

Prot. n. 570/DG

Rome, 11/12/2025

Estemeed

BioReliance Ltd.

Glasgow, Scotland, at Unit 5, Todd Campus,
West of Scotland Science Park, G20 0XA

Mail: christiane.hill@merckgroup.com

Subject: Contract for the activation of analytical services necessary to develop assays for the presence of replication-competent retroviruses in 2 Master Cell Banks and in their respective viral vectors for research activities at the Pharmaceutical Laboratory of the Bambino Gesù Pediatric Hospital.

CUP Code: E83C22003170001

In implementing the research and development activities carried out by the Tumor Gene Therapy Research Unit, part of the Oncohematology Research Area and Pharmaceutical Laboratory of the Bambino Gesù Children's Hospital, it is necessary to activate analytical services necessary for the development of assays for the presence of replication-competent retrovirus in 2 Master Cell Banks and in the respective viral vectors for research activities at the Pharmaceutical Laboratory of the Bambino Gesù Children's Hospital.

BETWEEN

Bambino Gesù Children's Hospital - Scientific Institute for Research and Treatment - Institution of the Holy See with headquarters in Rome, Piazza Sant'Onofrio 4, in one of the extraterritorial zones recognized by the Lateran Treaty of 1929, Fiscal Code 80403930581 ("Bambino Gesù Children's Hospital" or "Hospital" or "OPBG"), represented by the General Director, Antonio Perno (hereinafter "OPBG" or "Contracting Authority")

AND

BioReliance Ltd with registered office in Glasgow, Scotland, at Unit 5, Todd Campus, West of Scotland Science Park, G20 0XA, Tax Code 6805014990 / VAT number GB 845 3370 24, represented by its legal representative Alison Armstrong, born in Dumfries (UK) on 08/08/1964, Tax ID Code GB 845337045 (hereinafter also "BioReliance" or "Company")

PREMISES

With Contracting Decision no. 154 prot. 516/DG of 12/11/2025, the General Director of the OPBG has established the completion of a procedure through direct award pursuant to art. 50, paragraph 1, letter b) of Legislative Decree no. 36/2023 for the following supply:

- **Activation of analytical services necessary for the development of assays for the presence of replication-competent retroviruses in 2 Master Cell Banks and in their respective viral vectors for research activities at the Pharmaceutical Laboratory of the Bambino Gesù Pediatric Hospital.**

The Sole Project Manager, pursuant to Article 15 of the Public Contracts Code, is Dr. Monica Gunetti, Service Manager, Pharmaceutical Laboratory Research Unit of the "Bambino Gesù" Pediatric Hospital, who is assigned the duties established by the provisions of Legislative Decree 36/2023 and subsequent amendments, including that of signing the documentation for the procedure in question, with the right to avail herself of the collaboration of technical and administrative officials of the OPBG as she deems necessary.

On November 20, 2025, the OPBG sent the invitation letter and related attachments to Bioreliance Ltd., indicating 6:00 PM on December 4, 2025, as the deadline for submitting the tender documentation.

In response to the invitation letter, Bioreliance Ltd. submitted its best technical and economic offer, No. R-11469846.P.1, which was acquired by the OPBG on November 21, 2025, accompanied by all required digitally signed documentation and the Technical and Contract Specifications, which were returned countersigned.

In an evaluation document dated November 24, 2025, the technical offer was reviewed by Dr. Rossana Bugianesi; this offer was deemed appropriate for the amount of €35,125.00 (thirty-five thousand, one hundred and twenty-five/00), plus VAT, where applicable, as reported in the Contract Decision.

The technical and financial offer was accepted by the Sole Project Manager in a note dated November 24, 2025.

The Contractor has demonstrated compliance with the requirements set forth in the tender documentation, and the Contracting Authority has verified compliance pursuant to Article 105 of the Public Contracts Code.

This contract is signed pending the release by the Territorial Office of the Government of Rome of the anti-mafia communication requested on October 21, 2020 on the BDNA, pursuant to art. 88, paragraph 4-bis and article 92, paragraph 3 of Legislative Decree no. 159 of September 6, 2011, and, in any case, following the acquired declaration made by the Contractor regarding the non-existence of the causes for prohibition, forfeiture, or suspension pursuant to article 67 of Legislative Decree no. 159/2011; consequently, the contract is subject to a condition of termination, in the event that a negative outcome of the aforementioned anti-mafia checks were to result, which would result in the invalidity of the contract itself, with all legal consequences.

The payment terms for the supply in question are listed below:

➤ **Milestone 1:** Generation of the 009820NRT.BUK test and evaluation of the biocompatibility of the viral vector (CLEC2A and B7H3):

- 55% invoiced upon laboratory initiation;
- 40% invoiced upon laboratory completion;
- 5% invoiced upon order completion.

- **Milestone 2:** Biocompatibility assessment of master cell banks (CLEC2A and B7H3):
- 60% invoiced upon order booking;
 - 40% invoiced upon laboratory completion

Payment of invoices issued by the Company for supplies performed in a workmanlike manner and in full and proper compliance with the contractual provisions is due within 30 (thirty) days, at the end of the month, from the date of issue of each individual invoice.

In submitting the offer, the Contractor accepted, among other things, every clause in the Specifications and the Technical Specifications.

With this contract, the Contracting Authority intends to award BioReliance Ltd. the contract for the supply necessary to increase the instrumental package already available to the Hospital as part of the PNRR initiative and the creation of a National Center for RNA Therapy and Gene Therapy.

HAVING REGARD TO ALL THE ABOVE

The Parties, as constituted above, agree and stipulate as follows:

Article 1 – Premises, annexes and regulatory provisions

1. The preamble and documentation listed below constitute an integral and substantial part of this contract:

- a) Contract Resolution No. 154, ref. 516/DG of 12/11/2025;
- b) Deed of Appointment of the Sole Project Manager, ref. 517/DG of 12/11/2025;
- c) Letter of Invitation sent on 20/11/2025;
- d) Specifications sent on 20/11/2025;
- e) Technical Specifications sent on 20/11/2025;
- f) ESPD signed by BioReliance Ltd.;
- g) BioReliance Financial Offer No. R-11469846.P.1 of 21/11/2025;
- h) Technical Adequacy Evaluation Document dated 24/11/2025;
- i) Technical and Economic Evaluation Document dated 24/11/2025;
- l) Award Decree prot. 546-547/DG dated 25/11/2025.

2. The above-mentioned documents are considered integral and substantial parts of this contract, even if not physically attached thereto, as they are deposited with the Contracting Authority.
3. In the event of a conflict and/or incompatibility between the provisions of this contract and the above-mentioned contractual documents, the interpretation most favorable to the timely and optimal performance of the contracted service shall prevail, in compliance with applicable legislation.

Article 2 - Object of the contract

The purpose of this contract is to activate the analytical services necessary to develop assays for the presence of replication-competent retroviruses in 2 Master Cell Banks and their respective viral vectors for research activities at the Pharmaceutical Laboratory of the Bambino Gesù Children's Hospital, as detailed in the Technical Specifications and the official offer.

Article 3 - Contractual amount

1. The list price for the supply of the items indicated in Article 2 is €35,125.00 (thirty-five thousand one hundred and twenty-five/00), plus VAT, where applicable, as reported in the Contracting Decision.
2. The amount expected for the purchase of the supply in question falls within the budget approved by the OPBG for the National Center for Research and Development of Gene Therapy and Drugs with RNA Technology.
3. The offer submitted by BioReliance Ltd. is €35,125.00 (thirty-five thousand one hundred and twenty-five/00), plus VAT, where applicable, as reported in the Contracting Decision.
4. The expenditure is charged to the financial resources allocated within the research project relating to the National Research Center on Gene Therapies and RNA Technology Drugs provided for by the Call for Proposals funded under the PNRR - NextGenerationEU, Mission 4 Component 2 from Research to Business, Investment 1.4, within the Research Program "Strengthening research structures and creation of "national R&D champions" on some Key Enabling Technologies", approved with Directorial Decree of the Ministry of University and Research no. 3138 of 16 December 2021, amended by Directorial Decree no. 3175 of 18 December 2021, with total funding for OPBG equal to approximately €20,040,000.
5. The price is fixed, invariable and inclusive of the interventions due by the Company for the entire period covered by the warranty.

