D6.4 Risk management and quality assurance plan and Ethical impact assessment

MONITORING SYSTEM OF THE ENVIRONMENTAL AND SOCIAL SUSTAINABILITY AND CIRCULARITY OF INDUSTRIAL BIO-BASED SYSTEMS

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LIST OF ACRONYMS

AI	Artificial Intelligence
BIC	Biobased Industry Consortium
CBE JU	Circular Bio-Based Europe Joint Undertaking
CWA	CEN Workshop Agreement
DG AGRI	Directorate-General for Agriculture and Rural Development
DMP	Data Management Plan
EC	European Commission
GA	Grant Agreement
GUI	Graphical User Interface
LCA	Life Cycle Assessment
LCC	Life Cycle Cost
LCI	Life Cycle Inventory
MB	Management Board
MOOC	Massive Open Online Course
PDEC	Project Dissemination, Exploitation, and Communication
PM	Preventive measures
PMT	Project Management Team
PO	Project Officer
PSILCA	Product Social Impact Life Cycle Assessment Database
PU	Public
P2P	peer-to-peer
SB	Steering Board
S-LCA	Social Life Cycle Assessment
SOA	State Of The Art
SSL	Secure Sockets Layer
UX	User Experience
VPN	Virtual Private Network
WP	Work Package
WPL	Work Package Leader

EXECUTIVE SUMMARY

This document covers the risk management and quality assurance plan and ethical impact assessment of the BIORADAR project, funded under CBE JU. BIORADAR aims at developing metrics, methods, and digital monitoring tools to be used by policymakers and investors to assess the performance of industrial bio-based systems in terms of material circularity and environmental, economic, and social impacts. The selected use cases for the project belong to three industry sectors: bio-based textile, fertilizer, and packaging. The BIORADAR consortium is composed of seven partners and the project execution is structured into six work packages.

The Risk Management Plan aims to establish a procedure for identifying and addressing risks during the project's execution. It involves a continuous process, encompassing risk identification, analysis, monitoring, control, and reporting. The strategy outlined in the plan not only addresses technical and management risks but also considers other factors that may impact project progress. The plan proposes mitigation actions to be implemented promptly. As the risk assessment is ongoing, the plan will be updated throughout the project's duration. A key aspect is providing a methodology for risk mitigation to minimize unexpected effects and ensure project execution. The plan outlines identified risks, their estimated impact, and details monitoring and mitigation through contingency planning.

A Project Quality Assurance Plan is a comprehensive document outlining the strategies and processes implemented to ensure that a project meets predetermined quality standards and objectives. It includes procedures for quality planning, assurance, and control, detailing how quality will be managed throughout the project lifecycle. The goal is to enhance project outcomes by systematically addressing and monitoring quality at every phase of the project.

The ethical impact assessment aims to identify potential ethical issues that might emerge during the BIORADAR project or its potential future implementation and how they can be mitigated. The identified and assessed ethical issues for BIORADAR concern ‘’Research subjects’’ in terms of human participants, ‘’Personal data’’, and ‘’AI technology’’. Through this assessment, an ethically responsible research endeavor of BIORADAR can happen.

1 INTRODUCTION

Risk refers to any unforeseen event, whether positive or negative, that can impact the project and put its goals at risk. These risks can encompass various project-related factors, including individuals, processes, technology, and resources. Project risks are those risks that have the potential to affect at least one project objective. Every project inherently carries risks, and risk assessments, such as the one presented here, employ a process to recognize, evaluate, and manage these risks to minimize their influence on the project.

The purpose of the quality assurance plan is to outline the methods that will be utilized throughout the project to ensure the quality of project deliverables and outcomes. The quality assurance plan is geared toward ensuring that the project aligns with established quality standards. This plan delineates quality management processes and encompasses procedures for reviewing internal management and quality progress reports, in addition to evaluating the overall project deliverables. It also considers event assessment and describes the management procedures and tools used for measuring and monitoring the project's progress.

Furthermore, throughout the project's research activities, ethical risks may arise, potentially leading to significant consequences that need to be addressed. To ensure ethical responsibility throughout the project, an ethical impact assessment is detailed in this deliverable.

2 RISK MANAGEMENT PLAN

2.1 Roles and responsibilities

2.1.1 Project partners

Risk management is a shared obligation among all members of the consortium. Each partner bears the duty of promptly notifying their designated Work Package Leader (WPL) in the event of any potential risk that could impact the project's goals or its successful implementation. Any deviations to the project's deliverable timelines or budget allocations should also be communicated to the relevant WPL. Subsequently, the WPL will inform the project coordinator, and, if needed, the Project Officer (PO).

2.1.2 Work package leaders

The Work Package Leaders (WPLs) are assigned with overseeing and supervising the activities within their respective work packages. Additionally, they are accountable for ensuring harmonization among the leaders of tasks within their own work package and aiding the Project Management Team (PMT) in coordinating cross-cutting activities across all work packages. In this capacity, they serve as the initial level in the risk management process, with a focus on recognizing and managing risks specific to their work package. Furthermore, they hold the responsibility of promptly reporting newly identified risks and any changes in the status of known risks to the PMT.

2.1.3 Project management team

The PMT is responsible for the definition and implementation of the risk management process. Moreover, this team has the final responsibility for the monitoring and control of risks of all project activities and lead this important activity.

2.1.4 Steering board

The purpose of the Steering Board (SB) is to support the BIORADAR project in attaining the impacts expected by the call topic and the related CBE JU Strategic Innovation Agenda Objectives. The BIORADAR steering Board is composed by members from BIC (Biobased Industry Consortium) and the European Commission, representing both DG RTD (Directorate-General for Research and Innovation) and DG AGRI (Directorate-General for Agriculture and Rural Development). Expected outcomes for the Steering Board are:

- Political guidance for the project
- Policy frameworks integrating learnings
- Input to a reference document collecting environmental ‘best available techniques’
- First-hand information from the project’s progress and achievements

By providing political guidance for the project and monitoring its progress and achievements, the steering board ensures BIORADAR project is on track and decreases the risk of project failure.

2.2 Detailed Risk Identification and Management at Work Package level

During proposal phase, all BIORADAR partners contributed to identifying potential risks of project implementation and its mitigation measures as summarized in Table 3.1e of the proposal. After the project has started, the partners have gained more insight into project implementation risks in each work package (WP) and their impact on the other WPs and tasks. In the upcoming sub-sections, encountered risks for each WP, together with their likelihood, impacts, and mitigation measures are listed in separate tables.

