

„We set things in motion –
and keep them moving”

Metronomia Clinical Research Services



METRONOMIA 

A woman with short brown hair, wearing a white lab coat, is focused on adjusting a wooden model of a DNA double helix. She is using a small metal tool to work on the structure. The background is a warm, yellowish-orange color. The image is partially obscured by a light blue vertical bar on the right side.

„Our customers love the fact
that we keep up with their
individual tempos.“

Dorothea Wessiepe, Director Biostatistics

Metronomia: Managing the Measurable

Our name, “Metronomia”, is derived from the Greek expression Μετρονομία, and means “managing the measurable”, precisely describing our core mission, which is to collect, process and analyse high-quality clinical data, and draw valuable and reliable conclusions from the data.

We are Metronomia

Metronomia is a mid-size, owner-driven CRO based in Munich, Germany, offering high-quality clinical research services to pharma, biotech, and medical device companies. Since 1990, Metronomia has successfully been involved in more than 500 clinical projects, covering all clinical stages and project sizes across all major therapeutic areas. Based on our clients’ individual needs, we provide a full service or tailored functional services.

Our Commitment

Our clients are at the heart of all of our activities. We have systems in place to guarantee consistent high-quality results and productive, long-lasting, trustful relationships. Therefore, we commit ourselves to outstanding clinical trial know-how, efficient processes, state-of-the-art technology, personal service through stable project teams, and exceptional flexibility.

A woman with long blonde hair, wearing a grey long-sleeved top, is holding a white paper airplane in her right hand. She is looking upwards and to the right with a thoughtful expression. The background is a solid, bright yellow color. In the top right corner, there is a quote in teal text and a name in black text below it.

