AIDA

An Artificially Intelligent Diagnostic Assistant for gastric inflammation

INCLIVA | VLC

Instituto de Investigación Sanitaria

Aspectos éticos en el proyecto AIDA

Ana Miralles- Marco

Project manager en oncología - INCLIVA

Madrid, 15 de marzo de 2024

Co-funded by the European Union

UK Research and Innovation

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¿Qué es AIDA?

Qué nos han pedido…

1. durante la fase de propuesta
2. tras la concesión

¿Qué hemos aprendido?

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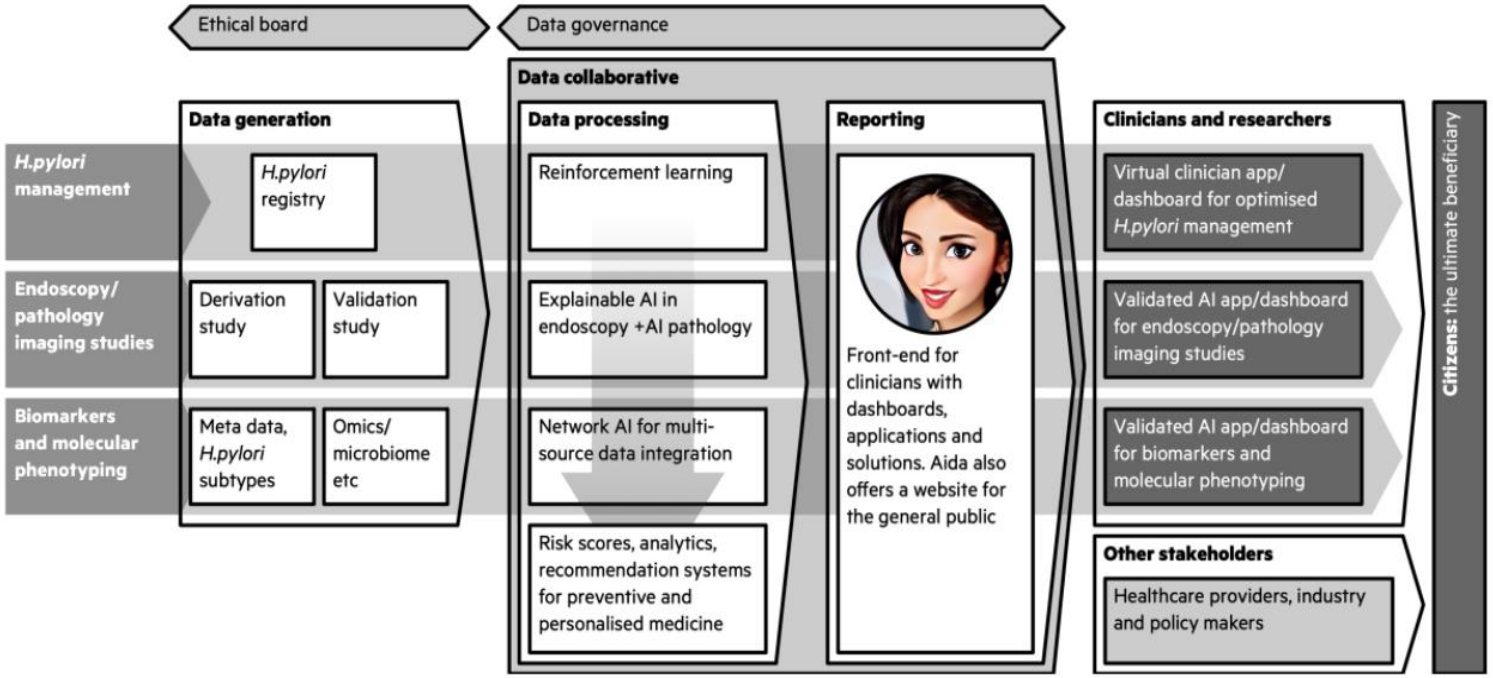

HORIZON-HLTH-2022-STAYHLTH-02

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¿Qué es AIDA?

Name	Address	PIC	Status
1. FUNDACION PARA LA INVESTIGACION DEL HOSPITAL CLINICO DE LA COMUNITAT VALENCIANA, FUNDACION INCLIVA (INCLIVA)	AV MENENDEZ PELAYO 4, VALENCIA 46010, Spain	999637187	BENEFICIARY
2. LATVIJAS UNIVERSITATE (LU)	RAINIS BOULEVARD 19, RIGA 1586, Latvia	999871830	BENEFICIARY
3. I3S - INSTITUTO DE INVESTIGACAO E INOVACAO EM SAUDE DA UNIVERSIDADE DO PORTO (i3S)	UA ALFREDO ALLEN 208, PORTO 4200-135, Portugal	892061180	BENEFICIARY
4. SERVICIO MADRILENO DE SALUD (SERMAS)	PLAZA CARLOS TRIAS BERTRAN 7, MADRID 28020, Spain	999481987	BENEFICIARY
4.1. FUNDACION PARA LA INVESTIGACION BIOMEDICA DEL HOSPITAL UNIVERSITARIO LA PRINCESA		934181781	AFFILIATED ENTITY
5. FUNDACIO CLINIC PER A LA RECERCA BIOMEDICA FCRB-CERCA)	CARRER ROSSELLO 149, BARCELONA 08036, Spain	999477525	BENEFICIARY
5.1. HOSPITAL CLINIC DE BARCELONA (HCB)		905096816	AFFILIATED ENTITY
6. CENTRE HOSPITALIER UNIVERSITAIRE DE NANTES (CHU-Nantes)	Allee de l'Ile Gloriette 5, NANTES 44093, France	999915868	BENEFICIARY
6.1. NANTES UNIVERSITE		888458988	AFFILIATED ENTITY
7. LIETUVOS SVEIKATOS MOKSLU UNIVERSITETO LIGONINE KAUNO KLINIKOS (LSMU)	EIVENIU 2, KAUNAS 50009, Lithuania	923616832	BENEFICIARY
8. INSTITUTO PORTUGUES DE ONCOLOGIA DO PORTO FRANCISCO GENTIL, EPE (IPO Porto)	RUA ANTONIO BERNARDINO ALMEIDA, PORTO 4200-072, Portugal	999988424	BENEFICIARY
9. ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM (Erasmus MC)	DR MOLEWATERPLEIN 40, ROTTERDAM 3015 GD, Netherlands	917133837	BENEFICIARY
10. STRATEJAI (Stratejai)	AVENUE LOUISE 209/A, BRUSSELS 1050, Belgium	890166673	BENEFICIARY
11. DIGESTIVE CANCERS EUROPE DICE (DiCE)	RUE DE LA LOI 235, BRUSSELS 1040, Belgium	895346570	BENEFICIARY
12. IMPERIAL COLLEGE OF SCIENCE TECHNOLOGY AND MEDICINE (Imperial)		999993468	ASSOCIATED PARTNER

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Fase de propuesta

Estudio Clínico

- Aprobaciones éticas
- CRD
- HIP y CIs

ENTREGABLE

	WP	Lead	Type	Dissm	**Month**
1 – Clinical Study Protocol and Informed Consent Form	1	INCLIVA	Ethics	PU	**6**

Fase de propuesta

Tres entregables obligatorios en estudios clínicos:

1. Paquete de inicio del estudio (antes de la inscripción del primer participante en el estudio) que incluya:
   - Número de registro del estudio clínico en un registro que cumpla los criterios del Registro de la OMS
   - Versión final del protocolo del estudio aprobado por el/los comité(s) de ética
   - Aprobaciones éticas (si corresponde, institucionales) requeridas para la inscripción del primer participante en el estudio (en el caso de estudios clínicos multicéntricos, basta con presentar aprobaciones para el primer centro clínico)
2. Informe de reclutamiento intermedio
3. Informe de resultados

