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# From Setbacks to Strategies: Rethinking Disease Modification in Parkinson's Disease

## Market Trend Summary

Saadiq Hasan M.P.H. | December 2024

# Navigating Opportunities and Obstacles in PD Disease Modification



Refined strategies, precision medicine, and sustained collaboration could unlock transformative breakthroughs.

## Strengths

**Thriving investment:** Major collaborations like Vesalius-GSK and public-private initiatives like AMP PD fuel innovation and research for DMTs.

**Robust pipeline**: Numerous early-phase therapies offer promise in addressing the unmet need in disease modification.

**Biomarker innovation:** Development of α-synuclein SAAs provides new tools for disease detection and potential monitoring.

**Technology advancements**: Novel SC pumps, DBS, and FUS provide effective symptom management for advanced-stage PD patients, bridging the gap while DMT development continues.

## Weaknesses

**Repeated clinical trial failures:** Historical setbacks with compelling therapies like prasinezumab and buntanetap undermining confidence in current approaches.

**Primary outcome selection:** The MDS-UPDRS's low sensitivity to disease modification in early-stage PD is attributed to insufficient progression, imprecise score summation, and reliance on change-from-baseline measures, underscoring the need for alternative approaches such as TTE.

**Limited disease understanding:** Incomplete comprehension of Parkinson's disease progression and underlying mechanisms.

**Biomarker limitations:** α-synuclein SAAs are limited by their binary nature and inability to distinguish PD co-pathology from other parkinsonian syndromes.

## Opportunities

**Personalized medicine potential:** Increasing focus on patient subgroup-specific therapies considering age, disease stage, and comorbidities.

**Emerging clinical trials:** Upcoming Phase 2 trial data for minzasolmin and BIIB122 offer potential MOA validation.

**Non-motor symptom biomarkers:** Advancing digital biomarkers (e.g., REM sleep behavior) offers an opportunity to enhance early detection and develop composite progression scores to optimize DMT trial outcomes.

**Advanced diagnostic technologies:** Developing objective measurement tools to aid digital phenotyping, including wearable devices and AI-driven assessments (e.g., PDCORE).

## Threats

**Regulatory hurdles:** Challenges in designing trials that can definitively demonstrate disease modification (e.g., recruiting prodromal or de novo patients, selecting sensitive endpoints).

**Investor skepticism:** Failure of near-term readouts may reduce investment appetite in PD therapeutic development.

**Complex disease mechanism:** Difficulty in developing universal treatments due to Parkinson's complex and heterogeneous nature.

**Limited treatment windows:** Challenges in identifying and intervening at optimal disease stages, particularly in prodromal phases.

