Phase I Unit

EARLY PHASE TRIALS

COMAC MEDICAL

MORE THAN A CRO
THE UNIT

FULL-SERVICE
Integrated services resulting in cost- and process-effectiveness

ACCESS TO
Large (drug naïve) patient pools

COLLABORATIVE PARTNERSHIP
With Clients based on open communication

DEDICATED
Clinical and Monitoring Teams

RELIABLE
Strategic planning to accelerate drug development

RAPID STUDY START-UP
And fast enrollment in Bulgaria

COMPETITIVE
Pricing Model

FLEXIBLE SERVICE
Offering tailored to Client needs

MORE THAN A CRO
FACILITIES

1200
M2 OF AREA
(access control system)

42
HOSPITAL BEDS
(including 1 intensive care ones)

24h
DEDICATED MEDICAL TEAM
(physician present)

POSSIBILITY TO SEPARATE COHORTS/ TRIALS

TEMPERATURE MONITORING & RECORDING SYSTEM

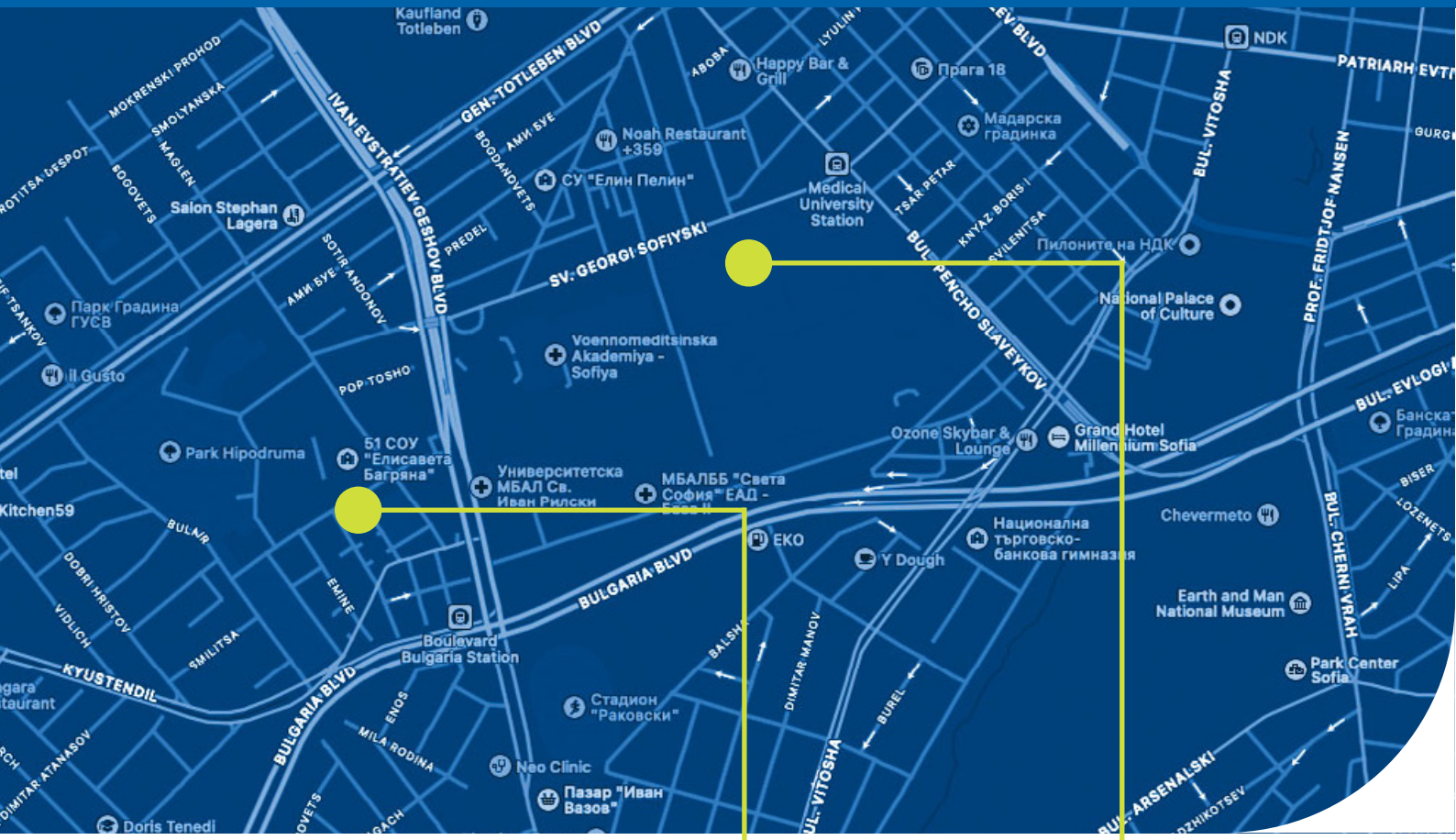
24h
EMERGENCY CARE TEAM/AMBULANCE

DEDICATED PHARMACY
(laminar flow cabinet for aseptic drug preparation)

24H VIDEO SURVEILLANCE

EXPERIENCED IN EPCD CLINICAL TEAM

MORE THAN A CRO
LOCATION



SECONDARY LOCATION
1 Sv. Georgi Sofiyski Str.

PRIMARY LOCATION
13 Urvich Str.

Our Phase I Unit is situated at two locations within the heart of the city nearby to major hospitals and medical academia campuses and within close distance of major transportation lines, making it convenient for study participant to commute.

CLICK BELOW
TO MAKE A 3D TOUR OF OUR FACILITIES

CPU location 1 | CPU location 2 | Laboratory location

MORE THAN A CRO
COMAC PHASE I BENEFITS

Expertise and Specialization

Specializing in Phase I studies demonstrates a deep understanding of the intricacies and challenges associated with early-phase clinical trials. *This expertise is translated for Sponsor studies into a more efficient trial planning, execution, and troubleshooting, leading to faster results and informed decision-making.*

Accelerated Timelines

Comac Medical has the proven ability to provide rapid study start-up due to the fact that additional site contract negotiations are avoided (i.e. Comac is the site), and study set-up is streamlined internally utilizing the synergies between all involved teams. By leveraging our capabilities Comac Medical is able to quickly activate the site and begin enrolment immediately after receiving approval.
