

Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR)

NÚM. EXPEDIENT: 2025-034 GENOMIC ANALYSIS OF PEDIATRIC TUMORS

**DOCUMENT OF TECHNICAL SPECIFICATIONS
NOT HARMONIZED TRADE – OPEN PROCEDURE**

SERVICE PROVIDER OF A COMPREHENSIVE TOOL FOR GENOMIC ANALYSIS AND ONLINE BIOLOGICAL DATA INTERPRETATION OF PEDIATRIC TUMORS FOR THE CHILDHOOD CANCER AND HEMATOLOGIC DISEASES GROUP OF THE FUNDACIÓ HOSPITAL UNIVERSITARI VALL HEBRON - INSTITUT DE RECERCA (VHIR)

"PI21/01661" titled "COMIK v2.0: Integration of Functional and Genomic Screening in a Personalized Medicine Program for Childhood Cancer." This study has been funded by the Instituto de Salud Carlos III (ISCIII) and co-financed by the European Union.



"PMP21/00073" titled "SEHOP-PENCIL - National strategy for the implementation of personalized medicine in children and adolescents with cancer." This project has been funded by the Instituto de Salud Carlos III and the European Union Next Generation EU, which provide funding for initiatives under the Recovery and Resilience Mechanism (RRM).



"ICI21/00076" titled "Phase I trial of ABTL0812 in children with relapsed or refractory neuroblastoma and extracranial solid tumors." This project has been funded by the Instituto de Salud Carlos III and the European Union Next Generation EU, which provide funding for initiatives under the Recovery and Resilience Mechanism (RRM).



"PI24/01576" titled "Incorporation of targeted therapies and immunotherapy for treatment of children and adolescents with relapsed neuroblastoma with a deep biological characterization and development of the BEACON2 trial." This study has been funded by the Instituto de Salud Carlos III (ISCIII) and co-financed by the European Union.



Clause 1. Aim of the tender

The object of this tender procedure is the contracting of the service of a comprehensive tool for genomic analysis and online interpretation of data derived from Whole Genome Sequencing (WGS), Whole Exome Sequencing (WES) and RNA sequencing (RNAseq) of tumor samples of pediatric patients and patient-derived xenograft (PDX) models by the projects:

- PI21/01661 titled "COMIK v2.0: Integration of Functional and Genomic Screening in a Personalized Medicine Program for Childhood Cancer." This study has been funded by the Instituto de Salud Carlos III (ISCIII) and co-financed by the European Union.
- PMP21/00073 titled "SEHOP-PENCIL-National strategy for the implementation of personalized medicine in children and adolescents with cancer." This project has been funded by the Instituto de Salud Carlos III and the European Union Next Generation EU, which provide funding for initiatives under the Recovery and Resilience Mechanism (RRM).
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intended for the research group "Childhood Cancer and Blood Disorders" of the Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR), as stipulated in the present Technical Specifications.

The Childhood Cancer and Blood Disorders Group does not have a comprehensive tool for the genomic analysis and online biological data interpretation of WGS, WES and RNAseq data, and therefore must outsource this service to an external provider

This tender is not divided into lots because it is related to only one service, which is the genomic analysis and online biological data interpretation of WGS, WES and RNAseq data from tumor samples of pediatric patients and PDX models. Although the data may originate from different sequencing techniques, the genomic analysis and interpretation must be carried out in an integrated manner. To ensure consistency and comparability across all data analyzed within the projects, this service must be conducted using the same comprehensive tool.

Throughout this specification, the tasks included within the object of this contract are specifically described, as well as the scope of the proposed service.

Clause 2. Maximum budget of the tender.

In the present tender procedure, the maximum tender budget and the estimated value of the contract match.

The maximum total budget, corresponding to the total duration of the projects, is **“SEVENTY-SEVEN THOUSAND FOUR HUNDRED EIGHTY-SIX EUROS AND NINETY-FIVE CENTS” (77.486,95 €)** without VAT, plus **“SIXTEEN THOUSAND TWO HUNDRED SEVENTY-TWO EUROS AND TWENTY-SIX CENTS” (16.272,26 €)** corresponding to VAT, which adds up to the amount of **“NINETY-THREE THOUSAND SEVEN HUNDRED FIFTY-NINE EUROS AND TWENTY-ONE CENTS” (93.759,21 €)**.

