Hub de Inovație în Sănătate România

STRATEGIC PLAN FOR THE DEVELOPMENT OF CLINICAL TRIALS IN THE FIELD OF MEDICINES FOR HUMAN USE IN ROMANIA

JUNE 2024

Content

Abbreviations

Abbreviation	Original	Translation
ACCSCR	Association of Leading Clinical Trials Companies in Romania	
ACRP	Association of Clinical Research Professionals	Association of Clinical Research Professionals
I ACT	Accelerating Clinical Trials in the EU	Accelerating clinical trials in the EU
AEMPS	Spanish Agency for Medicines and Health Products	Spanish Agency for Medicines and Medical Equipment
HERE	Agency for Clinical Investigation and Biomedical Innovation	Agency for Clinical Research and Innovative Medicine in Portugal
ANMCS	National Authority for Quality Management in Health	
ANMDMR	National Agency of Medicines and Medical Devices in Romania	
APIFARM	Agency for Clinical Investigation and Biomedical Innovation	Portuguese Association of the Pharmaceutical Industry
BNDMR	Banque Nationale de Données Maladies Rares	French National Registry for Rare Diseases
CNAS	National Health Insurance House	
CRO	Clinical Research Organization	Contract Research Organization
EFPIA	European Federation of Pharmaceutical Industries and Associations	European Federation of Associations and the Pharmaceutical Industry
EMA	European Medicines Agency	European Medicines Agency
EU-CTR	European Union Clinical Trials Regulation	European Union Regulation on Clinical Trials
FDA	US Food and Drug Administration	US Food and Drug Administration

G6-UMF	University Alliance of UMFs from Bucharest, Cluj-Napoca, Craiova, Iasi, Târgu Mureș, Timișoara	
GDPR	General Data Protection Regulation	EU General Data Protection Regulation
HMA	Heads of Medicines Agencies	Heads of Medicines Agencies
HTN	Health technology assessment	Evaluation of medical technologies
IBEC	Bioengineering Institute of Catalonia	
ICD-10	International Classification of Diseases, 10th Revision	International Classification of Diseases, 10th revision
LIF	De forskande läkemätelsföretagen	Swedish Association of Manufacturers of Innovative Medicines
MDS	Minimum date set	Minimum data set
MRC	Medical Research Council	UK Medical Research Council (MRC).
MVP	Minimum Viable Product	Minimum Viable Product
IHN	National Health Institute	UK National Institute of Health
NIHR	National Institute for Health and Care Research	UK National Institute for Health and Research
Pr	Socialstyrelsen	Swedish National Patient Registry
WHO	World Health Organization	
NGO	Non-governmental organization	
P.I	Principal Investigator	Principal Investigator
GDP	Gross Domestic Product	

PPC	Purchasing Power Parity	
PfP	Public-private partnerships	
Reece	Registro Español De Estudios Clínicos	Spanish Agency for Clinical Studies
R-RCTs	Randomized controlled trials	Randomized clinical trials
SMO	Site Management Organization	The organization for managing the site
VAT	Value Added Tax	
UCR	Uppsala Clinical Research Center	Uppsala Clinical Research Center
eu	european union	
UMF	University of Medicine and Pharmacy	

Introduction

The Strategic Plan for the Development of Clinical Trials in Romania represents a strategic document that is the basis of the sustainable development of the field of clinical research in Romania.

The clinical trials sector represents an important pillar, with **growth potential** , which brings **benefits both for patients and the health system** , as well as **contributions to the state budget** . Thus, the development of this sector through the implementation of the Strategic Plan, represents a key component in the national project proposed by the Ministry of Health and the Ministry of Economy, based on the Memorandum approved by the Government of Romania in May 2024, for the development of the pharmaceutical field and the increase of Romania's economic competitiveness. The implementation of a competitive model for clinical trials in Romania, by continuing and consolidating the efforts already made in this field, generates the opportunity to connect Romania to international medical research, increases patients' access to innovative treatments, attracts foreign investments, contributes to the retention of medical personnel, technological transfer, can lead to the creation of new jobs and increased revenues to the state budget.

The objective of the strategic plan is to position Romania as one of **the important players at the regional level** in the field of clinical trials. Thus, Romania proposes a series of coordinated actions and country indicators, such as **tripling the number of clinical trials** carried out in 2026 compared to 2023.

Achieving the objective will be done by considering **values and ethical principles** , as well as a **transparent communication and implementation** from the parties involved. The activities in the field of clinical trials are developed on the principle of ensuring adequate financial and human resources in order to ensure integrity, ethics in research and the access of Romanian patients to innovative treatments.

The strategic plan also aims to **to create the necessary work context** for the involvement of as many stakeholders as possible, such as national authorities, patient associations, professional associations/societies, universities, medical teams, etc.

Importance of clinical trials in Romania there is one **vital** , in the conditions of a population that shows trends of increasing median age, correlated with an underfunding of the health system compared to the rest of the European Union (EU) countries. In addition to those listed, the lack of drugs or the delay with which drugs become available in the market is another element that must be considered.

Clinical trials are also extremely important in the medical field, because the offer o **solid basis for the development of new treatments and innovative medicines** . They facilitate the assessment of the safety and effectiveness of new therapies, the identification of risk factors and disease prevention strategies

In Romania, the importance of clinical trials is recognized and reflected in **increasing the number of approved trials**. This demonstrates the country's commitment to contributing to the advancement of innovative treatments and medicines.

The European Union recognizes the importance of clinical trials with the initiative in mind **Accelerating Clinical Trials in the EU (ACT EU)** . The goal of this initiative is to transform the way clinical trials are initiated, designed and conducted. The initiative is led jointly by the European Commission, the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) and aims to develop the EU as a competitive center for innovative clinical research.

Key elements of ACT EU include improving the quality, safety and efficacy of medicines, more effectively integrating clinical research into the European health system, modernizing good clinical practice by adopting and implementing new EU guidelines for clinical trial design, facilitating innovation in clinical trial methods by publishing a methodological map and further development of guidelines for decentralized clinical trials.

Clinical trials contribute to the creation of a **modern healthcare system oriented towards innovation** , generating **positive impact** on the health of patients, offering them a connection bridge to the latest technological innovations.

In this context, the tripling of the number of clinical trials **would position Romania closer to the European average** , would contribute significantly to reducing the pressure on the health budget and would bring a **positive economic impact** .

The clinical trial market in Romania is estimated[1] to 45-50 million Euros in the year 2022, bringing a contribution to the state budget over 12 Million Euros annually only from the collection of VAT, taxes and fees paid with the personnel employed in the industry. A tripling of the number of clinical trials conducted by 2026 would bring the market to around 150 million euros annually.

Achieving the objective will be done starting from **five strategic areas of intervention** relating to:

Informing and educating patients and stakeholders about clinical trials

[1]estimate – the estimate was made starting from the 2019 country report made by IQVIA, using the extrapolation method. The methodology comprises summing up the contributions to the state budget generated by the clinical trial industry, taking into account VAT, direct taxes paid to the authorities, including salary taxes. In the same report, it is highlighted that every 1 million Euros generated by the clinical trial market results in 270 thousand Euros for the state. It is necessary to update them in the following stages (Country Report)

Patient mobilization and recruitment mechanism

Development of the human resource involved in the conduct of clinical trials

International promotion of Romania's potential

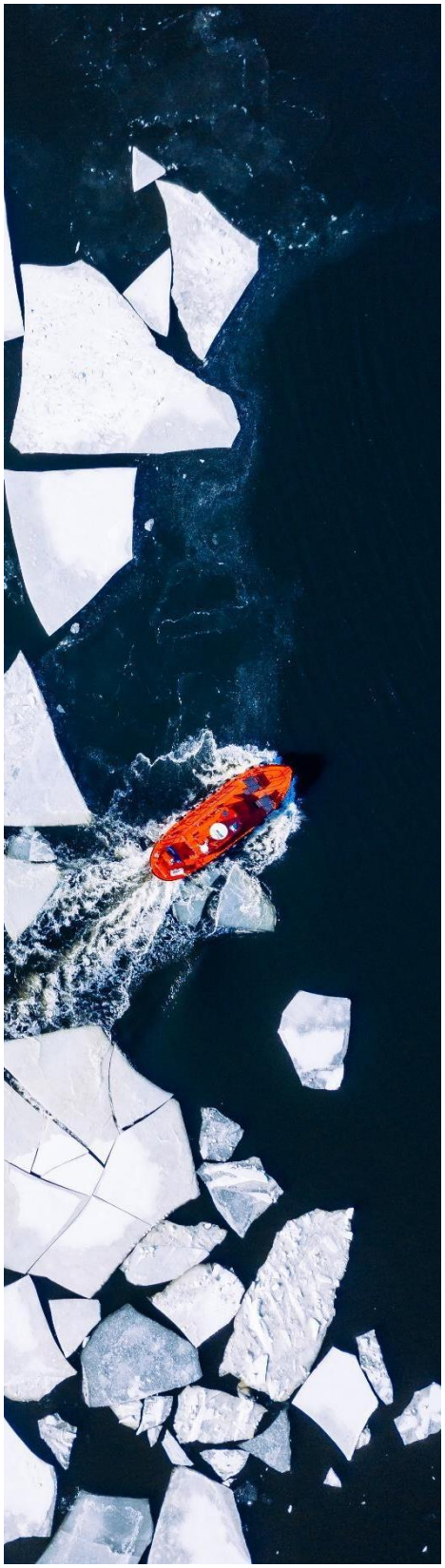
Economic and fiscal measures to create a favorable context for clinical trials and the stimulation of innovation

Starting from these strategic areas of intervention, more **strategic objectives** were identified and developed, taking into account the current context, the opinion of local experts, the identified good practices and the potential benefits following implementation.

The strategic objectives were framed in a **general development plan** , to be developed and implemented as part of Romania's plan to develop the clinical trials sector.

Strategy implementation and monitoring it will be done taking into account **KPIs** aligned with the project goal as well as by involving all stakeholders.

Vision, Mission, Goals and Values



Vision

The vision of Romania's National Strategy for Clinical Trials is that of a **develop a competitive model for clinical trials** in Romania.

The vision focuses on five strategic areas, to serve as a guide for attracting and supporting the conduct of clinical trials in Romania:

1. **Promoting clinical trial education:** The aim is to increase awareness and understanding of clinical trials among patients, healthcare professionals, sponsors and other stakeholders.
2. **Ensuring an efficient recruitment mechanism:** It is desired that the patient recruitment mechanism be efficient and provide better access to drugs and state-of-the-art technologies for all eligible patients.
3. **Encouraging human resource development and clinical trial centers:** It is intended to stimulate the training and continuous development of medical personnel specialized in clinical trials and the necessary infrastructure.
4. **Improving the external image of Romania regarding the conduct of clinical trials:** The aim is to position Romania as a regional leader in the field of clinical trials.
5. **Ensuring a competitive economic and fiscal environment to stimulate investments in clinical trials:** It is desired to create a favorable environment for conducting clinical trials in Romania and to stimulate actors from a sector of a sector with a high level of scientific rigor, which contributes with considerable added value

Mission

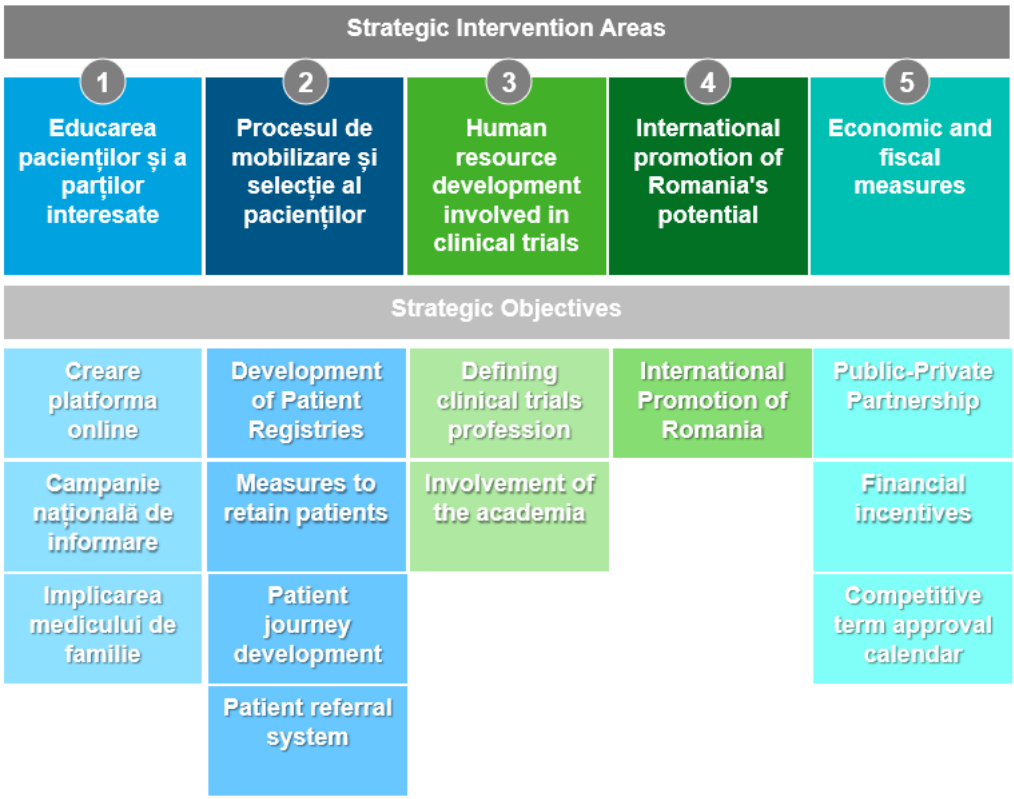
The mission of the National Plan for the development of Clinical Trials aims to support clinical research activities by ensuring an appropriate legal and logistical framework that facilitates collaboration between public institutions, the academic environment, the public and private health institutional environment, as well as patients, so as to lead to tripling the number of clinical trials carried out in Romania in 2026 compared to 2023.

The mission and vision can be fulfilled through the development of strategic directions of intervention, the definition of objectives, recommendations, the action plan, but also changes to the legal framework that provide long-term sustainability to the framework for conducting long-term clinical trials.

Goals

Each of these five strategic areas includes several objectives and strategic recommendations, with the aim of improving the current situation and bringing elements of innovation that will allow Romania to triple the number of clinical trials by 2026.

By promoting collaboration between different stakeholders, developing policies or procedures to support innovation, investing in technology, developing training and education programs, and economic measures, Romania can become an important player at the regional level in the conduct of clinical trials.



Values

The vision, the strategic objectives as well as the directions of action will be aligned with the following values:

Patient focus: Designing and conducting clinical trials with the patient's best interests at heart

Transparency: Open communication regarding the design, conduct and results of clinical trials

Collaboration: Cooperation between various stakeholders such as patients, national authorities, doctors, clinical trial centers, sponsors, as well as any other stakeholders

Ethical conduct: Respect for the rights and well-being of patients and participants in clinical trials, as well as respect for the ethical code of the medical profession

Innovation: Promoting innovation and innovative technologies in Romania

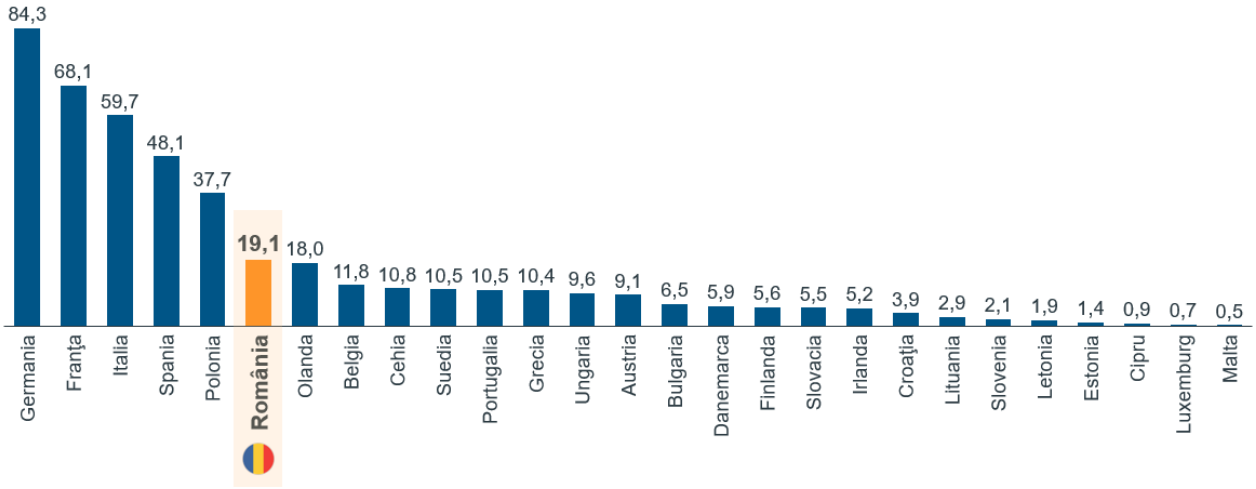
Conducting clinical trials in Romania – Context Analysis

Context analysis

Demography

The population of Romania reached 19.1 million in 2023, slightly increasing compared to 2022. Romania occupies the sixth position in the EU with a higher number of inhabitants than neighboring countries such as Hungary, Serbia, Bulgaria or Moldova. In terms of EU countries in the Central and Eastern Europe region, Poland stands out with a population that is almost double[1] [2] .

