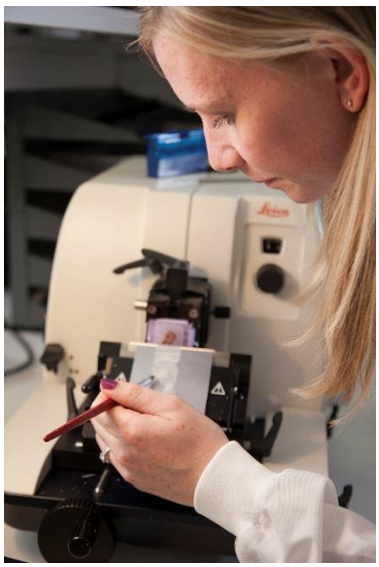
Overcoming Barriers to Molecular Diagnostics and Digital Pathology Uptake

NCRI's CM-Path Industry Engagement Workshop, 5 October 2016





We are grateful to the following organisations for sponsoring this event:

Executive Summary

CM-Path is a National Cancer Research Institute (NCRI) initiative, which aims to reinvigorate academic pathology in the UK. Over the past 15 years, the academic pathology workforce has experienced substantial attrition. In order to maintain innovation in pathology, this decline needs to be reversed.

To advance research in pathology, providing scope for wider and faster implementation of novel technology for patients' benefit, CM-Path recognises the value of collaborating with industry. To this end, a meeting between the CM-Path Technology and Informatics Workstream and industry representatives took place in October 2016, which addressed challenges and solutions for technology adoption in pathology within both the NHS and academia.

The challenges in **molecular diagnostics** and other related technologies were identified as being:

- opportunities for further training for pathologists
- clinical need and justification
- need for validated standards and consistency
- better communication between pathology and industry
- industry access to biosamples

The challenges in **digital pathology** and other related technologies were identified as being:

- need to define the requirement for digital pathology in the NHS
- need for evidence of safety and validation standards
- need for digital pathology research funding
- need for a suitable pathology-informatics community and training opportunities

The areas in which **CM-Path** can have an impact are as follows:

- collaboration between the pathology community and industry
- scoping of the current molecular diagnostic and digital pathology attitudes and provisions across the UK
- supporting business planning activities
- expanding funding opportunities for digital pathology
- exploring the development of a suitable informatics community and training opportunities

An overarching theme of this work will be continued communication of CM-Path with industry representatives to highlight areas of need and future collaborative opportunities. Thus, CM-Path will be starting this collaborative venture by setting up the **CM-Path Industry Forum**.

Introduction

Cellular-Molecular Pathology is the science of understanding diseases at the level of cells, genes and molecular pathways. In this era of personalised medicine, there is a rapidly escalating need for innovative molecular testing and application of a wide spectrum of technology to inform patient management and facilitate translational research. However, over the past 15 years academic Pathology in the UK has severely declined.

The new National Cancer Research Institute (NCRI) initiative in cellular molecular pathology, CM-Path, aims to achieve the change needed to support academic cellular molecular pathology in the UK and make the resulting benefits available to the wider research community. The initiative is chaired by **Dr Karin Oien**, University of Glasgow.

The CM-Path workstream structure has been distilled from topics that the pathology community has identified as priorities to achieve the change needed to invigorate research in CM-Path in the UK.

Skills and capacity: Led by Professor Manuel Salto-Tellez and Professor Louise Jones

The skills and capacity Workstream has its focus on education and continuous up-skilling of the cellular molecular pathology workforce

Clinical trials: Led by Dr Alex Freeman

The clinical trials Workstream represents profession-wide engagement with clinical trials and other research needing relatively straightforward cellular and molecular pathology support.

Discovery: Led by Professor Gareth Thomas

The discovery Workstream reflects activities predominantly located in 'hub' centres of excellence, investigating the biology of cancer and its treatments

Technology and informatics: Led by Dr Stefan Dojcinov

The technology and informatics Workstream is the 'middle ground' of R&D, weighted towards 'D' for continuous innovation in cellular molecular pathology and pathology informatics, and to disseminate the uptake of new technologies/tests

Members of the 'Technology and Informatics' workstream of CM-Path and representatives of pharmaceutical, biotechnology and digital pathology industries (Appendix 2) convened on 5 October 2016 for a workshop to generate a consensus on the barriers and solutions to the uptake of molecular diagnostics and digital pathology into the NHS and academia. This report summarises discussions that took place on the day and outlines the areas that CM-Path aims to address in the future, over its 5 year life-span.

Molecular Diagnostics

Molecular Diagnostics are designed to decipher the molecular alterations that underlie the development, progression and treatment of diseases. Their applications include: diagnosis and classification; prediction of drug responses; detection of residual disease under therapy; and prognostication. Whilst new molecular diagnostic technologies are continually being developed, their translation into the clinic can be a lengthy process.

During the CM-Path-Industry workshop, mixed group (pathologists and industry representatives) breakout sessions took place, with the aim to identify challenges in the adoption of new molecular diagnostic technologies; the outcomes are summarised below.

1. Opportunities for Further Training for Pathologists

In order to implement, carry out and interpret results from new molecular diagnostic tests and other technologies, a highly skilled workforce is required. Training opportunities in this area would therefore be welcomed. Whilst industry-related training courses are available, the pathology community is not always aware of these. In addition, whilst University training programmes are now available in this area, funding remains an issue. The following activities may therefore be useful:

- wider dissemination of information around industry-related training opportunities
- opportunity for industry-sponsorship for courses

Existing initiatives in this area

- there is an increasing availability of Masters level training in Molecular Pathology or Molecular Diagnostics via Universities and other providers and with various funders e.g. MRC/ESPRC, CRUK, Genomics England

2. Clinical Need and Justification

A key factor in choosing new tests to implement in the laboratory, is the clinical need and level of cost-efficiency. However, most molecular diagnostic tests lack these analyses and this can be a barrier to their uptake. Other economic issues such as lack of funding, the need for better communication with procurement and lack of knowledge around writing successful business cases were also cited as barriers to molecular diagnostics uptake. Solutions include:

- partnerships with industry to reduce costs
- increased dialogue with NICE to facilitate clearer specification for diagnostic requirement
- education of procurement or business case templates for use by pathologists

Existing initiatives in this area

- BIVDA Procurement Working Group
- Royal College of Pathologists Resources

3. Need for Validated Standards and Consistency

Whilst NEQAS standards exist and are nationally accepted for a spectrum of testing platforms, the majority of the newer molecular diagnostic tests have no nationally accepted standards. This is a barrier for the uptake and use of new technologies, especially in smaller pathology laboratories that lack resources and external pathology expertise. While representatives of information technology (IT)

and software industry involved in the production of laboratory information systems were not present at the meeting, lack of standardised requirements in this area to facilitate adequate integration of data from a variety of sources has been identified as a barrier. Solutions include:

- scoping activities to determine existing guidance and regional variation in standards that are followed and which new tests are introduced, in collaboration with the CM-Path Clinical Trials Workstream
- highlighting existing guidance to the pathology community, in collaboration with the CM-Path Clinical Trials Workstream
- liaison with IT and software industry to facilitate development of standardised requirements for laboratory management systems and data integration

Existing initiatives in this area

- UK Pharmacogenetics and Stratified Medicine Network (UK PGx Network)
- UK National External Quality Assessment Service (NEQAS)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Royal College of Pathologists
- CM-Path Clinical Trials Workstream

4. Better Communication between Pathology and Industry

In order to direct industry activities, and for the NHS to plan for new industry developments, an improved dialogue between the pathology community and industry is essential. Whilst there are other initiatives working in this area, CM-Path can also play a strong role by providing a direct link between pathologists and industry representatives, by:

- the creation of a CM-Path Industry Forum to ensure continued communication between industry representatives and pathologists working in both academia and the NHS

Existing initiatives in this area

- British *in vitro* Diagnostic Association (BIVDA)
- Association of the British Pharmaceutical Industry (ABPI)
- Chief Scientific Office for NHS England Leadership and Cultural Change
- National Institute for Health Research Diagnostic Evidence Co-operatives (NIHR-DEC)

5. Industry Access to Biosamples and Biobanking Sustainability

One recurring concern that was raised was the lack of industry access to biosamples, and also a concern for the sustainability of biobanks. In order to validate technologies for use on human tissues, industry requires access to human tissue. Thus, lack of access to such tissues presents a barrier to the transition of new technologies from bench to bedside. Whilst no solutions were identified on the day, the CM-Path Discovery Workstream is working in this area and can be consulted in the future.

Other initiatives/organisations working in this area

- Innovate UK
- Abcodia
- CM-Path Discovery Workstream, working with the Confederation of Cancer Biobanks (CCB)

Digital Pathology

Digital pathology is the transformation of pathology images into an electronic format. Digital pathology is likely to play a significant role in the future of academic and NHS service pathology. It has the potential to transform the quality and delivery of pathology services, allowing rapid provision of second opinions, more flexible workflows, more inter-institutional collaboration and future use of image analysis to improve diagnostic consistency. However uptake of digital pathology for diagnosis in the UK has been slow, and pathologists are often not very familiar with using the technology.

Mixed group breakout sessions at the CM-Path-Industry workshop were tasked with identifying and discussing potential solutions for the challenges to the uptake of digital pathology technologies.

1. Need to Define the Requirement for Digital Pathology in the NHS

Although there is general agreement that digital pathology could benefit pathology research and service delivery, the adoption of digital pathology in the UK is patchy. Only a few centres have implemented it, and these are often small or limited deployments. Efforts to increase its use would benefit from clear evidence of safety, utility and cost-effectiveness. Possible solutions for this are:

- scoping of the current digital pathology landscape and attitudes in the UK
- raising awareness of the benefit of digital pathology
- demonstrating value via case studies, showing real evidence of utility and cost-effectiveness
- increasing the exposure of pathologists to digital pathology (e.g. in workshops or during training)
- engaging with NHS management at a senior national level to discuss digital pathology

Existing initiatives in this area

- BIVDA Digital Pathology Working Group

2. Need for evidence of safety and validation standards

The slow adoption of digital pathology could be due to a lack of trust in its safety and validation. It is therefore essential that we generate consistency of approach via the production of standards and guidelines for digital pathology implementation, academic and clinical use, and disseminate information about what validation work has been done so far.

Current guidance:

- College of American Pathologists (CAP), 2013: Validation
- American Telemedicine Association (ATA), 1999: Telepathology
- Digital Pathology Association (DPA), 2011. First WSI guidelines
- Food and Drug Administration (FDA) Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices: Draft Guidance for Industry and Food and Drug Administration Staff
- Canadian Association of Pathologists (CAP-ACP).
- Centers for Medicare & Medicaid Services (CMS/ CLIA).
- Centers for Disease Control and Prevention (CDC/ CLIAC).
- Society of Toxicologic Pathology (STPath).
- European Commission (EU-EC).
- Spanish Society of Anatomic Pathology (SEAP-IAP).
- The Royal College of Pathologists (RCP). Telepathology guidelines
- The Royal College of Pathologists of Australasia (RCPA).

3. Need for Digital Pathology Research Funding

To support academic research in digital pathology, and the implementation of digital pathology solutions, more funding opportunities are needed. These may be achieved by:

- achieving academic support from the NIHR, including funding for programmes of research to study the accuracy, efficiency and utility of digital pathology
- raising awareness of the necessity for high quality digital pathology research within funding bodies such as the MRC and ESPRC e.g. by digital pathology experts to sit as panel members
- recognising the need to develop a research community with the necessary skills to study and develop digital pathology. This includes a broad range of specialisation including computer scientists, pathologists, imaging scientists and psychologists
- identification of funding opportunities for project transition, i.e. the time during which digital pathology solutions are validated alongside a departments pre-existing pathology workflow

4. Need for a Suitable Pathology-Informatics Community and Training Opportunities

In the US, there is a more mature informatics landscape than in the UK. The College of American pathologists have a "Digital Pathology Resource Guide" and mature informatics support. Fellowships in informatics are seen as a legitimate career choice for pathology trainees, and these lead to director level posts in pathology informatics. An Association for Pathology Informatics has been established by this community, including academic activities, a yearly conference, and a journal of pathology informatics. As a result, major US hospitals are equipped with medical staff that have formal training in informatics, (including digital pathology and genomics informatics) with management responsibilities. These individuals are ideally placed to lead their institutional use of digital pathology. Potential solutions to replicate this scenario in the UK include:

- identification of routes to developing a pathology informatics community in the UK
- identification of resources to support the development of a UK pathology informatics network, with the development of suitable training modules for general pathologists
- facilitation of more specialised training for interested trainees

Existing initiatives in this area

- Not known in the UK
- US – College of American Pathologists
- Association for Pathology Informatics

CM-Path Technology and Informatics - Immediate Actions

Pathology-Industry Collaboration

Aim Ensure continued communication between industry and the pathology community to deliver collaborative working approaches

Action Set up and manage a CM-Path Industry Forum

Outcomes

- identification of future collaborative ventures
- dissemination of industry-related training opportunities to the pathology community
- opportunity to work with industry to generate best-practice case studies to define the role of digital pathology in the NHS
- industry integration across all CM-Path workstreams e.g. Discovery Workstream to enable conversations around access to biosamples, and Clinical Trials Workstream to enable conversations around guidance for quality assurance of molecular diagnostic tests

Molecular Diagnostics Scoping Work

Aim Scoping of current access to and attitudes towards molecular diagnostic technologies and their implementation procedures across the UK;

Action Generate a survey to be sent to all UK pathology departments

Outcomes

- baseline data of molecular diagnostic provisions in the UK
- information to guide further CM-Path activities in this area
- comprehensive register of technological capabilities and specific tests to facilitate easy access and enhance communication for diagnosticians and researchers

Timescale Data analysis completed by mid-2017

Digital Pathology Scoping Work

Aim Scoping of current access to and attitudes towards digital pathology across the UK

Action Work with the BIVDA Digital Pathology Working Group to generate a survey to be sent to all UK pathology departments

Outcomes

- baseline data of digital pathology provisions in the UK
- information to inform further CM-Path activities in this area
- generation of a database of pathologists that are interested in being involved in a digital pathology forum to share skills, experience and information

Timescale Data analysis completed by mid-2017

CM-Path Technology and Informatics - Future Actions

Support for Business Planning Activities

Aim

To support pathologists that are submitting business cases to implement new molecular diagnostic or digital pathology technologies

Action

- scope existing business plans that are available, e.g. from the Royal College of Pathologists, and publicise via CM-Path
- engage in discussions with manufacturers to identify further resources that can support pathologists in this area

Outcomes

Increased number of successful business cases for pathologists and therefore an enhanced uptake of new technologies across the NHS and academia

Expanding Funding Opportunities for Digital Pathology

Aim

Increase the number of successful high quality applications for funding in digital pathology research projects

Action

- encourage digital pathology experts to apply for funding committee positions
- raise awareness of the need for digital pathology research funding within funding bodies
- scope opportunities to develop funding for project transitioning

Outcomes

Increased opportunities for digital pathology research across the UK

Explore the Development of a Suitable Informatics Community and Training Opportunities

Aim

Progress the infrastructure that will support the development of individuals trained in pathology informatics, who are ideally placed to lead their institutional use of digital pathology

Action

- scoping of opportunities or routes to develop a pathology informatics community in the UK
- scope for and promote existing resources to encourage pathologist engagement with pathology informatics
- discuss with the Royal College of Pathologists regarding the development of pathology informatics training modules for general pathologists

Outcomes

Development of a more mature pathology-informatics infrastructure that will support digital pathology implementation and use

Appendix 1 - Summary of Presentations

Sarah Coupland: CM-Path and Molecular Diagnostics - Bridge the Gap

There has been a rapid development in the technology potentially available for pathological and molecular diagnosis. In particular, genome sequencing has undergone phenomenal development, and with plunging costs and molecular diagnostic aids, these are also affecting other 'omics" - e.g. Transciptomics, Proteomics, Metabolomics, Interactomics, Microbiomics. At present, however, there is a noticeable gap between academic and diagnostic pathology, and the implementation of these novel and promising techniques in routine medical care. This large gap needs to be bridged, and can only be done so through collaborative efforts of Industry, Academia and those involved in Health Care.

Stephen Hall: Molecular Diagnostics and the Pharmaceutical Industry

The pathway from a preclinical development to an implementable test from a perspective of a biopharmaceutical company is complex, involving internal, Global Pre-Clinical Development, followed by Clinical Trial Validation and finally Regional Market adoption of “Validated” testing in routine Pathology labs. The FDA Companion Diagnostic test is by definition the gold standard for selecting patients for the specific therapy, as the test is proven in a prospective clinical trial. The implementation phase is, likewise, a complex process, depending on the identification of local diagnostic need for specific biomarkers, availability of technological testing platforms, logistics (transport, turnaround times, human resource capabilities) and proficiency (External quality assurance and accreditation).

Jayson Wang: Molecular Diagnostics and the NHS

Implementation of new molecular diagnostic tests in the NHS is a complex process which is intimately linked and in a reciprocal relation with research in molecular pathology and education and training in molecular pathology. At present this is affected adversely by the lack of awareness over molecular pathology amongst pathologist and deficient drive to educate at all levels. Research within the NHS is secondary to diagnostic service and faces various obstacles such as lack of infrastructure (biobanking, equipment), funding and regulatory framework (ethics, HTA). In identifying technologies, platforms and targets to implement in practice there is discrepancy between “necessary” and “desirable” tests and economic considerations. This is also dependent on guidance and regulation (NHSE, UKAS, EQA, CE-IVD, other local), however, with little guidance on how to implement tests. In future, to achieve sustainability, this has to address need for proofing of platforms, choice of type of companion diagnostics (open vs proprietary) and dual usage for diagnosis and research. Industry may and is likely to play a greater role in this process in future, providing partnership in research and education, closer ties between NHS, pharma and diagnostic companies to monitor diagnosis-therapy pipelines, future-proof systems adaptable to new targets, provide shared platform for diagnostics and research and understanding of NHS economics and ability to offer cost-effective solutions as well as knowledge of regulations and support on implementation of tests.

Angela Silmon: Successful Industry/NHS Collaborations

The Newcastle Molecular Pathology Node is a partnership between Newcastle University and Newcastle upon Tyne Hospitals (NUTH) NHS Foundation Trust to drive advances in Molecular Pathology and bring research back into the heart of pathology laboratories. It does this by supporting the research environment with training and opportunities for distance learning, access to a unified laboratory environment and advanced tools for data analysis and visualization and micromanipulation techniques. Integrating industry within the management Board of the Node and collaborating with industry to develop novel approaches for disease stratification provides scope for innovation in to AND out of the NHS; representing the needs of industry with realistic evaluation of the marketplace and supporting commercial development of innovation.

An exemplar project, a performance evaluation of a Biocartis NV product by the Node and its partners, NewGene Ltd, Diagnostic Evidence Cooperative Newcastle and the Cellular Pathology department of Newcastle Hospitals NHS Foundation Trust was presented as a model for engagement between industry, academia and the NHS.

Eddie Blair: Adoption of New Technologies – Who Needs to be Involved?

Adoption of new technologies particularly in the context of the NHS is a complex process with numerous potential obstacles. In addition to readily identifiable components in this process (researchers, biopharmaceutical companies, regulatory bodies and NICE diagnostic bodies), there is a "hidden layer" of "links" which is frequently omitted in projects planning which occasionally may significantly affect implementation and adoption. Such "links" are administrative, fiscal and operational structures within the NHS institutions, which may not be directly involved in the diagnostic process, e.g., procurement departments, which may have considerable independence in decision making. The implementation & adoption process must therefore be alert and aware of such components and rely on past experience and construct business cases accordingly to anticipate for this. In practice, this has led to an emphasis on evidence provision, development of MDT interpretation processes and demonstration of sustainable clinical pathways.

Rifat Hamoudi: Extracting Meaningful Outcomes from Big Data

Recently, Next Generation Sequencing as well as other digital healthcare data such as those from Apple and Google and others led to the explosion is what is termed as *Big Data* for healthcare and biomedicine. Handling *Big Data* and generating semantically meaningful interpretations presents formidable challenges from Computer Science perspective, namely in the storage, analysis and integration of *Big Data* to identify unique genomic patterns in disease. Overcoming those computational challenges and integrating omics data from different modalities such as genomic, transcriptomic and epigenetic are key in providing better diagnostic and prognostic testing of various diseases across the NHS and provide novel computational algorithm and methodologies that can be used to solve bottlenecks in computer science for example development of adaptive software for LIMS or adaptive variant calling algorithms. Further work in highlighting the challenges from biomedicine and computer science perspectives as well as educating computer scientists and software engineers via different societies such as British Computer Society will address these issues.

Darren Treanor: CM-Path and Digital Pathology

Digital pathology has the potential to transform the quality and delivery of pathology services, allowing rapid provision of second opinions, more flexible workflows, more inter-institutional collaboration and future use of image analysis to improve diagnostic consistency. A number of barriers to the adoption of digital pathology were identified including a lack of information on the need/ demand across the NHS, lack of suitable informatics community and training, and lack of research funding for digital pathology. Further work will address these issues.

Peter Hamilton: Digital Pathology Overview

Digital pathology is a growing industry; this is marked by the uptake of whole slide scanning, precision medicine initiatives including CM-Path and increased application of computation pathology. A convergence of many factors such as LIMS, image analysis, data analysis and storage have made the transformation of digital pathology in recent years possible. Academic and industry partnerships are important to progress digital pathology research; one success story has been PathXL. PathXL has a deep expertise in web-enabled workflow, case management, research collaboration and cellular image analysis software. PathXL was originally a spin-out company from Queen's University Belfast, which was driven by academic findings from the University. PathXL software tools include educational software "tutor", digital pathology project and workflow management software "Xplore" and image analysis software "tissue mark". Recently, PathXL has aligned with Philips bringing new opportunities and the promise to further explore computation digital pathology.

Bethany Williams: Digital Pathology in the Clinic – An NHS Perspective

NHS Trusts scattered throughout the country are initiating and deploying digital pathology for practical applications in a number of domains, including frozen section reporting, the provision of second opinions, MDT support, and more recently, the provision of primary diagnosis. The technology has the potential to affect restructuring of service delivery, staff recruitment and retention in pathology. Potential benefits of digital pathology in clinical practice include improvements in safety, efficiency and reporting quality, in addition to its role as a platform for future digital analysis technologies. The principal barriers to adoption include lack of clarity on digital pathology regulation and validation, initial start up and maintenance costs of hardware, software and digital storage, and reluctance to change existing working and reporting practices on the part of some pathologists. These issues need to be overcome with research and clearer guidance on how to validate digital pathology for clinical use, the minimum specifications of hardware components in a digital pathology diagnostic system and the demonstration of efficiency savings/improved value of digital reporting. For wide scale NHS adoption, an evidence based approach should be applied to allow clinicians access to quality assessed data on digital pathology, and pathologists should have access to digital pathology training and educational resources.

Barbara Fallowfield: Overview of the BIVDA Digital Pathology Working Group

British *in vitro* Diagnostics Association (BIDVA) represents industry sector issues and concerns to policy makers and other stakeholders. In 2015 it established a Digital Pathology (DP) Working Party to work with a range of stakeholders and identify issues restricting adoption, develop and implement strategies to encourage and facilitate adoption and promote adoption of standards within DP. The working group is chaired by Tony Sackville (Philips), with the main industry attendees including GE, Leica, Philips, Roche, Sectra, Sysmex (Hamamatsu). External attendees include Dr Bruce Tanchel (Heart of England), Dr Olaf Ansorge (Oxford University Hospitals), Keith Miller (UK NEQAS) and Rachel Dunscombe (CIO Salford Royal). In its activities to date the working group has agreed three workstreams for: ROI, Clinical Effectiveness and Education. The objective is to give joint industry presentation at PathSoc meeting in January 2017, and PathSoc meeting in June 2017.

Simon Kimber: Barriers and Opportunities to Digital Pathology Uptake

Digital Pathology is already established in research and academia. There is increasing interest and uptake in routine clinical histopathology services, notably where there are networked services, need for expert opinion and remote sharing, requirement for MDT meeting support and in a setting of staff shortages. This technology is proving useful in optimising patient pathways, facilitating quicker diagnosis and treatment and facilitating efficiencies (e.g. faster case retrieval), achieving financial savings. It provides easier access to expert opinion through out-of-hours cover, external second opinions and holiday/sickness cover. Adoption of this technology requires conceptual change of attitude and diagnostic practice, including shift from a microscope to the screen, adjustment to a particular level of image quality and recognition and acceptance of potential benefits. The technical prerequisites include good communication bandwidths needed and appropriate storage facilities for archiving and recovery. Successful implementation is dependent on evidenced business cases to show efficiency gain at pathologist level, saving on retrieval of archived slides, prospects for merger of departments saving pathologist numbers, reduced turnaround time and efficiency change in patient pathways.

Appendix 2 – Workshop Delegates

Name	Job Title	Organisation
Eddie Blair	Biomarker Contractor, Immuno-Oncology	Bristol-Myers Squibb Pharmaceuticals Ltd
Carlo Bottari	Account Manager	Vela Diagnostics
Sarah Coupland	Honorary Consultant in Pathology and George Holt Chair of Pathology, University of Liverpool Director of the Liverpool Tissue Bank (LTB), University of Liverpool Director of the North West Cancer Research Centre, University of Liverpool	CM-Path
Maria da Silva	Business Development Manager	Sectra
Stefan Dojcinov	Consultant Histopathologist, University Hospital of Wales Head of Department of Cellular Pathology, University Hospital of Wales	CM-Path
Barbara Fallowfield	Managing Director	BIVDA
Michael Gandy	Translational Research Manager	The Doctors Laboratory
Sophie Gray	Medical Affairs Advisor	Pfizer
Stephen Hall	Marketing Director of Companion Diagnostics	Novartis
Peter Hamilton	VP for Research and Development, PathXL Professor of Tissue Biomarker Imaging, Queen's University Belfast	PathXL
Rifat Hamoudi	Senior Lecturer in Computational and Molecular Diagnostics, University College London	CM-Path
Vicky Hargreaves	Healthcare Manager, Oncology & Haematology	Novartis
Jen Harrow	Program Manager, Population Sequencing	Illumina Cambridge Ltd.
Merouan Hemamda	European Manager, Digital Pathology	Leica Biosystems
William Howat	Team Leader – Molecular Pathology Group	AstraZeneca

Emma Hughes	Programme Manager	Cancer Research UK
Simon Kimber	Business Development Manager (Digital Pathology)	Sysmex UK Ltd
Susan Kohlhaas	Head of Strategy and Initiatives	NCRI
Jessica Lee	CM-Path Programme Manager	NCRI
Graham Linforth	Head of Life Sciences	Sysmex UK
Darren Marjenberg	Sales Channel Manager	Agilent Technologies
Kennet Mattsson	Market Development Manager, UK & Ireland	Qiagen
Stuart McCann	Healthcare Development Manager	Roche Diagnostics
Karin Oien	Clinical Reader and Honorary Consultant, University of Glasgow	CM-Path
Jonathan Peat	Business Development Manager	QuantuMDx Group Ltd
Nischalan Pillay	CRUK Clinical Scientist, UCL Cancer Institute Honorary Consultant Histopathologist, Royal National Orthopaedic Hospital NHS Trust	CM-Path
Kevin Poon	Global Product Manager	Agilent Technologies
Tony Sackville	Head of Strategy & Business Development (UK/I)	Philips GB
Marietta Scott	Senior Research Scientist, Personalised Healthcare and Biomarkers	AstraZeneca
Angela Silmon	Chief Executive Officer	NewGene
Frank Smith	EMEA Marketing Manager – Translational Research	Affymetrix UK Ltd
Simon Smith	Sales Director of Pathology Imaging, EMEA	Leica Biosystems
Darren Treanor	Consultant Pathologist, Leeds Teaching Hospitals NHS Trust Honorary Clinical Associate Professor, University of Leeds Guest professor in Digital pathology, Linköping University Sweden	CM-Path
Jayson Wang	Consultant Histopathologist, St George's University Hospitals NHS Foundation Trust	CM-Path
Mike Watkins	National Biomarker Account Manager	Merck
Bethany Williams	Leadership and Management Fellow in Digital Pathology, University of Leeds	CM-Path

Stuart Wilson	Northern European Marketing Manager - Molecular Diagnostics	Qiagen
Kim Wood	UK / Ireland Clinical Account Manager (Next Generation Sequencing)	ThermoFisher

Others consulted via teleconference:

Name	Job Title	Organisation
Carla Deakin	Associate Director - Diagnostics Assessment Programme	NICE

Appendix 3 - Authorship

This document was compiled by the CM-Path Technology and Informatics Workstream, including:

Dr Stefan Dojcinov, University of Wales
Dr Karin Oien, University of Glasgow
Miss Jessica Lee, CM-Path Programme Manager
Professor Sarah Coupland, University of Liverpool
Dr Darren Treanor, University of Leeds
Dr Bethany Williams, University of Leeds
Dr Philip Macklin, University of Oxford
Dr Ioannis Roxanis, Oxford University Hospitals
Dr Jayson Wang, St George's Hospital London
Dr Rifat Hamoudi, University College London Hospitals
Dr Nischalan Pillay, Royal National Orthopaedic Hospital NHS Trust
Dr Karwan Moutasim, University of Southampton
Dr Peter Hall, University of Edinburgh
Professor Simon Cross, University of Sheffield
Dr Philippe Taniere, University Hospitals Birmingham

For further information please contact the CM-Path Programme Manager at jessica.lee@ncri.org.uk.

The CM-Path initiative is funded by 10 of the NCRI partner organisations: