Statement of Work
Simfonia

1. Statement of Work

1. This Statement of Work ("SOW") dated as of December 05, 2022 (the "Effective Date") is made among Fundació De Gestió Sanitaria De L'Hospital De La Santa Creu I Sant Pau ("FGSHSCSP") and Fundació Institut De Recerca De L'Hospital De La Santa Creu I Sant Pau (""FIRHSCSP") (both hereinafter referred to jointly as ("PARTNERS")) and Roche Diagnostics International Ltd ("ROCHE"). Upon full execution, this SOW will become a part of, and will be subject to, the Framework Collaboration Agreement ("FCA") by and between PARTNERS and ROCHE dated May 3rd, 2022, (the "Agreement"). Capitalized terms not otherwise defined in this SOW will have the meanings given to them in the Agreement. In the case of a conflict between this SOW and the FCA, the FCA shall govern unless the SOW explicitly calls out an exception, and the specific, impacted, section of the FCA.

2. Simfonia Project Description

1. PARTNERS and ROCHE will work to identify how the overall lung cancer patient survival rate, through a data driven and evidence based approach to the health system capacity optimization within the PARTNERS organizations, could be increased. The Partners and Roche will collaborate to design, test and validate an approach on what data; technical and operational requirements are required to achieve such a Healthcare System Capacity optimization (HSCO). The PARTNERS and Roche will aim to understand what key foundational elements are required and how the basis for health system optimization is achievable through the creation and visualization of actionable insights generated through the convergence and analysis of operational, economical and patient data. In order to attain this, ROCHE will analyze three (3) sets of data, provided by and through the PARTNERS. The ambition is to integrate and visualize that data into a single dynamic and digital representation of the Lung Cancer Health in the PARTNERS organization.

3. Objectives

1. To gain and collate the objective and subjective perspectives of patients and multidisciplinary healthcare professionals (HCP) on the lung cancer care pathway that will help to determine where and how HSCO can be achieved;

2. To structure and use patient data to create a digital and granular map of the lung cancer care pathway and its outcomes so that opportunities for healthcare system capacity optimization (HSCO) can be readily identified; and

3. To use the structured patient data to configure the PPSM (Per Patient Spend Model) so that pathway and patient costs can be generated to create a visibility of spend which enables redistribution of budgets that support HSCO.

4. Funding

1. This study is funded by all parties equally. The funding is made up of an equal contribution of time, effort, and resources and is to be defined as a fair exchange. There will be no payments or financial transactions between PARTNERS and ROCHE.

5. Structure, Milestones & Deliverables

1. This Statement of Work as detailed in Annex I consists of 5 Work packages.
    1. Work package 1. Project initiation
    2. Work package 2. Operational interviews
    3. Work package 3. Patient Data model
    4. Work package 4. Per Patient Spend model
    5. Work package 5. Final Analysis and End report

6. Work package 1: Project Initiation

6.1.1. Ethics Committee Approval

2. Final sign-off all required legal documents (Confidentiality Agreement, Framework Collaboration Agreement, Statement of Work)
3. Internal PARTNERS communication
4. Internal PARTNERS information events
5. Standard kick-off sessions and definition of basic agreements in terms of Governance
6. Collection of Informed Consent for interviewees
7. Coordination of activities with 3rd parties

7. Work package 2: Operational Interviews

1. All interviews with the PARTNERS employees and patients will be conducted by two Roche employee. The Roche employees will have no commercial relationship with PARTNERS. Both Roche employees must be present during each interview. Duration of interview will be between 50 and 60 minutes, however time will be flexible and fully adaptable to the participants. At the beginning of the interview, interviewers will ask for permission or not to record the interview by means of a recording device, and once collated into HAF (Hospital Assessment Framework: please see Annex I for HAF details) tool, the recording will be deleted. Furthermore, an introduction to the questions and the scoring of it will be briefed. PARTNERS shall ensure that (1) any patients willing to be interviewed have executed an informed consent to participate in the project prior to such interview, and (2) such informed consent complies with all applicable data privacy and security laws, and provides the necessary authorizations for the primary and secondary uses of the data, as applicable. Whenever possible, interviews will be conducted in person, and if not, they will be conducted by telephone or an online virtual meeting.
2. As a collaborative process, the content of the questionnaires and the questions of interviews will be developed and reviewed by the research team, including staff from PARTNERS, and shall require approval by each of the parties prior to finalization.
3. The limited data the HAF stores is the score of answers and the generic type of stakeholder that answered the question. For example, nurse or nurse manager. The name of the person or specific role is not collected at any point.
4. **Quantitative interviews** addressed to different lung cancer care stakeholders on their perspective of the hospital's operations and processes will be conducted to provide critical insights on opportunities for improvement both in areas of high performance and areas of concern. Guided interview conducted by means of a questionnaire administered by interviewers to patients and professionals, each questionnaire with a special focus on their area of expertise. A quantitative analysis will be carried out by giving scores for each question in the questionnaire. The areas with the lowest scores (areas of concern) and those with the highest scores (high performance) will be

