

Accelerating Genetics-Enabled Clinical Trials & Research

Genetic counseling access together with genetics-focused administrative, operational, coordination, and educational support for genetics-enabled clinical trials and research programs.

For sponsors, CROs, and research teams integrating genetics into clinical trial design and delivery

The Evolving Role of Genetics in Clinical Trials & Research

As precision medicine continues to evolve, genetics is playing an increasingly important role in clinical trials and research. From biomarker-driven enrollment and genomic sequencing to pharmacogenomics, hereditary risk assessment, and return-of-results workflows, many studies now include genetics as an integral component of protocol design and participant engagement. These advances create new operational, participant education, and coordination needs that often require specialized genetics expertise.

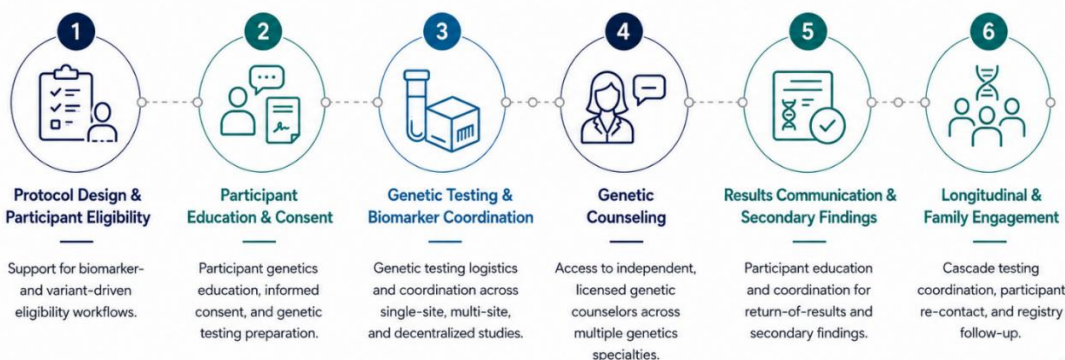
Genetics-Focused Research Challenges

Many organizations lack dedicated genetic counselors and the specialized expertise needed to support participant education, testing coordination, and results communication, while study teams are often stretched across competing priorities. These challenges may include:

- Access to genetic counselors across research sites
- Return of genetic results and secondary findings
- Genetics-related consent complexity
- Family communication and cascade testing
- Participant education and enrollment challenges
- Decentralized participant engagement
- Multi-state genetic counseling access

Key Genetics Touchpoints in Clinical Research

Genetics expertise may be integrated at multiple stages of the research lifecycle, depending on protocol needs.



FLEXIBLE SUPPORT. GeneticCare360™ can engage at one or multiple touchpoints based on the needs of your protocol, participants, and research objectives.



How GeneticCare360™ Supports Clinical Research

GeneticCare360™ provides access to genetic counselors together with genetics-focused administrative, operational, coordination, and educational resources that integrate seamlessly into existing clinical research programs.

Support may include participant education, multispecialty genetic counseling, genetic testing coordination, laboratory workflow support, telehealth delivery, multi-site and decentralized study support, and multi-state licensure coordination.

Resources are tailored to each study and may include licensed genetic counselors, pharmacogenomics consultants, laboratory specialists, genetics operations expertise, and research coordination support, whether for a single protocol, one therapeutic area, or a multi-study portfolio.

Core Capabilities

Genetic Counseling Access Independent licensed genetic counselors across multiple genetics specialties.	Multispecialty Genetics Support Hereditary cancer, rare disease, prenatal, pharmacogenomics, tumor profiling, cardiogenomics, neurogenomics, and other genetics-enabled research.	Genetics Operations & Research Coordination Participant support, testing coordination, laboratory workflows, research coordination, and protocol implementation support.	Nationwide Telehealth & Multi-State Coverage Secure telehealth delivery and multi-state licensure coordination for decentralized and multi-site studies.
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Programs We Support

GeneticCare360™ is well-suited for programs where genetic information plays a central role in participant identification, engagement, or communication.

Program Type	Common Challenge	How GeneticCare360™ Helps
Precision Oncology	<i>Biomarker screening and tumor profiling; germline reflex and hereditary findings; return-of-results and cascade needs</i>	Tumor profiling and biomarker testing coordination , germline reflex-testing workflows, participant resources on somatic & germline findings, and return-of-results coordination aligned to protocol requirements
Pharmacogenomics	<i>Protocol-required PGx, companion diagnostics, or pre-treatment safety genotyping (e.g., DPYD, TPMT/NUDT15, UGT1A1) with sample- and decentralized-collection logistics</i>	Coordination of PGx and companion-diagnostic testing , sample collection, and decentralized/home-collection logistics; education alongside protocol-aligned pharmacogenomics support
Rare Disease	<i>Diagnostic odyssey, families need navigation; family-based engagement critical</i>	Family history support and variant education , cascade communication resources, at-risk relative outreach, and coordination of extended family testing needs
Gene Therapy & Genomic Medicine	<i>Complex informed consent; secondary finding disclosure protocols required</i>	Pre-consent genetic education and coordination support for secondary-findings disclosure workflows, aligned to ACMG recommendations and sponsor-defined consent protocols

Reproductive & Carrier Screening	<i>Participant understanding of inherited risk and reproductive implications</i>	Access to pre- and post-test counseling , family communication resources, coordination support, and participant education on inherited and reproductive risk
Decentralized & Hybrid Trials	<i>Limited genetics expertise across distributed sites; remote participant access</i>	Telehealth counseling access in confirmed licensure states; multi-site coordination; remote consent education across distributed research sites
Observational / Registry / Biobank	<i>Long-term engagement; re-contact when new findings emerge</i>	Longitudinal counseling access and re-contact support , ongoing participant education, and coordination for evolving findings over the life of the study
Population Genomics	<i>Large-scale participant support across diverse populations</i>	Flexible telehealth access across diverse participant populations, with coordination support for large-scale outreach, subject to licensure and capacity

How We Engage

Every engagement follows a structured, compliance-first path, from the first conversation through ongoing support.

1	Initial Discussion We learn your study type, therapeutic area, participant population, and genetic focus to understand where external genetics support fits.
2	Program-Specific Scoping We assess licensure coverage, capacity, workflow integration points, and program requirements, then develop the recommended service model, resource plan, and scope that form the basis of the proposal.
3	Proposal & Agreements We develop a program-specific proposal outlining the scope of services, commercial terms, and supporting agreements (MSA, BAA, and Scope of Work), defining roles, responsibilities, and compliance boundaries.
4	Onboarding & Integration We verify counselor licensure for your target states, assign resources, and align SOPs, systems, and communication workflows with your sites.
5	Ongoing Coordination & Support We deliver day-to-day coordination and participant engagement, with agreed reporting and regular check-ins so support adapts as your program evolves.

Let's Discuss Your Protocol

Initial conversations are scoping discussions; formal proposals are developed once program needs are confirmed

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GeneticCare360™ provides administrative, operational, coordination, and educational support for clinical research programs. Genetic counseling services are provided independently by licensed genetic counselors. GeneticCare360™ does not provide medical advice, diagnosis, treatment, or determine study eligibility, and all clinical and enrollment decisions remain with the sponsor, site, and investigators.