

Cutting edge solution for patient adherence in clinical trials

Medicodose's patented smart pharmaceutical packaging and adherence platform

- + Enable real-time and simultaneous remote patient monitoring
- + Allow direct feedback and data collection from patients
- + Improve medication intake and ePRO adherence

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Patient adherence

Clinical trials greatly rely on patient self-reported adherence data yet medication adherence rates have traditionally been estimated **between 43-78%**

Among the major challenges the clinical trial enterprise is facing is patient non-adherence to Trial's requirements:

Medication regimen

- + Right time (am, noon, pm)
- + Right conditions (before, with or after meals)
- + Right interval (1 pill, 2 times a day or 2 pills once a day)

ePRO data

- + Completion within specified time windows
- + Objectivity of answers 'from the patient to the database'
- + Real-time ePRO data (both adherence and scores)

STAND-ALONE PACKAGING

SMART IT PLATFORM

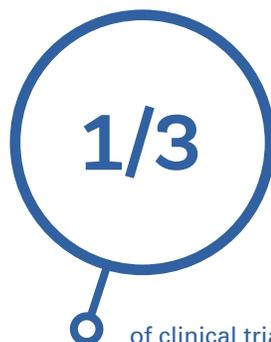


***Decrease** in medication adherence

=



***Increase** in sample size in order to maintain sufficient statistical power



of clinical trials have **missing** or incomplete data

of patients **forget** to take their medications



of patients **dump** study drugs

In an effort to conceal their failure to take the medication correctly



SUCCESSFUL CLINICAL TRIALS

= \$20
Million

Extra to enroll
additional patients

*Source: Apply Clinical Trials

of patients provide **erroneous**
answers to questionnaires



MEDCOMPILER

*Introducing world's first stand-alone
adherence packaging and software suite*

- + **Medcompiler™** – A smart pharmaceutical packaging with embedded software and microelectronics. It monitors and reports patient adherence with medication regimens.
- + **Telephone reminders** – Our clinical software suite reminds patients to take their drugs by automatically issuing telephone calls, emails, and SMS messages indicating when to take the right medication.
- + **ePRO Clinical Suite** – Sites/CROs/sponsors can access real-time interactive patients/site/study dashboards.

*Smart packaging with proprietary
design and unique features:*

- + **Records and reports medication intake events**
Time, date, and pill position
- + **Stand-alone technology**
No hardware (readers / scanners), WiFi, Bluetooth, NFC needed to download data nor device's software updates
- + **Child resistant and senior-friendly**

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One-stop-shop solution

Affordable and easy to integrate

KEY BENEFITS

- 1 Reminder
- +
- 2 Smart packaging
- +
- 3 Adherence platform
- +
- 4 ePRO

ADDED VALUE

Increased adherence and data quality

+

Real-time Ambulatory Patient Monitoring and Cross-Adherence™

Simultaneous medication intake and ePRO data access

+

Cross-Adherence™ is the reflection of the patient's behavior towards medication intake, eDiary answers versus their predefined **time windows and the order of their execution**

BUSINESS IMPACT ON TRIAL COST AND TIMING

- ↓ Risk
- ↓ Sample Size
- ↓ Trial Length
- ↗ Profit

A cross-industry technology platform meets the expectations of many stakeholders, Sponsor/CRO/EDC

- + The missing link between CTMS and patient adherence to clinical trials protocol is no longer actual.
- + Simultaneous and real-time access to Cross-Adherence™ between patient medication intake and ePRO is, today possible.

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Overview of the solution

How does it work?

STEP
1

Automatic drug intake reminder

(phone or web-based)



STEP
2

Patient takes medication

Adherence code generated



STEP
3

IVRS, IWRS-based data capture

565334

Adherence code processed



ePRO



STEP
4

Real-time access

to subject adherence, ePRO as well as to Cross-Adherence™ data



Dynamic Investigator, CRO, Sponsor Dashboard



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Potential savings

From current practices

Real-time site monitoring

\$960K
SAVING¹

From site monitoring costs only (not including site management)

Decrease patient visits to the clinic

\$95
PER PATIENT
PER VISIT⁴

Saved on transportation and food

Ambulatory Patient Monitoring and real-time cross compliance

\$2500
SAVED PER PATIENT³

Reducing number of required visits from 25 to 3

For each 1% improvement in patient adherence

\$336K
SAVING⁵

Reducing additional patients needed to maintain statistical power

Input: Acquiring additional hardware

\$2000
SAVING⁶

By using our stand-alone smart blister pack

Unique BYOD ePRO technology

\$400
SAVED PER PATIENT²

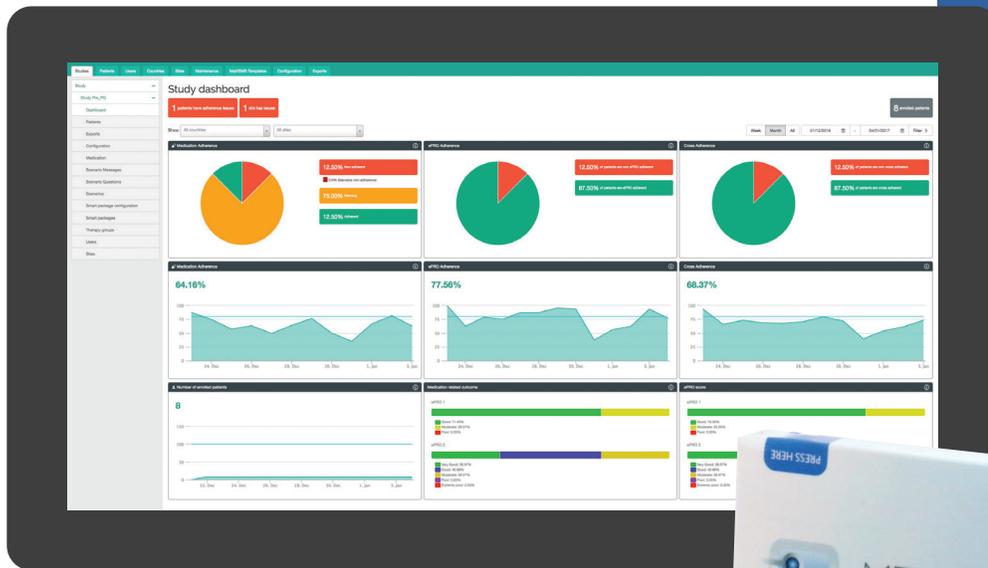
Avoiding extra cost for providing devices to patients

Sources: 1) Boston Medical Center, NIH. 2) DRK Research. 3) Pfizer pilot study result. 4) Nimblify. 5) *Journal of Clinical Epidemiology*, Tuft University. 6) Medicodose research on several clinical sites.

IVRS, IWRS-based ePRO solution

User-friendly, compatible and seamless integration with any EDC platform:

- + Automated medication intake reminders
- + Access to reliable patients adherence data in real-time
- + Maximize patient's satisfaction and retention
- + Understand patient's behaviors and transform your trials to truly patient centric



ePRO Dashboard

Just one vendor

Medication intake/ePRO single solution – EDC compatible



At Medicodose Systems, we not only strive in developing state-of-the-art smart pharmaceutical packaging, but also offer user-friendly, non-invasive technologies that translate into better patient adherence in clinical trials.

- + One-stop-shop business model
- + Innovative patented technology
- + Worldwide real-time data access
- + Validated and 21CFR part11 compliant platform
- + Competitive and logistical expense savings
- + Hassle-free data transfer to the regulatory institutions
- + High rate patients adherence



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We would love to hear from you!

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