



GLOBAL  
**SELF-CARE**  
FEDERATION

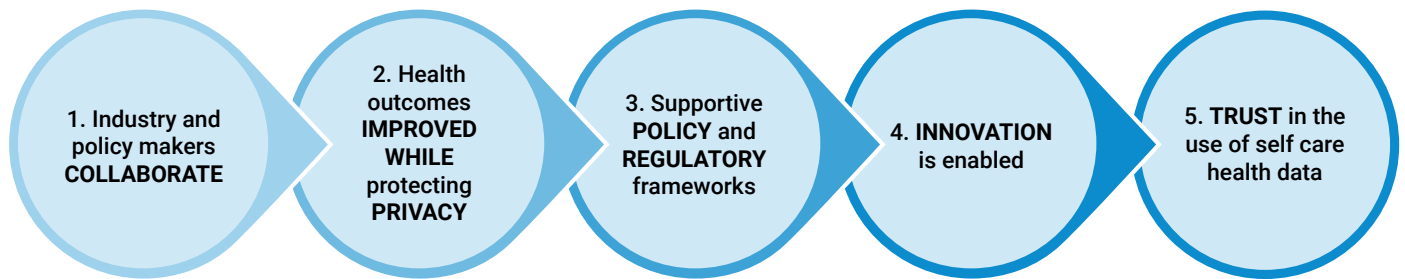


GSCF HEALTH DATA  
**FUTURE VISION  
AND GUIDING  
PRINCIPLES**

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# FUTURE VISION

GSCF strives for a future where the potential of self-care health data to improve health outcomes is fully realized.



## GSCF MEMBERS ENVISION A FUTURE IN WHICH:

1. A wide range of relevant **stakeholders collaborate and communicate to shape** a legal, policy and regulatory **environment that is supportive of the safe and appropriate use of self-care health data**<sup>1</sup> to the benefit of both individual health and society. Stakeholders involved in this close collaboration include industry, policy makers, regulators, and civil society, including patient and consumer groups.
2. All stakeholders recognize that self-care health data plays an important role in improving people's quality of life and lowering healthcare spend. Self-care health data is used to the widest extent possible to **improve health outcomes**. Individual **privacy and autonomy** around self-care health data is protected, ensuring data is **collected transparently, with informed consent** and always kept **secure and protected** with appropriate technologies and administrative, digital, and physical safeguards<sup>2</sup>.

<sup>1</sup> GSCF understand as Self-Care Health Data any data about an individual related to their health and wellbeing, including medical and non-medical data, generated through both online and offline activities.

<sup>2</sup> See the GSCF Principles on the Safe and Appropriate Use of Self-Care Health Data for further information.

3. **Regulatory frameworks** are rooted in a risk-based approach<sup>3</sup> and are clear, fit-for-purpose and based on internationally-recognized best practices. They set out minimum standards for the safe and appropriate use, and quality of self-care health data. This helps protect patients' privacy, reduces data fragmentation, and enables the generation of high-quality data on a large scale. Regulatory frameworks continuously evolve to address challenges arising from new technologies and innovations.
4. This enables **innovation to thrive using the insights gained from self-care health data**, supporting, and improving individuals' health and well-being. Rapid approval processes enable continuous improvements and benefits.
5. All stakeholders work together to **build and maintain trust** in the use of self-care health data through efforts to improve health and digital literacy, privacy awareness, and understandings of how health data is used and the benefits that come from it.

<sup>3</sup> Aiming to provide protective action to individuals if a product, action or policy has a suspected risk of causing harm to individuals. The greater the risk, the stricter the regulation. For a similar approach applied to medical devices, see IMDRF "Software as a Medical Device" 2014.





# GSCF PRINCIPLES ON THE SAFE AND APPROPRIATE USE OF SELF-CARE HEALTH DATA

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GSCF defines Self-Care Health Data as any data relating to an individual's health and wellbeing, including medical and non-medical data, generated through both online and offline activities. It is used to produce insights and drive behavior change to improve health outcomes.

GSCF members are aware that these data are highly sensitive and thus comply with all applicable laws and regulations, ensuring the respect of privacy, and the safe and appropriate use of self-care health data.

## OUR MEMBER COMPANIES ACT<sup>4</sup> ACCORDING TO THE FOLLOWING PRINCIPLES:

### 1. AUTONOMY

- Self-care health data is used to promote personalized care and **empower** people to take an active role in managing their own health.
- **Individual rights** are always respected, enabling individuals to autonomously determine what data they provide and for what aim, as well as how, and with whom, it is shared. Accordingly, data is collected on a valid legal basis in ways that are in line with the intentions and understanding of the individual. Individuals can **access and correct** their own data.<sup>5</sup>

### 2. PRIVACY AND SECURITY

- **Human well-being and safety** is ensured.
- Individual data is always kept secure and protected with **appropriate technologies** and **administrative, digital and physical safeguards**<sup>6</sup>.
- In **clinical trials and real-world data collection settings**, precautions are in place in the collection and handling of data to ensure the safety and privacy of the data and the individual.
- **Cybersecurity policies and controls** are continuously reviewed to ensure we implement fit-for-purpose policies and controls.
- Data shared with third parties is always anonymized, preserving individual privacy.

<sup>4</sup>GSCF member associations promote adherence to these principles to their member companies.

<sup>5</sup>To the extent technically possible, as anonymized data can no longer be edited or removed.

<sup>6</sup>Administrative safeguards include internal procedures, trainings and building employee capabilities to prevent human error. Digital and physical safeguards relate to access protocols to data and facilities.

### 3. TRANSPARENCY

- Individuals should always be able to **understand how their personal data is being used and for what purpose**. They are informed in an appropriate, understandable, clear, and concise manner about what personal data is collected, processed, and stored, and for what purposes. They are also informed of their rights and what steps they can take to exercise those rights.

### 4. NON-DISCRIMINATION & NON-MANIPULATION

- Data is collected in an **inclusive and non-discriminatory** manner, while upholding high clinical and scientific standards.
- Individual data is not used for discriminatory, manipulative, or other purposes than those agreed, or when such use may cause harm to the individual.

### 5. ACCOUNTABILITY & RESPONSIBILITY

- These principles are implemented through effective **governance, clear standards, and training and monitoring activities**, reflecting the ethical aspects of self-care health data collection and use.
- Companies **comply with** all applicable **data privacy rules when collecting, processing and retaining individual data**.
- Within companies, there is a publicly **designated contact person responsible for data protection and confidentiality**.

### 6. QUALITY AND INTEGRITY OF DATA

- **Information provided** to individuals is **based on current, accurate evidence drawn from data**, supported by science and not manipulated in a misleading way. In case data is found to be inaccurate, casting doubt on the information provided to individuals, the responsible company will promptly delete or rectify the data.
- Companies **document and pursue mechanisms to mitigate risks of bias or personal detriment**, where the quality, completeness or accuracy of data entails such risks.

### 7. ACCESSIBILITY AND LITERACY

- Highest levels of **accessibility** are in place to facilitate access to digital self-care health services and products for all individuals, especially those with low digital literacy.
- **Health and digital literacy** are encouraged and fostered through effective targeting of interventions to drive engagement, standardization, and civic participation in collecting, managing, using and understanding self-care health data.

