

Optimizing Clinical Trials

USING ELECTRONIC MEASUREMENT AND ANALYSIS OF DRUG ADHERENCE

At best, poor adherence reduces the statistical power of a trial and underestimates the drug's efficacy. At worst, poor adherence obscures outcomes and leads to a failed proof of concept.

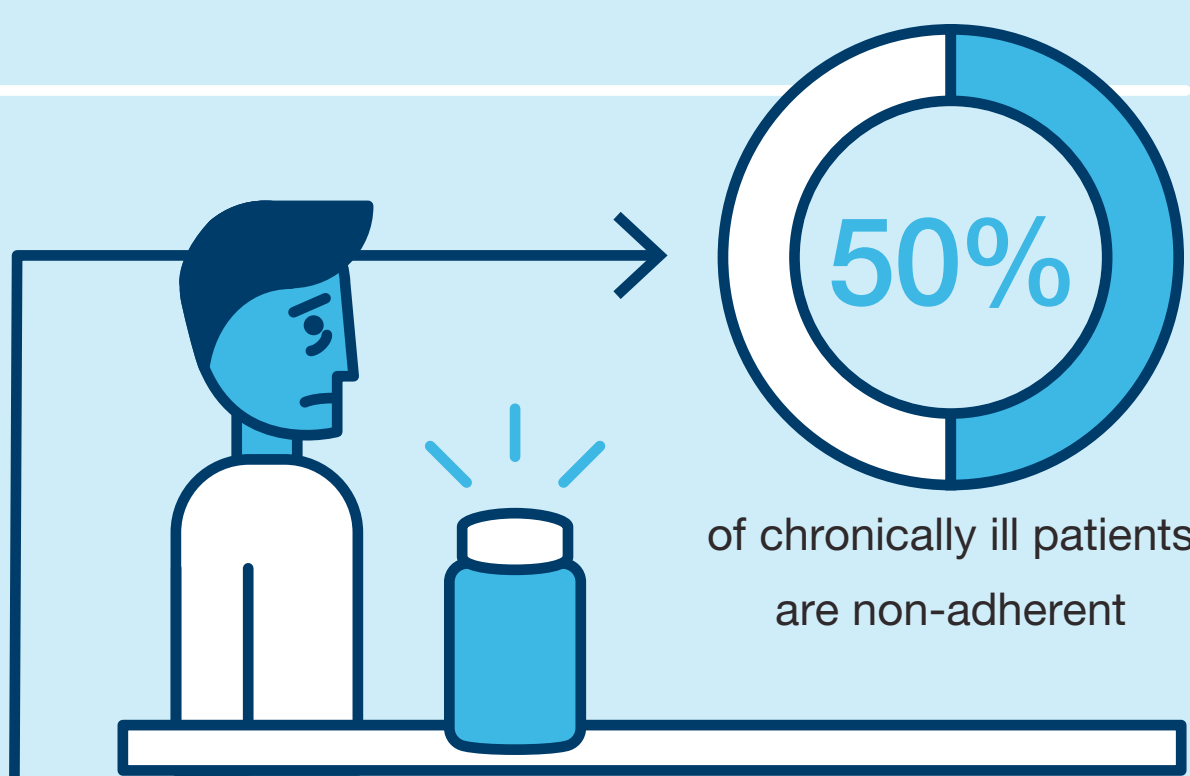
Impact of Non-Adherence

REDUCED ACCURACY AND EFFICIENCY OF CLINICAL TRIALS



When left unmonitored or unmeasured, adherence in clinical trials is generally assumed to be near ideal

IN FACT, THE OPPOSITE IS TRUE



If non-adherent patients can't be distinguished from non-responders early on, drug developers can face costly phase III failures, jeopardizing entire programs

Monitoring Adherence

Accurate adherence measurement enables maximized therapeutic action, both for new medications in development and for medications already used routinely in clinical care.

