

**PNRR Mission 4, Component 2, Investment 1.4 "Strengthening of research and research facilities"**

**creation of "national R&D champions" on some Key Enabling Technologies"**

**Initiative funded by the European Union -- NextGenerationEU.**

**National Center for Gene Therapy and Drugs based on RNA Technology**

**Development of gene therapy and drugs with RNA technology**

**MUR project code: CN00000041 – CUP UNINA: E63C22000940007**

## **UNIVERSITY OF NAPLES FEDERICO II**



### **DEPARTMENT OF PHARMACY**

#### **SPECIAL TENDER SPECIFICATIONS**

**Open procedure with the application of the criterion of the most economically advantageous offer identified on the basis of the best value for money, pursuant to art. 71 and 108 paragraph 1 of Legislative Decree no. 36/2023 as amended and supplemented concerning the supply of an "Automated mRNA Production System at scale suitable for drug discovery and preclinical development with Critical Reagent Supply and Processing System".**

**CUP: E63C22000940007 - CUI: F00876220633202400035**

#### **Art. 1 – Object of the contract**

The contract concerns the supply of an **"Automated mRNA Production System at scale suitable for drug discovery and preclinical development with Critical Reagent Supply and Processing System"**.

The scientific instrumentation, which is the subject of these specifications, must be supplied complete with everything necessary for its operation.

The supply must also be equipped with all the necessary accessories, even if not detectable in these Specifications, to give the supply itself finished and fully functional.

All materials, appliances and equipment supplied and functioning must be of the highest quality, worked in a workmanlike manner and corresponding to the service for which they are intended. The systems will have to be certified in accordance with current regulations.

Therefore, the supply includes ancillary and related services of delivery, installation in a workmanlike manner and according to the provisions of these Specifications, possibly supplemented, where necessary, by the indications specifically provided by the Sole Project Manager, configuration, testing, training and operational start-up of the equipment, as well as the warranty management of the equipment.

This tender is funded under the PNRR project Mission 4, Component 2, Investment 1.4 *"Strengthening research facilities and creation of 'national R&D champions' on some Key Enabling Technologies"* Initiative funded by the

European Union – NextGenerationEU- National Center for Gene Therapy and Drugs based on RNA Technology  
Development of gene therapy and drugs with RNA technology - MUR project code: CN00000041 – CUP UNINA:  
E63C22000940007.

The contract concerns the supply, installation, testing and training of an "Automated mRNA Production System at scale suitable for drug discovery and preclinical development with Critical Reagent Supply and Processing System".

## Art. 2 – Procurement regulations

This contract is regulated, by way of example but not limited to, by the following laws and regulatory texts:

- Legislative Decree No. 36/2023, containing the "*Code of Public Contracts in implementation of Article 1 of Law No. 78 of 21 June 2022, delegating to the Government in the field of public contracts*";
- Decree-Law no. 77/2021 as amended;
- Law no. 241/1990;
- Rules of the Civil Code;
- Current PIAO approved by Board of Directors Resolution of 30/01/2024 which includes the measures to prevent Corruption and University Transparency;
- Current University Code of Conduct, attached to the current PIAO approved by Board of Directors Resolution of 30/01/2024;
- Presidential Decree no. 81 of 2023 containing the "National Code of Conduct for Public Employees";
- Provisions contained in the Legality Protocol Memorandum of Understanding for the legality and prevention of criminal infiltration attempts in the legal economy of the Prefecture of Naples, to which the University adhered on 10/12/2021;
- Rules on the traceability of financial flows pursuant to Law no. 136 of 13 August 2010;
- Additional special laws apply.

## Art. 3 – Description and methods of execution of the supply

All the equipment to be supplied must be delivered, made operational and validated at the full expense of the economic operator, under the coordination of the Sole Project Manager in order to meet all the specifications of these Specifications and the tender documents. The contractor must also guarantee the following activities, to be considered fully remunerated in the price offered at the time of the tender: transport, unloading, assembly, on-site positioning, separate collection, packaging disposal, installation, configuration, training, warranty, etc.

