

Collaborative Framework for Delivering on Ways That Digital Technologies Can Help to Optimize New Parkinson's Treatment Trials



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PARKINSON'S^{UK}
CHANGE ATTITUDES. FIND A CURE. JOIN US.

Background and Objectives

Development of effective therapies for Parkinson's is a high risk and costly endeavor. Recently, a focus on data collected using new digital technologies has been introduced to improve the assessment of day-to-day experience of people living with Parkinson's. Worldwide collaborative initiatives are in place to take advantage of mobile sensors and devices as new tools to inform drug development decision-making.

The Critical Path for Parkinson's (CPP) consortium, a public-private partnership sponsored by Critical Path Institute, Parkinson's UK and industry aims to advance innovative new tools to optimize clinical trials. (1)



Objective: To present CPP's pre-competitive collaborative worldwide network and describe how all stakeholders are working together to advance the utility of digital technologies for use in Parkinson's trials.

Critical Path for Parkinson's consortium

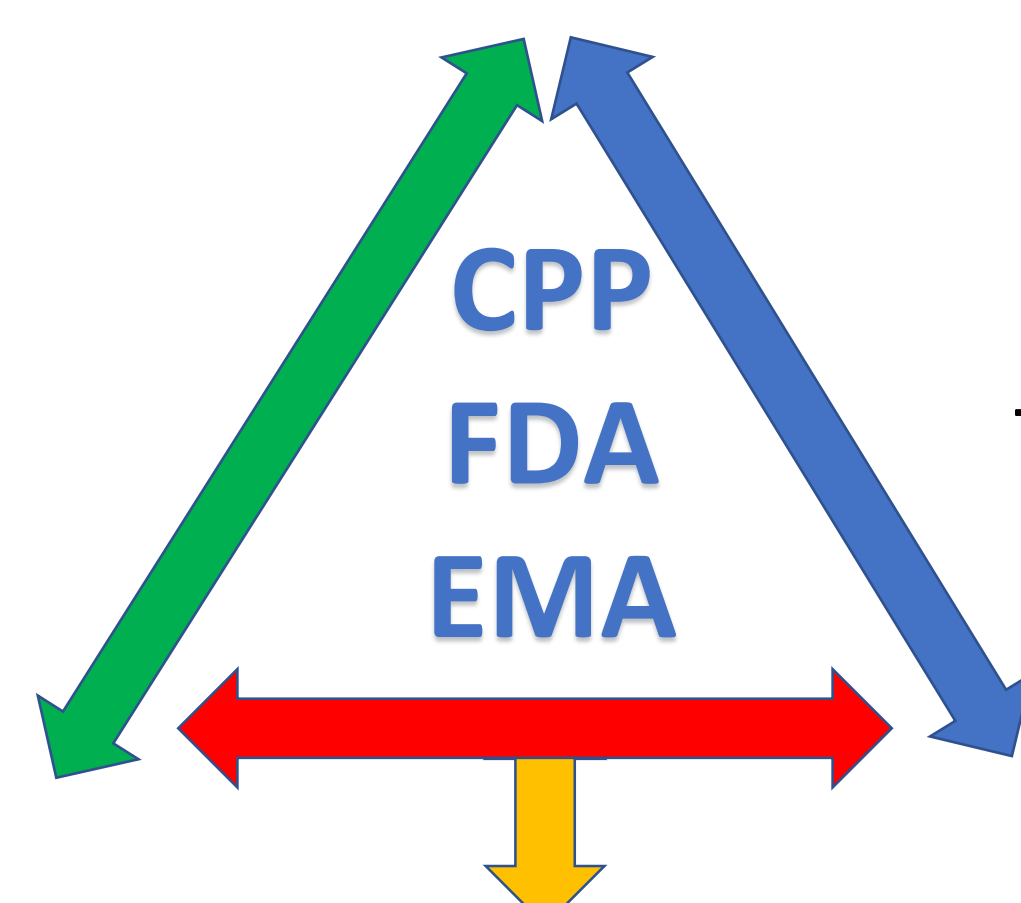


What is Important to you?

TODAY:
How do we measure what is important to you?

Scores, scales, markers, neurological examination etc. (things that your doctors use today)



Better trials to test medications that positively impact what's important to you

Sleep
Mood
Cognition
Apathy
Rigidity
Postural Instability

Methods

Five nonprofit/research charity organizations from around the world have convened under the CPP consortium in partnership with industry and academic experts to participate in a working group with the goal of defining ways to optimize the use of digital technologies in Parkinson's clinical trials. The strategy includes near term focus on the following goals 1) to identify what symptoms and measurements are important to people living with Parkinson's and 2) to assess the landscape of digital measurement of signs/symptoms by carrying out a comprehensive data inventory of studies being carried out around the world.

Results

The CPP initiative recognizes the need to catalogue and inventory relevant Parkinson's studies where data collection by digital technologies have been implemented to date. The findings will inform best practice for data collection using digital technologies in future studies.

- "Participants emphasized the difficulty of living with...progression of symptoms. Many described living with daily motor symptoms which included **bradykinesia, dyskinesia, tremor and dystonia**. ...participants also highlighted **sleep disturbances, cognitive impairment, fatigue, and constipation**."
- "...patients were asked to identify up to three symptoms that have the greatest impact on daily life. **Motor symptoms, impaired balance and coordination, cognitive impairment, and sleep disturbances** received the highest number of responses."
- "Several participants highlighted the **cognitive effects** of Parkinson's disease on their day to day activities."
- "Comments regarding **fatigue** resonated with meeting participants."
- "Several participants commented that they experienced significant **depression and anxiety**."
- "Participants shared that their symptoms, particularly **motor symptoms, impaired balance, and cognitive impairment**, had significant impacts on their ability to perform at their job."
- "Many participants commented that the **lack of energy, anxiety, and motor symptoms** led to social isolation."

(2) FDA VOP report Parkinson's Disease; Public Meeting: September 22, 2015 Report Date: April 2016, CDER

TOMORROW:
How can we improve the way we measure what is important to you?



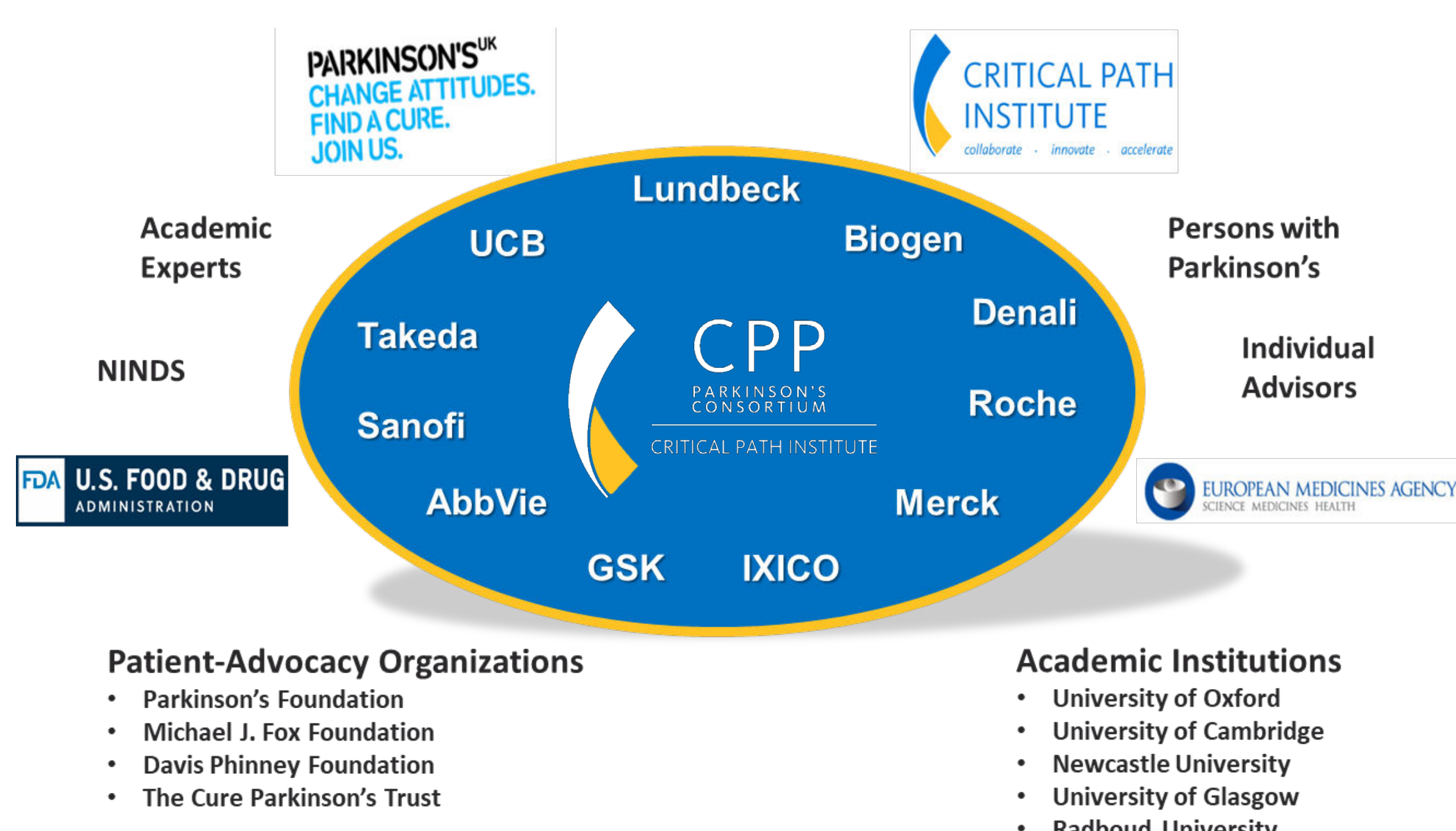



TECHNOLOGY:

E. Ray Dorsey (3)

Arora et al., 2018 (4)

Critical Path for Parkinson's Consortium



Conclusions

The information gathered from CPP's assessment of the use of digital technology in Parkinson's studies will apply learnings from other consortium initiatives to develop novel tools to improve Parkinson's clinical trials. A robust collaboration between all stakeholders around the world centered on data standards and data sharing is key for success in the future.

References

- (1) Stephenson et al., 2015; J. Parkinson's Dis 5(3): 581–594.
- (2) FDA 2016 Parkinson's Disease Voice of the Patient Report [Internet]. U.S. Food and Drug Administration; 2016 Apr.
- (3) E. Ray Dorsey, 2018 unpublished
- (4) Arora et al., 91(16): Neurology 19, e1528–e1538.

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