

Aidia System

Category:

Best Digital Health Solution

Company Name:

AdhereTech

Number of employees:

11-50

Turnover and/or Funding:

We have raised \$17 million in the past year, our main investor is Argentum PE.

Product/Solution Name:

Aidia System

Corporate Name:

Digital Medical Technologies LLC

Date of Approval:

2023-04-27

Indications:

Psychiatry, oncology, neurology, cardiology

Therapeutic Areas:

Cardiovascular, solid tumors, HIV, leukemia, glaucoma, mental health, ADHD, asthma, epilepsy, sickle cell disease, cystic fibrosis, diabetes, kidney transplant, hyperparathyroidism, hepatitis C, addiction, menopause, and sleep studies

General Information File Document upload:

N/A

Background information and need for drug / device:

An estimated 50% of Americans don't take their medications as prescribed, leading to over \$100 billion in avoidable healthcare costs and 125,000 preventable deaths annually. This problem begins when medicines are developed, but fail to account for human behavior.

Quoting Mark Twain, \"It ain't what [we] don't know that gets [us] into trouble. It's what [we] know for sure that just ain't so.\"

Over \$80 billion is being annually invested in the clinical trial industry worldwide, but only 7.9% of these trials result in new drugs successfully reaching patients. Despite the clinical trial market being projected to nearly double, reaching \$153.59 billion by 2033, trial success rates for phases II and III are declining. The economic and humanitarian consequences of such failures are immense. Yet, little consideration is given to one of the most influential factors: Are patients even taking their medication(s)?

If the processes involved in establishing and remaining adherent, add to patient burden, it's unlikely to become an established habit. Unsurprisingly, humans often struggle to take their medication consistently, resulting in 40% of clinical trial participants becoming non-adherent after 150 days.

To compensate, studies must enroll additional participants to maintain statistical power. For instance, a Phase III study with 368 patients with 40% nonadherence would require researchers to enroll 460 additional participants, adding an estimated \$14.31 million to trial expenses. The MOUNTAIN Phase III trial for Major Depressive Disorder (MDD) (SAGE therapeutics) offers evidence of the significant consequences of failure to account for nonadherence, including layoffs, over a billion loss in estimated peak annual sales, and the prevention of access to a potentially life-altering treatment for patients.

Despite these consequences, trials continue to use dated and highly inaccurate adherence measures, such as e-diaries and pill counts, which have repeatedly been shown to underestimate actual adherence, estimated to be only 27% and 60% accurate respectively.

While more direct measures, such as expensive, intrusive blood draws are sometimes used, white coat adherence can occur (when a patient is more adherent to their regimen only in the days leading up to a study site visit). Without assessing these measures daily, which places an additional burden on patients by requiring them to take time off work, find childcare, or cover transportation costs, such measures may not accurately reflect the patient's true adherence. While video capture systems have been developed to address these downsides, their ability to determine adherence remains limited. Given these devices often require patients to log into a mobile application and record themselves, the additional burden and intrusion into patient lives associated with these further risks adherence.

Given the issues posed by existing measures, an ideal solution must work with patients, as opposed to against them, by minimizing burden, enhancing autonomy, and integrating seamlessly into their daily routines. Working in real-time to support and monitor adherence enables timely intervention, which is fundamental for ensuring that the billions invested in clinical trials translate to tangible benefits for patients, ensuring

life-saving treatments reach patients in need.

Background File Document upload:

[AdhereTech Aidia System References Background.pdf](#)

History of the development of the solution/product:

Medication nonadherence is one of the largest global health crises. About 50% of patients with chronic conditions do not take their medications as prescribed, contributing to 10% of hospitalizations, 125,000 preventable deaths, and over \$100 billion in unnecessary healthcare spending annually. As early as 2003, the WHO emphasized the need to address this crisis, citing that "increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments."

AdhereTech was founded in 2011 to directly address the pitfalls of existing adherence monitoring systems by creating a patient-centered solution that minimizes burden and seamlessly integrates into patient's daily lives. The company's original product, the Smart Bottle, resembled a traditional pill bottle, allowing patients to take their medication normally while automatically tracking doses in real-time via cellular data. This eliminates the need for manual input, mobile app installation, smartphones, invasive monitoring systems, and/or WiFi. Over time, AdhereTech advanced the smart bottle with 4G AT&T global coverage, and a rechargeable battery, lasting up to 10 months. AdhereTech's impact on medical device innovation has been widely recognized. The company won the Healthcare Innovation World Cup in 2013, received the A'Design Award in the medical devices category for 2016-2017, and was featured by the Smithsonian Design Institute in 2017.

AdhereTech's clinical promise has been reinforced by numerous studies. In 2019, a randomized trial in multiple myeloma patients found a 12.6% increase in adherence (100% v. 87.4%, $P = 0.001$) and higher dosing precision (83% v. 22%, $P < 0.001$) in patients with activated AdhereTech devices. In 2021, a pivotal HIV study demonstrated a high correlation between AdhereTech bottle openings and drug concentrations, validating the system's clinical accuracy (+278 v. -38 fmol/punch, $p = 0.04$). A 2023 Phase II Asthma study using AdhereTech found that 90% adherence was achieved by more than 90% of participants by the end of the trial at week 12.

