Clinical Phases

2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030 2031 2032 2033 2034 2035 2036

Phase Gates

Preclinical (P) — Phase 0 (0) — Phase I (1) — Phase II (2) — Phase III (3) — FDA Approval — EMA Approval

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Preclinical

- Preclinical
- In Vitro
- In Vivo

Phase 0

- Phase 0
- Human Microdosing

Phase I

- Phase I
- Single Ascending Dose
- Multiple Ascending Dose
- Food Effect

Phase II

- Phase II
- Proof of Concept
- Definite Dose-Finding

Phase III

- Phase III
- First Trial
- Second Trial
- Third Trial
- Regulatory Submission

Phase IV

- Phase IV
- Postmarketing Surveillance
- Ongoing Technical Support