

DEDICATED TO SERVICE

Clinical Operations in CEE Region



COMPANY PROFILE

- Austrian based CRO, founded 1997 and cooperating with pharmaceutical, CRO and biotech companies in all phases of clinical development program
- Providing broad range of professional services, information and partnering solutions with highest quality, personal attention and customized to the needs of the client
- Reliable partner ensuring proper study conduct required by local law, GCP standards, client SOPs
- High professional experience, appropriately qualified and trained personnel, dynamic and success-oriented team devoted to the project, proactive and open to new challenges

WHY ZAK

MISSION STATEMENT

Zero deviation

As a service provider we are not only committed to our clients to **meet the targets of our projects** but also to monitor the individual project steps and to ensure maximum transparency

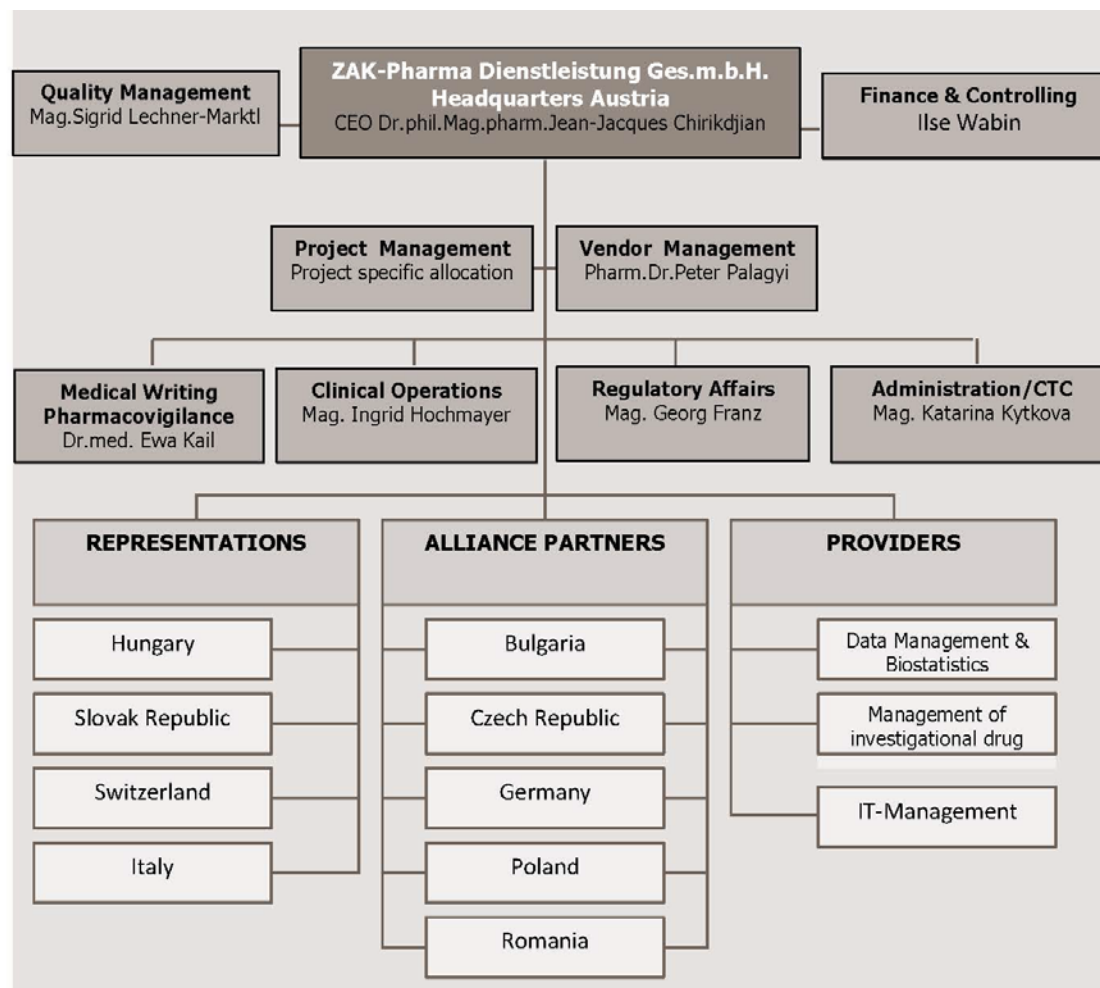
Attention to detail

We consider **active listening, precise research, finding of solutions and consequent action** as the foundation of our services. Also within the highest complexity we pay **attention to the detail** and consider correctness and accuracy the top principles when handling with confidential data

Know-how and competence

