



Clinical Trial Framework – CTF Integrated Trial management

**Fast database lock shortens time to
publication and market**

Medical Science Online
MedSciNet™
Internet Database Solutions

Since introduction of its Web-based EDC solution, Medscinet has successfully helped to collect over 3 000 000 records on over 400 000 patients world-wide.

In the years since introducing its Web-based electronic data capture (EDC) solution, Medscinet has successfully helped many research organisations, groups and universities achieve the benefits of EDC. Research groups and life science companies are under increasing pressure to lower development costs and bring more drugs to market. Academic research organisations are being forced to deliver research results and publications in a shorter time with the limited resources and funding. This, in addition to recent drug safety concerns, substantial increases in data volume, and rising cost pressures, present these organizations with some very significant challenges. Clinical studies and randomised trials account for the bulk of the activities of the organisations. However, fine-tuning existing, paper-based trial processes to lower costs has reached its limits. Changing to electronic data capture (EDC) based studies and trials can help organisations achieve significant cost savings, as well as time, efficiency, and quality gains.

Moving to EDC

If you decide to make transition to EDC, you need to look into Medscinet solutions. Medscinet can provide you with all necessary experience and tools for single-site Phase I trials to global multi-site Phase IV trials.

Design

Every trial and study starts from design. Medscinet Specification Tool will dramatically shorten the time required to create electronic case report forms (CRFs) and trial workflow. Predefined validation rules, custom rules and extensive repository of standard components will help you in creation of your own unique trial structure. Specification Tool instant preview function will give you the possibility to test forms while you create them. Advanced trial workflow engine will guide you through the process of total trial structure creation. You even may generate your trial on your local system and start testing immediately. Training for Specification Tool is provided through instructor-led training.

Data Collection and Monitoring

Medscinet has performed research on the usability of the internet interfaces for the best performance and user satisfaction. CTF was built based on the best practices from this research. Thus, users will benefit from the clear and simple user interface. Medscinet web-based solutions are known for the best user satisfaction. Even help, definitions, SOPs and all other documentation is just one-click away. Unique design of the Adverse Event forms leads to very simple and fast registration of these events and instant submission to regulatory organizations, trial managers and administrators.

1-Patient inclusion data

Patient sex: 1 - Female ?

Diagnosis: Other

Stage: Not applicable

Conditioning: Mb Kostman
Elektivt reducerad konditionering med Fludara +

Date sample taken: 2004-09-29 (yyyy-mm-dd)

Sample not taken:

Save Cancel Queries

[Created 2004-11-22 15:07:08 by mlar | Updated 2005-06-21 11:49:42 by princ]

Audit trail

Electronic CRF with queries and audit trail

Medscinet has developed very simple yet extremely powerful engine for monitoring and query generation. With just a few clicks investigators, monitors and auditors have access to all aspects of the queries in the trial.

1. Missing forms and forms saved as draft

PatID	Donor	Patient	TX	Vacc	Tests	Control	Tests	Infl	Details	Lab	End	Centre	
3	OK	OK	OK	OK	OK	OK	OK	OK	OK	Draft	Draft	OK	KUS-H
5	Empty	Empty	Empty	Empty	Empty	Empty	Empty	Draft	OK	Draft	Empty	Empty	KUS-H
6	Empty	Empty	Empty	Empty	Empty	Empty	Empty	Empty	Empty	Empty	Empty	Empty	KUS-H
8	Draft	Empty	Empty	Empty	Empty	Empty	Empty	Empty	Empty	Empty	Empty	Empty	KUS-H

Total number of records: 4

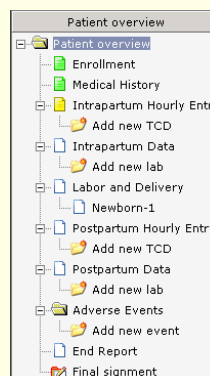
Go to page: 1

Rows in page: 20 Update

Alert system form draft saved and missing forms

Alert system

Comprehensive alerting system eliminates need for tedious job of finding out incomplete data sets and missing forms. Alerts provide efficient way for global monitoring by trial administrators and gives immediate view of the trial performance site by site.



Trial workflow

Data export

Medscinet solutions enable trial data managers (DM) to retrieve data directly from the web interface in a variety of formats including SAS, Excel and delimited ASCII files.

