Legal and Regulatory Framework Overseeing Tax, Fiscal and Competition in Regard to Clinical Research Services - Romania, October 2025

I. Navigating Tax Challenges in Clinical Trial Operations

A. VAT implications on clinical research

Clinical research is an essential component in the pharmaceutical development process, with significant implications not only from a medical point of view, but also from a fiscal point of view. Within the framework of European and national regulations concerning Value Added Tax (VAT), the tax treatment applicable to these activities presents several questions relating to the VAT regime governing services rendered in the context of clinical trials.

The VAT regime applicable to clinical research in Romania and in the EU reflects the complexity of the interaction between medical research and tax legislation. Directive 2006/112/EC on the common system of VAT, whose mandatory provisions are transposed into national legislation, provides a general framework for the VAT exemption applicable to medical services, but its applicability in the case of clinical studies varies across EU Member States, depending on how the actions carried out within clinical trials are interpreted and how they are classified in relation to exempt medical activities. In Romania, the approach has been to exclude clinical research activities from the scope of exempt medical services, based on the assessment that such actions do not constitute medical care.

In this context, it is essential for institutions involved in clinical research to thoroughly assess their VAT-related tax obligations, properly document the transfer of goods, and apply the correct VAT treatment. Legislative clarity, harmonization of interpretations, and collaboration between

authorities and the private sector are necessary steps to support a predictable and favorable fiscal framework for the development of medical research in Romania.

- *VAT regime at EU level*

At the level of the European Union, the VAT regime is established by Directive 2006/112/EC. This directive provides for the applicability of VAT exemption for hospitalization, medical care, and related activities provided by bodies governed by public law or, under social conditions comparable to those applicable bodies governed by public law, by hospitals, medical treatment or diagnostic centres, and other similar institutions that are duly recognized.

Most EU Member States apply VAT to commercial clinical trials, unless these trials are part of medical care (e.g., France, Italy, Spain, Belgium, Austria, Netherlands, Germany).

- *VAT regime in Romania*

In Romania, the VAT regime is governed by the provisions of the Fiscal Code, which stipulates the application of VAT exemption for hospitalization, medical care, and operations closely related to these services, carried out by authorized units for such activities, regardless of their organizational form, such as: hospitals, sanatoriums, rural or urban health centres, dispensaries, medical offices and laboratories, medical care and diagnostic centres, treatment and recovery facilities, ambulance stations, and other units authorized to perform such activities.

However, the VAT law explicitly states that the VAT exemption does not apply to services provided by investigator physicians for conducting clinical trials with medicinal products for human use, as defined in art. 21 of the Norms on the implementation of good practice rules in the conduct of clinical trials with medicinal products for human use, approved by Order of the Minister of Public Health no. 904/2006.

As a result, an increasing number of healthcare operators — clinics, research centres, or medical institutions — simultaneously carry out VAT-exempt medical services and clinical research activities, such as sponsored clinical trials which are subject to 21% VAT. This combination of activities requires careful fiscal analysis, as the obligation to register for VAT purposes may arise upon exceeding the threshold of RON 395,000 from taxable operations (such as clinical trials) as well as exempt operations with the right of deduction (such as exports of goods); however, VAT-exempt medical services are not included in this threshold.

Once the VAT registration obligation arises, the healthcare operator becomes subject to various other fiscal obligations, such as issuing invoices and submitting them through the RO e-Invoice system, filing VAT returns, but also the possibility of applying the pro-rata deduction since its taxable activities allow for the full or partial deduction of VAT, while common expenses (e.g. rent, utilities, equipment) will be deducted proportionally to the share of taxable activities.

- *Transfer of goods within clinical trials*

Within clinical trials, the transfer of goods—such as investigational medicinal products (IMPs), medical equipment, or laboratory materials—between European Union Member States may trigger a VAT registration obligation in the destination country, at least until 2028 when the provisions regarding the “single VAT registration” are set to take effect. These obligations arise for goods shipped directly to testing centres or hospitals, without the involvement of a local intermediary.

However, the interpretation of these situations is not uniform across the EU, as the VAT registration obligation may differ, although the requirements to monitor such transfers of goods within the European Union through inclusion in the VIES reporting system exists in all Member States. In Romania, VAT registration is the mechanism that facilitates the fulfilment of this reporting obligation for both Romanian and foreign entities that bring such goods into Romania from another Member State. This lack of harmonization creates legal uncertainty for clinical research operators, who should analyse the legislation and fiscal practices of each individual Member State. However,

from 2028, the "single VAT registration" will be available, allowing the reporting of all these movements in the Member State of residence, and this rule will be applied uniformly at EU level.

It is also important to verify whether the goods are used exclusively for research purposes or if they can be considered part of a broader medical service, as this may affect the applicable tax regime.

B. Tax deductions and incentives granted in the field of R&D

In Romania, there are tax incentives for research and development ("R&D") activities, such as an additional 50% deduction of eligible expenses when calculating corporate income tax or income tax exemption for employees involved in R&D activities.

