



in association with



# Workshop on Biobanking in Support of Clinical Trials

**12 March 2010**

**09.30 – 16.30**

The King's Fund, London

A one-day conference organised by the National Cancer Research Institute's (NCRI) Confederation of Cancer Biobanks (CCB) in association with Wales Cancer Bank (WCB) and Experimental Cancer Medicines Centre Network (ECMC).



## Welcome

On behalf of the NCRI Confederation of Cancer Biobanks (CCB) I would like to welcome you to this meeting, the third annual CCB workshop. Our previous workshops on quality management in biobanking ("Quality Matters", January 2008) and ethics and governance ("Ethics and Governance in Cancer Biobanking", January 2009) were great successes. Both featured a range of expert speakers and were complemented by large and engaged audiences. If you missed them, the presentations from both previous events are available for download from our website, as well as a monograph reporting the proceedings of the 2009 event ([www.ncri.org.uk/ccb/](http://www.ncri.org.uk/ccb/)).

With this workshop today we wish to build upon the successes of previous events. Once again we have an excellent programme of distinguished speakers and we believe that the subject matter— biobanking in support of clinical trials— is an increasingly important activity across a range of industry and academic initiated clinical studies. Following this workshop we will publish the presentations and a monograph of the proceedings as a service to delegates and the wider clinical and scientific communities.

We hope that you enjoy the workshop and that you will continue to support CCB events in the future.



Dr Brian Clark  
Chief Executive Officer, onCore UK

onCore UK provides the secretariat of the CCB on behalf of NCRI and is a founding member of the CCB.

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## Sponsors

We would like to thank the following sponsors for their support of this meeting:



# Programme

09.30 – 10.00	<b>Registration and refreshments</b>	
10.00 – 10.10	<b>Opening Address</b>	<b>Dr Brian Clark, onCore UK</b>
<b>Session 1</b>	<b>Why do clinical trialists want to collect samples?</b>	<b>Chair – Prof Rick Kaplan, National Cancer Research Network</b>
10.10 – 10.35	Academic perspective	<b>Dr James Brenton, University of Cambridge</b>
10.35 – 11.00	Industry perspective	<b>Dr Anne Heatherington, Pfizer Ltd</b>
11.00 – 11.10	Questions	
<b>Session 2</b>	<b>Biobankers and clinical trials</b>	<b>Chair – Prof Chris Foster, University of Liverpool</b>
11.10 – 11.30	Quality management requirements for clinical trials and implications for sample handling	<b>Dr Jeff Cummings, Paterson Institute for Cancer Research</b>
11.30 – 11.55	What can biobankers offer trialists?	<b>Dr Alison Parry-Jones, Wales Cancer Bank</b>
11.55 – 12.05	Questions	
12.05 – 13.00	<b>Networking Lunch</b>	
<b>Session 3</b>	<b>Patient participation, ethics and governance</b>	<b>Chair – Derek Stewart OBE, Chair CCB</b>
13.00 – 13.25	Why would a patient want to be a “guinea pig”?	<b>Neil Formstone, Founder Lay Member Wales Cancer Bank</b>
13.25 – 13.50	Ethics and governance issues related to biobanking for clinical trials	<b>Dr Catherine Elliott, Medical Research Council</b>
13.50 – 14.00	Questions	
<b>Session 4</b>	<b>Ownership, Custodianship, Access and Usage</b>	<b>Chair – Dr Brian Clark, onCore UK</b>
14.00 – 14.25	Academic perspective	<b>Prof Andy Hall, Northern Institute for Cancer Research</b>
14.25 – 14.50	Industry perspective	<b>Prof Chris Womack, AstraZeneca</b>
14.50 – 15.00	Questions	
15.00 – 15.20	<b>Networking Break</b>	
<b>Session 5</b>	<b>Practical considerations for sample collection, processing, storage and release in international multicentre trials</b>	<b>Chair – Prof Barry Gusterson, University of Glasgow</b>
15.20 – 15.45	Case study 1 – Colorectal cancer trials	<b>Prof Tim Maughan, University of Cardiff</b>
15.45 – 16.10	Case study 2 – Haematological cancer trials	<b>Prof Alan Burnett, University of Cardiff</b>
16.10 – 16.20	Questions	
16.20 – 16.30	<b>Closing address</b>	<b>Prof Sir Kenneth Calman, Chair National Cancer Research Institute</b>
16.30	<b>CLOSE</b>	

The Royal College of Pathologists has awarded 5 CPD credits to this meeting.

