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Quality and innovation in clinical trial services

# News Release

## Trialwise Deploys Innovative Risk Adaptive Monitoring Approach in Multicenter Phase 1 HIV-Related Clinical Trial

Boutique CRO's Proprietary Risk Based Methodology Advances Clinical Trial Monitoring Techniques

**FOSTER CITY, CA,** June 10, 2024 — A multi-site Phase 1 clinical trial of up to three dozen participants living with HIV is receiving the benefits of the rollout of Trialwise's proprietary framework to enable risk-based monitoring in early phase clinical trials. Working in collaboration with the study sponsor since May 2022, Trialwise finalized its Risk Adaptive Monitoring Plan for the trial and implemented the methodology this year.

Biotech industry nonprofit TransCelerate Biopharma established its Risk Based Monitoring (RBM) initiative in 2012 with the goal of transforming the way clinical trials are monitored to gain improved data quality and patient safety while reducing efforts spent on low-value activities. Risk Based Monitoring received renewed attention during the pandemic as traditional monitoring approaches proved unworkable.

Adaptation of a risk-based approach to Phase 1 trials limited by smaller data sets, however, proved to be a challenge. Trialwise founder and president, Beth Brinsdon, has long been searching for creative ways to implement this new approach for the early phase studies the company specializes in.

"Many sponsors have the misconception that a risk-based approach is about doing less," says Brinsdon. "But this is not the case. The risk adaptive process relies less on issue identification followed by corrective action and more on risk identification and assessment that is forward-looking followed by proactive initiatives.

"This new study and the proprietary methodology we developed for it," Brinsdon adds, "demonstrates how risk-based monitoring can become workable for smaller, multicenter, Phase 1 studies as well. The method is a fit for purpose approach with no platform fees that leverages available data sources."

**About Trialwise**
Trialwise, Inc. is a woman-owned contract research organization (CRO) founded in 1999. The company specializes in Phase I and Phase II clinical studies. As a boutique CRO, Trialwise functions as an extension of a sponsor's organization to ensure the clinical trial process is managed expertly and efficiently without compromising quality, accuracy, or adherence to protocol and regulatory compliance.
https://trialwise.com/

**Media Inquiries**
Beth Brinsdon
info@trialwise.com