

SPIRIT-ROUTINE Checklist Improves RCT Protocol Reporting for Routinely Collected Data

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Randomised controlled trials (RCTs) increasingly leverage routinely collected health and care systems data, such as electronic health records or registries, to streamline research processes and potentially reduce costs. However, challenges related to data quality, governance, and regulatory complexities can undermine reproducibility and bias assessment in these trials. The SPIRIT-ROUTINE extension to the SPIRIT 2025 guideline provides a checklist and explanation to improve the reporting of RCT protocols that incorporate such data sources.¹

KEY TAKEAWAYS

- **The Pivot:** The SPIRIT-ROUTINE extension addresses specific reporting gaps in RCT protocols that utilise routinely collected data.
- **The Data:** The checklist aims to enhance completeness, transparency, and usability of protocols for investigators, funders, ethics committees, journal editors, and peer reviewers.¹
- **The Action:** Investigators should integrate the SPIRIT-ROUTINE checklist into their protocol development for trials involving cohorts or routinely collected data.

The integration of routinely collected data into randomised controlled trials offers advantages, including potentially streamlined recruitment, intervention delivery, and follow-up, both within the trial and long term. This approach may also contribute to lower trial costs.¹ Despite these benefits, several issues can compromise the integrity and utility of trials relying on such data. These include the absence of clear information governance pathways, variability in data quality, delays in data recording and acquisition, and intricate regulatory or ethical considerations. These factors collectively hinder reproducibility and the accurate assessment of bias when routinely collected data are incorporated into trial designs.¹

The SPIRIT-ROUTINE Extension

To address these reporting deficiencies, Kearney, McCarthy, and Rengarajan introduced the SPIRIT-ROUTINE extension to the SPIRIT 2025 guideline.¹ This extension comprises a checklist and an accompanying explanation, specifically designed to improve the reporting standards for trial protocols that depend on cohorts or routinely collected data sources.¹

The primary objective of SPIRIT-ROUTINE is to enhance the completeness, transparency, and usability of these trial protocols.¹ The authors state that the extension is intended for use by a broad range of stakeholders involved in clinical research. This includes investigators who design and conduct trials, funders who allocate resources, ethics

committees responsible for oversight, journal editors who publish protocols, and peer reviewers who evaluate them.¹ By promoting more comprehensive and transparent reporting, the SPIRIT-ROUTINE extension aims to support the conduct of higher-quality research, which can subsequently inform better healthcare decisions and improve patient outcomes.¹ The SPIRIT 2025 guideline provides a framework for reporting trial protocols, and SPIRIT-ROUTINE builds upon this by adding specific considerations pertinent to the use of routinely collected data. This includes guidance on aspects such as data linkage, data quality assessment, and the management of information governance. The detailed explanation accompanying the checklist provides further elaboration on each item, assisting users in understanding the rationale and practical application of the reporting recommendations.¹

The SPIRIT-ROUTINE extension is structured to address key areas where routinely collected data introduce unique challenges. For instance, it provides specific guidance on how to report data sources, including details on their origin, scope, and any pre-existing quality assessments. This is crucial for evaluating the potential for selection bias and understanding the generalizability of trial findings. Furthermore, the extension emphasizes the importance of transparently reporting data linkage procedures, including the methods used for pseudonymisation or anonymisation, and the legal and ethical frameworks governing such linkages. This level of detail is essential for ensuring data security and privacy, which are paramount when working with sensitive patient information.

Another critical aspect covered by SPIRIT-ROUTINE is data quality assessment and management. Protocols are encouraged to detail plans for assessing the completeness, accuracy, and consistency of routinely collected data, as well as strategies for handling missing data or data errors. This proactive approach to data quality helps mitigate the risk of biased results and enhances the reliability of trial outcomes. The extension also prompts investigators to describe the information governance structures in place, outlining the roles and responsibilities of various stakeholders in data access, use, and security. This clarity is vital for navigating the complex regulatory landscape associated with routinely collected health data.

Clinical Implications and Future Directions

The implementation of the SPIRIT-ROUTINE checklist holds significant clinical implications. By promoting more robust and transparent reporting of trial protocols utilizing routinely collected data, it facilitates a more accurate assessment of the methodological quality and potential biases of such studies. This, in turn, allows healthcare professionals to make more informed decisions when interpreting trial results and considering their applicability to clinical practice. Improved protocol reporting also enhances the reproducibility of research, a cornerstone of evidence-based medicine, by providing sufficient detail for other researchers to understand and potentially replicate the trial design.

Looking ahead, the widespread adoption of SPIRIT-ROUTINE is anticipated to foster greater confidence in the findings of trials leveraging routinely collected data. This could accelerate the translation of research into clinical guidelines and patient care pathways, ultimately leading to more efficient and cost-effective healthcare interventions. Future efforts

should focus on disseminating the SPIRIT-ROUTINE guidelines widely among the research community and integrating them into existing training programs for clinical trialists. Furthermore, ongoing research will be necessary to evaluate the impact of SPIRIT-ROUTINE on the quality of published protocols and the subsequent reporting of trial results, ensuring its continued relevance and effectiveness in an evolving data landscape.

CLINICAL IMPLICATIONS

The introduction of SPIRIT-ROUTINE represents a necessary step towards standardising the reporting of trials that leverage routinely collected data. Clinicians increasingly rely on evidence from pragmatic trials, many of which integrate electronic health records or administrative claims data. Without clear, transparent reporting on how these data sources are managed, their quality assessed, and their use governed, the validity and generalisability of trial results become questionable. This checklist provides a framework for investigators to articulate these critical details, allowing clinicians to better evaluate the applicability of trial findings to their patient populations.

For the pharmaceutical and medical device industries, adherence to SPIRIT-ROUTINE will become an expectation, not an option. Funders and regulatory bodies will likely integrate these reporting standards into their requirements, pushing companies to adopt more rigorous data management and reporting practices from the outset of trial design. This could lead to increased upfront investment in data infrastructure and expertise, but ultimately yield more credible and reproducible evidence, potentially accelerating market access for therapies supported by robust, transparently reported data.

Patients stand to benefit from this enhanced transparency. As trials increasingly move towards real-world data, the ethical implications of data privacy, consent, and data security are paramount. Clear reporting on these aspects, as encouraged by SPIRIT-ROUTINE, ensures that patient data are handled responsibly and that the research conducted is both scientifically sound and ethically justifiable. This fosters greater trust in clinical research and ensures that the drive for efficiency does not compromise patient rights or data integrity.

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REFERENCES

1. Kearney PM, McCarthy M, Rengarajan S. Reporting of Cohort and Routinely Collected Data in Randomised Controlled Trial Protocols (SPIRIT-ROUTINE): extension checklist with explanation and elaboration. *BMJ*. 2026;372:e088234. doi:10.1136/bmj-2025-088234

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