



ACS Life Sciences - Clinical Data Services

The life sciences companies are moving quickly to embrace “emerging” markets as the next growth driver. Emerging markets present both an opportunity as well as a challenge for an industry already working around the obstacles of a mature market, suffering from slowing revenue growth, an impending “patent cliff” and an increasingly stringent regulatory environment.

According to IMS Health figures quoted in Data Monitor report on "2012 trends to watch" by 2014 the "pharmerging" markets will contribute 50% of the annual growth of the global market and make up 26% of the value. Maintaining leadership and focus requires accurate, effective and efficient methods of managing large volumes of clinical data from global sites. A proactive reformulation of the drug development process has the potential to reduce, time value

and costs. The industry is increasingly exploring strategic partners with proven experience in clinical transformation to provide tangible benefits in clinical data Management processes and technologies.

ACS Clinical Services

We offer strategic end-to-end clinical services. Our Clinical Services have unique and proven clinical transformation experience with leading life sciences companies in Europe and across the globe. The unit is housed within our Life Sciences Practice which delivers Knowledge Process Outsourcing (KPO), IT and Consulting Services and Solutions to 27 of the Top 30 Pharmaceuticals. companies; 9 of the top 10 Biotechnology companies; and 12 of the Top 20 Medical Devices companies.



Cognizant's Clinical Data Services Span the Gamut

Our clinical data services provide:

- Proven and mature clinical data management processes with inbuilt transition, quality control and assurance,

training, continuous process improvements and transformative approach leveraging IT – KPO synergy.

- Simplified study set-up processes.
- Database lock time reduction of 30%.
- Robust and scalable data management platform services

Clinical Data Management Practice at ACS



1) Clinical Data Management Consulting Services

Our consultants have deep domain understanding, detailed process knowledge and extensive industry experience to provide

- Clinical Data Business Strategy
- Clinical Data Process Maturity Assessment
- Clinical Data Process Re-engineering and Optimization
- Streamlining Clinical Data Process Automation
- Clinical Transformation Strategy
- Clinical Data IT Strategy and Roadmap
- Evaluation of Clinical COTS (Commercial Off the Shelf) systems.

2) Clinical Data Management KPO Services

End to End Clinical Data Management Services

We have an extensive experience delivering end-to-end knowledge processing outsourcing (KPO) services for clinical data management (CDM). Our team is comprised of 500-plus professionals delivering study set-up services and 1200-plus professionals delivering study conduct. Assume various platforms. Our teams deliver CDM across Phase I to Phase IV in various therapeutic areas of cardiovascular, gastrointestinal, diabetology, neurology, oncology, infections, respiratory and vaccines.

We are continuously investing in certification of clinical data managers to ensure our commitment to industry recognized standard clinical data management practices. We have 41 plus clinical data managers certified from Society for Clinical Data Management (CCDM) which is roughly 51% of the total SCDM pool in India. We have 30-plus MedDRA certified Coders, which underscores our commitment to this initiative.

We ensure metrics-driven delivery of clinical data processes from strategic global delivery locations across the U.S., India, Europe, Argentina and China. This uniquely networked delivery approach provides 24 x 7 coverage as well as onshore, near-shore and offshore advantages.

Clinical Data Management Experience

CRF Design:- **400-plus studies**

Study database build and validation: **1110 studies**

Trial-specific report generation: **7000-plus reports**

Integrations: **210-plus integrations**

Data Loading: **372,000-plus files**

Data Management: **495-plus studies**

Safety Data Management: **384k cases reconciled**

Medical Coding: **416-plus terms coded**

Integrated scanning, indexing and archival services leveraging strategic partnerships: **3 million-plus pages**

Medical Coding Services

- We have proven expertise in medical coding and have successfully executed four medical coding engagements. Our team has 60plus medical coders consisting of health care professionals (HCPs). We have processed ~ 416,972 verbatim terms in MedDRA and WHO-DD with a throughput of 5000-6,000 verbatim terms per day across engagements. ACS is committed to quality deliverables with 97% accuracy across all engagements and 100% quality check for all deliverables. High productivity standards achieved through continuous improvements with average of 120 codes per day per coder.
- Our medical coding team has extensive experience of clinical data management Systems such as OC TMS, Inform, Clintrial and RAVE.
- We have experience of working on medical coding applications such as OC 4.5.3, TMS, MedDRA and WHODRUG.

