Your Project Manager World

Achieving Excellence Guided By Integrity And Quality

ClinSERV
CPMO

ClinServ born CRO, now 18 years, is first and only Non profit CPMO

18 YEARS
of
Quality & Innovation in Healthcare Consultancy
&
Impactful Social Responsibility

Mission:

Actively, socially, sustainably contributes to clinical research and drugs develop ment process in more than 45 countries

Vision:

Driving scientific expertise and MEA connections and alliances, to serve drugs development and patient access

Objectives:

a. Serves life sciences industry and institutions, as a full services CRO printed in the whole MEA region, with 18 years of international expertise and over 45 countries partners

a. With its alliances with over 60 small and mid size CROs worldwide and its project management platforms, serves as global CPMO lead

a. Belonging to a philanthropic foundation, works in a highly professional & SR manner daily, then dedicates profits to philanthropic actions in MEA

www.clinserv.net

ClinServ is a full service CPMO and CRO **established in Paris in 2002** and expanded through the **Middle East, Southern Europe, Africa, and Near East** countries.

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

01 Clinical Project Management

02 Pre-Feasibility and Feasibility Studies

03 Clinical Research Monitoring

04 Clinical Trials Documentation

05 Regulatory Affairs Management

06 Data Management

07 Biostatistics

08 Medical Writing & Translation

We aspire to become the market leader in healthcare R&D in the Middle East, South Europe, Africa, and Near East by 2022 with a sustainable qualitative growth.

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Service 1

Project Management – CPMO

Experienced Project Managers
PMP (Project Management Professional) / ICPM (Institute of Certified Professional Managers)
And solid history of PM experience.

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.

Defined and monitored Key Performance Indi cators for all the activities / processes / projects with continuous monitoring, analysis and improvement.

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.

Remote and risk based monitoring plans, modules, methodology and tools customization per project

Service 2

Pre-Feasibility and Feasibility Studies

Advanced e-feasibility database per country, therapeutic area and disease

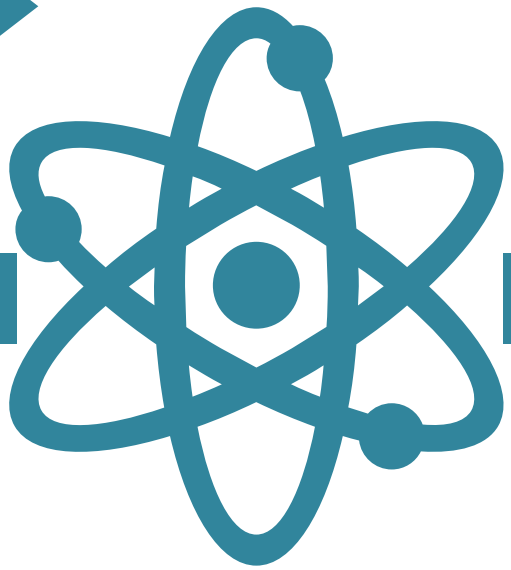
Feasibility at country level and regulatory requirements / milestones

Matching between "Client Request" and "Countries / Sites / PIs"

Large database of KOLs / PIs per country and therapeutic area

Based on its large experience, ClinServ can suggest new countries / sites to client in order to meet the expected recruitment and timelines

Service 3



Site Monitoring & Management

- Clinical Research Associates (CRAs) and Clinical Trial Administrators (CTAs) experienced respectively in different therapeutics areas, clinical trial phases and filing/archiving system.
- In-house CRAs with Scientific/Medical background, possessing a large experience in Clinical research.
- Full study monitoring from site selection till close out visit for phases 1b to 4 in different therapeutic areas with full mastering of local culture and regulatory environment.
- Remote and risk based monitoring modules and methodology experience.

