2020 CTMS Marketplace Review

CRO Focus

July 2020

Agenda

Introduction

Current CTMS Solutions Environment
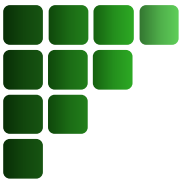
CTMS Key Competitors – Overview

CTMS Key Competitors – Commonalities

CTMS Key Competitors – Differentiators

CTMS Selection Best Practices

Conclusion

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Introduction

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Successfully building and enhancing clinical research organizations and biopharma clinical development functions.


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- Pharma Initiatives Partnership is a management consultancy dedicated to operationalizing business strategy in clinical development, in both industry and CROs.

- Our teams have driven **hundreds of operational strategy projects** with biopharma organizations of all sizes.

- We define and drive change initiatives in organization development, process optimization and information technology strategy.

- We have worked with over a **dozen organizations to select, replace or modify their Clinical Trial Management Systems** (CTMS).

- Our proven approach to change management as well as PMI certified program managers ensure that change is understood, accepted and embraced by the organization.

- In addition to managing programs, our consultants are skilled trainers and developers of training materials, supporting a range of training modalities.

- Our values place emphasis on providing to our clients the **experience** to rapidly analyze the situation, the **creativity** to identify unique solutions, and the **discipline** to complete our work within challenging timelines.

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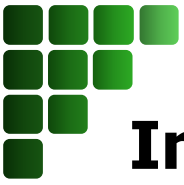
Introduction

- Overall, there has never been a better time to be in the market for a Clinical Trial Management System (CTMS) because:

  - All the software solutions are offering Software as a Service (SaaS) solutions, requiring minimal investment by the CRO in infrastructure

  - Growing understanding of the past challenges of configuring CTMS solutions have led to better out-of-the-box solutions and much more user-friendly, powerful system configuration and tailoring tools

  - Improved APIs make integrating new CTMS solutions into existing data infrastructure more efficient

- This analysis should serve as a basis to start considering the viable alternatives

This CTMS competitive analysis was developed based on the experience of Pharma Initiatives gained through multiple, detailed CTMS selection and implementation projects.
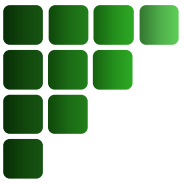
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Introduction
Challenge of Syndicated Market Research

- Two significant syndicated market research tools available to purchase:
  - ISR Reports: _CTMS Market Dynamics and Service Provider Benchmarking (2nd Edition)_ – 06/18
  - Global Market Insights: _Clinical Trial Management System Market - CTMS Share Report 2024_ – 04/18
- Worth reviewing, but in no way definitive
- Both reports have **SIGNFICANT** methodological errors:
  - ISR
    - Includes data management (EDC)-only solutions with CTMS solutions
    - Mixes Academic/Site Focused CTMS solutions with Sponsor/CRO focused solutions, which are almost entirely different market segments
    - Mixes CROs with proprietary CTMS solutions with standalone CTMS solutions
  - Global Market Research
    - Mixes Academic/Site Focused CTMS solutions with Sponsor/CRO focused solutions, which are almost entirely different market segments
    - Mixes Quality Management Systems (QMS) with CTMS solutions, not competitive software solutions
    - Completely ignores the mid/small tier of CTMS competitors
    - Market sizing methods are based on simplistic assumptions of market growth instead of potential install growth

While Pharma Initiatives has reviewed these sources, given their limitations Pharma Initiatives has based this presentation on its industry knowledge and all opinions are those of Pharma Initiatives only
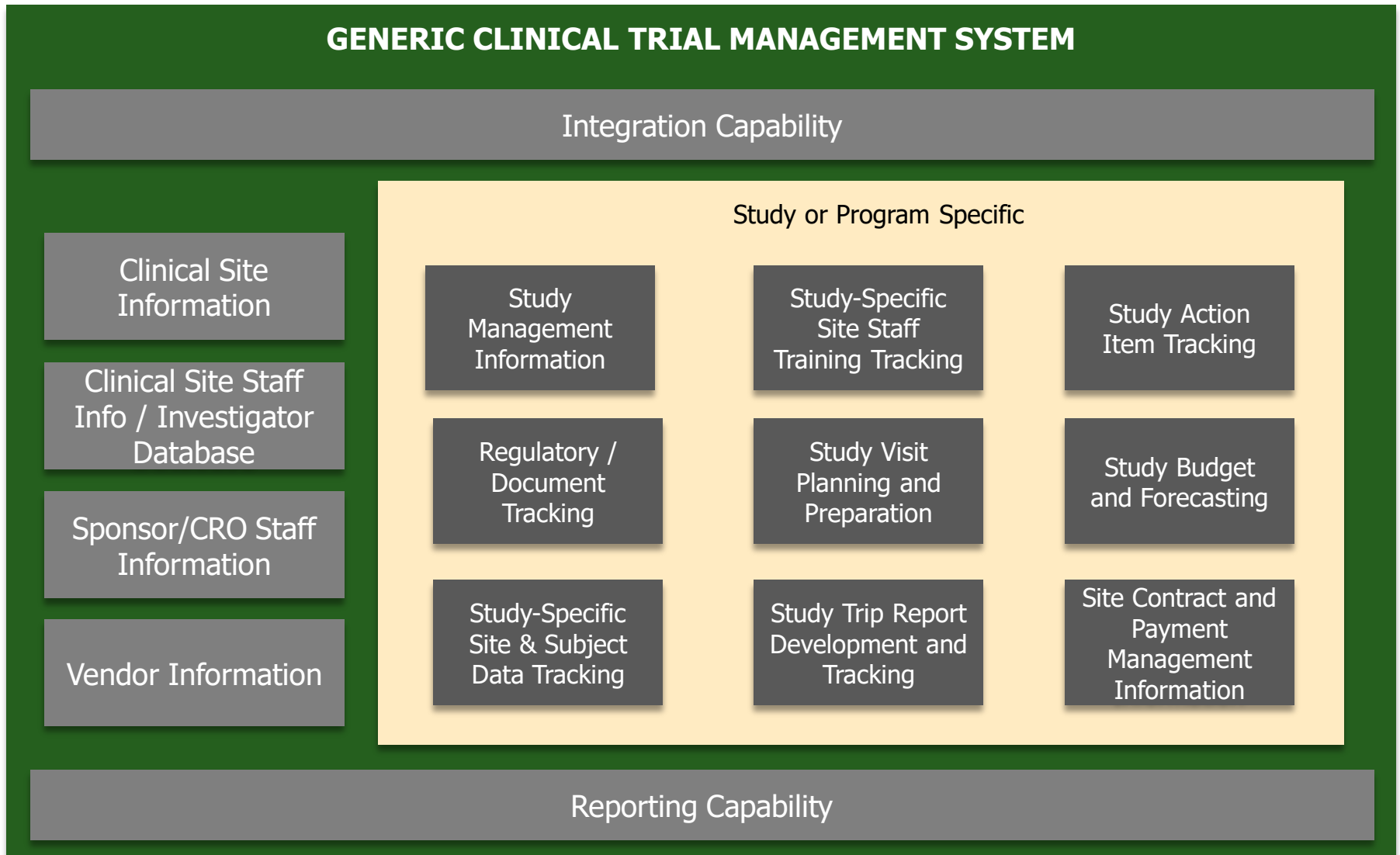
Current CTMS Solutions Environment

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Current CTMS Solutions Environment
Generic Framework of a CTMS

GENERIC CLINICAL TRIAL MANAGEMENT SYSTEM

Integration Capability

Study or Program Specific

| Clinical Site Information | Study Management Information | Study-Specific Site Staff Training Tracking | Study Action Item Tracking |