Many companies still do not access them due to bureaucracy and the lack of clarity regarding eligible operations, making it truly necessary to conduct a more detailed substantive analysis of the activities carried out and their classification as R&D activities in line with local legislation and industry standards.

Although there are indeed no specific tax incentives for clinical trials at this time, e.g. deductions from corporate income tax/tax reductions for personnel engaged in clinical trial activities or reductions in pharmaceutical contributions paid by pharmaceutical companies for investments in clinical trials (as already exist in other EU countries such as France, Hungary, Greece), the general tax incentives for R&D activities above could be explored for clinical trials as well. In this regard, a specific and case-by-case analysis of the specific activities carried out at the level of local pharmaceutical companies/CROs is required in relation to the conditions required to be met under tax legislation and related guidelines (e.g. Frascati Manual) to verify the classification as research and development activity and the applicability of this incentive in the field of clinical trials.

As a general rule, we include below some mentions and examples regarding clinical trials from the Frascati Manual that are relevant in the aforementioned analysis, as potential research and development activities must comply with standards in the field and it is necessary that the activities carried out by taxpayers be verified with the guide and examples from the Frascati Manual.

Before medicines, treatments or vaccines for human use are brought to the market, they are systematically tested on human volunteers to ensure that they are effective. These clinical trials have 4 standard phases, 3 of which take place before manufacturing permission is granted. For the purpose of international comparison, by convention, phases 1, 2 and 3 of clinical trials can be treated as research and development. Phase 4 clinical trials, which continue testing of the medicine or treatment after approval and manufacturing, should only be treated as research and development if they bring about further scientific or technological progress.

However, a clinical trial, regardless of its phase, has several stages of research and development, and some are not considered research and development activities. Thus, while the concept stage (consultation, relevance of the study, recourse to experts) and the methodological stage (definition of the study phase, protocol development, positioning the study in the general context of the disease strategy and its treatments) would qualify as eligible stages, the ineligible stages would be the feasibility stage (assessment of the situation in the field, availability centres, etc.), the implementation stage (operations of choosing a country where the tests will take place, carrying out regulatory and ethical procedures, approval by ad hoc bodies, for training the staff of the protocol centres), the recruitment/designation stage of patients.

Furthermore, not all activities that occur before the manufacturing process are considered to be research and development activities, especially when there is a long period of time after the completion of phase 3 testing, during which marketing activities and process development can be initiated.

Thus, depending on the stage of the clinical study and the activities actually carried out in Romania, a possible qualification as research and development activity and, implicitly, eligibility for the facilities for research and development activities mentioned above, could be explored on a case-by-case basis in line with the applicable legislation.

C. Transfer pricing implications

Activities related to the conduct of clinical trials in Romania for other group entities must be remunerated appropriately in line with the substance of the transactions and the applicable local transfer pricing rules. Services provided by local entities for the benefit of another group entity (the sponsor that effectively finances the conduct of the trial) may include the development and conduct of clinical trials, including administrative activities that support the services related to the clinical trials. Local group entities may perform these services directly or by contracting affiliated or unaffiliated parties to partially or fully perform these responsibilities.

For these services, the local group entities are entitled to remuneration covering all direct and indirect costs incurred for the coordination and supervision of the studies. These costs should be subject to an "arm's length" mark-up to ensure compensation at the market level, in line with the provisions on transfer pricing. Specifically, "pass-through" expenses (expenses incurred in relation to third parties, mainly for payments to investigators, materials for clinical trials, travel, clinical grants, other contractors/professional services), which usually represent the most significant part of the costs incurred, should be included in the basis on which the mark-up is applied. Excluding these types of expenses from the application of the mark-up may raise questions from tax authorities, including potential transfer pricing adjustments, which may result in additional tax liabilities at the level of the local entities together with interest and late payment penalties.

Thus, local pharmaceutical entities carrying out clinical trial activities should pay high importance to these aspects and ensure strong documentation to support the remuneration at the market level in line with the provisions of local legislation.

II. Regulatory Challenges in the Field of Clinical Research Studies

A. Guaranteeing a free and competitive market by strictly following competition rules and those prohibiting unfair trade practices

The clinical trials market in Romania can only develop if national and European competition rules and those prohibiting unfair commercial practices are respected by all players. The Competition Council must act both preventively, by providing the necessary guidance, and reactively, by correcting possible anti-competitive behaviours such as agreements to align or impose prices or other commercial conditions, direct or indirect exchanges of sensitive information, especially in oligopolistic markets, or various forms of abuse of dominant position through which companies with large market shares and/or superior bargaining power impose commercial conditions and terms, take advantage of the dependence of smaller players and thus distort competition.

Anti-competitive practices are discouraged through a combination of supervision, legislation and severe sanctions. In terms of supervision, at national level, this is carried out by the Competition Council, and at European Union level, by the European Commission. As regards the application of legislation in the field, in Romania, the Competition Council applies Competition Law no. 21/1996 which sanctions anti-competitive behaviour such as price cartels, abuse of dominant position, discrimination, as well as Law no. 11/1991 on unfair competition which sanctions, among other unfair practices, the abuse of a superior negotiating position by exploiting a state of dependence. At European Union level, the European Commission applies Articles 101 and 102 TFEU which prohibit and sanction the same anti-competitive behaviours in a mirror image.

