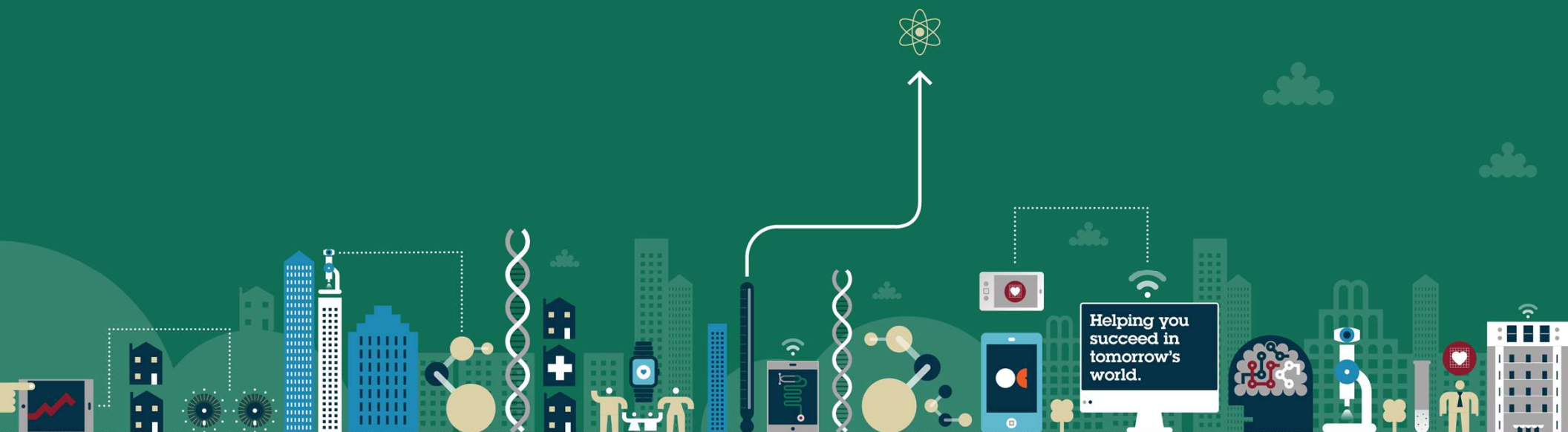


Navigating GDPR when using AI in the Life Science Sector

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Presenting today



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Agenda

Introduction

Key GDPR Principles for AI used in Life Science Sector

Where can data come from to Train AI for the Life Science Sector?

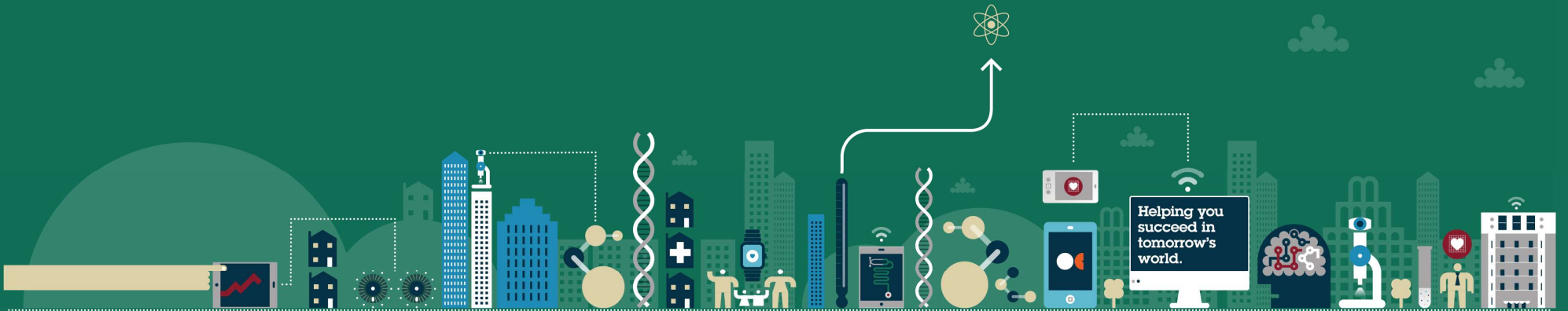
AI/GDPR checklist for Life Science Sector

Key Take Aways for GDPR compliance and AI in Life Science Sector

Q&A



Introduction



Relevance of GDPR for non-EU companies?



