WHITE-LABEL SHOP FOR DIGITAL INTELLIGENT ASSISTANCE AND HUMAN-AI COLLABORATION IN MANUFACTURING

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VERSION HISTORY

Nr.	Date	Author (Organization)	Description
0.0	31/08/2023	SINTEF, MEWS, KU Leuven	Submitted version of D1.1
0.1	04/09/2023	SINTEF	Updated version removing potentially sensitive information on case partner. Resubmitted.
0.2	10/01/2024	SINTEF	Added updated white-label shop description based on input from WP3
0.3	20/02/2024	TRIMEK	Revised version of TRIMEK use case for D1.1 added.
0.4	20/03/2024	SINTEF	Internal update with revision of expected benefits and related KPIs for all use case partners
0.5	06/05/2024	SINTEF	Restructured document, added section on requirement elicitation work in the M6-M15 period
0.6	10/05/2024	SINTEF	Updated descriptions of use cases for each use case partner
0.8	15/05/2024	SINTEF	Updated sections in conclusions, version sent for internal review
0.9	28/05/2024	SINTEF	Removed outdated information from D1.1
1.0	31/05/2024	SINTEF, KU Leuven	Added information on the D3.5AI Act, incorporated feedback from partners, finalised

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DISCLAIMER

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EXECUTIVE SUMMARY

WASABI focuses on intelligent digital assistance solutions because they help humans achieve their goals without marginalizing them - this will contribute to human-centered manufacturing. The WASABI vision is that digital assistance and conversational AI become standard practices to reach sustainability goals in manufacturing. Humans will use it, for instance, to identify and assess opportunities to turn waste into a resource and to reorganize work to minimize carbon footprints. Access to these benefits will be as simple as selecting and configuring Apps from an online store, and interoperability minimizes vendor lock-in and maximizes information valorization. New AI-focused training services for employees will be a general practice too. They let workers experience solutions and teach them about AI's capabilities, risks, and limitations in manufacturing. Digital assistance solutions will blend into Europe's emerging legal framework for AI, and they will be affordable and manageable even for small producers.

The scope of D1.4 is to report the work performed in the context of T1.1 "Situation analysis and use case detailing" and T1.3 "Evaluation of expected benefits for use cases". The overall objective of this document is to provide the outline of the requirement analysis to help structure the technical analysis and development of intelligent digital assistance solutions. D1.4 is the updated version of D1.1, a collection of testable requirements, accompanying stakeholder needs, wants, and believes, starting KPIs for the evaluation, and the expected measurable benefits.

The WASABI project is structured around five use case partners: CROMA (sterilization of surgical equipment), EPISCAN (production of personal protective equipment), REINOVA (testing and validation of e-mobility components), SILK-BIO (solubilization and casting of silk fiber) and TRIMEK (metrology systems, solutions, and machines). All use case partners contributed to the process or requirement elicitation through a combination of self-reporting and joint workshops (digitally or physically) following templates for information collection.

The report describes each use case partner separately. For each use case partner there is a high-level description of the use case partner, a situational analysis of their goals, functional requirements, system technical requirements, additional requirements, if any, and expected benefits and related KPIs. When preparing this report, we have made it as comprehensive as possible. This means we have kept all old relevant information from D1.1, but removed and replaced outdated or wrong information. The major updates reported here are:

- Updates on the white-label shop requirements
- Updated use case description for TRIMEK
- Revised and updated expected benefits and related KPIs for all use case partners
- Data questionaire from UNIMORE
- Legel framework update from D3.5

The legal framework update was conducted in parallel with this deliverable in D3.5. The section included in this report only identifies what this is about, some key questions that must be addressed by the project as well as how these must be addressed. The report ends with some conclusions. The most important is that, while the exact details of the user needs and wants vary, the overall goal for the DIA is process support. The users have different procedures they want followed, often to the letter, and use of the DIA is intended to ease that process. In addition, all users face documentation requirements as to whether their process has been followed or not. Their expected goals supported this. As regards the white-label shop the use case partners requirements have been met in WP3 (outcome of workshops fall2023). Regarding the legal framework the project is operating under the AI act regulate this and there is a need for the whole project to address this in the upcoming months.

1. INTRODUCTION

This document presents the requirements of the WASABI project regarding the five different use case partners, analyses of the current situations at the use case partners, and the expected measurable benefits and related KPIs that are defined for the evaluation of the solution.

The requirement elicitation in WASABI started in M1 and will continue out M24 with reports in M6, M15 and M24. This document is the intermediate requirement report in M15, deliverable D1.4. This document is the updated version of D1.1. Therefore, it contains all information from D1.1 that is still valid and relevant at M15 of the project, including descriptions of the initial data collection, analysis, and conclusions. Several sections have been revised with updated information and descriptions, in particular the situation analysis and use case detailing for all use case partners, the expected benefits and related KPIs, and the section covering the white-label shop. Finally, the section on regulation has been updated, and more importantly for the project a new document on this now exits in the form of D3.5.

1.1 Purpose and Objectives

This report is the intermediate description of use case requirements in WASABI. It outlines the situation for the use case partners in WASABI at the start of the project and adds development up to M15. According to the Description of Action, this deliverable should be a: "*Collection of testable requirements, accompanying stakeholder needs, wants, and believes, starting KPIs for the evaluation and the expected measurable benefits.* Most importantly, it should be a foundation for developing the various other components of WASABI in WP2 and WP3. This report is that, but the reader should take into account that this deliverable is not the only one describing use case partners, as deliverable D1.2 "Use cases and scenarios" was written in parallel with D1.1, the earlier version of this report. This intermediate report serves the same purpose, but it has been updated with information that has become available in the period M6 to M15.

1.2 Terminology in the report

In WASABI, there is no one-to-one relationship between use cases and use case partners. Use cases aim at creating a solution to some problem that exists in different settings in several enterprises. WASABI has three use cases to realize and evaluate concepts and technologies. Each use case represents a specific but widely relevant need in manufacturing. The three use cases in WASABI are:

1. *Augmented waste management and valorization*: Enabling reusing of "waste" from one production process in another process (possibly in another enterprise). The development of this use case takes place in T2.2, led by SYXIS.
2. *Assisted Workforce Management*: Onboard and integrate workers faster by employing AI-based digital assistance. The development of this use case takes place in T2.3, led by BIBA.
3. *Assisted Quality Assurance for sustainable products*: Augmenting product quality to increase product and worker safety, carbon footprint, workers cognitive skills, and reduce the burden of repetitive and error-prone activities. The development of this use case takes place in T2.4, led by UNIMORE.

Use case partners are enterprises with instantiations of one or more use cases. There are five use case partners: CROMA, EPISCAN, REINOVA, SILK-BIO, and TRIMEK. Each enterprise has one or two instantiations, and the distribution is as given in Table 1:

Table 1: Distribution of use case partners in use cases

Use case	CROMA	EPISCAN	REINOVA	SILK-BIO	TRIMEK
Augmented waste management and valorization	X				X
Assisted workforce management		X			
Assisted quality assurance for sustainable products	X	X	X	X	X

In the report, we will use the term use case partner as a term for one or more of the enterprises, while use case is one of the three solutions. We will organize the description of the requirements after use case partner, one setoff each use case partner. If the use case partner is involved in two use cases, both use cases are discussed in the presentation.

Finally, the project uses the term "User dialogue" or "User story". These are structured examples of human-machine (bot) interactions showing in detail the steps of a process and where and how the Digital Intelligent Assistant (DIA) offers support. An overview of all user dialogues is found in Table 9.

1.3 Relation to other WPs and Tasks

This deliverable uses no other deliverable as input but relies on data collection as outlined in section 2, "Approaches and Methods" and is done as part of the work of the following tasks:

- Task 1.1: Situation analysis and use case detailing
- Task 1.2: Use case de-risking and concretization
- Task 1.3: Evaluation of expected benefits for use cases

Figure 1 shows how D1.1 is related to other WPs and Tasks.

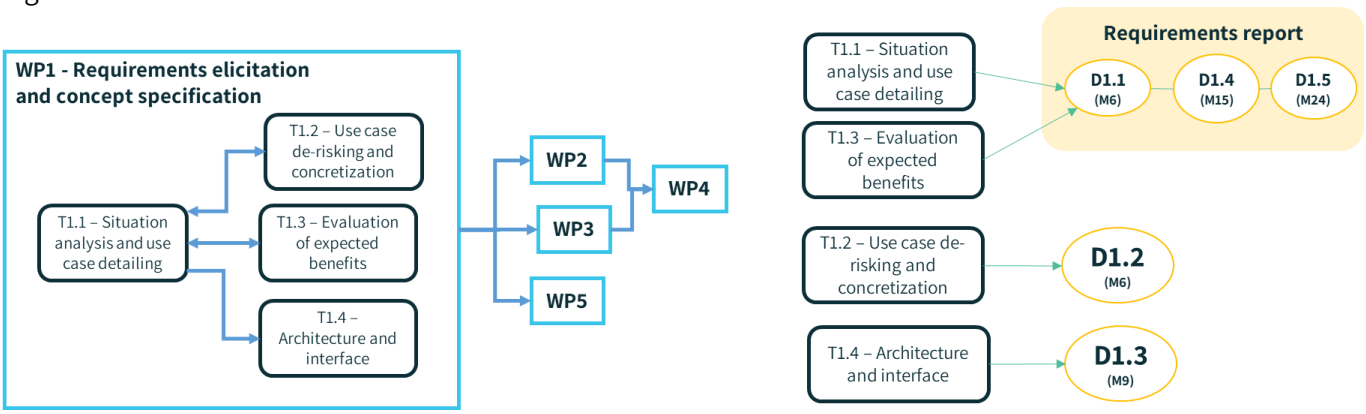

Figure 1: Relation to other WPs and Tasks

It should be noted that in WP2, development takes place in three different tasks, one for each use case.

1.4 Update from D1.1 and D1.2 to D1.4

This report is an intermediary report following up on D1.1. The data collected, and major steps in the creation of the report, have been described in section 2.2.9 on requirement elicitation in M6-M15. The following key updates have been made:

- Added a section on requirement elicitation work in M6-M15
- Added further details, added clarifications and corrected errors identified by the use case partners related to their respective situation and use case descriptions
- Updated the expected benefits and related KPIs for each use case partner
- Revised and updated the chapter on the white-label shop
- Revised and updated the chapter on Legal requirements
- Added updates to the conclusion section

Text and information from D1.1 that is still valid and relevant have been carried over to D1.4, however, with smaller adjustments and corrections of spelling and grammatical errors.

