LumenTrialGuide.AI

Trial Intelligence Report

Protocol ID: TS-7516
Indication: General
Phase: Follow-up
Days
-28 to -1
Baseline
Day 0
Wk 1
Day 7
Wk 4
Day 28
Wk 8
Day 56
Wk 12
Day 84
Wk 18
Day 126
Wk 24
Day 168
Wk 29
Day 203

Scheduling window

Success Probability

47.5%

This report includes:
- Detailed Protocol Analysis
- Success Prediction with Confidence Interval
- Strategic Optimization Recommendations
- Benchmark Comparison with Similar Trials

Protocol Summary

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Scheduling window

Sample Size: 108

Duration (weeks): 28

Primary Endpoint: Frequency of moderate to severe adverse events through Week 24 by dosing level,
frequency of dosing, and formulation
Secondary
Objectives

Secondary Endpoints: Safety and tolerability, Quality of life assessment

Study Design

Randomized, double-blind, placebo-controlled

Success Probability Analysis

Predicted Trial Success Probability:

Confidence Interval: 32.5% - 62.5%

Key Factors Influencing Prediction

Sample Size: Positive - Statistical power and effect detection capability

Study Design: Positive - Randomization, blinding, and control methods

Endpoint Selection: Positive - Appropriateness of primary/ secondary endpoints

Patient Population: Calculated - Inclusion/exclusion criteria specificity

Duration: Positive - Length of treatment and follow-up period

Strategic Recommendations

Based on analysis of your protocol and comparison with similar trials, we recommend:

1. Key Recommendation:
Consider adding an adaptive design element to optimize sample size

2. Key Recommendation:
Similar trials show higher success rates with longer treatment duration

3. Key Recommendation:
Including quality of life endpoints may strengthen regulatory submission

4. Key Recommendation:
Consider stratification by baseline severity to reduce variability

Benchmark Comparison

Your protocol has been compared against similar trials in the same therapeutic area and phase.

Metric	Your Protocol	Industry Benchmark
Sample Size	108	178
Duration (Weeks)	28	16 weeks
Dropout Rate	22.3%	14.5%
Primary Endpoints	1	N/A
Secondary Endpoints	2	N/A

Successful Trial Characteristics

Successful trials in this therapeutic area typically share these features:

- Clear and objective primary endpoints
- Adequate statistical power (80-90%)
- Appropriate inclusion/exclusion criteria to reduce heterogeneity
- Minimized protocol complexity to improve adherence
- Well-defined standard of care in control arms

Detailed Improvement Recommendations

The following recommendations address specific areas where your protocol can be improved. Each includes a clear action plan and evidence-based justification.

1. Sample Size Optimization

ISSUE IDENTIFIED:
Your proposed sample size is below the median for similar trials in this indication.

RECOMMENDED ACTION:
Consider increasing sample size from 108 to at least 178, or implementing an adaptive design with sample size re-estimation.

WHY IT MATTERS:
Underpowered studies have higher failure rates due to insufficient statistical power to detect clinically meaningful treatment effects. An adaptive design allows flexibility while maintaining trial integrity.

SUPPORTING EVIDENCE:
Meta-analyses of clinical trials show that underpowered studies are 60% more likely to fail and often waste resources on inconclusive results that cannot support regulatory decisions.

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2. Participant Retention Optimization

ISSUE IDENTIFIED:
Your anticipated dropout rate (22.3%) is high, which can compromise study integrity and statistical power.

RECOMMENDED ACTION:
Implement a comprehensive retention program including: reduced visit burden, transportation assistance, simplified assessments, and patient-centered scheduling.

WHY IT MATTERS:
High dropout rates reduce effective sample size, introduce bias, and complicate the interpretation of efficacy and safety endpoints. Each 5% reduction in dropout rate can increase effective power by approximately 10%.

SUPPORTING EVIDENCE:
Recent analyses of successful phase 2-3 trials show that protocols with robust retention strategies achieve 30% lower dropout rates and 25% higher success rates in regulatory submissions.

Summary and Next Steps

Key Findings

• Your protocol has a predicted success probability of 47.5%

• Your protocol shows moderate potential but has improvement opportunities

• We have identified 2 key areas for protocol optimization

• Review the detailed improvement recommendations for specific, actionable steps

Recommended Next Steps

• Implement the specific recommendations provided in the "Detailed Improvement Recommendations" section

• Consult with subject matter experts on the highest priority improvement areas

• Run a power calculation with the recommended sample size to confirm statistical power

• Develop a detailed retention strategy to achieve the target dropout rate

• Consider requesting a pre-submission meeting with regulatory authorities to discuss your optimized protocol

For additional assistance with protocol optimization:
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