Shafi Consultancy Ltd.

Shafi Chowdhury
Managing Director

“At Shafi Consultancy, we have a well earned reputation for our Risk-based-monitoring application. CRAs in over 70 countries have already used our easy-to-use system. We go the extra mile to meet all your expectations.”

About Shafi Consultancy

Founded in 2001, Shafi Consultancy Ltd. is an established Consultancy firm based in the U.K. with significant **offshore** support from our office in Bangladesh.

We provide **SAS programming and Web application support** for all aspects of the clinical trial process, from **aiding site monitoring visits** and writing **data checking programs**, to producing analysis datasets, tables, listings and figures. Our consultants have experience with data from phase I to phase IV studies, registry studies and mega trials in many different therapeutic areas, including respiratory and oncology. We have been involved in risk based monitoring for many years, and our **WHAT-2-SDV is ideal** for all types of trials, including **outcome studies**.

Who are our clients?

Our client base includes multinational pharmaceutical companies, CROs and management consultancy firms from the U.K., France, Germany, Switzerland and the U.S. Most of our work is **repeat business**, demonstrating the quality and reliability of everything we do.

Our experienced consultants are trained to join your team running!

Our many years of experience in risk-based monitoring means we can **share our knowledge** and quickly implement the solution that is perfect for your needs.

Our standard programs and macros make it possible to implement client specific solutions with the minimum of effort.

Contact us to see how your organisation can benefit from a growing partnership with us

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Risk-Based Monitoring with WHAT-2-SDV

Did you know?

- ✓ WHAT-2-SDV web application has been developed with CRAs
- ✓ Used by CRAs in more than 70 countries
- ✓ Can be implemented within 2 months

Contact us to see a demonstration of WHAT-2-SDV

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Risk-Based Monitoring with WHAT-2-SDV

What is WHAT-2-SDV

WHAT-2-SDV is a web application for risk-based SDV that **improves the quality** of data in clinical trials. This has been developed together with CRAs to ensure that it supports their monitoring visits and is both **intuitive** and **easy-to-use**.

WHAT-2-SDV is a proven tool that is used on a daily basis by CRAs in more than **70 countries** for almost **3 years**. The system has overwhelming support from the CRAs, especially how it helps them to plan their visits and save time. **The system specifies what to SDV for which patient**, and so they no longer have to do 100% SDV. This now leaves them more time to amongst others, perform GCP checks, staff checks and training, look for fraud and check compliance issues.

WHAT-2-SDV integrates with all existing systems and can be used with minimum training. It can be implemented within 2 months.

Time to stop 100% SDV?

Quality risk management in clinical trials is often interpreted as risk elimination when it comes to SDV. Pharmaceutical companies attempt to eliminate risk by performing 100% SDV. However, the cost of on-site monitoring is now around a third of the cost of a trial, so **performing 100% SDV is a very expensive method of eliminating risk**.

On-site monitoring involves many more tasks than just SDV, including tasks that are important for the overall quality and compliance, and so must be performed. So how does the monitor perform **100% SDV** and all the other tasks without spending an **inconsiderate number of hours** at the investigator site?

Risk of not performing 100% SDV

Studies have shown that less than 1% of data is changed due to **100% SDV**, and the effect of this **change on the primary analysis is negligible**. Therefore quality risk is not directly affected by 100% SDV.

It was also often thought that regulators preferred 100% SDV, and therefore not to do this may raise quality risk concerns. However, recent **papers from FDA** (Guidance for Industry - Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring, August 2011) **and EMA** (Reflection paper on risk based quality management in clinical trials, August 2011) are positively **encouraging** pharmaceutical companies to abandon the 100% SDV approach in preference to a more **risk-based source data verification**.

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What is centralised risk-based SDV approach?

Centralised monitoring can be thought of as moving a little bit away from manual and subjective process to an **automated and logical process**. As things are programmed, it is also possible to then identify key data issues for the monitor to check, and therefore in effect ask the **monitor to target their SDV**, and just check the data which they are asked to check.

This process has a risk associated with it, as the monitor is not performing all the checks manually, and they do not look at 100% of the data. However, the **advantages of automating** these processes **far outweigh the previous manual process**.

Advantages of using WHAT-2-SDV for a centralised risk-based SDV approach

Systematic errors are easy to spot by looking at data trends and protocol violators

- Data errors, outliers, missing and inconsistent data are **identified with programs and logic** rather than the luck of the eye
- More complex **fraud checks** and statistical analysis can be programmed
- **Site** characteristics and **performance metrics** can be monitored over time by looking at high screening failures rates, eligibility violations, delays in reporting the data
- The automated checks can be **submitted routinely** on the database without the need to visit the site
- **CRAs have less data to check** when they are at the site, and so can not only verify the data, but they actually have time to check the data
- **CRAs have more time** to perform GCP and Process checks, and provide more training at the site
- CRAs **visit sites with issue more often** and spend longer time there, and **visits sites without issues less frequently**

Risk of using WHAT-2-SDV

WHAT-2-SDV is taking a risk-based approach. So by definition there is an element of risk that some mismatches between source data and the database maybe missed.

It can also happen that the risk assignment is wrong. The risk factor should therefore be continuously updated based on the latest data, meta data and CRA feedback. This will mean that the **risk factor will increase over time for risky sites**.

Conclusion

Although on-site monitoring can cost around a third of the total trial cost, the **quality of the trial data must be unquestionable**. Quality risk management is therefore essential. Applying a **centralised risk-based SDV** approach will reduce the amount of data the CRAs have to verify at every site, allowing them **more time to target problem areas**, whether that means visiting specific sites more often or specific issues within a site.

WHAT-2-SDV is therefore the perfect solution. This will not only **increase the chances of identifying data issues**, both random and systemic, it will also help to check for fraud and **increase the quality of the trial**. As more time will be spent on automatic checks, and less on on-site monitoring, the **overall cost** of on-site monitoring **will be reduced**, and the savings will increase as the size of the trial increases from small to medium to mega trials.

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