

# HCI ESG Policy Report 2025

## Environmental, Social & Governance (ESG) Policy – Full Document

### 1. Introduction

HealthCare Innovation (HCI) is a national and Euro-Mediterranean cluster dedicated to advancing health technologies, digital transformation, and innovation capacity across Tunisia and beyond. As a multi-stakeholder organization working with startups, hospitals, universities, scientific societies, industry, investors, and international institutions, HCI recognizes that impactful innovation must be responsible, inclusive, ethical, and sustainable.

This ESG Policy outlines the principles, regulations, standards, and operational mechanisms that guide HCI's commitment toward **environmental stewardship**, **social responsibility**, and **ethical governance**. It applies to all staff members, board representatives, trainees, suppliers, sub-contractors, and partners involved in HCI activities.

The policy also ensures alignment with **Tunisian regulations**, **EU frameworks**, and **international standards** relevant to health technology, data protection, medical innovation, and organizational integrity.

### 2. Regulatory & Standards Framework

HCI operates under a robust compliance framework integrating national Tunisian law, European regulations (when relevant), and internationally recognized standards.

#### 2.1 Tunisian Legal Framework

HCI complies with:

##### 2.1.1 Personal Data & Health Data Protection

- **Organic Act 2004-63**

Regulates the collection, processing, transfer, and storage of personal and sensitive data, including health data.

HCI applies national obligations related to consent, transparency, purpose limitation, data security, and lawful cross-border transfer.

### **2.1.2 Whistleblower Protection & Anti-Corruption**

- **Organic Act 2017-10**

Provides protections for whistleblowers and establishes procedures for reporting misconduct in public and private institutions.

HCI ensures confidential reporting, non-retaliation, and ethical procurement practices.

### **2.1.3 Prevention of Violence & Harassment**

- **Organic Act 2017-58**

Covers workplace violence, discrimination, and harassment.

HCI enforces zero tolerance for harassment, implements preventative measures, and ensures access to fair reporting channels.

### **2.1.4 Environmental Protection & Waste Management**

- **Law 96-41 on Waste Management and Pollution Control**

HCI adopts responsible environmental practices, including proper disposal of IT equipment, electronic waste, and medical-adjacent supplies.

## **2.2 European Union Regulations (Applicable to EU Partnerships)**

HCI aligns voluntarily with key EU frameworks when collaborating with European partners or managing activities involving EU stakeholders.

### **2.2.1 General Data Protection Regulation (GDPR)**

Establishes obligations for processing personal data of EU residents.

HCI applies GDPR principles for all cross-border projects, including DPIAs, data minimization, privacy-by-design, and secure transfers.

## **2.2.2 EU Medical Device Regulation (MDR 2017/745)**

Relevant for digital health solutions, SaMD, and clinical validation projects.

HCI promotes MDR principles of safety, performance, traceability, and risk management for startups and innovation partners.

## **2.2.3 EU Artificial Intelligence Act**

Applies to AI systems used in healthcare and high-risk applications.

HCI follows requirements for data governance, risk classification, documentation, transparency, and human oversight.

## **2.2.4 European Health Data Space (EHDS)**

Supports responsible access, sharing, interoperability, and secondary use of health data.

HCI adopts EHDS principles in digital health projects and Living Lab activities.

## **2.2.5 NIS2 Directive**

Defines cybersecurity requirements for essential and digital service providers.

HCI improves cyber resilience through incident response procedures, supplier audit controls, and secure digital architecture.

## **2.2.6 Digital Services Act (DSA)**

Regulates transparency and accountability of digital platforms.

HCI applies DSA-inspired measures for any online platforms used for community engagement or innovation support.

## **2.2.7 EU Corporate Sustainability Reporting Directive (CSRD) & EU Taxonomy**

HCI refers to CSRD and Taxonomy guidelines to align sustainability reporting when partnering with EU-funded programs and institutions.

# **2.3 International Standards Adopted by HCI**

To ensure quality, reliability, and integrity, HCI aligns its activities with:

- **ISO/IEC 27001** – Information Security Management
- **ISO 27701** – Privacy Information Management

- **ISO 13485** – Quality Management for Medical Devices
- **ISO 14971** – Risk Management for Medical Devices
- **IEC 62304** – Software Lifecycle for Medical Device Software
- **ISO 20121** – Sustainable Event Management
- **WHO & OECD guidelines** on health innovation, ethics, and patient safety

## 3. Environmental Commitments (E)

HCI is committed to minimizing environmental impact in all operations.

### 3.1 Resource Optimization

- Reduction of paper and material consumption
- Energy-efficient equipment and cloud-based infrastructure
- Hybrid or virtual events to reduce travel emissions

### 3.2 Sustainable Procurement

- Preference for eco-friendly suppliers
- Encouraging low-impact logistics, packaging, and manufacturing
- Evaluating suppliers on environmental responsibility

### 3.3 Waste Management

- Responsible e-waste disposal in compliance with Law 96-41
- Waste sorting and recycling practices during events and innovation programs

- Safe disposal procedures for medical-adjacent and chemical materials

### **3.4 Support for Climate-Smart HealthTech**

HCI prioritizes innovation that reduces the environmental footprint of healthcare systems, such as telemedicine, remote monitoring, and energy-efficient clinical technologies.

## **4. Social Commitments (S)**

HCI advances social inclusion, equity, and community well-being.

### **4.1 Access & Equity**

- Ensuring equitable access to training, mentoring, and innovation programs
- Including regional hospitals, public health institutions, and underserved communities
- Supporting startups addressing public health needs

### **4.2 Diversity, Inclusion & Gender Equality**

- Implementation of a Gender Equality Plan aligned with EU recommendations
- Gender-balanced representation in events, governance, and leadership
- Programs encouraging youth, women, and students in STEM and digital health

### **4.3 Safe Work & Event Environments**

- Zero tolerance for harassment or discrimination
- Accessible and inclusive events and training activities
- Confidential and safe reporting channels

## 4.4 Community & Capacity Building

HCI works closely with:

- Universities
- Scientific and medical societies
- Civil society organizations
- Hospitals and clinics
  - to strengthen health innovation capacity and raise awareness about responsible digital health practices.

## 5. Governance Commitments (G)

### 5.1 Ethical Conduct

HCI ensures that all stakeholders act in accordance with integrity, transparency, and professional ethics.

Conflicts of interest must be declared and addressed proactively.

### 5.2 Anti-Corruption & Whistleblowing

HCI enforces:

- A confidential whistleblowing mechanism
- Non-retaliation guarantees
- Ethical procurement practices
- Transparent management of funds and partnerships

### 5.3 Data Protection & Privacy

HCI ensures:

- Compliance with Tunisian law and GDPR when applicable
- Documentation of processing activities
- Secure systems for health data
- DPIAs for high-risk activities

## 5.4 Cybersecurity & Digital Integrity

HCI implements:

- Strong access control
- Incident response procedures
- Secure cloud and on-premise environments
- Regular training for staff and partners

## 5.5 Transparency & Accountability

HCI maintains clear governance structures, financial transparency, and formal approval processes for major decisions.

# 6. Implementation & Monitoring

HCI ensures operational adoption of this policy through:

- Annual ESG compliance review
- ESG KPIs: environmental impact, gender parity, inclusion metrics, governance indicators
- Staff capacity-building on ethics, data protection, and sustainability
- Supplier and partner compliance evaluation

- Integration of ESG into program design, contracts, and project management

## **7. Review & Updates**

This ESG Policy is reviewed annually by the HCI Executive Board. Updates may occur earlier if required by new Tunisian laws, EU regulations, or international standards.