"One moon dispels the darkness, not thousands of stars."

Chanakya Pandit

VESTRA CLINICS s.r.o.

Dedicated Research Clinics

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Executive summary

We offer Sponsors and CROs the best solutions for their clinical trials while reducing their costs, time and risks by our increased effectiveness. We are a high quality Dedicated Research Clinic, exclusively supporting Sponsors and/or their CROs:

1) to quickly identify carefully selected prescreened patients in numbers negotiated before,
2) to nominate properly selected investigators as well as other professionals,
3) by performing quality assurance and management that includes quality data delivery in compliance with the protocol.

Our objective: to understand needs of the Sponsor/CRO and carefully prepare for the trial. Vestra Clinics supports quick and efficient initiation and completion of each study.

Our spotlight: pre-screen patients that fulfill the criteria and prepare the resulting Exact Target Population (ETP) for participation in the clinical trial. Vestra Clinics is prepared well in advance for each of the clinical trials. We carefully pre-screen the desired patient population and enrollment for each clinical trial start is launched proactively, all at once and it's momentum is kept until all the eligible patients are found. While ensuring the best for our patients we guarantee the highest possible enrollment numbers.

Our target: include the ETP into the particular clinical trial while providing an optimal and focused environment for clinical trial conduct.

The basis of our success consists mainly of:

1) Maintaining perfect source documentation;
2) Strict adherence to ICH-GCP;
3) Strict adherence to the inclusion and exclusion criteria;
4) Close and frequent communication with CRA and other appointed personnel of the Sponsor / CRO;
5) Skilled clinical trial teams led by experienced PIs who provide detailed personal conduct and oversight of clinical trial procedures;
6) Focused attention and specialization on the key areas of the research;
7) Site management and Quality assurance of each clinical trial;
8) Effective PI-centered approach with central governing and supply systems supported by Vestra Clinics as detailed below;
9) Direct access for the Sponsor to best selected Investigators and other clinical research professionals, who will comply with recommended industry standards (GCP, GLP and GMP).

Detailed overview of our Services and Qualities

Who are we?

Vestra Clinics is a privately owned clinical research facility founded in 2008 and dedicated exclusively to clinical research. Formerly known as the CTC Rychnov nad Kněžnou s.r.o., which assumed the functions and expertise of Principia Clinical Research s.r.o. Ladislav Pazdera, M.D. is the sole owner of the company. He did part of his stroke neurology fellowship in Boston hospitals associated with Harvard Medical School. Vestra Clinics is investigator-based and is Central Nervous System focused in nature.

Vestra Clinics is engaged in the clinical trials on a nonexclusive basis. Ladislav Pazdera, M.D. was established as the Key Opinion Leader for some of cooperating Sponsors / CROs.

We seek to establish a firm, long lasting and productive relationship with the Sponsor or CRO based on mutual trust and cooperation. We aspire to assist the Sponsor and the CRO in the planning stage prior to the clinical trial. The scope of our services will be aligned with needs of Sponsor and its CRO for each particular clinical trial.

We truly aim to follow Sponsor's instructions, the applicable protocols as well as GCP and other applicable regulations, yet honest mistakes may happen. If any mistake occurs, we discover it promptly, notify as necessary and prevent it from happening again through a detailed CAPA plan (Corrective and Preventive Action plan).

Vestra Clinics supports Sponsors and their CROs in ensuring that a specific plan is developed for each trial and oversight in line with the FDA guidance document on principle investigator's responsibilities. Vestra Clinics maintains quality assurance functions such as in house data quality assessments, trainings, guidelines and Standard Operating Procedures (SOPs), as well as the carefully selected Start-up Procedures.

Vestra Clinics is clustered around its site director and experienced clinical coordinators. Assessment, management and auditing is also part of our routines. We are capable of efficient data management and our SOPs ensure for prompt and complete adverse events reporting in accordance with GCP and protocol.

We work on area of 300 square meters. There are 13 members of the team, most of them full time employed, including 4 Raters, 4 Sub-investigators, 3 Principal Investigators, Administrator, Clinical Nurses and Coordinators and the Site Director. The complete list with all functions, IDs and contacts is available as the separate Start-Up Document.

Where do we deliver the value?

Vestra Clinics supports the delivery of useful and reliable data to CRO/Sponsor under the agreed budget. The added value that contributes to the successful quality data delivery to CRO/Sponsor is rendered in key parts of each clinical trial by:

1) Planning all details of each trial in advance through personal and close cooperation with the CRO/Sponsor;
2) Identifying reputable Investigator for Sponsor's approval;
3) Access to a vast patient population supporting excellent recruitment results;
4) Ensuring cost effectiveness of trials through supporting Sponsors in:
5) Negotiating promptly budget and contract for each trial;
6) Fast mono-phasic recruitment of large numbers of appropriate subjects;
7) No rework due to high compliance to the protocol;
8) Adherence and strict obedience to the rules governing conduct of clinical trials and ICH-GCP.
9) Placing every trial into the best clinical research environment.

We grant your CRA efficient and timely monitoring. We are known for adding value by rendering full accountability in all parts of each clinical trial. We are valued for adherence and strict obedience of the rules governing conduct of clinical trials and ICH-GCP. At Vestra Clinics all the needs of the Patients, the Sponsors, CROs and the Investigators are fully met. We are equipped with full time staff and proper environment. Vestra Clinics ensures that the clinical trials are conducted in compliance with ICH-GCP, local regulations and FDA, EMEA, HHS and HIPAA regulations. We have very stringent internal processes to assure high quality of data and financial management in our company and obviously observe all ethical standards.

