

Critical Path for Parkinson's

 consortiapedia.fastercures.org/consortia/cpp/

Research Areas



Tool Development

Regulatory



Biomarker Research

Disease Progression, Genomic
Biomarker



Data-Sharing Enabler

At a Glance

- Status: **Active Consortium**
- Year Launched: **2015**
- Initiating Organization: **Critical Path Institute**
- Initiator Type: **Nonprofit foundation**
- Location: **International**

Abstract

Critical Path Institute has partnered with Parkinson's UK, the world's largest patient-led charity for Parkinson's, to establish a global collaborative consortium that promises to pave the path to new treatments. By facilitating collaboration among scientists from the biopharmaceutical industry, academic institutions, government agencies and patient advocacy organizations, CPP fosters consensus and data driven research to increase efficiency and speed in developing new therapies. The goal of CPP is to accelerate the development of therapies for PD by advancing drug development tools for regulatory endorsement and public dissemination.

Mission

The mission of CPP is to serve as the main international vehicle to develop new, regulatory endorsed drug development tools based on the most current scientific insights into early Parkinson's, by combining detailed patient data, expertise in clinical trials from companies and academia, and the unique neutral facilitator role of non-profit organizations.

Consortium History

CPP has established a global PD community of the willing: clinical investigators, the pharmaceutical industry, regulatory agencies and charity organizations.

In collaboration with CDISC and NINDS, the first Parkinson's clinical data standard for use in clinical trials and regulatory review was completed and is publically available

Acquired patient level data from >4000 individual patient records and it is anticipated this number will grow substantially by acquiring and pooling data from global longitudinal cohorts and clinical trials.

Achieved Letter of support from regulatory agencies recommending the use of molecular imaging of the dopamine transporter as an enrichment biomarker for PD clinical trials targeting early PD.

Roadmap for CPP published in J. Parkinson's disease: Stephenson D., Hu MT, Romero K, Breen K, Burn D, Ben-Shlomo Y, Bhattaram A, Isaac M, Venuto C, Kubota K, Little MA, Friend S, Lovestone S, Morris HR, Grosset D, Sutherland M, Gallacher J, Williams-Gray C, Bain LJ, Avilés E, Marek K, Toga AW, Stark Y, Forrest Gordon M2, Ford S (2015). "Precompetitive data sharing as a catalyst to addressing unmet needs in PD." J. Parkinson's Disease, 5(3), 581-594

Structure & Governance

CPP members consist of 9 pharmaceutical companies, four European academic institutions, 5 charity organizations and >12 PD experts who serve as advisors. The infrastructure of CPP consists of a core leadership team (CPP executive director, Parkinson's UK co-director, industry co-director) with voting participation for regular members. CPP executive director has expertise in the field of PD drug development. A total of 3 working groups, a coordinating committee and a nonprofit organization forum are active and progress to achieve milestones that are defined for the first 3 yrs based on a specific scope of deliverables and regulatory achievements. There is a dedicated focus on sound contract development and negotiation utilizing C-Path legal counsel, maintenance of membership agreements and related documentation, sound project management, data security and privacy practices.

Financing

Funding for CPP's mission and deliverables is primarily from Parkinson's UK with additional funding from participating industry members. Funding is aimed at supporting the expenses of the consortium staff and infrastructure as well as the database development, integration, analyses and regulatory submissions and communications.

Intellectual Property

Intellectual property is out of scope for CPP as this is a noncompetitive consortium aimed at delivering tools that will be disseminated publicly.

Patent Engagement

CPP has several people living with PD who serve as advisors and champions for the mission of the consortium.

Specific examples of CPP's patient engagement are highlighted below:

PD patient/advocate Dr. Kevin Kwok participant on CPP workshop panel at the World Parkinson's congress, Sept 2016

Coauthored abstract poster with FDA on patient focused drug development for PD:

- Diane Stephenson, Theresa Mullin, Eric Bastings, Billy Dunn, Susanne Goldstein, Gerald Podskalny; "The FDA is listening: integrating the voice of the patient in drug development for Parkinson's disease." World Parkinson's Congress (WPC), Portland, OR, September 21-23, 2016.

JPD data sharing blog by patient Sue Dubman facilitated by CPP:

<http://www.journalofparkinsonsdisease.com/call-action-sharing-patient-level-data-parkinson%E2%80%99s-research-and-care>

Data Sharing

CPP has data sharing core the success of the consortium. The success of CPP in this space is aligned with other consortia of the Critical Path Institute in which this core competency in responsible data sharing has enable success across a variety of disease states.

In 2016 CPP has partnered with patients with PD to communicate the importance of data sharing.

Impact/Accomplishment

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Strong external presence: Three abstracts at Movement Disorders Society meeting, two abstracts and one workshop panel at the World Parkinson's Congress. Three press releases.

Links/Social Media Feed

Website: <https://c-path.org/programs/cpp/>

Points of Contact

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Sponsors & Partners

- Parkinson's UK
- Michael J. Fox Foundation
- Davis Phinney Foundation
- The Cure Parkinson's Trust
- Parkinson's Disease Foundation
- NINDS
- FDA
- EMA
- AbbVie
- AstraZeneca
- Biogen
- G.E. Healthcare
- H. Lundbeck A/S
- Lilly
- Merck Sharpe & Dohme
- Pfizer
- UCB
- University of Cambridge
- University of Oxford
- University of Glasgow
- Newcastle University

Updated: **11/01/2016**