

Wellcome Trust Clinical Research Facility | Winter 2009

# Review

The Southampton Wellcome Trust Clinical Research Facility has seen many exciting events and changes in 2008/09, including the opening of our 500th study. As well as continuing work in Southampton's world class research programmes in cancer, respiratory medicine and nutrition, a research highlight has been the ability of the unit to respond to the national agenda in pandemic influenza. One of only five centres in the NIHR-funded head to head study of the UK H1N1 vaccines in children, the WTCRF enrolled 277 out of a total of 940 children. Nearly 200 children were enrolled in one 48-hour period.

Following the award to Southampton of Biomedical Research Units (BRUs) for respiratory disease and nutrition, diet and lifestyle, the Wellcome Trust Clinical Research Facility (WTCRF) has continued to play a key role in their setting up and administration. This has contributed to a seamless transition from concept to operation, while avoiding duplication of local resources. Many of the appointed BRU research nurses were trained in the WTCRF so ensuring a high quality group of researchers to prime these new developments. We are delighted to be able to maintain such close working relationships with staff we know.

We have made some fantastic additions to our team in 2008/09. In particular, our quality assurance manager, Claudia Fellmer, children's senior research sister, Michelle Casey, and translational scientist and laboratory manager, Luanne Hall-Stoodley, have brought considerable new expertise and enthusiasm to their areas, and we have welcomed many new faces in our teams to replace staff appointed to the BRUs and other clinical research posts across the campus. In addition, our senior research sister, Carol Gough, has won an NIHR studentship to pursue a Masters in clinical research. Our three new WTCRF clinical research fellows have allowed essential medical support to studies and all are progressing well with their plans to pursue research towards a PhD.

The WTCRF once again hosted a successful translational research conference in 2009, with the keynote University Wade Lecture given by Professor Dame Sally Davies, director general of research and development at the Department of Health. Finally, the Facility upgrade and extension has significantly increased our research capacity and allowed us to accommodate the BRU staff while continuing to meet all regulatory standards. Looking to the future, as well as the opening of the new infection-prevented bronchoscopy/endoscopy suite and WTCRF volunteer lounge, we are working

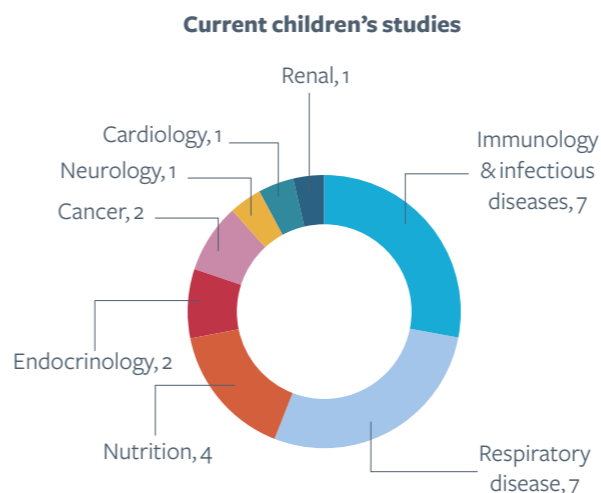
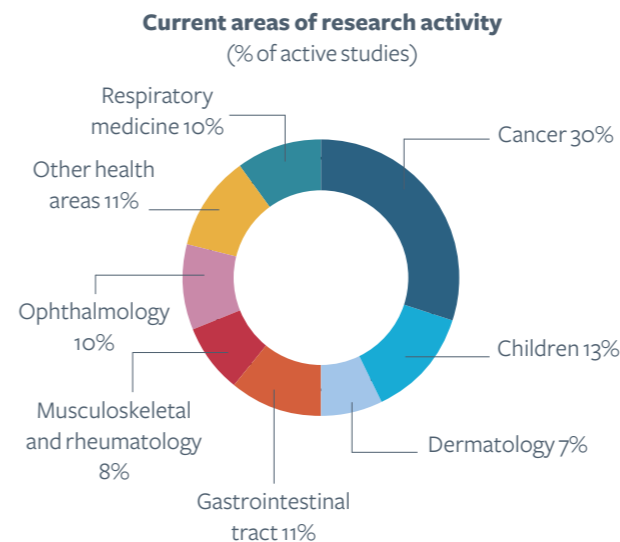
hard to welcome new investigators and studies into the WTCRF to maximise the use of this unique research space.

