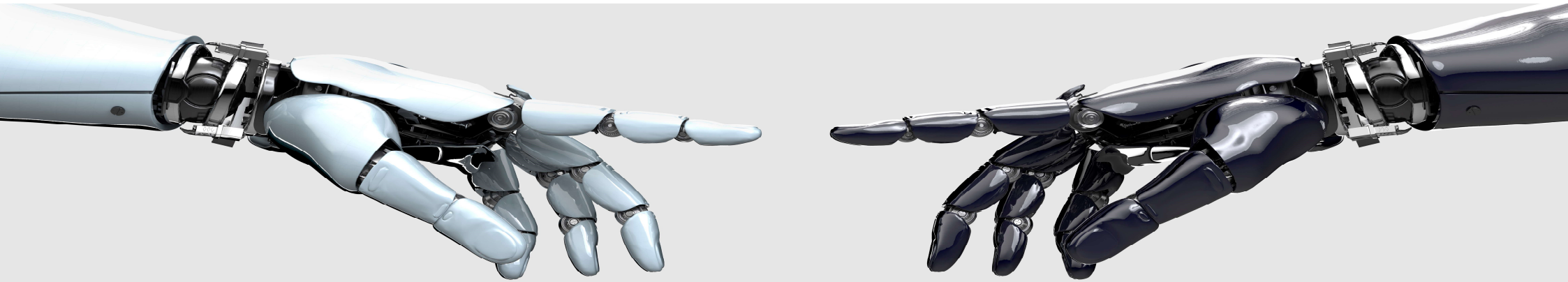# Data related EU regulatory landscape and EU-Japan relations

BJA Digital Event: Opportunities for Belgium-Japan Cooperation in Digital MedTech
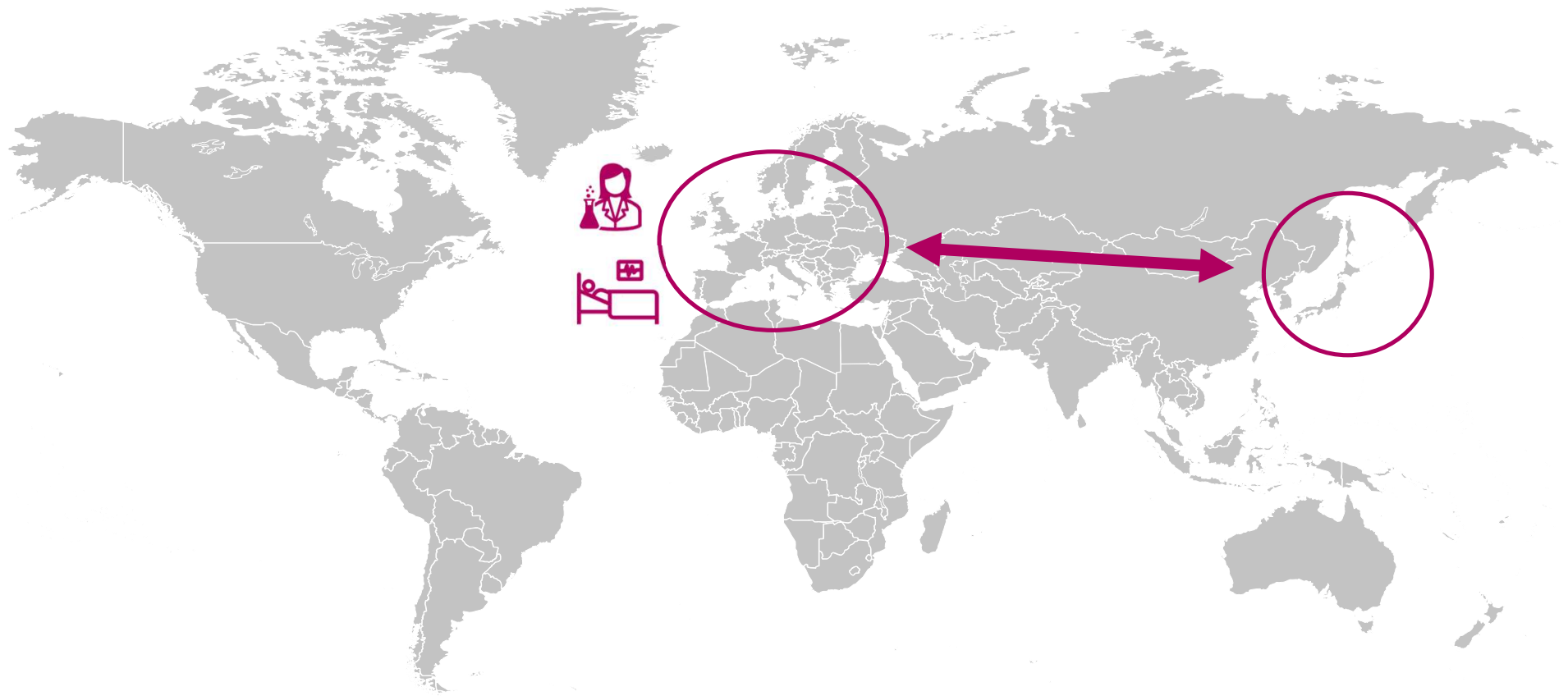
Tanguy Van Overstraeten

