

TsRAP

台灣醫藥品法規學會

Taiwan Society of Regulatory Affairs for Medical Products

2024 RAPS SHARING: E-LABELING

YILING TSAI 蔡懿玲

臺北護理健康大學 健康事業管理系 助理教授

2025/03/28

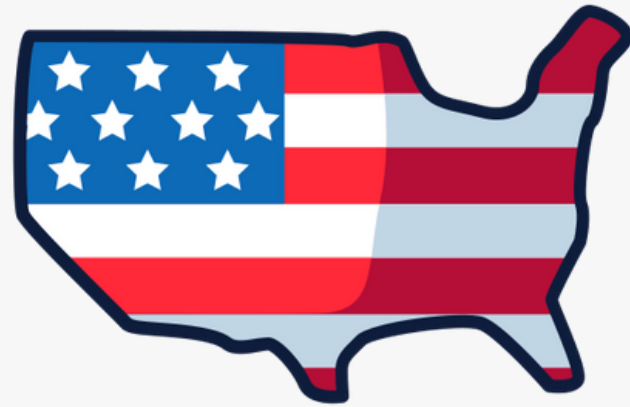
RAPS Convergence

LONG BEACH, CALIFORNIA, USA • 17-19 SEPTEMBER 2024



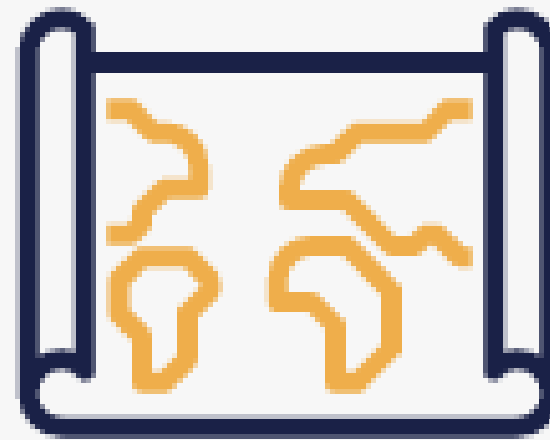
2000+

RAPS
Convergence
2024 Attendees



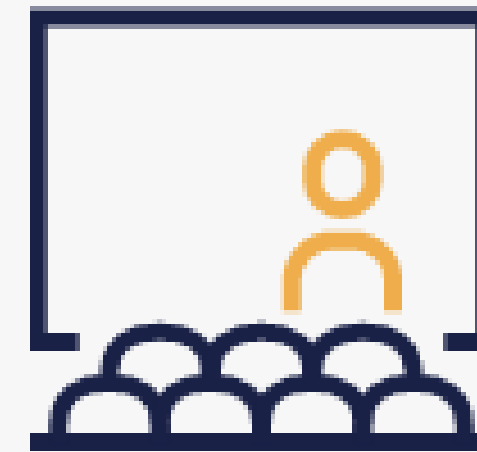
40

US States



37

Countries



> 160

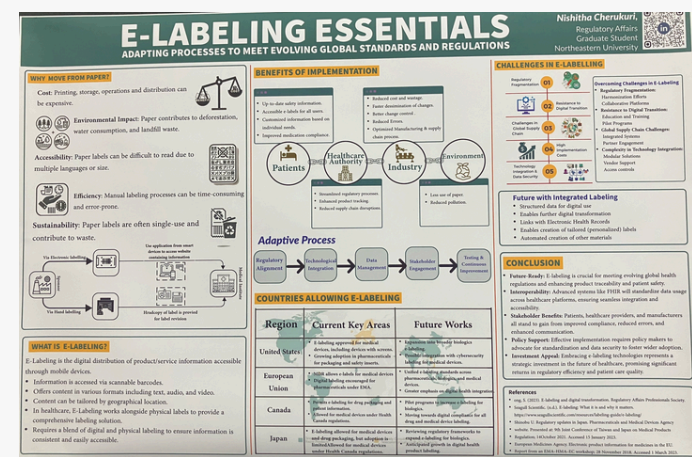
Sessions in
Pharmaceuticals,
Medical Devices, IVD,
and AI



320

Expert
Speakers

OUTLINE



E-Labeling Essential

A poster from Nishitha Cherukuri,
Northeastern University



ePI for EU medicines: the EMA-HMA-EC initiative

Presented by Elizabeth Scanlan,
ePI Product Owner, EMA



Digital Labeling and eIFU

Presented by Glenda C. Marsh
Sr. Director EMEA Regulatory Affairs
Johnson & Johnson MedTech

Digital Labeling and eIFU Enhance Customer Experience, Facilitate Compliance, and Improve Operational Efficiencies and Agility

 Wednesday, September 18, 2024  1:00 PM – 2:00 PM PDT  Location/Room: 102

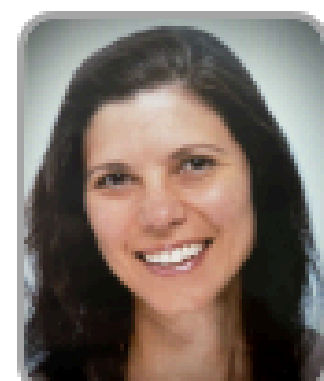
Presenter(s)



Nataliya Deych

VP Regulatory Affairs EMEACLA
Edwards Lifesciences Sarl, Switzerland

[Slides](#)

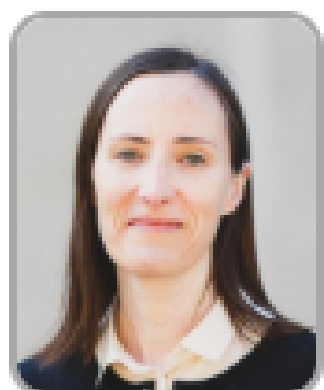


Glenda Marsh

Sr. Director, EMEA Regulatory Affairs
Johnson & Johnson Medtech, Switzerland

[Slides](#)

Presenter (Remote)(s)



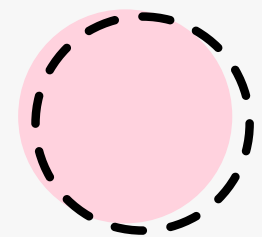
Elizabeth Scanlan, MSc, PhD

Scientific Communication Officer
European Medicines Agency, Netherlands

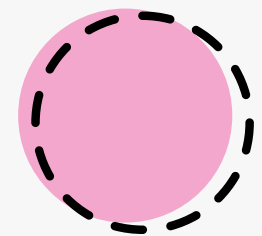
[Slides](#)

E-Labeling Essential

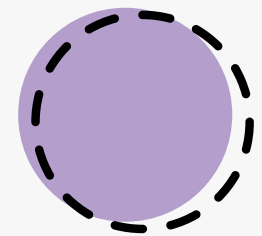
E-Labeling is the digital distribution of product/service information accessible through mobile devices.



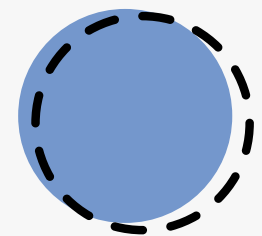
Information is accessed via **scannable barcodes.**



Offers content in **various formats including text, audio, and video.**



Content can be tailored by **geographical location.**



In healthcare, **E-Labeling works alongside physical labels to provide a comprehensive labeling solution.**

benefits of e-labeling



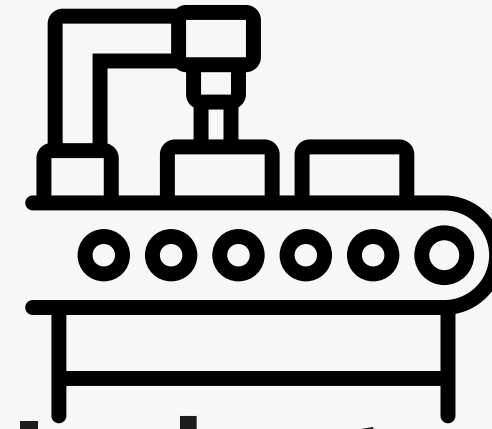
Patient

- **Up-to-date** safety information
- Accessible e-labels for **all users**
- **Customized** information based on individual needs
- Improved medication **compliance**



Healthcare Authority

- **Streamlined** regulatory processes
- Enhanced product **tracking**
- Reduced **supply chain** disruptions



