

# Address/Address-2 Newsletter

The ADDRESS-2 initiative is supported by Diabetes UK and the Juvenile Diabetes Research Foundation, and coordinated by the NIHR Diabetes Research Network and NIHR Medicines for Children Research Network, which are part of the National Institute for Health Research Clinical Research Network

Issue 1 - September 2013

## 2,500 participants join ADDRESS and ADDRESS-2

**W**e are very pleased to tell you that more than 2,500 participants have signed up to ADDRESS and its second generation project ADDRESS-2. This is a really impressive achievement. We would like to thank you all for joining ADDRESS and ADDRESS-2.

The information we have obtained from interviewing you, looking at your medical notes and collecting your blood samples has contributed to a very valuable set of data that is helping us to understand more about type 1 diabetes in England and Wales in the 21st century. This would not have been possible without your support; both participants and parents.

Currently we are analysing all the data and we plan to let you know what we find out later this year.

### Who is involved in running ADDRESS and ADDRESS-2?

**D**iabetes consultants and consultant paediatricians in 78 hospitals in England are helping us to run the ADDRESS project. ADDRESS-2 is running at even more hospitals in England and Wales: 124 in total. Most of the hospital doctors involved in ADDRESS are now involved in ADDRESS-2, but we also have many more doctors and their teams helping to run ADDRESS-2.

The majority of participating hospitals were invited to take part by their local Diabetes Research Networks and Medicines for Children Research Networks. Some hospitals approached us directly about joining after hearing about ADDRESS and ADDRESS-2.

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Map pins show the locations of the hospitals participating in ADDRESS-2 (a subset are participating in ADDRESS).

## Current research opportunities

We are including a selection of current research studies with this newsletter to give you a flavour of the research opportunities being offered to ADDRESS and ADDRESS-2 participants who might be eligible for them.

Participants of both ADDRESS and ADDRESS-2 can view all of the research opportunities being offered by going to our website: [www.address2.org](http://www.address2.org)

For more information about research studies and how they are conducted see:

<http://www.crnc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/PPI/Documents/Clinicaltrialswhattheyareandwhattheyrenotweb.pdf>

<http://www.jdrf.org.uk/research/getting-involved-in-research>

**Professor Colin Dayan** from Cardiff University explains how ADDRESS-2 has helped to increase numbers of people screened for the MonoPepT1De-1b trial that he is running with Professor Mark Peakman from King's College London, and the impact it is having:

*“ADDRESS-2 has been very useful. In our MonoPepT1De-1b study we have doubled the rate of recruitment since we linked up with ADDRESS-2 at the end of last year. That means we will finish our study recruitment by the end of this year when it was at risk of running into the following year. We have to wait for the results of each study before designing the next one, because we can't tell what we want to do next until we know results of the study before. By getting the answers on time we can move on to the next study more quickly and build on our knowledge of different treatments more quickly.”*



Many of you have already been contacted with details of at least one opportunity to take part in type 1 diabetes research since you joined ADDRESS or ADDRESS-2.

There have been fewer trials of new treatments for people soon after diagnosis than we anticipated and there have been limited opportunities for siblings and for young children so far. However, new opportunities are coming through, so if you have not been contacted yet, there might be a suitable study for you around the corner.