Deliverables

D 1 – Clinical Study Protocol and Informed Consent Form
D 2 – Quality and Risk Management Plan
D 3 – Data Management Plan
D 4 – First year summary report
D 5 – Second year summary report
D 6 – Third year summary report
D 7 – Final summary report

Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D1.1	Clinical Study Protocol and Informed Consent Form	WP1	1 - INCLIVA	R — Document, report	PU - Public	6
D1.2	Quality and Risk Management Plan	WP1	1 - INCLIVA	R — Document, report	PU - Public	10
D1.3	Data Management Plan	WP1	1 - INCLIVA	DMP — Data Management Plan	PU - Public	6
D1.4	Mid-term recruitment report	WP1	1 - INCLIVA	R — Document, report	PU - Public	30
D1.5	Posting of results to the study registry	WP1	1 - INCLIVA	DATA — data sets, microdata, etc	SEN - Sensitive	48

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Fase de propuesta

Gestión de datos

- Reglamento general de protección de datos (RGPD)
- Armonización con espacios Europeos de datos, principios FAIR y ALTAI
- Comisión “Data collaborative governance board”, además de “Steering committee” and “General assembly”
  - Reuniones trimestrales (al menos)

DELIVERABLES

	WP	Lead	Type	Dissm	Month
2 – Quality and Risk Management Plan	1	ICV	D	PU	10
3 – Data Management Plan	1	ICV	Dmp	PU	8

Fase de propuesta

Inteligencia Artificial

- Los algoritmos de IA no están regulados, pero actualmente está pendiente de adopción en la UE una propuesta para establecer normas para la inteligencia artificial (the Artificial Intelligence Act)
- La CE nos recomendó seguir “Ethics by Design” y “Ethics of Use Approaches for Artificial Intelligence”: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-by-design-and-ethics-of-use-approaches-for-artificial-intelligence_he_en.pdf

Orientaciones sobre el uso de herramientas de IA generativa para la elaboración de la propuesta

Al considerar el uso de herramientas de inteligencia artificial (IA) en la preparación de la propuesta, es imperativo actuar con cautela y considerar cuidadosamente. Los contenidos generados por IA deben ser revisados y validados minuciosamente por los solicitantes para garantizar su idoneidad y exactitud, así como su conformidad con la normativa de propiedad intelectual. Los solicitantes son plenamente responsables del contenido de la propuesta (incluso de las partes producidas por la herramienta de IA) y deben ser transparentes a la hora de revelar qué herramientas de IA se utilizaron y cómo se utilizaron.

Específicamente, los solicitantes deben:

• Verificar la exactitud, validez e idoneidad del contenido y las citas generadas por la herramienta de IA y corregir cualquier error o inconsistencia.

• Proporcionar una lista de las fuentes utilizadas para generar contenido y citas, incluidas las generadas por la herramienta de IA. Revisar dos veces las citas para asegurarte de que sean precisas y estén debidamente referenciadas.

• Ser conscientes de la posibilidad de plagio cuando la herramienta de IA pueda haber reproducido texto sustancial de otras fuentes. Revisar las fuentes originales para asegurar de que no se está plagiando el trabajo de otra persona.

• Reconocer las limitaciones de la herramienta de IA en la preparación de la propuesta, incluida la posibilidad de sesgos, errores y lagunas en el conocimiento.

Fase de propuesta

Call: HORIZON-HLTH-2022-STAYHLTH-02
(Staying healthy (Single stage, 2022))

Topic: HORIZON-HLTH-2022-STAYHLTH-02-01

Type of Action: HORIZON-RIA

Proposal number: 101095359

Proposal acronym: AIDA

Type of Model Grant Agreement: HORIZON Action Grant Budget-Based

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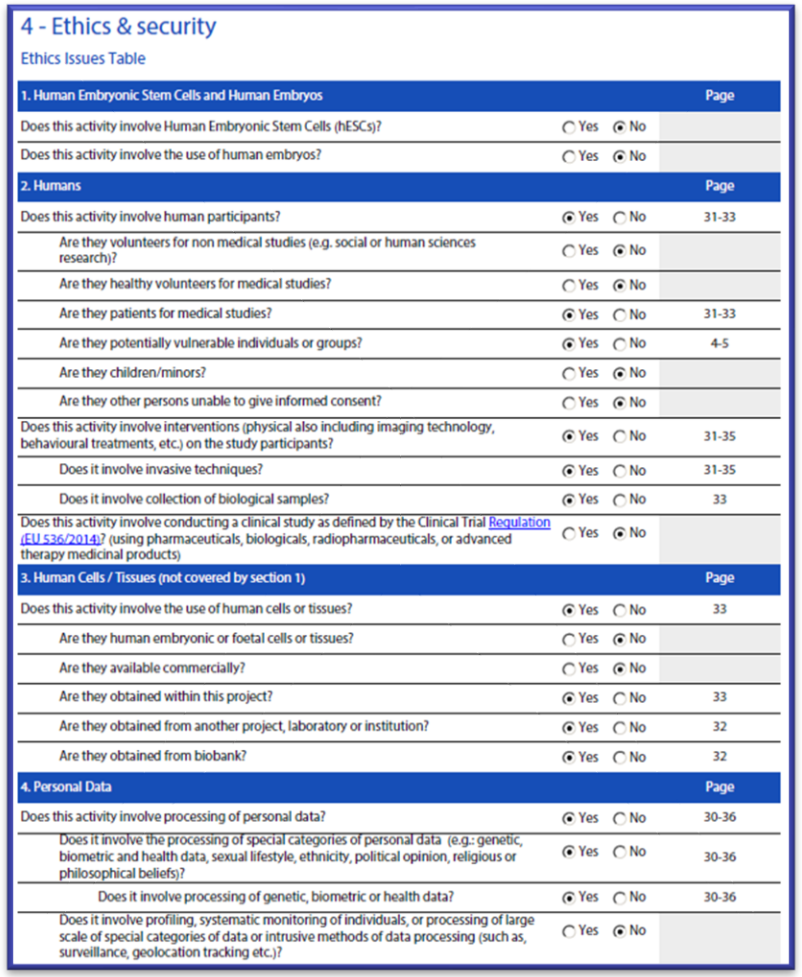
Fase de propuesta



