

2024



HOSPITAL BASED PHASE ONE UNIT

Sofia, Bulgaria



Our mission

- ❖ To deliver quality product in timely manner with respect to timelines
- ❖ To establish connection between Pharma industry needs and scientific medical team understanding and further develop medical standards
- ❖ To protect patient/ subject health and well-being in early phases of research
- ❖ To ensure and maintain best practices and become a preferable service provider for complex early phase protocols





A tailored and client-specific approach.



A facility with cutting edge technical resources to guarantee patient safety and proper execution of complex protocols.



A management committed on clients' needs and race with timelines with no compromise on quality of data.



A team with clinical, medical, scientific and regulatory experience and culture to meet high client expectations



Advantages





A quality of work and timelines respect to have the client back again for new tasks



A flexible utilization of the research facilities to best meet client needs and protocol specifics

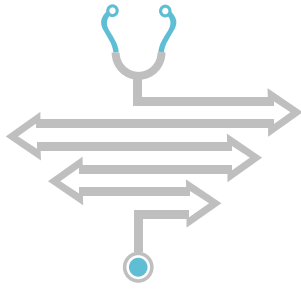


An ongoing development of hospital base and integration of new facilities for conducting large sample size BE/BA studies

Advantages (con't)



An excellent work pattern for specific (FIM/ FIP) and complex protocols



To develop medical research teams for different therapeutic areas

To increase the number of studies and to decrease the turn-around time

To ensure sustained development of team professional skills, therapeutic and research expertise and regulatory knowledge

To expand hospital facilities into a new adjacent building and to complete the BE/BA, Phase I studies facility