2. APPROACH AND METHODS

2.1 Overall overview of data collection

The primary data collection was jointly undertaken for both D1.1 and D1.2, and it was conducted by several partners working collaboratively. All data has been uploaded to the WASABI repository and is available there.

The primary data collection from the use case partners took place in the period of May-August 2023 as a combination of:

- Self-reported descriptions of each use case partner at the kick-off meeting and following a template in May (M3)
- Workshops (physical or digital) with use case partners and researchers in June/July (M4, M5)
- Individual follow-up questions and completion of some forms in August as needed (M6)

The primary data collection was followed up with further data collection in M6-M12, as described in section 2.2.9

Data was collected in this order, with self-reported data being used as preparation and input for the workshops. The workshops themselves employed a set of methods described in section 2.2. Follow-up with the use case partners was done as needed as part of the finalization of this report. Most of the data was generated in the workshops in dialogue with the use case partners. This holds true after M6 as well, but the use case partners now also provide data and documentation specific to them as follow-up from the workshops.

2.2 Detailed description of data collection by topic

2.2.1 Self-reported descriptions

Use case partners were all introduced at the kick-off meeting in April 2023. The presentations from the meeting have been used both in the description of the use case and for illustrations. Some use case partners also provided technical descriptions of their process; these have been uploaded to the repository and are referenced where appropriate.

As a preparation for the data collection in workshops with each partner, a template for self-description was sent to all partners (template available at the WASABI project repository). This template asked for the following information:

- The overall idea of the use case
- Situation analysis
- De-risking (risk analysis)
- Functional requirements
- System technical requirements
- Additional requirements
- Expected benefits and related KPIs

In this way, both researchers and use case partners prepared for the workshops by developing and completing the forms. All use case partners completed the forms before the workshop, and the forms were uploaded to the repository.

2.2.2 Workshops

The initial workshops were conducted either as a set of digital workshops of two-hour discussions or as physical workshops for two-day meetings at the premises of the use case partner. If the workshops were physical, a visit to the premises and the production site was included. In all cases, manager and worker representatives were invited and participated, as well as technical personnel as needed. From the researchers' side, SINTEF and MEWS were always present, while researchers from other partners participated as much as possible and according to their needs for information.

Physical workshops were conducted in:

- REINOVA (20th-21st June 2023)
- SILK-BIO (22nd-23rd June 2023)
- CROMA (27th-28th June 2023)

Digital workshops:

- EPISCAN (14th, 29th June, 9th, 10th August 2023)
- TRIMEK (26th, 29th June 2023)

The Digital workshops were recorded, and recordings and transcriptions were uploaded to the project repository.

Broadly speaking, the topics covered were the same as the self-reported descriptions. However, several different methods and data collection strategies were employed and are described in detail further below. In addition to the topics from the self-reported descriptions, we also carried out a short analysis of the white-label shop.

2.2.3 Overall idea and situation analysis: Value stream analysis

Based on the information in the self-reported descriptions, SINTEF and MEWS prepared a value stream analysis of the situation. This initial understanding was presented with the Klaxoon tool, a program for supporting digital meetings in the form of a digital online board. With Klaxoon, drawings could be made, ideas expressed and noted, and various files with information could be uploaded. A Klaxoon board was prepared for all use cases, and it was shown and discussed with use case partners. Based on this, both the "As-Is" analysis and the "To-Be" analysis were conducted. The To-Be is presented in D1.2 in the form of process mapping and analysis combined with user

dialogs to demonstrate how the use case partner could benefit from a DIA. For the use case partners which were visited physically; illustrative pictures were taken as permitted and included in the As-is description.

It should be noted that the Klaxoon tool was always updated and adjusted during the workshops, filling the role of information repository as well as a tool for QA and correcting misunderstandings. The process mapping and analysis that was finalized as a set of "To-Be" figures relied heavily on the work with the Klaxoon. The same was true for other topics where Klaxoon was used as a note board for all workshop participants. This use of Klaxoon was done in both the physical and digital workshops.

2.2.4 Functional requirements

Functional requirements were discussed as part of the overall analysis of each use case partner, guided by the overall question, "If the system is to function in this use case, which requirements must be met?". No specific method apart from dialogue was followed.

2.2.5 System technical requirements

In addition to the initial requirements in the self-report, this was discussed in the workshop following a template developed by SYXIS. The template collected information on: Data sets (several questions), data format, data transfers, standardization and data model, deployment of component and platform software and tools, and existing infrastructure. The completed templates have been uploaded to the repository for each use case partner.

2.2.6 Additional requirements

Additional requirements were discussed in the workshops as part of risk management (a risk could be translated into a requirement). A special focus was given from the researchers on possible resistance to the adoption of new systems and ethical and GDPR issues. Possible resistance was covered in the risk process.

2.2.7 Evaluation of expected benefits

The evaluation of expected benefits followed the methodology and the principles of evaluation for the COALA project. The work was carried out as part of Task 1.3. Task T1.3 is centered around the definition of change monitoring and management as well as the assessment of use cases. Its primary objectives include:

- Enhancing the Objective Key Results (OKRs) initially outlined in the project proposal to assess the project's performance, impact, and acceptance of its outcomes.
- Establishing the baseline KPIs for each use case to serve as a reference for evaluation.

This task is supported by the information presented in Section 2 of this deliverable, which focuses on devising specific methods and metrics for evaluating trust in the DIA, the usability of the WASABI solution, and the enhancement of worker performance and satisfaction. We have investigated the latter through an ethnographic observation study conducted at the factories of CROMA, REINOVA, SILK-BIO, TRIMEK, and EPISCAN.
In order to accomplish the objectives outlined above, we have conducted multiple workshops, initially with each business partner individually and subsequently with the technical partners. In these workshops, we initiated the process by assigning tasks to each business partner where they outlined the following:

- Expected benefits from WASABI
- The most pertinent capability related to each benefit
- The category to which the benefit belongs (as categorized in **¡Error! No se encuentra el origen de la referencia.**)
- The value of the benefit (High, Medium, Low)

- The timeframe for realizing the benefit: Short (within a few months, less than six months), Medium (within six months), Long (after approximately a year)
- Primary KPI
- Baseline for this KPI
- Direct relevance of the benefit to WASABI
- Alignment with the proposal's indicators (Trust, Usability, Performance, Satisfaction)
- Owner
- Examples

Table 2: Benefits categories.

Benefits category	Acronym
Business: Customer satisfaction, business growth, improved branding, etc..	BUS
Environmental sustainability	ENSU
Financial: Increase of revenue, decrease of costs, etc..	FIN
Health and safety	HESA
Operational: Improved effectiveness & efficiency, improve change & release process, etc..	OPR
Organizational: Better performance & compliance, future readiness, closure alignment to organizational goals, etc..	ORG
Technology: Improved quality of deployment, integration, outcomes	TECH

During each workshop session, we collaborated with our business partners (CROMA, REINOVA, SILK-BIO, TRIMEK, and EPISCAN) along with their respective technical counterparts to collectively assess the benefits they had documented. In the subsequent sections, we will share the outcomes of these workshops for each individual business use case.

2.2.8 Analysis of white-label shop

The vision of WASABI is that: «*Digital assistance and conversational AI become standard practices to reach sustainability goals in manufacturing*» and *access to these benefits will be as simple as selecting and configuring Apps from an online store, and interoperability minimizes vendor lock-in and maximizes information valorization. New AI-focused training services for employees will be a general practice too*."

In the discussions, the use case partners had no problem understanding the first part and the usefulness of a conversational assistant and seeing possibilities in how to employ it. The idea of employing other assistants, especially selecting and training them themselves, was more difficult to understand.

In the project, this key goal is to be realized:

- **RO 3.1: Federated white-label shop for digital assistance solutions**: An online shop built with open source software and in-built shared dataspace for shop instances. Grants access to a wide range of software, hardware, and non-technical services needed for sustainability and resilience-oriented assistance solutions.
- **RO 3.2: Skill-interoperability demonstrator**: A prototype presenting how different digital assistant frameworks could use the same skill. This result will suggest how standardization could increase the adoption of digital assistants in the industry. (KER 6)

In order to acquire some information about the possibilities for such a system, the following exercise was carried out in the workshops:

First, the vision and the idea behind the white-label shop was presented. The metaphor "Google play"/ App store was used to explain to people what such a shop could be. Then we asked the participants to answer the following:

- *Regarding the white-label shop, what would be the most important aspects? What are your key questions? Please write them as «post-its» (on Klaxoon). Note: We will NOT answer (none of us). We do not need to agree/rank/align on anything. Just questions- but you can follow up with more questions?*

This resulted in a set of questions that gives us some insight into what the use case partners see as the main concerns that should be met for such a tool to be useful. It is not technical requirements; it is more a set of concerns.

2.2.9 Requirements elicitation M6-M15

In the period after M6 and the submission of D1.1 and D1.2, the following requirements elicitation has been carried out:

1. Joint WP1-WP3 workshops on white-label shop, 2023-09-11 and 2023-09-13
2. Clarification workshops at the GA in Bremen, 2023-11-28
3. Joint WP1/WP2 visit to EPISCAN, 2024-01-21 to 2024-01-26
4. Joint WP1/WP2/WP3 workshops on KPIs, OKRs, technical requirements, and use case dialogues 2024, organized by SINTEF with contributions from BIBA, UNIMORE, and MEWS, an open for all interested partners,
    a. CROMA (Thursday 18th January 2024)
    b. SILK-BIO (Friday 26th January 2024)
    c. EPISCAN (Friday 26th January 2024)
    d. REINOVA (Monday 5th February 2024)
    e. TRIMEK (Thursday 8th February 2024)
5. Updates and inputs from partners based on the meetings above
6. WP2 regular work package meetings (Bi-weekly from October)

The first four represent formal requirement elicitation meetings where there has been an agenda, possibly some other information-collecting techniques, and a dialogue between the use case partners and the other partners on some issues relevant to an update of D1.1. The fifth is a follow-up from the various workshops, where partners have provided documentation and data relevant to their use case.

The sixth is the regular WP meeting for WP2, where the WP1 manager has participated. Requirement elicitation is not an item on the agenda, but relevant information on the use case partner and questions from the other WPs pop up. As can be seen from the list the data collection has been done jointly with the other WPs, and since the other WPs participate in WP2, this ensures that communication and relevance between the partners are strengthened. The various meetings and discussions were also followed up by direct emails, various documents (updates of parts of D1.1 and D1.2), and questions between the researchers and the use case partners. No list for this has been created, but relevant documents have been uploaded to the repository.