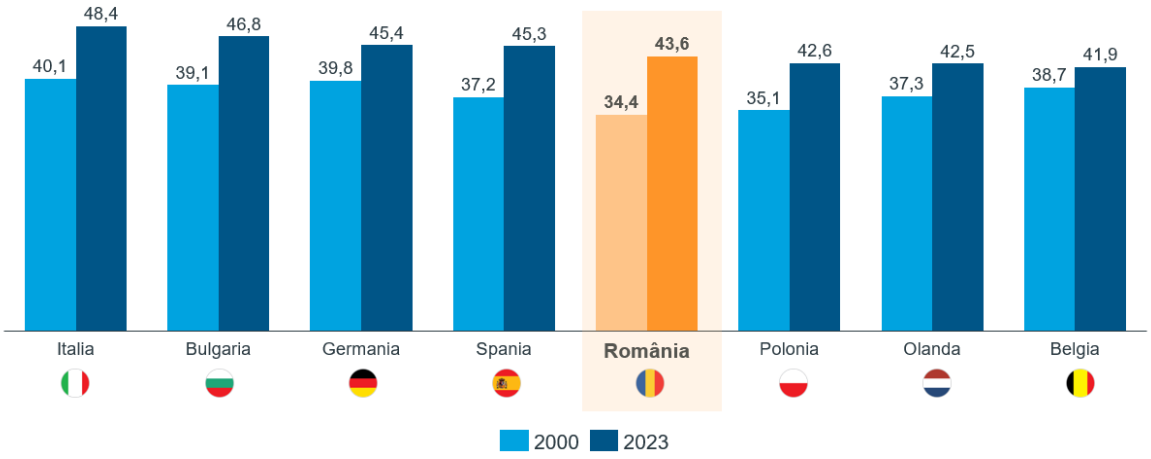
Illustrative 1. Population of Romania and the rest of the EU countries [2023, Mil.][1]



Median age

The median age in Romania increased by approximately 27%, from 34.4 years in 2000 to 43.6 years in 2023, revealing the significant shift towards an older population structure[3].

Illustrative. 2 Median age in selected EU countries [2023, Years][3]

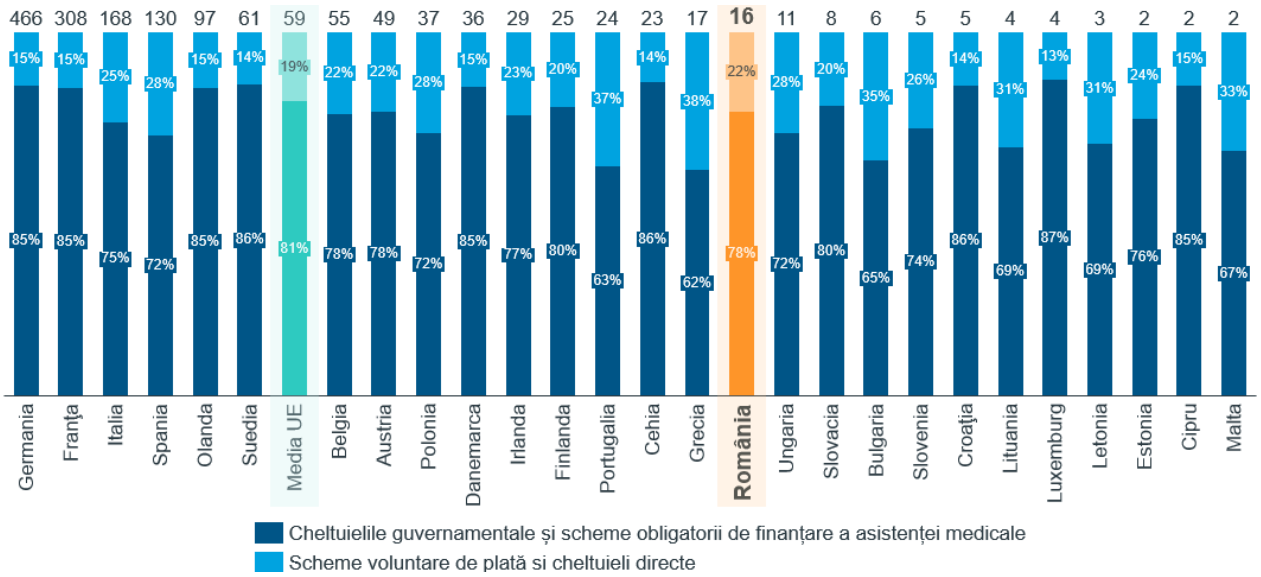


Health costs

In Romania, the state bears approximately 80% of health expenses, a percentage similar to that in other countries[4] .

However, the total amount allocated for health expenditure indicates that the system is underfunded, the amount being lower compared to other countries. For example, Germany, which has a population roughly four times that of Romania, allocates a total of almost 30 times more to health spending. Among the countries of Central and Eastern Europe, Romania allocates a budget similar to the Czech Republic and higher than that of Hungary, Slovakia or Bulgaria (all countries with a significantly smaller population than Romania)[4].

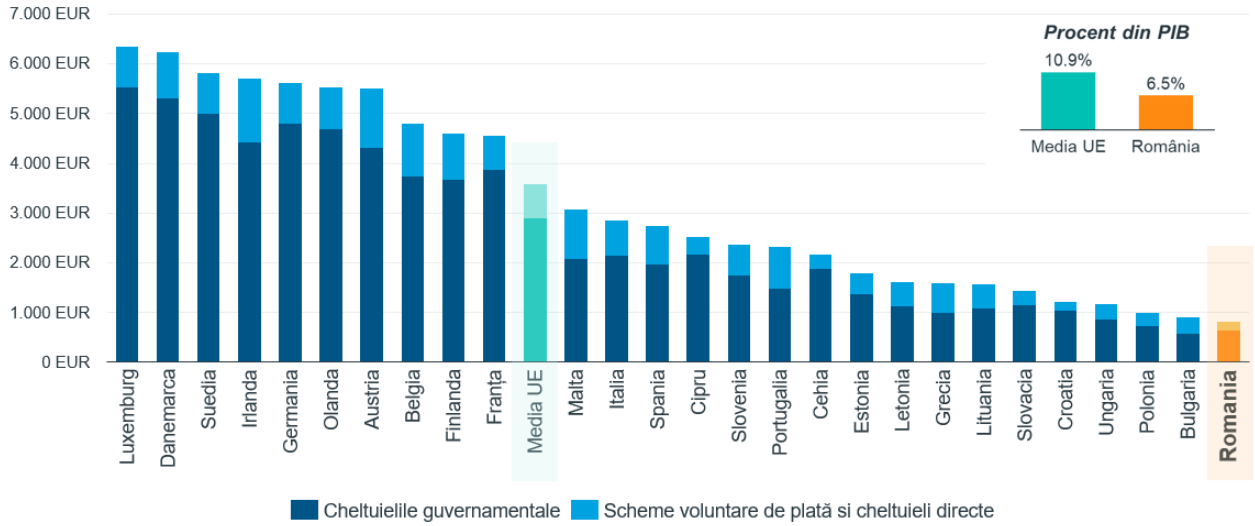
Illustrative 3. Health Expenditure [2021, Mld. Eur][4]



The amount allocated for health in Romania was approximately 817 Euros per inhabitant, this being the lowest value recorded in the EU. The average in the EU is approximately 4.5 times higher than in Romania, reaching 3,562 Euro per capita, which indicates a major underfunding of the health system in Romania[4].

In terms of the percentage of GDP allocated to health, it is also one of the lowest in the EU[4].

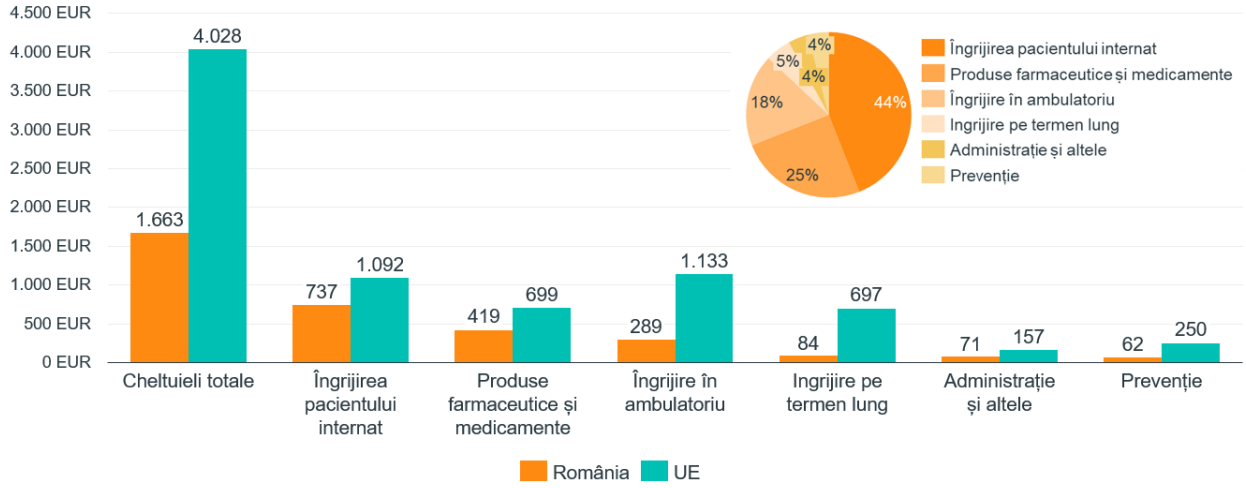
Illustrative 4. Health expenditure per capita and % GDP allocated to health (public + private sources) [2021, Euro][4]



When we discuss the allocation of health expenses expressed in Euro currency taking into account PPC (purchasing power parity), Romania allocates in all analyzed categories a smaller amount compared to the EU average.

For example, the allocation of expenditure on pharmaceuticals and medicines is 67% higher at the EU average compared to Romania. This discrepancy underlines the importance of clinical trials and how they can bring benefits in areas where innovative drugs are not yet on the market or are insufficient[5] .

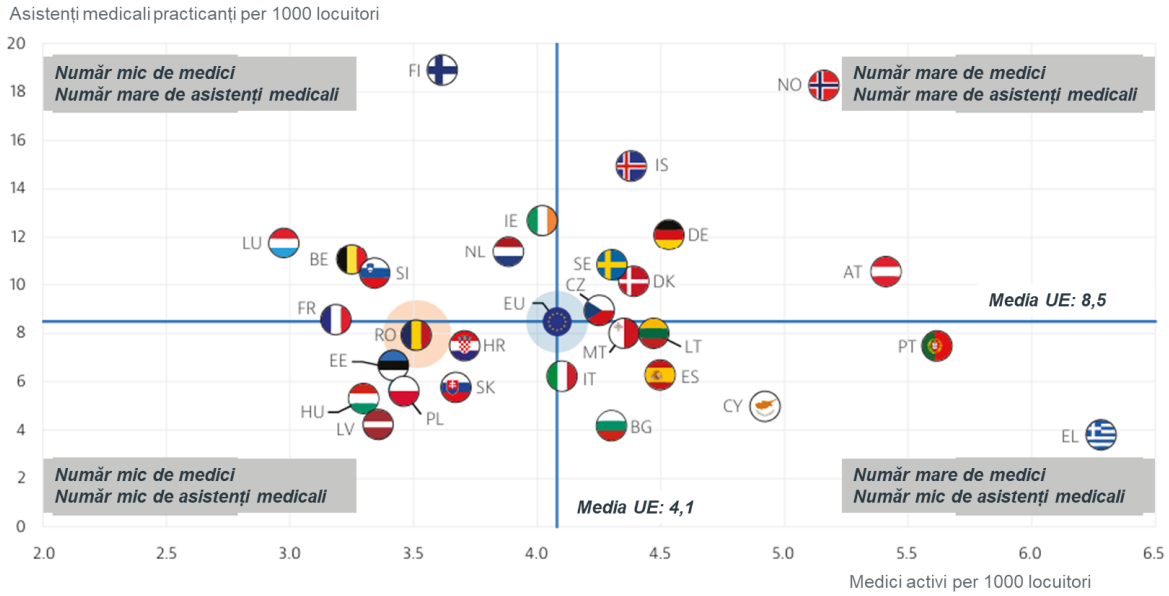
Illustrative 5. Health expenditure per capita [2021, Euro PPC][5]



Healthcare professionals

Regarding the number of doctors and nurses per 1,000 inhabitants, Romania is part of the group of countries with a number below the EU average for both categories, along with Estonia (EE), Croatia (HR), Slovakia (SK), Poland (PL) , Hungary (HU), Latvia (LV).

Illustrative 6. Number of doctors and nurses per 1,000 inhabitants at EU level [2021][5]



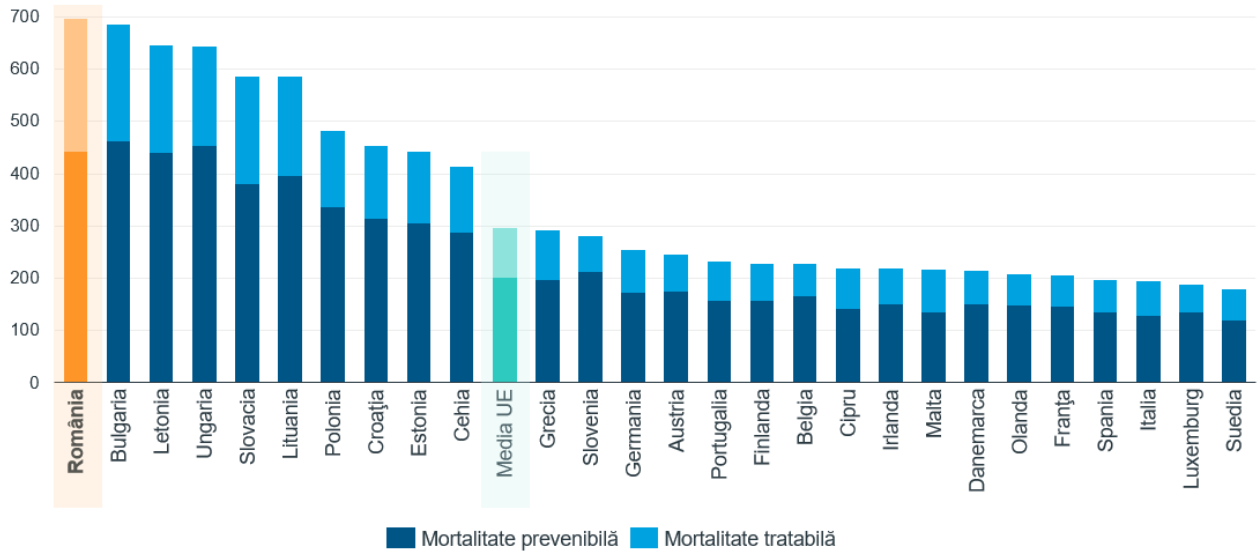
Mortality rate

Romania ranks first in the EU with a number of 255 deaths per 100,000 inhabitants in terms of the treatable mortality rate (from treatable causes). The rate is more than 150% higher than the EU average of 93[6].

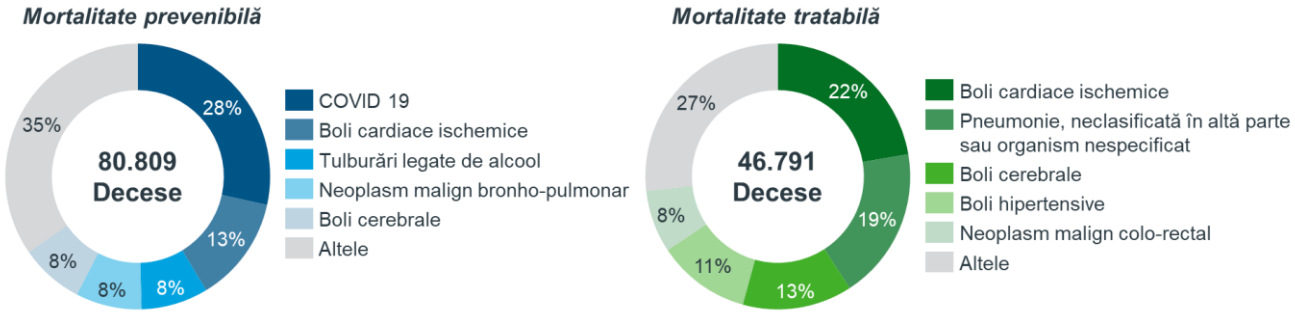
Regarding the preventable mortality rate, Romania is in third place, after Bulgaria and Hungary. This means that in Romania there are 440 avoidable deaths per 100,000 inhabitants. Comparatively, the EU average is 201 avoidable deaths per 100,000 inhabitants. Thus, the avoidable mortality rate in Romania is more than twice higher than the European average[6].

The main causes of these deaths include cardiovascular disease, alcohol-related diseases and lung cancer[6].

Illustrative 7. Preventable and treatable mortality of residents (rate per 100,000 inhabitants) [2021][6]



Illustrative 8. Preventable and treatable causes of mortality in Romania [2021][6]



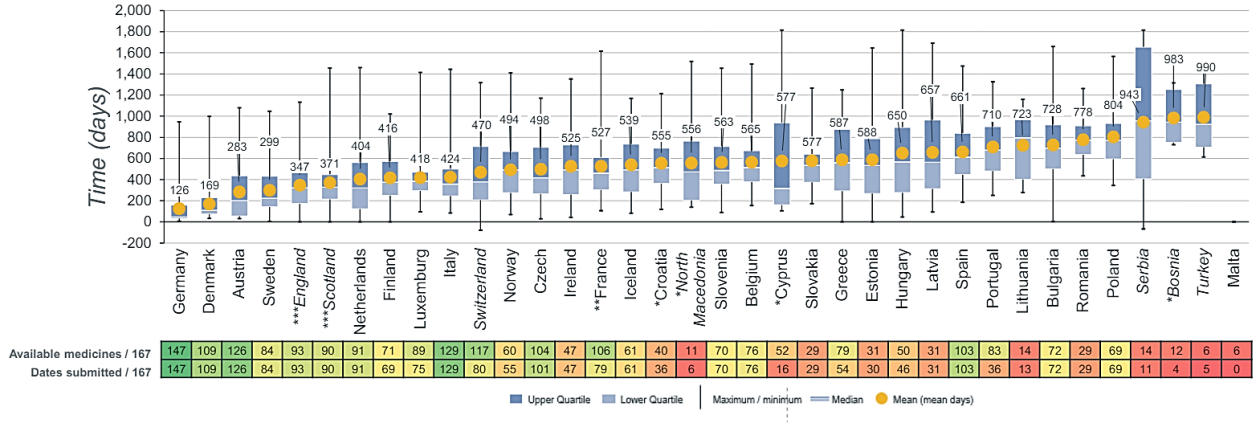
Romania's access to innovative medicines

The time from central approval to availability is the days between marketing authorization and the date of patient availability in European countries (for most this is when products gain access to the reimbursement list). The date of marketing authorization is the central authorization date throughout the EU[7].

