

HOW SMART PACKAGES ENABLE DIGITAL MEDICATION ADHERENCE MONITORING FOR SUCCESSFUL CLINICAL TRIALS

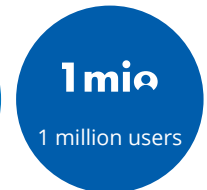
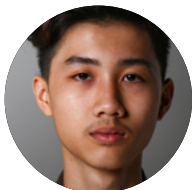
As a drug developer, you have been working hard from the laboratory to the clinical phases. Now it is time to assess your medication in a phase II/III clinical trial.

Patient compliance with, or adherence to, medications is an important factor, that can put the success of your study at risk.

To manage medication adherence, some sponsors use biased measurement methods such as pill counting, some others have chosen digital medication adherence monitoring.

Electronic compilation of dosing history data, enabled by smart packages, is an effective way to monitor, identify, manage, and document the risks associated with poor patient adherence to medications in clinical trials.

What is your opinion about that? Will you continue to overlook this risk in your planned clinical trials or will you implement a mitigation plan based on a proven digital medication event monitoring system?



Key risks associated with patient non-adherence to study medications

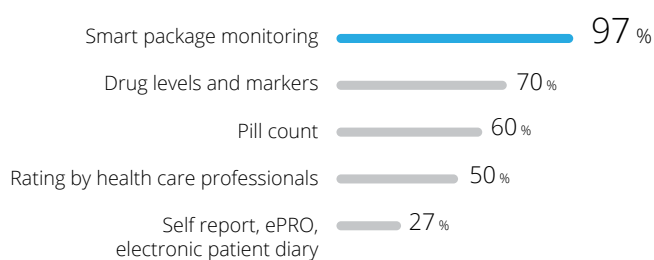
- Underestimated drug efficacy to the point of trial failure
- Delayed approval of the investigational product
- Compromised patient safety
- Unduly large sample sizes
- Flawed regulators' benefit-risk assessment at the time of drug registration

Poor Medication adherence is a threat to drug development

- 50 % of patients involved in clinical trials do not adhere to the dosing regimen specified in the protocol
- Typically, by month 12, 40% of participants stop taking treatment against protocol specifications and a further 15% do not implement the study dosing regimen
- Those protocol deviations go undetected by preelectronic measures of adherence like pill counts, blood sampling and subjects' self-report

Stop using unreliable methods to assess medication adherence!

Accuracy of the measurement methods



Advanced digital medication adherence monitoring gives you complete oversight of the adherence metrics and risk indicators that matter most for the success of your study.

Most important benefits in using digital medication adherence monitoring

- Improved medication adherence, data quality, and integrity
- Ensure high fidelity to the dosing regimen specified in the clinical trial protocols
- Optimize drug development using adherence-informed clinical trials
- Enable compliance with the FDA and ICH guidances for clinical trials
- Support proactive evidence-based risk mitigation strategies
- Provides key patient behavioral data for a successful marketing strategy



Digital medication adherence monitoring at a glance

- Straightforward and easy to implement in a clinical study without delays in the supply chain
- Applicable to all study participants without additional burden for the patients
- Mature solution with track records in over 1 Million patients in research and 200+ phase II/III clinical trials

Maximize the chances of success in your clinical trials by using an evidence-based digital adherence monitoring system. Sponsors can improve drug efficacy by managing patient adherence to the study medications. With digital medication adherence monitoring, pharmaceutical companies can build a stronger argument about the efficacy of their medication from the development stage to commercialisation.

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1mia

1 million users

76

70 countries

35

35 years



800+ Publications



200+ Clinical Trials

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REFERENCES:

- (1) Eliasson L, Clifford S, Mulick A, Jackson C, Vrijens B. How the EMERGE guideline on medication adherence can improve the quality of clinical trials. Br J Clin Pharmacol; 86:687-697; 2020.
- (2) Breckenridge A, Aronson JK, Blaschke TF, Hartman D, Peck CC, Vrijens B. Poor medication adherence in clinical trials: consequences and solutions. Nat Rev Drug Discov; 16(3):149-150; 2017.
- (3) Morrison R., Removing Uncertainty Through Clinical Trial Best Practices. 2016. Available from: https://www.contractpharma.com/contents/view_experts-opinion/2016-01-04/removing-uncertainty-through-clinical-trial-best-practices/
- (4) Blaschke TF, Osterberg L, Vrijens B, Urquhart J. Adherence to Medications: Insights Arising from Studies on the Unreliable Link Between Prescribed and Actual Drug Dosing Histories. Annu Rev Pharmacol Toxicol; 52:275-301; 2012.
- (5) Zijp TR, Mol PGM, Touw DJ, van Boven JFM. Smart Medication Adherence Monitoring in Clinical Drug Trials: A Prerequisite for Personalised Medicine? EClinicalMedicine; 15:3-4; 2019.
- (6) Alsumidaie M. Non-Adherence: A Direct Influence on Clinical Trial Duration and Cost. Available from: <http://www.appliedclinicaltrials.com/non-adherence-direct-influence-clinical-trial-duration-and-cost>