PODCAST
To listen to the entire interview, log on to **www.futurepharmaus.com**

Up North

Future Pharmaceuticals speaks with Directors of England's Biomedical Research Centers **PHILIP BAKER** in Manchester, **PATRICK CHINNERY** in Newcastle, and **PETER WINSTANLEY** in Liverpool

Future Pharmaceuticals **Can you tell us a little about the Biomedical Research Centers (BRCs) in the U.K.?**

Philip Baker The National Institute for Health Research Biomedical Research Centers are national centers of excellence in translational research. They are selected by an international panel of experts and funded by the National Institute for Health Research (NIHR) for up to $78.4 (£50) million over five years.

The U.K. has designated 12 BRCs to accelerate progress in innovation and translational research in biomedicine within the British National Health Service (NHS) and university partnerships. The goal is to sustain scientific excellence and contribute to the nation's international competitiveness as a major component of our 'knowledge' economy. Nine of the BRCs are in the South and the other three are in Liverpool, Manchester and Newcastle.

The NIHR itself was formed in 2006 as part of the U.K. government's 10 year, $26.7 (£17) billion commitment to healthcare research. The mission of the NIRH is to create a health research system that enables the British National Health Service to support researchers and collaborators, working in world-class facilities and conducting leading-edge research focused on the needs of patients and the public. The BRCs were specifically created to accelerate the translation of lab-based research into clinical practice.

The BRCs were selected in two stages through open competition by an independent international selection panel. This panel had substantial experience in translational clinical research and to ensure its independence, none of its members worked in England. Dr. Tachi Yamada, President, Global Health Program, Bill and Melinda Gates Foundation and Professor Garret FitzGerald, Director, Institute for Translational Medicine & Therapeutics, University of Pennsylvania School of Medicine, were among its panel of experts. There were also observers from the Higher Education Funding Council for England (HEFCE) and the Medical Research Council (MRC) to ensure the views of two of our key funding partners were represented.

FP **What factors were most critical to your selection as a BRC?**

PB To be successful, the Manchester Partnership had to demonstrate an international reputation for basic medical research and an established track record for translating that research into the clinic, ultimately benefiting patients. We have leveraged our genetic technology expertise with multi-disciplinary clinical expertise and combined them with the following:

- A strong partnership between the U.K.'s largest university and one of the country's leading hospital Trusts (six hospitals, $783 (£500) million turnover, 1400 beds)
- A new, major clinical and academic campus — $783 (£500) million private financing initiative nearing completion, access to patients (including the new Children's Hospital) and access to Wellcome Trust Clinical Research Facilities, Nowgen, NW Embryonic Stem Cell Center and the Maternal and Fetal Health Research Center
- Significant support from and strong relationships with Northwest Regional Development Agency (NWDA), Manchester City Council and MIDAS
- A strong ethos of collaboration with other NHS Trusts and various research networks
- Leading national experts, such as Hanley, Crow, Lavender, Beaver, and we are recruiting 12 further clinical academic chairs

Patrick Chinnery Newcastle's track record in aging and age-related diseases was a key factor. The Center for Ageing and Health was founded in 1994 in partnership with Newcastle University and NHS. There is an exceptionally strong culture of cross-disciplinary and translational engagement between these groups, as well as international collaborations with other world leaders. There are also extensive and developing collaborations with industry with multinationals and Small, Mid-sized Enterprises (SMEs).

Newcastle has gained international recognition for multinational, interdisciplinary biomedical research in major European FP6 programs including the following:

- Genetics of healthy aging
- Genetics of Parkinson's disease
- Biomarkers for dementia
- Mitochondrial disorders

In collaboration with Newcastle Hospital's NHS Foundation Trust, Newcastle University began an extensive building program to form the Campus for Ageing and Vitality. This venture consolidates core basic science in biogerontology with hospital and community-based clinical research on one site, which is where the $7.8 million U.K. Medical Research Council Center for Brain Ageing and Vitality is based. Newcastle also enjoys strong links with six other research institutes including the Institute of Health and Society (HIS), Institute of Human Genetics (IHG) and Institute for Cell and Molecular Biosciences (ICaMB).

Peter Winstanley The Liverpool BRC is now the U.K.'s leading specialist research center for microbial diseases. The center is jointly run by the Liverpool School of Tropical Medicine, Royal Liverpool University Hospital and the University of Liverpool. We have a strong track record in the discovery and collaborative development of medicines, notably for malaria. We are also strong in research into drug toxicity and training, and have recently been awarded a Medical Research Council (MRC) center and Clinical PhD Program by the Wellcome Trust.

FP What is the focus of your respective BRCs?

