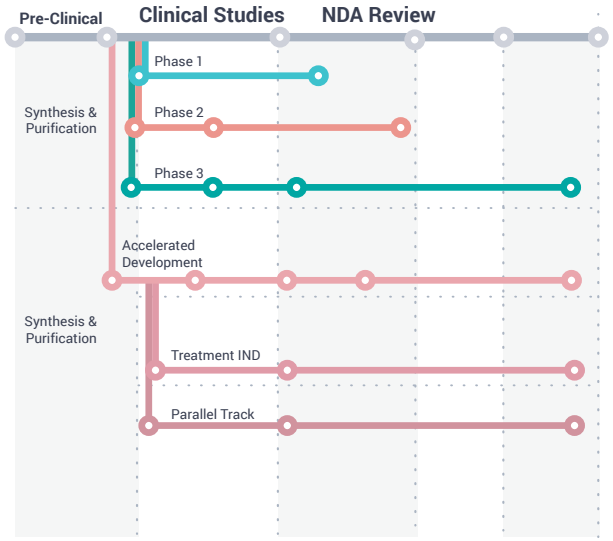
TrialVend®
On-Demand Clinical Research Vendor Services

CLINICAL TRIAL JOURNEY



Drug Approval Process

Patient

In the pursuit of finding an appropriate therapy a patient may consider participating in a clinical trial designed to test new treatment approaches.

Education and research

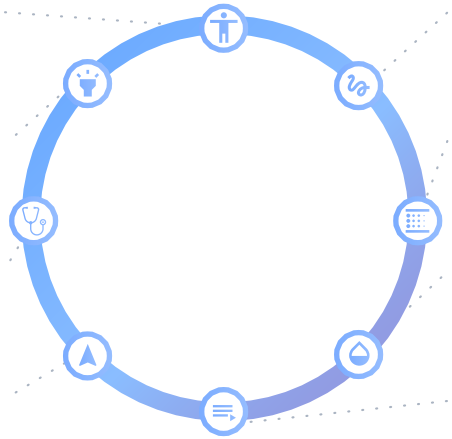
Translational medicine is evidence-based research that aims to improve human health and longevity by determining the relevance to the disease of interest.

Healthcare professionals

The circle of care starts with the patient and the people around them that care. Healthcare providers advise standard of care, advancing therapies, and scientific literature to treat patients.

Access to care

The ability to receive treatment is an ultimate factor in clinical trial participation. Certain websites such as clinicaltrials.gov can advise regions and sites that offer different studies.



Circle of Care

Informed consent

Eligible patients acknowledge the study involves research, any foreseeable risks or discomforts, description of benefits, disclosure about alternative treatment, participation is voluntary.

Screening

Clinical trials will specify inclusion and exclusion criteria. Clinical laboratory testing may be required to further determine patient eligibility and in some cases establish a baseline of metrics.

Participant assigned treatment approach

Depending on the model of research there may be a randomization process to determine the treatment approach. Sham control methodology is used when treatment is not revealed.

Outcomes

Biomarkers, or biological characteristics, identified to determine if the treatment is effective will be analyzed to decide the future of the investigational product.

Clinical Investigation Professionals

Sites

Patients participating in clinical trials will most likely be living in the area where the research site is located. Getting the right data starts with the clinicians who enroll, treat and evaluate the clinical trial patients. Site selection requires due diligence on the part of the sponsor to ensure that the proposed clinical trial site meets all the considerations listed above. One of the most important decisions the sponsor makes when embarking on a new clinical trial is the choice of the principal investigator. One simple method one can utilize to assess the ability of a clinical trial center to recruit a specific number of patients that meet the protocol entry criteria over a given period is to perform a retrospective review of their patients to determine the actual number of patients that meet the inclusion and exclusion criteria of the protocol over a several month period. The selection for certain sites are based on opinion leaders that see patients and who practices in their area of profound expertise.

Labs and support services

Biomarker-driven clinical trials utilize methods of analysis usually carried out by a laboratory. The complexity and number of samples collected during studies will factor into the selection of strategic partnerships such as drug and device production and distribution. Nonclinical, preclinical, clinical and commercialization services maintain revolutions within the clinical trial journey. Central and esoteric laboratories will anaylze biomarkers for safety review and study endpoints. A Laboratory Developed Test is an in vitro diagnostic test that is used within a single laboratory. A Clinical Trial Management System is a software system used in clinical research. Clinical, medical, and statistical experts will improve the quality of your study design and identifying appropriate endpoints that are measurable and interpretable. Partnerships with experienced vendors will ensure clinical development planning, operations, and financial investment into the trial meets its full potential.

Sponsors & CROs

If Phase 1 is successful, the company will target a mental illness for a Phase 2 study. The Investigational Product dose will be determined and the therapies efficacy studied. Clinical studies can be sponsored, and funded, by pharmaceutical companies – and most are. A sponsor is a company or organization, like a contract research organization, that takes the responsibility to initiate, manage or finance the clinical trial. CRO services include regulatory affairs, site selection and activation, recruitment support, clinical monitoring, data management, trial logistics, pharmacovigilance, biostatistics, medical writing, and project management, among others. Sponsors are responsible for submitting an Investigational Drug Application to the FDA and ensure investigators are compliant with the protocol. A late stage trial will carry a lot of weight in the ultimate usage of a therapy. The clinical trial agreement defines what sponsors may do with the PHI.