Failure Risk in Clinical Trials? An Easy-to-Swallow Solution

By Valerie Sullivan, President and CEO, etectRx

Clinical trials are now a household topic thanks to COVID-19. With the eyes of the world upon our industry, several drug companies have – with success – developed and tested effective COVID-19 vaccines and treatments in record time.

Yet it is worth a reminder that drug development is usually an exceptionally long process, with many pitfalls along the way. Pharmaceutical companies spend enormous amounts of time and money ensuring that new medications are efficacious, safe, and well tolerated. The reality is that the work of conducting a clinical trial is painstaking, and while a faster path to trial results is desirable, researchers know all too well that speed and quality do not always go hand-in-hand.

When Clinical Trials Fail

According to a review article published in *The Journal of the American Medical Association* in December 2016, 344 of 640 trials for novel therapeutic drugs failed. The majority failed due to the inability to demonstrate efficacy. This is an alarming number. The estimated cost of a single clinical trial between 2015-2017 ranged from $12 million to over $33 million according to a *BMJ Open* June 2020 publication. The pharmaceutical industry is estimated to spend a minimum of US$180 billion globally in 2022 on R&D expenditure according to ABI Research published in April 2020. The spend on a single clinical trial is magnified when trials fail.

One of the biggest risks to a clinical trial is patient non-adherence to study medication, which can negatively affect the ability to demonstrate drug efficacy and safety. There are countless options available to combat the problem, such as journal tracking, blister packs, pill counts, electronic pill bottles and patient interviews/observation. But none of these have been proven to unequivocally demonstrate medication ingestion.

The Digital Pill Solution

etectRx has a new solution for medication adherence: a digital pill system with a coinciding time stamp of ingestion. etectRx, a digital health company, received FDA clearance in late 2019 for its four-part ID-Cap™ System. The Class II medical device is comprised of a hard gelatin capsule embedded with an ingestible sensor. Most oral medications can be re-encapsulated inside the ID-Capsule, which sends a digital message from within the patient's body to a wearable reader to confirm patient ingestion of prescribed medication. Patients and clinicians can view ingestion data as dosing occurs; when needed, the clinical team can intervene to support trial participants in their efforts to stay adherent to study medication.

Since its FDA clearance, the etectRx ID-Cap System has demonstrated the ability to provide researchers and clinicians with objective confirmation of ingestion, thus producing reliable data around medication adherence. This real-time ability to monitor dosing allows greater

confidence in efficacy and safety data collected and reduces the risk of inaccurate data … or at worst, a failed trial due to poor adherence.

ID-Cap System in Real-World Settings

Another trend supporting the need for digital pill solutions like the etectRx ID-Cap System is the lightning-fast growth of telehealth in 2020, largely due to COVID-19. Telehealth adoption increased by 154% in March 2020 alone, according to the CDC. Remote patient monitoring not only lowers the costs of clinical trials, but combined with the etectRx ID-Cap System, can increase drug efficacy in real-world settings.

In a study at Fenway Health, researcher Dr. Peter Chai used the etectRx ID-Cap System to measure adherence to once-daily TRUVADA as pre-exposure HIV prophylaxis. Among individuals within the study population who were interviewed prior to the study start, 63% responded favorably to use of a digital pill system. In a recent study, the etectRx ID-Cap System was shown to be 98% accurate when used correctly. Tracking since January 2021, the etectRx ID-Cap System is demonstrating over 99% accuracy in an ongoing clinical research trial.

etectRx has 15 IRB-approved clinical studies completed; over 5,900 ingestions in almost 300 study participants; 15 issued patents; and an industry-leading product roadmap.

Widespread use of digital pills in conjunction with remote patient monitoring will take time to achieve. However, research teams within pharmaceutical companies can see immediate benefits through the implementation of digital pill solutions in clinical trials to reduce failure rates due to poor medication adherence.