

STEERING AI: LEGAL CHALLENGES AND ETHICAL STANDARDS FROM AN ENGINEERING PERSPECTIVE

Pavia, 18 aprile 2024

At the Crossroads: Balancing Legislation for a Responsible Use of AI in Healthcare

About me



- ❑ **ReD OPEN**
 - Innovative start up & Spin off of University of Milano-Bicocca
- ❑ Cyber Law Expert



- ❑ **University of Milano-Bicocca**
 - PhD Students in Legal Informatics
- ❑ Thesis Proposal
 - Governance of AI – Healthcare sector

Agenda

- SETTING THE SCENE: AI & HEALTHCARE
- THE REGULATORY LANDSCAPE
- A PRECAUTIONARY APPROACH
- PROCESS FRAMEWORK: HOW TO SET THE PACE
- CONCLUSIONS





SETTING THE SCENE: AI & HEALTHCARE

THE REGULATORY LANDSCAPE

A PRECAUTIONARY APPROACH

PROCESS FRAMEWORK: HOW TO SET THE PACE

CONCLUSIONS

Setting the scene



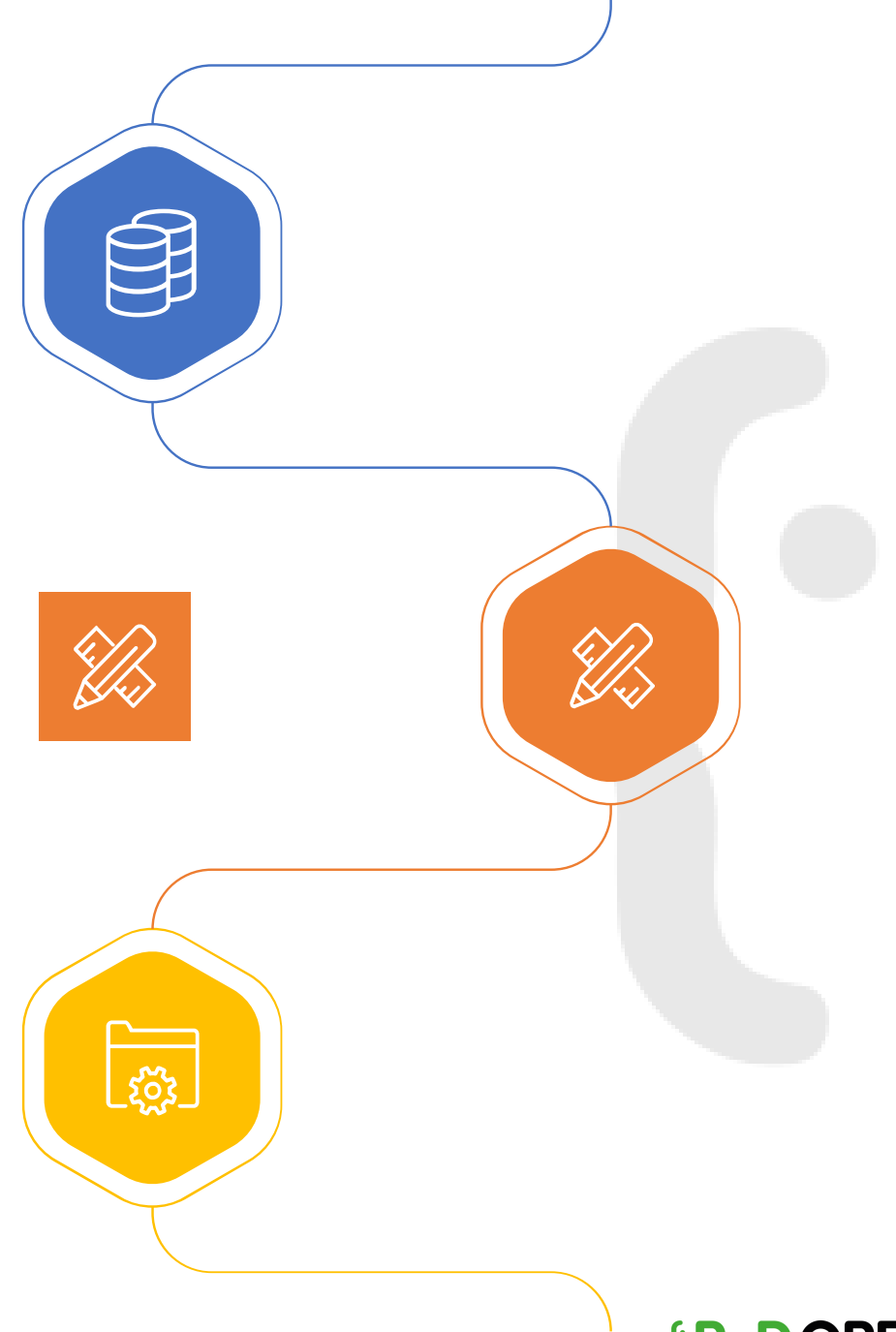
«'AI system' is a machine-based system designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments»
Art. 3, AI Act

«Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity»
Preamble of the Constitution of the WHO, 1948



«**AI systems in health** could be defined as means software that is developed with one or more of the techniques and approaches related to ML; DL and NLP for a given set of human-defined objectives in the areas of physical, mental and social well-being, generate outputs as content, predictions, recommendations, or decisions **influencing the environments they interact with, including public health, health and care services, self-care and health systems.**»

European Commission, Directorate-General for Health and Food Safety, *Study on health data, digital health and artificial intelligence in healthcare, 2022*



Setting the scene: AI and Healthcare in sectors

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- Clinical usage
- Scientific research and drug-development
- Patient care
- Professional education
- Public Health
- Medical devices (IoT)
- Healthcare as industry



Setting the scene: AI and Healthcare in numbers



AI in healthcare - global market

- In 2021, 11 billion US dollars
- By 2030, 188 billion US dollars (compound annual growth rate of 37 percent from 2022 to 2030)

AI in improving patient care

- 83% of patients report poor communication
- Reduce error in self-administration of medications
- 64% of patients are comfortable using Ai virtual nurse assistants

AI to support clinical diagnosis

- Reduce treatment costs by 50%
- Improve health outcomes by 40%

Source: IBM, the benefits of AI in healthcare, 11 July 2023, available at:<https://www.ibm.com/blog/the-benefits-of-ai-in-healthcare/>

Setting the scene: AI and Healthcare in risks

Information & Data

- Inflation & fragmentation of information
- Data
 - Source
 - Stability
 - Security
 - Resistance
- Personal Data Protection
- Bias and Discrimination



«Collateral» risks

- Liability
- Ethics and Culture
- Relationship with patients
 - Awareness
 - Responsibility
 - Transparency
 - Discrimination
 - Explainability
- Labour and employment

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The Regulatory landscape

Health

- EHDS, Proposal for a regulation - European Health Data Space, May 2022
- Directive on the application of patients' rights in cross-border healthcare, April 2011
- MDR, Regulation on medical devices, April 2017
- IVDR, Regulation on in vitro diagnostic medical devices, April 2017

Personal Data and Data Protection

- GDPR, applicable since May 2018
- ePrivacy Directive, 2009
- Proposal for an ePrivacy Regulation, 2017
- European Convention on Human Rights, right to private life, 1950
- Charter of Fundamental Rights of the European Union, private life and protection of personal data

Artificial Intelligence

- AI Act, Proposal, last consolidated text March 2024
- AI Treaty, waiting for the AI Act

Liability

- AI Liability Directive, Proposal for a directive on adapting non-contractual civil liability rules to artificial intelligence Sept 2022
- New PLD, Proposal for a revision of the Product Liability Directive, Sept 2022

Non personal Data

- Data Governance Act, applicable since Sept 2023
- Data Act, applicable from Sept 2025
- Regulation on a framework for the free flow of non-personal data in the EU, Nov 2018

Cybersecurity

- NIS 2 Directive (update and replace NIS), applicable from Oct 2024
- EU Cybersecurity Act, June 2019
- Cyber Resilience Act, Proposal for a regulation on horizontal cybersecurity requirements for products with digital elements, Sept 2022
- CER Directive – Directive on the resilience of critical entities, transposable up until Oct 2024



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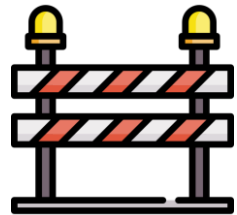
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A precautionary approach

«The precautionary principle is an approach to risk management, where, if it is possible that a given policy or action might cause harm to the public or the environment and if there is still no scientific agreement on the issue, the policy or action in question should not be carried out. However, the policy or action may be reviewed when more scientific information becomes available» EUR-Lex, Precautionary Principle