Article 4 - Place of supply

1. This supply must be delivered to Officina Farmaceutica OPBG, Viale F. Baldelli, 38, 00146 Rome, within 20 days of receiving the order, at no additional cost to OPBG.
2. The Company undertakes to deliver all of the above supplies at no additional cost, safeguarding OPBG's needs and without hindering, disrupting, or interrupting any ongoing business operations.
3. Resources assigned to supply the OPBG will be able to access the OPBG in compliance with all relevant security and access requirements, subject to notification to the OPBG of their names and personal data, along with identification document details, at least 5 (five) days before the start of the aforementioned activities.
4. The Company, therefore, must ensure that it has trained the technical personnel who will perform the above services to ensure their security.

Article 5 – Termination of the contract

1. Either Party may terminate this Agreement for any material breach of this Agreement, provided that such breach is not cured within thirty (30) days after receipt of written notice from the non-breaching Party specifying the details of such breach. Either Party may terminate this Agreement immediately by written notice to the other Party if the latter abandons its business, becomes insolvent, is subjected to voluntary or involuntary bankruptcy, composition with creditors, arrangement with creditors or other similar proceeding which is not filed within thirty (30) days from the commencement thereof, makes an assignment for the benefit of its creditors, or consents to the appointment of a trustee, receiver or other fiduciary over all or a substantial portion of its assets. The Company may terminate this Agreement, but not any services commenced or in progress, at any time, with or without cause, by giving at least thirty (30) days' written notice to OPBG.

Article 6 – Changes to the supply

1. If, during the performance of this contract, it becomes necessary to increase or decrease the supply, the Company is obligated to execute the variation request with reference to the prices indicated in the financial offer.
2. Such variations may be requested for a value that cannot exceed one-fifth of the contract amount.

Article 7 – Payment

1. Payment of invoices issued by the Company for supplies performed in a workmanlike manner and in full and proper compliance with the contractual provisions is due within 30 (thirty) days, at the end of the month, from the date of issue of each individual invoice. The Company will issue invoices for the consideration following OPBG's acceptance of the supply.

In the event of a negative acceptance, OPBG will pay the portion of the invoice relating to the supply not rejected.

2. Invoices must: (i) include references to the Contract and related Execution Orders; (ii) contain, at the bottom, the wording "Invoice bearing a non-transferable credit"; (iii) indicate the Supplier's bank details for payment by OPBG; (iv) indicate the reference CUP code **E83C22003170001**.

Invoices must be sent electronically via the Revenue Agency's System Data Interchange (SDI) with the following information:

Company name: Bambino Gesù Children's Hospital

Address: Piazza Sant'Onofrio 4, 00165 Rome

Tax ID: 80403930581

Recipient code: SDI QRL4YE1

Electronic invoices must be sent with a PDF copy of the invoices themselves and any necessary explanatory technical documents, free of sensitive or special data in accordance with applicable data protection legislation.

The payment terms for the supply in question are listed below:

➤ **Milestone 1:** Generation of the 009820NRT.BUK test and evaluation of the biocompatibility of the viral vector (CLEC2A and B7H3):

- 55% invoiced upon laboratory initiation;
- 40% invoiced upon laboratory completion;
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➤ **Milestone 2:** Biocompatibility assessment of master cell banks (CLEC2A and B7H3):

- 60% invoiced upon order booking;
- 40% invoiced upon laboratory completion

Payment of invoices issued by the Company for supplies performed in a workmanlike manner and in full and proper compliance with the contractual provisions is due within 30 (thirty) days, at the end of the month, from the date of issue of each individual invoice.

3. Any errors, incompleteness, or omissions in the data reported in the invoices pursuant to the above, or inconsistencies in the explanatory technical documents, as well as non-compliance with current legislation, will result in the rejection of the invoices by OPBG, which will therefore be unable to proceed with payment and will consequently not be required to pay any late payment interest requested by the Company.

