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EU Directive raises concerns for UK clinical trials

A new European Directive, *Good Clinical Practice in Trials of Medicinal Products*, could prevent or delay UK publicly funded clinical trials...

So said an MRC-led steering group in response to the Medicines and Healthcare products Regulatory Agency (MHRA) consultation on draft UK legislation to implement the Directive.

The group submitted their assessment of the impact of the Directive to the MHRA in May 2003. Chaired by Professor Stephen Evans of the London School of Hygiene and Tropical Medicine, the group included trialists and representatives from Cancer Research UK and the NHS Health Technology Assessment Programme. It also drew on the experience of other funders.

In general, the group supported the Directive's broad aims of protecting trial participants and simplifying regulation across Europe. However, they raised major concerns about the Directive's inflexibility, as it assumes that systems designed for managing commercial trials should be applied also to all publicly funded trials of the kind run by the MRC, charities and the NHS.

The group also thought that the European Commission had not recognised how publicly funded trials lead the way in setting standards, methodology development, clinical leadership and trials management. Their report, *Good Regulation of Clinical Trials for Patients*, emphasises that publicly funded trials have saved many lives world-wide and need to be protected. Such trials often address important questions of little commercial interest, tackle neglected areas such as trials in children, and promote innovation in trial design. Professor Stephen Evans stressed that his group was not arguing for lower standards. "The key issue is that the systems for achieving high standards need to be appropriate to the risks involved. Where a lot of safety information already exists, as in many MRC trials, the kind of intensive monitoring that the industry uses for new products would be unnecessary and expensive."

Find out more online

Good regulation of clinical trials for patients in downloadable pdf format:

www.mrc.ac.uk/index/public-interest/public-news/public-good_regulation_clinical_trials.htm

MRC *Guidance on Good Clinical Practice in Clinical Trials*:
www.mrc.ac.uk/index/publications/publications-ethics_and_best_practice/publications-clinical_trials_guidelines.htm



Key concerns about the Directive:

- The requirement for one 'sponsor' organisation to take responsibility for all aspects of a trial. Current UK practice is for collective sponsorship by funders, universities, trusts and investigators.
- Complex authorisation and registration processes for new trials, and a potential wait to re-authorise existing trials.
- Potentially rigid, over-elaborate and expensive monitoring and pharmacovigilance procedures.
- Excessive and unnecessary new burdens and costs stemming from new good manufacturing practice requirements.
- Additional hurdles for trials involving patients' consent in emergency and, potentially, mental health settings.

EU countries will be legally obliged to comply with the Directive by 1 May 2004. This means a lot of work must be done urgently to safeguard the future of publicly funded trials in the UK. The MHRA, the MRC and the Department of Health (DoH) are already working together to address some of the issues the Directive raises. The MHRA has made a commitment to clarify and simplify its requirements, and the DoH and the MRC are establishing a joint task force, working with the MHRA and other stakeholders, to ensure that the new regulations will allow existing best practice to be used wherever possible, keep added burdens to a minimum, and allow trials to avoid unnecessary new expense through optimum use of public resources.

Chronic fatigue syndrome in the spotlight

Choosing an effective treatment plan for CFS/ME can be a challenge for doctors and patients alike. Two new MRC-funded clinical trials should help make the process easier in the future

The first trial, entitled *Pacing, Activity and Cognitive behaviour therapy: a randomised Evaluation (PACE)*, will be one of the largest ever of CFS/ME treatments. It will compare the benefits of adding adaptive pacing therapy ('pacing'), graded exercise therapy (GET), or cognitive behaviour therapy (CBT) to the patients' usual medical care.

Putting pacing to the test

Pacing is an approach in which patient and therapist work together to determine the patient's ability to carry out various mental and physical activities. This is the first time that pacing will have been evaluated and compared for effectiveness with the more established treatments of GET and CBT. Although GET and CBT help some patients, others experience deteriorating symptoms when using them outside a research setting. Furthermore, previous trials of these treatments have been criticised for being too small or selective to evaluate their effectiveness definitively.

The leading ME charity, Action for ME, has helped to develop the pacing treatment manual. If the trial proves that pacing is effective, patients and doctors will have a valuable new treatment option. Leading the PACE trial will be Dr Peter White of Queen Mary School of Medicine and Dentistry based at St Bartholomew's, London, Dr Michael Sharpe of the University of Edinburgh and Dr Trudie Chalder of King's College London. Funding is by the MRC, the Department of Health and the Department for Work and Pensions, and the Scottish Chief Scientist's Office.