Industry

- **Reduced cost and wastage**
- **Faster** dissemination of changes
- Better **change control**
- Reduced errors
- Optimized manufacturing & supply chain process



Environment

- Less use of paper
- Reduced pollution

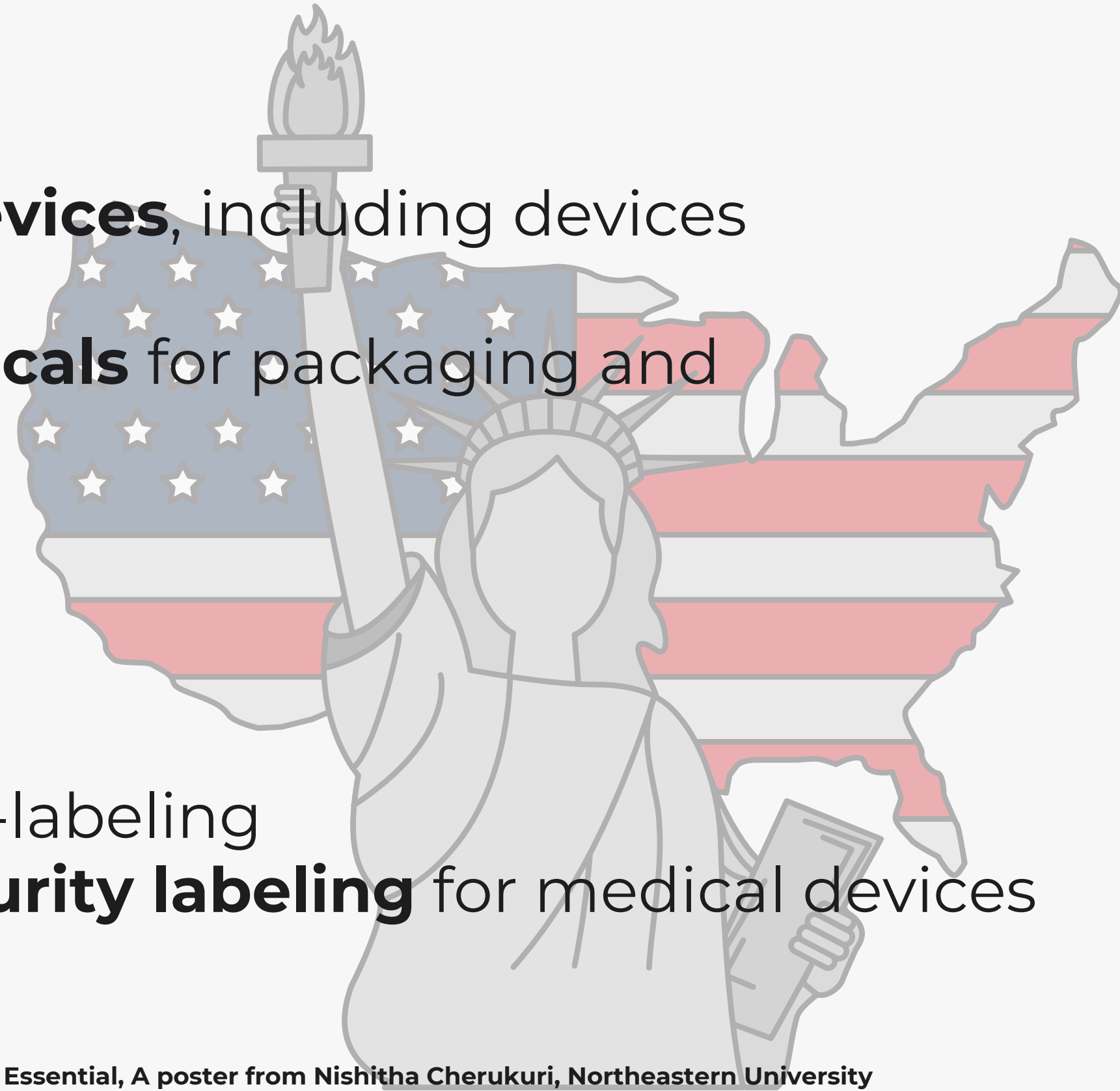
E-labeling in USA

Current areas

- E-labeling approved for **medical devices**, including devices with screens
- **Growing adoption in pharmaceuticals** for packaging and safety inserts

Future works

- Expansion into broader **biologics** e-labeling
- Possible integration with **cybersecurity labeling** for medical devices



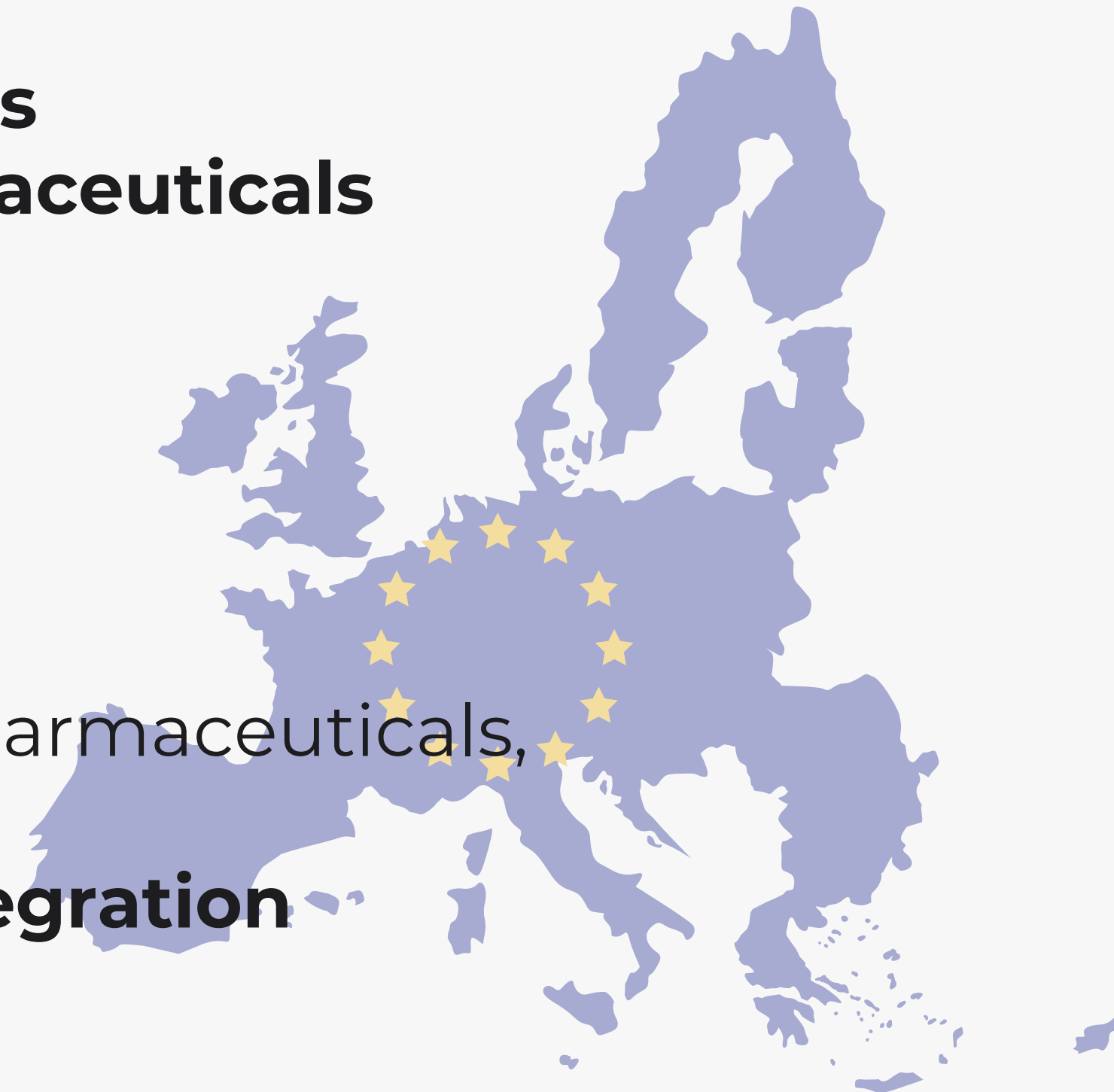
E-labeling in European Union

Current areas

- MDR allows e-labels for **medical devices**
- Digital labeling **encouraged for pharmaceuticals** under EMA.

