

Call for Proposal on therapeutics in rare diseases

Frequently Asked Questions based on the Webinar held on 20.12.2022

Q1: Which rare diseases are considered under this call?

A1: Proposals on Inherited rare diseases (genetic) which have a prevalence of 1 in 1000 or less in Indian population will be considered under this call.

Q2: By description, does inherited disorders include only those with Mendelian pattern of inheritance and not complex disorders that have a genetic predisposition and environmental factors associated such as CNS autoimmune disorders like neuromyelitis optica spectrum disorder or multiple sclerosis?

A2: Yes

Q3: Is beta-thalassemia and haemophilia A and B included under this call?

A3: Haemophilia A and B are included whereas beta-thalassemia is excluded under this call.

Q4: Can we propose any research or drug discovery for already researched molecule in India/World. Or various devices needed in the journey, including eye tracker, Bipap, Vent & some innovative devices.

A4: Yes

Q5: Can we submit proposal for a gene therapy product development under this call?

A5: Yes, if it is targeted for any inherited rare disease.

Q6: Can a disease which is sporadic as well as inherited be considered under this call?

A6: No sporadic diseases are considered under this call.

Q7: Can we introduce other system of medicine for rare disease under this call?

A7: No

Q8: Can we include purification of the viral-vector based gene therapy, only *in-vitro* studies?

A8: Yes, but as a part and not as the whole project and it must be targeted for any inherited rare disease.

Q9: Will a proposal for detailed mechanistic studies in a model organism with the goal of identifying and validating targets for therapy be encouraged?

A9: Yes, but as a part and not as the whole project.

Q10: Does corrective strategies or supportive therapy such as spinal braces for scoliosis are included?

A10: Yes, corrective measures to improve the quality of life of patients suffering from rare disease are included.

Q11: Are collaborations allowed?

A11: Collaborations are encouraged under this call (with or without DSIR certificate) with the following criteria:

National collaborations/ Industry collaborations: ICMR funding will only be provided to the collaborators with DSIR certificate (if not exempted). No funding will be provided to non-DSIR laboratories.

Q12: Will PIs from companies be eligible for submitting project proposal for this call from ICMR?

A12: Yes, if the company holds a valid DSIR certificate and have a saving account or an interest-bearing current account.

Q13: If we already have a rare disease project from ICMR, can we propose a new project?

A13: Yes, a PI can undertake up to 5 projects at any point of time in ICMR.

Q14: Does the call allow travel/ training/ workshop?

A14: No

Q15: What is the prescribed budget cap?

A15: 1.5 crore for 3 years for projects. However, outstanding projects can also be considered as single-centre/ multi-centric Task Force with 2.0 crore for 3 years/ centre.

Q16: How many projects will be funded?

A16: There is no upper/lower limit for the number of projects to be funded under this call. Projects with clear deliverables will be included.

Q17: For preparation of an investigational product for a rare disease, if the drug is not listed in the official monograph of Indian pharmacopeia or foreign pharmacopeia, does the site need to apply for a test license to manufacture the investigational product?

A17: Licensing does not come under ICMR preview.

Q18: Are start-up companies incubated in a DBT incubator eligible?

A18: As per DSIR rules- DSIR has announced relaxation in 3 years of existence for granting short term fresh recognition to Biotech start-ups established in Incubation Centre or Technology Parks.