NCRI Pathology Group Priorities 2022 - 2025

NCRI Partners

NCRI is a UK-wide partnership between research funders working together to maximise the value and benefits of cancer research for the benefit of patients and the public. A key strength of NCRI is our broad membership with representation across both charity and government funders as well as across all four nations in the United Kingdom.

Contents

Introduction

The NCRI Groups bring the cancer research community together to develop practice-changing research, from basic to clinical research and across all cancer types, supporting NCRI's strategy. The NCRI Pathology Group is a multi-disciplinary community of researchers and consumers focused on developing research to improve outcomes for cancer patients and identify areas of unmet need.

Each NCRI Group engages in a prioritisation process to identify the priority areas in its area of research (Appendix A). This process dictates the work of the group as well as providing an assessment of the state of research for the wider research community.

The NCRI Pathology Group has identified its research priorities based on feedback from their three-year review in March 2019 and further suggestions from a meeting with the NCRI Strategy Advisory Group in 2020. Due to pressures on staff time during the COVID-19 pandemic, many of these areas of activity were not taken forward but are however still felt to be relevant today and therefore form the basis of the strategic priorities outlined in this document. An overview of those who participated in the strategy-setting process can be found in Appendix B.

There are multiple areas the NCRI Pathology Group has identified as priorities, an overview of which can be seen below with full details on pages 9-10 of this document. The Group will initially focus on priorities 1-4, forming time-limited working groups to address these priorities. When one working group finishes, capacity will be transferred to address the next priority. An overview of the NCRI Pathology Group structure can be found on page 6.

The strategies of NCRI Groups will be refreshed every three years. In addition, the research landscape will continue to be routinely assessed by NCRI to ensure the most pressing questions in the pathology research landscape are addressed over the course of this three-year strategy.

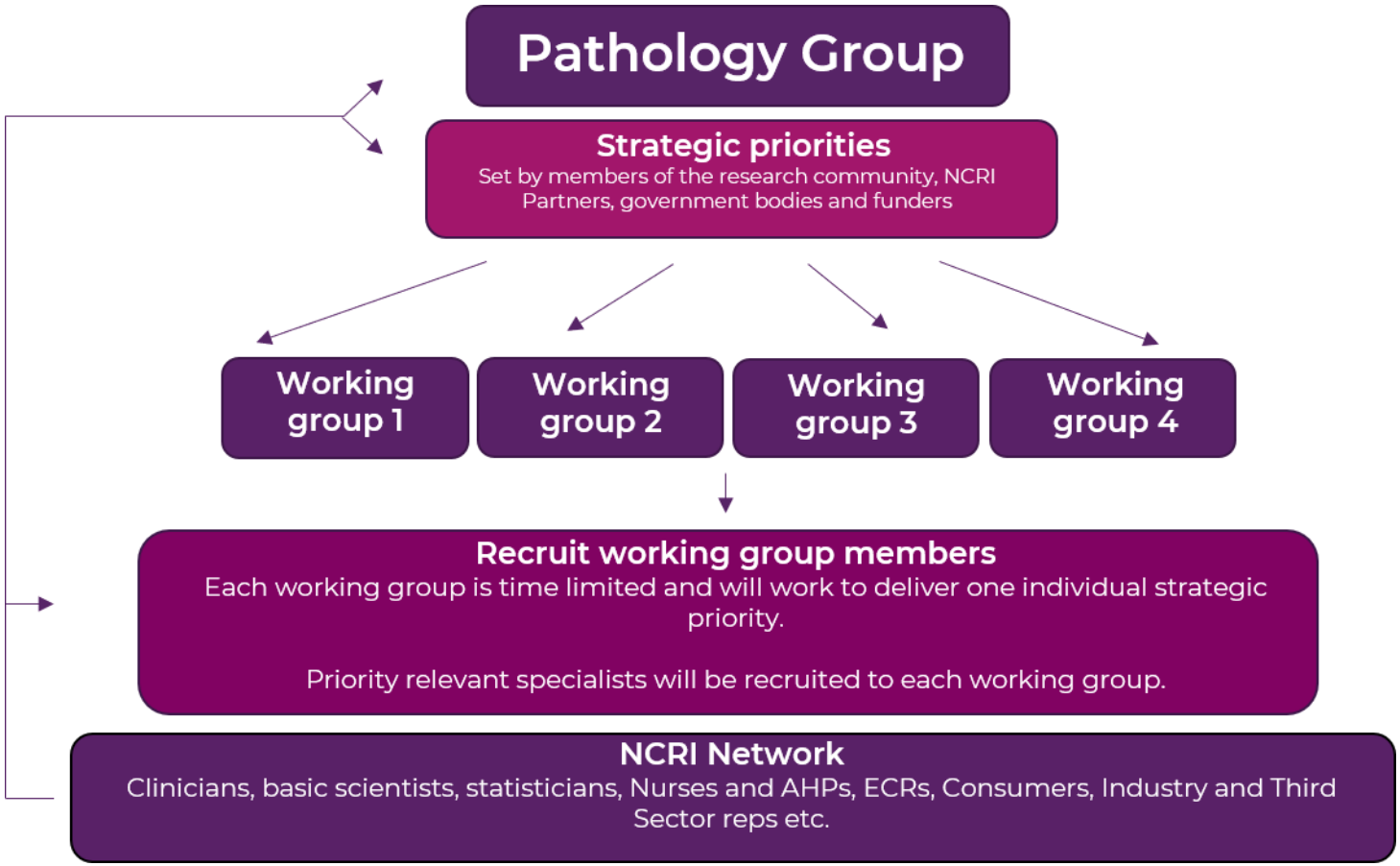
NCRI Pathology Group strategic priorities at a glance