Our services are based on the **knowledge, experience and competence of our employees**. Hence we provide customised training, continuous further education and professional as well as individual support to all members of our staff

ORGANIZATIONAL STRUCTURE



SERVICES

CLINICAL TRIALS

PHASE I-III, PHASE IV, NIS

- Site selection, country and site feasibility
- RA/EC submissions, review and regular update of approval and reporting requirements
- Site monitoring / Site management
- Site contractual negotiations
- Site/Investigator payment process
- Project management
- Safety management / Pharmacovigilance
- Medical Writing
- Clinical Supplies Management (GDP certificate)
- Data Management & Statistics

SERVICES

REGULATORY AFFAIRS

- Evaluation and dossier preparation
- Pharmaceutical, pre-clinical and clinical reports, summary and overview acc. to CTD, e-CTD
- National, MRP, DCP
- Renewals, variations, Life Cycle Management
- Communication with Competent Authorities

SERVICES

QUALITY ASSURANCE

- GCP auditing
- SOP review / SOP writing
- Quality control/oversight

MEDICAL WRITING

- Protocol writing
- Clinical Study Report writing
- Periodic Safety Update Documents (PSURs) and other pharmacovigilance documents
- Informed Consent Forms
- Medical / Scientific Literature Reviews

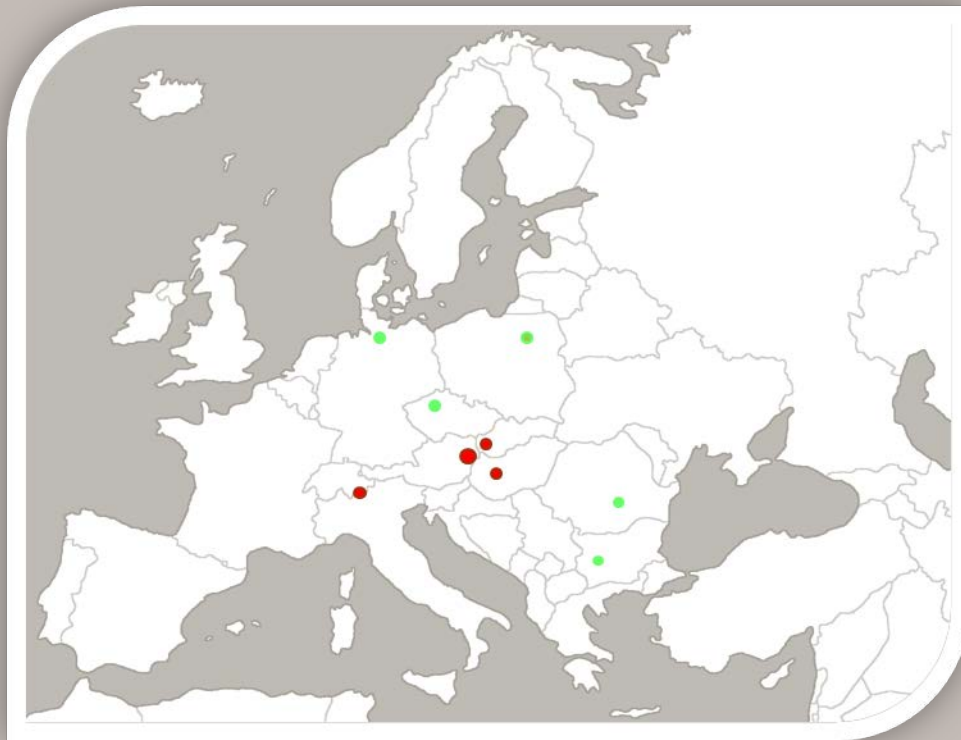
SERVICES

MEDICAL OVERSIGHT

Medical Monitor is a licensed physician who has extensive experience in the therapeutic area