3. USE CASES

3.1 CROMA

CROMA Gio.Batta España (CROMA) is a leading company in the construction and management of sterilization centers serving public and private hospitals. They combine the management of the sterilization process with the management of surgical instruments according to the surgical specialties performed in each hospital.

CROMA Gio.Batta España's use case in WASABI is the Sterilization Centre managed by CROMA at the Burgos University Hospital, Burgos, Castilla y Leon, Spain.

Sterilization is the process of reconditioning medical devices (surgical instruments) after they have been used between surgeries. Sterilization results in the (almost) total destruction of any microbial form, i.e., the killing of all pathogenic microorganisms in both their vegetative and spore forms. A material is considered sterile if the sterility assurance level (SAL) is less than 10-6, i.e., when the probability of finding a microorganism is less than one in a million. Sterilization is, therefore, one of the main steps in the process of preventing and controlling hospital infections.

3.1.1 Situation analysis and use case detailing

As a sterilization center responsible for handling, maintaining, cleaning, and sterilizing medical equipment, there are very strict operational procedures at CROMA. Accordingly, the use case is characterized by several quality control steps during the overall sterilization process. For WASABI, two overall objectives are identified for CROMA:

- Supporting operators in different types of quality control during the overall sterilization process, such as checking and registering whether a specific instrument is present in a set of instruments.
- Give suggestions regarding instruments that need to be taken out of the process to be repaired.

The AS-IS sterilization process at CROMA Sterilization Centre at the Burgos University Hospital consists of the following main steps/areas:

1. Acceptance of instruments collected after surgery.
2. Manual washing
3. Automated washing
4. Packing
5. Sterilization
6. Warehouse/Delivery

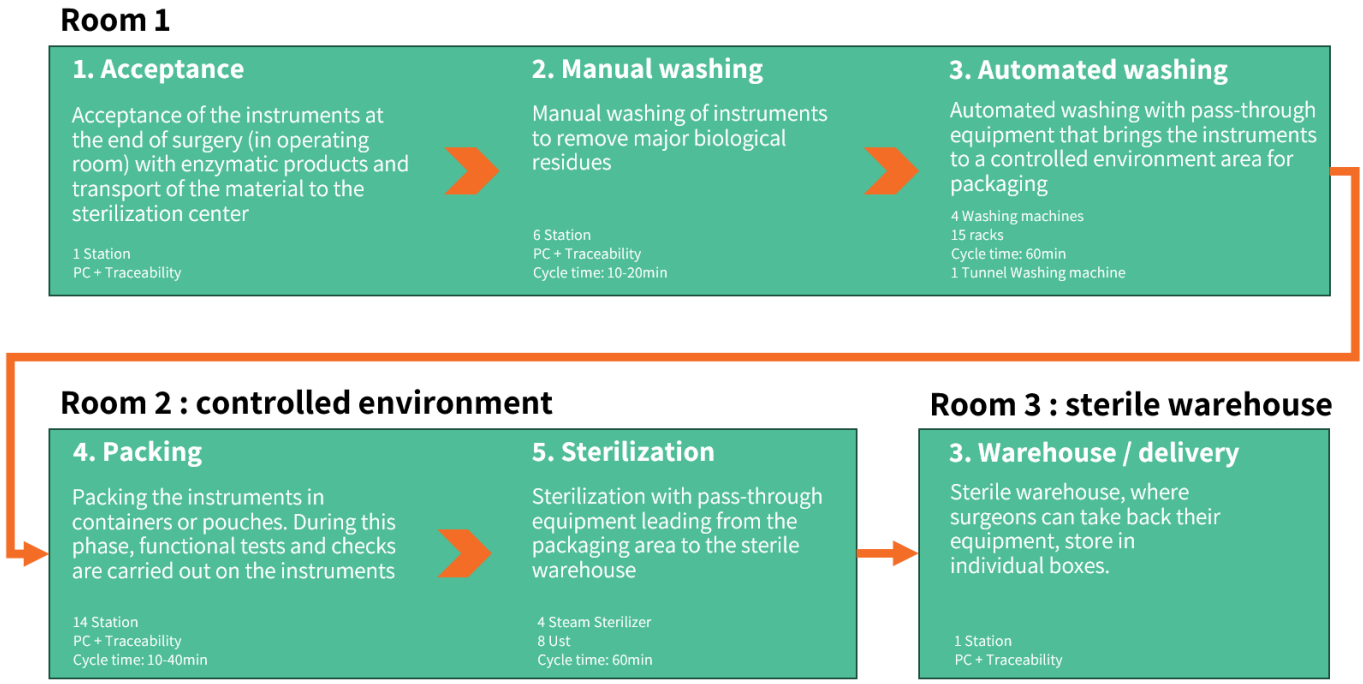

Figure 2: CROMA As-Is process

Figure 3: Acceptance of the instruments and transport of the material to the sterilization centre

Figure 4: Manual washing of instruments

Figure 5: Automated washing with pass-through equipment that brings the instruments to packaging area

Figure 6: Packing of instruments in containers or pouches

Figure 7: Sterilization with pass-through equipment leading from the packaging area to the sterile warehouse

Figure 8: Sterile instruments are stored in boxes in sterile warehouse

As shown in Table 1, CROMA participates in use case 1: “Augmented waste management and valorization” and use case 3: Assisted quality assurance for sustainable products.

The Assisted quality assurance for sustainable products use case for CROMA has been described in sections 3.1.1 to 3.1.4 in D1.1 as well as in D1.2. Very briefly, this is a DIA that supports the sterilization process. The development of this has been carried out in T2.4, led by UNIMORE, and demonstrated in D2.4 in spring 2024.

It is planned that CROMA will use Edge deployment rather than cloud deployment. An assistant demonstrator with simulated data has been introduced in D2.4 in M15. The IT department of Burgos Hospital will support the development, including integration and connection with the Aesculap software. This deployment plan covers both use cases.

The use case "Augmented waste management and valorization" for CROMA has not been described in D1.1 and is therefore outlined here. It is a subprocess of the overall process and starts in step 4 in Figure 6 described in the AS-IS process described in Section 3.1.1. At this point, the operator performs functional tests and checks all instruments included in a set. If a broken instrument is found in the set, it must be taken out of the set and replaced. It must then be decided what can and should be done with the broken instrument. In some cases, the instrument can be fixed at CROMA; in others, it must be sent back to the OEM for remanufacturing or repair. In other cases, the instrument may have to be recycled or disposed of. What to do with the instrument depends on the existing contracts between the OEM and the hospital. Some OEMs have a "return all equipment policy", where all equipment should always be returned to the OEM. In such cases, the broken and unrepairable equipment is simply returned by post. If no such agreement exists, however, CROMA must take responsibility for disposal or re-use. This is where the rEUse platform will be employed to register the equipment for re-use or sale.

As a sub-process of the overall process, this does not change the requirements identified earlier much. A sub process is initiated in Step4. A future improvement might be that The DIA should be able to inform of 'return all equipment policy' before creating a new record in the rEUSe platform. However, this requirement is not included in the DIA delivered in the frame of D2.4 in M15 but is a candidate for further improvement and this may be a requirement for Assisted Quality Assurance before triggering the Waste Inspector.

3.1.2 Functional requirements

- Management of checklists. Either dictated by the system that knows, for example, a list or by voice recognition of the operator who perhaps identifies a tool on a list.
- Completion of a worksheet with saving of data; for example, an operator fills in a production sheet verbally communicating the parameters to be entered.
- Voice communication in a noisy environment
- Communicate with Instacount
- Understand native language (Spanish)
- Handle noise in the washing area
- Operators must be able to use their hands freely during the processes but are already operating touchscreen PCs to search in the set list for each instrument

The sterilization process is strongly linked to the operators' manual activity and their interaction with the equipment.

3.1.3 System technical requirements

Connectivity with current software systems

- System for equipment
- Aesculap's Instacount instrument tracking software (most important)

3.1.4 Additional requirements

Since the washing area was noisy operators might want to use some sort of airplugs/airpods to listen to the instructions from the DA. The system was expected to run on a tablet/phone and be able to communicate with such devices.

Beyond that no additional requirements were mentioned in the kick-off meeting presentation, the self-reported descriptions or in the workshop discussions. A short discussion on personal data and GDPR yielded no specific additional requirements, save the general requirements of adherence to the relevant regulatory requirements. See also section **¡Error! No se encuentra el origen de la referencia.** for a discussion of those.

3.1.5 Expected benefits and related KPIs

The expected benefits and related KPIs for CROMA have been focused and shortened from 6 to 4. There are now baselines for #1 and #3 (depending on set) and #4. It should be noted here that the #4 is an innovative KPI that aims at creating a new value chain. The Kg of recyclable steel recovered is an indication of its benefit, and there is no base data available. #4 is categorized as operational since it focuses on operations and value chains, but it is also an environmental goal. It should thus contribute towards the OKRs, but exactly how is a topic for further discussion in the project. Finally, we can note that the first three KPIs are all connected to the use case: "Assisted quality assurance for sustainable products. The use case description is found in D1.2 and 3.1.1, and development of the solution is part of T2.4. The last KPI is related to the "Augmented waste management and valorization" use case and is described in **¡Error! No se encuentra el origen de la referencia.**. User stories for CROMA are C-US1, C-US2, and C-US3 (see Table 9).

Table 3: Revised expected benefits and related KPIs for CROMA

#	Benefits	Cat	Value (Low/Medium/High)	When (Short/Medium/Long)	KPI	Base	Target	Indicator (Perf/ Impact/ Accept/ Trust/ Usability)
1	Increased operators' productivity	OPR	Medium - High	Short (3/4 months)	Average number of boxes processed per day	100–150 sets on average	Increase of 10-15%	Perf.
2	Reduced number of process repetitions /errors	OPR	High	Short	Average number of errors/process repetitions per day	6 process repetitions	50 % reduction	Perf.
3	Reduction of packaging time	FIN	Medium	Long	Reduction of set packing activities prior to sterilization	Average time: 20 min.	20% time reduction	Perf.
4	Establishing a new value-chain for discarded instruments	OPR	Medium	Long	Kg of steel recovered (recyclable)	Zero	Identification of at least one supplier willing to take back used instruments for raw material recycling	Imp.