FINE looks at home-based treatments

The second trial, *Fatigue Intervention by Nurses Evaluation (FINE)*, will test two treatments that are particularly suitable for patients who are too ill to attend a specialist clinic. Pragmatic rehabilitation, a new brief self-help treatment, will be compared with supportive listening and treatment as usual by the primary care team. Pragmatic rehabilitation is delivered by specially trained nurses, who give patients a detailed physiological explanation of symptom patterns. This is followed by a treatment programme focussing on graded exercise, sleep and relaxation. An earlier smaller study has shown some success with this approach in secondary care. The trial will involve patients in the North West of England and North Wales. It is funded by the MRC and will be headed by Dr Alison Wearden at the University of Manchester.

Encouraging research

The MRC is keen to stimulate more research into CFS/ME. With this in mind, it issued a highlight notice at the beginning of May to encourage proposals from across the research spectrum, from basic to applied. The MRC uses highlight notices to alert scientists about areas for which it would particularly welcome proposals. The applications are assessed against the normal criteria, including scientific excellence, but have the extra weight of relating to a current MRC strategic priority.

The MRC also wants to harness the wealth of existing data from national population studies and databases for use in epidemiological research about CFS/ME, which could yield valuable insights into the extent and distribution of the conditions in the UK population. To explore how this could be achieved, the MRC is holding a meeting of experts in the use of such data, chaired by Professor Phil Hannaford of the University of Aberdeen, on 10 September. To provide an international perspective, a representative from the CFS/ME research programme at the USA Center for Disease Control will also be attending.

These initiatives are in response to the strategy to advance research into CFS/ME developed by an MRC-led advisory group at the request of the Department of Health for England in early 2002. The strategy report was published in May 2003, after a process of wide-ranging consultations with patients, carers, charities, patient groups, researchers and clinicians throughout 2002. Key themes include case definition; an epidemiological framework; the biology of CFS/ME; interventions; health services research; research capacity and the value of lay participation. The long-term and short-term recommendations for research will lead to greater understanding of CFS/ME and advances in patient care, and will enable researchers and funders in the UK and elsewhere to press ahead with work on this complex and debilitating illness.

The advisory group was chaired by Professor Nancy Rothwell of the School of Biological Sciences, University of Manchester, who said: "We've made our recommendations based on what is attainable in the short term, and what has to be developed over a longer period ... they will be a stimulus for research and the field will then evolve naturally as more is done and other possibilities present themselves. I'd like to thank everyone who took time to feed into the development of this strategy, particularly those directly affected by the illness. The personal testimonies we received were invaluable and we appreciate the time and effort we know it involved."

Terminology

The terms chronic fatigue syndrome (CFS) and myalgic encephalomyelitis or encephalopathy (ME) are used to describe an illness where patients suffer from unexplained disabling fatigue, and may also have varying combinations of other symptoms. CFS/ME does not refer to a specific diagnosis. It is an umbrella term used to encompass a range of serious and debilitating conditions.

Strategy report recommendations

- Recognition that significant advances that can improve health and quality of life for CFS/ME patients can be made without the need to fully understand the underlying causes or triggers.
- Encouraging researchers to develop high quality research proposals on case definition, symptomatology and new approaches to managing the illness including diagnosis and treatment.
- Ensuring that future research is as inclusive as possible of the full spectrum of severity and age range, including the severely ill and children.
- The need to nurture the researcher-funder-lay partnership. This will benefit the future design and management of research and dissemination of results, and make the most of the valuable role patient organisations can play in these activities.

Find out more online

Development of CFS/ME research strategy, including report in downloadable pdf file format:

www.mrc.ac.uk/index/public-interest/public-topical_issues/public-cfs_me.htm

Research centre news

Results of FIS consultation

May 27 was the final day of the initial Forward Investment Strategy (FIS) stakeholder consultation about proposals for four key MRC sites that need major investment over the next 10 to 15 years. The FIS Subcommittee has now reviewed all responses and reported to the MRC Council.

