

**NRRP Mission 4, Component 2, Investment 1.4 "Strengthening of 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**

**RNA Gene Therapy and Drug Development**

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

**UNIVERSITY OF NAPLES FEDERICO II**



**DEPARTMENT OF PHARMACY**

### **SPECIAL CONDITIONS OF THE CONTRACT**

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 articles 71 and 108 paragraph 1 of Legislative Decree no. 36/2023 as amended, 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 – Lot 1; " Automated System for GMP mRNA production at scale for clinical stages and commercial production with Critical – Lot 2".

**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 - Lot 1***" and an "***Automated System for GMP mRNA production at scale for clinical stages and commercial production with Critical - Lot 2***".

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 they cannot be found in these Specifications, to give the supply finished and in perfect working order.

All materials, appliances and equipment supplied and in working order, must be of the best quality, processed in a workmanlike manner and corresponding to the service for which they are intended. The systems must be certified in accordance with current standards.

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

This contract is funded under the PNRR project Mission 4, Component 2, Investment 1.4 "*Enhancement of 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 is divided into two distinct lots, including:

- **LOT 1:** 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".
- **LOT 2:** 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 rules

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

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

All the equipment supplied for each lot must be delivered, made operational and validated at the full expense of the economic operator, under the coordination of the Single 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 during the tender: transport, unloading, assembly, on-site positioning, separate collection, packaging disposal, installation, configuration, training, warranty, etc.

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

**LOT 1:** Department of Pharmacy of the University of Naples Federico II, via Tommaso De Amicis floor -1 (NA) (NUTS

code ITF33);

**LOT 2:** Department of Pharmacy of the University of Naples Federico II, via Tommaso De Amicis floor -1 (NA) (NUTS code ITF33).

Supplies shall be made as follows for each batch:

**LOT 1: within 4 months** from the signing of the contract (or from the report of early execution, pursuant to Articles 17 paragraph 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);

**LOT 2: within 8 months** from the signing of the contract (or from the early execution report, pursuant to Articles 17 paragraph 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).

These times include the transport and commissioning of the entire supply. The delivery of the supply for each Lot must take place in a single solution, at the end of which a specific 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 the 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 with:

- 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 by Law no. 142 of 19 February 1992;
- Safety requirements (e.g. IMQ) and electromagnetic emission requirements (e.g. FCC) certified by recognized bodies at European level;
- The equipment supplied must comply with the provisions of Legislative Decree no. 80 of 18 May 2016 regarding 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), implemented by Legislative Decree no. 27 of 4 March 2014 and subsequent amendments;

After delivery, for each Lot, their installation and commissioning must be carried out. For installation and connections of all kinds, the contractor shall provide:

- the state-of-the-art installation of the equipment supplied;
- post-installation electrical safety checks as per current legislation;
- connection to existing systems;
- any other work that may be necessary, even if not explicitly provided for herein.

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

The above-mentioned activities shall be carried out in accordance with the contract, these special conditions and the technical specifications for supply and any other requirements arising from the tender documents, as well as the contractor's technical offer.

For the delivery of each Lot, the Supplier, together with the Project Manager, must draw up a special "delivery and assembly report", in consultation with the Contracting Administration, 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 next phase of "Configuration and Operational Start-up".

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

The contractor shall also help 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 operation of the instrumentation.

Travel expenses and the costs of the technicians' labor 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 of it, as indicated in art. 6.

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

Participation in the procedure and the conclusion 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 obliged 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, according to which no measure financed by the notices must cause harm to environmental objectives, in line with Article 17 of Regulation (EU) 2020/852. This principle is intended to prove that the planned investments and reforms do not hinder climate change mitigation;
- the additional cross-cutting principles provided for by the NRRP, 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 empower young people;
- the obligations referred to in art. 47 D.L. 77/2021 that are applicable in relation to its corporate size, in 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 shall be considered as an integral and substantial part of the contract:

- the special conditions of the contract;
- the technical supply drawing;
- 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 for LOT 1 and within 8 months for LOT 2 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 a timely manner.

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

The Director of Enforcement initiates the performance of the contractual services by providing the contractor with all necessary instructions and directives. The contractor is obliged to follow the instructions and directives provided by the contracting authority for the commencement of the execution 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 an adversarial hearing with the contractor. The Director of Execution shall draw up a specific report of the commencement of the performance of the contract in consultation with the contractor. The minutes are drawn up and signed by the Director of Contract Execution and the Contractor. The same applies in the case of early delivery of the supply.

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

For the discipline and hypotheses of possible suspension of the contract, art. 121 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.

Therefore, in the light of those provisions, the successful tenderer:

a) shall issue an electronic invoice, indicating the Unique Identification Office Code reported 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 prior communication referred to above by the Single 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 period is 30 days from the date of receipt of the invoice by the competent accounting offices.

Payments will be made exclusively by crediting a bank or postal account, or with other payment instruments suitable to allow full traceability of the transactions. The contractor in charge of 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 responsibility for payments made with the aforementioned method.