4 - Ethics & security

Ethics Issues Table

1. Human Embryonic Stem Cells and Human Embryos			Page
Does this activity involve Human Embryonic Stem Cells (hESCs)?	○ Yes	◉ No	
Does this activity involve the use of human embryos?	○ Yes	◉ No	
2. Humans			**Page**
Does this activity involve human participants?	◉ Yes	○ No	31-33
Are they volunteers for non medical studies (e.g. social or human sciences research)?	○ Yes	◉ No	
Are they healthy volunteers for medical studies?	○ Yes	◉ No	
Are they patients for medical studies?	◉ Yes	○ No	31-33
Are they potentially vulnerable individuals or groups?	◉ Yes	○ No	4-5
Are they children/minors?	○ Yes	◉ No	
Are they other persons unable to give informed consent?	○ Yes	◉ No	
Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants?	◉ Yes	○ No	31-35
Does it involve invasive techniques?	◉ Yes	○ No	31-35
Does it involve collection of biological samples?	◉ Yes	○ No	33
Does this activity involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)	○ Yes	◉ No	
3. Human Cells / Tissues (not covered by section 1)			**Page**
Does this activity involve the use of human cells or tissues?	◉ Yes	○ No	33
Are they human embryonic or foetal cells or tissues?	○ Yes	◉ No	
Are they available commercially?	○ Yes	◉ No	
Are they obtained within this project?	◉ Yes	○ No	33
Are they obtained from another project, laboratory or institution?	◉ Yes	○ No	32
Are they obtained from biobank?	◉ Yes	○ No	32
4. Personal Data			**Page**
Does this activity involve processing of personal data?	◉ Yes	○ No	30-36
Does it involve the processing of special categories of personal data (e.g.: genetic, biometric and health data, sexual lifestyle, ethnicity, political opinion, religious or philosophical beliefs)?	◉ Yes	○ No	30-36
Does it involve processing of genetic, biometric or health data?	◉ Yes	○ No	30-36
Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (such as, surveillance, geolocation tracking etc.)?	○ Yes	◉ No	
Does this activity involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)?	◉ Yes	○ No	30-36
Is it planned to export personal data from the EU to non-EU countries? Specify the type of personal data and countries involved	○ Yes	◉ No	
Is it planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country? Specify the type of personal data and countries involved	○ Yes	◉ No	
Does this activity involve the processing of personal data related to criminal convictions or offences?	○ Yes	◉ No	
5. Animals			**Page**
Does this activity involve animals?	○ Yes	◉ No	
6. Non-EU Countries			**Page**
Will some of the activities be carried out in non-EU countries?	◉ Yes	○ No	1-45
United Kingdom			
In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues?	◉ Yes	○ No	1-45
United Kingdom. RGPD will be totally fulfilled in all countries, including non-EU			
It is planned to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?	○ Yes	◉ No	
Is it planned to import any material (other than data) from non-EU countries into the EU or from a non-EU country to another non-EU country? For data imports, see section 4.	○ Yes	◉ No	
Is it planned to export any material (other than data) from the EU to non-EU countries? For data exports, see section 4.	○ Yes	◉ No	
Does this activity involve low and/or lower middle income countries, (if yes, detail the benefit-sharing actions planned in the self-assessment)	○ Yes	◉ No	
Could the situation in the country put the individuals taking part in the activity at risk?	○ Yes	◉ No	
7. Environment, Health and Safety			**Page**
Does this activity involve the use of substances or processes that may cause harm to the environment, to animals or plants.(during the implementation of the activity or further to the use of the results, as a possible impact) ?	○ Yes	◉ No	
Does this activity deal with endangered fauna and/or flora / protected areas?	○ Yes	◉ No	
Does this activity involve the use of substances or processes that may cause harm to humans, including those performing the activity,(during the implementation of the activity or further to the use of the results, as a possible impact) ?	○ Yes	◉ No	
8. Artificial Intelligence			**Page**
Does this activity involve the development, deployment and/or use of Artificial Intelligence? (if yes, detail in the self-assessment whether that could raise ethical concerns related to human rights and values and detail how this will be addressed).	◉ Yes	○ No	1-45
9. Other Ethics Issues			**Page**
Are there any other ethics issues that should be taken into consideration?	○ Yes	◉ No	
I confirm that I have taken into account all ethics issues above and that, if any ethics issues apply, I will complete the ethics self-assessment as described in the guidelines How to Complete your Ethics Self-Assessment	☒		

Cuestionario sobre:

- Uso de embriones y células embrionarias
- Reclutamiento de personas
- Uso de células humanas
- Uso de datos personales
- Uso de animales
- Presencia de países non-EU
- Medioambiente
- IA

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Fase de propuesta

Ethics Self-Assessment

1) Ethical dimension of the objectives, methodology and likely impact (5000 characters)

Explain in detail the identified issues in relation to:

- *Objectives of the activities (e.g. study of vulnerable populations, etc.)*
- *Methodology (e.g. clinical trials, involvement of children, protection of personal data, etc.)*
- *The potential impact of the activities (e.g. environmental damage, stigmatisation of particular social groups, political or financial adverse consequences, misuse, etc.)*

Ethical dimension of the objectives, methodology and likely impact
The project's objective is the development and the validation of a multidisciplinary AI-powered assistant, Aida, that helps clinicians diagnose precancerous inflammation, suggests personalised therapeutic strategies for medical treatment and follow-up, and makes personalised recommendations for monitoring patient health status, thus contributing to gastric cancer prevention. Aida is meant as a tool to investigate the transition from chronic gastric inflammation to gastric cancer and the oncogenetic triggered along the way, as well as prevention and treatment strategies and their efficacy. The methodology involved to achieve such objective includes a two-phase clinical study. Its phase I will allow the assignment of a risk score of developing gastric cancer to individual patients based on a list of epidemiological and clinical information parameters, followed by the design of an AI-driven HP Eradication Therapy Recommendation and AI-driven GIM risk score assessment of pre-cancerous lesions, using imaging modalities. On the other hand, phase II will comprise the analysis and inclusion of additional epidemiological, clinical, pathological and molecular data from patients with a background with H. pylori infection or gastrointestinal metaplasia (GIM), for testing in a second cohort of patients with the same inclusion/exclusion and withdrawal criteria as in Phase I. Thus, this project will involve the use of retrospective clinical and epidemiological information and images, as well as the prospective collection of biological samples (gastric biopsies, blood and saliva), gastrointestinal images, as well as clinical and epidemiological information. As required by all applicable regulations and guidelines, the participation of patients in this study will be voluntary and subject to informed consent (IC) after being duly informed by their medical doctors and receiving the patient information sheet. During the visits to the site, eligible subjects will receive information regarding the study from a trained member of the research team. Subject participation implies the cession of samples and data for research use. The patient information sheet will contain information regarding the use of biological samples in this study and other clinical data. The sample collection will be performed only after subjects have read the information sheet and have signed the IC form, previously approved by the Ethical Committee of each centre involved. After the ethical approval from the competent local/national Ethical Committee, as for any clinical trial, detailed information on the IC procedures will be provided. Associated to it, the risks linked to the sample collection are within the clinical daily practices, and the patients will be treated according to the medical and patient decisions, all based on the clinical practice protocols of each clinical site, and without additional risks for the patient participation. Related to the project's impact, incidental findings may occur since the project will involve patients under treatment. In such circumstances, the responsible physician will be contacted and will take the necessary decisions and actions for patient care. In all cases, patients will be informed of the specific tests that will be performed for each sample collected. Regarding the results and their later validation, the scientific and clinical advisory boards will provide support to assess the importance of the findings, as well as the establishment of specific action plans. Additionally, before the performance of data processing a Record of Processing Activities and a Data Protection Impact will be performed. Moreover, Aida will follow open and Findable, Accessible, Interoperable and Reusable (FAIR) data principles, embedding open data standards of the health sector, and ensuring there is a clear methodology for stakeholders to publish data whilst minimising negative impacts. The latter involves techniques such as data minimisation, pseudonymisation, publishing structures for algorithms and respecting ethics in all data-driven projects.

2) Compliance with ethical principles and relevant legislations (5000 characters)

Describe how the issue(s) identified in the ethics issues table above will be addressed in order to adhere to the ethical principles and will be done to ensure that the activities are compliant with the EU/national legal and ethical requirements of the country or countries where the tasks are to be carried out.