identified. Depending on the stakeholder type interviewed, 50-70 questions will be asked, with the questionnaire being administered only once to each participant.

7.5. **Qualitative interviews** with selected stakeholders to understand the current situation and add more information about either personal experience and/or professional expertise focused on previously identified areas. The questions will be decided based on the data from the quantitative interviews and will be jointly agreed and designed between PARTNERS and ROCHE.

8. Workpackage 3: Patient Data Model

1. The PARTNERS shall sign a separate Data Processing Agreement with IOMED Medical Solutions S.L. This enables the relevant and required Patient data to be structured and standardized as far as possible before any structuring and aggregation of variables can be completed. Only once this has been completed will the required Simfonia data (Agreed Variables) be anonymized, extracted, and provided to ROCHE. The variables for the required patient data model will be applied to all patient records between 2016 and 2021. Roche will never directly access any electronic hospital patient records and will only receive fully anonymized and structured data sets based on the agreed variables. The external party in charge of executing Workpackage 3 (see Table 3 of Annex I) is IOMED MEDICAL SOLUTIONS S.L,located in: Recinto Modernista de Sant Pau, Pabellón de Sant Manuel, C/ de Sant Antoni Maria Claret, 167, Barcelona.
2. Patient data collected through NLP (Natural Language Processing) will be anonymized and without a code that allows for re-identification. IOMED staff and the PARTNERS will retain access to the structured patient records database, and Roche will receive anonymized and aggregated data only.
3. Data will be extracted from electronic health records (EHR) and mapped to the OMOP CDM. The OMOP CDM includes a standard representation of health care experiences (such as information related to drug utilization and condition occurrence), as well as common vocabularies for coding clinical concepts, and enables consistent application of analyses across multiple disparate data sources.
4. Structured and unstructured data from the EHR is used and integrated into a database in the OMOP CDM. Data is extracted combining all the available resources and departments (inpatient hospital, outpatient hospital, emergency room) for all patients. Structured data is extracted, transformed to the OMOP standard and loaded into the database, while clinical notes (unstructured data from EHR) will be mined with an AI-based NLP framework that uses Machine Learning (ML) and other pattern recognition methodologies to extract relevant information (IOMED, Barcelona, Spain). NLP algorithms allow converting unstructured text into a structured

form from administrative and clinical patient data, among others. This framework allows capturing data from the clinical notes in an automatic manner, which is equivalent to filling a case report form (CRF) based on the content of a clinical note. All the variables of the study will be queried from the resulting OMOP CDM database, considering both structured and unstructured data sources.

5. The GDPR defines health data and clarifies that it covers "data concerning health" and treats them as a "special category" of personal data which is considered to be sensitive by its nature. In this sense, IOMED complies with the GDPR of the EU and the Spanish data protection regulations for the processing of these data. Moreover, all data that IOMED processes is always anonymized.
6. All hospital data, before being processed for any purpose, is anonymized by IOMED. The existing unique patient identifiers, such as the patient number, will be discarded and a random unique identifier will be assigned to each user. All the personally identifiable information (PII) such as names and surnames of the patient, as well as professional career, family or medical data, telephone numbers, references to places or addresses, email addresses, etc. are discarded and only the anonymized identifier of the person is available in the OMOP CDM database.
7. A second anonymization process is performed in the clinical notes using NLP, where multiple algorithms are used to identify character strings for names, surnames, telephone numbers, references to places or addresses, email addresses, etc. and replaced through randomized content generation.
8. The result is a structured database, which cannot be associated with unique individuals without additional information and inordinate effort, time and cost considering currently available technologies.
9. The PARTNERS will always maintain custody of the data since the software will be installed on their servers. All the data created is stored within the hospital and no data will ever be stored outside the PARTNERS internal systems. The data will be accessible from the site's database and will be anonymized on its servers.