28 September 2023

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EU Digital regulatory Digital MedTech

EU digital regulatory landscape

EU digital regulatory landscape

	Ratio legis
GDPR (2016/679)	• Regulates the processing/ (incl. transfer) of personal data
EU Data Governance Act (2022/868)	• Facilitates data sharing across sectors and EU countries
Proposed EU AI Act	• ensure AI systems in the EU are safe and respect fundamental rights

Proposed EU Data Act	• Aims to boost the EU's data economy by:
	  o unlocking IoT data
	  o fostering a competitive and reliable EU cloud market

Proposed ePrivacy Regulation	• GDPR applied to electronic communication data
Proposed EU Health Data Space Regulation	• Provides a secure access to and processing of health data

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EU digital regulatory landscape

	Personal data	*Non-personal data*
GDPR (2016/679)	✓	✗
EU Data Governance Act (2022/868)	✓	✓
Proposed EU AI Act	✓	✓
Proposed EU Data Act	✓	✓
Proposed ePrivacy Regulation	✓	✓
Proposed EU Health Data Space Regulation	✓	✓

EU General Data Protection Regulation (GDPR) (2016/679)

About

- Protection of individuals' data
- **Health related personal data** = higher protection (e.g. patients' data)

Status

- Applicable as of 25 May 2018
- Interplays with the ePrivacy Directive 2002/58

ePrivacy Directive due to be replaced by a Regulation (still under approval process)

Relevant to

- All organisations in the EU (data controllers)
- Individuals
- Extraterritorial effects

Key relevant obligations

- Maintain the integrity of personal data
- Purpose driven and legal ground to justify processing
- Empower individuals (rights of access, etc.)
- More flexibility for scientific research (e.g. pseudonymised data)
- Controllers vs processors relationship
- Enforcement rules

EU Data Governance Act (2022/868)

About

- Fostering data sharing by public bodies
- Create a framework for data intermediaries
- Data altruism

Status

- Adopted 30 May 2022
- In force since 23 June 2022
- Applicable as of 24 September 2023

Primarily relevant to

- Public bodies
- Data intermediaries (*linking individuals, data holders and data users*)
- **Companies wishing to share / acquire data**

Key relevant obligations

- Rules on reuse of public data
- Limitations (e.g. IP, DP)
- Via anonymisation, secured environments, etc.
- Data intermediaries to become subject to strict obligations (notification, not for profit structure)
- Promotion of data altruism (data sharing for free)

The proposed EU Data Act

About

- Regulating access and use of IoT data (e.g. connected MedTech equipment, wearables)
- Making easier to switch cloud service providers