Compliance with ethical principles and relevant legislations
The consortium will implement and ensure full compliance with the ethical aspects at the beginning and throughout the project. The clinical study will not start until the Ethical Committee of every clinical site gets its approval. The scientific and clinical advisory will be done by the foundation's boards and committees and will oversee that all the clinical partners perform such submission. It will be conducted following the Declaration of Helsinki and will conform to current international and national legislations. Although the clinical studies do not include medicinal products, the principles of Good Clinical Practice (GCP) will be strictly followed. Currently, AI algorithms are not regulated, but a proposal for setting rules for artificial intelligence is currently pending adoption in the EU (the Artificial Intelligence Act). This regulation could impact project activities. Consequently, the corresponding board will evaluate the AI algorithms with the Assessment List for Trustworthy Artificial Intelligence (Altai), to assess, mitigate and/or avoid potential risks. In order to offer a general level of risk related to Aida's algorithms, we briefly cover the seven sections of the Altai assessment. Informed consents. All participants will receive written and verbal information, maximising efforts towards the communication and full understanding of the objectives, risks and inconveniences of the study. Potential participants who lack the mental capacity to understand the nature of the study and who lack the ability to provide their IC will be excluded. The IC will specify: • Subject participation is voluntary and they have the right to: - Ask questions and receive understandable answers before making a decision; - Know the degree of risk and burden involved in their participation; - Know who will benefit from their participation; - Know the procedures that will be implemented in the case of incidental findings; - Withdraw themselves, their samples, and data from the project at any time; - Know how their biological samples and data will be collected and used during/beyond the project, and where they will be kept, and ask their permission for this. - Know the potential commercial exploitation of the research. • Who will have access to those data and tissues. • The patient's decision to not participate in the study will have no impact on her/his current medical care. • Information on arrangement for feedback to the individual of information generated during the research that is relevant to their health, health care, and counselling. Data protection. Any data storage and handling processes will ensure patient data protection and confidentiality. All the partners will treat and handle personal data under Regulation (EU) 2016/679. Patient clinical data will be kept confidential, it will be pseudo-anonymised and its access will be strictly restricted to the physicians in charge of the patient and, with their explicit authorisation, to data managers in charge of the study, study monitors and authorised regulatory bodies. Assessment according to applicable legislation. A Data Management Plan will be developed. Most relevant international regulations and guidelines to follow include: • The Charter of Fundamental Rights of the European Union of 12 December 2000. • The Convention on Human Rights and Biomedicine of the Council of Europe (Oviedo, 04.IV, 1997). • Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (Strasbourg, 25.I.2005). • The revised World Medical Association Helsinki Declaration (Fortaleza, 2013). • Recommendations of the Council of Europe. • Recommendation No. R (64)1 on human tissue banks of 14 March 1994. • Recommendation No. R (97) 5 on the protection of medical data of 13 February 1997. • Recommendation No. R (97) 18 concerning the protection of personal data collected and processed for statistical purposes of 30 September 1997. • Recommendation Rec (2006)4 on research biological materials of human origin of 15 March 2006. • Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001. • Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016. • ICH-GCP Guideline for good clinical practise E6 (R2). 14 June 2017. • International Ethical Guidelines for Biomedical Research involving Human Subjects, Council for International Organizations of Medical Sciences, Geneva 1993. • WHO: Operating Guidelines for Ethics Committee that Review Biomedical Research, Geneva, 2000. Shipments. The following guidelines will be employed to ensure the good compliance with the legal aspects related to the shipments of biological samples: • UNECE (United Nations Economic Commission for Europe). UN Recommendations on the Transport of Dangerous Goods. Model Regulations. • WHO: Transport of infectious substances, 2005. • IATA (International Air Transport Association). Dangerous Goods Regulations 2005.

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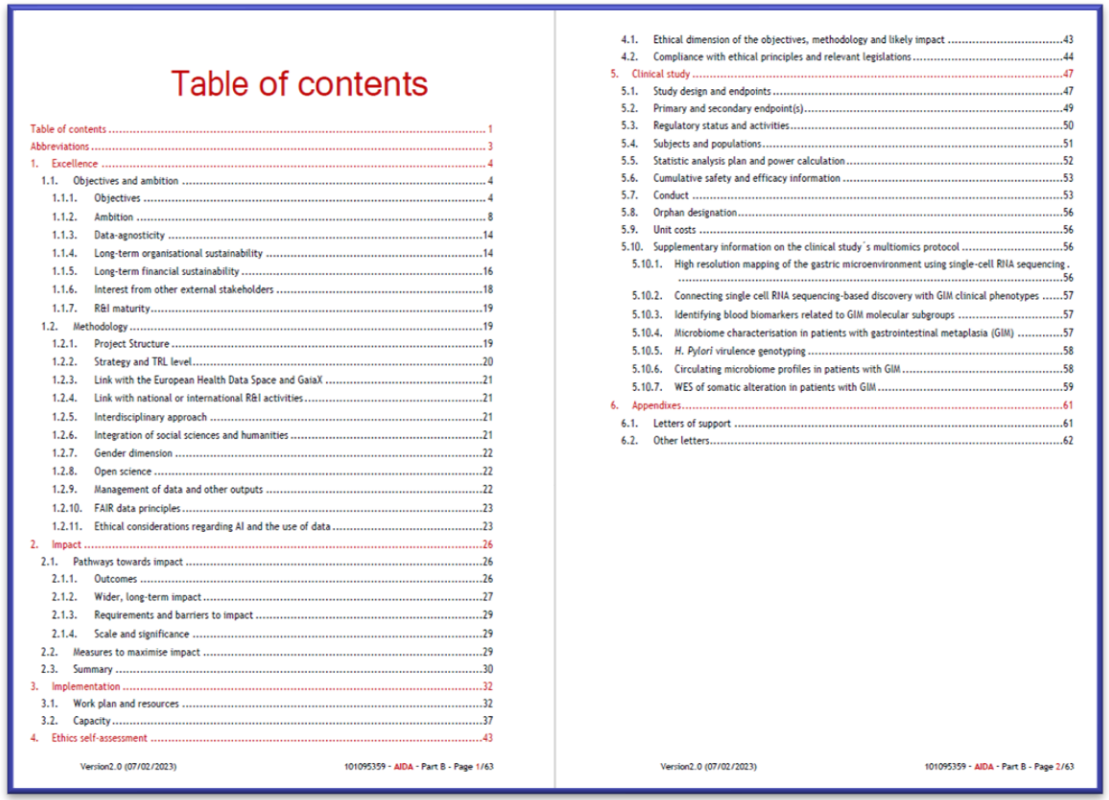
Tras la concesión

Aprobación comité ético



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GENERALITAT VALENCIANA
Hospital Clínic Universitari
DEPARTAMENT CLÍNIC MALVA-ROSA

HOJA DE INFORMACIÓN AL PACIENTE

TÍTULO DEL ESTUDIO: "Asistente con soporte de la inteligencia artificial en el diagnóstico y el manejo de la inflamación gástrica crónica y los cambios del epitelio que preceden al cáncer gástrico"	
CÓDIGO DEL ESTUDIO	**101095359 – AIDA**
INVESTIGADOR PRINCIPAL	Dra. Tania Fleitas Kanonnikoff
SERVICIO	Oncología Médica
CENTRO	Hospital Clínico Universitario de Valencia

Nos dirigimos a usted para informarle sobre un estudio de investigación en el que se le invita a participar. El estudio ha sido aprobado por el Comité de Ética de la Investigación de su centro, de acuerdo a la legislación vigente, Ley 14/2007, de 3 de julio, de Investigación biomédica. Nuestra intención es que usted reciba la información correcta y suficiente para que pueda decidir si acepta o no participar en este estudio. Lea esta hoja de información con atención y nosotros le aclararemos las dudas que le puedan surgir. Además, puede consultar con las personas que considere oportuno.

