HCL

Growth partnership for a self-care centric lifestyle

Innovation | Acceleration | Growth

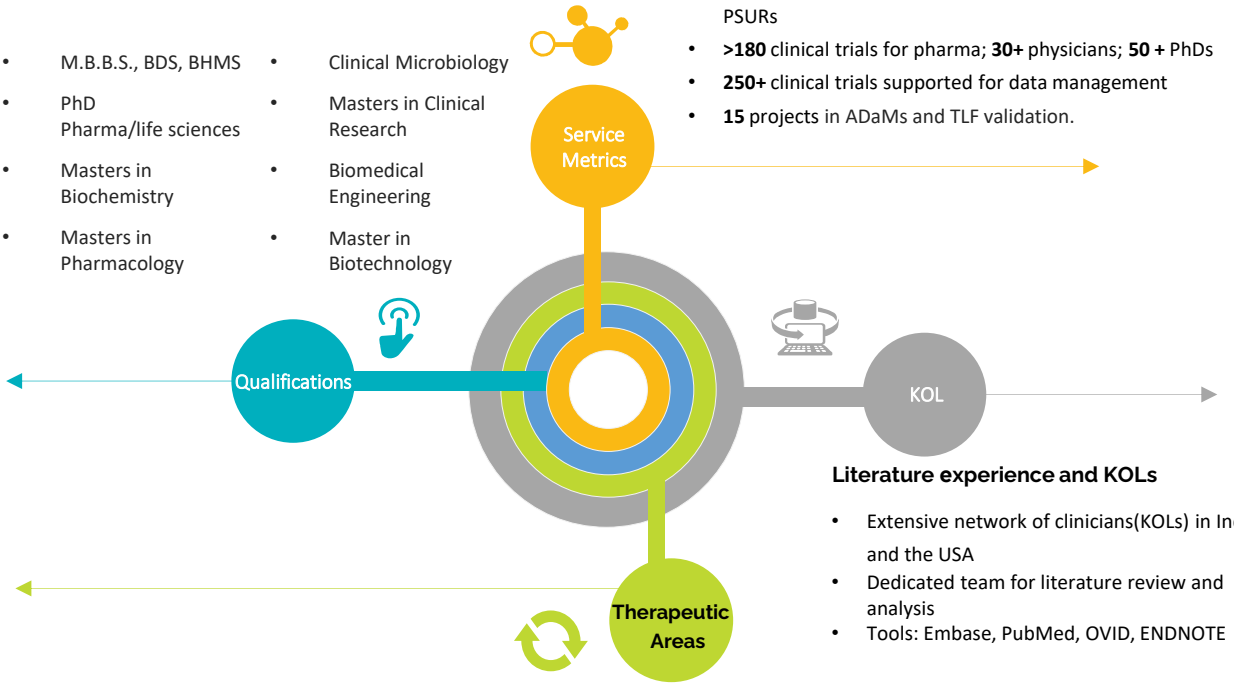
HCL Medical Affairs Center of Excellence

Medical affairs CoE

Global presence – 400+ resources USA, EU, Canada, India

- **500+** CERs for medical devices; **600+** PMS Reports and PSURs
- **>180** clinical trials for pharma; **30+** physicians; **50 +** PhDs
- **250+** clinical trials supported for data management
- **15** projects in ADaMs and TLF validation.

- M.B.B.S., BDS, BHMS
- PhD Pharma/life sciences
- Masters in Biochemistry
- Masters in Pharmacology
- Clinical Microbiology
- Masters in Clinical Research
- Biomedical Engineering
- Master in Biotechnology



Literature experience and KOLs

- Extensive network of clinicians(KOLs) in India and the USA
- Dedicated team for literature review and analysis
- Tools: Embase, PubMed, OVID, ENDNOTE

- Trauma, orthopedics
- Joint surgery
- Robotic surgery
- Pulmonology
- Dermatology
- Gastroenterology
- Cardiology
- Gynecology
- Vascular surgery
- Neurosurgery
- Pain management
- Ophthalmology
- Plastic surgery
- Spinal surgery
- Thoracic surgery
- ENT
- Urology
- Nephrology

Medical device clinical evaluation report and PMS services

- Gap assessments for CER
- Creation/update of clinical evaluation plan and report for EU, China, Australia
- Periodic risk evaluation reports (PRER) – China

- Creation and update of PMS plan, PMS report, PSUR,
- Creation of SSCP, PMCF plan and report
- Validation of clinical claims

- Literature search and analysis
- Complaint analysis – medical records
- Risk-benefit analysis
- Risk management file review

