GTO is part of the ***Pharma-Job Group***, has unique advantages that serve our customers' needs:

- **29 years of accumulated experience** in the BioPharma and Medical Device areas.
- More than **46,000 interviewed candidates** in Pharma-Job's database.
- Close relations with **more than 2,500 customers,** including multinational corporations.
- Thorough familiarity with the **multinational corporates' culture**.
- **Wide network** and close relations with **partners around the world**.
- Broad spectrum of **multidisciplinary services** from **small to large organizations**.
- High **flexibility**, using **diversified array of working models** in **Israel and worldwide**.
- Operating model designed to address customer's needs in **efficient and cost effective** ways.
- **One Stop Shop** for all services that you need.

GTO offers a wide range of services including:

Clinical Trials Phase 0 - Phase IV

Study Start-up

- Trial planning and project management
- Site identification, qualification and selection
- Investigator identification and recruitment
- Investigator agreements/payments
- Study supply management
- Central laboratory services
- Central laboratory management

Study Documents

- Study/regulatory manual preparation and distribution
- CRF design, development, printing and shipping
- Preparation, submission and tracking of ethics documentations
- Protocol writing and development

Study Personnel

- Investigator and initiation meetings
- Site training
- Investigator/patient recruitment and retention strategies
- Medical monitoring

Site Visits

- On-site monitoring (pre-study, initiation, routine, close-out)
- On-site audits
- ICH-GCP compliance
- Query and discrepancy resolutions
- Site training and education

Biometrics

- ICH E9 compliance
- CRF design (EDC or paper)
- e-CRF (EDC)
- Database design and creation
- Data entry and cleaning
- Statistical analysis planning
- Analysis tables, listings and graphs
- Online data review
- Interim analyses
- Integrated summaries of efficacy and safety
- Exploratory and meta analyses
- Multi-study data integration

Regulatory Affairs

- Regulatory strategy at all product's life cycle stages – regulatory submissions, pharma and medical devices (Israeli MOH, FDA and EMEA)
- NDA & eCTD writing and reviewing
- Lab (GLP) and site (GCP) audits
- FDA / EMEA meetings and presentations
- Post-marketing approval maintenance (variations)
- Pharmacoeconomic submissions (reimbursement submissions)
- Qualified Person (QP), appointed pharmacist and Pharmacovigilance (PV) services

Product Development Services

- Pharmaceutical drugs and medical devices
- Product development plan
- Innovative and generic product development
- Regulatory strategy at development stage
- Human resources due diligence services
- Global presence and alliances that facilitate services in Israel, Europe, Asia and the US
- QA, Auditing and CMC services

Other tailor-made services per customers' needs

Our experienced staff will be happy to meet with you and your team, present our services and discuss how we can best support your organization in achieving its needs in the most professional and cost effective way.

We are at your disposal for any clarification.

You can contact us by mail : office@gto-cro.com

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