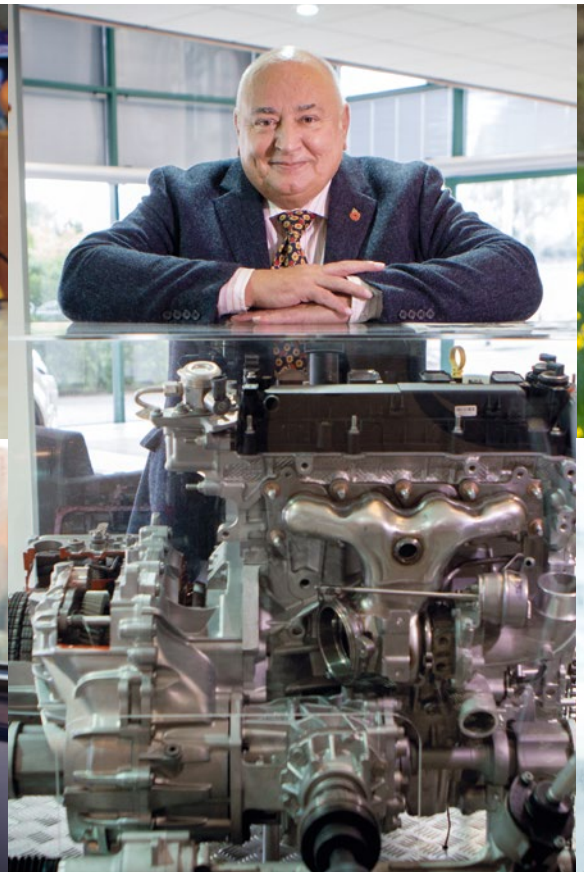
Volunteer Outreach Programme

THINKING ABOUT TAKING PART IN DIABETES RESEARCH? HERE'S SOME MORE INFORMATION



changing diabetes®

novo nordisk®

RUPA SHREE APPA
Principal Scientist, PhD, Novo Nordisk
Denmark

"Maybe you can do something for future generations. I don't want people to go through what I go through every day.

If we can find a cure, or something to make things better, then everything will have been worthwhile."

PAUL
Research participant

Introduction

Clinical research plays an invaluable part in the development of treatments that change the lives of people with diabetes.

Patient participation is central to clinical research, which is why we have developed the Volunteer Outreach Programme.

This booklet is intended to provide you with information on the programme and clinical research in general. We hope you will find it informative. We hope you find it useful and we encourage you to get involved. Details on page eight.

Novo Nordisk: 90 years leading diabetes care

Novo Nordisk was founded in Denmark in 1923 and has since become a global healthcare company with 90 years of innovation and leadership in diabetes care.

We have a strong commitment to patients and offer a wide portfolio of diabetes products. Our aim is to defeat diabetes by improving treatment and raising awareness, while increasing early detection and prevention of the disease.

Novo Nordisk is committed to working with the NHS to improve patient healthcare, under the Joint Working Framework of the Department of Health and the Association of British Pharmaceutical Industry.

"At Novo Nordisk we continue to build on the legacy left by our founders and will do everything we can to change diabetes.

The number of people living with diabetes is rising at such a rate that it is now a global pandemic and within the next 25 years, one in ten people in the UK will have the disease.

Our mission is to improve the lives of people living with diabetes by creating new, innovative treatments. Clinical trials are vital for the development of these life-changing treatments and are only possible with the support of the volunteers who take part in our trials.

Help us develop new treatments for people with diabetes in the UK and please consider volunteering for our groundbreaking trials."

DOXIE JORDAN
Corporate Vice President UK & Ireland
Novo Nordisk Ltd

Why is diabetes research important?

The number of people affected by diabetes is rising at such a rate it is now a global pandemic. Diabetes UK, in its Facts and Stats report 2015, projects a 55% increase in diabetes in the next 25 years, when one in ten people will have the disease. One person every two minutes is diagnosed with diabetes. 90% of them have type 2.

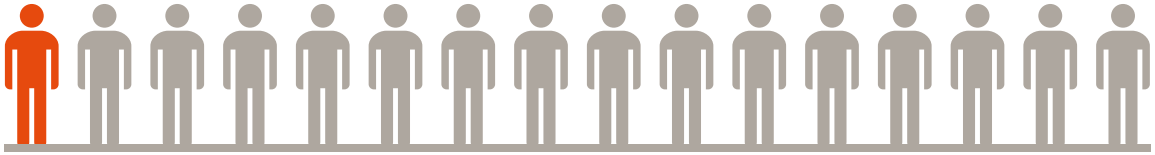
Changing the future of diabetes is our passion and we can achieve this by making more innovative treatments available. Conducting high quality research is an integral part of that process.