I hope this review gives some flavour of the range and extent of WTCRF activities and its position at the heart of translational research and experimental medicine in Southampton.



**Dr Saul Faust**  
*Director*

# Activity & finances



Activity		
No. of studies approved to November 2009	500	
Funding sources for 196 currently active studies		
Charities	35	18%
Department of Health/Research Councils	38	19%
Commercial companies	79	40%
Investigator led, commercially supported	14	7%
Other non-commercial studies	30	15%

Volunteer visits in last 12 months (November 2008 to end October 2009)	
All volunteers	7066
Visits to WTCRF	5022
Outreach	1998
Overnight	46

Wellcome Clinical Research Facility Finance Report for the 2008/09 financial year	
Income	£
Income deferred from 2007/08	0
National R&D funding 2008/09	1,220,650
Non-commercial R&D income	51,495
Other income	12,496
Income deferred to 2009/10	372,346
<b>Total Income 2008/09</b>	<b>912,295</b>
Expenditure	£
Pay	602,231
Non-Pay	120,179
Overheads	189,885
<b>Total expenditure</b>	<b>912,295</b>
<b>Net Income</b>	<b>0</b>

## Facilities

A substantial programme of extension and refurbishment was completed in early 2009, providing additional consulting rooms, storage and office space, a new suite for patients receiving therapeutic infusions on trials, and a larger seminar room with updated IT for meetings and education. A Facility-wide refrigeration monitoring system has been installed, ensuring sample viability, security and regulatory compliance.

Further improvements are planned as part of the Biomedical Research Unit building programme adjoining the WTCRF, which opens in 2010. A new negative pressure, two-room endoscopy/bronchoscopy suite, together with designated areas for volunteers with infectious diseases and flexibly configured consulting rooms will increase our capacity to facilitate a wider range of research. Resource use will be optimised by using a centralised booking system.



WTCRF bronchoscopy suite

# Respiratory

**Asthma is a common respiratory disorder characterised by variable respiratory distress with underlying airway inflammation and airflow obstruction.**

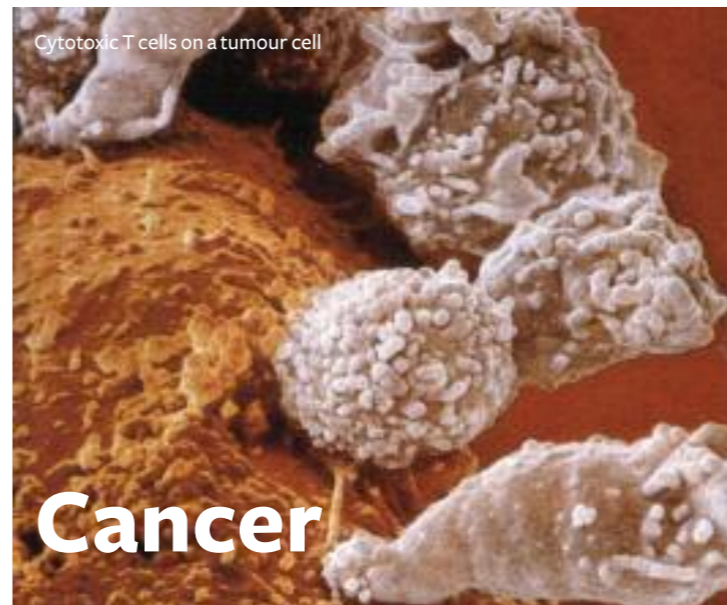
Asthma incidence in the United Kingdom has risen inexorably over the last 50 years, in common with most of the developed world, so that now approximately 30% of children in the UK have a diagnosis of asthma and nearly 25% routinely carry inhalers. The airways in asthma are structurally different to those of normal individuals from a very early age and these structural differences (called airway remodelling) appear to make the lungs of asthmatic patients 'stiffer' and less responsive to treatment. The causes of remodelling in the asthmatic airway are currently unknown, making it difficult to develop treatment or prevention interventions.

