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# CTI Newsletter

## Working with Patient Populations in Early Phase Trials

Traditionally, early phase trials are performed in healthy volunteers. However, in recent years, a trend has emerged in the industry in which sponsors have begun to collect more data from patient populations in early phase trials. This occurs for a variety of reasons, including

- safety concerns for healthy volunteers
- a desire to collect additional data to identify early trends in efficacy or pharmacodynamic measures
- concerns that patient populations may react to or absorb the investigational product differently than healthy volunteers
- proof of concept

This trend can create challenges for sponsors looking for early phase units who can work with patient populations in addition to healthy volunteers. Below are two considerations to take into account when you are searching for the right early phase unit for your program.

### Experience Introducing Patient Cohorts into Traditional Phase I Designs

When choosing sites for this kind of a program, it is important to assess the sites' ability to incorporate patients into study models that are traditionally run with healthy volunteers. This experience is beneficial in terms of study design, execution, and managing issues that may arise during the trial.

CTI's team has experience in adapting study design to accommodate all the necessary

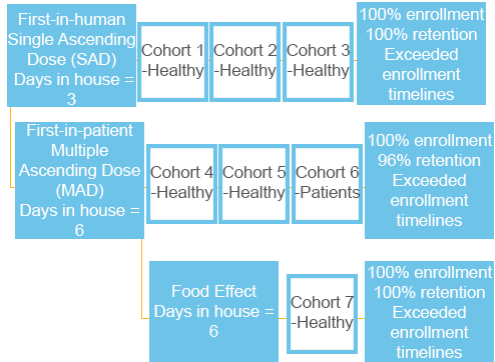
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food effect arm, or other adaptations to meet regulatory agency requirements. Our staff is well versed in many types of patient populations and trial designs, as well as managing enrollment timelines and any issues that arise throughout the course of the studies.

SAD/MAD with Food Effect and Patient Population



**Recruitment of Patient Populations**

When identifying sites for your early phase program, you want to be sure to look for a team with experience recruiting patient populations as it requires a different kind of strategy than recruiting healthy volunteers.

CTI has a dedicated recruitment team that is responsible for identifying subjects for research trials and maintaining the robust database of existing subjects. For each trial, a recruitment plan is created that details strategies for finding the specific patients required for the trial. These plans include patient outreach, advertising via radio, television and social media as well as a partnering plan with local physician groups.

CTI Clinical Research Center Experience with Common Early Phase Patient Populations

- |  |  |
|--|--|
| <p><u>CNS</u></p> <ul style="list-style-type: none"> <li>• Sleep Disorders</li> <li>• Pain</li> <li>• Psychiatric</li> <li>• Neurological                             <ul style="list-style-type: none"> <li>- Parkinson's</li> <li>- Essential Tremor</li> <li>- Alzheimer's</li> </ul> </li> </ul> <p><u>Cardiology</u></p> <ul style="list-style-type: none"> <li>• Hypertension</li> <li>• Hypercholesterolemia</li> <li>• Hyperlipidemia</li> </ul> | <p><u>Endocrinology</u></p> <ul style="list-style-type: none"> <li>• Type 2 Diabetes</li> <li>• Obesity</li> <li>• NASH/NAFLD</li> </ul> <p><u>Gastroenterology</u></p> <ul style="list-style-type: none"> <li>• IBS</li> <li>• IBD</li> <li>• Crohn's</li> </ul> <p><u>Immunology</u></p> <ul style="list-style-type: none"> <li>• Rheumatoid Arthritis</li> <li>• Allergy</li> <li>• Psoriasis</li> </ul> <p><u>Respiratory</u></p> <ul style="list-style-type: none"> <li>• Asthma</li> <li>• COPD</li> </ul> |
|--|--|

**How the CTI CRC Can Help**

CTI's Clinical Research Center (CRC) has been conducting both early and later phase clinical trials for more than 20 years. These trials have involved the enrollment of healthy volunteers in typical Phase 1 designs such as FIH, SAD/MAD, DDI, FE, BE, as well as patient populations in later phase studies. The CRC staff has extensive experience working with and managing the needs of patients in a variety of medical conditions. With more than 900 studies of experience in both early and later phase studies and our database of thousands of patients and healthy volunteers, the CTI CRC is uniquely positioned to execute and enroll your early phase program involving a patient population.



To find out more about how we can help you with your program, [visit our website](#) or fill out our contact form to [start a conversation](#) with one of our team members.

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Every month, we choose a theme highlighting characteristics of our company culture, something we describe as "The CTI Way." This month's theme is "strengthen."

The CTI Way is to  
**STRENGTHEN**

Whether providing hope to our patients, confidence to our sponsors, or encouragement to our coworkers, we strive to lend strength to all those with whom we interact.



## The Year of the Employee

Every month, we'll be spotlighting one of our employees and their contributions to CTI. We are successful as a company because of our passionate and talented employees, who work tirelessly to bring life-changing drugs to patients around the world.

## Meet the CTI CRC Team



“Having worked in a clinical setting before starting my career in research, I encountered patients who struggled to find effective treatments for their conditions. As an Investigator at the CTI CRC, it's been very rewarding to be actively involved in the development of new therapies that might offer hope to these patients.”

**Karen Leadbitter**  
Investigator and Nurse Practitioner

Want to join Karen and our CTI team? [Click to hear more from our team members](#) or [click to see our current job opportunities](#), including [new expansion across the United States!](#)

## Additional Highlights

### Upcoming Meetings We'll be Attending

#### **ASGCT**

Washington, DC  
April 29 - May 2

#### **ISPOR**

New Orleans, LA  
May 18-22

#### **International Society for Cell and Gene Therapy (ISGCT)**

Melbourne, Australia  
May 29-June 1

#### **American Transplant Congress**

Boston, MA

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King of Prussia, PA  
May 21-22

**BIO 2019**

Philadelphia, PA  
June 3-6

**Alliance for Regenerative Medicine Cell & Gene Washington Forum & Fly-In**

Washington, DC  
May 21-22

**SLEEP Annual Meeting**

San Antonio, TX  
June 8-12

**DIA Annual Meeting**

San Diego, CA  
June 22-28

**CTI Cares**

This month we are supporting Camp Kesem, a nationwide community, driven by passionate college student leaders, that supports children through and beyond their parent's cancer. Kesem is the largest national organization dedicated to supporting children impacted by a parent's cancer, at no cost to families.

[Learn more and donate](#)

**New Hires & Promotions**

CTI is thrilled to welcome all of our new employees, and to congratulate our recently promoted employees!

[View New Hires and Promotions](#)

**Join Our Team!**

[We're growing across the United States!](#)

We're looking to build our team in the following new cities:

- Atlanta, GA
- Boston, MA
- Chicago, IL
- Dallas, TX
- Houston, TX
- Indianapolis, IN
- San Diego, CA
- Washington DC

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