

Resource on the State of the Art of Rare Disease Activities

2025 Report for Romania

National Mirror Group

Romania does not currently have a National Mirror Group (NMG). The collection of data for this report has been overseen by a data contributing committee, based on the previous submission teams delivering this work in the past. Contributors are listed at the end of this report.

Definition of a Rare Disease

Romania adopts the formal European Union (EU) definition of a rare disease (i.e. those with a prevalence of no more than 5 patients per 10,000 persons. This definition is laid down in Regulation EC no. 141/2000 on Orphan Medicinal Products, Directive 2011/24/EU on Cross Border Healthcare as well as in the Council Recommendation on an action in the field of rare diseases of 8 June 2009.). The National Plan espouses this definition and there are no instances when a different definition is used.

Status Quo of any National Plan or Strategy for Rare Disease

What is the status quo?

Romania has a live, time-bound National Plan for Rare Disease. The National Plan for Rare Disease sits within Romania's National Strategy for Health and in the National Framework Program for Health. The current National Plan is time bound, covering the period 2021-2027. The plan is currently being updated for 2030, due to the way in which the National Strategy for Health is framed.

This is the 2nd national plan for Rare Disease in Romania. The first was adopted by the end of 2013, and was included within the National Public Health Strategy for 2014-2020 ("Prosperity of Health"). The National Public Health Strategy and Action Plan for implementing it were approved by Government Decision no. 1028/2014. After it expired at the end of 2020 it was replaced by the current plan.

Elaboration and Adoption/How was the original plan elaborated?

The body tasked with adopting the national plan initially is called the National Council for Rare Diseases.

A larger stakeholder community has been involved in the process of updating the national plan – this is called the ‘The National Coalition for updating and implementation of the NPRD’ and involves:

- Representatives from Romania’s National Alliance of rare disease patient organisations (RONARD)
- National Council for Rare Diseases - NCRD
- Individual Patients
- Individual experts
- The Ministry of Health
- Researchers/clinicians from rare disease centres of expertise
- ERN coordinators or representatives in the country
- ARPIM - The Romanian Association for Innovative Drug Producers
- National Health Insurance
- National Drug Agency
- Medical Universities).

Once it was agreed that the current plan needed to be updated, working groups were organised that included representatives from the National Council for Rare Diseases, patient organisations, centres of expertise, healthcare providers and government representatives. These groups then met with the drafting team for the National Strategy for Health to advocate for objectives relating to rare disease being included there too.

Is there funding for the Plan? How is it Implemented and/or Monitored or Evaluated?

A different group is responsible for overseeing the implementation of Romania’s National Plan for Rare Disease, as well as suggesting methods for improvement. The group meets regularly. Within the group, the following stakeholder types are included:

- Patients/people with lived experience of rare condition
- Romania’s National Alliance of rare disease patient organisations
- Health Ministry/Competent National Authority in charge of Health or Care
- Researchers/clinicians from rare disease centres
- ERN coordinators or representatives

No formal evaluation or monitoring has taken place of Romania’s National Plan for Rare Disease. However, the annual national EUROPLAN conferences do monitor the implementation of the national strategy for health and the objectives for rare disease.

Romania’s National Plan for Rare Disease has a dedicated budget of €119 million. The budget is included in the National Strategy for Health through dedicated objectives. The funding allocation mainly comes from the PNRR - National Program for Recovery and Resilience and Operational Program for Health.

Romania has an official National Council for Rare Diseases (NCRD), which was established in 2013. At the end of 2024, the NCRD was reorganised by Ministry of Health. The NCRD still includes 3 members from the Romanian National Alliance for Rare Diseases (RONARD) and they have voting rights.

Research in National Plans or national research strategies relevant to rare disease

Romania's National Plan addresses rare disease research. Research related activities within the plan are financially supported. In particular, there is dedicated funding for the Genomic Centre in Bucharest. The current National Plan includes specific mention of IRDiRC. It also promotes alignment with other international/transnational rare disease research collaborations.

Romania's National Plan for Rare Disease is aligned with other relevant strategies in Romania including the genomics strategy. Within Romania's National Cancer Plan Law, there is a separate chapter for rare cancers.

Romania has considered the French model when developing their first National Plan for Rare Disease.

Select Achievements of the National Plan

The following are five key achievements resulting from Romania's National Plan(s) for Rare Disease:

- Accreditation of 45 Centres of Expertise
- Participation in European Reference Networks
- Establishment of new services for patients e.g. NoRo Centre, Genomic Centre Timisoara
- Continuous updates to the Orphan Drug list
- Cross border collaboration

Rare Disease Research Programmes and Funding

There are no specific programmes or funding calls reserved just for rare disease research in Romania but specific projects for rare disease are funded from general research programmes.