Future works

- **Unified e-labeling standards** across pharmaceuticals, biologics and medical devices
- Greater emphasis on **digital health integration**



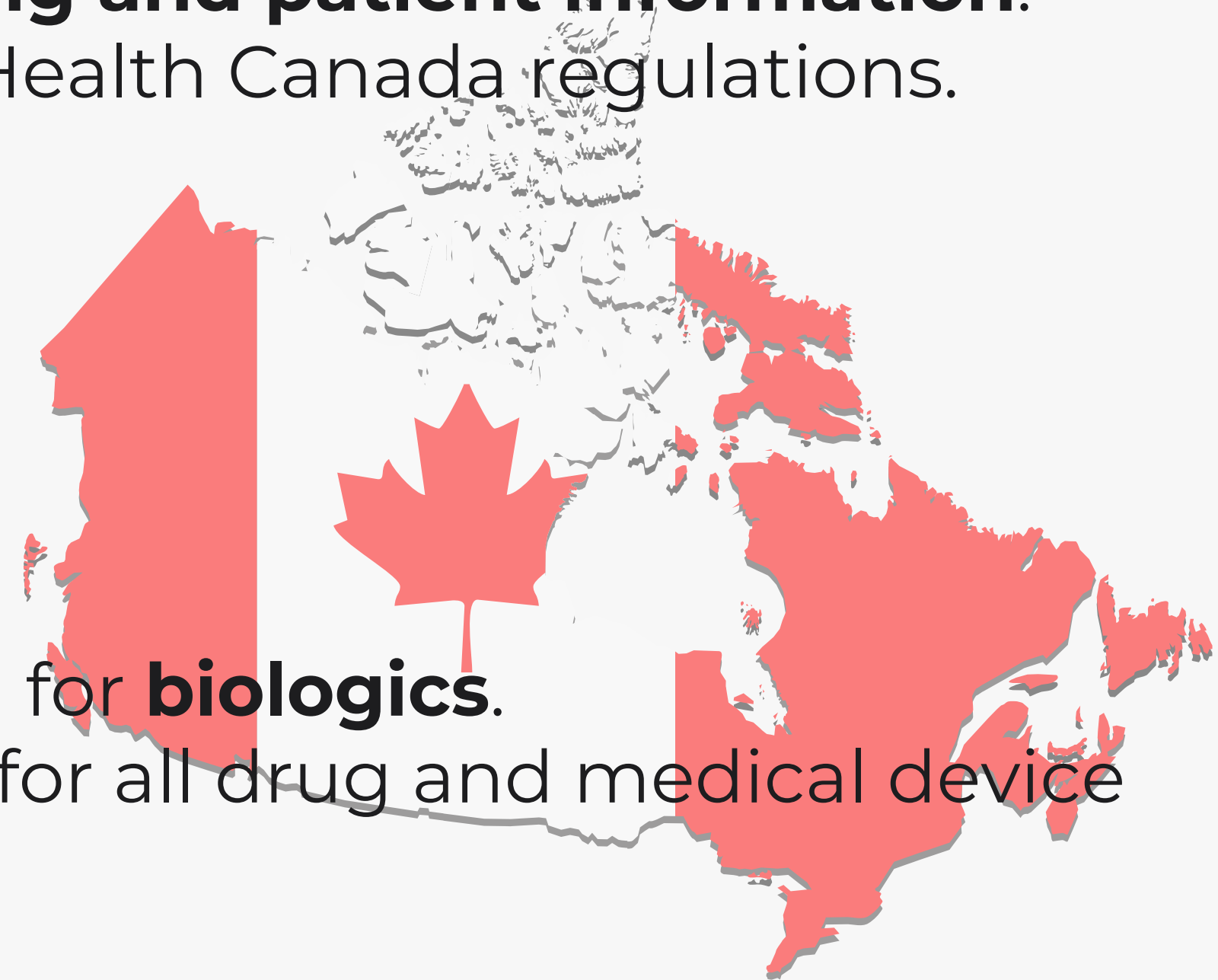
E-labeling in Canada

Current areas

- Permits e-labeling for **drug packaging and patient information**.
- Allowed for **medical devices** under Health Canada regulations.

Future works

- Pilot programs to increase e-labeling for **biologics**.
- Moving towards **digital compliance** for all drug and medical device labeling.



E-labeling in Japan



Current areas

- E-labeling allowed for medical devices and drug packaging, but **adoption is limited.**

Future works

- Reviewing regulatory frameworks to expand e-labeling for **biologics.**
- Anticipated growth in **digital health** product labeling.

Overcoming challenges in E-Labeling

Regulatory Fragmentation

- Harmonization Efforts
- Collaborative Platforms

Resistance to Digital Transition

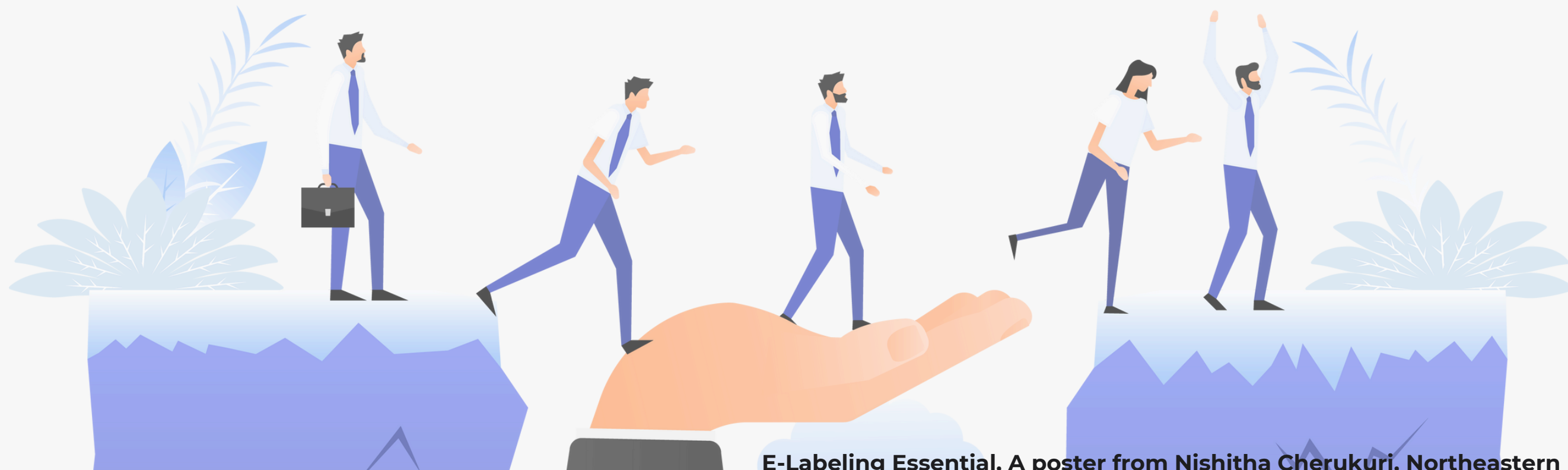
- Education and Training
- Pilot Programs