Romania is one of the countries with the highest number of days from the central approval of the drug to its availability on the market. In the period 2019-2022, it took an

average of 778 days for a medicine to be available on the market in Romania, from the moment of central approval by the EMA[7].

Illustrative 9. Time from central approval to availability [2019-2022][7]



Romania is also one of the countries with a relatively small number of drugs that reach the market, so out of 167 approved drugs, 29 drugs ended up being available on the Romanian market. Malta, Turkey, Bosnia, Lithuania and North Macedonia are the only countries that have a lower number of medicines available in the analyzed period[7].

The lack of innovative medicines has a significant impact on patient treatment, such as the impact on long-term patient health, increased costs for patients and the health system, increased susceptibility for elderly patients or those with multiple conditions, etc.

Thus, drugs from clinical trials can play an essential role in the development and improvement of medical care. For some conditions, participating in a clinical trial offers the only chance to receive a potentially beneficial treatment that may take years to become commercially available.

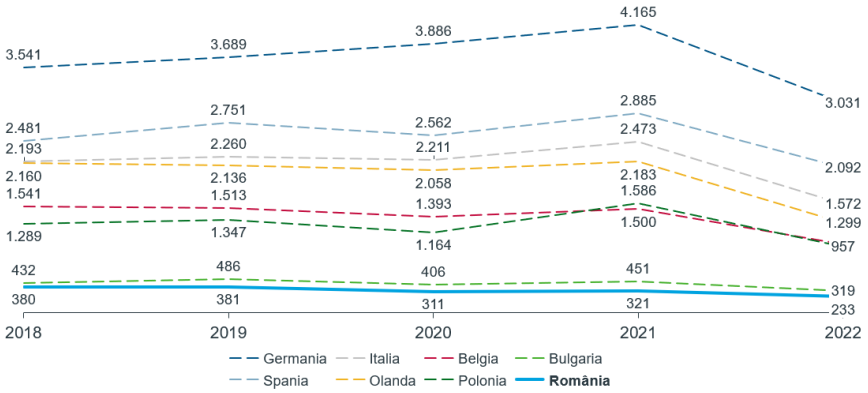
In addition, drugs in clinical trials can reduce the pressure on drug spending by providing more effective options compared to current treatments, and improved patient access to therapy.

Clinical trials are closely monitored for efficacy and safety, with every drug and treatment used in medical care today having been tested in a clinical trial beforehand.

Clinical Trials in Romania

Even though it has a considerable population, Romania is among the countries with the lowest number of clinical trials registered within the EU. According to data from the World Health Organization (WHO), Romania carried out 233 clinical trials in 2022, their number showing a decreasing trend in the period 2018-2022[8].

Illustrative 10. Number of registered clinical trials [2018-2022][8]

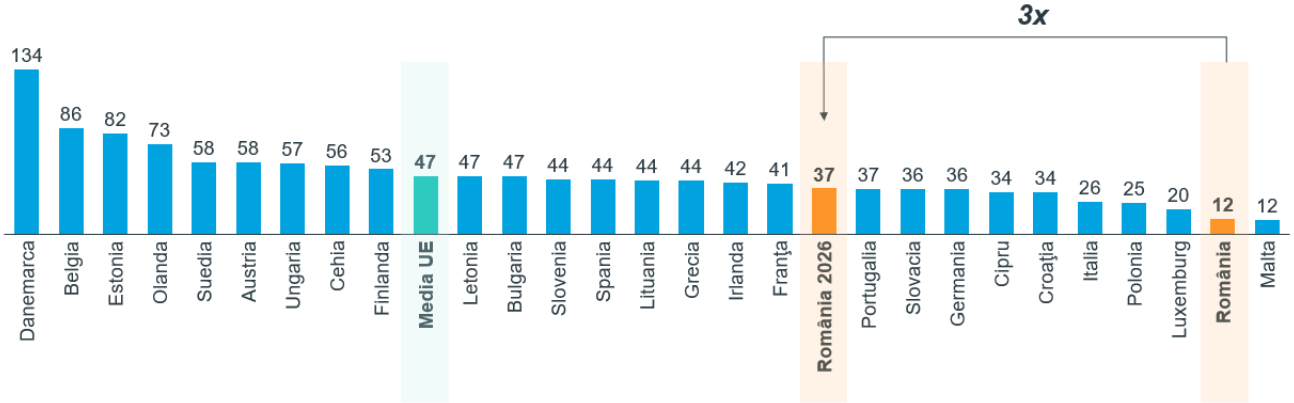


The number of clinical trials in Romania is lower than in countries with a smaller population such as Bulgaria or Belgium which recorded 319 and 957 clinical trials respectively in 2022[8].

A trend can be observed at the level of 2022, where the number of clinical trials decreased compared to 2021 in all countries that were taken as a reference for this comparison. According to the European Federation of Pharmaceutical Associations and Industries (EFPIA), the trend is attributed to a reorientation of investments in research and development to other areas such as North America or Asia[9].

The number of clinical trials per million inhabitants in 2022 places Romania in last place, with a number of 12 clinical trials/million inhabitants, equal to Malta. Among the countries in the region, Hungary and Bulgaria registered a number 5 and 4 times higher than Romania, respectively[1] [8].

Illustrative 11. Number of clinical trials per million inhabitants [2022][1] [8]

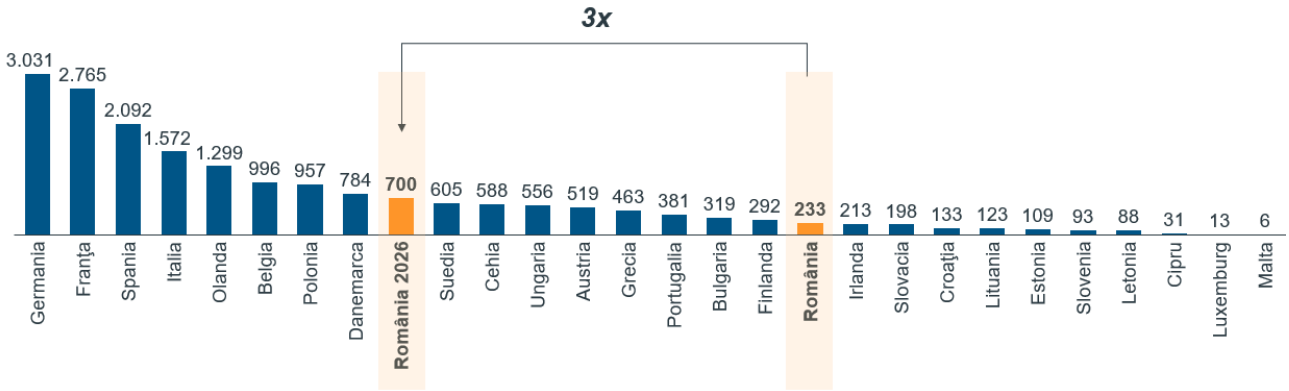


The tripling of the number of clinical trials would position Romania in 9th place in the EU, compared to the 17th position in 2022, above some countries in the region such as

Hungary, Greece or Bulgaria, which have a smaller population and a higher number of clinical trials than Romania.

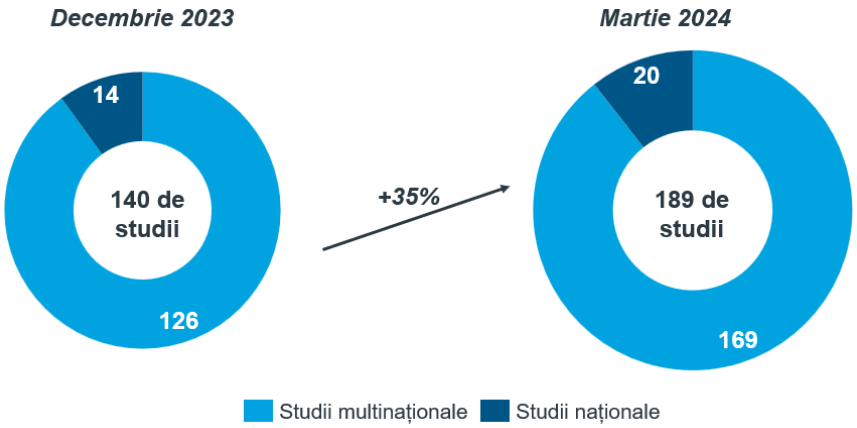
When it comes to the total number of clinical trials per million inhabitants, tripling the number of clinical trials would position Romania closer to the EU average, on a par with Portugal, namely 37 clinical trials per million inhabitants, compared to 12 currently.

Illustrative 12. Number of clinical trials [2022][8]



Although Romania is in the second part of the ranking when it comes to authorized clinical trials, progress has been made in the last year. Thus, according to the EFPIA reports from December 2023 and March 2024, the number of clinical trials registered from January 31, 2022 increased from 140 to 189 [10] [11].

Illustration 13. Number of authorized clinical trials [Dec 2023, March 2024][10] [11]



SWOT analysis

STRENGTHS

- **Quality:** The research is carried out at a high level of quality, comparable to Western European countries, and the quality of the data and results obtained is recognized by authorities such as the FDA and EMA as well as sponsors
- **Expertise:** Investigators currently leading clinical trials are generally physicians with considerable experience in the field, some with over 20 years of experience
- **Population** : Romania benefits from a larger population compared to countries in the region, which translates into a larger number of patients suffering from various pathologies
- **Clinical study centers:** The existence of both public and private centers where clinical trials can be conducted
- **Collaboration:** There is effective collaboration between ANMDMR and the Ethics Commission
- **Patient associations:** Maturity of patient associations, as well as involvement in patient education
- **Academic environment:** The existence of a Master's program dedicated to Clinical Trials within the UMF (such as Carol Davila from Bucharest)

WEAKNESSES

- **Education:** Patient and general public education about clinical trials is still lacking, with some level of reluctance still existing
- **Visibility:** The lack of a national space on the availability of clinical trials contributes to ineffective communication
- **Communication :** The absence of patient awareness campaigns leads to insufficient understanding of the benefits of clinical trials
- **Patient registers:** At the moment, in Romania there are not enough national disease registries or integrated medical files for each patient. This lack of registries contributes to the deficiency of generating statistics on diseases present in the population, as there is no possibility to extract data
- **Patient identification:** Disease codes in the medical system are not unified, using both ICD-10 and 999 codes, thus the diseases patients suffer from are identified inefficiently and do not ensure rapid enrollment, the approach being ad hoc and non-unitary
- **Incentives:** Lack of programs to stimulate clinical trials

- **Historic:** Romania's history of difficult approval of clinical trials positions Romania as a country that attracts clinical trials with difficulty
- **Medical and auxiliary staff:** The medical and auxiliary staff trained to conduct clinical trials is insufficient, in particular, more doctors, nurses, technical coordinators, statisticians, medical content creators, etc. are needed.
- **Under research funding:** The development and funding of basic research in university hospitals and centers of excellence is insufficient
- **Financial compensation for clinical trials:** It is considered to be below the level of most EU countries

OPPORTUNITIES

- **Patient registers:** Romania's participation as a pilot country in the EuroHeart project (which is based on the national registries in Sweden and Great Britain) for the development of the cardiovascular disease registry (acute coronary syndromes, heart failure, valvulopathies, atrial fibrillation, etc.)
- **International context:** In the context of the conflict between Russia and Ukraine, there are new opportunities for attracting clinical trials to Romania, as both countries have been excluded from most trials
- **Approval procedure:** IMPLEMENTATION OF the procedure for the centralized approval of clinical trials at the European EU-CTR level
- **Promotion:** The promotion of Romania at the international level can highlight the attractiveness for conducting clinical trials
- **Information:** Information about clinical trials at various scientific events, which allows the information to be distributed also to doctors who would not otherwise have access to this data
- **Family doctors:** Involvement of GPs in informing patients about clinical trials to guide them towards relevant treatments and research
- **Future professionals:** The interest of young medical professionals in participating in clinical trials, in dedicated courses offered by the main Universities and Associations/Professional Societies
- **Development of Centers of Excellence in Research:** that can coordinate clinical trials at national level

CHALLENGES

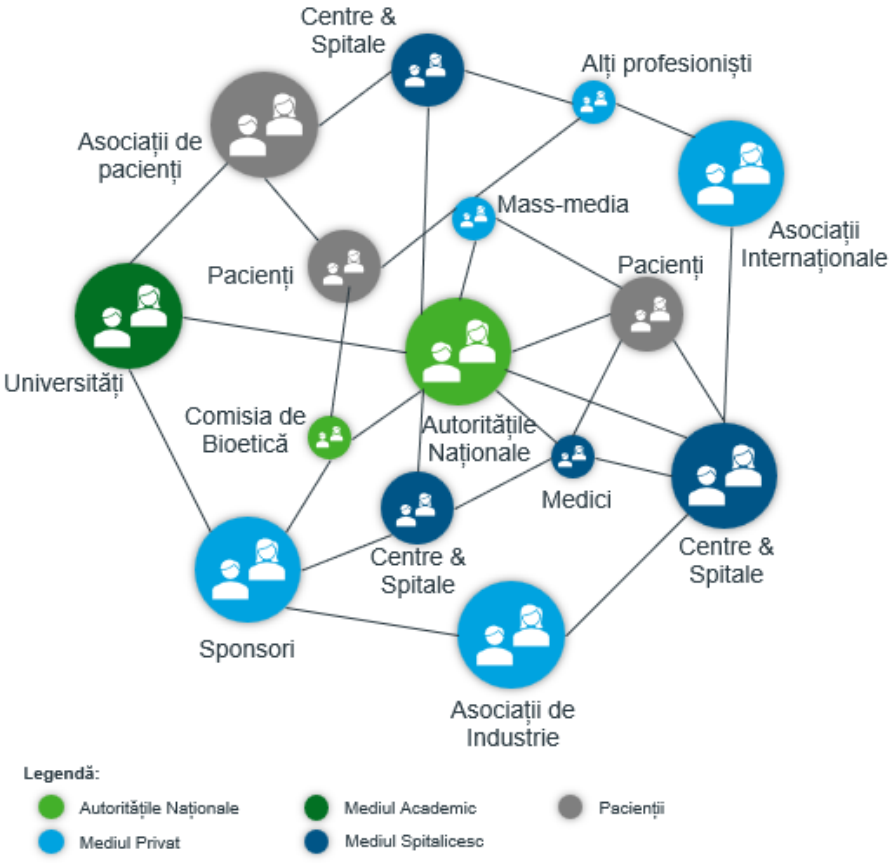
- **EU-CTR transition:** In the context of EU-CTR (European Union Clinical Trials Regulation) implementation, Romania has not finished transferring all clinical trials started before January 2023, the transition process ending in January 2025
- **International competition:** Non-EU countries can grant approvals for clinical trials in a much shorter time frame compared to EU-CTR, thus making them attractive to sponsors
- **Administration:** Delays in the approval process caused by inadequate completion of clinical trial dossiers when submitted for verification to the Bioethics Commission
- **Digitization:** Other EU countries are more progressive in digitizing the healthcare system and can therefore more effectively attract potential sponsors

Stakeholders

The field of clinical trials is a complex ecosystem that brings together a variety of entities and groups from the public and private sectors. These include patients, clinical research centers (hospitals, clinics, or other research centers), universities, pharmaceutical companies, professional associations/societies, non-profit organizations, researchers, etc. Each of these parties plays an essential role in conducting clinical trials. , be it study design, data collection, outcome analysis, or ensuring ethics and patient safety.

To improve the conduct of clinical trials, close collaboration between all these groups is essential. This involves open communication, effective coordination and mutual respect for each other's expertise and perspectives. It is also important that all parties involved collaborate to address the challenges and set a framework with clear roles that will contribute to the realization of the National Plan for the development of Clinical Trials in Romania.

Illustrative 12. The Stakeholder Ecosystem in Conducting Clinical Trials



Stakeholder breakdown

Pacienții sunt cei afectați de diverse afecțiuni care participă la cercetări pentru a pemite cercetarea unor tratamente noi necesitând informații corecte și o participare etică și sigură

Ministerul Sănătății este responsabil pentru politici, reglementări și investiții majore în sănătate, iar bugetul public este stabilit anual de guvern și aprobat de Parlament

Agenția Națională a Medicamentului și Dispozitivelor Medicale este autoritatea națională care reglementează și supraveghează medicamentele și dispozitivele medicale din România.

Alianța Universitară G6-UMF are ca obiective promovarea intereselor învățământului superior medical precum și de a crea un cadru comun de cooperare în domeniile educaționale, științifice și extra-curriculare

Investigatorii principali sunt esențiali în procesul de dezvoltare a unui medicament, aceștia fiind experți în criteriile de selecție a pacienților, alegând cu rigurozitate participanții potriviți pentru studiile clinice

Comisia de Bioetică a Medicamentului și a Dispozitivelor Medicale - organism independent, constituit din profesioniști din sănătate și alte domenii, responsabil cu protecția drepturilor și bunăstării participanților la studiile clinice

Coaliția Organizațiilor Pacienților cu Afecțiuni Cronice **(COPAC)**, Asociația Pacienților cu Afecțiuni Autoimune **(APAA)**, Alianța Națională pentru Boli Rare **(ANBR)**, Alianța Pacienților Cronici din Romania **(APCR)** etc.

Alte grupuri de interes: Guvernul României, ARPIM, LAWG, ACCSCR, Ministerul Finanțelor, experți financiari, alte Asociații Profesionale etc.