Clinical Site Staff Info / Investigator Database

Regulatory / Document Tracking

Study Visit Planning and Preparation

Study Budget and Forecasting

Sponsor/CRO Staff Information

Study-Specific Site & Subject Data Tracking

Study Trip Report Development and Tracking

Site Contract and Payment Management Information

Vendor Information

Reporting Capability

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Current CTMS Solutions Environment
Introduction – Capabilities NOT Typically Found in CTMS

- Electronic data capture

- eTMF

- Portal

- Accounting and time tracking systems

- IVRS / WRS / Randomization

- Safety / PV tracking and management

- Learning management systems

- Data statistical management tools

- Biological sample management

- Lab data tracking

Note: Systems listed in BLUE are often Integration to CTMS

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Current CTMS Solutions Environment
Sponsor/CRO Solution Competitors – Overall by Market Penetration

- **Largest / Most Established**
  - Oracle – Siebel CTMS
  - Parexel* – Impact CTMS
  - Medidata – Medidata CTMS
  - Veeva – Veeva CTMS
- **Bigger / Established**
  - ArisGlobal – LifeSphere CTMS
  - Bioclinica – CTMS
  - DataTrak – UX CTMS 360
- **Smaller / Less Established**
  - Anju Life Science Software – ClinPlus CTMS
  - BGO Software – CliniCube CTMS (No US offices)
  - BSI – BSI CTMS (No US offices)
  - CloudByz – CloudByz CTMS
  - eNNOV – eNNOV CTMS
  - ERT – Connected Trial Management System
  - Fortress Medical – Clindex CTMS
  - Intrinsic – CTMS
  - MedPace - ClinTrak
  - Phoenix Software - Entrypoint i.4 — limited CTMS as part of EDC
  - SureClinical – SureCTMS (released Q4 2018)
  - Pharmaseal - (Just Launched)

Sponsor/CRO Solution Competitors	
19	Viable Competitors
4	Largest/Most Established
3	Bigger/Established
12	Smaller/Less Established

*Note: Impact CTMS is generally not considered viable for CRO's seeking a CTMS since Parexel is a major CRO competitor.

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Current CTMS Solutions Environment
Academic/Site Competitors – Not Relevant for CROs

- Academic/Site Focused
  - Forte – Allegro
  - EasyTrial – easytrial.net
  - Bio-optronics – Clinical Conductor
  - Realtime – Realtime CTMS
  - ClinTrialWorks – ClinTrialWorks CTMS

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Current CTMS Solutions Environment
CRO Solution Competitors – Targeting CROs

- **Largest / Most Established**
  - **Oracle – Siebel CTMS**
  - Parexel* – Impact CTMS
  - **Medidata – Medidata CTMS**
  - **Veeva – Veeva CTMS**
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These solutions have demonstrated an active interest in competing for CROs through pricing, flexibility and attempting to reduce the burden of configuration

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CTMS Key Competitors - Overview

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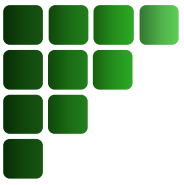
CTMS Key Competitors
Overview

- We will focus on the following Key Competitors:

  - Bioclinica

  - DataTrak

  - Medidata

  - Oracle

  - Veeva

- Collectively represent significant market share of the CRO marketplace and have a range of different strengths, weaknesses and approaches to support to provide

- We will present the commonalities between all five solutions, then break down the positive and negative differentiators of each system

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CTMS Key Competitors
Background

	Bioclinica	DataTrak	Medidata	Oracle	Veeva
Deployment Approach	SaaS and On Premise	SaaS Only	SaaS Only	SaaS and On Premise	SaaS
Pre-integrated with	SharePoint/MS Office Bioclinica Cloud: EDC, RBM, IRT	DataTrak Cloud: EDC, RBM, IRT, Trial Design, BA, Training	Medidata Clinical Cloud: Rave EDC	Oracle InForm EDC	Vault eTMF, Vault EDC, Vault Start Up
Ownership	Private	Public (DTRK)	Public (MDSO)	Public (ORCL)	Public (VEEV)
Employees	3,000+	50+	2,000+	137,000+	2,200+
Offices	8+, in 7 Countries	2, USA	12+, in 8+ Countries	80+, in 60+ Countries	16+, in 8+ Countries
Database	MS SQL Server	Oracle DB RAC/SAN	MySQL	Siebel Server / Database	AWS Linus
Help Desk	24/7 365	24/7 365	24/7 365	24/7 365	24/7 365

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CTMS Key Competitors – Commonalities

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CTMS Key Competitors – Commonalities
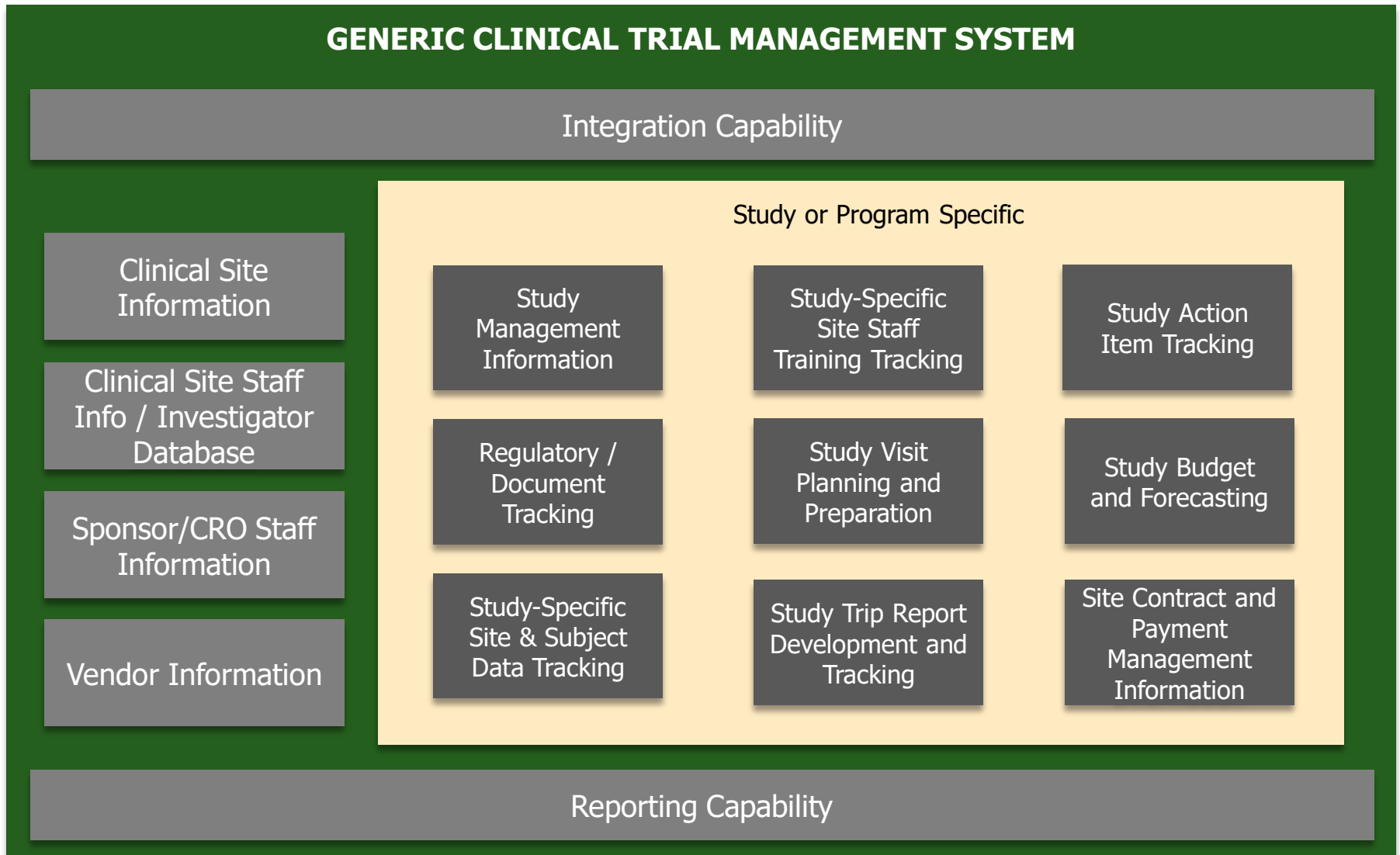## Technical Environment