The transport will be carried out by and at the expense of the contractor, who must provide with personnel at his disposal for the delivery to the supply floor in the following premises:

- Department of Pharmacy of the University of Naples Federico II, via Tommaso De Amicis floor -1 (NA) (NUTS code ITF33);

The supply must be made **within 4 months** from the signing of the contract (or from the report of early execution, pursuant to Articles 17 par. 8, 9 of Legislative Decree 36/2023 as amended, and Article 8 of Law No. 120 of 11 September 2020, converting into law, with amendments, Legislative Decree No. 76 of 16 July 2020);

The above times include the transport and commissioning of the entire delivery. The delivery of the supply must take place in a single solution, at the end of which a special delivery report will be drawn up and a specific conformity check will be carried out. It is understood that the supply must be completed within the time limits indicated above. All equipment supplied must bear the certification marks recognized by all countries of the European Union and must comply with the standards relating to electromagnetic compatibility. The Supplier must ensure that the equipment complies with CEI standards or other recognized international provisions and, in general, with the laws, regulations and technical standards in force governing the components and methods of use of the equipment for the purposes of user safety.

By way of example and not limited to, the equipment supplied must comply:

- The requirements established in Legislative Decree no. 81/2008 and subsequent amendments;
- The ergonomic requirements established in EEC Directive 90/270 transposed into Italian legislation with Law no. 142 of 19 February 1992;
- Safety (e.g. IMQ) and electromagnetic emission (e.g. FCC) requirements certified by bodies recognized at European level;
- The equipment supplied must comply with the provisions of Legislative Decree no. 80 of 18 May 2016 relating to Electromagnetic Compatibility (EMC) and consequently be CE marked and certified;
- The immunity requirements defined by the EN55024;
- The requirements relating to the restriction of the use of hazardous substances provided for by current legislation, and in particular by Directive 2011/65/EU, (RoHS II), transposed by Legislative Decree no. 27 of 4 March 2014 as amended;

After delivery, they must be installed and put into operation. For installation and connections of all kinds, the contractor must provide:

- the installation of the equipment provided in a workmanlike manner;
- post-installation electrical safety checks as per current regulations;
- connection to existing systems;
- any other work that may be necessary even if not explicitly provided for in this document.

The economic operator must provide for the complete disposal of the resulting material (packaging, etc.), at its own care and expense, as a charge included in the supply price.

The execution of the activities indicated above must take place in compliance with the contract, these special tender specifications and the technical supply specifications and any other prescription deriving from the tender documents, as well as the contractor's technical offer.

For the delivery, a special "delivery and assembly report" must be drawn up by the Supplier, together with the Sole Project Manager, in consultation with the Contracting Authority, in which the suitability of the places where the equipment is placed must be acknowledged, as well as the following information must be reported:

The date and place of delivery and assembly;

- the object of the supply;
- The date and number of the order (contract, etc.)

The serial numbers of the equipment and any additional elements;

The signing of the report by the person in charge of the Supplier and the Administration will conclude the "Delivery and Assembly" activities, allowing the start of the subsequent phase of "Configuration and Operational Start-up".

#### **Art. 4 – Training and warranty assistance**

The contractor must also aid and support to the contracting authority by carrying out training activities.

In addition to the above, the supplier must guarantee the proper functioning of the equipment supplied for a period of at least 12 (twelve) months from the date of passing the verification of conformity of the instrumentation. This warranty must include repairs or replacements of parts (with the exception of the so-called "consumable" parts clearly identifiable in the accompanying documentation) necessary for the optimal functioning of the instrumentation.

Travel expenses and labor costs of technicians at the delivery and installation site must also be considered included in the warranty.

#### **Art. 5 – OBLIGATIONS OF THE CONTRACTOR**

The contractor, in the performance of the supply, must use the diligence required by the nature of the service due on the basis of the provisions of the contract and all the documents that are an integral and substantial part thereof, as indicated in art. 6.

Participation in the procedure and the stipulation of the contract by the contractor is equivalent to a declaration of perfect and complete knowledge and acceptance of all the regulations in force on public procurement contracts, the rules governing this contract, as well as the conditions relating to the execution of the supply.

Participation in the procedure and the stipulation of the contract by the contractor is also equivalent to a declaration of the existence of the conditions that allow the immediate execution of the supply.