3) Clinical Transformation Services

Our proven and unique methodology helps transform clinical operations. This clinical transformation methodology leverages appropriate transformational levers of transition, change management, digital ideation center, innovation, information technology and business process synergy, harmonization training and cross-functional synergies, as well as our ACS 2.0 global project and knowledge management platform..

We have successfully transformed clinical operations for one leading European pharmaceutical company . The client's pre-transformation state consisted of around 1100 client associates and 50-plus clinical IT systems to execute end-to-end data management activities. Post transformation, clinical activities are achieved through centralization and streamlining of systems and processes, and a greater number of studies are executed with 300-plus members of our clinical data management team, 50-plus of the client's associates and 20-plus of our clinical Check edit ...IT systems team. This has contributed to significant cost savings and operational efficiencies available for strengthening core R&D activities

We optimized client's clinical development operating model through:

- Standardization :
 - One set of standard operation procedures .
 - One set of standard data management processes ensuring zero defects.
- Reduced average critical cycle time of LSLV to DBL by 18 %.
- Quality data delivered, right first time, leading to faster study submissions and an overall reduction in the client's drug development cycle times.
- Optimization of redundant IT applications by 52 %.
- Successfully implementing five transformational business cases which were shortlisted from 258 business transformation cases.

Our proven levers for delivering operational excellence in clinical services engagements include:



• CARES Transition Lever

Proven in over 100-plus+ transitions, our connect, assess, re-design, execute and stabilize (CARES) transition methodology to ensure risk free transition to steady state.

• Training Lever

We ensure customized training plans for each engagement focusing on each role and experience level. The plans are designed to ensure continuous trainings for all skills required for a successful engagement. Training programs are delivered through class-room sessions lead by expert trainers, e-learnings, interactive learning mode such as memory aids, podcasts, videos, etc. We have strategic partnerships with certified training partners to deliver certified training.

• Quality Management Lever

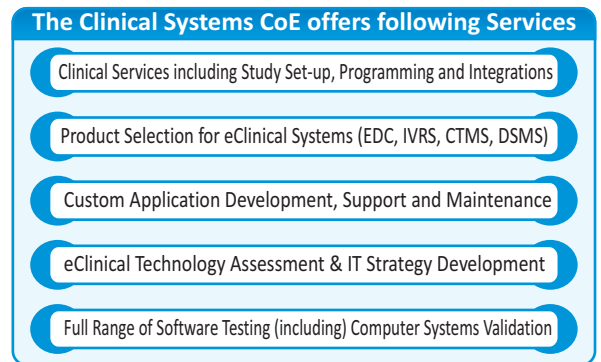
We offer a unique and customized quality management plan (QMP) for each engagement that covers all quality KPIs and requirements specific to each project. The QMP consists of transactional quality control (QC) and comprehensive quality

4) Clinical Systems Center of Excellence (CoE) Services

Our clinical systems center of excellence (CoE) focuses on aligning technology to core business objectives around clinical data management processes including data acquisition, data management and trial management. We have a 500-plus-member strong global team possessing both domain and product specific knowledge in the EDC, CDMS, IVRS/IVRS and CTMS platforms. This CoE has an extensive experience in setup of clinical studies InForm, Oracle Clinical and Rave. We have 10-plus+ years of experience in study setup activities using InForm where more than 500-plus studies setup has been successfully completed.

Our System CoE offers end-to-end services for study setup activities which include specification preparation, study set-up, validation, custom functions development, integrations using batch upload functionality, data extracts and reports (using BO and Crystal reports). We have used this dual experience in EDC activities as well as CDM capabilities to create overall transformation of clinical operations programs.

The knowledge and experience in the EDC, CDMS, IVRS/IVRS and CTMS platform areas includes:



assurance (QA). This culmination of QC and QA aids to achieve high quality deliverables throughout the lifecycle of an engagement.