„All our customers get
first-class service.“

Christine Fuest-Parakenings, Senior Clinical Data Manager

Always the Right Choice

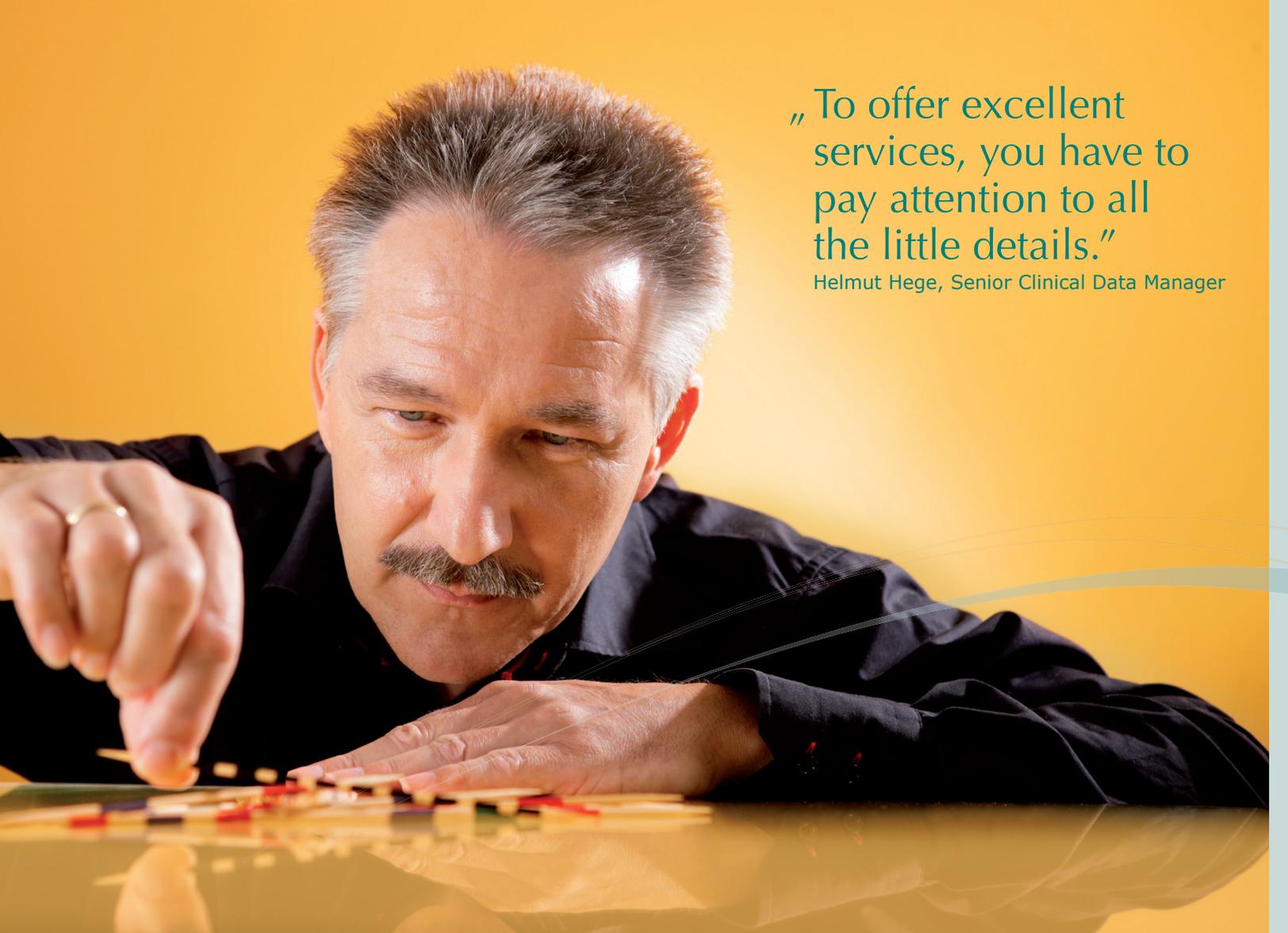
We approach each study, large or small, Phase I or Phase IV, with dedicated and highly-motivated project teams, and a strong pledge to always meet our clients' objectives. To help meet the individual and specific needs of our clients', we offer two different business approaches:

Full-service

- Study design consulting
- Protocol and CRF development
- Feasibility research and feasibility studies
- Project management
- Clinical operations:
 - Regulatory and ethics committee submissions
 - On-site and remote monitoring
 - Risk-based and data driven monitoring approaches
- Drug safety services
- Clinical data management
- Statistical services
- Randomisation / IWRS services
- Quality assurance audits
- Medical writing

Functional services

- Clinical data management and eCRF support
- Statistical services and statistical programming
- Statistical consulting
- DSMB involvement
- CDISC SDTM and ADaM services
- Randomisation / IWRS services



„ To offer excellent services, you have to pay attention to all the little details.“

Helmut Hege, Senior Clinical Data Manager

Clinical Data Management

Key factors of our extraordinary performance in clinical data management are people, processes and technology: Our well-established standard operating procedures are put into practice by well-trained, experienced teams supported by high-end clinical data management solutions. Inspection readiness is vital and our systems and processes have successfully passed FDA, EMA and national inspections.

We offer the complete range of clinical data management services, in eCRF and paper CRF format, or combinations of both:

- (e)CRF design and testing
- Data management and data validation plan
- Database set-up following CDISC CDASH and SDTM standards
- Programming and validation comprehensive data checks
- Manual medical and data management data review
- Query management
- Medical coding
- SAE management
- Integrating data from external sources
- (e)PRO support
- Customised status reporting
- Supported systems: Oracle's Clintrial, Quadratek's clincase and Medidata's RAVE
- eCRF specific services:
 - User training including self-training infrastructure
 - Global 24/7 helpdesk
 - User management
 - eCRF archiving
 - Data hosting
- Paper CRF specific services:
 - Paper CRF tracking and scanning
 - Double data entry

Statistics - Our origin, our passion!