Broadly speaking, the overall policy and forward strategy for three of the sites were well received: for the MRC Clinical Sciences Centre in Hammersmith, London; the MRC Mammalian Genetic Unit in Harwell, and the MRC Laboratory of Molecular Biology in Cambridge. However, the majority of responses were about proposals for the National Institute for Medical Research in Mill Hill, London, and were less positive. After reviewing these, the MRC Council decided that there was a need to speed up work on plans for NIMR's scientific future. This would include consideration of a broader range of options about the size and location of NIMR and further consultation with stakeholders.

An expert task force will be set up for the next phase of the consultation process. Initially it will be chaired jointly by MRC Chief Executive Sir George Radda and Chief Executive-Designate Colin Blakemore. The group will include MRC Council members, independent national and international experts, and senior scientists from NIMR. It will complete an interim report to the MRC Council by the end of October 2003, to inform RCUK's long-term capital spending plans as part of the submission for the 2004 government spending review. The final report to the MRC Council is planned for completion by mid 2004.

Epidemiology Unit reorganisation

The MRC Environmental Epidemiology Unit in Southampton is to close in October when its current Director, Professor David Barker, retires. A new MRC Resource Centre for Epidemiology in Southampton and an MRC Epidemiology Unit in Cambridge will be launched to coincide with the closure.

MRC to support IEH for two more years

Following the review of future options for the Institute for Environmental Health, the MRC Council has accepted the recommendations that the MRC should continue to support the IEH until October 2005, but not in the longer term. The MRC will assist in planning IEH's future after MRC funding ends in two years' time.

HRH The Princess Royal opens SGDPDC

On 13 February HRH The Princess Royal opened the MRC's new Social Genetic and Developmental Psychiatry Centre at the Institute of Psychiatry in London. During a tour of the Centre she met SGDPDC researchers and learnt about their work on depression, autism and the early development of twins.



HRH The Princess Royal is greeted by young participants in the SGDPDC Twins Early Development Study

Opportunities

MRC awards

The MRC offers support for talented individuals who want to develop research careers within the biomedical sciences, public health and health services. A complete portfolio of personal award schemes is available, with each one tailored to a particular stage in a clinical or non-clinical career path.

Closing dates for the majority of MRC awards are in the Autumn – see the box opposite for details. So if you are interested in applying but have not done so yet, make sure you visit www.mrc.ac.uk for further details about the awards and how to apply.

'Striking back at MS' Fellowships

To mark the Multiple Sclerosis Society's 50th year, the Society has launched two anniversary fellowships in partnership with the MRC. One is a Clinical Research Training Fellowship and the other a four-year non-clinical Career Development Award. Both will help to 'strike back at MS' by attracting bright young scientists to carry out research that advances understanding and treatment of the disease. For further details visit www.mrc.ac.uk

Calls for proposals

The MRC has just announced a call for expressions of interest in strategic consortia grants for E-science grid application projects relevant to clinical trials or longitudinal studies. A call for proposals in sexual health and HIV research has been issued and calls for proposals in Functional Proteomics, and the cross-council Brain Sciences programme will follow over the summer.

Look out for further details in MRC Network, and on the MRC website www.mrc.ac.uk

Closing dates for MRC awards

Clinical Research Training Fellowship:
05.09.03 and 30.01.04

Special Research Training Fellowship in Health Services Research and Health of the Public:
19.09.03

'Discipline hopping' Award:
23.09.03

Senior Non-Clinical Fellowship:
03.10.03

Career Development Award:
31.10.03

Clinician Scientist Fellowship: (to run concurrently with Senior Clinical)
14.11.03

Senior Clinical Fellowship: (to run concurrently with Clinician Scientist)
14.11.03

Special Research Training Fellowship in Bioinformatics, Neuroinformatics and Computational Biology:
21.11.03

Joint Collaborative Career Development Award in Stem Cell Research:
09.02.04

Department of Health Clinician Scientist Award:
17.05.04

Improving animal welfare in medical research

Research involving animals has been behind many of the most important breakthroughs in medicine. It will continue to be needed to help scientists tackle major health problems in the future ...



The 3 Rs

The MRC supports the use of animals in well-justified medical research provided that there are no other ways to advance scientific knowledge and that every effort is made to:

Replace the use of animals by humane alternatives wherever possible, for example, cell tissue cultures.

Reduce the numbers of animals used.

Refine husbandry and procedures to minimise suffering and improve welfare overall.