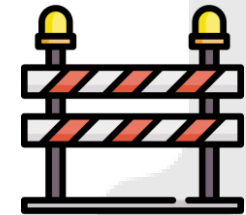
▷ Art. 191 (2), TFEU



SCIENTIFIC
UNCERTAINTY

&

POLITICAL
RESPONSIBILITY



A strategy to risk management — A decision ~~making~~ system — A process to steer innovation

IMPACT ASSESSMENT

➡ AI Act

A precautionary approach

IMPACT ASSESSMENT



- Lack of quantitative indicators
- Low or absent AI literacy and awareness
- Lack of categorisation (based on sector, interest or role in the organization)
- Focus on principle, whereas legal instruments deal with products

PROCESS FRAMEWORK



*based on the information available to date

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Process Framework: how to set the pace

« Process frameworks are reference models that support the description, assessment, and optimization of business processes.»

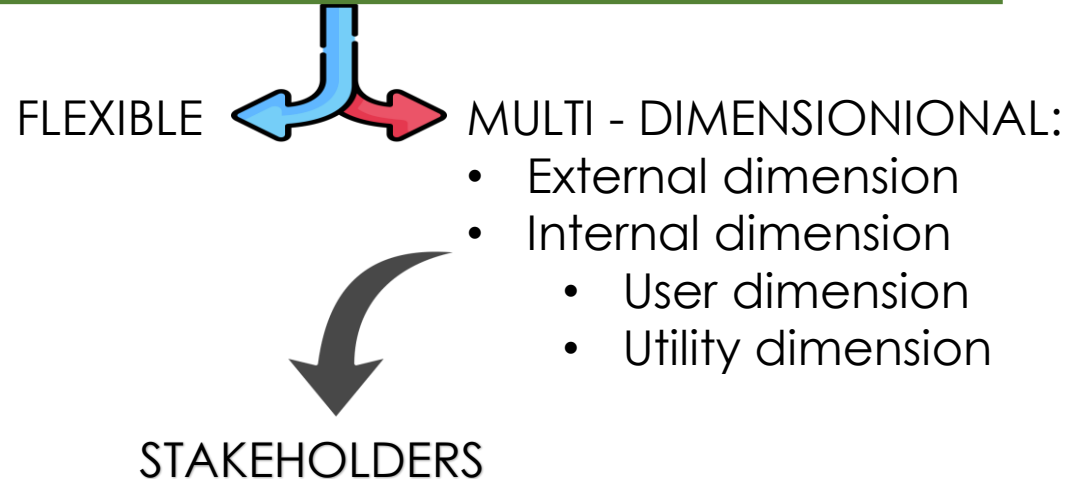
OEGB Certification Guide, 2011

«Process frameworks are essentially lists of all the key processes performed in an organization, grouped hierarchically to show how they relate to each other.»

APQC (American Productivity & Quality Center)

« Process frameworks are **qualitative guidance** that **enable systematic and actionable tasks for implementing responsible AI systems.**»