Technical environment for solution delivery used to be a major differentiator but many of the competitors are trending toward a common approach:

- Almost all are primarily pushing their Software as a Service (SaaS) solutions:
  - Oracle still offers on-premise but they are not pushing
  - Bioclinica still offers on-premise and appears agnostic
- Some issues with EU-based data centers for EU data – not all clients require it
- Most support all modern browsers – some exceptions – Bioclinica IE Only
- Difference around upgrade forcing in SaaS:
  - Most force upgrades, usually after a period of time
    - Oracle (forces after support for old version ends, long time)
    - DataTrak (immediate upgrade)
    - Veeva (immediate upgrade)
  - Some allow users to select <u>when</u> or <u>if</u> to upgrade
    - Bioclinica
    - Medidata

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CTMS Key Competitors – Commonalities
Functionality Overview

GENERIC CLINICAL TRIAL MANAGEMENT SYSTEM

Integration Capability

Study or Program Specific

Clinical Site Information

Clinical Site Staff Info / Investigator Database

Sponsor/CRO Staff Information

Vendor Information

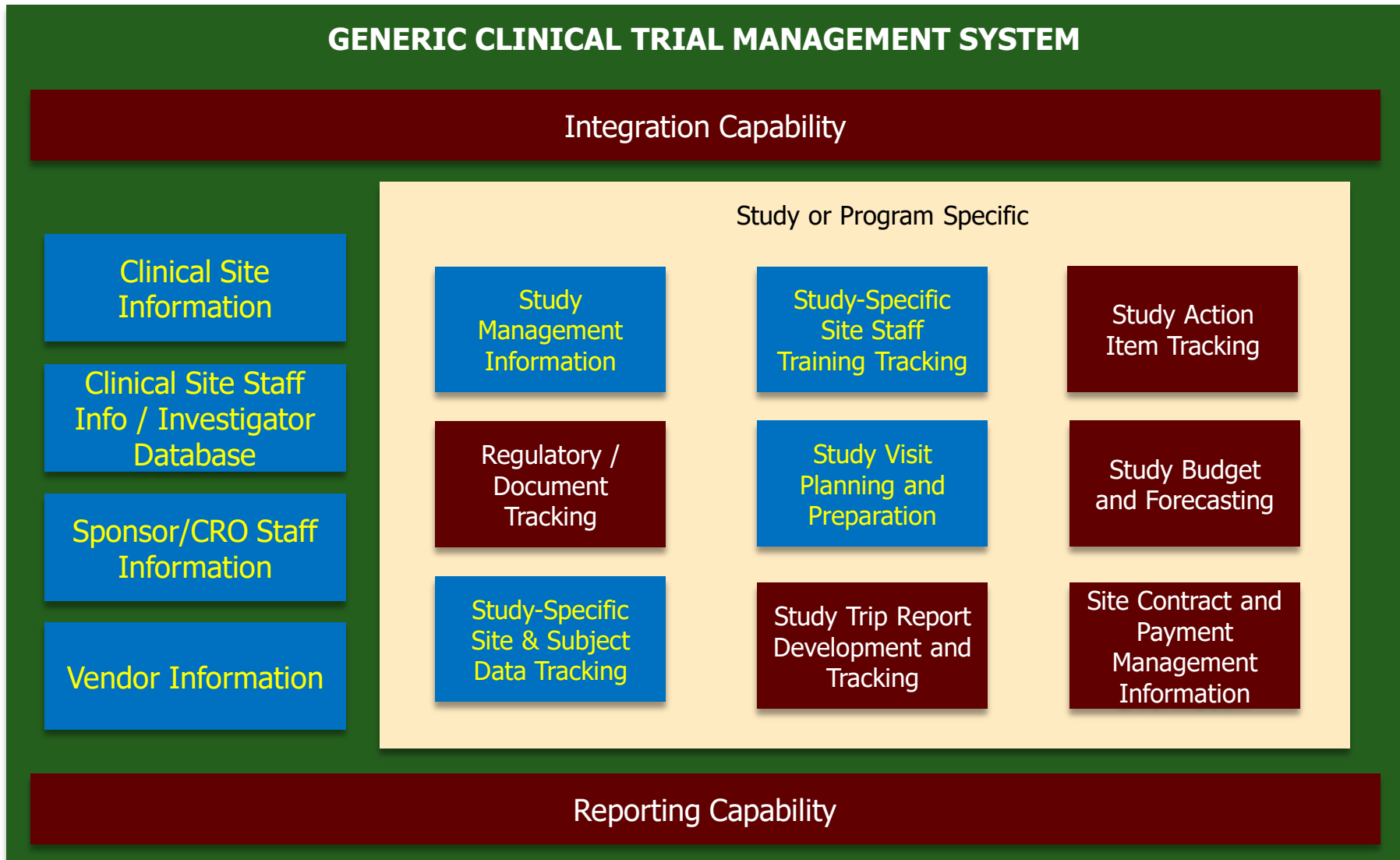|		
Study Management Information	Study-Specific Site Staff Training Tracking	Study Action Item Tracking
Regulatory / Document Tracking	Study Visit Planning and Preparation	Study Budget and Forecasting
Study-Specific Site & Subject Data Tracking	Study Trip Report Development and Tracking	Site Contract and Payment Management Information

Reporting Capability

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CTMS Key Competitors – Commonalities
Functionality Overview (continued)

Significant Commonalities

Significant Differentiators

GENERIC CLINICAL TRIAL MANAGEMENT SYSTEM

Integration Capability

Study or Program Specific

Clinical Site Information	Study Management Information	Study-Specific Site Staff Training Tracking	Study Action Item Tracking
Clinical Site Staff Info / Investigator Database	Regulatory / Document Tracking	Study Visit Planning and Preparation	Study Budget and Forecasting
Sponsor/CRO Staff Information	Study-Specific Site & Subject Data Tracking	Study Trip Report Development and Tracking	Site Contract and Payment Management Information
Vendor Information			

Reporting Capability

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CTMS Key Competitors – Commonalities
Functionality Overview (continued)

The Functionality Commonalities are the capabilities that all the top vendors offer to some degree – but even within these broad areas of consistency some differences remain.
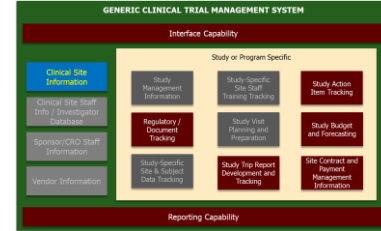
CTMS VENDOR SELECTION TIP

- As we review each category, consider what is more important to your organization

- If your needs are largely met by the capabilities listed as "Common", it is likely that these areas will not drive your vendor selection

- If your needs are listed as "Some Differentiation", you will need to carefully consider each vendor in terms of this category of capabilities to ensure that you do not select a system that ultimately will not meet your needs
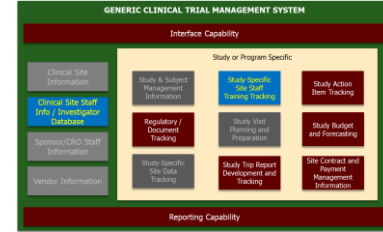
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Most solutions share fairly common functionality in terms of Clinical Site Information, but there are some areas of differentiation:

- General Site Information

  – <u>Common</u>: Name; address; related institution; related contacts (including Investigators); IRB/EC information; related protocols; therapeutic areas

  – <u>Some differentiation</u>: Study-specific regions; satellite site tracking; capabilities; evaluations; some systems treat sites as existing only in the context of the protocol (otherwise just an account and contact)

CTMS Key Competitors – Commonalities

Clinical Site Staff Info / Investigator Database and Staff Training Information Functionality
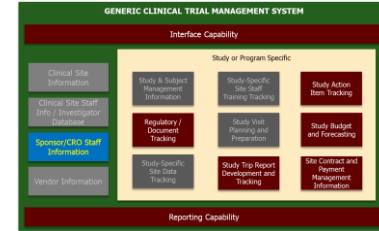

Most solutions are share fairly common functionality in terms of Clinical Site Staff Info / Investigator Database & Study Specific Site Staff and Staff Training Information but there are some areas of differentiation:

- General Site Staff Information

    – Common: Name; titles; address/email; phone; credentials; disqualifications; related sites; other related contacts; related protocols

    – Some differentiation: Ease of client-specific coding (e.g. TA expertise); evaluations; regional associations

- Investigator Database

    – Common: Designation of site contacts as Investigators

    – Some differentiation: Ease of views limited to Investigators and further refined by TA/past experiences; evaluations; additional fields for just Investigators (e.g. Alma Matter, Certifications, etc.)

- Site Staff Training

    – Common: General training achievement of Site Staff by study

    – Some differentiation: Detailed tracking of training by study – including assigning training requirements; tracking progress and tracking training expiry

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CTMS Key Competitors – Commonalities
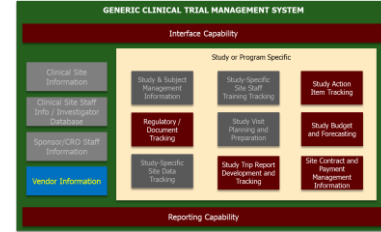## Sponsor/CRO Staff Information Functionality

Most solutions share fairly common functionality in terms of Sponsor/CRO Staff Information, but there are some areas of differentiation:

- General CTMS User Staff Information

  - <u>Common</u>: Login info; name; titles; address/email; phone; credentials; system role; role by study; study start and end date

  - <u>Some differentiation</u>: Multiple roles within one study

- Sponsor Staff Information (for CROs)

  - <u>Common</u>: Tracked as general contact (name, titles, address/email, phone, credentials)

  - <u>Some differentiation</u>: Associating multiple sponsor staff with a study, assigning study-specific roles; assigning multiple roles to a single Sponsor contact

- Sponsor/CRO Staff Training

  - <u>Common</u>: NONE

  - <u>Some differentiation</u>: Varies very widely; some track nothing; some track study-specific training requirements and related data; some track general training requirements and study-specific training
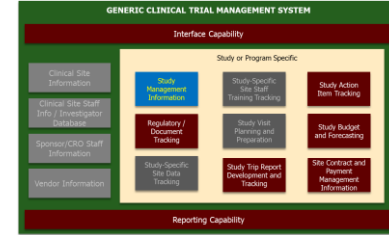
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Most solutions share fairly common functionality in terms of Vendor Information, but there are some areas of differentiation:

- General Vendor Information

  – <u>Common</u>: Name; address; related contacts; type; status; notes; associated vendors

  – <u>Some differentiation</u>: All past associated studies; evaluations; contracts directly with vendor and with sponsor (for CROs); study role; study primary contact
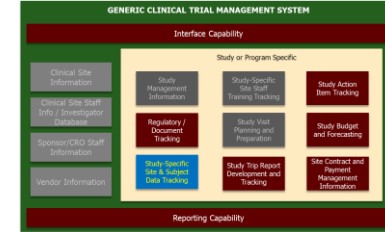
Most solutions share fairly common functionality in terms of Study & Subject Management Information, but there are some areas of differentiation:

- General Study Information

  – <u>Common</u>: Protocol name; associated product and indication; description; type; phase; associated program; sponsor; number of expected sites; number of actual sites; associated sites; number of expected subjects; number of actual subjects; total counts of subjects by status

  – <u>Some differentiation</u>: Protocol alias; protocol long-name; support of more than one product and/or more than one indication; specific subject counts (e.g. screened, screen-fail, randomized, enrolled, etc.); associated contacts with the study (vs. sites); documents associated with the protocol (vs. sites)

- Study Milestones

  – <u>Common</u>: First site activated; first subject enrolled; date of database close; some type of user-defined milestone tracking

  – <u>Some differentiation</u>: Date of protocol approval; last subject enrolled; last follow up visit; number of user-definable milestones

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CTMS Key Competitors – Commonalities
## Study-Specific Site & Subject Data Tracking Functionality

Most solutions share fairly common functionality in terms of Study-Specific Site & Subject Data Tracking, but there are some areas of differentiation:

- Site Feasibility, Selection & Activation Information
  - <u>Common</u>: Tracking the feasibility process; tracking selection of sites; tracking of site activation visits; tracking of site status through activation; tracking of all dates associated with site feasibility; selection and activation
  - <u>Some differentiation</u>: Tracking and support of feasibility questionnaires; tracking and access to site performance evaluations from previous studies

- Site Study Closeout Information
  - <u>Common</u>: Tracking the closeout process; tracking of closeout dates
  - <u>Some differentiation</u>: Support for templated closeout checklists

- Study-specific Site Staff Information
  - <u>Common</u>: Study-specific role; study-specific start and end dates in role
  - <u>Some differentiation</u>: Study-specific regional association; study-specific qualifications; study-specific site/satellite site association

- Subject Tracking Information (entered directly or through EDC Integration)
  - <u>Common</u>: Subject ID; subject status; subject status dates; subject visit calendar; subject visits actual completed date; subject visit SDV status; subject unscheduled visit date
  - <u>Some differentiation</u>: Subject visit calendar user-friendliness varies considerably; subject site re-assignment support

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Study Visit Planning and Preparation Functionality
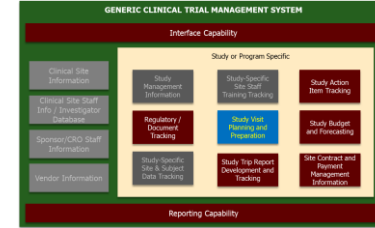
Most solutions share fairly common functionality in terms of Study Visit Planning and Preparation, but there are some areas of differentiation:

- Site Visit Planning

  - <u>Common</u>: Site visit scheduled date; site visit actual date; site attendees; monitor; output of future scheduled visits; lists of visits by monitor

  - <u>Some differentiation</u>: Computing/entering duration for multi-day visits; co-monitors; managing required vs. optional visits; type of visit (e.g. remote vs on-site vs central driven)

- Site Visit Preparation

  - <u>Common</u>: Generating a pre-visit letter which includes open follow up items and subjects to be SDVd based on a standard template

  - <u>Some differentiation</u>: Source of output (e.g. Word or directly from system)

- Site Visit Collective Visibility

  - <u>Common</u>: Produce list of all scheduled and completed visits across all studies with monitors associated; produce overall metrics on visits completed as scheduled

  - <u>Some differentiation</u>: Specific metrics

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CTMS Key Competitors – Commonalities
Common Exceptions – Regions and Notifications

This section is focused on common capabilities between the CTMS solutions, but even among this shared set of common capabilities, two areas remain differentiated:

- Regions

  - Regions are user-defined groups of sites (usually based on country or sets of country) that are used to summarize results within a study or across studies for a CRO that has consistent regions