The MRC believes that it is vitally important to maintain high standards of animal welfare in laboratories. Although the reasons for this are essentially ethical, careful attention to animal welfare also helps to ensure accurate and replicable data. To meet the scientific community's need for independent advice and guidance about use of animals, the MRC set up the Centre for Best Practice for Animals in Research (CBPAR) in May 2001.

The CBPAR maintains, develops, disseminates and implements best practice relating to every aspect of animal-based research. This involves working with a wide range of stakeholders: the scientific community, research funding bodies, animal welfare organisations, learned societies, the Home Office Animals (Scientific Procedures) Inspectorate, and the public. The guiding principles behind the Centre's work are summed up by the 'three Rs' shown in the box opposite. Its activities to promote 'replacement, reduction and refinement' of animal use by the scientific community include:

• Care of primates

The CBPAR has developed guidelines for the use of macaques and marmosets in MRC-funded research, which the MRC Council has approved in principle. Issues covered include the source of animals, accommodation and social environment, veterinary care and staff training.

• Welfare of genetically modified (GM) mice

The CBPAR is coordinating a multi-disciplinary working group on welfare assessments for GM mice, on behalf of the main UK biomedical research funders. The group will take forward the recommendations of the 2001 Animals Procedures Committee report on biotechnology, and produce a report and recommendations that the funding bodies will consider how to implement.

• Experimental design and statistical analysis

In February the CBPAR held a meeting with stakeholders to discuss problems of statistical analysis and experimental design in biomedical research, particularly that involving animals. As a result, a working party has been set up that will address this UK-wide issue through consultation.

• Communication with animal technicians

CBPAR initiatives aimed at the technical staff who look after laboratory animals include: a quarterly newsletter; a first annual symposium in September 2003; and a new prize for the best contribution to animal welfare by a technician working in academic research.

• 3Rs research funding

The CBPAR manages a dedicated funding scheme to support research into any of the 3Rs (see box). For information about the scheme, email 3rs@headoffice.mrc.ac.uk.

CBPAR Head Vicky Robinson, a former MRC scientist who came to the Centre from the Research Animals Department at the RSPCA, said: "I think we have already achieved a great deal – working with the scientific community to make a positive difference for animals and the research they are used in."

Find out more online

Centre for Best Practice for Animals in Research:
www.mrc.ac.uk/index/public-interest/public_ethics_and_best_practice/public-use_of_animals_in_research/public-cbpar.htm

Government rejects S&T Committee's most serious criticisms of the MRC

The Government has firmly refuted serious allegations by the House of Commons Science and Technology Select Committee that MRC's funds had been mismanaged and that its research strategies were misguided.

The Government response to the Select Committee Report on the MRC did, however, accept their recommendations in certain areas. It agreed that the MRC should do more to inform the research community about its

funding policies and to reduce year-on-year funding and award rate fluctuations, that it should improve the quality of information it provides, and that it should review the Co-operative Group Grant (COGG) scheme. Work that was already underway in these areas before the Select Committee review is now being boosted by specific initiatives. Enhancements to the MRC's financial management systems will help to smooth funding for new awards from one academic year to the next,

and a detailed review of its information management systems will improve the quality of information provided to stakeholders.

COGG Review

An independent review of the COGG scheme, which was timetabled for 2003 when COGGs were launched five years ago, has already started. It will take into account questions raised by the Select Committee and should show whether or not COGGs add value and are sustainable. The MRC

Monitoring and Evaluation Steering Group (MESG), which finalised plans for the review earlier this year, is overseeing the work. An initial scoping study by independent MESG members will gather opinions from COGG holders and applicants about the strengths and weakness of the scheme at both individual and institutional levels. This will prepare the ground for a full evaluation of the scheme, scheduled for later this year, which will involve external consultants and

key stakeholders including the MRC Advisory Board, the wider research community and other research users and funders. The final review report is expected by the end of 2003.

Find out more online

The Government response to Science and Technology Select Committee's report on the Medical Research Council:
www.ost.gov.uk/research/councils/govresponsestcomm.htm

MRC international

The first in a series of features looking at MRC work overseas focuses on clinical trials in developing countries

The MRC is one of the largest funders of medical research in developing countries. So it is no surprise to learn that when the European and Developing Countries Clinical Trials Partnership (EDCTP) begins operating later this year, the MRC will be its UK representative. An international initiative based in The Hague, EDCTP has been set up to develop and support applied clinical research in developing countries. It will help to combat the global problem of poverty-related infectious diseases by creating a long-term partnership between European researchers, industry and developing countries. The focus will initially be on African countries, which suffer the greatest burden of poverty-related disease, with particular emphasis on HIV/AIDS, tuberculosis and malaria. The European Union has agreed €200 million funding for EDCTP's first five years.

