AI Platform for Integrated Sustainable and Circular Manufacturing

Deliverable

D7.3 Liaison with AI4MAN Ecosystem, Didactic Factories Network, Legal and Ethical issues - 1st version

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Definitions and acronyms

AAS	*As a Service*
AI	*Artificial Intelligence*
AI4MAN	*AI for Manufacturing*
CA	*Consortium Agreement*
CE	*Circular Economy*
CT	*Circular TwAIn*
DIH	*Digital Innovation Hub*
DoA	*Description of Action*
DPP	*Data Privacy Policy*
EO/EG	*Ethylene Oxide/Ethylene Glycol*
EC	*European Commission*
EU	*European Union*
GA	*Grant Agreement*
HDT	*Human Digital Twin*
H2020	*Horizon 2020: The previous EU funding program for research and innovation from 2014 to 2020.*
IP	*Intellectual Property*
IoT	*Internet of Things*
IT	*Information Technology*
LIFT	*Learning and Innovation Factory Training*
LIBs	*Lithium-Ion Batteries*
OECED	*Organization for Economic Cooperation and Development*
PPE	*Personal Protection Equipment*
PC	*Project Coordinator*
R&D	*Research and Development*
SME	*Small and Medium-sized Enterprises*
TC	*Technical Coordinator*
TEFs	*Training and Experimental Facilities*
WP	*Work Package*
WEEE	*Waste Electrical and Electronic Equipment*

Disclaimer

Executive Summary

The document "Circular TwAIn D7.3 Liaison with AI4MAN Ecosystem, Didactic Factories Network, Legal and Ethical Issues" provides a strategic framework for the integration of Artificial Intelligence (AI) and sustainable production in the manufacturing sector, with a focus on Didactic Factories. These factories play a central role in linking research and practical application and make an important contribution to the digital transformation of industry. The document emphasizes the importance of legal and ethical standards and outlines the legal review process and regulatory framework relevant to Circular TwAIn technologies and pilot implementations.

What has been done?

The document describes the efforts to integrate Circular TwAIn into the AI4MAN ecosystem and highlights synergies and learning opportunities from the collaboration with EU projects such as AI REGIO and DIMOFAC. It underlines the role of Didactic Factories as innovation and learning centers that combine education and industrial application. The document also covers a new skills service in the form of a workshop for which required skills and personas of the future are collected and made available in the form of a catalog. The document also addresses the legal and regulatory challenges, which include comprehensive legal reviews, stakeholder consultations, human rights impact assessments under ALTAI and the exploration of regulatory sandboxes. The importance of developing legal and ethical frameworks for the responsible use of AI in manufacturing is also highlighted.

How was it done?

For the AI4MAN integration, the public results were analyzed and the knowledge within the project team was used. Gathering needed skills and future personas was achieved through workshops and stakeholder interviews that fostered a collaborative environment for sharing knowledge and practical experiences. At the same time, legal and regulatory considerations were taken into account by conducting legal assessments, engaging stakeholders and exploring regulatory sandboxes to seamlessly integrate compliance and ethical considerations into project development.

Why was it done?

When it comes to circular economy and AI, it is important to first understand the needs of the industry. By laying the foundations for educational innovation and a solid understanding and adherence to legal and ethical standards, the project aims to create a manufacturing industry that is not only efficient and productive, but also adaptable, sustainable and responsible.

What has been learned, what are the challenges/obstacles and opportunities?

The document highlights the challenges of integrating AI into the manufacturing industry, including technological complexity, the need for continuous education and the importance of complying with legal and ethical standards. However, it also highlights the opportunities that arise from this approach, such as the creation of innovative educational programs, the promotion of sustainable production processes and the strengthening of industry competitiveness. The document also provides a basis for future iterations of the project, recommends adaptations to changing requirements and encourages continuous dialog between all stakeholders.

I Introduction

The document "Circular TwAIn D7.3 Liaison with AI4MAN Ecosystem, Didactic Factories Network, Legal and Ethical Issues ToC Proposal" provides an in-depth exploration of the integration of Artificial Intelligence (AI) with sustainable production methods in the manufacturing sector. It focuses on the central role that didactic factories play in this integration process, alongside key legal frameworks and ethical considerations. It presents the key initiatives of the AI4MAN ecosystem, all of which aim to accelerate the digital transformation of the manufacturing industry through the adoption and application of advanced AI technologies. These technologies are highlighted for their ability to make production processes more efficient, adaptable and environmentally sustainable.

Didactic factories are highlighted as crucial nodes between theoretical knowledge and practical application. These facilities are not only cradles of technological innovation, but also serve as vibrant platforms for experiential learning and research. They provide a unique environment in which new ideas can be tested, refined and ultimately integrated into the wider manufacturing sector. The document explains the essential contribution of these factories to the Circular TwAIn project, highlighting in particular their efficiency in combining education, innovation and industrial practice.

In addition, the document addresses the legal and ethical frameworks that underpin the responsible use of AI technologies. It engages in a thorough discussion on topics such as privacy, security, transparency and the ethical use of AI systems and aims to create an environment in which AI can be used safely, effectively and for the benefit of society.

In addition to outlining the synergy between advanced technology, educational innovation and a solid legal and ethical foundation, the report also details the activities undertaken and the results achieved with regard to the project's legal and regulatory challenges. It provides a detailed account of the factual basis of the legal review and describes the main legal frameworks relevant to the Circular TwAIn technologies and pilot initiatives. Insights into the initial stakeholder consultations and a human rights impact assessment conducted by ALTAI underline the technological progress of the project. A look into the regulatory sandboxes further illustrates the project's innovative edge. From these efforts, the consortium has distilled the key legal and ethical requirements for the Circular TwAIn technologies and pilots, which are meticulously captured in this document.

2 The Environment of Circular TwAIn

The Circular TwAIn project is an initiative that aims to reshape the manufacturing industry through the integration of artificial intelligence (AI) and sustainable production methods. As an integral part of this initiative, a comprehensive analysis of the current project landscape within the European Union was carried out. Particular attention is paid to Didactic Factories (DFs), which act as an innovative intersection between research and practice-oriented application. The research aims to gain a detailed understanding of the initiatives that address the progressive development of the manufacturing industry through advanced technologies.

Within the Circular TwAIn project, didactic factories are not only witnesses of technological advances, but also active participants and shapers of digital transformation. They serve as testing grounds for the implementation and refinement of concepts developed in the AI4MAN projects and are thus a central element in the effort to equip SMEs for the digital future.

The following section introduces the key initiatives of the AI4MAN ecosystem and explains how each project contributes to the digital and sustainable transformation of the manufacturing industry. By identifying synergies and gathering insights critical to the continuation and success of Circular TwAIn, these projects are collectively shaping the basis for a more efficient and sustainable manufacturing landscape.

The inclusion of the Didactic Factories in the Circular TwAIn project provides a unique opportunity to develop real-world experience and technical skills needed to manage and shape the future of manufacturing. The DFs within Circular TwAIn, enriched by the DR-BEST model and supported by a network of Digital Innovation Hubs, act as key nodes in the AI4MAN ecosystem, enabling education, innovation, and collaboration to flow together to create a resilient, sustainable and technologically advanced manufacturing sector.

2.1 The AI4MAN Ecosystem

The AI4MAN ecosystem includes a variety of projects dedicated to revolutionizing the manufacturing industry through the integration of artificial intelligence and sustainable practices. Each of these projects - AI REGIO, DIMOFAC, MODUL4R, DaCapo, RE4DY and AI REGIO 5.0 - makes an important contribution to achieving this goal by addressing specific challenges and offering innovative solutions for small and medium-sized enterprises.

AI REGIO serves as a catalogue for the dissemination of AI technologies in the manufacturing industry, with a special focus on regional innovation systems and didactic factories. DIMOFAC improves the flexibility of production through modular and scalable solutions, while MODUL4R focuses on the modularisation and reconfiguration of production systems.

DaCapo focuses on the reuse of production components, which increases sustainability, and RE4DY aims to increase the digital maturity of companies and prepare them for the challenges of Industry 4.0. Finally, AI REGIO 5.0 brings the latest developments in AI into practice and supports companies in implementing these advanced technologies.

The following table outlines the specific objectives, intended outcomes and potential synergies of these projects to provide a clear overview of the dynamic environment in which Circular TwAIn operates:

Table 1: Overview of AI4MAN Environment

Name	AI REGIO [1]	DIMOFAC [2]	MODUL4R [3]	DaCapo [4]	RE4DY [5]	AI REDGIO 5.0 [6]
Logo						
Start date	01.10.2020	01.10.2019	0..01.2023	01.01.2022	01.06.2022	01.01.2023
End date	30.09.2023	31.03.2024	30.06.2026	30.06.2026	31.05.2025	31.12.2025
Project Description	Regions and DIHs alliance for AI-driven digital transformation of European Manufacturing SMEs	Digital Intelligent MOdular FACtories	Industrial Manufacturing strategies for distributed control and resilient, rapidly responsive and reconfigurable supply chains.	Digital assets and tools for Circular value chains and manufacturing products	European Data as a PRoduct Value Ecosystems for Resilient Factory 4.0 Product and ProDuction ContinuitY and Sustainability	Regions and (E)DIHs alliance for AI-at-the-Edge adoption by European Industry 5.0 Manufacturing SMEs
Scope	AI integration in European manufacturing, focusing on SMEs	Develop a modular factory solution for flexible production lines.	Revolutionize manufacturing strategies with distributed control and	Enhance Circular Economy adoption using digital tools, AI, and Digital Twins.	Transform manufacturing through data space management, AI, and digital twin automation.	Propel Industry 5.0's digital transformation, focusing on SMEs.
Objective	Establish a robust network of DIHs, enhance regional strategies, and leverage existing digital production platforms.	Address market demand changes through digital twins, reconfigurability, and resource efficiency.	Adapt to global market dynamics like shorter product lifecycles and increased demand volatility.	Improve sustainability and efficiency in manufacturing value chains and product lifecycles.	Build resilient, data-driven manufacturing, and supply networks with digital continuity and sovereign data spaces.	Strengthen SMEs through sustainability, digital innovation hubs, and AI-at-the-edge facilities.
Impact	Model for sustainable AI adoption, enhancing skills, data management, and fostering collaborative manufacturing in Europe.	Complement AI-driven manufacturing goals, particularly in resource efficiency and production adaptability.	Transform traditional manufacturing systems to be more responsive and adaptable.	Promote sustainable and efficient manufacturing solutions, advancing circular economy principles.	Enhance AI applications, sustainable practices, and foster collaborative industry ecosystems.	Foster collaborative potential, integrating AI technologies and leveraging collaborative networks for sustainable manufacturing.
Website	https://www.airegio-project.eu/	https://dimofac.eu/	https://www.modular-project.eu/	https://www.dacapo-project.eu/	https://re4dy.eu/	https://www.airedgio5-0.eu/

While these projects are individual in their focus, they collectively contribute to a more connected, efficient and sustainable manufacturing landscape. They complement each other through their research and development work, which aims to unlock the benefits of digital transformation and artificial intelligence for SMEs. By connecting these initiatives and fostering collaboration and knowledge transfer, the AI4MAN ecosystem can be seen as a whole, pushing the boundaries of what is possible and leading the manufacturing sector into a new era.

2.2 Didactic Factories

Moving on to the concept of Didactic Factories, we find ourselves at the interface where theoretical concepts are translated into practical applications. These factories, complemented by Digital Innovation Hubs (DIHs), are not just production sites, but living ecosystems of learning and innovation. They are the fusion hubs where the theoretical knowledge from the AI4MAN projects is tested and refined, symbolising the ideals of sustainable and AI-integrated manufacturing.

The core aspects of the Didactic Factories, combined with the supportive role of the DIHs, create a multi-layered environment that encourages learning, experimentation and customisation. These aspects include:

- Realistic environment: Didactic factories reflect the complexity of actual production environments and enable the practical application of the theories learnt. This hands-on experience bridges the gap between academia and industry, while DIHs provide a gateway to cutting-edge technologies and innovative strategies.
- Testing and experimenting: These factories are fertile ground for trialling new concepts and technologies. Whether researching AI applications, circular economy models or modular manufacturing techniques, the DIHs support these activities with their expertise and cooperation networks.
- Improvement of skills: The practical experience gained in didactic factories enhances technical skills and deepens understanding of the nuances of manufacturing. In addition, the DIHs offer training courses and workshops on new digital tools and methods.
- Adapting to Industry 5.0: Didactic factories fit perfectly with the ideals of Industry 5.0 as they focus on human-centred, sustainable and resilient manufacturing processes. DIHs contribute significantly to this adaptation by fostering innovation and providing important support.
- Innovations in training methods: The use of advanced equipment and simulation of real-life scenarios ensures that learning in didactic factories is both engaging and resilient. DIHs reinforce this by providing access to cutting-edge technologies and fostering a climate that encourages innovation and creativity.
- Simulation, virtual reality and augmented reality: these immersive technologies create hyper-realistic scenarios that simulate the complexity of real-world manufacturing, with DIHs often providing the necessary infrastructure and expertise for integration.
- Interactive learning: The hands-on workshops and activities in didactic factories facilitate deep understanding and knowledge perseverance. DIHs contribute to this by organizing interactive events such as hackathons and collaborative projects that bring together different perspectives and expertise.
- Integration of machine learning and AI: Training in didactic factories incorporates the use of machine learning and AI and enhances the educational experience, with DIHs providing the essential data sets, platforms and expert guidance.

- Customized learning tracks: The ability of didactic factories to provide customized learning tracks accommodates the diverse skill requirements of modern manufacturing, supported by DIHs that provide a wealth of resources, expertise and networking opportunities.

In this complex web of learning and innovation, the DR-BEST services within the AI REGIO project are a key example of how these elements work together. DR-BEST stands for Data, Remotization, Business, Ecosystem, Skill and Technology and embodies a complete strategy aimed at supporting SMEs on their digital transformation journey. Each facet of DR-BEST harmonizes with the foundational elements of Didactic Factories and DIHs, ensuring that the path towards digital mastery is not only accessible, but also comprehensive and forward-thinking.

- **D**ata and **R**emotization: They reflect the real-world application of data analytics and remote operations in didactic factories and are in line with DR-BEST's focus on using data to make insightful decisions and promote remote management skills.
- **B**usiness and **E**cosystem: In line with the business-oriented and collaborative nature of the didactic factories and thus with DR-BEST's goal of increasing operational efficiency and fostering a dynamic ecosystem for innovation and growth.
- **S**kill and **T**echnology: They reflect the skills-enhancing and technology-oriented environment of the Didactic factories and reflect DR-BEST's commitment to upskilling its workforce and integrating cutting-edge technologies into its manufacturing processes.

This integration of Didactic Factories, DIHs and DR-BEST services forms a robust framework that not only meets the immediate needs of manufacturing, but also anticipates and prepares for future challenges. It is a testament to the power of collaborative innovation and the potential of a digitally empowered workforce in shaping the future of manufacturing in line with the principles of Industry 5.0.

2.2.1 Didactic Factories within Circular TwAIn

To gain a better understanding of the resources available within the Circular Twain team, a template was created that was completed by each of these Didactic Factories on our team. All three Didactic Factories offer a range of events including site visits, training sessions, workshops, practical use cases and open pilot lines. They are aimed at researchers, companies and students. In addition, each factory has dedicated workshops and technological infrastructure to support its educational and research objectives. Essentially, the Didactic Factories within Circular TwAIn, with their robust infrastructure, diverse workshop offerings and alignment with the DR-BEST model, serve as key hubs in the AI4MAN ecosystem. They not only facilitate the practical application of theoretical concepts, but also ensure that the workforce is equipped with the skills, knowledge, and insights they need to navigate and shape the future of manufacturing. As we continue to explore the specifics of these Didactic Factories and SSF's role in orchestrating a comprehensive training action plan, we reaffirm our commitment to a future where education, innovation and collaboration come together to create a resilient, sustainable, and technologically advanced manufacturing sector.

Table 2: Overview Mini-FACTORY 4.0

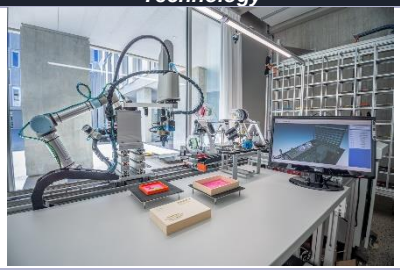
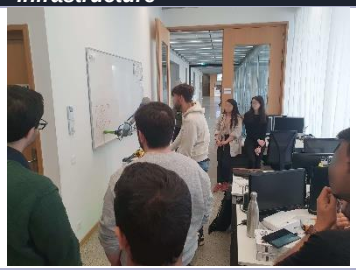
Mini-FACTORY 4.0 **Polo universitario Lugano, Campus Est** **Via la Santa 1** **CH-6962 Viganello**	MINI FACTORY 4.0
Description	
The Mini-Factory stands as a cutting-edge IIOT production facility dedicated to applied research and education. Its primary objective is to explore and implement contemporary, advanced production technologies within the framework of Industry 4.0. The Mini-Factory serves as a nexus where researchers, students, and industries converge to foster the exchange and enhancement of knowledge. Participants gain exposure to traditional automation subjects such as PLC, MES, SCADA programming, precision axes control, and pneumatics, alongside immersion in sophisticated technologies characteristic of state-of-the-art smart factories, including IoT, vision systems, simulation, digital twin, advanced measuring techniques, and intelligent production management systems. *Developed by adhering to guiding principles like modularity, integration of diverse technology vendors, innovation, and product customizability, the SUPSI Mini-Factory embodies the principles of Industry 4.0. These principles enable flexible automation, showcasing the resilience of factory behaviour and easy re-configurability, while also overcoming communication barriers through the integration of varied technology vendors. The Mini-Factory illustrates the effectiveness and production efficiency of Industry 4.0 technologies, showcasing adaptability to diverse and evolving customer requirements.* *This facility aligns with the contemporary Industry 4.0 vision, offering an environment conducive to research endeavours, testing pioneering technological and organizational approaches, and, most importantly, educational purposes aimed at enhancing the technical and interpersonal skills of emerging engineers. Students benefit from a comprehensive Industry 4.0 hands-on approach, engaging in interdisciplinary activities, collaboration, and the practical transfer of technology between the academic and industrial spheres. The training spans various disciplines, covering automation, mechanics, production management, and computer science. Emphasis is placed on applying acquired knowledge in a hands-on manner, enabling students to solve scientific problems in a real production environment.* *The SUPSI Mini-Factory has already facilitated numerous research projects focused on education, involving various European academic partners. Simultaneously, its integration into regular engineering courses at SUPSI has further enriched the educational landscape, providing students with valuable exposure to Industry 4.0 concepts and practices.*	
Organisation Promotion Materials	***Website***
https://www.youtube.com/watch?v=_aVCCwVUmCE https://www.youtube.com/watch?v=Tigo_u4mfPE (previous campus)	*https://minifactory.spslab.ch/* *https://www.supsi.ch/en/mini-factory-4.0*
General Type of Events held in the DF	***Yes/No***
On-site Tour	*Yes*
Virtual Tour	*No*
Best Practice	*Yes*
Training	*Yes*
Workshop	*Yes*
Hands-on use-case	*Yes*
Open pilot line	*Yes*
other	*No*
Visitors/Audience	***Yes/No***
Researcher	*Yes*
Companies	*Yes*
Students	*Yes*
Existing Workshops within the Didactic Factory	
Industrial Control	*Bachelor's degree in Management Engineering*
Industry 4.0	*Bachelor's degree in Management Engineering* *Bachelor's degree in Computer Science Engineering* *Bachelor's degree in Data Science and Artificial Intelligence*
Mechatronics	*Master of Science in Engineering (MSE)*
Intelligent manufacturing	*Bachelor's degree in Management Engineering*
3-day hands-on experience in Mini-Factory for high-school students	*3-day stage where high-school students have the chance to approach Industry 4.0 technologies*
Technology	***Infrastructure***
	 

Table 3: Overview Polimi Industry4.0Lab

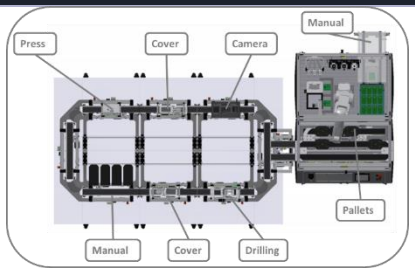
POLIMI INDUSTRY4.0LAB	INDUSTRY4.0 lab
Description	
The laboratory Industry4.0Lab at the School of Management of Politecnico di Milano since 2016 is an initiative on which are focused people and investments of Department of Economics, Management and Industrial Engineering of the School of Management with involvement other departments of the University, in an effort toward a multidisciplinary vision of production environments for the realization of a "teaching factory" for educational and research purposes. Since the beginning of 2014 a research program has been activated aimed at defining the paradigm of the Factory of the Future, which envisions highly reconfigurable, fully informed production systems, integrated in the overall logistics process and with the properties of product / service delivered according the general framework of "Industry 4.0" initiative in Italy. *POLIMI engages its "Industry4.0Lab" to practically implement business models and to develop required tools for deployment and assessment of Intelligent Business Processes. Sustainability, cost effectiveness and ROI drive the adoption models and evaluation of actual results of their implementations.* *The core of the Lab is constituted by the fully automated assembly and manufacturing line with a robotic cell with a high precision 7 axis articulated robot. An AGV and two collaborative robots, controlled by open and independent informative systems, complete the industrial-like scenario with several vertical-integration solutions.*	
Organisation Promotion Materials	***Website***
https://www.linkedin.com/company/polimi-school-of-management-manufacturing-group/mycompany/	*https://www.industry40lab.org/*
General Type of Events held in the DF	***Yes/No***
On-site Tour	*Yes*
Virtual Tour	*No*
Best Practice	*Yes*
Training	*Yes*
Workshop	*Yes*
Hands-on use-case	*Yes*
Open pilot line	*Yes*
other	*No*
Visitors/Audience	***Yes/No***
Researcher	*Yes*
Companies	*Yes*
Students	*Yes*
Existing Workshops within the Didactic Factory	
CORE LAB	*Demonstration and testing of wearable sensors and machine learning algorithms to enhance ergonomics and performance of human operators.*
Digital Twin Futurability	*Researchers participating in a study on digital transformation in manufacturing companies complete a 24-item questionnaire simulation. This is followed by a knowledge sharing activity to derive best practices.*
Technology	***Infrastructure***
	

Table 4: Overview SSF

Switzerland Innovation Park Biel Bienne Swiss Smart Factory Switzerland Aarbergstrasse 46, 2503 Biel	
Description	
Since its opening, the Swiss Smart Factory has established itself as the first test and demonstration platform for Industry 4.0 in Switzerland. It has become a supermarket of ideas where companies of all sizes are welcome to learn and find what technology fits the needs of their company and product. Furthermore, with more and more innovation projects successfully entering the market, the testing and demonstration infrastructure is continuously updated. Thus, our ongoing evolution fosters the next innovation cycle of our customer's products and services. With this lighthouse project, an entire production ecosystem is to demonstrate how Industry 4.0 can already function today. The initiator of the project is Swiss Smart Factory of SIPBB. The team around research manager Dominic Gorecky and project manager Michael Wendling brings the know-how to the project as well as the network of SSF. The support association "Swiss Smart Factory" already has over 70 members, 60 of whom are involved in the lighthouse project. With the lighthouse project, we are heading towards the "transparent factory". Visitors to SSF can follow the entire product lifecycle along the production ecosystem - from product design to packaging. The big challenge is to show this networking in production. To build smart production and generate higher added value, technologies are not used individually, but together. In doing so, we focus not only on the machines, but on the entire environment - building, infrastructure and machine. Through this comprehensive data continuity of all work steps, information flows from developer to developer; from developer to machine; from the machine to the product; from the product to the customer and from the customer back to the manufacturer. Our out-of-the-box thinking allows us to do test runs without generating huge investments at the company. The important thing about the lighthouse project is that the focus is never on the product (a drone in the first project) but always on the means of production. Whether drones or shoes are produced is irrelevant.	
Organisation Promotion Materials	**Website**
https://www.linkedin.com/showcase/swiss-smart-factory/ https://www.youtube.com/@switzerlandinnovationparkb4385	https://www.sipbb.ch/forschung/swiss-smart-factory/
General Type of Events held in the DF	**Yes/No**
On-site Tour	yes
Virtual Tour	no
Best Practice	Yes
Training	Yes
Workshop	Yes
Hans-on use-case	Yes
Open pilot line	Yes
other	no
Visitors/Audience	**Yes/No**
Researcher	Yes
Companies	Yes
Students	Yes
Existing Workshops within the Didactic Factory	
Digital Lean, workshop	https://www.sipbb.ch/forschung/swiss-smart-factory/workshops/digital-lean/
Big Data and Machine Learning, workshop	https://www.sipbb.ch/forschung/swiss-smart-factory/workshops/big-data-machine-learning/
Chatbots, workshop	https://www.sipbb.ch/forschung/swiss-smart-factory/workshops/chatbots/
Low Code in an industrial environment, workshop	https://www.sipbb.ch/forschung/swiss-smart-factory/workshops/low-code/
Augmented Reality for the industry, workshop	https://www.sipbb.ch/fr/ar-ausbildung/
Technology	**Infrastructure**
	

3 Liaison with the AI4MAN Ecosystem and Training for the future Manufacturing Environment

In exploring the AI4MAN ecosystem, we have seen a number of projects that are preparing the manufacturing industry for a future where AI, digital processes and sustainability take center stage. The AI REGIO project, with its focus on data, remotization, enterprise, ecosystem, skills and technology, has been instrumental in creating a framework to help small and medium-sized enterprises (SMEs) adapt to new technologies.

When discussing the connection with the AI4MAN ecosystem and training for the future manufacturing environment, it is important to mention SSF's involvement in Task 7.4 - "Didactic Factory Network and Training Action Plan". Task 7.4 is not the main focus, but rather the reason why we focus on the S-Service, a workshop aimed at developing the skills needed in the manufacturing sector.

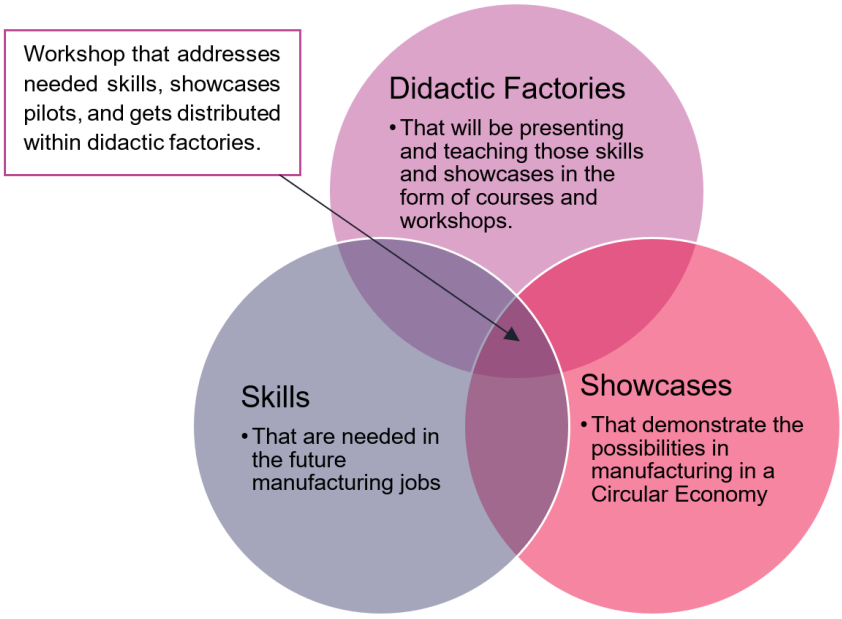


Figure 1: Venn diagram showing the position of the workshop.