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

The contractor is required to comply with all the obligations set forth in 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 to:

- 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 in the contracts with the subcontractors a specific clause 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**

The provisions of art. 125 of the Code regarding the advance payment of the price to the extent of 20%, which can be increased up to 30% in accordance with the procedures provided for therein. The disbursement of the advance is subject to the provision of a bank or insurance guarantee for an amount equal to the advance plus the legal interest rate applied to the period necessary for the recovery of the advance. The aforementioned guarantee is issued by banking companies authorized pursuant to Legislative Decree no. 385 of 1 September 1993, or insurance companies authorized 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 price revision, submitted by the contractor to the Administration, must be accompanied by an explanatory report and the supporting documentation of the request for revision. On the requests made by the contractor, the 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 considers the indices of consumer prices, producer prices of industry and services and the indices of contractual hourly wages and any additional categories of indices or further typological or commodity specifications of the categories of indices identified according to the provisions of art. 60, par. 4 of the Code. On the requests made by the contractor, the Administration shall give its opinion within sixty days with a reasoned decision. If the contractor's claims are granted, the measure shall determine the amount of compensation awarded to the contractor. The price revision can only be requested once per contract year. Apart from 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 – CONTROLS 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 such verification activities possible.

The Contracting Authority shall highlight any "non-conformities" found with respect to the contractual obligations in writing and the Contractor shall be 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 contractual breaches, has the right to terminate the contract.

#### **Art. 16 – FINAL WARRANTY**

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

The guarantee 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. 8D.lgs. 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 contractor.

#### **Art. 17 – SAFETY**

In the execution of the contract, the contractor must take all the precautions necessary to prevent the possibility of damage in general and especially of 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 of third parties.

The Supplier will be directly liable for any damage to persons, property or existing structures caused by the performance of the supply, remaining at its complete and exclusive responsibility for any compensation from civil and criminal liability, without the right of recourse or compensation against the Administration and the personnel appointed by it to control and verify the service. Furthermore, considering that the contract concerns the supply of 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 Division, it is not necessary to draw up the DUVRI. However, the supplier is required to take all necessary precautions to ensure full compliance with current legislation on safety in the workplace and to assess, before the start of the contract, the existence of additional and/or various interference risks not already foreseen, which, if detected, must be brought to the attention of the Administration in order to draw up any subsequent DUVRI.

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

Without prejudice to the hypothesis of subjective modification referred to in art. 120, par. 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 deriving from the contract.

In order to be enforceable against the contracting authority, assignments of claims must be concluded by means of an authentic deed or a notarized private deed and must be notified to the debtor authorities.

Without prejudice to compliance with traceability obligations, the assignment of receivables for contract consideration is effective and enforceable against the Contracting Authority if the latter does not reject them with a notice to be notified to the transferor and the transferee 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, subject to the conditions, limits and methods set out therein.

## **Art. 21 – PENALTIES**

In the event of delay in the performance of the services and/or in the delivery of the goods supplied with respect to the timing of the contract and the specifications, a penalty commensurate with the days of delay will be applied. The daily penalty is equal to 0.5 per thousand of the net contract amounts.

In any case, the penalties may not exceed, in total, 10 per cent of this net contractual amount.

The Contractor shall 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 final guarantee for the relevant amount, with the obligation of the supplier to proceed with its reinstatement within the deadline prescribed by the Administration.

In addition, pursuant to Article 47 paragraph 3 of Legislative Decree No. 76 of 2021, converted into Law No. 108 of 2021, economic operators who employ a number equal to or greater than 15 employees and not more than 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 send 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, individually/in associations, 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 set out therein are met.

In particular, the contract may also be terminated due to 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 or she initiates the procedure governed by Article 10 of Annex II.14 to Legislative Decree 36/2023 in an adversarial manner with the

contractor. At the end of the procedure, the contracting authority, on the proposal of the RUP, declares the contract terminated by written deed communicated to the contractor.

If, apart from the provisions of the preceding paragraph, the performance of the services is delayed due to negligence on the part of the contractor in relation to the provisions of the contract, the Director of Execution 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. At the end of this period, the minutes shall be drawn up in an adversarial manner, if the non-compliance persists, the contracting authority shall terminate the contract, by written document communicated to the contractor, without prejudice to the payment of the penalties imposed.

In all cases of termination of the contract, the contractor shall only be entitled to payment for the services relating to the duly executed deliveries.

### **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 terminate the contract at any time, holding the contractor harmless by paying for the supplies regularly executed as well as the value of the useful materials existing in the warehouse, in addition to the 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 communication 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 from the completion of the supply, the Project Manager will proceed with the verification of compliance, 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 timing, in accordance with the contractual provisions and agreements.

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

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

### **Art. 26 CONTRACT COSTS**

Stamp duty and tax registration costs and all other costs related to the contract shall be borne by the Contractor.

### **Art. 27 ELECTIONS OF DOMICILE**

The contractor undertakes to communicate his/her legal domicile to which the University Administration may send, notify, communicate any judicial or extrajudicial act relating to the contractual relationship in progress, with express exemption of the University Administration from any charge regarding any non-contact information not attributable to it.

### **Responsible for the Project**

Dr. Mariarosaria Persico