CTF Features

- Scalable Internet-based architecture, supporting high volume, global clinical trials
- Intuitive, workflow-based Graphical User Interface
- Fully integrated real-time trial reporting
- Extensive library of configurable standard reports and ad hoc reporting
- Extensive monitoring and query processing features
- Integration with Medscinet Clinical Trial Framework CTF data management system
- Available as ASP hosted solution for rapid deployment or enterprise adoption option for in-house operation
- Global support

Client Software:

Microsoft Internet Explorer 6.0
Adobe Acrobat Reader

Server Operating System:

Microsoft® Windows 2003
Server Standard or Enterprise
Edition

Database System:

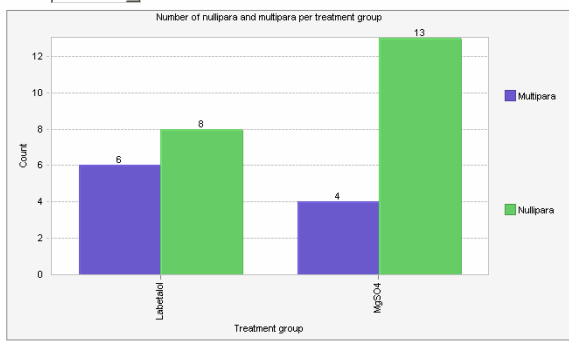
Microsoft® SQL Server 2000
Standard or Enterprise Edition

4. Number of nullipara and multipara per treatment group

Total of randomized patients n=31

[Table view] Type: Count Percent (%)

Center: All centres



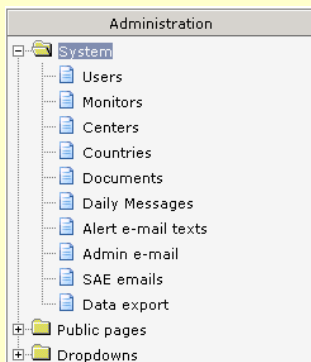
Electronic CRF is designed for best investigator, monitor and auditor performance. All necessary functions are available within the reach of the one-click. No unnecessary time waiting for performing data entry, change history, audit or monitoring functions.

3. List of all queries - Query history view.

QID	PID	Form	Data field	Opened	Due	Query text	Status	Monitor	User
34	36	REG	Gravidity	9/10/2005	9/20/2005	Are you sure this patient is first time pregnant?	Opened	monitor	user
33	11	MED	S.A. at inclusion	8/29/2005	9/6/2005	Is it 255555	Closed	monitor	user
31	3	LAB2	Hemoglobin (%)	8/12/2005	8/22/2005	HTC is to low, why?	Closed	monitor	princ
30	6	INTRADAT	Medication side effects	8/12/2005	8/22/2005	Are you sure there was no side effects?	Answered	monitor	user

Total number of records: 4

Medscinet CTF provides up to the millisecond accurate overview of the global trials. Comprehensive filter and search functions will help you to feel the pulse of the trial wherever you are.



Complete trial administration through the web based interface.

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With the powerful integrated reporting capabilities investigators, monitors and sponsors may follow the trial performance from the global perspective.

Because we know regulatory compliance and security are of paramount importance to you, Medscinet implementation solutions are designed, developed, and delivered according to ISO 9001:2000 Software Development Life Cycle (SDLC) practices and Medscinet Services Standard Operating Procedures (SOPs).

Implementation services include:

- Definition
- Project planning
- Installation planning
- Configuration planning
- Validation planning
- Systems infrastructure planning
- Application architecture planning

Deployment

- Training
- Study mentoring and support
- Data and process integration
- Design and Development
- Installation
- Configuration
- Validation
- Design and development of a standard forms and rules library, to maximize reuse and lower time and cost of study set-up

Maintenance and Support

- Global support
- Upgrade and data migration

3-Patient Status at vaccination

Date patient sample taken: 2005-09-04 (yyyy-mm-dd)
 Sample not taken:
 Patient vaccination date: 2005-09-01 (yyyy-mm-dd)
 Vaccination not performed: (violation, complete End report)

Previous IG: YES NO
 If Yes, date: (yyyy-mm-dd)
 Ongoing GVHD: YES NO

Medication for GVHD

No.	Drug	Start date	Dose (mg)	If other, specify
1.	Cyclosporin	2005-09-01	50	
2.	Prednisolone	2005-09-01	12	
3.				
4.				
5.				

Complete available rows. If require more rows, click Save draft.

Queries
 [Created 2005-09-18 12:26:04 by maku]
 Audit trail

Powerful query generation and viewing functions will dramatically cut down the time to database lock.

Search/List

PatID	Initials	Included	Group	Status	TX	Vaccinated
8	MAA	2005-07-22	No vaccin (B)	2-Eligible		vaccinated
7	FADF	2005-05-04		1-Not eligible		
6	OI	2005-06-01	Vaccin (A)	2-Eligible		
5	WWW	2005-05-12	Vaccin (A)	2-Eligible		
4	H-O	2005-01-20	No vaccin (B)	5-Completed	2005-02-24	2005-04-30
3	J-E	2004-09-29	Vaccin (A)	Withdrawn	2004-10-21	
2	S-S	2004-09-20	No vaccin (B)	Withdrawn	2004-09-30	2005-01-13

Total number of records: 7

Regulatory Compliance

The CTF has been designed to enable our customers to deploy it as part of a validated system to enable compliance with GCP predicate rule requirements, laws and regulations applicable to the conduct of clinical trials and post marketing, and FDA CFR 21 Part 11 pertaining to the use of electronic records and signatures.

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