3.2 EPISCAN

EPISCAN is a Canarian-based company that produces personal protective equipment (PPE). The PPEs of EPISCAN have been approved by the Spanish Agency for Medicines and Health Products (AEMPS). EPISCAN currently has 11 workers employed and a typical annual turnover of 2.339.645,54 euros.

3.2.1 Situation analysis and use case detailing

The main products produced by EPISCAN are masks (surgical and FFP2 without exhalation valves). These are produced in two separate production lines at EPISCAN's facilities. Masks are produced in very high volumes. In the surgical mask production line, a total of 35,000 masks can be produced in an 8-hour working day. In the FFP2 mask production line, a total of 15,000 masks can be produced in an 8-hour working day.

Surgical mask production line

Here is the as-is process of surgical mask production.

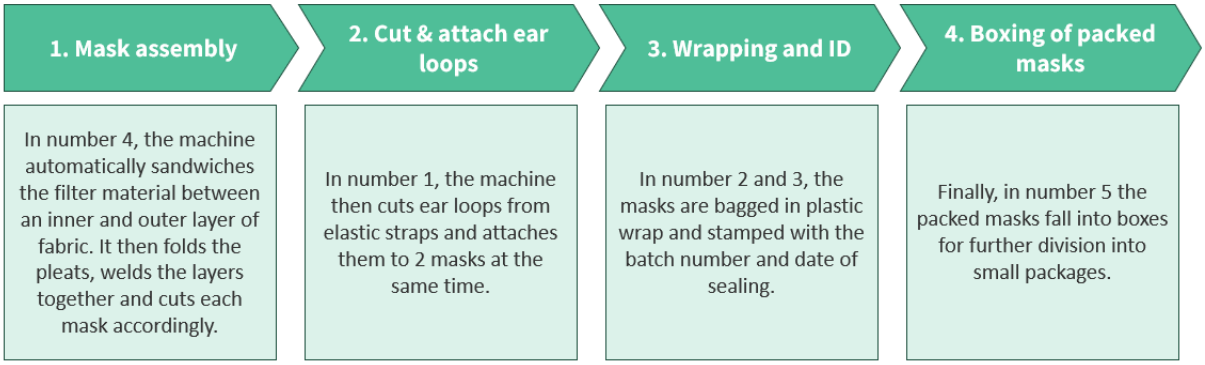

Figure 9: EPISCANs As-Is process - Surgical mask

FFP2 mask production line

Here is the as-is process of FFP2 mask production:

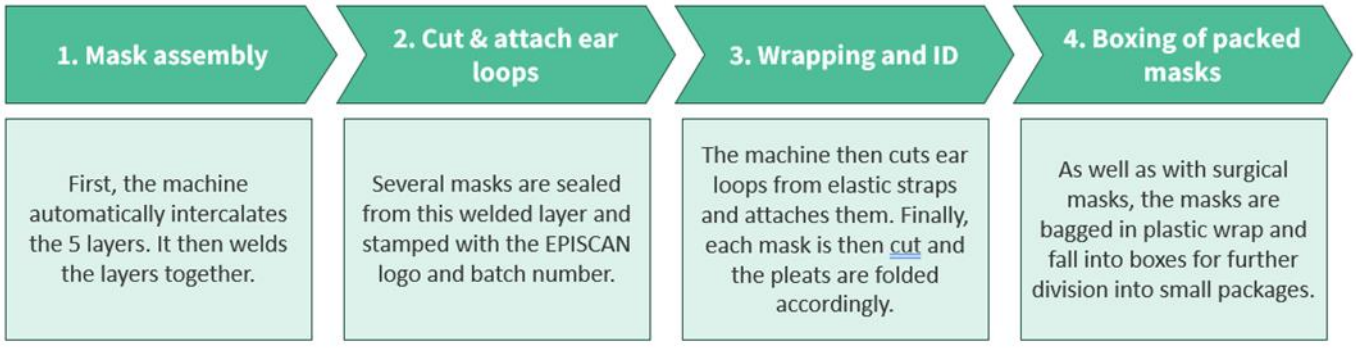

Figure 10: EPISCAN As-Is process – FFP2 mask

For each 8-hour working day (production shift), EPISCAN needs to keep track of and document data related to mask production. Today, there are three ways data from the production lines are maintained:

1) **Production shift document:** A document (paper sheet) to be filled by the technicians for each production shift

2) **Excel file:** An Excel file with data from all production shifts, manually entered based on the production sheet documents
3) **ERP system:** Updated based on the Excel file.

The **production shift document** has to be filled by the technician in charge of each production shift. In the document, the technician notes down the following:

- The material quantity required for the production shift:
  - The first part of the document details the amount of material that is already in the manufacturing plant and the amount of material withdrawn from the warehouse necessary in the manufacturing shift.
- The material quantity used and at which time (hour of the day) it was changed
  - The second part of the document explains when it was necessary to change the material, specifying the time, quantity, and number of masks produced at the time of the change.
- The total number of masks produced
- The registered waste after the production shift is over, specified as to whether it is reusable, unusable, or useable for donation or testing, plastic and flow packs
- The name of the technician in charge of the production shift
- The production date
- The batch number of the masks produced in the production shift
- Any incidents that occurred during the production shift
- Maintenance work that had to be carried out on the production line

The **Excel file** is updated once a week by the production manager with (1) all production shift documents and (2) the invoices for the provision of materials.

EPISCAN has been using an open-source **ERP system** software since January 2022. EPISCAN's production manager uses the manufacturing module and the warehouse management module of the system. The warehouse management module is updated each time EPISCAN receives the provision of materials. In the manufacturing module, the production managers enter the total number of masks produced, and then the system automatically calculates the material used in kilograms. The system also generates graphs from the production data entered.

The overall objectives and vision related to WASABI for EPISCAN concerns the following two areas:

- Support in progress reporting during and after each production shift
- Training of new employees in operating the two production lines

As seen from Table 1 EPISCAN is involved in use case 2 'Assisted workforce management' and use case 3 'Assisted quality assurance for sustainable products'.

Use case 2 for EPISCAN is focused on onboarding of new employees. The new employees must learn how to operate the mask production machine. Currently, this training requires supervision from an experienced employee. New employees must be trained in the following operations and aspects:

- Starting operation
- Emergency stop-reset operation
- Change from manual to automatic operation
- Automatic operation
- Machine touch screen navigation, symbols, warnings, and available information

In use case 3, 'Assisted quality assurance for sustainable products' for EPISCAN, new scenarios related to inventory and manufacturing descriptive analysis based on information from the mask production line and existing systems have been added. Information for inventory analytics includes quantity on hand per product, total costs per product, and statistics on source and destination location, operation type etc. Information for manufacturing analytics includes various manufacturing statistics per day, such as products produced, quantities, and manufacturing durations.

The current plan for deployment is to run the stack in EPISCAN's own cloud infrastructure.

3.2.2 Functional requirements

- Collect vocal input from operators
- Store data input from operators
- Transmit input from operators to an Excel sheet
- Ability to show videos and/or photos for a basic use of the machines.
- Manage learning path of user to allow for end of training validation and resume of training at a given unvalidated step
- Present learning cases for operational training (procedural instructions)
- Smaller learning cases (nuggets) should be linked to a larger in order to teach all operations and measure overall progress
- Understand native language (Spanish)
- Understand other languages for rapid onboarding of non-native speakers
- Requirement for Assisted QA :
    - Support live production reporting through update of production quantities and raw material changeover declaration
    - Support inventory management and raw material quality analytics based on ERP data

3.2.3 System technical requirements

- Read/Write to Excel. EPISCAN has suggested to not integrate the DIA with the production lines nor the ERP system, keeping all communication through the Excel sheet that the ERP system reads. Information from the production lines should then be communicated by voice by the operators to the DA, which writes this information to the Excel sheet.
- Provide information on production status when required by production management

3.2.4 Additional requirements

No additional requirements were mentioned in the kick-off meeting presentation, the self-reported descriptions or in the workshop discussions. A short discussion on personal data and GDPR yielded no specific additional requirements, save the general requirements of adherence to the relevant regulatory requirements. See also section **¡Error! No se encuentra el origen de la referencia.** for a discussion of those.

3.2.5 Expected benefits and related KPIs

The revised expected benefits and related KPIs from EPISCAN are clearly improved as tools for evaluating progress. They are much closer to SMART (Specific, Measurable, Attainable, Realistic, Timebound) approach. The total number of KPIs has been reduced from 6 to 5. We now have base measurements for all KPIs and targets for improvement. Further work is needed to establish a connection to the OKRs.

Table 4: Revised expected benefits and related KPIs for EPISCAN

#	Benefits	Cat	Value (Low/Medium/High)	When (Short/Medium/Long)	KPI	Base	Target	Indicator (Perf/ Impact/ Accept/ Trust/ Usability)
1	Reduced training time for workers	ORG	High	Medium (6 months)	**1.1** Number of hours spent by a new employee learning how to turn on the machine with all pre-checks executed **1.2** Number of hours spent by new employees learning how to modify the configuration on the machine on its screen **1.3** Number of weeks spent by a new employee learning machine' screen messages	**1.1:** 3 hours **1.2:** 6 hours **1.3:** 2 weeks	**1.1:** 1 hours **1.2:** 2 hours **1.3:** 8 hours	Performance
2	Reduced waste due to improved process quality	ENSU	Low	Long	Number of waste kilograms in a mask production shift	0,25 kg	50% reduction	Impact
3	Reduce operators' time spent on non-value-adding activities (reporting/writing on documents)	OPR	Medium	Long	Number of hours spent registering production data from the start of the production shift until the production data is entered into the ERP system	4 hours	30 minutes	Performance
4	Reduced errors in data entry	OPR	Medium	Long	Average number of errors in data entry per month	14 errors	80% reduction	Impact
5	Predicts emerging manufacturing disruptions through analytics of ERP data	OPR	Medium	Long	Average number of emerging disruptions per week	5 disruptions	50% reduction	Impact

3.3 REINOVA

REINOVA provides testing and validation of e-mobility components such as modules and battery packs. They specialize in consultancy, training, and other electric mobility services to support customers in the transition to electricity with innovative processes and methods.

Their services consist of analysis of design, materials, structure, and competitors. Environmental impacts are also assessed. Electromagnetic compatibility testing with high-performance technologies and equipment is a part of their expertise.

