



## **Proposed Centre of Excellence for ME Patients in Norfolk**

### **Executive Summary for MPs**

This is a summary of the current status regarding Invest in ME's proposal for a Centre of Excellence for ME Research and Treatment

**STATUS UPDATE August 2014**

### **Background**

- Seriously inadequate standard of medical care for ME patients in UK
- Very little funded UK biomedical research into condition
- Confusion between ME and chronic fatigue has led to unscientific research and ineffective treatment regimes
- NHS resources focus on symptom management therapies whilst underlying condition left untreated
- Medical professionals lack understanding of and training in ME -serious risk of mis-diagnosis and missed diagnoses
- International research has revealed much about biomedical basis of ME
- ME now identified as both highlighted area and high priority by MRC
- ME is leading cause of long-term absence from school due to sickness for students and teachers
- ME is recognised by the Department of Health as a chronic neurological illness

### **Project Outline**

- Biomedical research and treatment institute for ME in East Anglia, based in Norwich within the Norwich Research Park utilising and based on university and institute facilities and resources
- Hub of scientific and clinical excellence for ME within Europe
- Research arm to be funded initially by private/charitable donations leading to applications to major public research funding bodies such as the NIHR, NIH, MRC etc.
- Clinical diagnosis and treatment arm to be funded by CCGs (formerly agreed with Norfolk PCT)

### **Service Commissioning**

- GP referral, via normal NHS channels
- Consultant physician to diagnose patients according to international scientific criteria



## UK Centre of Excellence for ME

- Based at Norfolk and Norwich University Hospital, subject to agreement
- GPs with special interest to be linked to Institute
- Treatment of patients based on up to date biomedical research findings
- Hub and spoke model: dissemination of expert knowledge to GPs and ME clinics nationwide
- Out of area referrals included
- Correctly identified patient cohorts considered for Institute research projects
- Training opportunities for medical students and other consultants, nurses etc.

## Invest in ME (Research)

- UK charity campaigning for biomedical research and treatment of ME
- Founder member and current Chair of European ME Alliance
- Organises annual international CPD-accredited international ME conference
- Organises annual international ME research colloquium
- Allied to a patient led campaign called Let's Do it for ME to raise funds for Invest in ME Research
- Has initiated UK gut microbiome project to study ME as well as a UK rituximab clinical trial
- Founding member of European ME Alliance
- Holds worldwide contacts with ME organisations, physicians and researchers

## Research

- Based at Norwich Research Park, including University of East Anglia and Institute of Food Research and utilizing other institutes such as The Genome Analysis Centre
- Advanced fundamental research, initially using virology and immunology
- Key component: accurate definition of patient cohort, giving scientific validity to results
- Translational research -potential for direct patient benefit
- Dovetails with national identification of ME as priority area (NIH initiative and MRC highlight notice)
- Initial projects: "A role for a leaky gut and the intestinal microbiota in the pathophysiology of myalgic encephalomyelitis" The majority of the immune system can be found in the gut and it is therefore highly desirable to study the gut microbiota in ME patients. The gastrointestinal tract contains a microbiota consisting of a vast number of bacteria and viruses
- Includes cooperation with other national/international research facilities (network already in place)



## Benefits

- Unique opportunity to establish European hub of scientific and clinical excellence
- Attraction of international interest and research funding to East Anglia
- Early and correct diagnosis
- Establishment of standard protocols for effective diagnosis
- Establishment of clinical trials
- Development of effective treatments, leading to highly significant public savings
- Hub and spoke. model to address seriously inadequate levels of clinical service for ME in East Anglia and nationwide
- Development of network of domiciliary services to support severely affected patients (currently seriously neglected)
- Savings on existing consultant referrals and staff -ME examination focused in one area
- Financially viable – Institute can start small and grow as further funding becomes available

## Current status

- All elements of the Institute model are ready to be put in to place with the exception of Norfolk and Norwich University Hospital, which has previously declined to provide a service locally as they do not feel that they “can provide a satisfactory high quality service on the basis proposed” – despite offering no service currently to ME patients.
- The healthcare reforms have removed the promise made by Norfolk PCT to perform full examinations on ME patients by a qualified consultant. This now has to be renegotiated with CCGs.
- The charity met with one CCG head and Dr Martin McShane – NHS Commissioning Board Authority, Director for Improving the quality of life for people with Long Term Conditions
- Dr Amolak Bansal from Epsom and St Helier CFS clinic in Surrey is providing accurately diagnosed patients for research purposes. He is involved already in the research funded by the charity.
- The Foundation project at IFR/UEA examining the gut microbiota in ME patients started in October 2013
- The rituximab preliminary study prior to a clinical trial began in 2014
- A paediatrician at Norfolk & Norwich University Hospital has shown interest in becoming involved in ME and gut microbiota research at IFR/UEA and the charity is exploring that possibility

## Expansion of Scope

In order to augment the concept of a Centre of Excellence for ME the charity has initiated other research to expand the scope of research and form a strategy of



## UK Centre of Excellence for ME

international collaboration in biomedical research of ME. This is an ongoing commitment.

### Rituximab Clinical Trial

Following the charity's research meetings and cooperation with European ME groups and researchers, especially the Norwegian Bergen researchers where a multi-centre study is about to begin, an intent was made in 2012 to initiate a clinical trial of rituximab for ME in the UK. This culminated in the Invest in ME 2013 Biomedical Research into ME Colloquium 3 in London which resulted in the following -

- Jonathan Edwards, Emeritus Professor of Connective Tissue Medicine at UCL became the charity's clinical trial advisor in July 2013
- A study looking at B cells in ME patients is ready to start at UCL in London
- Fundraising was initiated for a clinical trial to treat ME patients with rituximab, a monoclonal antibody used to treat certain types of cancer.
- £350K has been raised so far and UCL has expressed interest in performing such a trial
- Professor Edwards has been working with the Norwegian Bergen researchers and the charity set up a visit to Bergen in September 2013

### Hypothalamus Study

- A study looking at antibodies binding hypothalamus has been accepted to be performed by Dr Bansal at St Helier and Epsom NHS Trust Hospital

### Further Research

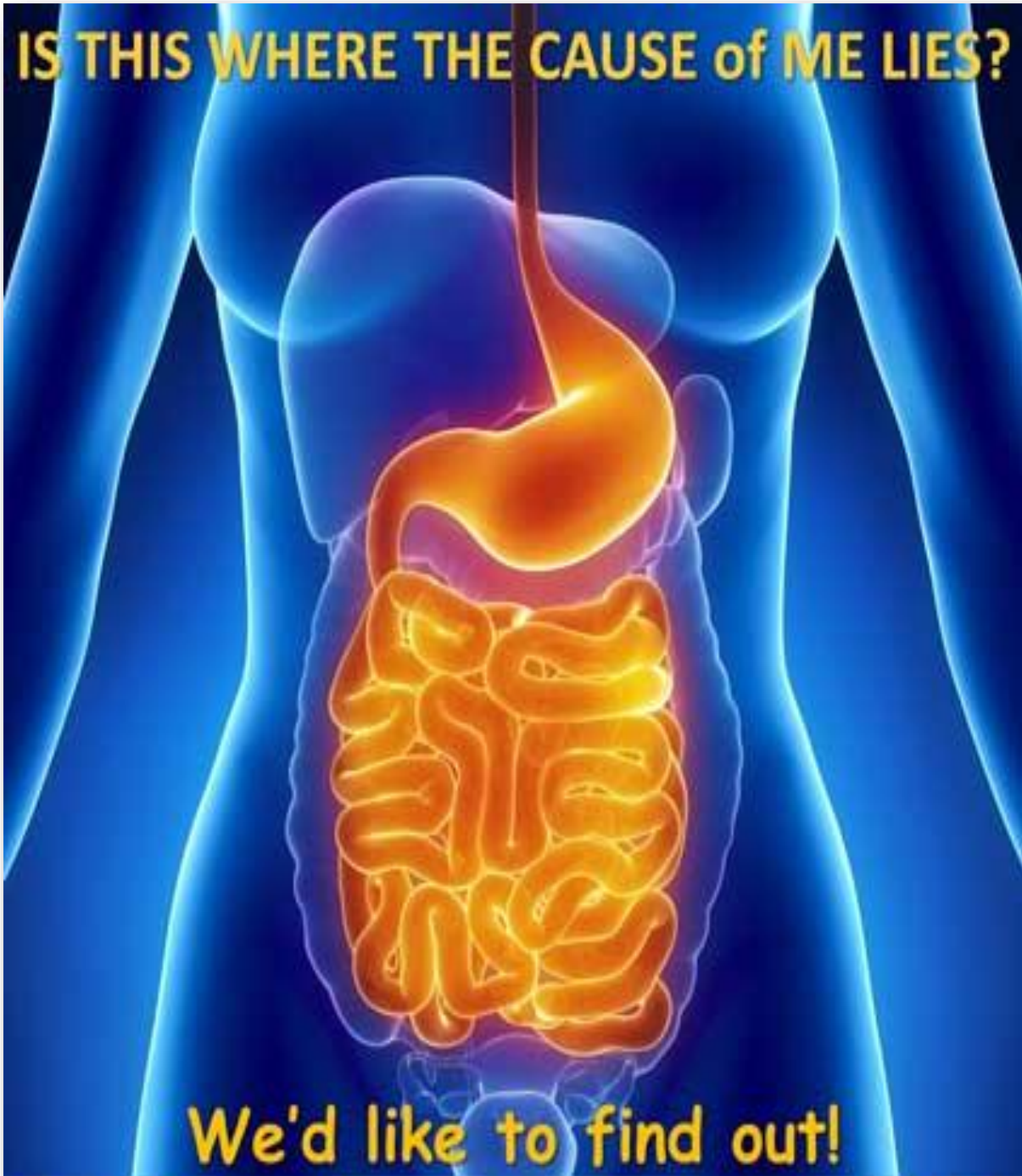
- The charity has set up the iIMER Advisory Board and is actively looking at complimentary projects which will increase the research knowledge base and translate research into treatments.

Invest in ME is therefore asking Norfolk MPs to engage actively with this project with a view to securing the final, and vital, elements of the project.

Further details: **Invest in ME (Research)**

email: [info@investinme.org](mailto:info@investinme.org)

**IS THIS WHERE THE CAUSE of ME LIES?**



**We'd like to find out!**

Myalgic Encephalomyelitis (ME) is a serious, chronic neurological disease. This is one project UK Charity Invest in ME wishes to initiate to determine whether changes in the gut microbiota contribute to ME. Other biomedical research projects will follow. Please support our proposal for an examination and research facility for ME in the UK and help us to help people with ME. Let's Do It for ME.

See - <http://www.investinme.org/research.htm>

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