The attached Venn diagram illustrates the relationship between Didactic Factories, skills and showcases and forms the basis of our educational strategy (see adjacent figure). It shows that the Didactic Factories are centers for learning and teaching where new skills are developed through courses and workshops. These skills are required for future jobs in the manufacturing sector, which are shown in the "Skills" part of the diagram. Then there are the 'showcases', practical examples of how these skills can be applied in manufacturing in a way that supports a circular economy and emphasizes the need for sustainable manufacturing practices.

The S-Service workshop was developed to meet the changing demands of the manufacturing world. It is a practical program that puts the ideas from the DR-BEST model into practice. This workshop is designed to equip participants with the skills, knowledge and insights they need to meet the demands of Industry 5.0.

In this chapter, we look at the structure and objectives of the S-Service workshop. This workshop, to be developed on the basis of the DR-BEST framework and delivered in the Didactic Factories, is an important part of our training concept. It is designed to give participants the tools they need to make the technological and environmental changes that are shaping the future of manufacturing.

3.1 Topics and Content for a Circular TwAIn Workshop

As we look at the structure and content of the workshop, it is crucial to consider the outcomes of two key workshops previously held (Workshop 1: 02. December 2022, Workshop 2: 27. January 2023) as part of the Circular TwAIn project. These workshops were instrumental in identifying the skills and roles that are important for the manufacturing landscape of tomorrow. The first workshop focused on creating detailed personas for future manufacturing jobs, emphasizing the soft skills and interdisciplinary knowledge critical to success in a sustainable manufacturing environment. The second workshop built on this foundation and identified a bouquet of skills and reference roles that will be of utmost importance in the job market.

The insights gained in these workshops are of great value for the design of the new S-Service workshop. They give a clear indication of the industry's move towards a socially skilled workforce, where emotional intelligence, creativity and strategic thinking are as important as technical skills. These insights will have a direct impact on the topics and modules of the S-Service workshop to ensure it addresses the right mix of skills required for an AI-driven circular economy.

3.1.1 Workshop I – Future Manufacturing Job – Personas

Context

Workshop I, entitled "Future Manufacturing Job - Building Personas", focused on envisioning the evolving landscape of manufacturing jobs. This workshop aimed to create detailed personas that reflect the different roles and skills that will be needed in the future of sustainable manufacturing. Through interactive discussions and collaborative brainstorming, participants sought to understand and define the characteristics, competencies and challenges of future manufacturing professionals, paving the way for a more informed and strategic approach to workforce development in the age of Industry 5.0.

Organizer

Swiss Smart Factory

Participants

GFT Italia

Engineering Ingegneria Informatica

Politecnico di Milano

AIMEN Centro Tecnológico

Workshop

The "Future Manufacturing Job - Building Personas" workshop began with an introduction in which the objectives of the workshop were clearly outlined and the role of personality development in the context of future manufacturing was emphasized. This was followed by a check-in phase in which the participants introduced themselves and described their background and expectations of the workshop.

The session then moved into a brainstorming activity focusing on potential roles in future manufacturing. During this phase, a variety of ideas emerged, reflecting the different experiences of the participants.

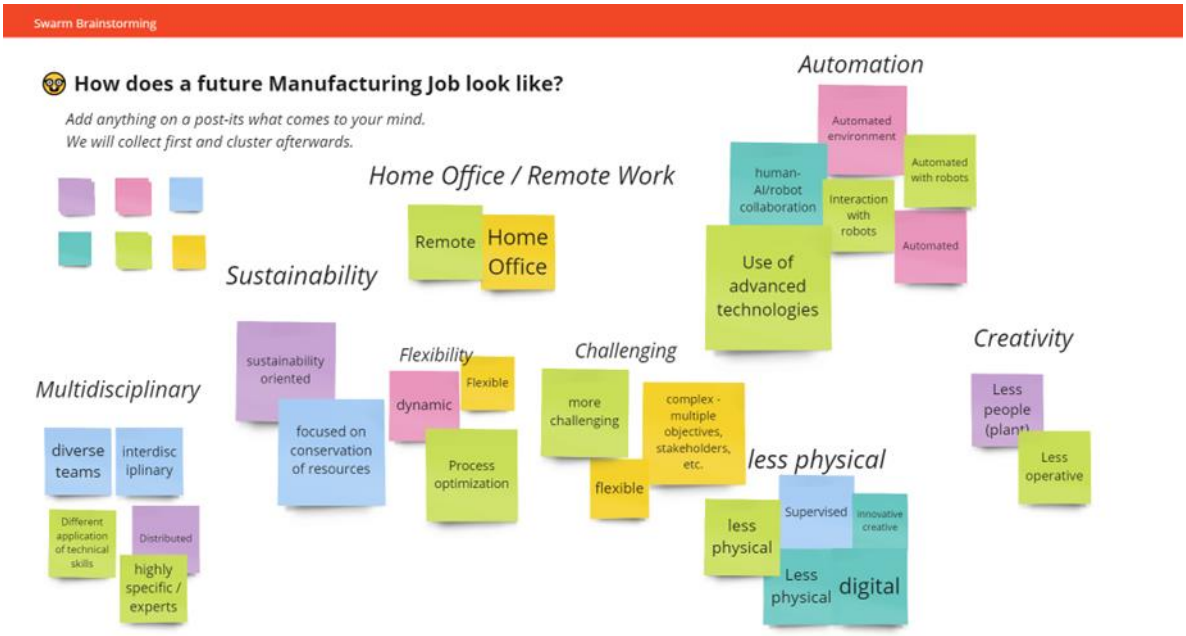


Figure 2: Brainstorming Session of the Workshop

The outcome of this brainstorming session reveals a multifaceted view of future manufacturing jobs, highlighting key attributes and trends such as:

- Multidisciplinary: Emphasizing the importance of diverse, intersectoral teams with a range of technical skills.
- Sustainability: Focused on sustainability orientation and the conservation of resources.
- Home Office / Remote Work: Recognizing the growing trend of remote work environments.
- Automation: Noting the rise of automated environments, including human-robot collaboration.
- Flexibility: The need for flexible and dynamic job roles that allow for process optimization.
- Challenging: Acknowledging that future roles will be more challenging, with complex objectives involving multiple stakeholders.
- Less Physical: A movement towards less physically demanding roles due to increased digitalization.
- Creativity: The necessity for innovation and creativity in the workplace.

A voting process subsequently helped in identifying the most significant characteristics for future roles. In breakout sessions, teams worked on developing detailed personas, incorporating these key traits. Participants collaboratively identified key characteristics such as creativity, technical expertise, and a drive for innovation. These personas also encapsulated the various gains sought in modern jobs, like enhanced oversight and productivity through technology, and the associated pains, such as increased stress and competition.

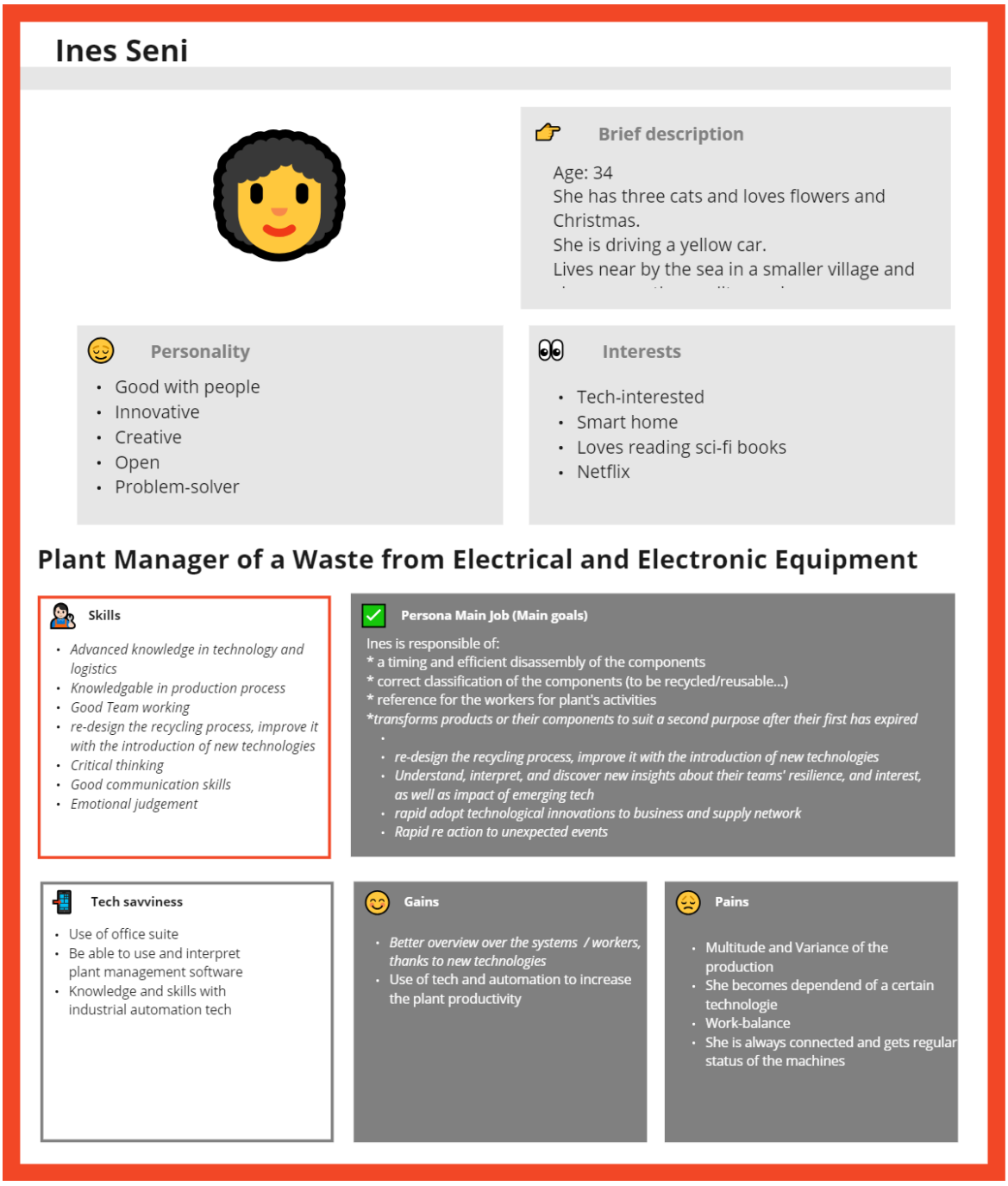


Figure 3: Example Persona from the Workshop

Each group later presented their personas, leading to a detailed discussion that critically evaluated and refined these profiles. This collaborative effort was aimed at ensuring the personas were realistic and relevant to anticipated industry trends. Collectively, the workshop's outcomes present a rich tapestry of potential roles within the future workplace, emphasizing the shift towards more technologically integrated and multi-faceted job profiles.

The workshop concluded with a final segment where participants collectively reflected on the outcomes, highlighting the key insights and considerations for future initiatives in manufacturing and workforce development.

3.1.2 Workshop II – Future Manufacturing Job - Define bouquet of skills and reference roles.

As the world of work is constantly evolving, it is vital that we stay ahead of the curve by identifying and developing the skills that will be in demand in the coming years. In this workshop, we explored the key skills and reference roles that will be important for success in the future.

Organizer

Swiss Smart Factory

Participants

GFT Italia

Engineering Ingegneria Informatica

Politecnico di Milano

AIMEN Centro Tecnológico

Suite5 - Data Services and Analytics for Intelligence

CORE Innovation Athens

Workshop

The workshop opened with a structured introduction in which the agenda of the session was briefly outlined and the participants were familiarized with the objectives of the day. This was followed by a check-in during which participants briefly outlined their expectations, creating the basis for a common discourse.

A summary of the first workshop served to weave the threads of the previous discussions into the current context and ensure a seamless transition to the agenda. The brainstorming phase was a focused effort to draw out a variety of skills that reflect future roles in the industry.

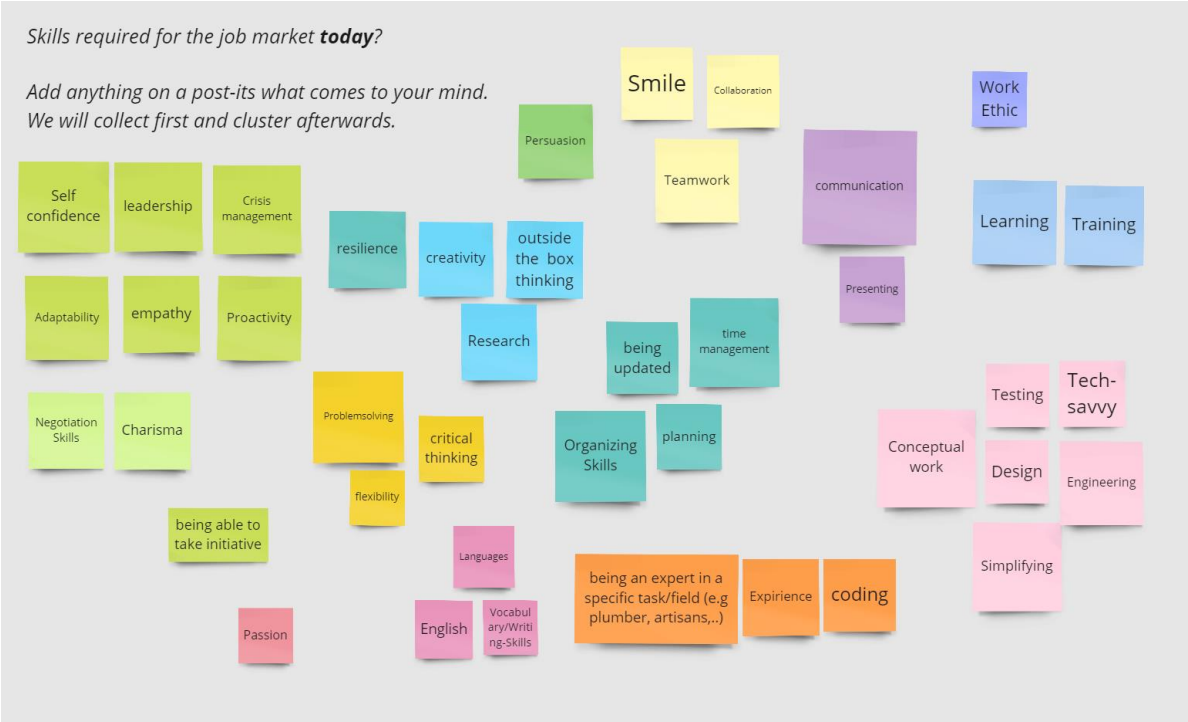


Figure 4: Outcome of Brainstorming of required skills for the job market today.

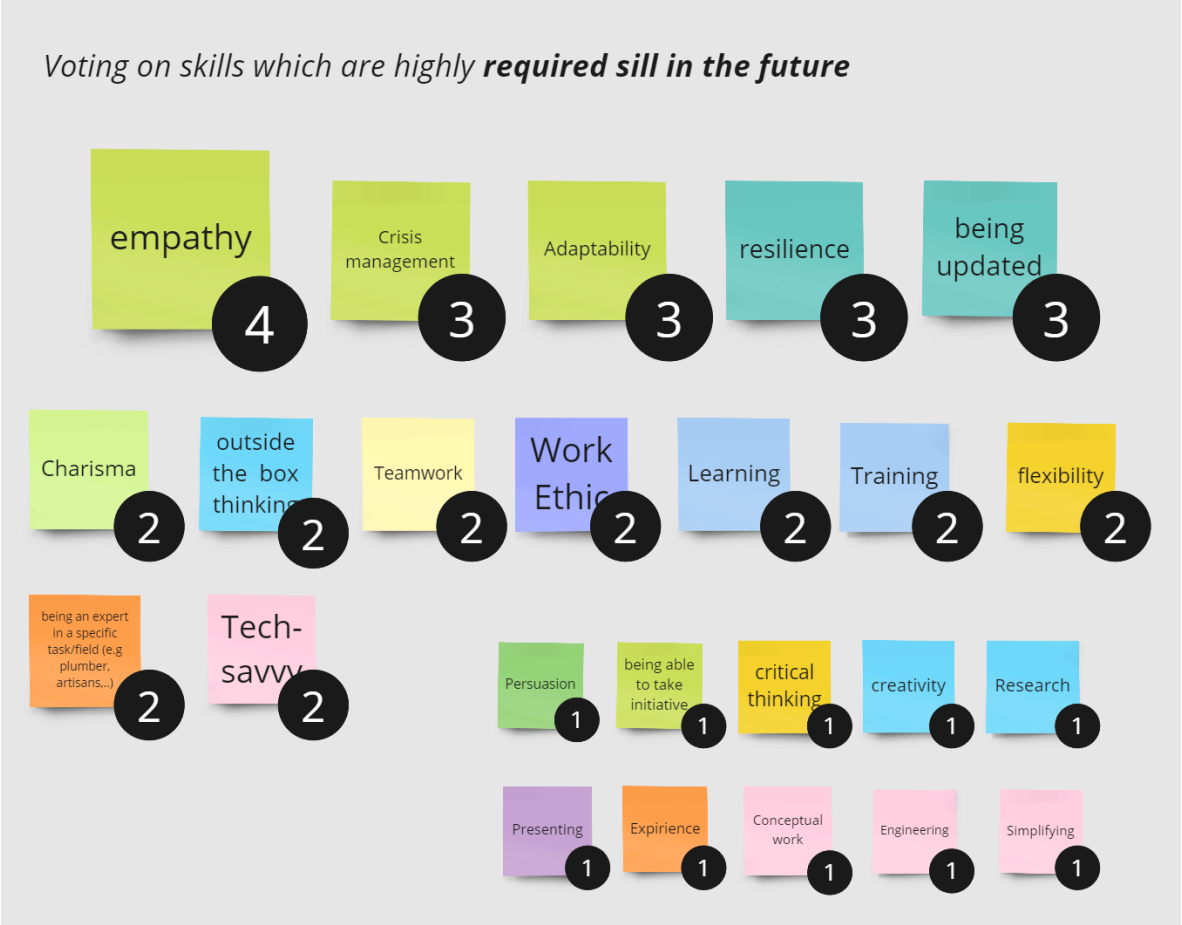


Figure 5: Voting result of most important of skills.

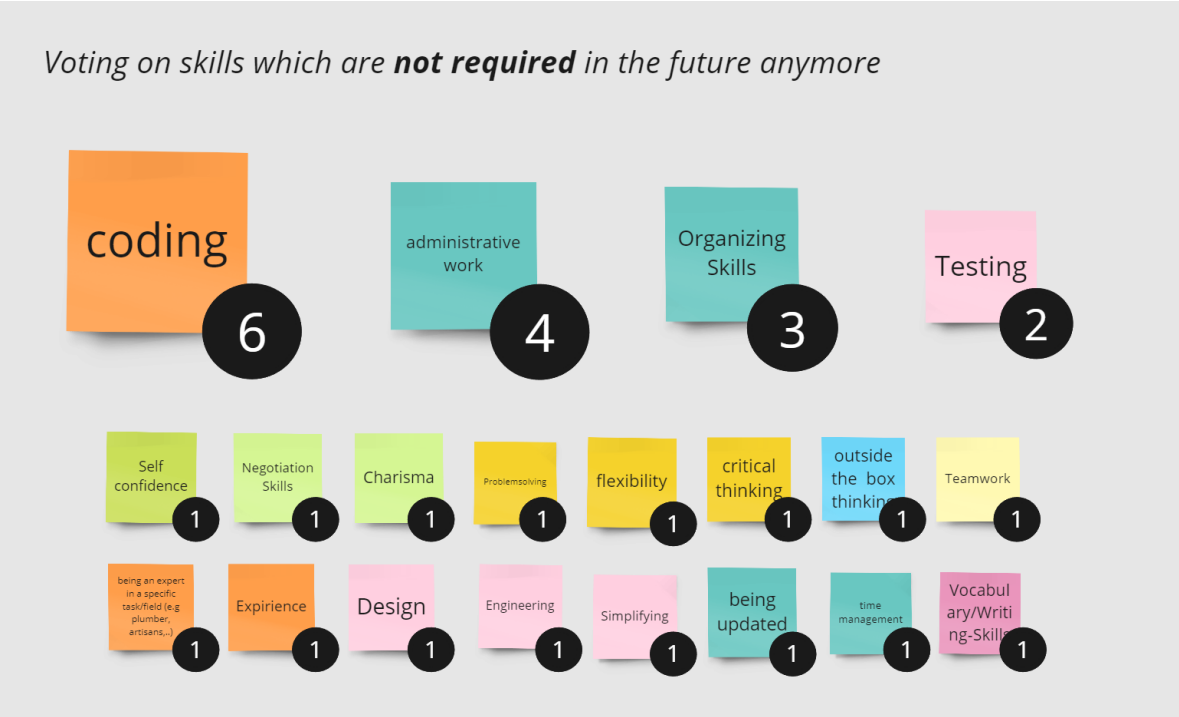


Figure 6: Voting result of least important skills

The outcome of the brainstorming session on the skills required for the future job market revealed a range of competencies. Skills such as programming, design, engineering and technical understanding were rated as less important for the future. In contrast, attributes such as empathy, adaptability, resilience and creative thinking were seen as very important skills in the future. This shows that soft skills and the ability to deal with change will be more important in the future than purely technical skills. The exercise highlighted the consensus on the growing importance of emotional intelligence and flexibility in the changing world of work. The brainstorming session was followed by an analytical look at current and future job roles as presented on LinkedIn.

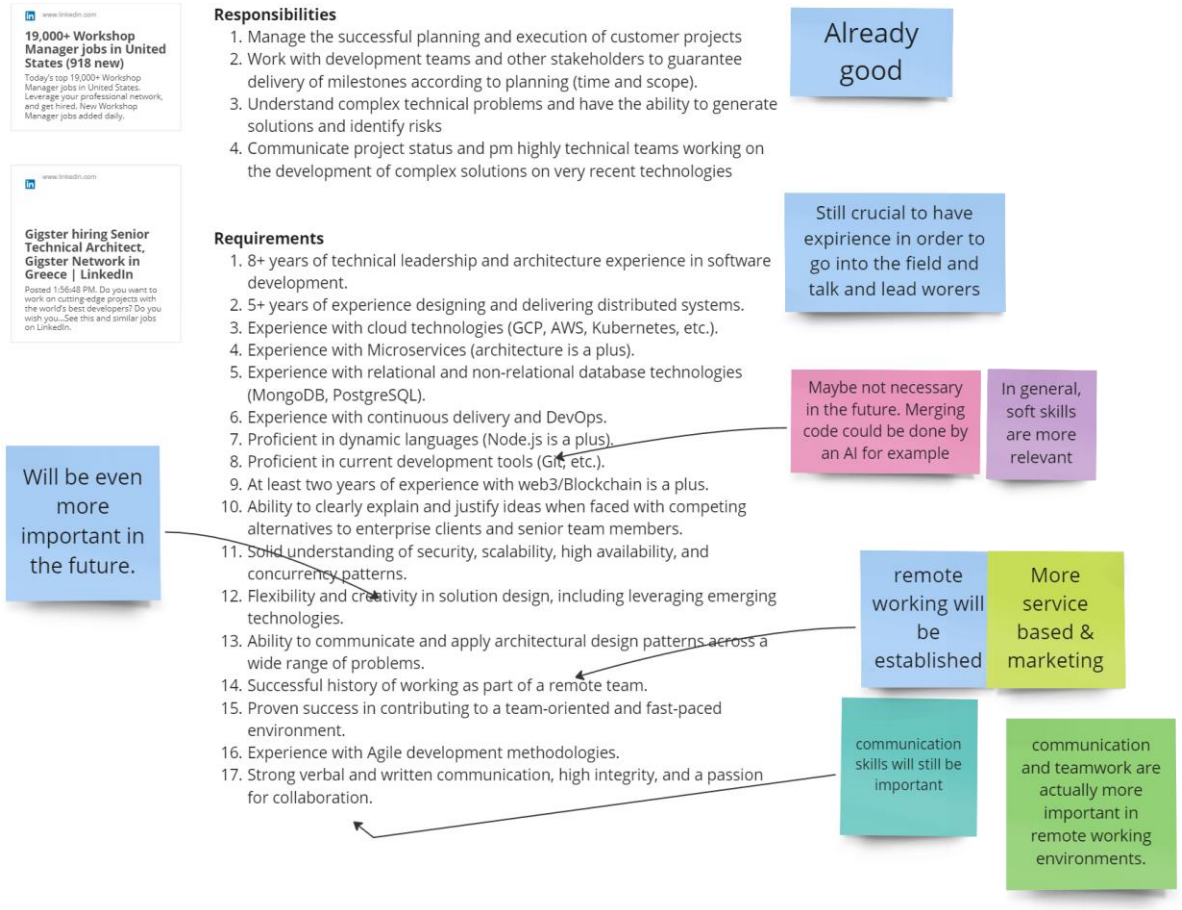


Figure 7: Reference Role collected from LinkedIn.

Plant Director: This role is being transformed by increased factory digitization, reducing the need for supervising factory workers directly. The modern Plant Director must exhibit advanced problem-solving skills, exceptional communication, and leadership capabilities, with a strong emphasis on flexibility to oversee plant operations, drive digital transformation initiatives, and integrate IoT technologies to enhance efficiency and productivity. The profile places less importance on experience, highlighting the necessity for a global mindset and strong leadership qualities to manage less hierarchical team structures effectively.

Workshop Manager & Technical Architect: This composite role is seen to retain its core functional responsibilities, with a growing importance placed on creativity, soft skills, and the ability to work remotely. Although experience remains critical for leading and communicating effectively within the field, the requirement for proficiency in development tools may decline, as AI technologies could assume responsibilities like code merging. The role also anticipates a more service-based focus, aligning with user needs and market demands.

R&D Manager: The R&D Manager is expected to bring strong leadership, organizational skills, and a proactive approach to their role. Critical thinking and continuous learning are vital as open innovation and customer engagement become increasingly important. Big data and AI will play a crucial role in R&D processes and product lifecycle management, with crisis management and sustainability considerations, such as digital product passports and life cycle assessment, becoming standard requirements.

Sustainability Leader: Charged with developing and implementing sustainability strategies, this leader must have a profound strategic vision and the ability to manage projects and teams, possibly from remote settings. The role entails driving the company's environmental policy, managing the sustainability of the supply chain, and staying abreast of industry-wide regulatory requirements and emerging trends. Strong communication and persuasive skills are essential to gain board support for sustainability initiatives, alongside the capability to interpret complex data sets and foster a collaborative and productive team environment.

The detailed exploration of these roles underscores a transition towards strategic leadership capable of leveraging digital advancements, with a pronounced focus on sustainability and the ability to lead innovative changes in manufacturing practices.

3.1.3 Conclusion of Workshop

The conclusion of the workshops within the Circular TwAIn project reflects a profound understanding that the future of manufacturing necessitates a multifaceted skill set and the development of diverse personas. The first workshop underscored the need for multidisciplinary teams, placing a strong emphasis on soft skills such as creativity, sustainability awareness, and adaptability. Building on these insights, the second workshop highlighted a shift in emphasis away from traditional technical skills towards emotional intelligence and strategic thinking. These workshops collectively underscore a pivotal shift towards job roles that harmoniously blend technical expertise with innovative and sustainable approaches, ensuring that the workforce is well-prepared to meet the challenges of Industry 5.0. This evolution in skill requirements and the nature of job roles is essential to maintain the competitiveness and sustainability of the manufacturing sector. The insights gleaned from these workshops are instrumental in shaping a future where the workforce is not only adept at leveraging technological advancements but is also resilient, adaptive, and aligned with sustainable practices.