Figure 11: Pictures from REINOVAs facility

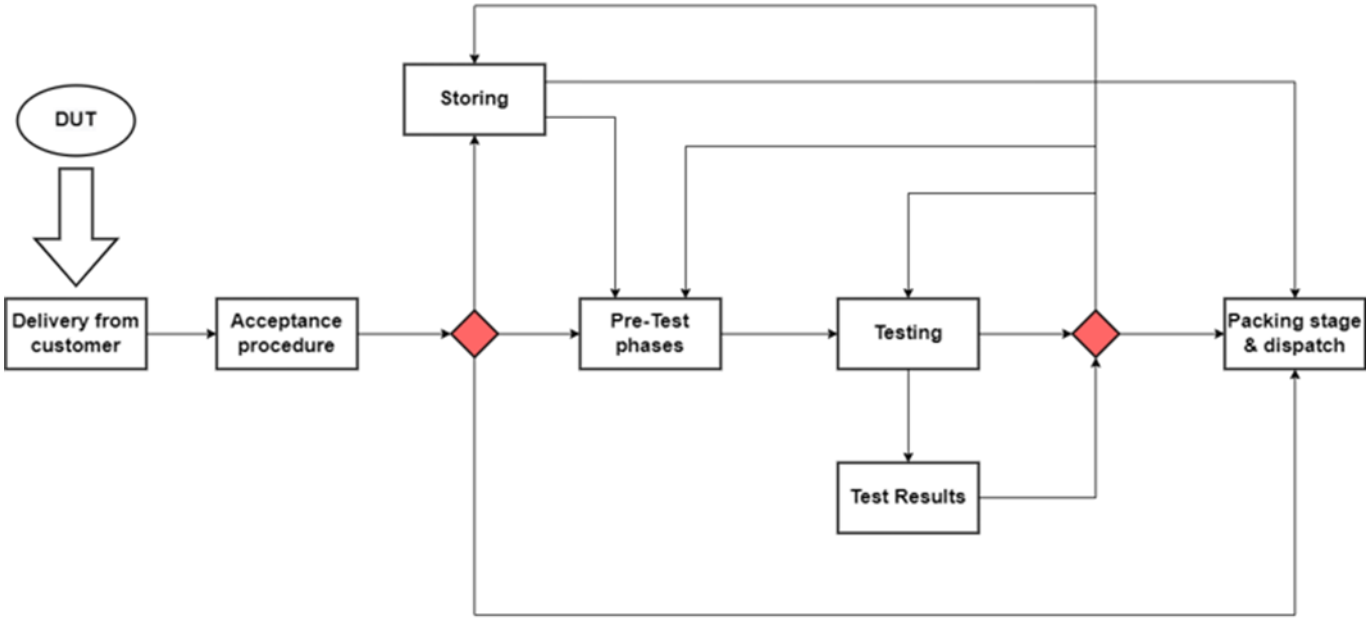

Figure 12: REINOVA As-Is process

3.3.1 Situation analysis and use case detailing

The DIA should aim to assist technicians and engineers in a laboratory setting where advanced test machines are running, often long-lasting, tests on various devices (Device Under Tests, DUT). By providing real-time status updates and presenting retrospective data, the DIA can contribute to the safety of the work environment and improve work efficiency in general.

The DIA will be linked to the testing machines through APIs and provide alerts in case of any irregular incidents, thus allowing technicians and engineers to respond quickly and prevent potential accidents. The goal is also to provide real-time status updates on the machines, allowing users to track the progress of tests and make informed decisions. Adding additional input to the user for decision support is also of interest.

Retrospective analysis based on historical data will also be made available, allowing users to analyze past performance and identify areas for improvement. This can help to optimize the testing process and improve efficiency.

The DIA is to be implemented in a laboratory setting to assist technicians, operational engineers, and test engineers in performing tests on customer devices. The assistant should support two functions:

Alarm and Emergency Notification: The assistant notifies users (or user groups) about alarms from tests and emergencies from devices, such as fire and gas events or sensor faults. REINOVA currently has a Telegram Bot service for this purpose but feels there is a need for upgrade.

Machine Status Request: Users should be able to query the assistant about the status of a particular machine or the overall status of the laboratory.

Currently, a mobile app prototype, which is based on the Telegram BOT platform with [1]similar functionalities is in use, and users can send requests to the bot and receive emergency notifications. This process can be improved [2]by:

- Implementing more sophisticated responses, increasing the amount of information provided, and suggesting possible solutions in case of faults or malfunctions.
- Another potential new feature is implementing power consumption information from machines, allowing the assistant to warn about abnormal statuses.

The main elements involved in providing data to the assistant are the test machines situated in the laboratory. Each machine has its own data communication protocol which must exchange data with a “wrapper” software that communicates with the assistant. By using this upgraded assistant integrated with the DA, users can be more effective in using the laboratory and develop their ability to take action on less severe faults that currently require intervention by personnel.

The operational context is a warehouse laboratory where industrial testing of large electrical components, such as electrical car batteries, takes place. These tests are conducted using huge machines and can last for years. Despite the size of the machines and the duration of the tests, the laboratory is not too loud.

In the same building as the laboratory, there are offices where other personnel work. These individuals may be indirectly involved in different aspects of the testing process, or they may have other roles within the organization.

Overall, the environment is characterized by a combination of industrial testing and office work. The laboratory provides a controlled environment for conducting long-lasting tests on large electrical components, while the offices provide a space for a variety of personnel to carry out their work.

REINOVA participates only in use case “Assisted quality assurance for sustainable products”, see Table 1. The main focus of this use case is alarm management. The DIA will be linked to the testing machines through APIs and provide alerts in case of any irregular incidents, thus allowing technicians and engineers to respond quickly and prevent potential accidents.

[1] A description of this platform has been uploaded on the WASABI project repository for inspection as needed.
[2] The idea is not to replace the Telegram platform, but to add functionality via a DIA.

3.3.2 Functional requirements

The operations of REINOVA are centered around executing advanced testing performed by large-sized machines on a variety of components in a large laboratory setting. Test operators and engineers apply their area of competence to prepare, supervise, and assess the operations.

The case of REINOVA is divided into two use-case scenarios:

1. A need for notifications and procedural support if an incident is under development, if there is an emergency incident taking place, and the ability to access essential information throughout the lifespan of the incident.
    a. Also, procedural support is requested in terms of which actions to execute in a given event is a desired feature.
2. The provision of step-by-step process support during any given DUT-procedure.

In the frame of scenario 1, the DIA will provide alert distribution, decision support, and work instructions:

- The DIA will provide alert distribution to user roles.
    - The system must support the ability for a user to assign an alarm to a different user or user role. This is in order to provide the ability to delegate based on available resources and competencies. At the moment no definition of user roles exists.
    - The alarms should preferably provide as much contextual information as possible. Currently, the information provided in the app is very limited.
- Decision support – provide suggestions for steps taken in the context of the alarm.
- Work instructions – provide suggestions for steps taken in the context of the given work procedure.

In the frame of scenario 2, the DIA will provide process guidance and decision-making support:

- The DIA should be able to suggest the need to initiate the start of a process based on data from the internal ERP system, ALPS.
- The DIA should provide instructions for the steps of the initiated process.
    - Logging of the steps is done by the DIA at the user's request.
- Upon request the assistant should respond with the main status of the given machine (e.g., "running a test", "not running", "ready", "emergency") and the status of its sub-items (e.g., sensor readings). In case of machine malfunction, the assistant can also provide the user with the required actions to restore operational status.

3.3.3 System technical requirements

- The DIA should provide alert distribution to different user roles and be able to differentiate based on different attributes.
    - This functionality will depend on an integration, most likely via an API, to the system currently in use (the Telegram bot app).
- The alarms should provide as much contextual information as possible.
    - In some cases, this might depend on an API to the actual testing machines in the laboratory.
- Decision support – provide suggestions for steps taken in the context of alarms.
    - Requires written procedures by REINOVA.
- Work instructions – provide suggestions for steps taken in the context of a given work procedure.
    - Requires written procedures by REINOVA.

- The DIA must support Android.
- The assistant must have an authentication procedure (i.e., SSO with AZURE).
    - The main software can be located on the company server.

3.3.4 Additional requirements

Social Related Requirements

- Involve users in the development and implementation process:
    - Involve user groups and take their feedback into account.
- Develop an implementation plan to provide training and support.
- Obtain leadership buy-in:
    - Crucial for the successful adoption of new technology. Leaders can promote the benefits of the technology, provide resources for its implementation, and encourage its use among employees.
- Ensure alignment with company values:
    - This can help ensure that it is well-received by employees and integrated into the company's operations in a way that is consistent with its overall mission and goals.

Ethics Related Requirements

- Transparency:
    - Helps build trust with users and ensure that they are fully informed about the technology and its potential impacts.
- Privacy:
    - Ensure that personal data is collected, stored, and used in a responsible manner and that users have control over their own data in compliance with GDPR and national law.
- Accountability:
    - Strive towards awareness of possible adverse impacts that may arise and commit to addressing them in a timely and effective manner.

User and Usability Related Requirements

- Training
- Voice input
- Support for Italian

3.3.5 Expected benefits and related KPIs

Table 5: Revised expected benefits and related KPIs for REINOVA, updated February 2024

#	Benefits	Cat	Value (Low/Medium/High)	When (Short/Medium/Long)	KPI	Base	Target	Indicator (Perf/ Impact/ Accept/ Trust/ Usability)
1	Reduced cycle time for alarm management	OPR	Low	Medium	Average alarm duration	REINOVA provides a baseline	REINOVA specifies a target	Perf
2	Reduced alarm frequency due to REINOVA equipment failure / decreased number of errors from the testing devices. (all errors to come from the DUTs).				To be decided	to be decided	to be decided	
3	Reduced number of testing unit breakdowns				Average time between two consecutive errors	Baseline to be defined	10% improvement?	

4	Improved planning through improved status monitoring				Daily Work Plan Compliance = (Number of Completed Tasks as Planned / Total Number of Planned Tasks) x 100	REINOVA provides a baseline	REINOVA specifies a target	
5	Improved employee satisfaction/data trusteeship/confidence through improved information exchange				User satisfaction survey	Questionnaire must be developed/agreed upon	TBD after defining questionnaire	

The updated KPI table has been focused and shortened from 8 to 5 KPIs. For each KPI there is still a need to identify a baseline and target for the KPI to be included in the final set of KPIs. A question here is whether there are any additional tasks that can be done quicker with the assistant? Regarding category, value, and time (when) it is possible to propose this based on the original KPIs. However, since we are in an ongoing discussion on the whole set of expected benefits and related KPIs for REINOVA this has not yet been done. #5 has a defined measurement that can be used, but also this KPI needs a baseline established through a pre-measurement before the introduction of a DIA to compare with.

