Partnering of PD researchers with patient groups needed to improve effectiveness of clinical trials

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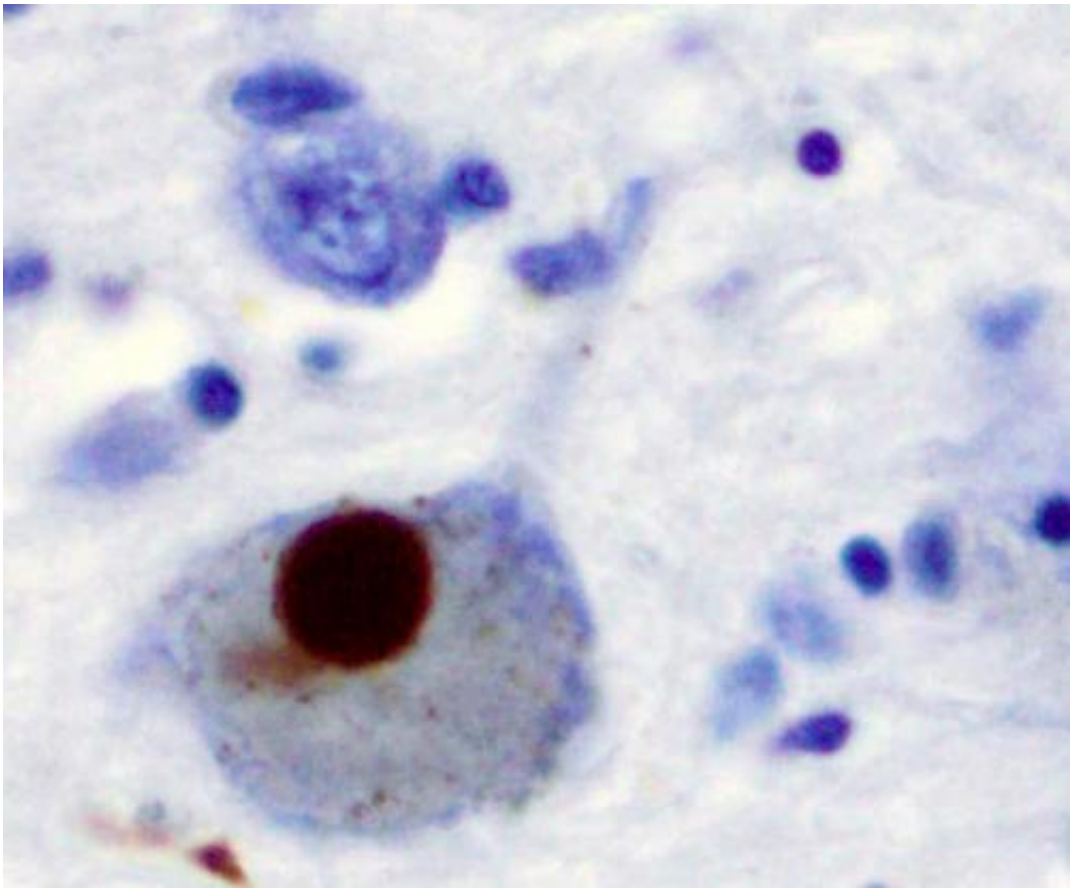

Immunohistochemistry for alpha-synuclein showing positive staining (brown) of an intraneural Lewy-body in the Substantia nigra in Parkinson's disease. Credit: Wikipedia

Despite an urgent need for new medications, clinical trials in Parkinson's disease (PD) have a relatively low rate of success. The reasons for this are complex, prompting a group of investigators from PD advocacy groups to conduct a survey of the principle stakeholders, PD scientists, patients, and caregivers, to determine some of the underlying barriers. Their results are published in the *Journal of Parkinson's Disease*.

"With development of a new drug estimated to cost between $1 and $3 billion and taking as long as 15 years, the successful execution of clinical trials is essential," explained lead investigator Tom Isaacs, Co-Founder of The Cure Parkinson's Trust, London, UK. "Our findings identified the most significant obstacles to carrying out effective clinical trials for those involved in conducting research as lack of funding and support. For those with Parkinson's, the principal barriers to their participation in medical research were found to be fear of potential adverse consequences, interruption of their ongoing medical regimen, and concern about receiving placebos."

Lack of funding was cited by 66% of researchers surveyed, with the administrative burden to managing the trials noted by 46%. Recruitment of subjects was viewed as a barrier by 43%.

In most clinical trials, recruiting study subjects takes substantial effort and time and often results in significant delays in drug development. From the point of view of 240 potential study subjects and care partners, the authors found that 56% of the respondents were concerned with potential adverse consequences or side effects from the trial, while 53% did not want to disrupt their current medication. Fully 38% were worried that they might receive the placebo.

"It seems likely that the gap between the willingness of people living with Parkinson's to participate in clinical trials and the reality of the shortfall in recruitment numbers could be closed if there were better

understanding, information, and communication between those conducting the trials and the participants," commented Isaacs. He and his co-authors further noted that Involvement of the patient community from the outset contributes to a culture of partnership and collaboration.

The results of the survey of more than 300 people with a connection to PD were presented at the Rallying to the Challenge meeting of Parkinson's patients held in September 2014 at the Van Andel Research Institute, an independent biomedical research and science education organization in Grand Rapids, Michigan, USA. Based on discussions of these results at the meeting, recommendations in the areas of communication, education, funding, recruitment and compliance were developed.

As a result of the Rallying to the Challenge meeting, a steering committee will be formed, comprised of both scientists and patients, to draft a Clinical Trials Charter to help bridge the gaps uncovered in the survey. The authors remind us that the "Parkinson's Movement seeks to develop and deliver stronger partnerships between the research and patient communities, and in so doing, expedite the search for better treatments and ultimately a cure."

More information: "Rising to the Challenges of Clinical Trial Improvement in Parkinson's Disease," by Soania Mathur, Steve DeWitte, Israel Robledo, Tom Isaacs, and Jon Stamford (DOI: 10.3233/JPD-150541), Journal of Parkinson's Disease, Volume 5, Issue 2 (2015).

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