Trial Intelligence Report - TS-5621

Protocol Summary

Indication: General

Phase: Follow-up Days -28 to -1 Baseline Day 0 Wk 1 Day 7 Wk 4 Day 28 Wk 8 Day 56 W

Sample Size: 108

Duration (weeks): 26

Dropout Rate: 9.1%

Primary Endpoint: Frequency of moderate to severe adverse events through Week 24 by dosing level, freq

Success Prediction

42.8%

Assessment: Significant risk of failure

Strategic Recommendations

- 1. Reassess sample size current value may be insufficient.
- 2. Consider extending trial duration for more robust outcomes.
- 3. Implement enhanced participant retention strategies.
- 4. Review eligibility criteria to ensure appropriate population targeting.