## Biographies

**Brian Clark** is a histopathologist. He has held: academic posts at the University of Glasgow (Anatomy and Pathology) and the Institute of Ophthalmology at University College London (Pathology); clinical posts at Moorfields Eye Hospital London (Consultant Pathologist); and posts in industry in Pharmagene Laboratories Ltd (Vice President for Ethics and Pathogenesis). He previously led a group from the Bioindustry Association, the Association of the British Pharmaceutical Industry and the British In Vitro Diagnostics Association in advising government on the Human Tissue Act 2004. Since January 2005, Brian has been the Chief Executive Officer of onCore UK - a cancer tissue banking charity set up as a joint initiative of the Department of Health, Medical Research Council and Cancer Research UK.



**Richard Kaplan** is Associate Director of the National Cancer Research Network (NCRN). He also serves as Programme Leader at the Medical Research Council (MRC) Clinical Trials Unit and Professor of Clinical Cancer Studies at the Leeds Institute of Molecular Medicine. Professor Kaplan is a medical oncologist with 30 years in clinical research in the US and previously was Chief of the Clinical Investigations Branch, National Cancer Institute (NCI), National Institutes of Health (NIH). He was Program Director for the NCI's national program of Cooperative Group clinical trials of cancer treatments, and Program Director for NCI's Brain Tumor Consortia. He has been responsible for scientific coordination of NCI-funded or sponsored treatment trials in brain, urological, and gastrointestinal malignancies, and has served on advisory committees and panels for NCI, NIH, Food and Drug Administration (FDA) and for other government agencies and professional organizations, as well as for clinical trials networks in the UK, Ireland, and Europe. As Industry Lead for NCRN, a major focus of Prof Kaplan's effort at present is in promoting collaborative efforts, both commercial and academic investigator led, between the NHS and companies in the pharmaceutical, biotechnology, and device industries.



**James Brenton** James Brenton carried out his medical oncology and cancer biology training at the Royal Marsden Hospital, the Wellcome Trust/Cancer Research UK Gurdon Institute of Cancer and Developmental Biology, Princess Margaret Hospital/Ontario Cancer Institute and the Department of Oncology, University of Cambridge. He has been a Cancer Research UK funded group leader since 2001 and leads the translational ovarian cancer research program in the Cambridge Research Institute and Cambridge Cancer Centre. His research focuses on the identification of prognostic and predictive markers in ovarian cancer, with particular emphasis on genomic profiling of tissues from clinical studies and bioinformatic analysis to identify mechanisms of taxane and platinum resistance.



**Anne Heatherington** is Head of Clinical Research for Pfizer Ltd in Sandwich where she has overall responsibility for the clinical programs up to proof-of-concept within the pain, allergy and respiratory, and new opportunities research units. As part of this position, Anne has brought together scientists across research to form a "Human Tissue Network" to facilitate the acquisition of human samples and tissue in support of drug discovery. Prior to this appointment in 2009, Anne spent 4 years in clinical pharmacology at Pfizer Ltd and 8 years focusing on biotherapeutics at Amgen Inc. Anne obtained her BSc in Pharmacy from Queens University Belfast and was awarded a PhD from the School of Pharmacy, University of Manchester.

**Chris Foster** is George Holt Professor of Pathology at the University of Liverpool. He is a specialist in the Cellular and Molecular Pathology of Human Cancers, particularly of the breast, prostate and bladder. Professor Foster was a Senior Lecturer in Pathology at the Royal Postgraduate Medical School, London prior to his appointment in 1994 to the George Holt Chair of Pathology at the University of Liverpool. Here, he is in charge of an internationally-recognised research group concerned with the identification of genes responsible for promoting the invasive and metastatic phenotype of human cancers. For the past ten years, in addition to his academic work, Professor Foster has played a central advisory role, both in the North West and nationally to the DoH, in establishing Pathology Modernisation. Currently he is a member of the National Pathology and Research Taskforce and is a member of the Histopathology Research Subcommittee of the Royal College of Pathologists.