Developing urgently needed treatments

The EDCTP's strategy for encouraging the development of effective, affordable treatment for poverty-related diseases in developing countries includes: supporting

clinical trials; absorbing much of the financial risk of trials as an incentive for pharmaceutical companies to invest in developing affordable treatments; networking and promoting co-operation between European and developing countries' national programmes and helping to strengthen developing countries' research capability.

The MRC helped to prepare the ground for the EDCTP by working to establish the initiative's aims and scope. It will now represent the UK in the EDCTP's legal structure, contribute to further development of the strategy, and take a leading research role. In addition, the MRC will foster closer links with the Department for International Development (DFID) and other UK stakeholders, and maintain close dialogue with other EU states to ensure that their policies and decision-making reflect the EDCTP's mission. An MRC advisory group will be set up to review UK HIV/AIDS, tuberculosis and malaria research in the international context.

"MRC is proud to be at the forefront of this important initiative ... a new spirit of partnership in Europe will help us achieve great things for those who are ill, irrespective of where they live."

Professor Sir George Radda, Chief Executive Officer of the MRC

Major AIDS treatment trial starts in Africa



Members of DART International Coordinating Group, DART Trial Steering Committee and Data and Safety Monitoring Committee at the Grand Imperial Hotel in Kampala, Uganda on 12 March 2003

A clinical trial on the Development of Anti-Retroviral Therapy (DART) in Africa is a prime example of how the principles behind EDCTP could work in practice.

Triple-drug Anti-Retroviral Therapy (ART) has vastly improved the prospects of people living with HIV/AIDS. It has transformed AIDS from an inevitable lingering death, to a long-term illness in which drug toxicity is the

main factor affecting quality of life. Unfortunately, ART is not a viable healthcare option for many patients in the African countries worst affected by AIDS due to the lack of resources and health infrastructure. DART is looking at ways that ART could be made more accessible to patients in such settings

DART will help to address clinical and scientific uncertainties in areas of

particular relevance to developing countries. To find out whether ART can be delivered safely and effectively by health agencies with limited capacity to undertake tests for monitoring effectiveness and toxicity, DART will compare the benefits of clinical monitoring alone against both clinical and laboratory test monitoring. DART will also investigate whether pulse therapy (in regular on-off cycles) which might reduce ART's side-effects, is as safe and effective as continuous ART at fighting HIV/AIDS. The results are expected in 2008.

The DART trial is the largest of its kind in Africa, and one of Africa's first multi-centre, multi-country HIV treatment trials. It has now started to recruit

3,000 volunteers from sites in Kampala and Entebbe in Uganda, and Harare, Zimbabwe. The participants will take part for up to five years and will all receive triple-drug antiretroviral therapy using licensed drugs in line with international guidelines. The DART trial will help to establish partnership between the participating African research institutions, strengthen research capacity including trial management, and develop long-lasting links with international research organisations such as the MRC.

DART is funded by the MRC, the Rockefeller Foundation and DFID, and is co-ordinated by scientists and clinicians from the three African sites (The Joint Clinical

Research Centre, Kampala; the MRC/DFID/Uganda Virus Research Institute (URVI)- programme on AIDS, Entebbe; and the University of Zimbabwe Medical School, Harare), Imperial College, London and the MRC Clinical Trials Unit. Other partners include TASO (The AIDS Support Organisation, Uganda) and the Academic Alliance (Kampala). The pharmaceutical companies Boehringer Ingelheim, Gilead and GlaxoSmithKline are supplying drugs for the study. The Ugandan and Zimbabwean Ministries of Health have made notable commitments to provide appropriate care and support for trial participants when DART is over.

Research roundup

Bursting the bubble

MRC scientists and their colleagues have developed a fresh approach to gene therapy that may prove to be more efficient and safer than existing methods. Gene therapy aims to introduce working genes into a patient's cells to substitute for defective genes that cause disease. At the moment viruses are often used to carry genes into cells, but this approach sometimes causes unwanted side-effects. In the new technique, the genes are carried inside microscopic bubbles, which release the genes into target cells when an ultrasound pulse bursts them. The research was led by Dr Martin Blomey, an MRC Career Establishment Grant holder working at Hammersmith Hospital, and also involved scientists from the MRC Clinical Sciences Centre and the Imaging Sciences Department, Imperial College. Their data suggests that microbubbles are much more efficient than other methods in delivering genes to cells and also cause less tissue damage.