Over 80 volunteers with mild asthma have been recruited to a study led by Dr Peter Howarth investigating potential mechanisms underlying the remodelling of the airways in asthma. Volunteers have undergone fiberoptic bronchoscopy in the WTCRF, before and after inhalation challenges designed to trigger specific biochemical pathways within the lungs that might be responsible for airway remodelling.

At the time of bronchoscopy, fluid which is passed into the lungs via the bronchoscope is removed by suction and then rapidly processed on site, to enable analysis of both cellular and soluble markers of inflammation and remodelling; biopsies of the bronchial mucosa are also taken for subsequent processing and analysis. In addition, brushings of the epithelial lining of the lung are performed which enable ex vivo growth of the cells that are obtained, allowing environmental exposures to be modelled in the laboratory as well as in volunteers. This is especially useful for exposures which would be unethical to perform in humans, such as viral infections, inhalation of cigarette smoke or environmental pollution such as diesel particulates.

Initial results from over 100 bronchoscopies have demonstrated evidence of airway remodelling in response to inhalation challenges that trigger specific pathways and lead to release of specific molecules within the lungs. These pathways and molecules were not previously known to be involved in airway remodelling, and some have not previously been examined in humans. It is expected that the results from the study, to be published in early 2010, will lead to a paradigm shift in the understanding of how airway remodelling in asthma is triggered, suggesting new avenues for exploration in the treatment or prevention of the problem in our patients.

**“We found the whole experience efficient, straightforward, very well organised and everyone very pleasant and very good with the children.”**



## Cancer

**The WTCRF works closely with the Southampton Experimental Cancer Medicine Centre (Director, Prof P Johnson) to enrol patients to early phase cancer trials.**

Two key oncology trials conducted in the WTCRF have published significant results in the last year. An open-label, single arm, multicentre, phase II trial with anti-CD20 (ofatumumab) in patients with relapsed diffuse large B-cell lymphoma (DLBCL) ineligible for transplant or relapsed after autologous transplant was performed in successful collaboration with the pharmaceutical company, Genmab.

The antibody was made by Professor Martin Glennie while on sabbatical at Genmab, so Southampton researchers were involved from the preclinical stage, and Professor Peter Johnson was the UK Chief Investigator for this first in man study. The trial recruited rapidly and the antibody is now licensed to GSK for global development. The UK NCRI lymphoma group is running the first phase III trial of this agent in the NCRN.

A phase I/II study of CMC-544 administered in combination with rituximab in subjects with follicular or diffuse large B-cell Non-Hodgkin's lymphoma recruited rapidly and an extended phase II study, led by Professor Peter Johnson, following an initial phase I dose escalation has demonstrated important activity in recurrent lymphoma. This novel immunotoxin antibody combination therapy is now going into phase III studies in the UK and internationally and the UK NCRI lymphoma group will run phase III studies in the NCRN. This is the first demonstration of clinical efficacy of this novel immunotoxin when administered in combination with rituximab.

Additional important results demonstrated in 2008-9:

- First demonstration of efficacy and safety of the rituximab/bortezomib combination in non-Hodgkin's lymphoma, with a particularly high response rate in Waldenstrom's macroglobulinaemia. Follow-on phase II studies are now in design (PI Prof P Johnson).
- Data from anti-CEA and anti-PSMA DNA vaccine studies suggest benefit for immune responders in time to disease progression, and consistent induction of durable T cell responses in 70% of patients, respectively, warranting further phase II trials (PI Prof C Ottensmeier).
- Phase I/II trial of idiotypic vaccination for multiple myeloma using a genetic approach in patients post autologous stem cell transplant has seen immune responses in 40% of patients evaluated so far. A novel delivery strategy, electroporation, is being planned in a second cohort (PI Prof C Ottensmeier).

# Nutrition and allergy

**The development of childhood allergic disease is frequently preceded by immunological differences that are most evident in the neonatal period. With rising allergic disease rates, there is a continuing urgency to identify the pathways involved and to explore the effects of early interventions that could favourably influence the functional development of T-cell responses and prevent allergic disease.**

The WTCRF has supported a number of studies investigating the effects of dietary n-3 polyunsaturated fatty acids (PUFA). Professor Philip Calder randomised 123 allergic, pregnant women at 20 weeks gestation with low habitual intake of oily fish to consume two portions of salmon per week or to continue their normal diet until delivery. Neonatal PUFA levels and detailed immunological responses to various stimuli were measured at birth. Early indications suggest that increased oily fish intake during pregnancy resulted in higher neonatal status of long-chain n-3 fatty acids, which may result in improved children's growth, health and development.

