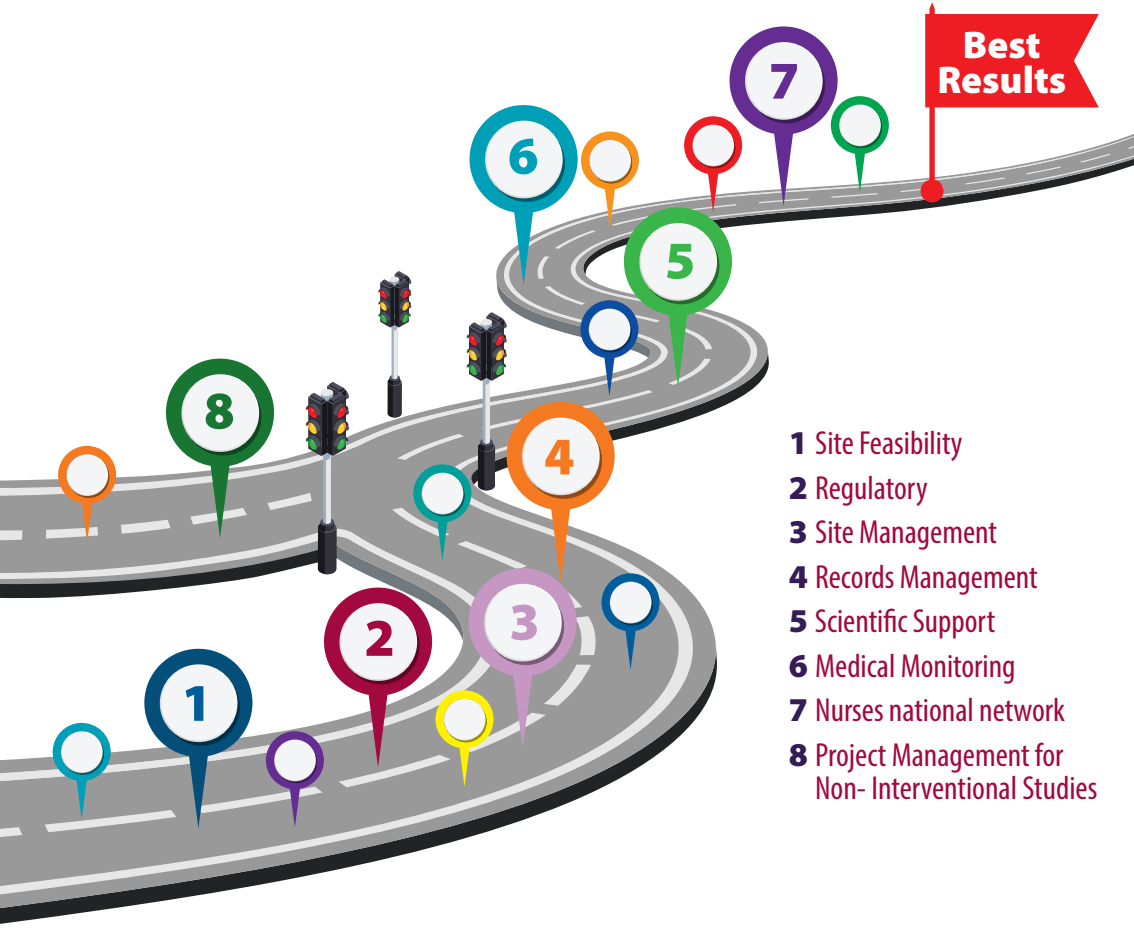
Target SMO

Commitment and Quality

Make your clinical trials' road easier with TARGET SMO



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7 Nurses national network
8 Project Management for Non- Interventional Studies

OUR SERVICES

SITE FEASIBILITY

- Optimization of feasibility process as we collaborate with institutions and investigators in multiple locations across Romania
- Rapid site identification based on the requirements of Sponsors/ CROs. Recommendation of suitable sites from our network for a specific study protocol. Support our sites to provide fast answers to feasibility questionnaires received from Sponsors/CROs.
- Provide input for protocol feasibility (e.g: eligibility criteria that are not medically significant but may drastically limit the enrollment, some local particularly treatment protocol etc).

REGULATORY

- Timely compilation/ editing / upload of documents required for submission according to EU-CTR.
- Ensure the site is registered in SPOR-OMS for studies submitted under EU-CTR procedure.

SITE MANAGEMENT

- Allocate highly trained Site Coordinators (SCs) who are delegated by PIs to perform administrative and non-medical study activities.
- Contract negotiation and finalization in compliance with local regulations. Payment process optimization: calculating site staff fees, invoicing expenses and pass-through costs, ensuring the payments are done in accordance with local tax requirements.
- Collaborate with Sponsors/ CROs monitors to ensure efficiency of the monitoring visits from the site initiation until site close-out.

RECORDS MANAGEMENT

- Setting up and maintaining the paper or electronic Investigator Site File (ISF), according to GCP and Sponsor SOPs.
- Perform periodic quality checks and reconciliation with the Sponsor TMF to ensure completeness of the expected documentation and reduce TMF operational burden.

SCIENTIFIC SUPPORT

- Summaries of Advisory Board Meetings provided by qualified personnel which attend the meetings between the medical departments of the Sponsors' Companies and the KOLs, and review the discussed medical topics.
- ICH – GCP – Good Clinical Practice training and customized study protocol training for each study team role.

MEDICAL MONITORING

- Monitoring of safety information collected during the clinical trial and cross check of adverse events and concomitant medications.
- Verification of subject eligibility based on the review of the protocol.

NURSES NATIONAL NETWORK

- Home healthcare services for clinical trial patients: home visits, collection of vital signs, collection of laboratory samples, administration of IP.
- National study nurses' team to support decentralized clinical trial activities in multiple locations across Romania.
- Experienced research nurses with background covering a broad spectrum of therapeutical areas.

PROJECT MANAGEMENT FOR NON-INTERVENTIONAL STUDIES

- Statistical input for development of Study Protocol/ Observational Plan.
- End to end comprehensive clinical data management services, from developing the Data Management Plan to data archiving.
- Site management and pharmacovigilance reporting.
- Safety Data Management & Reconciliation.
- Medical writing and scientific advice for study report and publication.

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