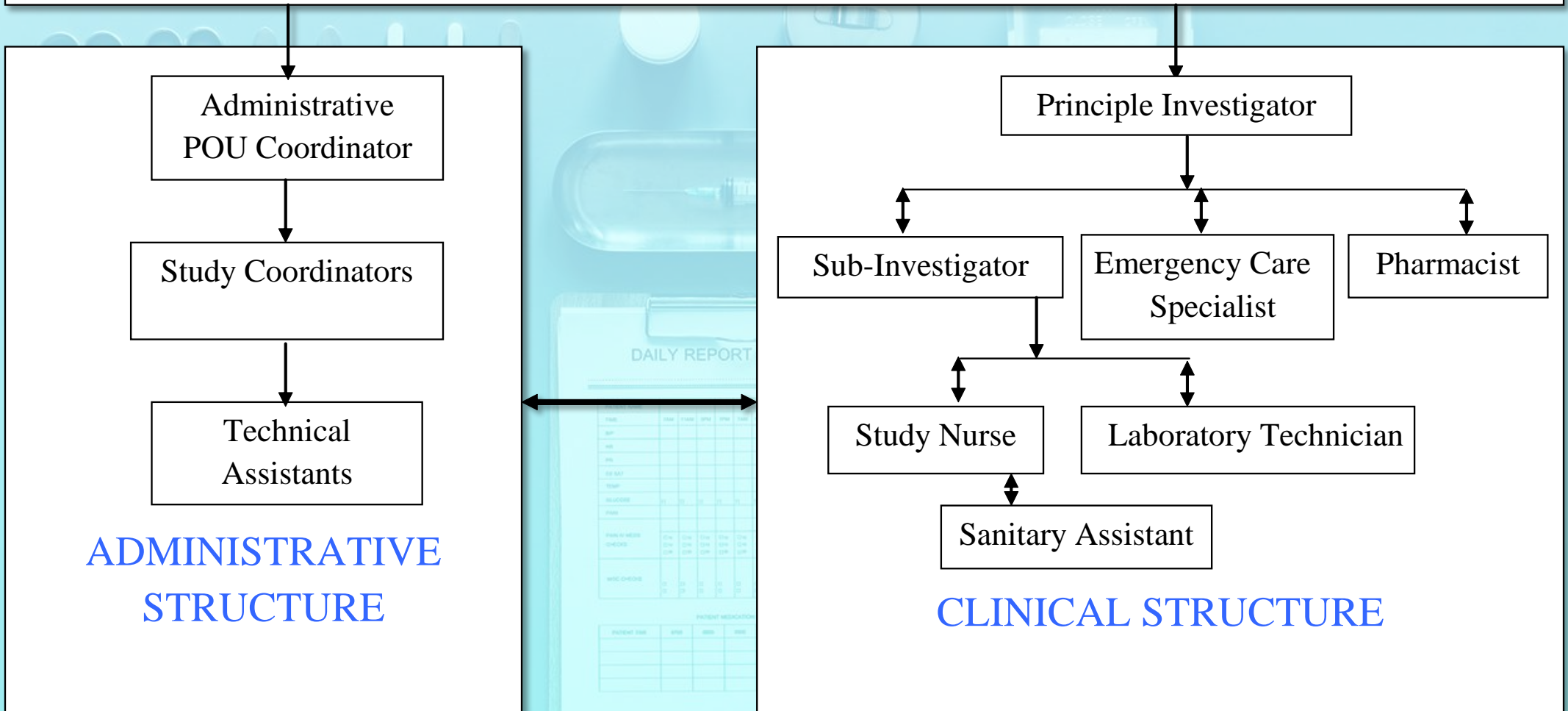




POU Organization Chart



Manager Phase One Unit



Outstanding achievements

- ❖ Phase I biosimilar study in 156 healthy male subjects (FIM) – subjects enrolled in 1.5 month
- ❖ PoC study in 24 patients with RA
- ❖ Piezo-electric Misting Device PK study in 24 HV
- ❖ Implantation of stem cells on patients after thrauma /ongoing/
- ❖ Determination of Reference Values for Troponin in 180 HV /ongoing/
- ❖ Phase I biosimilar study in 162 HV
- ❖ 24 BA/ BE studies in healthy volunteers
- ❖ Phase II medical device study in stem-cell therapy in incontinence treatment
- ❖ Phase II study in OA treatment (multicenter) with #2 top result for EU area



Site Staff Experience

32 BA/BE studies in healthy volunteers

15 BA/BE studies with patient volunteers

(3) Phase I biosimilar study in healthy volunteers (1 – oncology and 2 endocrinology)

2 Phase I biosimilar in PV (rheumatology)

2 PoC patient study (rheumatology)

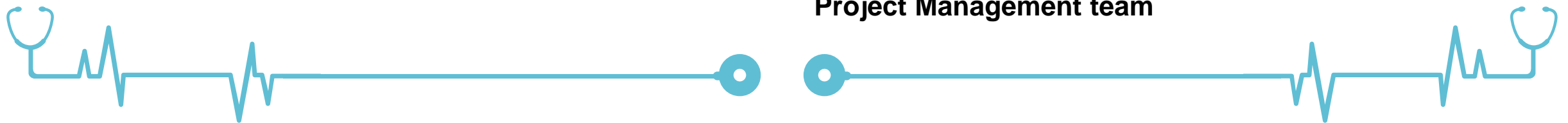
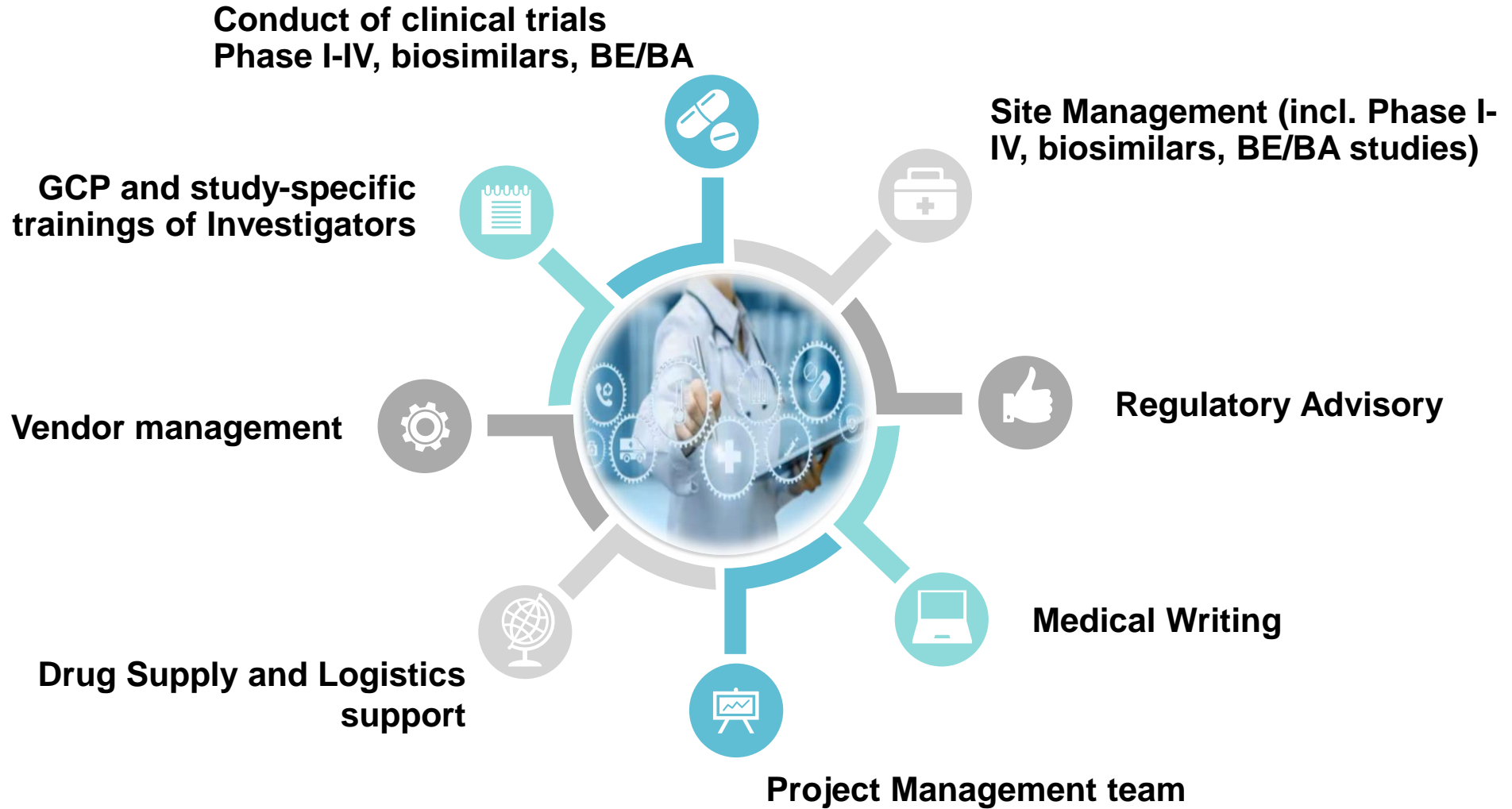
12 Phase I clinical studies (as part of multicentre study design)

