INSIGHTS TO ACTION: A tech-enabled operational monitoring and reporting framework to achieve high adherence in clinical trials

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Methodological issue being addressed

Good medication adherence is necessary for clinical trials. While tech-enabled tools can provide mechanisms to uncover non-adherence, ongoing data monitoring and effective interventions at the clinical site and participant levels are still needed to drive adherence outcomes for trials.

Introduction

- In a clinical trial, participant non-adherence to study medication can poorly impact efficacy outcomes, reduce statistical power, and require increased sample size.
- Non-adherence can be intentional or non-intentional and may be dependent on external influences.
- Timely site-led intervention, or participant follow-up, is an effective way to alter a participant's behavior and restore adherence. However, behavior from both the site staff and participant influence adherence outcomes, and the site must have insight to when non-adherence occurs.
- Advancements in artificial intelligence have made it possible to deploy a smartphone-based computer vision tool (Platform) to directly observe medication ingestion, allowing sites to detect participant non-adherence with confidence. Yet, there are many sites that are not effective or consistent at taking interventional action to restore participant adherence.
- Clinical Quality Improvement (QI) methodology such as Six Sigma can be utilized to facilitate data-driven outcomes and is commonly used in hospitals to improve patient outcomes.
- We developed a QI based operational monitoring and reporting framework (**Clinical Site Monitoring; CSM)** to drive adherence outcomes utilizing Platform data.

Figure 1: *Medication adherence capture via the Platform*

Disclosures:
One or more authors report potential conflicts which are described in the program.

Methods

Methodology - Clinical Site Monitoring (CSM)

- CSM is a two-pronged approach utilizing Plan, Do, Study, Act (PDSA) cycles at the sponsor-level and Rapid Improvement Cycles (RIC) at the site-level to drive adherence outcomes on a clinical trial.
- Within our PDSA cycle we agree upon standardized success metrics prior to the start of a clinical trial, align on strategy, complete short-cycle monitoring and analysis of data against our success metrics, and drive improvement initiatives.
- Upon trial commencement, we use RIC to monitor Platform collected adherence data in real-time and intervene with the site, prompting timely and effective participant follow-up.
- On a quarterly basis, results of the site-level RICs are aggregated, analyzed, and fed back into the sponsor PDSA cycle.

Figure 2: *PDSA Cycle (Sponsor/CRO)*

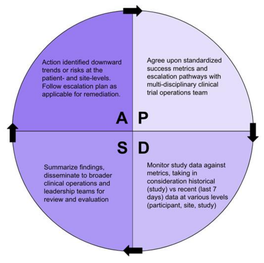


Figure 3: *RIC (Site)*

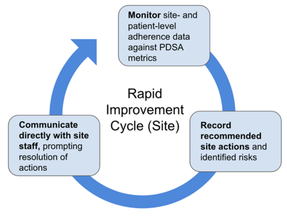
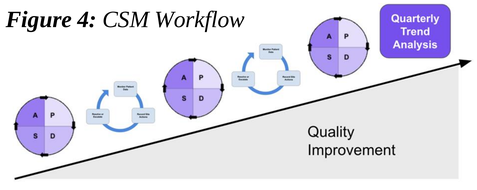


Figure 4: *CSM Workflow*



Methods - Study Design

- A retrospective cohort study to evaluate medication adherence rates of clinical trials using the Platform, before the implementation of CSM (PRE) and after (POST).
- We obtained de-identified participant adherence data from 38 (25 PRE; 13 POST) phase I-III clinical trials that utilized the Platform from 2021-2024.
- A total of 7967 participants from 42 different countries were included.
- Overall medication adherence rates for each participant were calculated as a percentage of expected doses taken and included all possible dose reporting mechanisms in the platform (visual confirmation, self-report, or site-confirmed).
- Nonparametric tests were used to compare outcomes between groups.

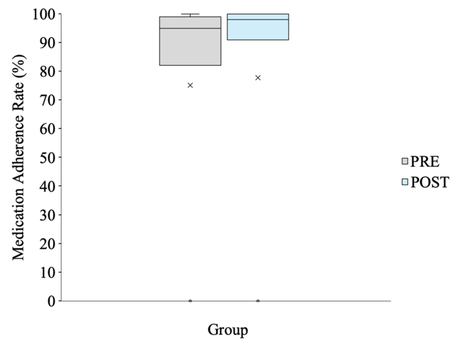
Results

We saw significant improvements in the POST-CSM group for overall medication adherence, visually confirmed medication adherence, and the number of missed doses per participant.

Table 1: *Summary of Results*

	PRE	POST	*p*
Overall medication adherence, median [IQR]	95 [82, 99]	98 [91, 100]	<0.001*
Visually confirmed medication adherence, median [IQR]	90 [71, 98]	95 [84, 99]	<0.001*
Missed doses per participant, median [IQR]	4 [1, 16]	1 [0, 8]	<0.001*

Figure 5: *Overall Medication Adherence*



Conclusion

CSM is an effective, data-driven approach to achieving improved targeted adherence goals on large scale clinical trials. Timely engagement with sites and patients during a clinical trial is essential to maintaining adherence.

Discussion & Next Steps

- We utilized the first 14 days of the participants clinical trial participation (Critical Window; CW) to support them in building a habit of logging daily medication, and had focused key drivers during this time. Next steps would be to evaluate the effectiveness of the CW and correlation to overall medication adherence rates.
- Quantify feedback from clinical operations and site teams
- Evaluate CSM effectiveness by team engagement measures such as action item resolution time.