Infermed MACRO® -
Electronic Data Capture according to GCP

Dipl. Inf. A. Fischer

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ELN European LeukemiaNet

Topics

I. From paper to EDC
II. Requirements by GCP
III. Software MACRO®
IV. MACRO for use in ELN trials

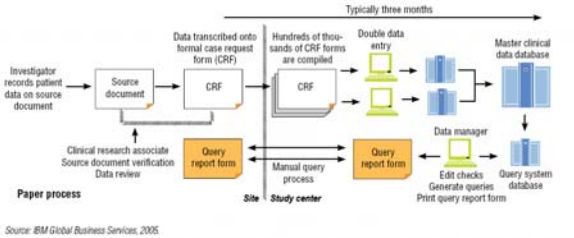
From paper to EDC

History

- Idea born in 1970s
- 1980 - early 1990s: Remote Data Entry
  - computer hardware and software provided from sponsor
  - data periodically transmitted by a modem connection over an analog phone line
  - investigators with one computer and software for each trial
- Internet in 1990s: Electronic Data Capture
  ⇒ fast, convenient, ergonomic

From paper to EDC

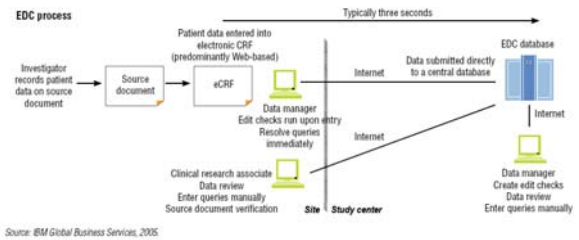
Paper-based data capture



Source: IBM Global Business Services, 2005.

From paper to EDC

Electronic Data Capture



Source: IBM Global Business Services, 2005.

From paper to EDC

Benefits of EDC

✓ No double data transfer from paper to database
⇒
- **Cost and time reduction**
- **Error diminishment**

✓ Instant data checks at inputting stage
- ➢ No missing values
- ➢ No inexact or out of range values
- ➢ No implausible values
- ➢ No wrongly recruited patients

⇒
- **Fewer queries**
- **Clean data fast available**

From paper to EDC

Benefits of EDC

✓ Fast access to patient data
- ➢ Instant reaction to protocol problems, adverse events or other trends

⇒ **Improved patient safety**

✓ Modern and competitive trial management

⇒ **Positive image at sponsors and public**

✓ Patient data capture with software implementing technical standards and GCP requirements

⇒ **Trial conducted with high quality standards**

From paper to EDC

Obstacles on the way to EDC

❖ At investigator site
- ➢ Poor Internet connectivity
- ➢ Computer-phobia
- ➢ No remaining copy of delivered subject data ?

❖ At study center
- ➢ Change of operational processes
- ➢ Redistribution of tasks and responsibilities

From paper to EDC

Impact of EDC on clinical trial queries

	EDC	Paper
Percentage of **enrolled subjects** that are invalid	7.5%	15%
Cost of raising and resolving a query	$10	$60
Number of **queries**/subject	0.25-1	5-20
Cost of validation / subject	**$2.5-10**	**$300-1200**
Percentage of queries caused by inconsistent data	5%	35%
Percentage of queries caused by out of range data	0.1%	8%
Percentage of queries requesting clarification	0%	6%
Percentage of queries due to invalid data	0.05%	0.1%

Source: CDISC- CenterWatch Collaborative Project, 2002. N = 712 companies

Good Clinical Practice

Why GCP?

EU Directive "Clinical trials": 2001/20/EC
- "... approximation of the laws, regulations and administrative provisions of the Member States ..."
- applies to all interventional trials

Article 1(4):

"All clinical trials (...) shall be designed, conducted and reported in accordance with the principles of good clinical practice."

Good Clinical Practice

Why GCP?

Germany (AMG)

§ 40 General conditions of clinical trials:

"The sponsor, the investigator and all other persons involved in a clinical trial (...) have to keep the requirements of good clinical practice."

12th amendment of AMG (August 6th, 2004):

GCP is now mandatory for all clinical trials (also investigator-initiated trials)

Good Clinical Practice

ICH-GCP

= GUIDELINE FOR GOOD CLINICAL PRACTICE

by International Conference on Harmonisation (...)

Art. 5.1.1:

'The sponsor is responsible for implementing and maintaining quality assurance and quality control systems (...)'

Art. 5.1.3:

'Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.'

Good Clinical Practice

ICH-GCP

Art. 5.5.3:

When using electronic trial data handling and/or remote electronic trial data systems, the sponsor should:

(a) Ensure and document that the electronic (..) system conforms to the sponsor's (..) requirements for completeness, accuracy, reliability, and consistent intended performance.

(b) Maintains SOPs for using these systems.

(c) Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (.. audit trail..)

...

