

Technology aligned™

ClinPhone **RTSM**

**Imaging**

**CTMS**

**EDC**

**ePRO**

**Solutions**

**IMPACT® TrialWorks™ Initiator™**

# Proven CTMS Solutions

for Companies of All Sizes





Are you managing the  
most important part of  
your business with

# paper or spreadsheets?

Clinical trials are the most expensive and lengthiest components of the investigational product development process. For both sponsors and CROs, planning and managing clinical trials is a complex task involving the coordination of multiple departments that span the entire enterprise.

Left on their own, individual stakeholder groups, such as clinical project management, clinical operations, regulatory affairs, finance and senior management, will create their own repositories for trial management information. Each group will develop isolated processes focused solely on their individual parts of the clinical

trial process. This results in trial information becoming scattered across the organization, frequently duplicated and out-of-date. It becomes difficult and time consuming to get a complete and accurate picture of the trial status and progress, making proactive management impossible. Cross-departmental processes lack coordination and information sharing, making them inefficient, slow and vulnerable to regulatory compliance risks.

These inefficiencies multiply exponentially with each additional trial, limiting the organization's ability to scale and grow.

**“When viewed over the entire value chain, the clinical trial, not discovery, has the greatest potential to adversely impact the cost of drug development.”**

Health Industry Insights: An Overview of the Clinical Trial Management System Market

## There is a Better Way: CTMS

It takes a well-coordinated and informed enterprise to efficiently and safely run clinical trials. An enterprise-wide, full featured clinical trials management system (CTMS) is the solution.

A CTMS will:

- Provide a single centralized repository of all trial-related information needed by the entire enterprise
- Deliver transparency of trial data providing timely and accurate information to all stakeholders
- Facilitate effective cross-departmental processes

- Enforce and facilitate regulatory compliance
- Enable intelligent decision making based on sound measures and metrics

The core value of a CTMS is increased efficiency of clinical trial operations resulting in lower costs, reduced cycle times and higher regulatory compliance.

Integrating a CTMS with other clinical trial systems, such as RTSM (Randomization and Trial Supply Management) solutions and/or EDC (Electronic Data Capture), magnifies these benefits by enabling key data to automatically flow into the CTMS in near real time. This not only provides information to CTMS stakeholders faster, but also improves data quality by eliminating the errors inherent in manual data entry.

The screenshot displays two main sections of a CTMS interface. The top section, 'My Reports', is a table listing various reports with columns for Number, Name, Type, and Source. The bottom section, 'Investigator Invoices', provides a detailed financial overview for a specific investigator (Boken, Tom 81) on study URT456. It includes summary statistics for earnings, payments, and holdbacks, followed by a table of individual invoices with columns for Invoice #, Amount, Currency, USD Amount, Payee, Pay Type, Requested Date, Requestor, Paid?, and Check #. Below the invoice table is a 'Details for Invoice TW-0002' section, which is a table showing the breakdown of the invoice into three subject-related entries with columns for Amount, USD Amount (Study Curr), Type, Description, Dept., Account, Payee Ref #, and Payee Ref Date.

Number	Name	Type	Source
*	Program Overview™	Ad-Hoc	Studies
*	TrialWorks User Manual®	External	C:\projects\General\Release Management\Upgrades\3.2.0.0.0.0 - WEB 2.1.
1	All Cardiologists in USA	Pre-Defined	Address Listings > Investigators > All Investigators A-Z
2	All Unresolved SAEs	Ad-Hoc	Patient SAEs
3	URT456 - Pt/Site Accruals	Pre-Defined	Finance > Investigators > Visit Liability Detail (Delimited)
4	URT456 - Essential Docs	Pre-Defined	Study Documents > Site Essential Document Tracking > Summary Report
5	CRF Transmittal Log	Pre-Defined	Study Patients > CRFs > Pages Log Summary
6	URT456 Combined Projections	Pre-Defined	Study Planning > Study Planning (Delimited) > Combined Study Projections
7	URT - Total Spend by Product	Pre-Defined	Finance > Rollups > Finance Rollup By Product
8	Monitoring Metrics	Ad-Hoc	Monitoring Visits
9	Sponsor A -- Payment Details	Pre-Defined	Finance > Vendor
10	Vendors Needing Pymt	Pre-Defined	Finance > vendor