PW Our aim is to take research from the 'laboratory bench' and translate it into real patient benefit. We have 13 exceptional projects that will, in some cases, help us develop new ways to test for specific conditions to improve treatment or reduce the impact of some major infectious diseases. We also have several projects that are likely to lead to the development of new drugs or vaccines for some of the most lethal health conditions worldwide, including pulmonary infections, sexual health, hospital and community acquired infections and the safety of antimicrobials.

We hope that funding from the National Institute for Health Research (NIHR) will ensure that the city becomes a pioneer in the development of new drugs and diagnostic tools. Over the next five years, the center will deliver 13 ground breaking projects. Examples of what the projects will deliver include the following:

- A new diagnostic tool to predict who is more susceptible to acquiring *Clostridium difficile* to enable hospitals to more effectively tackle hospital acquired infections at an earlier stage
- Using DNA and genetic testing techniques to develop a way of testing who is likely to be allergic to penicillin so that more effective alternatives can be used earlier
- A way to detect patients infected by *H pylori* to see who is at risk of developing gastric cancer, the second most common cause of cancer-related death worldwide, which may lead to a new cancer therapy,
- A method to identify a specific, harmful and life threatening bacteria in those people with Cystic Fibrosis in less than six hours — it currently takes between seven and 10 days
- A new vaccine for pneumococcal diseases — a major cause of death in children and adults worldwide
- A new way to accurately diagnosis severe sepsis, which affects 18 million globally each year and is 30 and 50 percent fatal
- Identify the factors that cause HIV patients to develop resistance to drug therapies

PHILIP BAKER
Director
NIHR BIOMEDICAL RESEARCH CENTRE

Philip Baker is Director of the NIHR Biomedical Research Centre in Manchester, and Head of Research for Central Manchester & Manchester Children's University Hospitals NHS Trust. He is also an honorary consultant obstetrician at St. Mary's Hospital, Manchester, and directs a leading pregnancy research group. Previously, Professor Baker was Research Dean within the Faculty of Medical and Human Sciences, University of Manchester, and has been the interim head of the medical school, which is the largest in Europe.

PATRICK CHINNERY
Director
NEWCASTLE SPECIALIST BIOMEDICAL CENTRE FOR AGE RELATED DISEASE

Professor Chinnery completed his clinical training in Neurology in 2002, and has been a Wellcome Trust Senior Fellow in Clinical Science since August 2003, allowing him to continue to study the inheritance and expression of mitochondrial disorders both in the clinic and in the molecular laboratory. He was appointed Professor of Neurogenetics in 2004. While pursuing his own interest in developing new treatments for mitochondrial diseases, Professor Chinery has been studying mitochondrial mechanisms in healthy ageing and multifactorial disease.

PETER WINSTANLEY
Executive Director
NIHR BIOMEDICAL RESEARCH CENTRE

After Graduating from Liverpool Medical School in 1979, Professor Winstanley trained in Liverpool, London, Leeds and Kenya before taking up his academic post at Liverpool. His interests focus on the clinical study and formal development of anti-malarial drugs. Professor Winstanley's is also the Head of the University's School of Clinical Sciences and Director of the Wellcome Trust Tropical Center, including a new Clinical PhD Program at Liverpool University.

PC Newcastle is a specialist Biomedical Center in Ageing Medicine. Its initial work will focus on seven research programs aimed at improving health care in an expanding ageing population. The Newcastle BRC focuses on the effects of age and aging on organ dysfunction with considerable cross fertilization with researchers in the Institute for Ageing and Health, the Institute of Cellular Medicine and the Institute of Neuroscience.

There are several significant developments which support the BRC, including the Clinical Research Facility at the Royal Victoria Infirmary site, the Clinical Ageing Research Unit on the Campus for Ageing and Vitality at the Newcastle General Hospital, adjacent to Magnetic Resonance and

Positron Emission Tomography imaging in the Newcastle Imaging Center. Research at the Newcastle BRC is focused on the following seven themes:

- Dementia and Neurodegenerative Diseases
- Stroke and Cardiovascular Ageing
- Mitochondrial Abnormalities in Ageing and Age Related Diseases
- Ageing and Type 2 Diabetes
- Liver Disease in Ageing
- Musculoskeletal Disease in Ageing
- Preservation and Restoration of Age related Visual Failure

Each theme has as one or more of its aims, the discovery and validation of biomarkers for early diagnosis, predicting disease progressing and monitoring response to treatment. All of the themes also include a development of novel treatment approaches and improving the risk benefit ratio of currently available therapeutic modalities through the development and use of tissue banks.

PB The focus of the NIHR Biomedical Research Center in Manchester is Genetics and Developmental Medicine. In addition, it is developing themes around "Tissue Injury and Repair" and "Experimental Therapeutics." Over the next four years we will undertake research on major killers such as heart disease, as well as on other crucial areas such as inflammatory bowel disease, learning and developmental disabilities, and complications of pregnancy.