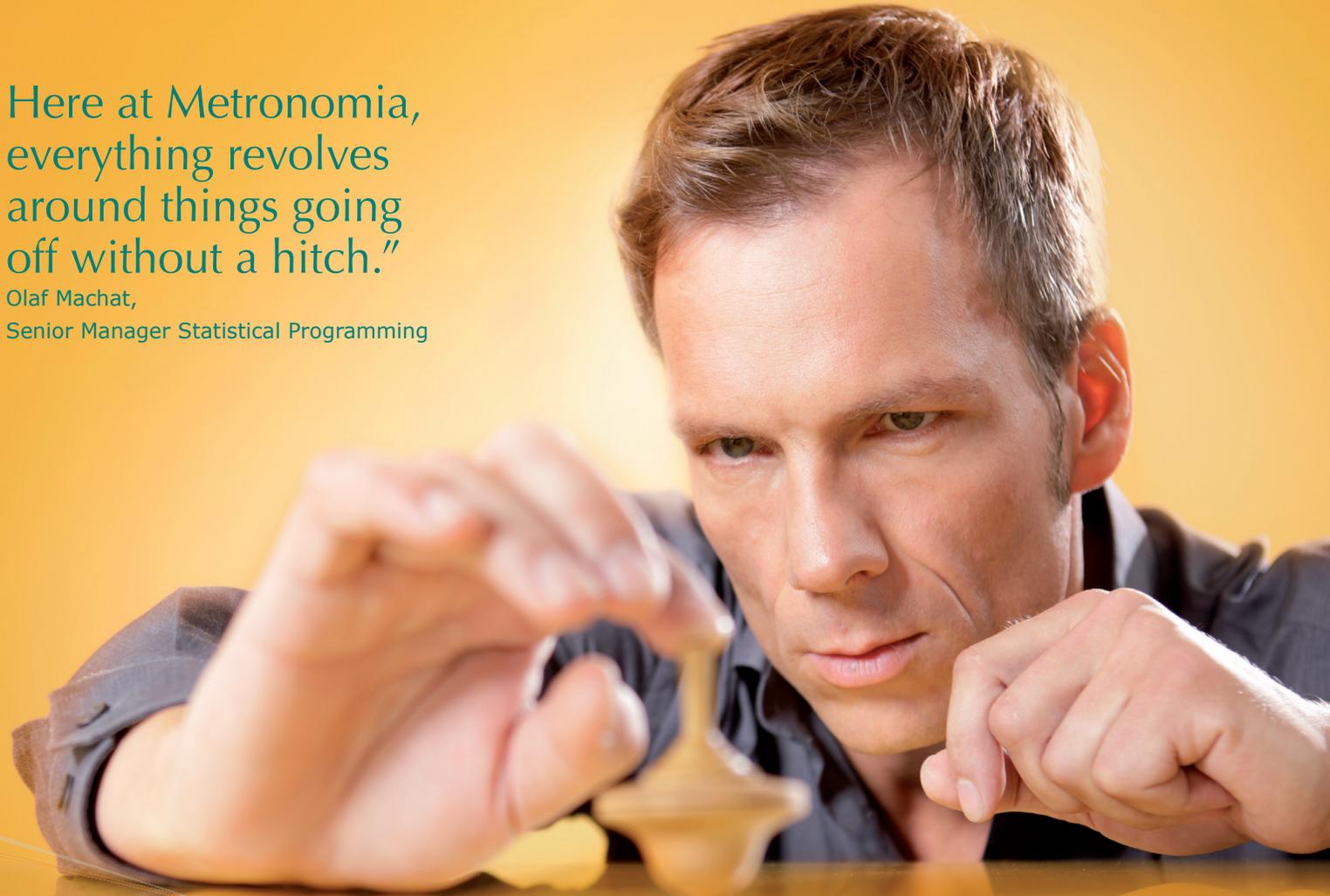
With our experienced team of senior statistical experts, biostatisticians and statistical programmers, Metronomia is able to offer the complete range of biostatistical services – from consulting projects, through specific or niche statistical projects, to the management of large submissions projects. Our clients regularly entrust all of their statistical requirements to Metronomia, collaborating with us as an external statistics department, or using Metronomia as a single data centre.

