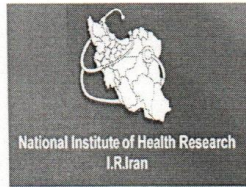




CIS ORPHAN
CONSORTIUM



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**Memorandum of Understanding
on cooperation in the field of rare (orphan) diseases
between
the CIS Orphan Consortium
and
IR Iran's National Institute for Health Research
Date: [“” _____ 2026]**

1. Parties and Authority

1.1. **CIS Orphan Consortium** (the “Consortium”), represented by its President **Rumyantsev Alexander Grigorievich**, acting on the basis of the Consortium Council’s decision dated 30.10.2024, /Protocol No. 1,

and

IR Iran's National Institute for Health Research (The “Partner”), a legal entity duly organized under the laws of the Islamic Republic of Iran (reg. No. [14004405880], address: No. 70, East Bozorgmehr Street, Vesal Shirazi Street, Keshavarz Boulevard, Tehran, Iran, National Institute for Health Research), represented by its Head **Dr. Ali Akbarisari**, acting under **Tehran University of Medical Sciences**, jointly the “Parties”.

1.2. This MOU is not an accession agreement to the Consortium and does not grant membership, voting rights, or representation in the Consortium’s governing bodies. Any future accession—if contemplated—shall follow the Consortium’s governing documents and formal procedures.

2. Purpose and Guiding Principles

- 2.1. Purpose: foster international collaboration to improve access to diagnostics, treatment, rehabilitation, and research for patients with rare (orphan) diseases, and exchange knowledge and best practices.
- 2.2. Principles: legality and ethics; scientific integrity; transparency; respect for patient rights; mutual benefit; non-exclusivity; and no delegation of the Consortium’s governance powers.
- 2.3. Nature of the agreement. Sections 8–17 are legally binding; all other sections express the Parties’ intentions.

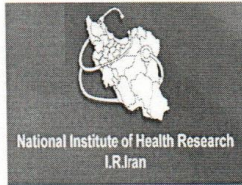
3. Areas of Cooperation

Without limitation, the Parties intend to cooperate in:

- a) Scientific research: organization and conduct of joint research on rare diseases; development of new diagnostic and treatment methods.



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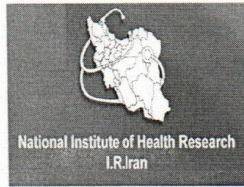
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- b) Clinical trials: international clinical trials to evaluate efficacy and safety of new medicinal products and treatment approaches.
- c) Education and outreach: educational programs and seminars for healthcare professionals and the public; development and dissemination of informational materials on rare diseases.
- d) Information support: creation and maintenance of a unified information platform for exchange of data and research results among participants; support for patients and families through information resources and counseling.
- e) Real-world clinical practice: collection and analysis of real-world clinical practice data to improve diagnosis and treatment.
- f) Innovation: development and implementation of innovative technologies for the treatment of rare diseases.
- g) Clinical practice standards: development of unified requirements for clinical guidelines and criteria for quality of medical care.
- h) Systems and organization: development and implementation of information and organizational technologies for the treatment of rare diseases.
- i) Methodology and access: development of methodological recommendations to improve the efficiency of pharmaceutical provision and the organization of medical care; preparation of policy and regulatory initiatives to improve access to treatment.
- j) Exchange and internships: Facilitation of exchange of faculty members, researchers, staff, and students; and creation of opportunities for internships, service learning, and research training at the Partner's institutions

4. Forms of Cooperation

- 4.1. Information and expertise exchange, mutual consultations, and experience sharing.
- 4.2. Joint projects, programs, and events (including research, clinical studies, and educational activities) agreed in writing by the Parties with defined objectives, deliverables, responsibilities, timelines, and KPIs.
- 4.3. Working groups established by agreement of the Parties for specific directions or projects.
- 4.4. Co-development of documents (clinical guidelines, methodological recommendations, informational materials) and co-authored publications.
- 4.5. Preparation and submission of policy proposals and regulatory initiatives consistent with applicable law.

5. Status of the Partner (non-member)



- 5.1. The Partner may attend Consortium events and activities as a partner/observer upon the Consortium's invitation.
- 5.2. The Partner shall not participate in votes nor elect/be elected to the Consortium's governing bodies; it may submit proposals for consideration.
- 5.3. Use of the Consortium's name and logos requires prior written consent of the Consortium and must follow agreed brand/use-of-name rules.

6. Governance and Coordination

The Parties will coordinate through designated focal points specified in Section 14 (Notices).

7. Funding and Costs

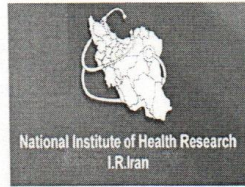
- 7.1. Each Party bears its own costs unless otherwise specified.
- 7.2. Where funding is involved, financial terms are set in a project-specific written agreement.
- 7.3. This MOU does not, by itself, create financial obligations.

