

CLINGROUP

**The Health Industry Experts
Partner**

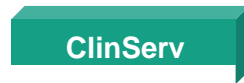
18 YEARS

of

Quality & Innovation in Healthcare Consultancy
&
Impactful Social Responsibility



Our Solutions



Clinical Project
Management
Organization



Information Health
System



Regulatory and
Logistics



Professional
Education
Programs



Quality
Management
System

Quality Management System

- ISO 9001 from Paris since 2009 for its global Quality Management System
- US-FDA 21 CFR 11 Compliant
- Each entity compliant with utmost Operational guidelines in its appropriate GxPs
- Extensive Quality Management System
- Quality engagement and ethics commitment: Internal Quality plan including 5%QC activities over all the projects, given as free of charge to client, in order to secure smooth project execution and high-quality projects deliverables.
- Implementation of an advanced ERP System (Enterprise Resource Planning) to plan, monitor, control, report and analyze the activities, resources and projects
- Defined and monitored Key Performance Indicators
- More than 70 successful International Audits – with an average of 12-15 Audits per year

CLINGROUP



Our Mission

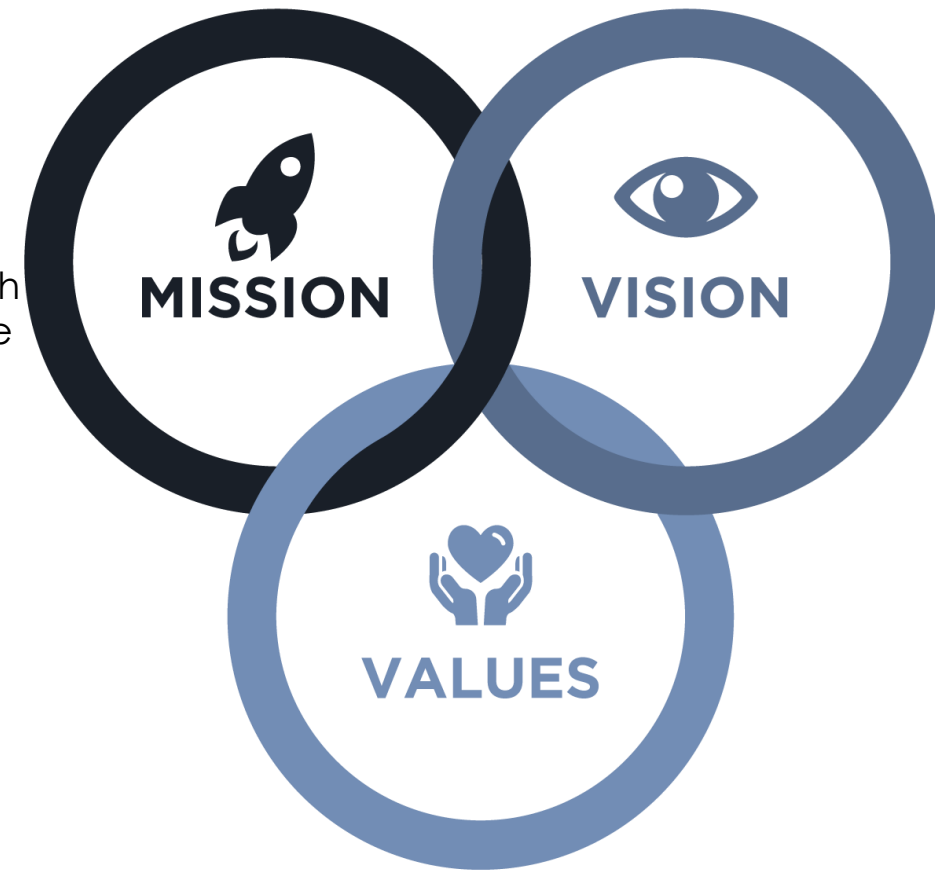
- Actively, socially, sustainably contributes to health systems development and maintenance process in more than 45 countries

Our Vision

- Driving scientific expertise and MEA connections and alliances, to serve health system and R&D development and patient access. We aspire to become the market leader in health Quality Systems and R&D in the Middle East, South Europe, Africa, and Near East by 2022 with a sustainable qualitative growth.

Our Values

- Serves life sciences industry and institutions, printed in the whole MEA region, with 18 years of international expertise and over 45 countries partners
- With its alliances with over 60 small and mid size partners worldwide and its project management platforms, serves as global CPMO lead
- Belonging to a philanthropic foundation, works in a highly professional & SR manner daily, then dedicates profits to philanthropic actions in MEA



ClinGroup is a full service health industry established in Paris in 2002 and expanded through the Middle East, Southern Europe, Africa, and Near East countries.