Material scope

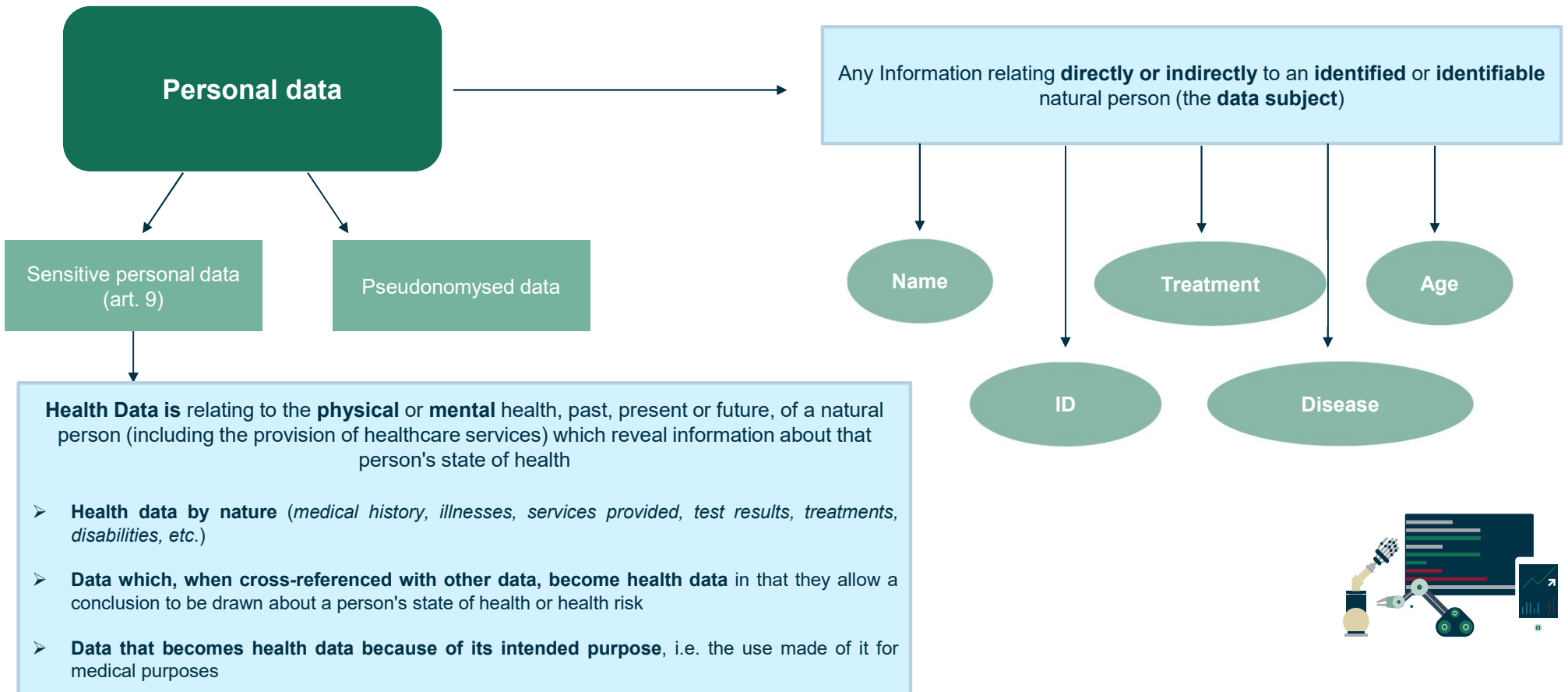
- The GDPR applies to the **processing of** personal data wholly or partly **by automated means, and to the processing of personal data by** non-automated means
- **Size** or **activity** are not factors to be taken into account