Table 5: Resulting Catalog of Skills

Skill-Category	Skill	Description
Technical Proficiencies	*Artificial Intelligence and Machine Learning*	*Understanding and applying AI/ML algorithms for predictive analytics, automation, and problem-solving.*
	Data Analytics and Big Data Management	*Proficiency in handling, analyzing, and interpreting large datasets to drive decision-making.*
	Internet of Things (IoT)	*Skills in integrating and managing IoT devices to enhance manufacturing processes and data collection.*
	Digital Twins and Simulation	*Ability to create and utilize digital twins for production planning, monitoring, and optimization.*
Sustainable Practices and Resource Management	*Sustainability Strategy Development*	*Knowledge in developing and implementing strategies focused on sustainability and resource conservation.*
	Circular Economy Principles	*Understanding the principles of circular economy and applying them to minimize waste and optimize resource use.*
Adaptive and Flexible Production	*Flexible Production Line Management*	*Skills in managing and adapting production lines quickly in response to market changes or demand fluctuations.*
	Supply Chain Resilience	*Ability to build resilient supply chains that can withstand disruptions and adapt to changing market dynamics.*
Innovation and Problem-Solving	*Creative Thinking and Innovation*	*Ability to think outside the box, generate innovative solutions, and apply them to complex manufacturing challenges.*
	Complex Problem-Solving	*Skills in analyzing complex problems, breaking them down into manageable parts, and devising effective solutions.*
Leadership and Strategic Management	*Collaborative Leadership*	*Ability to lead in a less hierarchical, more collaborative, and team-oriented environment.*
	Digital Transformation Leadership	*Skills in leading and managing digital transformation initiatives, integrating advanced technologies into business processes.*
Emotional Intelligence and Interpersonal Skills	*Empathy and Resilience*	*Capacity to understand and respond to team members' emotions, fostering a supportive work environment.*
	Change Management	*Skills in managing organizational change, addressing resistance, and ensuring smooth transitions in dynamic environments.*
Role-Specific Competencies	*Plant Director*	*Advanced problem-solving, overseeing digital transformation, and integrating IoT technologies.*
	Workshop Manager & Technical Architect	*Balancing core responsibilities with creativity, soft skills, and remote work capabilities.*
	R&D Manager	*Leadership in open innovation, customer engagement, and proficiency in big data and AI.*
	Sustainability Leader	*Strategic vision in sustainability, understanding of environmental policy, and data interpretation skills.*

3.2 Roadmap for Circular TwAIn Workshop Implementation

A future-oriented workshop is to be developed as part of the second project phase of Circular TwAIn. This is based on the results from the workshops in chapter 3.1, the catalog of required skills and the developed personas of the future. The primary aim of the workshop is to train and prepare researchers, developers, students, and employees of companies for the challenges of the future using interactive content.

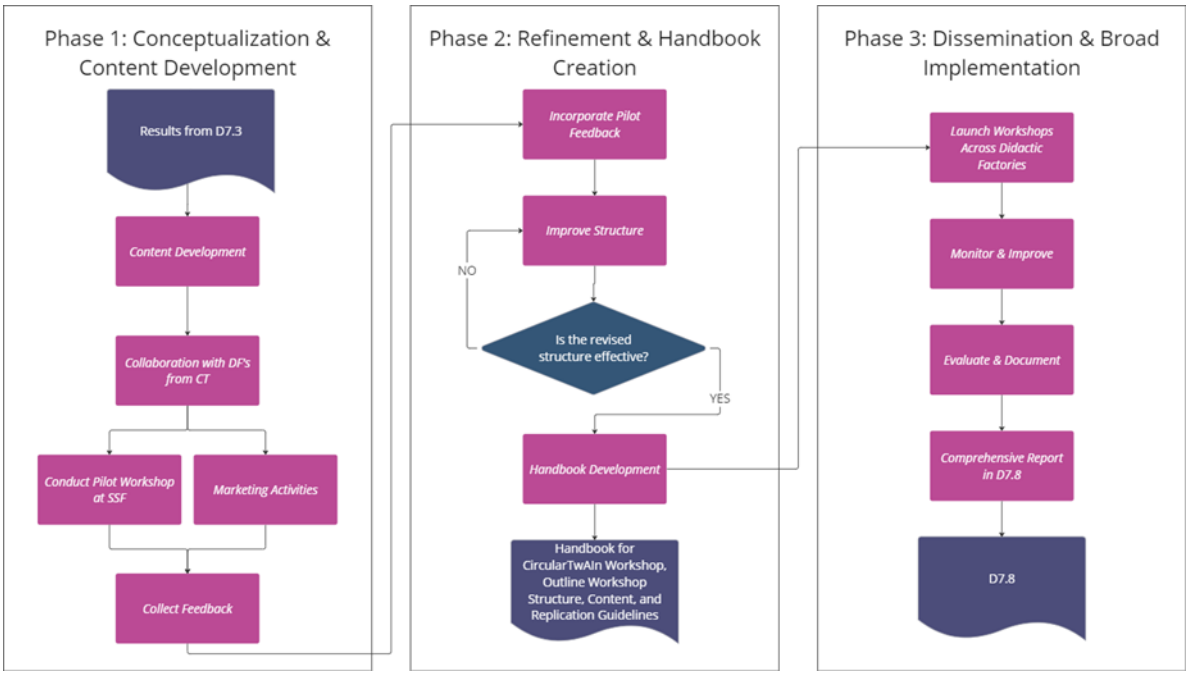


Figure 8: Roadmap for the new Workshop.

The pilot phase of the workshop will take place at the Swiss Smart Factory. The aim is to obtain practical feedback that will be used to optimize and adapt the workshop concept. The knowledge gained from the pilot workshop will be incorporated into the development of a handbook. This will document the workshop in the form of a "recipe", which will serve as a guide for other institutions.

Subsequently, the handbook will be disseminated within the Circular TwAIn consortium and adapted to the specific needs of the various institutions. Through this iterative process, the handbook will be continuously expanded and improved. The experience gained and best practices will be recorded and finalized in Deliverable D7.8. This comprehensive report serves as a basis for the broad dissemination and implementation of the workshop results and methodology and contributes to the creation of a sustainable educational offering for digital transformation in the industry.

4 Legal and Ethical Issues and Circular TwAIn Regulatory Sandboxes

Following the detailed examination of the AI4MAN ecosystem collaborations and the integration of the Didactic Factory in Chapters 2 and 3, the focus shifts in Chapter 4 to the regulatory and ethical framework that underpins the project. This section describes the main activities performed and outcomes achieved in relation to the legal and regulatory issues of the project. After the description of the factual basis of this legal review, the document moves outlining the key reference regulatory framework applicable to its technologies and piloting activities, as well as the finding of the first consultation with the stakeholders. The ALTAI-driven Human Rights Impact Assessment of the technological breakthroughs of the project is outlined, followed by a snapshot of the regulatory sandboxes of the project. This section ends with the elicitation of the legal and ethical requirements for Circular TwAIn technologies and pilots.

4.1 Factual basis for the legal and ethical analysis and for the requirements elicitation

To comprehensively understand the legal and ethical landscape surrounding the Circular TwAIn project, it's crucial to delve into its factual basis. This section will explore the technological underpinnings of Circular TwAIn, including the pivotal role of Artificial Intelligence (AI), Digital Twins, and Data Spaces. Moreover, it will provide insights into the Industrial Pilots driving the project's real-world application, with a focus on the WEEE, Battery, and Petrochemical Pilots. Each pilot showcases innovative approaches to sustainability and efficiency, accompanied by legal considerations crucial for their implementation. Let's explore the intricate details of Circular TwAIn's technological framework and its practical manifestations in industrial settings.

4.1.1 Factual basis for Circular TwAIn Technology

The main technologies involved in Circular TwAIn are:

1. **Artificial Intelligence**: AI applications, mainly linked with Digital Twins are used to support Pilot's scenarios execution in:
    I. product/part recognition through machine vision
    II. disassembly operations
    III. production and shopfloor process optimization.
2. **Product, Process and Human Digital Twins**: legal and ethical aspects are relevant mostly for the Human Digital Twins (HDT). In Circular TwAIn, HDT will serve as mapping of operators' skills and knowledge, with the main goal of supporting operators upskilling and reskilling. In this regard, legal and ethical aspects should be considered because this information can be misused (e.g., to punish or fire operators with low skills levels). Also, this information is exploited by the Process DT, which assigns operators to tasks, keeping also track of the task execution. Here, ethical aspects are relevant to avoid the Process DT assigning simple and repetitive tasks to low-skilled operators, without caring about their well-being and personal satisfaction. Again, the information provided by the Process DT could be misused against the operators (e.g., to demote operators that are slower than expected), thus legal and ethical aspects should be considered also at this level. Finally, the results of the activities carried out by operators could be stored also in the Product DT (e.g., quality of disassembled products), raising the same issues highlighted for the

Process DT. Concerning the Process and Human DTs, their main role is to return process plans (Process DT) and operators reskilling/upskilling programs (Human DT), which may possibly replace human decisions (e.g., Operation Managers and Human Resource Managers). In this view, Circular TwAIn promotes the usage of DTs as support tools, i.e., tools that suggest decisions to take, putting the final decision back to the human.

3. **Data Space**: data sharing environments as enabler for information exchange in a trusted and protected ecosystem. Circular TwAIn's Data Spaces adhere with reference IDS RAM which defines the schemas and protocols required for entities to publish data, negotiate usage agreements, and access data as part of a federation of Data Spaces

4.1.2 Factual basis for Circular TwAIn Industrial Pilots

WEEE Pilot

WEEE management is the safe, technological, and scientifically sound methods to remove/dispose the electronic waste from the environment. It includes reusing, refurbishing, and recycling at the end of the product life. Although the WEEE management may differ from one enterprise to another. In Circular_Twain project there are two WEEE recycler and managers, Revertia and Recyclia. WEEE Pilot aims to provide a sturdy framework to automate part of the waste treatment process by developing an automated tool to help human operators in the disassembly of waste. In its final stages of development, WEEE Pilot aims to implement a decision-support tool to assess different WEEE Markets and providing insight to an expert to determine how to best proceed with the WEEE treated.

WEEE Pilot is divided into 5 Use Cases:

1. UC-A: Computer-vision driven product identification for the disassembly of IT equipment.
2. UC-B: Characterization and assessment of components and subcomponents
3. UC-C: Real-time planning of the disassembling operations
4. UC-D: Collaborative robotics for the support of manual operations
5. UC-E: *Market-oriented holistic decision-support-system for WEEE de- and re-manufacturing*

Battery Pilot

The Circular TwAIn battery pilot is focused on the circular value chain of e-mobility Li-Ion battery packs.

Automotive battery systems are complex components and their circular value chain is peculiar: they share with the rest of the vehicle only the central part of the linear value chain (assembly, distribution, usage). Their manufacturing and end-of-life management instead, follow dedicated routes. The current circular value chain for automotive battery systems lacks of optimization in the recovery of functionalities and materials from these components. Nevertheless, it already excludes both landfilling and energy recovery as viable options. Nowadays, batteries are managed by a transport and logistic actor which ensures their distribution to an authorized dismantler for discharge and disassembly. Finally, the battery modules or battery cells, core of the whole system, undergo pyrometallurgical recycling for the recovery of target cathode metals, especially Co.

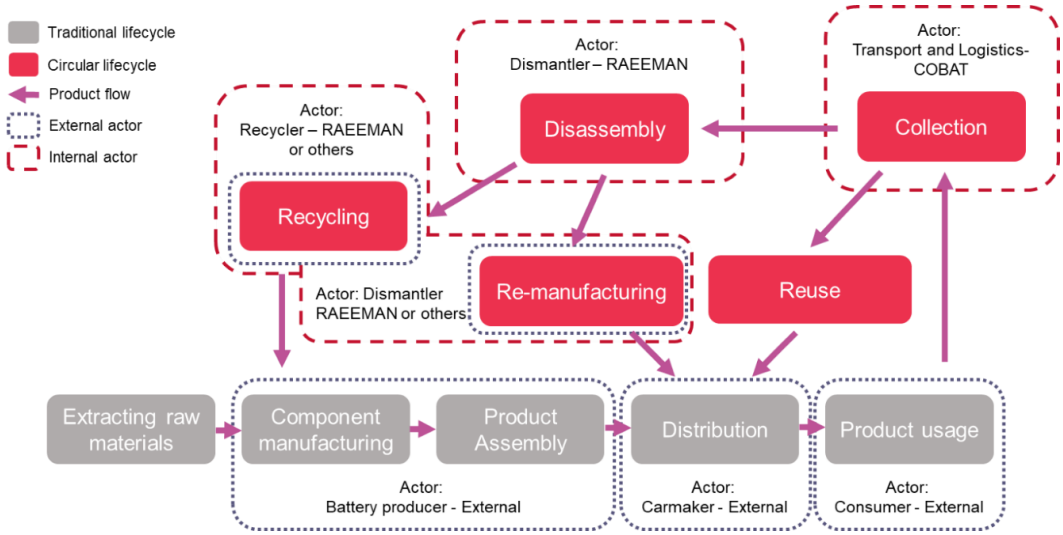


Figure 9: Battery Pilot overview; circularity and actors.

The concept behind the Circular TwAIn battery pilot is to overcome the current value chain by integrating innovative circular economy nodes of the following framework (Figure 9):

- E-mobility battery systems which reach their end-of-life are collected by transport and logistics operators.
- Preliminary tests assess the reusability of the battery without any manipulation. The compliant batteries are directly reused in automotive or stationary domains.
- Those battery packs whose direct reuse is not applicable are disassembled and tested at modules and eventually cells level.
- The units (modules and cells) suitable for reuse are reassembled in second life batteries.
- The units with no residual electric properties compliant for reuse are recycled exploiting combined mechanical and hydrometallurgical processes for a more efficient recovery of raw materials.

Battery Pilot will implement and integrate the AI modules in the battery remanufacturing facility that will foresee the integration of CPS in the target facilities (sensors, cameras, actuators, etc.), implementation of data spaces and digital twins for the battery re-manufacturing domain and implementing AI modules at the cloud/edge.
The following use-cases are implemented by the Pilot actors.

- UC -1A: Computer-vision driven collaborative robotics for the disassembly of LIB packs.
- UC -1B: Machine learning aided automated disassembly of LIB modules.
- UC -1C: AI tool for the characterization of the LIBs state-of-health combining historical and testing data.
- UC – 1D: AI tool for optimized mechanical recycling of degraded LIBs.
- UC -1E: Market oriented holistic decision-support-system for the LIBs de- and re-manufacturing

Petrochemical Pilot

Petrochemical processes are complex, contain multiple steps, are energy-intensive and produce greenhouse gasses as a byproduct. This pilot is focused on Ethylene Oxide (EO) production, CO2 emission, and energy consumption that drive from the production of EO. It is used to produce mono-ethylene glycol, a flammable colorless gas with a sweet odor at

room temperature. To be generated process digital twin of the EO stripper with a physic-based surrogate model of the plant and integration of data from various sources will be a controller to the data-driven predictor. HCT will be used for the development of what-if analysis and predictions which can be used to handle various scenarios for optimization of stream consumption and decision-making. Steam is produced in the boilers of the steam generation unit. In boilers, water is heated to produce high-temperature, high-pressure steam. Natural gas is used as fuel to heat the water. The steam produced is used as a heating medium in SOCAR's process plants. By decreasing steam consumption of the process plants, natural gas consumption, which is the raw material, can be reduced. Also, during steam production, water is heated by burning natural gas. The CO2 formed because of the combustion process is released into the atmosphere. Reducing the steam requirement of the process facilities will cause a decrease in the amount of steam produced, thus reducing the formation and emission of CO2. Also, currently the CO2 produced in the EO reactor is released to the atmosphere from the EO Recovery unit, this unit involves absorber and stripper. By using this waste CO2 and H2 from Steam-Methane Reforming Unit, DME production can be carried out. Therefore, the DME Process has been chosen for circularity. However, at use case premises, there is no DME plant, so Aspen engineering suit models will be created for the DME production process and DME yield data will be generated using historical CO2 disposal flow data. An AutoML module will be developed to help the end users, i.e., operators and managers at the factory and to have a generic framework applicable in other plants. Enriched with a wizard-like flow and easy-to-use graphical user interfaces, AutoML will cover every step of data-driven machine learning. In the first case, the working conditions of the distillation column, C-205, will be optimized, and the column will be operated at the lowest temperature possible. This will lead to a decrease in the energy consumption. The plant operators will benefit from AutoML by getting optimized working conditions. If operators would think that it is suitable, they will implement the proposed conditions. DME process will be simulated on ASPEN Plus Engineering Suite, and the CO2 concentration values from the top of the D-205 will be used as an input to the simulation. The kinetics of the bifunctional catalyst will be used in the reactor modelling, and the DME production results will be monitored by R&D specialists. The results from ASPEN Engineering Suit will be shown on the digital twin screens (in engineer or executive level) to be able to show the feasibility of a DME plant. The pre-feasibility of the investment of the DME plant will be based on the simulation results.

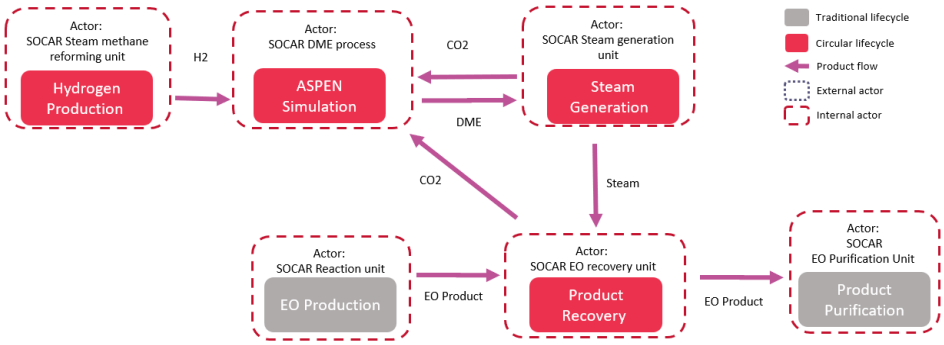


Figure 10 Petrochemical Pilot Overview

Use cases include data collection, integration, analysis, optimization, and AI module development to enhance operational efficiency, maintain product quality, and reduce environmental impact. Each use case has a specific purpose to improve the overall

manufacturing process within the plant. Legal analysis for each use case may vary depending on regulatory frameworks, industry standards, and data privacy laws applicable to the manufacturing plant's location and operations. Nevertheless, here are some general legal considerations that can apply to each use case:

Use case 1a: Data acquisition and representation for AI framework

This use case involves the collection of data from process control systems, including Distributed Control System (DCS) to monitor various aspects of the production process. Data are gathered for analysis and optimization of the production process.

Legal Considerations:

- Data Privacy
- Data Ownership
- Interoperability

Use case 1b: Developing a hybrid circular twin of the process.

This use case focuses on the development of a Hybrid Circular Twin (HCT) that combines data-driven Digital Twin technology with a first-order physical model. The purpose is improving predictive capabilities, optimizing, monitoring, and controlling the physical system.

Legal Considerations

- Model Accuracy
- Intellectual Property
- Liability

Use case 1c: Use of data analytics, AI and model verification to understand process unit failures

This use case revolves around the application of data analytics and AI to comprehend process unit failures and prevent unplanned shutdowns by utilizing data analytics and AI to understand process unit failures, identify abnormal conditions, prevent shutdowns, and manage variable feed and demands.

Legal Considerations

- Data Security
- Transparency
- Data Retention

Use case 1d: Developing AutoML module for Process Industry

This use case centers on the development of an AutoML (Automated Machine Learning) module tailored for non-expert users in the process industry by simplifying data preprocessing, model training, and selection for operators and managers.

Legal Considerations:

- Data Consent
- Fair Algorithms

- Intellectual Property
- Data Security

Use case 1e: Generation of a tool for process optimization

This use case pertains to the development of an AI-App aimed at optimizing the production process, with a focus on maximizing on-spec product production while minimizing undesired by-products.

Legal Considerations:

- Environmental Compliance
- Product Quality
- Liability
- Data Security

4.2 The legal and ethical reference framework

4.2.1 The legal and ethical reference framework at European level relevant for Circular TwAIn Technology

This paragraph contains an overview of the key EU-level legal, regulatory, and ethical sources relevant for Circular TwAIn technologies and their application, without providing a throughout description of the identified sources, which would fall outside the scope of this document, but considering them as paramount to elicit the legal and ethical requirements for the project's outcomes and activities. The legal and ethical landscape will be further monitored in the upcoming months in order to be fully aware on any regulatory development which could affect Circular TwAIn, towards delivering a value-driven and legal-respectful technology.

Table 6: European Regulatory Reference Framework

Artificial Intelligence	
AI Act (AIA) Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union legislative acts.	The AI Act (AIA) is the first-ever legal framework for AI, proposed by the EC in April 2021, building on the Commission White paper on AI. It is aimed at giving rise to trustworthy and ethical AI systems in the European market, balancing innovation with safety, security, and privacy. It is intended to protect the safety and fundamental rights of people and businesses, whilst fostering AI innovation and use across the EU through an innovation-friendly landscape. After a long negotiation among the Parliament, the Council and the EC (so-called the "trilogue"), a provisional agreement has been reached on December 9 2023), incorporating safeguards for general-purpose AI, as well as limitations or bans for AI applications, like social scoring, manipulation, biometrics, etc. The agreed text will now have to be formally adopted by both Parliament and Council to become EU law. In particular, it will become law 20 days after its publication in the Official Journal of the European Union. This will reasonably happen during the summer of 2024. Pending the formal adoption, the EC adopted the so-called AI Pact, anticipating the implementations of some AI Act requirements with companies acting as early adopters on a voluntary basis, especially in order to address concerns regarding the rapid adoption of generative and general-purpose foundational models and AI systems. It is expected to foster the development of best practices and procedures, also in view of supporting the companies to pledge to work towards compliance. The AIA gives a crucial role to the European Standard Organisations (ESOs), such as CEN/CENELEC and ETSI, for homogenizing standards on AI in response to its provisions. In this direction, CEN/CENELEC were requested in the last quarted of 2023 to start preparing homogenised standards in support to the AIA. Such standards are expected to be generated in the next couple of years. The AIA is expected to be applied after two years after its entry into force: therefore in 2026 the AIA /and the standards that will support it) will be applicable to all the AI-based products and services. The AI Regulatory Sandboxes (Title V, art. 53 ss.) could play an important role to support companies, especially SMEs and start-ups, in applying the AIA provisions during this transition period, thereby facilitating compliance. The first official sandbox was launched in November 2023 by the Spanish government and European Commission. This sandbox, being a controlled experimentation and testing environment in the development and pre-marketing phase aimed at ensuring compliance of the innovative AI solution with the AI Act (and the other relevant Union and Member States legislation), could represent a powerful tool both to foster AI innovation and to increase the legal certainty for innovators. The Spanish AI Sandbox Pilot will run until 2025. Afterwards, its outcomes and implementation guidelines, good practices and lessons learnt, will be communicated to the Member States and the EC. The AIA is governed by the so-called risk-based approach, aiming at classifying the AI applications according to a typology of risks from none to high-risk, as follows: i) unacceptable risk AI systems, with harmful uses of AI that contravene EU values. These systems are banned, with some exceptions; ii) High risk AI systems, negatively affecting safety or fundamental rights, for which a range of mandatory requirements (including a conformity assessment) are foreseen. All high-risk AI systems will be assessed before going to the market and throughout their lifecycle; iii) Limited risk AI systems, such as those that generate or manipulate image, audio or video content, are subject to a limited set of obligations (e.g. transparency); iv) Minimal risk AI systems. Comprising all other AI systems, can be developed and used in the EU without additional legal obligations than existing legislation.