In another Calder study, 120 people awaiting carotid endarterectomy were randomised to consume n-3 PUFA capsules or a control capsule until surgery and the fatty acid composition of plasma and carotid plaque phospholipids, plaque features and the expression of inflammatory genes were determined. The team found that long-chain n-3 fatty acids are readily incorporated into atherosclerotic plaques and this is associated with decreased inflammation and increased plaque stability, thereby potentially protecting against cardiovascular disease mortality.



# Immunology and infectious diseases

## Children's swine flu vaccines

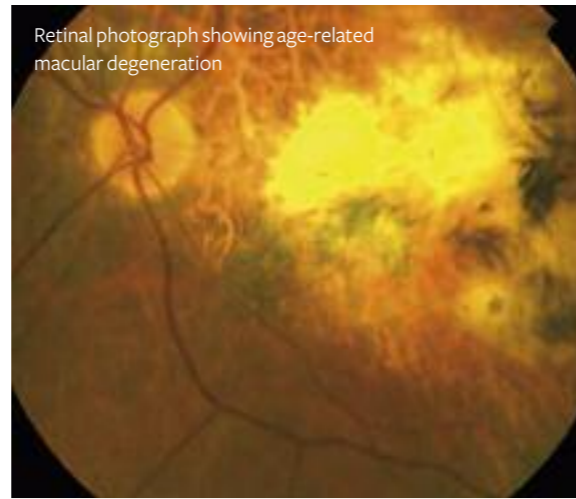
Funded by the NIHR HTA pandemic influenza research clinical trials programme, the WTCRF was one of five co-applicant centres, together with the Health Protection Agency, to participate in a head-to-head study of the two pandemic H1N1 (swine flu) influenza vaccines purchased by the Department of Health for use in the UK (Pandemrix, GSK, and Celvapan, Baxter). This randomised study aimed to evaluate their safety, tolerability and immunogenicity. In Southampton, Dr Saul Faust and his team enrolled 277 children aged 6 months to 12 years of the total 940 children in the study; nearly 200 children visited the WTCRF to receive their initial vaccine dose in a single 48-hour period. By its participation in this study, the WTCRF has demonstrated its ability to respond rapidly to national research priorities, maximising the use of its infrastructure and resources.

## Adult influenza vaccines

Over the last 18 months, the WTCRF has developed a successful collaboration with Professor Adrian Hill (Churchill Centre for Vaccinology and Tropical Medicine, Oxford University) and Dr Sarah Gilbert (Jenner Institute, Oxford University) to maximise recruitment for a Wellcome-funded phase IIa study to assess the safety and efficacy of a new influenza vaccine, MVA NP+M1, in healthy adults. It represents an exciting new step in building working relationships by sharing strengths and resources between research centres within the newly formed South Central NHS region.

Our experienced and responsive research team enabled the trial to reach an ambitious recruitment target within testing time constraints. The multi-disciplinary team screened over a hundred volunteers, including blood specimen processing, supported by the hospital's dedicated pharmacy clinical trials unit who safely delivered the live GMM vaccine to volunteers, with full accountability tracking and fully monitored storage conditions. The study was also a successful initiation of the WTCRF's new healthy volunteer database which is intended to help us with recruitment to similar early phase trials in the future.

The H1N1 (swine flu) virus



## Ophthalmology

### Molecular studies of inflammatory and genetic determinants of macular degeneration led by Professor Andrew Lotery have identified a new genetic risk factor for AMD.

The gene, named SERPING1, is faulty in up to 25% of sufferers. Following the case-control study of nearly 1000 UK patients, a secondary high-density genotyping study across the SERPING1 gene region revealed five additional SNP variants similarly associated with AMD.

Research is continuing raising the possibility of genetic screening for AMD and the development of biological agents to control it. Since appearing in *The Lancet* in November 2008, this publication has earned Professor Lotery the Royal College of Ophthalmologists' Nettleship medal for the best research paper produced in the last four years.