Gene Ther. 10, 396-405

HDT is star performer for bone marrow cancer

MRC-funded research has demonstrated the value of high dose chemotherapy (HDT) in the treatment of the bone marrow cancer, multiple myeloma. Although HDT was known to be useful for treating patients with the relapsed form of the disease, its value as a first-line treatment has been uncertain until now. The MRC Myeloma VII trial showed that not only do patients treated with HDT survive for longer than those receiving chemotherapy, but they are also more than four times as likely to make a complete recovery. An overview of all available world data has backed up this finding. It is a significant step forwards for treatment of multiple myeloma. The disease affects around 3,500 people in the UK each year and is notoriously difficult to treat with less than 20 per cent of victims surviving for more than five years.

N Engl J Med. 348, 1875-1883

Vital roughage

A Europe-wide study has shown that people can almost halve their risk of bowel cancer by eating twice as many fibre-containing cereals, fruits and vegetables. The European Prospective Investigation into Cancer and Nutrition (EPIC) is investigating the diets of more than half a million people in 10 European countries as part of the biggest study so far of European eating habits and health. MRC scientists Professors Nick Day from Cambridge University and Sheila Bingham from the MRC Dunn Human Nutrition Unit in Cambridge helped to lead the research. The finding contradicts those of earlier but smaller studies in the US, Finland and Sweden which found no evidence that fibre prevents cancer, and has important implications for UK health. Bowel cancer is the second highest UK cause of cancer death, and kills more than 16,000 people a year.

Lancet 361, 1496-1500

Another study of diet and cancer, led by Dr Maria Maynard of the MRC Social and Public Health Sciences Unit, found evidence that eating plenty of fruit in

childhood may protect against cancer in adulthood. The research traced the health records of nearly 4,000 people who had taken part in a 1930s survey of what families ate in a week, and related diet to cancer deaths. It found that people who ate the most fruit as children were the least likely to develop cancer as adults, and had lower death rates from all causes.

J Epidemiol Community Health 57, 218-225

Vif vs CEM15: revealing the relationship

A ground-breaking advance in understanding how the body's defences combat HIV infection has been the result of a joint study by the MRC's Laboratory of Molecular Biology and King's College London. The human protein CEM15 is known to be able to slow the spread of HIV infection but is usually prevented from doing so by an HIV protein called Vif. The new research has shown that CEM15 works by inducing mistakes in replicating viral DNA, making the virus less infectious, and that Vif overcomes this effect. If scientists can go on to find out how Vif inhibits CEM15, and work out how to tip the balance in favour of CEM15, this work could lead to new antiviral therapies. The work was supported by the Leukemia Research Fund, the Arthritis Research Campaign, the Royal Society and the Elizabeth Glaser Paediatric AIDS Foundation.

Cell 113, 803-809

Early breast cancer and birth weight

Work by MRC Research Fellow Valerie McCormack at the London School of Hygiene and Tropical Medicine shows an association between a woman's size at birth and her risk of developing early breast cancer. Dr McCormack looked at the medical records of more than 5,000 Swedish women born between 1915 and 1929. She found that larger birth size – in particular length and head circumference – was strongly associated with increased breast cancer risk in women under 50. Her findings suggest that growth rate in the womb might influence the risk of early breast cancer. However, this effect would only cause a fraction of all cases, because the incidence in women under 50 is low. On a positive note, larger birth size is associated with decreased risk of heart disease, a much more common condition.

BMJ 326, 248-251

Doctors witness attack!

MRC scientists and their Cancer Research UK colleagues are behind a sophisticated technique that enables doctors to watch anti-cancer drugs attacking a patient's tumour as it happens. New imaging technology developed by the former MRC Cyclotron Unit in London and the Northern Institute for Cancer Research in Newcastle, uses Positron Emission Tomography to enable doctors to track an anti-cancer drug's activity inside tumours and assess how well it is working in real time. Not only will this allow doctors to spot early on if a drug is not working and switch quickly to an alternative treatment, but it also avoids the need to take tissue samples from the patient for later analysis. What's more, the technique should help speed up clinical trials of new drugs.