Territorial scope

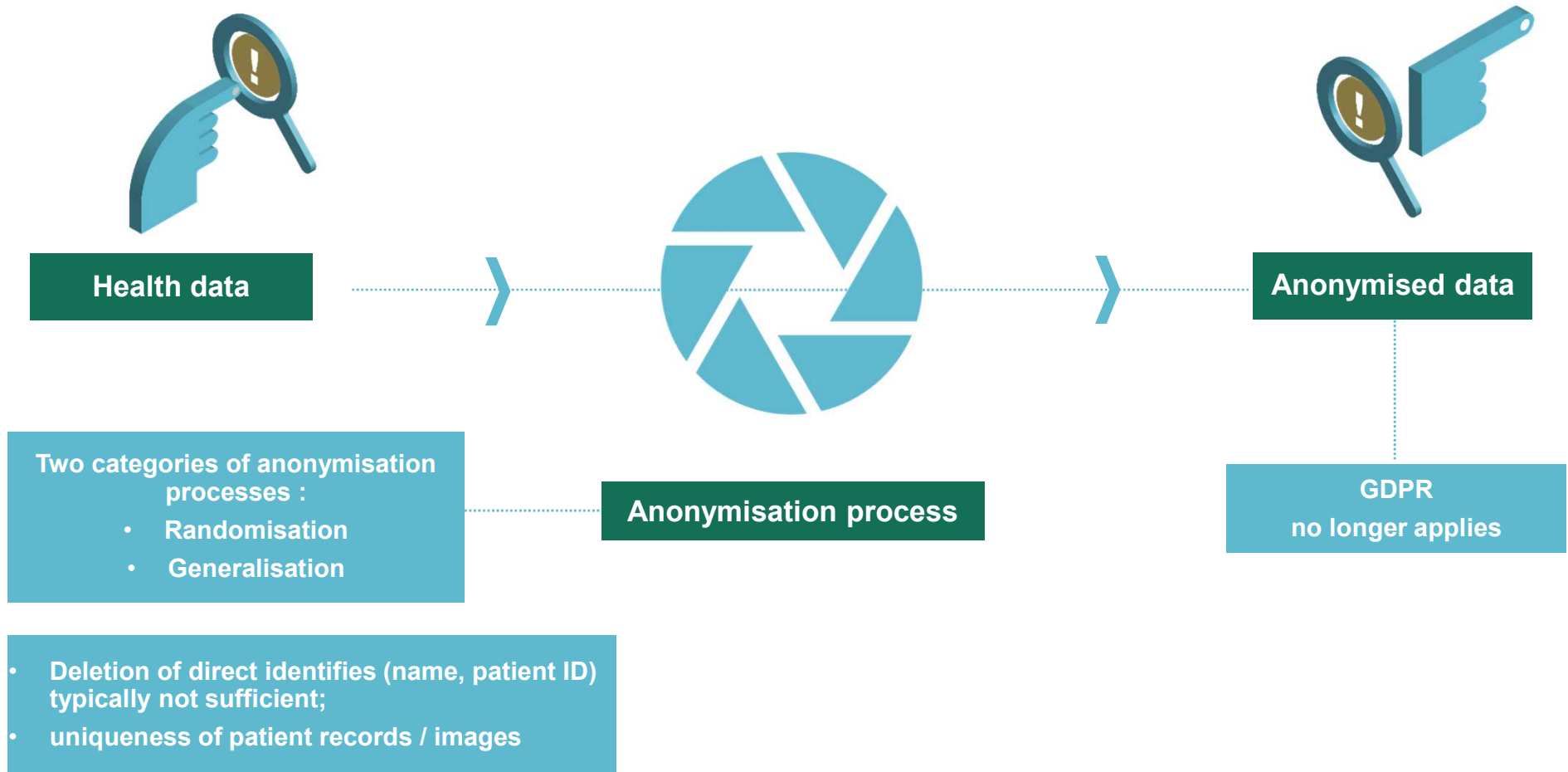
- **Establishment criterion:** any data controller or processor established on EU territory
- **Targeting criterion:** any data controller or processor established outside the EU but whose processing relates to data of EU individuals for the purpose of offering goods or services or monitoring behaviour



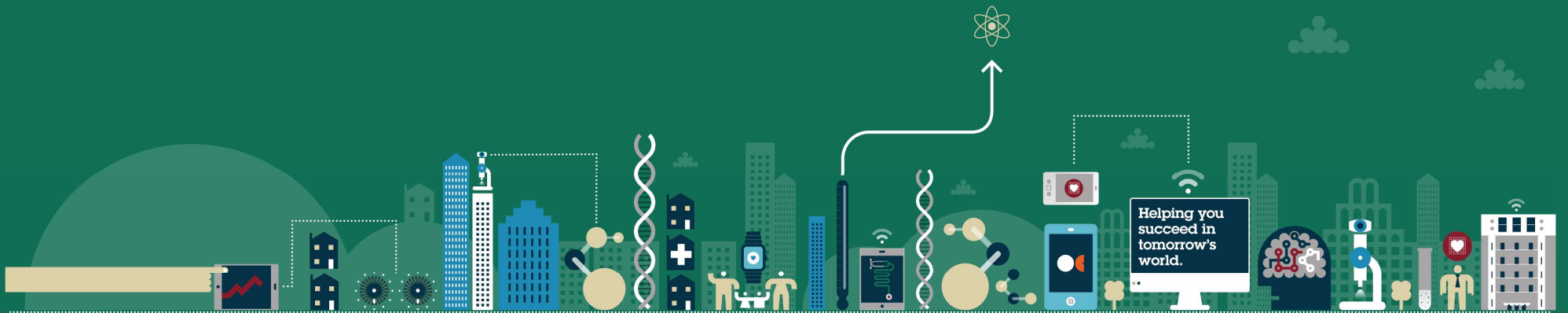
What is a personal data under GDPR?



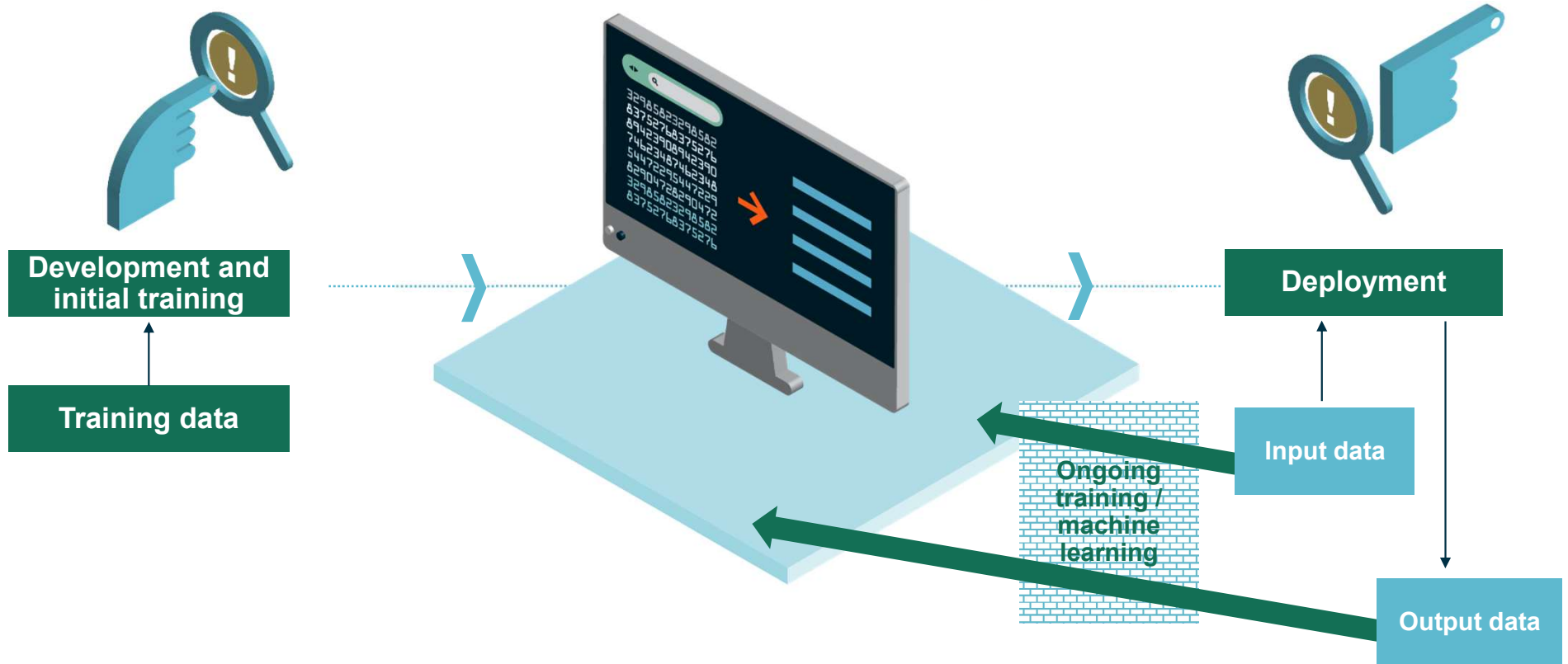
What is required to have anonymized data under GDPR ?



Key GDPR Principles for AI used in Life Science Sector



How do we look at AI to determine GDPR requirements?