A Matrix for Selecting Responsible AI Frameworks, June 2023

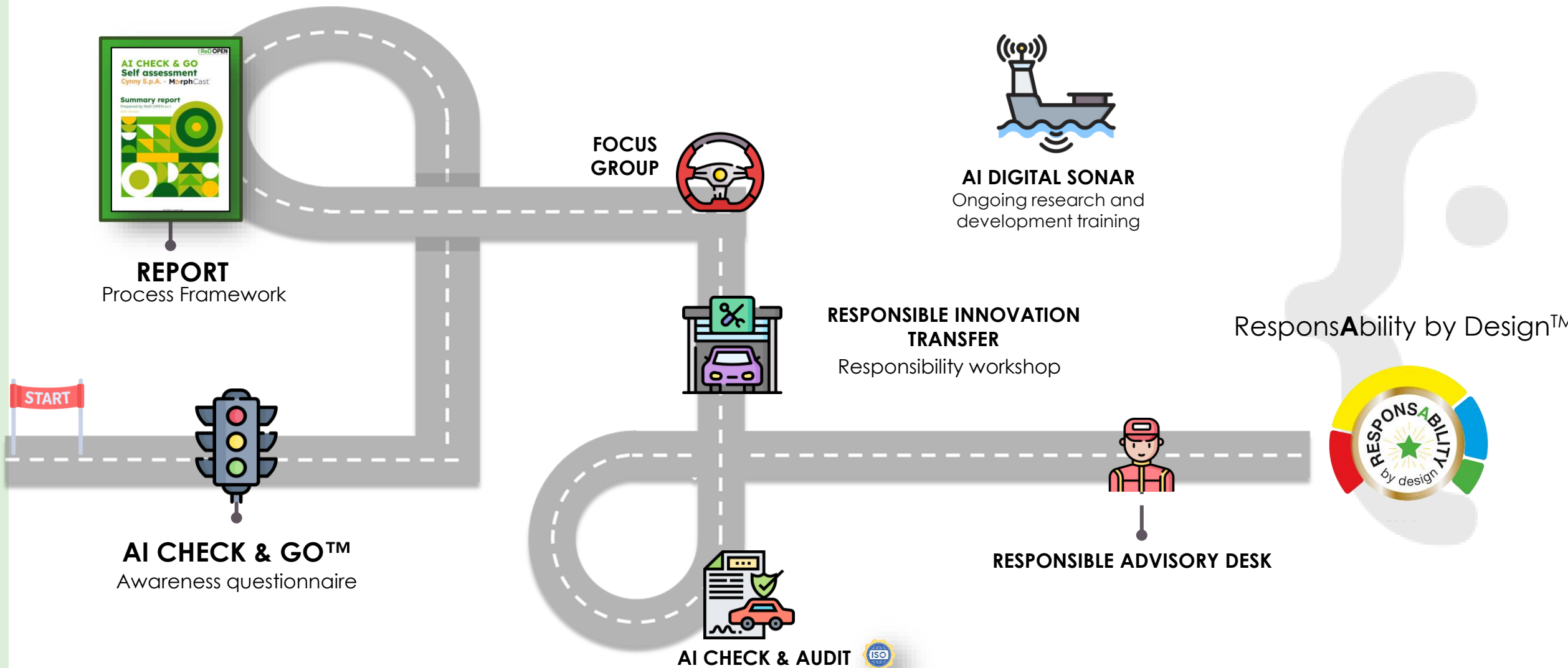


service delivery, the health workforce, health information systems, access to essential medicines, financing, and leadership and governance

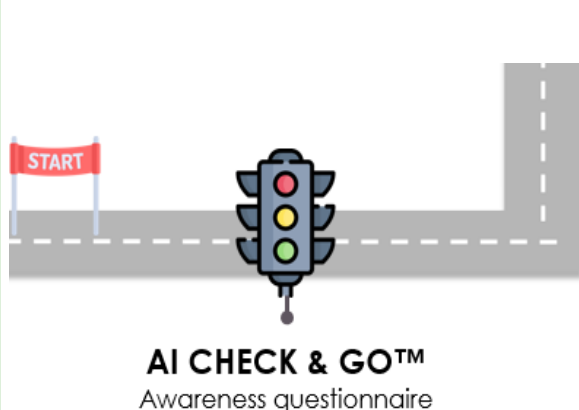
WHO, Ethics and governance of artificial intelligence, Guidance on large multi-modal models, 2024

From Business: ResponsAbility by Design™

From Process Framework to a Responsible path of implementation



ResponsAbility by Design™



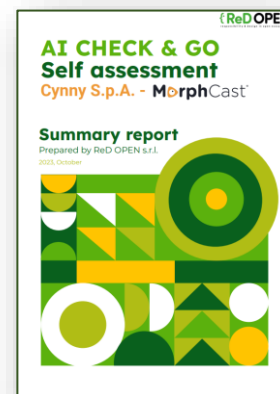
- A self-assessment questionnaire
- **Organization's awareness** of the impacts and risks of **AI**
- Individually administered
 - **a sample of employees** from various sectors
 - **Role in the organization**
 - **Role of AI** in the value chain



Pillars

1. General context;
2. **Declared purposes and objectives;**
3. **Organizational impact;**
4. Transparency and accountability;
5. Non-discrimination and fairness;
6. Privacy, data protection, and data governance;
7. Environmental impact.

