
Critical Path for Parkinson's Announces Milestone Publication Highlighting FDA Support for Novel Biomarker to Advance Precision Medicine Strategies

Journal of Parkinson's Disease recognizes a decade of collaborative progress culminating in regulatory endorsement for biomarkers to enable early intervention

TUCSON, Ariz., August 25, 2026 — Critical Path Institute® (C-Path) today announced the publication of “Regulatory endorsement for the application of alpha-synuclein seed amplification assay (αSyn-SAA) as a susceptibility and risk biomarker for clinical trials targeting synucleinopathies” in the *Journal of Parkinson's Disease*, marking a significant milestone for its Critical Path for Parkinson's consortium. Published findings detail scientific, regulatory, and collaborative efforts culminating in a U.S. Food and Drug Administration (FDA) biomarker Letter of Support for this work.

This consensus publication demonstrates how cross-sector collaboration among patients, academic investigators, regulators, industry partners, and nonprofit organizations accelerates biomarker development and regulatory endorsement. This biomarker initiative was enabled by C-Path's long-standing partnership with The Michael J. Fox Foundation (MJFF) for Parkinson's Research. Consensus and data-driven strategies represent a clear model for advancing future biomarkers, improving clinical trial efficiency, and supporting the development of therapies for Parkinson's disease with a focus on early intervention.

“Building on more than a decade of collaborative regulatory science at Critical Path for Parkinson's, we are dedicated to pushing forward with new biomarker milestones for neurodegenerative diseases,” said Diane Stephenson, Ph.D., Vice President of Neurology and Executive Director of Critical Path for Parkinson's. “Powered by rigorous cross-sector partnership, αSyn-SAA enables greater precision in identifying trial participants to ultimately accelerate our path toward effective treatments focused on the underlying biology of disease.”

The FDA Letter of Support stems from significant evidence collected as part of MJFF's flagship Parkinson's Precision Medicine Initiative (PPMI), a flagship observational study that first [reported](#) the αSyn-SAA biomarker results in April 2023. The αSyn-SAA, for the first time, provides a way to detect the earliest biological signs of Parkinson's in living people. This could enable earlier testing of new treatments, when there may be the greatest opportunity to delay or prevent disease onset and progression.

“This milestone reflects the power of collaboration, open science, and the unwavering commitment of the Parkinson's community led by C-Path and multiple stakeholders,” said Kevin Kwok, a member of both the C-Path's Parkinson's patient advisory council and MJFF Patient Council, and a former PPMI Community Advisory Board member. “The letter of support for the α-synuclein seeding assay as a susceptibility and risk biomarker brings us closer to biological staging and a future of precision medicine, where people at risk can be identified and treated earlier.

Most importantly, this achievement would not have been possible without the thousands of research participants who generously donated their cerebrospinal fluid and participated in clinical studies. Their extraordinary contributions are advancing science today and creating hope for future generations affected by Parkinson's disease.”

Appearing in the Journal of Parkinson's Disease, the manuscript arrives more than a decade after the same journal published the original Parkinson's consortium roadmap upon its launch in 2015. Today's updated roadmap demonstrates how a collaborative vision achieved meaningful regulatory progress, culminating in the FDA Letter of Support for ?Syn-SAA. Together, the 2015 and 2026 publications chart a decade of advancements, spanning from establishing a collaborative framework for regulatory science to achieving a significant biomarker milestone for Parkinson's disease. Sustained collaboration consistently proves valuable in driving development of new therapies.

To read the full open access publication, visit
<https://journals.sagepub.com/doi/10.1177/1877718X261463936>.

Groups interested in joining CPP's ongoing efforts or accessing relevant information and materials may contact Diane Stephenson at dstephenson@c-path.org or visit c-path.org/cpp.

About Critical Path Institute

Founded in 2005, as a public-private partnership in response to the [FDA's Critical Path Initiative](#), C-Path's mission is to lead collaborations that advance better treatments for people worldwide. Globally recognized as a pioneer in accelerating drug development, C-Path has established numerous international consortia, programs and initiatives that currently include more than 1,600 scientists and representatives from government and regulatory agencies, academia, patient organizations, disease foundations and pharmaceutical and biotech companies. With dedicated team members located throughout the world, C-Path's global headquarters is located in Tucson, Arizona, and C-Path's Europe subsidiary is headquartered in Amsterdam, Netherlands. For more information, visit c-path.org.

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Media Contacts:

Roxan Triolo Olivas
C-Path
520.954.1634
rolivas@c-path.org

Kissy Black
C-Path
615.310.1894
kblack@c-path.org