CASE STUDY

Return on Investment (ROI) Analysis of Bioclinica CTMS

The following clinical trial management activities are provided as universal examples of the many significant time-saving operations performed by Bioclinica Clinical Trial Management System (CTMS). This Office-Smart solution has been designed to do the labor-intensive work for users by automatically performing common and/or repetitive tasks based on preselected configuration settings. This adaptable logic frees up knowledge workers to focus on quickly resolving those exception issues that inevitably occur during the conduct of clinical trials, which in turn translates into completing studies in less time and at lower cost.

For companies looking to reduce operating expenses and streamline trial management activities, an investment in the right CTMS has numerous financial benefits. Just because your company is growing, the number and complexity of studies is increasing and the total number of clinical sites and enrolled subjects is leaping exponentially, the total number of employees does not have to balloon as well.

The scenarios provided below demonstrate the typical time and cost savings recouped when Bioclinica clinical solutions are applied to an average clinical study designed to enroll 300 subjects from 25 participating clinical sites spanning 40 payees over a period of approximately 18 months.

TIME AND COST SAVING RESULTS USING BIOCLINICA CTMS BASED ON AN AVERAGE CLINICAL STUDY DESIGNED TO ENROLL:

300 SUBJECTS

25 SITES

40 PAYEES

18 MONTHS

Example scenarios

1. **Automated creation and management of site regulatory document records**
2. **Automated calculation and administration of individual subject treatment schedules**
3. **Automated generation and processing of investigative grants based on completion of corresponding subject activity**

1 Automated creation and management of site regulatory document records

Regulations require that in every clinical trial, the sponsor and/or their CRO(s) must collect, verify and track a predefined set of regulatory documents for each of the participating clinical sites. This is a much more complex process than simply filling out and submitting a packet of forms; institutional review boards (IRBs) must review and approve many of the documents, there are often numerous possible workflow paths depending on specific document types, most of the documents are time-sensitive and site personnel need to be trained in their review and management. Based on this information, a clinical study can generate the need to track several linear feet of accumulated paperwork. Compound these time-intensive activities by the number of sites needing to be identified, evaluated and opened for enrollment, and it becomes clear why an automated system targeted at handling this exact scenario is so valuable for reducing costs and completing studies on or ahead of schedule.

Typical activities when managing site regulatory document records	Average time per clinical site without CTMS*	Average time per clinical site with Bioclinica CTMS	High-level description of how Bioclinica CTMS is designed to save time and reduce costs	Average time savings for a typical study with 25 total clinical sites
Determine the correct subset of document records needed for a clinical site	.5 hour	Automatic	The specific documents needing to be collected from each type of clinical site can be configured	12.5 hours
Generate and accurately categorize the document records needed to track a clinical site's regulatory files	3 hours	Automatic	Document records automatically created as placeholders when the site becomes qualified for participation in the study	75 hours
Input applicable tracking dates and maintain site-specific document versions	4 hours	2 hours	Document metadata can be easily updated directly or via data source integration links	50 hours
Notify designated approvers when document files and/or workflow procedures are ready for review and sign-off	1 hours	Automatic	Alerts and/or email notifications can be generated automatically based on predefined triggers and workflow tracking statuses	25 hours
Track upcoming dates of expiring document files	3 hours	.5 hours	The system tracks this for users and notifies them appropriately	62.5 hours
Perform a pre-monitoring document review prior to each scheduled site visit	1.5 hours	.5 hours	To simplify reconciliation, the physical storage location(s) of document files can be tracked	25 hours
Generate and distribute periodic document status and/or missing file reports	1 hour	Automatic	Ad-hoc reports can be built and scheduled to auto-distribute, and real-time dashboards setup	72 hours (assumes weekly reports for 18 months)
Totals:	**14 hours**	**3 hours**		**Over 40 person-days**

* These time estimates represent the total amount of effort taken to complete specific regulatory document management activities over the course of a typical 18-month study on a per-site basis. They will vary for each organization depending on their unique situation.

2 Automated calculation and administration of individual subject treatment schedules

One of the most labor-intensive activities required during the management of clinical trials is calculating individual subject treatment schedules based on the protocol parameters and the study component into which each subject is placed or randomized. In addition to generating these forecasts, manually maintaining them for the duration of the study can often increase the number of needed employees, especially when considering the need to keep the 'actual dates' accurate over time.

Beyond these laborious scheduling tasks, there are also many special considerations that must be accounted for, such as the identification of protocol deviations due to 'out of window' visits as dictated by the protocol, the downstream shifting of target dates when a visit is rescheduled (or not, depending on the situation) and maintaining each subject's current status based on the successful completion of study visits and other trial milestones.