The contractor is required to carry out the supply in accordance with what is proposed in the technical offer, which constitutes a contractual obligation. Failure to comply with what was offered during the tender therefore constitutes a serious breach of contract.

Finally, since this is a contract financed with funds from the resources of the PNRR, the contractor is required to comply with:

- the "*Do No Significant Harm*" (DNSH) principle, i.e. "*do no significant harm*", according to which no measure funded by notices must cause damage to environmental objectives, in line with Article 17 of Regulation (EU) 2020/852. This principle aims to prove that the planned investments and reforms do not hamper climate change mitigation;
- the additional cross-cutting principles provided for by the PNRR, such as, among other things, the principle of contribution to the climate and digital objective (so-called tagging), the principle of gender equality and the obligation to protect and enhance young people;
- the obligations referred to in art. 47 of Legislative Decree 77/2021 that are applicable in relation to its company size, in the pursuit of the principles of equal opportunities, generational and gender, as well as to promote the employment inclusion of disabled people.

#### **Art. 6 – DOCUMENTS THAT ARE PART OF THE CONTRACT**

The following are considered to be an integral and substantial part of the contract:

- the special tender specifications;
- the technical supply document;
- the contractor's technical offer;
- the contractor's economic offer.

#### **Art. 7 – DURATION OF THE CONTRACT AND DELIVERY TIMES OF THE SUPPLY**

The equipment covered by this supply contract must be delivered to the contracting authority **within 4 months** from the signing of the contract or from the early delivery of the supply.

The term is intended to encompass all activities, not only the "delivery" of equipment, but also installation, configuration, start-up.

#### **Art. 8 – DIRECTOR OF CONTRACT EXECUTION**

Pursuant to Article 8, paragraph 4 of Annex I.2 and Article 32 of Annex II.14 to the Code, since these are "*particularly complex interventions from a technological point of view*", and specifically "*supplies of particular importance for an amount exceeding € 500,000.00*", the Director of Contract Execution is appointed. The name of the DEC shall be communicated to the contractor in good time.

#### **Art. 9 – START OF THE EXECUTION OF THE CONTRACT**

The Director of Execution shall initiate the performance of the contractual services by providing the supervisor with all the necessary instructions and directives. The contractor is required to follow the instructions and directives provided by the contracting authority for the start of the performance of the contract. If the contractor does not comply with the terms and conditions of the contract, the contracting authority has the right to terminate the contract after establishing an adversarial debate with the contractor. The Director of Execution draws up a special report of the start of the execution of the contract in consultation with the contractor. The report is drawn up and signed by the Director of Contract Execution and the Contractor. The same procedure is followed in the event of early delivery of the supply.

#### **Art. 10 – SUSPENSION OF THE PERFORMANCE OF THE CONTRACT**

For the discipline and the hypotheses of possible suspension of the contract, art. 121 of Legislative Decree 36/2023.

#### **Art. 11 – INVOICING AND PAYMENTS**

With regard to invoicing and payments, the provisions of Ministerial Decree no. 55 of 3 April 2013, which came into force on 6 June 2013, which established the effective date of the obligations to use electronic invoicing in economic relations with the Public Administration pursuant to Law 244/2007, art.1, paragraphs 209 to 214, apply.

Therefore, in the light of those provisions, the consultant:

- a) must issue an electronic invoice, indicating the Unique Identification Office Code shown in the contract, the CIG and the CUP, only after receiving communication of the certificate of verification of conformity. In order to speed up the aforementioned assessment, the company may issue a pro forma invoice to be sent to the Sole Project Manager; please note that the electronic invoice will be refused by the University itself if it has been issued by the Company in the absence of the aforementioned prior communication from the Sole Project Manager;
- b) upon receipt of the electronic invoice issued by the company, the competent University structure will carry out the consequential obligations;
- c) the payment term is 30 days, starting from the date of receipt of the invoice by the competent accounting offices. Payments will be made exclusively by crediting a bank or postal current account, or with other payment instruments suitable for allowing full traceability of transactions. The contractor holding these accounts must communicate, at his own expense, the identification details of the latter to the University, in compliance with the provisions of art. 3 of Law no. 136/2010 and subsequent amendments. mod., expressly exempting the Administration from any liability for payments made by the aforementioned method.