Important note: No additional contract negotiation required for Comac Medical CRU.

Cross-Functional Collaboration

While the Phase I unit operates independently, there's the benefit of valuable cross-functional collaboration within Comac Medical. For instance, experts from the Phase I unit will collaborate directly with other teams (such as biostatistics, regulatory affairs, and medical writing) to ensure comprehensive study planning and reporting.

Independent Structure (COMAC CRU)

The separation between the CRO team and the Phase I units eliminates conflicts of interest. This separation ensures that decisions are made solely based on the best interests of the client and the trial's scientific integrity, without any undue influence from business-related considerations.

MORE THAN A CRO
PARALLEL CONDUCT OF TRIALS

Comac Medical's Phase I Unit includes a large, experienced, and well-trained study team comprised of physicians, study nurses, coordinators, and recruitment specialists that enables the quick and efficient launch and management of all types of clinical trials.

The Phase I Unit can perform 24-hour and weekend PK sampling, as well as support sample acquisition and processing at all hours.

Due to experience with adhering to highly structured processes, the Phase I Unit offers the possibility of running parallel studies:

- Without any risk of detrimental impact to study procedures. This is a commonly used approach, and our teams are used to coping with such logistical challenges, ensuring at all times that the appropriate resources are allocated.

- We usually delegate a large number of staff to studies (i.e. >40) in order to ensure constant coverage and oversight, so the same team can be used for both the renal and the hepatic studies.

- Prior to launching the two studies, the clinical team will create study-specific internal organizational charts that will be tailored to all procedures and that will strictly be observed in order to ensure seamless execution.

COMAC MEDICAL

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