Guidelines for the inclusion of pathology in clinical trial protocols: SPIRIT-Path

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An international group of cancer researchers, led by the National Cancer Research Institute's (NCRI) Cellular Molecular Pathology Initiative (CMPath), has published guidance to address the variability in how pathology is planned and delivered in clinical trials.

The guidance, which has been published today in *The Lancet Oncology*, was produced through the development of international consensus, drawing on expertise from Africa, Asia, Australasia, Europe and North America and from all sectors of the clinical trials community including funders, regulators, statisticians and data managers, patient advocates, industry representatives, laboratory scientists, medical publishing representatives, and clinicians.

This guidance, called SPIRIT-Path, was developed as an extension to the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) 2013 Statement which provides evidence-based recommendations to address the variability in quality and content of clinical trial protocols. The SPIRIT Statement is widely endorsed by medicines developers, academia, regulators and medical journals.

Co-Chair of the NCRI's SPIRIT-Path working group Dr. Tim Kendall said,

"Pathology is an integral component in the planning and delivery of clinical trials. To ensure methodological rigour in trials requiring pathology evaluation, for trial eligibility or outcome assessment, there is increasing recognition of the need for pathologists to be involved early in trial planning and design. However, this is not always the case."

"The SPIRIT-Path extension will allow investigators to comprehensively address the cellular and molecular pathology aspects of trial protocols, ensuring adequate skills and resources are available at trial commencement and fully leverage the value of biospecimens for

translational research."

Co-Chair of the NCRI's SPIRIT-Path working group Dr. Max Robinson said,

"The SPIRIT-Path extension was conceived as a means of both maximising the value of pathology content of clinical trial protocols and facilitating its execution. This guidance is the first international consensus project to formalise pathology input into clinical trials and is the necessary first step towards enabling next-generation pathology that fully meets the needs of precision medicine."

SPIRIT-Path recommends that protocols should document the individuals, processes, and standards for all cellular and molecular pathology components of the trial protocol, including all stages of the specimen pathway, any digital pathology methods, and with specific consideration of the value of trial data and tissue for additional translational studies.

The CMPath team are now embarking on a follow-on project to develop guidelines for the reporting of pathology-related activities to complement the SPIRIT-Path extension. They are also developing a Good Clinical Practice training module in 'Trials Pathology' with the intention that completion of the training by interested members of staff, irrespective of the nature or location of their department, will build a community of research-ready clinical trial pathologists.

More information: Timothy J Kendall et al, Guidelines for cellular and molecular pathology content in clinical trial protocols: the SPIRIT-Path extension, *The Lancet Oncology* (2021). DOI: 10.1016/S1470-2045(21)00344-2