



Monitoring Force

The Cutting edge of Clinical Research

Medical Research Group Companies in Eastern Europe

Brief overview

General information

- **Medical Research Monitoring Force Co. in Eastern Europe is one of the oldest Contract Research Organizations founded in Romania. The original organization was founded in Romania in May 1999, as a Romanian-German co-partnership. Then, other Medical Research Monitoring Force companies opened: the Medical Research Monitoring Force and the Medical Research Group are the most active ones.**
- **Managing Director and administrator of the Medical Research Monitoring Force's companies in Eastern Europe - Alina Musetescu, MD, PhD**

Services

- **Project Management in ICH-GCP clinical trials**
- **All regulatory parts from approvals until reporting to the authorities and IRBs**
- **Audits**
- **Medical writing and medical reviewing**
- **Monitoring clinical trials phases I to IV**
- **Professional GCP Training services for CRAs and Investigators**
- **Staffing - ICTM, PM, CPL, CRAs, CPAs, RA, PhV**
- **Contract management of clinical trial sites and investigator's team**

- **Whole services in phase I clinical trials**
- **Excellency in Diabetes, Nephrology, Cardiology phase I clinical trials**
- **Excellency in Oncology phase I clinical trials**
- **Fundamental research with the University of Medicine and Pharmacy - Bucharest**

- **Medical device clinical trials and registration**
- **Marketing of special medical devices in Rehabilitation, Dermatology, Radiology and Imagistics**

Therapeutic Areas

- **Neurology**
- **Psychiatry**
- **Diabetes mellitus**
- **Dyslipidemia**
- **Oncology**
- **Orthopedy**
- **Gastro-enterology**
- **Nephrology**
- **Atrial fibrillation**
- **Myocardial infarction**
- **Arterial hypertension**
- **Immunology&Rare Dis.**
- **Dermatology**
- **Pneumology**
- **Endocrinology**
- **Obesity**
- **Thrombosis**
- **Urology**
- **Gynecology**
- **Rheumatology**
- **Medical Devices**

■ the fields where we have developed more than 60% of our activities

Presence (cont.)

- ***The Medical Research Monitoring Force*** has become one of the most important companies in providing CRAs to pharmaceutical companies in Romania. It is one of the most active companies when it comes to registering pharmaceutical products and medical devices.
- ***Monitoring Force*** is the first company in Eastern Europe performing Phase I and II ICH-GCP clinical trials on medical devices (2000). We have actively supported the authorities in implementing the EU regulations for medical device clinical studies in Romania.
- **Quality maintenance:** regular training of our staff and investigation teams, plus rigorous internal audits.
- **Recognized as excellent** for our staffing services and quality data maintenance which started at the beginning of 2005.
- **Our main goal is to provide our partners with**
 - ***stability***
 - ***loyalty***
 - ***professionalism***

Diabetes Studies Expertise

- **More than 40 clinical trials in Diabetes and diabetes related diseases (metabolic diseases); 11 clinical trials in diabetes mellitus in children.**
- **Around 25 clinical investigation sites with a high/medium recruiting potential all over the country and another 20 good recruiting sites in the region.**
- **Monitoring of more than 2500 randomized patients in long/short term studies with expanded/focussed monitoring.**
- **Excellent contacts with opinion leaders.**
- **Experience in site training for specific procedures, such as glucometer use, CGMS (also in children), electronic diaries etc.**
- **Launching, promoting and marketing a top class glucometer and CGMS devices.**

Oncology Expertise

- **More than 25 clinical trials in Oncology with indications of: Hemato-Oncology (lymphoma, multiple myeloma, lymphoblastic leukemia) prostate, breast, pancreatic, colon, ENT cancers, NSCLC/SCLC.**
- **Around 15 clinical investigation sites with a high/medium recruiting potential all over Romania, and more than 15 good recruiting investigation sites in the region.**
- **Monitoring of 1200/900 screened/randomized patients in long/short term studies with expanded/focussed monitoring.**
- **Excellent contacts with opinion leaders.**
- **Experience in site management.**
- **Experience in site training for specific procedures, such as central reading and devices used in clinical trials (e.g. electronic diaries).**

Neurology Studies Expertise

- 17 clinical trials in Neurology, with indications of Parkinson's disease, stroke and multiple sclerosis.
- Around 25 clinical investigation sites with a high/medium recruiting potential in the whole region.
- Monitoring of more than 1400 randomized patients in long/short term studies with expanded/focussed monitoring.
- Excellent contacts with “opinion leaders”.
- Experience in site training for specific procedures, such as scales, electronic diaries etc.
- Launching, promoting and marketing of an under-patent medical device for patient recovery after stroke.

Cardiology Studies Expertise

- More than 20 clinical trials in cardiology with indications of: myocardial infarction and instable angina, arterial hypertension and atrial fibrillation.
- Around 15 clinical investigation sites with a high/medium recruiting potential all over the country and another 10-12 good recruiting sites in the region.
- Monitoring of 1000/800 screened/randomized patients in long/short term studies with expanded/focussed monitoring.
- Excellent contacts with opinion leaders in Cardiology.
- Experience in site training for specific procedures, such as hemochron using, central reading, 12 lead ECG transmission, electronic diaries etc.
- Experience in negotiating contracts with institutions and investigators in the best interest of our customers.

Medical Devices Clinical Trial Expertise

- 17 clinical trials in medical devices with indications of: Cardiology (patients with heart failure NYHA IV), Orthopaedic (vertebral fracture, knee and hip prosthesis) , Nephrology (dialysis), Intensive care unit (anaesthesia), Immunology (HIV and Oncology patients), Allergy, Depression in patients with major diseases, Neurology – stress reduction.
- We are the first company in Romania performing clinical trials on stress reduction.
- We provide customized services, which can be carried out on a stand alone basis or as part of an integrated “full-service” solution.
- We provide our customers with the most professional and best recruiting sites.