Strategic Intervention Areas

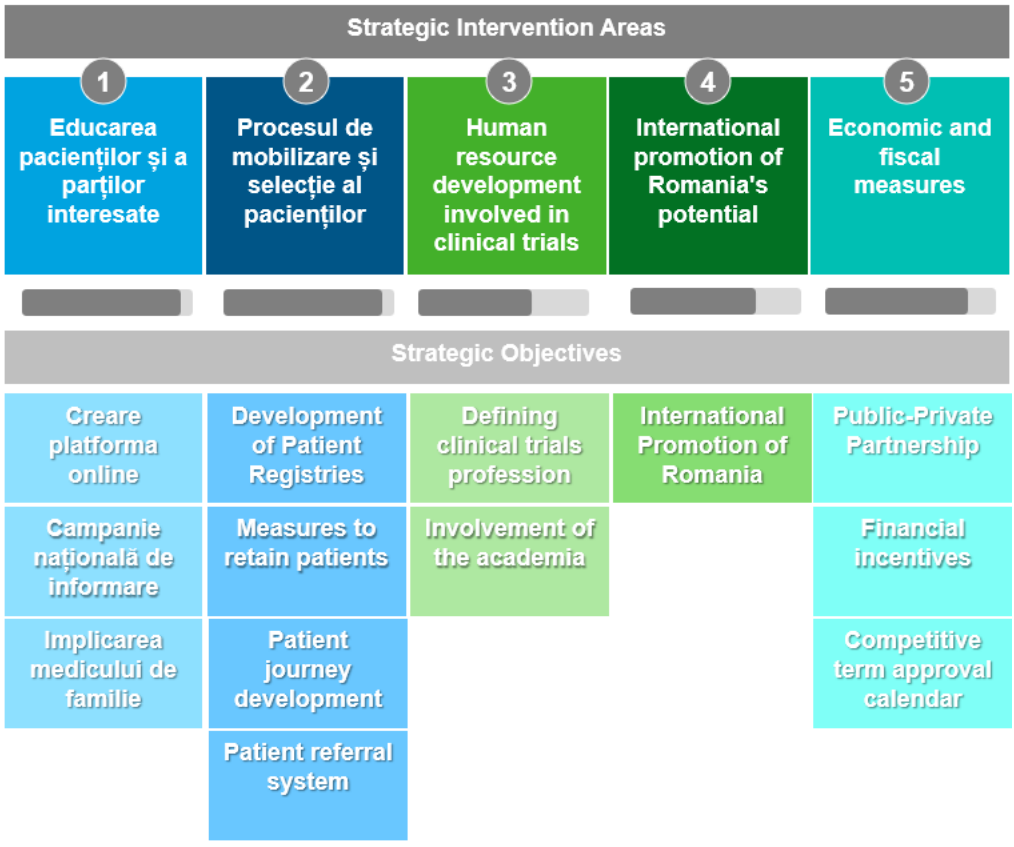
Overview of the strategic areas of intervention

The Strategic Intervention Areas were defined in collaboration with local experts[2] , being considered to be the vital areas where Romania has the potential to boost the development of clinical research through effective changes.

These areas were established considering both the current context and future trends, thus constituting the foundation of the National Strategy for the Development of Clinical Trials in Romania.

This chapter details each area of intervention, providing an overview, summarizing the views of local specialists, illustrating good practices from other countries (Belgium, France, Germany, Hungary, Italy, Poland, United Kingdom, Spain, Sweden), and suggesting recommendations for implementation.

Illustrative 13. Strategic intervention areas and strategic objectives



[2]Representatives of G6-UMF, Principal Investigators, ACCSCR, COPAC, APAA, ANBR, ARPIM, LAWG and others (details in the Annex)

Strategic Intervention Area I: Educating patients and stakeholders

Objective 1: Create an online platform for clinical trials

General information

The online information platform is a resource that patients, patient associations, doctors, health facilities, as well as other stakeholders can access to find out information about the clinical trials available in Romania, classified by therapeutic areas and geographical distribution.

The platform may also include educational components about clinical trials, such as: what clinical trials mean, what is the conduct and enrollment process, how can patients express their desire to participate, what are the criteria for participation, how important is continuity in a clinical trial etc.

Context

Romania currently does not have a centralized website/online platform that all stakeholders can access to discover approved and ongoing clinical trials in the country, as well as other information of interest.

The opinion of local experts

- The existence of a platform that facilitates access to information is seen as an essential element by local experts:
  - This platform can help increase the transparency of information about clinical trials available in Romania for patients, doctors and other stakeholders
  - Contributes to patient education about clinical trials, including recruitment criteria, selection process, and general information about clinical trials
- National authorities are perceived to be primarily responsible for creating, updating the online platform and making information transparent
- Interest groups involved:
  - patient associations
  - professional associations/societies
  - universities of medicine and pharmacy

Examples of good practices identified

Spain – clinical trials are registered with the Spanish Agency for Clinical Trials (**REec**) which was subordinated to the Spanish Medicines and Medical Equipment Agency (AEMPS). **Reece** make available to any stakeholders free information on clinical trials including inclusion criteria, timing of conduct, contact details, sponsor details, selected clinical centers, etc.[12].

Belgium – existing clinical trials in Belgium are made available through the platform **"clinicaltrial.be"** . The platform aims to help patients find information about clinical trials in a simple and focused way on the educational component[13].

United Kingdom – through the National Institute of Health and Research (NIHR), the platform is made available to patients and other stakeholders **"Be Part of Research"** which provides information on available studies by location or pathology. The platform also has an educational component offering articles and information about clinical trials[14].

Portugal - makes available through the "Portugal Clinical Trials" platform information for various interest groups: for patients, information is made available about the clinical trials conducted in Portugal, as well as educational information or about the centers where the clinical trials are conducted. Information about the conduct of clinical trials in Portugal, as well as the conduct process, is made available to sponsors. The platform is a joint initiative of the Agency for Clinical Research and Innovative Medicine (AICIB) and the Portuguese Association of the Pharmaceutical Industry (APIFARMA)[15].

Sweden - the hiks.se platform, developed with the help of LIF (Swedish Association of Manufacturers of Innovative Medicines), provides information about clinical trials taking place in Sweden. Selection can be made according to several criteria: region/location, pathology, study phase, study sponsor, patient enrollment status, etc. [16].

Potential benefits

Number of patients treated: It may increase the number of patients enrolled in clinical trials

Easy communication between stakeholders: Facilitates communication between various stakeholders, such as physicians, patients and sponsors of clinical trials

Access to information: It improves accessibility and how different stakeholders can access the necessary information

Personalization of content: It can provide content tailored to the needs and interests of its users, such as specific information about clinical trials relevant to a particular pathology or patient group

Dissemination of information: The Platform can help ensure compliance with ethical and legal regulations by providing appropriate guidance and tools; at the same time, it would allow the dissemination of the results of trials with major implications for patients

Education: By providing accessible and easy-to-understand information, the platform can help promote the importance and benefits of clinical research to the general public

Recommendation

I. **Development of a platform** similar as in Belgium, Great Britain, Portugal, Spain or Sweden is a main objective of the National Strategy for Clinical Trials

II. In the medium and long term **developing a mobile application** that emulates platform content is recommended based on platform usage metrics (e.g. number of users, feedback, etc.)

Objective 2: National communication campaign

General information

The nationwide communication campaign, organized under the supervision of the national authorities, aims to disseminate information about clinical trials validated by medical experts, the benefits resulting from conducting and participating in clinical trials, the harmonization of legislation with the EU, the innovation resulting from clinical research, etc. through various means of communication.

These may include short promotional videos on television and radio, posts on national authority social media pages that can be picked up by patient associations and professional associations/societies, press releases and promotion at national scientific events.

Context

Currently, communication regarding clinical trials is carried out through initiatives of patient associations, industry associations or sponsors, however there is no integrated communication guided by the national authorities at the country level.

The opinion of local experts

- A national communication campaign, led by national authorities and supported by all relevant actors, is essential and can play a crucial role in improving knowledge about clinical trials
- Contribute to informing and educating patients about the progress of innovation, provide relevant information about clinical trials and help combat widespread misperceptions (e.g. the idea of "guinea pigs")
- Improves the level of information for family doctors so that they can more easily refer patients to the centers involved
- It facilitates more effective communication from patient associations and would increase the credibility of the message
- It can increase the involvement of health facilities to refer patients to involved centers where clinical trials are conducted

Examples of good practices identified

Belgium – national authorities are involved in informing patients, doctors and other stakeholders together with patient associations, universities and hospitals[17].

United Kingdom – The National Institute of Health (NHI) supports information about clinical trials not only through the online platform, but also

through articles, materials posted on blogs or events organized together with other stakeholders [18] [19].

Potential benefits

Public perception: It can help improve public perception of clinical trials, which can lead to greater acceptance and participation

Increasing innovation: By increasing awareness and understanding of clinical trials, the campaign can drive medical innovation

Increasing collaboration: The campaign can facilitate collaboration between different stakeholders, such as doctors, patients and regulators

Increase in the number of patients treated: It can increase the number of patients enrolled in clinical trials, providing faster access to innovative technology and generating savings to the health budget by absorbing costs through clinical trials

Reaching a large number of stakeholders: Disseminate information through various channels reaching a large number of stakeholders

Recommendation

I. It is recommended that **national authorities to initiate a communication campaign** to strengthen public confidence in clinical trials. It is recommended that this campaign be disseminated through various communication channels and be carried out in collaboration with patient associations, the College of Physicians, professional associations/societies and other stakeholders.

II. **Involvement of Patient Organizations** is essential for spreading the message, they have the role of ambassadors in the community. Through their activities, these organizations can help increase awareness and understanding of clinical trial information.

III. **Clarification of the legislative framework for the promotion of clinical trials** so that their promotion is done in a transparent way, meeting the necessary criteria to ensure the safety and well-being of the patient.

Objective 3: Involvement of the family doctor

General information

Family medicine provides primary and continuing health care, promoting individual, family and community health. The GP is the first point of contact for healthcare and may recommend further investigations or referral to specialists, including hospitalisation, as needed.

In cities where there are no clinical trial centers or in rural areas, the family doctor can be a central point of information regarding the existence of trials.

Context

At the moment in Romania, family doctors do not have an essential role in disseminating information about clinical trials as it happens in other European countries.

The opinion of local experts

- It is important that GPs are informed about their patients' participation in clinical trials, as they can help monitor and keep patients in the trial. Thus, investigators involved in conducting clinical trials should send a letter at the beginning and end of the clinical trial to family physicians with all the necessary information.
- Informing family doctors about the existence of clinical trials is necessary at the level of the whole country.
- The relationship between patients and family doctors is a very important one, and disseminating information about the existence of clinical trials can increase the number of patients treated through clinical trials.
- Family doctors can be the most important communication channel for rural areas or areas with an underdeveloped hospital infrastructure

Examples of good practices identified

Germany – The results of a study among family doctors showed that family doctors are open to being involved in clinical trials. The study concluded that clear planning and communication to GPs is needed[20].

United Kingdom - In the UK, scenarios are being considered whereby GPs could be included in a program of financial incentives to facilitate the recruitment of patients into clinical trials, under the government's ambitious plans to quadruple the number of participants in clinical trials in the next four years[21] .

Potential benefits

- **Dissemination of information:** better informing GPs about patient enrollment in clinical trials can help retention in clinical trials

Recommendation

I. **Family physician involvement in information dissemination** regarding clinical trials. The GP can play a key role in bridging the gap between patients and patient centers by providing fundamental information about how clinical trials are conducted

Strategic Intervention Area II: Patient recruitment and mobilization process

Objective 4: Development of Patient Registries

General information

Patient registries are databases that collect information about people with specific diagnoses or risks.

They are essential in various contexts, such as studying the characteristics of rare diseases, evaluating the effectiveness of treatments, monitoring

the evolution of diseases or monitoring the quality of patient care.

Patient registries help identify potential clinical trial participants who meet eligibility criteria. This can speed up the recruitment process and improve the representativeness of the study sample.

Context

In Romania, patient registries are underdeveloped, and there are initiatives for their development[22]. An example of an identified patient register is the National Register of Dermato-venereal Diseases, being available to all specialist or primary dermato-venereal doctors, members or non-members of the Romanian Society of Dermatology[23].

Another example is the National Registry of Acute Coronary Syndromes, part of the EuroHeart program of the European Society of Cardiology[24] [25].

The opinion of local experts

- Local experts believe national patient registries are vital for identifying eligible patients for national clinical trials
- A unified national strategy is needed to ensure data consistency between hospitals
- Patient registries can accelerate progress in medical research by giving researchers access to a large database of patients
- Patient registries allow the assessment of the quality of medical services, as well as adherence to the recommendations of good medical practice guidelines This information can help to set priorities in certain therapeutic areas

  The use of patient registers allows the monitoring of the Priority Actions of the Ministry of Health and the National Programs of the National Center for National Health and Welfare.

Examples of good practices identified

Sweden - Swedish National Patient Register (NPR)[26] is a comprehensive database containing information on episodes of medical care in both hospital (inpatient) and specialist outpatient care. Examples of information collected:

- Data, since 1964, on all completed admissions (nationally since 1987).
- Information on patients treated by doctors in specialized ambulatory care since 2001.
- Data on patients admitted to psychiatric care since 2010.
- Emergency department waiting times since 2016.

France – The French National Register for Rare Diseases (BNDMR) was established under the second National Plan for Rare Diseases. Its objective is to gather a minimum data set (MDS), which consists of approximately 60 patient items, from all rare disease specialist centers in France. This data can be collected either through a web application (BaMaRa) or directly from the patient's electronic medical record[27].

United Kingdom – There are several patient registries for different conditions. Some examples include: Spinal Muscular Atrophy Patient Registry, Myotonic Dystrophy Patient Registry, Facioscapulohumeral Muscular Dystrophy Patient Registry, etc. needles stea collects information about the impact of the condition on patients and any changes, their quality of life and daily activities[28] [29].

Potential benefits

Easy identification of patients: It facilitates the identification of patients for clinical trials, speeding up the recruitment process

"Real World Data -> Real World Evidence": Patient registries allow for the collection of longitudinal data on the health status of patients, the treatments they have received and their outcomes. These data can be used to assess the safety and effectiveness of long-term treatments

Recommendation

I. Is required **creation of a national system of patient registries.** The Swedish model could be implemented due to its maturity. In order not to overload the capacity of the health system, it is recommended that the implementation of patient registries be done gradually, starting from the development of registries for the most frequent pathologies, and then in the long term the implementation should target the rest of the pathologies. The use of patient registries by national authorities enables the provision of epidemiological data in the form of standardized recurring reports.

Objective 5: Measures to retain patients in clinical trials

General information

Patient retention in clinical trials is vital to their conduct, given that it affects both the integrity of the data and the validity of the results.

A high retention rate leads to results with superior validity. Promoting retention is essential and must be a priority throughout the clinical trial.

Context

At the moment there is no public information on the retention rate in clinical trials in Romania.

The opinion of local experts

- The retention mechanism is an essential factor influencing the success of clinical trials, with some experts considering retention to be the most important element of the clinical trial.
- Ongoing patient communication is perceived as a key element in patient retention in clinical trials
- Lack of communication and failure to provide relevant information in a

timely manner may lead to permanent discontinuation of study medication or withdrawal from the study

- Although the digitization rate in Romanian hospitals has increased, there is still an opportunity to improve the interaction with the patient, especially by standardizing the IT systems in health facilities
- Clinical trial centers are generally in large cities, making them less accessible to patients in rural areas or small towns

Examples of good practices identified

United States of America - In the context of the COVID-19 pandemic, the authorities have changed policies to allow the use of telemedicine as a means of interaction with the patient (information, education, reporting, remote assessment, etc.)[30].

European union – In the absence of public data, IQVIA international experts pointed out that the support offered to patients in clinical trials varies from one trial to another, and may include aspects such as reimbursement of transport costs, providing accommodation where necessary, as well as providing meals for patients.

European union – A report analyzing the use of telemedicine by doctors, patients and authorities concluded that it is widespread in EU countries and the WHO European area, and contributes to improving clinical outcomes for patients, offering logistical advantages for both patients and teams doctors involved in clinical trials[31].

Potential benefits

Telemedicine:

- ***Informing patients:*** increases patients' access to relevant information, facilitating interaction between patients and the medical team
- ***Patient accessibility to clinical trials:*** allows patients to be recruited for studies regardless of their geographic location
- ***Quality of clinical trials:*** ensures high study quality through early management of potential adverse events

Incentives:

- ***Patient retention:*** Benefits (eg: reimbursement of transport costs, provision of accommodation where necessary, provision of meals, etc.) for patients may increase their retention rate in clinical trials

Recommendation

I. Filling out **the supporting elements of the patient** (payment of transport, meals, accommodation) by offering medical leave during the study visits.

II. **Implementation of telemedicine solutions and other decentralization measures** in conducting clinical trials is inexpensive and can generate multiple benefits.

III. **Ensuring continuous treatment ("post trial access")** and the necessary care for patients who have been part of clinical trials, even after their completion

Objective 6: Patient journey development

General information

The development of pathways for patients, tailored to individual conditions, would guide how they navigate through the health system and the contact points where they could be informed and discover opportunities for involvement in clinical trials.

These pathways facilitate the systematic identification, by centers or study teams, of the most appropriate group of patients who could be informed about the possibility of benefiting from a Clinical study. Their lack complicates the recruitment campaign, requiring additional effort and time for the search, and also generating additional costs.

Context

At the moment in Romania there are no predefined routes for patients at the national level.

The opinion of local experts

- Pathways for patients with certain conditions (cardiovascular and cerebrovascular diseases, oncology, rare diseases, etc.) are an essential factor influencing their recruitment process, depending on which the success of a clinical trial is ensured

Examples of good practices identified

Italy - There are care pathways for oncology patients, covering cancers such as breast, prostate, lung and colorectal, with the first doctor involved being the family doctor[32]. In addition, it is recognized the need to define pathways during treatment that facilitate better communication, without adding additional responsibilities to the medical staff involved in clinical trials[33].

Potential benefits

- ***Additional information:*** increases patients' access to relevant information, facilitating interaction between patients and the medical team
- ***Early diagnosis and treatment:*** A predefined pathway for patients would speed up diagnosis and treatment, reducing waiting time

Recommendation

I. Elaboration of some **routes for the main conditions** from Romania (cardiovascular and cerebrovascular diseases, oncological diseases) **for starters**, as well as for rare diseases, which can have a significant impact on how patients are identified for clinical trials. By collecting relevant information such as disease stage, patient medical history and current treatment, these pathways can

help direct patients to the right clinical trials.

Objective 7: Patient referral system

General information

The medical referral system is an important element of health systems, with the aim of ensuring patients' quick access to specialized medical care.

This system facilitates how a physician, faced with insufficient resources or lack of expertise to manage a patient's clinical condition, requests the assistance of another medical facility or physician to assist the patient in the care process.

Context

Currently, in Romania there is a system by which the family doctor sends the patient to specialist doctors, for their expertise, however, such an institutionalized system of medical recommendations is not used in the context of recommendations for clinical trials.

