

Why perform clinical trials in Eastern European countries?



PATIENTS

- Difficult access to specialized drugs and advanced therapies / lack of adequate therapies
- Caucasian population across the region
- Large population of treatment naïve patients (e.g. trials per mil citizens in Bulgaria: 15.2, Poland: 10.4, Romania: 6.7)
- Access to patients through centralized healthcare systems - recruitment of pools of patients across a relatively small number of sites
- High recruitment rate
- Ideal for rescuing recruitment on existing study



- Harmonized drug registration regulation across EU countries
- non-EU member countries within EE aligned local regulatory requirements with ICH GCP standards, EMA and FDA requirements

- Highly motivated, experienced and GCP trained investigators and study site personnel
- Lower number of clinical trials



QUALITY

- High level quality of trials (proven by FDA and EMA inspections)
- Collection of superior quality data
- Competitive study start up / recruitment times

COSTS

- >20% lower clinical trial costs
- Favourable logistics environment



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I have been working with fantastic professionals in the CEE countries during the last decades, both within the clinical research organizations and at the investigational sites. Patient care and data quality are of utmost importance for these people. These basic principles, combined with the drive for continuous learning and developing new skills, give reassurance that the studies are taken care of appropriately, even when new treatment or trial methodologies are applied.

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**Nataša Mihajlov**

Senior Clinical Operations Director



Based in Serbia,
10 years within Optimapharm



Optimapharm is a leading, mid-sized, full-service CRO that operates globally with:

- ✓ active trials in **40 countries**
- ✓ **510+** staff members
- ✓ track record of **1700+ projects**
- ✓ **85%** of repeat business
- ✓ **30+** Medical Doctors

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