**Dr Jeff Cummings** Dr Jeff Cummings is a Staff Scientist working within the Clinical and Experimental Pharmacology Group of the Paterson Institute for Cancer Research, responsible for the implementation of the group's quality assurance system and policy on biomarker method validation. Jeff has over 28 years experience in cancer pharmacology and has been at the forefront of all the major developments in academic quality assurance over the past 10 years. He was instrumental in setting up the NTRAC QA Group and acted as its first and only Chair for 3 years and now sits on the steering committee of the ECMC Bioanalysis and Quality Assurance Group (BAQA). Jeff has published over 160 research papers and book chapters and recently guest edited a special issue of the Journal of Chromatography on Quantitative Analysis of Biomarkers by LC/MS.



**Alison Parry-Jones** is the Manager of the Wales Cancer Bank (WCB). She is responsible for the day to day running of the WCB and is based at the University Hospital of Wales in Cardiff. She is the Designated Individual on the WCB licence issued by the Human Tissue Authority and is therefore responsible for governance and compliance across all WCB sites in Wales. She has extensive project management experience in academia and is a PRINCE2 project management registered practitioner. Her background is in analytical chemistry and before moving into project management she worked in bioanalytical laboratories specialising in phase I and II clinical research.



**Derek Stewart OBE** As a former cancer patient, Derek is very active in ensuring that the patient's voice is heard and understood in all aspects of service delivery and research. Derek helped facilitate the early meetings of the Confederation which led to him becoming the Chair. He is currently the Associate Director for patient & public involvement with the National Institute for Health Research, Clinical Research Networks Coordinating Centre (NIHR CRN CC).



**Neil Formstone** is a founder member of Wales Cancer Bank and a Macmillan Cancer Voice and Research Trainer. Since becoming a cancer patient in 1994 he became interested in the involvement of patients where they can make constructive input into the types of research undertaken and where they can influence research priorities. He has a specialist interest in research and active lay/patient involvement in research activities. Neil is also Chair of the Royal College of Pathology Lay Committee. Neil's view is that patients/lay people can make a valuable contribution in encouraging and facilitating other patients to become donors and are a resource that is under used by a majority of researchers.



**Catherine Elliott** is a graduate from Edinburgh University Medical School. She trained as an Obstetrician and Gynaecologist, including four years as a Clinical Lecturer at Imperial College, London studying the molecular mechanisms of preterm labour. She completed a Masters degree in Medical Law, with a dissertation on the new UK Human Tissue legislation. Since moving from clinical practice she initially worked in medical defence, dealing with the defence of medical negligence claims and also disciplinary proceedings and complaints against medical professionals. Catherine has been working with the Medical Research Council (UK) since 2005 and is Head of Clinical Research Support and Ethics. This post includes leading on regulatory and ethical aspects of research funded by the MRC and providing guidance to researchers on current legislative and good practice requirements. As part of this role Catherine coordinated the CURE project, reviewing governance and ethics review of medical research in the UK and in China. She has been closely involved with the development of the recent Embryology Bill in the UK, in particular the legal aspects of regulating research involving human admixed embryos and other human embryo research. She also wrote the MRC guidance on Research Involving Adults Lacking Capacity to Consent.



**Andy Hall** is currently Director of the Newcastle Cancer Centre at the Northern Institute for Cancer Research, Newcastle University. Andy trained as a haematologist but decided to take a few months out to do some research in 1988 and hasn't gone back to full-time clinical work since. His research interests are focussed on the mechanisms underlying the emergence of drug resistance in childhood leukaemia. Evaluation of these studies has convinced him of the value of using primary cells over cell lines or animal models whenever possible. As a consequence Andy helped to establish a local biorepository and he acts as the Designated Individual for the Newcastle Biomedicine Biobank. He acts as the Chair of the Biomarkers and Imaging Discovery and Development Committee for CRUK- involved in assessing funding applications to support sample collections for cancer research.



