No Q-11022/24/2021-HR(ICMR)/eoffice- 8118872
Government of India
Ministry of Health and Family Welfare
Department of Health Research

2nd Floor, IRCS Building,
1, Red Cross Road, New Delhi-110001
Dated the 8th October, 2021

ORDER

Subject: - Establishment of National Consortium for Research and Development on Therapeutics for Rare Diseases in India - regarding.

The Ministry of Health and Family Welfare has notified “National Policy for Rare Diseases, 2021” which envisages setting up of the National Consortium with a mandate to include research and development, technology transfer and indigenization of therapeutics for rare diseases. Accordingly, Hon’ble Union Minister for Health & Family Welfare has accorded approval for establishment of National Consortium for Research and Development on Therapeutics for Rare Diseases in India (NCRDTRD).

2.1 The National Consortium will have the National Apex Committee with the Secretary DHR & DG ICMR as the Chairperson, representatives from scientific departments as the members, experts, and other stake-holders. The composition of the Apex Committee is as follows:

National Apex Committee for Rare Disease Research Consortium in India		
1	Secretary DHR	Chairperson
2	Prof. I C Verma, Advisor, Ganga Ram Hospital Delhi	Clinical Geneticist
3	Prof. Madhulika Kabra, Deptt. Of Paediatrics, AIIMS, Delhi	Clinical Geneticist
4	JS dealing with Rare diseases, Department of Health and Family Welfare	Member
5	Representative of Department of Biotechnology	Member
6	Representative of Department of Pharmaceuticals	Member
7	Representative of Department of Science and Technology	Member
8	Representative of Council of Scientific & Industrial Research	Member
9	Representative of Indian Council of Medical Research (ICMR), Head, BMS Division	Member
10	Expert from Storage Disorder (LSDs & GSDs) Research group	Member
11	Expert from Small molecule IEMs Research group	Member
12	Expert from Skeletal dysplasia’s Research group	Member
13	Expert from Primary Immune deficiencies Research group	Member
14	Expert from Neuromuscular disorders Research group	Member
15	Expert from Haematological Disorders Research group	Member
16	Representative of Patients’ group	Member
17	Representative of DCG(I)	Member

18	Director, ICMR-National Institute of Immunohaemotology (NIIH), Mumbai	Member
19	Other Expert(s) as and when needed	Co-opted Member(s)
20	Joint Secretary, DHR	Convenor

2.2 The secretariat of the consortium will be housed in ICMR under Basic Medical Sciences Division. The secretariat will enhance the data management and coordinate various activities under the consortium. The ICMR Secretariat will also recruit project staffs to aid in the proceedings of the Consortium meetings, to coordinate activities with various Research Groups and any other task assigned by the Consortium.

2.3 The Terms of Reference of the consortium will be as follows:

I. The National Consortium for Research and Development on therapeutics for Rare Diseases (NCRDTRD) shall have the mandate to include research & development, both basic and translational, technology transfer and indigenization of therapeutics for rare diseases.

II. Collaborate with Department of Medical Genetics in the State hospitals once these are established by the State Governments.

III. Collaborate with concerned departments to promote local development and manufacturing of the drugs for rare diseases.

IV. Take measures for creating conducive environment for indigenous manufacturing of drugs for rare diseases.

V. Ensure facilitation of an integrated research pipeline to promote the development of new drugs, for which pharmaceutical companies would be encouraged and research organizations as well as funding agencies would be involved in this important endeavor.

VI. Create mechanisms to avoid duplication of proposals for research to be undertaken at the rare diseases and evaluate these in terms of scientific merit, feasibility, methodology, statistical validity, potential benefit or risk to patients.

VII. Seek outputs and outcomes from Nidan Kendras & Centre of Excellence (COE) under the various activities in rare diseases wherever funding has been provided.

VIII. Communicate with other relevant bodies, including other research and/or ethics committees, in the interests of facilitating high quality, ethical research.

IX. Identify the gaps and potential areas of research & development, technology transfer and indigenization of therapeutics for rare diseases.

X. Develop protocols/guidelines/policy based on outcome of the research activities carried out by all the stakeholders.

2.4 The Apex Committee will meet at least once in six months to review and monitor all activities under various research groups & collaborative partners.

2.5 In order to implement the purpose as outlined in Section 12 (b) of the National Policy for Rare Diseases, 2021, the National Consortium would execute research & development on therapeutics for Rare Diseases through constituent research groups formulated with approval of Secretary, DHR & DG, ICMR. The Constituent Groups will look into the scientific and program needs following identification of common roadblocks, gaps and priorities, and execute activities specific with the partnering institutes. At the outset, following constituent groups are proposed:

- Storage Disorder (LSDs & GSDs) Research group
- Small molecule IEMs Research group
- Skeletal dysplasia's Research group
- Primary Immune deficiencies Research group
- Neuromuscular disorders Research group
- Hematological disorders Research group

2.6 Based on the research need, the number of research groups shall be increased. Each group will work in defined areas based on either priority of disease or more importantly key questions to be addressed. The Constituent Groups will have a period of three to five years to progress towards achieving the goal 12(b) and 13(a) of the National Policy 2021. The chairperson/expert member of various research groups will also be the part of Apex committee.

3. Further, a webpage will be designed on the website of DHR/ICMR to display the details of the Consortium. The webpage will have the mandate of the consortium, list of partners, types of research, call for proposals and other details including but not limited to the names of the researcher, institute, funds received, name of the funding agencies and publications/patents/ innovations etc. A dashboard will also be set on DHR website under Rare Disease Consortium Webpage to demonstrate the total number of partners under consortium, total number of projects funded/ongoing/completed, total amount of funds given etc.

8/X/2021
(D.R. Meena)
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To

1. Secretary, DHR, New Delhi.
2. Prof. I C Verma, Advisor, Ganga Ram Hospital Delhi (icverma@gmail.com).
3. Prof. Madhulika Kabra, Deptt. Of Paediatrics, AIIMS, New Delhi.
4. Smt. Rekha Shukla, Joint Secretary(dealing with Rare diseases), Department of Health and Family Welfare, New Delhi (rekha.shukla@nic.in).
5. Secretary, Department of Biotechnology, New Delhi (Email: secy@dbt.nic.in).
6. Secretary, Department of Pharmaceuticals, New Delhi (Email: secy-pharma@nic.in).
7. Secretary, Department of Science & Technology, New Delhi (Email:dstsec@nic.in).
8. Director General, CSIR & Secretary, DSIR, New Delhi (Email: dg@csir.res.in , dgcsir@csir,res.in).
9. Head, BMS Division, Indian Council of Medical Research (ICMR), New Delhi (Email: chatterjeens.niced@gov.in) – with the request to take further necessary action as outlined above for establishment of National Consortium for Research and Development on Therapeutics for Rare Diseases in India.
10. Expert from Storage Disorder (LSDs & GSDs) Research group.
11. Expert from Small molecule IEMs Research group.
12. Expert from Skeletal Dysplasia's Research group.
13. Expert from Primary Immune Deficiencies Research group.

14. Expert from Neuromuscular Disorders Research group.
15. Representative of Patients' group.
16. DCG(I), New Delhi (dci@nic.in).
17. Director, ICMR-National Institute of Immunohaemotology (NIIH), Mumbai (directorniih@gmail.com , director-niih@icmr.org.in).
18. Joint Secretary, DHR

Copy for information to:

1. Sr. PPS to Secretary, DHR & DG, ICMR.
2. PPS to JS (AN), DHR.