  - Regions can be a critical point for some clients, especially CROs, who view their divisions regionally

  - Oracle, Bioclinica natively support

  - Medidata, DataTrak, Veeva do not support except through tailoring / customization

- Email notifications / alerts

  - Email notifications / alerts are used to notify a user if a condition has been met/passed

  - Some systems have these deeply integrated, others only allow this ability through a separate reporting system which makes them much less useful

  - Bioclinica, DataTrak, Veeva natively support this

  - Medidata, Oracle do not except through separate report writer

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CTMS Key Competitors – Commonalities
Implementation Support

All the vendors offer a "quick start" generically configured system for baseline implementation:

- Quick starts configurations are generally aimed at sponsor-centric users
  - They are for marketing purposes and few, if any, customers can use the system "out of the box" since many operational parameters critical to running their operations will not be natively supported
  - Some are better thought out than others and offer a better starting point for CROs

With the exception of DataTrak, all the vendors profiled require their system to be configured with their assistance:

- DataTrak is built for user-configuration and they offer a short training on their self service configuration tool then leave it in the hands of the users
  - This tool allows almost complete field and screen changes as well as drop down menus
- All other vendors assign a project team with a Project Manager and lead expert to help walk the users through the configuration and determine how to work around limitations
  - Some vendors include in their configuration services the adding of additional fields, the removal of fields or the changing of field labels (Veeva)
  - Other vendors charge extra for field changes (Oracle, Bioclinica, Medidata)

> *The set up and management of templates and reports will be covered during the vendor by vendor review*

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CTMS Key Competitors – Differentiators

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CTMS Key Competitors – Differentiators
Functionality Overview

Significant Commonalities

Significant Differentiators

GENERIC CLINICAL TRIAL MANAGEMENT SYSTEM

Integration Capability

Study or Program Specific

Clinical Site Information

Clinical Site Staff Info / Investigator Database

Sponsor/CRO Staff Information

Vendor Information

Study Management Information

Study-Specific Site Staff Training Tracking

Study Action Item Tracking

Regulatory / Document Tracking

Study Visit Planning and Preparation

Study Budget and Forecasting

Study-Specific Site & Subject Data Tracking

Study Trip Report Development and Tracking

Site Contract and Payment Management Information

Reporting Capability

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CTMS Key Competitors – Differentiators
Summary

	Bioclinica	DataTrak	Medidata	Oracle	Veeva
Regulatory / Document Tracking	Neutral	Weakness	Neutral	Neutral	Strength
Study Trip Report Development and Tracking	Weakness	Weakness	Strength	Strength	Strength
Study Action Item Tracking	Neutral	Strength	Neutral	Strength	Strength
Study Budget and Forecasting	Neutral	Weakness	Neutral	Neutral	Weakness
Site Contract and Payment Management Information	Strength	Weakness	Strength	Neutral	Neutral
Reporting Capability	Neutral	Neutral	Strength	Neutral	Strength
Integration Capability	Neutral	Weakness	Weakness	Strength	Neutral
Implementation	Weakness	Strength	Weakness	Neutral	Strength
Cost & Rep	Strength	Strength	Weakness	Neutral	Weakness

CTMS Key Competitors – Differentiators
Vendor Review
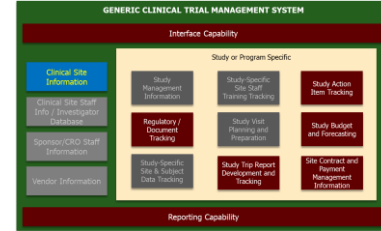
The CTMS vendor by vendor review provides the detail behind the summary evaluation. No vendor is perfect – it is important to see each solution in terms of trade offs.

CTMS VENDOR SELECTION TIP

- As we review each Vendor, focus on those strengths that are aligned with your organization's priorities

- Understand that each vendor is a mix of different strengths and weaknesses which is why a selection process needs to be robust and structured

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CTMS Key Competitors – Differentiators
Bioclinica

Bioclinica is unique in its reliance on SharePoint for configuration beyond baseline and reliance on MS Office for its trip reporting and work flow. With a limited number of updates in the past two years, it is reasonable to question the long term focus on this product among the range of their services.

- Regulatory / Document Tracking – **Neutral**

  - Positive Differentiators: Broad range of documents trackable; capable to tracking a link directly to the document in eTMF; documents can be linked directly to tasks; templates of standard documents can be built and applied to multiple studies/sites; tracking of a wide range of dates (e.g. sent, received, due, expiry, last contact) per document; associated external contact with a document; version tracking; all tracking at the study; region and site level

  - Negative Differentiators: No pre-built integration with an eTMF; no ability to directly enter a document into an eTMF

- Study Trip Report Development and Tracking – **Weakness**

  - Positive Differentiators: Support for comments throughout templated questions; creation of new versions of previously approved trip reports; supports role delegation; trip reports linkable with eTMF; some offline report support through MS Word

  - Negative Differentiators: Bioclinica needs to create/update all templated outputs for trip reports and letters; all trip reports moved to MS Word without audit trail; workflow is managed by separate SharePoint capability; no linking of trip reporting with milestones/payments

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CTMS Key Competitors – Differentiators
Bioclinica (continued)

- Study Action Item Tracking – **Neutral**

  - <u>Positive Differentiators</u>: Tracking action items including created date, due date, last updated date,, status, completed date, antecedent task; audit trail of all tasks; tasks differentiated between follow up items for sites vs. internal tasks; tasks associate-able with documents and trip reports; pre-built templates of tasks can be applied at the study, region and site level; templated tasks can be modified once applied

  - <u>Negative Differentiators</u>: Cannot track owner, external owner for each task; no alert capability associated with tasks; no metrics reports based on task dates; cannot generate lists of overdue or soon to be overdue tasks by owner; cannot reassignment of multiple tasks with one action

- Study Budget and Forecasting – **Neutral**

  - <u>Positive Differentiators</u>: Manage per subject and/or per unit budgets by study and portfolio of studies; auto-populate actual information from payments module; track site payment caps; allow manual entry of actual expenses outside of payments; track actual payments against caps; support budget reconciliation; support multiple budget versions with creation, start and end dates

  - <u>Negative Differentiators</u>: Cannot track percentage of FTE assigned to a site over a time period; cannot project FTE utilization across all studies; cannot forecast expected future costs based on budget; cannot provide graphical output of progress against budget

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Bioclinica (continued)

- Site Contract and Payment Management Information – **Strength**

  – <u>Positive Differentiators</u>: Track site contracting information; track contractual versions and associated dates; associated multiple contracts with a single site; associate payment amounts with subject site visits by study; associate payment amounts based on achieving milestones; support payments based on subject status; support pre-payments/drawdown payments; ability to vary the payment amounts by site within a study; compute payment owed based on subject information (from EDC); support user review and modification of auto-generated payment amounts; support payment approval workflow within the system; support amount tracking in different currencies; generate a single payment amount for a payee out of a group of sub-payments and maintain detail of all sub-payments

  – <u>Negative Differentiators</u>: Cannot support ratio-based payments (e.g. pay for 2 of every 3 screen failures); cannot split a payment between multiple payees; cannot do currency conversions; cannot report on contractual cycle times (e.g. average time from first draft to signed)

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CTMS Key Competitors – Differentiators
Bioclinica (continued)

- Reporting Capability – **Neutral**

  - <u>Overview</u>: Data listings available within CTMS; a connected SharePoint environment pre-configured to interface with most of the data in CTMS is used for business intelligence

  - <u>Positive Differentiators</u>: Number of pre-built reports and dashboards are available within the SharePoint tool; ad hoc reports and dashboards allow "drill down" into detailed data (from business intelligence tool); data is easily exportable into a range of outputs

  - <u>Negative Differentiators</u>: Not all data in CTMS is pre-configured to interface with their SharePoint business intelligence tool – notably absent is audit trail information; SharePoint business intelligence ad hoc tool is not end user friendly (requiring some visibility in SQL)

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Bioclinica (continued)

- Integration Capability – **Neutral**

  – <u>Overview</u>: Bioclinica's CTMS is pre-integrated with SharePoint which it uses to support outputs and pre-configured to interface with Bioclinica Cloud EDC additional interfaces are supported via its Cloud Transformation Gateway and its API

  – <u>Positive Differentiators</u>: Bioclinica has interfaced with the top tier of EDC and eTMF vendors in the past; supportive of third-party developed integrations with their API

  – <u>Negative Differentiators</u>: Focused resources on CTMS integration appear to be limited; reputation (see Implementation Services section)

PHARMAINITIATIVES

CTMS Key Competitors – Differentiators
DataTrak

DataTrak's CTMS solution is the most recently developed from ground up and as a result offers the most easy user-driven customization and field level changes. As the newest solution, it has a small install base and some limitations to overcome.