**“I was impressed at the lengths doctors and nurses went to explain the procedures to me... this put me at ease.”**

After many years of collaboration with the WTCRF, Professor Lotery is also the Principal Investigator for our 500th study application since opening in 2001. With the support of WTCRF research nurses, he and his team at the Southampton Eye Unit are conducting a randomised controlled trial of an experimental drug, Microplasmin, in patients with focal vitreomacular adhesion. The study will evaluate the safety and effectiveness of the drug when injected directly into the eye and its potential as an alternative to eye surgery.

Muscle fibres

## Developmental origins

**The SWS aims to understand how factors in early life determine bone growth, cardiorespiratory disease and atopy in order to inform novel public health strategies to improve bone and immune health in childhood, with a resultant decrease in atopic disease and osteoporotic fracture in later life. In the most recent stage of a long term involvement with this unique study, over 450 six-year old children visited the WTCRF this year for body composition, lung function tests and allergy challenges.**

Sarcopenia (the loss of muscle mass and strength with age) has profound implications for the older person in terms of disability, morbidity and mortality. This reflects the central role of muscle in both physical and metabolic function. Evidence from a series of novel studies conducted in the WTCRF by the MRC Epidemiological Resource Centre suggests that influences operating across the life course may be important determinants of sarcopenia, skeletal muscle morphology, mass and strength.

The Hertfordshire Sarcopenia Study is investigating mechanisms underlying the observed associations between small size at birth and sarcopenia. The first part of this novel study was conducted by NIHR Academic Clinical Fellow, Dr Harnish Patel (supervised by PI Prof A Ahie Sayer), over a period of 14 months in a cohort of over 100 healthy men who underwent detailed quantification of muscle mass and strength and a muscle biopsy of the vastus lateralis. The men, aged between 68 and 76, stayed in the WTCRF overnight as part of the study. Muscle tissue was processed for immunohistochemical and molecular

studies in laboratories within SUHT. Myofibre composition and molecular analyses of muscle tissue are currently ongoing.

Building on the successes in recruitment and the reported tolerability of the muscle biopsy procedure, a subgroup of participants have been invited back for further tests to assess quadriceps muscle strength and endurance as well as to use peripheral quantitative CT scanning to assess muscle cross sectional area at the calf and forearm. They will also have tests to assess vascular function through venous congestion plethysmography and endothelial microparticle analysis.

This study demonstrates that muscle biopsy is feasible and acceptable in older people participating in epidemiological research. Availability of biopsy tissue will allow morphological and molecular studies to be integrated into other research work identifying modifiable causes to inform the development of beneficial interventions that maintain independence and quality of life in our ageing population.

# Bone and joint

**Musculoskeletal diseases present a major burden to individuals and society. In the last year, the bone and joint group have continued to work on studies across osteoarthritis (OA) and inflammatory rheumatic diseases.**

A key study (VIDEO) led by principal investigator Professor Nigel Arden is exploring the effect of vitamin D supplementation in individuals with knee OA. Clinical studies in rheumatoid arthritis (RA) are investigating the importance of inflammatory bursitis in the forefoot of individuals with RA using ultrasound (FEETURA; PIs Dr C Edwards, Prof N Arden). This work has already led to the award of a PhD for an academic podiatrist, Dr Cathy Bowen, and the continuation of the project has been ensured by recent success in achieving an NIHR fellowship. Interaction with immunologists has also led to a number of novel studies looking at the role of suppressor cells in inflammatory rheumatic diseases and ERAP1 in ankylosing spondylitis.

Over the last 20 years, the UK has led the way in developing biological therapies for rheumatoid arthritis and other inflammatory diseases through academia-industry collaborations.

Current examples involving the WTCRF include:

- A phase I, single-blind, randomised, placebo-controlled, multicentre, single dose, dose escalation, safety and tolerability study of MDX-1342 (anti-CD19 human monoclonal antibody) in combination with methotrexate in patients with active RA (CI Dr C Edwards). This phase I trial of a B cell-depleting anti-CD19 antibody expands on work using the anti-CD20 antibody, rituximab, for the treatment of RA. The study is being conducted in collaboration with Medarex Inc.
- A randomised, placebo controlled, double blind, parallel group study to compare the safety and reduction in disease activity with the combination of rituximab (MabThera) and tocilizumab (RoActemra) versus tocilizumab therapy in patients with active RA with an incomplete response to methotrexate. This study in collaboration with Roche involves a unique combination of two biological therapies to treat severe RA (CI Dr C Edwards).