Clinical trials – End-to-end services

Medical writing

- Clinical trial documents
- Publications
- Posters, brochures, flyers, manuscripts
- Scientific slide decks
- Medical information documents
- Standardized process flow for content creation

Biometrics

- Study setup phase
- Data management
- EDC platforms and standards
- Statistical consulting
- Statistical analysis plan
- SAS programming
- Reporting and analysis

Safety management

- Review subject eligibility
- SAE management
- Medical monitoring
- Medical coding
- PSURs, PBRERs, PADER, clinical overview documents

Clinical data management service overview

Study start up phase

- Protocol finalization
- DMP development
- eCRF/DB Design
- DB testing and UAT
- Edit check specifications programming and validation
- Go-Live

Study conduct phase

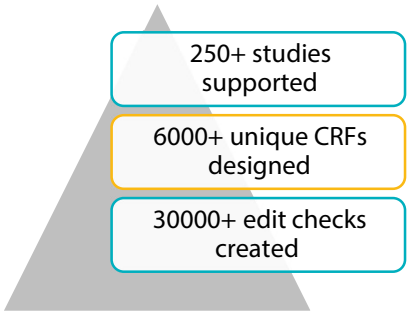
- Discrepancy management
- Medical coding
- External data reconciliation
- SAE reconciliation
- Manual listings review

Study close out phase

- Clean patient tracking
- Quality review
- Pre-database lock activities
- Database lock

Capabilities and platform

- Clinical data management offers flexible service offerings
- Several customer audits with <5% minor observations and been part of ISO and DCGI audits



Platform

- Oracle clinical
- OC RDC
- eTrials
- RAVE
- Oracle InForm
- AgClinical

Standards

Medical coding

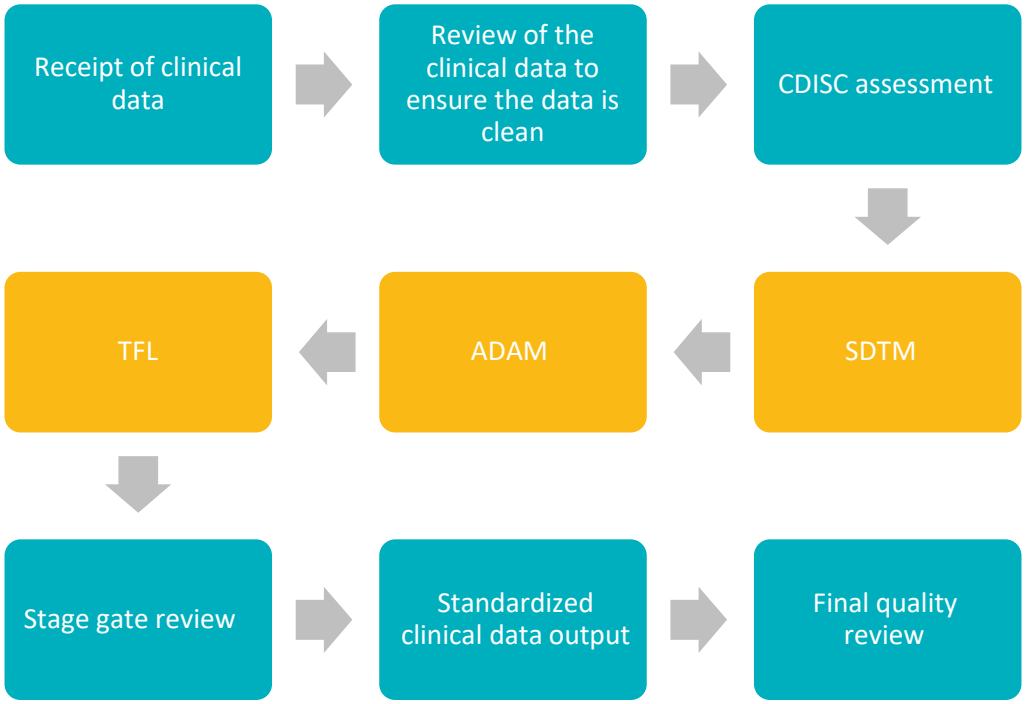
- MedDRA, WHOdDrug Industry standards
- CDISC
- CDASH
- SDTM
- ADaM

Oncology | Cardiovascular | Dermatology | Respiratory | Gastroenterology Endocrinology | Nephrology

