OPRA: Data Sheet

R2 compliance, central monitoring and RBM made simple!

OPRA is the leading platform for anyone wishing to oversee quality, and practice central monitoring or risk-based monitoring for their clinical trials. OPRA is cloud based, fully validated, 21 CFR part 11 compliant and very simple to use. Our technology enables companies to prove their compliance to ICH E6 (R2) through the innovative combination of data visualization, statistical modeling, decision-making support, activity management, and time base audit trials. If you are looking to improve trial data quality, reduce trial monitoring costs and prove compliance to ICH E6 (R2), then OPRA is all you need.

Central and risk-based monitoring
OPRA offers full support for both central and risk-based monitoring approaches.

Dynamic user interface
OPRA features a fully dynamic interface, allowing users to get the exact view on data that they need.

Study and site dashboards
View study data at the level you need to assess and make data driven decisions.

Source data agnostic
Full, time-stamped audit trail of activities and system changes.

TRI is a complete solution provider for ICH E6 (R2) compliance, quality management, central monitoring and RBM.

KRI library
Choose from a library of 20 industry standard, pre-validated indicators or choose your own.

Integrated statistical models
Our KRIs use a range of statistical models, which are fully integrated into our data visualizations.

Quality trend analysis
View study data at the site and KRI level to see how actions are impacting quality over time.

Configurable thresholds and weighting
Study data can be rolled back at any time to show how visualizations looked at a previous assessment point.

Drill down and data review
Drill down from study to site to patient data and perform data review and root cause analysis.

Historic data view
Roll back data at any time through the UI to see how the data looked and see why decisions were made at that time.

21 CFR Part 11 compliant
OPRA has gone through a full SDLC, is fully validated and 21 CFR part 11 compliant.

Audit trail
A complete, searchable audit trail allows a comprehensive view of who did what and when in the system.

Per study pricing
Simple per study, per month pricing structure scaling on study complexity.

Activity management
Create observations and actions at site and KRI levels. Manage actions through to completion.

Engage with one of our specialists to find out how we can help your firm become ICH E6 (R2) compliant.	US & Canada: **+1 484 803 2984** Europe: **+44 (0) 20 8817 5296** Email: **info@tritrials.com** Website: **https://tritrials.com**

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