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Professor Dame Sally Davies visiting the new NIHR clinical research building development

# Public engagement

**A new national initiative is the annual UKCRF Open Day, which aims to raise the profile and public awareness of clinical research and the facilities available in the WTCRF, identify opportunities for public involvement, demonstrate how research improves health, and highlight careers in Healthcare Research. In September 2009 the WTCRF welcomed over 160 members of the public as part of the Southampton University Hospital Trust open day.**

Our exciting and stimulating Open Day programme for members of the public includes a number of interesting hands-on activities:

- learning about blood composition and how blood and other samples are prepared for storage or shipping in our preparation laboratory, with an opportunity to view blood cells and other samples under a microscope
- obtaining samples from patients' lungs via simulated bronchoscopy on a manikin
- performing lung function tests
- taking height, weight and body composition measurements, learning the importance of healthy eating using a fake fat model
- observing SimMan & SimBaby, fully automated adult and baby manikins that allow practice of basic and

advanced life support skills. The models realistically simulate a variety of physiological responses. Blood pressure, heart rate, respiratory rate and oxygen saturations are displayed on a video screen and the manikins can talk, cough, retch and wheeze

- using eye glasses to simulate eye conditions (blindness, glaucoma etc), models depicting anatomy and physiology of the eye, and an ophthalmoscope to view the inside of specialist eye models
- understanding the importance of correct hand hygiene using a special light box and disclosing fluid to teach proper hand washing technique
- exploring the skeletal system with skeleton, knee, wrist, shoulder joints and hand models.

# Integration

The success of the WTCRF relies on its collaborative nature, both internally and among the wider research community. Key to this is the way in which the WTCRF embraces the interaction of University and NHS researchers and NHS clinicians under one roof.

**We bring together NIHR investigators, research nurses, scientists, methodologists and administrative support in teams that best suit each research study. We believe that pooling multidisciplinary skills, building partnerships and setting uniformly high standards are the most effective methods of generating research excellence.**

## NIHR Biomedical Research Units

In 2008, Southampton was awarded two Biomedical Research Units (BRUs) by the National Institute for Health Research (NIHR), in respiratory medicine and in nutrition, diet and lifestyle. The WTCRF has been closely involved throughout the application and set-up process, including integrating operational functions, recruitment, mentoring, and capital project management. This will house the BRUs, some WTCRF activities and other translational research infrastructure. The in-house experience of the WTCRF in running a high quality research environment provides a vital resource to the successful establishment of the BRUs.

## Southampton Clinical Research Institute

The WTCRF is a core member of the Southampton Clinical Research Institute ([www.scri.soton.ac.uk](http://www.scri.soton.ac.uk)), which brings together the WTCRF, NIHR Research Design Service, University of Southampton (UoS) Clinical Trials Unit, UoS Dept of Public Health Science and Medical Statistics, the BRUs, SUHT Research and Development and the Hampshire and Isle of Wight CLRN. The SCRI ensures that different support functions across the Trust, University and Research Networks are not replicated, and our aim is to enable investigators to conduct research projects with minimum bureaucracy and maximum

effectiveness. By clearer signposting and rationalising of roles and processes, the SCRI strives to streamline the research process, from study methodology development and grant-writing, through ethical and governance approvals, to efficient, safe study conduct and translation of results into improved clinical practices or therapeutic developments. The SCRI also promotes collaborations between specialties and across traditional academic and clinical boundaries.

The UoS/SUHT Translational Clinical Research Conference, organised by the WTCRF for the SCRI, is now an annual fixture, attracting over 200 delegates in 2009. Professor Dame Sally Davies, director general of research and development at the Department of Health, presented the keynote University of Southampton Wade lecture, detailing improvements to the research environment that have been initiated since the launch of the National Institute for Health Research.

## NIHR Networks

Many networks have been established by NIHR in recent years to improve the delivery of clinical research across the UK. The WTCRF collaborates with the Comprehensive Local Research Network (CLRN), among others, in recruitment, training and costing. A particular example of our close relationship is our involvement in establishing the CLRN Research Nurse Forum,

an inclusive organisation for all research nurses working across Hampshire and the Isle of Wight. The increase in paediatric activity at the WTCRF contributed to South Central being the highest recruiter of all Strategic Health Authorities to NIHR Medicines for Children's Network Trials in 2008/09.