- Patient eligibility confirmation
- Medical expertise to the study team, ensuring protocol understanding by the investigator
- Safety oversight and information about the study product
- Accountability for safety across the study
- Review of study level data including protocol deviations, identification of protocol deviations, risk management, mitigation action plan to avoid reoccurrence
- Targeted therapeutic area training to CRAs
- Coordination, review and approval of key study documents such as clinical study protocol and clinical study report

CEE COVERAGE



ZAK Head Quarter and Representation Offices:

- Vienna
- Budapest
- Bratislava
- Como
- Lugano

ZAK Alliance Partners:

- Bucarest
- Hamburg
- Prague
- Sofia
- Warsaw

CLINICAL OPERATIONS COOPERATIONS / ZAK ALLIANCES

- Standardized selection procedures for „preferred providers“ in non ZAK countries
- Consistency, high quality, cost efficiency guaranteed
- Performance of all contractors evaluated on regular basis and reviewed by QA auditing process

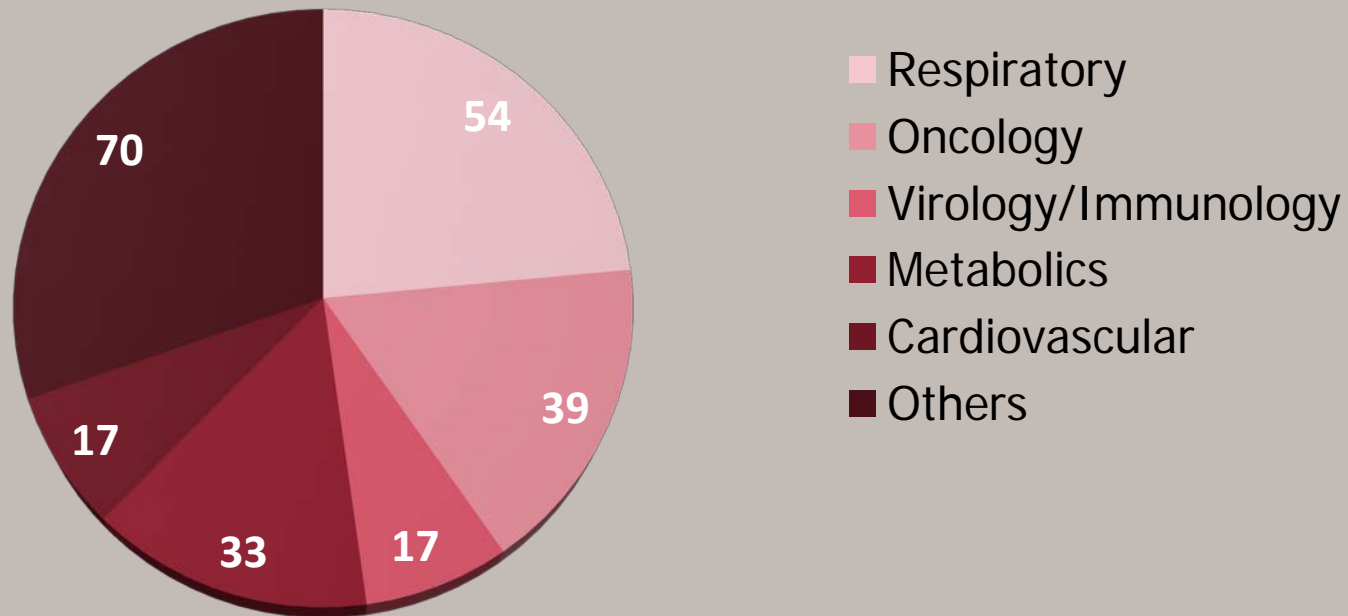
CLINICAL OPERATIONS

AREAS COVERED / ZAK ALLIANCES



THERAPEUTIC EXPERIENCE

**Number of Trials Phase I – IV
(including NIS & Registries)
1997 – 2012**



INDICATIONS

More than 200 projects since 1997 in the following areas:

Oncology	Renal cancer, breast cancer, prostate cancer, head and neck cancer, hepatocellular cancer, multiple myeloma, ovarian cancer, lung adenocarcinoma, NSCLC, solid tumors
Hematology	Haemophilia A