Article 8 - Traceability of financial flows

1. The Company assumes, under penalty of absolute nullity of the contract, all financial flow traceability obligations pursuant to Article 3 of Law 136/2010 and subsequent amendments.
2. The Company further declares that the identification details of the bank account dedicated, even if not exclusively, for public procurement are as follows:

IBAN GB20DEUT40508116695200

and that the personal details and tax code of the persons authorised to operate on the indicated current account are:

- Mrs. Alison Massey, CFO UK and Ireland;
- Mrs. Alison Armstrong, Chief Executive Officer.

Article 9 - General responsibilities of the Company

1. In performing the supply, the Company will, on its own initiative, adopt all reasonable means and precautions necessary to prevent damage in general, particularly injury, including to third parties.
2. The Company also undertakes to comply, under its sole responsibility, with all regulations regarding occupational health and safety and, in general, regarding the treatment and protection of workers.
3. The Company declares and acknowledges that it has fulfilled all obligations set forth in Legislative Decree No. 81 of April 9, 2008, as amended, as well as all other applicable regulations regarding occupational health and safety. This does not affect the specific obligations to be observed in accordance with the regulations in force in the context of the Covid-19 health emergency and the related instructions provided by the OPBG.

4. Limited Service Guarantee. The Company's commitment to perform as set forth in this Agreement constitutes a service contract. The only warranty relating to its services is that the Company will perform the services under this Agreement with due diligence, in accordance with the applicable protocol, estimate, or equivalent, generally prevailing industry standards, and applicable law. Any claim by OPBG for a breach of this warranty must be submitted in writing to the Company no later than the first anniversary of the date of delivery of the final report to OPBG. If the provision is found to have failed to meet the warranty set forth herein, OPBG's sole remedy for the breach of this warranty, at the Company's discretion, will be (a) for the Company to re-perform the services or the portion thereof that gave rise to such breach, taking into account the Company's pre-existing obligations, or (b) for OPBG to accept a refund of the fees paid for the services or the portion thereof that gave rise to such breach.

5. Disclaimer. The warranty set forth in the preceding paragraph is in lieu of any other warranty relating to the services to be provided, whether express or implied, written or oral, including, but not limited to, any implied or statutory warranty of merchantability, fitness for a particular purpose, or non-infringement, whether arising by statute, course of dealing, course of performance, usage of trade, or otherwise, all of which are expressly disclaimed.

6. Consequential Damages. In no event shall the Company be liable to OPBG or any third party making claims against or through OPBG for any cause whatsoever, whether based in contract, tort, negligence, strict liability, or any other legal theory, for indirect, consequential (such as lost profits and lost business opportunities), incidental, special, exemplary, or punitive damages, even if advised of the possibility of such damages and regardless of whether the Company has been advised of the possibility of such damages.

7. Direct Damages. The liability of the Company and its affiliates to OPBG and its affiliates for any claim or breach of any term or condition of this Agreement and/or any quotation (except for any breach of the limited service warranty set forth above, which will be governed by the remedy set forth therein for such breach of warranty) will be limited to direct damages in an amount not to exceed the fee paid by OPBG to the Company for services in connection with the study or the portion of the study that gave rise to such breach.

8. Client Indemnity. Except where caused by the Company's gross negligence or willful misconduct in the performance of this Agreement, OPBG will indemnify, defend and hold harmless the Company, its parent, subsidiary and affiliated companies and their respective officers, directors, employees and agents (the "BioReliance Indemnitees") from and against all expenses (including, but not limited to, reasonable attorneys' fees), damages, judgments, settlements and losses incurred or suffered by such Indemnitees of the BioReliance Indemnification against any claim, demand or cause of action made or brought by any third