## UKCRF Network

The UK Clinical Research Facilities (UKCRF) Network was established in December 2007 with funding from the Department of Health to support a portfolio of activities across all components of the UK's experimental medicine research infrastructure, including Clinical Research Facilities, Experimental Cancer Medicine Centres and NIHR Biomedical Research Centres and Units. The Southampton WTCRF senior nurse manager plays a key role in the Strategic Planning Team.

A bespoke information platform hosted on the NIHR website enables information, documents and developments in best practice to be shared and disseminated. Workstreams, identified by the UK Nurse Managers' Association and developed with the assistance of our staff, have been adopted by the Network and facilitated by the website (Study Intensity Tool, Quality Assurance, Education and a Paediatric Forum). Other Network activities include: organisation of nationwide CRF Public Open Days; coordinated engagement with national and

international professional groups; and oversight and support of the multi-professional annual UKCRF Conference.

The UKCRF Network has become a recognised and invaluable focal point for the collaborative growth and sharing of translational clinical research expertise, here and abroad. In addition to being the Network lead for the UKCRF Paediatric Forum, WTCRF senior nurse manager, Jennifer Allison leads on international engagement and is an inaugural member of the recently formed International Association of Clinical Research Nurses, based in the USA.

The UKCRF Paediatric Forum, convened by WTCRF director, Dr Saul Faust, first met in October 2008 in a joint conference with the NIHR Medicines for Children Network. Paediatric CRFs now have dedicated space on the UKCRF web portal and regular workshops at its annual conference.

## Primary Care

Through our outreach programme, WTCRF research nurses provide support to primary care investigators working in the local community. Recent examples include the Helicobacter eradication versus aspirin toxicity (HEAT) pilot study, and ALDDDES, a targeted screening study for the early development of alcoholic liver disease, using liver fibrosis markers developed in the WTCRF.



WTCRF research nurse with a young volunteer

## Quality

Ensuring volunteer safety and dignity is fundamental to the conduct of clinical research. The WTCRF upholds the highest standards of care and strives to ensure complete adherence to national and international regulations.

In spring 2007, five senior managers from the millennial WTCRFs established the UKCRF Quality Assurance Workstream. The overarching objective was to obtain MHRA phase I accreditation for these five non-commercial CRFs. By adopting a collaborative approach, the group were able to present to the MHRA inspectors phase I systems that had been widely agreed, with a high level of quality consistency. The remit of the group has since moved beyond phase I into wider issues of QA, such as regular, self-conducted audit programmes.

During 2008 and 2009, the membership of the QA Workstream has changed significantly, as most CRFs were able to appoint new staff with a specific QA responsibility. Dr Claudia Fellmer leads Southampton participation. Among the achievements are that Standard Operating Procedures are now shared via the NIHR UKCRF web-portal, a poster on the role of the QA manager was accepted at the July 2009 UKCRF conference in Cambridge and, in October 2009, a meeting was

**“This is the second time I have come down to Southampton. On each of the occasions the feedback received has been excellent and has resulted in discussions with my GP which has to be good.”**

arranged with two senior MHRA Inspectors for a consultation on how the phase I accreditation scheme could be transferred into the non-commercial sector.

The WTCRF has also appointed a new translational scientist/laboratory manager this year. Dr Luanne Hall-Stoodley is a biofilm microbiologist who will ensure the WTCRF laboratories continue to meet all regulatory standards including the appropriate training in ‘GCP in Laboratories’ for users, as well as develop a research programme in translational clinical biofilm research.

## Education

The WTCRF continues to act as a “research nursery” for clinical investigators, students, trainees and qualified staff from all disciplines.