- Regulatory / Document Tracking – **Weakness**

  - <u>Positive Differentiators</u>: Broad range of documents trackable as tasks; templates of standard documents can be built and applied to multiple studies/sites as tasks; all tracking at the study; region and site level

  - <u>Negative Differentiators</u>: No ability to integrate with an eTMF; no storing of eTMF links; limited version tracking; no support of document related workflows; documents cannot be linked directly to additional tasks; cannot tracking of a wide range of dates (e.g. sent, received, due, expiry, last contact) per document; cannot associate external contact with a document

- Study Trip Report Development and Tracking – **Weakness**

  - <u>Positive Differentiators</u>: User-administered trip report template driven outputs; support for comments throughout templated questions; one step review and approval process; workflow contained entirely within the CTMS for traceability; support role delegation; support of visit related tasks not visible on trip reports

  - <u>Negative Differentiators</u>: No linking of trip reporting with eTMF; no creation of new versions of previously approved trip reports; no workflow alerts for reviewers; no linking trip reports with milestones/payments; no support for confirmation/follow up letters; no off-line report support

PHARMA**INITIATIVES**

CTMS Key Competitors – Differentiators
DataTrak (continued)

- Study Action Item Tracking – **Strength**

  - <u>Positive Differentiators</u>: Tracking action items including created date, due date, last updated date, owner, external owner, status, completed date, antecedent task; audit trail of all tasks; tasks differentiated between follow up items for sites vs. internal tasks; tasks associate-able with documents and trip reports; reassignment of multiple tasks with one action; pre-built templates of tasks can be applied at the study, region and site level; templated tasks can be modified once applied

  - <u>Negative Differentiators</u>: No alert capability associated with tasks; no metrics reports based on task dates; cannot generate lists of overdue or soon to be overdue tasks by owner

- Study Budget and Forecasting – **Weakness**

  - <u>Positive Differentiators</u>: Manage per subject and/or per unit budgets by study and portfolio of studies; auto-populate actual information from payments module; support multiple budget versions with creation, start and end dates

  - <u>Negative Differentiators</u>: Cannot track percentage of FTE assigned to a site over a time period; cannot project FTE utilization across all studies; cannot track site payment caps; cannot forecast expected future costs based on budget; cannot allow manual entry of actual expenses outside of payments; cannot track actual payments against caps; cannot provide graphical output of progress against budget; cannot support budget reconciliation

PHARMAINITIATIVES

CTMS Key Competitors – Differentiators
DataTrak (continued)

- Site Contract and Payment Management Information – **Weakness**

  - <u>Positive Differentiators</u>: Track site contracting information; track contractual versions and associated dates; associated multiple contracts with a single site; associate payment amounts with subject site visits by study; compute payment owed based on subject information (from EDC); support user review and modification of auto-generated payment amounts; support payment approval workflow within the system; support amount tracking in different currencies;

  - <u>Negative Differentiators</u>: Cannot support pre-payments/drawdown payments; cannot support ratio-based payments (e.g. pay for 2 of every 3 screen failures); cannot associate payment amounts based on achieving milestones; no ability to vary the payment amounts by site within a study; cannot support payments based on subject status; cannot generate a single payment amount for a payee out of a group of sub-payments and maintain detail of all sub-payments; cannot do currency conversions; cannot split a payment between multiple payees cannot report on contractual cycle times (e.g. average time from first draft to signed)

PHARMAINITIATIVES

CTMS Key Competitors – Differentiators
DataTrak (continued)

- Reporting Capability – **Neutral**

  - <u>Overview</u>: Data listings, pre-built reports available within CTMS; they recently introduced a Sisense business intelligence pre-configured integration for dashboards and ad hoc report writing

  - <u>Positive Differentiators</u>: Number of pre-built reports are available within the CTMS tool; ad hoc reports and dashboards allow "drill down" into detailed data (from Sisense business intelligence tool); data is easily exportable into a range of outputs; Sinsense is a fairly end user friendly business intelligence solution

  - <u>Negative Differentiators</u>: Not all data in CTMS is pre-configured to interface with their Sinsense business intelligence tool – notably absent is audit trail information; modifications of existing pre-built reports is not end-user friendly

PHARMAINITIATIVES

CTMS Key Competitors – Differentiators
DataTrak (continued)

- Integration Capability – **Weakness**

  – <u>Overview</u>: DataTrak CTMS is pre-configured to integrate with DataTrak Cloud EDC and has a published Open API and does not actively develop integrations for customers

  – <u>Positive Differentiators</u>: Supportive of third-party developed integrations with their API

  – <u>Negative Differentiators</u>: 100% reliant on third-party developed integrations with their API – they cannot address if and how many times their product has been interfaced with EDC and eTMF vendors

PHARMAINITIATIVES

CTMS Key Competitors – Differentiators
Medidata

Medidata's CTMS solution currently struggles to compare favorably to the marketplace given its dated interface and limited flexibility. It's primary strength is its tight integration with the Rave Clinical Cloud.

- Regulatory / Document Tracking – **Neutral**

  - <u>Positive Differentiators</u>: Broad range of documents trackable; capable to tracking a link directly to the document in eTMF; templates of standard documents can be built and applied to multiple studies/sites; tracking of a wide range of dates (e.g. sent, received, due, expiry, last contact) per document; associated external contact with a document; version tracking; all tracking at the study; region and site level

  - <u>Negative Differentiators</u>: Documents cannot be linked directly to tasks; no ability to directly enter a document into an eTMF; no document work flow

- Study Trip Report Development and Tracking – **Strength**

  - <u>Positive Differentiators</u>: User-administered trip report and related letters template driven outputs; support for comments throughout templated questions; one step review and approval process; workflow contained entirely within the CTMS for traceability; metrics and alerts; support role delegation; support of visit related tasks not visible on trip reports; trip reports linkable with eTMF

  - <u>Negative Differentiators</u>: No offline report support; no linking of trip reporting with milestones/payments; no workflow notifications; no creation of new versions of previously approved trip reports

PHARMAINITIATIVES

CTMS Key Competitors – Differentiators
Medidata (continued)

- Study Action Item Tracking – **Neutral**

  - <u>Positive Differentiators</u>: Tracking action items including created date, due date, last updated date, owner, status, completed date, antecedent task; audit trail of all tasks; tasks differentiated between follow up items for sites vs. internal tasks; tasks associate-able with documents and trip reports; pre-built templates of tasks can be applied at the study, region and site level; templated tasks can be modified once applied

  - <u>Negative Differentiators</u>: Cannot track external owner for each task; no alert capability associated with tasks; no metrics reports based on task dates; cannot generate lists of overdue or soon to be overdue tasks by owner; cannot reassignment of multiple tasks with one action