Typical activities when managing subject treatment schedules (planned & actual)	Average time per subject without CTMS*	Average time per subject with Bioclinica CTMS	High-level description of how Bioclinica CTMS is designed to save time and reduce costs	Average time savings for a typical study with 300 total subjects
Calculate a subject's target treatment schedule based on correct study component	.5 hour	Automatic	The system uses each subject's baseline date to automatically generate the target schedule	150 hours
Maintain a subject's actual visit dates including updates to all corresponding records	3 hours	1 hour	Treatment visits can be easily updated directly or via data source integration links	600 hours
Create necessary protocol deviations if out-of-window	2 hours	1 hour	Users are automatically notified when these situations occur	300 hours
Reschedule treatment visits for 15% of subjects due to dosing delays or holidays	1 hour	Automatic	Users select whether the system should shift downstream subject visits for mid-schedule changes	45 hours
Update each subject's status based on the completion of individual treatment visits	1 hour	Automatic	The appropriate subject status for each stage of the treatment can be defined in study setup	300 hours
Track CRF page collection status on a per visit basis	2.5 hours	Automatic	Case report form (CRF) status can be updated via data source integration links	750 hours
Generate and distribute periodic subject enrollment and treatment reports	1 hour	Automatic	Ad-hoc reports can be built and scheduled to auto-distribute, and real-time dashboards setup	72 hours (assumes weekly reports for 18 months)
Totals:	**11 hours**	**2 hours**		**Over 277 person-days**

* These time estimates represent the total amount of effort taken to complete specific subject treatment scheduling activities over the course of a typical 18-month study on a per-subject basis. They will vary for each organization depending on their unique situation.

3 Automated generation and processing of investigative grants based on completion of corresponding subject activity

One of the most critical and time-consuming processes in clinical trials is coordinating payments to clinical sites or vendors. It is difficult to forecast expenditures based on the terms negotiated with each investigative site and to calculate the accrued totals for a given payment period based on the completed subject activity (if this information is available). And, processing invoices through the correct review, approval and payment workflow series is complicated and error-prone, leading to further delays.

This process is further complicated for international studies, due to currency conversion. On-time, correct payments and satisfied investigators are possible with automatic acknowledgement of completed subject activity into corresponding invoice line items and a streamlined invoice processing system.

Typical activities when generating and processing investigative grants	Average time per payee without CTMS*	Average time per payee with Bioclinica CTMS	High-level description of how Bioclinica CTMS is designed to save time and reduce costs	Average time savings for 40 total payees (25 being clinical sites)
Management of multiple contract versions linked to applicable system records	2 hours	.5 hour	Users define which records are linked with each new contract version and system then tracks	60 hours
Conversion of completed subject activity into correct individual invoice line-items	9 hours	Automatic	Completed subject activity can be based on treatment visits, CRF page status, screen fails, etc.	225 hours
Calculation of invoice line-item amounts based on site-specific budget settings	8 hours	Automatic	System automatically calculates proper site overhead, payment holdback, site prepayment, etc	200 hours (applies to sites only)
Track payee milestones and their subsequent repayment	4 hours	1 hour	Customized payee milestones can be defined and managed	120 hours (applies to sites only)
Currency conversions based on applicable exchange rates	.5 hour	Automatic	System handles international studies for applicable currencies	10 hours (applies to ½ payees)
Tracking of accrued totals based on completed but (as yet) unpaid subject activity	8 hours	Automatic	Real-time accrued totals are always available at the study, site and/or subject levels	200 hours (applies to sites only)
Processing invoices through the review, approval, and paid workflow procedures	5 hours	1 hour	Each workflow step is an individual permission control and alerts are auto-generated	160 hours
Creation of check requests according to invoice status	4.5 hours	Automatic	Finance folks are notified when an invoice is ready to be paid	180 hours (applies to all payees)
Generate and distribute periodic payee, invoice and/or payment reports	1 hour	Automatic	Ad-hoc reports can be built and scheduled to auto-distribute, and real-time dashboards can be setup	72 hours (assumes weekly reports for 18 months)
Totals:	**42 hours**	**2.5 hours**		**Over 153 person-days**

* These time estimates represent the total amount of effort taken to complete specific contract management and invoice processing activities over the course of a typical 18-month study on a per-payee basis. They will vary for each organization depending on their unique situation.

The total time saved by using these automated features of Bioclinica CTMS accumulates into over 470 person-days for a typical study of 25 clinical sites, 300 subjects and 40 total payees.

Using an average annual salary of $65,000 and not including the loaded cost of employees, this can equate to a total expenditure reduction of over $117,500.00 for just a single 18-month study!

For any sponsor, CRO or site network involved in more than one clinical trial, the Bioclinica solutions deliver a considerable return on investment in a very short period of time.

TIME SAVED:

470
PERSON-DAYS

COST SAVINGS:

$117,500

For additional information regarding Bioclinica CTMS, visit us at bioclinica.com.