- A new full time research education lead has been appointed by the WTCRF to provide training and governance support to research nurses and all health professionals both in and outside of the WTCRF.
- The WTCRF QA manager leads the campus ICH GCP training programme for clinical researchers.
- Eighteen 4th year medical students intending to complete all or part of their project in the Facility attended the WTCRF induction in 2009.
- The WTCRF director leads the University of Southampton Academic Foundation Training Core Research Skills programme.
- Throughout 2009, the WTCRF has provided essential support and facilities for the work of many of Southampton’s academic foundation trainees, academic training fellows (ACFs), clinical lecturers and research training fellows as well as numerous PhD students and other scientists’ research.
- Three WTCRF research fellows were appointed in 2009 to support early phase trials and experimental medicine research whilst preparing for their own PhD funding applications. These posts have become invaluable in the successful management of an increasingly complex research portfolio.
- Senior research sister, Carol Gough has commenced the new University of Southampton Masters in Clinical Research having won an NIHR Studentship for 50% of her time, which we hope will become an annual opportunity for our staff.

# Perspectives



### Volunteer

*Christina Perryman*

**Christina has rheumatoid arthritis, an inflammatory disease of the joints characterised by painful, debilitating ‘flare-ups’ and periods of remission, in some cases leading to permanent disability.**

When she was first diagnosed, Christina was invited to join a research study. This randomised, double-blind, placebo-controlled clinical trial involves a test drug aimed at halting the disease in the early stages so that flare-ups do not recur.

As well as receiving the recommended first line treatment, Christina receives the trial drug or placebo as fortnightly injections for 18 months. These can be self-administered and, despite preliminary concerns, Christina now finds this aspect of the study empowering.

Christina has identified a number of benefits from participating in the clinical trial:

- Relief from symptoms
- Frequent study visits at the start of the trial (and when just diagnosed) gave lots of opportunities to ask questions just when she needed it most
- Access to expert specialist staff who all take a keen interest in her progress
- Seeing the same staff at each visit in a calm, friendly environment. All staff have been very ‘informative and friendly’ and never make her feel ‘foolish or over-fussy’
- Sense of pride and accomplishment at administering her own injections, and from feeling ‘more in control’ of her illness.



### Research Nurse

*Tracey Payne*

**I have been nursing for many years and have had various experiences with research in the clinical field. I joined the WTCRF two years ago and entered a world that is very different from front-line clinical work.**

Although it took a bit of getting used to, it is just as enjoyable and rewarding as ward work, and can be as busy. The WTCRF fosters an ethos of team work and education and demands excellent clinical practice so we always make time for study days and continuing professional development. Our emergency skills are maintained by simulated resuscitation scenarios, an initiative of our Education team.

I feel that my varied background is very useful in my role as a research nurse, where one needs to develop excellent communication, administrative, organisational and IT skills alongside the clinical skills of a study. For example, I can be assisting with bronchoscopies in the morning and seeing patients in the afternoon on eye, MS or renal studies. A research nurse needs to be able to deal with the unexpected, be flexible and have a good sense of humour.

The core of our role is always being the participant advocate – this is vitally important when recruiting and consenting to studies. These vary in length from a single visit to seeing volunteers regularly over a number of years, in which case one develops a strong bond with them that is especially rewarding if the treatment has improved their quality of life or prognosis. The extra time one has to spend with volunteers in clinical research is one of the best aspects of the role; it isn’t always possible to go the extra mile for patients on a busy ward. Variety is certainly the spice of the research nurse’s life and one of the many reasons why I continue to work in research.



### Investigator

*Dr Mark Wright, Consultant Hepatologist, Clinical Lead in Specialist Medicine*

**Hepatology is a rapid developing field particular in the sphere of viral hepatitis. There are numerous new drugs coming into use, which will make a massive difference to the lives of people affected with both hepatitis C and hepatitis B.**

I have run a number of such trials through the Wellcome Trust as part of international multi-centre randomised controlled trials. It simply would not have been possible for me to do this without the facilities and experience of the Wellcome Trust staff. The patients require frequent visits and close monitoring and the coordination and execution of this by the WTCRF staff has been invaluable.

From the user point of view, it is an extremely friendly place to do business and I have always found with my studies so far that the attitude of the place is one of ‘we are here to help you’.

As well as the viral studies I have also done a number of other more investigative studies and the facility that the unit provides is really first rate. As a busy clinician, the amount of time that I have to spend on research is limited and it is a great advantage to me to have such a Facility as the WTCRF, which maximizes the efficiency with which I can practice my research.

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**Translational Scientist & Laboratory Manager:** Dr Luanne Hall-Stoodley