- Study Budget and Forecasting – **Neutral**

  - <u>Positive Differentiators</u>: Manage per subject and/or per unit budgets by study and portfolio of studies; auto-populate actual information from payments module; track site payment caps; allow manual entry of actual expenses outside of payments; track actual payments against caps; support budget reconciliation; support multiple budget versions with creation, start and end dates; provide graphical output of progress against budget

  - <u>Negative Differentiators</u>: Cannot track percentage of FTE assigned to a site over a time period; cannot project FTE utilization across all studies; cannot forecast expected future costs based on budget

PHARMAINITIATIVES

CTMS Key Competitors – Differentiators
Medidata (continued)

- Site Contract and Payment Management Information – **Strength**

  - <u>Positive Differentiators</u>: Track site contracting information; track contractual versions and associated dates; associated multiple contracts with a single site; associate payment amounts with subject site visits by study; associate payment amounts based on achieving milestones; support payments based on subject status; support pre-payments/drawdown payments; ability to vary the payment amounts by site within a study; compute payment owed based on subject information (from EDC); support user review and modification of auto-generated payment amounts; support payment approval workflow within the system; support amount tracking in different currencies; generate a single payment amount for a payee out of a group of sub-payments and maintain detail of all sub-payments; supports currency conversions; allows split a payment between multiple payees

  - <u>Negative Differentiators</u>: Cannot support ratio-based payments (e.g. pay for 2 of every 3 screen failures); cannot report on contractual cycle times (e.g. average time from first draft to signed)

PHARMA**INITIATIVES**

CTMS Key Competitors – Differentiators
Medidata (continued)

- Reporting Capability – **Strength**

  – Overview: Medidata has pre-built, standard reports and dashboards as well as business intelligence capabilities like configurable dashboards and ad hoc report built directly into the CTMS system

  – Positive Differentiators: Number of pre-built reports are available within the CTMS tool; ad hoc reports and dashboards allow "drill down" into detailed data; data is easily exportable into a range of outputs

  – Negative Differentiators: Medidata users that use both CTMS and Payments need to go to separate modules to report out – data is not shared in reporting between those modules; ad hoc report writing and dashboard customization is not end user friendly

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Medidata (continued)

- Integration Capability – **Weakness**

  – <u>Overview</u>: Medidata's CTMS is pre-configured to interface with Medidata RAVE EDC.

  – <u>Positive Differentiators</u>: Medidata has developed integrations with most of the top and second tier EDC and eTMF vendors

  – <u>Negative Differentiators</u>: No API available; not very supportive of third-party developed integrations; cost and reputation (see Implementation Services section)

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CTMS Key Competitors – Differentiators
Oracle

Oracle's Seibel solution, with its large and diverse install base, support of some of the largest biopharma and CROs, and integration with one of the leading EDC systems is a giant of the CTMS market.

- Regulatory / Document Tracking – **Neutral**

  - <u>Positive Differentiators</u>: Broad range of documents trackable; capable to tracking a link directly to the document in eTMF; documents can be linked directly to tasks; templates of standard documents can be built and applied to multiple studies/sites; tracking of a wide range of dates (eg. sent, received, due, expiry, last contact) per document; associated external contact with a document; version tracking; all tracking at the study; region and site level

  - <u>Negative Differentiators</u>: No pre-built integration with an eTMF; no ability to directly enter a document into an eTMF

- Study Trip Report Development and Tracking – **Strength**

  - <u>Positive Differentiators</u>: User-administered trip report and related letters template driven outputs; support for comments throughout templated questions; two step review and approval process; creation of new versions of previously approved trip reports; workflow contained entirely within the CTMS for traceability; metrics and alerts; support role delegation; support of visit related tasks not visible on trip reports; trip reports linkable with eTMF; some off-line report development support

  - <u>Negative Differentiators</u>: No linking of trip reporting with milestones/payments

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CTMS Key Competitors – Differentiators
Oracle (continued)

- Study Action Item Tracking – **Strength**

  - <u>Positive Differentiators</u>: Tracking action items including created date, due date, last updated date, owner, external owner, status, completed date, antecedent task; audit trail of all tasks; tasks differentiated between follow up items for sites vs. internal tasks; tasks associate-able with documents and trip reports; reassignment of multiple tasks with one action; pre-built templates of tasks can be applied at the study, region and site level; templated tasks can be modified once applied; generate lists of overdue or soon to be overdue tasks by owner

  - <u>Negative Differentiators</u>: No alert capability associated with tasks; metrics reports based on task dates

- Study Budget and Forecasting – **Neutral**

  - <u>Positive Differentiators</u>: Manage per subject and/or per unit budgets by study and portfolio of studies; auto-populate actual information from payments module; track site payment caps; support budget reconciliation; support multiple budget versions with creation, start and end dates

  - <u>Negative Differentiators</u>: Cannot track percentage of FTE assigned to a site over a time period; cannot project FTE utilization across all studies; cannot forecast expected future costs based on budget; cannot allow manual entry of actual expenses outside of payments; cannot track actual payments against caps; cannot provide graphical output of progress against budget

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Oracle (continued)

- Site Contract and Payment Management Information – **Neutral**

  - <u>Positive Differentiators</u>: Track site contracting information; track contractual versions and associated dates; associated multiple contracts with a single site; associate payment amounts with subject site visits by study; associate payment amounts based on achieving milestones; ability to vary the payment amounts by site within a study; compute payment owed based on subject information (from EDC); support user review and modification of auto-generated payment amounts; support payment approval workflow within the system; support amount tracking in different currencies; split a payment between multiple payees

  - <u>Negative Differentiators</u>: Cannot support pre-payments/drawdown payments; cannot support ratio-based payments (e.g. pay for 2 of every 3 screen failures); cannot support payments based on subject status; cannot generate a single payment amount for a payee out of a group of sub-payments and maintain detail of all sub-payments; cannot do currency conversions; cannot report on contractual cycle times (e.g. average time from first draft to signed)

PHARMAINITIATIVES

Oracle (continued)

- Reporting Capability – **Neutral**

  - <u>Overview</u>: Basic pre-built reports are available within the CTMS; additionally, a business intelligence system sold by Oracle has a pre-configured interface with the CTMS is available for more complex and ad hoc reports (which is sold separately)

  - <u>Positive Differentiators</u>: Number of pre-built reports within CTMS; a number of pre-built reports and dashboards are available within the business intelligence tool; ad hoc reports and dashboards allow "drill down" into detailed data (from business intelligence tool); data is easily exportable into a range of outputs

  - <u>Negative Differentiators</u>: Not all data in CTMS is pre-configured to interface with their business intelligence tool – notably absent is audit trail information; business intelligence ad hoc tool is not end user friendly (requiring some visibility in SQL); modifying pre-built reports is not end user friendly (requiring access to specialized tool and knowledge)

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CTMS Key Competitors – Differentiators
Oracle (continued)

- Integration Capability – **Strength**

  - <u>Overview</u>: Oracle Siebel CTMS is pre-configured to interface with Oracle InForm EDC and Oracle Clinical Data Analytics business intelligence platform; Oracle leverages the Siebel Enterprise Application to support integrations and has a web services API, supports SFTP, has a range of outbound dataflow support

  - <u>Positive Differentiators</u>: Oracle has a such a large install base that they have experience integrating their CTMS with just about all first and second tier EDCs and eTMF solutions

  - <u>Negative Differentiators</u>: Only reluctantly willing to support third-party integrations with their API, cost and reputation (see Implementation Services section)

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CTMS Key Competitors – Differentiators
Veeva

Veeva's strong position in the eTMF market allowed it to capitalize on its install base to support a full clinical suite, including a CTMS. At this point, Veeva's CTMS solution has matured into one of the most solid solutions in the marketplace – however it is constrained by the tight integration to eTMF.

