

**Title:** Evolution of Parkinson's disease trial characteristics 2005 - 2017

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**The Methodological Question Being Addressed:** How have the relationships among various aspects of the Parkinson's disease (PD) clinical trial design (including: study phase, disease severity, indication, employed outcome measures) evolved since 2005?

**Introduction:** In the past 20 years, phenomenal progress has been made, helping researchers understand the chain of events that leads to the damage and loss of dopamine producing brain cells in Parkinson's disease. There, however, are still no approved neuroprotective/interventional drug treatments for Parkinson's disease that have been shown to slow, halt, or reverse progression. A longitudinal analysis of PD study characteristics may provide a deeper understanding of clinical trials dynamics and demonstrate how research paradigms have been changing across the years. This poster aims to fill this knowledge gap by providing unique insight into PD clinical trials methodology by analyzing research activity in terms of study phase prevalence and selected internal aspects of study complexity.

**Methods:** Data concerning 453 Phase I – IV industry-led Parkinson's disease studies, available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov), were downloaded on 05Jul2018 and reviewed. Inferential statistics were used to calculate differences between selected study characteristics.

**Results:** A total of 453 Parkinson's disease trials have been initiated between 2005 and 2017. The number of trials initiated per year fluctuated slightly, showing a mild, non-significant downward trend (from 260 trials initiated in 2005 - 2009 to 204 studies initiated between 2015 - 2017). A significant increase in the number of Phase I studies has been noticeable since 2009 (from 23 trials in 2005 – 2008 to 38 new studies initiated every three years since then) and it has been followed by an increase of Phase II studies within the past three years (20 studies in 2012 – 2014; 38 studies in 2015 – 2017;  $\chi^2 = 33.52$ ,  $p < 0.05$ ). At the same time, the number of Phase III studies has decreased from 38 – 40 studies initiated every three years between 2005 and 2011 to 18 – 20 in 2012 - 2017. Thus, the total number of studies initiated between 2010 and 2015 appears to be relatively low, as fewer studies were conducted on average during that time. Such a picture is, however, somewhat misleading, as the increasing number of Phase I and II studies shows that new (or repurposed) compounds are being introduced and tested. In the current evaluation, various methodological solutions, such as employed outcome measures, study designs, and types of interventions will be reviewed and conclusions will be drawn.

**Conclusions:** Authors provide a comprehensive overview showing evolution of the PD clinical trial dynamics in Parkinson's disease Phase I – IV industry-led studies across a 13-year time span. An analysis limited to data available in [clinicaltrials.gov](http://clinicaltrials.gov) will be summarized. Complete analysis of characteristics of PD studies will be presented in the final poster.

**Disclosures:** KS, JM, AP and LK are employees of Syneos Health.