Service 4

Regulatory Affairs Management

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

Clinical Trial Agreements customization and budget Negotiation

Regulatory Consultancy & submissions

Service 5

Trial Master File Management

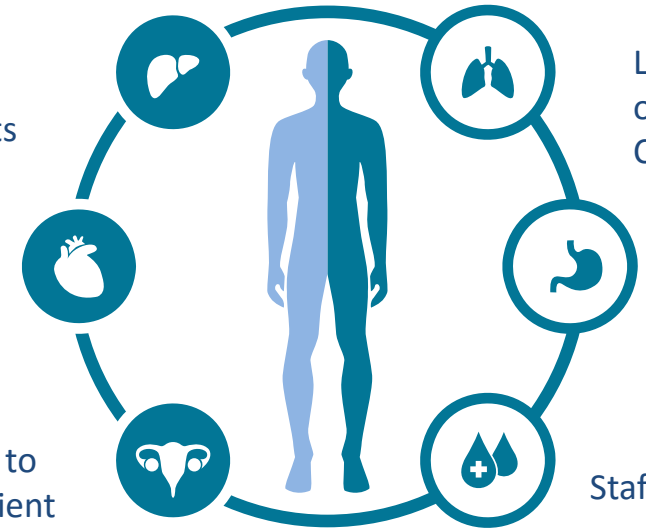
- In-house designed TMF, with a unique indexing and structuring technique
- Electronic and hard documents management
- Quality Controlled and Internal periodic audits
- Archiving system availability

Service 6

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 ClinServ books and records

Staffing of CRAs, PMs, CTAs (Junior, Mid-Senior and Senior)

Service 7

Pre & Post Registration Clinical Data Management

ClinGroup provides end-to-end clinical data management services, from early phases until post-marketing studies.

- **CRF/eCRF design & development**
- CRF Annotation & Review
- **Edit checks programming, validation & testing**
- Data Management Plan development
- **Database design**
- Study Management & Quality control
- **Data Entry (Single or Double)**
- Electronic Data Capture (EDC)

- **Medical Coding (latest version of MedDRA & WHO dictionaries)**
- Safety Data Management & Reconciliation
- **Query Management**
- Data Cleaning
- **Data Management Report Writing**
- Randomization
- **Data Mining**
- Data Anonymization

Service 8

Pre & Post Registration Biostatistics

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

Service 9

ClinSERV CPMO

Pre & Post Registration Medical Writing

Our medical writing solutions are designed to support your clinical trial, regulatory, 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

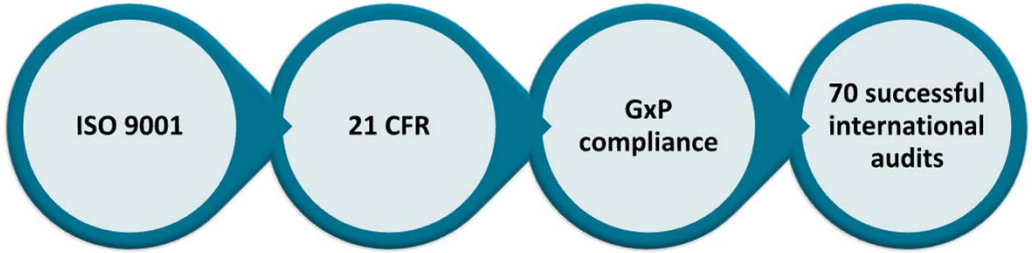
11 Medical Magazines

12 IMPD

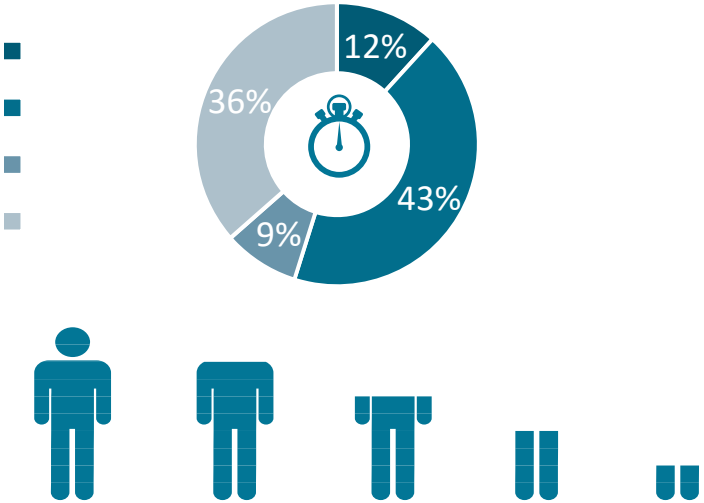
13 CTD writing & eCTD formatting/submission