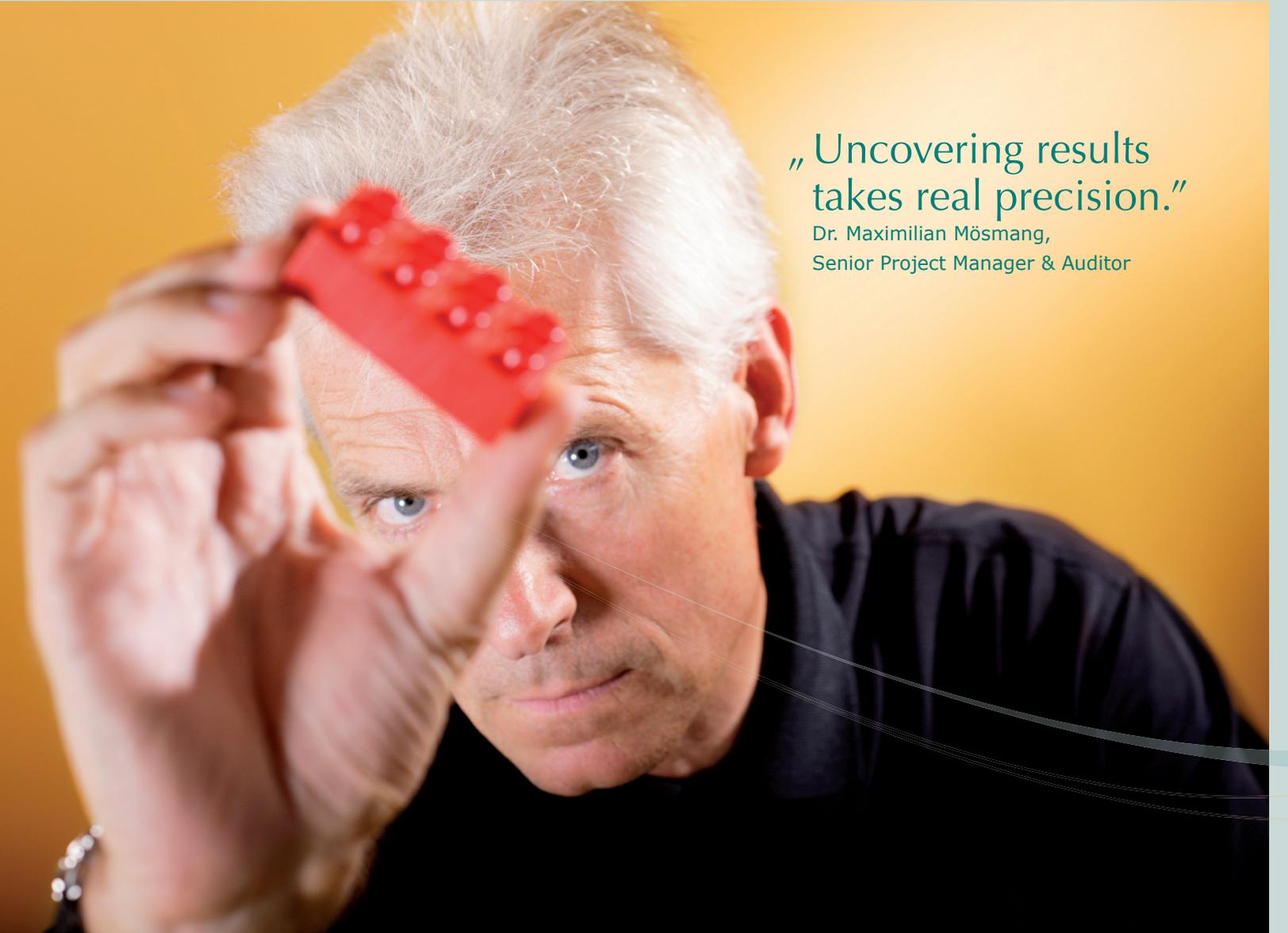
Expertise:

- Statistical planning of clinical trials including:
 - Proof of concept studies
 - Dose-response or dose-finding studies
 - Non-inferiority and bioequivalence studies
 - Flexible designs
- Input into study protocols, CRF review
- Sample size and power calculation, simulations
- Statistical analysis plan and shell table specifications:
 - Interim and final analysis
 - QoL und PRO data analysis
 - PK/PD analysis
 - Integrated analyses
 - Meta-analyses
- Definition and programming of CDISC SDTM and ADaM datasets
- Programming and validation of statistical output
- (Blind) data review meeting
- Randomisation services (including IWRS)
- Preparation of clinical study reports
- Participation in DSMBs and independent data monitoring committee statistician
- Active participation in meetings with regulatory agencies (EMA, BfArM, PEI, FDA)

„ Here at Metronomia,
everything revolves
around things going
off without a hitch.“

Olaf Machat,
Senior Manager Statistical Programming





„Uncovering results
takes real precision.“

Dr. Maximilian Mösmang,
Senior Project Manager & Auditor

Support at Every Stage

Early Phase Services

Partnering with Phase I units and expert pharmacologists ensures world class services in the development of:

- Phase I, First-in-Human studies
- PK/PD and BA/BE studies
- Food-drug and drug-drug interaction studies
- Phase IIa / proof of concept studies

Phase II and III Clinical Trials

We have significantly contributed to several FDA, EMA and national submissions. By providing well-equipped, well-trained teams experienced in conducting complex and large Phase II and Phase III trials, we ensure adherence to deadlines whilst keeping costs low and quality high. We constantly and consistently strive to improve the efficiency of our services. We invest in services based on top e-technologies to help us deliver data faster while ensuring patient safety, timely collection of data, and providing efficacy results to satisfy regulators.

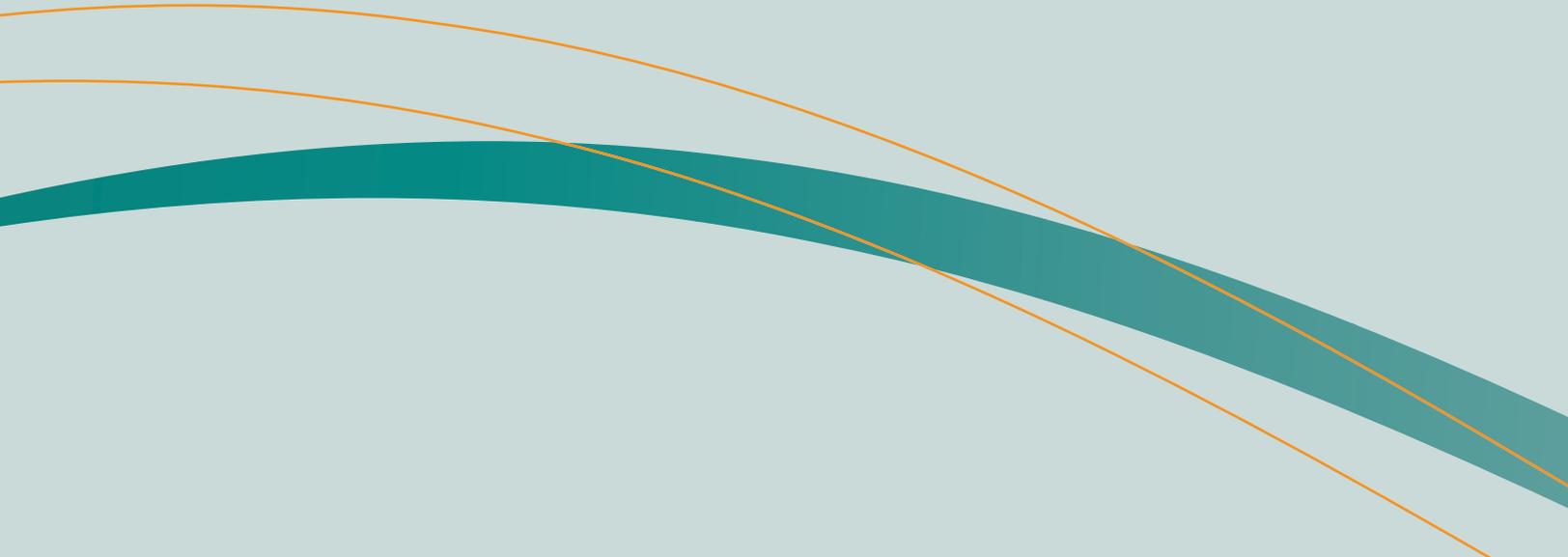
Late Phase Services

Preparing a product ready for the real world, Metronomia helps to manage new challenges:

- Phase IIIb and IV randomised clinical trials
- Observational / non-interventional studies and registries
- PASS or PAES studies
- Health economics and outcomes research
- Competitive marketing claims studies

Our Philosophy: Quality, Economic Success & Sustainability!

Our goal is to be economically successful while behaving respectfully and responsibly towards our clients, employees, suppliers, and the environment. We believe in long-lasting, fair business relationships and to find the right way to deliver high quality at fair prices to our clients, while paying fair salaries to our employees and paying our taxes. Our ethos of doing business this way has been rewarded by long-term, trustful client relationships, a low employee turnover (< 5% per annum) and constant rate of growth over the past decade.



Commitment to Quality

Metronomia has successfully passed all client audits as well as inspections from EMA, BfArM and the FDA, through our commitment to high quality in all areas of our business. We conduct projects efficiently and in line with international quality standards, best practices and ethical principles to ensure the very best services for our clients. Our quality management system is designed to ensure adherence to these principles, with detailed standard operating procedures and regular internal audits. Our desire to deliver the best results efficiently has helped us to foster a climate of continuous improvement of all our processes.

Social and Environmental Responsibility

Metronomia places particular emphasis on its social and environmental responsibilities, and actively supports various organisations and initiatives worldwide such as providing financial support to a South African NGO working HIV/AIDS affected people (www.gezubuso.com) for more than 10 years; engaging in various health-related projects (e.g. allowing employees to regularly donate blood during working hours; contributing to the fight against leukaemia by organising and covering the costs of tissue typing, and registration of new potential stem cell donors amongst staff); supporting local social projects; "green office" policy (e.g. only renewable energy, constantly seeking new ways of energy reduction).

Facts & Figures

Founded: 1990

Number of employees: > 50

Number of completed projects: > 500

Therapeutic indication expertise

- Allergology
- Gynaecology
- Pulmonary and respiratory diseases
- Anti-Coagulation
- Haematology
- Rheumatology
- Cardiovascular diseases
- Immunology
- Surgery
- CNS
- Infectious diseases
- Urology
- Dermatology
- Nephrology
- Transplantation
- Endocrinology
- Oncology
- Wound therapy
- Gastroenterology
- Ophthalmology

Experienced in

- Small molecules, biologicals, phytopharmaceuticals
- Biosimilars & generics
- Medical devices
- Orphan diseases
- Paediatric clinical trials

We are highly experienced throughout all stages of clinical development:

Phase I
20%

Phase II
25%

Phase III
20%

Phase IV
15%

NIS
25%

„ We stay focused on
your projects.“

Jens Knösel, eClinical Project Manager



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