Regarding #2 and #3, we are lacking a defined KPI, baseline and target. Also, in the discussions on these two, it is possible that they are more or less the same measurement, namely a measurement of quality of the REINOVA equipment. It is important to understand that REINOVA is not interested in reducing the number of alarms and errors per se. REINOVA tests equipment, that is what "Device under Test" Indicates. Failures on the DUT are likely, indeed expected and desired. The client needs to learn the limits of the equipment. However, REINOVA want to avoid failures due to REINOVA equipment breaking down. REINOVA therefore needs to distinguish between DUT failure and REINOVA equipment failure, which can be seen as maintenance failure. Thus, REINOVA wants an analytic system that can support its maintenance. A KPI defining how this can be measured should be defined. This might simply be "mean time between failure", MTB. Overall progress has been made, but some work remains to get a KPI table fit for evaluation.

3.4 SILK-BIO

SILK-BIO is challenging the status quo in regenerative medicine by leveraging silk as a powerful, scalable, and biocompatible scaffold material. SILK-BIO is targeting different clinical indications in the orthopaedic, vascular, and drug release markets via several technology platforms.

Several clinical needs remain unmet, particularly in orthopaedics, vascular surgery, and sports medicine. No regenerative platform has so far been able to solve them all properly.

SILK-BIO has created a set of technologies that exploit the mechanical flexibility and regenerative capacity of silk fibroin. SILK-BIO is currently at a clinical stage with a guide for nerve repair and advancing other preclinical assets in rotator cuff repair, vascular and bone grafting, and drug release indications.

3.4.1 Situation analysis and use case detailing

The DIA will support the process of solubilization and casting of silk fiber. It will support the operators' manual activity and their interaction with the equipment involved. Potentially, it can be applied in all process steps where the operator has to make a check or where he has to give a confirmation of activity. This is today done by an operator writing up steps performed, and actions taken on a piece of paper, documenting each step of the procedure, and signing off the paper when the process/subprocess has been completed. There are at least 15 such subprocesses to be documented for each "production batch". All documentation is then entered manually into a spreadsheet. It is necessary to keep the documentation for years to be able to retrieve it and present it when clients, customers, authorities, or other with a right-to-know asks. Pictures in Figure 13 and Figure 14 illustrate the situation as is:

Figure 13: Measuring process at SILK-BIO

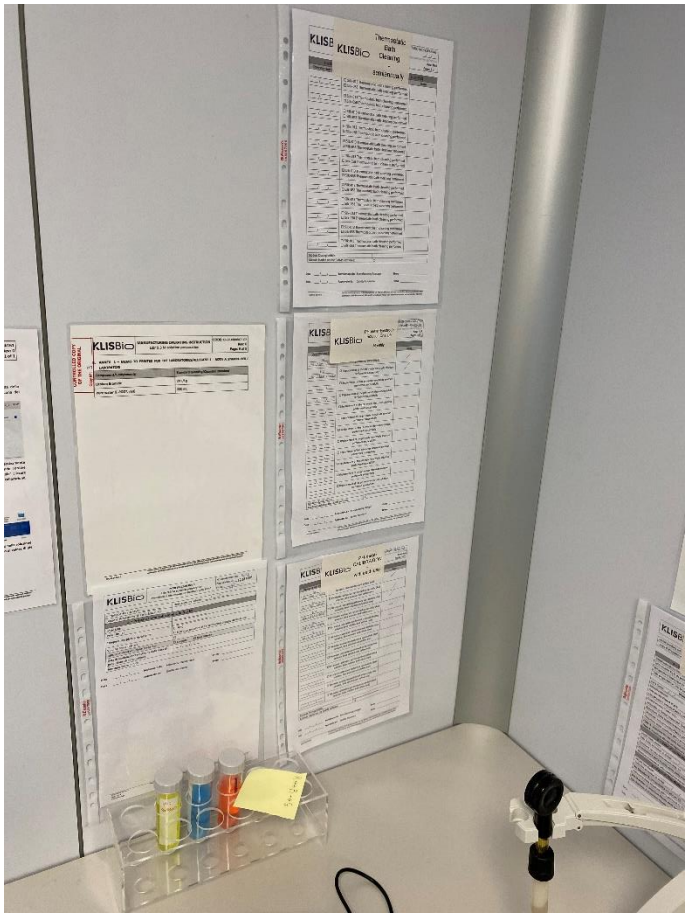

Figure 14: Wall of documentation at SILK-BIO

The operator follows the process and registers max and min measurements. Afterwards, this is documented on the sheets and signed. The signed sheet is put back into the plastic folder for later entry into an electronic system. From an organizational point of view, the process would not change as the process is bound by specific steps. The documentation process could, however, be supported by a DIA, allowing the operator to register steps and confirm actions along the way. Also, cycle time, traceability maintenance, and safe handling would benefit.

The process that the DIA will support is that of solubilization and casting of silk fiber. The DIA will support the operators' manual activity and their interaction with the equipment involved. Potentially, it can be applied in all process steps where the operator has to make a check or where he has to give a confirmation of activity.

From an organizational point of view, the process would not change as the process is bound by specific steps. However, cycle time, traceability maintenance, and safe handling would benefit.

The implementation of the DIA aims to improve the cycle time of a process, provide traceability, reduce manual documentation, and increase safety in several ways. So, examples being:

- Improving cycle time: A DIA can provide real-time information and guidance to users. This can reduce the need for manual documentation and significantly reduce the cycle time of a process, making it faster and more efficient.
- Providing traceability: A DIA can provide real-time tracking and monitoring, making it easy to track and trace, and perform analysis in retrospect. This can help to improve traceability and provide greater visibility into the process.

- Reducing manual documentation: The DIA can reduce the need for manual documentation by capturing vocal inputs from the user and storing data in a digital format. This can save time and reduce the risk of errors associated with manual documentation.
- Increasing safety: A DIA can help to improve safety by providing real-time instructions to users, helping them to identify and address potential safety issues before they become a problem.

SILK-BIO participates in use case 3 'Assisted quality assurance for sustainable products. The use case will target the solubilization process. In this process, the operator is to follow a set of clear procedures for quality control, as indicated in user dialogue S-US1. The quality control procedure is performed for each batch and includes checking and controlling the temperature, pH, weight, and validity of the chemicals in the solution. User dialogue S-US1 solubilization and casting procedure has been implemented and demonstrated in D2.4. For deployment, a cloud solution is preferred as the easiest solution.

3.4.2 Functional requirements

- The DIA must provide descriptions of each step, and task instructions where needed.
- It must be able to save data and provide data input from earlier steps by request.
- Experienced users must be able to perform the process without unnecessary prompts from the DA, meaning a role-based modes of functioning.

3.4.3 System technical requirements

- Support for detailed procedures.
- Support for changing of procedures.
- Digital data storage in compliance with medical standards.

3.4.4 Additional requirements

No additional requirements were mentioned in the kick-off meeting presentation, the self-reported descriptions or in the workshop discussions. A short discussion on personal data and GDPR yielded no specific additional requirements, save the general requirements of adherence to the relevant regulatory requirements. See also section **¡Error! No se encuentra el origen de la referencia.** for a discussion of those.

3.4.5 Expected benefits and related KPIs

The revised list of expected benefits and related KPIs for SILK-BIO is more focused and the total number has been reduced from 7 to 5. It includes benefits and KPIs related to two different types of errors, #2a and #2b. There are now also baselines and targets for all KPIs. As such, the expected benefits are ready for evaluation, however, the connection to the OKRs must be established.

Table 6: Revised expected benefits and related KPIs for SILK-BIO

#	Benefits	Cat	Value (Low/Medium/High)	When (Short/Medium/Long)	KPI	Base	Target	Indicator (Perf/ Impact/ Accept/ Trust/ Usability)
1	Reduced cycle time / Increased speed of technician's tasks (reporting mostly) (for new operators)	OPR	Medium	Short	Time spent for each cycle / Time spent on each specific task	75 min	45 min	Perf.

2a	Reduced risk of reporting errors	OPR	High	Short	Number of filling errors	20 errors x 100 worksheets	5 errors x 100 worksheets	Perf.
2b	Reduced risk of operative errors for new operators	OPR	High	Short	Number of discarded solutions/material	10 % discarded solutions	1 % discarded solutions	Perf.
3	Increased operator's satisfaction score	HUM	High	Medium	Operator satisfaction survey that ask how operators experience work after the introduction of the DIA	Questionnaire must be developed	TBD after questionnaire has been developed	Impact
4	Reduced material consumption	ENSU	Medium	Short	Number of gloves and paper consumed per production sheet for the process under consideration	16 gloves + 4 papers	4 gloves + 1 paper	Perf.

3.5 TRIMEK

TRIMEK specializes in metrology systems, solutions, and machines. They design and manufacture Coordinate Measuring Machines (CMMs) of different models and sizes and have developed the M3 software for capture and analysis of point clouds. The CMMs measure the geometry of physical objects by sensing discrete points on the surface with a probe. The typical 3D "bridge" CMM allows probe movement along three axes, X, Y, and Z, which are orthogonal to each other in a three-dimensional Cartesian coordinate system. Apart from the devices manufactured, TRIMEK provide dimensional inspection services by using the mentioned technologies.

Figure 15: Machines for measuring 3D objects

3.5.1 Situation analysis and use case detailing

On one side, TRIMEK designs, manufactures, and sells calibration artifacts (see Figure 16) for the verification of the CMMs. A CMM calibration artifact is used to ensure that the measurement data created by the CMM is accurate through regular calibration. The CMM calibration artifact also includes an ISO-17025 accredited certification and most CMM calibration can be accomplished through the use of a calibration artifact. It is an important tool that helps to gauge any inconsistencies or errors in the CMM measurements, by providing accurate calibration data and fixing or integrating any inconsistencies into the data. A CMM machine can have errors along 21 different measurement axes, thus depending on the severity of the errors, calibration may or may not be required more often. The process involves measuring the artifact along with a fixed measurement plan and comparing the data points against the known dimensions of the artifact to check for consistency. By doing so, any error that prevents the CMM from accurately performing its function and measuring the inspected parts would be removed.