The opinion of local experts

- Medical referrals in Romania are largely based on professional or personal relationships between doctors, which can influence how patients are directed to certain specialists or clinical trials.
- Verbal recommendations or without having full information about the existing options, can generate an uneven distribution of patients to certain health facilities or specialists
- This aspect can generate an uneven distribution of patients, based more on the popularity and professional relationships of doctors than on the actual needs of patients.

Examples of good practices identified

Poland – According to experts, some centers have implemented a structured referral system to facilitate the transfer of patients from neighboring facilities.

Italy - According to experts, the patient referral process involves direct communication between physicians or, alternatively, referral through national referral centers, especially for specialized conditions such as rare diseases, with data from national research centers.

Potential benefits

- ***Quick access to specialized care:*** Patients can receive specialized assessment and treatment in a shorter time, which can reduce distress or complications associated with delays in care.
- ***Better patient monitoring and management:*** Through referrals, physicians can collaborate to more effectively monitor and manage complex cases, ensuring ongoing and coordinated patient care, including inclusion in clinical trials
- ***Improving communication between health professionals:*** A referral system can facilitate the

exchange of information between physicians, including regarding clinical trials, promoting collaboration and knowledge sharing to improve the quality of medical care.

Recommendation

I. Establishing uniform procedures for redirecting patients to specialists or medical centers where clinical trials are conducted.

II. **Screening of medical databases** to identify eligible patients for the enrollment phase. Initiatives based on artificial intelligence and the conclusion of collaboration protocols with medical centers.

III. In the long term, the implementation of an electronic platform to facilitate fast and secure communication between doctors for the transmission of recommendations and the exchange of relevant information about patients.

Strategic Intervention Area III: Human resource development involved in clinical trials

Objective 8: Defining the profession in the field of clinical trials

General information

The team of specialists plays a crucial role in the effective implementation of clinical trials. This includes a variety of experts such as the Principal Investigator (PI), Sub-Investigators, Study Coordinators, Study Nurses, Data Manager, Clinical Pharmacist and others.

Their role is essential to ensure adherence to protocol and maintaining quality in research.

Context

At the moment clinical roles are not defined in the Nomenclature of Qualifications in Romania.

The opinion of local experts

- Modification of the legal framework is necessary
- The existence of a clinical research department, which includes medical staff dedicated to clinical trials, is recommended in centers where there is intense activity
- The existence of a scientific director, specified by the legislative framework, responsible for research activity, including attracting and coordinating clinical trials, in university hospitals or hospitals with more than 400 beds
- The shortage of staff has led to an overwork of doctors involved in clinical research
- The Clinical Pharmacist is considered a potential resource that could be more actively involved in clinical research

Examples of good practices identified

United Kingdom – the composition of the team for a clinical trial can be influenced by factors such as the complexity of the trial and the financial

resources available. In general, studies involving large numbers of patients benefit from the assistance of dedicated teams of clinical experts within Clinical Trial Units affiliated with hospitals or universities. Professions within clinical trial teams are regulated by the Medical Research Council (MRC)[34] [35] .

Italy – In centers and hospitals with significant clinical research activity, there are dedicated staff to conduct clinical trials. According to IQVIA experts, in the mentioned centers, the scientific director is responsible for the management of clinical trials, as well as for the contractual relationship with sponsors. The structure and number of members of a team are not regulated, but are adapted according to the needs of the clinical trial.

Potential benefits

Improving internal organization: The clear allocation of roles and responsibilities within the health unit, as well as the medical team allows for better organization and functioning

Quality of medical services: A well-defined structure can lead to the improvement of the quality of medical practice and medical research and to the training of experts in clinical trials

Medical staff training and retention: Ensuring a legal framework can contribute to the training and retention of medical professionals

Recommendation

I. It's recommended **the development of a legal framework** to facilitate **establishing roles** during clinical trials. Revision of the Nomenclature of Qualifications in Romania is a necessary step for defining the medical team involved in clinical trials

II. **Elaboration of a legal framework regarding employment in public health facilities** for staff dedicated to clinical trials, as well as rules regarding the size of teams dedicated to clinical trials **.** For example, the appointment of the scientific director in the centers with significant clinical activity, as well as the implementation of a structure for the teams dedicated to clinical studies (researchers, nurses, lawyers, accountants, clinical pharmacist, etc.).

III. **Giving clinical trial centers the opportunity to re-establish the position of Scientific Director** (eg in university hospitals or in hospitals with more than 400 beds).

IV. **Providing the possibility to establish structures/teams dedicated to clinical research** (for example in university hospitals and hospitals with more than 400 beds, under the Scientific Director, which should also include legal and accounting experts).

V. Active involvement a **the clinical pharmacist** in the conduct of clinical trials. However, it is recommended that each team create a structure adapted to their needs.

Objective 9: Involvement of the academic environment

General information

The participation of the academic environment is essential for the training of personnel involved in clinical trials, thus contributing to the development of the necessary skills to take part in these trials.

In addition, universities can provide a platform for conducting clinical trials, having the expertise and infrastructure necessary to organize clinical research. At the same time, universities can establish departments dedicated to conducting and monitoring clinical trials ("academic research organization"), and at the G6-UMF level they can organize networks of centers involved in clinical trials.

Context

In Romania, there is a Master's program dedicated to clinical trials at the Carol Davila University of Medicine and Pharmacy in Bucharest. Several universities have shown interest in developing similar programs.

The opinion of local experts

- The introduction of several master's programs as well as a residency training course for all medical specialties is seen as a factor that can contribute to the training of future experts.
- The implementation of accredited courses or postgraduate certification programs can ensure the continuous training of new specialists, but also the updating of the knowledge of the personnel involved in clinical research.
- Collaboration with universities and clinical research centers abroad, as well as collaboration with pharmaceutical companies, is essential for the training of experts and the development of clinical research in Romania.
- The participation of universities in the conduct and monitoring of clinical trials, through collaborations with pharmaceutical companies, as well as through the organization of networks of centers involved in clinical trials, can stimulate the growth of the number of trials and improve public confidence.

Examples of good practices identified

United Kingdom – higher education institutions such as the University of Warwick, the University of London, the University of Oxford and other universities offer master's programs and training courses for professionals interested in clinical research. They allow the accumulation of theoretical and practical knowledge. In addition, universities such as "The University of Edinburgh", "University College London" or "University of London" have departments dedicated to conducting clinical trials[36].

Netherlands - Erasmus University in Rotterdam offers a master's program

specialized in clinical trials, with the aim of training specialists in the field[37] .

France – universities such as those in Paris, Sorbonne, Paris Saclay have developed study programs in clinical research over the years. These universities have departments dedicated to conducting clinical trials. For example, the Sorbonne University has established Scientific Research Groups, bringing together specialists from hospitals and academia[38] .

Sweden – Uppsala University is known for its research tradition and is actively involved in clinical trials through the Uppsala Clinical Research Center (UCR). UCR was established in 2001 as a collaboration between Uppsala University and Uppsala University Hospital. The center is recognized for its expertise in registry-based randomized clinical trials (R-RCTs), contributing to significant innovations in health and medical practice globally[39].

Potential benefits

Competence Development: It contributes to the development of essential skills and trains new specialists dedicated to clinical research.

Improving education: Improving stakeholder knowledge of approved clinical trials by disseminating information in an academic context.

Increasing the number of clinical trials: Supporting the increase in the number of clinical trials by establishing partnerships with pharmaceutical companies and health facilities.

Increasing public confidence: Guaranteeing compliance with the rules of good medical practice in clinical research.

Attracting own funds : Attracting funds from clinical trials, later used to stimulate research in universities.

Recommendation

I. **Creating educational programs** for clinical trials (master's degree, postgraduate courses), as well as the inclusion of dedicated courses in residency training programs.

II. Establishment of **Partnerships** with universities and international clinical research institutions, as well as with sponsors or other entities involved in conducting clinical trials, with the aim of developing expertise through **through practice programs** .

III. Establishment of **clinical research partnerships** with companies involved in clinical trials and clinical research centers. For a good performance, the existence of a legal framework that can take the form of a public-private partnership is necessary (Objective 11)

IV. **The establishment in universities of departments dedicated to the conduct and monitoring of clinical trials,** as well as the organization of networks of centers involved in clinical trials.

Strategic Intervention Area IV: International promotion of Romania's potential

Objective 10: International Promotion of Romania

General information

Promoting Romania as a country with a favorable environment for conducting clinical trials is an essential component. Promotional methods, both nationally and internationally, are vital to attract interest to the country's potential in this sector.

Romania has a number of assets that make it attractive, such as the diversity of the population and the expertise of medical professionals.

Context

The changes in the context of EU-CTR implementation, but also of initiatives such as the National Strategy for Clinical Trials represent a favorable moment for the international promotion of Romania.

The opinion of local experts

- Improving Romania's international reputation is considered a priority by local experts, most of whom believe that significant progress has been made in recent years to create an environment conducive to conducting clinical trials.
- Participation in international conferences, congresses and exhibitions such as "ACRP", "Clinical Trial Supply Europe", "Precision in Clinical Trials Summit" etc. is a factor that can attract more clinical trials.
- Creation of promotional materials for both national and international scientific events.
- Romania must attract the most important events dedicated to clinical trials on the territory of the country.
- Increasing international collaboration, through the creation of Centers of Excellence, as well as through direct participation in the organization and publication of clinical trials.

Examples of good practices identified

Belgium – is one of the active players in Europe promoting itself through various methods, including country reports (for example, “Belgium as a location for clinical trials in Europe 2022”), distributing the country report through various channels and participating in international conferences[40].

United Kingdom – NIHR holds webinars and online discussions with stakeholders to discuss clinical trials.

Spain – became one of the most important "hubs" in Europe thanks to the promotion undertaken by REec through various methods (especially online)[41]. Spain is also the host of BIOSPAIN, an international reference event in the biotechnology sector, where the challenges of translating scientific knowledge into tangible benefits for patients are discussed [42].

Potential benefits

Increased local collaboration **:** Increasing the degree of collaboration between the stakeholders of the clinical trials ecosystem in Romania.

Increasing notoriety: It contributes to increasing the visibility of Romania at the international level among sponsors, contract research organizations (CROs), researchers and other stakeholders.

Increasing the number of publications in international journals with a high impact factor: It contributes to increasing Romania's international prestige.

Increasing the number of clinical trials : It can contribute to increasing the number of clinical trials conducted in Romania.

Romania's economic activity: the development of the clinical trials sector, contributes to the increase of investments and the economic productivity of the country.

Recommendation

I. **Create a country report** , which will provide in-depth information on the context, the legislative framework and the benefits of conducting clinical trials in Romania

II. **Participation in the main international events**, where Romania can be represented by groups of experts

III. **Increasing international collaboration,** by creating Centers of Excellence

IV. Fundraising or obtaining grants for **organization of international events** dedicated to clinical studies in Romania

Strategic Intervention Area V: Economic and fiscal measures

Objective 11: Public-Private Partnership (PPP)

General information

Public-private partnerships are forms of collaboration between government and private institutions.

These partnerships aim to generate a positive impact on the evolution of clinical trials in Romania and may include various fields of cooperation, such as information campaigns, clinical research programs and the development of clinical centers.

Context

Currently in Romania there are few examples of public-private partnership, in the past not having a favorable framework for cooperation[43]. At the beginning of 2024, new regulations on public-private partnership were adopted to increase the involvement of the business environment[44].

The opinion of local experts

- Cooperation between public and private entities is seen as an

important factor that can stimulate the creation of a favorable environment for clinical trials in Romania.

- The Health Innovation Hub serves as a positive example of collaboration between the public and private sectors, providing a solid foundation for expanding cooperation.
- In order to facilitate public-private partnerships, Romania requires a legislative framework that allows them to be carried out without bureaucratic impediments, so that the financing and implementation of projects can take place efficiently.

Examples of good practices identified

Belgium – Public-private partnership is considered a crucial element that has contributed to the development of an environment favorable to clinical trials. An example of a public-private partnership is the "PROTECT-trial" involving 19 public and private partners from all over Europe, with the aim of establishing new standards for the clinical use of proton radiotherapy[45].

Spain - has become one of the most important "hubs" in Europe thanks to the public-private partnership in which national authorities, legislators, clinical trial centers, medical professionals, hospitals and patients collaborate. An example is the collaboration between the Bioengineering Institute of Catalonia (IBEC) and Vitala Technologies, a spin-off company founded by IBEC researchers, who have undertaken three public-private partnership projects with a collective budget of almost 4 million euros[46] . Another example is the collaboration between Vall d'Hebron Barcelona and IQVIA through which the clinical research center has become a "main center" for conducting clinical trials[47].

Potential benefits

Skills development: PPPs can contribute to the transfer and exchange of knowledge between teams involved in clinical research.

Increasing credibility: PPPs can strengthen the credibility of research among the patient population.

Increasing quality: PPPs can contribute to improving the quality of the medical act.

Recommendation

I. **Creating public-private partnerships** using the updated legislation (Law no. 7/2024) in potential areas such as:
   - Developing and improving patient access to innovative medicines, particularly in areas of unmet need
   - Collaborations between academia and the private sector for human resource development
   - Developing practices that can increase the quality and efficiency of clinical trials

- Attracting "main center" type centers where clinical research centers or universities can develop together with the private sector priority centers in clinical research

II. **Involvement of Site Management Organizations** to support study compliance, patient recruitment, data collection, and other services related to clinical research activity, etc.

III. Facilitating the deployment of **independent clinical studies** with various funding sources (government, non-profit organizations, universities, private companies, etc.)

IV. TAKING **partnerships with imaging centers and other medical laboratories** , which can contribute to faster identification of patients in clinical trials.

Objective 12: Financial Incentives

General information

The implementation of an economic and fiscal framework that supports the conduct of clinical trials can boost their growth.

It is important to assess economic and fiscal measures in a wider context, as the field of clinical trials is one where the benefits obtained (eg collection of fees and taxes, savings to the CNAS budget, etc.) outweigh the short-term impact generated by the potential measures to stimulate the development of the sector.

Context

Currently, clinical trials do not benefit from financial incentives or tax deductions.

The opinion of local experts

- It is considered that the provision of tax deductions for pharmaceutical companies sponsoring clinical trials (for example, the possibility to deduct the costs of investments in the conduct of clinical trials from the clawback tax) are beneficial measures that will stimulate the increase in the number of clinical trials in Romania.
- The exemption of clinical trials from the payment of VAT is seen as an alignment with other laws that provide exemption from the payment of VAT for certain medical services (for example, Law no. 88/2023).
- Identifying a simpler way of deducting the costs of transport, accommodation, meals given to the patient as well as certain investigations.
- Romania's alignment with the European Union in terms of financial compensation for clinical trials

Examples of good practices identified

Greece – Allows the deductibility of clinical trial expenses from the clawback fee paid by pharmaceutical companies to the national health budget[48].

France – Settlement of certain Research and Development expenses is

allowed from the clawback tax paid by the pharmaceutical companies[49].

Bulgaria – Starting in 2022, the regulations provide for a VAT exemption for supplies of medical products for clinical trials and the conduct of clinical trials. The regulations also include various clarifications related to the related VAT deduction procedures and rules[50].

Hungary - Starting from 2023, Hungary allows pharmaceutical companies tax exemptions. Thus the exceptional tax and/or clawback payment obligation is reduced by up to 50%, with the value of investments in fixed assets or in research and development[51].

Potential benefits

Attractive economic environment: Fiscal and economic measures can create an attractive environment in Romania compared to other countries, and can represent an important differentiating factor

Long-term savings: By providing innovative medicines to enrolled patients, savings can be generated to national health budgets, contributing to budget sustainability.

Positive impact in the economy: According to the study carried out by the McKinsey Health Institute, every $1 spent on clinical trials brings $3 to the economy, contributing positively to the development of the local economic environment[52] [53].

recommendation

I. The inclusion of clinical research activities in the area of medical services, to benefit from **VAT exemption**, thus reducing the costs associated with conducting clinical trials and, at the same time, stimulating innovation in the medical field.

II. The use of information resulting from the conduct of clinical trials in the framework **HTA methodology** , so that the assessment of clinical effectiveness is a criterion used in the inclusion of the drug on the Reimbursement List and for the degree of compensation (expanding the list of drugs to include other types of innovative drugs, not only orphans).

III. **Deduction of expenses** with transport, accommodation and meals provided to the patient within a predefined budget.

IV. Deduction of expenses for drugs used in clinical research from **clawback fee** . This would require a change in legislation to allow pharmaceutical companies to deduct the costs of drugs used in clinical trials from the clawback fee.

V. **Creation of a public fund** for funding research studies. An example can be represented by KCE Trials in Belgium, which is a funding program for non-commercial, multi-centre and large-scale pragmatic randomized clinical trials[54].

Objective 13: Competitive term approval calendar

General information

The contracting process in the field of clinical trials is an important stage in their conduct, any delay contributing to the late start of clinical trials.

A partial standardization of the contract or certain parts would decrease the waiting time for the approval of the study, because it would reduce the aspects that require analysis to the clauses that can be modified by each sponsor according to the specific preferences and objectives of the study, thus facilitating the file evaluation process.

Context

In previous years, the industry producing innovative medicines and the ACCSCR, have developed a standardized model/contract, agreed with the relevant public institutions, including the Biotics Commission. The model was made available to ANMDMR in 2022, before the publication of OMS3390, but it was not implemented.

The opinion of local experts

- Partial standardization would provide a clear and easy procedure for both research centers and CROs.
- Elaboration of a standard contract model, accompanied by a note of recommendation or the existence of a Master Service Agreement (for each company), with an annex included for each individual clinical study
- In order to be able to implement the partial standardization of contracts and their elements, an alignment between the stakeholders involved in the conduct of clinical trials is necessary
- The publication of the contract models on the ANMDMR website is necessary to facilitate quick access for all stakeholders.
- The introduction of electronic systems, standardized and transparent, in order to monitor the payments made within the clinical trials

Examples of good practices identified

Netherlands – An optional model was created by Nefarma (the association of innovative medicines in the Netherlands) and approved by the national authorities for the legal context of clinical trials. All hospitals agreed to use it, thus ensuring a faster start of the clinical trial after the budget was established. If this model does not undergo changes, the only time-consuming part remains the budgeting, due to the negotiation process[55].