1. Identify the challenges of providing cellular and molecular pathology and laboratory medicine support for research in all cancer types and establish a consensus on 'next generation' pathology.
2. Develop CONSORT-Path guidelines.
3. Develop a code of practice to maximise the value extracted from clinical samples.
4. Build a research ready workforce.
5. Maximise the value and utilisation of pathology images from UK clinical trials by computational methods.
6. Establish a costing template for cellular and molecular pathology activity in clinical trials in the UK.
7. Promote the development of laboratory medicine diagnostics that can be incorporated into established NHS laboratory medicine working practises.

"We have moved rapidly towards an era of personalised medicine in cancer where the presence of specific genetic mutations or dysregulated pathways help define which patients may benefit most from treatments targeting those pathways. Consequently, the information needed from a tissue sample to guide treatment or assess suitability for clinical trials has moved beyond simply a morphological diagnosis. We are seeking to define a pathology approach suitable for clinical trials to maximise the value of clinical samples, next-generation pathology for precision medicine, and create a workforce able to undertake clinical trial work and translate research into clinical practice. A core priority of the NCRI Pathology Group is to enhance the value of cellular and molecular pathology activity in clinical trials by providing specialist support for pre-submission proposal guidance meetings. This will build on the previous work of the Clinical Trials Pathology Advisory Group (CTPAG), a function which has helped inform ways of working and has now been centrally adopted across the NCRI Groups and their associated networks."

Dr Tim Kendall, Chair of NCRI Pathology Group

NCRI Pathology Group structure at a glance



NCRI Pathology Working Groups

Initial working groups in set up

The NCRI Pathology Group has identified seven strategic priorities, full details of which can be found on pages 9-10 of this document. Time-limited working groups will be set up to address the first four priorities for the NCRI Pathology Group, each of which are outlined below. Once one working group reaches completion, capacity will be transferred to the next priority.

Working group 1

Identify the challenges of providing cellular and molecular pathology and laboratory medicine support for research in all cancer types and establish a consensus on 'next generation' pathology.

By addressing this priority, we aim to establish a joint consensus on the future of 'next-generation' pathology that is required to support clinical trials in all study areas across the UK. There will be particular focus on research with personalised study designs and maximising the research value and utilisation of tissue or other clinical samples. The work of this group will also address ways to encourage collaboration in research as opposed to competition. Greater collaboration and data sharing will ultimately result in higher quality multi-centre studies. This working group will produce and publish a position paper addressing challenges such as:

- Early engagement of pathologists and other laboratory scientists in trial planning
- Profile and availability of trials-ready laboratory medicine staff
- Governance and value maximisation of trial-related clinical samples
- Sharing trial data and facilitating digital pathology research

This paper will also include a summary of the achievements from the previous 5-year strategy of the NCRI Pathology Group.

Working group 2

Develop CONSORT-Path guidelines.

This working group will build on the foundations laid by the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)-Path Working Group to develop and publish guidance to address the variability in how cellular and molecular pathology activity, including eligibility and outcome assessment, in clinical trials is reported. To realise the benefits of this outcome the group will work to embed both Consolidated Standards of Reporting Trials (CONSORT) and SPIRIT-Path guidelines into funder, regulator and industry practice.

Through this work we aim to increase the transparency of trial activity to allow more informed, rigorous assessment that ultimately increases confidence in reported trial data. Further, complete documentation and publication of the specific contributions of laboratory medicine staff to trial processes will raise their profile and increase awareness of the value of early engagement amongst future trial protocol authors.

Working group 3

Develop a code of practice to maximise the value extracted from clinical samples.