• Continuous Process Improvement Lever

We leverage Six Sigma and Lean concepts for continuous process improvements to reduce process variations and improve process quality and timeliness approach enables us to take preventive measures to avoid re-occurrence of defects and ensure high productivity with quality deliverables in the steady state of the engagement.

• Seamlessly Integrated Metrics Lever

We ensure that all clinical services engagements have an integrated metrics measurement and reporting component. These well-defined metrics are standardized and benchmarked against operational best practices. The metrics are captured and accessed in near real-time through an interface that provides visual insights into the health of the engagement through dashboards, graphs, and charts in regular status reports.

Typical Clinical Data Management Metrics include

Timeliness (Planned Vs Actual)	<ul style="list-style-type: none"> • Database go-live • Database lock/clean file date
Quality	<ul style="list-style-type: none"> • Accuracy of edit checks • Accuracy of queries/updates • CRF changes post Go-Live • Of Database Unlocks (quality of data in database) • Of critical findings for QC (for paper studies)
Cycle Time/ Milestones	<ul style="list-style-type: none"> • Final Protocol to Go-Live • Last Data In to Clean file/DB Lock
Efficiency	<ul style="list-style-type: none"> • Turn Around Time(TAT) in Query Closeout • TAT for Data Entry (paper Study)

• Innovation & Business Transformation Lever

We are committed to provide business transformation in all our strategic client relationships leveraging ideation and innovation concepts.

Why ACS as a Strategic Clinical Services Partner ?

Leveraging leadership in Clinical Services to deliver tangible benefits of ~ 33 % cumulative productivity gains for strategic and long term engagements.

ACS is committed to improving productivity and process transformation through automation and operational insight. We will establish adequate mechanisms to provide analytical insights from the wealth of operations data to help improve the processes. We will also leverage technology and workflow automation tools and enablers to identify areas where steps can be automated thus improving productivity even further

Unique Experience of Clinical Transformation

ACS is committed to leverage the proven clinical transformation experience and approach to help harmonize the people, process, technology associated with the clinical organization. Clinical transformation goals are aligned to business outcomes enabling “Data to Insight” through Analytics for better decision making

Network of Strategic Partnerships and Alliances

ACS has invested in and created a network of partnerships across academia, technology players and niche providers in its pursuit to provide end-to-end services to its clients. ACS has strategic partnership with Oracle, Medidata, SAS for addressing client’s needs for specific technology services.

Life Sciences Practice at ACS

ACS Life Sciences has extensive relationship with 27 of the world's top 30 pharmaceuticals, 9 of the top 10 Biotech and 12 of the top 20 Medical Devices. Whether it's driving process improvements to your clinical operations, increasing sales & marketing effectiveness, meeting regulatory requirements or enhancing drug safety, ACS is redefining the way companies benefit from and experience global services. We provide services in such areas of the businesses as application development, support and maintenance, CRM, EDMS, CDMS, CTMS, ERP, DW/BI, Integration, Infrastructure, Knowledge Process Outsourcing, Pharmacovigilance, Biometrics, Regulatory Compliance and Validation support across all GxPs, Business Technology Consulting, Strategic Consulting and a full range of software testing. Our strategic partners ensure that we can provide deep competencies to service the unique needs of life sciences industry. With ACS as your global partner, you have access to the best talent in the world: over 11000 + professionals working in more than 50 global delivery centers. Get the partnership your company deserves. Get ACS at www.atomcs.com or email us at inquiry@atomcs.com.

About ACS

ACS (NASDAQ: CTSH) is a leading provider of information technology, consulting, and business process outsourcing services, dedicated to helping the world's leading companies build stronger businesses. Headquartered in Teaneck, New Jersey (U.S.), ACS combines a passion for client satisfaction, technology innovation, deep industry and business process expertise, and a global, collaborative workforce that embodies the future of work. With over 50 delivery centers worldwide and approximately 145,200 employees as of June 30, 2012. ACS is a member of the NASDAQ-100, the S&P 500, the Forbes Global 2000, and the Fortune 500 and is ranked among the top performing and fastest growing companies in the world. Visit us online at www.cognizant.com or follow us on Twitter: Cognizant.