The estimated number of patients to be studied within the 4 projects is as follows:

1. Genomic analysis of WES/WGS/RNAseq data from 103 pediatric patients with solid tumors, within the “SEHOP-PENCIL” and “COMIKv2.0” projects.
2. Genomic analysis of WES/RNAseq data from 92 (46 PDX models and their 46 matched patient samples), within the “COMIKv2.0” project.
3. Genomic analysis of WES/WGS/RNAseq data from 25 pediatric patients with solid tumors, within the “ABTL0812” project.
4. Genomic analysis of WES/WGS/RNAseq data from 50 children and adolescents with relapsed/refractory neuroblastoma, within the “BEACON2” project.

Unit Price of genomic analysis per patient (VAT excluded):

Comprehensive tool for genomic data analysis and interpretation	Price
WES DNAg tumor/constitutional (coverage >90x to >200x) + RNAseq RNA tumor (>90 M PE reads)	(*) 252,64 €
WES DNAg tumor/constitutional (coverage >90x to >200x)	(*) 210,54 €
WGS DNAg tumor/constitutional (99Gb (30x) to 165Gb (50x)) + RNAseq RNA tumor (>90 M PE reads)	(*) 452,64 €
WGS DNAg tumor/constitutional (99Gb (30x) to 165Gb (50x))	(*) 368,43 €

(*) Price that the tenderer, will be able to improve in the ECONOMIC OFFER.

Therefore, the maximum total budget for each unit of service to be carried out will be:

Comprehensive tool for genomic data analysis and interpretation	Estimated Patients/PDX	Price
WES DNAg tumor/constitutional + RNAseq RNA tumor	109	27.537,76 €
WES DNAg tumor/constitutional	86	18.106,44 €
WGS DNAg tumor/constitutional + RNAseq RNA tumor	50	22.632,00 €
WGS DNAg tumor/constitutional	25	9.210,75 €

The maximum total budget is financed in the following way:

- For the project PI21/01661 "COMIK v2.0", expenditure of "THIRTY-SIX THOUSAND THREE HUNDRED EIGHTY EUROS AND SIXTY CENTS" (36.380,60 EUROS) VAT excluded.
- For the project PMP21/00073 "SEHOP-PENCIL", expenditure of "NINE THOUSAND TWO HUNDRED SIXTY-THREE EUROS AND SIXTY CENTS" (9.263,60 EUROS) VAT excluded.
- For the project ICI21/00076 "ABTL0812", expenditure of "NINE THOUSAND TWO HUNDRED TEN EUROS AND SEVENTY-FIVE CENTS" (9.210,75 EUROS) VAT excluded.
- For the project PI24/01576 "BEACON2 trial", expenditure of "TWENTY-TWO THOUSAND SIX HUNDRED THIRTY-TWO EUROS" (22.632,00 EUROS) VAT excluded.

The estimated value for this tender is "**SEVENTY-SEVEN THOUSAND FOUR HUNDRED EIGHTY-SIX EUROS AND NINETY-FIVE CENTS**" (77.486,95 €) without VAT, plus "SIXTEEN THOUSAND TWO HUNDRED SEVENTY-TWO EUROS AND TWENTY-SIX CENTS" (16.272,26 €) corresponding to VAT, which adds up to the amount of "**NINETY-THREE THOUSAND SEVEN HUNDRED FIFTY-NINE EUROS AND TWENTY-ONE CENTS**" (93.759,21 €).

Concept	Price (VAT not included)
Maximum budget	77.486,95 euros
Possible modifications	0,00 euros

Possible extensions	0,00 euros
Total	77.486,95 euros

The cost of the genomic analysis service was estimated based on the experience with previous projects and quotations received from several companies.

Clause 3. Duration of the contract.

The duration of the service object of this tender will coincide with the validity of the aforementioned projects which is, overall, until **31 December 2027**.