J Natl Cancer Inst. 95, 675-682

Stem cell update

Stem Cell Forum working group

In Issue 1, Network reported on the first meeting of the International Stem Cell Forum and its decision to set up a working group to co-ordinate a world-wide effort to characterise human stem cell lines. The working group held its first meeting in May 2003. It was chaired by MRC Chief Executive George Radda and agreed the group's terms of reference and immediate goals. One of its first tasks is to draw up globally accepted criteria for working with and characterising all human stem cell lines. The group will also identify opportunities for international sharing of resources, materials, data and working practices and will co-ordinate national banking activities.

At its meeting this July the Forum approved the working group project to set international scientific benchmarks which conform to legislation in different countries. Professor Peter Andrews at the University of Sheffield Centre for Stem Cell Biology will co-ordinate the project, working with scientific representatives from the 12 member countries. Researchers from laboratories around the world will examine new and existing stem cell lines, using standardised tools and procedures. Their data will be collated and added to a new registry of stem cell lines, and made available to the international research community through a website that the MRC is developing for the Forum. The website will also hold information on research and training opportunities and on international practice on ethical and patenting issues.

The working group will meet again in about nine months' time for an update on how the work is going and to discuss new tasks.

Forum members

- Medical Research Council, UK
- Israel Academy of Sciences and Humanities
- Canadian Institutes of Health Research
- National Institutes of Health, USA
- National University of Singapore
- Juvenile Diabetes Research Foundation, USA
- National Health and Medical Research Council, Australia
- Academy of Finland
- Scientific Council for Medicine, Swedish Research Council
- INSERM, the French Institute of Health and Medical Research
- Max Plank Institutes, Germany
- Centre for Developmental Biology, RIKEN, Japan
- Ministry of Education, Culture, Sports, Science and Technology, Japan
- The Netherlands Organisation for Scientific Research

Call for proposals

MRC's recent call for proposals in stem cell research is now closed. The call generated a good response and the applications are now being peer reviewed.

Finding out what the public thinks

The MRC is one of a number of organisations with an interest in stem cell research that have teamed up to commission a MORI survey to find out what the public thinks about the issue. The survey revealed that around 70 per cent of the British public support use of human embryos for medical research to find treatments for serious diseases and for fertility research.

Find out more online

International Stem Cell Forum:
www.mrc.ac.uk/index/public-interest/public-news/public-stem_cell_lines.htm

MORI poll findings:
www.mrc.ac.uk/index/public-interest/public-consultation/public_mori_human_embryo_survey.htm

Events diary

8 to 30 September

Medical Research Revealed, an exhibition of paintings by Dr Lizzie Burns, inspired by the work of MRC scientists, at the Salford Museum and Art gallery. Admission is free.

www.salfordmuseum.org

The exhibition opening coincides with the 2003 British Association for the Advancement of Science Festival at Salford University.
www.britassoc.org.uk

14-16 September

Stem Cells: Shaping the Future. A conference at the Millennium Gloucester Hotel, London. This conference, which was planned by the MRC together with other research councils, charities and government departments, will showcase current UK stem cell research. There will also be a series of parallel workshops aimed at informing strategy development, and a learning zone. Register at www.livegroup.co.uk/stemcellsconference2003/index2.php

16 September

Climate Change in the UK: Impact on Environment and Health – the MRC Institute for Environment and Health 10th Anniversary Open Seminar, University of Leicester. Tickets are £30 including lunch and refreshments. For a registration form and further details contact: The Seminar Secretary, MRC Institute for Environment and Health, University of Leicester, LE1 7DD. Tel: 0116 2231600, email: ieh@le.ac.uk or visit www.le.ac.uk/ieh/news/news.html

UK Biobank enters new phase

CEO appointed

Dr John Newton has joined the UK Biobank as its first Chief Executive Officer. Previously consultant epidemiologist at Oxford University's Unit of Health Care Epidemiology, Dr Newton's expertise in epidemiology and public health makes him ideally suited to leading this challenging project.

UK Biobank structure

The UK Biobank's funders – the MRC, the Wellcome Trust and the Department

of Health – have announced that the University of Manchester has been chosen to host the project's Co-ordinating Centre. It will co-ordinate the work of six Collaborating Centres that will contribute to the project's design, participant recruitment, and data and sample collection. The Collaborating Centres each consist of a consortium of academic and research institutions and together span mainland UK (see box). To find out more visit www.ukbiobank.ac.uk

A Science Committee, has also been set up. It will be chaired by Professor John Bell, and will advise the UK Biobank on strategic direction and its overall approach to developing the project's scientific content.

