Profile 2020

ClinFo 1T

8 YEARS

of

Quality & Innovation in Healthcare Consultancy
&
Impactful Social Responsibility

Who We Are

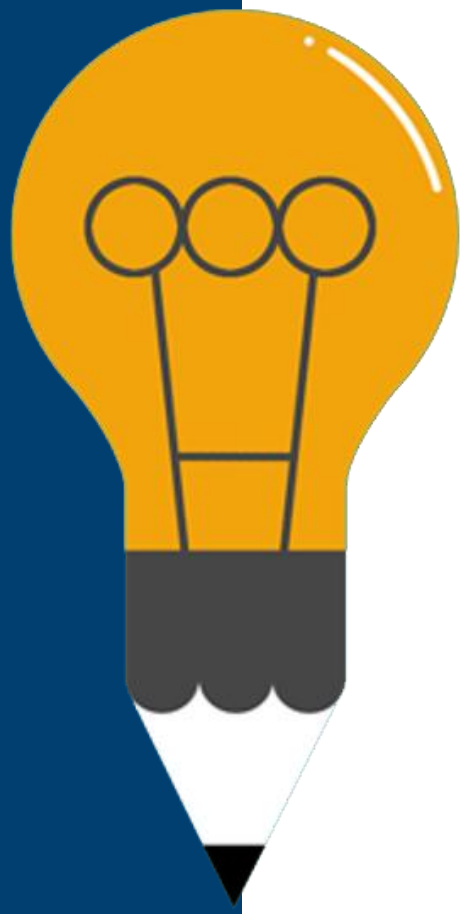
ClinFo1T is the first of its kind Solution Provider for Health Information Management and part of ClinGroup Holding that was established in 2012 as a spin-off handling Global Comprehensive services with the highest levels of Expertise & Understanding of Local need as per international requirements in response to the high demand of these services in the Southern & Eastern Europe, Africa ,Middle East & Central Asia continues.

ClinFo1T is the pioneer of the healthcare information management and technology, providing a wide range of services and products to clients in the healthcare industry.

ClinFo1T cherishes more than a decade of international clients' trust, matching international expertise with regional needs, while completing consultancy assignments and delivering medical communication services in clinical (phases I, II, III, IV) and non-clinical research studies.

Clinfo1T

ClinFo 1T



Vision:

We continuously work on overcoming challenges and adapting our workflow and services to adjust to market changes. We aspire to become the preferred service provider to key players in the research field, through reliability, growth, and innovation.

Mission

Our mission is to bring innovation to every client by providing the highest level of value in our service in all matters related to the Health Information Management

Registration and Post Master Files & Projects Management

01 **Patient Support Programs**

Excellence in caring for patients

02 **Nutri/Pharmacovigilance**

Food supplements, Fortified foods and bever ages, and Drug safety monitoring and case management

03 **Medical Device Service**

04 **Mobile Nursing**

Our Services 1

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Patient Support Program

Because Their Lives Matter The Most

A Disease Management

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

B Adherence Compliance Management

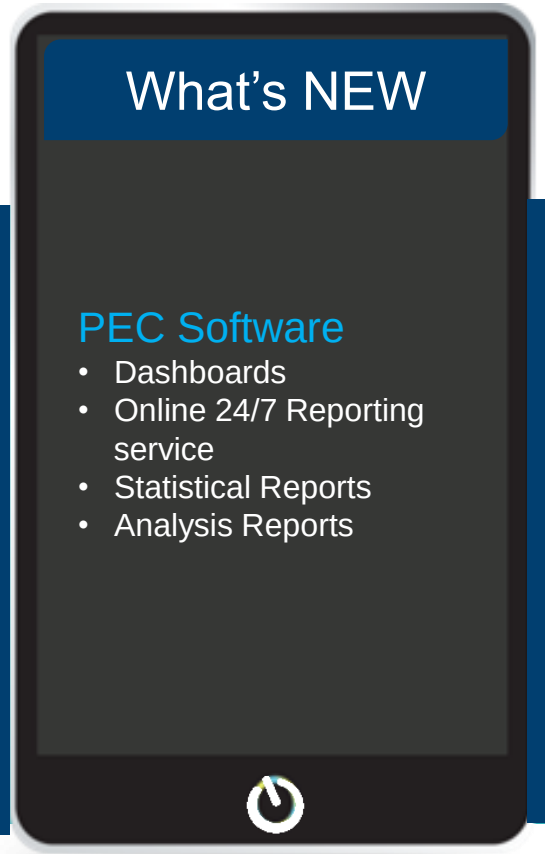
- Call Center
- Mobile Application
- SMS Reminder
- Access Agreements (hospitals, drug stores & banks)

