18 YEARS OF EXCELLENCE IN RESEARCH

cliantha research®

BIOMETRICS

Clinical Data Management Solutions

Cliantha Research also offers Biometric services. This division focuses on the management, analysis and reporting of data from clinical trials and post-marketing surveillance. As experts in clinical data, we provide competent outsourcing solutions for Clinical Data Management, Biostatistics, Statistical Programming.

Clinical Data Management Experience

70+ Indications	170+ Studies	45000+ Patients	120+ CodeAngelo Projects

Experience – By Study Phase

Healthy/ Patient PK – 31	Phase I 36	Phase II 22	Phase III 44	Phase IV 38

- Biostatistics
- Data Management
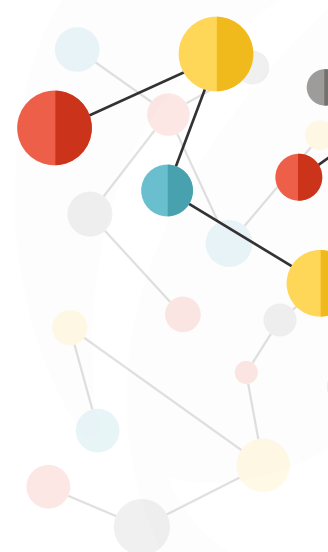- CDISC (SDTM & ADaM)
- CodeAngelo (e-clinical suite)

"Your trusted partner for all your Data Operations needs"

BIOMETRICS

Experience in different Therapeutic Area: (but not limited this)

- Oncology
- Metabolic Disorders
- Respiratory
- Women and Men's Health
- Rheumatology
- Vaccine Studies
- Opthalmic

- Dermatology
- Medical Device
- CNS
- Ophthalmology
- Renal & Urinary Disorders
- Gastrointestinal Disorders

Clinical Data Management

Process

- Robust process for database set-up, conduct, and close-out
- 18 Global SOPs and standard templates
- Standardized CRF pages in compliant with CDASH standards
- Medical coding (MedDRA, WHO Drug)

People

- Global team of 40+ data managers
- Multi-platform experience: Medrio, Inform, SAS Pheedit, Acceliant, Oracle Clinical (OC-RDC), Medidata Rave, Amedon
- Dedicated Data entry/Data Acquisition team

Technology

- Proprietary CodeAngelo EDC platform
- Fully validated as per the 21 CFR part 11 requirements, web-based tools with advanced reporting function.
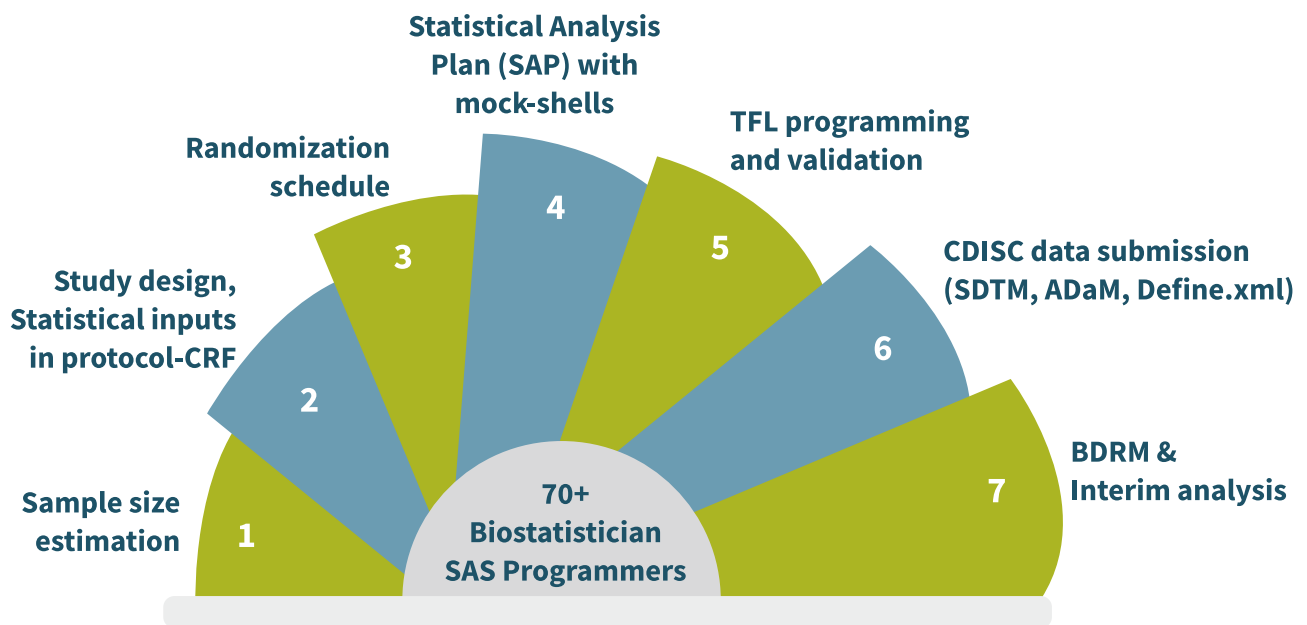
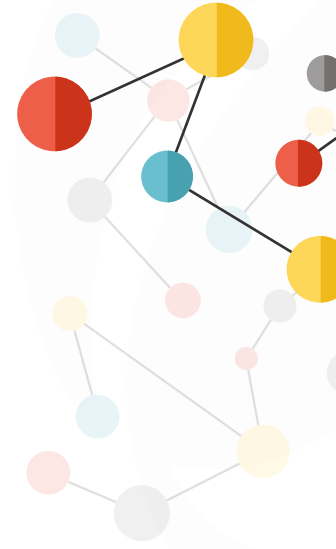## "Successful track record of 170+ eCRF Studies".

Biostatistics & Programming

4500+ BA/BE
80+ CT
950+ CDISC
studies completed

Statistical Analysis Plan (SAP) with mock-shells

Randomization schedule

TFL programming and validation

Study design, Statistical inputs in protocol-CRF

CDISC data submission (SDTM, ADaM, Define.xml)

3

4

5

6

Sample size estimation

2

70+ Biostatistician SAS Programmers

7

BDRM & Interim analysis

1

Statistical Tools