Establishing a Clinical Trial Management System (CTMS) Globally: Integrating with other core functions of the clinical trial.

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As clinical trials become more complex and the organisations more international and global, so managing them becomes more time consuming and important. Technology is being implemented to support many of the core functions of the trial such as lab. data measurements, drug supply shipments, the clinical database, project management, study finance and document management. To implement any of these systems without reference to the interactions and potential benefits of those interactions could prove damaging to trial efficiency in the long term.

The Clinical Trial Management System (CTMS) is the nerve center of this integration. Some may say it is a Data Warehouse but who really knows what that is!? One thing a CTMS is is a database for collecting data from a wide range of sources enabling this data to become information and in turn the information can become knowledge. Knowledge of processes, investigators, centers, CRF design etc.

Implementing a local CTMS for a limited group of users in one location is far less complex than a global implementation. Strategies for both require a slow, careful and phased process where all people involved are informed and can participate if they so desire. The extra level of complexity for a global system is the aspect of communication. Where in a local implementation the implementation team can visit and discuss issues face to face, in a global implementation communication is via e-mail and other passive communication where interpretation and perceptions are not so easily expressed.

If the problems of implementation can be overcome, social, organisational and technical, the advantages can be there. The global CTMS can manage information into knowledge to act as a basis for decision making or a reality check after decisions are made using other information.
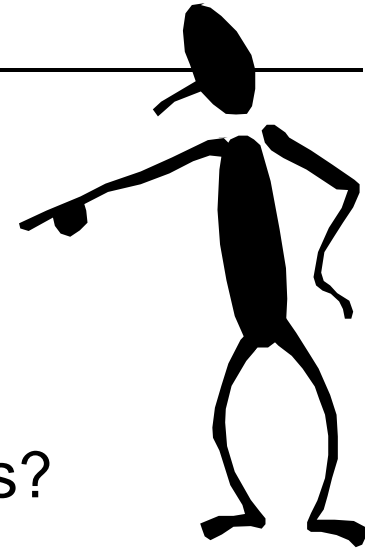
Establishing a Clinical Trial Management System (CTMS) globally: integrating with other core functions of the clinical trial.

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Introduction

- What is a CTMS?

- What should it do?

- How can it integrate with other IT systems?

- How will it make the clinical trial process more effective?

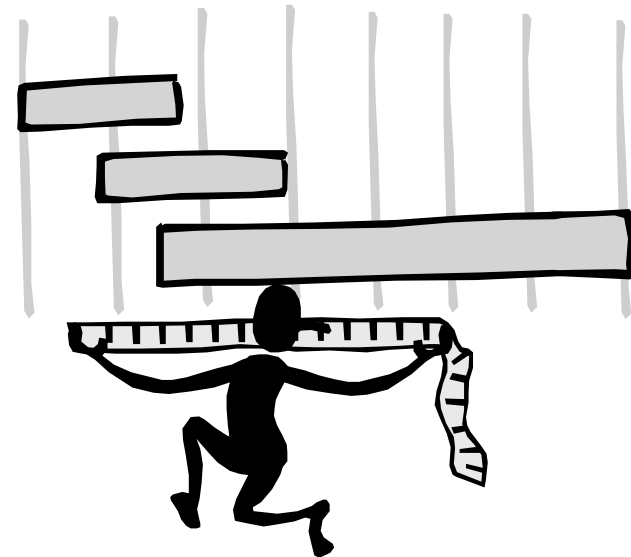- Build or Buy

- Going Global

- Costs and benefits

What exactly is a CTMS?

- ## Planning
  - using historic data to plan better
  - keeping track of how study planning is going
  - reporting of planned trials and timelines

- ## Progress
  - trial progress against timelines
  - tracking of anything trackable

- ## Performance
  - how did we do
  - how can we do it better

- ## Resource management
  - human and financial

What part of the clinical trial do we want the CTMS to manage?

- Patient enrollment
- CRF, DRF tracking
- Project planning
- Drug supply systems
- Document tracking
- Finance systems
- Progress reports
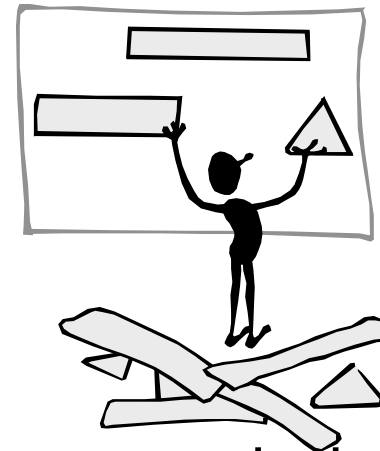- Post study evaluation

How can the CTMS integrate with these?