14 Medical Translation

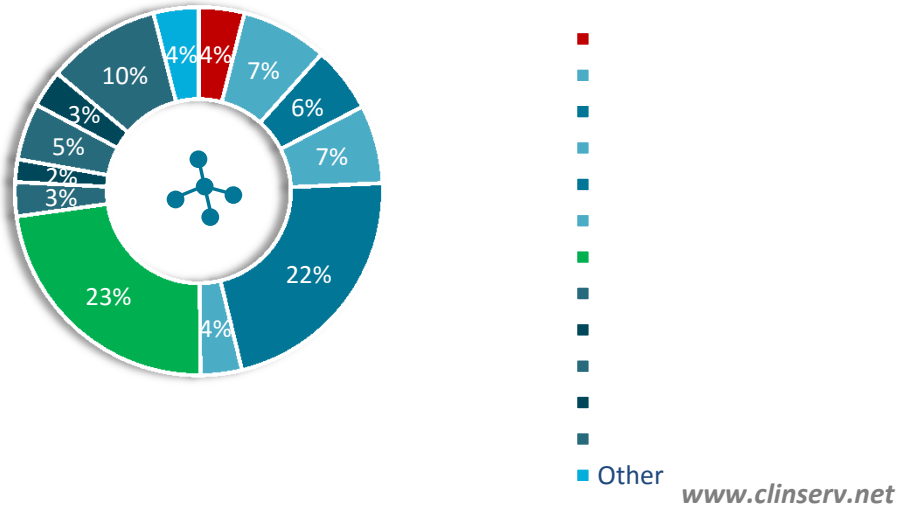
Quality Commitment



% of Studies Per Phase

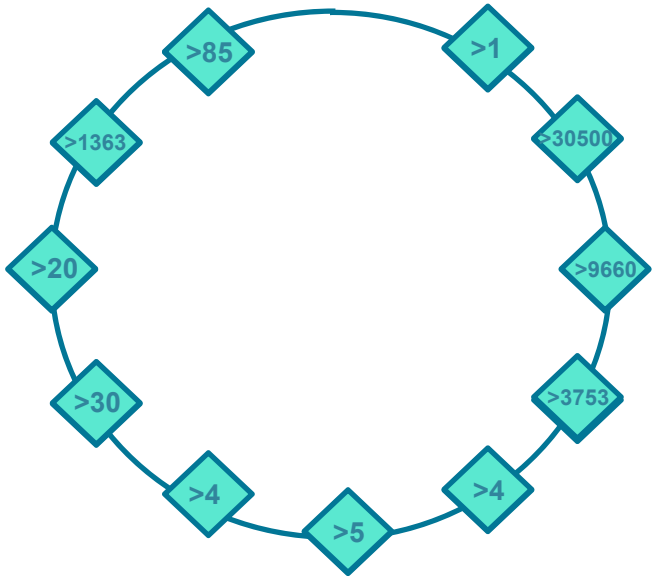


% of Studies Per Therapeutic Area



General

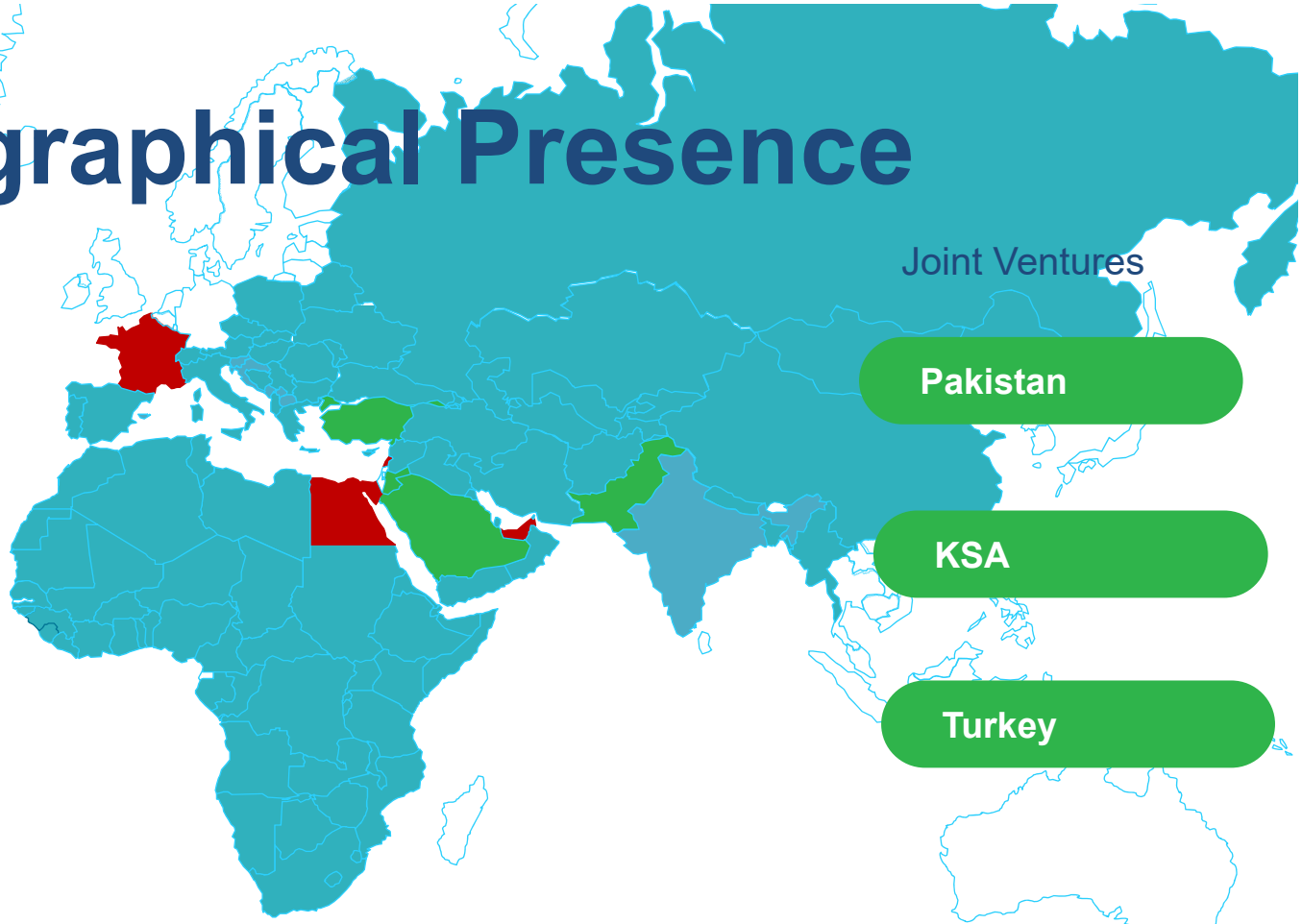
Parameters	ClinServ in Numbers
Covered Countries	**>25 countries**
Projects	**> 360**
Therapeutic Areas	**>12 in the last 15 years**
Patients Enrolled and Treated	**>6,500 patients**
Clients	**>95 International Clients** **>25 Regional &Local Clients**
KOLs in Regional Network	**>500 KOLs**
research focused HCPs	**>3,000 HCPs**


>85
>1
>1363
>30500
>20
>9660
>30
>3753
>4
>4
>5

Geographical Presence

Offices

- France
- Lebanon
- Egypt
- UAE
- Coverage/Alliances



Joint Ventures

- Pakistan
- KSA
- Turkey

ClinServ activities cover Southern & Eastern Europe, Africa ,Middle East & Central Asia continues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About Our Services?
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CPMO
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