Global Supply Chain Challenge

- Integrated Systems
- Partner Engagement

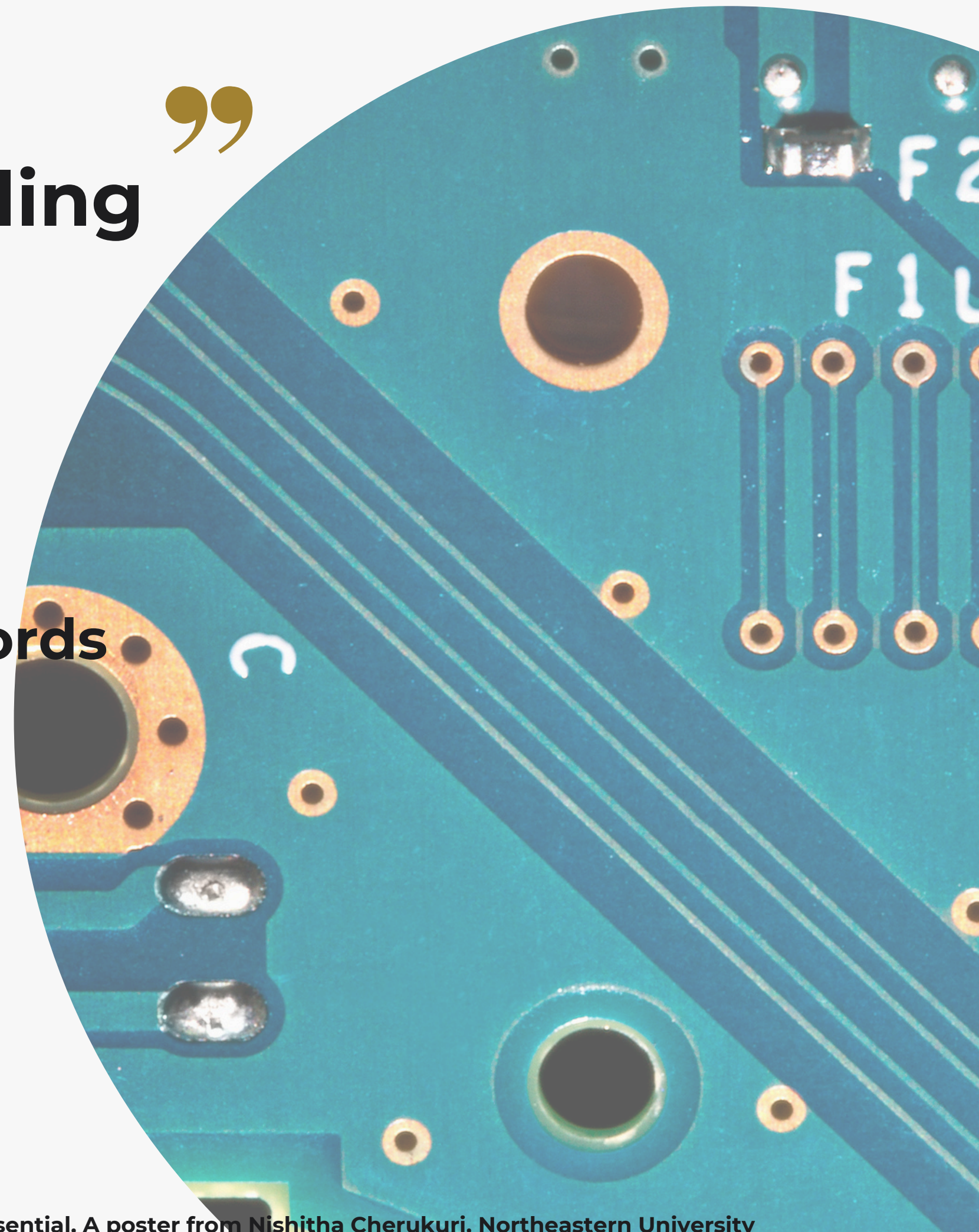
Complexity in Technology Integration

- Modular Solutions
- Vendor support



Future with integrated Labeling”

- **Structured data for digital use**
- **Enables further digital transformation**
- **Links with Electronic Health Records**
- **Enables creation of tailored (personalized) labels**
- **Automated creation of other materials**



ELECTRONIC PRODUCT INFORMATION FOR MEDICAL PRODUCTS IN EU

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ePI definition

ePI is authorised, statutory product information for human medicines (i.e. **summary of product characteristics, package leaflet and labelling**) in a semi-structured format created using the **EU ePI Common Standard**. ePI is adapted for electronic handling and allows dissemination via the web, e-platforms and print.

**Key principles outline ePI benefits:
published January 2020**



ePI definition

ePI refers to the **authorised product information for medicines** adapted for handling in electronic format and dissemination via the web, e-platforms and in print. ePI includes:

- the summary of product characteristics (SmPC), **intended for healthcare professionals**
- Annex II (for centrally authorised products)
- labelling, with outer and inner packaging information, and
- the package leaflet, **for patients and consumers**.



Benefits for patients & healthcare professionals.. ..regulators & companies

accessibility, searchability and multilingual capabilities

Patient apps

Digital & Video content

Accessibility features

Update alerts

Targeted searches

Rapid updates

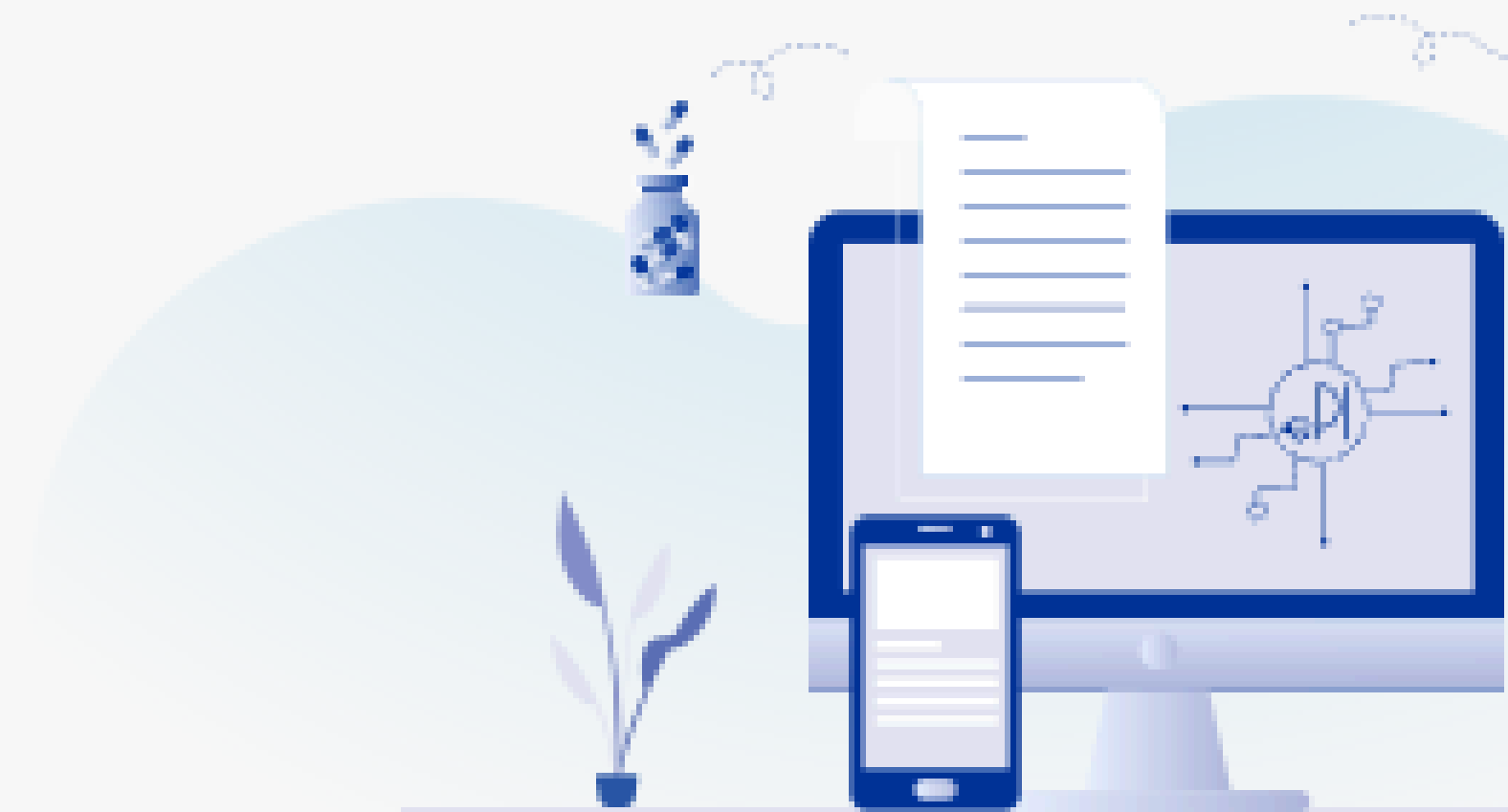
Link to national language
ePI

Timely access to up-to-
date information in
patient's language at
point of need

Support mitigation of
medicine shortages

Optimise signal validation

Administrative efficiencies



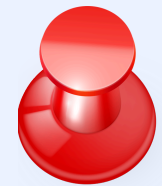
ePI pilot

- **Agencies:** EMA, Spain, the Netherlands, Sweden, Denmark
- **Duration:** July 2023 – July 2024
- **ePIs published:** <https://plm-portal.ema.europa.eu/ePIAll/>

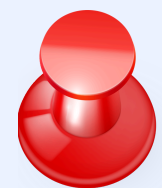
Publication of ePI makes it available at the public webpages of the PLM portal and via a read-only application programming interface (API).