C Patient's assistance

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

D AT-HOME TRAINING & SUPPORT

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



Our Services 2

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Pharmacovigilance

Safety is a choice you make

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

Coverage

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

Our Services 3

Medical Device Service

The purpose of **materiovigilance** is to study and follow incidents that might result from using medical devices and guarantee **health** and **security** of **patients** and **users**.

Clinfo1t consult supports manufacturers and/or distributors of medical devices with accurate safety management.

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.

Our Services 4

Mobile Nursing

❖ Remote site clinical services:

- ✓ With Clinfo1t, sponsors, CROs, and site investigators can be confident that our alternate-site visits will be carried out with the same quality and care as on-site visits across all therapeutic areas and ensure strict adherence to clinical trial protocols, Good Clinical Practices (GCP), Stand ard Operating Procedures (SOPs), applicable regulations, and deadlines
- ✓ Clinfo1T directly employ, train and certify Registered Nurses who understand the complex and unique requirements of mobile clinical trial research.

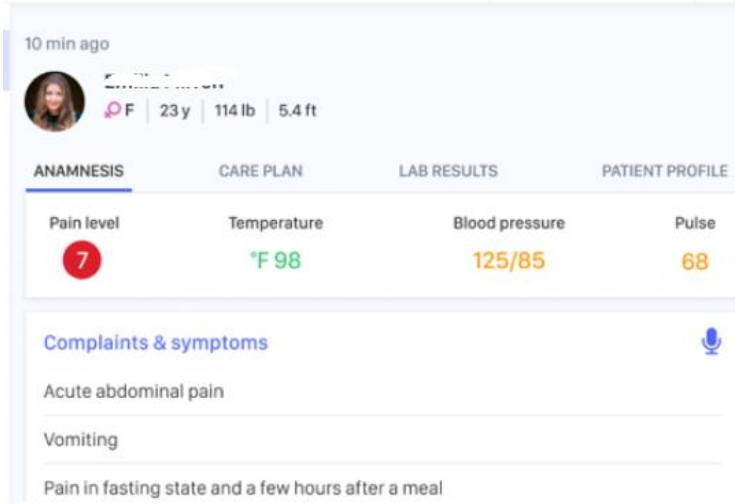
❖ Mobile Research, delivered anytime, anywhere, includes anything within the scope of practice of an RN with portable equipment, such as:

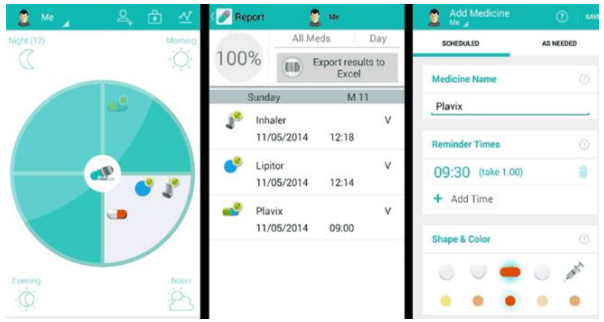
- ➢ Infusions, blood draws, injections, medication dosing, and observation
- ➢ Collection of blood samples and other biologic samples
- ➢ Patient training and education for self-administration
- ➢ Clinical assessments and questionnaires
- ➢ Recording vital signs
- ➢ Completion of visit documentations
- ➢ 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

Our Services 1.1 ePSP Software (PEC)