Así mismo, podrá solicitar cualquier explicación que desee sobre cualquier aspecto del estudio y sus implicaciones a lo largo del mismo contactando con el investigador principal del proyecto, la Dra. Fleitas en el teléfono 961973517 (INCLIVA)

1. Participación voluntaria

El motivo de su participación en este estudio es porque le ha solicitado una gastroscopia con finalidad diagnóstica y cumple los criterios de ser un **sujeto sano**. Su aceptación para participar implica su consentimiento a tratar algunos de sus datos personales y en permitir la toma y análisis de 5 muestras de biopsia gástrica, una analítica de sangre y saliva. Además, se le realizará una encuesta en la que se le preguntarán datos relativos a la dieta, su antropometría, actividad física, estado socioeconómico, consumo de tabaco, alcohol y sal, así como los antecedentes médicos relacionados con la gastritis. Su participación en el estudio no supondrá ninguna modificación de su tratamiento y debe saber que es voluntaria y que puede decidir NO participar. Si decide participar, puede cambiar su decisión y retirar el consentimiento en cualquier momento, sin que por ello se altere la relación con su médico ni se produzca perjuicio alguno en su atención sanitaria.

Debe saber que su participación en este estudio es voluntaria y que puede decidir NO participar. Si decide participar, puede cambiar su decisión y retirar el consentimiento en cualquier momento, sin que por ello se altere la relación con su médico ni se produzca perjuicio alguno en su atención sanitaria.

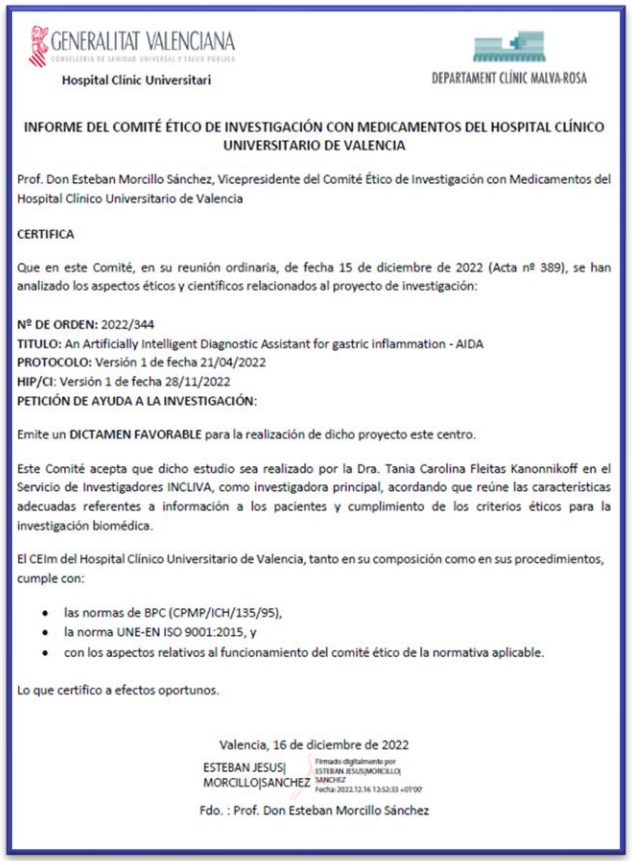
Su aceptación a participar en este estudio, implica su consentimiento a tratar algunos de sus datos personales, de la manera posteriormente descrita.

2. Justificación y Objetivo del estudio

Este estudio se realiza con el objetivo de conocer mejor aspectos relativos a la inflamación crónica y los cambios en el epitelio de la mucosa del estómago que preceden al diagnóstico del cáncer gástrico de tal manera a poder identificar a aquellos pacientes en riesgo de forma temprana y poder guiarlos a un seguimiento estricto.
El objetivo principal de este estudio es el de desarrollar una herramienta asistida por inteligencia artificial que integrará todos los datos clínicos, de factores de riesgo como la infección por *helicobacter pylori*, patológicos y moleculares de la inflamación de riesgo de la mucosa gástrica que pueden acabar en cáncer gástrico de manera a aplicar medidas eficaces de prevención.

3. Descripción del estudio

Este estudio forma parte de la estrategia del proyecto: "Consorcio Europeo para el desarrollo de una herramienta asistida por inteligencia artificial para el diagnóstico y manejo de la inflamación gástrica crónica".



GENERALITAT VALENCIANA
Hospital Clínic Universitari
DEPARTAMENT CLÍNIC MALVA-ROSA

INFORME DEL COMITÉ ÉTICO DE INVESTIGACIÓN CON MEDICAMENTOS DEL HOSPITAL CLÍNICO UNIVERSITARIO DE VALENCIA

Prof. Don Esteban Morcillo Sánchez, Vicepresidente del Comité Ético de Investigación con Medicamentos del Hospital Clínico Universitario de Valencia

CERTIFICA

Que en este Comité, en su reunión ordinaria, de fecha 15 de diciembre de 2022 (Acta nº 389), se han analizado los aspectos éticos y científicos relacionados al proyecto de investigación:

Nº DE ORDEN: 2022/344
TITULO: An Artificially Intelligent Diagnostic Assistant for gastric inflammation - AIDA
PROTOCOLO: Versión 1 de fecha 21/04/2022
HIP/CI: Versión 1 de fecha 28/11/2022
PETICIÓN DE AYUDA A LA INVESTIGACIÓN:

Emite un **DICTAMEN FAVORABLE** para la realización de dicho proyecto este centro.

Este Comité acepta que dicho estudio sea realizado por la Dra. Tania Carolina Fleitas Kanonnikoff en el Servicio de Investigadores INCLIVA, como investigadora principal, acordando que reúne las características adecuadas referentes a información a los pacientes y cumplimiento de los criterios éticos para la investigación biomédica.

El CEIm del Hospital Clínico Universitario de Valencia, tanto en su composición como en sus procedimientos, cumple con:

- las normas de BPC (CPMP/ICH/135/95),
- la norma UNE-EN ISO 9001:2015, y
- con los aspectos relativos al funcionamiento del comité ético de la normativa aplicable.

Lo que certifico a efectos oportunos.

Valencia, 16 de diciembre de 2022

ESTEBAN JESUS| MORCILLO|SANCHEZ
Firmado digitalmente por ESTEBAN JESUS|MORCILLO|SANCHEZ
Fecha: 2022.12.16 12:52:33 +01'00'