Our research will harness genetic technologies to improve diagnosis and treatment in key areas such as:

- Sudden cardiac death
- Diagnosis of developmental disease
- Risk factors in disadvantaged populations
- Stratifying complex inflammatory disease
- Placenta diagnostics / biomarkers
- Statinsin Neurofibromatosis
- Pharmacogenetics/ Treatment complication
- Proteomic / Metabolomic technologies

There is an ancillary benefit to being designated as a National Biomedical Research Center, and that is an enhancement in your ability to attract top talent. We are looking for some exceptional clinical academics to take up these new posts, and help Manchester achieve its ambition to be a world-class center for clinical research and excellence. The BRC can offer all the technical support and facilities they will need to deliver major research programs, working as part of a close-knit team of surgeons, doctors and scientists.

FP What are some of the recent changes to the NHS that have improved the U.K. as a platform for clinical research?

PW The establishment of the National Institute for Health Research (NIHR) has enabled a considerable amount of government funding to be deployed to have a greater impact than before. NIHR initiatives stretch from translation (the BRCs) through clinical trials networks (managed by the U.K. Clinical Trials Network) through to pragmatic assessment of interventions in the 'real world' (Health Technology Assessment).

PB It is notable that the U.K. Clinical Research Network makes it possible for all patients and health professionals across England to participate in relevant clinical trials. Other NIHR programs, like the Patient Research Cohorts Initiative help identify and enroll groups of patients with the same illness in clinical research to help understand how diseases progress.

A constant throughout this period, however, is a well developed network of medical professionals and the means with which to engage them in collaborative partnerships. Some of the networks which the Manchester BRC uses include the following:

- Greater Manchester Cancer Research Network
- Greater Manchester Lancashire & South Cumbria Medicines for Children Research Network
- Manchester Integrating Medicine & Innovative Technology
- NW Diabetes Local Research Network
- NW Stroke Research Network

These programs dramatically improve the quality, speed and coordination of clinical research throughout the country. They help ensure that patients and health care professionals from all parts of the country are able to participate in and benefit from clinical research, integrate health research and patient care, and increase the collaboration with industry partners.

PW It is hard to overestimate the added benefits that success in such a major national competition brings. The BRC has transformed the hospital's view of research from a relatively fringe activity to a central part of its business. This enables much closer links between hospital and university and amplifies the importance of each step in the process of translational medicine. One tangible result is the establishment of newly refurbished BRC facilities in Liverpool which include a clinical research facility that enables Phase I and Phase II trials to be conducted in a hospital setting.

PC By its very nature, the British National Health Service provides unique opportunities for translational research. Unlike many other health care systems, the NHS remains "free at the point of need," ensuring that patients of all backgrounds and cultures access the same services on the same site. This means that clinical researchers connect directly with their local community, and are in a position to study both common and rare diseases in community-based cohorts. A byproduct of our health care system is a high-level of patient engagement, which greatly enhances recruitment and compliance.

FP How do industry partners contribute to your success?