Status

- Proposal 23 February 2022
- Political agreement 28 June 2023
- Need for formal approval + 20-month transition

Primarily relevant to

- Manufacturers and **users (incl. companies)** of IoT products
- Providers and **users** of cloud services

Key relevant obligations

- IoT manufacturers
  - must design IoT products enabling to provide data to users
  - complex obligations to licence IoT data on FRAND terms
  - Interoperability
- Cloud service providers
  - Customer right to terminate and switch on 30 days notice

The proposed EU AI Act

About

- First regulation worldwide on use of AI
- Before ChatGPT
- Extended to generative AI – foundation model

Status

- Proposal 21 April 2021
- Trilogue in progress ➜ adoption late 2023?
- Likely to apply not before 2025

Primarily relevant to

- Manufacturers, distributors and **users** of AI systems, esp. in high risk areas

Key relevant obligations

- Tiered regulation with 4 (or 5) levels:
  - <u>Prohibited uses</u>: clear threat to people (e.g. public social scoring)
  - <u>High-risk</u>: subject to extensive rules for the systems (e.g. safety - **AI application in robot-assisted surgery**)
  - [<u>Foundation models</u>: range of specific obligations]
  - <u>Minimum risk</u>: transparency obligations (eg: Chatbots)
  - <u>No risk</u>: all others – only general principles applying to all

Also draft AI Liability Directive

The proposed European Health Data Space Regulation

About

- Vertical regulation based on DGA and DA
- Creation of a single market for health data with resolution of cross border issues

Status
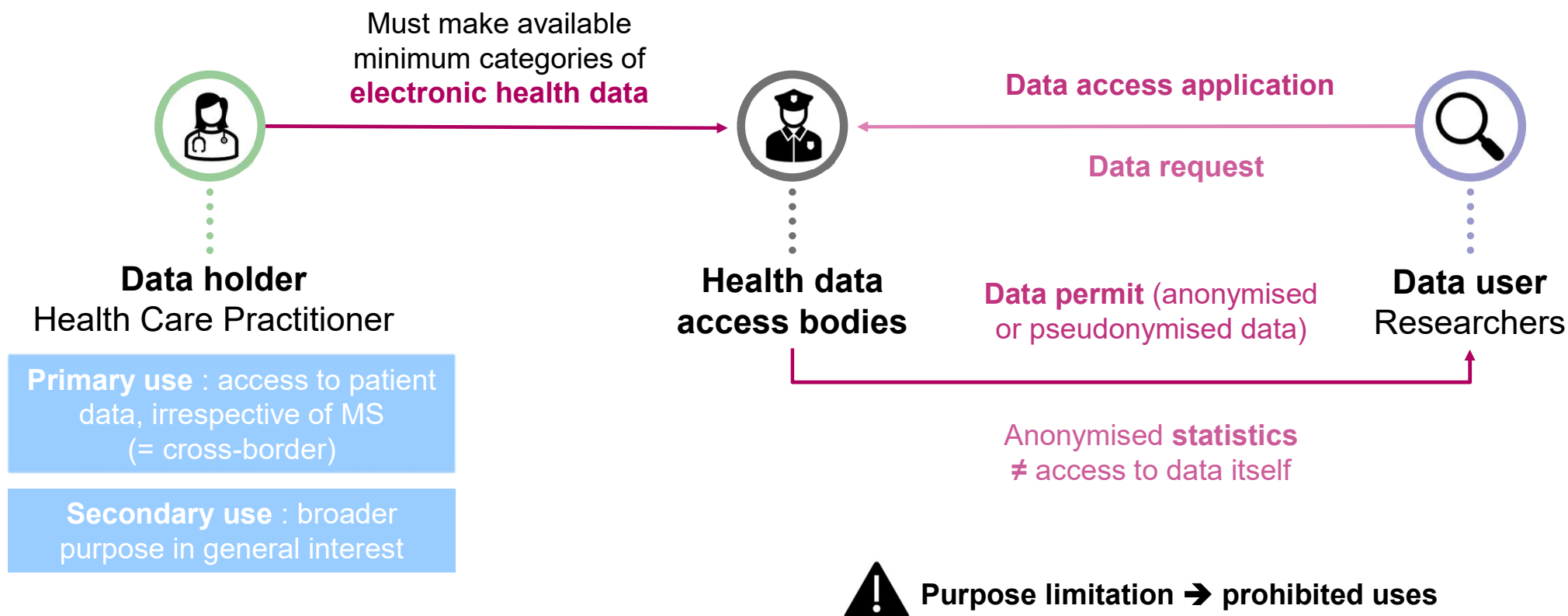
- Proposal 3 May 2022
- Likely to be adopted in 2024