We guarantee highly professional environment, an uninterrupted workflow and data processing with a focused attention to trial procedures. The quality of care for the patients and the consistency and reliability of the data delivered to CRO and the Sponsor are thus not compromised by any distractions. After clinical trial placement in our research environment we work tightly and effectively with CRO and the Sponsor to facilitate the completion and submission of all required regulatory documents. Vestra Clinics will negotiate the contract and the compensation with the investigator and other staff and is ultimately responsible for paying them under the agreed budget.

All the above leads to a robust, powerful, efficient, quick, flexible, and transparent delivery that contributes to the completion of clinical trials in a cost-effective and timely manner.

How do we identify proper Clinical Trials? What is our therapeutic focus?

While our clinical trial skills are applied to Central Nervous System (CNS) trials, we have particular experience in performance of clinical trials in phase II & III mainly. We focus on:

2) MCI, Dementia and Alzheimer disease;
3) Neuropathic and low back pains;
4) Osteoarthritis pain and Fibromyalgia;
5) Migraine;
6) Vertigo;
7) Movement disorders like Parkinson disease, Restless Leg Syndrome;
8) Stroke prevention;
9) Epilepsy;
10) Spasticity;
11) Sleep disorders
12) Neurotic disorders, Stress-related and Somatoform disorders, Binge eating disorders, Anxiety clinical trials.

How do we care for patients?

Vestra Clinics focus on safe, effective, patient-centered, timely, efficient and equitable patient service and has to be respectful of individual patient preferences, needs and values, as identified by the Picker Institute 8 main characteristics:

1) Respect for the patient's values, preferences and expressed needs;
2) Coordinated and integrated care;
3) Clear, high-quality information and education for the patient and family;
4) Physical comfort, including pain management;
5) Emotional support and alleviation of fear and anxiety;
6) Involvement of family members and friends, as appropriate;
7) Continuity, including through care-site transitions;
8) Easy access to all types of care.

Our site may accommodate up to 180 patients. We are specialized in the therapeutic areas listed above and we are located where large numbers of patients are present. We are famous for our dedication to providing the best possible accommodation of the patients.

How do we support Sponsors/CROs in patients' enrollment?

Recruitment strategies are our passion.

Vestra Clinics offers centralization of patients' recruitment for your clinical trials. Quickly enrolls enough subjects from a large pool of preselected and prescreened patients, who are willing and able to participate in clinical trials. We have access to a population of almost 300.000 population for all diagnostic indications mentioned above. The patients are chosen for each particular clinical trial with the topmost care. We do not chase the patients; we aim at securing their attention and cooperation in compliance with applicable laws and regulations. We provide specialized PR and utilize all approved marketing means, elaborated in details in our Recruitment and Start-Up material.

For instance, we continuously prescreen a treatment naive population with Mild Cognitive Deficit. We also have put together a huge database of treatment naive or already pretreated dementia patients in accordance with applicable data privacy and other regulations. We have set up "Time is Brain" program, which explains the necessity of timely diagnosis and consequent cognitive rehabilitation with the possibility of participation in clinical trials for demented patients.

We have a full time recruitment and educational specialists in the team in our Start-Up and Recruitment unit. We have processes for effectively seeking preliminary subject consent in compliance with applicable legal and ethical requirements:

1) Identifying targeted patient population (by using database and established networking means);
2) Maintaining Database, Medical records sorting and keeping the pre-screen patient log;
3) Memory Clinic of Neurology Department is part of Vestra Clinics recruitment;
4) We run Cognitive Training Clinic for our MCI patients;
5) Developing a marketing plan, advertising design and budget operating;
6) Copywriting (newspapers, official web page, internet micro-sites, blog,);
7) Placing advertisings and promotions;
8) Educating patients and their families (conducting seminars and meetings for them);
9) Discussing the Inform Consent with patients and families;
10) Managing for Lunch & Learn and Buffett Dinner Seminars (with referring medical staff: GPs, nurses, specialists in Jan, Apr, Jun, Sep, Nov L&L and March and October the BDS);
11) Source data accountability;
12) Follow Up Reports & Statistics.

We have a network of about 50 cooperating physicians and nurses. We regularly meet with nurses five times per year and with physicians twice yearly for a Lunch & Learn or Buffett Dinner Seminars, where clinical research topics are presented and discussed.

We advertise in 3 local newspapers in the vicinity of 60 km. Adds are placed into the regional public transportation (buses). A radio spot takes 30 second, covers the Eastern Bohemia region (Hradec Králové, Liberec, Pardubice, Mladá Boleslav, Jičín) and reaches almost 1 million people. We organize press conference and distribute flyers and posters.

Since our recruitment methods are professionally geared towards the given patients' population, we can aim for much higher patient enrollment numbers than any stand-alone investigator. Hence, we frequently score up as the best recruiters e.g. for trials in dementia, epilepsy, spasticity, neuropathic pain, newly diagnosed PD and some others.

How do we support Sponsors/CROs in identifying PIs?

Our Principal Investigators (PIs) used to executing all their ICH-GCP prescribed duties in time, truly oversee all trial and patients' related activities performed at Vestra Clinics in person and in accordance with European legislation, local laws as well as FDA CFR and the FDA guidance document on responsibilities of Principal investigators. They are:

1) Research enthusiasts;
2) Fully board licensed therapeutic area specialists;
3) Skilled investigators;
4) Fluent English speakers;
5) Good communicators towards the Sponsor /CRO;
6) True team leaders who leave their fingerprints on every step of the trial;