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The online platform facilitating the access to clinical trials in Romania has been launched

Patients in Romania, their relatives, the medical community and the general public can access information about ongoing clinical trials in Romania, through a new online platform, in Romanian, which is connected to the European Union database.

The National Agency for Medicines and Medical Devices of Romania (NAMMDR) together with the Health Innovation Hub have developed and launched the online platform facilitating the access to clinical trials in Romania, available at <https://studiiclinice.anm.ro/>.

"The online platform facilitating the access to clinical trials in Romania is the first major deliverable of this project, within the Health Innovation Hub, serving as both an information and educational tool.

We thus support the development of a competitive model for clinical trials in Romania, providing patients with the opportunity to make informed decisions and the access to advanced therapeutic opportunities. Certainly, the decision to enrol a patient in a trial belongs exclusively to the patient and the attending physician, respecting the inclusion or exclusion criteria and the clinical assessment of the patient.

*We want this platform to strengthen public trust and support the evolution of a predictable, efficient and people-oriented medical research framework", said **Conf. univ. dr. farm. Răzvan Mihai Prisada**, President of the NAMMDR and coordinator of the project.*

Claudiu Damian, Secretary of State in the Ministry of Health, who attended the event, highlighted: *"Today, we emphasize an essential aspect for the future of Romanian medicine: the development of high-level medical research, a field without which we cannot talk about making real progress in patient care. The most concrete expression of this development is represented by clinical trials with medicinal products for human use, which bring direct and multiple benefits to both patients and the entire health system. For patients, clinical trials mean access to the newest molecules, to innovative therapies, at the same time and under the same conditions as patients from any other European Union state. It is an opportunity for modern treatment, rigorous supervision and international quality standards."*

The initiative is the result of an extensive collaboration between the Ministry of Health, the G6-UMF University Alliance, the Local American Working Group Association (LAWG), the Coalition of Organisations patients with chronic diseases in Romania (COPAC), the Autoimmune Disease Patients' Association (APAA), the National Society for

Medical Oncology in Romania (SNOMR), the Association of Clinical Trial Leading Companies in Romania (ACCSCR) and other interested entities. The project was implemented with the technical support provided by the IQVIA Romania.

Prof. univ. dr. Alexandru Rafila, President of the Committee for Health and Family of the Chamber of Deputies, who was present at the launch event, stated: *"Teamwork and multi-sectoral collaboration made the difference in the case of the Innovation Hub. The approval of the National Strategy and the legislative amendments have increased the number of clinical trials 3 times in the last year and implicitly the patients' access to innovative medication! The inauguration of the Platform on the NAMMDR website significantly improves access and transparency for patients and physicians. I wish to thank everyone who contributed to this successful project carried out in the last 2 years!"*

Prof. univ. dr. Carmen Orban, Chair of the Senate Subcommittee on Population and Development, added: *"The need for clinical trials is obvious. The platform represents a valuable resource for patients, physicians and the medical community, providing real-time information, in Romanian, about available clinical trials, classified by therapeutic areas and geographical distribution. Rapid access to such information can be crucial for patients, and feedback from both patients and physicians is essential for the continuous improvement of the platform."*

The platform represents the resource which patients, patient associations, physicians, healthcare facilities, and other interested parties can access in order to find out information, in Romanian, about clinical trials available in Romania, classified by therapeutic areas and geographical distribution. The information is taken in real time from the CTIS (the European Medicines Agency database). The platform also fulfils an educational objective, by providing clear and accessible information for patients, investigators and the general public regarding the conduct of clinical trials.

As a representative of the medical and pharmaceutical academic environment, **Prof. univ. dr. Viorel Jinga**, Rector of the "Carol Davila" University of Medicine and Pharmacy of Bucharest, G6-UMF University Alliance, believes that *"The clinical trials' transparency is essential for rebuilding public trust in research. Patients need to know what trials are being conducted in Romania, where they can participate, which are the benefits and risks, who coordinates them and which are the outcomes. Correctly presented information generates trust both in the medical system and in the country's ability to be an international partner in the development of innovative therapies. All the same, the platform will be a valuable tool for researchers and universities. For the academic environment, this means quick access to real data, an indispensable resource for publishing scientific papers, supporting grants or initiating international consortia."*

Prof. univ. dr. Radu Iliescu, Vice-Rector of the "Grigore T. Popa" University of Medicine and Pharmacy of Iași, University Alliance G6-UMF, stated during the event: *"The platform is important because it makes something essential visible: the fact that*

clinical research is an integral part of what modern medical practice should mean. If we want medicine in Romania to truly be evidence-based medicine, then the Romanian clinician must be not only a consumer of scientific information, but also a generator of it. Evidence-based medicine is sustainable only in an environment where professionals understand research methodology, participate in trials, lead projects and are able to critically evaluate new evidence."