2.2.1 Work Package 1: Identifying and Assessing Sustainability aspects of Industrial Bio-based Systems

Description of risk	Affected tasks/ WPs	Probability	Impact	Proposed risk-mitigation measures	Responsible partners for mitigation
Lack of primary data to carry out Life Cycle Assessment (LCA)	T1.2	Medium	High	Constant communication with producers will be carried out. In addition, supported and trustful databases have been identified. We will use them in case of needed to complete LCA with secondary data (e.g., ecoinvent, environmental footprint). Literature reviews and networking with projects of a similar topic will be made use of.	NTT, CETENMA, IRIS
Delay in the development of LCA	T1.2	Medium	High	Partners involved will start to recover information from the beginning of the project. In the case that the LCA is too lengthy to carry out in time due to the length of the Life Cycle Inventory (LCI), secondary data will be made use of to speed up the process. If primary data becomes available, the assessment will be updated.	NTT, CETENMA, IRIS
Difficulty to find tailor-made indicators	T1.2	Low	Medium	Continue analysis of state of the art (SOA) and other sources of information (e.g., Eurostat - EU commission circular economy indicators and Ellen Mc Arthur foundation). Increase the level of communication with the data providers, facilitating them the gathering of data (by for example specific Excel files)	CETENMA

Description of risk	Affected tasks/ WPs	Probability	Impact	Proposed risk-mitigation measures	Responsible partners for mitigation
				to ensure timing and data quality. We will also contact with other EU projects to gather information.	
Lack of primary data to carry out Life Cycle Cost (LCC)	T1.3	Medium	High	Constant communication with bio-product producers will be carried out. In addition, literature review will be used to do the calculations, as well as networking with similar projects and industries.	NTT, CETENMA, UNI
Lack of primary data to carry out S-LCA	T1.4	Medium	High	Constant communication with companies and workers will be carried out. In addition, supported and trustful databases have been identified. Complete Social Life Cycle Assessment (S-LCA) with secondary data (e.g., Product Social Impact Life Cycle Assessment database (PSILCA)) and data from literature reviews and similar projects. Secondary data can also be obtained from Annual and Sustainability reports of companies within the sector.	NTT
Results from sustainability assessment are not according to literature	T1.2, T1.3, T1.4	Low	Medium	The BIORADAR consortium will contact other projects where the consortium is involved to gather primary data from those partners Several methodologies will be used and compared to determine the environmental impacts of bio-based products.	NTT, CETENMA, IRIS
Assumptions (limits) of the systems are not according to reality	T1.2	Low	Medium	The consortium counts with experts in the development of sustainability assessment, with experience working with the 3 selected sectors. Several methodologies will be made use of, and an extensive review of literature and similar projects will be consulted on how to overcome these barriers.	NTT, CETENMA, IRIS

Description of risk	Affected tasks/ WPs	Probability	Impact	Proposed risk-mitigation measures	Responsible partners for mitigation
Lack of primary data for iLUC risks and carbon removal potential	T1.5	Medium	High	Constant communication with producers will be carried out. Supported and trustful databases have been identified to complete data.	NTT, CETENMA, IRIS, HAW

2.2.2 Work Package 2: Identifying and Assessing Circularity aspects of Industrial Bio-based Systems

Description of risk	Affected tasks/ WPs	Probability	Impact	Proposed risk-mitigation measures	Responsible partners
Difficulty to evaluate circularity with existing metrics	WP2, WP3	Medium	Medium	Literature review will be consulted since the beginning of the project and an assessment of the methodology will be carried out prior to the development of the circularity study to guarantee solid indicators. An initial analysis of current metrics on circularity will be done to adjust and tailor-made the circularity indicators to each sector/system. A screening system will be applied to select the most useful indicators, namely those that both capture circularity in a comprehensive way and that are easy to use/understand.	CETENMA
Difficulty to find useful LCA indicators for circularity metrics	WP1, WP2, WP3	Low	Medium	The consortium counts with experts in LCA who analyse LCA indicators and their suitability for circularity metrics. The most common indicators for circularity according to proven LCA methods such as the Product Environmental Footprint will be made use of. Some developments towards the inclusion of circularity metrics with LCA are being carried out in the industry (e.g., OpenLCA's circularity package), a revision and critical assessment will be	CETENMA

Description of risk	Affected tasks/ WPs	Probability	Impact	Proposed risk-mitigation measures	Responsible partners
				performed to select the most suitable ones.	
Difficulty to couple indicators among methodologies	WP2, WP3	Medium	Medium	Critically assess the mapped methodologies, highlighting the potential synergies. There are some applications being developed in academia of this couplings, even though not always adding that much value. "Coupling of methodologies" will also be explored as the building of a measuring package or framework that contains different methodologies harmonically, rather than merely producing complex indicators.	CETENMA
Difficulty to gather Packaging use case related indicators hence collaboration with another EU project is necessary	WP1, WP2 & WP3	Medium	High	Plan A. Meetings held with common partner from BIORADAR & PRESERVE. Try obtaining the information from PRESERVE. Plan B. Check IRIS database with previously executed project and provide information	IRIS

2.2.3 Work Package 3: Developing and Validating Digital Monitoring Dashboard/Tools

Description of risk	Affected tasks/ WPs	Probability	Impact	Proposed risk-mitigation measures	Responsible partner
Delay in definition of parameters and/or requirements	T3.1	Medium	High	Constant communication with biobased industries and projects and support from literature review. Continuous Risk Management.	IRIS, NTT, HAW, YAG, CET
Software incompatibilities with hosts of the digital platform	T3.2, T3.3	Low	Medium	Continuous communication with the hosts and request their support and cooperation. Continuous risk analysis and requirements stablished in the early stage of the project Communication with software developers and	IRIS

Description of risk	Affected tasks/ WPs	Probability	Impact	Proposed risk-mitigation measures	Responsible partner
				research in software forums.	
Delay in the development of the AI-based models	T3.2, T3.3	Medium	Medium	Continuous communication with the data providers to ensure timing and data quality.	IRIS
Continues data collection from the industrial use-cases	T3.3, T3.4	Low	Low	Continuous communication with industrial hosts and provide them with a well and strict stablished calendar for collecting data and suppling it to the data consumer partners,	IRIS, NTT, HAW, YAG, CET
Low data quality from use-cases	T3.3, T3.4	Low	Low	Continuous communication with industrial hosts and provide them with a well and strict stablished calendar for collecting data and suppling it to the data consumer partners, Revision of data quality by all partners. Partners will fill in data gaps or low-quality data with updated and relevant data gathered from other sources.	IRIS, NTT, HAW, YAG, CET
Lack of primary data on soft and hard law and policies for regulatory tracker tool	T3.5	Medium	High	Constant communication with CBE JU and policy makers will be carried out.	UNI, YAG

2.2.4 Work Package 4: Upscaling and Replicating the project results

Description of risk	Affected tasks/ WPs	Probability	Impact	Proposed risk-mitigation measures	Responsible partner
Low interest of the stakeholders to participate in the upscaling and replication	T4.1	Low	Low	The project relies on the extensive network of stakeholders already developed by the project's partners in each country. Some key stakeholders have been already approached by the partnership, and a key pool of stakeholders has already been secured.	HAW

Description of risk	Affected tasks/ WPs	Probability	Impact	Proposed risk-mitigation measures	Responsible partner
				Additional stakeholders to be involved will be approached from the project start onwards through suitable channels and means to increase their motivation to participate.	
Quality of available data in project partner countries to promote the results	T4.1	Medium	Medium	Data availability and quality will be discussed before the start of the work, necessary adjustments will be done. A project specific network will be set-up and used to the promotion of the solutions developed by the project.	HAW
Lack of input characteristics	T4.2	Low	Medium	Preliminary output from WP1&2 subtasks show useful input characteristics for Task 4.2. Further risks can be mitigated by focusing on one of the already determined indicators by Task 2.1.	WP 1 & 2 participants
Difficulties obtaining enough data from different cases in order to establish a baseline for comparison	T4.2	Low	Medium	Data is constantly generated and uploaded to our shared file hoster. Incomplete data might be accompanied by further literature research to combine already established baselines.	WP 1 & 2 participants
Difficulties obtaining data and information for packaging and textile use cases	T4.2	Low	Medium	Some data from the packaging and textile use cases were already extracted by WP2. In a worst-case scenario, it might be possible to purchase more data from already established databases for these specific use cases.	WP 1 & 2 participants
Difficulties finding participants for the replication facility and Massive Open Online Course (MOOC)	T4.5	Medium	Medium	Finding participants for online video courses is easier if there is no barrier for login. As video hosting will probably be done via a separate Video Platform (e.g., YouTube or Vimeo), we are considering making	HAW

Description of risk	Affected tasks/ WPs	Probability	Impact	Proposed risk-mitigation measures	Responsible partner
				parts of the course available publicly to drive more participants to our platform.	