party (including, but not limited to, officers, employees and agents of OPBG) for or in connection with: (a) personal injury or death to any person or damage to or destruction of property arising out of or based upon the design, manufacture, sale or use by OPBG of any quantity of Test Materials, or any derivative thereof, whether such design, manufacture, sale or use occurred prior to the termination of the Services or thereafter and whether such design, manufacture, sale or use occurred in reliance, in whole or in part, on the Services or any part thereof; (b) infringement, unlawful disclosure or misappropriation of copyrights, patents, trade secrets or other intellectual property by reason of the performance of the Services on the Test Materials; (c) any breach by OPBG of any of its obligations (or any of its affiliates, if applicable) or representations and warranties under this Agreement; (d) any negligent act or omission or willful misconduct by OPBG, its affiliates, if applicable, or its or their directors, officers, employees, agents, or subcontractors; (e) any instructions, directions, recommendations, or specifications provided by OPBG or any of its affiliates, if applicable, (or its officers, directors, employees, agents, or subcontractors) to Company (including, without limitation, any test materials or protocols provided by OPBG) that are materially followed, adhered to, adopted, implemented, and/or performed by Company; or (f) OPBG's use of the Data, Services, or Provisions.

9. **Company Indemnity.** Except where caused directly by OPBG's gross negligence or willful misconduct, and subject to the limitations set forth in this Agreement, BioReliance will indemnify, defend, and hold harmless OPBG, its parent, subsidiary, and affiliated companies, and their respective officers, directors, employees, and agents (the "Indemnified Customers") from and against all expenses (including, but not limited to, reasonable attorneys' fees), damages, judgments, settlements, and losses incurred or suffered by such Indemnified Customers as a result of any claim, demand, or suit made or brought by any third party (including, but not limited to, BioReliance's officers, employees, and agents) for or in connection with: (a) personal injury or death to any person or property damage caused by BioReliance's performance of the services hereunder; or (b) breach of this Agreement or any BioReliance quotation; provided, however, that in all cases BioReliance shall have no obligation to indemnify, defend and/or hold harmless the Indemnified Customers to the extent OPBG has an obligation to indemnify, defend and/or hold harmless the Indemnified Customers pursuant to the preceding paragraph of this Section.

Article 10 - Special charges for the Company

1. The Company will cover the following specific costs:

a) The Company will not require any additional payment.

Art. 11 – General obligations and obligations of the supplier company

1. The Company shall be responsible for the following obligations and responsibilities:
 - a) delivery and installation of the items specified in the Specifications;
 - b) subject to the limitations contained herein, compensation to OPBG for any damage to property or persons caused by the Company or its personnel;
 - c) fulfillment of all obligations towards its employees pursuant to applicable laws and regulations and the relevant national collective bargaining agreement (CCNL) regarding labor and social security, assuming all related costs and excluding any liability for OPBG;
 - d) in the event of malfunctions after delivery, the Company shall comply with the warranty provisions set forth herein.
2. The Company undertakes to guarantee and fulfill, at its own expense, all obligations towards the personnel employed in connection with the Contract, arising from applicable legislation, including those relating to insurance, social security, and employment relationships in general. The Company also guarantees that all personnel employed by it possess all the qualifications necessary to perform the services under the Contract and further undertakes to communicate in advance to the OPBG Internal Contact the names of the personnel authorized by the Supplier for this purpose to access the OPBG websites.
3. The Company undertakes to provide the services under the Contract without causing any harm to the Hospital's operations, also in light of the Hospital's specific research and treatment activities.

Article 12 – Person responsible for the execution of the Contract (“Internal Contact Person”)

1. The Supplier's internal contact is Dr Christiane Hill.
2. The Hospital's internal contact is the Sole Project Manager, Dr. Monica Gunetti, who coordinates the proper execution and monitoring of the Contract. In this context, she also provides the necessary operating instructions to the Supplier, with whom she maintains the relevant relationships and ensures verification of the quantity and quality of the services covered by the Contract.
3. For communications necessary for the execution of the Contract, each Party will refer to the Internal Contact of the other Party.
4. Any changes to the Internal Contact must be communicated by the affected Party, through a representative with legal representation and signature powers, to the other Party via certified email (PEC), addressed to the latter's Internal Contact and, in the case of the OPBG, also to the Supply Chain Department.

5. If the sender and/or recipient do not have a certified email address, such communication must be made by registered mail with acknowledgement of receipt addressed to the registered office of the other Party as identified in the Contract, addressed to the same recipients as identified in the previous paragraph.

Article 13 - Force majeure

1. Neither party shall be liable for failure to fulfill its contractual obligations when force majeure occurs, i.e. circumstances beyond its reasonable control.