#### **Art. 12 – TRACEABILITY OF FINANCIAL FLOWS**

The contractor is required to fulfil all the obligations provided for by art. 3 of Law no. 136/2010 in order to ensure the traceability of financial movements relating to the contract. In particular, the contractor is required:

- a) to communicate to the contracting authority the data relating to the dedicated current account to which the payments of the contract fees will be made;
- b) to carry out any transaction relating to the contract using banks or Poste Italiane Spa, exclusively with payment instruments permitted by art. 3 of Law 136/2010;
- c) to use the CIG in the context of relations with suppliers and service providers employed in the development of the performance of the contract.

The contractor must include a specific clause in the contracts with the subcontractors with which they undertake to fulfil all the obligations provided for by art. 3 of Law 136/2010 in order to ensure the traceability of financial movements relating to the subcontract.

#### **Art. 13 ADVANCE PAYMENT OF THE PRICE**

The provisions of the combined provisions of Articles 125 of the Code and 48 paragraph 1 of Legislative Decree 77/2021 on the advance of the price in the amount of 20% which can be increased up to 30% according to the procedures provided therein apply. The disbursement of the advance is subject to the provision of a bank or insurance guarantee for an amount equal to the advance increased by the legal interest rate applied to the period necessary for the recovery of the advance itself. The aforementioned guarantee is issued by banking companies authorised pursuant to Legislative Decree no. 385 of 1 September 1993, or insurance companies authorised to cover the risks to which the insurance refers and which meet the solvency requirements provided for by the laws governing their respective activities. The guarantee may also be issued by financial intermediaries registered in the register of financial intermediaries referred to in Article 106 of Legislative Decree No. 385 of 1 September 1993. The amount of the guarantee is gradually and automatically reduced during the performance of the service, in relation to the progressive recovery of the advance by the contracting authorities.



## **Art. 14 PRICE REVISION**

Pursuant to art. 60 of the Code. The contract prices may be revised under the conditions and in the manner indicated below. The revision of prices is recognized as a result of changes in individual prices of materials/services that determine increases or decreases of more than 5 percent of the total amount and operate to the extent of 80 percent of the variation itself, in relation to the services to be performed. The request for revision of the price, submitted by the contractor to the Administration, must be accompanied by an explanatory report and supporting documentation for the request for revision. On the requests made by the contractor, the Sole Project Manager, supported by the Director of Contract Execution, conducts a specific investigation in order to verify the occurrence of the conditions that legitimize the acceptance of the request for revision. This investigation takes into account the indices of consumer prices, producer prices of industry and services and the indices of hourly contractual wages and any additional categories of indices or further typological or commodity specifications of the categories of indices identified in accordance with the provisions of art. 60, paragraph 4 of the Code. The Administration shall rule on the requests made by the contractor within sixty days with a reasoned decision. If the contractor's requests are accepted, the measure determines the amount of compensation awarded to the contractor. The price revision can be requested only once for each year of the contract. Except for the cases governed by this article, any revision of prices is excluded and Article 1664, first paragraph, of the Civil Code does not apply.

## **Art. 15 – CHECKS ON THE EXECUTION OF THE CONTRACT**

The contracting authority has the right to verify the performance of the contractual services at any time. To this end, the contractor undertakes to cooperate fully in making these verification activities possible.

The contracting authority highlights any "non-conformities" found with respect to the contractual obligations in writing and the contractor is called upon to respond to the contracting authority, highlighting the corrective actions it intends to take to ensure the regular fulfilment of the contractual conditions, without prejudice to the application of the penalties provided for in these specifications.

The contracting authority, if the "non-conformities" objectively highlight the conditions of serious breach of contract, has the right to terminate the contract.

## **Art. 16 – FINAL GUARANTEE**

Pursuant to art. 117 of Legislative Decree 36/2023, in view of the signing of the contract, the contractor provides a guarantee, at his choice in the form of a deposit or surety with the characteristics and methods provided for by art. 106 of Legislative Decree 36/2023, in an amount equal to 10% of the contract amount. The reductions provided for by art. 106, paragraph 8 of Legislative Decree 36/2023.