2.2.5 Work Package 5: Communication, Dissemination and Exploitation activities

Description of risk	Affected tasks/ WPs	Probability	Impact	Proposed risk-mitigation measures	Responsible partner
Reluctance among key stakeholder to interact with BIORADAR in the fear of cannibalising their current business model	All Tasks WP5	Medium	Medium	The project dissemination, exploitation and communication (PDEC) plan will include tailored messages addressed at these groups, pointing to the opportunities related to new business (i.e., servitisation), but also benefits from acting as first-mover, and robust, realistic business models.	KNEIA
Lack of response and engagement of target audiences on BIORADAR communication channels.	T5.1 and T5.2 WP5	Low	Low	The PDEC plan will include details on the website and chosen social media channels and specific messages to address the target audiences. Performance of the website and social media channels will be monitored, and strategies updated accordingly.	KNEIA
Lack of participation of partners in internal communication procedures implemented to ensure up-to-date reporting and communication and dissemination of project progress and results.	T5.1, T5.2 and T5.3 WP 5 and 6	Medium	Low	Internal reporting procedures have been established and documents created to help ensure that activities are recorded and communicated. These documents will be consistently monitored and the PDEC plan updated periodically.	KNEIA

No standardisation activities identified/low support among stakeholder to set-up new standards	T5.5	Low	Medium	Involvement of all project partners in Task 5.5 and continuous discussion and exchange with all project partners and the relevant standardisation committees about the progress of the standardisation activities.	UNI
Not getting to the publication of the CWA (CEN Workshop Agreement) during the project if CWA is not accepted by CEN, for example because other standardization activities on the same topic are underway.	T5.5	Low	Low	A public deliverable (Roadmap) will be produced including the same standardization scenarios defined by the CWA and will be disseminated to the relevant Technical Bodies that can use it as a starting point for future standardization activities.	UNI

2.2.6 Work Package 6: Project Management

Description of risk	Affected tasks/ WPs	Probability	Impact	Proposed risk-mitigation measures	Responsible partner
Indicators defined in WP1 and WP2 are too ambitious and thus cannot be achieved within the current project scope.	All	Low	High	Robust methodology aimed at re-confirming the KPIs by literature review and aided by self-assessment and benchmark analytics platform.	CETENMA, NTT
An internal partner dispute prevents project plan progressing in accordance with time plan, risking delay to expected deliverables.	All	Low	Medium	Robust project governance structure approved by all partners provides dispute resolution mechanism. The coordinator will negotiate with the internal partner to reach a solution that benefits all and addresses the core problem behind the issue.	YAG
Bankruptcy of a partner	All	Low	High	Close follow up of work progress and payments.	YAG
Inadequate Coordination	All	Low	Low	PMT is experienced, shortage of coordination	All

Description of risk	Affected tasks/ WPs	Probability	Impact	Proposed risk-mitigation measures	Responsible partner
				actions can be taken up by partners who can follow-up the Grant Agreement commitments and invoke the relevant procedures of the consortium agreement if needed.	
Delays of key deliverables belonging to the critical route	All	Medium	Medium	Although the work is structured as collaborative work, there exists a hierarchical coordination with strong focus on technical tasks. Stronger focus on work package leaders and delivery by PMT.	YAG
Budget overruns	All	Low	High	Budgets will be followed closely by the PMT, reallocation of budget that becomes available will be done based on priorities for the project. Strong supervision by CBE JU.	YAG
Changes in personnel involved, corporate organizations and consortium partnership	All	High	Low	When key personnel are replaced, the involved partner has the obligation to update the new employee. Coordination team will set up a teleconference to align with the person and to facilitate a fast take up of activities and keep close contacts.	YAG, All
Partner not delivering expected quality	All	Low	Medium	As part of the activities of the PMT, a continuous monitoring of project activities will be carried out. In case problems are identified, also P2P communication and written warnings will be given before the PMT can declare a partner to be partner in breach. The PMT can act swiftly. The complete definition of a partner been in breach will be part of the Consortium Agreement and will be approved before the Grant	YAG

Description of risk	Affected tasks/ WPs	Probability	Impact	Proposed risk-mitigation measures	Responsible partner
				Agreement enters into force.	
Unexpected delay in achieving milestones/ deliverables	All	Medium	Medium	Strict control with clear timelines from the beginning. A periodic internal reporting and risk register will be set up. The PMT can decide to re-shuffle certain tasks. The project manager will support the WP leaders and task leaders by getting other partners (potentially even partners not initially involved in the WP) to provide resources to complete the deliverables in time.	YAG
Partner(s) fail(s) to agree on the consortium agreement	All	Low	Low	Project partners have discussed the outlines of the consortium agreement during proposal preparation. The Consortium Agreement will be discussed more in detail and agreed before the kick-off meeting.	All

2.3 Looking forward and future risk identification

The PMT has planned to capture unforeseen risks to the project in short and long-terms. For this purpose, in every monthly management board (MB) meeting, the WP leaders are requested to update the short-term risk table of their WP and propose mitigation strategies. Moreover, in consortium meetings (every six months), all partners present and discuss long-term risks and propose next steps to mitigate the risks. The mitigation strategies are discussed with relevant partners and proper actions (such as WP interlink meetings, early start of some tasks, or finding more data sources) will be planned accordingly.

3 QUALITY ASSURANCE PLAN

3.1 Overall project quality assurance

The PMT is the board responsible for the project quality management. The PMT will ensure that the project activities necessary to design, plan and implement BIORADAR are effective and efficient with respect to the purpose of the objectives and its performance.

3.1.1 Communications

To always guarantee constant communication and a contact point, when necessary, an Excel contact list was established that contains all relevant contact information from consortium partners (email address and phone number). This contact list is structured into an overall contact list, that contains all contact information from each consortium partner's individuals with their associated role (e.g., project manager or financial manager). Additional sheets in this contact list show relevant contacts that are part of the management board (MB) and who to contact for each WP.

3.1.2 Project meetings

The PMT conducts monthly MB meetings, typically held as online conferences, to verify that project activities align with the GA objectives. To ensure consistent monitoring of the project's tasks, WPLs are requested to provide updates on their respective WP's progress during these monthly MB meetings. To facilitate this, WP leaders should gather feedback from task leaders and endeavor to present information covering the following aspects:

- A summary of the activities carried out during the preceding month.
- Any issues or delays encountered in executing these activities. In the event of issues, WP leaders should also identify other tasks that may be affected and outline a plan to mitigate associated risks.