Fdo. : Prof. Don Esteban Morcillo Sánchez

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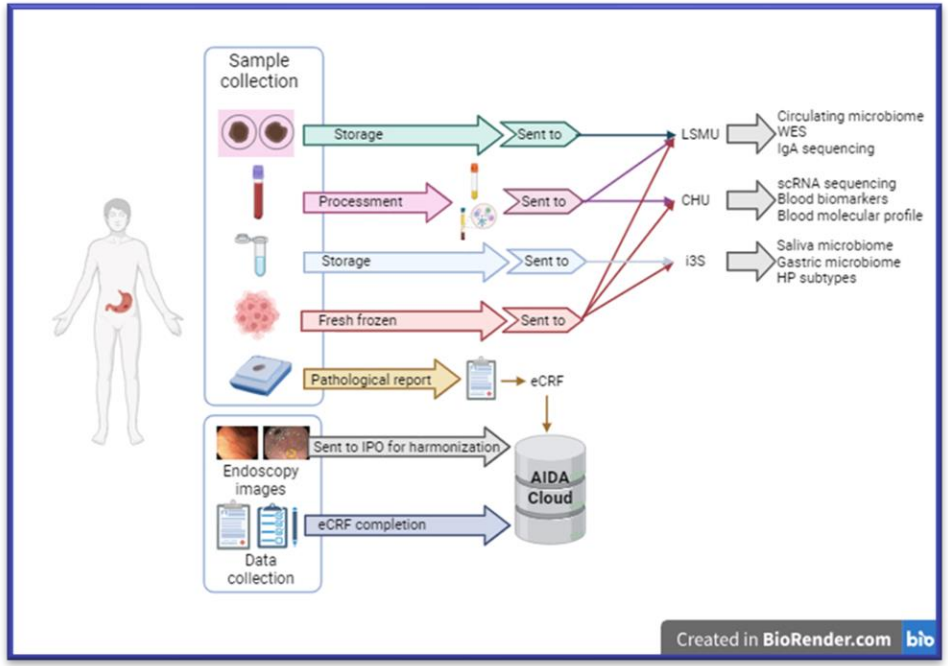
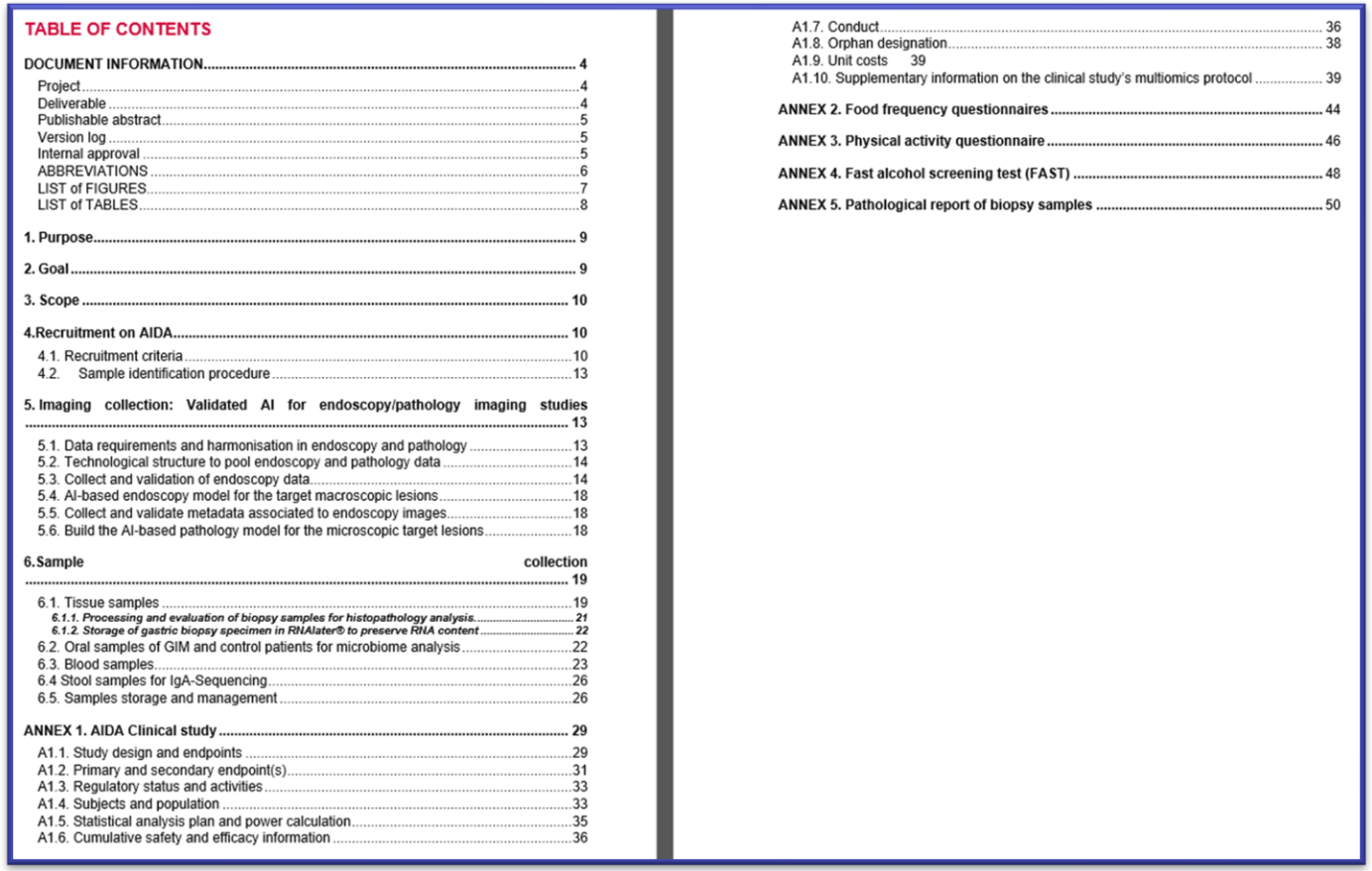
Tras la concesión

Lab handbook





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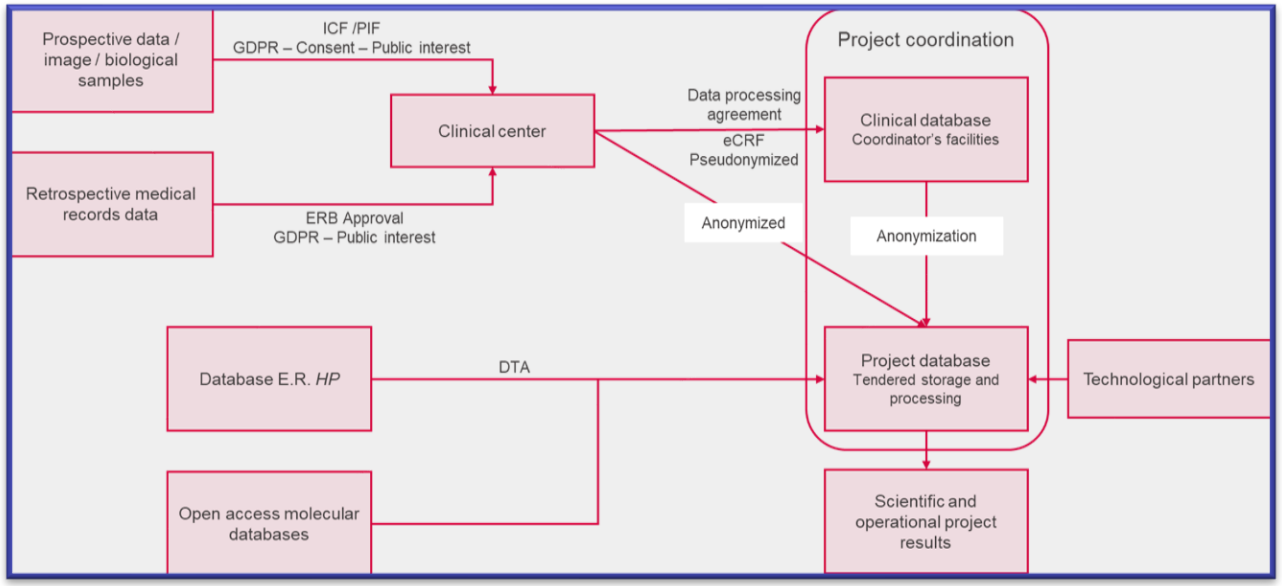
Tras la concesión