France – From April 2022, sponsors wishing to conduct clinical trials with French hospitals are obliged to use new versions of the previous official contracts ("Convention Unique") published in 2016. The main changes in the new contracts are related to the new regulations, including the Clinical Regulation European and GDPR, and the increase in hospital fees. There are adjustments

regarding biological materials, confidentiality and electronic versions of the contract, but many clauses remain unchanged, especially those regarding intellectual property rights and publication[56].

Potential benefits

- ***Reduction of negotiation time:*** Shortening the negotiation period with public institutions and relieving legal resources.
- ***Easier file analysis:*** The existence of a partially standardized contract implies a simplified analysis process, as it requires the verification of only certain clauses.

Recommendation

I. **Partial standardization of parts of the contract** and the implementation of this measure is recommended to simplify the contracting process. In order to identify the main parts that can be subject to standardization, an alignment is needed between the stakeholders to agree on the contracts, payment terms and roles of each party. Standard contracts will be optional.

II. **Promotion of contracts** on a platform (the platform for the promotion of clinical trials) or the ANMDMR website is a necessary measure for their identification by all stakeholders.

III. **Signing contracts** with the clinical research centers, to fall within a maximum period of 60 calendar days, in order to have a competitive advantage.

IV. The introduction of some **electronic, standardized and transparent systems** , in order to monitor the payments made within the clinical trials.

Action Plan

General implementation of the action plan

A general action plan is a strategic tool that provides an overview of the objectives and recommendations proposed for implementation. In addition, the overall action plan can be used as a tool to monitor progress, and provides flexibility in adjusting the strategy according to developments in the context and feedback received.

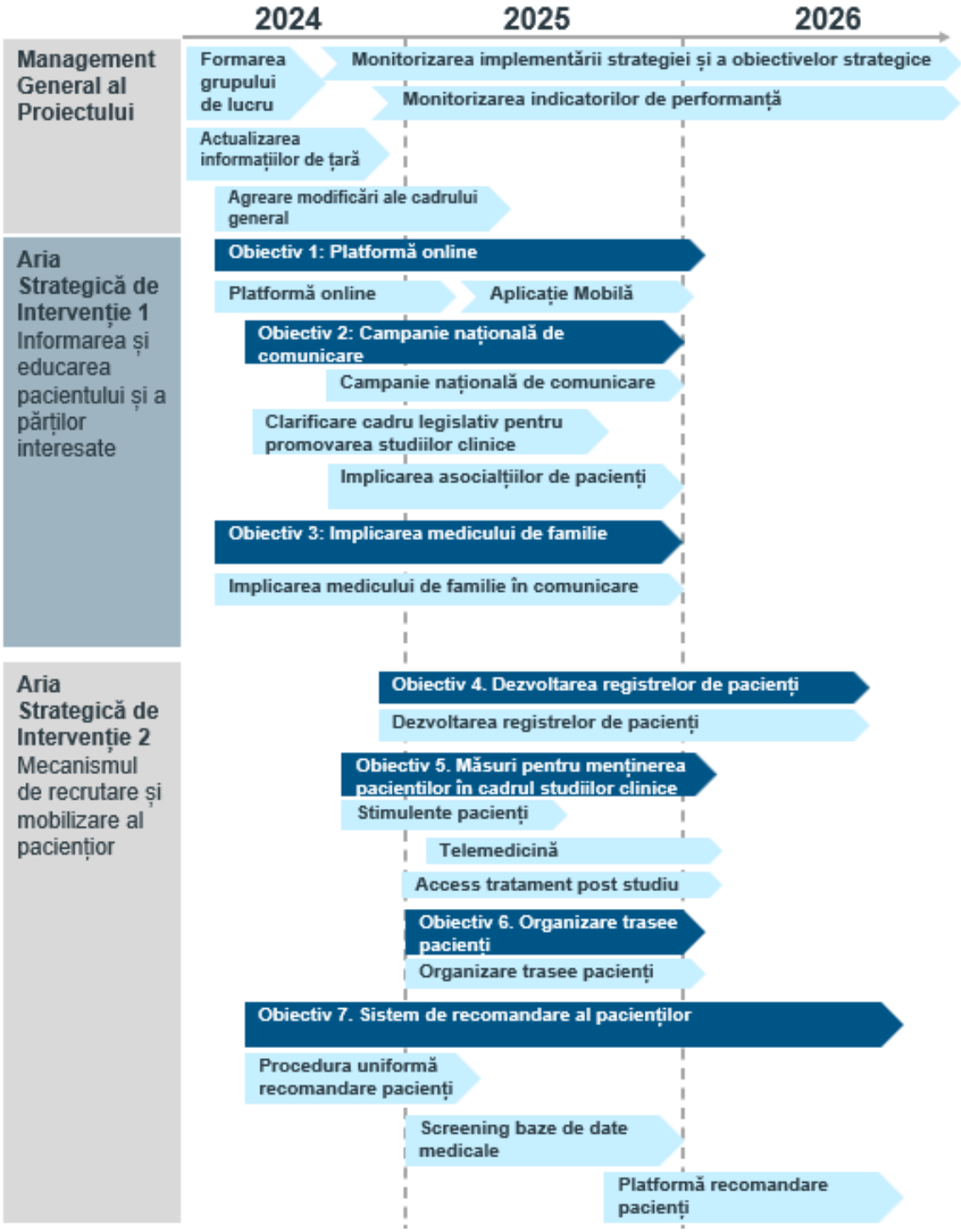
General Project Management

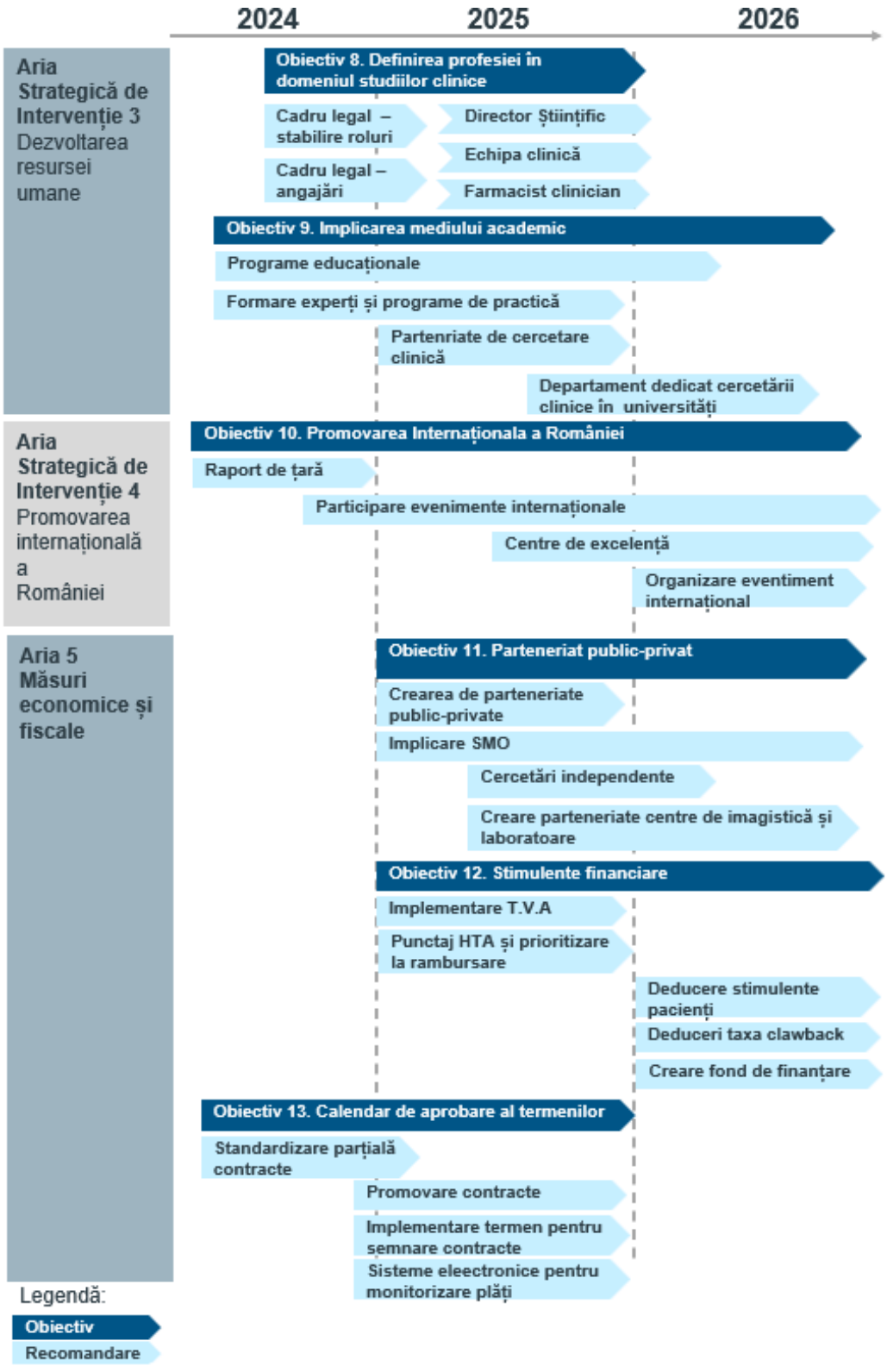
The overall management of the project is an essential component for the successful implementation and monitoring of the strategy and considers the following elements:

1. **Formation of a working group:** The first step in the effective management of the strategic plan is the formation of a working group. It should be composed of professionals representing various stakeholders under the coordination of the competent authority. The working group will be responsible for planning, coordinating and supervising all aspects related to the implementation and monitoring of the strategy.
2. **Update of essential country information on the conduct of clinical trials:** It is essential that the working group has all the relevant information regarding the conduct of clinical trials in Romania. This includes regulations, statistical information on the number of clinical trials, therapeutic areas and types of clinical trials, available medical infrastructure and other aspects that may influence the conduct of the clinical trial.
3. **Monitoring the implementation of the strategy and action plan:** Once the strategy and action plan is agreed upon, the working group will need to closely monitor their implementation. This involves periodically checking progress, identifying any problems or obstacles, and taking the necessary steps to ensure that the implementation is proceeding according to the original plan.
4. **Evaluation of the effectiveness of the implementation of the national strategy:** The working group will be responsible for monitoring the performance indicators. Monitoring these indicators will allow the working group to assess the effectiveness of strategy implementation and make proposals for adjustments if necessary.
5. **Approval of potential changes to the general legal framework:** Identification of the main components of the legislative framework proposed for modification. They establish what are the working norms, the roles of the health units regarding clinical research and education, as well as the involvement of the private environment and how it can contribute to the improvement of the medical infrastructure for carrying

out clinical trials, including public-private partnerships and contracts for the provision of services

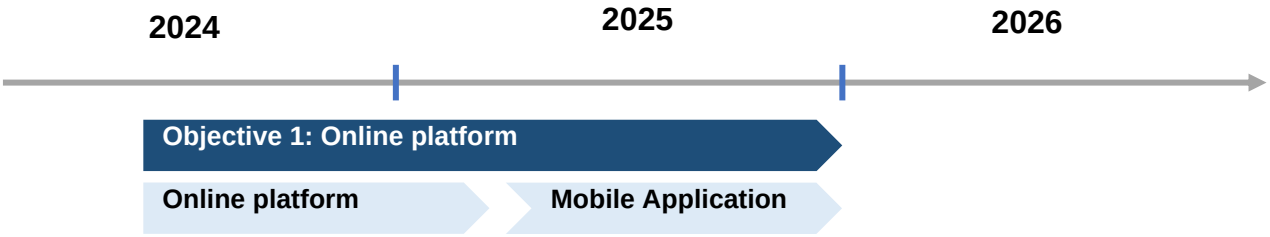
Illustrative 13. Strategic Areas of Intervention and Strategic Objectives




2024
2025
2026
Aria Strategică de Intervenție 3 Dezvoltarea resursei umane
Obiectiv 8. Definirea profesiei în domeniul studiilor clinice
Cadru legal – stabilire roluri
Director Științific
Echipa clinică
Cadru legal – angajări
Farmacist clinician
Obiectiv 9. Implicarea mediului academic
Programe educaționale
Formare experți și programe de practică
Partenriate de cercetare clinică
Departament dedicat cercetării clinice în universități
Aria Strategică de Intervenție 4 Promovarea internațională a României
Obiectiv 10. Promovarea Internațională a României
Raport de țară
Participare evenimente internaționale
Centre de excelență
Organizare eventiment internațional
Aria 5 Măsuri economice și fiscale
Obiectiv 11. Parteneriat public-privat
Crearea de parteneriate public-private
Implicare SMO
Cercetări independente
Creare parteneriate centre de imagistică și laboratoare
Obiectiv 12. Stimulente financiare
Implementare T.V.A
Punctaj HTA și prioritizare la rambursare
Deducere stimulente pacienți
Deduceri taxa clawback
Creare fond de finanțare
Obiectiv 13. Calendar de aprobare al termenilor
Standardizare parțială contracte
Promovare contracte
Implementare termen pentru semnare contracte
Sisteme eleectronice pentru monitorizare plăți
Legendă:
Obiectiv
Recomandare

Objective 1. Creation of a national platform for clinical trials

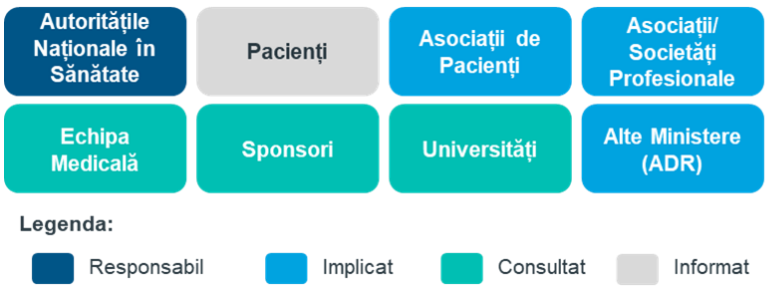
Time horizon



General action plan

1. Creation of the team responsible for the development of the platform. ANMDMR is a key factor in the development of the platform.
2. Defining the purpose, objectives and main components ("must"), as well as secondary ones ("nice to have")
3. Identifying the financial sources necessary for the development of the platform
4. Aligning all stakeholders on proposed models for the online platform (such as but not limited to Belgium, UK, Portugal, Spain, Sweden) and selecting the best model to fit the local context
5. Creation of a minimum viable product (MVP) that can be tested by a limited number of users from different interest groups (investigators, sponsors, patient associations, etc.) in order to collect feedback
6. Implementation of feedback and development of the platform implementing the features identified in the MVP
7. Platform launch
8. Development of the mobile application in a later phase, contextualizing its need according to the metrics available on the online platform (number of users, number of accesses, user feedback, etc.)

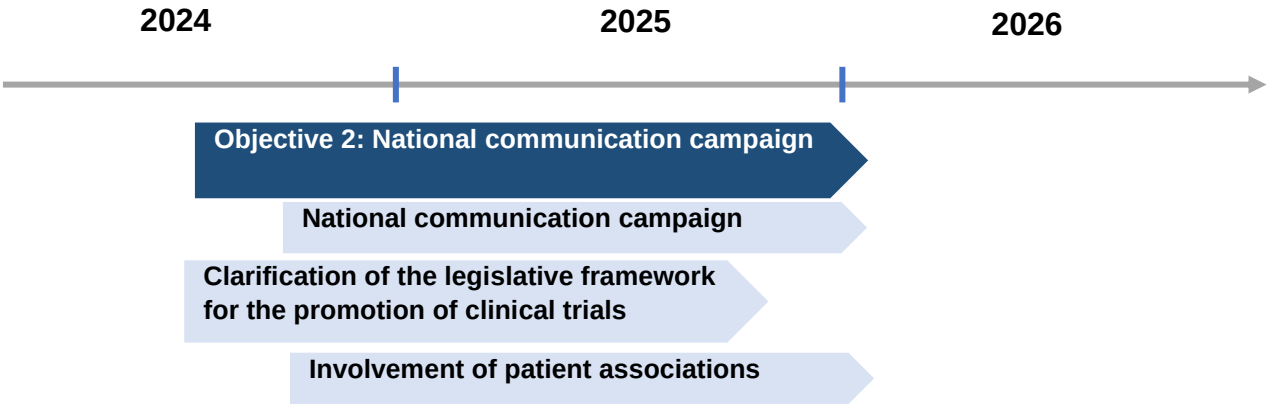
Roles and Responsibilities



ADR = Agency for Digitization of Romania

Objective 2. National communication campaign

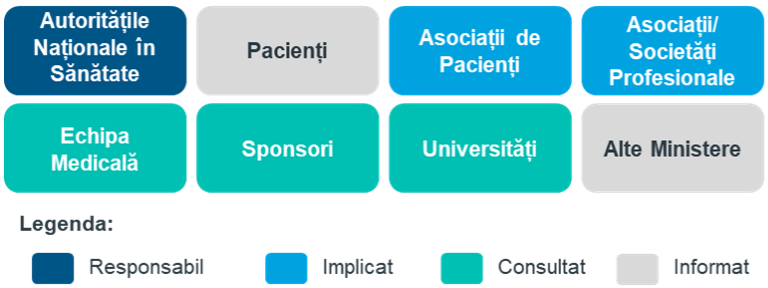
Time horizon



General action plan

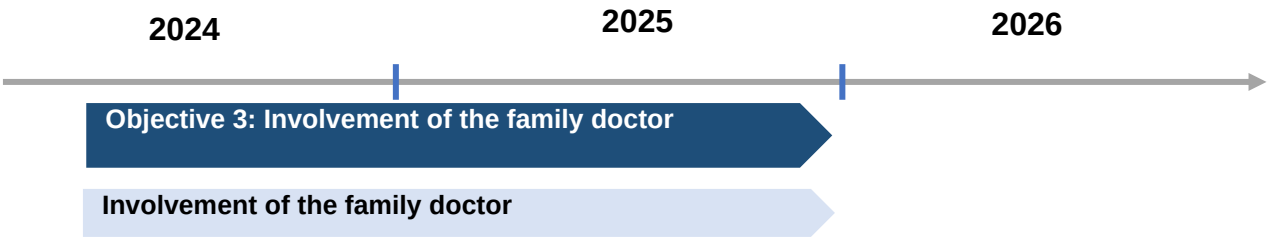
1. Creation of the task force responsible for the management of the national campaign
2. Defining the purpose, objectives and main components of communication. In this stage the key audience and the channels used to disseminate the information will be defined
3. Identifying the financial sources needed for the communication campaign
4. Alignment of all stakeholders on tactical plan and material development
5. Development of the tactical plan and the necessary materials for the promotion
6. Validation of materials with a panel of experts from national authorities, patient associations, professional associations/societies, industry associates, etc.
7. Promotion campaign launch
8. Monitoring and evaluating campaign impact (e.g. involves progress analysis, impact analysis, measurement of relevant metrics, etc.)