Moreover, the PMT arranges other meetings including consortium meetings (M01, M06, M12, M18, M24, M30, and M36), Steering board meetings (M03, M09, M15, M21, M27, and M33) and WP interlink meetings (on monthly basis) to:

- Provide point of contact between the consortium and the CBE JU for all contractual and formal reporting matters
- Coordinate and monitor the progress of all project activities
- Organize and preside over SB meetings and sets the agenda to facilitate discussions regarding progress within and across the WPs and the potential need for corrective actions.
- Address anticipated challenges in a WP that may hinder the achievement of objectives or deliverables.
- Identify the necessity for harmonizing activities across different WPs.
- Tackle obstacles and barriers that may impede progress and affect other WPs relying on the output of a specific WP as a starting point.

- Assess the requirement for task reallocation within or among WPs if it becomes necessary.
- Handles security or privacy concerns that arise during the design and implementation of the Data Management Plan (DMP).
- Address issues related to partner performance or malfunctions.
- Manage innovation-related matters to support the overall business plan.

3.2 Quality assurance for deliverables/ Peer review of deliverables

3.2.1 Document guidelines and templates

3.2.2 Internal coding procedure

For smooth coordination of internal deliverables and other project documents, BIORADAR consortium has defined document and email coding procedures. This coding will increase traceability of project documents and communications during the project implementation. BIORADAR document coding structure is as defined below:

Project	-	Company	-	Work Package	-	Document number	-	Version	-	Title
BIORAD	-	YAG	-	WPX	-		-	01	-	

- For general documents WPX will be replaced by GEN.
- Document numbers are unique, will start from 001 and increase continuously.
- Versions start from 01.
- Company abbreviations will be according to Table 1.

Table 1 Partner abbreviations used in coding system

Partner	Abbreviation in coding
Asociacion Empresarial Centro Tecnologico De La Energia Y Del Medio Ambiente De La Region De Murcia (CETENMA)	CET
Hochschule Fur Angewandte Wissenschaften Hamburg (HAW Hamburg)	HAW
IRIS Technology Solutions, Sociedad Limitada (IRIS)	IRS
KNEIA SL (KNEIA)	KNE
Next Technology Tecnotessile Societa Nazionale Di Ricerca R L (NTT)	NTT
Ente Italiano Di Normazione (UNI)	UNI
YAGHMA B.V.	YAG

3.2.3 Internal review process

To ensure the highest possible quality of the deliverables, all deliverables undergo the same iterative procedure that commences one month prior to the contractual deliverable date. This five step-procedure, illustrated in Figure 1, unfolds as follows:

1. When a lead partner (deliverable leader) completes a deliverable, the respective task participants are requested to review the deliverable and provide internal comments. This process takes one week.
2. Subsequently, the deliverable leader has 0.5 weeks to review and incorporate these placed comments to then forward it to the final designated internal reviewer within the consortium. The final reviewers (see 3.2.4) vary for each deliverable throughout the project to avoid bounded rationality by just one fixed reviewer.
3. The designated final reviewer then has 1.5 weeks to review the document and propose suggestions before sending it back to the deliverable leader.
4. The deliverable leader then verifies and incorporates these final comments, finalizes the deliverable within 0.5 weeks, and sends it to the coordinator (if the coordinator is not the leader of the deliverable itself).
5. The coordinator conducts a final check/revision on aspects such as format, etc. (0.5 weeks) to then submit the finalized version of the deliverable to the portal.

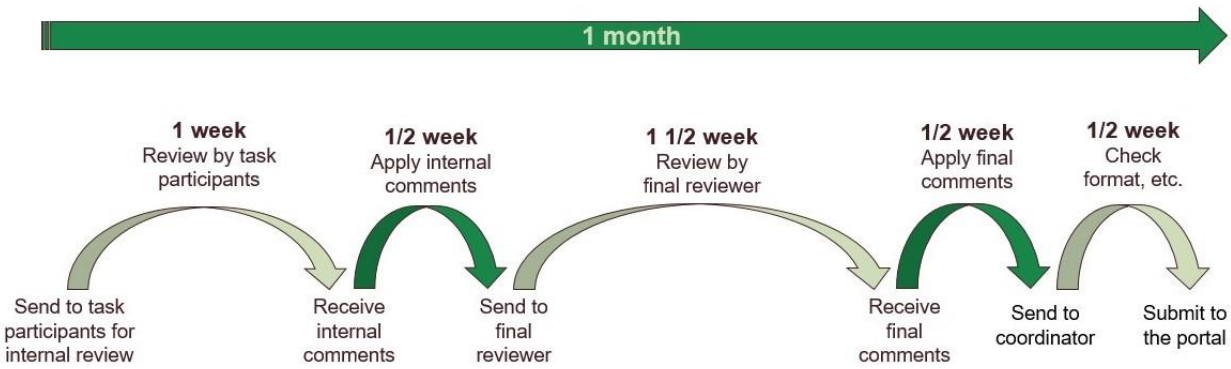

Figure 1 Internal reviewing procedure for finalizing deliverables

3.2.4 List of appointed reviewers

A list of the appointed reviewers concerning the internal reviewing process outlined in the previous section is shown in Table 2.

Table 2 List of appointed final reviewers for deliverables

No.	Name	WP	Lead Partner	Final Reviewer
D1.1	Report on identification of bio industrial bio-based value systems for project analysis	WP1	CETENMA	HAW
D1.2	Evaluation of EIA on selected bio-based systems	WP1	CETENMA	NTT
D1.3	Report on Life Cycle Cost for the selected bio-based systems	WP1	NTT	CETENMA
D1.4	Report on Social LCA assessments	WP1	NTT	CETENMA
D1.5	Report on assessing carbon removal potential and iLUC risks of bio-based solutions	WP1	NTT	CETENMA

No.	Name	WP	Lead Partner	Final Reviewer
D2.1	Report on identification of circularity indicators methodologies for industrial bio-based systems	WP2	CETENMA	IRIS
D2.2	Report on evaluation of existing/new metrics on circularity for industrial bio-based systems and proposition of new indicators	WP2	CETENMA	IRIS
D2.3	Study of end-of-life issues of the selected bio-based products	WP2	CETENMA	NTT
D2.4	Economics aspects of circularity	WP2	NTT	HAW
D3.1	BIORADAR AI-driven benchmark and analytics platform	WP3	IRIS	HAW
D3.2	BIORADAR self-assessment tool	WP3	IRIS	YAG
D3.3	Testing, validating, and training of the self-assessment tool	WP3	IRIS	NTT
D3.4	BIORADAR regulatory tracker tool	WP3	YAG	UNI
D4.1	BIORADAR replication facility	WP4	HAW	KNEIA
D4.2	BIORADAR implementation scorecard	WP4	HAW	IRIS
D4.3	Novel business model report and CaaS servitisation	WP4	YAG	UNI
D4.4	Business models set up for replication and upscaling	WP4	HAW	CETENMA
D4.5	MOOC Active and accessed by 500 participants	WP4	HAW	KNEIA
D5.1	Project Website & press release	WP5	KNEIA	YAG
D5.2	Project Video (an introductory video)	WP5	KNEIA	YAG
D5.3	Project Video (results video)	WP5	KNEIA	ALL
D5.4	PDEC - Full version of Dissemination & Exploitation & Communication Plan	WP5	KNEIA	HAW
D5.5	PDEC – Final Dissemination & Exploitation & Communication Plan	WP5	KNEIA	HAW
D5.6	Towards a new standard: CWA project plan	WP5	UNI	YAG
D6.1	Data Management Plan and IPR agreements	WP6	YAG	IRIS
D6.2	Data Management Plan and IPR agreements	WP6	YAG	IRIS
D6.3	Data Management Plan and IPR agreements	WP6	YAG	IRIS
D6.4	Risk management and quality assurance plan and Ethical impact assessment	WP6	YAG	UNI
D6.5	KPI and Impact questionnaire year 2023	WP6	YAG	KNEIA
D6.6	KPI and Impact questionnaire year 2024	WP6	YAG	HAW
D6.7	KPI and Impact questionnaire final	WP6	YAG	NTT