AI Liability Directive (AILD) Proposal COM (2022) 496 final "Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence"	Following what stated in the White Paper on Artificial Intelligence, on 28 September 2022 the European Commission adopted, with the aim of promoting the uptake of artificial intelligence and addressing the risks associated with certain of its uses, not only the AI Act proposal, but also the AI Liability Directive Proposal. It is going to provide a new set of liability rules specifically targeted at AI, tackling consumers' liability claims for damage caused by AI-enabled products and services. This instrument, intended to complement the AIA, is directed to ensure that individuals harmed by AI systems enjoy the same level of protection as persons harmed by other technologies. This proposal was based on the Report on Artificial Intelligence Liability, where specific challenges posed by artificial intelligence to existing liability rules were examined. The main purpose of this Directive is to improve the functioning of the internal market through uniform rules for certain aspects of non-contractual civil liability for damage caused with the involvement of AI systems. The source tackles in particular the issues regarding the difficulties of proof linked with AI, ensuring that justified claims are not hindered, addressing specific issues with causality and fault linked to AI systems.
Revised Product Liability Directive (RPLD) Proposal COM (2022) 495 final, "Proposal for a Directive of the European Parliament and of the Council on liability for defective product"	Another important source is the proposal for a new directive on liability of defective products, adopted by the EC in September 2022, directed, together with the AI Liability Directive, to renovate the existing Product Liability Directive (adopted in 1985) in order to properly address the needs of the digital age, circular economy business models and global value chains. Both of these Directives will now needed to be adopted by the European Parliament and the Council. The RPLD contains provisions to address liability for products such as software (including artificial intelligence systems) and digital services, affecting how the product works (e.g. navigation services in autonomous vehicles), besides alleviating the burden of proof for victims under certain circumstances and clarifying the liability rules for companies that substantially modify products before resale to extend the product lifecycle (circular economy). It covers all tangible and intangible unsafe products (including embedded or standalone software and digital services necessary for the products' functioning) and modernizes the existing rules on the strict liability of manufacturers for defective products, providing the companies with legal certainty and ensuring that victims get fair compensation when defective products cause harm. The current applicable Directive (PLD) establishes a framework for strict liability (i.e. no fault) regime for defective products across the EU; the new proposal extends the scope of claims that can be brought, expanding the range of damages that can be recovered and simplifying for consumers to prove their case. Furthermore, the proposal established the strict liability for defects resulting from cybersecurity risks, connectivity risks, software updates (or lack of updates), with limited exceptions. On the other hand, as regards recoverable damages, now they comprise not only personal injury, death and damage to personal property, but also loss or corruption of data and medically recognised harm to psychological health. The non-exhaustive list of factors to take into account in assessing defect includes also product safety requirements (including safety-relevant cybersecurity requirements), foreseeable misuse and self-learning abilities.
Regulation (EU) 2023/1230 on machinery and repealing Directive 2006/42/EC and Council Directive 73/361/EEC	This Regulation was adopted by the co-legislators on 14 June 2023 and and published in the Official Journal on 29 June 2023. It addresses machinery products, repealing Directive 2006/42/EC and Council Directive 73/361/EEC. The instrument lays down health and safety requirements for the design and construction of machinery, related products and partly completed machinery, with the main goal of ensuring an high level of protection of the health and safety of individuals (mainly consumers and professional users), and, to some extent, of domestic animals, property and environment. The proposal of Regulation was adopted on 21 April 2021, within the overall legislative package on Artificial Intelligence (AI). It is worth mentioning, first of all, the provisions regarding the risks stemming from the emergence of new technologies, such as robotics, the Internet of Things and Artificial Intelligence. Whilst the current Directive does not deal with the potential risks generated by new technologies, such cobots working alongside human in a shared space, the new source applies also to systems using AI technologies and potentially impactful on the safety of the machine. It is important that the risk assessment considers both the evolution of the behavior of machines designed to operate with different levels of autonomy and the learning phase, implementing adequate safety circuits to limit the behavior of the machine according to the limits considered in the risk assessment. Another case regards the autonomous mobile machines (i.e. without driver), which replace the manual handling of objects in several and diversified sectors (production lines, warehouses, hospitals, etc.): the safety and health protection requirements applicable to mobile machines now also comprises parts for these autonomous mobile machines. Another case pertains to human-machine collaboration: on the basis of the acknowledgement that traditional methods of protecting people (such as the segregation of hazardous areas) are no longer applicable in case of collaborative robots (cobots), whit humans and machines sharing a common workspace. The proposed Regulation therefore modifies the essential safety and health protection requirements pertaining to the risks due to moving elements, in order to ensure the safety of people in collaborative applications, as well as the psychological stress aspects that these work environments can cause. Another aspect regards the cybersecurity risks: the remotely controlled machines must be able to resist malicious attacks, which are increasing due to the larger use of connected technologies, in order to prevent a cyber-attack (for instance from modifying the

	operating settings or deactivating the safety systems of a machinery product, thus posing a risk to the operator). An important revision is the inclusion, for the first time, in the Safety Components of digital components, including software, thereby making this regulation applicable also to intangible products. The software performing safety functions, if placed on the market separately, must have an EU declaration of conformity as well. The Annex I contains the list of products considered to be at high risk: the products are the same of the ones contained in the Annex IV of Directive 2006/42 / EC, but some more have been added: systems providing safety functions and using machine learning approaches and machines incorporating systems with safety functions which have not been independently placed on the market.
"Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics" COM(2020) 64 final	This report, together with the White Paper on Artificial Intelligence – A European Approach to excellence and Trust was adopted in 2020 and highlighted the fact that it is paramount, in order to foster AI growth and its wide adoption, the adequate consideration at policy level of the liability topic, notably the liability for damage caused by AI-systems, especially in relation to high-risk AI systems The White Paper, whilst only sketching the issue of liability and AI, acknowledged the need to improve the legal framework to address the uncertainty regarding the allocation of responsibilities between different actors. Also, the European Parliament's Resolutions adopted in October 2020 called for harmonising the legal framework for civil liability claims and for a regime of strict liability on operators of high-risk AI systems. This Communication was relevant to move ahead in addressing the challenges in terms of product safety and liability related to the emergence of new digital technologies like AI, the IoT and robotics raise and paved the way for the regulatory reforms under development in this domain (on product safety, machinery, liability)
Ethics Guidelines for Trusworthy AI [1] **and ALTAI Assessment List** [2]	The "Ethics Guidelines for Trustworthy Artificial Intelligence" were elaborated by the High-Level Expert Group on Artificial Intelligence (AI HLEG), appointed by the EC in 2018, with the objective to foster an ethical, trustworthy approach to AI, functional to enable responsible and sustainable AI innovation in Europe. The Ethics Guidelines were published in 2019. They are not legally binding: nevertheless, they describe ethical principles relevant to build a trustworthy AI, which must display the following three characteristics :i) Lawfulness, relying on the "human-centric approach" to AI, being fundamental human rights deemed as the foundation of Trustworthy AI; ii) Robustness, considering the ability of AI to operate in any situation, especially if unpredictable events or malicious attacks occur; iii) Ethically-soundness, requiring that the technological design, development and use of AI are compliant with the EU ethical values listed in the Guidelines themselves. The Guidelines, identify ethical principles governing AI and translate them into the following seven ethical requirements for AI technologies: Human agency and oversight; Technical robustness and safety; Privacy and data governance; Transparency; Diversity, non-discrimination, and fairness; Societal and environmental wellbeing; Accountability. The same High-Level Expert Group on Artificial Intelligence (AI HLEG) also elaborated the "Assessment List for Trustworthy Artificial Intelligence" (ALTAI) for self-assessment, presented in its final release on the 17 of July 2020. It is aimed at supporting the actionability of the seven key requirements outlined by the Ethics Guidelines for Trustworthy Artificial Intelligence, by translating them into an accessible and dynamic checklist
EC's Comminications. COM (2020) 65 final, "White Paper on Artificial Intelligence – A European Approach to Excellence and Trust" EC COM (2019) 168 final "Building Trust in Human-Centric AI"	The White Paper was directed to promote a European ecosystem of excellence and trust in AI and, in this direction, it proposed: i) Measures for streamlining research, fostering collaboration between Member States and increasing investment into AI development and deployment; ii) hints for a future EU regulatory framework that would determine the types of legal requirements that would apply to relevant actors, with a particular focus on high-risk applications. On the other hand, the importance to adopt a human-centric approach to AI is stressed in the Communication "Building Trust in Human-Centric AI"
OECD principles	These principles, adopted in May 2019, promote the innovative and trustworthy use of AI, as well as respectful of human rights and democratic values. They principles comprise: i) Trustworthiness and explainability, for improving the trustworthiness of AI systems and interaction between humas and AI systems, enabling understanding of how outputs are generated and the outcomes; ii) Promoting fairness and avoiding biases, for ensuring safe datasets and tools without bias and the proper consequent monitoring of AI systems; iii) Robust, secure and safe AI, regarding traceability of datasets, processes and decisions; systematic risk management to assess privacy, digital security, safety and bias; implement fall back mechanisms; iv) Ensuring privacy and proper governance, dwelling upon the proper governance to foster the availability of data and AI safe development, the protection of users' and data's privacy; the privacy governance implementation; v) Respecting Intellectual Property Rights, for ensuring that copyrighted works used as training data is done properly; vi) Protect innovation around AI and works generated by AI, promoting human oversight and a human-centric AI; vi) Controllability of automated AI systems, regarding Human in the loop.
AI Standards	There is a plethora of standards dealing with different aspects of AI. Considering that the AI Act contains plenty of mentions of standards, it is important to mention also this source, in particular the Harmonised Standards. "Harmonised standards" means standards aligned with EU directives and legislation, the adherence to which ensure that the products and applications delivered are aligned

	with European laws and values. This kind of standards will play an important role in the operational aspects of the compliance with the AIA. The existing standards, mainly by ISO, can be classified (with a not exhaustive list) in: Robust, secure and safe AI. O ISO/IEC 25059: Quality model for AI systems. O ISO/IEC DTR 5469: Functional safety and AI systems. O ETSI SAI: Several standards on securing AI. System Operations O ISO 17065: Conformity assessment. Requirements for bodies certifying products, processes and services. O ISO/IEC 23053: Framework for AI Systems Using ML. O ISO/IEC 22989: AI concepts and terminology. Trustworthiness and explainability. O ISO/IEC CD TS 6254: Objectives and approaches for explainability of ML models and AI systems. O ISO/IEC TR 24028: Overview of trustworthiness in AI. O ETSI GR SAI 007: Explicability and transparency of AI processing. Promoting fairness and avoid biases. O ISO/IEC TR 24027: Bias in AI systems and AI aided decision making. O ISO/IEC DIS 5259: Data quality for analytics and ML. O IEEE ECPAIS: The Ethics Certification Program for Autonomous and Intelligent Systems. AI and Data Governance. O ISO/IEC CD 42005: AI system impact assessment. O ETSI ENI GS 001: Specifications for a Cognitive Network Management system. Promote Human oversight and a human-centric AI. O ISO/IEC TS 8200: Controllability of automated artificial intelligence systems. O ISO/IEC AWI 42105: Guidance for human oversight of AI systems. Data interoperability ISO 20614: Data exchange protocol for interoperability and preservation.
Data	
European Data Strategy COM (2020) 66 final, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions “A European strategy for data”	The European Data Strategy is directed to create a single market for data that will ensure Europe’s global competitiveness and data sovereignty, rotating around access to data and the ability to use as paramount for innovation and growth. In this framework, it emphasizes the role of the Common European data spaces for ensuring that more data becomes available for use in the economy and society, while keeping the companies and individuals who generate the data in control. The Data Governance Act and the Data Act were adopted as part of its data strategy.
Data Act Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act)	The Data Act contains provisions for ensuring fair access and use of data functional to allow to the users to stay in control (individuals or businesses) and with a focus on interoperability and data processing. It was proposed by the EC on 23 February 2022. A political agreement was reached by the European Parliament and the Council on 28 June 2023. Following its entry into force, the Data Act will become applicable in 20 months, i.e. 12 September 2025. The new rules define the rights to access and use data generated in the EU across all economic sectors and will make it easier to share data, in particular industrial data. The Data Act is applicable to manufacturers and users of products, data holders, data recipients, and public sector bodies in the EU, as well as providers of data processing services. It fosters the fairness in the digital environment by clarifying who can create value from data and under which conditions. It will also stimulate a competitive and innovative data market by unlocking industrial data, and by providing legal clarity as regards the use of data. It provides a framework to make more data available for use, clarify the rules governing data usage and for which purposes across all economic sectors in Europe. The users of connected products are enabled to access the data generated by the devices, and to share such data with third parties. Public sector bodies are entitled to access and use data held by the private sector to help respond to public emergencies or when implementing a legal mandate. The businesses are protected from unfair contractual terms in data sharing contracts that one contracting party unilaterally imposes on the other. This is very important for the small and medium-sized enterprises (SMEs) and might allow them to participate more actively in the data market. The customers are allowed to switch seamlessly (and eventually free of charge) between different cloud providers. There are also measures to promote the development of interoperability standards for data-sharing and for data processing services, in line with the EU standardisation strategy.

Data Governance Act (DGA) Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 may 2022 on European Data Governance and amending Regulation (EU) 2018/1724 (Data Governance Act)	The DGA is an important part of the European strategy for data, and in particular for increasing trust in data sharing, strengthening mechanisms to increase data availability and overcomeing technical obstacles to the reuse of data, as well as for supporting the set-up and development of common European data spaces in strategic domains. The Data Governance entered into force on 23 June 2022 and, following a 15-month grace period, is applicable since September 2023. It comprises mechanisms and/or measures: i) aimed at simplifying the reuse of certain public sector data that cannot be made available as open data, such as health data; ii) ensuring that data intermediaries will function as trustworthy organisers of data sharing; iii) facilitating for citizens and businesses making their data available for the benefit of society; iv) facilitating data sharing, making it possible for data to be used across sectors and borders, and enabling the right data to be found for the right purpose. The DGA seeks to increase trust in voluntary data sharing for the benefit of businesses and citizens, fostering mechanisms to increase data availability and overcome technical obstacles to the reuse of data. Wherever personal data is concerned, the General Data Protection Regulation (GDPR) applies.
GDPR Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)	The GDPR is a comprehensive regulatory framework, repealing the Directive 95/46/EC, which lays down provisions for ensuring that personal data enjoys a high standard of protection everywhere in the EU and for giving individuals back control over of their personal data. It became a model for many other laws around the world, such as Turkey, Japan and Brazil.The personal data can only be gathered and handled legally under strict conditions and for a legitimate purpose. The subjects collecting or handling personal information must protect them from misuse and respect data subject's rights. The Regulation comprises provisions on the responsibilities for organisations to ensure the privacy and protection of personal data and also foresees data subjects' rights. Its main provisions, whose complete description falls outside the scope of this deliverable, regard: lawful, fair and transparent processing; limitation of purpose, data and storage; data subject rights; consent and other legitimate basis for the data collection and processing; personal data breaches, Privacy by Design paradigm; Data Protection Impact Assessment; Data transfers; Data Protection Officer; Awareness and training
Regulation on the free flow of non-personal data Regulation 2018/1807 on a framework for the free flow of non-personal data in the European Union	This regulation lays down rules applicable to any kind of data other than personal data and is directed to give rise to a harmonized approach to the free movement and portability of data in the EU, as well as to improve legal certainty and create a level playing field for all market players. It complements the GDPR provisions in aspects related to non-personal data within the Digital Single Market.

e-Privacy Directive Directive 2002/58/EC on privacy and electronic communications, replacing the Directive 97/66/EC and partially amended by Directive 2009/136/EC **e-Privacy Regulation Proposal** COM(2017) 10 final 2017/0003, "Proposal for a Regulation of the European Parliament and of the Council concerning the respect for private life and the protection of personal data in electronic communications and repealing Directive 2002/58/EC (Regulation on Privacy and Electronic Communications, ePrivacy Regulation)	The ePrivacy Directive regulates the processing of personal data and the protection of privacy in the sector of electronic communications, telecommunications networks, and internet services, complementing the GDPR in this domain and extending on some of its requirements considering the specificities of communications services. It comprises the obligation of taking security measures adequate to the risk, the protection to confidentiality of the communications among individuals, rules for the traffic data and location data and user's consent, data retention, and others. In order to modernize this framework, the EC adopted the proposal of Regulation on Privacy and Electronic Communications (E-privacy Regulation), though objectives and principles are unchanged. The proposal is an effort to better align with GDPR provisions and to address new challenges to privacy. The proposal "applies to the processing of electronic communications data carried out in connection with the provision and the use of electronic communications services and to information related to the terminal equipment of end-users". It is not clear when it will enter into force. However, it is important to monitor its progress and align with it.
Open Data Directive (including High Value Datasets) **Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information (recast)**	It concerns open data and the re-use of public sector information, laying down common rules for a European market for government-held data for making public sector and publicly funded data re-usable, building around two key strands of the internal market: transparency and fair competition. It entered into force on 16 July 2019, replacing the Public Sector Information (PSI) Directive. In January 2023 the EC published a list of high-value datasets that public sector bodies to be made available for re-use, free of charge, within 16 months. The Directive defines six categories of such high-value datasets, which might be extended at a later stage to reflect technological and market developments: geospatial, earth observation and environment, meteorological, statistics, companies and mobility. They have to be available in machine-readable format, via an Application Programming Interface and, where relevant, as bulk download. These datasets have a high commercial potential and can speed up the emergence of value-added EU-wide information products. They will serve as key data sources for the development of Artificial Intelligence
IDSA Rulebook 2023	The IDS Data Sovereignty paradigm is expected to help in building trust in data sharing thanks to the technological enforcement of contractual provisions for enabling the data providers to keep a certain control and self-determination over the reuse of the data they provide. An important document concerning the IDS Data Sovereignty is the IDSA Rulebook *[3]*. Its version 2.0 has been elaborated to facilitate the application of the IDS architecture as a basis for data spaces, supporting the data space initiatives in defining their rules, governance mechanisms, and legal basis. This Rulebook i) offers guiding principles for building and defining data spaces with architectures and rules rotating around the data sovereignty principle and ii) provides the requirements to develop. and operate data spaces based on IDS, listing mandatory and optional functionalities that a data space can have.
Study on technological and economic analysis of industry agreements in current and future digital value chain *[4]*	The Industry Agreement (or Industrial Agreements, IA) are an important tool for the design, development and future uptake of the data space for manufacturing and for the collaboration among key players, providing the industry players with a taxonomy of key aspects to investigate for the adoption of common rules, the definition of voluntary B2B data sharing schemes, as well as to set a minimum quality standards or common performance measures/ metrics functional to reduce information asymmetries within the supply/value chain and between industry and their customers They can be defined as "bi- or multi-lateral (voluntary) contractual frameworks/model agreements, designed to support the development and functioning of such data spaces…they are designed to address the

	different building blocks required to develop an industrial data space – technical specifications (e.g. IAA, exchange protocols), data specifications (e.g. data structure, semantics) and governance and legal dimensions – encompassing all possible stages of the data life cycle" *[5]*. The "Study on technological and economic analysis of industry agreements in current and future digital value chain" *[5]* outlines an analysis of the Industry Agreements. It also identified factors representing barriers for the industry players for the development and implementation of IAs, such as the lack of trust among the stakeholders, data quality, technical complexity and regulatory uncertainty
Miscellaneous	
2030 Digital Compass & Path to the Digital Decade COM(2021) 118 final. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, "2030 Digital Compass: the European way for the Digital Decade. Decision (EU) 2022/2481 of the European Parliament and of the Council of 14 December 2022 establishing the Digital Decade Policy Programme 2030	The Digital Compass Communication, published on 9 March 2021, outlines the EC's priorities for a successful digital transformation of Europe's economy and society by 2030. It encourages to agree on a set of digital principles and to prepare a legislative proposal setting out a robust governance framework, empowering businesses and people in a human-centred, sustainable and more prosperous digital future, with the focus ondigital skills, digital infrastructures, digitalisation of businesses and public services. The Path to the Digital Decade depicts the concrete plan to achieve Europe's digital transformation by 2030. The Digital Decade policy programme is guiding the Europe's digital transformation, encompassing also an annual cooperation mechanism involving the Commission and Member States.
The Digital Services Act Package: European Digital Services Act (DSA) & European Digital Markets Act (DMA) European Digital Services Act (DSA): Regulation (EU) 2022/2065 of the European Parliament and the Council of 19 October 2022 on a Single Market for Digital Services and amending Directive 2000/31/EC (Digital Services Act) European Digital Markets Act (DMA): Regulation of the European Parliament and the Council of 14 September 2022 on contestable and fair markets in the digital sector and amending Directives (EU) 2019/1937and (EU) 2020/ 1828 (Digital Markets Act)	The Digital Market Act (DMA), entered into force on 2 May 2023, concerns competition and targets the largest cloud players, which are essential for AI systems and regulates internet corporations/gatekeepers (e.g., social media platforms, search engines), safeguarding users by prohibiting practices that make it difficult to use non-gatekeeper providers. By renovating the landscape set by the e-Commerce Directive, it is expected to become a standard-setter at global level, addressing the online marketplaces and consumer trust in the digital economy, requiring the respect for users' fundamental rights and advocating for rules to underpin a competitive digital environment in Europe. The Digital Service Act (DSA), on the other hand, addresses the protection against illegal content and users' rights, as well as regulates liability. It applies to intermediary services and online platforms. It will enter into force on February 16, 2024 (some provisions apply earlier), providing rules without prejudice to the e-Commerce Directive and the GDPR.

e-commerce Directive Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (e-Commerce Directive) **Platform-to-Business Regulation** Regulation 2019/1150 on promoting fairness and transparency for business users of online intermediation services (Platform-to-Business Regulation - P2BR)	The e-Commerce Directive, adopted in 2000, represents the key legal framework for online services in the EU. It is directed to remove obstacles to cross-border online services and was paramount in the development of online platforms in Europe, setting out, among other aspects, harmonised rules on the transparency and information requirements for online service providers and on electronic contracts and limitations of liability of intermediary service providers, besides enhancing the role of self-regulation. On the other hand, the Platform-to-Business Regulation (P2BR), which is part of the legislative measures promoted by the EC for the Digital Single Market strategy, establishes rules in the area of business platforms for creating a fair, transparent and predictable business environment for smaller businesses and traders on online platforms. It is directed to ensure that the consumers receive the highest quality goods and services. Among other, it encompasses a list of fairness and transparency-oriented measures towards tempering the natural asymmetries characterizing the relationship between the platforms and their suppliers, in view of giving rise a fair and trustworthy innovation-driven ecosystem. It also contains the settlement of effective out-of-court redress mechanisms such as internal handling systems for business users and mediation procedures.
Directive on contracts for the supply of digital content and digital services Directive 2019/770 on certain aspects concerning contracts for the supply of digital content and digital services	This Directed, adopted on 20 May 2019, together with the Directive (EU) 2019/771 on certain aspects concerning contracts for the sale of goods (the "Sales of Goods Directive"'), complement the Directive 2011/83/UE on consumer rights, in order to achieve a genuine digital single market. It ensures a high level of protection to consumers paying for or providing personal data in exchange of digital content and services. Furthermore, it imposes that digital contents or services fit to their expected purposes and have the qualities and performance features, which the consumer may reasonably expect.
European Convention on Human Rights, adopted in 1950 (Rome, 4 November 1950) **Charter of Fundamental Rights of the European Union** (2000/C 346/01)	These sources, together with the milestone document in the history of human rights (Universal Declaration of Human Rights, 1948) enshrine into EU law a wide array of fundamental rights enjoyed by EU citizens and residents, setting common European standard of achievements. The European Court of Human Rights' jurisprudence is a useful instrument for interpretation of human rights legislation.
NIS 2 Directive Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive)	Despite from a legal perspective, the requirements related to security are mainly coming from the GDPR and the ePD, it is important to consider also the NIS2 Directive, offering guidance and technical indications for the operators of essential services and Digital Service Providers. The Directive is an EU-wide legislation on cybersecurity, laying down legal measures to boost the overall level of cybersecurity in the EU. The Network and Information Security (NIS) 2 Directive was adopted in November 2022 and became enforceable as of 16 January 2023. By 17 October 2024, Member States must adopt and publish the measures necessary to comply with the NIS 2 Directive. Directive (EU) 2016/1148 (the NIS Directive) is repealed with effect from 18 October 2024. The NIS2 Directive ensures that cybersecurity measures are taken across seven sectors, which are vital for our economy and society, and which rely heavily on ICT, such as energy, transport, banking, financial market infrastructures, drinking water, healthcare and digital infrastructure. The Directive updated the existing legal framework to keep up with increased digitisation and an evolving cybersecurity threat landscape, providing legal measures to boost the overall level of cybersecurity in the EU

4.2.2 Regulatory Framework relevant to Circular TwAIn Pilots

WEEE Pilot

Table 7: WEEE Pilot Regulatory Framework

Regulatory Source	*Relevant content*	*Legal and/or ethical issues concerned*
Spanish Royal Decree 283/2001 of 16 March 2001 amending certain articles of the Corporate Income Tax Regulations on the deduction for investments in environmental protection.	Article 40 addresses environmental protection, amongst others to promote the reduction, recovery, or treatment of industrial waste.	This Royal Decree creates fiscal incentives for companies for investments contributing to environmental protection and can therefore promote eco-innovation.
Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives	How be this regulatory source applied to the Circular TwAIn experiments?	The Directive establishes the legislative framework for the handling of waste. It defines key concepts such as waste, recovery and disposal and puts in place the essential requirements for the management of waste, notably an obligation for an establishment or undertaking carrying out waste management. It also establishes major principles such as an obligation to handle waste in a way that does not have a negative impact on the environment or human health. The Directive encourages to apply the waste hierarchy (prevention, preparing for re-use, recycling, other recovery, disposal) and, in accordance with the polluter-pays principle, a requirement that the costs of disposing of waste must be borne by the holder of waste, by previous holders or by the producers of the product from which the waste came.
RoHs Directive: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment Text with EEA relevance	How be this regulatory source applied to the Circular TwAIn experiments?	EU legislation restricting the use of hazardous substances in electrical and electronic equipment (EEE) and promoting the collection and recycling of such equipment. The legislation provides for the creation of collection schemes where consumers return their used waste EEE free of charge. The objective of these schemes is to increase the recycling and/or re-use of such products. The legislation also requires certain hazardous substances (heavy metals such as lead, mercury, cadmium, and hexavalent chromium and flame retardants such as polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE)) to be substituted by safer alternatives.
Law 2/2011, of 4 March, on Sustainable Economy	How be this regulatory source applied to the Circular TwAIn experiments?	Transversal legislation on sustainable economy. Includes public procurement rules focusing amongst others on the savings and efficient use of materials, the environmental lifecycle costs, processes and methods of ecological production, the generation and management of waste, the use of recycled, reused, or ecological materials.
Law 22/2011, of 28 July, on waste and contaminated soils.	How be this regulatory source applied to the Circular TwAIn experiments?	Transposes Directive 2008/98/CE, the Waste Framework Directive.
WEEE Directive: Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)	How be this regulatory source applied to the Circular TwAIn experiments?	The objective of the Directive is to promote re-use, recycling, and other forms of recovery of waste electrical and electronic equipment (WEEE) in order to reduce the quantity of such waste to be disposed and to improve the environmental performance of the economic operators involved in the treatment of WEEE. The WEEE Directive sets criteria for the collection,

		treatment, and recovery of waste electrical and electronic equipment.
Royal Decree 110/2015 of 25 February **on wastes of Electric and Electronic Equipment**		This Royal Decree is key to the topic of circular economy as it is the main instrument for the treatment of electrical and electronic products. It transposes Directive 2012/19/UE. It takes better into account the whole value chain and details the obligations of the different stakeholder categories. It sets concrete objectives and targets not only for the recycling but also for the reuse of EE products (the only EU member state to set targets for reuse) and creates "Centres for Reuse". It creates a harmonised data management at both the national and Comunidades Autónomas (CCAAs) level, to guarantee traceability. It also systematises the obligation of information on the part of the producers.
General Data Protection Regulation (Regulation (EU) 2016/67952)	How be this regulatory source applied to the Circular TwAIn experiments?	Provisions on the processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes
Royal Decree 1364/2018 of 2 November amending Royal Decree 219/2013 of 22 March on restrictions on the use of certain hazardous substances in electrical and electronic equipment.	How be this regulatory source applied to the Circular TwAIn experiments?	This Royal Decree modifies RD 219/2013, to promote the transition to a circular economy. Its purpose is to facilitate secondary market operations that involve the replacement of spare parts, the updating of functionalities, or the improvement of capacity, thus allowing the reuse of electrical and electronic devices. It includes provisions for certain equipment to remain in the production and consumption cycle for longer, thus limiting the waste that comes from electrical and electronic equipment.
Law 7/2022 of 8 April on waste and contaminated soils for a circular economy.	How be this regulatory source applied to the Circular TwAIn experiments?	Among the aspects of Law 22/2011 of 28 July that are subject to revision are the responsibility of the waste producer, the application of the concepts of by-product and end-of-waste, the updating of the penalty regime and the reinforcement of separate collection, which is mandatory for some waste fractions in all areas, not only in households, but also in the service and commercial sectors, in order to enable high quality recycling and stimulate the use of quality secondary raw materials. This separate collection, in the area of waste under local responsibility, will also facilitate increased rates of preparation for re-use and recycling and will lead to substantial environmental, economic and social benefits and accelerate the transition to a circular economy

Battery Pilot

Table 8: Battery Pilot Regulatory Framework

Regulatory Source	Relevant content	Legal and/or ethical issues concerned	Other
Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC	It frames end-of-life mobility batteries in the wider category of "batteries and accumulators", imposing their waste management accordingly	E-mobility batteries are covered by the Extended Producer Responsibility concept. The stakeholder commercializing a battery, namely the carmaker, must guarantee the legally compliant management of batteries at their end of life. There are two options: - The carmaker manages autonomously the network of collection and recycling of the battery. - The carmaker assigns the management of its end-of-life batteries to a third party, namely the transport and logistic waste manager.	The business scale-up of any pilot result must be compliant with the law in force about the management of end-of-life batteries.
Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020	It better defines the family of mobility batteries. It introduces the digital product passport.		No final version of the law available yet.