Primarily relevant to

- **Patients**
- **Health care professionals and researchers**

Key relevant obligations

- Empower patients
- Obligation for health care professionals to grant access to patient's data
- **Secondary uses allowed for purposes that benefit society (e.g. research)**
- Request for a data permit granted by a health data access body

Health data usage under the EHDS

Must make available
minimum categories of
electronic health data

Data access application

Data request

Data holder
Health Care Practitioner

**Health data
access bodies**

Data permit (anonymised
or pseudonymised data)

Data user
Researchers

Primary use : access to patient
data, irrespective of MS
(= cross-border)

Secondary use : broader
purpose in general interest

Anonymised **statistics**
≠ access to data itself

⚠ **Purpose limitation ➔ prohibited uses**

Cooperation between Japan and the EU

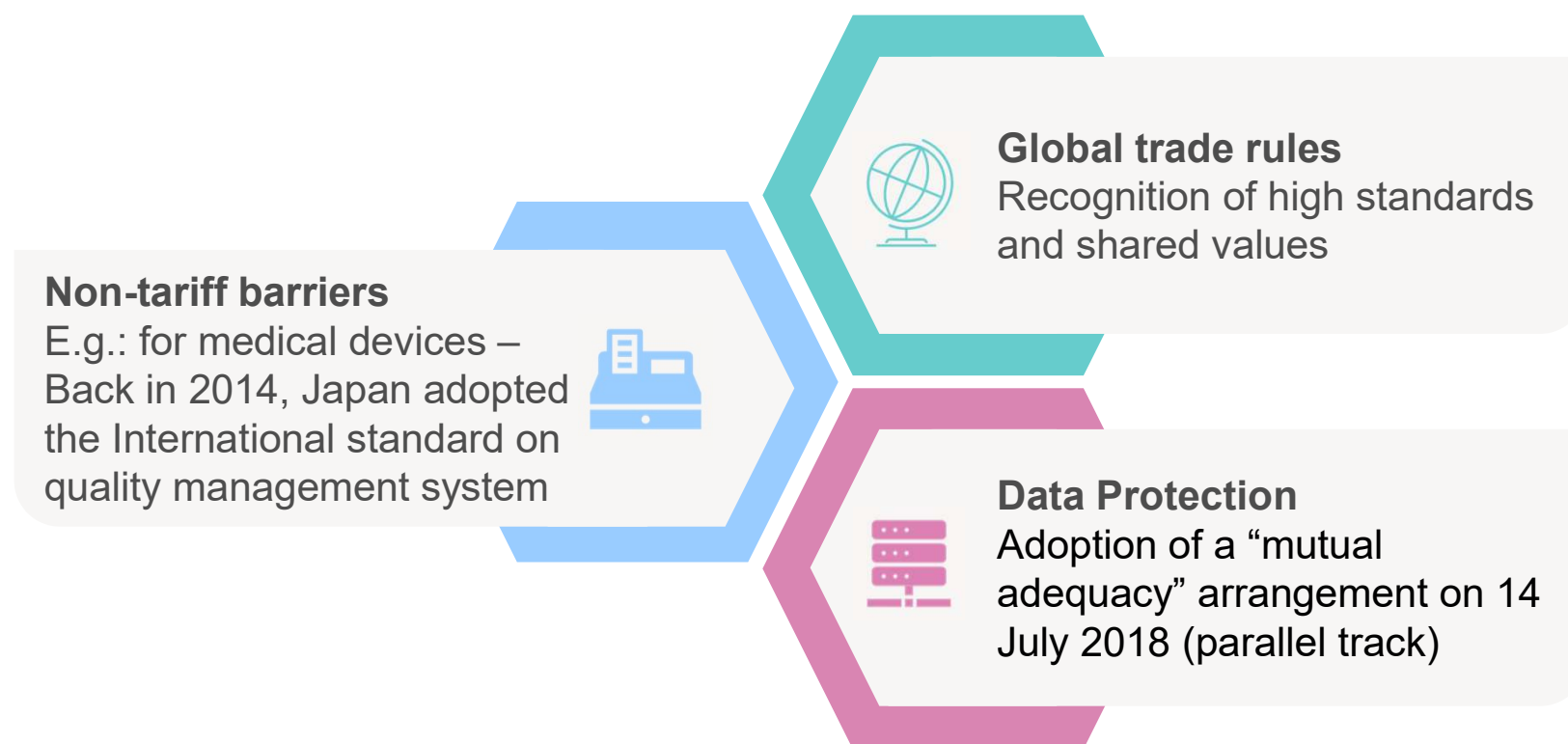# EU – Japan Economic Partnership

Economic Partnership Agreement (EPA)