Biostatistics overview

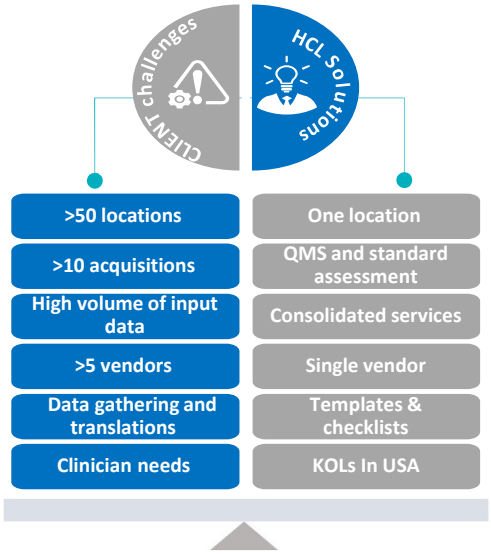
- Support end-to-end activities including protocol development, study design, sample size estimation, randomization schedules and programming activities
- Statistical analysis plans (SAP)
- SAS® programming (generation of tables, listings and figures programming)
- Statistical/medical reporting as per ICH E9/E3 guidelines
- CDISC® Study Data Tabulation Model (SDTM) mapping and conversion, generation of ADaM (Analysis of Data Models)
- Analysis dataset programming and documentation
- Interim analysis for early decision making
- Tables, listings and figures validation and quality control
- Ad hoc statistical support
- Interpretation and reporting of data for clinical trial reports and publications

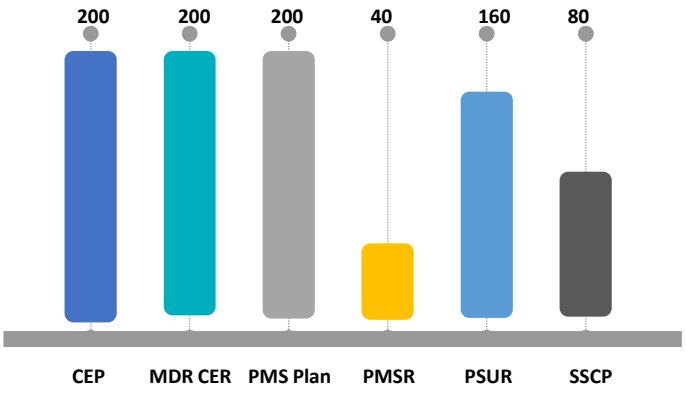
Statistical programming flow



- Successfully completed around 15 projects in ADaMs and TLF validation
- 10 ongoing projects in medical devices
- 100 % high accuracy rate and client appreciation for on-time delivery

Centralized clinical support for a large medical device leader





Volume increase from 100 to 680+ documents in 5 years

CER creation template creation

Support in notified body audits

Flowchart for PMCF assessment

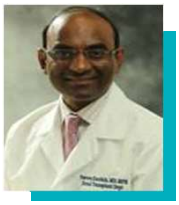
Dedicated medical writing team comprising technical writers, medical writers, SMEs, expert quality reviewers and copy editors

30%
Reduction in cost

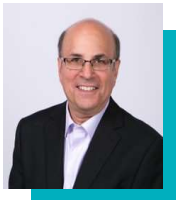
100%
Adherence to timelines

One-stop solution

Case study : Centralized clinical support for a large medical device leader

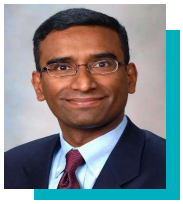


Dr. Praveen Kandula
Nephrologist



Dr. Ira Davis
Pediatric Nephrologist

Dr Prashanth Sreeramoju
General Surgeon



Dr. Rahul Pannala
Gastroenterologist

Dr. Joshua
Cardiothoracic Surgeon

Dr. Swetha Kandula
Dermatologist

Dr. Radha Annamalai
Ophthalmologist

Dr. Suresh Chandra Surgical
Gastroenterologist & Laproscopic Surgeon

HCL medical affairs - Subject matter experts

Dr. Sreedhar Bunga
MBBS, MPH
19yrs in Clinical Research

Dr. Padma Priya
MBBS, MSc CRRA
15+yrs in Pharma & Medical Devices

Dr. Arun Bhaskar
MBBS, MMST (IIT Kharagpur)
10+ years in Clinical Research

Rashmi Angeline Grace V
MBA,Msc IT
13 yrs in Clinical Data Management

Thambidurai Muthusamy
Masters in Pharmacy
10+yrs in Pharma & Medical Devices

Lakshmi C A
Masters in Biotechnology
13+ years in Clinical Research

Bharath Kumar Yakkala
Masters in Statistics
8+ years in Clinical Research

HCL experience with notified bodies

Notified body review comments

Clarifications on clinical evidence of devices based on available information, appraisal criteria, request for submission of device promotional materials, query on PMCF plan requirement, CER sections on device claims and clinical benefits to substantiate scientifically sound evidence

