

Parkinson's UK policy statement Clinical trials

"Clinical trials are one of the most important methods of getting possible future treatments to people with Parkinson's. It is vital that more trials of Parkinson's treatments take place and access to them is made as easy and timely as possible for potential participants. Any barriers that can prevent or delay trials from taking place unnecessarily need to be removed."

Claire Stephenson, Research Support Network Manager,
Parkinson's UK

What we believe

Parkinson's UK believes that people with Parkinson's should have timely access to appropriate clinical trials. It is important that participation in clinical trials for Parkinson's drugs is maximised across all countries and regions.

In order to increase the number of clinical trials taking place and the amount of patients taking part in trials a number of improvements need to take place.

- Sufficient opportunities to take part in clinical trials should be provided by healthcare professionals and researchers.
- Appropriate regulation of clinical trials needs to be in place to ensure the safety of patients. However, this regulation should not be unnecessarily rigorous to the point that crucial trials are prevented from moving forward.
- The Government needs to support clinical research and clinical trials within the NHS and make a long-term commitment to funding clinical research. The NHS is a permissive environment for clinical trials and should be supported.
- Awareness of clinical research needs to be raised among healthcare professionals in order for them to encourage their patients to take part in clinical research as part of their treatment.
- More information should be made available to people affected by Parkinson's informing them of the opportunities to take part in appropriate studies.
- Researchers should be encouraged to involve people affected by Parkinson's in all stages of clinical trials including study design.
- Many clinical trials taking place today are unregistered and unpublished, meaning that the vital knowledge they produce is not available to the scientific community or the public. Greater transparency of the sharing of research results is needed.

Why we believe this

One of the key aims for Parkinson's UK is to find a cure and improve life for everyone affected by Parkinson's. Clinical trials are crucial for Parkinson's research. They are studies designed to test whether medical interventions are safe and effective and form part of the pathway of a treatment getting from the lab to patients.

Parkinson's is a progressive, degenerative condition and current treatments only address the symptoms. There needs to be a sense of urgency in the search for a cure.

What's the evidence?

The UK's activity in clinical trials has decreased. In particular, between 2002 and 2006 the UK's global share of patients in trials fell from 6% to 2–3%, a trend that has continued since then.¹

The European Commission has also quoted a decrease of 25% of clinical trials conducted in the EU during the period between 2007 and 2011.

Obtaining approval for a clinical trial

The time taken to initiate trials can be one of the largest obstacles to clinical research in the UK. Numerous regulatory bodies are involved in approving trials and it can take years to complete the approvals process and recruit enough participants.

The steps managed by the Medicines and Healthcare Regulatory Agency and the National Research Ethics Service are processed within defined approval timelines. However, obtaining research and development permissions can be one of the more difficult processes. For many trials that process has lacked oversight, with no agreed timeline or incentive for completion. Consequently, a trial may already be underway in other countries while the UK is yet to start.²

Regulations

In 2001 the Clinical Trials Directive was implemented to govern clinical trials across Europe. This has been widely criticised due to the difficulties experienced in implementing these regulations and them causing unnecessary delays and increased costs.

In addition, some aspects of the Clinical Trials Directive are open to interpretation, leading to EU members states implementing them differently. This has complicated the process, particularly for multi-centre trials, incurring unnecessary costs and delays.

Difficulties in starting a trial have also been experienced due to high levels of bureaucracy. For example, since the Clinical Trials Directive was put in place the average delay for launching a clinical trial has increased by 90% to 152 days. This delay and the general fall in clinical trial activity can not solely and exclusively be attributed to the directive. However, it has had a direct effect on the cost and feasibility of conducting clinical trials – contributing to a decline in clinical trial activity in the EU.³

The cost of conducting clinical trials has also increased since the directive was put in place. The number of staff needed for industry sponsors to handle the clinical trial authorisation process has doubled (107%), and their insurance fees have increased by 800%. For non-commercial sponsors, the increase in administrative requirements has led to a 98% increase in administrative costs.³

¹ NESTA, 2011, *All together now: Improving cross-sector collaboration in the UK biomedical industry*,

http://www.nesta.org.uk/library/documents/Report_67_Biomed_web.pdf

² Houses of Parliament, parliamentary office of science and technology, POSTNOTE, number 390, October 2011

³ European Commission, Proposal for a regulation of the european parliament and of the council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

In 2012 a new Clinical Trials Regulation was proposed by the European Commission to replace the directive. This aims to improve the legislation giving clinicians and researchers a better framework for developing and testing treatments while maintaining high standards of patient safety.