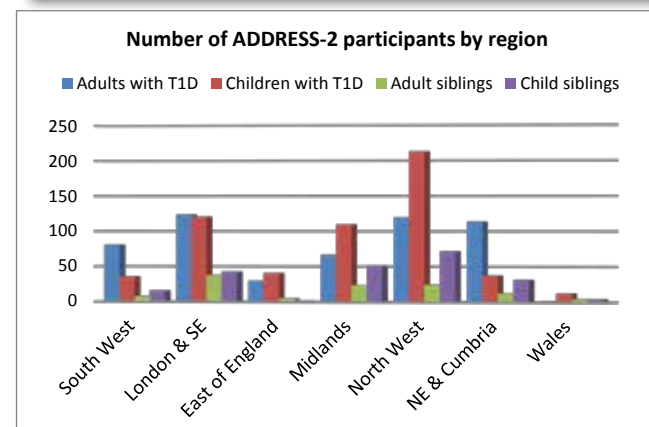
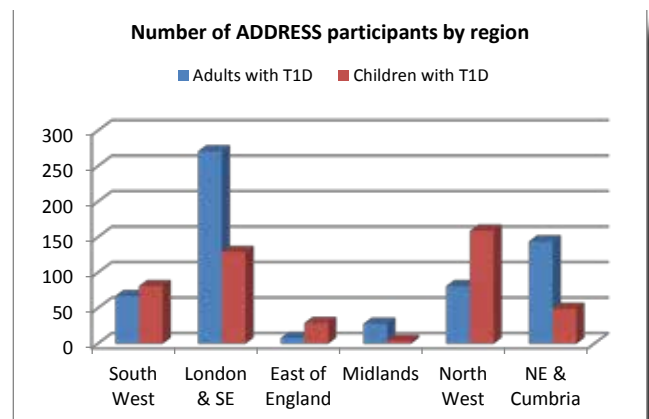
It doesn't matter if it is 6 months, a year, or a few years since you were diagnosed, we will continue to look for suitable studies for you; ADDRESS and ADDRESS-2 participants alike. Even if you decide not take part in any further research, the information we have collected about you in ADDRESS/ADDRESS-2 is important to us and is helping us to understand more about type 1 diabetes.

### Who has participated so far?

In ADDRESS more adults than children have joined (57% are adults aged 16 and over, 43% are children aged 5-15). The vast majority of the participants are from the North of England and the South of England with very few from the Midlands and the East of England (shown above right). This is because more hospitals in the North and South of England are participating in ADDRESS than in the Midlands or the East of the country.

In ADDRESS-2, more children than adults have joined (55% are children aged 5-15 and 45% are adults aged 16-60). Three quarters of the participants have type 1 diabetes and one quarter are siblings without diabetes.

Participants are more evenly spread across England and Wales, reflecting the more even distribution of contributing hospitals. More participants come from the North West that any other region because we have the greatest number of participating hospitals in Cheshire, Greater Manchester, Lancashire and Merseyside (shown below right).



## Who else is involved in running ADDRESS and ADDRESS-2?

The hospital teams that help to run ADDRESS and ADDRESS-2 include the doctors, diabetes specialist nurses and research nurses. These doctors and diabetes specialist nurses are vital to the success of ADDRESS and ADDRESS-2 because it is through their contact when caring for patients newly diagnosed with type 1 diabetes that individuals are offered the opportunity to participate.

The research nurses are the people dedicated to carrying out the research - without them we would have no participants and no data. Their role includes consenting participants, interviewing them, taking blood samples and collecting data from medical records. The research nurses are part of the local Clinical Research Network (local Diabetes Research Network or Medicines for Children Network).

Rosamund Paisey is a diabetes research nurse at Torbay Hospital in Devon. She said: *"As a research nurse I feel really privileged that our clinical team have asked permission of newly diagnosed individuals and their families at the start of their diabetes journey for me to approach them to explain about research. I tend to introduce myself and the wider healthcare team giving an overview of how research has helped provide an evidence base for our current treatments and care pathways. I think the joy of working on studies like ADDRESS and ADDRESS-2 is to be able to have time to answer those broader questions which don't always come up at the time of clinical care and most importantly listen to their story. Then if they are interested in research, I can offer that first step to become involved, and contribute towards the future knowledge base."*



Research nurses and administrators from the local Diabetes Research Network and the local Medicines for Children Research Network also help to co-ordinate ADDRESS and ADDRESS-2 on a regional level.

That leaves the central co-ordinating team, which includes the chief investigator, study co-ordinator and support staff.



**Professor Desmond Johnston**

Chief Investigator of ADDRESS and ADDRESS-2  
Director of the NIHR Diabetes Research Network

**Dr Helen Walkey**

Study Co-ordinator for ADDRESS and ADDRESS-2



## What's New?

### Type 1 diabetes research support group

We are setting up a support group for people who have recently joined or are considering taking part in a type 1 diabetes clinical trial. We are looking for young people with type 1 diabetes, parents of children with type 1 diabetes, and people with type 1 diabetes of any age within 5 years of diagnosis who would be willing to share their experiences of taking part, or their child taking part, in health research.

This is not restricted to ADDRESS/ ADDRESS-2 participants; anyone with type 1 diabetes and any parent of a child with type 1 diabetes can be part of the support group. Someone with experience of a drug or device trial would be ideal, but experience of research could just mean involvement in ADDRESS or ADDRESS-2.

