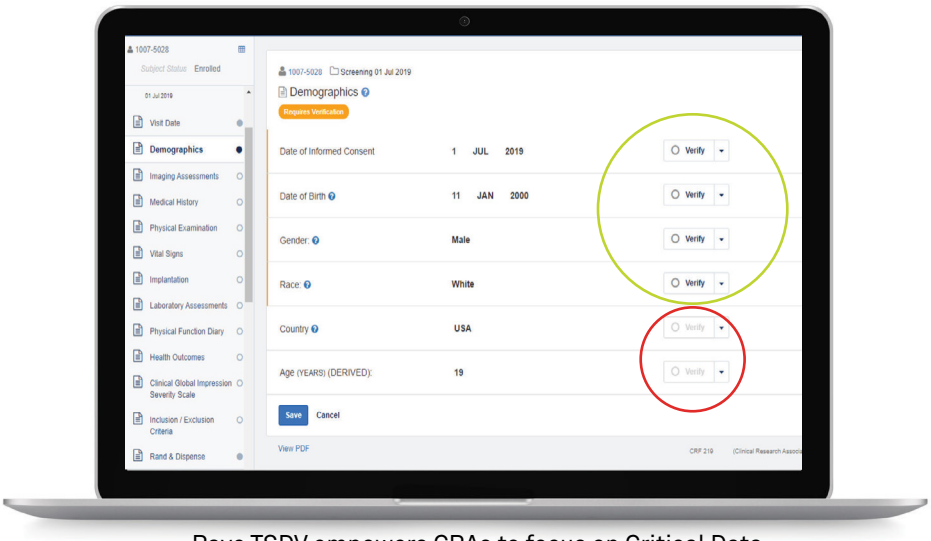
Rave TSDV
Improve Clinical Research Associate (CRA) Efficiency and Reduce Site Burden

Source data verification (SDV) is a critical activity within clinical trial monitoring, yet the traditional approach focused on 100% SDV is limited in its ability to quickly identify issues and prevent them from recurring. In taking an RBQM (Risk-based Quality Management) approach to trial management, 100% SDV is not an effective use of valuable CRA resources. Rave TSDV (Targeted SDV) , unified with Rave EDC, enables CRAs to focus on critical to quality (CtQ) factors identified within risk management activities. It identifies Rave EDC folders, forms, and data fields that will be selectively 'targeted' for SDV. Rave TSDV provides a simplified approach to defining, monitoring, and adjusting SDV strategies, resulting in reduced CRA and site burden, reduced data cycle times, and improved data quality.



Rave TSDV empowers CRAs to focus on Critical Data

Product Benefits

Rave TSDV is simple to implement and can be configured as your study needs change and grow. The reduced effort to implement and adjust Rave TSDV allows your cross-functional teams to focus on other, more important activities.

Easily Execute a Reduced SDV Strategy

- Define simplified SDV tiers based on criteria identified as part of study-level risk assessment
- Assign subjects as they are enrolled using statistical methods
- Execute SDV while tracking and remediating issues as they are identified

Better Manage Your Study Team's Time

- CRAs complete targeted SDV activities with the same strategy used for 100% SDV
- Data managers can pre-set study and site-specific SDV plans
- Study managers have full visibility into SDV assignments, progress, and modifications made during the trial lifecycle

Features

Supports ICH GCP E6 (R2) & E8 (R1) Compliance

Apply a risk-based approach to clinical operations activities while maintaining a complete inspection ready record of what was verified and not verified

Study-specific and site-specific SDV plans configuration

Data managers can plan study-specific and site-specific SDV all the way down to the data field, form and patient visit levels

TSDV Efficiency Quantified

33% ↓

in Monitoring Days On-Site versus Studies without TSDV

4 monitoring days / year / site for a study[1]

12% ↓

in Total Query Rate versus Studies without TSDV

Total Query Rate: # of Queries per 1000 data points[2]

[1] For studies with TSDV and < 50% SDV coverage; Statistically significant with $p<0.05$
[2] For studies with TSDV and < 50% SDV coverage; Statistically significant with $p<0.05$

The Medidata Advantage

Rave TSDV, unified with Rave EDC on the Medidata Platform, is a foundational step towards clinical optimization. In a matched cohort analysis of over 25,000 studies, Rave TSDV showed a significant reduction in on-site monitoring effort, with no significant negative impact on data quality. When implemented as part of a robust RBM/RBQM strategy, Rave TSDV enables study teams to focus their efforts efficiently and effectively.