This working group will develop a code of practice for retention and access to patient samples collected and stored for research use during a clinical trial. Participants in clinical trials regularly consent to provide blood, tissue, or other clinical samples for no immediate personal benefit. Such altruistic sample provision is critical to advance understanding. All those involved in trial execution should ensure that maximum value be extracted from the gifted material although no code of practice exists to formalise this.

By addressing this priority, we aim to provide a mechanism that allows trial sponsors and investigators to improve the governance of trial samples and permit the maximum research value to be gained from them, in accordance with the wishes of trial participants.

Working group 4

Support the development of a research ready workforce.

There is a need to enhance training of those working in cellular and molecular pathology or as laboratory scientists so that staff have an understanding of future possible contributions to clinical trials.

By addressing this priority, we aim to encourage appropriately funded clinical work in laboratory medicine such that trials work is considered a routine and valued part of working life, beginning with input into the earliest phase of specialist training. This working group will engage with multiple stakeholders, including NIHR, RCPath and other learned societies to embed SPIRIT-Path and CONSORT-Path into training curriculums and as a separate clinical trials GCP course.

NCRI Pathology Group strategic priorities in full

Priority 1: Identify the challenges of providing cellular and molecular pathology and laboratory medicine support for research in all cancer types and establish a consensus on 'next generation' pathology.

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Priority 5: Maximise the value and utilisation of pathology images from UK clinical trials by computational methods.

The aim of this priority is to define how the application of AI and digital pathology can complement traditional subjective pathological assessment and enhance the information yield from stained sections related to UK clinical trials. We aim to define a consensus road map for UK stakeholders in computational pathology that will maximise the value of stained sections and associated data from clinical trials. A clear route for developing digital pathology tools and workflows suitable for incorporation into routine practice will be established. We also aim to agree mechanisms for the deposition of clinical trials pathology images and data in the UK to promote cross-disciplinary studies that exploit these resources, improve trial transparency, and ensure maximum use of available data.

Priority 6: Establish a costing template for cellular and molecular pathology activity in clinical trials in the UK.

By addressing this priority, we will allow cellular and molecular pathology activity to be included and appropriately costed in clinical trial protocols and associated application documents as they are being developed. This promotes early engagement with laboratory medicine staff including pathologists and laboratory scientists and is in keeping with SPIRIT-Path guidelines. This also ensures that cellular and molecular pathology laboratory activity in successfully funded trials can be undertaken efficiently and with minimal further negotiation during trial set-up.

Priority 7: Promote the development of laboratory medicine diagnostics that can be incorporated into established NHS laboratory medicine working practises.

This priority aims to promote the development of laboratory medicine diagnostics, including biomarkers, that can be more easily incorporated into NHS laboratory medicine working practises. We intend to do this by highlighting the value of early engagement of NHS laboratory medicine staff, including cellular and molecular pathologists and laboratory scientists, through production of educational materials made freely available through appropriate channels. The production of these materials will sign-post those developing laboratory diagnostics who may not be familiar with the working practises of NHS laboratories towards engagement with subject-matter experts. This will allow clearer lines of sight towards clinical practice during development and increase the speed and efficiency with which new diagnostics and biomarkers can be of clinical benefit.

NCRI Cross-cutting priority

Identify barriers resulting in a lack of diversity in clinical trials and propose solutions to improve equality, diversity, and inclusion.

Barriers resulting in a lack of diversity in clinical trials across cancer types has been raised as an issue in many of NCRI's discussions with researchers. For this reason, this priority will be addressed collaboratively in a working group comprising experts from across NCRI Groups. This priority aims to establish the reasons behind a lack of diversity in clinical trials and provide solutions to increase participation of a diverse cohort of patients in future studies. A working group will address the common issues across the board, as well as identifying cancer-type specific barriers, and produce guidelines on the steps to take to improve the inclusion of patients from a range of backgrounds into clinical trials from their inception. More details on this working group will be decided in due course.

