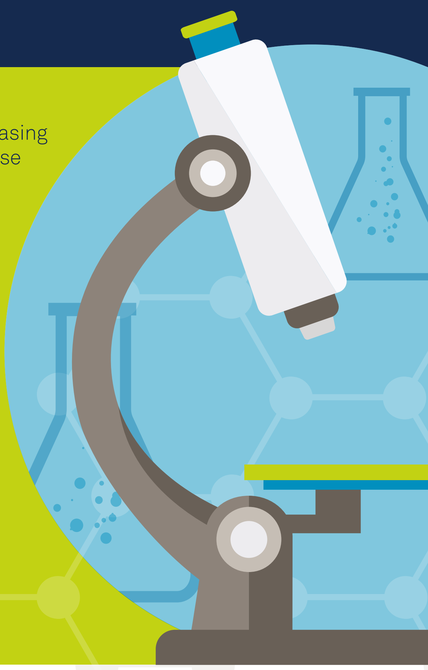
The Winning Formula for Consistent, High-Quality Clinical Data: **Rave CSA** (Centralized Statistical Analytics)



Today's clinical trials are faced with increasing digital sources, more sophisticated disease states, greater regulatory scrutiny, and more advanced genomic research, all adding to increased trial complexity.

This, coupled with tight time constraints, recruitment issues, potential fraud, data quality, and manual processes, makes trials more challenging than even just a few years ago, impacting chances of regulatory approval. With up to **one in six[1] new drug applications** failing during first-cycle approval, this can have significant impact on revenues. The difference in approval time between applications receiving first-cycle approval and those requiring multiple cycles is **17.9 months.[2]** That is a year and a half faster to market by securing first-cycle approval.

As currently proposed regulatory guidance[3] recommends, analytics in monitoring are a required part of any quality-assurance plan. What are the tactics that can help your organization identify issues, and ensure quality data for regulatory submissions?

Here are some steps to consider

Access automated analysis techniques

The ability to collect and compare **thousands** of different fields, without the need to standardize the data first, can save **weeks** of manual investigation and increase your chances of clinical-trial success.

Reveal and resolve data anomalies

Identify data anomalies sooner by providing a dashboard of patient profiles, data listings, summary tables, and cross-tabs.

Understand patients remotely

Prepare for site visits in advance by remotely accessing patient information beforehand.

Gain immediate insights

To better understand potential problems and risks, consolidate data across multiple sources to build in-depth patient profiles and protect data quality.

Access centralized collated data

Increase productivity across your workforce with easy access to clinical and operational data, collated in one location.

Rave CSA processes over **1,000,000** data points and finds over **4,000** patterns in less than one hour, helping to quickly detect and resolve data changes—injecting certainty into your clinical trials. A comprehensive solution, it provides immediate insight into performance and data quality, as well as in-depth reports for each subject, making it even easier for your teams to carry out successful clinical trials and be better prepared for regulatory submissions.

To see how you could benefit from Medidata CSA, visit:
https://www.medidata.com/en/products/centralized-statistical-analytics/

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[1] Scientific and Regulatory Reasons for Delay and Denial of FDA Approval of Initial Applications for New Drugs, 2000-2012, JAMA. 2014;311 (4):378-384
[2] Why NMEs and Therapeutic Biologicals Fail in the First FDA Review Cycle, The RPM Report, Elsevier Business Intelligence, March 2013, with slight modification.
[3] http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Addendum_Step2.pdf