In 2023, AdhereTech launched the Smart Cap, which retains all the Smart Bottle features, but fits directly onto patients' existing medication bottles. This eliminated the need for costly and time-consuming drug stability retesting, further reducing patient burden and expanding opportunities to support global clinical trials. Like the bottle, the smart cap includes a robust, backend data platform that provides sponsors with the ability to track and actively manage patient adherence behaviors in real-time, allowing timely interventions and insights into patient populations. Additional capabilities include temperature sensing, internal sensors to detect if patients are dumping or skipping doses, refill prediction and monitoring, and battery tracking, minimizing patient burden and ensuring accurate adherence assessment.

Given the company's success in previous clinical trials, the company's recent strategic shift to focus on clinical trials has driven significant momentum, leading to new partnerships with AbbVie and BMS within the past year. Throughout its evolution, AdhereTech has remained committed to empowering patients and delivering a practical, tech-enabled, and low-burden solution to one of healthcare's most persistent and costly challenges.

Development File Document upload:

[AdhereTech Aidia System References Development.pdf](#)

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

AdhereTech's Aidia system offers a groundbreaking, real-time, data-driven, and patient-friendly innovation for assessing adherence within clinical trials. Patients are familiar with taking pills from bottles. AdhereTech leverages this to fit seamlessly into their routines, partnering with them to help establish and maintain adherent behaviors. Traditional methods, such as e-diaries and pill counts, rely on retrospective and often inaccurate reporting, increasing patient burden and the risk of a failed trial. While blood draws and plasma levels are more objective, they are expensive, intrusive, and susceptible to "white coat adherence," jeopardizing data integrity.

Meanwhile, existing electronic and video systems introduce added complexity, requiring apps, video uploads, or stable Wi-Fi, which disrupt habits and complicate routines. The intrusive nature of this approach also raises significant privacy concerns across non-US countries. These limitations can lead to misinterpretation of a drug's efficacy and failed treatments, not because they don't work, but because patients don't take them consistently.

Aidia directly addresses these gaps with a patient-centered, cellular-based approach that seamlessly integrates into patients' lives. Its smart devices are customized to each patient, minimizing burden and automatically tracking adherence in real-time. The system is designed to work with patients to help establish and maintain adherence behaviors, gently nudging those at risk of nonadherence via lights and chimes, followed by text messages prompting patients to explain missed doses. Behavioral reinforcement messaging encourages patients, while escalation protocol alerts clinical trial sites when patients require intervention, enabling timely support and preserving trial integrity.

The system's innovation lies in both its patient-centered design and infrastructure recognized by the Smithsonian Design Institute. It operates globally via cellular data, eliminating the need for Wi-Fi or smartphones to ensure broad accessibility and consistent data transmission. Devices store up to 500 readings offline, which upload automatically once back in range. Study investigators gain instant access to detailed adherence behavior, enabling proactive patient support. This precision allows for notification of missed or skipped doses, that could otherwise skew efficacy outcomes or

mask a drug's true therapeutic potential.

Numerous studies emphasize Aidia's effectiveness. Ellsworth et al. (2021) demonstrated a significant increase in TFV-DP levels in patients with HIV (+278 v. -38 fmol/punch, $p = 0.04$). The 2019 Avella multiple myeloma study showed a 12.6% adherence increase ($P = 0.001$) and greater dosing precision (83% v. 22%, $P < 0.001$) among users of Aidia's activated devices compared to controls, underscoring its clinical relevance.

Aidia ensures that clinical trial data reflects true drug efficacy, reducing the risk of promising treatments failing. Broadly, Aidia is reshaping the design and conduct of clinical trials. Most trials currently enroll at least 15% more participants than necessary to offset the effects of nonadherence on a study's power. By improving adherence, Aidia holds the ability to maintain statistical power with fewer participants and optimize effect size. With 80% of trials struggling with delays due to recruitment challenges, costing up to \$40,000 daily, this technology offers the potential for meaningful cost savings for sponsors and the acceleration of access to life-saving treatments.

Innovation File Document upload:

AdhereTech Aidia System References Solution.pdf

Please provide appropriate references (PubMed, Abstract, Website):

AdhereTech. (2025). AdhereTech.Com. <https://adheretech.com/>

Ellsworth, G. B., Burke, L. A., Wells, M. T., Mishra, S., Caffrey, M., Liddle, D., ... & Gulick, R. M. (2021). Randomized pilot study of an advanced smart-pill bottle as an adherence intervention in patients with HIV on antiretroviral treatment. *JAIDS Journal of Acquired Immune Deficiency Syndromes*, 86(1), 73-80.

Mauro, J., Mathews, K. B., & Sredzinski, E. S. (2019). Effect of a smart pill bottle and pharmacist intervention on medication adherence in patients with multiple myeloma new to lenalidomide therapy. *Journal of Managed Care & Specialty Pharmacy*, 25(11), 1244-1254.

Newman-Casey, P. A., Niziol, L. M., Lee, P. P., Musch, D. C., Resnicow, K., & Heisler, M. (2020). The impact of the support, educate, empower personalized glaucoma coaching pilot study on glaucoma medication adherence. *Ophthalmology Glaucoma*, 3(4), 228-237.

Siddiqui, S., Wenzel, S. E., Bozik, M. E., Archibald, D. G., Dworetzky, S. I., Mather, J. L., ... & Prussin, C. (2023). Safety and efficacy of dexpropionresorcinol in eosinophilic asthma (EXHALE): a randomized controlled trial. *Journal of Allergy and Clinical Immunology*, 152(5), 1121-1130.

References File Document upload:

AdhereTech Aidia System Ellsworth et al 2021.pdf

AdhereTech Aidia System Mauro et al.pdf

AdhereTech Aidia System Siddiqui et al 2023.pdf

AdhereTech Aidia System Newman et al.pdf