3.2.5 Method to be used by deliverables' reviewers

Reviewers are encouraged to provide detailed and constructive feedback, including references where possible, to assist the authors in enhancing the deliverable. In Word documents, reviewers must work in "Track Changes" to provide their comments and contributions. If the revision is based on a PDF document, reviewers should insert notes into the text. To ensure version control and backup, all files under review should be

stored in the designated file area within the BIORADAR OneDrive folder. Below, a guiding list of review criteria for document reviewers is suggested:

- Are the title, type, and dissemination level in alignment with the definitions provided in the GA?
- Does the scope and content of the deliverable correspond with its definition in the GA?
- Are the deliverable's objectives and its activities clearly and explicitly stated?
- Is the deliverable consistent with its predefined objectives?
- Is the Executive summary sufficiently informative, especially when considered as a standalone document?
- In case of any deviation, is it justified and mentioned explicitly?
- Is the structure of the deliverable complete (including components like the introduction, objectives, methods, results, conclusion, and references)?
- Does the document adhere to the provided BIORADAR template? (Encompassing aspects such as project branding, front page, second page, table of contents, table of figures, list of tables, fonts, headings, spacing, and captions for figures and tables)
- If symbols or abbreviations are introduced in the document?
- Is the scientific/technical approach employed in the document sound, adequate, and reflective of the latest practices in the field?
- Do the interpretations and conclusions within the deliverable demonstrate sound reasoning, justification based on data, and consistency with the predefined objectives?
- Is the quantity of data presented within the document sufficient, and does the content substantiate the document's length?
- Are all the figures and tables included in the document necessary for the purpose, and are they complete, with clear captions, and of high quality?
- Are the references cited in the report both relevant and up to date, and are all the cited references appropriately listed in the References section?
- Is the document composed with good syntax and grammar, using language suitable for the intended target audience(s)?

3.3 Quality assurance of digital tools and services

Several digital tools/ services will be developed in BIORADAR project:

- AI-driven benchmark and analytics platform (D3.1)
- Self-assessment tool (D3.2)
- Regulatory tracker tool (D3.4)
- Implementation scorecard (D4.1)

Before delivering these tools, it is of utmost importance for BIORADAR partners to ensure that the tools they create meet the quality standards and specifications detailed in their respective reports. This entails providing comprehensive information on the functionality and usage of the tool.

The Digital Tool Quality Assurance process will run concurrently with the individual Quality Control and Assurance policies and procedures of technical partners. Its purpose is to establish a shared framework of best practices for all partners and contribute to the project's quality assurance goals. However, quality control will primarily depend on each partner's policies since the digital tool type and development techniques align closely with each partner's expertise.

The BIORADAR Digital Tool Quality Assurance process will engage partners at every stage of tool development. This includes the design of the architecture in one phase, coding and testing in another phase, as well as debugging during the pilot demonstrations in WP3. Consequently, the process will remain active throughout the project's entire duration.

Given that multiple partners will concurrently develop modules in WP3 and WP4, a critical Digital Tool Quality Assurance rule is introduced to support technical partners in achieving their primary objective, which is the punctual delivery of functional tools. The quality assurance process seeks to meet digital tool release and integration deadlines, adhere to all specifications, deliver full functionality, and create user-friendly interfaces, especially for the pilot phases. All digital tool development teams are required to provide functional prototypes for interface and integration validation three months in advance of their respective due dates. This rule plays a vital role in preventing potential delays arising from simultaneous software development.

In any event, the teams' progress will undergo regular monitoring during project progress meetings, and appropriate adjustments will be suggested to ensure the seamless development and production of the overall system in collaboration with the management team.

3.3.1 Methodology and steps to be carried out for capture of requirements

The Agile methodology will be used for capturing the requirements, which is illustrated in Figure 2. Five steps, from left to right, are followed in order to capture and refine the user requirements.

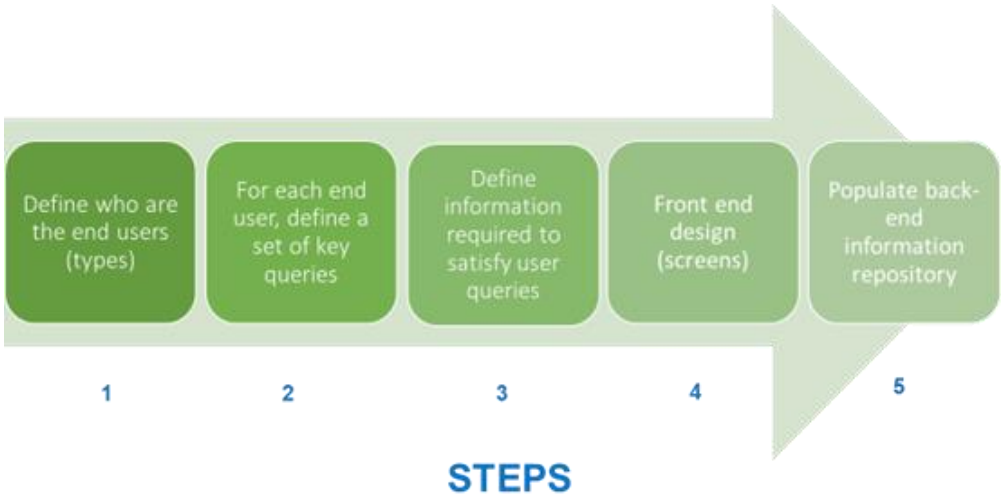

Figure 2 Schematic of Agile methodology

The capture of requirements (steps 1 to 3) allows the final two steps (4 and 5) to be implemented.

First, to obtain a first set of ideas for requirements, all digital tool owners should tackle independently to the respective partners from the WPs which were considered relevant as potential end users and data suppliers and obtain the relevant information. Organisation of workshops and interactive sessions are highly recommended.

3.3.2 Design and Development of the Digital tools

3.3.2.1 Accessibility

To gain a comprehensive understanding of the technological environment impacting this project, an exploration of foundational concepts is warranted. Respective entities will be responsible for their own data storage and in case of the necessity, IRIS cloud could be used as the common folder.

