Solution Overview

'AccelCTMS' is a ready-to-use packaged cloud-based clinical trial management solution offered by Techsol using Oracle Siebel CTMS and Oracle Clinical Data Analytics applications.

Our solution enables holistic management of critical clinical trial activities from study start to site closeout for global studies. Emerging biopharma, device manufactures, and contract research organizations can leverage AccelCTMS to plan, manage, and track early to late-stage clinical trials.

AccelCTMS - Solution Models

With AccelCTMS, customers are given the choice of three solution models each of which has a host of feature functionality choices to plan, manage, and fully track all clinical operations activities.

Solution Feature	AccelCTMS Standard	AccelCTMS Premium	AccelCTMS Premium Plus
➢ Program & Protocol Management ➢ Study Budget & Expense Tracking ➢ IP & Document Tracking ➢ Site Management ➢ Site Visit Trip Reports ➢ Project & Resource management ➢ Resource and timesheets tracking ➢ Standard Risk-based Monitoring ➢ Subject Recruitment Tracking ➢ Investigator Payments ➢ Study Performance Tracking: Specific to Project, Protocol, Site, Site Visit Activities ➢ Subject Visit, Trip Report Templates, RACT, Activity Templates, Assessment Templates, Training Topics, and Plans are One-time configuration and utilize specific to Program, Study, Country, Site, Vendor, and Investigator specific. ➢ Contracts Management ➢ Site, Investigator and Account assessment templates based on TransCelerate standards ➢ Offline access of application ➢ Browser and device agnostic application user interface	X	X	X

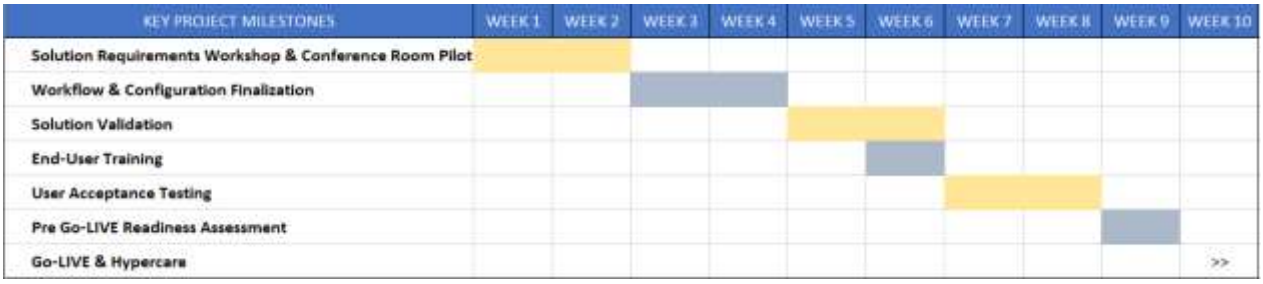
Solution Feature	AccelCTMS Standard	AccelCTMS Premium	AccelCTMS Premium Plus
➢ Tracking of Protocol Deviations, Adverse Events, and Supplies specific to Site, Country, and Study.	-	X	X
Advanced Risk-based Monitoring with Key Risk Indicators (KRIs)	-	X	X
230+ Pre-built Reports and dashboards for Trend Analysis with KPIs	-	X	X
EDC and eTMF Integration	Add-on	Add-on	Add-on
Associated Technology Service Offerings			
System Environments	QA & PROD	QA & PROD	QA, PROD & DR
Support Coverage	12x5 Business Hours	12x5 Business Hours	24x7 Business Hours
Custom Reports	Up to 2 Reports	Up to 2 Reports	Up to 5 Reports
Disaster Recovery	RTO up to 72 hours RPO up to 48 hours	RTO up to 72 hours RPO up to 48 hours	RTO up to 4 hours RPO up to 30 mins.

AccelCTMS packages can be further customized where additional modules and functionality can be included or excluded based on specific customer needs. Such decisions would be discussed during the time of scope finalization and pricing.

AccelCTMS – Solution Implementation Approach & Timelines

AccelCTMS Standard edition solution implementation and rollout will be delivered within 10 to 12 weeks to clients using Techsol's fast track validation package. Our consultants will engage closely with the client's business team to conduct a hands-on requirements workshop of the CTMS solution.