Respiratory	Asthma, COPD
Reumatology	Osteoarthritis, rheumatoid arthritis, osteochondral knee lesions, surveys of medical management of OA in CEE
Nephrology	Renal failure
Metabolic	T2DM, diabetic foot infection, hypercholesterolemia
Infect. diseases	Hepatitis C, HIV/HCV co-infection

INDICATIONS cont.

More than 200 projects since 1997 in the following areas:

Neurology/Psychiatry	Alzheimer´s disease, parkinsons disease, epilepsy, bipolar disorder, schizophrenia, depression, insomnia, multiple sclerosis
Gastroenterology	Ulcerative colitis
Cardiovascular	Hypertension, non-valvular atrial fibrillation, heart valve transplantation (Medical Device)
Urology	Benign prostate hyperplasia, prostate cancer
Pediatric studies	Haemophilia A, ENT, asthma
Pain treatment	

QUALIFICATION

HIGH LEVEL OF EDUCATION AND CONTINUOUS TRAINING

- Medical doctors, pharmacists, biochemists, nutritional scientists

YEARS OF EXPERIENCE

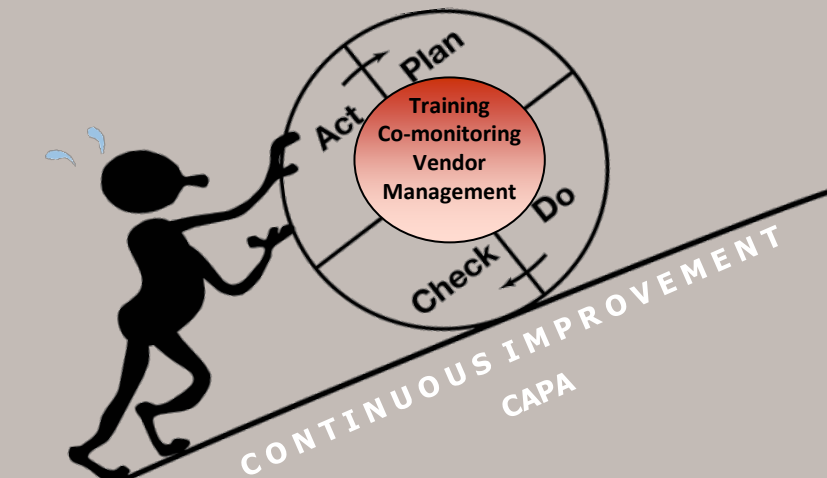
- Average years experience of key staff: **12 years**
- Minimum years experience of CRA: **2 years**

STAFF TURN OVER

- Average employment duration: **4 years**

QUALITY ASSURANCE

- Implemented ISO 9001-certified Quality Management System



HIGH QUALITY CRO/CRA WORK

21

SPONSOR & SYSTEM AUDITS

10

RA INSPECTIONS

NO

CRITICAL FINDING

APPROPRIATE SELECTION OF TRIAL SITES

RECRUITMENT: 90-120 %
(AT,HU,CZ)
(analysed trial 2006 -2012)

CONTACT US

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