ClinServ is considered a sustainable Health systems and R&D infrastructure in the region, in terms of:

1. **Clinical Project Management**
2. **Pre-Feasibility and Feasibility Studies**
3. **Clinical Research Monitoring**
4. **Clinical Trials Documentation**
5. **Regulatory Affairs Management**
6. **Data Management**
7. **Biostatistics**
8. **Medical Writing & Translation**
9. **Staffing of Qualified Candidates**



Clinfo1T is considered a sustainable Health systems and R&D infrastructure in the region, in terms of:

1. Patient Support Program (PSP)
2. Pharmacovigilance (PV)
3. Medical Devices Services
4. Mobile Nursing



ClinPharm is in charge of managing logistics and regulatory affairs, in terms of:

1. Clinical Trials Laboratory Logistics
2. Clinical Trials Depot Logistics
3. Regional Regulatory Services



ClinAcademy is a provider of training sessions and courses for health professionals, in terms of:

1. Health Professional Capacity Building
2. Training Sessions
3. Webinars



QSI is a provider of Quality Management System Solutions, in terms of:

1. ISO & FDA Consultancy
2. GxP Audits
3. Standards Writing
4. Plutus for eClinical Payment Solution
3. Cold Eye for Environmental Monitoring

Our Team



Dr. Nadia Cheaib

Chairwoman

International life sciences R&D Social Entrepreneur. Doctor of Pharmacy and clinical research from France, Nadia Cheaib founded her enterprise ClinServ (www.clinerv.com) in Paris in 2002 then expanded to MEA region to become ClinGroup (www.clingroup.net) pioneer in life sciences RD in the MEA since 2010.

Her group today counts over 600 international and regional RD success stories projects in more than 25 countries . Dr Cheaib received several international renowned prizes as a recognition to her leadership and significant sustainable development contribution, in sciences, health and social activities, as to name latest six consecutive years of Forbes most influential Mideast women. Dr Nadia is a social entrepreneur dedicating company profits to Hope MCF carrying her late father legacy, impact fully sustainably active in healthcare women empowerment and children education in the MEA region (www.hopemcf.org) and also supporting liver major associations in Egypt and Africa.

Our Team



Dr. Youssef Rihani

CEO

Entrepreneur in technology and business management and over twenty years of experience in the field of digital computing and services.. Enthusiastic and well-focused on achieving the company's goals. Leads and motivates a group of talented people towards Excellency in all ClinGroup services.



Nemer Rizk

CFO

Has more than 20 years of experience in Finance Management and a Master's degree from USA. Very detail oriented, strong analytical personality and passionate to facts. Responsible for the Group's Finance unit and oversees the accounting & administrative functions.



Dr. Ali Berro

Legal Advisor

ClinGroup Legal Advisor, Maître Berro is Corporate Lawyer for many renown and prestigious institutions, and has, and still is, significantly contributing to regulations mainly in terms of leadership, corporates , transparency and social responsibility

Our Team



Dr. Dany Kharrat

Business Development Director

Dr Dany Kharrat, Dr in pharmacy, business development director at ClinGroup Holding.

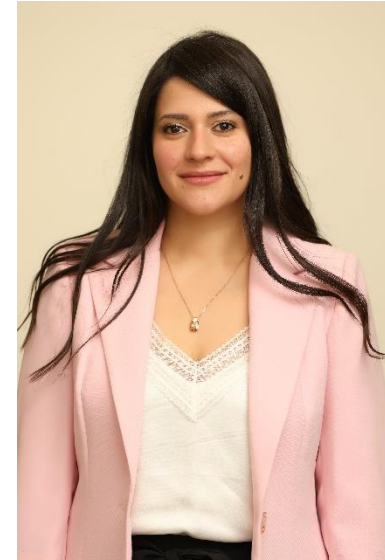
Dr Kharrat Carries over 20 years of experience in various fields of major pharmaceutical companies. He contributed to developing the concept of joint collaboration with medical centers for several therapeutic areas, for enhancing and promoting the clinical research within those centers, all in respect with major international guidelines.



Carmelita Khawand, MSc., PMP

Business and Resources Dep. Manager

Holding a Master's Degree in Pharmaceutical Industry with honors. Project Management Professional, Certified Quality Auditor for GSDP of pharmaceutical products and ISO 9001:2015 lead auditor from reputable international institutions. Carmelita joined ClinGroup with an extensive experience in the fields of Quality Auditing, Business Development and Senior Management Consulting and Training.



Jessy Tannous, MSc.

Proposals and Process Manager

QA Professional & University Lecturer with 10 years of experience in Auditing, Coaching & Training in Healthcare & Food Safety Sectors and holding Master Degree in Quality Management, and a BSc in Bio-Chemistry.

