

Research Support Directorate: Project Check List

The purpose of the RSD is to aid investigators in submitting and managing grant proposals as well as carrying out collaborative research. It does not seek to evaluate the scientific or ethical questions raised by the proposal which are the purview of the IRB. The RSD also seeks to ensure that the investigator(s) have ensured that they have all the resources required to successfully carry out their work and that the hospital is able to provide any additional resources required. This requires prior identification of resources and cost implications as well as avoiding duplication of equipment.

The form provides a check list that will help in filling up the resource requirements in most grant forms. These need to be completed early on in the grant submission process so finance, HR, estates etc have provided the right input where necessary. We would recommend that the form is submitted at the time of the grant application. Not all fields are applicable to all grant applications and you can enter "Not Applicable"

The form is self explanatory. Please send the form to the RSD by email. It will be reviewed by a member of the team and they will come back to you with any questions. We aim to complete the approval process within 7 working days.

We hope you will find the form useful in planning your application. RSD will use the information provided to update the administration of future resource requirements for research, the annual research report and submissions to national authorities for regulatory and tax purposes. If you have any suggestions for the form please let us know.

Research Support Directorate: Project Check List

RSD Project Number:0

Date received by RSD: 01/07/2020

Reviewer Comments:

Date Approved by RSD: 1/01/2020

Approved on Behalf of RSD by: Signature

(above to be filled in by RSD only)

Section A Project Details

Title of Project: "A Phase IV, Prospective, Open Label, Multi-Centre Study of Vorasidenib in Indian Adult and Paediatric Participants 12 Years and Older with Grade 2 Astrocytoma and Oligodendroglioma with a Susceptible IDH1 or IDH2 Mutation following Surgery including Biopsy, Sub-Total Resection, or Gross Total Resection".

Name of Investigator / Applicant : Dr. Rimpa Basu Achari

Department: Radiation Oncology

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Co Investigators

Name: Dr. Aiswarya Raveendran
Oncology

Department: Radiation

Name: Dr. Paromita Roy

Department: Pathology

Name: Dr. Reghu KS

Department: Paediatrics Oncology

Dr. Susmita Sadhukhan
Dr. Mahima Pant

Medical Oncology
Radiation Oncology

Add more if necessary

Start Date: 01/11/2026

End Date: 01/11/2028

Project Summary

Please list aims, objectives and expected outcomes (maximum 250 words)

This Phase IV, prospective, open-label, multi-centre clinical study is designed to evaluate the safety and effectiveness of vorasidenib in Indian adult and paediatric participants 12 years and older with grade 2 astrocytoma and oligodendroglioma with a susceptible IDH1 or IDH2 mutation.

The primary objective of the study is to evaluate the safety of vorasidenib, with the key primary endpoint of analysing the incidence of Treatment Emergent Adverse Events (TEAEs). All participants with a confirmed diagnosis of Grade 2 Astrocytoma and Oligodendroglioma with a susceptible IDH1 Or IDH2 mutation following surgery including biopsy, sub-total resection, or gross total resection will undergo screening procedures within 28 days before enrollment. Upon enrolment, participants will begin treatment with oral vorasidenib once daily, starting on Cycle 1 Day 1 (C1D1).

Each treatment cycle will last 28 days, with continuous daily dosing throughout the cycle. Participants will be treated for six cycles (with no planned inter cycle rest periods), unless discontinued earlier due to any adverse event, disease progression or death, TEAEs resulting in discontinuation, confirmed pregnancy, or withdrawal of consent. A window period of ± 3 days will be allowed for all Treatment visits. The End of Treatment (EOT) visit will be conducted within +3 days from the last study treatment dose of Cycle 6. The safety follow-up (SFU) visit will be conducted within 7 weeks from the last study treatment dose.

Project Budget (Lakhs) (Leave as 0 if not applicable)

Total 0.00

Salaries 0

Consumables 0.00

Equipment

Is this is a multi-institutional project Yes ☒ No ☐

If no go to section C

Section B External Collaboration

Which is the lead centre?

No lead center, as the study will go on in different institutes separately.

Who is the PI?