- Patient enrollment - Clinical database

- CRF, DRF tracking - Intranet/Extranet

- Project planning - Microsoft Access or other database

- Drug supply systems - bar codes

- Document tracking - Documentum etc.

- Finance systems - SAP R/3

- Progress reports - Merged documents and Intranet

- Post study evaluation - reports and statistics (Excel)

- OPEN ARCHITECHTURE

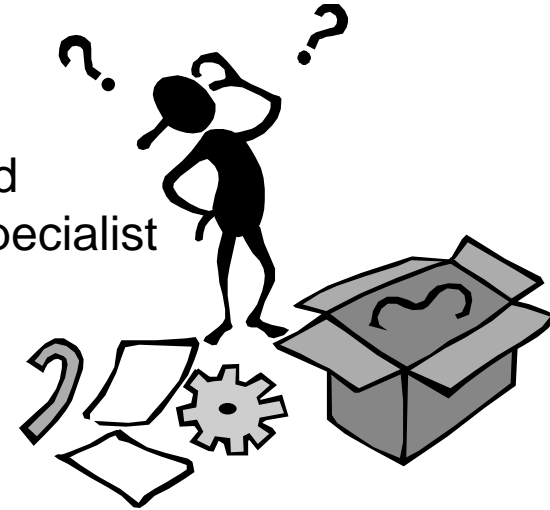# How can the CTMS make the clinical trial process more effective?

- Information is collected and stored only once and used many times

- Real time progress reporting
  - better decision making

- Real performance measures
  - better future planning

- Information available across time-zones and when key people are absent

Build it or buy it - the never ending story!

- Build
  - flexibility in design
  - disadvantages in maintenance
  - internal systems development staff required
    - Human-Computer Interaction design specialist
    - business systems analysts
    - programmers

- Buy
  - restricted in design
  - advantages in maintenance
  - internal systems development staff required
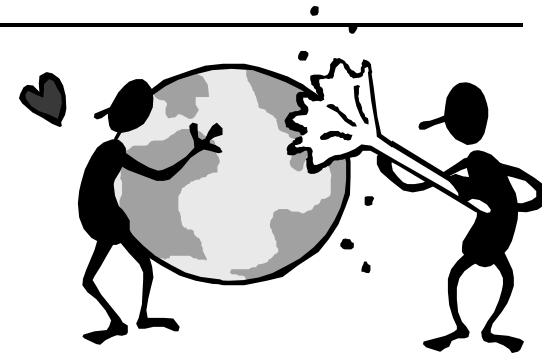   - business systems analysts

- Depends entirely on your organisation and current skills

Build it or buy it (2)

- **What can you build it with?**
  - a database with application programming ability
    - Oracle
    - Microsoft Access
  - PowerBuilder

- **What can you buy?**
  - the choices are limited
  - look carefully at what you get for your money

Contract

Making the CTMS Global

- ## What are your global needs
  - real time or near real time
  - static integrated summary reporting

- ## Implement in stages - Darwin's theory of evolution, not the big bang!
  - don't rush
  - involve everybody from the start - directly and indirectly affected persons
  - train the users properly and effectively

- ## A Global CTMS can uncover global differences in performance etc.

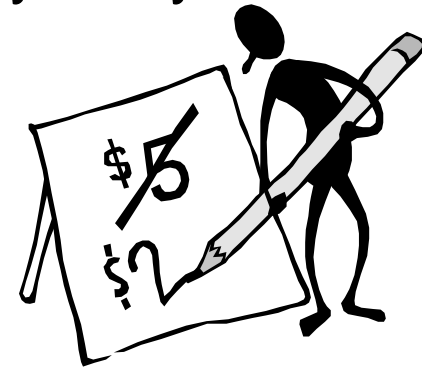- ## A Global CTMS can identify local strengths
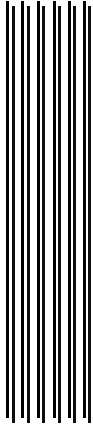
Identifying the costs

- Implementing a Global CTMS takes time, effort and money.

- A poor implementation will produce lower effectiveness and negative social inertia (lack of good will)

- Implementation takes resources away from core business projects
  - spend a bit now to save a lot in the future is hard to accept when the pressure is on

- Are there cultural barriers to overcome
  - or are they just personal differences

Identifying the benefits

- Real time information for effective decision making using less resource to get it

- A database of information for future planning based on real figures

- An opportunity for global team work

- Tangible cost savings can be proved if you try hard

Thank you

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