Plan de gestion de datos



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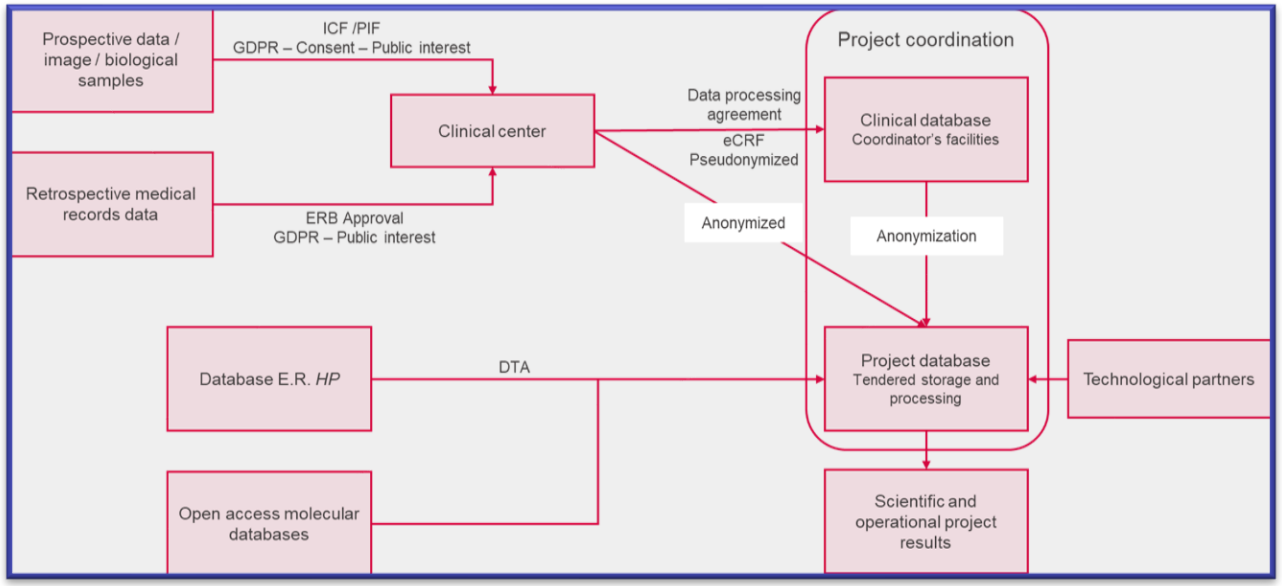
Tras la concesión

Plan de gestion de riesgos



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Tras la concesión

Evaluación de impacto de la protección de datos (DPIA)

Una Evaluación de Impacto de Protección de Datos (EIPD) es un proceso que identifica y minimiza sistemáticamente los riesgos relacionados con el tratamiento de datos personales. Ayuda a demostrar el cumplimiento de las obligaciones de protección de datos y las obligaciones de responsabilidad del responsable del tratamiento.

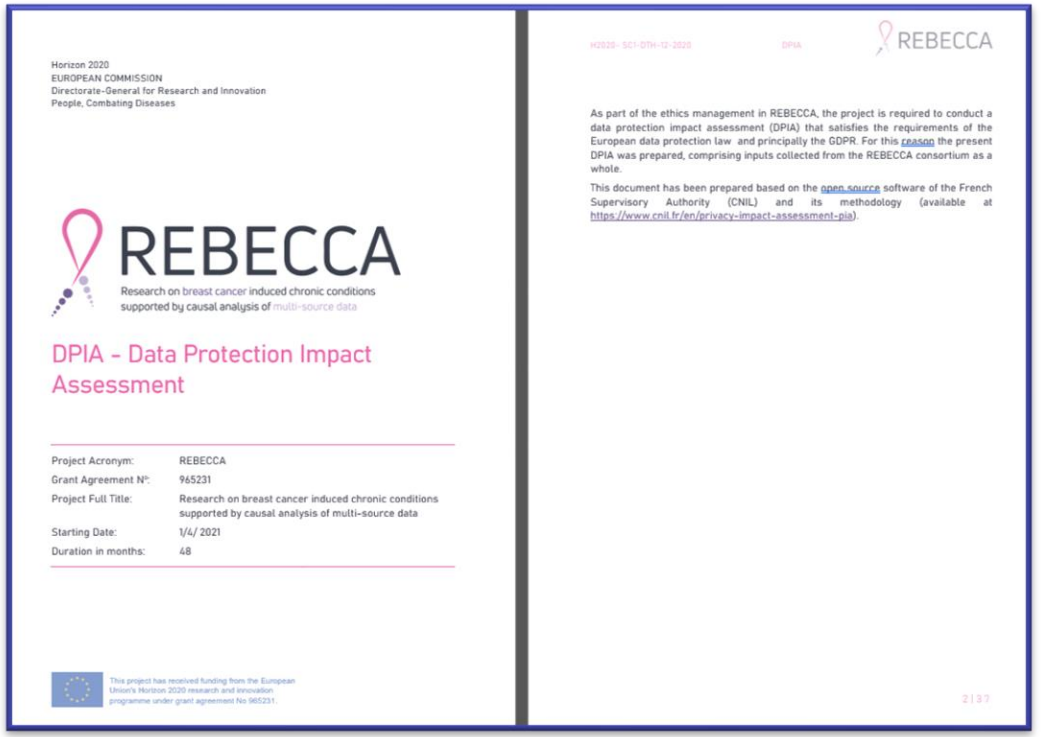
La EIPD es un procedimiento formal que tiene como objetivo registrar y evaluar una actividad específicamente relacionada con el tratamiento de datos personales y evalúa el nivel de riesgo teniendo en cuenta tanto la gravedad como la probabilidad de impacto en las personas.

Se debe llevar a cabo una EIPD siempre que el controlador planee

(a) utilizar perfiles sistemáticos y extensos con efectos significativos

(b) tratar datos sobre categorías especiales o delitos penales a gran escala, o

(c) monitorizar sistemáticamente lugares de acceso público a gran escala.



Horizon 2020
EUROPEAN COMMISSION
Directorate-General for Research and Innovation
People, Combating Diseases

REBECCA
Research on breast cancer induced chronic conditions supported by causal analysis of multi-source data

DPIA - Data Protection Impact Assessment

Project Acronym:	REBECCA
Grant Agreement N°:	965231
Project Full Title:	Research on breast cancer induced chronic conditions supported by causal analysis of multi-source data
Starting Date:	1/4/ 2021
Duration in months:	48

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965231.

REBECCA

As part of the ethics management in REBECCA, the project is required to conduct a data protection impact assessment (DPIA) that satisfies the requirements of the European data protection law and principally the GDPR. For this reason the present DPIA was prepared, comprising inputs collected from the REBECCA consortium as a whole.

This document has been prepared based on the open source software of the French Supervisory Authority (CNIL) and its methodology (available at https://www.cnil.fr/en/privacy-impact-assessment-pia).

Tras la concesión

Comité ético externo

- Contribuir a la elaboración de los documentos "ético-sensibles" mediante la asesoría durante su etapa de redacción o la revisión de los documentos antes de su aprobación por cualquier otro consejo interno o externo.
- Presentar informes periódicos a la CE a los meses [6, 12, 24, 48].