In addition, an Interim Advisory Group is developing an ethics and governance framework through consultations with scientists, health professionals, parliamentary representatives and the public.

Collaborating Centres' consortia

Central England: University of Oxford

Fosse Way: Universities of Leicester, Birmingham, Bristol, Warwick, Nottingham, Sheffield and the Peninsula Medical School

London: London University – Imperial College; University College; King's College; Queen Mary College

North West & Wessex: Keele Universities' Medical School, Manchester; University of Southampton Medical School; MRC Environmental Epidemiology Unit, Southampton

Scotland: Universities of Glasgow, Edinburgh, Aberdeen, Dundee

Wales: University of Wales College of Medicine, Cardiff; Swansea Clinical School; Bangor

MRC people



Professor Colin Blakemore

- Professor Colin Blakemore is soon to leave Oxford University's Centre for Cognitive Neurosciences to join the MRC. He will take over as Chief Executive when Professor Sir George Radda retires at the end of September. An early priority for Professor Blakemore will be to visit universities around the country to introduce himself in his new role and to hear the views of the scientific community.



Professor Kay Davies



Professor Venkatraman Ramakrishnan

- Three MRC scientists have been made Fellows in this year's Royal Society elections: Professor Kay Davies, MRC Council Member and Honorary Director of MRC's Functional Genetics Unit (Oxford); Professor Venkatraman Ramakrishnan, Senior Scientist at the MRC Laboratory of Molecular Biology (LMB, Cambridge); and Dr Mariann Bienz, a Senior Staff Member at LMB. Meanwhile, north of the border Professor Howard Cooke (MRC Human Genetics Unit) Professor Austin Smith, (MRC Research Professor and Head of Institute for Stem Cell Research) and Professor Alan Wright (Western General Hospital) have been elected Fellows by the Royal Society of Edinburgh, Scotland's national academy.



Dr Mariann Bienz



Professor Howard Cooke



Professor Austin Smith



Professor Alan Wright



Professor Sir Philip Cohen



Dr Dario Alessi



Professor Alan Fersht



Professor Alan Hall

- The Institute for Scientific Information, Philadelphia, USA has ranked four MRC scientists amongst the world's top 200 most cited scientists in their field. Professor Sir Philip Cohen, Director of the MRC Protein and Phosphorylation Unit at Dundee University, his colleague Dr Dario Alessi and Professor Alan Fersht, Director of the MRC Centre for Protein Engineering occupy second, 44th and 83rd positions respectively in the Biology and Biochemistry rankings. Professor Alan Hall, Director of the MRC Cell Biology Unit, was ranked 16th in Molecular Biology and Genetics.

- Professor Sally Macintyre, Director of the MRC's Social and Public Health Sciences Unit in Glasgow, was recently named as one of the top ten leading people in public health by *The Independent on Sunday*.



Professor Sally Macintyre

Your feedback please

MRC Network is for anyone who has an interest in the work of the MRC, including scientists, doctors, and health professionals involved in medical research, government departments and parliamentarians, and university staff and students. The aim is to provide a quick, easy-to-read summary of activities across the MRC, from research news through to funding, grant schemes and policy issues, with pointers to more in-depth information on websites and in other publications.

We hope you find Network interesting and informative. Now that we have reached Issue 2, we are very keen to receive feedback from readers. If you have any comments, including suggestions for new features that you would find useful, please let us know. Just email newsletter@headoffice.mrc.ac.uk

MRC Network is produced by the MRC Publications Team and is available in print and in downloadable pdf format at www.mrc.ac.uk

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Infowatch



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The MRC Applied Psychology Unit
Reynolds L.A. and Tansey E.M. (eds) (2003)

The Wellcome Trust Centre for the History of Medicine:
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ISBN 0 85484 088 5



Coalition for medical progress

The MRC has joined with a cross-section of organisations – commercial, charitable, academic and funding – to provide public information about the benefits of medical research involving animals. Their collective activities come under the banner of the Coalition for Medical Progress (CMP).

For information on the coalition or on how you can help visit www.medicalprogress.org

Look out for the new, fully interactive CMP site which will be launched in September.