USCIN ID	Name of established product	Manufacturer	Establishment type	Reference ID#	Established in	Product description	Product of establishment
Established in	Name of established product	Manufacturer	Establishment type	Reference ID#	Established in	Product description	Product of establishment
1000000001	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets	Manufacturer	1000000001	1000000001	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets
1000000002	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets	Manufacturer	1000000002	1000000002	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets
1000000003	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets	Manufacturer	1000000003	1000000003	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets
1000000004	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets	Manufacturer	1000000004	1000000004	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets
1000000005	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets	Manufacturer	1000000005	1000000005	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets
1000000006	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets	Manufacturer	1000000006	1000000006	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets
1000000007	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets	Manufacturer	1000000007	1000000007	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets
1000000008	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets	Manufacturer	1000000008	1000000008	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets
1000000009	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets	Manufacturer	1000000009	1000000009	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets
1000000010	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets	Manufacturer	1000000010	1000000010	Amphetamine/Aspirin Tablets	Amphetamine/Aspirin Tablets

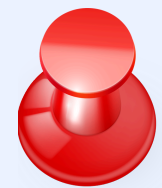
ePI pilot objectives



Enable EMA & national regulators using ePI in live procedures to assess tooling and business processes



Collect feedback from companies creating ePI & medicine information providers using the API (application programming interface)



Support ePI team in determining outstanding functional requirements & inform roadmap to implementation

Key performance indicators (KPIs) defined prior to the start of the pilot included targets for

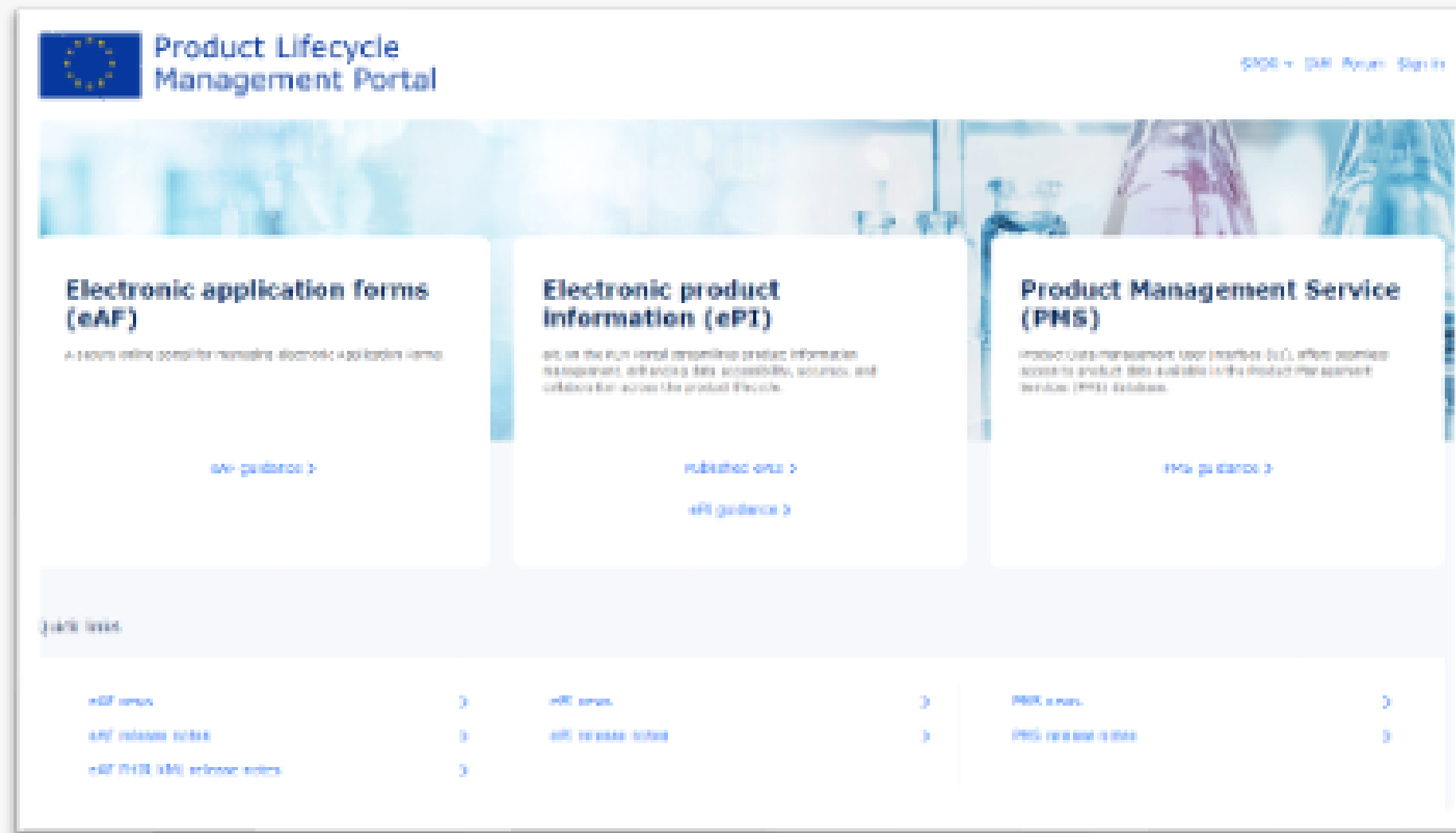
- **Time** taken to create ePI
- **Percentage** of ePIs from co-opted procedures **successfully created and published**
- **Usability** of the ePI tooling at the Product Lifecycle Management (PLM) portal
- **Usefulness** of guidance materials
- **Feasibility** of proposed business processes
- **Rating of editor functionality**

Ref: ePI pilot report :Experience gained from creation of ePI during regulatory procedures for EU human medicines (2024)



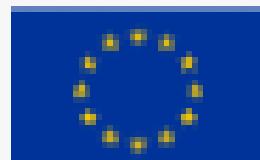
ePI at Product Lifecycle Management Portal

<https://plm-portal.ema.europa.eu/>



From the same portal, applicants can manage ePI, electronic application forms and product data. ePI features:

- ePI authoring & management
- Rich-text editing
- ePI export to FHIR/Word
- Repository & API



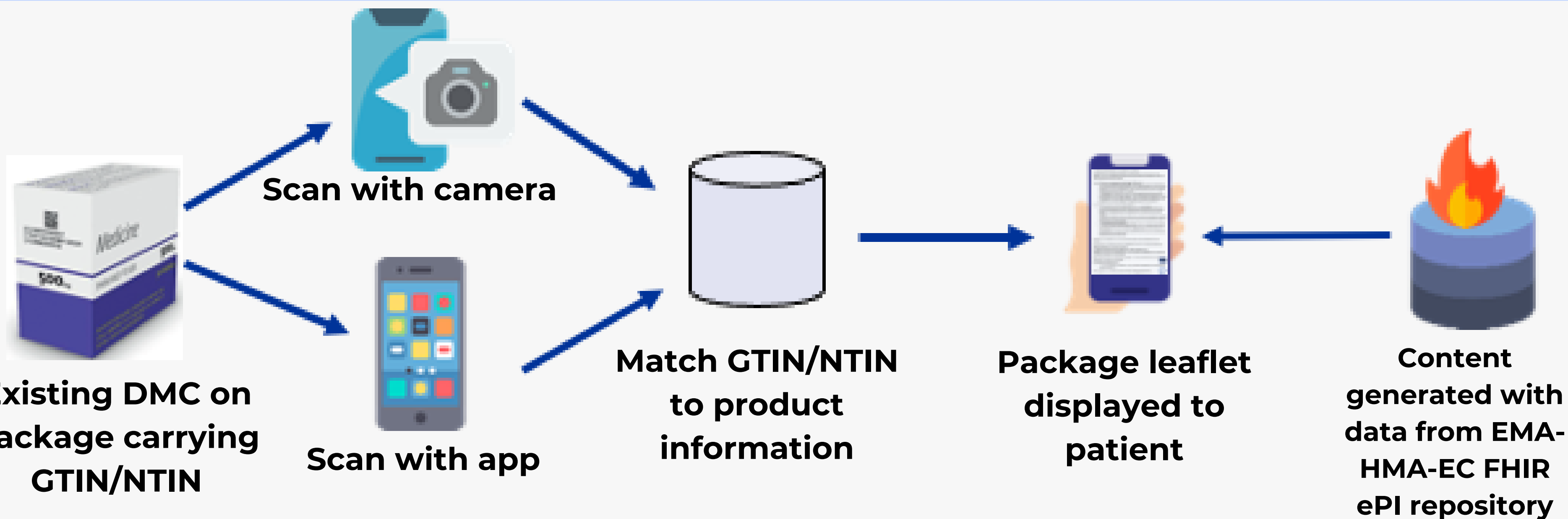
Developed with funding by the European Union