Following is a high level, indicative timelines and associated milestones using our pre-defined validation package.



AccelCTMS Premium and AccelCTMS Premium Plus deployments involve additional 5 and 8 weeks (in addition to AccelCTMS Standard timelines) and may vary depending on the size and complexity of integrations and custom report requirements respectively.

AccelCTMS - Salient Solution Features and Implementation Approach

Rapid Cloud on-boarding Model:

- Fast track implementation with phased approach for global roll-outs
- Continuance guidance from SMEs for business process design
- Business-user training (Train the trainer, Classroom, Remote)

Solution Validation Readiness:

- AccelCTMS comes with ready validation kit (deliverables as per risk based approach defined by GAMP 5 guidelines) and is UAT ready
- Offered with 2 environments (VAL, PROD) for AccelCTMS Standard, AccelCTMS Premium and 3 system environments (VAL, PROD and DR) for AccelCTMS Premium Plus
- Solution is certified for regulatory compliance (21 CFR Part 11, EU Annex 11)
- Continuous support from SMEs for PQ/UAT execution

Service Desk & Disaster Recovery:

- 24x7 or 12x5 business hours (depending on the package) Technical & Functional support (Requests, Incidents, Change)
- Preventive Maintenance & Cloud Monitoring

- Technical support for ongoing configurations management
- Functional support for troubleshooting business workflows

Custom Report Development:

- Rapid custom report development with templated approach
- Experience with various industry standard BI tools such as OBIEE, Cognos, Qlik, Logi etc.

Specialized Add-ons:

With AccelCTMS, customers can choose to have any of the following add-ons as part of regular solution implementation. These value-add services will be priced based on time & effort.

- External Data Load and Migration → Studies, Study Specific Contacts, Sites, Site Specific Contacts, Accounts (Vendors), Investigators, Subject Visits, Load
- EDC and IWRS Integration
- eTMF, Content Management integration
- Integration with CDA → Provides Decision Making Stack/KPI
- Customized or configuring any Ad-hoc Reports
- MPP Integration → For Project Task Integration.

Following are the Siebel Clinical modules of AccelCTMS solution:

Siebel Clinical Module	AccelCTMS Standard	AccelCTMS Premium & Plus
➢ Siebel CTMS Base Module ➢ CTMS Protocol Builder ➢ CTMS Document Tracking ➢ CTMS Trip Reports ➢ Resource and Project Management ➢ Payments ➢ Cost Tracking ➢ Business Intelligence Publisher (BIP) ➢ Additional Siebel CRM modules	X	X
➢ Clinical Data Analytics	-	X

What are the key solution features of AccelCTMS?

AccelCTMS can be tailored with flexible configurations in alignment to your clinical trial management business process. At a broad level, our solution can fully address the core activities involved in following clinical trial milestones with the prebuilt application features & modules.

Clinical Study Planning	Study Startup
Protocol Development • Manage and track multiple clinical programs and associated clinical studies • Track Regulatory submissions and approvals **Budget Planning & Allocation** • Plan and forecast trial budget • Budget allocation to study teams **Vendor Selection** • Define new vendor contracts • Select existing vendors based on past performance	**Project & Resource Management** • Identify study team at various levels • Perform Resource Allocation • Define activities, timelines and targets for team members **Sites & Investigator Selection** • Perform Site Evaluation & Feasibility Analysis • Perform Investigator selection based on past performance • Plan for Investigator Meetings **Manage Study Go-LIVE** • Plan for Site Initiation • Track IMP Dispensing • Track Contract Payments
Study Conduct	**Study Closure**
Site Visits Management • Prepare site visit activity templates & plan site visits • Define, update and track site visit activities • Track and maintain site specific study documents **Subjects Tracking** • Define Subject Visit templates • Perform CRF tracking • Monitor trial progress of subjects	**Sites Closeout** • Proactive Planning for Site Closeout Visit • Define, Update and Track Site closeout Visit Activities • Track Drug Accountability • Complete pending payments **Study Documents Archival** • Site specific essential documents reconciliation • Trial Master File Documents Archival • Update and closure of Contracts and Agreements