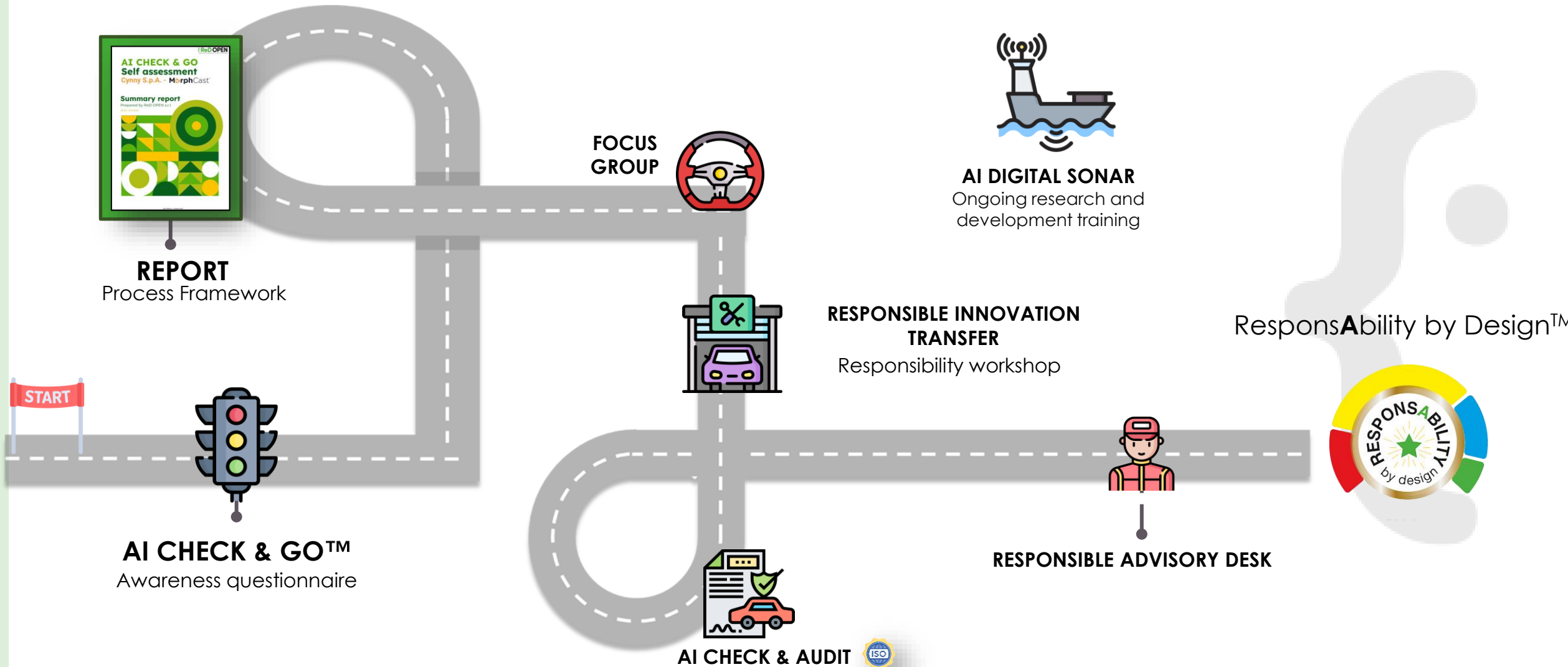
PROCESS FRAMEWORK



Case study: MorphCast
– Facial Emotion Recognition AI
<https://www.morphcast.com/advantage/responsible-approach/#redopen-report>

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Conclusions

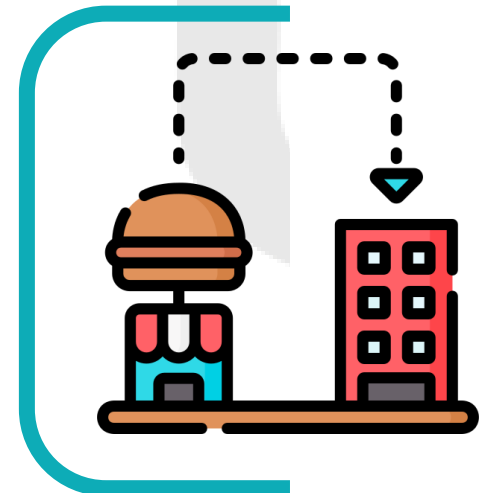


What we know:

- The regulatory landscape is dense, complex and ever-evolving
 - Protection of **principles** and fundamental rights
 - **AI** is mainly addressed as a **product**
- Healthcare is a **complex environment** with **many interests** at stake which may confront differently with AI.
- Efforts toward **transparency**, explainability and fairness

What shall we do:

- **Raise awareness**
- **Document and justify** decisions, possibly with external certifications
- Data Protection and Privacy compliance
- **Pathway** approach
- Identify and differentiate by **stakeholders**



THANK YOU FOR YOUR TIME!

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