45 Phase II clinical studies

152 Phase III clinical studies

40 Phase IV clinical studies

Services



Trainings



- ❖ Investigator education and continuous GCP training
- ❖ Patient recruitment facilitation (protocol review with investigators)
- ❖ Patient retention management
- ❖ Staff training on EDC, IxRS and else systems
- ❖ Continuous Site Oversight/ Guidance



AUDITS (Early phase studies)

2017

Sponsor system audit in 2017 without any findings

2017
-
2018

Sponsor study audits (late 2017 and a confirmatory one in 2018) with no major findings

2022

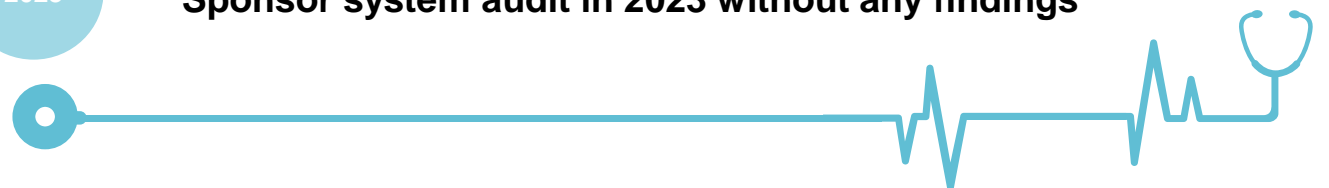
Sponsor system audit in 2022 without any findings

2022

EMA site assessment, Site of Excellence

2023

Sponsor system audit in 2023 without any findings



Regulatory Advisory



Ensure best regulatory approach for complex protocols



Ensure best medical/ scientific advise for protocol writing



Support for scientific advise meetings



Close collaboration with KOL experts



Medical review



Pharmacovigilance support



Phase I Unit Gallery



Area of 480 sq.m each floor

36-beds Phase I, FIM, BE/BA unit (*number of volunteers/ patients could be multiplied by 6 = example 36, 72, 96*) to meet necessary BE/BA protocols sample size.

4 beds intensive care unit (24/7 medical care and monitoring).

Beds



Experienced research staff
Dedicated medical team (physician present 24H), 24 hours reception
Reanimation and Recuscitation care guaranteed (24H Emergency Care team)



Certified and calibrated hospital devices



Safety Laboratory



Pharmacy and Sampling rooms





Physicians' offices and patients' lockers

Facilities (wrap-up)

- Area of 480 sq.m each floor
- 2x18 hospital beds and 4 beds intensive care unit
- Dedicated medical team (physician present 24H)
- 24H Emergency Care team
- Possibility to separate cohorts/ trials
- Physicians' offices
- Storage room
- Sampling rooms
- Safety laboratory
- Pharmacy
- Emergency Care equipment
- 24/7 Ambulance
- 24/7 Reception
- X Ray, CT, ECG, Ultrasound in-house
- Central clock system
- Patient alarm system
- High-speed Internet connection
- Fire alarm system
- Access control system
- Alternative light enhancements
- Back-up generator
- Ventilation/ Air conditioning
- Cardiac monitoring capability
- Special pharmacy services including IV dose preparation, randomization blinding
- Refrigerated and ambient centrifuges
- Alarmed refrigerators/ freezers(-20, -70 and -80 degrees) monitored daily by site staff
- Caterer prepares meals and protocol mandated special diets if required
- MDs on call



CONTACT US