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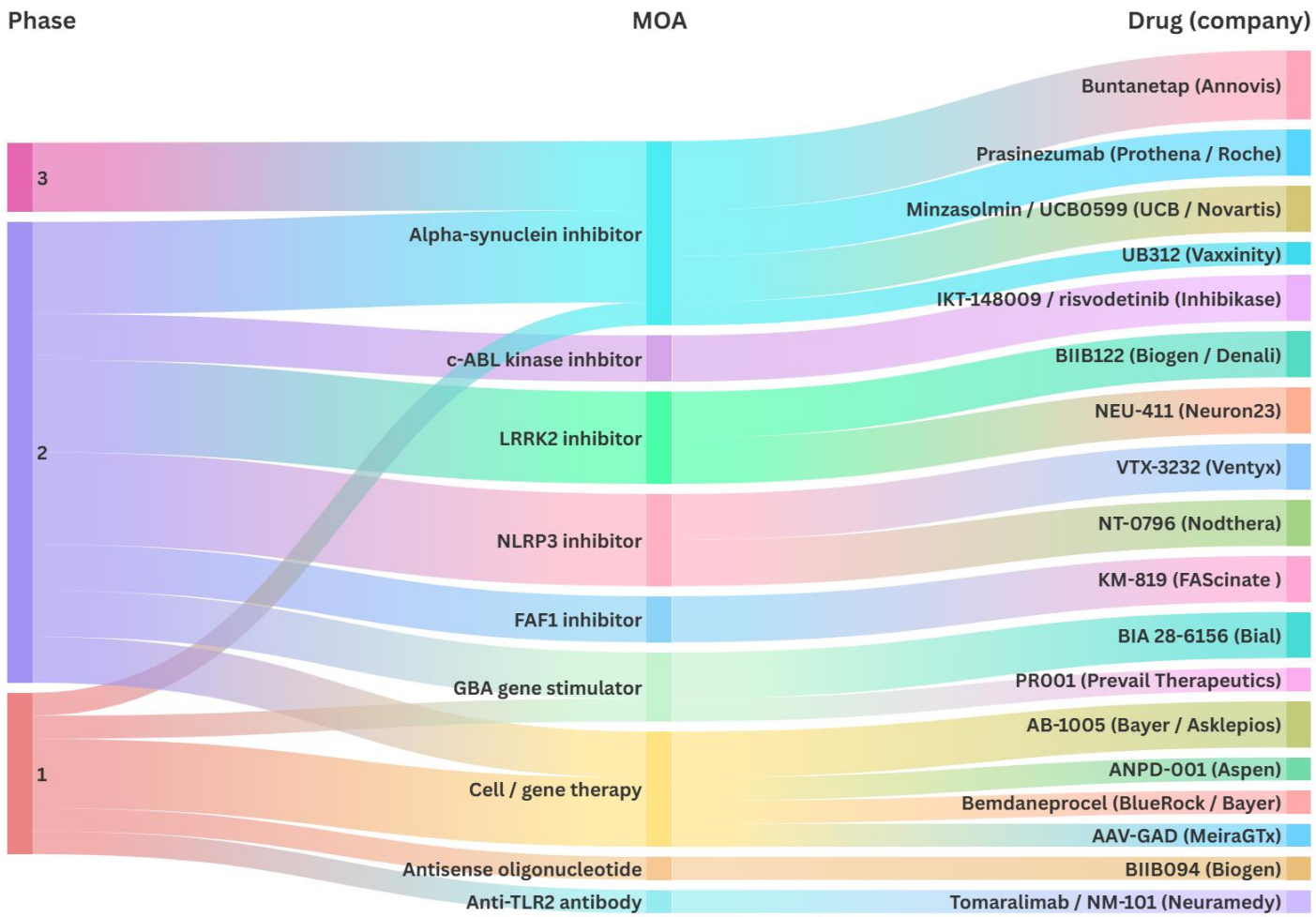
SAA: seed amplification assay; SC: subcutaneous; DBS: deep brain stimulation; FUS: focused ultrasound; TTE: time-to-event

# Parkinson's Disease Pipeline

## Disease-modifying therapies




## Clarivate's takeaways

### Thriving investment and collaboration

The pipeline for potential disease modification in PD is robust, with a variety of therapies being assessed. The indication continues to attract significant investment driven by public-private partnerships and strategic alliances, although few candidates have progressed to Phase 3.

### Anticipation grows for upcoming trial data

Top-line Phase 2 data for **minzasolmin** and **prasinezumab** are expected by year end and may validate α-synuclein as a disease-modifying target. Meanwhile, Biogen / Denali's LRRK2 inhibitor **BIIB122** is progressing in the Phase 2 LUMA trial, with results expected in H1 2026. Together, these trials will offer critical insights into two distinct pathways, advancing strategies for disease modification in PD.

# About the author

## Saadiq Hasan, M.P.H.

**Senior Healthcare Research & Data Analyst**

Saadiq Hasan, M.P.H., is an analyst on the CNS/Ophthalmology team at Clarivate. In this role, he covers the neurology space, specializing in Parkinson's disease. He conducts extensive primary and secondary market research and analysis of the treatment of Parkinson's disease, as well as other neurologic diseases. Prior to joining Clarivate, Mr. Hasan earned his master of public health degree from the University of Virginia.

Saadiq.hasan@Clarivate.com

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healthcare.support@clarivate.com
clarivate.com
+1 215 386 0100 (U.S.)
+44 (0) 20 7433 4000 (Europe)

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