The service will start on the day following the formalization of the contract.

As of the date of publication of this tender, the duration of the projects is as follow:

- Project **PI21/01661** runs until **31 June 2026**.
- Project **PMP21/00073** is until **31 December 2025 (possible extension 31 June 2026)**.
- Project **ICI21/00076** runs until **31 December 2025 (possible extension 31 June 2026)**.
- Project **PI24/01576** is until **31 December 2027**.

However, if this project were to be found, for any unforeseen reasons, subject to the request of a possible extension, the end date will be susceptible to being extended, at most to the one that is finally authorized.

Clause 4. Description of the service and scope of the object of the contract.

The service will support multiple projects requiring genomic analysis using WES, WGS, and RNAseq techniques. As part of the Personalized Medicine projects, it will involve analyzing WES, WGS, and RNAseq data from tumor samples of pediatric patients to identify genomic alterations that could guide targeted therapy recommendations and expand treatment options. Additionally, the service will include WES and RNAseq data analysis of patient-derived xenograft (PDX) models.

Within the Phase I clinical trial for the drug ABTL0812, the service will focus on analyzing WES, WGS, and RNAseq data from patient samples to identify predictive biomarkers of response to ABTL0812.

Finally, in the context of the BEACON2 clinical trial, the service will encompass WGS, WES, and RNAseq data analysis of tumor samples from children and adolescents with relapsed

and refractory neuroblastoma enrolled in the study, to enable the rapid identification of druggable genomic aberrations suitable for targeted therapies.

The service must include the following conditions:

1. Technical specifications for the genomic analysis of pediatric tumors:

A comprehensive tool for genomic analysis and online biological data interpretation: This tool should integrate bioinformatics software for processing raw data from high-throughput sequencing (WES, WGS and RNA-seq) with an online interface for interpreting biological data. Additionally, it should enable the creation and export of customizable reports.

A. Type of samples and sequencing data:

- Raw data from high-throughput sequencing (WES, WGS and RNAseq)
- Type of samples from pediatric cancer patients or patient derived xenografts:
 - Constitutional DNA
 - Tumor DNA
 - Tumor RNA

B. Bioinformatic analysis characteristics of the tool:

- Alignment, variant identification, and annotation
- Quality control of sequencing data
- Detection of somatic alterations, including:
 - SNV (Single Nucleotide Variants) and Indels (small Insertions and Deletions)
 - CNV (Copy Number Variants): amplifications, gains, deletions, losses and copy neutral loss of heterozygosity
 - Copy number alterations profiles
 - Fusions: mainly Inframe and Frameshift
 - Tumor Mutational Burden
 - Mutational Signatures
 - Microsatellite Instability
 - Optional detection of Structural Variants
- Identification of germline alterations, including:
 - SNV (Single Nucleotide Variants) and Indels (small Insertions and Deletions)

C. Online interface characteristics of the tool:

- Comprehensive visualization and analysis of the patient's complete molecular tumor profile, including: circo plots, Variant Allele Frequency (VAF) distribution graphs for somatic mutations, Copy Number Alteration (CNA) profile plots, mutational signatures graphs and tumor mutational burden graph.

