



CHECKLIST FOR SELECTING A CLINICAL TRIAL MANAGEMENT SYSTEM

SYSTEM CAPABILITY	REQUIREMENT	DESIRABLE
Manage sponsor contracts, services and invoicing		
Manage milestone payments		
Build a budget		
Build an MCA or Coverage Analysis		
Create and manage study specific subject calendars		
Provide ability to track budgets and actual costs per trial		
Provide trial statuses – PI, Pt, documentation, milestones		
Track 1572 documentation such as cv's and medical licenses		
Demonstrate work load assessment of each staff member according to trial assignment		
Allow for subject tracking per visit completion		
Provide check off list of CRF completion		
Provide tracking of study drug or device		
Has ability to interface with electronic IRB system		
Has ability to interface with additional system within facility (Cancer CTMS, Independent Data Management System)		
Provides interface to the Financial Management System		
Provides interface to EMR		
Provides interface to scheduling system if different than above		
Ad hoc reporting for report development with export to Crystal Reporting, Excel or other system requirement		
Available to staff remotely 24/7		
Support by vendor for implementation and training		
Support by vendor by telephone once implemented		
Provide use of various coding dictionaries or creation of data dictionaries		
Concomitant Med Pick List		
Traceable data base changes and validation		
21 CFR Part 11 compliant		
Electronic signature capability		