Dr. Rimpa Basu Achari

Collaborating Centres

Centre

None

Name and Designation of PI at Centre

Dr. Rimpa Basu Achari, Senior Consultant, Radiation Oncology

(please add as necessary)

Section C Funding Details

Is this project externally funded Yes ☒ No ☐

If No go to section D

Which grant agency is funding this project

Servier India Private Limited

1703, 17th Floor, Crescenzo Business District, 'B' Wing, Plot Nos. C-38/39, 'G' Block, Behind MCA, Bandra Kurla Complex, Bandra (East), Mumbai 400 051, India.

Has the funding been awarded Yes ☐ Awaied ☒ Applied for ☐

Date award expected/received 01/10/2026

Total Amount of Award (in lakhs) 0

Total Amount to TMC PI (in lakhs) 0.00

Human Resources

Will you be appointing staff? Yes ☒ No ☐

If yes, please fill the following

Number of staff to be employed on the project 6

Details of staff (please fill for each staff)

Staff 1

1. Designation i) Clinical Research Coordinator , ii) Research Nurse, iii) Data Entry Operator
2. Start Salary a) 30000 b)30000 c)25000
3. Duration of Appointment Start: 11/07/20 End:
4. Is salary fully covered by the grant? Yes ☒ No ☐

If No – where is the shortfall being met from

5. Is salary fixed for the entire duration or will there be yearly increments?

Yes

Please inform Finance of salary calculations

6. Will staff be eligible for TMC health insurance/coverage? Yes ☐ No ☒

If yes, please ensure that this has been discussed with HR

Estates

Will staff require office space and desk? Yes ☒ No ☐

If Yes please fill the following:

Has space been identified Yes ☒ No ☐

Do they require IT support (email, computer, software) Yes ☒ No ☐

What is the budget for these resources?

To be decided in CTA

Please ensure that IT requirements have been discussed with IT

Laboratory Space

Will staff require laboratory space? Yes ☐ No ☒

If yes, please fill the following

Where is the space located ?

What equipment and resources are required?

What is the budget for these resources?

Who is in charge of this space?

Has this been discussed with the person in charge of this space? Yes ☐ No ☐

Biobank Facilities

Will biobank facilities be required Yes ☐ No ☒

If yes

Has this been discussed with the biobank and costed Yes ☐ No ☒

Hospital Facilities

Does the project require additional use of hospital facilities Yes ☒ No ☐

If Yes, please fill the following – if yes to any, please specify if existing or new facilities/equipment/tests are required

Clinical Space required

OP	Yes ☒	No ☐
IP	Yes ☒	No ☐
Daycare	Yes ☒	No ☐
OT	Yes ☐	No ☐
Others	Yes ☐	No ☐

Medical Equipment Required Yes ☒ No ☐

Diagnostic Laboratory Tests Yes ☒ No ☐

Radiology Yes ☒ No ☐

Section E Project Management

Finance

Does the project require audited financial report and/or external audit?

Yes ☒ No ☐

If yes, please discuss with Finance

Data Management

Please outline your data management plan (250 words) – how will data be collected and processed? How will it be stored and for how long? Have resources been identified for short term and long-term storage? What steps have been taken to ensure confidentiality and data protection?

As part of the responsibilities assumed by participating in the study, the investigator agrees to maintain adequate case histories for the patients treated as part of the research under this protocol. The investigator agrees to maintain accurate CRFs and source documentation as part of the case histories. These source documents may include diary cards, laboratory reports, ECG strips, and radiology reports.

Investigative site personnel will enter patient data into the CRF. The analysis data sets will be a combination of these data and data from other sources (e.g., laboratory data).

What percentage of time will you be spending on this project? 25%

How many projects are currently being handled by you? 5

Section F Other comments from the Applicant

Do you have any additional comments or issues?

No

Section G Conflict of Interest Declaration

Note if there are none, please use the default as entered.

For e.g if it is a pharma sponsored study and the hospital or you are receiving a payment, speakers fee, sponsored travel to meetings etc.

I have no conflicts of interest to declare

Form Filled By Sanghamitra Raha

Date

Please Email to: rsd@tmckolkata.com; Note: **attach additional sheet if required**