CERs completed
Class I, IIa, IIb & III – 500 CERs
MDR CERs - 50

PMS experience
Creation of 150 PMS plans, 200 PMS reports, 73 PSURs, 10 PMCF plans, 2 SSCPs

Notified body audits
BSI, TUV SUD, TUV Rheinland, DEKRA and DQS
20 engagements (US/Japan/EU customer)

- >100 CERs went through the NB review and had < 5% observations
- HCL has supported a US client during BSI's Assessment of technical documentation for one of the CERs and received positive feedback with no major findings on the CER
- HCL supported CE certification of two products belonging to Japan OEMs. Both the CERs written by HCL were accepted by NBs.

CDM case study 1

- The client is one of the world's largest pharmaceutical companies based in the US
- Handling huge volume of external data reconciliation including outliers while performing end-to-end activities for phase 3 study
- Reconciling vendor data (Lab & SAE)with clinical database data is time-consuming and tedious

Challenges

- Introduced SAS system to avoid manual reconciliation of vendor lab data and SAE
- SAS reports were programmed in such a way highlighting the discrepancies to be reviewed by data managers

HCL Solution

- Reviewers can easily compare the lab data, SAE data and clinical data in stringent timelines while reviewing overall data.
- Reconciliation process was streamlined with access to all key stakeholders
- Readily available metrics, reduced reconciliation time up to 75%

Outcome

CDM case study 2

- The client is a global pharmaceutical company dedicated to clinical trials. The challenge during reconciliation activities were vendor sending the external data (Lab data, SAE data)in a different format template from agreed over the initial agreement discussion
- Large multicentric clinical trial services involving multiple geography and vendors
- Delay in transferring the data impacts the whole reconciliation process delay and in analyzing the critical data

Challenges

- Established a procedure to ensure external data transfer in agreed format from all vendors. Maintaining uniformity in the reference ranges and units as defined in the protocol
- Perform test transfer before production
- Review and clean external data on an ongoing basis

HCL Solution

- Seamless functioning with multiple vendors and sites throughout the world
- Efforts been channelized properly and rework on reconciliation data format have been eliminated by 80%

Outcome

SAS programming case study 1

- Validating correctness of raw data for multicenter phase III study
- If data discrepancies are identified in later stages, like in reports, then the whole process has to be repeated and likely lead to corrections in SDTMS, ADAMS and REPORTS (also database unlock rarely)
- This could impact study timelines, cost and data quality

Challenges

- Use of standard macros for early detection of discrepancies from the raw data using edit check programming (both manual and system-driven).

HCL Solution

- 100% clean datasets
- Saves a significant amount of time

Outcome

SAS programming case study 2

Validation and output review for critical and most-critical data

Challenges

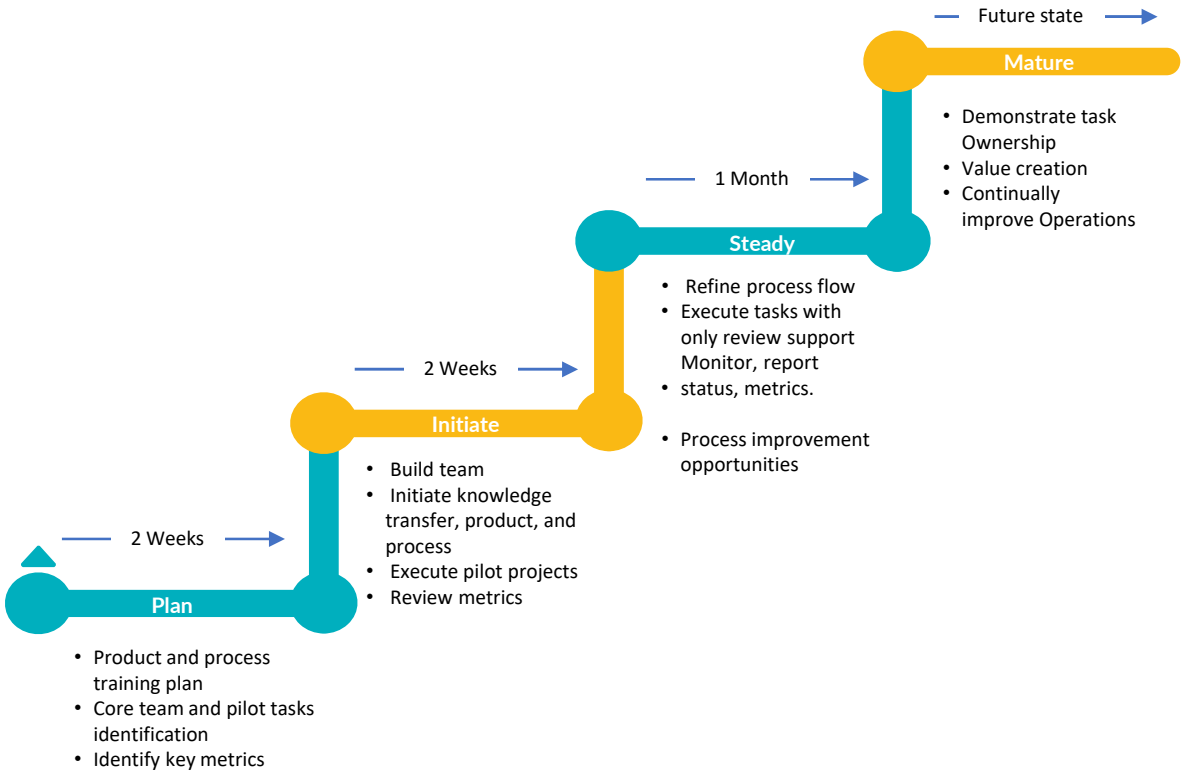
- Risk-based validation approach for primary and secondary endpoints
- Pass through multiple QC gateways
- Parallel approach on both production and validation process

