

Summer of
2014

**EXPANDING OUR
NETWORK**



LOCAL PRESENCE



**CLINICAL RESEARCH
IN BULGARIA**



**HEALTHCARE
REALITY**

NEWSLETTER



Summer of 2014

After launching our website in July, we spent the rest of the summer visiting clinical sites in Bulgaria. We were met by excited investigators, who are eager to participate in clinical research and be on the cutting edge of medical innovation. The sites have state of the art equipment for diagnosing and treating the most common diseases, such as cardiovascular, neurological and neurovascular, orthopedic, gastroenterology and pulmonary diseases.

**Eastern Europe -
a rising star in
clinical research**

Expanding Our Network

We have added 19 clinical sites to our clinical research network. Each is equipped with state of the art equipment, including angiograph(s), CT scanner, MRI (the most current models), hollters, echographs, ECGs, ultrasounds etc. All meet our criteria for rigorous clinical research in the following areas:

- 2 for neurology work
- 2 for orthopedics
- 2 for gastroenterology
- 2 for urology
- 3 for dermatology
- 17 for cardiology work including 11 for interventional cardiology/vascular surgery clinical research - 3 have experience and meet standards for transcatheter valve replacement.

There are over 40 catheterization labs all across Bulgaria and the interventional cardiology and vascular surgery fields are very well developed. This is the most innovative group of physicians and most of them have practiced abroad. Some sites are doing RDN procedures using commercially available products and are gaining experience with the procedure and are creating patient databases for hypertensive patients.

Most sites are within 2 hours drive and the 10 sites in the capital are within 30 min from each other making it easy to provide case support and monitor the sites.

Local Presence

In Bulgaria, we have recruited 3 CRAs with strong monitoring and submissions experience to provide on-site support including case support. One of the CRAs has cardio experience. One CRA is a nurse.

- We have connected with professional society groups and ex-regulators
- Selected a translating agency with strong medical and regulatory background
- We have attracted independent physicians as advisors and medical adjudicators

Visit Our Sites



State of the art equipment is used to diagnose and treat wide-spread illnesses, such as cardiovascular disease, stroke, cancer, ulcers, COPD, emphysema, prostate enlargement.

- We met with the EC chairs in most centers and the central EC to understand their thinking and relay our vision for collaborative relationship.



Clinical Research in Bulgaria

There are over 80 on-going studies in Bulgaria. The sites and investigators are experienced in clinical research, which is on the rise in the last 5-7 years. Some sites have dedicated clinical research centers to streamline study logistics. The patients are eager to participate in studies and follow through with all visits. Bulgarian sites have been top enrollers in a few studies and have been audited by sponsors, CROs and independent auditors.

Healthcare Reality

The healthcare reality in Bulgaria, and much of the rest of Eastern Europe is defined by two factors:

- (1) Poor diet, lack of exercise, epidemic smoking and stressful lives filled with uncertainty and impacted by global socio-economic and geo-political changes have defined the daily routine of many Bulgarians, especially those who are over 50. All of this has led to overall sick population.
- (2) Patients lack confidence in the system and thus don't visit their doctor when issues occur. This leads to late diagnosis and delayed treatment of diseases making clinical pathology complicated.

The result: There are large pools of cardio-vascular and hypertensive patients. Stroke and Parkinson's are daily bitter reality for the neurologists. Patients need to co-pay for their orthopedic implants and are thus motivated to enroll in studies. Smoking is widely-spread - emphysema and COPD are often. Due to budget difficulties, the single-payer system pays for only 20 valves / year.

All of this motivates patients to participate in clinical studies where they receive cutting edge treatments at no cost to them creating a win-win situation for clinical researchers and participants.