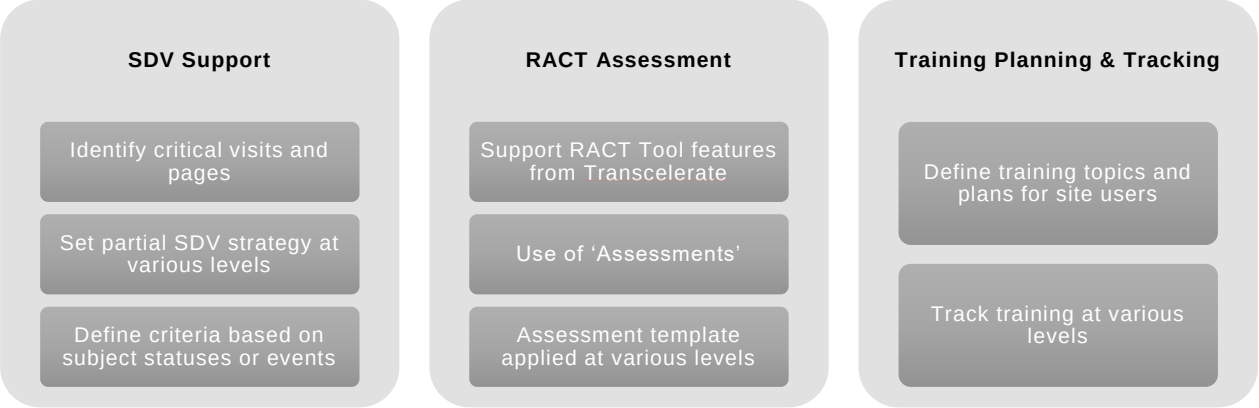
Clinical Supplies Management
- Define activities related to clinical supplies
- Track drug accountability
- Manage clinical supplies demand management

Payments Tracking
- Investigator Payments
- Site Payments
- Subject Reimbursements
- Vendor Payments

Stakeholders Performance Assessment
- Investigator Performance Assessment
- Site Performance Assessment
- Vendor Performance Assessment

Reporting of Clinical Study Outcomes
- Generation of Trial Summary Reports
- Reporting of Study Budget Expenditure
- Clinical Project & Program Outcomes Review

Latest version of AccelCTMS offers following advanced features to support RBM, SDV, RACT assessment and training & planning.



What are the Business Benefits of 'AccelCTMS'?

AccelCTMS offers the following advantages to sponsors and CROs:

- Manage Global Clinical Trials using a single system
- Easily implement strategic, risk-based monitoring to improve study data quality
- Make fast and accurate decisions with real-time subject enrollment and site performance metrics
- Facilitate multi-channel communications and compliance through automated workflows and notifications
- Improve investigator targeting and subject recruitment to achieve target study dates with built-in investigator intelligence

- Increase process efficiency and staff productivity at clinical sites through comprehensive performance analytics and mobility
- Real Time Budget Control with email alerts for Trip Report Management, Milestones, Invoice etc.
- Regulatory compliant audit trail available within the application
- Data Control Access across the application based on individual roles.
- iHelp feature helping users to access the application with ease.

With real-time visibility into clinical trial progress, Sponsors can establish improved relationships with vendors and principal investigators by having a centralized database for maintaining, tracking, and sharing:

- Site Contact information
- Qualification of key study team personnel
- Clinical staff resource utilization
- Clinical trial contracts & payments progress
- Study documentation status

About Techsol

Techsol Corporation specializes in offering cloud-based information technology services and innovative software solutions to global pharmaceutical, life sciences, and healthcare companies.

Founded in 2010, we are a market leader in providing highly configurable process-oriented technology solutions for digitally transforming pharmaceutical business operations across medical affairs, clinical development, drug safety, and medical information management.

Our domain-specific business solutions are focused on establishing cross-platform integrations, business process automation, facilitating stakeholder collaboration, risk-based validation, and providing operational insights with advanced data analytics. As a trusted technology partner, we continuously engage with industry leaders like Oracle to provide strategic consulting services for solutions implementation, systems validation, and cross-platform integration.

Contact Us

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