9. Workpackage 4: Per Patient Spend Model

1. Cost data will be generated by means of the per patient spend model (PPSM). The list of activities that need to be included in the per patient spend model will be extracted from the per patient model, once it is completed. ROCHE will create a digital pathway specifically for the PARTNERS, this pathway will contain a complete as possible list of all the activities conducted for lung cancer patients. This patient data will be provided to PA Consulting so that they calibrate the input sheet for the PPSM so it is mapped exactly to the PARTNERS lung cancer digital pathway. PARTNERS will complete the costs for all the activities in the input sheet. Once completed, the PPSM will

generate a total pathway cost for lung cancer. ROCHE will provide PA Consulting a copy of the extracted patient data. This will be uploaded into the PPSM model in order to generate the final cost per patient. Full Access to the outputs of the PPSM will be made available to the PARTNERS. The external party that owns, runs and operates the PPSM is PA Consulting. Located in: 10 Bressenden Place, London SW1E 5DN, United Kingdom

9.2. The data will be stored using cloud hosting, which conforms to international security standards (e.g. IS027001). Data will be encrypted at rest, and located in the EU aligned to GDPR and the PARTNERS legal environment..

10. Workpackage 5: Final Analysis and Evidence

1. Delivery of the final analysis and insights report will be provided via a secure portal and where possible in a dynamic and digital format, including but not limited to the convergence and visualization of the three previous datasets.
2. All results and analysis will be considered interim until approval of results have been obtained from Dra. Xenia Acebes and/or Dr. Jordi Surallés. It has been agreed that all draft reports and results will be shared directly for approval in advance of sharing with the extended PARTNER and ROCHE project team.

11. Milestone Timelines (See Tables in Annex I for activity details which support the deliverables in the table below)

	2022				2023				
	September	October	November	December	January	February	March	April	May
Workpackage 1		1. Ethics Committee Approval 2. Internal letter in the hospital 3. Kick off sessions							
Workpackage 2				5. Delivery of initial HAF results (Quantitative analysis)		8. Delivery of initial HAF results (Qualitative analysis)		11. Delivery of final results of HAF	
Workpackage 3			4. Definition of final list of variables	6. Structure and anonymize of patient data		9. Final extraction of data	10. Export of data to ROCHE		
Workpackage 4					7. Configuration of PPSM using patient data			12. Completion of cost calculation	13. Delivery of pathway and patient care cost
Workpackage 5									14. Delivery and acceptance of the final analysis and insights report

12. Other Provisions

1. Communications

Progress will be presented via monthly written updates and a PARTNER-ROCHE review meeting monthly. Additional meetings to address specific issues and topics will be scheduled as needed.

2. Project Management

Weekly review of activities completed and planned will be held between the nominated project managers from PARTNERS and ROCHE. Each Party will designate one person to coordinate the day-to-day implementation and operation of this Statement of Work.

3. Information Security Measures

The data provided by PARTNERS to ROCHE will be deidentified, anonymized, line item data and will be stored by ROCHE following standard safeguards and operating procedures to ensure data privacy and security.

4. Fair Exchange the PARTNERS Contribution

1. Access to the patients, employees and healthcare professionals that will be interviewed for quantitative and qualitative interviews
2. Access to EMR/EHR Systems for Data for the Per Patient Data Model
3. Financial spend numbers to include in Per Patient Spend Model
4. Project Management and coordination of internal people
5. Provide support guidance, feedback and input as defined in the project activity table in Annex I

5. Fair Exchange ROCHE Contribution

1. Overall initiative coordination and management across all parties
2. Generation and Development and of evidence, insights, intelligence, models, tools and methodologies
3. The provision and visualization of 12.5.2. using a customer centric approach to ensure the correct user experience and value creation/translation
4. Provide Health System Consulting and Subject matter expertise

12.5.5. Provide support guidance, feedback and input as defined in the project activity table in Annex I

13. Intellectual Property

1. The Intellectual Property provisions set forth in the FCA and below will govern and control this Statement of Work, except that:

2. List any unique IP arrangements here

    1. Roche and the PARTNERS retains exclusive rights on all primary foreground intellectual property. (PFIP). PFIP is hereby defined as all documents, data results, know-how, discoveries, inventions, source code, improvements or developments, as well as any technology, software, digital asset and machine learning algorithms, patient workflow, process simulation, predictive modeling and or augmented intelligence, data analytics, integration and visualization approaches and methodologies, achieved, produced, or developed by or for Roche and/ by or for PARTNERS specifically for the delivery of this project, or achieved via tools, platforms, or models owned by Roche or by PARTNERS. Without limiting the generality of the foregoing, PFIP shall also include any improvements to Roche or PARTNERS Background Intellectual Property resulting from this collaboration.
    2. ROCHE herewith grants to PARTNERS a worldwide, perpetual, non-exclusive, royalty-free, non-sublicensible license to use the PFIP´s ROCHE for internal, non-commercial purposes.
    3. In each case, the PARTNERS hereby grants ROCHE a non-exclusive, royalty-free, non-sublicensable license to use the PARNTNERS´s PFIP (internal, non-commercial) for the purpose of making this SOW and for the duration of this SOW.
    4. In the case of all other foreground IP generated as a result of the direct collaboration with the PARTNERS and/or ROCHE, ownership shall follow inventorship. In other words, in accordance with the Applicable Law, the ownership of the foreground IP generated as a result of the collaboration will be of the party that generated it.

3. For the avoidance of doubt, the Parties highlight the following Background Intellectual Property to this Statement of Work, which is in no way intended to limit the Background Intellectual Property owned, controlled or used by any party in connection with this SOW:

1. ROCHE
2. The following, of which is a non-exhaustive list, is ROCHE Background Intellectual Property:

    1. The concept and design of generating/converging and analyzing Operational Data via the Hospital Assessment Framework
    2. The use of patient data to digitally map and visualize patient pathways.
    3. The PPSM is a model designed to capture, standardize and generate a pathway and/or patient cost using patient data to configure the PPSM. The concept of generating a synthetic cost model that can be used to standardize the cost of care across multiple global health systems is proprietary of ROCHE. The concept of a per patient costs/spend as a synthetic data point is also proprietary to ROCHE
    4. The concept of generating insights and evidence from converged patient, operation and financial data which is used for Healthcare system capacity optimization is proprietary to ROCHE

13.4. PARTNERS

[the PARTNERS to add here if required]

14. Termination

Either Party may terminate this SOW immediately by giving written notice to the other if that other party commits a material breach of any provision of this Statement of Work and, in the case of a breach capable of remedy, fails to remedy the same within 30 days upon receipt of written notice giving full particulars of the breach and requiring it to be remedied.

15. Indemnification

Each Party (the "Indemnifying Party") will defend, indemnify, and hold harmless the other Party, its affiliates, and their respective officers, directors, shareholders, members, employees, agents, and representatives (collectively, the "Indemnified Party"), from and against any losses, liabilities, damages, liens and claims, including reasonable legal fees and expenses, costs of investigation, litigation, settlement and judgment, and any taxes, interest, and penalties arising from or related to the Indemnifying Party's: (i) material breach of the Agreement or this SOW (whenever there is fault or willful misconduct); (ii) failure to comply with applicable law; (iii) gross negligence or willful misconduct; or (iv) infringement or misappropriation of any intellectual property owned by a third party.

A Party that intends to claim indemnification (the "Indemnitee") shall promptly notify the other Party (the "Indemnitor"), in writing, of any claim for which it seeks indemnification. Upon receipt, the Indemnitor shall assume defense or settlement of such Claim (with counsel of its own choice and at its own expense). The Indemnitor shall take all reasonable steps to investigate, defend, or settle such Claim, provided however that the Indemnitor shall have no authority to settle any Claim on behalf of Indemnitee, without the Indemnitee's written consent, which will not be unreasonably withheld, delayed, or conditioned. The Indemnitee may participate in the defense or settlement of a Claim through its own counsel at any time, provided that the Indemnitee shall be solely responsible for the cost of such separate counsel. If the Indemnitee elects to participate in the defense or settlement of a Claim, the Indemnitor and the Indemnitee shall cooperate and provide one another access to any records, materials, or witnesses relevant to the defense or settlement.

16. Miscellaneous

This Statement of Work may be amended or supplemented pursuant to the terms of the Agreement.

Where this Statement of Work refers to items to be agreed to by the Parties in the future, such agreement may be reached (if at all) in each Party's sole and absolute discretion. Neither Party is obligated to reach any such agreement.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Parties have by duly authorized persons executed this SOW as of the Effective Date set forth above.

Roche Diagnostics International Ltd

_____	_____
Jason Schnabel Legal Counsel	Daniel Malarek Global Head of Marketing and Customer Insights

Fundació de Gestió Sanitària de l'Hospital de la Santa Creu i Sant Pau

Dr Adrià Comella Carnicé
Managing Director

Fundació Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau