MC.COMAC MEDICAL

EARLY PHASE CLINICAL DEVELOPMENT

part of:

COMAC MEDICAL

EXPERTS IN CLINICAL RESEARCH

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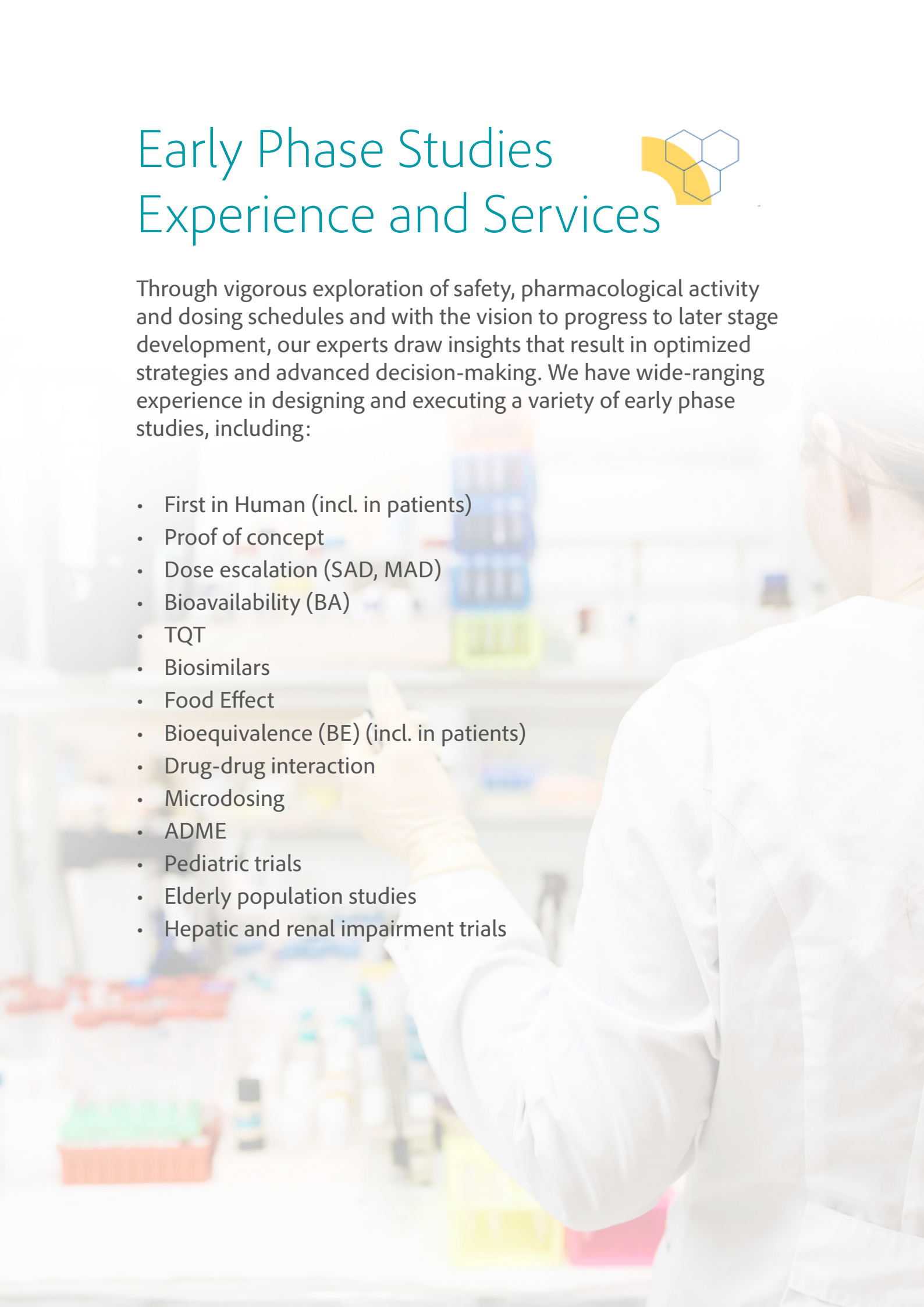
Early Phase Studies Experience and Services

Through vigorous exploration of safety, pharmacological activity and dosing schedules and with the vision to progress to later stage development, our experts draw insights that result in optimized strategies and advanced decision-making. We have wide-ranging experience in designing and executing a variety of early phase studies, including:

- First in Human (incl. in patients)
- Proof of concept
- Dose escalation (SAD, MAD)
- Bioavailability (BA)
- TQT
- Biosimilars
- Food Effect
- Bioequivalence (BE) (incl. in patients)
- Drug-drug interaction
- Microdosing
- ADME
- Pediatric trials
- Elderly population studies
- Hepatic and renal impairment trials



Phase I Clinical Research Unit Experience

Comac Medical's hospital-based Phase I Clinical Research Unit has 14 years of experience in early clinical research including over 227 completed clinical trials. The unit's facility is the largest one in Southeastern Europe and comprises 42 available beds and on-site pharmacy. Our specialized teams are dedicated to the conduct of early-phase studies in healthy volunteers, special populations, and patient populations over a range of diseases.

