

Phase 1-3 Clinical Trials of Parkinson's Disease Drug Therapies:

What Happened During the 4th Quarter of 2022?

primary data source: [ClinicalTrials.gov](https://clinicaltrials.gov)

posted on [PDTrialTracker.info](https://pdtrialtracker.info)

Q4 2022 Trial Status Headlines: What Clinical Trials Have . . .

<p>Begun recruiting patients?</p>	<p>Recruiting began for six trials (excluding a large Phase 3 trial from University College London of antidepressants in PD for which the clinicaltrials.gov record had not been updated in 4 years). Most notable was the STEM-PD stem cell trial in Europe and a Phase 2 trial from Jazz Pharmaceuticals of the T-type selective calcium channel modulator suvacaltamide for residual tremor despite standard of care therapy</p>
<p>Completed enrollment?</p>	<p>Five trials completed enrollment including two Phase 2 trials in patients with cognitive impairment due to PD or Lewy Body Dementia: NYX-458 a NMDA receptor modulator from Aptinyx and ATH-1017 (which enhances hepatocyte growth factor activity) from Athira</p>
<p>Reached clinical completion?</p>	<p>Another five trials reached clinical completion including Phase 2 trials of:</p> <ul style="list-style-type: none"> • The iron chelator deferipone from ApoPharma • The GLP-1 agonist liraglutide from Cedars Sinai hospital • The dopamine D3 antagonist mesdopetam (for levodopa-induced dyskinesia) from Integrative Research Laboratories
<p>Been delayed (or accelerated)?</p>	<p>Delays in completion date were disclosed for 15 studies (for 4 the previous completion date had already passed suggesting the sponsor was behind on updating clinicaltrials.gov). Eight studies disclosed a delay of at least 90 days. One study reported an accelerated completion date.</p>
<p>Completion projected within the next six months?</p>	<p>Twenty-one trials are projected to complete by Q2 2023 with 11 to complete in Q1 2023</p> <ul style="list-style-type: none"> • Included are the UK Phase 3 trial of antidepressants in PD and Cerevel's Phase 3 trial of tavapadon for motor fluctuations • Phase 2 highlights are trials of SunPharma's Bcr/Abl kinase inhibitor K0706 and Neuraly's pegylated exenatide

Q4 2022 Trial Results Headlines: What Clinical Trials Have . . .

Had results disclosed for the first time?	Results for eleven trials were disclosed for the first time. Included were negative Phase 2 trials with deferiprone (iron chelator) and AKST4290-211 (CCR3 inhibitor), a small Phase 2 study with PT320 (ER exenatide) that missed the primary endpoint but the sponsor (Peptron) was optimistic for further development based on secondary endpoints, and three early trials that lacked primary efficacy endpoints with statistical testing but had favorable results claimed on secondary efficacy, PK-PD and safety endpoints (AL101 from Elector & GSK, NE3107 from Biovie, and CST103 & CST107 from CuraSen Therapeutics)
Had additional detail on results disclosed?	Additional results were disclosed for six trials for which at least top-line results had been previously reported. Notable were peer-reviewed manuscripts for Enterin's positive Phase 2 study with ENT-01 for constipation, the Abbvie positive Phase 3 study with their sub-cutaneous LD/CD pump showing reduced motor fluctuations relative to oral LD/CD, and Annovis's Phase 1/2 study with butanetap for which secondary efficacy and safety results were stated to support further development. There was also a conference presentation on a Phase 2 study with PT-001 (ketamine) from Pharmather supporting efficacy for levodopa-induced dyskinesia

Note that clinical trial results are often disclosed for the first time via company press releases and/or investor presentations. For public companies this is often driven by requirements for timely disclosure of material events deemed likely to inform investment decisions. These corporate disclosures typically include only the key top-line results. More detailed trial results may be disclosed via posters or presentations at scientific conferences. Eventually comprehensive trial results are generally published in medical journals sometimes as a "pre-print" (that has not yet been reviewed by experts not involved in the trial) and ultimately as a final peer-reviewed manuscript. Trial results can also be posted by sponsors in the ClinicalTrials.gov database.

The Detailed Dashboards: Clinical Trials With . . .

1. A change in status (or newly listed)
2. A change in primary completion date
3. A primary completion date within the next six months
4. Results newly disclosed / Additional results disclosed

See Separate Links to PDF Files for Each of the Dashboards

Methodology

- Trial data for Parkinson's disease Phase 1, 2, 3 trials downloaded from ClinicalTrials.gov on first and last days of quarter.
- "Status" parameter compared at beg. and end of quarter to identify trials that: were registered, started or completed recruitment, or were completed or withdrawn during the quarter. "Primary completion date" parameter compared at beg. and end of quarter to determine trials with a change in expected primary completion date. Trials with "Primary completion date" within 6 months were also identified.
- Dashboards limited to Phase 1 to Phase 3 trials evaluating pharmaceuticals, including biologics, cell and gene therapies. The "Parkinson's Disease Drug Therapies in the Clinical Trial Pipeline" reports for 2020, 2021, 2022 and The Hope List were references in identifying pharma vs. non-pharma trials within the Phase 1-3 trials, along with some information in the "agent description" and "company/sponsor" fields.
- Dashboards on Trial Results based on alerts from PubMed.gov, review of conference abstract books, daily emails from Parkinson's News Today, the Science of Parkinson's Disease blog, pre-print servers, and the Parkinson's Research Interest Group on Facebook. It is challenging to capture all results disclosures, so if anything is missing, please let us know at PDTrialTracker@outlook.com.