Petrochemical Pilot

Table 9: Petrochemical Pilot Regulatory Framework

Regulatory Source	Relevant content	Legal and/or ethical issues concerned
ISO 14001, Environmental Management System	It helps organizations improve their environmental performance through more efficient use of resources and reduction of waste, gaining a competitive advantage and the trust of stakeholders. This improvement can take many forms, such as improved communications and employee awareness, improved environmental performance, and improved emergency planning and response programs.	Lowering CO2 emission
ISO 50001, Energy Management System	It provides a framework of requirements for organizations to develop a policy for more efficient use of energy, fix targets and objectives to meet the policy, use data to better understand and make decisions about energy use, measure the results, review how well the policy works, and continually improve energy management.	Lowering energy consumption
ISO 9001, Quality Management System	It helps businesses and organizations be more efficient and improve customer satisfaction. The primary focus of the ISO 9001 standard is to meet customer requirements and strive to exceed customer expectations. The standard is based on seven Quality Management Principles, including a strong customer focus, the motivation and implication of top management, the process approach and continual improvement.	Improvement of the production process
Environmental Law and Regulation on Environmental Management Services, Law no 2872	The purpose of this Law is to protect the environment, which is the common property of all living things, in line with the principles of sustainable environment and sustainable development. Obligation to audit, inform and notify about hazardous waste, hazardous chemicals, and dirty ballast etc.	Lowering CO2 emission

4.3 First Consultation with Stakeholders

The first consultation with stakeholders was conducted by the Consortium in order to capture their needs and expectations in relation to Circular TwAIn approach and trajectories, focusing on human-centricity and trustworthiness, as well as regulatory and ethical implications. It was launched online in June 2023 and remained open till mid-October 2023. The survey was directed to stakeholders of the manufacturing value chain, such as Regional Authorities/Agencies, other Public Authorities, Civil Society Organisations, Innovation Agencies, Vanguard Initiatives representatives, representatives from the workers, technology and/or service providers, etc.

The structure of the consultation consisted of the following sections:

- Section 1 **"About you"**
- Section 2 "Artificial **Intelligence and Data Spaces for Circular and Resilient Manufacturing"**
- Section 3 "**AI-enabled Human Digital Twins"**
- Section 4 "**Trustworthy Artificial Intelligence**
- Section 5 "**The evolving regulatory framework**

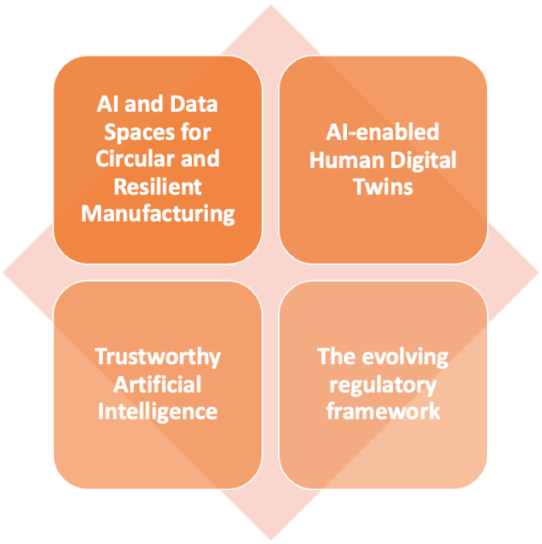


Figure 11: Key sections of the Consultation with Stakeholders

The main findings of the survey are reported on the next pages.

4.3.1 Artificial Intelligence and Data Spaces for Circular and Resilient Manufacturing

1. According to the respondents, the **most important features and services that an Industrial Data Platform (IDP) should have for supporting the circularity needs** have been identified include:
    - collaboration between the stakeholders along the value chain and information about the processes available.
    - resource optimization and good practices.
    - decision support system. Improved Decision Making towards optimized resource-usage in manufacturing and supply chains.
    - data sharing and data management, as well as quality of the data, data integration and aggregation, real-time data monitoring, data security and privacy, but also data collection and storage, data analytics, data visualization. Quality and Reliable Data, Compliance to Regulations, Data Richness, Data Sovereignty, Support for Data Processing/Analytics/Decision Making
    - integration with external systems, scalability, flexibility, traceability, collaboration and stakeholder engagement, certification, visualization, reporting, supporting optimization and simulation models.
    - information about product content and CRM's. Information about import of products, expected lifetime and use of data to estimate when it becomes waste. Origin of products, tracking of products, life cycle, CO2 eq, reused or new, repaired history. Knowing the traceability associated with a product and its associated components, from its manufacture to its correct recycling.
    - enable interoperable exchange of different platforms and protocols.
    - interconnectivity, Interoperability & Semantics homogeneity. Easy connection with existing platforms, systems and hardware already in place; Extensibility for new services and data sources; Standard compliance
    - excellent accessibility.
    - real time and easy access.
    - a fast search engine
    - tracking of Components, detecting their quality and ability for reusability
2. **AI can have a significant impact on promoting the Circular Economy (CE)** especially in these cases:
    - Resource optimization, where AI and CI are used to optimize the use of resources and reduce waste in manufacturing and supply chain processes.
    - Recycling and waste management, in which AI and CI can improve the efficiency and accuracy of recycling and waste management processes.
    - Sustainable design, where AI and CI serve as assistants in designing products and processes that are more sustainable.
    - Consumer behavior, where AI and CI can be exploited to promote more sustainable consumer behavior by providing personalized recommendations and feedback.

- Comparison of circularity and sustainability of different products in the market.
- Design for circularity, where AI and CE serve as assistants in designing products that are more circular.

3. **CE could support the AI in making decisions and provide inputs to AI for assessing the environmental burdens and circularity metrics** in each scenario. Notably, the respondents underlined that:
    - CE and AI should be aligned to enhance the attributes of each of them. In this sense, CE requirements should be included among the parameters to be considered for the AI.
    - clear CE criteria should be created that AI can use for decision making and problem solving.
    - it is unclear what possibility AI has for the circular economy yet. Despite the large availability of data and information nowadays, it is still not well identified if and how this can be utilized best with AI.
    - in a feedback scenario, the feedback model itself would generate improvements in the CE system itself, continuously improving thanks to AI. Many of these improvements are subject to data availability and bureaucratic simplification when diversifying waste and by-products management flows.
    - Circular Economy (CE) and Artificial Intelligence (AI) can work together to produce a powerful synergy that improves AI systems' ability to evaluate environmental impacts, optimize circularity metrics, and aid in decision-making processes. AI plays a critical role in accelerating the transition to a more sustainable and circular economy by leveraging the guiding principles and data-driven approaches of CE.
    - concerning the automotive battery, CE should require from producer a comprehensive label, and aligning production of batterie with same characteristics and most important same shape.
    - Circular economy can provide AI with data on the environmental impacts of different materials and products. This data can be used to train AI models to assess the environmental burdens of different scenarios. For example, AI could be trained to predict the amount of waste generated by a manufacturing process, or to estimate the energy saved by using recycled materials.
    - CE should provide the boundary conditions to impose the limit for AI reasoning, including optimization goals.
    - CE could support AI: knowing the objectives of CE and circularity indicators could be useful to implement the right AI tools.
    - This could be done by introducing the economic and environmental constraints, as well as by using CE indicators when comparing products and providing recommendations. AI should have focus on CE by suggesting how or where to repair and how to report reuse of products. Suggest the best recycling option, provide information about critical raw materials in products and so on. On the other hand, this could be achieved if comprehensive and real data is collected and summarized correctly, e.g. of Product from manufacturing to recycling. This data can be used afterwards to support the AI in making decision for the next

generation of the product. Data coming from CE loop can be helpful for training and using AI modules.

- It is important that funding research topics incline AI for circularity.
- Circular economy could support AI-based decision making by proving circular aspects to be considered. Specifically, the use of circular metrics (formulas and parameters) can be an input to AI for making decisions on the status of a component / product integrating circular aspects.
- AI should assist CE stakeholders to evaluate alternative decisions (e.g., product designs) faster.
- There may be a connection between a life cycle analysis (LCA) of a product from which data associated with environmental impacts are extracted and these in turn are connected to AI that identifies which of them should be substituted by other types of materials that are less scarce or generate a lower environmental impact.
- especially the data about the product operation and usage can provide relevant information for AI. However, this imply that a DPP should be updated and moved in all the steps of the lifecycle of the product. It is key the provision of additional types of data and information, as well as considering CE background knowledge.
- AI could be a tool to support CE, not the other way around. AI could facilitate the sharing and interpretation of life-cycle information and thus help to apply the right CE strategy.

4. The **most important features and services** that an **Industrial Data Space for circularity data** (i.e., waste, CO2, energy consumption, etc.) should have to effectively support AI application modules (for instance those covering materials, products or processes) include:
    - Depending on the application of the AI, different features apply. For instance, in AI is being applied in waste management, then you need to consider parameters related to the materials of the product/waste, processes to apply, potential outputs, etc.
    - optimal decision making in circular value chains, CO2 reduction, waste reduction, recycling, easy integration, information on waste and CO2 from the whole lifecycle.
    - management of confidential data, private access, data validation
    - how to best utilize/exploit the different materials from a recycling process. Most important is how we can secure reuse of materials, CRM's and so forth.
    - It is important to access to the categories of waste (standard categories, for example, the European List of Waste), logistics costs, and CO2 savings, among others, to determine synergies and areas of use and improvement. Likewise, the system itself should be seen as a market, that is, it should allow information to be exchanged between companies interested in doing business with the affinity of their processes, either by using waste or by outsourcing intermediate activities.

- Integrating and standardizing data, real-time monitoring, advanced analytics, visualization capabilities, simulation and what-if analysis, seamless integration with external systems, fostering collaboration, and ensuring robust data security are key features and services that an Industrial Data Space for circularity data should have to effectively support AI application modules covering materials, products, or processes.
- Provide information about carbon footprint of materials, information about material supply chain.
- Data collection and storage, Data analytics, Data visualization, Collaboration.
- In CE it is often useful to match demand and response in terms of materials.
- Energy consumption, water consumption, waste production, CO2 emission, by-product utilization
- Access to data (clean, filtered, aggregated, reliable data).
- Features and services to support products-oriented AI modules 9-10-11: - circular metrics calculation - to retrieve and store circular data per product (i.e. products breakdown components composition, regenerative or recycling flows, waste)
- data traceability and storage that later will be used by the AI applications.
- Wastes due to inefficiencies of the production process (e.g., product/process defects), wastes linked to materials, CO2, Machines Energy Consumption, Materials Energy, CO2 linked to logistics and supply chain process.
- data of a product lifecycle. So, it should have CO2, energy consumption and much more.
- the environmental impact associated with a product/component or material indicating different impact categories (CO2, water use, land use, eutrophication...) or also indicating the potential exploitation areas of that material and existing reserves.
- The mechanisms for data sharing should be simpler. Effective communication protocols that enable data sharing of live data from processes, products, and materials. Standardization of the data models (AAS for processes and products, DPP in AAS, etc.).
- It is difficult to answer this question (and the previous one) because an IDS is not defined. E.g. meta model definition and representation, API for it, traceability service, etc.
- collect and share consistent and semantic-rich data across different stakeholders in a trustworthy environment.
- Tracking of all the parts incl. their history

5. It was investigated **the stakeholders' perception in relation to the various challenges and barriers** that might inhibit the development and growth of the Data Space for the sharing of circularity data and generate a lack of trust among the industrial players and stakeholders. These challenges and barriers were identified especially as related to:

- the concerns and security issues related to the datasets potentially comprising protected/sensitive information, including the data protection, the commercially sensitive information, the trade secret protection, and the IP protection.
- the uncertainties regarding the evolving regulatory framework governing the status and value of data and data sharing, as well as its practical implications on the data sharing operations: businesses are often unsure if they are allowed to share data and under what conditions.
- the fear of losing the competitive advantage or the negotiation power when disclosing business information and Reluctance to share data with other stakeholders.
- the lack of certainties regarding data ownership.
- the concerns on how data will be used or reused when they are further aggregated.
- the concerns regarding the liability for inaccurate / erroneous data (which is closely related to "data quality").
- the uncertainties about the principles applicable to data sharing operations and about the definition of roles and processes.
- the integrity of the systems used to collect, exchange and store data (i.e., distrust in the system).
- Any attempt to support CE with technology should come with minimal additional costs and proven ROI.
- lack of knowledge to implement and operate AI-based CE-systems.

6. In the **development and operation of efficient industrial Data Space for Circular Manufacturing** it is important to ensure (in order of importance, according to the most of the stakeholders' perception):
    - IDS Data Sovereignty paradigm, to ensure the data sovereignty/ownership rules and policies.
    - Development of technical specifications and technical agreements (e.g., building reference architectures, interoperability frameworks, common standards platforms, assessments and criteria) to assure security and interoperability.
    - Solutions to technical challenges (e.g., secure technical infrastructure to support secure communications between parties), including safeguards at technological level for instance for the case of exchange sensitive information. More in general a set a series of technical measures should be ensured to help to build trust, to protect the confidential information and the data sovereignty/ownership.
    - Appropriate access and rights for data (re)use, and modalities (e.g., where data is stored, governance models) and time limits on use.
    - Efficient data governance mechanism

    Some respondents also considered: i) A level playing field, capable of avoiding disruption to competition and the emergence of monopolies/oligopolies; ii) Appropriate consent tools; iii) Operational agreements (including governance models, shared

operational processes, etc.) to establish trust for data re-use, to clarify the scope of secondary usage and, in general, to set common frameworks and rules for data sharing functional to build trustworthy relationships and a trusted environment for data sharing within and across industries; iv) Secure identification of users to avoid impersonation of users and access to confidential data; Interoperable semantics and ontologies for the seamless transaction of DATA (AAS, DPP, v) Integrate the Data Space with Internet of Things (IoT) devices and sensor networks to capture real-time data from machines, equipment, and other connected objects. This allows for continuous monitoring of production activities, tracking of material flows, and collection of environmental data for assessment of sustainability. Creating a flexible and modular architecture for the Data Space to handle changing business requirements and growing technology. This enables the easy integration of new data sources, applications, and services, as well as the capacity to adapt to developing circular manufacturing standards and protocols; vi) Trust between actors, sources data tracking, embedding database for any kind of manufacturing; vii) Security, Scalability; viii) data ownership ix) Circular Economy principles x) Intellectual Property (IP) Protection, Regulatory Compliance (e.g., GDPR, AI Act compliance); xi) The ability to share information in a fast an efficient way with little overhead in communications in order to support the information; xii) Standard conformance, use of commonly agreed semantics

4.3.2 AI- enabled Human Digital Twins

7. The stakeholders envisaged the following opportunities of the HDT in the workplace (in order of importance, according to most of the stakeholders' perception):
    - Identification of potential safety hazards and improvement of worker's safety, as well as more in general, identification of potential issues and thereby reduction costs by identifying them before implementing changes in the real world; Optimization of worker movements and improvement of ergonomics in the workplace, as well as of human in the loop processes. Support Industry 5.0 transition. Optimization of production processes.
    - Training of workers and simulation of different scenarios, for instance for evaluating the impact of changes in the production process (such as the introduction of new equipment or the implementation of new safety protocols);
    - Automation for implemented processes, reducing training times with operators or supervisors.
    - Emergence of potential new skills for workers in the future.
    - Identification and bringing a worker's knowledge gap.
    - Synchronisation of the real and physical world.
8. The following potential legal and ethical issues are perceived by the stakeholders (in order of importance, according to most of the stakeholders' perceptions):
    - Personal Data Challenges: the full exploitation of the potential of the HDT entails personal data collection, processing, and use. This regards not only to the real-time monitoring solution of the human-centered processes but also the worker himself/herself (physical twin) to capture his/her skills, preferences, memories, even the mood, fear/excitement, interactions with other people. In this way, the HDT will be able to analyze past behavior and predict the operator's needs and wishes, making appropriate suggestions.

- HDT can have a negative effect on the human interactions in the workplace: for instance, people could put their trust in the HDT instead of in human colleagues. This is a completely new situation extending not only to the cognitive but also the emotional dimensions in unpredictable ways. The problem might increase if more than one HDT are involved.
- Risk of discrimination and biases: for instance, if the data used to train machine learning don't accurately reflect the characteristics of a workforce, the predictive analysis by the digital twin could be misleading or even discriminatory.
- Potential inequities in the use of HDT: the high upfront costs of them (for instance related to high-performance computing) could create access and affordability issues for less affluent companies (such as SMEs and start-ups)
- Existing standards and regulations for digital twin implementation may not be adequate to address their application in complex systems.
- Liability issues in the complex interaction between human and autonomous systems' behavior across AI systems in the smart manufacturing context.

On the other hand, a minor part of the respondents also mentioned the following concerns:

- The workforce might become unsecure and afraid that its work will be replaced with an HDT. Fear that the HDT substitute the human operator.
- Difficulties might arise regarding how to represent human expertise, experience, long-term and short-term goals, etc. and how this information can be combined with real-time information about worker behaviour, movement, performance, etc.
- Many unexpected challenges might arise in the process, and some of them probably not expected during the preparation phase or even in the implementation and integration, such as possible unintended reactions of workers.
- Issues related to the framework for which the HDT is being designed, to make operators aware that HDT is intended to offer a collaboration and not a replacement of our criteria.
- Accuracy and liability of the model.
- Lack of trained personnel.

9. As regards some specific ethical challenges that might occur, the following feedback was provided by the participants:
    - Most of them do not know if the HDT might increase the **risk of stigmatization** for the worker and consequent social sorting; although some of them believed so, whilst others had the opposite opinion.
    - The risk of over-reliance on the machine for the operators, which might affect human autonomy, is considered high.
    - The risk of development of a disproportionate attachment to the AI System (and the subsequent risk of addiction) is considered low.
10. The main benefits and challenges of Industry 5.0 and the Collaborative Intelligence paradigm for the workers have been identified as follows:
    - Main benefits:

i. If the integration of both concepts is successful, then workers may have many improvements in their performance.
ii. enhanced decision making, by making people using the info the best possible way.
iii. Increased Efficiency and Productivity of the Worker and of the Manufacturing Enterprise.
iv. Better Ergonomics and Ease of Use of the Production System
v. possibility of consulting quickly a wide dataset and obtaining advice for any kind of issues.
vi. improved safety.
vii. increased creativity, individual support.
viii. improved collaboration between robots and humans.
ix. Better efficiency, increased quality and standardization.
x. It could motivate workers and improve the quality of their work, but it might also be the opposite.
xi. logical splitting of tasks between machines and humans. (repetitive, harmful tasks = machine; complex, interesting tasks = human)
xii. Providing DSS to operators and management.
xiii. human relieved from "easy" decisions.
xiv. It will benefit workers by enhancing job roles, increasing productivity, and improving safety.
xv. Machines can help to surpass the workers' limitations specifically in ergonomics and so on, but the humans can help in more cognitive operations.

- Main challenges:
  i. Shit in = Shit out(data), difficulties in making people trust the data, "Avoiding" people being afraid of losing jobs.
  ii. lower need for manpower
  iii. Job displacement, Skill requirements, Data privacy, training, and trust; skill gaps
  iv. liability issues - humans get used to trusting AI and stop applying critical thinking.
  v. the modeling of the human and the proper, goal-oriented, and dynamic interpretation of the data

11. the following kinds of hazards in a human-robot co-working environment were mentioned by the respondents:
    - In a human-robot co-working environment, various hazards need to be taken into consideration. These hazards include physical collisions, mechanical risks like pinching or crushing, ergonomic strains from repetitive tasks, programming errors, electrical hazards, communication challenges, and cybersecurity

vulnerabilities. Hits against moving objects, entrapments, cuts, and human factors related to lack of training and/or experience in robotic processes. Robots can be large and heavy, and they can move quickly. This can create a physical hazard for humans if they are not careful. For example, a robot could accidentally bump into a worker, or it could knock over a piece of equipment. Injuries due to human-robot coexistence and collaboration. Collisions, ergonomic hazards, privacy concerns, social isolation, etc. Also, Robots can be perceived as a threat by humans, especially if they are not properly trained on how to interact with them. This can create a psychological hazard if the worker feels anxious or stressed about working with a robot. Boundary controls between human and robotics activities are necessary. Injuries/Safety, Privacy risks.

- It is crucial to implement effective safety measures and protocols to address these potential dangers and ensure the well-being of workers in such collaborative settings.
- Hazards related to ethics in a global framework, including the whole universe of actors involved. For instance, Coworking with robots maybe can be demoralize humans, on the other hand over- reliance in robots can lead to superficial behaviour from humans. Likewise, social anxiety among humans, scepticism and unsecurity
- AI's feedback may be wrong.
- People losing their social abilities. ("talking/cooperating with machines)
- Social anxiety among humans, skepticism, and insecurity
- Wrong AI decisions accepted by humans.
- Humans adapting to robot pace (and it should be contrary)
- Sharing of spaces can lead to ineffective working environment if it was not designed for collaboration: the collaborative space needs to be properly designed and configured for collaboration since the very beginning.
- if implemented wrongly: deskilling / dilemma of automation.

The participants' views regarding if and how the HDT can be helpful in ensuring that the system corresponds to the variety of preferences and abilities in the workforce highlighted were partially homogeneous. Despite some of them being sceptical on this and others underlined that it depends on the level of preference and abilities that could affect standards processes or on its adaptability and modularity, most of the respondents were more positive. They mentioned that it can be achieved by assigning tasks by experience and training profile and that the Human Digital Twin (HDT) plays a crucial role in ensuring that the system aligns with the diverse preferences and abilities of the workforce by offering personalized customization, adaptive assistance, ergonomic optimization, accessibility considerations, and continuous monitoring tailored to the unique characteristics and requirements of each worker. HDT analyzing workers skills can optimize shifts and place a worker in a better working position. HDT can be used to personalize the workplace experience for each individual worker. This means that the workplace can be designed to fit the individual's preferences and abilities, which can lead to a more productive and satisfied workforce. For example, a worker who has difficulty standing for long periods of time could be given a job that allows them to sit or work from home. Through HDT's workers can be compared and analyzed. With this the

workforce can improve itself and tasks can be distributed more accurately. The HDT can model workers' preferences and skills (of any kind), and then this information can be inputted into other systems (e.g., decision-makers and AI assistants) to consider preferences and abilities for downstream tasks. For example, a job scheduler can assign tasks based on a worker's abilities (primary filter to avoid assigning tasks to workers not able to complete them), and then rotate jobs by considering the worker's preferences (secondary rule, to improve job satisfaction by assigning their preferred activities, and resorting to assign not preferred ones only if needed). It is key to customize the HDT in-line with the user's profile. The HDT can be helpful on design of the human-robot co-working. Usage of simulation and AR/VR combined with HDT can help on this process. Some opinions highlighted that this would require not only one HDT, but also collaboration and coordination between HDTs.

4.3.3 Trustworthy Artificial Intelligence

12. Most of the respondents confirmed that the standardization initiatives relevant for the ethical implications on the AI systems and, more in general, for Trustworthy AI (such as IEEE P7000TM series of standards projects developed by the IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems and the standards developed by ISO) are useful for “bringing ethics in action” towards trustworthiness. They underlined that it is crucial to set guidelines to help company in embracing AI systems, especially since sometimes it happens that even AI developers are not aware about the trustworthiness of their AI tools. Ethics should be addressed in parallel with the technical challenges. Initiatives to standardize are crucial for putting ethics into action and promoting reliability in AI. They create a solid structure, present precise rules, and offer best practices that help stakeholders comprehend and manage ethical issues. Organizations can show their commitment to moral principles, encourage ethical AI development and application, and support the creation of a reliable AI ecosystem by adhering to accepted norms. These activities are crucial in fostering trust among users and the public in addition to assisting stakeholders in successfully navigating the ethical landscape. These initiatives "force" most companies using AI to comply with a set of rules that are decided to protect the public. But then again, I think the military will see outside standards creating new systems (e.g. "Do not comply with standards, why should others do that). Standardization initiatives like IEEE P7000 are a valuable tool for bringing ethics in action towards trustworthiness. By providing a common framework for thinking about ethics in AI, offering guidance on how to implement ethical principles in practice, and helping to build trust in AI systems, these initiatives can help to ensure that AI is used for good.

13. However, most of the respondents were not familiar with the "Ethics Guidelines for Trustworthy Artificial Intelligence" and related "Assessment List for Trustworthy Artificial Intelligence".

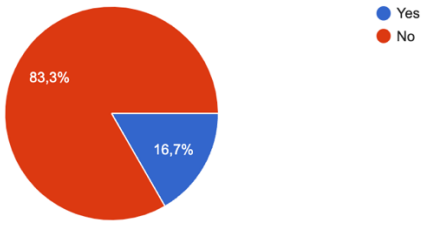


Figure 12: Survey Results

14. Some of the participants mentioned interesting communities or initiatives for Trustworthy AI, including in particular:

- OECD, ISO, MOMAI, and various EU projects' communities.
- the partnership on AI: (https://www.partnershiponai.org/) The Partnership on AI is a collaborative platform that brings together leading organizations and experts from academia, industry, and civil society to address the challenges of AI ethics. Their mission is to ensure that AI technologies are developed and deployed in a responsible, fair, and accountable manner. The Partnership on AI conducts research, develops guidelines, and facilitates dialogue on various ethical aspects of AI.
- the European AI Alliance, which is a European Commission project to engage stakeholders and encourage a broad dialogue on AI-related concerns such as ethics and trustworthiness. It brings together representatives from academia, industry, and civil society to share knowledge, discuss viewpoints, and provide advice on AI ethics and trustworthy AI policy and standards.
- AI4People: (https://www.ai4people.eu/) AI4People is a high-level European effort aimed at advancing the discourse on the ethical and societal elements of artificial intelligence. It brings together experts from diverse disciplines to provide suggestions and aid on AI concerns such as transparency, justice, accountability, and privacy. The effort aims to create real solutions and policies for trustworthy AI; Global Partnership on Artificial Intelligence (GPAI): (https://gpai.ai/) It is an international initiative established to guide the responsible development and use of artificial intelligence in a manner that respects human rights and the common democratic values of its members.
- the AI Ethics Lab: (https://www.aiethicslab.com/) The AI Ethics Lab is a non-profit research and consultancy group that focuses on the ethical aspects of artificial intelligence. They offer information, conduct research, and provide advice to individuals and organizations interested in addressing ethical issues in AI. Their endeavours include the creation of ethical frameworks, the facilitation of workshops, and the facilitation of conversations on AI ethics; AI Standards Hub (https://aistandardshub.org) The Hub's goal is to develop trustworthy and responsible AI as part of the United Kingdom's National AI

Strategy, with a focus on the role that standards may play as governance tools and in innovation processes.

15. Regarding the mechanisms could be established to evaluate the environmental impact of the AI system's development, deployment and/or use (for instance, the amount of energy used and carbon emissions, the stakeholders involved underlined that:
    - If not already considered. It should be calculated also the amount of energy required for cooling AI system's.
    - Common mechanisms already used to evaluate the environmental impact can be established.
    - LCA product data.
    - There are some IBM tools such as Adversarial Robustness Toolbox (ART), au Privacy 360, AI Explainability 360, and AI Fairness 360. They could be valuable in ensuring fairness and non-discrimination in decision-making processes, such as resource allocation, workforce management, and supply chain optimization. Also, could assist stakeholders in comprehending and justifying AI-based recommendations or actions, fostering transparency and trust. Interpreter could be used to enhance transparency and accountability in AI-driven processes, supporting decision-making regarding resource optimization, waste reduction, and product lifecycle management. Microsoft Responsible AI Toolbox can support organizations in ensuring that their AI systems adhere to ethical guidelines, comply with privacy regulations, and operate reliably within dynamic manufacturing environments.
    - optimize the processes to reduce the environmental impact using AI (e.g. less energy, less waste, less raw material, less impactful raw material, ...)
16. Some of the respondents mentioned as toolboxes to assess and improve AI trustworthiness (such * as AI Fairness 360, InterpretML, etc.) which could be useful in the Circular Manufacturing domain the following:
    - Experience with AI Fairness 360: Could be useful for manufacturing use case, but less than in other domains with larger amounts of sensitive data and more opportunities for unintended biases.
    - There are some IBM tools such as Adversarial Robustness Toolbox (ART), au Privacy 360, AI Explainability 360, and AI Fairness 360. They could be valuable in ensuring fairness and non-discrimination in decision-making processes, such as resource allocation, workforce management, and supply chain optimization. Also, could assist stakeholders in comprehending and justifying AI-based recommendations or actions, fostering transparency and trust. InterpretMLcould be used to enhance transparency and accountability in AI-driven processes, supporting decision-making regarding resource optimization, waste reduction, and product lifecycle management. Microsoft Responsible AI Toolbox can support organizations in ensuring that their AI systems adhere to ethical guidelines, comply with privacy regulations, and operate reliably within dynamic manufacturing environments.
17. Most of the respondents consider very important that i) the workers can understand how the AI system operates and its capabilities; ii) adequate measures are adopted by an

organization to explain the decision(s) of the AI system to the users; iii) ensuring the consideration of diversity and representativeness of workers in the data for the HDT.