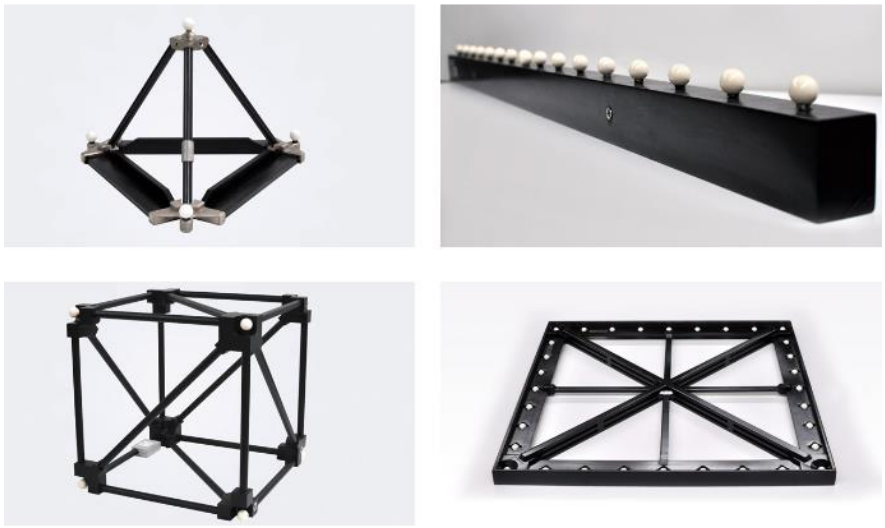

Figure 16: Calibration artifacts

These artifacts need recalibration procedures during its lifetime, a service also provided by TRIMEK. Each calibration process requires to gather specific data about the artifact, the calibration parameters, dates, and results. In this sense, artifacts will be defined as circular entities in the rEUse platform to have a better traceability of the calibration procedures performed during its lifetime. WASABI assistant will support the user (personnel of TRIMEK) in the data entry process into rEUse and in the retrieval of information already stored in the rEUse platform.

The use of the M3 software to share the dimensional results of the measurement of the artifacts and its interaction with the assistant for assessment or decision support is yet to be decided.

On the other side, a large part of TRIMEK processes require the use of CMMs and the M3 software to perform dimensional measurements and inspections to different type of parts, where each part might have a different procedure for dimensional inspection. TRIMEK clients need to deal with these processes as well and regularly they are not specialized in metrology as such, and the tasks can be challenging. Moreover, the personnel of TRIMEK needs to be trained and guided in the learning of the tasks. The idea is that TRIMEK will develop different “templates”, which are M3 project macros that contain sequences of actions that need to be followed for executing a measurement process for a particular type of part. For the project the parts are going to be the mentioned calibration artifacts; meaning that it will be a template for each type of artifact.

Then, the assistant will assist in deciding the adequate template for each artifact and once decided, provide support in completing the steps of that template (e.g., the alignment process in the machine and in the software).

The complete measurement procedure can have 6 steps from the definition of the coordinate system to the generation of results (Reporting), however for the scope of the project the first three steps will be covered.

This guidance will function both as a support for the client and new personnel as well as a validation protocol to guarantee that the task is performed in a correct and safe manner. During the project, the developments will be validated with TRIMEK personnel.

For the use case 'augmented waste management and valorization, WASABI will incorporate the rEUse platform and the assistant to improve the traceability and automation of TRIMEK processes to deal with the recalibrations of the artifacts.

The other use case, 'assisted quality assurance for sustainable products,' aims to improve workers' skills and understanding in operating the machine. This will result in a faster measurement process with fewer human errors, leading to increased productivity and time savings. The service could be sold to TRIMEK customers, resolving logistics and cost issues for TRIMEK.

3.5.2 Functional requirements

- Oral or manual assistance for registering an artifact as circular item in the rEUse.
- Oral or manual assistance for retrieving information stored in the rEUse.
- Oral assistance for deciding the correct "template" for a measuring process in the machine, depending on the part and purpose of the inspection. The template selection process will be based on a rule-based algorithm.
- Oral guidance for each step in the process.
- Other requirements will be defined as the project advances.

3.5.3 System technical requirements

- Integration with the TRIMEK M3 system, in the case is needed
- Authentication

3.5.4 Additional requirements

No additional requirements were mentioned in the kick-off meeting presentation, the self-reported descriptions or in the workshop discussions. A short discussion on personal data and GDPR yielded no specific additional requirements, save the general requirements of adherence to the relevant regulatory requirements. See also section **¡Error! No se encuentra el origen de la referencia.** for a discussion of those.

3.5.5 Expected benefits and related KPIs

The expected benefits and related KPIs for TRIMEK have been revised several times after discussions in the project, as described in 2.2.9. The two tables below show the expected benefits and related KPIs as of M15, one table for each use case TRIMEK is involved in.

The four KPIs in Table 7 focus on Use case 3: Assisted Quality Assurance for Sustainable products. They are focused on performance, but it should be noted that large part of this performance is achieved through training and better support in procedures. #1-3 will happen because the DIA guides and trains the employees efficiently. Finally, the employee satisfaction element indicates whether or not the employee feels satisfied with this work.

Table 7: Revised expected benefits and related KPIs for use case 3 for TRIMEK.

#	Benefits	Cat	Value	When	KPI	Base	Target	Indicator
1	Increased speed on technician's tasks	OPR	High	Medium	Average time spent on the alignment process	2 hours « *Typically 2 hours for placing the part in the machine, creating, executing*	1 h («50 % increase in speed»)	Perf.

						and verifying the alignment»		
2	Reduced risk of alignment errors (for new employees)	OPR	High	Medium	Average number of errors while aligning a part	3/5 times, or 60 % of all alignment processes (for new workers)	1/5 times (40% of error rate reduction)	Perf.
3	Reduced training time for new employees	ORG	High	Short	Training time for alignment process	6 months	2 months	Perf.
4	Higher employee satisfaction (potential benefit)	HESA	Medium	Medium	Employee satisfaction measured in survey	Questionnaire to be defined to assess the pre & post WASABI	15 % increase	Impact

Table 8 shows the KPIs related to the Augmented waste management and valorization use case. Similar to the other use case, there is a focus on performance and impact. The employee satisfaction is an indicator of success, indicating whether the employees prefer that solution.

Table 8: Revised expected benefits and related KPIs for use case 1 for TRIMEK.

#	Benefits	Cat	Value	When	KPI	Base	Target	Indicator
5	Improved accuracy and consistency of data entry during calibration process	OPR	Medium	Short	Accuracy in calibration data entry	Rate of errors or inconsistencies in calibration data before WASABI (to be measured later in the project)	Reducing the error rate in the entry of calibration data in a 20%	Perf.
6	Reduction of time and effort spent creating and auditing calibration certificates	OPR	High	Short	Efficiency in Creating Calibration Certificates Timeliness (How quickly data is entered into the system after it's received)	Current average time spent creating certificates before WASABI (to be measured later in the project)	Reduction of certificate creation time by 30%	Perf.
7	Ease of access and consultation of data related to artifacts stored in rEUse	ORG	Medium	Short	Access and consultation of data in rEUse database	Effort required to consult data of calibrated artifacts before WASABI (to be measured later in the project)	Reduction of data search time by 30%	Impact
8	Higher employee satisfaction (potential benefit)	HESA	Medium	Medium	Employee satisfaction measured in survey	Questionnaire to be defined to assess the pre & post WASABI	15% increase	Impact

3.6 Overview of user dialogues

As part of the D1.2, user dialogues were created and included in D1.2. Initially, 12 such user dialogues were created and included in D1.1. After the continued requirement elicitation process after M6, new user dialogues have been created and old ones have been updated, as shown in Table 9.

Table 9: Revised overview of user dialogues

Dialog code	Scenario	Title	Use case partner
E-US1	Full onboarding training	Full onboarding training in a first day of working of a new employee	EPISCAN
E-UP1	Mask Production	Request for product information	
E-UP2		Request for stored material information	
E-UP3		Check of manufacturing process	
E-US2	Full onboarding training	Self-training for new employees in their first day	
E-US3		Self-training for new employees in their first day	
E-US4	Elements of onboarding training	Self-training for new employees in the Starting operation	
E-US5		Self-training for new employees in the Starting operation	
E-US6		Self-training for new employees in the Starting operation	
E-US7		Self-training for new employees in the Emergency stop-reset operation	
E-US8		Self-training for new employees in the Emergency stop-reset operation	
E-US9		Self-training for new employees in Automatic operation	
E-US10		Self-training for new employees in Change from manual to automatic operation	
E-US11		Self-training for new employees in Change from manual to automatic operation	
E-US12		Self-training for new employees in Change from manual to automatic operation	
E-US13		Self-training for new employees in Change from manual to automatic operation	
E-US14		Self-training for new employees on Machine's touch screen.	
E-US15		Self-training for new employees on Machine's touch screen.	
C-US1	Process suggestion	Suggesting corresponding sterilization process	CROMA
C-US2	rEUse platform	Registering an instrument in rEUse	CROMA
C-US3		retrieving information from rEUse platform	CROMA
S-US1	Procedure	Solubilization and casting procedure	SILK-BIO
R-US1	Management of alarms	Decisions in managing alarms initial management	REINOVA
T-US1	rEUse platform	Creation of a new entity in the rEUse platform with Support of assistant	TRIMEK
T-US2		Updating rEUse with data from a calibration procedure	TRIMEK
T-US3		Search for information of an entity already existing in REUse	TRIMEK
T-US4	Measurement process	Selection of template for measurement process	TRIMEK
T-US5	Pre-alignment and alignment	Following the guidance for the implementation of M3 project template	TRIMEK
T-US6	Validation of measurement process results	Interaction with the assistant to validate if the measurement process is correct	TRIMEK

The dialogues in themselves are confidential for the use case partners, but for the project all user dialogues can be found on the project repository.

3.7 UNIMORE questionnaire on data

As part of the requirement elicitation, UNIMORE distributed a data collection template to all use case partners. It asked about data sources, data formats, frequency of measurements, file formats and availability of data for the WASABI DIA. The aim of the data collection was to support the analytics module in the DIA by clarifying what data was needed by each use case partner. The questionnaire was returned to UNIMORE and discussed at the elicitation workshops in January and February.

4. WHITE-LABEL SHOP

During the initial data collection for D1.1 we collected information about the use case partners requirements on the white-label shop. This was reported in D1.1. It was clear, however, that an update was needed and hence a set of workshops was carried out to gather information. The conclusions from these workshops define the requirements.

