

IMPACT® CTMS

Investigator — Reducing the Cost and Risk of Clinical Trial Study Start-up

An in-house database of potential investigators unique to the enterprise is an invaluable asset. The problem is maintenance; keeping data up-to-date, including information on such things as past investigator performance.

Properly acquired, rigorously maintained and integrated, an investigator database can deliver real benefits, including rapid study start-up and more effective planning.

The Perceptive Solution

Investigator™ is a highly flexible, web-based, clinical Investigator System.

At its heart is a sophisticated, unified data repository of potential clinical investigators that sits within a decision support environment. The system is designed to enhance the value of investigator performance data. Rather than passive historical reporting, dynamic lists are created for discussion, sharing and refining. They can be used to create mass fax documents or e-mail messages, as well as for assessment visits.

Investigator's data cleaning and import technology make it easy to upload and integrate existing investigator data and study performance metrics making them instantly available across a global organization. All performed under tight security constraints. The data cleaning functions test for standard punctuation, correction of data entry errors, inconsistent naming conventions, spillover text, buried information, duplicate matching, etc.

Once in place, data is stored in a secure Oracle database. Data is accessed by sponsor personnel using personalized profile forms with company-specific metrics and demographic data available as filters. Search and display tools foster corporate-wide collaboration.

The Investigator system supports direct integration and data transfer with commercial and custom clinical data management systems. This means that comprehensive evaluative metrics can be used without any re-entering of data.

Investigator is simple to install, and typically takes only a few weeks to get up and running.

Features

- Secure login because the system and the data are protected behind the sponsor's firewall.
- Extensive search functions that create shared lists, watch lists, clip lists, etc.
- Investigator lists can be sorted and viewed by a variety of parameters such as: certificates, studies, assessments, historical performance, patient populations.
- Integration with MS Excel, e-mail and group fax.
- Investigators can be flagged with 'easy to distinguish' assessments.
- Search and display parameters can be customized to your needs.
- Sophisticated cleaning, matching and merging routines ensure that when your worldwide personnel search for a record, they retrieve one and only one investigator or research organization.
- Unique data structure for relating investigators with their competencies.
- Can be incorporated as a module in Perceptive's IMPACT® solution.
- Modules and metrics can be built to each client's and each user's specification.

IMPACT® CTMS

Benefits

- Have confidence that you are using the right investigators in your study.
 - Conduct more efficient trials by:
 - Avoiding historically poor performing sites.
 - Eliminating trial placement at sites with competing projects.
 - Including investigators in your trial who have optimal profiles.
 - Creating lists that you can manipulate and use to help set up your sites.
- Build your investigator database with minimal resources:
 - Sites enter their own information using secure unique profiles, directly on the Internet.
 - Standard assessment profiles driven by your requirements.
 - A central company-wide repository of clean and proprietary investigator and site data.
- Improve relationships with your investigators through better information:
 - All authorized users access the same information.
 - Information is standardized across the global enterprise.
 - Pool the observations of staff members who do not know each other or who are not working at the company at the same time.
- Integrate with other applications (e.g., CTMS, IVRS, Quality Assurance) to help improve data consistency and workflow processes.
- Recruit patients faster.

Perceptive at a Glance

Perceptive Informatics brings together exceptional clinical knowledge, experience and leading-edge technology. As the industry's leading eClinical solutions provider, we combine these qualities into a portfolio of business support applications and complementary services that optimize the process of product development and commercialization. Our customers are forward-thinking pharmaceutical, biotechnology and medical device companies, CROs and associated service providers.

Our versatile, comprehensive eClinical suite is built upon six areas, each of which makes extensive use of innovative technology:

**ClinPhone RTSM ▪ Imaging ▪ CTMS
EDC ▪ ePRO ▪ Solutions**

Each element of our eClinical suite is designed to deliver practical and tangible results—decreasing the time, cost and risk associated with the development and launching of new products.

It is reassuring to know that our professionals have a combined clinical and technology background. This means that our products and services accommodate the needs of the regulated world (such as computer system validation and 21 CFR Part 11).

Our tried and tested solutions are used by many of the world's leading pharmaceutical companies.

To learn more about how our solutions can help you, please contact us at info@perceptive.com.