

****Enrollment Forecast****

The total number of sites is not specified in the provided sources. However, we can estimate the enrollment

According to [BiMCP], the average enrollment rate per site per month for similar studies is around 10-15 p

The total number of sites is not specified, but we can estimate it based on the precedent studies. Accordin

The total number of participants is not specified, but we can estimate it based on the enrollment rate and th

* Total number of participants = Enrollment rate per site per month x Number of sites
= 12.5 participants/site/month x 5 sites/region x 2 regions
= 125 participants

The screen failure rate is not specified in the provided sources. However, we can estimate it based on the

The months to full enrollment are not specified in the provided sources. However, we can estimate it base

* Months to full enrollment = Total number of participants / Enrollment rate per site per month
= 125 participants / 12.5 participants/site/month
= approximately 10 months

****Enrollment Optimizations****

1. ****Inclusion/exclusion criteria adjustments****: To improve enrollment, consider adjusting the inclusion/exc
2. ****Site selection optimization****: Optimize site selection by targeting sites with higher enrollment rates or t
3. ****Participant recruitment strategies****: Implement participant recruitment strategies such as social media

****Timeline****

The detailed milestone forecast is not specified in the provided sources. However, we can estimate the tim

- * FPI: approximately 2-3 months
- * 25%/50% LPI: approximately 4-6 months
- * DB Lock: approximately 6-8 months
- * CSR: approximately 10-12 months

****Cost Effectiveness****

The concrete cost levers are not specified in the provided sources. However, we can estimate the cost effe

The estimated savings ranges are not specified in the provided sources. However, we can estimate the co

****Site Selection & Facilities****

The recommended optimal regions and site profiles are not specified in the provided sources. However, w

The recommended optimal site facilities are not specified in the provided sources. However, we can estima

****Safety Monitoring****

The safety monitoring plan is not specified in the provided sources. However, we can estimate the safety m

****Pharmacokinetic & Pharmacodynamic Assessments****

The pharmacokinetic and pharmacodynamic assessments are not specified in the provided sources. Howe

****Exploratory Analyses****

The exploratory analyses are not specified in the provided sources. However, we can estimate the explora

****Conclusion****

Based on the provided sources, we can estimate the enrollment forecast, timeline, cost effectiveness, site