The representative of the innovative pharmaceutical industry, **Frank Loeffler, President of the Local American Working Group (LAWG)**, highlighted that *"This new national platform brings added transparency to clinical research in Romania. It provides patients, physicians and research centers with clear and real-time visibility into available trials and facilitates the connection of patients to innovative treatments in an easier and more accessible way.*

As we build on this progress, the next essential step is to develop a predictable reimbursement framework so that all patients can access innovations in Romania as quickly as in other European countries. Romania must assert its role as an international research hub in the development of innovative treatments, and Romanian patients must be able to exercise their right to access these innovations as quickly as all other European citizens."

The project was developed following proposals from patient organisations and professionals in the field, with the support and involvement of numerous partners of the Health Innovation Hub. The launch of this Platform represents an important step towards completing Romania's digital infrastructure in the healthcare sector.

"The proposal for development of this clinical trial platform came from patient organisations and I was pleased with the openness I found in the Health Innovation Hub and in the partnership with the NAMMDR. Both patients and physicians can access the platform for information about clinical trials, as well as to search for an ongoing trial in Romania. The collaboration with the European Medicines Agency allows for the daily updating of the platform, and the patient information area will be expanded so that patients can find educational materials which are as applicable to their searches as possible", said **Rozalina Lăpădatu, President of the Association of Patients with Autoimmune Diseases (APAA).**

"The platform is one of the few initiatives in healthcare which has brought together institutions, academia, industry and patient associations to contribute to its development, and it has only just begun. In the next step, we see the need for communication campaigns on clinical trials at national level, an open dialogue with multiple organisations which can support patients in identifying trials, as well as expanding the horizon of activities towards European approaches in the field of clinical trials", highlighted **Luminița Vâlcea**, Executive Director of the Coalition of Organisations of Patients with Chronic Diseases (COPAC).

Present at the meeting, **Rialda Răduc**, General Manager of the National Society for Medical Oncology of Romania (SNOMR) stated: *"The launch of this platform marks an important step for transparency and access to clinical trials in Romania. In order to recover the distance from advanced countries, the efforts of the partners in the Health Innovation Hub must be complementary and convergent. The SNOMR, through the projects submitted for European funding, has demonstrated clear directions of action: human resource training (training and mentoring programmes for young oncologists, advanced training and shadowing in accredited oncology centers), international promotion of the potential of Romanian centers and attracting sponsors. Through these steps, the SNOMR aims to strengthen Romania's credibility as a strategic partner in European clinical research."*

Clinical trials contribute to the creation of a modern, innovation-oriented healthcare system, generating a positive impact on patients' health, offering them a bridge to connect to the latest medical technological innovations. Romania is one of the few countries in the European Union which has developed a Strategic Plan in the field of Clinical Trials, coordinated by the NAMMDR and carried out with the support of the Health Innovation Hub in 2024. The platform facilitating access to clinical trials in Romania represents a priority action of the strategic intervention areas of the plan.

As President of the Association of Clinical Trial Leading Companies in Romania (ACCSCR), **Dr. George Tănăsescu** highlighted: *"I express my appreciation for the successful launch of the Online platform facilitating access to clinical trials in Romania, an initiative developed by the National Agency for Medicines and Medical Devices of Romania (NAMMDR) in collaboration with members of the Health Innovation Hub. This platform represents an important moment for the clinical research ecosystem in Romania. By integrating real-time data from the European Medicines Agency's CTIS database and by providing accessible information in Romanian, the platform offers patients, healthcare professionals, investigators and institutions a clear and comprehensive picture of ongoing and upcoming clinical trials, covering various therapeutic areas and geographical regions."*

The ACCSCR fully supports this initiative and remains committed to working alongside the NAMMDR, the Ministry of Health, academic institutions and all involved partners in order to expand Romania's capacity to attract and conduct high-quality clinical trials. Together, we can improve patient access to innovative therapies, increase research opportunities and position Romania as a preferred destination for global clinical development programmes."

Dr. Teodor Blidaru, Manager of the Health Innovation Hub, mentioned: *"This platform becomes a facilitator of the Romanian clinical trial ecosystem, offering physicians and patients real visibility into active trials at national level. Moreover, this platform represents a concrete deliverable of the Health Innovation Hub and proves that public-private partnerships can work when there are a shared vision and a clear objective."*

Data from the EU Clinical Trials Information System shows that in December, over 720 trials were ongoing in 385 medical centers in Romania, out of 10,513 trials conducted in Europe. Romania occupies a middle position in the ranking of Central and Eastern European countries in terms of the number of trials conducted and has made notable progress in this important area, in recent years.