Good Clinical Practice

ICH-GCP

Art. 5.5.3: (continued)

When using electronic trial data handling and/or remote electronic trial data systems, the sponsor should:

...

(d) Maintain a security system that prevents unauthorized access to the data.

(e) Maintain a list of the individuals who are authorized to make data changes.

(f) Maintain adequate backup of the data.

(g) Safeguard the blinding, if any. (..)

Software MACRO®

Validated EDC Software

- Vendor: InferMed Ltd, London
  - www.infermed.com
- Architecture: Client/Server
  - Kinds of clients:
    - network client
    - web client
    - remote client
  - Backend: MS SQL Server or Oracle Database
  - Webserver: MS Internet Information Server (IIS)

Software MACRO®

Scope of benefits

- GCP-conformant
  - ➢ password authentication and authorization of users by roles
  - ➢ detailed audit trail
- Support for multicentre trials
- Data validation and plausibility checks at inputting stage
- Reporting and data export
- Trial design tools

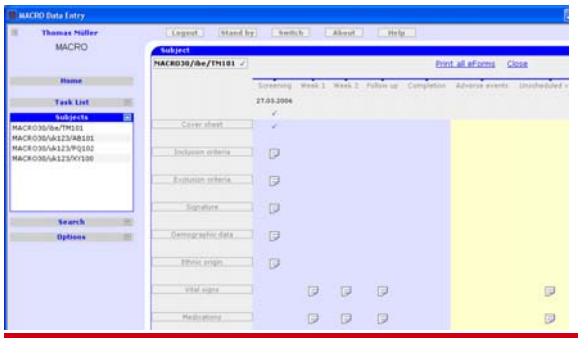
Software MACRO®

Minimum Client Requirements

- Network client:
  - 450 MHz Pentium II with 128 MB RAM and 500 MB free hard disk space
  - Windows 2000 Professional or XP Professional
  - Screen resolution of 1024 x 768
- Web client:
  - Internet Explorer with high (128-bit) encryption pack
- Remote client:
  - Local database: MSDE 2000 or SQL Server 2000

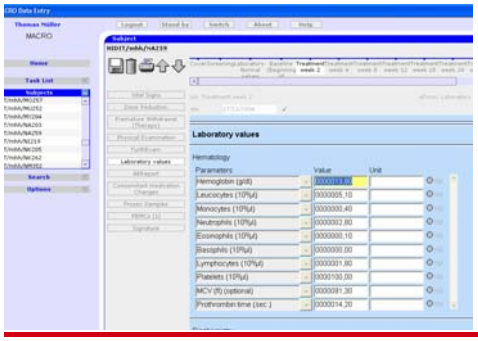
Software MACRO®

View: eCRFs overall schedule



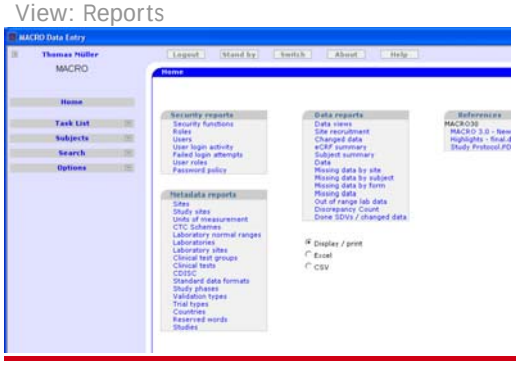
Software MACRO®

View: eCRF 'lab values'



Software MACRO®

View: Reports



MACRO for use in ELN trials

Installation in Munich (LMU)

- Operational since April 2006
- Security
  - Firewall
  - Secure Data Transmission (SSL) by high quality server certificate
- Newest patches (Version 3.0.79)
- Trials
  - ❖ in development : 7
  - ❖ open : 1
  - ❖ closed : 1

MACRO for use in ELN trials

Trial Implementation by WP 3

- WP 3 provides:
  - CRF design consulting, including specification of data dictionary
  - e-CRF implementation and e-CRF validation by SOPs
  - User management
  - User training and help desk
  - Trial homepage creation
  - Data view and report creation
  - Data export
  - Backup service
- WP 3 does not provide and support:
  - data entry from paper forms

MACRO for use in ELN trials

Costs concerning Electronic Data Capture

- Additional costs may arise for implementation, validation and management of either numerous trials or extremely complex trials
- Additional costs to be borne by the trial sponsor will arise from:

  Named users: 600 € per user + 100 € per user and year

MACRO for use in ELN trials

Summary

- Great potential cost and time savings by EDC
- Progressive and high quality trial data capture
- Validated installation of the GCP-conformant data capture software MACRO
- Available for clinical trials conducted by the ELN
- WP 3 provides a wide variety of support, e.g. crf design & validation, data exports, training
- Additional costs may arise, e.g. for user licenses

Thanks for your attention!

Questions?