The group will operate via a closed web forum so that the person seeking support will be able to post questions for all members of the support group to respond to at a time that is convenient for them. If you are interested in sharing your experiences and supporting people considering taking part in a clinical trial, or would like more information, please contact Helen Walkey: [h.walkey@imperial.ac.uk](mailto:h.walkey@imperial.ac.uk)

And if you would be willing to share your experience of participating in ADDRESS/ADDRESS-2 by giving a short quote to be used on the web site or other promotional material, please contact Helen Walkey as above.



# A brief history of trials of anti-CD3 and other treatments aimed at slowing progression of type 1 diabetes

In type 1 diabetes, the body's own immune system attacks the insulin-producing beta cells in the pancreas. This is why it is called an autoimmune condition. When type 1 diabetes is diagnosed most people have some functioning beta cells producing some insulin. Production of even a little insulin makes the condition easier to manage. As type 1 diabetes progresses the beta cells are gradually damaged, beta cell function decreases and eventually the body stops making insulin. People who produce some insulin after diagnosis have better blood glucose control and lower rates of complications associated with diabetes. This is why doctors and researchers want to develop and test treatments that aim to preserve beta cell function and hence insulin production.

In 2002 and 2005 promising results were reported from two clinical trials run in North America and Europe on people newly diagnosed with type 1 diabetes. These trials tested whether the decrease in beta cell function that occurs after diagnosis could be prevented by a short course of treatment with a monoclonal antibody called anti-CD3. It was thought that anti-CD3 would inhibit the body's immune response and limit damage to the pancreatic beta cells. The trials found that the group of people who received the treatment had better preserved beta cell function and required less daily insulin via injection to manage their diabetes compared to the group of people who didn't receive the treatment. This lasted for a period of 18 months to 2 years after the treatment was given. These trials were the first stage in the process of testing this treatment in type 1 diabetes to find out what it does and whether it is safe.

Further trials of anti-CD3 treatment since 2005 have not shown consistently that the treatment preserves beta cell function in people with newly or recently diagnosed type 1 diabetes. However, much more has been learnt about anti-CD3 treatment from these trials, in terms of its safety, and the doses and numbers of treatments that appear to work best. Also, doctors and researchers are looking at the group characteristics of those in whom the treatment has shown an effect on preserving beta cell function. This knowledge is helping in the design of future trials to build upon our understanding of the treatment and how it might work best.

Many trials into different treatments aimed at slowing progression or preventing onset of type 1 diabetes have taken place internationally over the last 30 years, and several are currently taking place. There are a number of different types of treatment, thought to work in different ways. To date, no trials of treatments have achieved a long-term change in the requirements for daily insulin in people with type 1 diabetes.

From 2007 to 2011 little of this research was conducted in the UK, but the situation is now changing. Currently we have two studies investigating new treatments that are running in England and Wales: MonoPepT1De-1b and DILT1D (more details are given on the study summaries section of this newsletter). These trials are at the early stage of testing the treatments and are looking at the safety of the treatments, what they do, and for DILT1D what dose works best. Other new trials are being planned which aim to recruit in the next 2-3 years. If these come to fruition there will be more opportunities to help build on knowledge of treatments that may slow down, or halt, progression of type 1 diabetes.

## Contact Us:

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## Find out more:

**ADDRESS-2:** [www.address-2.org](http://www.address-2.org)

**Diabetes UK:** [www.diabetes.org.uk](http://www.diabetes.org.uk)

**Juvenile Diabetes Research Foundation:** <http://www.jdrf.org.uk/>

**NIHR CRN Diabetes Research Network:** <http://www.drn.nihr.ac.uk/>

**NIHR CRN Medicines for Children Research Network:** <http://www.mcrn.org.uk/>

**National Institute for Health Research Clinical Research Network:** <http://www.crncc.nihr.ac.uk/>

**NIHR CRN. Clinical trials - what they are and what they are not:**

<http://www.crncc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/PPI/Documents/Clinicaltrialswhattheyareandwhattheyrenotweb.pdf>

**JDRF getting involved in type 1 diabetes research:** <http://www.jdrf.org.uk/research/getting-involved-in-research>