EU ePI Common Standard

- ePI uses a semi-structured format, based on a common electronic standard for product information.
- The EU ePI Common Standard is available, **based on Fast Healthcare Interoperability Resources (FHIR), a technical standard describing data formats and elements and an application programming interface for exchanging electronic health records.**
- The EU ePI Common Standard has been adopted by the **European medicines regulatory network** to support the provision of harmonised electronic information on medicines within the EU.
- The EU ePI Common Standard consists of:
 - ePI API Specification (PDF) and the associated ePI API service list (Excel)
 - A FHIR XML template based on the Quality Review of Documents (QRD) template for human medicines

Delivering ePI to patients

How ePI and PMS data can facilitate linking electronic information for consumers to the medicine package.



DMC: Data Matrix Code;GTIN:Global Trade Item Number; NTIN:National Trade Item Number;

Main recommendations

First published: 16/12/2024

- **Supplement Existing Guidance:** Enhance and highlight guidance, especially for new concepts and processes.
- **Specific Guidance for ePI Creation:** Address cases where ePI content differs from the Quality Review of Documents (QRD) template.
- **Minimize Regulatory Impact:** Ensure initial ePI introduction has minimal effect on regulatory evaluation and supervision.
- **Encourage Industry Adoption:** Consider a temporary process allowing first-time ePI submission outside regulatory procedures



Recommendations: ePI development at the PLM portal

First published: 16/12/2024

- **Import of FHIR (Fast Healthcare Interoperability Resources) format**, enabling companies to create ePI themselves and import it to the PLM portal for regulator publication, bypassing use of the editor.
- **ePI versioning** to enable access to current and previously authorised ePIs.
- **QRD template versioning** to support ongoing evolution of QRD templates.
- **Linking of ePI to the respective product in the network's Product Management Service (PMS)** so that data from both systems can be leveraged.



Recommendations: the ePI data itself and the flow of information in the business process

- **Separation of styling and content of ePI**, which enables styling to be added to ePI data by consumers of the data depending on their dissemination platforms and in line with accessibility criteria.
- **Integration of ePI into Product Lifecycle Management**, to facilitate business processes, including further integration with the electronic application form and procedure management system.



First published: 16/12/2024

Pilot conclusion

- **the network should progress towards ePI implementation**, building on the tooling and guidance already developed and incorporating the recommendations of this report
- This should **encourage partners and stakeholders**, including the regulatory network, pharmaceutical industry, medicine information providers, and patient and HCP representatives, to incorporate ePI into their planning and preparation activities.
- ePI will then be rolled out across NCAs in a **phased approach**, taking into account the **readiness and resources** of the Member States.



First published: 16/12/2024

ELECTRONIC INSTRUCTIONS FOR USE (EIFUS) FOR MEDICAL DEVICES IN EU

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eIFU (instructions for use) Policy Background

As per Implementing Regulation (EU) 2021/2226, instructions for use may be provided electronically (eIFU) instead of on paper for certain devices including:

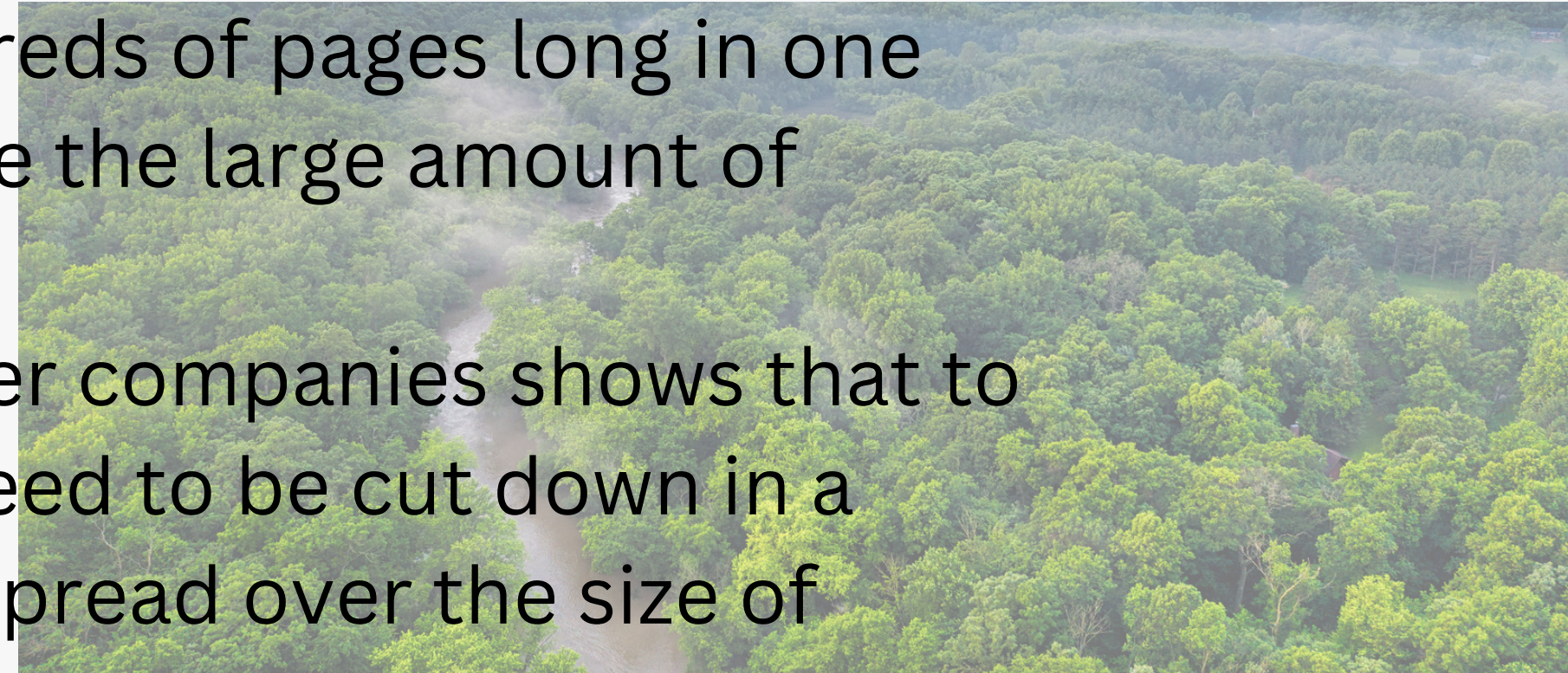
- **Implantable and active implantable medical devices and their accessories**
- **Fixed installed medical devices and their accessories**
- **Medical devices and their accessories fitted with a built-in system visually displaying the instructions for use**

eIFU (instructions for use) Policy Background

- **eIFU Allowed for Professional Use**
 - Permitted when devices and accessories are for **professional users only**.
 - **Exception: Software** under Regulation (EU) 2017/745 may include eIFU within the software itself.
- **Manufacturers must document a risk assessment covering:**
 - **User knowledge & experience**
 - **Device usage environment**
 - **Specific user needs**
- **Additional Compliance Conditions**
- **Paper IFU availability:** Must be provided within 7 calendar days upon request.
- **Labeling requirement:** Device labels must indicate that IFU is in electronic form

WHY eIFU (Instructions for use) ?

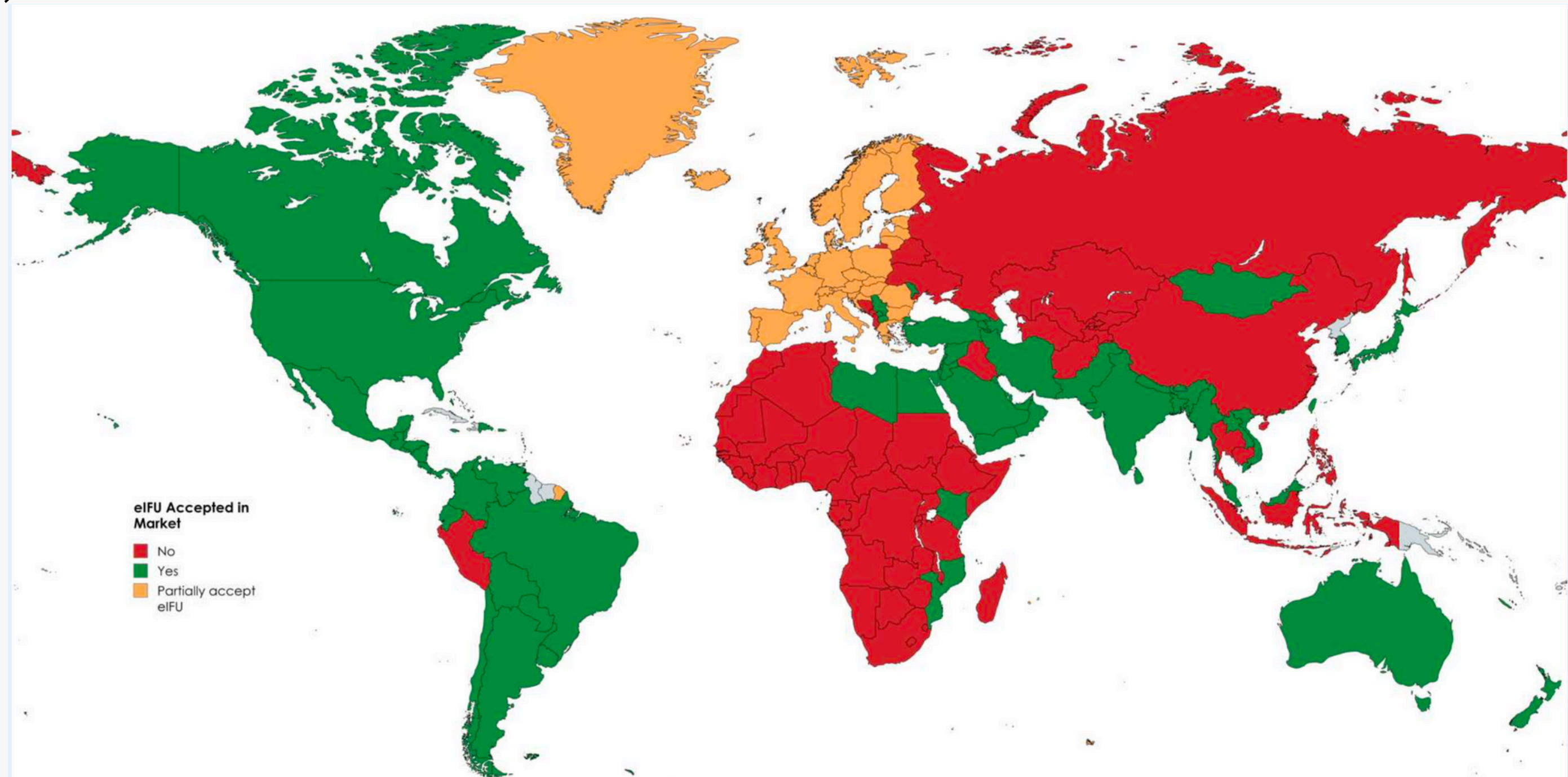
- Instructions for use (IFU) can be hundreds of pages long in one language. Translations further increase the large amount of paper needed.
- Data from 10 MedTech Europe member companies shows that to make their paper IFU, 6 billion trees need to be cut down in a year. This roughly accounts for trees spread over the size of Belgium or Costa Rica.*
- Paper IFU impact packaging size, warehousing space, shipment weight, and even sterilization.
- Managing content changes to paper IFU equals substantial operational burden and waste in a global scale.



*Let's Go Digital: Instructions For Use - Factsheet for healthcare professionals - MedTech Europe

Major jurisdictions worldwide allow e-IFU for medical devices for professional use

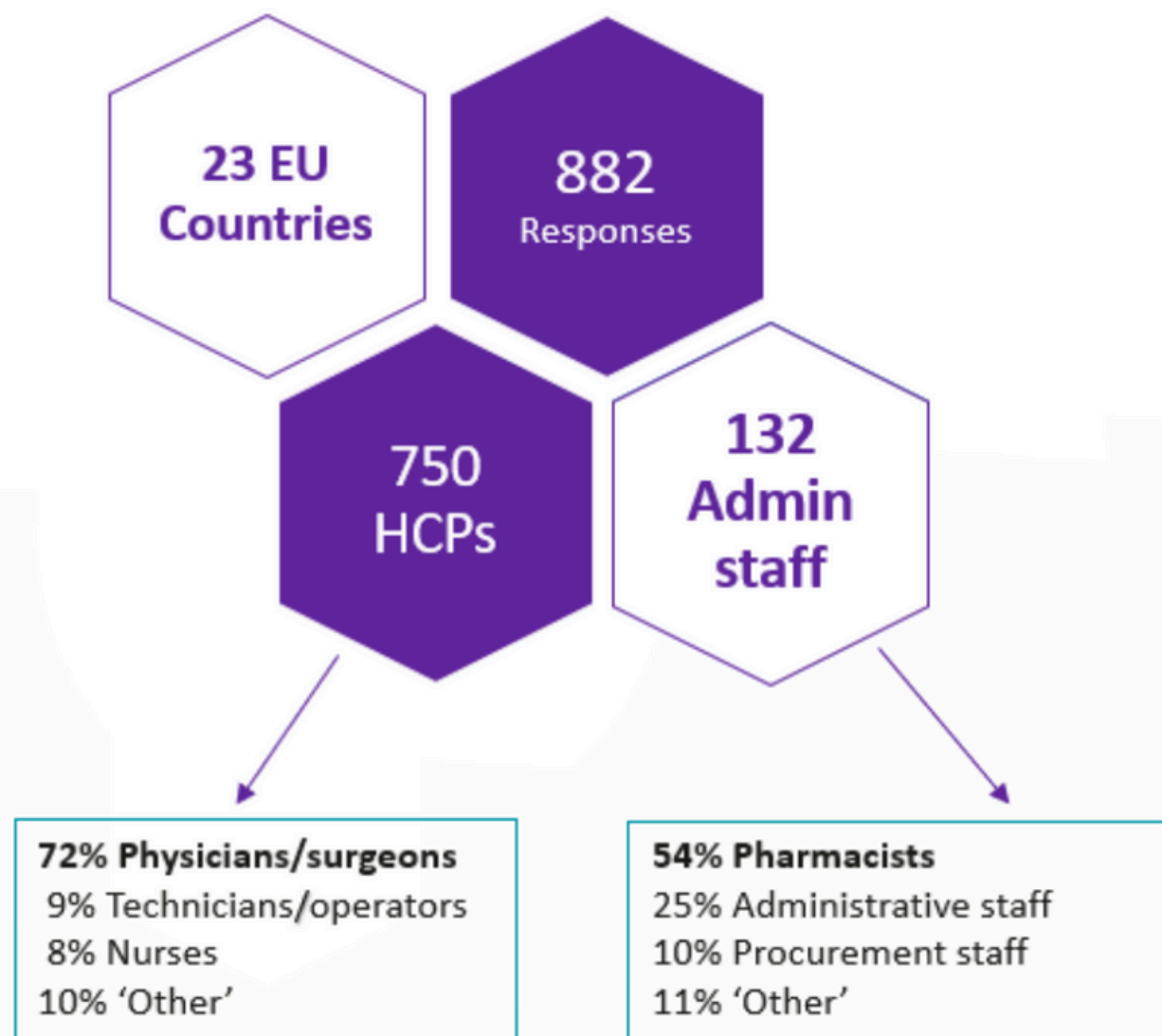
The United States, for instance, has allowed the use of electronic IFU for 20 years for all prescription devices. Other countries include Canada, Australia, Japan, South Korea, Brasil, Singapore, Saudi Arabia.