Investigator Invoices		Investigator: Boken, Tom 81		Study: URT456		Payment Status: Payment Due		Next Pay Due: May-2010	
Subject/Grant Earnings:	32575.00	Subject/Grant Pymts:	11880.00	Total Holdback:	3257.50	Ad-Hoc Payments:	0.00		
Holdback at 10.00%:	3257.50	Balance Due:	17437.50	Holdback Pd:	0.00	Reimbursements:	100.00		
Earnings - Holdback:	29317.50			Holdback Due:	3257.50	Tot Ad-Hoc/Reimb:	100.00		

Invoice #	Amount	Currency	USD Amount (Study Curr)	Payee	Pay Type	Requested Date	Requestor	Paid?	Check #
TW-0002	1980.00	USD	1980.00	Grants Office	Check	3-Nov-2005	Mary Money	<input checked="" type="checkbox"/>	21311
TW-0010	9900.00	USD	9900.00	Grants Office	Check	29-Jul-2009	Mary Money	<input checked="" type="checkbox"/>	26312
TW-0016	100.00	USD	100.00	Grants Office	Check	27-Aug-2009	Fred Finance	<input checked="" type="checkbox"/>	28888

Amount	USD Amount (Study Curr)	Type	Description	Dept.	Account	Payee Ref #	Payee Ref Date
500.00	500.00	Subject	0002-TQV - Baseline Apr 03, 2	0444	33333		
200.00	200.00	Subject	0002-TQV - Screening Apr 03,	0444	33333		
300.00	300.00	Subject	0002-TQV - Week 1 Apr 10, 20	0444	33333		

“When you combine the stakeholder population of CTMS with the duration of the average clinical trial, the potential savings are enormous.”

Health Industry Insights: An Overview of the Clinical Trial Management System Market

## TrialWorks™ : The Proven CTMS

Since 1999, TrialWorks™ CTMS has been enabling biopharmaceutical companies, CROs, medical device manufacturers and academic research organizations to effectively manage the clinical trials process. With one of the largest CTMS installed bases in the industry, TrialWorks has a proven track record of rapidly delivering the value of a CTMS through increased efficiency, reduced cycle times and improved regulatory compliance.

**As a mature and full-featured solution with over a decade of product advancement, TrialWorks provides the full range of enterprise-class CTMS features.**

### Study Planning

- Study timeline and milestone planning
- Study projections including site activation and patient enrollment
- Investigational product forecasting

### Study Start Up

- Investigator selection
- Investigator & site management
- Investigator, institution & site assessments

### Study Conduct

- Monitoring
- Vendor management
- Contact management
- Investigator contracts, budgets and payments
- Mass communications via email and mail merge
- Shipping exports

### Study Management

- Milestone tracking
- Recruitment tracking

- Patients, visits, CRFs, and queries tracking
- Patient exemptions and deviations tracking
- SAEs tracking
- Alerts and notifications
- Action items
- Over 200 standard reports as well as ad-hoc reporting capability

### Regulatory Compliance

- Essential document tracking
- Review board / ethics committee submissions tracking
- Regulatory authority approval tracking
- ClinicalTrials.gov interface for study registration

