

Driving Adherence with Smart Medication Packaging Solutions from Information Mediary corporation

Imagine if a package could know the time each dose was taken and use this information to drive customized reminders, in-app coaching and data analytics! That's the power of **Med-ic®**, the only smart blister package in the world deployed in a successful FDA submission.

A drug's efficacy is correlated with the level of adherence in its administration, and it is well known that patients are poorly adherent.

Adherence takes various forms based on these questions:

1. *Did the patient take the drug?*
2. *Did the patient take the drug on schedule?*
3. *Did the patient take the correct dose of a variable or titrated regimen?*
4. *Did the patient handle the drug as intended prior to taking it?*

Traditionally, pill counts and patient self-reports have been used to estimate adherence to the regimen. These methods don't answer the above four questions. It is therefore difficult to target adherence education ("coaching") to the patients who most need it.

With Med-ic and optional **CoolBlue-AI** for on-board temperature tracking, all four questions can be answered objectively. Adherence coaching and reminders can be scheduled and administered on a patient by patient basis, arming the investigator and clinical monitors with all the necessary information from an objective, accurate and reliable electronic source: the Med-ic® smart package or **eCAP™** smart bottle.

Once objective adherence data has been collected, it can be used to make AI or human covariance or survival analysis, and even streamline patient intake.

After the trial, data are available for each and every dose, even down to the temperature each dose was exposed to prior to the patient taking it.

That means the trial can be conducted more effectively, with greater confidence, significantly fewer patients, and yet have the same statistical power¹. Conversely, it means that studies which might have narrowly missed their endpoint would likely have succeeded with objective data being available to manage adherence².

IMC's ROI calculator shows the powerful financial benefits associated with using objective adherence data to manage patients and improve the quality of clinical research³.

"Does Med-ic improve adherence?" Yes it has:

Med-ic has identified large scale mishandling of drugs during significant trials and allowed the sponsor to take immediate remedial and patient coaching action. (Figure 1)

¹<http://www.appliedclinicaltrials.com/non-adherence-direct-influence-clinical-trial-duration-and-cost>

²<https://www.novartis.com/news/media-releases/novartis-paragon-hf-trial-suggests-entresto-benefit-hfpef-patients-narrowly-misses-primary-endpoint>

³<https://www.informationmediary.com/world-leader-in-medication-adherence-tools/roi-calculator/>

Med-ic has resulted directly in optimized package designs to improve patient usability. IMC nearly always ends up designing smaller, more user-friendly packages for Med-ic than the clients' packaging teams had proposed for the study. This alone improves adherence.

Med-ic has documented real-time adherence rates in trials, allowing clinical teams to improve study protocols, including patient follow-up interviews.

Med-ic is unique among adherence tools in **enabling the targeting of non adherent patients to address patient-specific behaviour**, rather than a simple broad-stroke approach.



Fig 1: Clinical Investigator Dashboard showing mishandling of package (40% of patients were found to de-blister medications)

Med-ic is also unique in that **it places no additional burden on the patient in terms of handling technology**. There is no Bluetooth to configure, no battery to recharge and not even a requirement for a mobile device in order to use Med-ic. In fact, Med-ic doesn't change the medication package or bottle in any noticeable way.

The optional CertiScan companion app for Android and iOS, can be customized and configured to the requirements of any specific research trial. With it, any patient who has a GooglePay equipped Android or any iPhone (7 and above) can load the data from the package into the CertiScan app. The app can also handle optional reminders, adherence histories and patient feedback. Furthermore, it accommodates the ability to have a "helper" function, allowing one or more caretakers or companions to participate in the patient's experience.

IMC even has a separate product line targeting direct to consumer patient engagement, with our **GopherCap™** Family Medication Management IOS app. Our electronic medication adherence technology has been used in many clinical trials to objectively measure if patients take the medications as prescribed.

The adherence graph (Figure 2) depicts typical real life clinical trial data, illustrating what often happens with medication adherence as the trial moves along its timeline. Our electronic measurement technology immediately identifies declines in adherence early in the trial and gives

the sponsor reliable tools to proactively correct the patient's behaviour, increasing the trial's chance of meeting its end points.⁴