Awareness

An online public survey of the UK Clinical Trials Gateway hosted by the National Institute for Health Research conducted in 2012 showed a lack of awareness of and information on clinical trials. For example, of the 645 people who responded only 28% had taken part in a clinical trial and 38% said they knew little or nothing about clinical trials and would like a clear and reliable source of information to learn more. And 64% said they would like to find out about trials recruiting in their local area.⁴

In addition a survey conducted by One Poll in 2012, on behalf of the National Institute for Health Research Clinical Research Network, found that 82% of people surveyed said it is important for the NHS to offer opportunities to take part in healthcare research.⁵

Opportunity to be involved in clinical trials

There is a general consensus from people affected by Parkinson's that they would be willing to take part in clinical research. From a survey conducted with 2,472 people with Parkinson's and their friends and family members, only 18% stated that they have taken part in a clinical trial yet 45% stated that they would like to. This indicates that there is a large number of people wanting to take part in clinical research but barriers are preventing them from doing so.

What Parkinson's UK are doing

Parkinson's UK are working to ensure that people with Parkinson's have timely access to appropriate clinical trials and aim to reduce any barriers that prevent people from taking part in them.

Our research team assists researchers looking for participants for trials, and actively seeks out and monitors trials that are looking for participants.

In order to fulfil our duty of care to our supporters, prior to encouraging their involvement in a trial we always ensure that the research is bona fide, has appropriate ethical approval, will ultimately deliver benefits for people affected by Parkinson's and follows our guidelines as per our 'Participant involvement guidelines for researchers' document.⁶

We currently publish a list of clinical trials that are looking for participants on our website and send details of opportunities to take part in trials to our Research Support Network across the UK. This network is a vital resource that helps us to make decisions about the research we fund and assist researchers to shape and steer their projects.

We work closely with the Dementia and Neurodegenerative Research Network to ensure that promotion and recruitment of Parkinson's research is maximised.

⁴ Denegri & von Hilderbrand (2012) UK Clinical Trials Gateway Public and Patient Survey, NIHR.

⁵ http://www.cmcc.nihr.ac.uk/news/news_archive/survey_raises_questions

⁶ http://www.parkinsons.org.uk/sites/default/files/participantinvolvement_guidelinesforresearchers.pdf

As part of our campaigning activity, we are working to influence the legislation and policy environment that impacts on clinical research to ensure that barriers to conducting clinical trials for Parkinson's drug treatments are reduced.

Campaigning in Europe

The European Commission plans to improve the research environment and streamline the process of conducting clinical trials through the publication of a new Clinical Trials Regulation. Parkinson's UK will feed into the debates on this to ensure the most effective regulation is implemented.

Parkinson's UK will campaign to influence members of UK and EU parliament who can shape the regulation.

Promotion and education

We will work to ensure that research is promoted by health bodies in the UK and EU and that Parkinson's research is high on the research agenda.

We will help to stimulate a research culture within the healthcare professional community to ensure that research is promoted within the NHS and patients are informed of appropriate research opportunities.

Acknowledgement

We are grateful for the advice and guidance of our Policy Panel and Research Support Network in shaping this position paper on patient data. The Policy Panel consists of people with experience of Parkinson's who meet on a regular basis to help guide the charity's position on a range of policy issues. The Research Support Network is a group of around 950 people with an interest in Parkinson's research.

Further information

Please contact the Policy and Service Improvement team on **020 7963 9394** or email **campaigns@parkinsons.org.uk**

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