The guarantee is provided for the fulfilment of all the obligations of the contract and for compensation for damages deriving from any non-fulfilment of the obligations themselves, as well as for the reimbursement of the sums paid in excess of the results of the final settlement, without prejudice to the possibility of compensation for greater damage to the contractor.

The warranty ceases to have effect only on the date of issue of the certificate of verification of conformity and in accordance with the procedures provided for by art. 117 co. 8 of Legislative Decree 36/2023.

The contracting authority has the right to avail itself of the guarantee, within the limits of the maximum guaranteed amount, for any additional expense incurred for the completion of the supplies or in the event of termination of the contract ordered to the detriment of the executor.

#### **Art. 17 – SAFETY**

In the execution of the contract, the winning company must adopt on its own initiative all those precautions that are valid to prevent the possibility of damage in general and especially accidents. The contractor shall be liable for any damage caused by its employees, during the performance of the service, to persons, equipment, works, furnishings of the Department or third parties.

The Supplier will be directly liable for damage to persons, property or existing structures caused by the performance of the supply, remaining at its full and exclusive expense any compensation from civil and criminal liability, without the right of recourse or compensation against the Administration and the personnel responsible for the control and verification of the service. Furthermore, considering that the contract has as its object the supply of the instrumentation, with connection to the electricity grid and in any case with an installation time equal to or less than 5 man-days, in accordance with the guidelines received from the competent Prevention and Safety Department, it is not necessary to draw up the DUVRI. However, the supplier is required to take all necessary precautions to ensure full compliance with the current legislation on safety in the workplace and to assess, before the start of the contract, the existence of additional and/or different interference risks not already foreseen, which, if detected, must be brought to the attention of the Administration for the purpose of any subsequent drafting of the DUVRI.

#### **Art. 18 – PROHIBITION OF ASSIGNMENT OF THE CONTRACT**

Without prejudice to the hypothesis of subjective modification referred to in art. 120, paragraph 1, letter d) of Legislative Decree 36/2023, the assignment of the contract is null and void.

#### **Art. 19 – ASSIGNMENT OF RECEIVABLES DERIVING FROM THE CONTRACT**

Pursuant to art. 120, paragraph 12 of Legislative Decree 36/2023, the provisions of Law no. 52/1991 apply to the assignment of receivables arising from the contract.

For the purposes of enforceability against the contracting authority, the assignment of receivables must be stipulated by means of a public deed or authenticated private deed and must be notified to the debtor authorities. Without prejudice to compliance with the traceability obligations, the assignment of receivables from contract consideration is effective and enforceable against the contracting authority if the latter does not refuse them with a notice to be notified to the assignor and the assignee within 45 (forty-five days from the notification of the assignment).

#### **Art. 20 – SUBCONTRACTING**

In accordance with the provisions of art. 119 of Legislative Decree 36/2023, subcontracting is allowed, under the conditions, limits and methods set out therein.

#### **Art. 21 – PENALTIES**

In the event of delay in the performance of the services and/or delivery of the goods to be supplied with respect to the timing of the contract and the specifications, a penalty commensurate with the days of delay will be applied.



Since this is a procedure financed by PNRR funds, art. 50, paragraph 4 of Legislative Decree 77/2021, which provides for the application of daily penalties for the late performance of services, to the extent of between 0.6 per thousand and 1 per thousand of the net contractual amount and cannot exceed a total of 20% of this amount, under penalty of termination of the contract. The Contractor must pay the amount of the penalty imposed by the Administration within the deadline indicated in the notice of imposition of the same. In the event of non-payment of the amount due, the Administration will withhold the amount corresponding to the amount of the penalty from the first useful invoice, without any formal notice or will provide for the definitive guarantee for the relevant amount, with the obligation of the supplier to proceed with the relative reinstatement within the term prescribed by the administration.