- Advanced filtering options, such as: gene filters (display all genes, cancer genes, incidental genes or specific gene), impact and consequence filters (high, moderate, low and unknown), filters for VAF, read depth and population frequencies and CNV thresholds for amplifications and deletions.
 - Somatic mutation exploration, with detailed data including: HGVSg, HGVSs, HGVSs nomenclature, B-allele frequency (BAF), copy number, VAF, depth, variant type, functional consequence, and recurrence in prior analyses. Integrated IGV browser for variant visualization.
 - Germline mutation exploration, displaying: HGVSg, HGVSs, HGVSs nomenclature. Data from constitutional DNA (BAF, copy number, VAF, depth) and tumor DNA (VAF, depth). Variant type, functional consequence, and recurrence in prior analyses. Integrated IGV browser for visualization
 - CNV visualization and identification, showing: genomic coordinates, size, type, cytoband, BAF, copy number, affected genes, cancer-relevant genes, annotations from DGV (Database of Genomic Variants) and DDD (Deciphering Developmental Disorders). Graphical CNV plots: LogR and BAF.
 - Fusion detection, including: short karyotype representation, strand orientation, spanning and junction read counts, FFPM, genomic location, transcripts, fusion type and graphic representation of gene fusion events.
 - Integrated access to multiple relevant databases, including: OncoKB, ClinVar and COSMIC
 - Links to clinical trials and treatment options
 - Variant classification, according to clinical significance: pathogenic, likely pathogenic, variant of uncertain significance (VUS), likely benign, benign. Option to apply custom user-defined classifications.
 - Customizable report generation and export: users can select which alterations to include and add personalized annotations. Automatically includes materials and methods section in the report.
2. Upload of fastq files via SFTP to a cloud-based server.
 3. Patient fastq files will be upload individually. Due to the urgency of obtaining results for relapsed patients in the personalized medicine program, these files will be prioritized for the bioinformatic analysis. For other studies, this urgency will not apply.
 4. As part of the personalized medicine program, the maximum turnaround time for bioinformatic analysis results from patient samples (WES and RNAseq) will be 48-72 hours (2 to 3 working days) after fastq reception. For all other samples (research), the maximum turnaround time will be 3 to 8 working days. For WGS data, the turnaround time will be 2 to 4 weeks.

5. The VHIR team will confirm via email the upload of the fastq files and the requested service. The awarded company/institution will acknowledge receipt of the fastq files via email and will also notify the VHIR team once the bioinformatics analysis is complete.
6. The awarded company/institution must provide support for resolving technical issues and orders, as well as addressing any questions or inquiries about the service or results, by email, with a response time of less than two business day (9 AM to 5 PM, Monday to Friday).

Clause 5. General Conditions.

- No type of subcontracting will be accepted in the global sequencing process.

Clause 6. Location and work time.

Location: The bidder will have to provide the service object of this tender in its own facilities, which must have the technology and personeel necessary.

Work time: The schedule will be determined by the center where the service is provided.

Clause 7. Billing and payment.

According to Law 25/2013, of December 27, 2013, on the promotion of electronic invoicing and the creation of the accounting registry of invoices in the Public Sector, in its Article 4, *"All suppliers who have delivered goods or provided services to the public administration may issue and send electronic invoices. In any case, they will be obliged to use the electronic invoice and to submit it through the corresponding general entry point..."*.

The awarded company will invoice electronically the services actually performed. The DIR3 codes to be able to issue the invoice are the following:

DIR3	ACCOUNTING OFFICE	DIR3	MANAGING BODY	DIR3	PROCESSING UNIT
A09006467	Fundació Hospital Universitari Vall d'Hebron-Institut de Recerca (HUVH IR)	A09006467	Fundació Hospital Universitari Vall d'Hebron-Institut de Recerca (HUVH IR)	A09006467	Fundació Hospital Universitari Vall d'Hebron-Institut de Recerca (HUVH IR)

A monthly invoice will be issued. In no case will the maximum amount be binding on the VHIR, but only the supply and service actually provided will be paid based on the prices finally awarded.

Each invoice issued must detail the period to which it corresponds, the breakdown/description of expenses by concept and the internal account that should be charged, as well as indicate the references **“L 2025-034 GENOMIC ANALYSIS SERVICE ONCOPEd” and PROJECT REFERENCE.**

In the event that the issuance of the electronic invoice is not feasible for exceptional reasons, the contractor will invoice each service rendered through its corresponding invoice, which must be sent to the following e-mail address: factures@vhir.org

The effective payment of the executed services will be performed by bank transfer, due 30 days / invoice date.

The contracting institution will make the payment of the supplies once they have been fully performed and once the invoice has been entered into its registry. In accordance with this paragraph, advance payment of part or all of the contract price is not contemplated.

In no case, the contractor will have the right to the revision of prices pertaining to any concept.

Therefore, the contracting entity will make the payment of the invoices using the currency conversion according to the common practices that the entity carries out in this type of case, so said payment will be made at the time of payment of the invoice.