Jessy joined ClinGroup bringing 5 years of experience as Quality consultant and Compliance for one of the most reputable hospitals in the region.

She is managing today a regional team of QA auditing professionals in addition to the organizations Accredited Training Programs & Diplomas.

Our Team



Dr. Hussein Sadek
PSP Manager

Talented, highly ambitious with strong initiative. Pharmacist with degree of honor and GCP certified. For the past five years, he's been leading PSP projects of several major pharmaceutical companies in the region. His role in ClinGroup adds a value in building and developing the PEC unit by putting patient's centricity and safety his major focus and priority.



Raneem Kotb
Senior Quality Officer

Pharmacist with eight years' experience in the drug research & development sectors. Her role as Preclinical/Clinical trials evaluator and GCP inspector gave her the strong knowledge of the international and the region's standards and guidelines. Her proven quality experience and intensive training and education sculpted her working figure and paved her career path as a Senior Quality Officer at ClinGroup



Mina Anis
Pharmacovigilance Manager

Pharmacist graduated with honor with more than eight years of experience in the PV field with extensive healthcare project portfolios. In his role as PV Project Manager, Mina fostered an environment of teamwork while overseeing performance and maintaining morale.

CLINSERV

www.clingroup.net

SERVICES AND PRODUCTS

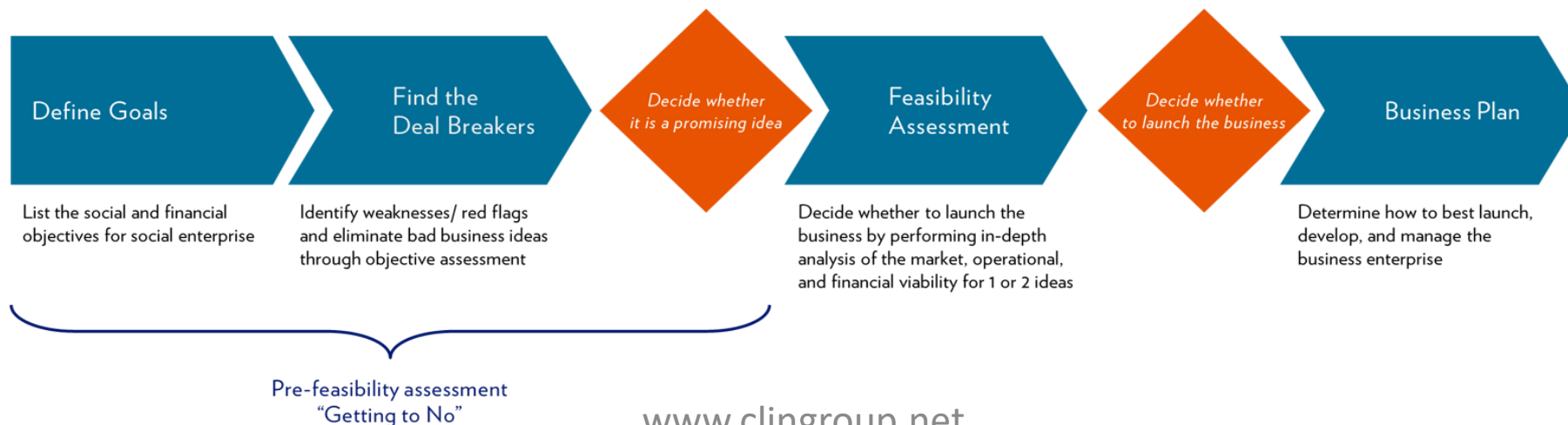
CLINGROUP

Service #1: Clinical Project Management – CPMO

- Experienced Project Managers PMP (Project Management Professional) / ICPM (Institute of Certified Professional Managers) And solid history of PM experience.
- Defined and monitored Key Performance Indicators for all the activities / processes / projects with continuous monitoring, analysis and improvement.
- Remote and risk based monitoring plans, modules, methodology and tools customization per project
- Project Plans generated at project setup including a network diagram and critical paths / schedule / budget and cost quality control & risk management / stakeholders / resources and communication plans.
- ERP and CTMS Systems responsible to track the project progress and related resources shared with and accessed by all stakeholders in full transparency and ease of accessibility.

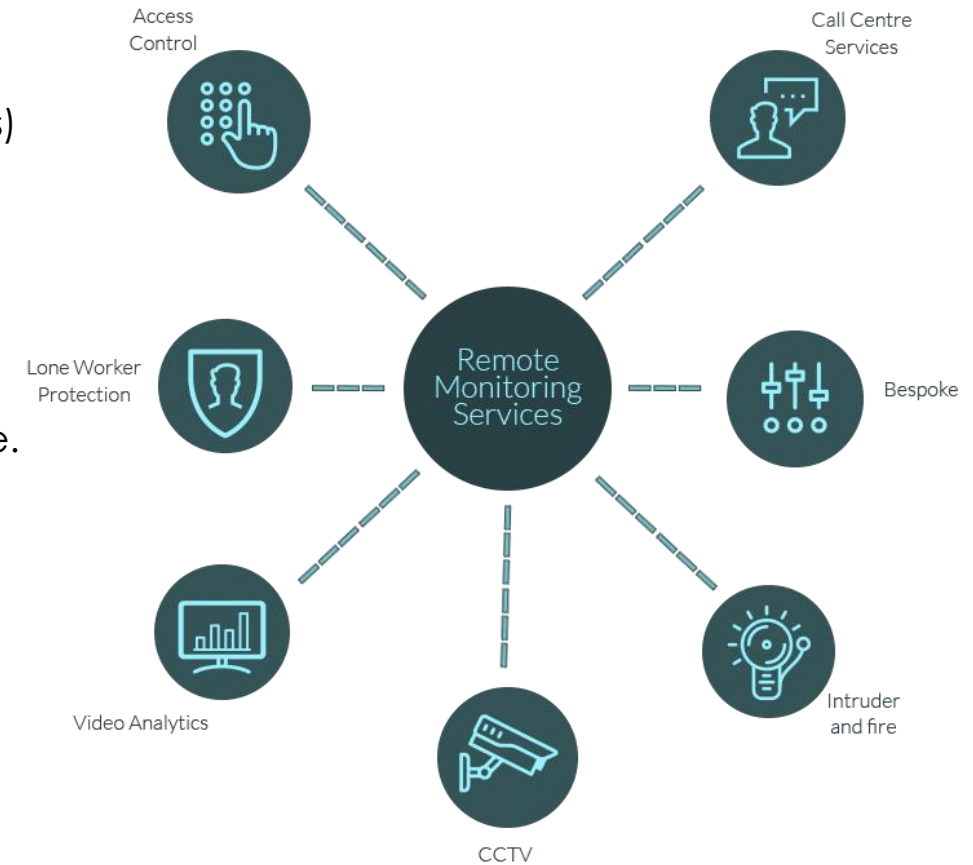
Service #2: CPMO Pre-Feasibility and Feasibility Studies

- Advanced e-feasibility database per country, institutions/ organizations/ therapeutic area and disease Feasibility at country level and regulatory requirements / milestones.
- Large database of KOLs / Pls per country, institutions and therapeutic area
- Matching between “Client Request” and “Countries / Sites / Pls”
- Based on its large experience, Clingroup can suggest new countries / sites to client in order to meet the requested health project feasibility, viability, recruitment and timelines

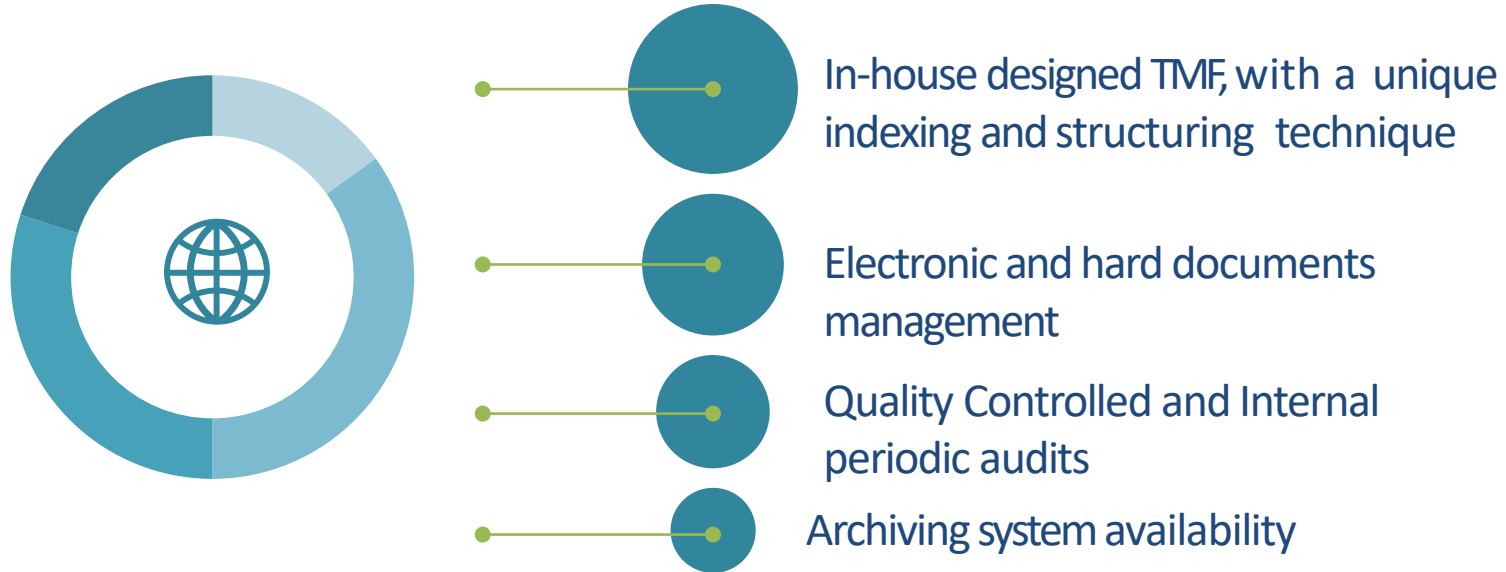


Service#3: Site Monitoring & Management

- Health Projects Associates (HPAs) and Health Projects Administrators (CTAs) experienced respectively in different therapeutics areas, phases and filing/archiving system.
- In-house HPAs with Scientific/Medical background, possessing a large experience in appropriate field.
- Full monitoring from site selection till close out in different areas with full mastering of local culture and regulatory environment.
- Remote and risk based monitoring modules and methodology experience.



Service #4: Project Master File Management



Service #5: Regulatory Affairs Management



Mastering all local regulatory submissions (EC/IRB) in compliance with local regulatory authorities' requirements per country



Regulatory Consultancy & submissions



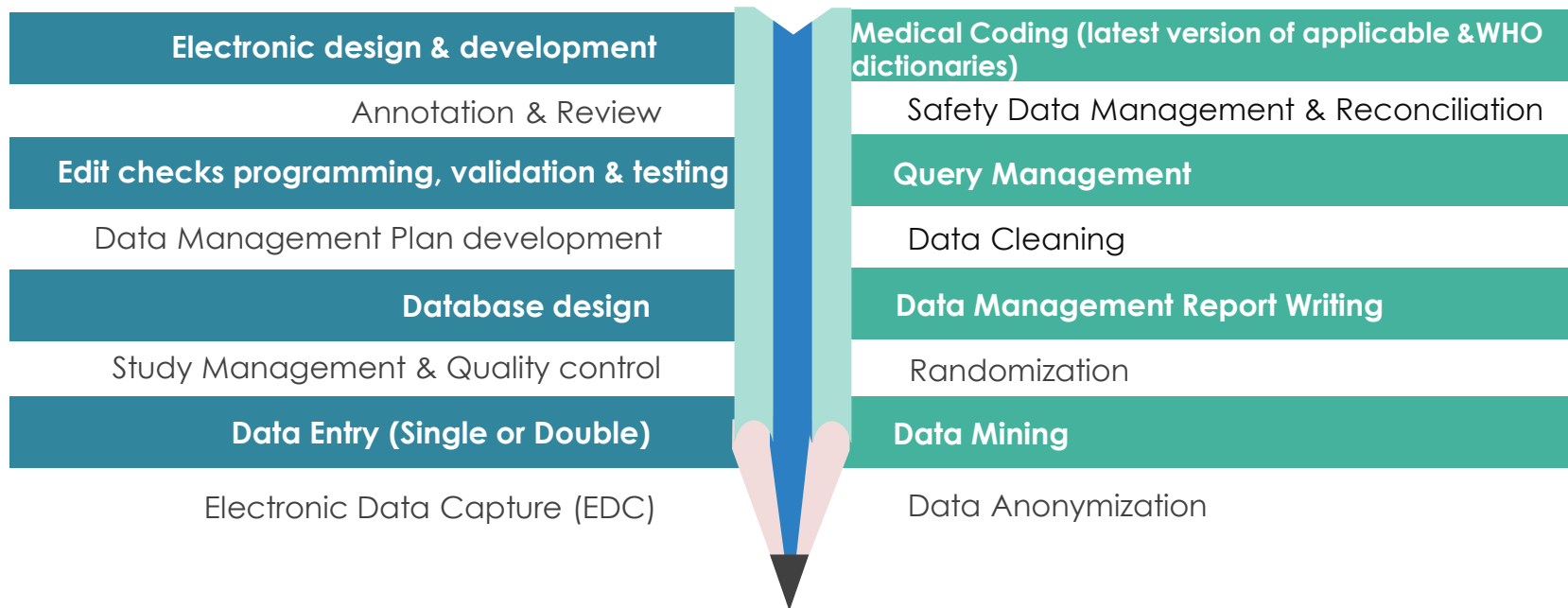
Clinical Trial Agreements customization and budget Negotiation

SERVICES AND PRODUCTS

CLINGROUP

Service #6: Health Data Management

ClinGroup provides end-to-end data management services, from **early phases studies, per system/country/disease/site.**



Service #7: Biostatistics

ClinGroup provides comprehensive biostatistics services, ensuring full support to our clients throughout **all phases of development.**



Service #8: Medical Writing & Translation

Our medical writing solutions are designed to support your **clinical trial, regulatory, epidemiology** and **publication writing needs**.



- 01 Manuscript Writing & Submission
- 02 Clinical Study Report (CSR) Writing
- 03 Study Design
- 04 Protocol Writing
- 05 CRF / eCRF
- 06 Informed Consent Form (ICF) Writing
- 07 Poster Design
- 08 Investigator's Brochure (IB)
- 09 Advisory Board Meetings MoM reports
- 10 Patient Leaflets
- 11 Medical Magazines
- 12 IMPD
- 13 CTD writing & eCTD formatting/submission
- 14 Medical Translation

CLEPIQS

Service #9: Staffing and Resources Out-Sourcing

- Part time and full time staffing for a defined period of time (based on projects milestones)
- Experienced and well trained staff ready to accommodate new projects (based on client requirements).
- Less burden on clients as staff will be operational at their level but legally at ClinGroup books and records

Educational Background

Professional Experience

Continuous Education

Skills



ClinFo 1T

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SERVICES AND PRODUCTS

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Service #1: Patient Support Program (PSP)

Disease Management

- Home Care Programs
- Safety Management
- Adverse Events Reporting
- Quality of Life Assessment

Patient's assistance

- Financial Support
- Moral Support
- Emotional support
- Reimbursement Assistance

Adherence Compliance Management

- Call Center
- Mobile Application
- SMS Reminder
- Access Agreements (hospitals, drug stores & banks)

AT-HOME TRAINING & SUPPORT

- Therapy administration
- Safety Management
- Practical, emotional support
- Educational support

What's NEW

PEC Software

- Dashboards
- Online 24/7 Reporting service
- Statistical Reports
- Analysis Reports



SERVICES AND PRODUCTS

CLINGROUP

Service #2: Pharmacovigilance (PV) / Nutrivigilance / Materiogvigilance

PV System set-up

- Creation and maintenance of local PV Master documents
- Provision of staff trainings
- Preparation for audits and inspections
- Development of KPIs
- Management and implementation of CAPAs



Scientific Literature Screening



Regulatory Intelligence



Document Preparation & Management

- Standard Operating Procedure (SOP)
- Pharmacovigilance System Master File (PSMF)
- Periodic Safety Update Report (PSUR)
- Risk Management Plan (RMP)



Local PV Services

- LQPPV provision
- Local Regulatory Review and Validation
- Medical and pharmaceutical information provision



Safety Reporting (Pre&Post registration)

- ICSRs preparation, submission and follow-up
- Safety database for reporting and archiving
- Safety information reconciliation
- Development of Safety Plans in clinical trials

SERVICES AND PRODUCTS

CLINGROUP

Service #3: Medical Devices Services

Clinfo1t provide a wide and varied range of Medical Device Vigilance services, through:

- ✓ Collection, investigation, and assessment of medical device incidents
- ✓ Submission of medical device incidents to Competent Authorities
- ✓ Expedited Reporting to Authorities
- ✓ follow up and/or final report management
- ✓ Training
- ✓ Field safety corrective action generation and submission.
- ✓ Creation and distribution of Field Notices (FSNs)
- ✓ Preparation of Periodic Summary Reporting

- ✓ Liaison with authorities.
- ✓ Writing and/or reviewing Standard Operating Procedures
- ✓ Audits/inspections and training on Medical Device Vigilance
- ✓ Trend Reports to National Competent.
- ✓ Working as Responsible person
- ✓ Storage and protection of medical device incidents records
- ✓ Audits and training on Medical Device Vigilance
- ✓ Literature search.
- ✓ Contact point with the Notified Body about problems emerged after the device commercialization.

Service #4: Mobile Nursing



Mobile Research, delivered anytime, anywhere, includes anything within the scope of practice of an RN with portable equipment, such as:

- Infusions, blood draws, injections, medication dosing, and observation
 - Collection of blood samples and other biologic samples
 - Patient training and education for self-administration
 - Clinical assessments and questionnaires
 - Recording vital signs
 - Completion of visit documentations
-
- Device management (centrifuges, ECG's, blood pressure monitors, etc.)
 - Pharmacy communication and coordination services
 - Secure, limited access, controlled, cold-chain environment
 - Delivery within stability parameters
 - Hazardous waste disposal
 - Tracking and return of all vials

ClinPHARM

Service #1: Clinical Trials Laboratory Logistics

- ▶ Project-specific strategic planning of study supplies at a country level and globally.

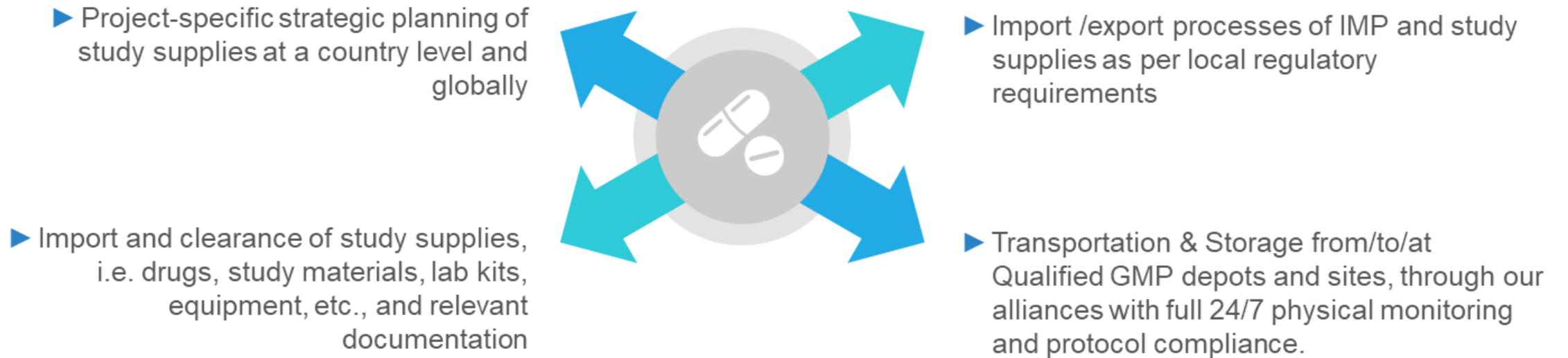
- ▶ Import and clearance of study supplies, i.e. study materials, lab kits, equipment, etc., and relevant documentation.



- ▶ Import /export processes of biological samples and study supplies as per local regulatory requirements

- ▶ Transportation & Storage from/to/at Qualified laboratories, through our alliances with full 24/7 physical monitoring and protocol compliance.

Service #2: Clinical Trials Depot Logistics





SERVICES AND PRODUCTS

CLINGROUP

Service #1: Health Professional Capacity Building

ClinAcademy is an internationally renowned Healthcare Academy & Medical Institution providing a diversified educational portfolio in mainly Healthcare, Medical and Quality Management sectors to thousands of students and professionals in multiple and various fields.



*In Partnership with most
renowned Middle East
Universities*

SERVICES AND PRODUCTS

CLINGROUP

CPD Accredited Certification

Become a more competent and effective professional

Promote a healthy learning culture leading to a more fulfilled workforce and retaining valuable staff

Accredited points & credits for trainings, conferences & seminars





Quality Systems International

www.clingroup.net



SERVICES AND PRODUCTS

Service #1: QMS Solutions

QSI-Paris is a French-Lebanese Company aiming to developing **Quality Systems** and to provide performance improvement solutions in the Healthcare, Management, Food & Drug Safety & Social sector in the EMEA (Europe, Middle East, Gulf, Africa and Turkey)



- GCP-GVP-GSDP-GLP-GMP
- Audits



- ISO
- Coaching



- Standard
- Documentation



- Computer System
- Compliance & Validation



- Certification/Accreditation
- Audit's Preparation



- QMS
- Consultancy



- Local Regulatory
- Requirements



- SOP
- Development



- Gap
- Analysis

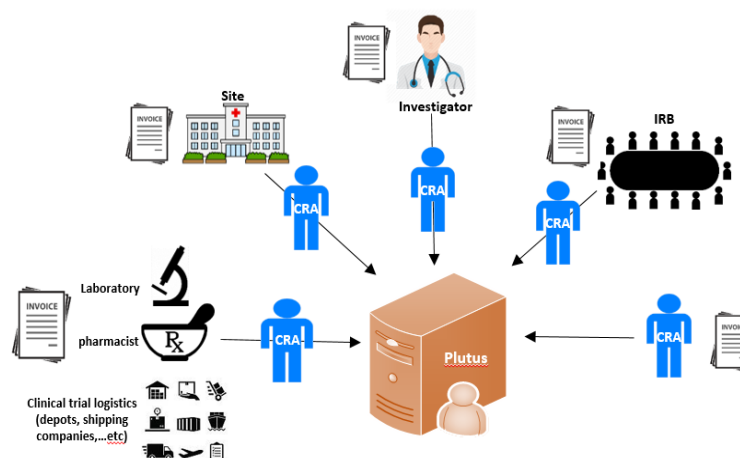
SERVICES AND PRODUCTS

CLINGROUP

Service #2: Plutus _ e-Clinical Payment Solution

Solution Benefits

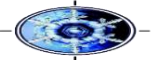
- Business Intelligence Fair Market Value
- Advanced analytics & accurate Financial insight
- Financial Transparency & Invoice reconciliation
- Quality Control by 3rd Party
- Consultancy services: Site budget setting, site negotiation & agreement
- Minimum sponsor involvement with maximum control



System Benefits

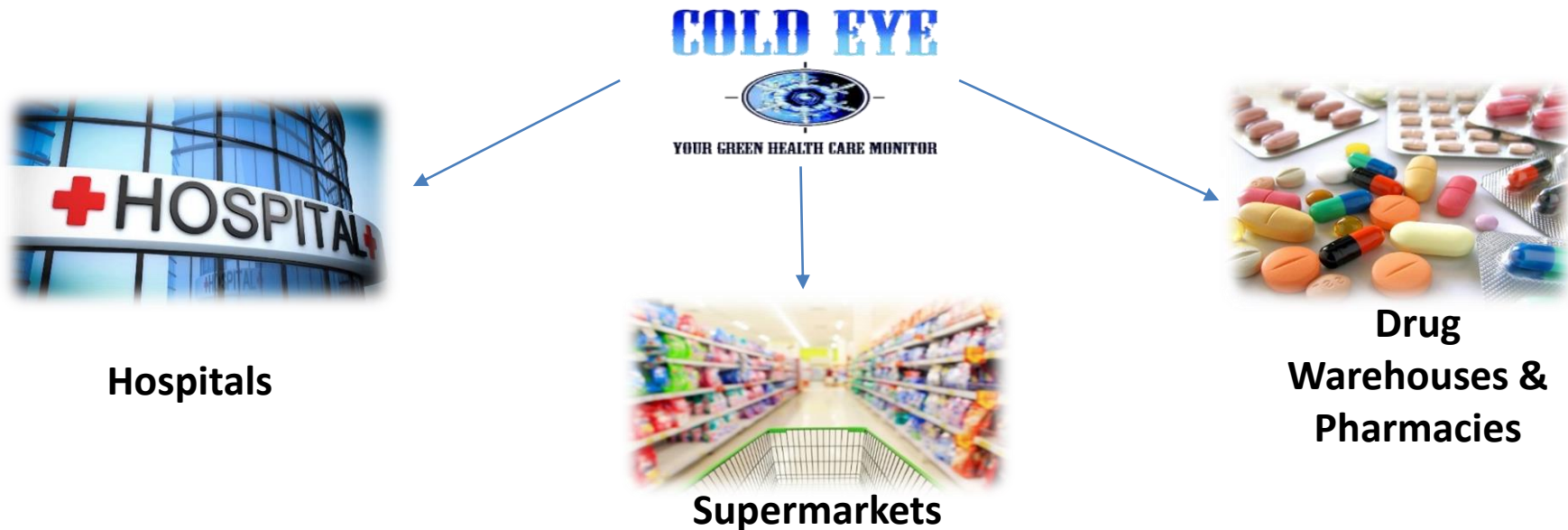
- Flexibility in Integration with any Data source (EDC, Oracle, SAP, CTMS)
- Ease of Payments and budget tracking
- User friendly Interface
- Payment Promptness & Security
- E-Invoice / Request for payment submission
- Financial and study Reports and Analysis Dashboards



**Service #3: Cold Eye _ Temperature & Humidity Monitoring**

An Environmental Monitoring System for real-time measurement of environmental factors in Food & Drug Institutions, to monitor and control:

- *Temperature*
- *Humidity*
- *Noise*
- *Lighting*
- *Quality of Air*



The Corporate Achievements





Geographical Presence

Offices

France

Lebanon

Egypt

UAE

Coverage/Alliances

Joint Ventures

Pakistan

KSA

Turkey

ClinGroup activities cover Southern & Eastern Europe, Africa, Middle East & Central Asia continues



Contacts & References

CLINGROUP

www.clingroup.net

The below Documents will be furnished upon request:

- Exhaustive list of survives.
- The list of references and testimonials.
- Our Capabilities in each country. For

more information ,please visit us:



www.clingroup.net