Article 14 – Contractual expenses

1. The contract and all related and consequent transactions are subject to the usual applicable taxes, duties, and levies.
2. It is understood that all taxes, duties, and levies, stamp duty, and registration costs related to the registration of the contract (if applicable) will be borne by the Company.

Article 15 - Disputes and legal domicile

1. The Contract shall be governed by the law in force in Italy.
2. For any dispute arising from the interpretation and performance of the Contract, the Parties preliminarily undertake to resolve any conflict amicably. Only if an agreement cannot be reached shall the Parties expressly submit to the exclusive jurisdiction of the Court of Rome and its subsequent courts.

Article 16 - Condition for termination

1. This contract is signed pending the release by the Territorial Office of the Government of Rome of the anti-mafia communication requested on October 21, 2020 on the BDNA, pursuant to art. 88, paragraph 4-bis and article 92, paragraph 3 of Legislative Decree no. 159 of September 6, 2011, and, in any case, following the acquired declaration made by the Contractor regarding the non-existence of the causes for prohibition, forfeiture, or suspension pursuant to article 67 of Legislative Decree no. 159/2011; consequently, the contract is subject to a condition of termination, in the event that a negative outcome of the aforementioned anti-mafia checks were to result, which would result in the ineffectiveness of the same, with all legal consequences.

Article 17 - Ethical conduct and transparency

1. Bambino Gesù Children's Hospital has adopted a Code of Ethics, available on the website www.ospedalebambinogesu.it.

2. Each Party undertakes to perform the contract in compliance with applicable law, with fairness and transparency, avoiding, within the context of its relationship with the Hospital, any behavior, act, or omission that may constitute mismanagement with unlawful intent and, more generally, that conflicts with the principles, values, and rules of ethical conduct and that may give rise to unlawful liability for the other Party or for itself.

3. Failure to comply with the above obligations and commitments constitutes a breach of contract, with the non-breaching Party entitled to terminate the contract pursuant to and for the purposes of Article 1456 of the Italian Civil Code, without prejudice to any action for damages.

Article 18 – Processing of Personal Data

1. The Parties declare that they comply with the provisions on personal data protection set forth in European Regulation No. 2016/679 (hereinafter "GDPR") and Legislative Decree No. 196/2003, as amended by Legislative Decree No. 101/2018, and will fulfill their obligations by adopting appropriate technical and organizational measures to ensure a level of security appropriate to the risk.

2. The personal data of employees, collaborators, and any person acting in the name and on behalf of each Party (name, company email address, etc.) will be processed by the other Party, as an independent Data Controller, exclusively for purposes strictly related and functional to the establishment and execution of the contractual relationship governed by this Agreement, as well as to fulfill any legal or regulatory obligations.

3. The data will be processed in compliance with the principles set forth in Article 5, paragraph 1, of the GDPR. 1 of the GDPR, in the manner further described in the information pursuant to Article 13 of the GDPR that each Party provides to its data subjects and for the period of time strictly necessary to achieve the purposes described above.

4. The Parties ensure that internal personnel involved in data processing are specifically authorized, trained, and instructed to ensure the adequate security and confidentiality of the personal data processed.

Article 19 - Provisions for the protection of confidentiality

1. The parties expressly agree that all information, concepts, ideas, procedures, methods, and/or technical data that the Company's personnel become aware of during the supply process will be considered confidential and covered by professional secrecy.

2. The parties undertake to maintain the confidentiality of all data and information, including that transmitted via equipment in their possession, and not to disclose it in any way or form, nor to use it for purposes other than those strictly necessary for the performance of the contractual activities.

If agreed to above, the Supplier is required to return a copy of this document and the attached Annex, duly signed for acceptance by its representative with adequate powers of representation and signature.

All.: c.s

- Exhibit 1 - HEALTH INFORMATION - Professional consultants_suppliers

Bambino Gesù Children's Hospital
The General Director
Antonio Perno

18.12.2025

Rome,

For acceptance:

BioReliance
The Legal Representative

Alison Armstrong

Alison Armstrong (23-Dec-2025 09:07:39 GMT)