The VHIR's fiscal data that must be included in the invoice are the following:

FUNDACIÓ HOSPITAL UNIVERSITARI VALL D'HEBRON - INSTITUT DE RECERCA
VAT: G-60594009
Passeig Vall d'Hebron, 119-129
08035 Barcelona

In the event that the invoice is not issued in accordance with the criteria established and referenced at the beginning of this clause, payment will not be made and the invoice will be withheld until the requested data is correctly indicated.

In the case of electronic invoicing, this will be rejected until the requested data is correctly indicated.

Once the contract ends, including any extensions that may be executed, VHIR will only accept invoices issued after the end of the contract as long as the period of execution of the same is within the term of the tender.

In the event that the invoice is issued after the end of the contract and in accordance with the above paragraph, VHIR will only pay invoices issued within two (2) months after the end of the contract.

The VHIR will only pay the successful bidder for the services actually provided, without, in any case, the VHIR being obliged to exhaust the estimated value of the contract/bid budget.

Clause 8. Responsible for the contract.

The person in charge of the contract will be Dr. Lucas Moreno Martín-Retortillo, Head of the Childhood Cancer and Blood Disorders Group of the Fundació Hospital Universitari Vall d'Hebron - Institut de Recerca and IP of the Projects PMP21/00073, PI21/01661, ICI21/00076 and PI24/01576, who will basically have the functions of management and supervision of the contracts and the billing; follow-up, control and provide instructions for the good execution of the agreements; determine whether the performance conforms to the prescriptions established for its execution, reception of the order after its completion and comply with the obligations assumed by VHIR

Clause 9. Confidentiality, Protection of personal data and Intellectual and Industrial Property

Notwithstanding the provisions of the current legislation on intellectual property, protection of personal data and confidentiality, the companies awarded in this call for tenders will expressly commit to not giving the information and / or data provided by VHIR, or any use not provided in this bidding document, and / or expressly authorized by the Head of the Research Grants Office.

The company that awards the contract derived from this bidding will have to extend to their employees the obligations assumed by the awarded company, regarding confidentiality, intellectual property and protection of data.

All rights worldwide will be exclusively granted to VHIR for the maximum time established in applicable laws and / or international treaties for their exploitation through any format and / or exploitation modality, including the exploitation of any discovery, invention, creation, work, procedure, idea, technique, drawing, design, image or any other intellectual or industrial property right generated, raised or acquired as a consequence of the work carried out by the contracting company (hereinafter "Intellectual Property and / or Industrial"), which derives directly or indirectly from the relationship between VHIR and the company awarded in this tender procedure.

The awarded company must inform VHIR of any discovery, creation, invention, idea or any other element that constitutes or is likely to constitute a right of Industrial and / or Intellectual Property partially or totally developed during the contract period.

In the event that the awarded company discovers or develops any creation of intellectual or industrial property, it will be understood that the discovery or development constitutes confidential information of VHIR.

The awarded company must sign all those public and / or private documents that are necessary, in VHIR's discretion, to allow the accreditation of the ownership of VHIR or the proper protection of the aforementioned Intellectual Property and / or Industrial rights in favor of VHIR or of any designated third party.

The awarded company authorizes VHIR to transform, modify, publish, communicate and exploit the work resulting from the execution of the contract derived from this tender procedure.

Clause 10. Allocation criteria

1. Criteria that can be assessed through automatic formula	Maximum 56 points
- Financial Offer	Maximum 26 points
- Automatic Evaluation Criteria	Maximum 30 points
2. Criteria that can be assessed through value judgments	Maximum 44 points

10.1 Criteria that can be assessed through automatic formula..... up to 56 points

The following criteria will be evaluated by automatic formula. The award criteria for assessing the contents of **Envelope 3** are as follows:

10.1.1 FINANCIAL OFFER.....up to 26 points

The formula will be applied to the value resulting from the following:

- 1) Multiply each unit price offered by the number of samples, which is 50.
- 2) Sum the amount of the previous multiplications.