18. Section 5 "**The evolving regulatory framework**". The EU, faced with the rapid technological development of AI and Data Economy, is moving forward to harness the many opportunities and address challenges of AI in order "to make the EU a world-class hub for AI, while ensuring that AI is human-centric and trustworthy". In this direction, a number of regulatory reforms have been promoted and are under development. In this section, the questions are aimed at exploring, on the one hand, the state of awareness of the respondents in relation to such reforms (such as the AI Act, the Digital Services Act, the Data Act, the Revised Product Liability Directive and the AI Liability Directive) and, on the other hand, their opinion regarding the usefulness of such reforms for increasing the * users' trust in AI solutions and thereby their larger adoption. The section also addresses specific topics of the reforms, such as the risk-based approach of the AI Act and the choice to reverse the burden of proof for damage caused by AI applications (such as autonomous drones, vehicles, or cobots) under certain conditions, pursued by both the Revised Product Liability Directive and the proposal of AI Liability Directive (AILD), thought with different approaches.

4.3.4 The Evolving regulatory framework

19. The following image shows the participants' status of awareness regarding the regulatory reforms under development potentially relevant for Circular TwAIn.

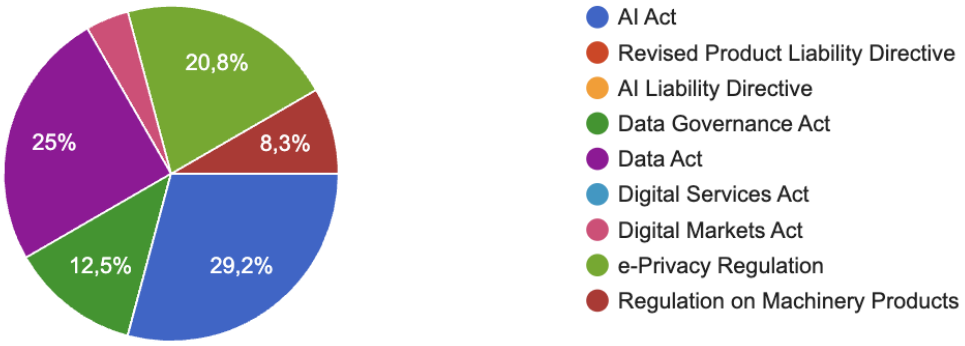


Figure 13: Status of Awareness regarding the regulatory reforms.

20. Most of them believe that these regulatory reforms underway can be useful for increasing the users' trust in AI solutions and thereby their larger adoption.

21. The risk-based approach adopted by the AI Act Proposal is considered as an important milestone and the right choice, introducing many powerful concepts, though it might occur that not all the AI systems can be classified only through 4 risk-levels. It is reasonable. Whatever may impact on workers' safety and security must be analyzed from the potential risk's perspective. Indeed, this metric is used also in different context. AI must become part of the traditional company risk analysis. However, many respondents were not able to provide their opinion on this.

22. Both the proposal of Revised Product Liability Directive and the proposal of AI Liability Directive (AILD) are directed to reverse the burden of proof for damage caused by AI

applications (such as autonomous drones, vehicles, or cobots) under certain conditions, though following different principles. For instance, the AILD sets forth a rebuttable presumption of causality, when a relevant fault has been established and a causal link to the AI performance seems reasonably likely. This approach is intended to simplify the legal process for victims. Some of the respondents considered this approach as potentially detrimental, and thought more attention should be paid to victims. Most of the participants did not have a clear vision of this, whilst a large part of them considered such an approach as useful.

4.4 Human Rights Impact Assessments

4.4.1 ALTAI-driven approach

As initially mentioned in D7.4 “D7.4 SMART standards and Exploitation Plan - 1st version”, Sect. 5.1, the Circular TwAIn Human Rights Impact Assessment (HRIA) is functional to determine the expected impact of Circular TwAIn AI tools on fundamental rights, as well as the potential factors and measures to monitor, in conjunction with the identification of the mitigating measures to ensure citizen-respectful results, in line with the Charter of Fundamental Rights of the European Union (CFR).

In fact, the AI, whilst have the potential to enhance human capabilities and improve decision-making processes and to bring significant advancements to various industries, helping in making products and services more user-friendly, cheaper, and more sustainable and increasing safety in the workplace (being dangerous tasks carried out by robots), on the other hand might have an impact on several human rights, such as the right to privacy and freedom from discrimination, posing a threat to privacy, bias, and accountability. Existing societal stereotypes and discrimination might be perpetuated by the AI algorithms, leading to significant violations of human rights, including the right to equality and non-discrimination. It is therefore essential that AI development, deployment and uses guided by ethical principles to prevent its negative impact on human rights.

The Human Rights (HRs) are “the rights inherent to all people, regardless of race, sex, nationality, ethnicity, language, religion, or any other status” *[6]* and are seen as equally essential to respect the dignity and worth of every person. They consist in universal legal guarantees for the protection of individuals and groups against actions interfering with fundamental freedoms and human dignity. Human rights are considered universal because they have their source in human dignity irrespective or any distinguishing characteristic, such as race, color, sex, ethnic or social origin, religion, language, nationality, age, sexual orientation, and disability. They are interdependent and indivisible, universal and inalienable, equal, and non-discriminatory. The terms interrelated, indivisible, and interdependent are related to the circumstance that the violation of one human right very often affects several other rights and that it is insufficient to respect only some human rights and not others.

Key regulatory sources define their substantive content, ranging from international treaties, conventions and declarations on human rights (such as the Universal Declaration of Human Rights), to Regional human rights instruments and the jurisprudence on the European Charter of Human Rights (and others), national HRs and thematic legislation and state constitutions (such as national human rights acts, non-discrimination laws and workplace health and safety laws).

Felner *[7]* and Götzmann *[8]* depicted a HRIA as a process for identifying, understanding, evaluating, and tackling with the adverse effects of business projects and activities on the

human rights enjoyment of impacted rights-holders such as workers and community members. It consists in a structured approach directed, on the one hand, to identify adverse human rights impacts, with a deep understanding of impacted rights-holders' perspective and, on the other hand, to determine proper mitigating measures, prevention and remediation to address any adverse human rights impacts identified.

Some literature, including for instance Latonero and Agarwal, argued that this instrument could be particularly relevant for identifying, mitigating, and remedying the potential risks and harms of artificial intelligence (AI) and algorithmic systems. However, despite the ongoing discussion related to the impact of AI on human rights, the knowledge and expertise for investigating the human rights impacts of AI and algorithmic systems are still limited, being the HRIA of AI only in their infancy, and several challenges and open points remain, such as evolving approaches and methods to identify algorithmic discrimination, which is a sensitive concern when it comes to assessing AI harms. Furthermore, thought the discussion is positive towards placing AI in the framework of human rights, still there are no legally binding instruments that specifically deal with AI under human rights law [9].

The Consortium is committed to the effective human rights protection in the design and deployment of the AI tools and algorithmic systems throughout their lifecycle — from conception to deployment. In Circular TwAIn the reference to a human rights framework and the implementation of a HRIA on key AI tools and algorithmic systems is expected to be a significant step towards the prevention of any harm to the operators and other human beings, since it will be capable of assessing and addressing the impact of such tools and systems on individuals, identifying adequate mitigating measures and providing hints for the future technological choices.

In this direction, the HRIA in the Project will ensure to avoid that an individual can experience a negative human rights impact because of Circular TwAIn technology design, deployment and testing, thereby ensuring that the Project's technology is designed, developed and validated in a human-rights respectful manner, proactively encompassing human rights safeguards and preventive measures, rather than reacting to unexpected incidents.

This approach is related to the implementation of the Circular TwAIn Ethical Policy and its Ethics-and-Privacy-by-Design-and-by-Default approach, as depicted in D1.2 "Ethical Analysis, Governance and Guidelines – 1st version". In addition, thanks to the Collaborative Intelligence paradigm and the AI-empowered Human Digital Twins solution, the efforts will be directed not only to prevent any infringement of human rights and ethics risks, but even to foster human rights and human empowerment and flourishing.

The elaboration of the Circular TwAIn HRIA underway will give rise to actionable results and recommendations for the future work of the technical team and of the piloting operations.

For this purpose, the development and future use of the HRIA for Circular TwAIn AI tools go beyond the traditional approaches and existing methodology for the HRIA, in order to tailor the approach to the specificities of the AI systems and the relationship between such systems and the most salient human rights risks and harms in this framework, aligning the methodology both to the risk-based approach of the AI Act Proposal and to the ALTAI checklist for Trustworthy AI.

Therefore, the Circular TwAIn HRIA enriches the common set of key criteria of the HRIA literature *[10]* with criteria derived from the Ethics Guidelines for Trustworthy and the

Assessment List for Trustworthy Artificial Intelligence (ALTAI), both elaborated by the High Level Expert Group on Artificial Intelligence set up by the European Commission (2020). In fact, the Trustworthy AI is interlinked with the human rights-based approach, since the ethical principles and requirements set by the Ethics Guidelines for Trustworthy AI and fine-tuned in the ALTAI, exactly uphold the fundamental rights and rotate around them.

Furthermore, the elaboration of the Circular TwAIn HRIA model also relies on the OECED Principles promoting values such fairness, transparency, safety, and accountability of AI Systems

The criteria used in Circular TwAIn HRIA cover several dimensions, as shown in the figure below:

Figure 14: Dimensions and topics covered by Circular TwAIn HRIA

In particular:

- **Fairness, non-discrimination, and avoidance of unfair biases,** regarding the equity, impartiality, egalitarianism, non-discrimination and justice. This encompasses the equal treatment between individuals or between groups of individuals, as well as the ability to seek and obtain relief when individual rights and freedoms are violated. Any inclusion of inadvertent historic bias, incompleteness, and bad governance models in the AI systems should be avoided, both for training and operation. Efforts should be directed to ensure inclusive and gender-responsive engagement processes, also considering the needs of individuals and groups at risk of vulnerability or marginalization.
- **Human empowerment**, regarding the enhancement of the degree of autonomy and self-determination. becoming stronger and more confident.
- **Human Agency and Oversight**, regarding the human autonomy. The AI system should support human agency and human decision-making, as well as the impact of such systems on human affection, trust and (in)dependence should be assessed, together with their effects on human perception and expectations. The governance mechanisms directed to guarantee human oversight are: i) human-in-the-loop (HITL) approach, which asks for the capability for human intervention in every decision cycle of the system; ii) human-on-the-loop (HOTL) approach, which relies on the capability for human intervention during the design cycle of the system and monitoring the system's operation; iii) human-in-command (HIC) approach, regarding the capability to oversee the overall activity of the AI system and the ability to decide if, when and how to use it in any given situation.
- **Transparency, traceability and explainability,** which regards the transparency of the system, both in relation to its comprehensibility, explainability, or

understandability from an external observer (interpretability), and to its being intelligible to non-experts, in particular those directly and indirectly affected (explainability) and its ability to track the journey of a data input and related processes through all stages of sampling, labelling, processing and decision making within the processes of the development of the AI system (traceability)

- **Privacy and Data Governance**, considering the possible impact of the AI systems on privacy and data protection, which are related to the integrity of the person.
- **Safety, technical robustness, and prevention of harm**, concerning the security, safety, technical robustness of the AI system and accuracy of data for preventing harm to human beings in line with the fundamental right to the integrity of the person.
- **Participation and right-older feedback,** regarding the meaningful engagement and feedback from affected or potentially affected rights-holders, duty-bearers and other relevant stakeholders/parties. In Circular TwAIn this is related to the 6P Methodology.
- **Risk-based approach and assessment of impact severity**, which relies on the risk-based approach envisaged by the AI Act[1], since the impacts have to be considered and tackled taking into account the severity of their human rights consequences and, therefore, considering their scope, scale and irremediability. The AI Act classification[2] comprises.
    - **Unacceptable risk**, regarding AI systems which are a clear threat to the safety, livelihoods, and rights of people. These AI systems are banned;
    - **High-risk**, concerning the AI systems used for example in the critical infrastructures, safety components of products, biometric identification systems, employment, workers management and access to self-employment and others. These systems are subject to strict obligations before they can be put on the market.
    - **Limited risk**, which are AI systems with specific transparency obligations: users should be aware that they are interacting with a machine so they can take an informed decision to continue or step back (an example is chatbot).
    - **Minimal risk**, which is most AI systems currently used in the EU. They represent minimal or no risk, thereby the AI Act allows the free use of them (such as AI-enabled video games or spam filters).
- **Accountability and risk mitigation.** Accountability is a concept linked with the responsibility one's own actions and necessitates that mechanisms are put in place to ensure responsibility for the development, deployment and/or use of AI systems. It comprises the ability to report on actions or decisions that contribute to the AI system's outcome, as well as the ability to respond to the consequences of such an outcome. Accountability is sometimes required by law, such as GDPR, but can also be expressed as an ethical standard, and fall short of legal consequences. Accountability is closely related to risk management, identifying and mitigating risks in a transparent way that can be explained to and audited by third parties. In case of unjust or adverse impacts, accessible mechanisms for accountability should be in place that ensure an adequate possibility of redress for minimizing the potential negative impacts of AI systems on those directly or indirectly affected.

[1] COM/2021/206 final, Proposal for a Regulation on Artificial Intelligence.

[2] *https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai*

- **Auditability**, which relates to accountability, refers to the ability of an AI system to undergo the assessment of the system's algorithms, data and design processes. The system's auditability can be achieved by ensuring traceability and logging mechanisms from the early design phase. Where it is necessary to priorities actions to address risks and impacts, severity of human rights consequences should be the core criterion (mitigation hierarchy).
- **Accessibility.** Accessibility should be granted: it refers to the extent to which AI systems can be used by people from a population with the widest range of user needs, characteristics, and capabilities to achieve identified goals in identified contexts of use (which includes direct use or use supported by assistive technologies). AI systems should be user-centric and designed in a way that allows all people to use AI products or services, regardless of their age, gender, abilities, or characteristics. Accessibility to AI for persons with disabilities is of particular importance. AI systems should not have a one-size-fits-all approach and should consider Universal Design principles addressing the widest possible range of users, following relevant accessibility standards.
- **Social Well-being**. Consideration of the possible positive and negative impacts expected from the AI system's deployment for individuals (operators, customers, technology providers, etc.) and society.
- **Impact on work and skills**. AI systems and their use may alter the work sphere and have an impact on the working environment, on workers, on the relationship between workers and employers, and on skills. It is key that AI systems support humans in the working environment and aim for the creation of meaningful work.
- **Environmental friendliness**. Potential negative or positive impact on the AI system on the environment. AI systems must work in the most environmentally friendly way possible in the entire supply chain. The AI system's development, deployment and use process, as well as its entire supply chain, should be assessed in this regard (e.g., considering the resource usage and energy consumption during training, opting for less net negative choices).

For conducting Circular TwAIn HRIAs, the exchange and interaction of a multi-disciplinary team, covering adequate interdisciplinary expertise (including for instance AI developers, data scientists, human rights & ethics experts) was paramount. Thanks to this interaction, it was possible to analyze and assess the Circular TwAIn AI-driven solutions from an holistic perspective, wherein ethics/social and technical factors are inherently intertwined, as well as to identify the necessary technical or organizational countermeasures for mitigating existing and future harms. In particular, the HRIA was conducted on the Circular TwAIn AI tools in synergy with the technical team involved in T3.2 Trustworthy AI and Collaborative Intelligence and T5.2 AI for Circularity and Resilience applications Toolkit, as well as with their partners involved in the AI-based DTs and the partners involved in the piloting operations.

The findings of the HRIA, evaluating the potential impact of the project's AI tools on human rights by considering the nature, context, scope, and purpose of the tools themselves, will be taken into account in the future development work of the project towards giving rise to ethical AI solutions in Circular TwAIn that prioritize transparency, fairness, and accountability while minimizing potential negative impacts on human rights.

4.4.2 AI-enabled Digital Twins, Circular Economy and AI: an outlook of Circular TwAIn breakthroughs

This Chapter outlines the findings of the Human Rights Impact Assessments conducted on the key AI-empowered Circular TwAIn breakthroughs, namely the AI Toolkit and the AI-enhanced Digital Twins (DT) for Circularity (Human DT, Process DT, Product and Material DT). Each of such HRIA is preceded by the description of the relevant technological asset, in order to better capture its human-rights implications.

4.4.3 HRIA of Circular TwAIn AI Toolkit

AI is central to CE in the Circular Twain project, as the main concept of the project lies on the utilisation of different AI algorithms and XAI outputs to facilitate the needs of circularity in various environments.

In this concept, the Circular Twain project aims to provide an AI Toolkit that will be used to deliver the required AI services to the engaged stakeholders that work in the manufacturing environments tackled by the project. As such, the AI Toolkit can be considered as the required infrastructure to design, train and execute different AI/ML models, covering both the needs of cloud-based, as well as local AI execution, facilitating different stakeholders to enter the world of AI by utilizing this infrastructure to design their own algorithms. As such, the toolkit does not come pre-loaded with algorithms that are specific to the different use cases and problems to be solved by the project (or by any project in general), but contains the necessary libraries and building blocks that, once combined, and configured, can formulate an AI pipeline that can be executed.

Moreover, the AI toolkit and the XAI outputs to be provided by the latter will be also used to execute the required analyses of the Digital Twin environments and serve them with the required information to operate.

Table 10 provides the findings of the HRIA conducted on the Circular TwAIn AI Toolkit:

Table 10: HRIA for the Circular TwAIn AI Toolkit

Human Rights Impact Assessment
Fairness, non-discrimination, and avoidance of unfair biases
The AI Toolkit, as a technological element is a system that is not having a negative impact on fairness. It can be used by any stakeholders and is not making any discrimination, nor is there any unfair bias to be directly related with the system itself, as by design the AI toolkit is including generic and well-respected artefacts that are not bias-related. The AI Toolkit is provided as a platform that is available to every user, without making any discrimination, as the user of the platform is now known to the platform apart from the username/password he/she has chosen.
Human Empowerment
The AI Toolkit will support XAI models helping decision-makers in making responsible choices. The XAI models will help the end-users in better understanding the main reasons underlying the AI suggested decisions, hence clarifying the real needs requiring attention. However, given its general nature, the AI Toolkit cannot prioritize humans well-being, which is a possible goal for the algorithms developed within the AI Toolkit.
Human Agency and Oversight
The AI Toolkit is an infrastructure that is allowing humans to design AI pipelines and execute them, and the oversight and control of each activity on the AI Toolkit is overseen and control by humans, who are the main users of the platform. Moreover, the AI toolkit provides various mechanisms to allow human to understand the state of the platform, as well as the outputs of the platform.
Transparency, traceability and explainability
The operations of the AI toolkit are fully transparent and can be traced as the overall system is using a sophisticated logging mechanism that records important decisions as well as other system parameters. Explainability is provided by the offering of various graphs that showcase the operations of the platform in an easy-to-understand manner to users, providing them also with dedicated messages that are able to convey the status of the platform as well as the status of the AI pipelines they have designed and are executing.
Privacy and Data Governance
Data used in the AI Toolkit are kept private and secure, as only the user (human operator) that has uploaded or generated these data the one that has access to them. The user can at any time withdraw the data from the AI Toolkit. It is noted that the administrators of the AI Toolkit do not have access on the data uploaded by users, unless the user chooses to provide access to this group by enabling certain access policies.
Safety, technical robustness and prevention of harm
The *AI Toolkit* as a system is a self-hosted application that is not actively interacting with other systems (in means of executing or triggering actions in other systems), is considered as safe, as it cannot be used to harm other systems or humans.
Participation and right-holders feedback
The AI Toolkit allows user to design their own AI tools and pipelines. However, the dialogue with all the stakeholders is not supported, i.e., the AI Toolkit does not support the collaborative design of AI tools or a feedback mechanism to collect comments and issues from the end-users.
Risk-based approach and assessment of impact severity
The AI Toolkit does not implement AI systems per se, but it supports the design of AI systems by providing a set of well-known AI implementations. In this view, the risks are intrinsic to the specific AI system developed by the AI Toolkit adopters. However, the AI Toolkit will make the adopters aware of the potential risks of the provided well-known AI implementations, when applicable.
Accountability and risk mitigation
The AI Toolkit keeps track of the designer of the AI systems, as well as of the training data used to train the algorithm. This evidence will support audits, also organized by third parties. However, the AI Toolkit cannot provide training activities concerning the legal framework applicable to the developed AI systems. Instead, the AI Toolkit could promote this kind of activities by asking the end users to declare they are aware of the legal framework and carefully considered the human rights risk before executing the defined pipelines (e.g., with a checkbox).
Accessibility
The AI Toolkit provides accessibility features that cover the basic needs of users. However, certain operations do not allow for building all interfaces to be compliant with accessibility norms, as there are limitations imposed by the different software development frameworks.
Societal well-being
The AI Toolkit can have an indirect impact to societal well-being, as it is a mechanism to construct AI pipelines for circularity scenarios, which if realised could positively impact society.
Impact on work and skills
The AI Toolkit can have an indirect positive impact to work and skills, as it is a mechanism to construct AI pipelines for circularity scenarios, which if realised could positively impact skills and work.
Environmental friendliness
The AI Toolkit makes use of state of the are cloud computing resources and mechanisms for scaling, to minimise the energy footprint for the design and execution of AI pipelines

4.4.4 HRIA of AI-enhanced Digital Twins (DT) for Circularity: Human DT, Process DT, Product and Material DT

Circular manufacturing aims to create a closed-loop system where resources are maximized, waste is minimized, and products are designed for multiple life cycles where product, process and human DTs play the role of enablers.

Product Digital Twins are virtual representations of physical products that enable real-time monitoring, tracking, and optimization throughout their entire life cycle. By integrating data from various sources such as sensors, supply chain systems, and customer feedback, product Digital Twins facilitate improved product design, predictive maintenance, and optimized resource allocation.

Process Digital Twins enables real-time monitoring and analysis of production activities, to support continuous improvement of manufacturing operations and the implementation of circular economy principles.

Human Digital Twins focuses on the workforce involved in circular manufacturing. By capturing data on employee skills, experience, and performance, human Digital Twins enable better workforce planning, training, and decision-making. They also facilitate collaboration and knowledge sharing across teams, enhancing overall productivity and innovation. The human Digital Twin scope is to model the human worker and to integrate human factors in complex manufacturing systems. The ultimate goal is to lower the barriers for humans to engage in AI-based sustainable manufacturing processes, while increasing the trust on them. Integrating the human factor in the manufacturing process is about considering humans' variability and limitations and creating an environment that enables the workers to be more efficient, safe, productive and satisfied. Modern manufacturing systems must have human awareness, while keeping human decision making in the loop at different levels of automation. Human workers can benefit from human Digital Twins supporting decision-making processes, minimizing environmental influences and individual skills and experience gap, and enabling human-aware technologies that can adapt to the worker's needs and facilitate human-machine interaction. The HDT may be used to evaluate the readiness of personnel who interact with the system or understand the errors and circumstances in which errors are made. Finally, the HDTs may be used to determine and assign tasks among workers or between humans and robots.

Table 11 provides the findings of the HRIA conducted on the Circular TwAIn AI-enhanced DTs.

Table 11: AI-Enhanced DTs

Human Rights Impact Assessment
Fairness, non-discrimination, and avoidance of unfair biases
A strategy or a set of procedures to avoid creating or reinforcing unfair bias in the HDT, both regarding the use of input data as well as for the algorithm design, will be considered, as well as diversity and representativeness of end-users and/or subjects in the data. The inclusion of strategies, ethical considerations, and responsible AI into the entire lifecycle of the process DT will contribute for fairness, non-discrimination while avoiding any unfair biases. In this context, data provided by the several data sources (HDT, Product DT, etc.) and ingested by AI algorithms within the Process DT will be deeply audited to prevent any misuse, to protect rights and well-being of individuals, and to ensure fairness and non-discrimination.
Human Empowerment
The well-being of end-users is prioritized, e.g., by embedding in the system techniques and approaches capable of making the end-users feel comfortable and enhance their competences. At the same time, the HDT pay attention to the needs of individuals. The process DT includes technologies and models to help the humans when interacting with the technology. It will be designed and developed with human values in mind. All the developed tools are designed to help humans in better performing their own activities.
Human Agency and Oversight
The AI system the HDT is based on has not yet been defined. Aspects such as whether it will be a self-learning or autonomous system, and whether it will be overseen by a Human-in-the-Loop or by a Human-in-Command, will be tackled in a later stage. The process DT is designed to monitor and control relevant process activities and tasks. Saying that, even if a great degree of automation is possible some of the critical decisions are not executed automatically and ask for the end-user validation and control. These validations are necessary to deliver the right control to the end-users while ensuring AI/ML models auditing.
Transparency, traceability and explainability
Measures that address the traceability of the HDT during its entire lifecycle could be put in place, as well as measures to continuously assess the quality of the input data to the HDT. Also, adequate logging practices to record the decision(s) or recommendation(s) HDT will be put in place. Models with high interpretability levels will be preferred to boost the explainability of model's prediction. The process DT is using a low-code flow-based programming platform to facilitate the development and monitoring of the automation logic. The operation of the system can be easily followed by the end-users. For more complex tasks such as orchestration of the actors within the process, finite-state-machines and behavior trees have been considered to model the behavior of the system instead of programming. Finally, since the AI toolkit in the above section is not capable to handle unstructured data, the process DT is embedding the execution of AI models for unstructured data processing. Next to this, the process DT also provide simpler XAI features to show humans how and why the AI algorithms are computing certain results.
Privacy and Data Governance
The impact of the HDT on the right to privacy, the right to physical, mental and/or moral integrity and the right to data protection will be taken into consideration. Depending on the use case, potential mechanisms that allow flagging issues related to privacy will be established. In case of data collected via wearable devices that fall under the category "health data", specific attention will be posted on data regulation policies (i.e., GDPR), asking workers their explicit consent while providing them with a clear explanation of their rights. The process DT retrieves essentially sensor data from the process. These data are not kept by the process DT (AAS, etc) and are used for enhancing the current processes with AI/ML algorithms. For the execution of a production plan the process DT needs to monitor each task of the plan, however these data are not used for monitor humans on the contrary they are used to find the best production plan given a certain set-up of the system.
Safety, technical robustness, and prevention of harm
Prevention of harm to privacy will necessitate adequate data governance that covers the quality and integrity of the data used, its relevance considering the domain in which the HDT will be deployed, its access protocols and the capability to process data in a manner that protects privacy. In a collaborative process the process DT will always prioritize the safety of humans. All the actions triggered during the execution of the plan are protected by external security systems such as all the safety mechanisms provided by CoBOT (ethical and security standard compliances) as well as security physical barriers for processes without CoBOTs.
Participation and right-holders feedback
The system's design, development and testing of HDT includes, whereas possible, the participation of end-users/other stakeholders for providing feedback and suggestions. The integration of the human feedback through CI/CD pipelines ensures the end-users to provide feedback on their experiences with the process DT.
Risk-based approach and assessment of impact severity
In relation to AI systems, according to the scope, scale, irremediability and interrelatedness of impacts on human rights (not only for end-users but also at societal level), we would classify the use of the AI system in HDT as: minimal risk. In relation to the process AI systems, their impact on humans is minimal since they are essentially used to process unstructured data for object classification and recognition. As for the execution of behaviour trees any impact on human is connected to the monitoring of the each task of the generated production plan. Here the process DT will be designed and developed to minimize the risk of any impact on human rights.
Accountability and risk mitigation
Accountability mechanisms will be put in place to ensure responsibility for the development, deployment and/or use of HDT, in close relation with risk management, identifying and mitigating risks in a transparent way that can be explained to third parties.