Cloud computing refers to the remote infrastructure of servers accessed over the Internet, this virtualization enables the rapid and efficient provisioning and release of these resources as needed. In fact, current technologies allow the creation of virtual versions of almost all components present on the internet, from storage devices to complex servers. These servers are distributed in global data centers. Cloud computing frees users and businesses from directly managing physical servers and running applications on their own machines, including software and databases.

In cloud applications, the user interacts with the application through a web browser and data processing occurs through a combination of the local device and a cloud-hosted solution. From the user's perspective, the cloud application behaves like a conventional website.

Cloud services can be public or private, delivered over the Internet, or kept within a company's network through an intranet. Sometimes companies use a combination of both. The physical location of the 'cloud' (whether in a corporate data center or a service provider's center) is not relevant, as cloud computing leverages the network to enable easy, on-demand access to a shared set of resources, including networks, storage, servers, services, and applications.

The most common solutions related to cloud computing are the following:

- IaaS (Infrastructure as a Service)
- PaaS (Platform as a Service)
- SaaS (Software as a Service)

In the framework of this project, and considering the application developed, we can consider it as a Software as a Service (SaaS). A SaaS service, based on the accessibility can be:

- Public: It is open to everybody.
- Private: Restricted to one or a group of business organizations.
- Hybrid: Combination of public and private infrastructure.

In the case of this project, the accessibility should be hybrid, everybody can connect to the platform, but the platform will contain restricted information, specific for the project's consortium.

3.3.2.2 Digital tool Architecture

The architectural structure of the project should align with a prevalent pattern widely adopted in the software industry, particularly within the web domain (Figure 3). This structure is characterized by the implementation of a conventional stack comprising three main components: the frontend, the backend, and the database.

- Front-end: The frontend represents the user interface and encompasses all the elements visible to the end-user. It is responsible for rendering the graphical user interface (GUI) and facilitating user interaction. This includes elements such as buttons, colors, images, and typography.
- Back-end: The backend, also known as the server-side, acts as an intermediary between the frontend and the database. It is the business layer responsible for processing user requests from the frontend, transforming raw data, and providing services tailored to specific user needs.
- Database: The database layer serves as the foundation for storing and retrieving application data.

This conventional architectural pattern provides a robust foundation for the project, allowing for efficient development, scalability, and maintainability. The separation of concerns between the frontend, backend, and database components facilitates modularity and ease of troubleshooting.

Figure 3 Digital tool Architecture scheme

1. The core of the platform

The '**Back-end**', acting as an intermediary between the 'Front-end' and the database, is technically referred to as the business layer. This layer undertakes the transformation of raw data and furnishes services tailored to respond to specific user requests. It manages user requests from the Frontend and provides the necessary information.

The key responsibilities of this layer include managing business logic, recovery, administration, data transformation, and interaction with databases for secure storage and access to information.

2. The user interface

User interaction and presentation are orchestrated through the Frontend, with a crucial focus on user experience (UX) analysis. This analysis is dedicated to creating an appealing navigation and interaction experience. The output of this analysis is the Graphical User Interface (GUI), designed for a variety of users and functions to ensure the simplest and smoothest interaction possible.

Each digital platform owner should use the most agile application/web framework as the user interface which is versatile, extends to web and mobile applications, native mobile, and native desktop, ensuring high performance, maintainability, and easy scalability.

3. The data storage

As the final layer of the architecture, the database layer focuses on storing and retrieving application data, ensuring the exposure of only accessible data without revealing underlying storage methods.

4. The server

All the previous items described, must run on a powerful physical infrastructure based on the respective operating system suitable for a wide range of devices including laptops, desktops and servers, It is recommended to be open source,

Other principal characteristics of the server could be the option of adjustment of the server's resources depending on the needs as new features gets developed.

For example, IRISs' analytics platform will be based on Linux. Linux is suitable for a wide range of devices including laptops, desktops and servers, it is open source, the Linux distribution used is Debian.

Debian stands out as one of the earliest and most reputable Linux distributions in the realm of free and open-source software. It serves as the base for Ubuntu, a widely recognized desktop Linux variant. Renowned for its stability, Debian's stable version often offers older software versions, potentially several years old. However, this choice implies utilizing software that has undergone extensive testing, resulting in fewer bugs.

Other principal characteristics of the server selected is because a dedicated server's resources can be increased or adjusted to growing needs as new features get developed.

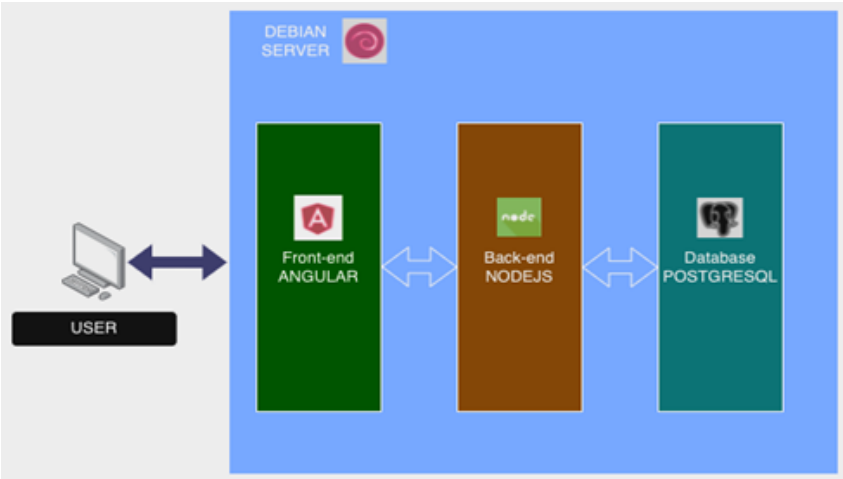

Figure 4 Server Infrastructure Overview

3.3.3 Security and Privacy Considerations

In order to safeguard both the integrity of the content and the privacy of the digital tool users, all the platforms should employ a robust set of strategies:

- User Password Encryption: To fortify user account security, all user passwords undergo encryption before being stored in the database. The encryption ensures that only the respective user possesses knowledge of their password, bolstering the confidentiality of user credentials.
- Data Transferring Encryption: The platform prioritizes the security of data during transmission. All communications between the user's computer and the platform are meticulously encrypted using Secure Sockets Layer (SSL) encryption. This encryption protocol guarantees a secure and private exchange of information, shielding sensitive data from unauthorized access during transit.
- Database Accessibility: Access to the database is meticulously secured through robust credential mechanisms. This approach ensures that only authorized individuals with the requisite credentials can access the database. This stringent control prevents unauthorized profiles from compromising the sanctity of the stored data, thereby maintaining the privacy and confidentiality of sensitive information.
- Server Security: The entire project operates on a server fortified with stringent security measures. External access to the server is restricted solely to a virtual private network (VPN), adding an extra layer of protection against unauthorized external access attempts. Access credentials for the server are privileged information, known only to the system administrator. This stringent access control assures that only authorized personnel can access and manage the server, mitigating the risk of unauthorized intrusion.

3.3.4 Data visualisation inside the platform

One of the key features of the platforms should be the effective visualization of data. This aids users in quickly and efficiently accessing relevant information. All the digital tools should employ a comprehensive data visualization system, enhancing user experience and facilitating seamless navigation.

3.4 Quality assurance of online course

Massive Open Online Courses (MOOCs) are freely accessible online courses open for enrollment to individuals from all backgrounds. Within the BIORADAR project, partner HAW is responsible for creating a MOOC focused on biobased transition. In the realm of online education, quality assurance involves the systematic procedure of guaranteeing that online courses and programs align with the predetermined standards and learning objectives. Learners should also familiarize themselves with the platform's features and capabilities prior to enrolling in a course.

A well-structured online course should incorporate elements that enhance quality assurance. These elements encompass:

- Course creation and development tools that empower instructors to generate interactive content and assessments.
- Tools for course management and administration that enable the monitoring of learner advancement and engagement.
- Tools for course evaluation and enhancement, which facilitate the analysis of data regarding learner satisfaction, learning outcomes, and the effectiveness of the course.
- Tools for ensuring course accessibility and usability, guaranteeing compatibility with various devices, browsers, and assistive technologies.

HAW will implement **Moodle** platform for the online course. Moodle is designed to serve instructors and students by enhancing traditional in-person instruction with online elements. This platform offers a range of functions and activities, including:

- Delivering educational materials (e.g., PDFs, JPEGs, or HTML files)
- Facilitating communication through participant lists, forums, and chats
- Providing tools for assessments and practice exercises
- Offering links to the library (including electronic reading lists from ELSE)
- Integrating various additional features and elements, such as wikis, hyperlinks, glossaries, and questionnaires.

4 ETHICAL IMPACT ASSESSMENT

This section covers all potential ethical issues that may arise during the lifetime of the BIORADAR project and how these issues are to be mitigated by the consortium. These ethical issues are classified into three sub-categories which fall under the identified ethical impact areas of BIORADAR: Research subjects which involves human participants throughout the project, personal data, and the AI component of BIORADAR. In the following these three aspects are elaborated with their ethical issues and mitigation strategies.

The designed mitigation strategies also align with the standardized requirements for the H2020 ethics evaluation.

4.1 Research subjects

Research subjects considered within BIORADAR are human beings. Their participation will occur within workshops, online events, focus groups, surveys, and interviews.

Concerning this the following risks with appropriate mitigation strategies were identified:

Risk #1: The human participants were not informed prior to their participation and have not given their consent for participating.	**Mitigation strategy #1**: Provide informed consent forms prior to research activities that contains human participants and requires their active participation (e.g., workshops, interviews). Keep the informed consent forms throughout the project (see Annex 1).
Risk #2: Details on procedures/criteria used to identify and recruit research participants are not apparent.	**Mitigation strategy #2**: Provide and keep details on the procedures and criteria that will be used to identify/recruit research participants (e.g., number of participants, inclusion/exclusion criteria, direct/indirect incentives for participation, the risks and benefits for the participants etc.) (see Annex 2).

4.2 Personal data

Due to the collected data during the BIORADAR project, potential ethical risks might emerge if it comes to personal data of humans, participants, companies, or other entities. With a link to D6.1 of BIORADAR, the Data Management Plan, the following data types that might conflict with personal data issues during the project's research are:

WP1:

- Data on social and socio-economic benefits of the implementation of the proposed products (e.g., local employment and number of jobs created)

WP3:

- Data to design and develop a deterministic model to reconfigure the bio-based product
- Data on possible changes in production requirements
- Dataset of bio-based project sustainability and circularity data for AI-driven benchmark
- Data from streamlined reporting
- Organization data

WP4:

- Economic, environmental, social, and circularity data of the use-cases used by the BIORADAR implementation scorecard.
- Data on scientific results, novel business models, inputs from stakeholders
- Data on economic expected quality, marketing support services, expected levels of investment, financial structures, and environmental and social indicators.

WP5:

- Data on project results is delivered in the format of project leaflets, brochures, posters, project video, newsletters, promotional materials, social media posts, online content on project website; scientific articles and papers, sessions, scientific workshops, course materials; events part of the BIORADAR agenda; stakeholder survey.
- Data on ecosystem and stakeholders' analysis, e.g., stakeholders' interest, attitude, influence, knowledge, and expectations
- Technical experts' feedback on standardization of project findings

The identified potential ethical risks in the field of personal related data are in the following elaborated with their appropriate mitigation strategies:

Risk: Data collected throughout the research from any type of method (workshops, online events, focus groups, surveys, and interviews, etc.) might contain sensitive personal information of participants (e.g., health, sexual lifestyle, political opinions, religious belief, etc.).	**Mitigation strategy**: Since sensitive personal data is not relevant for the research of BIORADAR (see above) such data is not considered to be collected. The data that will be collected will include only process-relevant information, such as meta-data on the sustainability aspects of biobased products and systems (environmental, economic, and social), and general personal non-sensitive information of the participants (e.g., professional background, occupation, or education). All personal data collected and processed within the project activities will be processed fairly and lawfully and used only for research purposes. Hence, in BIORADAR will be no sensitive personal data involved that allows for the

	identification of individuals. This is also stated and explained to the participants in the informed consent form (Annex 1). All project data will be stored in a password-protected OneDrive & Share folder which ensures frequent back-ups and contains the possibility to restore data. Data transfer between partners should always be protected by a password. All partners are responsible for ensuring data security by appropriate measures (e.g., encryption) and regular back-ups. However, if sensitive personal data is due to unforeseen reasons still collected, it will be stored in trusted/certified research data repositories. The security standards of the repository will apply in this case. The real-world data, if any, in the project will be anonymized and stored securely in encrypted servers with access controlled by strict authentication mechanisms such as university servers or private cloud infrastructure. Anonymized data will be retained for two years beyond the end of the project, and then destroyed. The rights of data subjects will be respected, namely, that participants will be able to access the information collected by the project about them. The data will not be processed for direct marketing. The data will be backed up periodically to prevent data loss and ensure data recovery if needed. The data transfer within BIORADAR may happen, if necessary, through encrypted channels. The minimum necessary amount of data can be transferred after anonymization or pseudonymization (more information on this can be also seen in the project's DMP D6.1).

4.3 AI technology

BIORADAR includes an AI technology (AI-driven Benchmark and Analytics) that allows to conduct benchmarking and self-assessment for industrial stakeholders within the bio-based industry. Since AI is an emerging technology entailing numerous ethical issues, such must also be addressed in the BIORADAR project.