The pharmaceutical industry has been intensively monitored by the competition authorities of the member states, including the Romanian Competition Council, with an important case history at European level in which various anti-competitive behaviours have been sanctioned (for example, actions that prevented or delayed the entry of new players or new medicines into the market, through pay-for-delay techniques or through the dissemination of false and defamatory information).

In situations where players have market power, which usually translates into superior bargaining power, certain practices and behaviours can generate negative effects on partners, the competitive phenomenon and the market in general. Most of the time, independent clinical trial centres, in a state of economic dependence and in an unequal power relationship are the most vulnerable. Such practices can lead an unsustainable decrease of prices, distorted competition and last but not least, can affect patients.

Such anti-competitive behaviour may take the form of imposing contractual terms (payment terms, budgets, delivery terms, etc.) beyond any objective justification during negotiations, as well as forcing the exclusive use of certain clinical trial centres or favouring some over others. Such practices may hinder the access of independent centres to the market, thus artificially limiting competition and market development.

Similar impacts on the market may result from practices that favour certain centres through more complex selection or authorization procedures, delays in centre authorization without clear justification, or by not treating independent centres equally in selection processes. At the same time, a possible exclusivity of large clinical trial centres to work only with certain sponsors can lead to market closure by limiting access to other interested sponsors.

The establishment of budgets and price elements in the clinical trials market, which are normally the preserve of the free market, can also be subject to anti-competitive behavior by players, consisting of concerted practices, information exchanges, even indirect ones, for example through

third-party organizations (contract research organizations), which can significantly influence the budgets allocated to the conduct of clinical trials. Moreover, the lack of balanced negotiation mechanisms can lead to a tendency for centres to act in a coordinated manner in the market to respond to the price pressure exerted by sponsors and third-party organizations.

Establishing the market from the outset on fair and balanced premises and mechanisms for negotiation and interaction between the various players can significantly contribute to a healthy development of the market in the long term. Such a proactive and preventive approach, which can come from the competent authorities, including the competition authority, can take various forms such as publishing specific guidelines on the negotiation and conclusion of contracts, letters of comfort on certain issues specific to the industry, providing model contracts/clauses that do not contravene competition rules, disseminating good practices found in other jurisdictions.

B. National regulation vs. European legislative framework in the field of clinical trials. The challenges of legislative harmonization in the field of clinical trials

The recognition of the need for a harmonised legal framework for clinical trials has led the European legislator to take significant steps in this direction. Thus, as of 31 January 2022, clinical trials conducted in the European Union are regulated by Regulation (EU) No 536/2014. The Regulation aims, among other things, to simplify and accelerate the procedures for authorising clinical trials in order to ensure that the European Union remains an attractive centre for clinical research. The Regulation provides a uniform framework but also allows Member States to adopt additional measures for implementation, including administrative or professional requirements.

Romania has transposed this Regulation into national legislation, but the analysis of the domestic legislative framework reveals the existence of additional requirements and approvals that may make it more difficult to conduct clinical trials in Romania compared to other Member States.

A relevant example is the definition of the investigator. According to European legislation, the investigator must be a doctor, as defined in national law, or a person exercising a profession recognised in Member State concerned as meeting the requirements for the position of investigator, by virtue of the scientific knowledge and the necessary experience in the field of healthcare. Other natural persons involved in the conduct of a clinical trial must have the appropriate qualifications to perform their tasks, obtained through education, training and experience.

In Romania, however, the legislation requires that the investigator, respectively the principal investigator, be a specialist physician, with more than 3 years of experience in the specialty or a primary care physician. The investigation team may include, in addition to the investigators, other appropriately qualified individuals who must have one of the following professions, as well as the qualifications necessary to exercise it: resident physician, researcher, pharmacist, physicist, biologist, chemist, medical assistant, psychologist or IT specialist. Although this requirement has not been eliminated from national legislation, in current practice this qualification is retained only for the principal investigators.

Another aspect that differentiates Romania is the approval procedure for genetically modified organisms (GMOs) at the Ministry of Environment, required for clinical trials for CAR-T therapies – gene therapies with viral vectors, recombinant ADN/RNA vaccines, modified bacteria. Although this approval is also required in other EU countries, in Romania the process is laborious, with an approval time that can reach up to six months.

The practice of national regulatory and ethical approval authorities to frequently request clarifications and additional documents (RFIs) for the purpose of clinical trial authorization can lead to a longer and more difficult to implement authorization process compared to other Member States. A series of additional local documents are required above European standards, thus limiting the number of eligible centres and investigators in Romania. These administrative barriers

can lead to significant delays and reduce Romania's attractiveness as a destination for clinical research.

It is essential that the national legislator and regulatory institutions constantly re-evaluate these requirements, aligning them with the goal pursued by the European legislator of simplifying and streamlining/accelerating the procedures for authorizing clinical trials. Only by implementing a transparent, harmonized and predictable legal framework Romania can become a competitive player in the field of clinical trials at the European level.