Comac Medical's Clinical Research Unit is fully integrated with Comac Medical CRO, a clear advantage for our clients. From consultation on protocol designs to developing innovative processes for complex trials, Comac Medical leverages decades of experience in clinical solutions in addition to a wide network of clinical experts covering many therapeutic areas to provide unique and tailored solutions in clinical development.

early phase clinical trials EXPERIENCE

167 TOTAL | for the last **5 years**

- **7** Gynecology
- **18** Respiratory
- **21** Rheumatoid Arthritis
- **3** Haema-tology
- **9** Metabolic Diseases
- **8** Immunology
- **10** Oncology
- **26** Cardiovascular
- **12** Dermatology
- **15** Infectious Diseases & Vaccines
- **17** Neurology (CNS)
- **8** Gastro-enterology
- **8** Nephrology
- **5** Ophthal-mology

Phase I
State-of-the-Art Facility

Our Phase I Clinical Research Unit is located in close proximity to the biggest medical academia campus in the country with outreach to the leading national medical experts and facilities. The Unit is easily accessible for patients and volunteers. The facility excellence in clinical solutions and provides high-end amenities to study participants. Highlights of the Unit include:

- Clinical team experienced in EPCD
- Area of 1200 m2 (access control system)
- 42 hospital beds (including 1 intensive care bed)
- 24h Emergency Care team/ 24h Ambulance
- Temperature monitoring & recording system
- Possibility to separate cohorts/ trials
- Sampling room
- Archiving facility
- Emergency Care equipment (cardiac monitoring)
- Central clock system
- Patient alarm system
- Hi-tech camera monitoring system
- Announcement and audio system
- Monochromatic light rooms
- Power back-up
- Fire-alarm system

comac-medical.com/phase-i-unit/

Clinical and Bioanalytical Laboratories

Comac Medical's laboratories provide impeccable scientific expertise with state-of-the-art technologies. With commitment to exceptional quality, our laboratory services accelerate pharmaceutical discovery and development for both small and large molecules.

The Comac Medical bioanalytical lab is dedicated to support clients to progress their trials by providing high quality and accurate results across all phases of clinical trials.

Our lab team is at the heart of our bioanalytical capabilities. Years of history in bioanalytical testing has resulted in a deep understanding of regulatory guidelines, requirements and the evolving expectations for bioanalytical processes.

We leverage the experience of our leaders, managers and scientists to effectively meet clients' requirements of accurate, timely, high-quality results with:

- Central laboratory services
- Logistics support
- Samples management
- Samples analysis
- Method development and validation
- Laboratory Project Management
- Lab data transfer
- Scientific consultancy

Areas of Expertise

We have been partnering with or clients during their clinical trials to accelerate timelines with best-in-class procedures and assays.

Comac Medical's laboratories are GcLP compliant and are strategically located close to our Phase I Clinical Research Unit to facilitate an innovative working collaboration and to enable time-critical results to be analyzed within rapid turnaround timeframes.

Clinical Laboratory

- Wide range of technologies and applications (Hematology, Clinical & Special Chemistry, Immunology, Microbiology, Biomarkers assessments)
- Preparation of Laboratory Manuals
- Preparation of laboratory kits and patient forms
- Sample handling, management and storage
- Dedicated laboratory project management
- Flexible logistics services
- Shipment monitoring
- Investigator support
- Data export capabilities (incl. in STDM compliant format)

Bioanalytical Laboratory

- Regulatory method development and validation (small & large molecules)
- Expertise in different analytical techniques (LBA and LC-MS/MS)
- Expertise in "Fit For Purpose" validation for early phase clinical studies and biomarkers
- Association with industry advisory groups
- GCP and GLP compliance
- Lab data transfer (incl. SDTM format)
- Immunogenicity analysis

Dedicated On-Site Clinical Trial Pharmacy

Our dedicated pharmacy supports patient safety, regulatory compliance and safe conduct of clinical trials. The team of research-trained pharmacists work in close collaboration with the other clinical trial teams to provide a streamlined service to patients and make sure the study drugs are available in a fast and safe manner. The pharmacy is conveniently located at the Phase I Unit. Some of the advantages our on-site clinical trial pharmacy offers include:

- Large team of qualified pharmacists
- Electronic system for monitoring temperature and humidity
- Integrated temperature alarm system
- Re-labeling of IMP
- Large working area for IMP handling
- Availability of refrigerators to store IMPs at any temperature range

Who We Are

Comac Medical is a full-service niche provider of CRO and SMO services with more than 290 full-time employees, operating at the best healthcare institutions in 30 European countries, USA and Canada.

Comac Medical's early development and clinical research solutions allow clients to maximize value in their clinical research studies by developing integrated programs supported by an experienced international team. Through leveraging best-in-class facilities and operational experts, we successfully execute clinical trials in both healthy volunteers and patients.

Why Us

We endeavor to deliver expert and high quality clinical development services by combining the advantages of cutting-edge facilities and technical resources with the experience of the highly engaged academic teams. We offer flexible solutions across the early development spectrum customized to fit client needs. Our core strengths are:

- Client comes first attitude to business
- Dedicated Phase I Unit and access to vast and specific patient pools
- Proven track record for quality and delivery
- Established and trusted relationships with KOLs
- Motivated and loyal Comac Medical team
- Flexible team who listens and reacts quickly to client needs
- Global full-service capabilities

We welcome the opportunity to arrange visits to our early phase premises & laboratories. Please contact us at business.development@comac-medical.com for additional information.

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