Roles and Responsibilities



Objective 3. Involvement of the family doctor

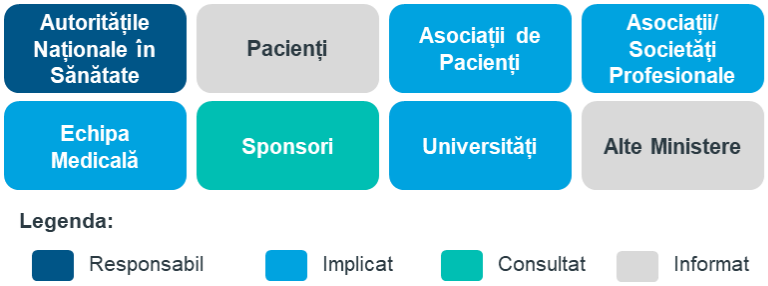
Time horizon



General action plan

1. Establishing a working group responsible for developing a plan to involve family doctors
2. Development of educational materials for GPs on clinical trials and the referral process for a patient in clinical trials
3. Communication of relevant materials to family doctors
4. Organization of free webinars with voluntary participation of family doctors

Roles and Responsibilities



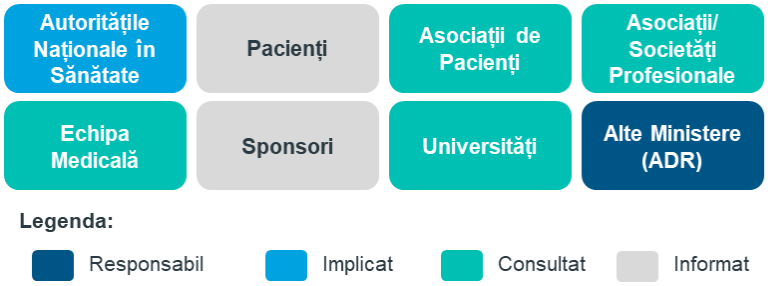
Objective 4. Development of patient registries

Time horizon

General action plan

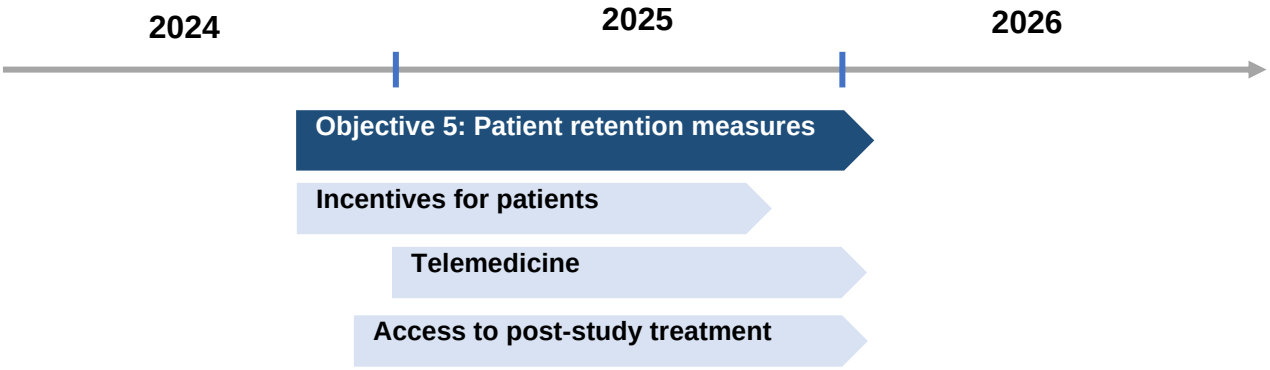
1. Creation of the working group responsible for the development of patient registries
2. Defining the purpose, objectives, implementation plan and informational components
3. Defining the main pathologies for which patient registries should be prioritized in phase I (for example, in phase I registries can be developed for the first 10 pathologies)
4. Identification of good practices at an international or local level (for example the National Registry of Dermato-venereal Diseases or the National Registry of Coronary Syndromes, part of the EuroHeart project of which Romania is a pilot country)
5. Implementation of patient registers at the national level, with the identification of the necessary financial sources
6. Expansion of patient registries in phase II, to other pathologies

Roles and Responsibilities



Objective 5. Measures to maintain patients in clinical trials (retention)

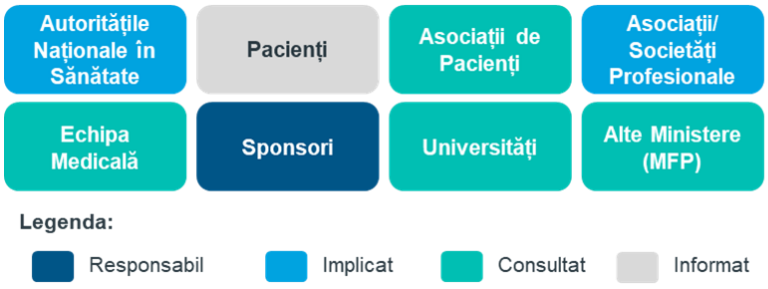
Time horizon



General action plan

1. Establishing a task force responsible for the implementation of patient retention measures
2. Initiating a public consultation to bring together the various stakeholders to discuss and validate potential standard measures that can be implemented for all clinical trials (medical leave, exemption from work, accommodation settlement, transport, food, etc.) and the implementation of telemedicine in clinical trials
3. Creating a plan and measures to implement
4. Testing the measures in 2-3 pilot clinical trials to track benefits and outcomes and improve the final proposal
5. Implementation of proposals by amending the legislative framework (if applicable)

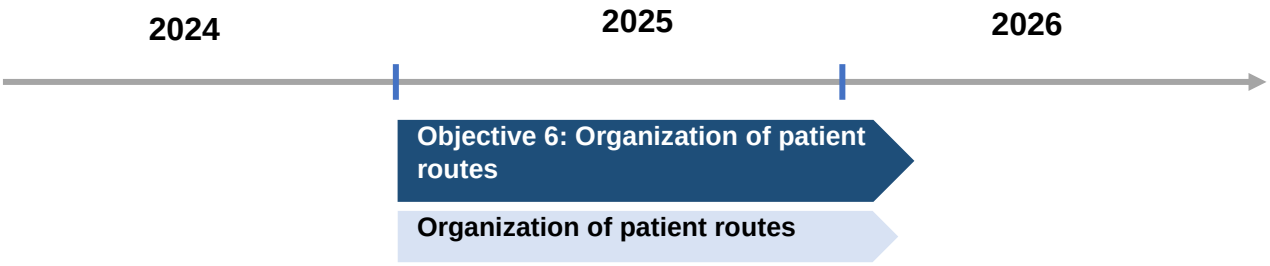
Roles and Responsibilities



MFP = Ministry of Public Finance

Objective 6. Organization of routes for patients

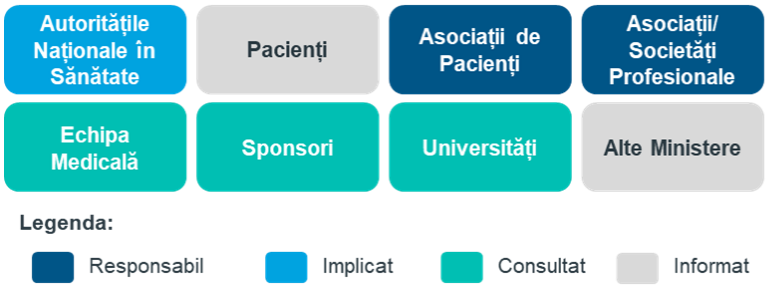
Time horizon



General action plan

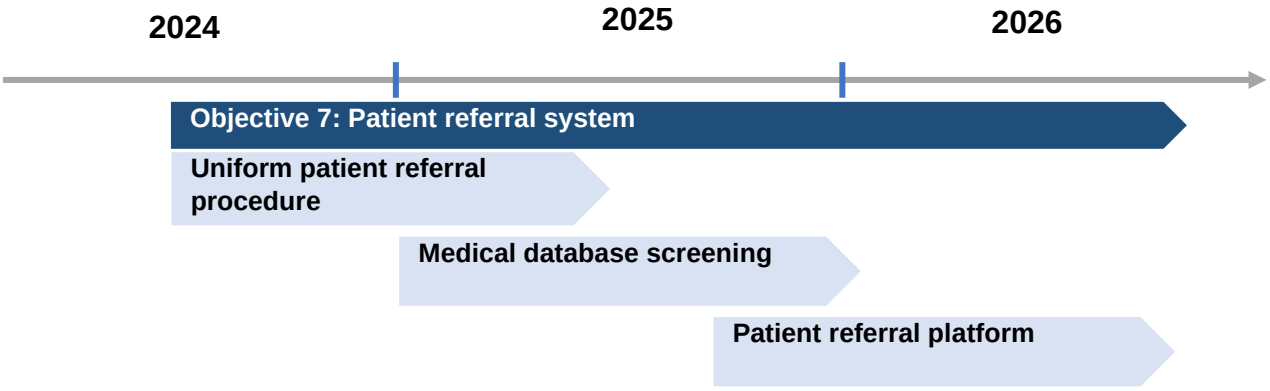
1. The establishment of a technical working group made up of experts from the Ministry of Health (including members of the Specialty Commissions), the Romanian College of Doctors, Patient Associations, CNAS, ANMCS for the development of routes for patients.
2. Selection of the most important pathologies for the development of patient pathways to begin with. After their implementation and testing, patient pathways can be extended to other pathologies.
3. Development of patient pathways and their validation.
4. Implementation of patient pathways, monitoring and optimization.

Roles and Responsibilities



Objective 7. Patient referral system

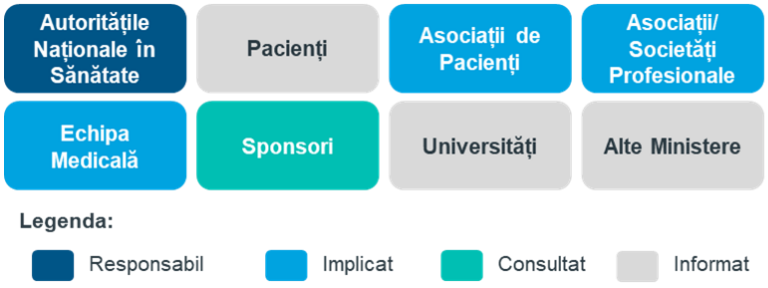
Time horizon



General action plan

1. Establishing a technical working group responsible for and defining technical solutions by which a doctor can refer a patient to a clinical center through a transparent, auditable and easy-to-use electronic system.
2. Identifying how the new system can be integrated with the existing technological infrastructure. Testing the system by creating users who can initiate the recommendation using the online platform (Strategic Objective 1).
3. Defining a concept that will be tested by users to validate system elements.
4. Implementation of the feedback and definition of the final solution to be implemented.
5. Implementation/integration of the solution in the IT system.
6. Carrying out an information campaign regarding the use of the patient referral system.
7. Monitoring and improving the referral system.

Roles and Responsibilities



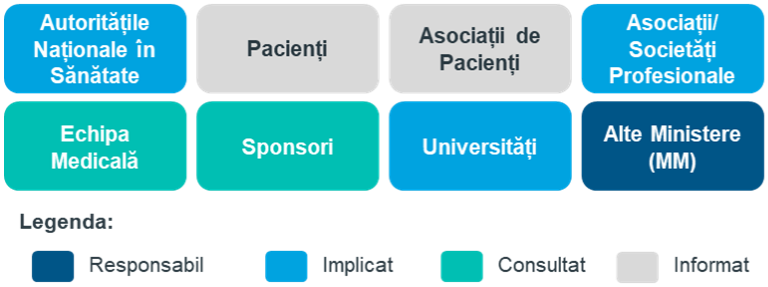
Objective 8. Defining the profession in the field of clinical trials

Time horizon

General action plan

1. Establishing a technical working group to bring together specialists in the field of health, as well as specialists from the Ministry of Labor
2. Defining the clinical professions and other roles involved in the conduct of clinical trials
3. Implementation of the proposal to modify clinical professions by modifying the Nomenclature of Qualifications in Romania
4. Inclusion of clinical trial specialists in the hospital organization chart
5. Re-establishment of the position of Scientific Director
6. Establishing structures dedicated to clinical research
7. Active inclusion of the clinical pharmacist

Roles and Responsibilities



MM = Ministry of Labour

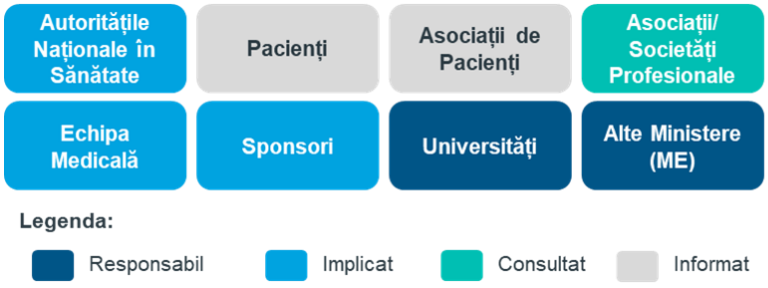
Objective 9. Involvement of the academic environment

Time horizon

General action plan

1. Establishing a working group made up of representatives of the UMF, industry associations, clinical centers/hospitals to organize a framework for the partnership.
2. Identification of common objectives and development of a collaboration plan for the 4 mentioned areas
3. Carrying out feasibility studies on the development of joint clinical research programs and the development of educational programs.
4. Implementation of the collaboration plan

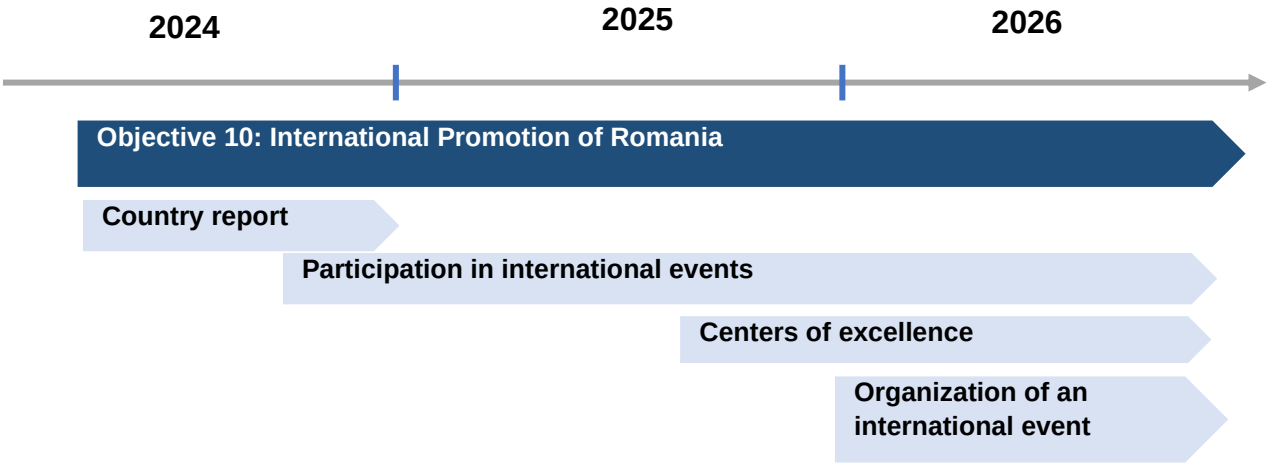
Roles and Responsibilities



ME= Ministry of Education

Objective 10. International promotion of Romania

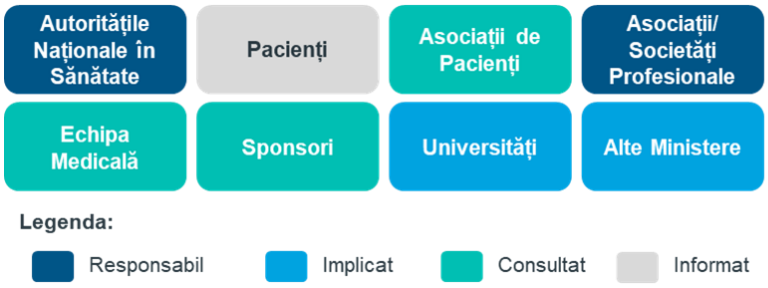
Time horizon



General action plan

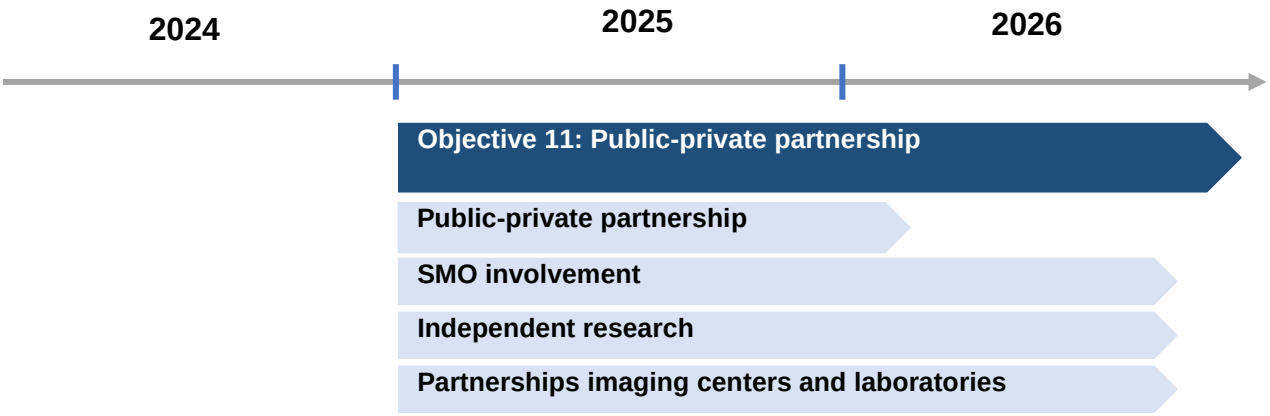
1. The establishment of a working group to coordinate the initiatives regarding the international promotion of Romania
2. Elaboration of a country report through which the clinical trials sector will be analyzed in depth, as well as the creation of simulations regarding Romania's potential. The document can be promoted on the clinical trials platform - a website that provides information about ongoing clinical trials in Romania, general information on clinical trials and external promotion of the local clinical trials sector.
3. Identifying the main events in the field of clinical trials at an international level
4. Development of materials for the promotion of Romania within national events and conferences, as well as at the level of embassies through economic and health attachés
5. Identifying funding sources for the organization of an international event in Romania
6. Romania's proposal as a host country for one of the international events
7. Organization of the international event in Romania
8. Carrying out an impact analysis for the international event
9. Creation of Centers of Excellence