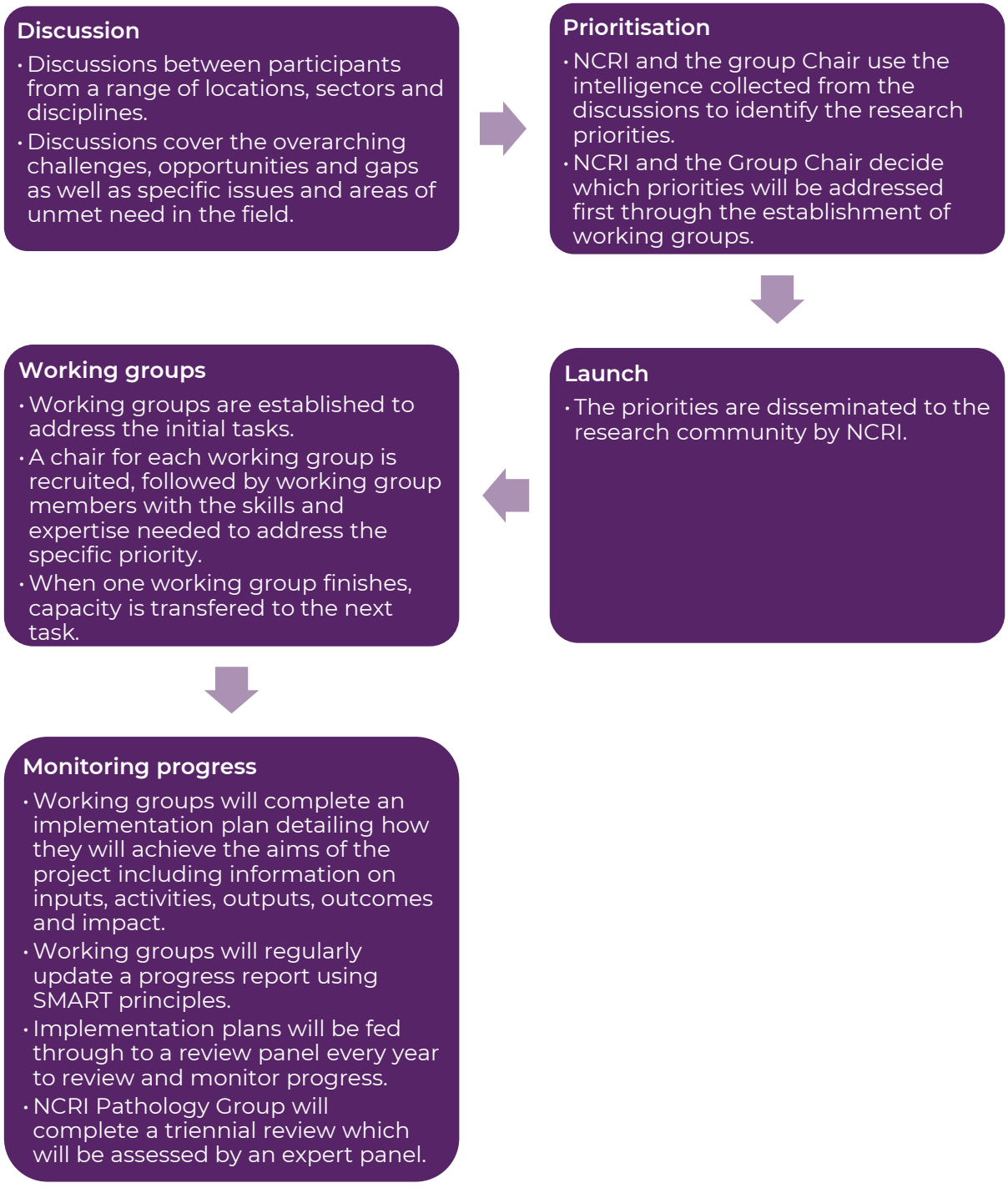
Next steps

Working groups addressing the highlighted tasks are currently being formed. These groups will be made up of the experts needed to address each research question. To be the first to hear about opportunities to join these working groups please sign up to the NCRI Pathology Network. The progress of these working groups will be published in the annual reports and triennial review of NCRI Pathology Group. These can be found on the NCRI website. Members of the NCRI Pathology Network will also be updated periodically on the progress of the group.

Please get in touch if you have any questions or comments regarding this report or if you are interested in joining one of the NCRI Networks, the NCRI Consumer Forum or our NCRI Early Career Researcher Forum.

Appendix A

NCRI Pathology Group priority setting process



Appendix B
NCRI Pathology Group priority discussion contributors

The NCRI Pathology Group developed their strategic priorities through discussions with professionals from a range of sectors and disciplines, including NCRI Consumer Forum members, early career researchers and NCRI Partners, as well as members of SPIRIT-Path, the NCRI Strategy Advisory Group (SAG), the Clinical Trials Pathology Advisory Group (CTPAG) and members of the Cellular and Molecular Pathology (CMPath) group. We thank all contributors for their invaluable input into these discussions and the subsequent priorities addressing the most pressing needs in pathology research today.

Advancing Cancer Research Together

Report produced by:

Abbie Fearon, Senior Programme Manager (Strategic Projects), NCRI
Laura Chambers, Senior Programme Manager (Groups), NCRI
Rachel Laurence, Communications Manager, NCRI
Nicola Keat, Head of Groups, NCRI

National Cancer Research Institute
2 Redman Place,
London, E20 1JQ

T: +44 (0)20 3469 8798
F: +44 (0)20 3014 7658

info@ncri.org.uk
www.ncri.org.uk