HCL Solution

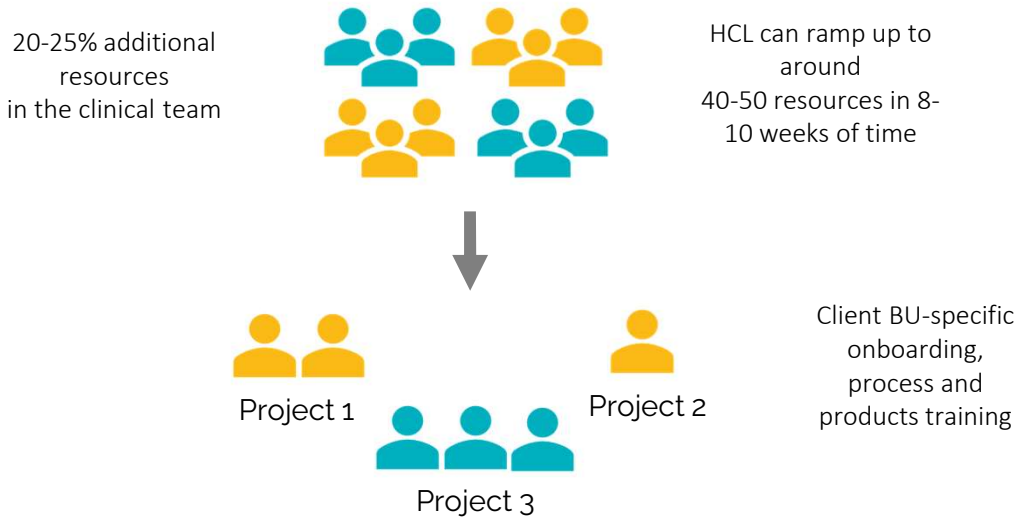
- First-time quality
- High accuracy
- On-time delivery of datasets (SDTM's, ADAM's)and TFL analysis reports

Outcome

Change management / transition approach



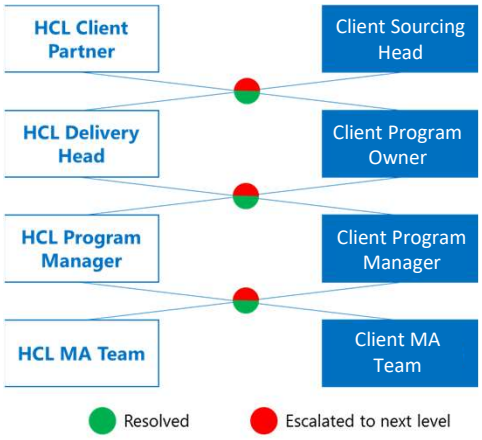
Scalability, training, and issue resolution



Project alignment

Associate development plan	Skill GAP assessment done for all associates and training are provided per the gaps identified
Critical resource developmental plan	Critical resources are identified and rated by HCL and client managers and a developmental are initiated.
Succession & Rotation Plan	Succession plan and rotation plan are put in a place to ensure associates are rotated to mitigate personal dependencies.

Strong governance mechanism jointly managed by HCL & Client



Continuous monitoring of program health and course correction through:

Weekly status reporting | Monthly project reviews | Quarterly business reviews

FOR MORE INFORMATION, PLEASE CONTACT

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