> Agreement signed on 17 July 2018

> Entered into force on 1 February 2019 (with progressive implementation)

> > The agreement is due to eliminate most of EU and Japan tariff lines

> Increasingly successful

> World's largest open economic area

In bn Yen

Trade between the EU-27 and Japan (2019-22)*
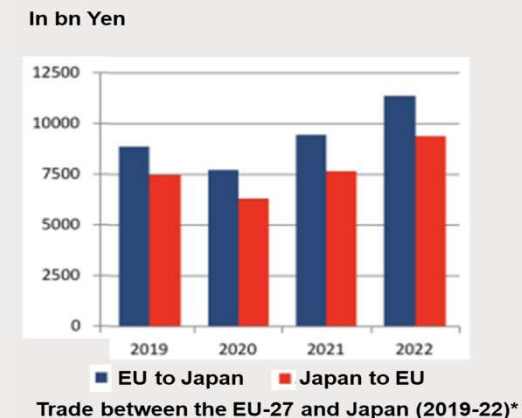
Source: excerpt from EU-JP-Trade-Report-2022.pdf (eu-japan.eu)

Some key aspects of the EU-Japan relationship

Global trade rules
Recognition of high standards and shared values

Non-tariff barriers
E.g.: for medical devices – Back in 2014, Japan adopted the International standard on quality management system

Data Protection
Adoption of a "mutual adequacy" arrangement on 14 July 2018 (parallel track)

EU-Japan Digital Partnership

Background

> **12 May 2022**
> > Digital Partnership during the 28th Japan-EU Summit in Tokyo
> **Purpose**
> > Advance cooperation on digital issues
> > Collaborative research on cutting-edge technologies (incl. AI)
> > Regulatory dialogue