A review of current national and European legislation identified no immediate restrictions on how researchers propose to deploy AI technologies during the project. Researchers

of the partner Yaghma will continuously monitor the regulatory agenda including EU AI Act for any future development which may impact the future development or deployment of AI-based BIORADAR technologies. During their review, researchers noted the publication of the "Ethics Guidelines for Trustworthy AI" (August 2019) by the European Commission's High-level Expert Group on Artificial Intelligence, and as a result will incorporate these recommendations into their AI model development process. The following section sets out how researchers intend to accommodate these guidelines during the project:

Risk #1: Human agency and oversight	**Mitigation strategy #1:** AI-based BIORADAR technologies will not make decisions on behalf of human operators at any point. This will be achieved by sensitively integrating the technology into supporting established and trusted decision-support processes and ensuring the primacy of the human operator's agency at all steps, e.g., the UI operators used to configure machine tools prior to manufacturing.
Risk #2: Privacy and data governance	**Mitigation strategy #2:** The design of the data architecture and infrastructure underpinning the BIORADAR system guarantees the highest level of privacy and data protection through the system's lifecycle. It also ensures compliance with international laws regarding the collection, processing, and storage of data. Furthermore, the architecture/infrastructure is continuously monitored and updated to ensure the highest level of security and compliance by utilizing a commercial level data handling platform.
Risk #3: Transparency	**Mitigation strategy #3:** All calculations generated by the BIORADAR AI models will be mathematically interpretable to human users. Furthermore, prior to first deployment during the demonstration program, users will be given a briefing on the safe and proper use of the BIORADAR technology – this includes a briefing on the technology's limitation.
Risk #4: Fairness, diversity, and non-discrimination	**Mitigation strategy #4:** Best possible efforts will be made to avoid unfair basis being engendered in the models derived through the AI solutions. The accessibility of future BIORADAR applications will be ensured through user centric design methodologies and the involvement of diverse design specialists.

Risk #5: Societal and Environmental Well-being	**Mitigation strategy #5:** The deployment of AI solutions in BIORADAR is driven by the desire to improve the environmental footprint of the bio-based industry through the intelligent use of industrial data to enable the reuse of secondhand machines. This is well aligned with both EU and UN objectives for adverting climate disasters precipitated by GHG emissions resulting from industrial operations.
Risk #6: Accountability	**Mitigation strategy #6:** All researchers directly involved in the development and deployment of AI solutions during the BIORADAR project will take responsibility for future applications of the future technology and its consequences. A robust and transparent project governance structure ensures the highest level of research accountability. The constant ethical analysis during the project will ensure that accountability principles regarding the use of AI in BIORADAR are being adhered to.

5 REFERENCES

European Commission. (2019). *Shaping Europe's digital future - Ethics guidelines for trustworthy AI*. https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai

6 Annex

6.1 Annex 1 – Informed consent form template

MONITORING SYSTEM OF THE ENVIRONMENTAL AND SOCIAL SUSTAINABILITY AND CIRCULARITY OF INDUSTRIAL BIO-BASED SYSTEMS

Grant Agreement Number 101112457

Informed consent form – BIORADAR project

The project is supported by the Circular Bio-based Europe Joint Undertaking and its members.
Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or CBE JU. Neither the European Union nor the CBE JU can be held responsible for them.

1

Principal investigator

This study is exclusively organized and executed by [company name]

The person within the company in charge of the investigation is:

- [Name of responsible person]
- [Position of the person in the company]
- [Address]
- [Email]

Purpose of the study

You are being asked to take part in a study for the BIORADAR project.
The BIORADAR Project, funded and supported by the EU's Horizon Europe programme and the Circular Bio-based Europe Joint Undertaking (CBE JU), aims to help organisations, policymakers and investors have the necessary information to step towards a more sustainable, bio-based economic model by taking a system perspective to fill the indicator gaps in material circularity and **evaluating the environmental and social impacts of industrial bio-based systems by developing digital monitoring tools** that will provide benchmarks and a self-assessment platform for bio-based industries. This will be done through:

- Improving metrics and frameworks for assessing environmental impacts and risks of industrial bio-based systems.
- Defining circularity indicators and develop circularity assessment framework for industrial bio-based systems.
- Evaluating the economic impact of closing the loop and climate change mitigation.
- Address the social implications of circularity and sustainability in industrial bio-based systems.
- Identifying patterns, best practices and up-scaling opportunities to from part of policy recommendations.

The purpose of this study is to [describe purpose here].

2

Participation

First of all, participation is voluntary. Before you decide to participate in this study, it is important that you understand why the study is being done and what it will involve. Please read the following information carefully. This informed consent sheet explains the further
processing of your data and information provided in the research process and documents your rights. Please ask or contact the responsible person (principle investigator) if there is anything that is not clear or if you need more information.

Data collection, storage, and protection

The project will respect and fully apply ethical principles and current international, EU and national law and regulation for any activities that involve human participants and processing of personal data. The participants in interviews, workshops and co-creation activities will be adults with voluntary consent to their involvement in research, on the basis of full, accurate, and clear information

During interviews, workshops or interactive co-creation events personal data might be collected. This may include your name, age, gender, occupation, professional background, education, and your personal opinions. Furthermore, the session might be recorded for research purposes and screen captures or videos might be taken.

The project will respect and fully apply ethical principles and current international, EU and national law and regulation for any activities that involve human participants and processing of personal data. All personal data collected and processed within the project activities will be processed fairly and lawfully, and used only for research purposes. Personal data is understood as any information, private or professional, which relates to an identified or identifiable natural person. No sensitive personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction) is collected within the project. Most partner organisations will have their own robust internal ethical review processes in place, such as ethics committees, that will provide crucial guidance on ethical regulation within the national context.

Data safety, data security and privacy issues in research activities of the project will be taken into account whenever personal data is collected for the research use. All measures will be taken to ensure the confidentiality of participants in the intervention. BIORADAR's research activities will comply with the EU's General Data Protection Regulation 679/2016 (GDPR). This regulation is applicable as of 25 May 2018 in all EU member states, and it applies to all forms of processing of personal data.

The data will be kept up to date throughout the project. Non-anonymised data will be retained for the duration of the project, after which it will be anonymised or

3

destroyed. Anonymised data will be retained for two years beyond the end of the project, and then destroyed. The rights of data subjects will be respected, namely, that participants will be able to access the information collected by the project about them. The data will not be processed for direct marketing. More detailed information will be provided in the data management plan.

The data generated within will only be used for research purposes only. This includes the processing for research purposes and dissemination activities, as deliverables, publications, reports, booklets and commentaries, policy briefs, blog posts, social media, journal articles, and books.

Withdrawal options

You can withdraw from the study and request your information be deleted at any time, without giving a reason up to the end of the study. If you should decide to deny your consent, please contact the leading investigator and let her/him know of your intention of leaving the study.

I have read and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Name of Participant	Date	Signature

4

6.2 Annex 2 – Recruitment of humans template

MONITORING SYSTEM OF THE ENVIRONMENTAL AND SOCIAL SUSTAINABILITY AND CIRCULARITY OF INDUSTRIAL BIO-BASED SYSTEMS

Grant Agreement Number 101112457

Recruitment of humans – BIORADAR project

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- [Email]

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- Evaluating the economic impact of closing the loop and climate change mitigation.
- Address the social implications of circularity and sustainability in industrial bio-based systems.
- Identifying patterns, best practices and up-scaling opportunities to from part of policy recommendations.

The purpose of this study is to [describe purpose here].

2

Participants' selection criteria and procedures

The following inclusion/exclusion criteria and selection procedures were selected to recruit human participants for the research activity:

Inclusion criteria:

- [describe inclusion criteria here (e.g., job, age)]

Exclusion criteria:

- [describe exclusion criteria here (e.g. job, age)]

Selection procedure:

- [describe selection procedure here (e.g., number of participants, direct/indirect incentives for participation, contact through email/personal contacting, etc.]

3