A Site Management Organization (SMO)

A SMO is an organization that provides clinical trial related services to a contract research organization (CRO), pharmaceutical company, biotechnology company, medical device company or a clinical site.

The site is usually a hospital or a similar health care institution that has adequate infrastructure to meet the requirements of the clinical trial protocol.

FRONTIER CLINICAL RESEARCH, LLC

- Frontier Clinical Research, LLC is a comprehensive Site Management Organization (SMO) that is focused on providing professional, high quality study conduct and drug/device development services.
- We bridge the gap between Pharmaceutical companies and patients by recruiting patients into clinical trials, allowing for more affordable and new cutting-edge medications to be approved in the market faster.
- We have an enviable record of having provided services to many of the top pharmaceutical and biotechnology companies, both large and small.
- Our clinical team has nearly 25 years of combined clinical research experience.

INDUSTRY STATISTICS

- **80%** of new principal investigators discontinue clinical research after their first clinical trial
- **Of the remaining 20%, Twelve percent (12%)** will leave the field after their first two years of clinical research
- **Thus 92% of principal investigators will FAIL to adopt a successful clinical research program at their facility**

Practices who are serious about developing their clinical research capabilities must develop a strategic plan to beat the odds.

CLINICAL RESEARCH DEVELOPMENT PARTNERING FOR SUCCESS

In an era of decreased margins, sponsors are looking to partner with research sites who can quickly and efficiently **recruit patients** and **produce quality data.**

Aligning your sites enrollment with the top 30% of clinical research sites cannot be understated. It is the single most important factor in determining the success of your clinical research program.

CHALLENGES TO CLINICAL TRIALS

- Takes an average of 31 weeks / 7 months from Site Identification to Site initiation
- 11% of sites selected are never activated due to their inability to enroll subjects
- Poor site selection can increase costs by 20% causing delay of study
- 80% of clinical trials fail to meet enrollment deadlines
- 54% of new investigators are never used again due to poor enrollment or poor data quality

OTHER OBSTACLES THAT MAKE SITE PERFORMANCE DIFFICULT

1. **Staffing**
   - Lack of experience, training, and orientation to the field
   - Inability to find staff or increase staffing to meet clinical trial program needs
   - Internal candidate is too busy or lacks commitment
2. **Physicians**
   - Lack of experience, interest, time and availability
3. **Lack of study opportunities**

OUR PROCESS

Frontier Clinical Research, LLC, provides clinical trial expertise and capabilities to emerging clinical research sites by:

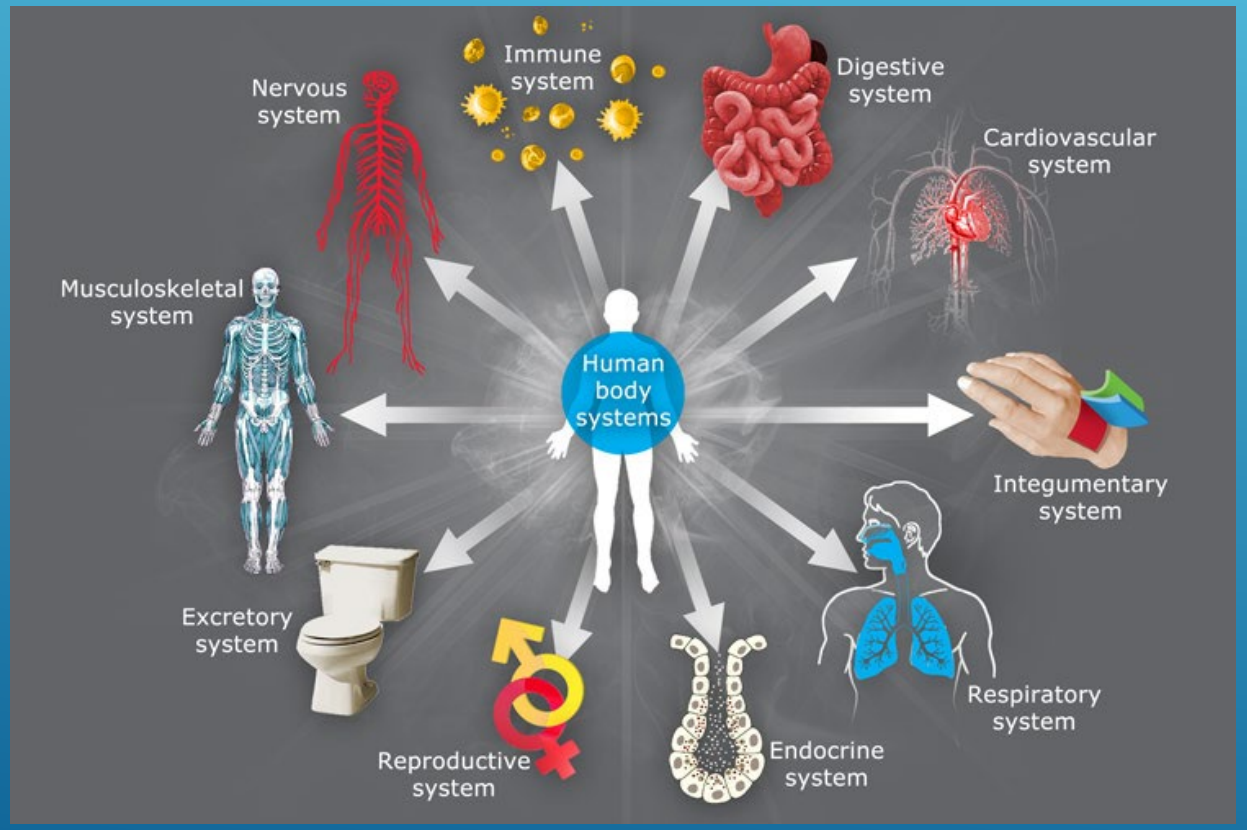
- Actively pursue new federally funded or privately supported clinical trials from feasibility to site selection.
- Work with sponsor to conduct the feasibility process to assist the site to secure their selection for clinical trials.
- We negotiate and execute clinical trial contracts.
- Site initiation and trial close-out operations.
- Provide sites with CRC staff knowledgeable of and qualified to conduct every aspect of clinical trials while maintaining a high level of patient care.
- We arrange for necessary office and medical equipment and supplies for set up of the research site as well as maintain yearly calibrations.
- We provide study oversight management of the conduct of clinical trials at your site to reduce potential ICH-GCP violations.

OUR PROCESS CONTINUED……

- Compensate patients for time and participation in the trial and issue 1099's as required.
- Help maintain current trial related certifications and trainings for PI's, Sub-I's and all study staff.
- Assist sites with FDA or Sponsor Audits.
- Store and maintain trial related records and retention samples as required by Federal Regulations (21 CFR 312.62) or Sponsor requirements. (Usually 15 years unless otherwise specified)
- Provide trial specific advertising for the site to assist with recruitment. While instilling a high focus on patient retention (Retention is Key).

RESEARCH EXPERIENCE

FRONTIER CLINICAL RESEARCH HAS BEEN AT THE FOREFRONT OF MEDICAL ADVANCES IN VARIOUS INDICATIONS BY PARTICIPATING IN DRUG, VACCINE, & MEDICAL DEVICE STUDIES OVER THE PAST 10 YEARS.



APPROVED STUDY MEDICATIONS & DEVICES

The research being conducted today becomes tomorrow's life-changing and life-saving treatments. The data collected from the patients enrolled in Frontier's research study projects have led to the success of the following FDA drug & device approvals:

- **Alder: Aimovig – Treatment of Migraines**
- **Astellas: VEOZAH – Treatment of VMS**
- **Astra Zeneca: Tudorza – Treatment of COPD**
- **Biocryst: Peramivir – Treatment of Influenza**
- **DermaSensor – Skin Cancer Screening Device**
- **Novo: Tresiba - Treatment of Diabetes**
- **Shionogi: Xofluza - Treatment of Influenza**
- **Sanofi: Soliqua - Treatment of Type 2 Diabetes**
- **Synergy: Trulance – Treatment of Idiopathic Constipation or IBS-c**
- **Vibrant Gastro: Vibrant – Treatment of Constipation**

CAPABILITIES

Frontier Clinical Research has a highly qualified and well-trained staff with a track record of meeting and/or exceeding enrollment, adhering to protocols and completing studies on time. We have quick turn-around times for initial documents (CDA, CTA, and budget), Central IRB approval, recruiting and start-up. Our thorough and accurate documentation has resulted in low query rates and favorable audits. We have extensive outpatient Phase II–IV trial experience in areas including proof-of-principle, devices, PK/Absorption, safety, efficacy and tolerability.

One of the Top Enrolling Sites for the Following Indications:

Anemia
Asthma
COVID-19
Diabetes
Influenza
Migraines
RSV
Vaccines
C. Diff
Constipation
Colorectal Cancer
Esophagitis

OUR PRINCIPAL INVESTIGATORS

Marcy Goisse, MD
Family Medicine

Tiffany Pluto, DO
Family Medicine

Frederick Ruthardt, MD
Gastroenterology

Ward Paine, MD
Internal Medicine

Jeffry Pilney, MD
Family Medicine

Kevin Blankenship, MD
Emergency Medicine

OUR SUB-INVESTIGATORS

Charles Calabrese, DO
Gastroenterology

Rod Ali Hojat, MD
OB/GYN

Bchara Janadri, MD
Pediatrics

Wilbur Sine, MD
Psychiatry/Family Medicine

Erica Murray, PA-C
Emergency Medicine

Robin Goodwin, FNP
Family Medicine

CLINICAL RESEARCH COORDINATORS (CRC)

Roles and Responsibilities

A Clinical Research Coordinator is responsible for conducting trials as per the GCP guidelines under the supervision of the Principal Investigator (PI). Although the PI has the overall responsibility for performing the trial, **it has been stated that the CRC is the heart and soul of the clinical trial and that, eventually, it is the CRC who carries ahead the research objectives**, in that way playing an important role in the success of the clinical trial.

- **Keep track of study activities at all times to make sure compliance with protocols and with all related local, state, and national regulatory and institutional polices so that the site is FDA audit ready at all times.**
- **Meticulous management of necessary records of study related activity which includes case report forms, drug dispensation records, maintenance of required legal research documentation within the regulatory binders, etc.**
- **Enroll subjects in the study as per the study protocol guidelines in order to meet the site's stated enrollment goals.**

CLINICAL RESEARCH COORDINATORS (CRC)

Roles and Responsibilities (cont.)

- Prepare for an be involved in quality assurance audits performed by study sponsors, FDA or any other regulatory authorities.
- Prepare for, be involved in, address the questions and queries of an FDA auditor during an inspection whether announced or unannounced.
- Record Adverse Events and Serious Adverse Event information, consult with investigators concerning causality and submit to the Sponsor, and IRB within the required 24-hour reporting timeframe requirement of the FDA.
- Create and Prepare any trial-related paperwork such as source documentation, protocol worksheets, adverse event report forms, procedural manuals and progress reports.
- Create, Prepare and submit initial, quarterly, and yearly study reports to the Investigational Review Board.
- Manage subject registration to make sure that informed consent is effectively obtained and properly recorded.

HOW TO SUCCEED

We are here to help your facility succeed in clinical research

- Clinical research expertise
- No financial constraints
- No disrupting your staff processes or training
- No administrative burden

Don't misjudge the amount of work involved, the initial capital needed, the amount of lag time before receiving payment, and the cost of conducting trials.

QUESTIONS

- What questions do you have regarding research?
- What questions do you have regarding Frontier Clinical Research?

We look forward to partnering with your clinical practice and building its clinical research capabilities to their utmost potential.