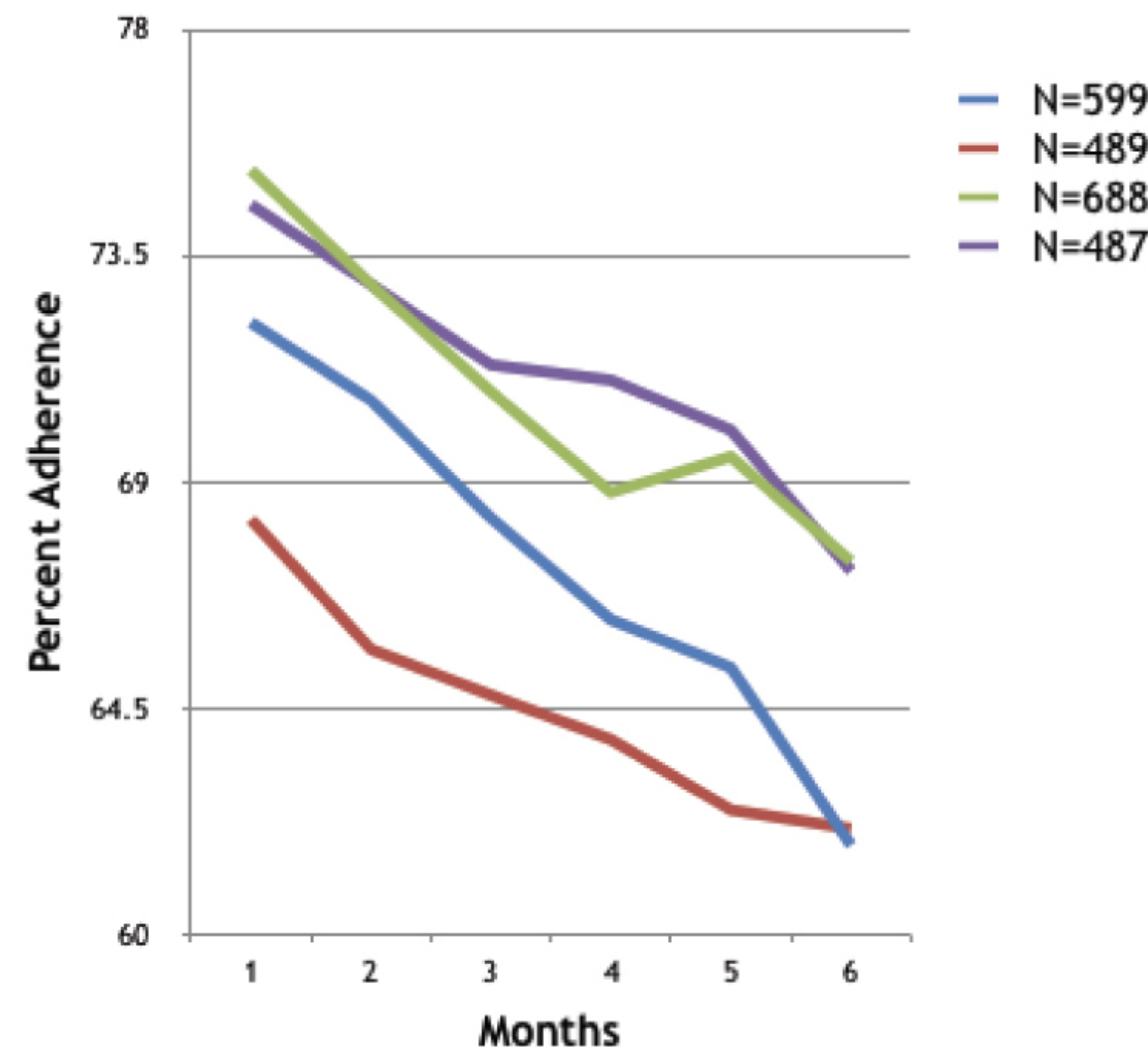


Figure 2: Adherence Drop without Intervention

The FDA requires that clinical trials generate reliable data, and adherence is a critical component. **There is powerful evidence showing that objective adherence data combined with reminders improves medication adherence.**⁵ Outpatient trials can greatly benefit from management of non-adherence using IMC's Med-ic solution.

The recent series of large Phase 3 studies by a large Pharma Company for a potential blockbuster drug used IMC's Med-ic smart package technology to measure and manage adherence. The sponsor employed over half a million Med-ic intelligent blister packages in those successful trials. IMC continues to provide helpdesk support to over 500 clinical investigator sites.

We are proud to lead the adherence revolution and be part of successful clinical research.

IMC's digital health platform provides researchers with de-risked tools, the advanced secure **NFC** wireless communication, novel patient engagement apps and of course the most robust smart package suite of solutions ever developed. This is backed by IMC's unyielding drive to provide quality, our industry partnerships, and an extensive portfolio of patents and intellectual property to assure freedom to deploy.

For more information, please contact:

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⁴<https://www.linkedin.com/embed/feed/update/urn:li:ugcPost:6582329517031866369>

⁵<https://www.avella.com/news/avellas-use-of-adheretech-improves-adherence-and-generates-one-to-two-additional-fills-per-patient-per-year-across-multiple-specialty-medications-and-diseases>