med-ic® Rx FOR THE THIRD MILLENNIUM

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INTERPHEX™

**SPECIAL REPORT:** Focus on Clinical Trials

# Compliance Monitor

Information Mediary Corporation

# How valid are your clinical trials data?

**Medication Non-compliance causes:**

- $100 billion annual U.S. health care system costs
- Over 100,000 patient deaths
- Over 1 million hospital admissions
- Antibiotic resistance
- Erroneous efficacy data from clinical trial studies

*By Allan Wilson, MD, Ph.D.*

It is widely accepted that patients participating in clinical trials are less than perfectly compliant with their medication regimens. The extent to which non-compliance affects the results of clinical trials is unknown. Several factors mitigate against the assessment of this phenomenon, principal of which is the lack of a methodology to monitor patient compliance in a non-invasive way.

Clinical research depends largely on pill counts and the use of medication diaries. Participating patients are interviewed at intervals and their remaining pills are counted. Strategies may involve giving patients extra pills to assess their compliance. Patients are known to not be forthcoming about non-compliance, generally from embarrassment or a desire to please the researcher. They are also known to fill out medication diaries retrospectively just before their interviews, often with less-than-perfect recollection.

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Compliance with prescribed medication is thought to decrease with the duration of therapy, the daily dosage, the side effects, and the breakthrough of clinical signs and symptoms.

Even patients who have interviews and correct pill counts may be non-compliant. With most medication trials, the aim is to keep plasma levels within a therapeutic window. Not taking medication on time, taking extra medication, missing one dose and dou-

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## IMC's Med-ic® ECM™ addresses pressing issue

Information Mediary Corporation has developed the Med-ic® ECM™ Electronic Compliance Monitor as an answer to the lack of information about patient compliance.

This device is a state-of-the-art smart RFID tag that can be integrated seamlessly in blister packaged medication or other types of compliance packaging. The Med-ic® ECM™ tag records the time at which the contents of a blister are expelled from the package, keeping a log of the patient's use of their medication. At a later time the data can be downloaded via a contactless reader for analysis.

In the area of clinical trials, Med-ic® provides more accurate patient compliance data during the trial. This will result in better decision-making about the future of new drugs, effectively increasing the power of clinical research trials. It also offers the possibility of using longer intervals between interviews with the trial monitor, especially where medications are taken at variable intervals according to an as-required strategy. In such situations, Med-ic® obviates the need for frequent follow-up interviews to remind the patient to keep the medication diary up to date.

# At Issue: Clinical Trials Data Accuracy

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bling up on the next call all result in plasma levels dropping below or exceeding the therapeutic window. The result may be ineffectiveness of the therapy due to inadequate plasma levels or side effects due to increased levels. Both have serious implications for the clinical trials decision-making process.

Although mechanical devices are sometimes used to address non-compliance, these are all flawed for various reasons. Currently available devices all interfere with the process of taking the medication by requiring the patient to behave differently when using them, and by their bulk and resultant inconvenience. They also affect the clinical trial methodology by their cost. For these reasons, they cannot be used to clarify the non-compliance issue. Proving efficacy—the ultimate goal in clinical trials—should not be left to data of questionable accuracy. More accurate patient compliance data during clinical trials is the key to better decision-making regarding investigational new drugs.


**Med-ic® provides effective compliance data using any existing standard blister packaging**

## Med-ic®: Easy Compliance Monitoring

In the case of clinical research trials, the Med-ic® ECM™ can replace pill counts and medication diaries along with their inherent weaknesses.

The Med-ic® ECM™ is the only compliance-monitoring device that does not alter the clinical pathway. The patient simply takes the medication in the usual manner. The medication package is externally identical to a regular blister package, unlike other, proprietary compliance-monitoring devices.

Med-ic® ECM™ also introduces the option of variable dose and variable interval clinical trials. As such, patients may be instructed to take one or two tablets according to severity of a symptom, and the time and number of tablets taken will be accurately recorded for subsequent analysis. In certain cases, such as migraine headache management, the trial may extend over weeks or even months.

With Med-ic®, obtaining accurate data unobtrusively, and over long periods of time is now finally possible.

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### About Us

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

IMC's recent flagship Med-ic® and Log-ic™ ECM™ 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® ECM™ Package there was no user friendly, seamless and accurate solution to the problem.

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