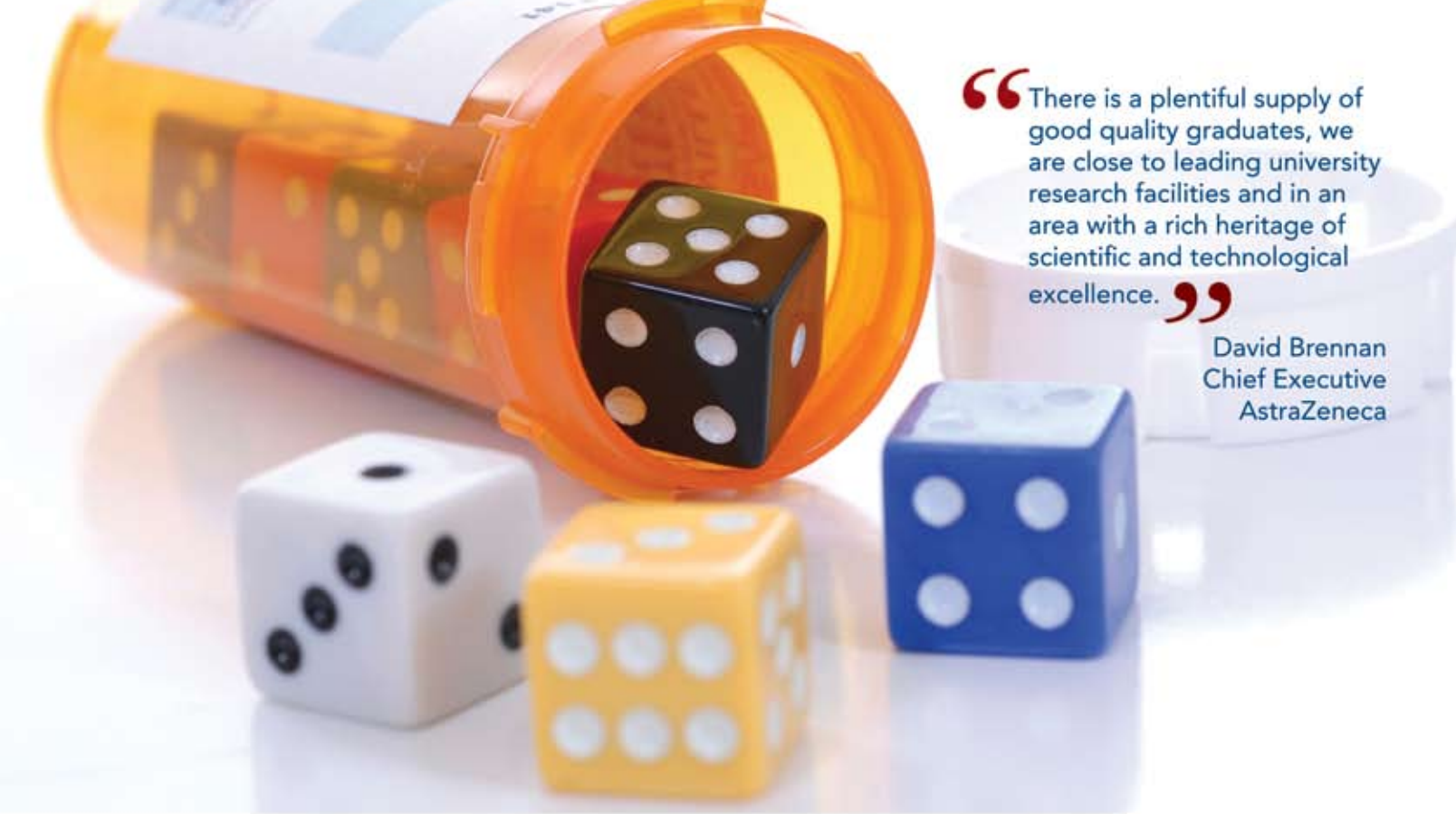
PC Commercial partnerships are a critical validation of the success of our programs. We are working closely with industry leaders and SMEs to bring these innovative technologies and therapies to patients. Current industry programs with the NIHR BRC in Newcastle include: Unilever, Organon, GE Healthcare, Janssen, Pfizer, GSK and SMEs including Sirtris and Santhera.

PW We have had emphasis of product translation for the benefit of patients for many years. Three current examples of this include Delphic Europe Ltd in Therapeutic Drug Monitoring, InTeraSeqLtd in Microbial diagnostics and Iota Nanosolutions Ltd in novel antimicrobials.

Major partnerships, some of which have been in place for over 20 years, include GSK & Pfizer in Drug discovery, National Biomanufacturing Center (NBC) in Biopharmaceutical development and Centers for Disease Control (CDC) in Atlanta, Georgia.

PB Manchester has developed excellent relationships with major pharmaceutical leaders such as Astra Zeneca, GSK and Lilly — plus a wide range of biomedical companies based in the Northwest of England.

We have links with businesses at the Manchester Incubator and Manchester Science Park plus Medilink members and contacts through Bionow. TrusTECH and the national NHS Technology Adoption Center are both based in Manchester. These permit Manchester to support every stage of the product lifecycle, from developing new drugs and treatments through to marketing and sales. **FP**



> "There is a plentiful supply of good quality graduates, we are close to leading university research facilities and in an area with a rich heritage of scientific and technological excellence."
>
> David Brennan
> Chief Executive
> AstraZeneca

Take the Risk Out of Drug Development

Lower risk and speed to market mean bigger impact — on your bottom line and on lives.

North England makes it less risky and more affordable to launch into Europe, where 34 percent of the world's healthcare dollars are spent.

How? North England has one of the largest concentrations of life science companies in the world. In fact, North England has been recognized as a member of the 'European Super League' of biotech clusters by Strategem.

Plus, we have 1.7 million technology workers, labor costs up to 30 percent less than London's and easy access to the world's largest patient pool for clinical trials. And that's just for starters.

The North of England Inward Investment Agency is your personal business ambassador. We provide the resources, connections, market feasibility studies and more to get your products to market faster, reduce your risk — and reduce your costs.

Thinking about expanding? Contact us for a free, confidential Business Expansion Assessment.

Scott Kozak, VP Life Sciences
(617) 973-5023 | scott.kozak@northengland.com
www.NorthEngland.com

THE NORTH OF ENGLAND

Your personal business ambassadors