**Chris Womack** has been a histopathologist in Oncology R&D early clinical development at AstraZeneca since 2006 and is the Alderley Park Site Biobank Head. His main activity is research into biomarkers in relation to disease target linkage in oncology drug development. He is also serves as a pathologist to Manchester Cancer Research Centre Biobank and is Professor in Histopathology Manchester University. Chris was previously a diagnostic consultant pathologist at Peterborough District Hospital and has been actively involved in tissue biobanking for 15 years. He is a Past President of the British Association for Tissue Banking.



**Barry Gusterson** is Professor of Pathology at Glasgow University. He was appointed as Professor of Pathology at the Royal Marsden Hospital and Institute of Cancer Research in 1986. He initiated the building of the UK's first dedicated Breast Cancer Research Centre and with Bill Freedman established the Charity Breakthrough Breast Cancer. Barry was responsible for the medical and scientific face of the charity and took forward the building of the Toby Robins Breast Cancer Research Centre and was the Founding Director. Since moving to Glasgow in 2000 Professor Gusterson has held the positions of Associate Dean for Research and Head of Cancer Sciences and is currently Head of Pathology and Forensic Medicine and Science. He initiated the idea to build the Beatson Translational Research Centre and is Scientific Advisor to the Pebble Appeal and Project Director for the build. He is Director of the Glasgow Biorepository which he initiated in 2001. He has over 250 publications with the main research interest breast cancer, head and neck cancer and soft tissue tumours.



**Tim Maughan** is Professor of Cancer Studies at the School of Medicine in Cardiff University and an Honorary Consultant Clinical Oncologist at Velindre Hospital specialising in gastrointestinal cancers and lymphoma therapy. He is the Chair of the NCRI Clinical and Translational Radiotherapy Research Group. The work of this group is broad-ranging in scope and ambitious in intent and aims to enhance radiotherapy related research across the UK. He is also the Clinical Director of the Wales Cancer Trials Unit, an NCRI accredited and Cancer Research UK core funded unit running a portfolio of major multicentre cancer trials, and the Clinical Director of the Clinical Research Collaboration Cymru Coordinating Centre. Professor Maughan's research is in the treatment of patients with colorectal cancer. He is the Chief Investigator of the MRC COIN trial, evaluating novel treatments in metastatic colorectal cancer, and of the MRC FOCUS 3 trial evaluating the feasibility of molecular selection of therapy in metastatic colorectal cancer.



**Alan Burnett MBE** was trained at Glasgow University. He did postgraduate research in the Ben May Laboratory for Cancer Research, University of Chicago, USA, and returned to Glasgow where he established the Stem Cell Programme and Autografting in AML. He was appointed Chair of the Medical Research Council Adult Leukaemia Working Party in 1989 and has acted as a coordinator of the MRC – 10, - 11, -12, -14, -15, -16 and -17 Trials. He was appointed Professor and Head of the Department of Haematology at the University of Wales College of Medicine (now Cardiff University) in 1992. In 2002, Professor Burnett was appointed as Chair of the NCRI Haematological Oncology Study Group. His main research interest is the development of treatments for Acute Myeloid Leukaemia. He is past President of the British Society of Haematology and Chair of the UK National Training Programme. He was elected as a Fellow of the Academy of Medical Science in 2002 and was awarded the Gold Medal of the British Society for Haematology in 2004 and was appointed as an MBE in the Queen's Birthday Honours for services to Medicine in 2008.



**Sir Kenneth Calman** is Chancellor of the University of Glasgow. He graduated in medicine in Glasgow and became Professor of Oncology in 1974. He remained in that post for 10 years. In 1984 he became Dean of Postgraduate Medicine and Professor of Postgraduate Medical Education at the University of Glasgow and Consultant Physician with an interest in palliative care at Victoria Infirmary, Glasgow. In 1989 he was appointed Chief Medical Officer at the Scottish Home and Health Department and in September 1991 he became Chief Medical Officer in the Department of Health in London. He was a member of the Executive Board of the World Health Organisation, and its Chairman from 1998-9. He was Vice Chancellor and Warden of the University of Durham from 1998 until 2007. He was a Member of the Statistics Commission from 1999 until 2007. He is President of the Institute of medical Ethics and a member of the Board of the British Library. He was awarded a KCB in 1996. His most recent books are "A study of storytelling, humour and learning in medicine" and "Medical Education: Past present and future".



