

Critical Path for Parkinson's Consortium achieves regulatory support in Europe for use of imaging biomarker in Parkinson's disease clinical trials

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London and Tucson, Ariz., October 10, 2016 — The Critical Path Institute (C-Path), in partnership with Parkinson's UK, announced today that the European Medicines Agency (EMA) has issued a letter of support for Parkinson's disease (PD). EMA is supporting the use of an imaging biomarker as a tool to help researchers select people in the earliest stages of PD to participate in clinical trials of new treatments for the condition.

The EMA issued a letter of support on Oct 7, 2016, supporting the use of neuroimaging biomarker dopamine transporter imaging as an exploratory biomarker for early PD. The public letter was issued to the Critical Path for Parkinson's Consortium (CPP), in response to the consortium's submission of data supporting the use of the biomarker.

Dopamine transporter activity, as assessed by single-photon emission computed tomography (SPECT) imaging, measures the expression of dopamine nerve terminal function in the living brain. Low levels of dopamine transporter binding serve as a marker of the loss of dopamine nerve terminals, a hallmark of PD. Use of this biomarker in patients at the time of early clinical presentation will help to identify patients who are likely to show clinical progression of motor symptoms.

The letter of support is a step along the way to CPP's ultimate goal of achieving biomarker qualification with EMA and FDA. Why is EMA qualification significant? According to Dr. Arthur Roach, Director of Research at Parkinson's UK, qualification would relieve trial sponsors of the burden of having to convince the regulators that the biomarkers are reliable and reproducible every time they run a trial. "Qualification could save both the regulators and sponsors a tremendous amount of time and money." CPP's executive

director, Diane Stephenson, states: “Parkinson’s disease treatments are urgently needed, and shaving off time and cost serves to incentivize companies to invest in more trials.... More shots on goal mean more chances of getting approved drugs past the finish line.”

Professor Donald Grosset, University of Glasgow, a key global leader in Parkinson’s disease research that is contributing data to CPP, commented that embedding biomarkers in clinical trials, with support from regulatory agencies, could ultimately facilitate their use as both prognostic and therapeutic indicators. “This will all happen more quickly due to the significant progress we are making in sharing data across several major studies,” Grosset wrote. “This action from the EMA is certainly good news for the field.”

In 2015, the US Food and Drug Administration (FDA) issued a letter of support for this same biomarker and its application in drug development. These letters convey that the FDA and EMA recognize the potential value of a biomarker and encourage its further evaluation. A total of seven FDA and three EMA letters of support have been issued to C-Path.

Global regulatory agencies see value in compiling data from several sponsors in a noncompetitive setting, rather than receiving data from one sponsor at a time in support of biomarker qualification. Integration of data across different clinical trials and longitudinal studies is a core competency of C-Path and a key goal of the multinational CPP.

About the organizations:



C-Path (Critical Path Institute) is an independent, nonprofit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the US Food and Drug Administration (FDA). C-Path’s mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established 12 global, public-private partnerships that currently include over 1,450 scientists from government and regulatory agencies, academia, patient advocacy organizations, and dozens of major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona. For more information, visit www.c-path.org.

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Every hour, someone in the UK is told they have Parkinson’s.

It affects 127,000 people in the UK—which is around one in 500 of the population.

Parkinson’s is a degenerative neurological condition, for which there currently is no cure. The main symptoms of the condition are tremor, slowness of movement and rigidity.

Parkinson’s UK is the UK’s leading charity supporting those with the condition. Its mission is to find a cure and improve life for everyone affected by Parkinson’s through cutting edge research, information, support

and campaigning.

For advice, information and support, visit www.parkinsons.org.uk or call our free, confidential helpline on 0808 800 0303.

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