

Call for proposal “Rare Disease Solutions Initiative: A Call for Proposals on Orphan Drugs, Diagnostics, Interventions & Specialized Nutrition”

Rare diseases are medical conditions that affect a very small number of people compared to more common illnesses. These diseases are uncommon and can vary widely in terms of symptoms and severity. Because they affect only a small portion of the population, they are often not as well-known or researched as more common diseases.

To be classified as a rare disease, the exact number of people affected can vary depending on the country, but generally, it's a disease that affects fewer than 1 in 2,000 people. Some rare diseases are genetic, meaning they are caused by changes in a person's genes, while others might be caused by infections, environmental factors, or unknown reasons. They are a public health concern in India, with an estimated burden of about 80 million cases. This is about one-fifth of the global burden.

1. Objectives:

The primary objectives of the Call for Proposals are as follows:

i. **Orphan Drug Development:** Encourage development and commercialization of orphan drugs that target specific rare diseases. Projects demonstrating strong scientific rationale, feasibility, and potential for commercial viability will be prioritized. Particular focus will be placed on:

- Developing and bringing to market generic drugs that have gone off-patent.
- Creating process chemistry for patented drugs to enhance affordability once their patents expire.
- Advancing the development and commercialization of repurposed drugs.

ii. **Diagnostic Advancements:** Support the creation and commercialization of advanced diagnostic tools and technologies designed for early and accurate detection of rare diseases. Projects that offer practical solutions and demonstrate scalability will be favored.

iii. **Special Medical Diets/ Food for Special Medical Purposes (FSMP):** Foster the development and commercialization of specialized medical diets tailored to the nutritional requirements of individuals with rare diseases. Emphasis will be placed on projects that offer safe, accessible, and sustainable dietary solutions.

v. **One-time interventions targeting Group 1 of NPRD 2021:** Encourage the development and commercial scale production of medical devices/ equipments etc. essential for carrying out groundbreaking one-time treatments or procedures designed to provide lasting or permanent benefits, often addressing the root cause of the disease. These interventions can be life-changing for individuals with rare diseases, where traditional, ongoing treatments may not be feasible or effective.

iv. **Commercial Viability:** Encourage proposals that outline clear pathways for the commercialization of the developed solutions. This includes considerations for manufacturing, distribution, regulatory compliance, and market access.

2. Scope:

Established industry as well as startups incorporated under the Companies Act, 1956/2013, are encouraged to submit proposals showcasing innovative technologies for development and commercialization. Rare diseases that finds mention **under Group1, 2 and 3 of the policy documents of NPRD 2021 (along with new additions)** to be targeted for the proposals.

For queries and further details contact:

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