The design and development of the process DT provides mechanisms to ensure the responsibility for the design, development, and deployment of the process DT. This means that authorization and authentication mechanisms (or more in general secure measures) will be provided to promote control. Finally, the process DT (AAS, etc.) operate within an IDMZ i.e. a network architecture or segment within an industrial environment designed to provide a secure and isolated zone for industrial control systems and processes. Finally, the deployment of the system in a simulated environment promotes preliminary testing and identification of potential risks.
Accessibility
HDT will be user-centric and designed in a way that allows all people to use it regardless of their age, gender, abilities or characteristics. The adoption of 2.0 software development strategies (such as low-code programming) will improve the democratization of the technologies developed.
Societal well-being
From an ethical perspective, if sensitive data are collected via sensors to monitor certain behaviors and make decisions, an active state of surveillance may result, possibly negatively affecting employee well-being, work culture, productivity, creativity, and motivation. Automation of the process through the deployment of process DTs can impact positively employee well-being by automating dangerous or tedious tasks, enhanced quality of products that in turn means longer product-lifecycle. On the contrary, the data gathering for behavior monitoring could possibly negatively affect employee well-being, work culture, productivity, creativity, and motivation. However, this is not the objective of the process DT.
Impact on work and skills
HDT will have an impact on work and skills. It will support humans in the working environment, and more in detail it will provide training opportunities and materials for re- and up-skilling. Also, the risk of de-skilling of the workforce will be considered and possible measures to counteract it will be investigated. The process DT will have an impact on work and skills. It provides: - automation of repetitive tasks while allowing human to focus on more complex tasks. - Human-Machine Collaboration: more close collaboration between humans and intelligent systems and algorithms. Moreover, it promotes a more informed decision-making process where humans can be aided by AI algorithms, statistical analysis and quality reports to make informed decisions. Finally, an environment made up of DTs and AI/ML algorithms triggers investment in reskilling and upskilling programs to ensure that the workforce is equipped with the necessary skills to work with such a system.
Environmental friendliness
Measures to secure the environmental friendliness of the DT will be taken into consideration where possible. Measures to secure the environmental friendliness of the DT will be taken into consideration where possible.

4.4.5 WEEE Pilot Regulatory Sandbox

4.4.5.1 WEEE Disassembly tool and of its use in Circular TwAIn HRIA

The goal of this tool is to provide help to a WEEE human worker during the PC cases disassembly tasks. This tool encompasses Use Cases A to D. Providing a full solution to assess the status of the WEEE visually (by using a combination of 3d and RGB cameras) and by software means (with a set of diagnosis tools) and detailing a plan to disassemble the case with the help of a CoBOT.

The following table provides the findings of the HRIA conducted on the Disassembly Tool in the WEEE Pilot Regulatory Sandbox.

Table 12: HRIA of the Disassembly Tool in the WEEE Pilot Regulatory Sandbox

Human Rights Impact Assessment
Fairness, non-discrimination, and avoidance of unfair biases
Given the nature of the tool and the data used to train it, no bias can be included that can discriminate anyone.
Human Empowerment
The system is designed to feel comfortable. Trying to help the operators and improve their performance.
Human Agency and Oversight
The system is designed to interact and guide a human worker. The tool can generate confusion in the user with its decisions, but they will be totally aware that it is an AI tools. The tool cannot generate over-reliance given its limitations and the scope of the problem faced. The tool cannot interfere the autonomy of the user. The tool doesn't simulate social interaction and cannot generate human attachment. The system is overseen by a human-in-the-loop. The humans will receive proper training to use the tool. The system has a built-in detection and response mechanisms as well as a stop button to avoid improper behaviours. We don't control the self-learning nature of the system (not applicable)
Transparency, traceability and explainability
Traceability of the decisions is assured by the technologies of the AI model. The quality of the model can be easily quantified, and its decisions monitored. By the nature of the model used, the explainability of the decisions is assured. Users are aware that they are working with an AI system, and they are aware about its benefits and limitations.
Privacy and Data Governance
The system doesn't need nor require private information in any aspects of its lifecycle.
Safety, technical robustness and prevention of harm

The system could have damaging effects in humans if misused. The system will be used in a closed environment, cybersecurity is not required. The risks of the system have been assessed and measured. The system is designed to be stable and reliable. No duplicate system is contemplated nor necessary. A system to automatically check the integrity of the system is not contemplated. The accuracy of the system doesn't result in a critical consequence. The data used in the training process is controlled to ensure its quality, and the accuracy of the model is measured before integrating it in the system. The system operation cannot invalidate the data used in to train the model. The system can cause critical damage due to low reliability. Well defined processes and tests have been defined to ensure the reliability and reproducibility of the system for the sake of the safety of the workers. The tool doesn't implement an online continual learning that can provoke negative consequences.
Participation and right-holders feedback
Stakeholders are contemplated in the design and development of the tool.
Risk-based approach and assessment of impact severity
Minimal Risk
Accountability and risk mitigation
The whole process of developing and designing has been recorded to traceback and audit the system. We foresee the external guidance of the ethics and legal teams of Circular TwAIn and its involvement during the development process.
Accessibility
Due to the narrow scope of application of the tool, it was designed only with the workers that are going to use it in mind.
Societal well-being
The tool will have no impact in society at large or democracy.
Impact on work and skills
The tool will impact the human work. Workers have been informed about the benefits of the tools and how is going to affect them. The tool is not going to de-skill the workers as is a support tool. The tool will require new digital skills to operate.
Environmental friendliness
There's no negative environmental impact of the system, but given the nature of the project, mechanisms to measure the impact of the tools in the environment has been designed.

4.4.5.2 WEEE Decision Support tool

The goal of this tool is to provide support to the sales expert of a WEEE treatment plant to determine best how to proceed with the waste processed. This tool is designed to assess the value of the different components of the WEEE and checks with the information contained in the dataspaces to evaluate and quantify if it is better to demanufacture or remanufacture the WEEE.

The following table provides the findings of the HRIA conducted on the Decision Support Tool in the WEEE Pilot Regulatory Sandbox.

Table 13: HRIA of the Decision Support Tool in the WEEE Pilot Regulatory Sandbox

Human Rights Impact Assessment
Fairness, non-discrimination, and avoidance of unfair biases
Given the nature of the tool and the data used to train it, no bias can be included that can discriminate anyone.
Human Empowerment
The system is designed to feel comfortable. Trying to help them and improve their performance. Given the nature of the system, its main goal is to provide data and information to a human expert to help it make the best-informed choice.
Human Agency and Oversight
The system is designed to interact and guide a human worker. The tool can generate confusion in the user with its decisions, but they will be totally aware that it is an AI tools. The tool can generate over-reliance by the end-user but is designed to only inform it about the best outcome, not to take decisions. The tool cannot interfere the autonomy of the user. The tool doesn't simulate social interaction and cannot generate human attachment. The system is overseen by a human-on-the-loop. The humans will receive proper training to use the tool. The system has a built-in detection and response mechanisms to avoid improper behaviours. (not applicable)
Transparency, traceability and explainability
Traceability of the decisions is assured by the technologies of the AI model. The quality of the model can be easily quantified, and its decisions monitored. By the nature of the model used, the explainability of the decisions is assured. Users are aware that they are working with an AI system, and they are aware about its benefits and limitations.
Privacy and Data Governance
The system doesn't need nor require private information in any aspects of its lifecycle.
Safety, technical robustness and prevention of harm
The system couldn't have damaging effects in humans if misused. The system will meet the cybersecurity standards. The AI will be exposed to corrupted data that may lead to its malfunction. The system will have measures to secure the integrity of the data. The risks of the system have been assessed and measured. The system is designed to be stable and reliable. No duplicate system is contemplated nor necessary. A system to automatically check the integrity of the system is not contemplated.

The accuracy of the system doesn't result in a critical consequence. The data used in the training process is controlled to ensure its quality, and the accuracy of the model is measured before integrating it in the system. The system operation cannot invalidate the data used in to train the model. The system can't cause critical damage due to low reliability. The tool doesn't implement an online continual learning that can provoke negative consequences.
Participation and right-holders feedback
Stakeholders are contemplated in the design and development of the tool.
Risk-based approach and assessment of impact severity
Minimal Risk
Accountability and risk mitigation
The whole process of developing and designing has been recorded to traceback and audit the system. We foresee the external guidance of the ethics and legal teams of Circular TwAIn and its involvement during the development process.
Accessibility
Due to the narrow scope of application of the tool, it was designed only with the workers that are going to use it in mind.
Societal well-being
The tool will have no impact in society at large or democracy.
Impact on work and skills
The tool will impact the human work. Workers have been informed about the benefits of the tools and how is going to affect them. The tool is not going to de-skill the workers as is a support tool. The tool will require new digital skills to operate.
Environmental friendliness
There's no negative environmental impact of the system, but given the nature of the project, mechanisms to measure the impact of the tools in the environment has been designed.

4.4.6 Battery Pilot Regulatory Sandbox

Robotic Disassembly tool

The aim of this tool is to aid human worker during the LIB pack and module disassembly tasks. This tool will be utilized in Use Cases A to B. Providing a full solution to assess the status of the Product, parts recognition through machine vision utilising the sensor and IR cameras.

The following table provides the findings of the HRIA conducted on the Robotic Disassembly Support Tool in the Battery Pilot Regulatory Sandbox.

Table 14: HRIA of the Robotic Disassembly Support Tool in the Battery Pilot Regulatory Sandbox

Human Rights Impact Assessment
Fairness, non-discrimination and avoidance of unfair biases
The structure and design of the tool is solely digitalised and intended for human assist and no biased characteristics have been carried out. The tools are designed regardless of the gender-specific and background.
Human Empowerment
The system is designed to complement and enhance human decision-making, with a focus on improving overall operational efficiency and providing digital guidance(identification of accessible joints of an unknown battery model to be disassembled) to the well-being and competence of end-users.
Human Agency and Oversight
The system's purpose is to communicate with and direct a human worker. The user may become confused by the tool's choices, but they will be well aware that it is an artificial intelligence tool. With all of its shortcomings and the size of the issue at hand, the tool cannot encourage over-reliance. The user's autonomy cannot be interfered with by the gadget. The instrument is unable to elicit human attachment or replicate social interaction. There is a human in the loop supervising the system. To operate the tool, humans will obtain the necessary training. In order to prevent inappropriate behaviour, the system has a stop button in addition to built-in detection and response systems.
Transparency, traceability and explainability
The AI model's technology ensure that decisions can be traced back. It is simple to measure the model's quality and keep an eye on its choices. The decisions are guaranteed to be explainable due to the nature of the applied model. Traceability of the decisions is assured by the technologies of the AI model operated in the localised systems. The end-users are aware of the reliability of the decisions and recommendations by AI tool.
Privacy and Data Governance
The processed data are compliant with UE regulation 2016/679 and all data is protected with the most efficient technologies available. The operators will be informed with information sheet. We will conduct an assessment of the risks to the rights and freedoms of data subjects. Video-surveillance and electronical badges for the access to our facilities are improvised for safety reasons.
Safety, technical robustness and prevention of harm

If the system is abused, people may suffer negative consequences. There is no need for cybersecurity because the system would operate in a closed environment. The system's dangers will be evaluated and quantified. The system is built with dependability and stability in mind. There is no need or intention to implement a duplicate system. It is not planned to provide a method to automatically verify the system's integrity. The correctness of the method has no significant ramifications. Before the model is integrated into the system, its accuracy is measured**,** and the quality of the data used in the training process is regulated for human safety. The data used to train the model cannot be invalidated by system operations.
Participation and right-holders feedback
Design, development and testing of the system are carried out in close cooperation with end users and stakeholders. Progress is monitored through meetings and information sharing. Problem analysis/progress/design issues are discussed at regular meetings.
Risk-based approach and assessment of impact severity
The AI tool will be designed to integrate with robot/operator mutual learning to always improve the efficiency of the collaborative disassembly of recurrent LIB packs. Therefore classified as high risk .
Accountability and risk mitigation
The entire process of data flow can be stored in the local system and can traced back into account. We foresee the external guidance of the ethics and legal teams of Circular TwAIn and its involvement during the development process.
Accessibility
AI tool will be design-specific with a user-centric approach, ensuring that the user interface is intuitive and accessible. Therefore no groups will be disproportionately affected by the outcomes of the AI system.
Societal well-being
The system has no adverse effects on the environment, methods have been developed to assess how the tools affect the environment. The instrument will affect what people do by hand. The advantages of the tools and how they will benefit the workers will be explained to them. As a support tool, it won't cause the workers' skills to decline.
Impact on work and skills
Positive impact on the human involvement is foreseen. Workers have been informed about the benefits of the tools and how is going to affect them. De-skilling of the workers is avoided as its a support tool. The tool will require new digital skills to operate.
Environmental friendliness
There's no negative environmental impact of the system. The primary goal of the tool is to develop computer-vision algorithm for the identification of product and parts of unknown battery model as a process support tool, therefore mechanisms to measure the impact of the tools in the environment has been designed as in-built feature.

4.4.6 Decision Support tool and of its use in Circular TwAIn

The Process & Product Digital Twin (PPDT) is developed to assess and characterize the battery SOH combining testing data and historical data followed by data driven decision support system for value added products from the recycling materials. This tool will be implemented in UC C,D and E. It will be a support system for the decision making by monitoring test conditions momentarily and comparing it with historical data. Development of mutual data and model driven AI supported methodology to certify the state-of-health, remaining useful lifespan of LIB cells and knowledge based Decision support system (DSS) for specific second-use requirements and the post-use conditions of re-usable cells. Engineers and human experts can examine and simulate different operating conditions of the battery desired for either second-use or post-use requirements.

Table 15 provides the findings of the Decision Support Tool in the Battery Pilot Regulatory Sandbox

Table 15: Decision Support Tool in the Battery Pilot Regulatory Sandbox

Human Rights Impact Assessment
Fairness, non-discrimination and avoidance of unfair biases
The structure and design of the tool is solely digitalised, and no biased characteristics have been carried out. The tools are designed regardless of the gender-specific and background.
Human Empowerment
The system is designed to complement and enhance human decision-making, with a focus on improving overall operational efficiency and providing decision support, contributing to the well-being and competence of end-users. Shared goal is to provide data and information to a human expert aiding optimised choice.
Human Agency and Oversight
The tool is developed to asses and characterize the battery SOH combining testing data and historical data. It will be a support system for the decision making by monitoring test conditions momentarily and comparing it with historical data. Engineers can examine and simulate different operating conditions of the battery desired.
Transparency, traceability and explainability

The quality of the model can be easily quantified, and its decisions monitored. By the nature of the model used, the explainability of the decisions is assured. The accuracy of the model can be monitored by comparing their operating data and the running process. Traceability and explainability of the decisions are assured by the technologies of the AI model operated in the localised systems. The end-users are aware of the reliability of the decisions and recommendations by AI tool.
Privacy and Data Governance
Personal data collection and processing information are not involved.
Safety, technical robustness and prevention of harm
Continuous risk assessment approach that aligns with the users' digital literacy and control over the AI system has been ensured as the system is installed on the user's server maintaining constant oversight, allowing them to actively monitor and manage risks and negative feed in real-time. This setup ensures the ongoing safety and reliability of the system throughout its lifecycle. Concerned to the cyber safety, the system will meet the cybersecurity standards. Robustness of the developed tool depends on the data quality and variety. If the model is trained on data that belongs to the same operating region and design conditions of the LIB battery, the flexibility of the digital twin would be narrow. Besides, the model cannot constitute any safety threat as it is not in a closed loop.
Participation and right-holders feedback
Design, development and testing of the system are carried out in close cooperation with end users and stakeholders. Progress is monitored through meetings and information sharing. Problem analysis/progress/design issues are discussed at regular meetings.
Risk-based approach and assessment of impact severity
The AI tool will be designed to enhance process optimization and improving overall process efficiency. Minimal Risk is ensured.
Accountability and risk mitigation
The entire process of data flow can be stored in the local system and can traced back into account.
Accessibility
AI tool will be design-specific with a user-centric approach, ensuring that the user interface is intuitive and accessible. Therefore**,** no groups will be disproportionately affected by the outcomes of the AI system.
Societal well-being
The system's primary goal is optimise the Process capabilities by providing valuable information and insights. While it can assist in identifying needs and facilitating decision-making, the final choices and actions are undertaken by a self-determined approach. The tool will have no impact in society at large or democracy due to its industrial task specific nature.
Impact on work and skills
Positive impact on the human 74elation74nt is foreseen. Workers have been informed about the benefits of the tools and how is going to affect them. De-skilling of the workers is avoided as I support tool. The tool will require new digital skills to operate.
Environmental friendliness
There's no negative environmental impact of the system. The primary goal of the tool is to mitigate the recycling waste, therefore mechanisms to measure the impact of the tools in the environment has been designed as in-built feature.

4.4.7 Petrochemical Pilot Regulatory Sandbox

"AUTOML Tool" HRIA

The Human Digital Twin (HDT) in our ethylene oxide production plant is designed to model the human worker and integrate human factors into complex manufacturing systems. Its primary aim is to lower the barriers for human engagement in AI-driven, sustainable manufacturing processes, while fostering trust and efficiency. The HDT considers human variability and limitations, creating an environment where operators are more efficient, safe, productive, and satisfied. It supports decision-making, minimizes environmental influences, bridges individual skills gaps, and facilitates human-plant interaction. The HDT also evaluates personnel readiness, understands error contexts, and aids in task assignment for operators.

Process Digital Twin (PDT) offers a virtual replica of the manufacturing process in real-time. The primary objectives are to maximize operational efficiency, reduce steam usage, and improve the circularity of CO2 to produce DME. By utilizing sophisticated data analytics and surrogate modelling, the PDT forecasts and identifies anomalies to guarantee a sustainable and uninterrupted process flow. It keeps human operators informed and in charge while enabling process optimization in near-real time; it achieves a balance between automation and human oversight.

The table below provides the findings of the HRIA conducted on the AUTOML Tool in the Petrochemical Pilot Regulatory Sandbox

Table 16: HRIA of the AUTOML Tool in the Petrochemical Pilot Regulatory Sandbox

Human Rights Impact Assessment
Fairness, non-discrimination and avoidance of unfair biases
The design and development of the digital twin and AutoML tools have been carried out without applying bias based on characteristics such as religion, language, race, or gender. User interfaces and tools have been designed to accommodate all users without customization based on these characteristics. During the design and development of the tools, consultations were conducted with operators and authorized personnel, regardless of their background or characteristics. The focus has been on achieving data-driven results without introducing bias. The tools are not gender-specific and can be used by anyone after the required training. Gender-responsive methods/tools have not been excluded.
Human Empowerment
The system is designed to complement and enhance human decision-making, with a focus on improving overall operational efficiency and providing decision support. While it may contribute to the well-being and competence of end-users by streamlining processes and reducing workload, its primary goal is to assist rather than replace human operators. The s'stem's primary goal is to enhance the capabilities of users by providing valuable information and insights. While it can assist in identifying needs and facilitating decision-making, the final choices and actions are determined by the users themselves, promoting a responsible and self-determined approach.
Human Agency and Oversight
End-users are adequately made aware that the results, decisions, advice, or outcomes they receive are the result of an algorithmic decision. They are familiar with digital tools and technologies and understand that AI algorithms provide the results. The AI system does not generate confusion for end-users regarding whether they are interacting with a human or an AI system. It is designed to provide clear interactions. The AI system is not designed to generate over-reliance by end-users. It is intended to assist and support human decision-making rather than replace it. The AI system does not interfere with the end'user's decision-making process in an unintended or undesirable way. It is designed to complement and enhance human decision-making There are no identified risks of addiction or manipulation for end-users. The system is designed to provide valuable assistance without manipulation. The AI system does not generate disproportionate attachment to itself among end-users. It is a tool meant to facilitate tasks and decision-making. The tool provides governance mechanisms to ensure human oversight. It follows a "human-in-the-"o"p," "human-on-the-"oop,""and "human-in-co"mand" approach, allowing human control and decision-making. The system is not an autonomous decision-maker; it is designed to complement and enhance human decision-making. As such, the ability to halt or override operations is retained by human operators, and established safety protocols and procedures are in place to ensure safe operation.
Privacy and Data Governance
There are measures in place to ensure the traceability of the AI system during its entire lifecycle. These measures allow for tracking and monitoring of the s'stem's activities and decisions. Measures have been implemented to continuously assess the quality of both input data to the AI system and the quality of its outputs. Regular evaluations are conducted to maintain data accuracy and system performance. It is possible to trace back which data was used by the AI system to make specific decisions or recommendations. The data sources and inputs are recorded and accessible. Traceability mechanisms are in place to identify which AI model or rules led to the decisions or recommendations made by the AI system. This ensures transparency in the decision-making process. Adequate logging practices have been implemented to record the decision-making process and recommendations of the AI system. These logs provide a detailed history of system activities. End-users can understand the decision(s) or recommendation(s) of the AI system. The system provides clear and interpretable results, making it comprehensible for users.
Safety, technical robustness and prevention of harm
The AI system is not going to use personnel data. In the processes, human involvement is limited to changing the set value of temperature, pressure, and flow within operating limits. Changes made do not adversely affect production and production safety, as technicians are not allowed to go beyond operational limits.
Participation and right-holders feedback
Our risk identification and assessment process take into consideration that users are knowledgeable about digital tools and are well-informed about the AI system. To eliminate any potential security issues, the system is designed to be installed on the 'user's server, ensuring that users have control over the security of their own infrastructure. This approach enhances the overall security posture of the system by leveraging the 'user's existing security measures and practices. We employ a continuous risk assessment approach that aligns with the user's digital literacy and control over the AI system. As the system is installed on the user's server, they maintain constant oversight, allowing them to actively monitor and manage risks in real-time. This setup enables users to promptly address any emerging security concerns, ensuring the ongoing safety and reliability of the system throughout its lifecycle. In the described use cases, human involvement is indirect. The AI system is primarily utilized for process optimization and anomaly detection, functioning as a decision support system for operators. This setup reduces the reliance on direct human intervention, enhancing fault tolerance and system robustness. In the Petro pilot, human data is not employed. Human involvement is limited within the process as operators adjust temperature, pressure, and flow set values within predefined operating limits through computer interfaces, without the need for physical intervention. Data used for system development and training data is validated, cleansed, and enriched to

ensure it remains up-to-date, high-quality, complete, and representative of the deployment environment. Regular data audits and validation checks are conducted to maintain data quality.
Risk-based approach and assessment of impact severity
Design, development and testing of the system are carried out in close cooperation with end users and stakeholders. Progress is monitored through meetings and information sharing. Problem analysis/progress/design issues are discussed at regular meetings.
Accountability and risk mitigation
The AI system will make recommendations to end users to prevent abnormal conditions and optimize the process. So that, it will be designed to enhance human decision-making, with a focus on improving overall process efficiency and providing decision support. Minimal risk to human rights is expected.
Accessibility
AI application results will be monitored in the existing data storage (process historian database) system. So that, it can be traced back.
The interface will be designed to be intuitive and user-friendly, with clear and concise instructions that cater to users with different levels of technical expertise. The design effectively communicates necessary information to the user through appropriate graphical representations. Additional features, such as screen magnification, text readers, motion tracking, or eye tracking, can be incorporated into the system to accommodate different needs. The control room and the field have been inspected; accordingly, AI system will be designed with a user-centric approach, ensuring that the user interface is intuitive and accessible.
Societal well-being
No potential negative impacts on the environment are foreseen.
Impact on work and skills
The system is designed to complement and enhance human decision-making, with a focus on improving overall operational efficiency and providing decision support. While it may contribute to the well-being and competence of end-users by streamlining processes and reducing workload, its primary goal is to assist rather than replace human operators. The system's primary goal is to enhance the capabilities of users by providing valuable information and insights. While it can assist in identifying needs and facilitating decision-making, the final choices and actions are determined by the users themselves, promoting a responsible and self-determined approach. 3 operators are involved in the process: foreman, process control technician, and field equipment technician. Technicians can decide to change the set value of temperature, pressure, and flow within operating limits. The system will be separated by the operators' responsibility and position. No de-skilling or up-skilling will be necessary.
Environmental friendliness
With the help of the digital twin, the released CO2 will be examined to determine whether it can be utilized in any other process or as a new energy resource.

4.5 Legal and Ethical Requirements for Circular TwAIn Technology

This section contains the first release of the legal and ethical requirements relevant to Circular TwAIn, namely for its design, development, and validation, as well as, to some extent, for its future uptake and operation after the end of the project.

It defines the initial set of guidelines and boundaries towards ensuring legal compliance and ethically-sound activities and results and was elaborated taking into account both the legal and ethical reference framework relevant for the project, as sketched in Sect. X “The legal and ethical reference framework at European level relevant for Circular TwAIn Technology”, and the Ethics & Privacy-by-Design-and-by-Default Approach described in D1.2 «Ethical Analysis, Governance and Guidelines – First Version» and the surrounding Consortium’ commitment to prioritize human well-being in Circular TwAIn developments and operations.

To facilitate their consideration by the technical team and partners involved in the industrial pilots, the requirements have been provided in table format. Furthermore, the requirements have been classified in “Must”, applying to the binding requirements whose fulfilment is necessary since they directly derive from the applicable legislation, such as GDPR, and “Recommended”, which are not strictly binding but recommended, for instance, because deriving from EC’s Communication or proposals of future regulatory sources (at the moment not in force yet), as well as preferable and advisable, for such as those related to ethical sources.

Some requirements might be quite challenging: therefore, it is important to interpret them considering the technological SoTA, the research nature of the project and the risk-based approach (common to both the GDPR and the AI Act). This implies a certain degree of flexibility in the assessment of their fulfilment and of the suitability of the measures taken, using a case-by-case basis analysis, considering a set of circumstances rotating around the severity of the risks and the reasonable efforts to face with them. The column “Priority” pertains to this aspect.

The legal and ethical requirements have been elicited considering the key project’s technologies and assets, whose key properties, features and functionalities relevant in terms of privacy, data protection and processing, data sharing, AI tools and other aspects are outlined in Sect. X.X “Factual basis for the legal and ethical analysis and for the requirements elicitation”: mainly AI applications, Product, Process and Human Digital Twins and Circular TwAIn’s Data Spaces.

This list reflects the initial project choices in terms of technological assets and developments and might be updated according to the project’s future work, once its technological developments are better shaped, till their final fashion, as well as considering the advancement in the regulatory instruments underway, such as the new AI innovation Package, launched by the European Commission on 24 January 2024, aimed at materializing Europe’s commitment to support ethical and trustworthy AI into action through a comprehensive set of strategies to support AI start-ups and foster innovation.

In a later stage of the project, we will refine or revise this list.