8. Confidentiality and Data Protection

- 8.1. "Confidential Information" means non-public information disclosed under this MOU that is marked as confidential or is confidential by nature.
- 8.2. The receiving Party shall: (i) use Confidential Information solely for purposes of this MOU/Projects; (ii) not disclose it to third parties without the disclosing Party's prior written consent; (iii) protect it at least as carefully as its own confidential information.
- 8.3. Any processing of personal data and patient medical data shall be based on a valid legal basis and consents, in full compliance with applicable laws at the place(s) of project implementation, including rules on cross-border transfers, localization, and security. Where needed, the Parties will sign a separate Data Processing Agreement.

9. Intellectual Property

- 9.1. Background IP remains the property of the Party owning it; licenses are granted only under separate agreements.
- 9.2. Foreground IP (results arising from joint activities) shall be owned according to contribution as defined in the relevant project agreement. If indivisible, Foreground IP shall be jointly owned with fair-use principles and a mechanism to settle share allocations.



- 9.3. Publications, abstracts, and press releases require prior coordination: a draft must be provided to the other Party before intended disclosure.

10. Ethics and Regulatory Compliance

The Parties shall ensure: (i) local IRB/ethics approvals and regulatory clearances (in Iran and any other relevant jurisdiction); (ii) adherence to ICH GCP for clinical research and to applicable GLP/GDP/ISO standards; (iii) valid informed consent; and (iv) appropriate safety oversight.

11. Anti-corruption Compliance

The Parties comply with applicable anti-corruption laws. A Party may suspend cooperation if continuation would breach such requirements.

12. Liability; Relationship of the Parties

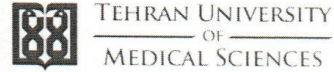
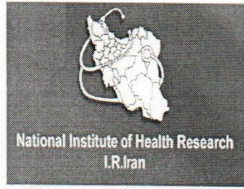
- 12.1. Each Party is responsible for its own acts/omissions; liability is limited to direct damages actually incurred, excluding indirect or consequential damages, unless otherwise agreed in writing.
- 12.2. Nothing in this MOU creates an agency, partnership, employment, or joint-venture relationship.

13. Term, Termination, and Survival

- 13.1. This MOU enters into force upon the date of the last signature and shall continue without limitation in time until terminated under §13.2.
- 13.2. Either Party may terminate this MOU without cause upon 60 days' prior written notice.
- 13.3. Sections 8–17, and any project-specific agreements then in force (unless the Parties agree otherwise), shall survive termination to the extent necessary to give them effect.

14. Notices; language

- 14.1. Notices are deemed received: by courier—on delivery; by email—on the date sent with confirmation of receipt.
- 14.2. Designated focal points (also for coordination under §6):
Consortium: Attn: Nuriya Musina; Executive director;
Email: musinan@orphan-cis.net
Partner: Attn: IR Iran's National Institute for Health Research; Address: No. 70, East Bozorgmehr Street, Vesal Shirazi Street, Keshavarz Boulevard, Tehran, Iran, National Institute for Health Research. Email: nihr@tums.ac.ir.



Focal point: Dr. Mohammadreza Mobinizadeh; Associate Professor. Email: mrmobinizadeh@tums.ac.ir

14.3. This MOU is executed in English.

15. Miscellaneous

- 15.1. Amendments must be in writing and signed by duly authorized representatives.
- 15.2. No assignment without the other Party's prior written consent.
- 15.3. No exclusivity.
- 15.4. Severability and waiver principles apply.
- 15.5. Counterparts and e-signatures are permitted; a PDF signature page is valid and binding.
- 15.6. Any difference or dispute between the Parties concerning the interpretation and/or application of any provision of this MOU shall be settled amicably through mutual consultation and/or negotiations between the Parties without reference to any third party.

Signatures

CIS Orphan Consortium

Address: Russia, Moscow, Chongarsky Boulevard, build 1, block 2, floor 1, premises 61, room 3/3.

By the President: **Rumyantsev Alexander Grigorievich**
 Authority: Consortium Council decision dated 30.10.2024 Minutes/Protocol No 1
 Signature: _____
Rumyantsev A.G.
 President
 Seal (if applicable)

IR Iran's National Institute for Health Research

Address: No. 70, East Bozorgmehr Street, Vesal Shirazi Street, Keshavarz Boulevard, Tehran, Iran.

By the Head: **Dr. Ali Akbarisari**
 Authority: [No. __, dated __]

Signature: _____
Dr. Ali Akbarisari
 Head
 Seal (if applicable)

26/04/2026
AK Ali



Dr Mohammadreza Mobinizadeh
as focal point of
IRAN NEHR for
this MOU