Legal Basis

Legal requirements for processing data for each purpose		
Development and training AI	Deployment at HCP / Hospital	Ongoing training / machine learning
Legal basis (art. 6 GDPR) : consent, public interest or legitimate interest etc.		
Exception (art. 9 GDPR) : express consent from the data subject, the information is made public by the data subject, processing is necessary for reasons of public interest in the area of public health		



Local requirements. Need to check if in your country a local requirement must be complied with. *Example of France:* Formalities with the CNIL for research projects and HDS certification for hosting personal health data; EU Member state specific permission grounds

Privacy Notice



Information to be provided where personal data is collected (art. 13 & 14 GDPR)

Risk

If the **data is re-used from databases**, there is a risk that data subjects may not be aware of the use of their data with AI



Solution

- ✓ **Check if a privacy notice** has been provided to data subjects
- ✓ Provide **appropriate (and practical) information** to data subjects
- ✓ Check whether an **exception art. 14 (5)** can be applied
 - Data subject already has this information
 - The provision of such information proves impossible or would require a disproportionate effort, in particular for scientific research purposes



Data Subject Rights

Data Subject Rights (art. 14-20 GDPR)

When the AI system involves the processing of personal data, **data subjects have the right to retain control of their data**. The data controller must explain how to exercise these rights (to whom, in what form, etc.). When they exercise their rights, individuals must, in principle, receive a response within one month

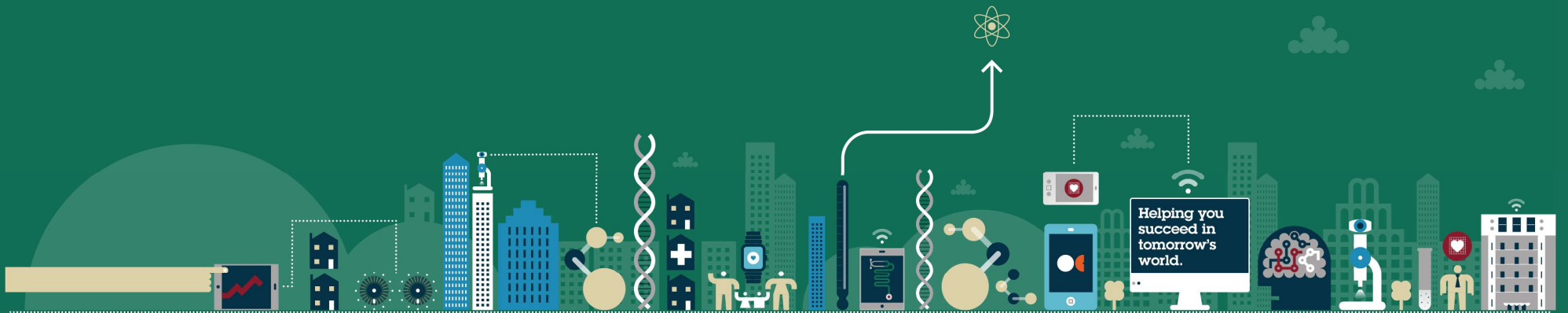
E.g. right of access to personal data by the data subject (Art. 15 GDPR)

Exemption (art. 11 GDPR)

If a purpose for which a controller processes personal data do no longer requires to identify a data subject, **the controller is not obliged to maintain, acquire or process additional information** in order to identify the data subject for the sole purpose of complying with the GDPR

In the event the controller is unable to identify the data subject, the controller shall inform the data subject accordingly. DSRs shall not apply, except where the data subject provides additional information which makes it possible to identify him/her

Where can data come from to train AI in the Life Science Sector?



Website Scraping is no option in Life Science Sector



Health Data:

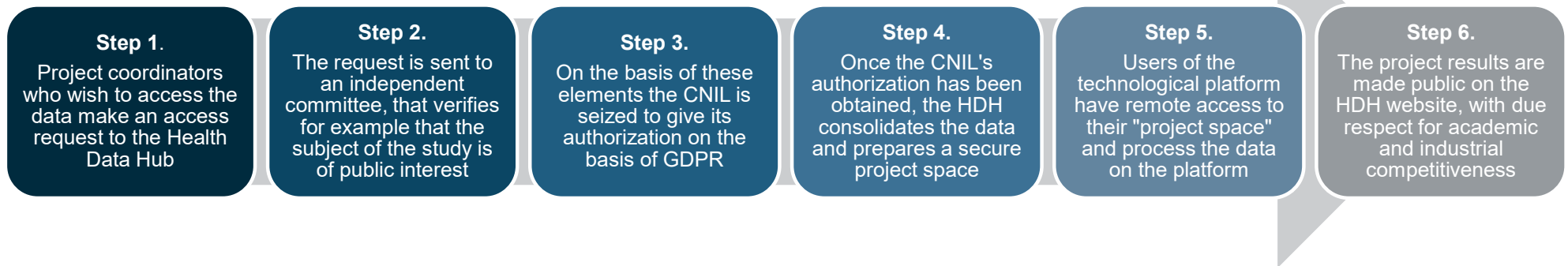
- Health data is **sensitive data** (art. 9 GDPR)
- Health data must be of **high quality**, and therefore obtained from reliable sources (ex: data spaces)

The French Health Data Hub and other health data spaces



**HEALTH
DATA HUB**

In France, the **Health Data Hub** is a **one-stop shop for accessing** data catalogues for health data. It was created by the July 24th 2019 law on the organisation and transformation of the healthcare system.

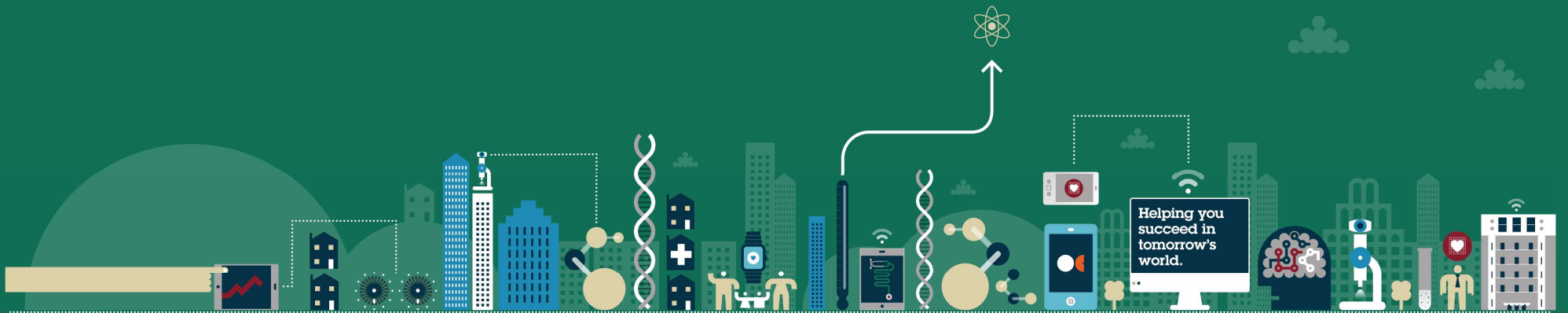


EU initiatives of Health Data Spaces :



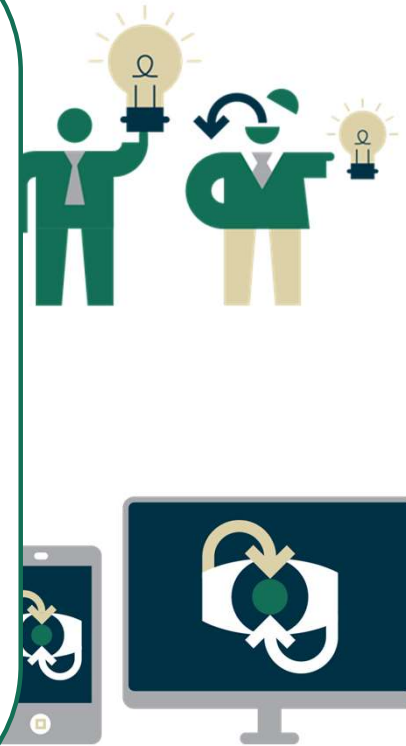
Bundesministerium
für Gesundheit

AI/GDPR checklist for Life Science Sector



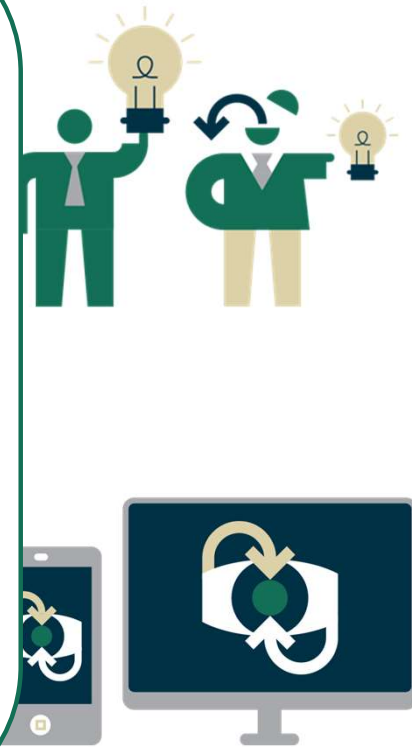
AI / GDPR checklist for Life Science Sector

