Case Study: Leveraging AI for Meaningful Clinical Trials

Clinical trial sponsors seeking to develop new drugs and therapies face unique challenges, particularly when it comes to understanding patient dosing and response to therapy. This aspect can be difficult, as patients often:

▶ Do not take their medicine regularly, or at all

▶ Take creative measures to hide their non-adherence

▶ Have symptoms that make it difficult for clinicians to monitor and measure adherence

Traditional standards for understanding patient dosing are a) inefficient (enrolling additional patients increases costs), b) unreliable (pill counts can be easily falsified), and c) inconclusive (blood draws for PK measures). Because of these challenges, solutions must be identified and implemented that support patients and trial sites as well as help address the unique approaches necessary for successful clinical studies.

Building a Solution That Works

Problems with patient compliance spurred the need to develop ways to accurately monitor and measure medication dosing. By using

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their own smart devices, patients can follow simple instructions for taking their medications per protocol, and an application can utilize the device's camera to recognize:

▶ That the patient is the correct person

▶ That the dose being taken is correct: it is the correct drug and the correct amount

▶ That the dose has been swallowed

This, coupled with dosing reminders and simple-to-use tools for receiving site support, help to keep even the most challenging patient populations more adherent.

Negative Symptom Detection

Additionally, leveraging AI and computer vision on a cellphone platform enables the detection of a range of digital biomarkers that are well-suited for addressing the specialized challenges presented by patients across therapeutic areas. This is particularly true of negative symptoms, such as lack of facial affect, the inability to show emotion and apathy. New applications, via artificial intelligence, monitor changes in facial affect as well as changes in vocal characteristics via the smart device's microphone. The AI also works to help identify doses that were confirmed to have been successfully taken, and flag any doses where patients require further support, sharing the latter with the study team. This helps save time, as it helps to decrease the amount of human review time typically needed with high-risk patient populations.

Optimized Patient Pools Via Predictive Technology

AI technology is also useful before the trial begins. Using facial and voice measures, this technology can be utilized to screen potential candidates and build accurate, predictive models that help to optimize the patient pool with those patients most likely to be reliable followers of the care plan.

Real Impact for Your Studies

By integrating technology into therapeutic studies, teams can expect real, measurable benefits:

▶ Increased patient engagement and adherence: Real-time recording of each dose, along with easy access to site support, build a foundation for compliance

▶ Optimized patient groups for more efficient, faster trials: Predictive technology lets you limit the number of patients enrolled to those most likely to deliver reliable data

▶ Decreased site burden: Using AI and technology enables the ability to flag possible problems in real-time, and site teams can focus on providing the right levels of support

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> **AiCure** *is an AI and advanced data analytics company that monitors patient behavior and enables remote patient engagement in clinical trials.*
> *For more information, aicure.com.*