

The purpose of a Clinical Trial is to test a scientific hypothesis that a medicine or a medical intervention has a positive impact upon patient outcomes. One of the key challenges, given that up to 60% of drug development costs are consumed in the execution of clinical trials¹, is the ability of a Sponsor to execute the study in the real world, as per protocol, to answer the scientific hypothesis under investigation.

How will a Clinical Trial Digital Monitoring Platform add value?

- 1. Increase R&D Productivity** driven by better informed key investment decisions about program progression or termination. Currently the industry's average success rate for an asset entering Phase I to becoming an approved medicine is circa 12%². Any system that improves the chances of progressing the right assets has significant value given that the cost to develop a medicine is circa \$2.6B³.
- 2. Accelerated Clinical Development / Time to Market.** Current industry standards demonstrate that 84% of studies are delayed by 1-6 months driven by challenges with patient recruitment and retention⁴.
- 3. Reduced Study Costs.** Smaller studies maintained by improvements in patient retention and adherence directly influence patient variable costs, representing nearly 24% of total trial costs.⁵



How can you gain an edge on uncertainty and protect your investment?

With the advent of the Internet of Medical Things (IoMT) and Cloud Based Data Management Systems there is an opportunity to transform how Clinical Trials are executed. Data sets collected in real time enable Study Investigators to more proactively manage study participants with richer insights testing the Scientific Hypothesis and supporting more informed decision making at key investment milestones.

What is the Clinical Trial Digital Monitoring Platform?

Our Platform remotely collects data from patients in a real-world setting, using the Internet of Medical Things, and is managed in a proprietary cloud-based data management system. The system is fully configurable to operate with different drug delivery systems, wearable technologies and smartphone platforms or a combination thereof. While the platform is device agnostic, Jabil Healthcare has also developed a ready-to-go connected re-usable autoinjector to provide a flexible cost-effective delivery device capable of supporting both clinical trials and commercial use. Following an in-depth review of the clinical portfolio of our target customer base, we have selected this connected re-usable autoinjector for our first iteration of the platform.

What will the Clinical Trial Digital Monitoring Platform enable?

The integration of these technologies has the potential to accurately measure, outside the study centre, real time adherence, correct usage of the drug delivery system, measurement of vital signs related to every dosing event, longitudinal measurement of surrogate efficacy biomarkers (i.e. activity, sleep) and longitudinal psychosocial data. Digital monitoring enables more consistent conversation and timely action with study participants, empowering more proactive management of the study by sponsors.

[1] Lechleiter, John, CEO Lilly, Forbes Magazine, July 21, 2015

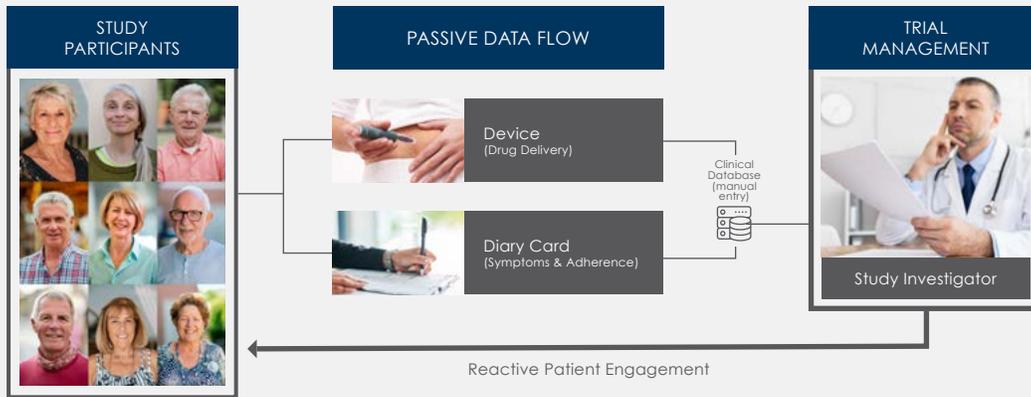
[2] Di Mazzi et al., Journal of Health Economics, Volume 47, May 2016, Pages 20-33

[3] Di Mazzi et al.

[4] Thadani et al., JAMIA, Volume 16, Issue 6, November 2009, Pages 869-873

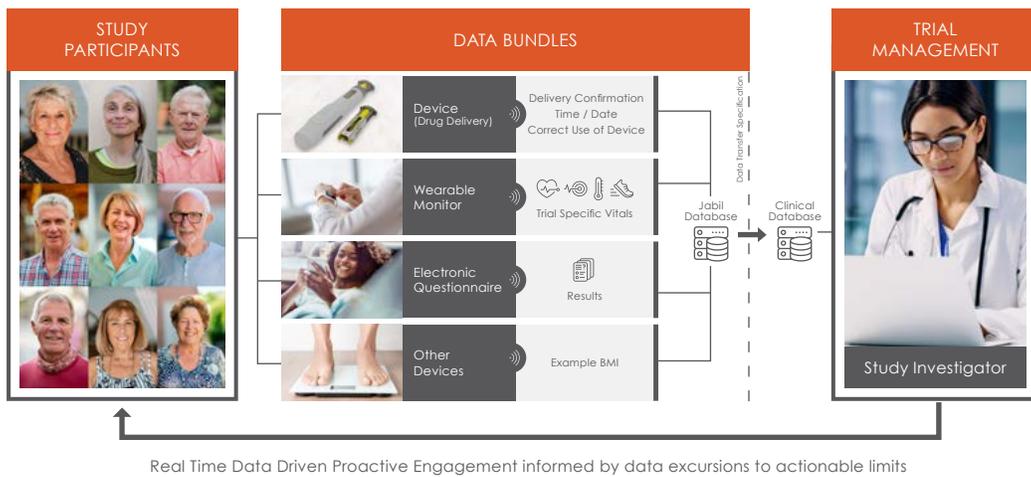
[5] Sertkaya et al., Report, U.S. Department of Health and Human Services, July 2014

TRADITIONAL METHOD



- Assumes adherence and correct usage
- Physiological attributes limited to study centre visits
- Patient reported outcomes limited to study centre visits
- Complex data workflow process
- More passive management of study participant in the absence of real time data

JABIL CLINICAL TRIAL DIGITAL MONITORING PLATFORM



- Assures real time adherence and correct usage
- Physiological attributes linked to dosing events
- Longitudinal measurement of physiological attributes
- E-patient reported outcomes not limited to study centre visits
- Data management solution works in parallel with current data workflow
- Informs decision making about patient recruitment / study timelines in real time

BENEFITS

Empowers Study Investigator to focus on those participants who struggle to follow the Study Protocol

Reduces Study Costs through improved patient retention, adherence, compliance, and persistence

Accelerates clinical development & time to market from smaller and shorter studies

Enables more effective study execution through data-driven participant engagement to test the Scientific Hypothesis

Enables better informed decision making at key investment milestones

Supports decentralised and hybrid clinical trial models and integrates seamlessly with existing business processes

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