

# Compliance Monitor

Information Mediary Corporation

## How much does your compliance data cost?



By Allan Wilson, MD, Ph.D.

Clinical trial costs are spiraling out of control. Recently completed studies have pegged the cost of bringing a new drug to market at from 500 to 800 million dollars. Data handling and pickup costs related to patient records account for a staggering 30 percent of drug development costs. Dig deeper into the issues Information Mediary Corp. has addressed in past reports and discover some further numbers on the cost of tracking non-

compliance in clinical trials settings.

Consider the cost of recording dosing times, tempered with a good deal of uncertainty as to when medication was actually taken. Factor in the time spent deciphering often-incomplete patient diaries, which are sometimes filled out in the waiting room just prior to the follow-up visit. Now imagine paying someone \$4.00 per page for the double data entry required to capture that information into an eCRF.

Are you in doubt as to when patients took their medication? Did they miss a dose? How does that affect your data? Is poor patient compliance adding noise to your study, making it more difficult to detect the signal (therapeutic effect)? In a clinical situation, how does

poor compliance affect your ability to make a rational clinical decision about further therapy?

A manual query about the dosing regimen can cost \$12 to \$20 per page of information.

How much does patient non-compliance cost you? The cost could be as high as \$2000 to \$10,000 per patient to record and handle data the reliability of which is suspect over the course of a study. What if you had a way to identify non-compliant patients early in a study? They could be removed from the study, educated to increase their compliance, or their compliance data could be co-varied out in the statistical analyses of the data. This would result in considerable savings due to increased accuracy of data leading to more convincing study outcomes.

What if there was a better way? A way to get all your patient compliance information with direct data capture right at the source. A foolproof method of recording to the time each tablet or capsule was ejected from a blister package. That's. Med-

### Estimated Clinical Trial Compliance Data Costs:

- \*Double Data Entry of Compliance records \$4.00 per page
- \*Compliance data Query \$20 per page
- \*Data handling costs for recording non-compliant patients range from \$2000 to \$10,000

## Med-ic® ECM™: Incorporating the Technical Controls for 21 CFR Part 11 Data Capture

With electronic record keeping comes the possibility of data tampering. FDA 21 CFR Part 11 was established in August 1997 to govern the use of electronic records and electronic signatures. This regulation outlines the criteria whereby electronic records and signatures will be considered equivalent to paper records and handwritten signatures. The regulation covers electronic records throughout their lifecycle. This includes creation, modification, storage, final submission to the FDA, and audit.

21 CFR Part 11 is designed to ensure that the data stored and modified via electronic media are trustworthy and transparent. Source data containing critical information relating to compliance must be reliable and authentic. Data integrity must be guarded and monitored, preventing unauthorized modification of the system. A detailed audit trail of all user activities must be kept and made available for audit activities.

A vendor cannot claim that their software products are certified 21 CFR Part 11 compliant. They can only claim that their product contains all of the Technical Controls for 21 CFR Part 11 compliance. The ultimate responsibility for 21 CFR Part 11 compliance lies with the system owner and system integrator.

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# At Issue: Compliance Data Costs

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ic<sup>®</sup>. That's ECM<sup>™</sup>-Electronic Compliance Monitoring - and it is commercially available in Q2 of 2003.

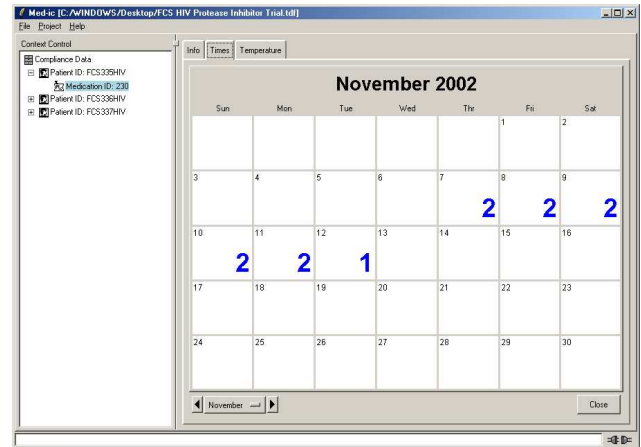
Med-ic<sup>®</sup> ECM<sup>™</sup> tags record when the patient removes a tablet or capsule from a blister package. Using the CertiScan<sup>™</sup> RF Reader and CertiScan<sup>™</sup>

Software, a clinical trial administrator can retrieve and display "at a glance" calendars of patient compliance. This adds up to true cost savings through Compliance Data Capture (CDC) going directly to the source where it can be interpreted and acted on...quickly and cost effectively.

**Allan Wilson MD Ph.D.** is Professor of Psychiatry, University of Ottawa and Director, Substance Use and Concurrent Disorders Program, Royal Ottawa Hospital. He has been involved in clinical pharmacology as a researcher for the last 25 years and has over 100 academic publications to his credit. He co-founded Information Meditary Corporation with Michael Petersen in 2001. IMC is an engineering company that focuses on synergistic problem-solving within the health care field. IMC manufactures the Med-ic<sup>®</sup> electronic compliance monitor (ECM<sup>™</sup>) and the eCAP<sup>™</sup> electronic bottle cap.



**Med-ic<sup>®</sup> ECM<sup>™</sup> packages capture your 21 CFR Part 11 relevant compliance data right at the data source...the patient!**



**Med-ic<sup>®</sup> CertiScan<sup>™</sup> has "at a glance" displays of patient compliance with dosing regimens.**

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## 21 CFR Part 11: Capturing Compliance at the Data Source

Use of an Electronic Compliance Monitoring system can assist in compliance with the regulation. Med-ic<sup>®</sup> ECM<sup>™</sup> incorporates several 21 CFR Part 11 compliance controls. CertiScan<sup>™</sup> \*.tdf (trial data file) files are in binary and checksummed format proprietary to IMC to ensure tamper proofing.

Complete and accurate copies can be viewed on screen using Med-ic<sup>®</sup> CertiScan<sup>™</sup> Software. Complete and accurate electronic copies are available by exporting the raw data files to \*.csv (comma separated value) files for viewing and printing in spreadsheets like MS-Excel.

Med-ic<sup>®</sup> obtains patient compliance data directly from the source and bypasses much of the need for complex rules of recording information, offering significant cost savings in the capture of patient compliance data.

**imc** / INFORMATION  
MEDIARY CORP.

### About Us

Information Meditary Corporation is dedicated to the convergence of medicine, logistics, high-technology, pharmacology, wireless, e-business and anthropology.

IMC's recent flagship Med-ic<sup>®</sup> and Log-ic<sup>™</sup> ECM<sup>™</sup> product development efforts underscore this commitment by recognizing and solving important issues. Compliance monitoring has been viewed increasingly as a problem in clinical research and clinical pharmacy over the past decade. Prior to the Med-ic<sup>®</sup> ECM<sup>™</sup> Package there was no user friendly, seamless and accurate solution to the problem.

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