### Integration

- IVR/IWR integration
- EDC integration

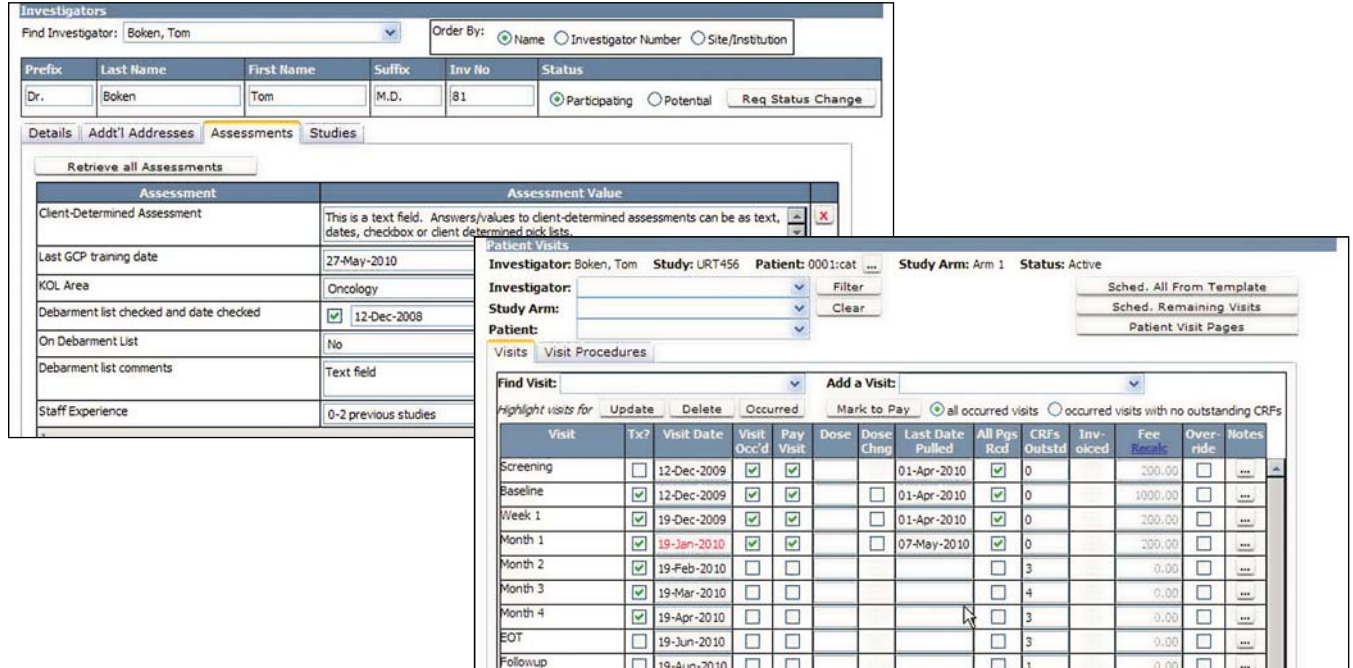
### Monitoring Module – Optional Module

- Site monitoring tool for CRAs and monitors

- Effectively manage downloaded site and visit information offline
- Create site visit reports, follow up letters, CRF transmittal forms
- Upload modified data to TrialWorks
- Track and maintain:
  - Site contacts' information
  - Assessments
  - Regulatory documents
  - Patient details, visits, CRFs, queries, exemptions and deviations, SAEs
  - Action items
  - Checklists

### Universal Data Transfer – Optional Module

- On-demand or scheduled transfers of data from other clinical systems
- Transfer of key data:
  - Patient enrollment
  - Stratification
  - Patient visits
  - CRF page status



## TrialWorks: Outstanding Value Proposition

Unlike many enterprise-class CTMS solutions, with a myriad of separately priced modules that can introduce unexpected costs, TrialWorks provides all the functionality needed to serve CTMS stakeholders across the enterprise. With only two optional modules, the Monitoring Module and the Universal Data Transfer, TrialWorks CTMS represents exceptional value for customers.

TrialWorks is easily implemented as a turnkey yet configurable solution providing the flexibility needed for organizations of all types. It does not require a host of expensive consultants to configure before customers can start using the solution. Known for rapid implementations, the typical customer implementation is measured in weeks, not months or years. This means customer organizations quickly

start seeing ROI from their CTMS investment. Furthermore, the concurrent user pricing model allows clients to name as many users as desired, facilitating a flexible environment for all stakeholders involved.

You can also choose the implementation model that best suits your organization. If you have an established IT infrastructure, you can choose TrialWorks as an on-premise, licensed solution and install it within your operating environment. If you have a less formal IT infrastructure, TrialWorks can be implemented as a hosted, SaaS (software as a service) solution.

The superior value proposition also includes the technology platform. TrialWorks is powered by Microsoft .NET® connection software and SQL Server®, a robust and proven technical framework that is cost effective, requiring minimal IT administration—all of which keeps the total cost of ownership to a minimum.

**“TrialWorks’ extensive feature set, combined with an easy-to-use interface, allows our organization to effectively track study progress and to improve transparency.”**

Kris Bentvelsen, Director, GCO Planning & Analytics, Abraxis Bioscience Canada Inc.

**For more information**

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The logo for Perceptive Informatics. It features the word "perceptive" in a dark blue, lowercase, sans-serif font. A small green square is positioned to the left of the letter "p". Below "perceptive" is the word "INFORMATICS" in a smaller, green, uppercase, sans-serif font. A registered trademark symbol (®) is located at the end of "INFORMATICS".