A recently published study in JAMA Oncology shows 6 years of analysis on 6-mercaptopurine's (6MP) actions in the treatment of Acute Lymphoblastic Leukemia

6MP HAS BEEN USED FOR 60+ YEARS

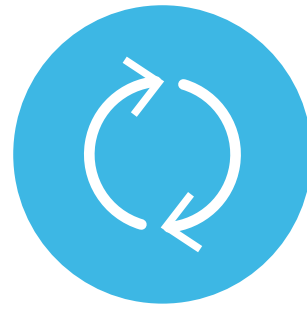
But its full therapeutic possibilities were not understood because adherence was not measured during drug development and the dose was not set correctly



Adherence data was evaluated using MWV's Medication Event Monitoring System (MEMS™)



MEMS monitors, measures, and analyzes patient adherence for real-time adherence-based adjustments

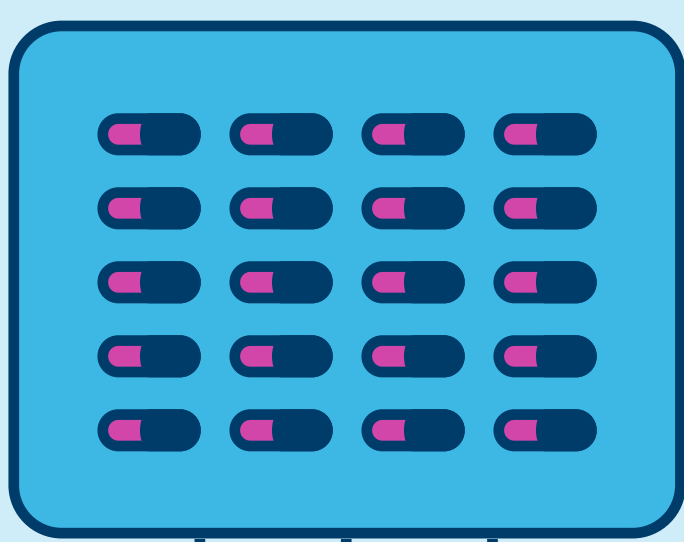


Patients with 6MP non-adherence (<95%) were **2.7 TIMES** as likely to relapse (P=0.01)

ADHERENCE MEASUREMENT MATTERS,
EVEN FOR KNOWN THERAPIES THAT TREAT LIFE-THREATENING DISEASES

How It Works

MEMS uses smart packaging to



Electronically track medication-taking behavior



Wirelessly transfer the data for analysis

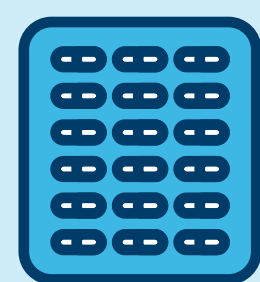


Provide real-time feedback to trial organizers and patients at point of care

SMART PACKAGING IS NOW AVAILABLE FOR MONITORING ADHERENCE WITH DIFFERENT FORM FACTORS



Standard drug containers

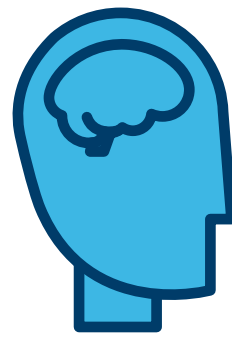


Blister packaging



Injectable medications

MONITORING ADHERENCE, INCLUDING THE TIME OF DOSING



Provides a true, evidence-based picture of dose-dependent drug response



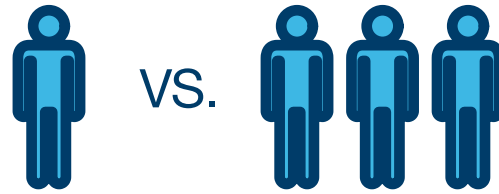
Adds robust, reliable, and actionable efficacy data



Helps to identify the appropriate dose



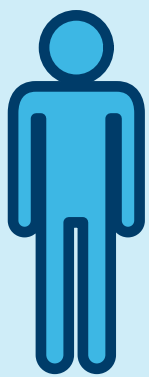
Underlines the need for adherence to achieve effective treatment



Is more statistically powerful than adding additional patients with the same unknown variability in adherence

MWV's Adherence Solutions

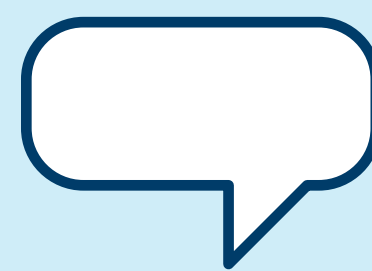
USED IN 1,000s OF CLINICAL STUDIES



INVOLVING MORE THAN 1,000,000 PATIENTS



LEADING TO THE PUBLICATION OF NEARLY 700 PEER-REVIEWED RESEARCH PAPERS



CITED 50,000 TIMES

LEARN MORE ABOUT ADHERENCE MONITORING AT WWW.MWVAARDEX.COM

