



Monika Panayotova

Business Development

Comac Medical

<http://www.comac-medical.com>

Bilateral Meetings

- Thursday (1:30pm - 6:00pm)

Description

Comac Medical is a full-service, boutique, Contract Research Organization and Site Management Organization, established in 1997, and owned by its CEO - Dr. Milen Vrabeovski. It is headquartered in Sofia, Bulgaria. The company operates at the best healthcare institutions in 18 CEE countries with a population of over 130 mln: Bulgaria, Romania, Serbia, FYR Macedonia, Croatia, Slovenia, Bosnia and Herzegovina, Montenegro, Moldova, Georgia, Kosovo, Albania, Cyprus (South Eastern Europe), Lithuania, Latvia, Estonia (Baltic region), Poland and Hungary.

Comac Medical offers Early Phase Clinical Development, Start-up & Monitoring of Clinical Trials Phase I-IV and BA/BE, Project Management, Site Management, Patient Recruitment Services, Regulatory Consulting, Medical Writing, Biometric Services, Pharmacovigilance, Bioanalysis, Safety Laboratory Services, Independent Quality Assurance.

As part of the Early Phase Clinical Development operations, the company has its own University Hospital-based Clinical Research Unit with a large patient/ healthy volunteers database and extensive referral physicians network.

Comac Medical has been chosen to participate and has successfully completed Phase 1 of the SME Instrument of Horizon 2020. The company has received a Seal of Excellence by the European Commission for its Horizon 2020 SME Instrument Phase 2 project proposal.

Organization Type

Company

Organization Size

101-250

Founding Year

1997

Email

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Country

Bulgaria

City

Sofia, South Side Business Centre 38, Maystor Aleksi Rilets Str., 5th fl. Res. Distr. Manastirski Livadi [Google map](#)

Offer

Clinical Trial Execution

- Early Phase Trials (I/IIa and BA/BE)
- Interventional Phase II/III & IIIb/IV Trials
- Clinical Monitoring
- Risk-based Monitoring
- Site Start-Up
- Regulatory Affairs
- Project Management
- Clinical Biostatistics
- Clinical Data Management
- Central and Bioanalytical Laboratory
- Safety & Pharmacovigilance

Keywords: CRO Clinical Trials Monitoring Regulatory Affairs Data Management Biostatistics Laboratory Pharmacovigilance

Cooperation Offered

1. Outsourcing co-operation
2. Technical co-operation

Offer

Early Phase Clinical Development

Conducting Early Phase studies at its own Clinical Research Unit and Partnering Clinical Centers with patients and healthy volunteers, such as:

- First-in-Human (incl. in patients)
- Proof of Concept
- Dose escalation (SAD, MAD)
- Bioavailability
- Bioequivalence (incl. in patients)
- Dose proportionality
- Food/ drug interaction
- Drug/ drug interaction
- Age/ gender interaction
- Phase I PK and PD testing
- Pediatric trials
- Hepatic and renal impairment trials

Keywords: Early Phase Clinical Research Unit Phase I/IIa BA/BE

Cooperation Offered

1. Technical co-operation
2. Outsourcing co-operation

Offer

Clinical Site Management

- Separate structure
- More than 60 sites database
- Site training- initial & ongoing
- Clinical supply activities & issues resolution
- Data entry (CRF / EDC) & Quality control
- Scheduling project activities
- Technical support

Keywords: SMO Clinical Site Management

Cooperation Offered

1. Outsourcing co-operation
2. Technical co-operation

Offer

Advisory Services

- Clinical Trial Planning & Design
- Generics Clinical Development

Keywords: CRO Advisory Services Clinical Trial Planning Clinical Trial Design Generics Clinical Development

Cooperation Offered

1. Outsourcing co-operation
2. Other

Offer

Patient Recruitment Services

Patient Recruitment Services via own Patient recruitment / Patient engagement models

Keywords: CRO SMO Patient Recruitment Services

Cooperation Offered

1. Outsourcing co-operation
2. Other

Offer

Independent Quality Assurance Services

The Quality Assurance team consists of dedicated quality assurance (QA) specialists.

The team can provide regulatory inspection support such as conduct mock regulatory inspections, provide site training and support the preparation of responses to regulatory findings.

Keywords: CRO SMO QA Quality Assurance Services

Cooperation Offered

1. Outsourcing co-operation
2. Other