Research involves conducting clinical trials on new medicines, medical treatments or devices. As a person with diabetes, your role in the trial is invaluable.

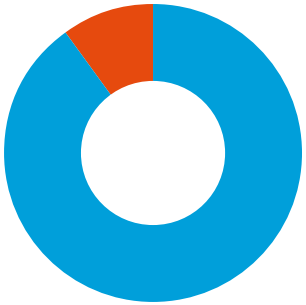
These clinical trials would not be possible without people like you taking part.

Diabetes in the UK

1 IN 16 PEOPLE HAVE DIABETES[1]



4 million
PEOPLE LIVING WITH DIABETES IN THE UK



90%
HAVE TYPE 2 DIABETES

Diabetes prevalence worldwide

2015 **415 million[1]**

2040 **642 million[1]**

1. Diabetes UK Facts & Stats, November 2015. Adults aged 20-70

The goal of diabetes treatment

Diabetes treatment aims to keep blood sugar levels at rates as close to normal as possible. A key measure for this is HbA_{1c} and a high reading is associated with increased risk of diabetes complications.[2]

Small improvements in HbA_{1c} can bring significant health benefits. A UK study[2] of people with Type 2 diabetes showed that a 1% drop in HbA_{1c} would reduce:

- **the number of heart attacks and strokes by 14%**
- **cases of blindness and kidney disease by 37%**
- **diabetes deaths by 21%**

What are clinical trials?

A clinical trial is a research study carefully designed to evaluate the effects of a medication, medical treatment or device.

Participation in a clinical trial is entirely voluntary and will only take place once all the relevant information has been discussed with you by the research team. Participation may involve using a product in an evaluation study, or being part of a control group. The control group is usually given either the best currently available alternative treatment, or when required by regulatory authorities, they may be given a 'dummy' treatment known as a placebo.

Participants are carefully monitored throughout the study and all relevant data is collected and recorded. These trials measure the ability of a medicinal product to treat a condition, any possible side effects and ensure that the product reaches the safety standards set by government agencies around the world.

Clinical trials are an important part of the research and development process, essential when making new medications available.

General information on clinical trials can be found online*:
National Institute for Health Research
UK Clinical Trials Gateway
or visit **www.nhs.uk** and search 'clinical trials'.

**Please note that Novo Nordisk is not responsible for the content of these websites, nor affiliated with the providers.*

Clinical trial ethics

Novo Nordisk-sponsored clinical trials are performed using one global standard. This standard is developed in accordance with the Declaration of Helsinki and the International Conference on Harmonisation Guidelines on Good Clinical Practice.

The Declaration of Helsinki, developed by the World Medical Association, is a standard of ethical principles in clinical trials. The ICH-GCP Guidelines ensure the rights and safety of trial participants and uphold the validity of trial data.

For anyone involved in clinical research, the interests of trial participants must take precedence over the interests of science.

"Research participation makes a real difference. It's vital to innovation, but it also has long-term health outcomes, as people learn to take an active role in their treatment and better manage their condition."

PROFESSOR STEVE BAIN
Clinical Lead, Diabetes Research Unit Cymru, Swansea University

2. *Stratton IM, Adler AI, Neil HA, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. BMJ. 2000;321:405–412.*

Who runs the trials and where do they take place?

We carry out our clinical trials in partnership with fully qualified doctors and nurses around the UK in hospital clinics or GP surgeries. These doctors and nurses will be fully responsible for your care if you choose to participate in any of our research studies.

All clinical trials must conform to globally approved scientific and ethical standards before they can proceed. All Novo Nordisk studies in the UK are also reviewed and approved by the Medicines and Healthcare Regulatory Agency (MHRA), the NHS National Research Ethics Service and the NHS Trust for the area where the research takes place.

During the trial, Novo Nordisk works closely with the research site to ensure that the study is running correctly and all participants are being well cared for. In addition, the Medicines and Healthcare products Regulatory Agency (MHRA) is authorised to inspect either Novo Nordisk, or a research site at any time, in order to ensure that the clinical trial is being conducted correctly.

3. E.D. Kennedy, et al., Networks offer new opportunities for diabetes research, Prim. Care Diab. (2009), oi:10.1016/j.pcd.2009.10.002

Clinical trials – benefits and risks

People with diabetes may benefit from taking part in a clinical trial in a number of ways. The monitoring of your diabetes and general health is usually more frequent than it would be in normal practice. You may also benefit from access to the latest diagnostic tests and treatments for diabetes. As you are likely to be in regular contact with your research team, you may learn more about your condition and improved ways of managing it[3].