Examples of Recruitment

Field	Indication	Phase of the trial	No. of rand. patients	No. of sites/Comments
Oncology	NSCLC (1 st line)	IIIa	62	3 sites (Romania - best recruiter)
Oncology	Prostate cancer (2 nd line)	IIIb	98	6 sites (Romania – 2 nd best recruiter)
Oncology	Multiple myeloma (2 nd line)	III	16	3 sites (Hungary – 2 nd best recruiter – still recruiting)
Cardiology	Acute myocardial infarction on patients requiring stenting	II	121	4 sites
	Acute myocardial infarction and instable angina non STEMI on patients requiring stenting	IIIa	202	3 sites (4 at the beginning, one closed-out prematurely; Romania – 2 nd best recruiter)
Diabetes	D. Mellitus in children	IIIb	56	5 sites
	D. Mellitus in children <6 y. old	IIa	8	3 sites (1 patient/site required; Romania - best recruiter)
	D. Mellitus in adults	IIIb	870	20 sites (Romania - best recruiter)
Medical Device	Heart failure (NYHA IV)	I	24	2 sites
	Heart Failure (NYHA IV)	IIa	61	4 sites (Romania – best recruiter)
	Nephrology (dialysis)	I	44	1 site (Republic of Moldavia)
	Knee prosthesis	IIa	73	3 sites
	Vertebral Fracture	IIa	35	2 sites (Romania – best recruiter)

Expertise in Regulatory Inspections/Audits

We KNOW!

- **KNOW** what regulators look for during inspections based on our work in preparing inspections, process safety and risk management guides.
- **KNOW** that our checklists reflect the expectations of regulators and help to ensure the intent of the regulations is covered. This is vital for performance-based regulations such as Process Safety Management Risk Management Programs.
- **KNOW** how to recompense the confidence our sponsors have in us: by having no major findings ever to local country or global regulatory inspections in trials we took part in!

Remark:

Our Quality Assurance Department ensures quality check and support for each CRA involved in a monitoring project of a certain sponsor, free of charge. Only pass-through costs for the co-monitoring visits are invoiced.

Expertise in Regulatory Inspections/Audits (cont.)

During years of activity, the company staff took part in:

- 19 inspections from NMAMD (former National Medicines Agency - Romania); *results: no inspection with major findings;*
- 2 inspections from the BDA (Bulgarian Drug Agency); *results: no inspection with major findings;*
- 1 inspection from OGYI (Hungary); *results: no inspection with major findings;*
- 7 FDA inspections; *results: no inspection with major findings;*
- 4 EMA (former EMEA) inspections; *results: no inspection with major findings;*
- more than 30 audits ordered by sponsors; *results: no audit with major finding as concerns the CRO/CRAs activities.*

ICH-GCP Training Programme

Our courses offer a flexible and cost effective learning opportunity to develop the GCP skills:

- of the investigational staff
- of the CPLs, CRAs, CPAs

Our training programs include (without being limited to):

- Basics of Good Clinical Practice where the *practical application of basic principles* in the workplace are emphasized;
- ICH-Good Clinical Practice – Advanced Module;
- Successful Clinical Research Project Management;
- New European, Romanian, Bulgarian, Hungarian, Moldavian Legislation in Clinical Research;
- How to deal with GCP Inspections and Audits;
- Pharmacovigilance in clinical trials;
- Sponsor-in house courses tailoring our seminars in order to suit sponsor's requirements.

Rewards of Excellence

- **2010: Romanian Companies Database - LISTA FIRME 1st District: Top of Romanian Business Companies, position I for “Research-Development in Engineering and Natural Sciences”**
- **2011: Romanian Companies Database - LISTA FIRME 1st District: Top of Romanian Business Companies, position I for “Research-Development in Engineering and Natural Sciences”**
- **2012: Romanian Companies Database - LISTA FIRME 1st District: Top of Romanian Business Companies, position I for “Research-Development in Engineering and Natural Sciences”**



LISTAFIRME

Diplomă

Locul 1 în Top Afaceri România 2010

MEDICAL RESEARCH MONITORING FORCE SRL

Top realizat pentru Romania Intreprinderi Mici, localitatea SECTORUL 1, domeniul 7219:

Cercetare-dezvoltare in alte stiinte naturale si inginerie, conform datelor de bilant raportate in anul 2010.

Certificat de
www.ListaFirme.ro



Diploma

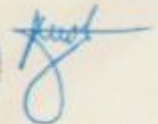
Locul 1 in Top Afaceri Romania 2011

**MEDICAL RESEARCH MONITORING
FORCE SRL**

Top realizat pentru Romania Intreprinderi Mici, localitatea SECTORUL 1, domeniul 7219:

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LISTAFIRME

Diploma

Locul 1 in Top Profit Romania 2012
**MEDICAL RESEARCH MONITORING
FORCE SRL**

*Top realizat pentru Romania Intreprinderi Mici, localitatea SECTORUL 1, domeniul 7219: Cercetare-dezvoltare in alte stiinte
naturale si inginerie, conform datelor de bilant aferente anului 2011.*

LOCUL

1

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LISTAFIRME

Diploma

Locul 1 in Top Afaceri Romania 2012
**MEDICAL RESEARCH MONITORING
FORCE SRL**

*Top realizat pentru Romania Intreprinderi Mici, localitatea SECTORUL 1, domeniul 7219: Cercetare-dezvoltare in alte stiinte
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