Focusing on Patient Education and Centricity, ClinFo1T has developed an e-PSP solution, to better manage PSP projects by providing:

- Mobile Application for Patients to help in:
  - ✓ Schedule medications
  - ✓ Report Adverse Event
  - ✓ Request Nurse visits





- Platform for Nurses/Program Coordinators:
  - ✓ Log visits and calls immediately
  - ✓ Fill and submit safety case reports
  - ✓ Schedule appointments
  - ✓ View patient history /progress
  - ✓ Statistics dashboard
  - ✓ Data export in XML/Word/Excel/PDF
  - ✓ Customized reports
  - ✓ Better accuracy in results and less human error possibility

Our Services 2.1 ePV Software

Cinfo1T is developing its state of the art e-PV platform designed to handle big data and aiming to improve work quality and efficiency through:

- Automated Literature Search for all local journals
- Collecting of Safety information from Social media
- ICSR tracking and assessment
- Statistical reports and dashboards

Automated LS software characteristics:

- >100 times faster than manual literature screening
- Better accuracy in results and less human error possibility
- Ability to screen a large number of journals using minimal resources
- Automatic reports generation
- Audit trail

General Achievements

ClinFo 1T

> 50 countries covered

Home Visits >20,000

>15 Clients

Years of Experience >8

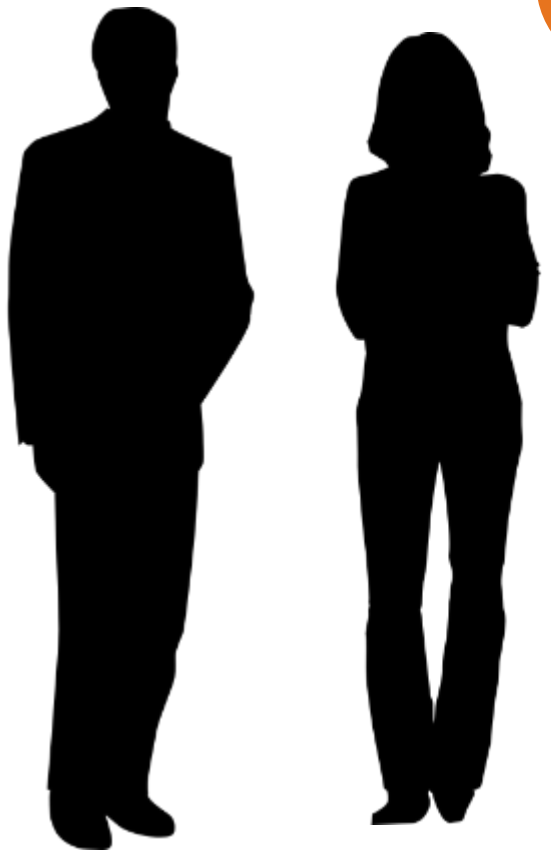
>250,000 Patients

Nurses >100

>40 Patient Support Programs

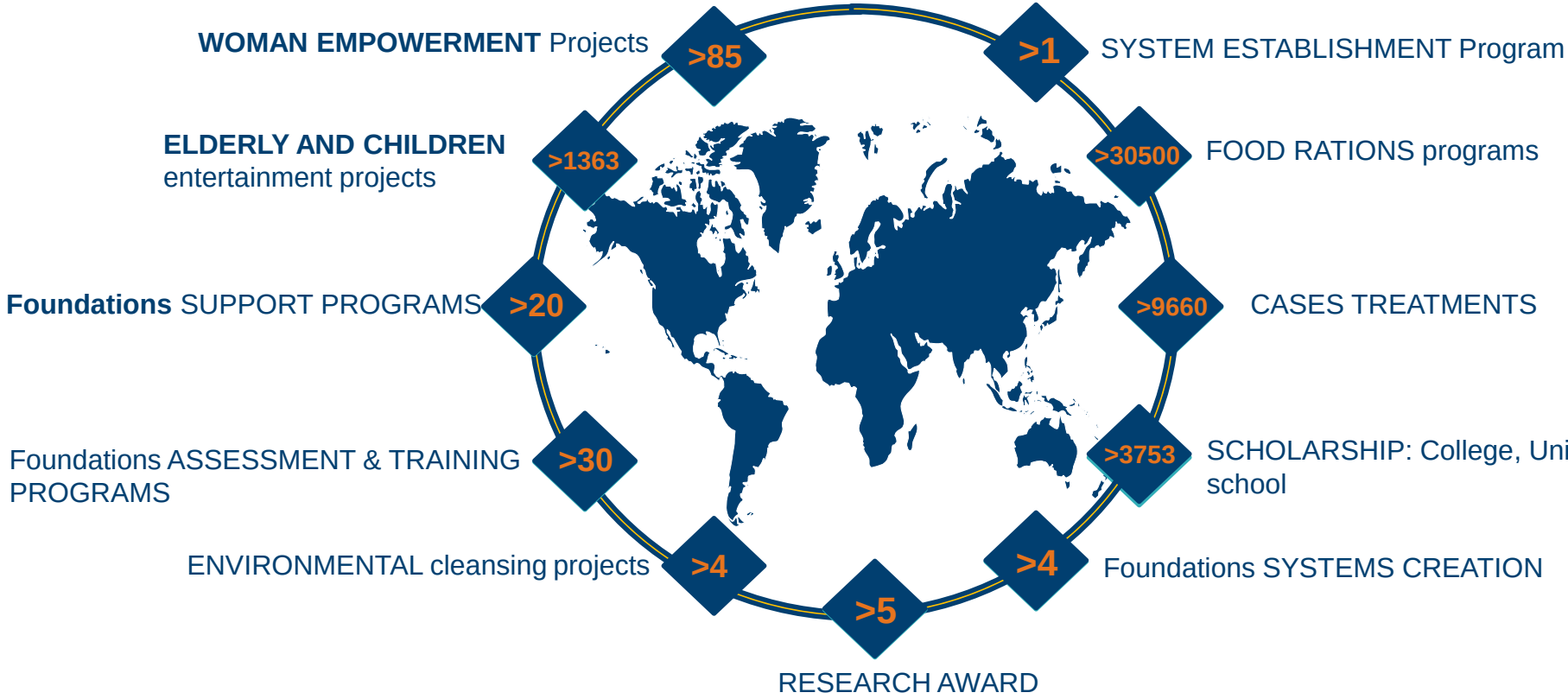
Safety Cases Reported >200,000

>35 Regional PV Consultancy Project