Rare Disease Registration and Biobanking

Romania does not currently have national nor regional rare disease registries. However, there are plans to create a national rare disease registry.

It is unknown if there are any biobanks for rare disease samples.

Organisation of Rare Disease Care

Centres of Expertise

There is a national policy in place in Romania for designating Centres of Expertise for both groups of rare diseases and specific rare diseases. Within Romania, there are 45 Centres of Expertise for rare

disease. Romania uses EUCERD criteria to designate Centres of Expertise for Rare disease. The criteria includes the following requirements:

- Bring together, or coordinate, multidisciplinary specialised medical and paramedical expertise such as physiotherapists, speech therapists, dieticians, genetic counsellors, etc
- Bring together, or coordinate, or liaise with social services or social workers, in order to serve the specific medical, rehabilitation and palliative needs of rare diseases patients
- Collaborate with patient organisations to bring in the patients' perspective
- Provide education and training to healthcare professionals from all disciplines, including paramedical specialists and non-healthcare professionals (such as schoolteachers, personal/homecare facilitators) whenever possible
- Contribute to and provide accessible information adapted to the specific needs of patients and their families, of health and social professionals
- Participate in data collection for clinical research and public health purposes

ERNs

Romania is involved in multiple European Reference Networks. For the latest details on participating HCPs, click [here](#).

Newborn Screening

2 conditions (Phenylketonuria and Congenital Hypothyroidism), plus congenital hearing loss, are included within Romania's newborn screening programme. Romania's Ministry of Health is responsible for making policy decisions about which conditions are included within the Newborn Screening programme.

Romania does participate informally in international initiatives relating to newborn screening including MetabERN and the International Society for Neonatal Screening (ISNS).

Under [Economic European Space \(EEA\) and Norway Grants](#), Romania has implemented a pilot project ([METABO^{MS}](#)) to expand the number of diseases included within their screening programme. The Ministry of Health has made a proposal to upscale the newborn screening programme in Romania to 22 conditions. However, the proposal is pending due to changes at Government level.

Diagnostics

Romania has seven Regional Centres of Genetics responsible for organising genetic testing.

There are no specific policies in Romania to facilitate cross-border genetic testing, beyond the EU Directive 2011/24 (the 'cross-border healthcare Directive') that codifies the right to receive health care across member state borders.

Romania participates to international initiatives for undiagnosed patients/people with currently undiagnosable conditions including JARDIN.

There is a policy in place in Romania to ensure that national providers provide genetic counselling for patients with a suspected or confirmed rare disease.

National Alliances of Rare Disease Patient Organisations

Romania does have a National Alliance of rare disease patient organisations called the Romanian National Alliance for Rare Diseases (RONARD). Further information is available [here](#). Through Romania's National Council for Rare Disease, RONARD are involved in setting the strategic direction for rare disease research within Romania. RONARD provides training and capacity building opportunities for patient engagement in rare disease research. RONARD are currently running a project for RONARD members on capacity building. Surveys are conducted through RONARD members about patient engagement in rare disease research.

Information Resources for Rare Disease

National Orphanet Engagement

There is an operational, national, Orphanet team within Romania. The Grigore T. Popa University of Medicine and Pharmacy (UMF Iasi.) hosts this Orphanet team. There is no specific funding for the Orphanet team, who work on a voluntary basis.

Helplines

Romania has a national helpline for rare disease - the NoRo Helpline. This is run by the Romanian Prader Willi Association and is part of the EURORDIS Network of Helplines. There is no dedicated funding for the running of the helpline. Anyone can contact the helpline via phone or email for information, and they will be connected with the relevant rare disease Centre of Expertise.

Training and Education

There are rare disease training activities in Romania, that are delivered as part of various projects. Available training includes the following topics:

- Diagnostics
- Raising awareness of rare disease
- Data management
- Standards and quality of genetics/genomics data in clinical practice and laboratories
- Registries

- Clinical research
- Case management

Training is provided by RONARD, patient organisations, centres of expertise and medical universities. Different training courses are aimed at patients, families, community nurses, clinicians, researchers and journalists. The majority of courses are offered free of charge, but some have a fee. Training courses are delivered in the Romanian language.

Orphan Medicinal Products (OMPs)

33 OMPs are available in Romania. Romania has a legal framework for compassionate use programmes under Order No. 962/2006 (under Law No. 95/2006) and later Order No. 861/2014. Criteria are set out and include methodology for permitting medicines under compassionate use. Under these rules, patients with a severe disease who have no other satisfactory treatment available may access unapproved (or not yet approved for their indication) medicines via compassionate use.

Romania is not involved in any formal efforts or initiatives with other countries to support access to medicines and therapies for rare diseases.



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The Data Contributing Committee of Romania, which provided this 2025 data (correct as of the end of November 2025) in the context of the Resource on the State of the Art of Rare Disease Activities, is composed of the following individuals:

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