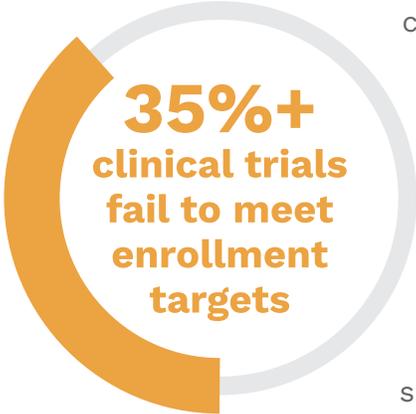




InformedDNA[®]
Genetics, Decoded.

Address Patient Identification Challenges for Gene Therapy Clinical Trials



35%+
clinical trials
fail to meet
enrollment
targets

Patient identification and enrollment continue to be the key challenges with clinical trials. Recent statistics show that over 85% of clinical trials are delayed* — with patient enrollment cited as the primary reason for those delays — and more than 35% of clinical trials failing to meet enrollment targets at all. Meeting enrollment targets is increasingly difficult as clinical trial populations become more targeted for precision medicine, focusing on specific genes or even specific genetic mutations, making small patient pools even smaller.

In order to ensure that clinical trials have the patients they need, sponsors and CROs need to expand their pool of potential participants.

Using Technology to Grow the Clinical Patient Pool

Traditionally, clinical trial sponsors have relied on large academic centers to find patients, largely bypassing community-based providers and patient advocacy groups as sources of patients due to the barriers associated with these populations:

- 1** Community physicians have limited time to devote to new programs, especially those that may only benefit a few of their patients.
- 2** Most community physicians are ill-equipped to facilitate, interpret, and disclose genetic test results to patients and families.
- 3** Rare diseases are frequently under-recognized and under-diagnosed outside of academic medical centers.

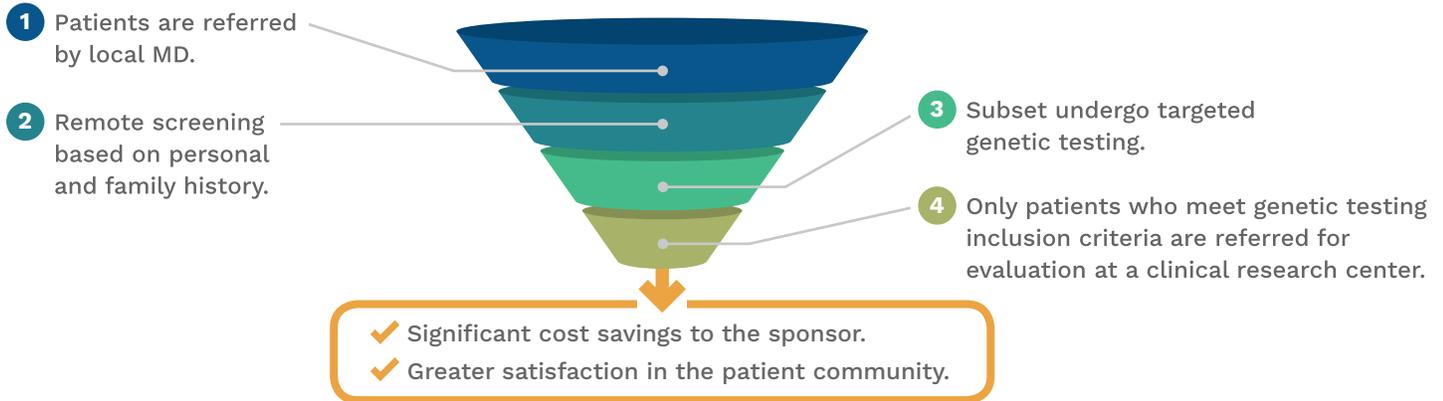
Telemedicine-based outreach and genetic screening can be used to support community practices AND to screen patients remotely for clinical trial eligibility.



InformedDNA brings specialty genetics services to patients in their homes via telemedicine. Patients have access to a rare disease genetic specialist, without the time or cost associated with travel. Our board-certified genetic counselors perform pre-screening of patients by gathering medical and family history and facilitating remote genetic testing. These capabilities allow us to determine whether a patient meets the inclusion criteria for a study without on-site evaluation. On an ongoing basis, our expertise allows us to support both the patient and their community-based physicians—increasing patient retention as well as patient identification.

* Source: TripleTree, "Opportunity Ahead: Community Health Systems and Clinical Trials"

Screening Process



Exceeding Patient Identification Goals: A Case Study

A leading gene therapy biotech company partnered with InformedDNA to:

- ◆ Implement a genetic testing program, with a custom, ideal test for the patient population
- ◆ Develop a screening questionnaire for physicians to use in determining eligibility for the genetic test, resulting in a very high sensitivity for the detection of patients with this rare disease.
- ◆ Provide telephone-based genetic counseling to patients participating in the genetic testing program. This eliminated geographic barriers and reduced screening costs.



- ✓ Hundreds of community retina physicians signed up; >50% stated they would not have participated without our genetic counseling support
- ✓ In this program, the most commonly cited reason for participation was to determine possible eligibility for a clinical trial or therapy.
- ✓ Most of the patients identified as eligible for gene therapy were identified through this program.

The InformedDNA Advantage

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



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

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