The following table includes a column indicating the relevance of each requirement to one or more of these assets and technologies.

Table 17: Requirements of assets and technologies.

Req. Nr.	Req. Name	Req. Description and Guidelines	Regulatory Source	Priority	Circular TwAIn Technology	Phases
1	**Privacy and Data Protection by Design and Privacy by Default**	The Consortium must adhere to the Privacy-by-design and by default approach: appropriate techniques and measures must be adopted since the very beginning "to implement data-protection principles, such as data minimisation, in an effective manner and to integrate the necessary safeguards into the processing in order to meet the requirements of this Regulation and protect the rights of data subjects"; "for ensuring that, by default, only personal data which are necessary for each specific purpose of the processing are processed. That obligation applies to the amount of personal data collected, the extent of their processing, the period of their storage and their accessibility" (art. 25 GDPR). The data storage must i) safeguard the protection of sensitive information, (ii) use techniques and measures to make hard for an adversary to learn the secret information required for any action (e.g., encryption, authentication, etc.), and (iii) credentials should be stored protected from eavesdropping / leakage	PDPL, AIA, ESL	Must	AI	R
2	**Ethics by-Design-Approach**	It is paramount, in order to give rise to truly trustworthiness and ethically-soundness of the Circular TwAIn technologies, that the Ethics by Design paradigm, as defined by the EC and described in D1.2 "Ethical Analysis, Governance and Guidelines – 1st version" is followed since the very beginning of the design process. The consideration of the ethical principles and regulatory mandates should be drive the asset/innovation development	ESL	Recommended	ALL	R
3	**Transparency and Interpretability**	The transparency requirement is common to several pieces of regulation. The GDPR i) requires that any personal data collection and processing is inspired to full transparency (functional to grant an adequate level of clarity of it, including all privacy-relevant properties and actions) and ii) lists the minimum list of mandatory information to be provided to the data subject (Art. 13). On the other hand, also the e-Commerce Directive and the DSA include the transparency requirement: information obligations are set for the conclusion of a contract with a consumer and liabilities are establi78elationlation to them (Sect. 4). Likewise, transparency requirements are foreseen also under P2BR Obligations. As regards Artificial Intelligence artefacts/systems, on the one hand, the AI Act mandates the disclosure of certain information to individuals and the public to meet the requirements of transparency, the EU AI Act mandates the disclosure of certain information to individuals and the public and, on the other hand, the Ethics Guidelines for Trustworthy AI and related ALTAI establish this requirement. They refer to the transparency, traceability and explainability for ensuring interpretability. The solutions should comprehensible, explainable or understandable from an external observer. The explainability demands for an AI system to be intelligible to non-experts, in particular those directly and indirectly affected by the same. In other words, its functionality and operations should be explained non technically to a person not skilled in the art. The degree to which explainability is needed depends on the context and the severity of the consequences of erroneous/ inaccurate output to human life. Also traceability should be guaranteed, concerning the ability to track and document the journey of a data input and related processes through all stages of the data lifecycle within the processes of the development of the AI system. There are also standards specifically dedicated to transparency.	PDPL, ESL, AIA HRs, ITSBL, SSPF	Must	ALL	ALL

4	**GDPR Obligations**	All the GDPR principles, informing and permeating all its provisions, must be followed: - The **lawfulness principle**: the data processing must be conducted in compliance not only with the applicable data protection legislation, but also with the whole legal landscape (i.e. any other applicable law and regulation).The GDPR (art. 6) indicates the legal bases on which the lawfulness of processing relies. They include, among others, the informed consent, which is "any freely given, specific, informed and unambiguous indication of the data su'ject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her" (art. 4 GDPR). - **Purpose limitation and legitimate aim principle**, demanding that i) the Circular TwAIn system/components serve a specific, explicit and legitimate purpose and the data have to be collected for it without further processing them in a way incompatible with it; ii) adequate safeguards against misuse have to be taken. - **Data Minimization Principle**, for which the collection and/or processing of personal data must be "adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed". The anonymization and pseudonymization techniques should be adopted to the maximum extent, including safeguards for mitigating the risks of re-identifying the individuals and for minimizing possible linkability and actual linkages; - **Storage Limitation Principle**: Art. 5 (1) (e) GDPR requires that personal data are either erased or anonymized as soon as it is no longer necessary for the purpose to identify the natural person. **Respect of the Data Subject's rights**: the data subjects must be effectively entitled to exercise their rights (Articles 12 –22 GDPR), encompassing: i) Transparent communication (Art. 12 GDPR); ii) Information on the controller's identity and the processing itself, including the means and purposes of the processing. There are two cases: personal data collected from the data subject (Art. 13 GDPR) and personal data not obtained from the data subject (Art. 14 GDPR); iii) Right of access (Art. 15 GDPR);iv) Right to rectification of inaccurate data (Art. 16 GDPR); v) Right to erasure, 'right to be forgotten' (Art. 17 GDPR); vi) Right to restriction of processing (Art. 18 GDPR); vi) Right to receive a notification from the controller regarding rectification or erasure of personal data or restriction of processing (Art. 19 GDPR); vii) Right to data portability (Art. 20 GDPR); viii) Right to object (Art. 21 GDPR);ix) Protection against automated decision-making, including profiling (Art. 22 GDPR).	PDPL, ESL, HRs,	Must	ALL	R, D, E
5	**Data sovereignty, DIN SPEC 27070 standard and contractual provisions**	It is paramount to ensure the data sovereignty for the creator of the data, in view of fostering data sharing and building trust among participants. Industry Agreements are advisable. The IDS standard DIN SPEC 27070, including parts of the current version of the IDS reference architecture should be considered. The technical infrastructure should be able to enforce data sovereignty, facilitating through flexible and pragmatic solutions the execution of contractual provisions on the use of data.	ITSBL, ESL, SSBF	Should	Data Spaces and tools	ALL
6	**Data Accuracy**	The data should be of high quality. Every reasonable step should be taken to prevent the use of inaccurate data.	PDPL, ITSBL, NRD, DSL, AIA	Mist	AI, Data spaces and tools	ALL
7	**Non-personal Data Portability**	Data portability between businesses is more and more relevant across a broad range of digital industries, in order to make possible the switching of service providers and the porting of data between different IT systems, in a structured, commonly used and machine-readable format.	DSL, SSPF	Should	Data Spaces and tools	ALL

		The Free Flow of non-personal data Regulation (and, to some extent, the competition law) provides horizonal rules horizontal applying to all sectors of the economy. Article 6 of the Free Flow of Non-Personal Data Regulation regards portability in relation to business-to-business interactions (between a professional user and a service provider) and opts for self-regulatory approach. There is no overarching EU legal framework on non-personal data mobility, but only a mosaic of distinct sectoral regulatory frameworks, imposing some forms of non-personal data mobility under some circumstances.				
8	**Human in the loop, Human autonomy and empowerment**	This regards both data tools and AI solutions. On the first point of view, it is necessary to ensure the individuals real control over their personal information, pursuant to both GDPR and the upcoming ePrivacy Regulation (ePR). As for the AI systems, the Ethics Guidelines for Trustworthy AI and other soft-law sources highlight the need to safeguard human autonomy and dignity. In particular, it applies to the solutions aimed at guiding, influencing or supporting humans in decision making processes: they should support human agency and human decision-making. Human oversight should ensure that AI artefacts do not undermine human autonomy: approaches and measures should be conceived and implemented, such HITL, HOTL, HIC. Moving forward, a step ahead could (and should) be moved, in order to allow human empowerment and flourishing through Collaborative Intelligence-driven innovations.	ESL, PDPL, AIA, SSPF, NRD	Recommended	AI, Data spaces and tools, DTs	ALL
9	**Technical robustness, safety and security**	The security, safety, technical robustness of the system should be ensured, in view of preventing harm to human beings. An AI system is trustworthy only if it is able to deliver services that can justifiably be trusted (dependability), besides being robust when facing changes (resilience). A preventative approach to risks during the development of an AI system/tool is recommended towards achieving technical robustness, reliable behaviour and the minimization of unintentional and unexpected harm. SoTA security of the data should be taken to ensure the integrity, confidentiality and availability of the data, especially personal data, and to prevent unauthorized or unlawful processing and accidental loss, destruction or damage. Appropriate technical and organizational measures should be taken, also to avoid cyber-security attacks (GDPR, Article 5, letter f). Appropriate technical and organizational measures must be implemented both for personal data processing (where relevant) and, in general, for AI design and development, considering the level of security appropriate to the risk (Art. 32 GDPR). Authorization and Access Control mechanisms should be ensured. The participating users must act according to the security, privacy and data sharing policies. Access to project's technologies and datasets should be possible only to authorized users.	ITSL, PDPL, ESL, SSPF, AIA, NRD	Must	ALL	R
10	**Fairness and avoidance of unfair biases**	The design and deployment of Circular TwAIn technology must adhere to the Fairness principle, comprising equity, impartiality, egalitarianism, non-discrimination and justice. The reference to the Fairness is common to the soft-law, the P2BR (in relation to the intermediation services ands other sources. For the AI systems, fairness mainly regards the avoidance of biases: it is important to prevent the exacerbation of prejudice and marginalization against certain individuals and/or groups, potentially due to AI systems suffering from the inclusion of inadvertent historic bias and incompleteness. Art. 21 European Charter of Fundamental Rights forbids any kind of discrimination: in the project's technical development work it is important to avoid that the overall solution and/or some of its components/tools might facilitate any kind of discrimination (race, gender, age, religion, disabled) or social sorting, as well as might cause undue or unjustified harm to anyone, including wrongfully stigmatization. The potential	HRs, ESL, P2BR, PDPL, AI	Must	ALL	ALL

		impact of the AI tools and their use on work and skills should be assessed as well: they may alter the work sphere and have an impact on the working environment, on workers, on the relationship between workers and employers, and on skills. The AI system should support humans in the working environment and aim for the creation of meaningful work..				
11	**Accessibility**	The technology should be designed and developed in a way that ensure that people from a population with the widest range of user needs, characteristics and capabilities can use (if opportune, via assistive technologies). This is also in line with the Collaborative Intelligence paradigm. Circular TwAIn technological artefacts should be user-centric and designed in a way enabling all people to use them, regardless of their age, gender, abilities or other characteristics. User and data protection friendly User Interface (UI) should be adopted. Accessibility to AI for persons with disabilities should be considered as well, referring to the Universal Design principles to address the widest possible array of users. Relevant accessibility standards should be followed.	HRs, ESL, SSPF, AIA	Recommended	ALL	R, D
	Accountability	According to the GDPR provisions, the principle of accountability requires organizations to be able to demonstrate compliance with GDPR. This requirement is related to trustworthiness and operational correctness and demands for mechanisms for ensuring responsibility and accountability for AI tools and their outcomes. It comprises i) the auditability, to enable the assessment of algorithms, data and design processes; ii) the minimization and reporting of negative impacts; iii) accessible redress mechanisms in place in case of unjust adverse impacts. It is necessary to be able to provide verifiable evidence on the correctness (i.e., correct configuration) of the current state of each component/system entities. Actions should be non-repudiable, as well as every system entity should be held accountable of its actions.	PDPL, NRD, ESL, SSPF	Must	ALL	R
11	**Risk-based approach**	Both the GDPR and the AI Act refer to the risk-based approach. The GDPR requires an objective evaluation of the ethics risks related to the data processing activities, assessing the particular likelihood and severity of each risk to data protection, taking into account “the nature, scope, context and purposes of the processing and the sources of the risk”. It has to be determined whether there “s a ”risk" “r a "high”risk". In the latter case, particular obligations are foreseen. Pursuant to Recital 75, 76, the risk level (in terms of likelihood and severity for freedoms and rights of individuals) determines what measures are appropriate in each case. The more severe and likely the risks are, the stronger measures will be required to counteract such risks. On the other hand, AI Act classifies risk according to their risk level: i) Unacceptable risk, and in this case the AI solution is banned; ii) High-risk, for which strict obligations are imposed; iii) Limited risk, for which there are only specific transparency obligations; iv) Minimal risk, for which the use is free.	PDPL, ESL, AIA	Must	AI, Data Spaces and tools	ALL
12	**P2BR Obligations**	In case of provision of online intermediation services during the post-project phase, the obligations provided by the P2BR must be accomplished, including for instance, i) the restriction, suspension or termination of a business users’ use of the given online intermediation service, including, for instance, providing a statement of the reasons; ii) the transparency requirement for providers of intermediation services, who have to inform, through clear, unambiguous and readily available contractual terms and conditions, about the treatment, the criteria used to rank their products and the requirements to suspend	ITSBL	Must	ALL	E

		or terminate their services. The Guidelines[3] published by the EC address the main requirements for online platforms identified in P2BR, covering the need to identify key algorithmic parameters behind ranking to their communication to businesses and other.				
13	**e-Commerce and DSA Obligations**	The following requirements are potentially relevant to the project in case of intermediary services, hosting services, online platforms: transparency reporting, measures against abusive notices and counter-notice, Vetting credentials of third-party suppliers ("KYBC"), risk management obligations and compliance officer, external risk auditing and public accountability. The set of DSA measures aimed at boosting the development of trustworthy data-sharing systems, must be in place i) measures to ensure that data intermediaries will play the role of as trustworthy organizers of data sharing or pooling within the common European data spaces; ii) measures to facilitate data sharing, making it possible for data to be used across sectors and borders, and enabling the retrieval of the right data for the right purpose	ITSBL, SSPF	Must	ALL	E
15	**Ethics Board set-up and involvement and Ethics Procedures**	The EAB should be set up and operate to monitor ethical and legal issues in the project and report to the EC. It should work closely with the consortium in order to address the ethical and legal issues. Furthermore, the consent procedures and the recruitment procedures should be implemented in the Industrial Pilots during their operations involving humans.	ESL	Recommended	ALL	R, D

Legend:

Priority: *Must – Recommended*
Phases*: R: Research phase, D: Demonstration phase, E: Exploitation phase, All: all the phases, both during the project and after its end;*
Nature*:*
PDPL*: Privacy and Data Protection Law;*
DSL*: Law in the field of Data Sharing;*
HRs*: Human Rights Law;*
ITSBL*: Telecommunication Law and/or Information Technology-Security Law; Platform-To-Business Regulation, e-Commerce Directive*
ESL*: Ethics and Soft Law;*
SSPF*: Sector-specific Policy Framework, including Standards;*
NRD*: New Regulatory Developments*
AIA*: AI ACT*

[3] *Commission Notice "Guidance Guidelines on ranking transparency pursuant to Regulation 2019/1150*

4.6 Legal and Ethical Requirements for Circular TwAIn Pilots

Each of the following paragraphs comprises, for the respective Circular TwAIn Pilot, the description of ethical and legal requirements. The information has been extracted from the Trial Handbook: such analysis and requirements elicitation might be enriched and/or updated in D7.8 at the end of the project.

4.6.1 WEEE Pilot

Table 18: Legal and Ethical Requirements of the WEEE Pilot

Req #	EL Requirement	Description	Priority	Application Area	Nature	Circular Twain Technology Asset	Business Process	Business Objective
01	Access to data	Access to relevant information for the market analysis	Critical	Production; sales; warehouse	Legal	AI and Data Space	De/Re-manufacturing processes using the AI decision-support tool	To improve the economic and environmental impact
02	Worker protection	Worker may refuse the AI decision-support tool	Critical	Production; sales; warehouse	Ethical	AI and Data Space	Improvement of the processes' efficiency using the AI decision-support tool	To process larger volumes of waste due to a faster data processing capacity.
03	Authorization for larger volumes or new processes	Potential new requirements or authorizations due to a larger volume of waste processed	Critical	Business	Legal	AI and Data Space	Improvement of the processes' efficiency using the AI decision-support tool	To process larger volumes of waste due to a faster data processing capacity.
04	Data protection	To comply with GDPR regulation	Critical	Production, logistics and warehousing.	Legal	AI and Data spaces	Use of digital tools and a vision system	To avoid legal consequences as a result of a non-compliance of the GDPR regulation.
05	Worker protection	To maintain the privacy and independency of the worker in his/her position	Critical	Production, logistics and warehousing	Ethical	Cameras, sensors, AI configuration.	Use of digital tools and a vision system	To improve the processes without harming the employee
06	License rights	Potential restrictions due to	Critical	Production, logistics and warehousing	Legal	AI and Data spaces	Use of digital tools and a vision system	To avoid legal consequences because of a non-

		license rights						compliance of the GDPR regulation.
07	Access to the information	Potential restrictions to access the manufacturing data	Preferred	Production, logistics and warehousing	Legal	AI and Data spaces	Configuration of the vision system	To avoid legal consequences as a result of a non-compliance of the GDPR regulation.

4.6.2 Battery Pilot

Table 19: Legal and Ethical Requirements of the Battery Pilot

Req #	EL Requirement	Description	Priority	Application Area	Nature	Circular Twain Technology Asset	Business Process	Business Objective
00	Data protection	To comply with GDPR regulation	Critical	Dismantling, Recycling, logistics and warehousing.	Legal	Data spaces	-	To avoid legal consequences as a result of a non-compliance of the GDPR regulation.
01	Worker protection	To maintain the privacy and independency of the worker in his/her position	Critical	Dismantling, Recycling, logistics and warehousing	Ethical	Cameras, sensors, AI configuration.	-	To improve the processes without harming the employee
02	License rights	Potential restrictions due to license rights	Critical	Dismantling, recycling, logistics and warehousing	Legal	AI and Data spaces	-	To avoid legal consequences as a result of a non-compliance of the GDPR regulation.
03	Access to the information	Potential access to the data	Preferred	Dismantling, recycling, logistics and warehousing	Legal	AI and Data spaces	-	To avoid legal consequences because of a non-compliance of the GDPR regulation.

4.6.3 Petrochemical Pilot

Use Case A

Data acquisition and representation for AI framework use case has 3 defined business processes i) Acquisition of required physical sensor data for AutoML tool, ii) Acquisition of laboratory data for EO, iii) Acquisition of laboratory data for CO2. Related Ethical and Legal (EL) requirements linked to the experiment as follows:

Table 20: Legal and Ethical Requirement of the Petrochemical Pilot – Use Case A

Rq #	EL Requirement	Description	Priority	Application Area	Nature
00	EL0	Data Privacy	Critical	EO Recovery Unit	Legal
01	EL1	Privacy of Documents, Engineering Drawings, and Specifications	Critical	EO Recovery Unit, DME Process Unit	Legal

Use Case B

Developing a hybrid circular twin of the process use case has 2 defined business processes i) Modelling of the C-205 EO stripper, ii) Construction of the DME simulation. Related Ethical and Legal (EL) requirements linked to the experiment as follows:

Table 21: Legal and Ethical Requirements of the Petrochemical Pilot – Use Case B

Req #	EL Requirement	Description	Priority	Application Area	Nature
00	EL0	DT of C-205 should not be shared with external sources	Critical	EO Recovery Unit	Legal
01	EL1	DME process simulation should not be shared with external sources	Critical	DME Process Unit	Legal

Use Case C

Use of data analytics, AI and model verification to understand process unit failures use case has one defined business process, identification of abnormal process conditions. Related Ethical and Legal (EL) requirements linked to the experiment is as follows:

Table 22: Legal and Ethical Requirements of the Petrochemical Pilot – Use Case C

Req #	EL Requirement	Description	Priority	Application Area	Nature
00	EL0	Analysis results should not be shared with external sources.	- Critical	EO Recovery Unit	- Legal

Use Case D

The use case AutoML module for the Process Industry has two business processes i) AutoML tool development, ii) AutoML tool testing. Related Ethical and Legal (EL) requirements linked to the experiment as follows:

Table 23: Legal and Ethical Requirements of the Petrochemical Pilot – Use Case D

Req #	EL Requirement	Description	Priority	Application Area	Nature
00	EL0	AutoML of C-205 should not be shared with external sources	Critical	EO Recovery Unit	Legal
01	EL1	AutoML testing results should not be shared with external sources	Critical	EO Recovery Unit	Legal

Use Case E

In the Generation of a tool for process optimization use case there is one business process, C-205 Process optimization. Related Ethical and Legal (EL) requirements linked to the experiment as follows:

Table 24: Legal and Ethical Requirements of the Petrochemical Pilot – Use Case E

Req #	EL Requirement	Description	Priority	Application Area	Nature
00	EL0	C-205 optimization tool should not be shared with external sources	Critical	EO Recovery Unit	Legal
01	EL1	Optimization and pilot test results should not be shared with external sources	Critical	EO Recovery Unit	Legal

4.7 Strategy for ensuring Circular TwAIn impact on policy makers.

Circular TwAIn AI platform for circular manufacturing value chains, capable of supporting the development of interoperable circular twins for end-to-end sustainability, is expected to

enabling human centric sustainable manufacturing, fostering the transition to Industry 5.0. Thereby, Circular Twain breakthroughs will contribute to unlock the innovation potential of collaborative AI-based intelligence in production relying on the use of cognitive digital twins combined with the use of trustworthy AI techniques and the planning of a pool of reskilling and upskilling activities for AI-based workplaces. Its innovative services, embedded in AI-based Digital Twins, supporting an unambiguous communication when realizing complex services for sustainable manufacturing, will be paramount to unleash the sustainability potential of AI technologies in circular manufacturing chains.

In this framework, Circular Twain makes ethical soundness, human centricity and trustworthiness core pillar of its technological development work and piloting experiences, in view of moving ahead towards the ethically-sound and human-centered definitive human-machine co-working environments operations. With the aim of contributing to the improvement to the maximum extent of the well-being, flourishing, safety and empowerment of the operator and, more in general, to move from ethical values to practical solutions via their operationalization in its technology (dignity, human flourishing, comfort, well-being and empowerment, inclusiveness, …), the Consortium dedicated (and is going to dedicated in the next months) relevant efforts in its regulatory sandboxes, due attention to the indications and guidelines on human-centricity depicted, for instance, by the European Factories of the Future Research Association (EFFRA).

The outcomes and findings of these activities will be described at the end of the project in the Circular TwAIn Workbook on responsible development and use of its technologies. The Workbook will comprise takeaways, recommendations and guidelines for ethically-aligned uptake and use of project's technology, based on the lessons learnt in the use cases (i.e. the Circular TwAIn Regulatory Sandboxes) and on the findings of the HRIAs and EDPIAs.

The Circular TwAIn Workbook will be disseminated to the Policy Makers at European, national and regional levels, innovation ecosystems and strategic initiatives, including, for instance, DG Connect, DG RTD DG REGIO DG GROW, Digitizing European Industry Initiative and Focus Area, DFA Digital Factory Alliance, Vanguard Initiative, Digital SME Alliance, Made in Europe Partnership, EFFRA, BDVA/DAIRO, AIOTI, ADRA through an array of channels, such as participation to conferences and workshop, Circular TwAIn social media, website and newsletters, as well as relying on the partners' network. The preparation of a Policy Brief and/or a paper reporting the key takeaways and lessons learnt will be also explored. Furthermore, the active participation to the standardization initiatives (including ISO SC41 IoT&Digital Twin, AAS with IDTA, and ISO SC42 AI, among others) and engagement with standardization bodies will also play a role to achieve an impact on policy makers, driving meaningful impact on the development of operational SMART standards that are machine-applicable, readable, and transferable, aligning with the overarching goals of Circular TwAIn.

5 Conclusion and Future Outlook

Over the past 18 months, Task 7.4 has laid the foundation for a training program in the form of a workshop. To this end, didactic factories in the consortium and their focus and infrastructure were familiarized with. The required skills that will be needed by workers in the future were identified for a concrete training program to cover these skills. Ideal personas were collected to have a template of what is needed.

Thanks to this preliminary work, nothing stands in the way of starting the development of the workshop and ensuring a quick integration into the didactic factories.

The European approach to AI centres on excellence and trust, aiming to foster research and industrial capacity, while ensuring safety and fundamental rights, and thereby making the EU a world-class hub for AI by ensuring that AI is human-centric and trustworthy.

This overall approach, which relies on the assumption that fostering excellence in AI will strengthen Europe's potential to compete globally, is at the basis of the AI Package, presented in April 2021, and of concrete rules and actions, such as the regulatory developments outlined in Sect. 4.3.1 of this document (the AI Act, the AI Liability Directive Proposal, the Revised Product Liability Directive Proposal and other pieces of legislation underway). Moving forward in this direction, in January 2024, the EC adopted the AI@EC Communication1, outlining the EC's own strategic approach to the use of AI, anticipating and preparing internally for the implementation of the EU AI Act, as well as including concrete actions about how the EC is going to build institutional and operational capacity to ensure the development and use of trustworthy, safe and ethical AI.

In alignment with this holistic vision, ethical values and fundamental rights have been put at the core of Circular TwAin design and development work. Section 4 of this document outlines the regulatory and ethical reference framework and sets the legal and ethical requirements, functional to ensure the legal compliance and ethical soundness of the Circular TwAIn technologies and piloting activities. Their fulfilment will ensure that the project's research and validation activities, as well as its results, are respectful of the applicable legal landscape, as well as value-driven and aligned with the highest ethical standards.

The main pieces of legislation relevant to Circular TwAIn technological breakthroughs and validation have been considered for the requirement elicitation, together with the findings of the First Consultation with Stakeholders, as reported in Sect. 4.

In the next period, this initial regulatory landscape can be enriched and updated, taking into account both the project progresses and the advancements in the legislative domain (both applicable and under development) . Likewise, the initial outline of the key features of the technologies and Industrial Pilots of Circular TwAIn, respectively reported in Sect.4.2.1. and Sect. 4.2.2, can be refined according to the project's progress.

In the first 18 months of the project, the Consortium also conducted the ALTAI-driven Human Rights Impact Assessment (HRIA) of key Circular TwAIn AI tools, namely the AI Toolkit and the AI-enhanced Digital Twins (DT) for Circularity (Human DT, Process DT, Product and Material DT). The HRIAs were also conducted in relation to the AI assets to be used in the Circular TwAIn Industrial Pilots, conceived as project's regulatory sandboxes for AI. Thanks to this exercise, the Consortium was able to identify, assess and address the potential impact of its AI tools and algorithmic systems on fundamental rights and to take opportune

measures and technological choices to prevent any harm to them. This is consistent with the Ethics-and-Privacy-by-Design-and-By-Default Approach depicted in D1.2 “Ethical Analysis, Governance and Guidelines – 1st version”, demanding to design and test (and, later on, use) the project’s technology in a human-rights respectful manner, encompassing human rights safeguard and promotion based on the identification and tackling relevant risks and opportunities, rather than reacting to unexpected incidents.

The future work pertaining to the legal and ethical activities in T7.3 ““Legal & Ethical Issues, Standardisation and Regulatory Sandboxes”, in conjunction with T1.4 “Ethics Assessment and Governace”, will encompass, besides the refinement of the HRIAs if opportune, a new iteration with Stakeholders for capturing the perspective on topics and issues relevant to the project’s overall progresses, and an update of the legal survey, taking into account also the underway regulatory reforms.

The outcomes and findings of the legal and ethical activities will be described at the end of the project in the Circular TwAIn Workbook on responsible development and use of its technologies, including takeaways, recommendations and guidelines for ethically-aligned uptake and use of project’s technology, based on the lessons learnt in the use cases (i.e. the Circular TwAIn Regulatory Sandboxes) and on the findings of the HRIAs and EDPIAs. The Circular TwAIn Workbook will be disseminated to the Policy Makers at European, national and regional levels, innovation ecosystems and strategic initiatives (such as Vanguard Initiative, Digital SME Alliance, Made in Europe Partnership, EFFRA, BDVA/DAIRO, AIOTI and ADRA).

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