decreases cost by reducing on site evaluations.**

Resolve VUS when possible, through facilitation of family member testing.

Collect and report patient experience data to aid in needs assessment for additional clinical trial sites and changes in study design to meet the needs of the patient population.

The InformedDNA Advantage

- Nation's largest staff of board-certified genetic counselors trained in ALL genetics sub-specialties
- Telemedicine platform supports patients nationally, with screening prior to referral to trial site
- Subject matter experts are well respected and have trusted relationships with referring healthcare providers
- Ensures clinical programs meet national guidelines and recommendations for genetic data collection, use, and reporting

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We've helped many clinical trial sponsors meet enrollment targets by engaging, screening, and recruiting appropriate clinical trial candidates remotely. Let's talk about how we can support your clinical programs.

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