4.1 Joint workshop on white-label shop with use case partners

In October 2023, joint WP1/WP3 workshops with the use case partners were carried out to explain the idea of the white-label shop and show the use case partners how the shop would eventually look like. The aim was to raise awareness among the use case partners on what the white-label shop is and can include, including possible benefits. If needed, new requirements for the white-label shop should be defined. The workshops (one with REINOVA, EPISCAN, and TRIMEK, one with CROMA and SILK-BIO) included a quick repetition of what the aim of the white-label shop was, how this had been discussed previously and a set of questions aimed to generate new requirements:

- How would you like to navigate in the shop and among the different DIAs/skills?
- Would you like guidance, e.g., from a person, chatbot?
- How would you like to identify the appropriate DIA?
    - How would you like a description of a DIA / skill to be in order to evaluate its usefulness for you?
        - Would you like to talk to someone to get that description?
    - What kind of assistance would you need to download, install and use such a DIA?
    - What technical information would you need to make choices?
    - What information would you need about prices?
    - What legal advice would you need to use the DIA?
- DIAs can be further developed by adding skills/modules that suits your need
    - How would you like to train the DIA to address your need? How should this happen?

The idea, the aim as well as the current status and ideas of how to do this was then explained by WP3/I-Deal by presentation of a demo video and a discussion with the use case partners. Having seen the video and discussed the ideas, the conclusion was that the current design ideas satisfied the use case partners and no further requirements were needed.

To enhance the understanding of the white-label shop, and based on the initial questions that were raised during the initial workshops with the use case partners (listed in section 4.2), WP3/I-Deal provided the following explanations to some key concepts and aspects of the white-label shop:

Content and Applications: The shop instances can contain a wide range of Applications, and the decision on whether to offer tailor-made or existing solutions is at the discretion of the instance owner. Customers can be involved through preliminary surveys, although this does not directly impact the white-label shop. Ordering new products is simplified by adding them to the cart.

Value Communication: Communicating the value of Applications is left to the instance owner, and the white-label shop receives a commission for its service. The commission collection is managed through NFTs, specifically by ICCS in T3.2.

Choosing Applications/Services: Customers can choose Applications or services by reading their descriptions on the instance. Each shop instance must provide guidance in the form of videos, images, etc. There is the possibility of related product suggestions.

Maintenance and Security: Maintenance responsibility differs; i-Deal manages the white-label shop infrastructure, while each instance owner handles content maintenance. Security measures, including access control, are under the purview of the instance owner.

Data Management: The white-label shop is not directly involved in data management. Understanding the division between what is managed by the white-label shop and the instance managers is crucial for clear vision and operation.

Payment Methods: Skills or products are paid to the shop instance owner through standard methods, while developers receive royalties via Crypto transfer. The value of functionalities, like automatic training program creation, is determined by the market, with the expectation that training providers will pay for such skills.

Business Model: The business model for the shop instances is customizable by the instance owner. It can cater to B2B or B2C, offer additional services, and minimize vendor lock-in by allowing multiple vendors.

Customer Support and Refunds: Customer support, refund policies, and additional services are at the discretion of the instance owner.

End Users: The end user of the white-label shop is the instance owner. The aim is to provide a replicable tool for creating shop instances. The choice of a new white-label shop over an existing one lies in its agnostic nature.

Integration and Requirements: Integration of open-call results and use cases is into the instances, not the white-label shop. Technical constraints for developers include meeting specific requirements of PrestaShop. Certificates and guarantees depend on the compliance of the single instance.

5. LEGAL KEY REQUIRMENETS FOR AI SYSTEMS

5.1 Previous and parallel work on this topic in D1.1 and D3.5

In the D1.1 Requirements deliverable there was included a section on "**Legal Key requirements for data protection-by-design, security, liability and ethics."** This section discussed general principles for software

design, including liability, ethics and security. It provided an overview of the existing legal framework, including some considerations for the EU AI Act, which was upcoming.

Since then, the AI Act has been finalized and the WASABI project has carried out an in-depth analysis of the tort law ecosystem and its implications for applying digital assistance solutions in manufacturing (including then assistance from the white-label shop) and discuss liability for lack of compliance with EU law. This is all done in the deliverable D3.5 Contract and tort law for AI-based digital assistants. D3.5 provides legal requirements for the DIAs and the solutions in the white-label shop, and it is strongly recommended to study that to ensure that these requirements are met.

This report then will not repeat these requirements here, but rather point out some key issues discussed in that report that must be addressed by the project as a whole.

5.2 Key issues to be addressed by the project

The AI-act is regulating AI. The first major issue to address for the project is whether or not the DIA in fact is an AI or not. In the section 4.1.1 of the D3.5 it is stated that: "*The AI Act defines an AI system as "…a machine-based system, designed to operate with varying levels of autonomy, and that may exhibit adaptiveness after deployment and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, or decisions, that can influence physical or virtual environments."*[3] *This definition is rather vague. For instance, it is unclear what "varying levels of autonomy" exactly means. According to recital 12 of the AI Act, AI systems exhibit autonomy if they have some degree of independence of actions from human involvement and of capabilities to operate without human intervention.*"

Is the DIA in WASABI operating with any level of autonomy or not? It could be argued that in its current form all interactions are initiated by users, thus, there is no autonomy for the system and there is no AI. Further, can it operate without humans? Whether or not these arguments against the digital assistant being an AI are valid, and if so, can we guarantee it stays like that in the future is unclear, thus the project needs to agree on that. D3.5 provides some strong arguments for this being the case and then discuss the situation if it is AI. Still the project should take a deliberate decision here.

However, there are several important discussions that needs to be taken in addition to this. The AI act is risk based with four major categories and some subcategories. Hence, we need to agree on which risk category the AI is, because this decides what must be done.

Further, while requirements are mostly based on user input the AI act places responsibility to providers putting services on the market. This would seem to imply that most items placed in the white-label shop gives the provider some responsibility and this is also the case for those developing the Ais. (Both groups have responsibility, but not the same.) This means that providers and developers need to meet the requirements for these groups in the AI act.

[3] Article 3(1) Regulation of the European Parliament and of the Council of 19 April 2024 laying down harmonized rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act). Available: CO_TA (europa.eu). (hereafter: AI Act).

5.3 Process forward

The WASABI project needs to answer these and possibly other key questions from the AI act. Answering these questions amount to defining some key requirements for the whole project. This should take place within the scope of T1.1 and be summarized as part of the final requirement report in M24. WP1 needs to set up some project wide discussions for this. Finally, it should be noted that there is an update planned for D3.5 as well and the process in WP1 should provide input to D5.4 in M39.

6. CONCLUSIONS

6.1 Overall goals for the use case partners

While the specific requirements and preferences of the use case partners may differ, the primary objective of the DIA remains consistent: to provide process support. In general, the use case partners require precise adherence to certain procedures within their industrial context, and the DIA is intended to facilitate and streamline this process. In addition, all use case partners face documentation requirements as to whether their process has been followed or not. The DIA offers a solution to that as well, by logging which steps have been followed at what time by whom. We should note that recording data physically on paper is common practice, and while the use case partners want to get rid of it, it has so far not been possible. It should be noted that while onboarding and training is indeed an issue, the training issue is simply to learn to follow the procedures. For several use case partners, the procedures must be strictly followed; otherwise, the work cannot be accepted. Medical equipment must be sterilized according to procedure, medical devices likewise, dimensional measurements of a manufactured piece need to be done correctly. Alarm management is likewise procedure oriented, and finally production of masks (again medical) needs to be done according to standards and procedures. Overall, the five use case partners have very little leeway regarding following their procedures.

This then gives the primary functional requirement of the DA. It must be able to follow and document progress in a pre-defined process. Broadly, this will include information about what is to be done, confirmation that it is done, logging of the progress continuously, some checks and loops and repetition at critical points, and confirmation of learning. The TRIMEK case is unique because it is the clients of TRIMEK who should be following procedures, which makes it more complicated to design the correct system. Also, their adherence to the procedures might be more challenging to ascertain.

Table 10: Overview of partners and functionality requirements

Use case partner	Real-time and analytics/predictive functionalities	Data entry functionalities	Process control support	Onboarding with integrated learning nuggets
REINOVA	X			
SILK-BIO		X	X	
EPISCAN	X	X		X
CROMA	X		X	
TRIMEK		X	X	

This table updates the required functionalities of the use case partners. Basically, four different types of functionalities are identified here: Real-time and analytics/predictive functionalities, data entry functionalities, process control support, and onboarding with integrated learning nuggets. The distribution of these goals among the partners is given in Table 10. It should be noted, however, that when a process control goal has been defined, the training and onboarding assistance for that task follows closely. Describing a work process in detail also provides instructions on how to carry it out and can therefore be considered a form of training. All three partners with process control goals also have KPIs related to training.

6.2 Expectations and understanding of the white-label shop

Having carried out joint workshops with the use case partners, WP1 and WP3 the conclusion was that the plans and designs of WP3 as outlined were satisfactory for the use case partners and no further design requirements were needed.

6.3 What benefits can be expected from DIA?

The use case partners were all able to identify several expected benefits from the DIA. They were quite varied, but most of these were operational and/or organizational and related to improved performance. The expected benefits from the DIA ended up as various performance improvements. Part of this was better adherence to procedures, and easier documentation of procedures and work processes. Regarding the OKRs, the use case partners in general held that introducing the DIA should result in reaching the OKRs, but the expected benefits were fewer for environmental goals.

The expected benefits and related KPIs have been revised carefully and is reported in detail for each use case partner. The revised expected benefits and related KPIs are more suitable for evaluation than the previous versions and in most cases more focused with fewer measurements needed. Also, base line measurements have now been provided to a much larger degree. Still, it should be noted that not all KPI lists are yet complete.

6.4 Legal requirements, personal data, and ethics

The use case partners had in general limited requirements for personal data, ethics, and similar functionalities. One reason was probably that for several use case partners, workers already have to log in a system and declare the actual work done and the organization have to make the information available for inspections by clients or authorities. Thus, it was not seen as particularly important that a worker could be identified by the system as the one having done a job. However, there should be a difference between the more random/hostile/erroneous leakage of personal information and the formal release of such information as part of a formal information seeking process. The requirements have been followed up in D2.4 where the information collected from the DIA is clearly described. The assistant does not collect personal information from the user.

Finally, looking forward, D3.5 provides some very important legal requirements for WASABI. These requirements are general and not connected to a specific instantiation of WASABI. Managing these requirements should therefore be done at project level and by the project as a consortium. The results from such a process will be formal requirements reported in D1.5 in M24.