Prof. Óscar Pastor
Director of the "Centro de Investigación en Métodos de Producción de Software (PROS)" at the UPV

AI expert

Prof. Esteban Morcillo
Director of the Privacy and Digital Transformation Chair Microsoft-UV

Clinical ethics expert

Prof. M Francesca Cordeiro
Faculty of Medicine, Department of Surgery & Cancer
Imperial College London

AI expert

Deliverable D8.1 – OEI - Requirement No. 1

Deliverable Number	D8.1	**Lead Beneficiary**	1. INCLIVA
Deliverable Name	OEI - Requirement No. 1		
Type	ETHICS	**Dissemination Level**	SEN - Sensitive
Due Date (month)	1	**Work Package No**	WP8

Description
The proposal raises numerous ethics issues. The Applicants show a significant level of awareness and an internal advisory board is envisaged. The main ethics issues are related to human participation, personal data processing (retrospective and perspective) and AI development. Attention is given to the Assessment List for Trustworthy Artificial Intelligence (Altai). However, the complexity of the raised issues and the breadth of the project imposes to have at least an External, Independent Ethics advisor from the start of the project with expertise in personal data processing (mostly health data' secondary use) and AI design, development and deployment (mainly to prevent biases in the developed model and to incur in inadvertent personal data memorization in the developed algorithms). It is advised to follow as well the Ethics by Design and Ethics of Use Approaches for Artificial Intelligence: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-by-design-and-ethics-of-use-approaches-for-artificial-intelligence_he_en.pdf. Periodic reports from the Ethics Advisor must be provided at months [6, 12, 24, 48]. The ethics report should discuss how ethical issues were handled by the research team during the reporting period, whether any new issues emerged, and how they should be addressed (if applicable).

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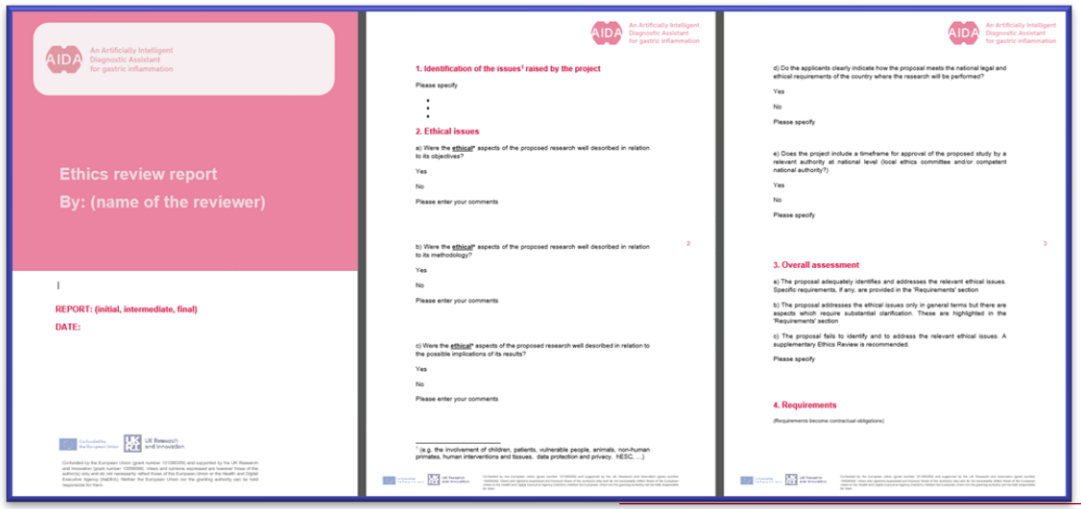
Tras la concesión

Comité ético externo

DELIVERABLES

	WP	Lead	Month
D8.1 - Requirement No.1	8	INCLIVA	1
D8.2 - Requirement No. 3	8	INCLIVA	6
D8.3 - Requirement No. 4.	8	INCLIVA	12
D8.4 - Requirement No. 5.	8	INCLIVA	24
D8.5 - Requirement No. 6.	8	INCLIVA	36



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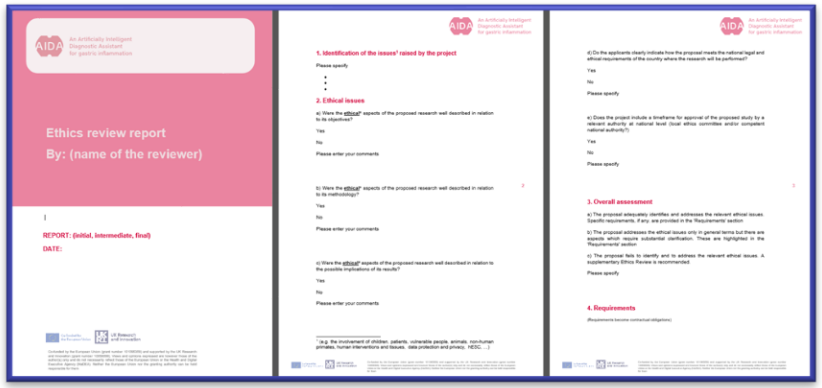
Tras la concesión

Comité ético externo



Ethical issues

a) Were the **ethical*** aspects of the proposed research well described in relation to its objectives

b) Were the **ethical*** aspects of the proposed research well described in relation to its methodology?

c) Were the **ethical*** aspects of the proposed research well described in relation to the possible implications of its results?

d) Do the applicants clearly indicate how the proposal meets the national legal and ethical requirements of the country where the research will be performed?

e) Does the project include a timeframe for approval of the proposed study by a relevant authority at national level (local ethics committee and/or competent national authority?)

Overall assessment

a) The proposal adequately identifies and addresses the relevant ethical issues. Specific requirements, if any, are provided in the 'Requirements' section

b) The proposal addresses the ethical issues only in general terms but there are aspects which require substantial clarification. These are highlighted in the 'Requirements' section

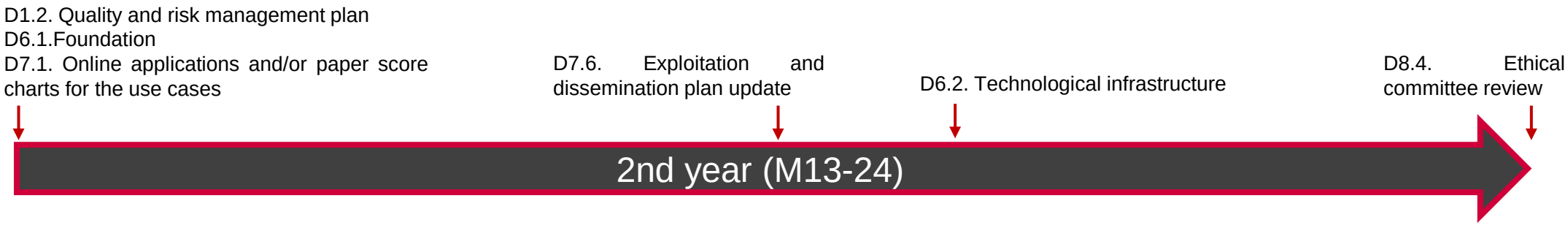
c) The proposal fails to identify and to address the relevant ethical issues. A supplementary Ethics Review is recommended.

Please specify

Requirements

Tras la concesión

¿Dónde estamos ahora?



- Revisión intermedia con los project officers y un comité de revisión externo (M18)
- La Comisión propondrá 2-3 evaluadores de las disciplinas involucradas en el proyecto
- Abarcará:
  - Paquetes de trabajo y tareas. Estado actual y logros (hitos y entregables)
  - Aspectos financieros
  - Aspecto éticos

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¿Qué es AIDA?

Qué nos han pedido…

1. durante la fase de propuesta
2. Tras la concesión

¿Qué hemos aprendido?

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¿Qué hemos aprendido?

- Son requisitos, no recomendaciones
- Necesidad de planificación y recursos
- Uso de nuevas tecnologías → incrementa la complejidad de los proyectos → Los requerimientos
- Perspectiva y bienestar del paciente → Esencial
- Proyectos multidisciplinares → Dejarse aconsejar
- Pedir soporte de expertos de comités éticos, departamentos de calidad, legal
- Estos requerimientos se terminarán implantando a nivel nacional
- Debemos ESCUCHAR

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En nombre del proyecto AIDA

Muchas gracias por invitarme y por vuestra participación

Ana Miralles Marco: amiralles@incliva.es

+34 689567412

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