Social Responsibility Achievements

ClinFo 1T



Quality Commitment

Quality Management System

- ✓ ISO 9001 from Paris since 2009 to our Global Quality Management System
- ✓ Fully compliant with FDA 21CFR11 , EMA, GDPR and GxP Requirements and Best
- ✓ More than 70 number of International Audits, with an average of 15 Audits per year.

- ✓ Advanced ERP System to plan, monitor, and analyze activities, resources and projects.
- ✓ Defined and solid KPIs for all activities, processes, and projects with continuous monitoring, analysis and improvements.
- ✓ Continuous training and development to internal staff based on the need, International standards, Local regulations and Industry Trends.

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Our Main Clients

COVANCE
SOLUTIONS MADE REAL®

Lilly

Roche

NOVARTIS

abbvie

Bristol-Myers Squibb

Julphar

novo nordisk®

panpharma

Johnson & Johnson

janssen
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

SANOFI

MSD

Biogen

Boehringer Ingelheim

BAYER

gsk
GlaxoSmithKline

synteract®

World Health Organization

ALEXION

Pfizer

ALGORITHM
PHARMACEUTICAL MANUFACTURERS

Pierre Fabre

AstraZeneca

ICON
A Symbol of Excellence

Syneos Health

MERCK

Lebanese Gynecologic Oncologic Group

REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

SGO
Society of Gynecologic Oncologists

THE LEBANESE ORDER OF PHARMACISTS

LSMO
Lebanese Society of Medical Oncology

AMAAC
Arab Medical Association Against Cancer

Asian Pacific Association for the Study of the Liver

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