It will be valued automatically, in accordance with the following formula:

$$P_v = \left[1 - \left(\frac{O_v - O_m}{IL} \right) \times \left(\frac{1}{VP} \right) \right] \times P$$

P_v = Bid Score to Rate

P = Economic criteria points

O_m = Best Offer

O_v = Offer to be Valued

IL = Bid Amount

VP = Weighting Value = 1

* If after applying the automatic formula to a submitted bid, the resulting value is negative, you will be directly assigned zero (0) points of the economic part.

10.1.2 AUTOMÁTIC EVALUATION CRITERIA.....up to 30 points

The bidders shall mark the automatic evaluation criteria in Annex No. 1 of the PCAP, which they must provide in **Envelope 3**, as well as the documentation accrediting this:

- Possibility of performing the bioinformatic analysis of WES/WGS from tumor DNA without the paired WES/WGS from normal (constitutional) DNA, using a reference panel of normal samples to identify CNVs.....8 points
- Possibility of performing a prior processing step using the Xenofilter software for PDX sequencing data (included in the price).....8 points
- Capability to deliver bioinformatic analysis results within 48 hours for very urgent patient samples, upon receipt of fastq files.....7 points
- Secure data transfer system through their own server. The cloud-based server used for uploading FASTQ files via SFTP must be secure, in order to ensure the confidentiality and integrity of sensitive genomic data.....7 points

10.2. Criteria that can be assessed through value judgments..... up to 44 points.

The following criteria can be assessed through value judgments. The value will be done in compared with the tenders submitted. The highest score will be given to the offer that best fits the technical requirements set out in this document. All other bids will be scored proportionally by comparison. Subsequently, the various proposals evaluated in descending order will be sorted out, and the following formula will be applied to obtain the score,

$$P_{op} = P \times \frac{VT_{op}}{VT_{mv}}$$

P_{op} = Score the offer to value

P = Criteria score

VT_{op} = Technical evaluation of the scored offer

VT_{mv} = Technical evaluation of the best scored offer

The following criteria will be evaluated by value judgments. The award criteria for assessing the contents of **Envelope 2** are as follows:

10.2.1 Drafting of a report on the specifications and technical characteristics of the service.....(up to 22 points)

Report on the provision of the service that includes:

- The technical specifications of the comprehensive tool for genomic analysis and online biological data interpretation, including the characteristics of the bioinformatic analysis and the online interface (see details in Clause 4).....up to 15 points
- Characteristics of the data transfer system.....up to 7 points

10.2.2 Drafting of a report on the provision of the service.....up to 22 points

Report on the provision of the service that includes:

- Work plan and organization during the provision of the service, including the turnaround times for the delivery of bioinformatic analysis results through the tool's online interface (see details in Clause 4).....up to 15 point
- The support plan for resolving technical issues, orders, questions, and inquiries regarding the service and results.....up to 7 points

In accordance with Directive 1/2020 on the Application of Evaluation Formulas and Scoring of Economic and Technical Proposals, a threshold is established for each criterion to be evaluated and subsequently scored, which in no case may be less than 50% of the evaluation of each criterion.

There are two possible options regarding the function of this threshold, depending on whether none of the bids exceeds it (option 1) or at least one of the technical bids exceeds it (option 2).

- Option 1 - If the evaluation of the bids exceeds the minimum evaluation threshold, all of them obtain as a score the value obtained in the evaluation phase and no bid is excluded from the tender.
- Option 2- If any of the bids exceed the threshold, all the bids are scored and no bid is excluded from the scoring phase, nor from the tender.

Therefore, the minimum scores for each sub-criteria in order to apply the formula will be:

- Drafting of a report on the specifications and technical characteristics of the service (11 points).
- Drafting of a report on the provision of the service (11 points).

A minimum total score of 27 points is required in the technical assessment so that the bidding companies can continue in the selection process and opt for the criteria that can be evaluated with automatic formulas. **Failure to obtain 27 points or more in the technical bid will be excluded from this tender procedure.**

Barcelona, August 14th, 2025.

CONTRACTING ORGANISM

Mrs. Montserrat Gimenez Prous

Manager

Fundació Hospital Universitari Vall Hebron– Institut de Recerca (VHIR)