Roles and Responsibilities


Autoritățile Naționale în Sănătate
Pacienți
Asociații de Pacienți
Asociații/ Societăți Profesionale
Echipa Medicală
Sponsori
Universități
Alte Ministere
Legenda:
Responsabil
Implicat
Consultat
Informat

Objective 11. Public-private partnership

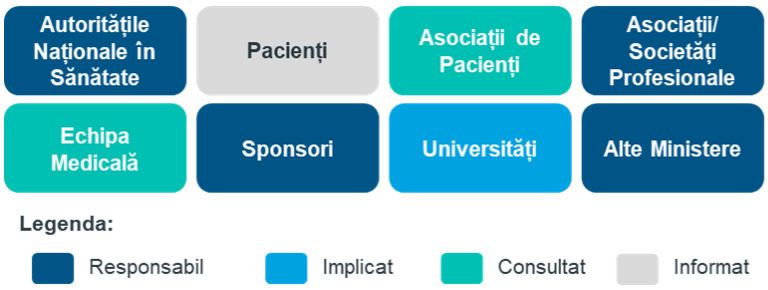
Time horizon



General action plan

1. Establishing a working group made up of representatives from national authorities, sponsors, universities, hospitals and clinical centers to outline the objectives of the potential public-private partnership.
2. Defining the purpose of the partnership and identifying the main objectives and areas of collaboration
3. Development of a plan for the public-private partnership that includes elements such as feasibility study, risk management, potential benefits, etc.
4. Implementation of the public-private partnership and its monitoring during implementation
5. Elaboration of an impact analysis at the end of the partnership, documentation and development of "lessons learned" type documents

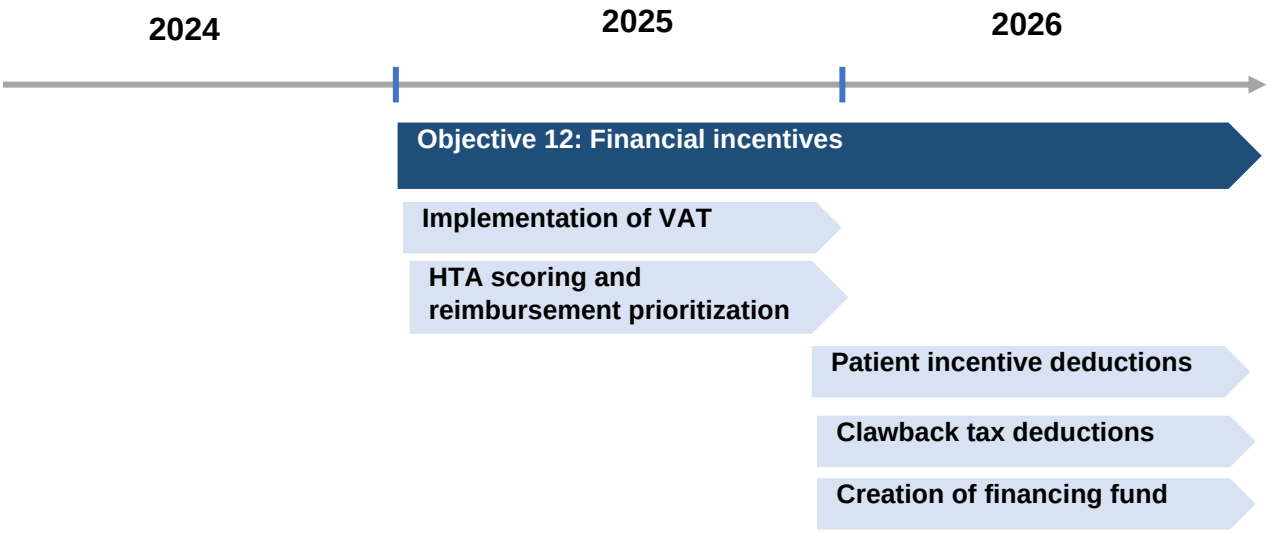
Roles and Responsibilities



Other Ministries: Ministry of Public Finance

Objective 12. Financial incentives

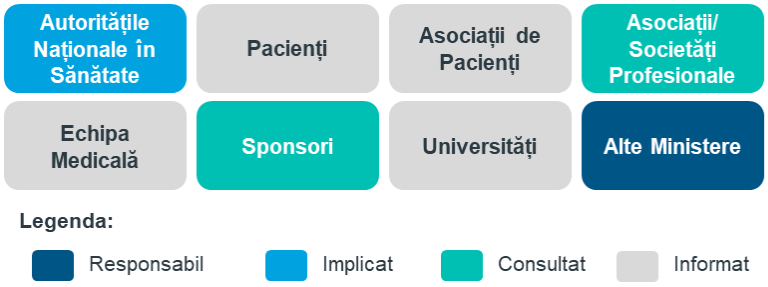
Time horizon



General action plan

1. Establishing a group responsible for carrying out the impact analysis of the proposed measures
2. Creating impact analyzes for proposed measures
3. Discussing the proposed measures in a technical group together with specialists from the Ministry of Public Finance, the Government and the Parliament
4. Discussing the measures regarding the legal changes regarding the implementation of the measures with a group of legal experts
5. Implementation of legislative changes

Roles and Responsibilities



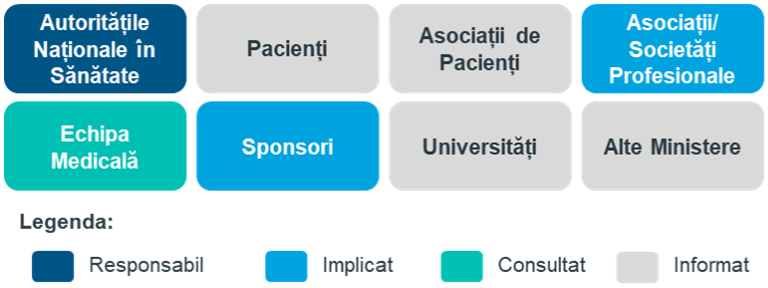
Objective 13. Competitive calendar for approval of contractual terms

Time horizon

General action plan

1. Establishment of a technical working group made up of experts from the Ministry of Health, ANMDMR, CNAS, Sponsors, Bioethics Commission, Representatives of study locations (hospitals, clinics, etc.), Associations/Professional Societies (ACCSCR), etc.
2. Definition of contractual elements that can be standardized, as well as definition of maximum terms for signing contracts
3. Development of standardized contracts
4. Their implementation and promotion on the websites of national authorities

Roles and Responsibilities



Importance of Strategic Objectives and Financial Implications

Name	Importance	Potential sources of funding		
		Public Authorities/ special funds	Private Environment	Academic Environment / Health Units
Strategic Intervention Area 1: Informing and educating patients and stakeholders				
Objective 1: Creation of the Online Platform	●			
Objective 2: National communication campaign	◕			
Objective 3: involvement the family doctor	◕			
Strategic Intervention Area 2: Recruitment and mobilization process				
Objective 4: Development of patient registries	●			
Objective 5: Measures to retain patients in clinical trials	◕			
Objective 6: Organization of routes for patients	◕			
Objective 7: Patient referral system	◕			

Strategic Intervention Area 3: Human resource development				
Objective 8: Defining the profession in clinical trials	◑			
Objective 9: Involvement of the academic environment	◕			
Strategic Intervention Area 4: International Promotion of Romania				
Objective 10: International promotion of Romania	●			
Strategic Intervention Area 5: Economic and fiscal measures				
Objective 11: Public-private partnership	◑			
Objective 12: Financial incentives	●			
Objective 13: Calendar of approval of the contractual terms	◑			

Legenda:

◔ Importanță redusă

● Importanță ridicată

Implicare financiară restrânsă sau inexistentă

Implicare financiară medie

Implicare financiară importantă

The implementation of the National Plan for the development of Clinical Trials requires, in addition to the collaboration between the various stakeholders, the identification of certain

funding sources for each objective. Funding sources can be provided by both the public and the private environment and can take various forms.

Among the sources of funding identified are:

- The State Budget
- Romania's National Recovery and Resilience Plan
- EU4Health
- International grants and programs
- Public-private partnerships
- Industry associations
- NGOs, associations/professional societies

Responsible Institutions

The implementation of the National Strategy for Clinical Trials will be done under the guidance of the National Agency of Medicines and Medical Devices in Romania, coordinated by the Ministry of Health.

As part of the implementation of the strategy, other institutions can be involved for the implementation of the directions of action that allow the achievement of the strategic objectives:

- Ministry of Public Finance
- Ministry of Labour
- Ministry of Education
- Ministry of Research
- National Agency for Digitization of Romania
- The Health Innovation Hub
- University Alliance G6-UMF
- Representative associations for the pharmaceutical industry and for the coordination of clinical trials
- Patient Associations
- Professional associations/societies

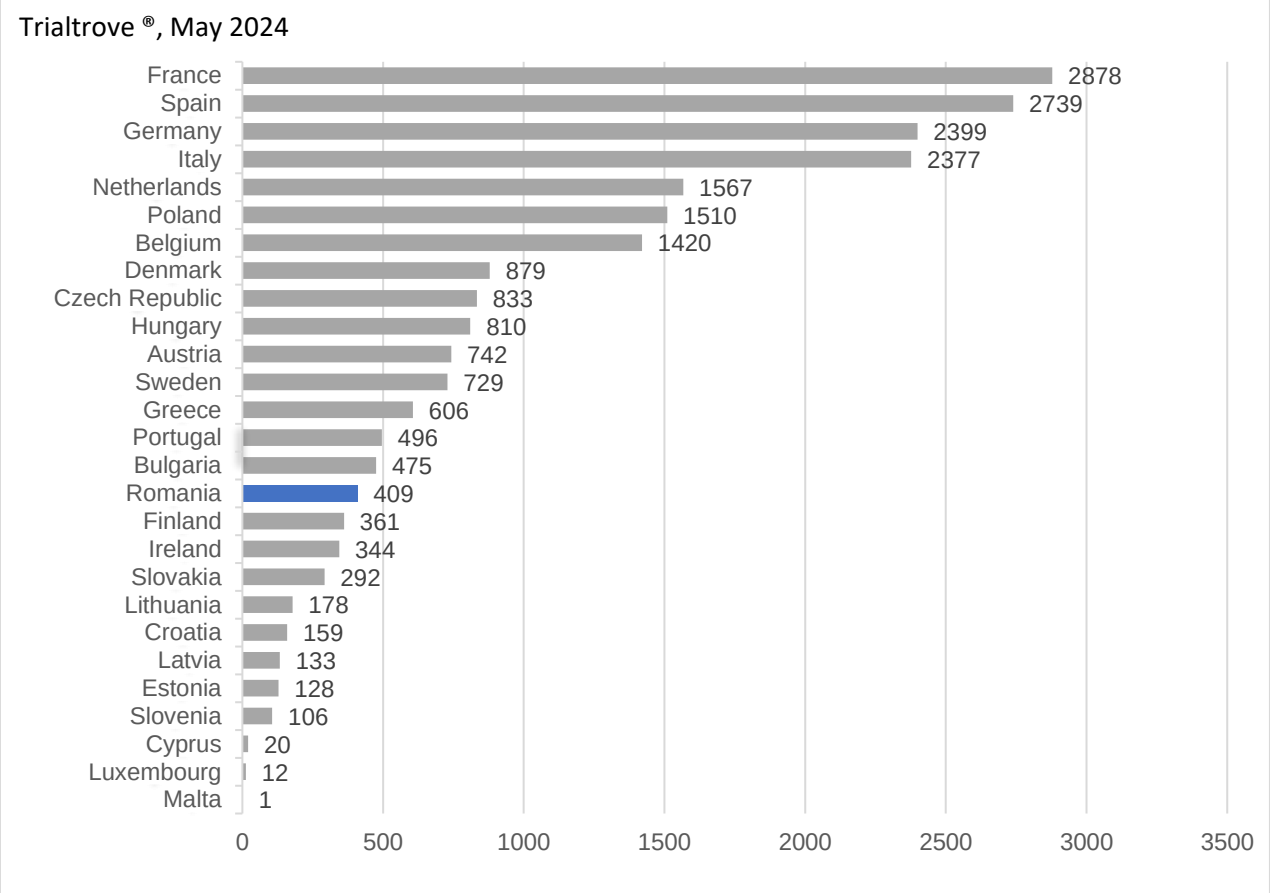
Monitoring

Monitoring performance indicators

The monitoring of this strategy is carried out annually by ANMDMR, based on the annual reports drawn up by the institutions involved in the implementation of the National Strategy for Clinical Trials. The results can be included in a report that will also include a revised action plan to support the implementation, drawn up at the proposal or in collaboration with the partner institutions involved in the implementation of the strategy. The annual reports prepared are published on the website of the National Agency of Medicines and Medical Devices in Romania.

Key performance indicator

Performance indicator name	Description	Value 2023*	Estimate 2026	Source
# Clinical trials record 	The number of clinical trials registered in a calendar year in Romania	*233 - the value from the year 2022 (will be updated)	699	World Health Organization
# Clinical trials in progress 	The number of ongoing clinical trials in Romania	409	1227	EUCROF and Citeline Trialtrove



Secondary performance indicators

One of the main initiatives of the monitoring of the National Plan for the development of Clinical Trials aims to improve the capacity of stakeholders to collect and analyze data. This involves various essential elements such as refining data collection methods, cultivating a data-oriented mindset, optimizing data management and improving data analysis skills, etc.

As the capabilities listed above develop, a series of secondary performance indicators can be tracked, such as:

- Number of patients included in clinical trials
- Patient retention rate
- The number of trained specialists
- The market value of clinical trials in Romania
- Number of centers where clinical trials are conducted
- Reducing the budget allocated to the treatment of patients
- Average time to sign contracts
- Performance in national and international audits and inspections
- Number of clinical trials conducted at phase level

Annexes

Detailing the groups of experts involved in the realization of the national clinical trials strategy

	Ministry of Health
	• Dr. Stefan Strilciuc - *Advisor to the Minister of Health*
	National Agency of Medicines and Medical Devices in Romania
	• Dr. Farm. Razvan Mihai Prisada - President of ANMDMR • Maria Vasilescu - ANMDMR
	The Health Innovation Hub
	• Dr. Teodor Blidaru, Health Innovation Hub Project Manager • Dr. Oana Matei, Country Medical Director, Roche Romania • Iulia Arif-Percă, LAWG Executive Director • Dr. Anca Bundoi, Corporate Affairs Director, AstraZeneca Romania • Dr. Mihaela Joita, Market Access and External Affairs Director, AbbVie Romania • Dr. Cătălin Bucerzan, Country Clinical Operations Manager, AbbVie Romania
	Representatives of the Universities of Medicine and Pharmacy
	• Prof. Dr. Vinereanu Dragoș (Bucharest) • Lecturer Dr. Stefan-Sebastian Busnatu (Bucharest) • Assoc. Prof. Dr. Şușman Sergiu (Cluj) • Assoc. Prof. Dr. Farm. Oancea Carmen Nicoleta (Craiova) • Prof. Dr. Streba Costin (Craiova) • Prof. Dr. Iliescu Radu (Iasi) • Assoc. Prof. Dr. Nistor Ionut (Iasi) • Prof. Dr. Tamba Bogdan (Iasi) • Lecturer Dr. Farm. Chereches Marius (Târgu Mureș)

	• Prof. Dr. Bălașa Rodica (Târgu Mureș) • Prof. Dr. Săndesc Dorel (Timișoara)
	**Principal Investigators** • Prof. Dr. Bumbea Horia • Prof. Dr. Ifteni Petru Iulian • Prof. Dr. Negru Şerban • Prof. Dr. Pușcașiu Lucian • Prof. Dr. Tănase Alina Daniela • Assoc. Prof. Dr. Constantin Magda • Assoc. Prof. Dr. Matei Valentin Petre • Assoc. Prof. Dr. Rădăvoi Daniel George • Assoc. Prof. Dr. Schenker Michael • Assoc. Prof. Dr. Stănculeanu Dana Lucia • Assoc. Prof. Dr. Stănculete Mihaela Fadgyas • Dr. Lăzăroiu Mihaela Cornelia • Dr. Lungulescu Cristian • Dr. Stoica Florina • Dr. Stanca Oana • Dr. Volovat Constantin
	**Patient associations** • Coalition of Chronic Disease Patient Organizations • Association of Patients with Autoimmune Diseases • National Alliance for Rare Diseases • The Alliance of Chronic Patients from Romania
	**Representative associations for the private sector** • Local American Working Group Association - LAWG • Association of Leading Clinical Trials Companies in Romania • Romanian Association of International Medicine Manufacturers

IQVIA	**IQVIA** • Local IQVIA experts • IQVIA experts from other countries (Belgium, Bulgaria, France, Germany, Italy, Poland, Portugal, Spain, Turkey, Netherlands)
	Other stakeholders involved • Prof. Dr. Doina Drăgănescu (Bioethics Commission) • Radu Comșa (Fiscal and economic measures expert)

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