

**Case Study** 

## Interactive Dosing Reminders Increase Medication Adherence

Elderly cardiovascular patients achieved as high as **98% compliance** at **18 months** on study.

## Research shows 40% of patients¹ become non-compliant at 5 months on study

### IMPACT OF POOR COMPLIANCE

The importance of consistent medication adherence for studies with self-dosing requirements cannot be overstated. As noted in Applied Clinical Trials, it has an exponential impact on the number of patients needed to reach the same statistical outcome.

Non-Adherence Rate

**Enrollment Increase Required** 

20%-30% non-compliance

50% more patients

50% non-compliance

200% more patients

Given the industry standard 40% non-compliance rate, an average Phase III trial will require an additional **460 patients** at an estimated cost of**\$12 Million**<sup>2</sup>- with costs even higher for certain therapeutic areas (e.g. lengthy cardiovascular studies and complex oncology trials)

### **OPPORTUNITIES TO IMPROVE**

The good news is, even an incremental improvement makes a significant difference in time and the bottom line. The Phase III trial referenced above would yield \$335k in cost savings for each 1% increase in adherence.

And as the following case study shows, technology like ClinOne's Dosing Manager helps patients, even in a challenging elderly patient demographic, achieve compliance rates as high as 98% at 18 months on study.



# Mobile technology that improves adherence without getting in the way of patients' lives



### STUDY DETAILS

Therapeutic Area: Cardiology Indication: Transthyretin with Amyloid Cardiomyopathy (ATTR-CM)

Patient Population: Elderly (average age of initial diagnosis was 74 years old)

Phase: Phase III
Dosing: 2x a day
Timeline: 18 month

### THE CHALLENGE

A leading pharmaceutical company sponsored a Cardiology trial that required elderly patients to self-administer cardiometabolic medication 2x/day over 18 months.

Published data for average medication adherence in cardiometabolic disease is just **56% over 12 months**<sup>3</sup>, with twice-a-day dosing having even lower adherence.

### THE SOLUTION

ClinOne helps improve medication adherence with interactive SMS messages on patients' personal phones and other mobile devices.

Dosing Manager sends protocol-specific automated text messages that prompt patients to take their medication at the scheduled time. More than just passive reminders, the system features interactive SMS asking patients to quickly and easily confirm the dose was taken - which also mitigates the risk of patients forgetting they already took a dose and over-medicating.

This simple process removes burden for elderly patients who (counter-intuitively) typically have higher technology compliance than younger people due in part to having more spare time and stronger relationships with their care team.

Sites also receive weekly compliance reports allowing them to identify patients who would benefit from additional support and follow-up.



### How ClinOne helped elderly patients achieve medication compliance rates as high as 98%

### PATIENT BENEFITS

Patients consistently demonstrated 2x daily medication adherence at 70%+ throughout the entire duration of the trial, with those at several major academic research centers reaching as high as 98% Adherence at 18 months on study.

Research Site / Institution	Adherence (18 months)
Cedars-Sinai Medical Center	97.79%
St. Luke's Hospital	94.86%
Mayo Clinic	92.47%
UWashington	87.76%
USouth Carolina	78.24%
UColorado	76.02%
UPittsburgh	63.36%

### LESSONS LEARNED

ClinOne always evolves its technology and service delivery best practices to ensure continual improvement. This trial faced some unique challenges and presented lessons learned since incorporated into future clinical trials:

- Make site participation mandatory Keeping it optional means fewer patients will receive benefit from Dosing Manager
- Focus on supporting ex-U.S. sites While our technology is inherently global, some countries may have specific deliverability issues that we can solve with our telecommunications partner if challenges arise. It is important to monitor compliance at ex-U.S. sites to identify and resolve issues proactively.
- Follow-up with non-compliant sites (and those with significant staff and study coordinator turnover) to ensure they are reviewing reports and discussing the importance of consistent dosing with low-adhering patients



With these best practices implemented during the latter part of this study, average compliance **rose to an average 86.5%** across participating sites - a promising and impressive trend that has continued with subsequent trials.

## A single platform to **connect**, **inform**, **and empower** patients in global clinical trials

In most studies, patient engagement diminishes the longer the study goes on. Yet with ClinOne, patients became **more engaged** with trial activities as the trial progressed.

Solutions used by ATTR patients during the trial included...

- Medication adherence
- Digital concierge
- Uber Health transportation
- Virtual visits (due to COVID)
- eConsent

### **6.9K PATIENT ENGAGEMENTS**

January 2019 - June 2020





True single platform



Global experience



Fastest deployment in industry



Cost-effective & scalable



To learn more about how Dosing Manager will improve medication adherence for your next trial, visit **clinone.com** 