1st meeting of EU-Japan Digital Partnership Council

> **3 July 2023**
> Cooperation in a wide range of areas
> > E.g.: **AI, promoting best practices to enable free flow of data with trust**, reciprocal access for researchers to supercomputers
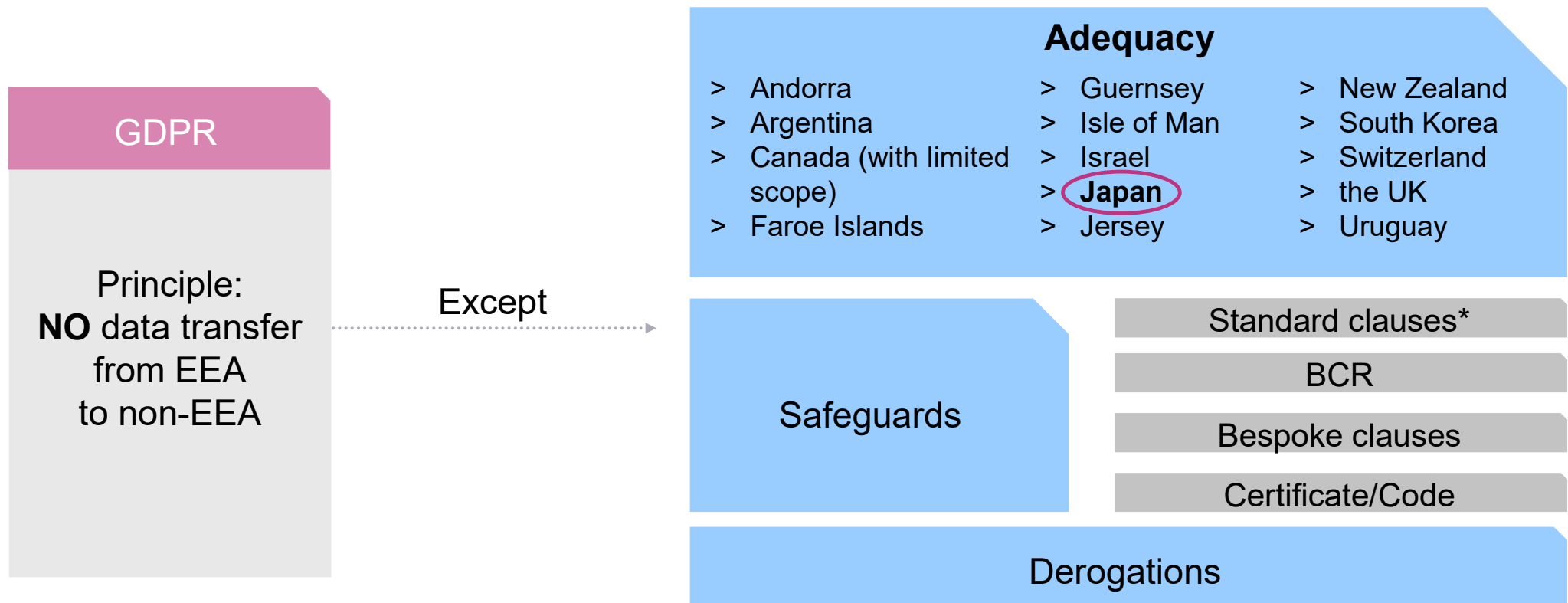> Memorandum of cooperation in other fields (eg: semiconductors)

Personal data transfers EU - Japan

Personal data transfer under the GDPR

GDPR

Principle:
NO data transfer
from EEA
to non-EEA

Except →

Adequacy

> Andorra
> Argentina
> Canada (with limited scope)
> Faroe Islands

> Guernsey
> Isle of Man
> Israel
> **Japan**
> Jersey

> New Zealand
> South Korea
> Switzerland
> the UK
> Uruguay

Safeguards

Standard clauses*

BCR

Bespoke clauses

Certificate/Code

Derogations

*MedTech Europe contributed to the consultation process re. new SCCs.

EU – Japan adequacy decision

Initial adoption

> **January 2019**
>> Based on enhancement of the Japanese legal rules
>> <u>Reciprocal</u> adequacy decision

Review Report

> **First review in April 2023**
>> Convergence between data protection frameworks
>> Positive feedback
>> Expanded scope (eg: academia + public sector)

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Conclusion

Evolving landscape =
Work in progress

Willingness to foster cooperation

Upcoming opportunities
BUT also threats

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