It may be that you receive no personal benefit from participation. It is possible you may experience some side effects from the treatment. The possible risks and benefits vary according to each particular trial design and treatment. Your study doctor and nurse will be available to discuss this with you in more detail before you agree to participate in a specific study.

A NOVO NORDISK PATIENT AND HEALTHCARE PROVIDER STUDY[4] IN 2014 SHOWED:

88% OF HEALTHCARE PROVIDERS

believed that patients' overall health has improved as a result of clinical trial participation

80% OF PATIENTS

said their involvement in clinical trials improved their HbA_{1c} level

4. HCP and patient survey, Novo Nordisk, 2014

"By referring patients into clinical trials, I get huge satisfaction that I'm helping my patients for the future… they may get a new treatment that will improve their care… and I like to be at the forefront of new developments."

DR BROMIDGE, G.P.

"It makes you feel much better to know that somebody's monitoring you... and it encourages you to follow the rules and try to get the best out of the project, for as long as it takes"

SHEILA
Research participant

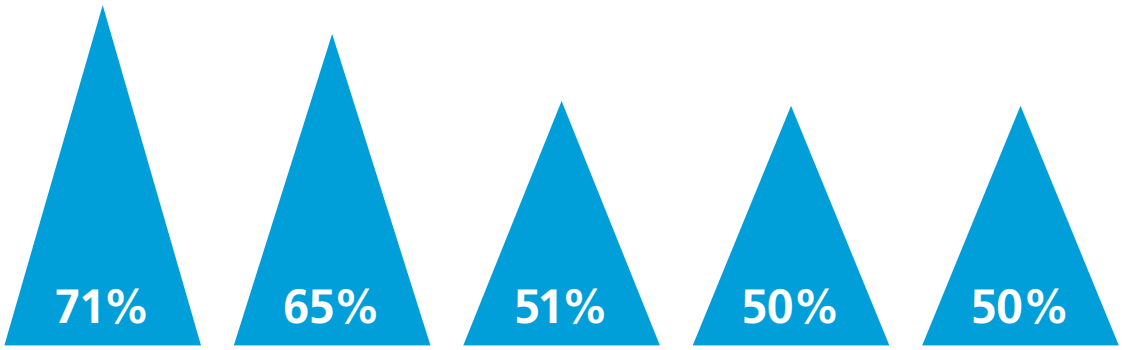
The impact of clinical trials, for patients

According to the respondents of Novo Nordisk's 2014 study, health improvement is just one benefit of patient participation in clinical research. Patients were asked to assess all the possible benefits, by ranking statements from the most to least important for them.

Top five benefits:

1. **Overall health improvements**
2. **Increased expertise and knowledge of healthcare providers involved in clinical trials**
3. **Improved blood sugar control**
4. **Increased knowledge of how to manage diabetes**
5. **Clinical research facilitates new products to market, which increases options for patients**

71% OF PATIENTS REPORTED IMPROVED EATING HABITS AS A RESULT OF TRIAL PARTICIPATION[5]



FOR PATIENTS WITH TYPE 2 DIABETES, LONG-TERM LIFESTYLE CHANGES ARE IMPORTANT, SO THE KNOWLEDGE AND SKILLS PATIENTS GAIN FROM RESEARCH PARTICIPATION HAS A LASTING VALUE:

85% OF PATIENTS[4]
say that participating in clinical research improved their understanding of diabetes

87% OF PATIENTS[4]
set health improvement targets

4.HCP and patient survey, Novo Nordisk, 2014 5. Percentage of patients stating areas of changed behaviour

We'd love you to join our Volunteer Outreach Programme and if you'd like to register your interest in potential opportunities to participate in a trial, it couldn't be easier.

Register online:
changingdiabetesresearch.co.uk
or call an advisor, free of charge,
on **0808 169 66 66**

If you have any questions about the Volunteer Outreach Programme, or research participation, call us now on Freephone **0808 169 66 66** and speak to one of our advisors.

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3 City Place
Beehive Ring Road
Gatwick
West Sussex RH6 0PA

Once registered, the information you provided either during our telephone call, or through the online registration process, will enable us to search for any ongoing clinical trials that are suitable for your participation. Confidentiality will be observed at all times.

If a suitable trial is found, we will then search your location to find any participating clinical trial sites in your area. The frequency and duration of clinical trials varies, so opportunities for participation fluctuate throughout the year.

If there is a clinical trial site in your area conducting a suitable study, your details will be passed on to the research team at the site and they will contact you to discuss the trial in more detail. If you think you might be interested in taking part, they will then send you further written information. When you have received all the information about the trial and had time to consider it, you will then be asked whether you wish to participate or not.

What's it like being on a diabetes clinical trial?
Watch this short video featuring patient and GP views.

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