# Exhibitors

## Brady

Brady's laboratory identification products (laboratory labels and printers) are designed to serve biotechnology, agricultural, environmental and forensic researchers to help maintain Good Laboratory Practices. These identification products meet four current labelling challenges associated with sample container tracking: sizing, legibility, durability and increased information requirements.

## Cell Cryogenics

Cell Cryogenics specialises in advanced technology for the precise and reproducible cryopreservation of cells and tissues. The products are fully compliant with GMP and the European Tissue and Cell directives making them ideal for use in the cryopreservation of clinical trial and therapeutic samples. Both the key product, the compact and portable EF600 liquid nitrogen-free and alcohol-free controlled rate freezer for cryovials or cryobags and, the new CellSeal closed system cryovials with sterile addition and removal of sample are unique, and offer an advanced and easier way to control rate freeze and store samples.

## ECMC

A major network of Experimental Cancer Medicine Centres (ECMCs) has been established across the UK to drive the development of biomarkers and new anti-cancer treatments. This is a joint initiative between Cancer Research UK and the Departments of Health in England, Scotland, Wales and Northern Ireland. The network was launched in October 2006 and ECMC status and funding awarded to 19 centres of scientific and clinical excellence in translational research. The aim of the ECMC Network is to bring together laboratory and clinical patient-based research to speed up the development of new therapies and biomarkers by evaluating new drugs and individualising patient treatment.

## Modul-Bio

Modul-Bio's products portfolio includes:

MBioLABEL®: traceability solutions for Life Sciences laboratories allowing biological samples identification for long term storage, from labelling to scanning.

MBioLIMS® BioBanking: a customized Laboratory Information Management

System based on MBioLIMS Core and Plug-in modules. Solutions specially designed for biobanking laboratories.

## NCRI

The National Cancer Research Institute (NCRI) is a UK-wide partnership between the government, charity and industry which promotes co-operation in cancer research among the 21 member organisations for the benefit of patients, the public, and the scientific community. It provides an independent forum for developing national resources and coordinating the funding of cancer research.

## Qiagen

QIAGEN is the leading provider of sample and assay technologies. Integrated solutions enable drug and vaccine discovery in the emerging era of translational medicine where the use of genetic information is central to the discovery and clinical assessment of new targeted medicines. The recent acquisition of DxS strongly complements the existing portfolio of personalised healthcare diagnostic solutions, making QIAGEN the leader in companion diagnostics.

## Thermo Fisher Scientific

Thermo Fisher Scientific has the world's largest breadth of offerings for biobanks, from biospecimen collection, processing, testing and storage to sample and data management. The end-to-end portfolio includes centrifuges, concentrators, freezers, robotics, 2D barcodes, microplate readers, mass spectrometers and comprehensive services that enable turn-key biobanking solutions. The company can showcase innovative services and software for biorepositories, including laboratory information management systems, laboratory equipment and storage and related services sold under its Thermo Scientific and Fisher BioServices brands.

## Tissue Solutions

Tissue Solutions Ltd. offers a single point of access to the entire range of human biological materials for all your research and development needs, including diseased and normal tissues in fresh, frozen and FFPE formats. Using our large network of ethical sources we find the tissues you require, to your specifications and will deliver them to your door. Our goal is to provide high quality, well characterised and ethically acquired samples to biotech companies, the pharmaceutical community and contract research organisations worldwide. We also organize customised and prospective tissue acquisition projects and give specialised advice relating to all aspects of the acquisition process, including intellectual input on project design.



**Our aims are to:**

- Promote and disseminate a collective view on best practices for biobanks and to promote transfer of knowledge and experiences between banks
- Work towards a seamless operation so that sample users experience what appears to be a single virtual biobank
- Work in a way such that individual member banks retain their full autonomy

[www.ncri.org.uk/ccb/](http://www.ncri.org.uk/ccb/)

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onCore UK ([www.oncoreuk.org](http://www.oncoreuk.org)) provides the secretariat for CCB on behalf of NCRI