

STUDY BUDGET CHECKLIST

Protocol Title	Phase III, Randomized, Open-label, Global, Multicenter Study of Rilvegostomig or Durvalumab in Combination with Chemotherapy as a First-line Treatment for Patients With Advanced Biliary Tract Cancer (ARTEMIDE-Biliary02)
Name of PI	Dr. Prashant Pandey

S No.	Elements	Choose from Following dropdown	Comments
A	Trial site		
1	Clinical site fee		Not Applicable
2	Trial start-up fee	1,00,000	
3	Site contract fee		Not Applicable
4	Site close-out fee	Not Decided	It will be submitted to finance for Review
5	Pharmacy set-up fee (As per Actuals)	Not Decided	After reviewing the CTA PI will decide.

Prepared by : Dr Indranil Mallick	Reviewed by: Prof Pattatheyl Arun	Approved by: Dr Pattatheyl Arun
IRB Member Secretary	TMC-IRB Chairperson	Head of the Institution



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6	Trial file storage (including post study completion)		
B	Study visits		
1	Screening visit fee	As per Actuals	
2	Treatment visit(s) fee	As per Actuals	
3	End of treatment visit fee	As per Actuals	
4	Followup visit(s) fee	As per Protocol	
5	Cost of investigations during the study	As per PI	
C	Study team		
1	Investigator fee	As per PI	
2	Data Manager fee	N/A	
3	Study nurse fee	As per PI	

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4	Study coordinator fee	30,000 - 35,000 (Approx)	Not finalised
D	Patient related		
1	Patient travel reimbursement	2000 / Per visit	
2	Reimbursement of medical bills in the event of SAE	As Per Actuals	
3	Financial compensation during SAE	As Per DCGI Recommendation	
4	Cost of Standard of care	As Per Actuals	
5	Cost of shipping investigational drug(s)		Sponsor will take care
6	Cost of collecting tissue samples and their shipping		Sponsor will take care
7	Cost of collecting radiology imaging and shipping		Sponsor will take care
E	IRB		
1	IRB fee	70,000 + GST	Yearly 70,000 + GST

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2	Cost of independent review by an expert		NA
F	Additional costs		
1	Institutional overhead	30%	
2	Any other		

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