- Regulatory / Document Tracking – **Strength**
  - Positive Differentiators: Broad range of documents trackable; capable to tracking a link directly to the document in eTMF; documents can be linked directly to tasks; templates of standard documents can be built and applied to multiple studies/sites; tracking of a wide range of dates (e.g. sent, received, due, expiry, last contact) per document; associated external contact with a document; version tracking; all tracking at the study; region and site level; pre-built integration with Veeva eTMF; ability to enter documents directly into Veeva eTMF
  - Negative Differentiators:
- Study Trip Report Development and Tracking – **Strength**
  - Positive Differentiators: User-administered trip report and related letters template driven outputs; support for comments throughout templated questions; two step review and approval process; creation of new versions of previously approved trip reports; workflow contained entirely within the CTMS for traceability; metrics and alerts; support role delegation; support of visit related tasks not visible on trip reports; trip reports linkable with eTMF
  - Negative Differentiators: No off-line report support; no linking of trip reporting with milestones/payments

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CTMS Key Competitors – Differentiators
Veeva (continued)

- Study Action Item Tracking – **Strength**

  - <u>Positive Differentiators</u>: Tracking action items including created date, due date, last updated date, owner, external owner, status, completed date, antecedent task; audit trail of all tasks; tasks differentiated between follow up items for sites vs. internal tasks; tasks associate-able with documents and trip reports; reassignment of multiple tasks with one action; pre-built templates of tasks can be applied at the study, region and site level; templated tasks can be modified once applied; generate lists of overdue or soon to be overdue tasks by owner

  - <u>Negative Differentiators</u>: No alert capability associated with tasks; metrics reports based on task dates; templated tasks can be modified once applied; generate lists of overdue or soon to be overdue tasks by owner

- Study Budget and Forecasting – **Weakness**

  - <u>Positive Differentiators</u>: *No Budgeting Capability in Current Release*

  - <u>Negative Differentiators</u>: Cannot manage per subject and/or per unit budgets by study and portfolio of studies; cannot auto-populate actual information from payments module; cannot track site payment caps; cannot allow manual entry of actual expenses outside of payments; cannot track actual payments against caps; cannot support budget reconciliation; cannot support multiple budget versions with creation, start and end dates; cannot track percentage of FTE assigned to a site over a time period; no projecting FTE utilization across all studies; cannot forecast expected future costs based on budget; cannot provide graphical output of progress against budget

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- Site Contract and Payment Management Information – **Neutral**

  - <u>Positive Differentiators</u>: Track site contracting information; track contractual versions and associated dates; associated multiple contracts with a single site; associate payment amounts with subject site visits by study; associate payment amounts based on achieving milestones; ability to vary the payment amounts by site within a study; compute payment owed based on subject information (from EDC); support user review and modification of auto-generated payment amounts; support payment approval workflow within the system; support amount tracking in different currencies; split a payment between multiple payees

  - <u>Negative Differentiators</u>: Cannot support pre-payments/drawdown payments; cannot support ratio-based payments (e.g. pay for 2 of every 3 screen failures); cannot support payments based on subject status; cannot generate a single payment amount for a payee out of a group of sub-payments and maintain detail of all sub-payments; cannot do currency conversions; cannot report on contractual cycle times (e.g. average time from first draft to signed)

Veeva has recently introduced this capability and has stated that it is intending to add additional capability to its solution.

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- Reporting Capability – **Strength**

  - <u>Overview</u>: Veeva has pre-built, standard reports and dashboards as well as business intelligence capabilities like configurable dashboards and ad hoc report built directly into the CTMS system

  - <u>Positive Differentiators</u>: All data in CTMS is available to be used for reporting; number of pre-built reports are available within the CTMS tool; ad hoc reports and dashboards allow "drill down" into detailed data; data is easily exportable into a range of outputs; ad hoc report writing and dashboard customization is fairly end user friendly

  - <u>Negative Differentiators</u>: NA

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CTMS Key Competitors – Differentiators
Veeva (continued)

- Integration Capability – **Neutral** (**Strength** if you use Veeva eTMF)

  – <u>Overview</u>: Veeva's CTMS is deeply integrated with Veeva's eTMF, so much so that it is not reasonable to consider whether they can interface with a separate eTMF. Veeva is pre-configured to interface with Veeva EDC. Veeva has a REST-based API for interface with other systems, especially EDC.

  – <u>Positive Differentiators</u>: Veeva has integrated with the top-tier EDC vendors; very supportive of third-party integrations

  – <u>Negative Differentiators</u>: Focused resources on CTMS integration appear to be limited; reputation (see Implementation Services section)

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CTMS Key Competitors – Differentiators
Implementation Support

CTMS requires significant implementation support, especially for customers that are not replacing an existing CTMS. Implementation support is a significant differentiator between different vendors. For competitors that offer implementation support, they tend to offer similar services:

Implementation Services

- Training on **Configuration** (e.g. changes to drop down lists, templates) tool/capabilities to be administered by the customer

- Supporting customer analysis of how to use the CTMS capability and Configuration capabilities in their environment (e.g. work arounds, alternate approaches, etc.)

- Identification and implementation of **Tailoring** (i.e. vendor-only configuration changes that are supported in future upgrades), especially adding fields and changing standard reports

- Identification and implementation of **Customization** (i.e. bespoke development maintained by the customer and not supported by future upgrades), especially integrations End-user, super-user and technical owner training

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CTMS Key Competitors – Differentiators
Implementation Support – Comparison

|	Bioclinica - **Weakness**	DataTrak - **Strength**	Medidata - **Weakness**	Oracle - **Neutral**	Veeva - **Strength**
Configuration	Configuration needed in both CTMS and SharePoint – templates can **never** be managed by customer	All configuration and tailoring is supported by the same set of user-friendly tools, making this process entirely customer self-service	Complex and difficult configuration processes make Medidata involvement critical	Considerable Configuration required, configuration tools have significant learning curve, especially the standard output configuration tool	Configuration tools seen as robust and fairly user friendly, and very complete with all screens modifiable and direct tie to outputs
Tailoring	Relies on SharePoint for all Tailoring, which can lead to confusion as data is in both systems		Tailoring is challenging and expensive	Very common to require tailoring, Oracle executes (becoming user serviceable in new version)	
Customization	Support for primarily integrations considered strong if right people involved	Do not offer customization services except to train on API	Extensive technical resources to support customizations of all types	Extensive resources and experience developing customization, usually integrations	Capabilities and experience developing integrations with EDC, little core system customization
Training	Good training materials, solid trainers	Basic but clear training materials	Basic, not well developed	Very limited, generally considered inadequate for the complexity of the system	Adequate and well developed

CTMS Key Competitors – Differentiators
CRO Reputation and Cost – Comparison

	Bioclinica – Strength	DataTrak - Strength	Medidata - Weakness	Oracle - Neutral	Veeva - Weakeness
Overall Reputation with Pharma Initiatives	Solid reputation for implementation support but limited knowledgeable staff	Disruptor in market with self-service tools	Challenging to work with, lacking in customer service orientation	Corporate responsiveness seen as slow, individual performers seen positively, need to fight for right people	Arrogant but knowledgeable, difficult to get their attention at times
Cost Stand Alone – CTMS Only*	Lower Middle	Lowest	High	Middle	Highest
Cost – Part of Package of Software*	Lower Middle	Lowest	Low	Middle	Highest

* Costs vary significantly year-to-year given current business climate, competitive situation and range of solutions purchased. Your experience may be significantly different.

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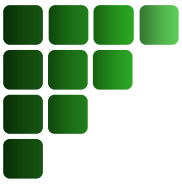
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