- ✓ **Governance structure: Allocation of responsibilities amongst the internal stakeholders; project plan with allocated tasks**
- ✓ **Understand how the AI works and how it processes personal data; determine the phases of the AI**
- ✓ **Understand the organization's role under GDPR for each phase: controller vs. processor vs. joint controller**
- ✓ **Determine the source of the personal data and the qualification as sensitive /non-sensitive**
- ✓ **Determine the purposes of the processing (link to phase of the AI)**
- ✓ **Analyse a legal basis (Art. 6 and 9 GDPR): Is consent required or are other legal bases available? What are the conditions?**
- ✓ **Practical considerations to obtain consent if required; understand your supply chain**

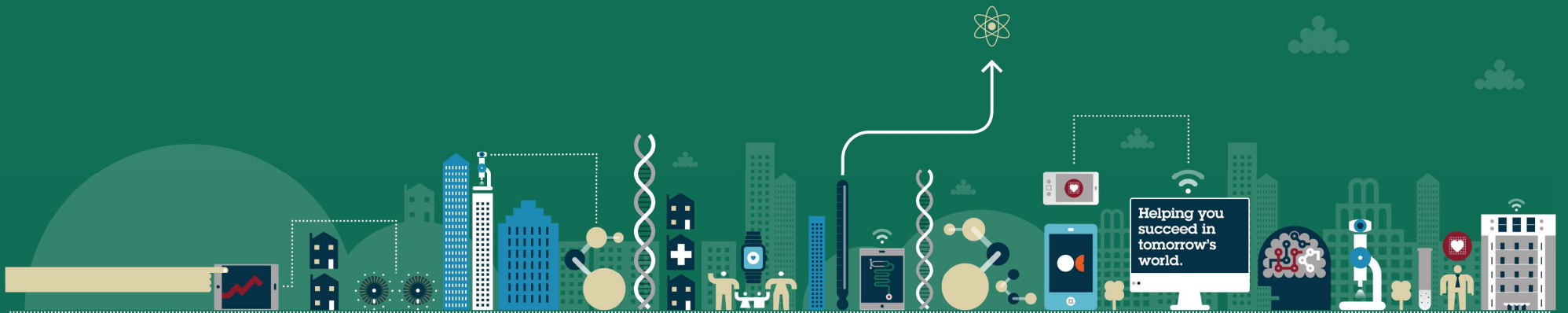


AI / GDPR checklist for Life Science Sector

- ✓ Consider general GDPR principles (data minimization, access restrictions, data retention, data transfer restrictions, supervise automated decision-making, documentation requirements) and implementation steps, such as eliminate certain data fields, access right concept, deletion schedule, agreements for international data transfer/TIAs, processes for human invention
- ✓ Governance structure to supervise continuous improvement of the AI system, e.g. regular touch points with IT, trigger for new legal review (e.g. new purposes, new data, changes to algorithm)
- ✓ Determine supervision and concept to protect individuals against the risks associated with AI models, including ethical considerations and discrimination
- ✓ Ensure full transparency for users and individuals
- ✓ Develop process for data subject rights and data subject transparency



Key Take Aways for GDPR compliance and AI in Life Science Sector



Key Take Aways for GDPR compliance and AI in Life Science Sector



- Privacy compliance is a big challenge when developing, training and using AI in the Health Care Sector
- For privacy compliance, starting point is to understand the life cycle and the phases of the AI and to dive into the details
- Do not accept any “black boxes”
- Always pay attention to the source of the health data
- Looking at the laws, permission grounds and conditions at EU Member State level is crucial; GDPR alone is not sufficient
- Specific attention must be paid to legal basis when using AI
- The regular process to comply with data subject rights might not be suitable to cover personal data processed via AI

Thank you

Questions?