The MedTech Europe survey...

Overwhelming preference of healthcare professionals for eIFU for medical devices.

Who responded to the survey?



Key messages



>99%

Internet Access

The overwhelming majority of healthcare professionals who took the MedTech Europe survey does have access to internet at work: over **99%** said yes, while under 1% does not have internet access at work.



90%

Hospital admin staff prefers eIFU

Over **90%** of the hospital administrative staff/hospital pharmacists would prefer to have eIFU for medical devices. Only a little above 9% would not prefer this.



88%

HCPs prefer eIFU

Over **88%** of healthcare professionals would prefer to have the electronic IFU if available. Only around 12% prefer paper version.

EU Commission Survey on Electronic Instructions For Use (eIFUs) for medical devices

August 1 - October 11 2024



This survey has not yet been published or has already been unpublished in the meantime as of March 24th, 2025

The European Commission is currently considering allowing the use of Electronic Instructions for Use for all professional use devices (i.e. devices that are used by healthcare professionals). **Healthcare professionals and or other persons working in or employed by a healthcare institution in the European Union** are kindly requested to contribute to this survey.

EU Commission Survey on Electronic Instructions For Use (eIFUs) for medical devices

August 1 - October 11 2024

In October 2024 the survey was closed and **87%** of respondents stated they would **prefer using eIFUs**, if available to them.

**proposed initiative would allow
instructions for use in electronic format
for all medical devices intended for
exclusive use by healthcare professionals.**

About this initiative

In preparation

Draft act

Feedback period

21 February 2025 - 21 March
2025

Feedback: Open

Summary

The proposed initiative would allow instructions for use in electronic format for all medical devices intended for exclusive use by healthcare professionals.

Topic

Public health

Type of act

Implementing regulation

Committee

[C49800](#)

Unlocking the power of digital labeling

1 連結數位內容與實體產品 (Connects digital content to physical product)

- 將條碼置於資訊生態系統的核心
- 透過不同條碼格式存取電子內容
- 再次利用製造過程中的條碼

2 增強使用者體驗 (Enhances customer experience)

- 單次掃描即可連結多種產品資訊
- 資訊隨時隨地可存取
- 產品資訊可即時更新
- 可透過更友善的格式分享資訊

3 確保法規合規性 (Facilitates compliance)

- 更快速、高效地執行法規要求
- 即時存取產品與包裝資訊
- 減少標籤處理過程中的錯誤風險
- 確保產品的持續供應
- 符合低需求市場的國家法規（如語言要求）

4 提高運營效率 (Improves operational efficiency)

- 提升使用者與患者對產品資訊的可及性
- 製造後無需額外標籤
- 縮短產品上市與修改的時間
- 降低複雜度
- 減少製造與庫存成本
- 具備可擴展性
- 增強供應鏈管理，避免中斷

How does digital labeling work?

Also known as electronic labeling (e-labeling)

REF 1504-40-102

LOT SAMPLE

2031-04-30

QTY 1
QUANTITY

REVISION CRS FEMORAL

2

LEFT

CEMENTED

(01)10603295042150(20)99

(17)310430(10)SAMPLE

2021-05-03
STERILE R

* GS1 linear barcode with expiry date & batch no

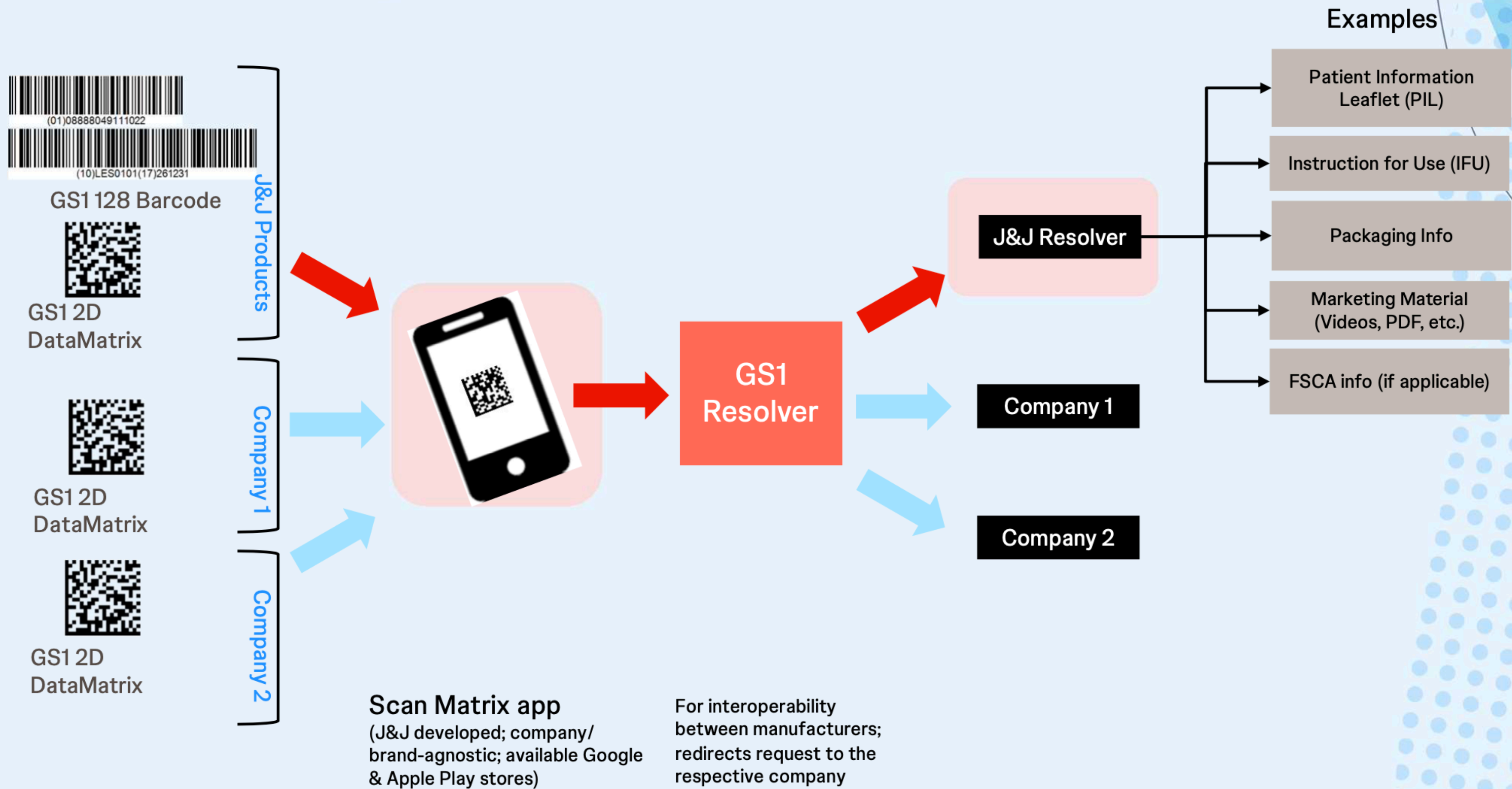
* GS1 linear barcode with GTIN & internal variant

* GS1 DataMatrix Code with GTIN, internal variant, batch no & expiry date (**preferred barcode**)

Examples



* GS1 is a not-for-profit international organization, developing and maintaining its own standards for barcodes and the corresponding issue of company prefixes

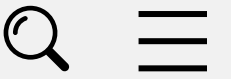


Summary: EIFUS FOR MEDICAL DEVICES IN EU

1. Harmonize and **standardize**
2. Provide **holistic approach** to product information
3. **Leverage** existing technology
4. Facilitates compliance with new regulatory requirements
5. Forge **strong partnerships** across industry and other stakeholders
6. Implement **interoperability** to revolutionize healthcare
7. Build **scalable** solutions

My learning

from RAPS 2024: E-labeling



借鏡歐洲的做法，確認台灣的 E-LABELING 實務指引是否足夠

考慮實施「電子標籤試辦計畫」，讓產官學界共同參與設計與測試

持續關注國際標準的制定，確保我國產品能無縫銜接全球市場

THANK YOU



FOR LISTENING