In addition, pursuant to Article 47 paragraph 3 of Decree-Law No. 76 of 2021, converted into Law No. 108 of 2021, economic operators employing a number equal to or greater than 15 employees and not exceeding 50 are required, within 6 months of the conclusion of the contract, to deliver to the contracting authority a gender report on the situation of male and female staff in each of the professions and in relation to the status of recruitment, training, professional promotion, levels, changes in category or qualification, other mobility phenomena, the intervention of the Cassa Integrazione Guadagni, dismissals, early retirements and retirements, as well as the remuneration actually paid. The economic operator is also required to transmit the report to the company trade union representatives and to the regional equality councilor. Failure to produce the report will result in the application of the penalties referred to in Article 47, paragraph 6, of Legislative Decree No. 76 of 2021, converted into Law No. 108 of 2021, to be commensurate with the seriousness of the violation and proportional to the amount of the contract or its performance (Article 47, paragraph 6 and for the quantification of Article 50 of Legislative Decree 77/2021), up to a maximum of 20% of the net contractual amount, as well as the impossibility of participating, in an individual/associated form, for 12 months in further award procedures relating to investments financed with resources from the PNRR.

## **Art. 22 – TERMINATION OF THE CONTRACT**

The contracting authority may terminate the contract pursuant to art. 122 of Legislative Decree 36/2023, if the hypotheses, assumptions and conditions reported therein occur.

In particular, the contract may also be terminated for serious breach of contractual obligations by the contractor, such as to compromise the success of the services.

When the Sole Project Manager ascertains a serious breach pursuant to the first sentence, he initiates the procedure governed by Article 10 of Annex II.14 to Legislative Decree 36/2023 in an adversarial debate with the contractor. At the end of the procedure, the contracting authority, on the proposal of the RUP, declares the contract terminated by a written document communicated to the contractor.

If, apart from the provisions of the preceding paragraph, the performance of the services is delayed by negligence on the part of the supervisor in relation to the provisions of the contract, the director of performance shall assign him a period which, except in cases of urgency, may not be less than 10 (ten) days, within which he must perform the services. Once this deadline has expired, and the adversarial report has been drawn up, if the non-compliance persists, the contracting authority terminates the contract, with a written document communicated to the contractor, without prejudice to the payment of the penalties imposed.

In all cases of termination of the contract, the supervisor is entitled only to payment for the services relating to the supplies duly performed.

## **Art. 23 – WITHDRAWAL FROM THE CONTRACT**

Without prejudice to the provisions of art. 88 par. 4-ter and 92 par. 4 of Legislative Decree 159/2011, the contracting authority, pursuant to art. 123 of Legislative Decree 36/2023, may withdraw from the contract at any time holding the contractor harmless by payment of the supplies regularly performed as well as the value of the useful materials existing in the warehouse, in addition to one-tenth of the amount of the supplies not performed, calculated in accordance with the provisions of Annex II.14 of Legislative Decree 36/2023.

The exercise of the right of withdrawal is manifested by the contracting authority by means of a formal notice to the contractor to be given in writing with a notice of not less than 20 (twenty) days, after which the contracting authority takes delivery of the supplies and verifies the regularity of the supplies carried out up to that point.

## **Art. 24 – CERTIFICATE OF VERIFICATION OF CONFORMITY**

Within 30 days of the completion of the supply, the DEC will proceed with the verification of conformity, pursuant to art. 37 of Annex II.14 to the Code, to certify compliance with the technical, economic and qualitative characteristics of the supply services, as well as the objectives and timeframes, in accordance with the contractual provisions and agreements.

## **Art. 25 – SETTLEMENT OF DISPUTES**

For any disputes that may arise both during the performance of the contract and at the end of the contract itself between the contracting authority and the contractor, which could not be settled with the amicable agreement pursuant to art. 211 of Legislative Decree 36/2023, the Court of Naples has exclusive jurisdiction.

## **Art. 26 CONTRACTUAL EXPENSES**

The costs of stamp duty and tax registration and all others relating to the contract are borne by the Contractor.

## **Art. 27 ELECTION OF DOMICILE**

The contractor undertakes to communicate its legal domicile to which the University Administration may send, notify, communicate any judicial or extrajudicial document relating to the contractual relationship in progress, with express exemption from any charge to the University Administration in relation to any non-delivery not attributable to it.

**Sole Project Manager**  
Dr. Mariarosaria Persico