APAC e-Labeling Session

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Potential ePI Use Cases

- **Personalization:** tailor ePI content to fit patient or healthcare professional's needs. E.g. , confirm if any ingredients are known allergens or a known effect.
- **Interactions:** Compare ePIs to confirm if the patient's current medications have drug:drug, drug:food interactions.
- **Contraindications:** Confirm if any of the patient's conditions are contraindicated with this medication.
- **Drug shortages:** Use ePI's product information (e.g., unique IDs for pack, drug, manufacturer) to find other drugs in the same class or category.
- **Advanced search:** Host all ePIs in a central portal (like EMA's) to facilitate content search.
- **Cross-border travel:** Allow HCPs or patients to identify the same or similar drug in another country.
- **Distribution:** Use packaging details in the ePI (e.g., product and pack identifiers) to facilitate supply chain ordering or tracking.
- **eHealth interoperability:** Reuse structured ePI content in apps like EHR, ePrescription, Apple Health or Google Health apps.

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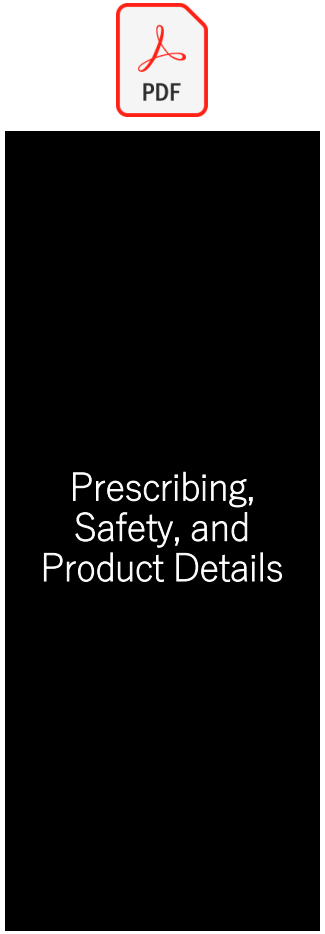
Un-structured vs. Structured



- Prescribing Information (Composition)
  - Section 1
  - Section 2
    - Indication 1
      - Semi-structured Text
      - Structured indication (SNOMED, ICD, MedDRA)
      - Version
      - Status
    - Indication 2
    - Warning 1
    - Warning 2
    - Posology 1
    - Posology 2
      - Semi-structured Text
      - Structured dose instructions
      - Version
      - Status
    - Side effect 1
    - Side effect 2
  - Section 3
  - Section 4
  - Section 5
  - Section 6
- Encoded Images (SVG)
- Medicinal Product
- Organization
- Regulated Authorization
- Manufactured Item
- Administrable Product
- Packaging
- Ingredients
- Clinical Use Definition
- Medication Statement

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Types of ePI

Recommended starting point

In development

ePI Type 1: Label Template Only	ePI Type 2: Product Details	ePI Type 3: Clinical Details	ePI Type 4: Full Structure

• Semi-structured text (Local template section headings, text, tables, bullets, images)
• Document metadata (language, date, identifier, version)
	• Type 1 and product details
	  ○ Product Name
	  ○ Ingredients
	  ○ Packaging
	  ○ Strength
	  ○ Manufactured
	  ○ Administrable dose forms
	  ○ Organization details
		• Type 1, 2, and clinical details
		  ○ Indication
		  ○ Interactions
		  ○ Contraindication
		  ○ Undesirable Effects
		  ○ Warnings
		  ○ Population demographics
			• Label content is made of structured components (E.g., Adverse event data is structured, and AE frequency tables are auto-generated)
			• Maximum personalization capability
			• Structured dose instructions

Simple search & analysis by section headings and text

Intermediate to advanced search & analysis; interoperability with ePrescription & EHRs; personalization

Auto-generate label template; interoperable with Generative AI

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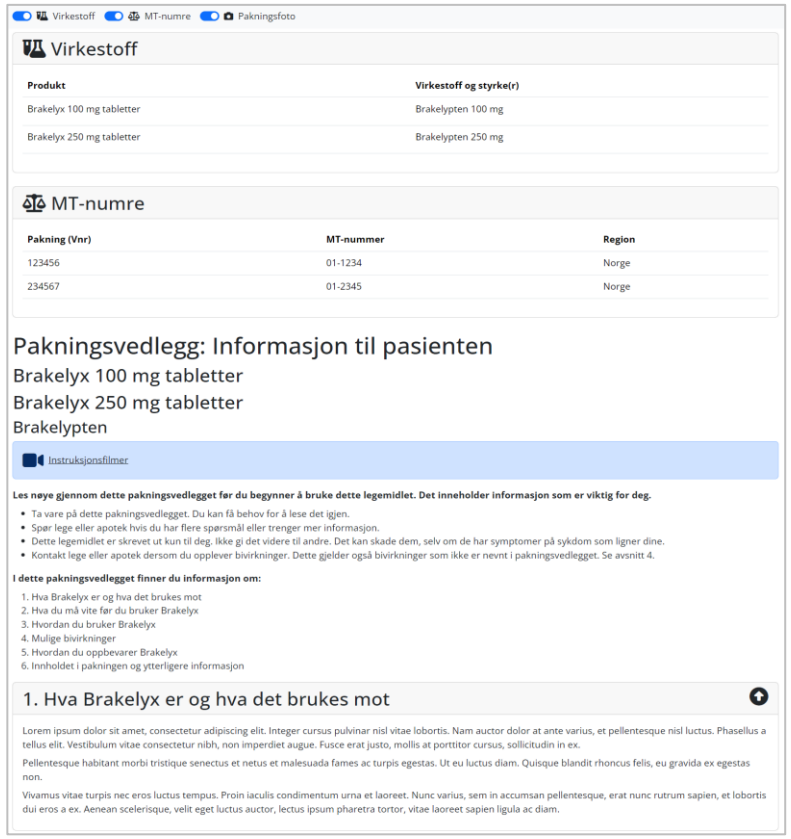
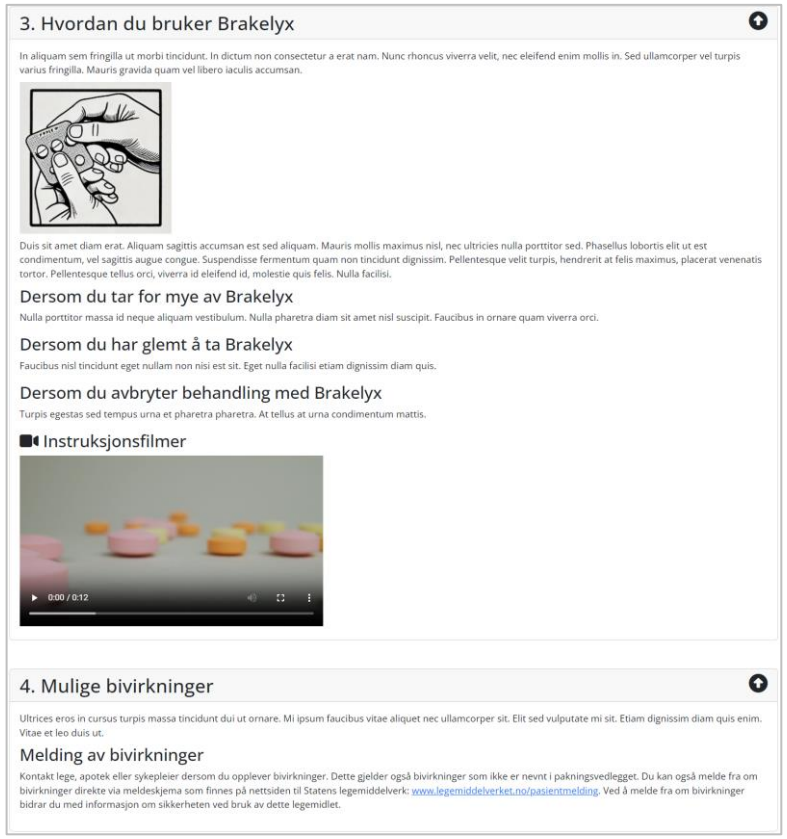
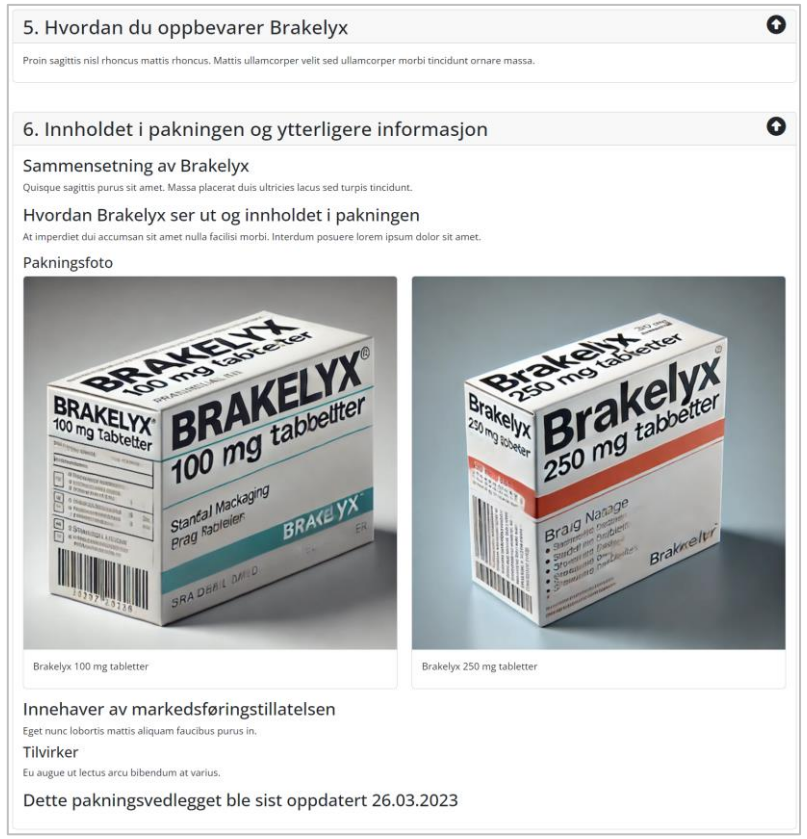
Use case: Easier to read web style content







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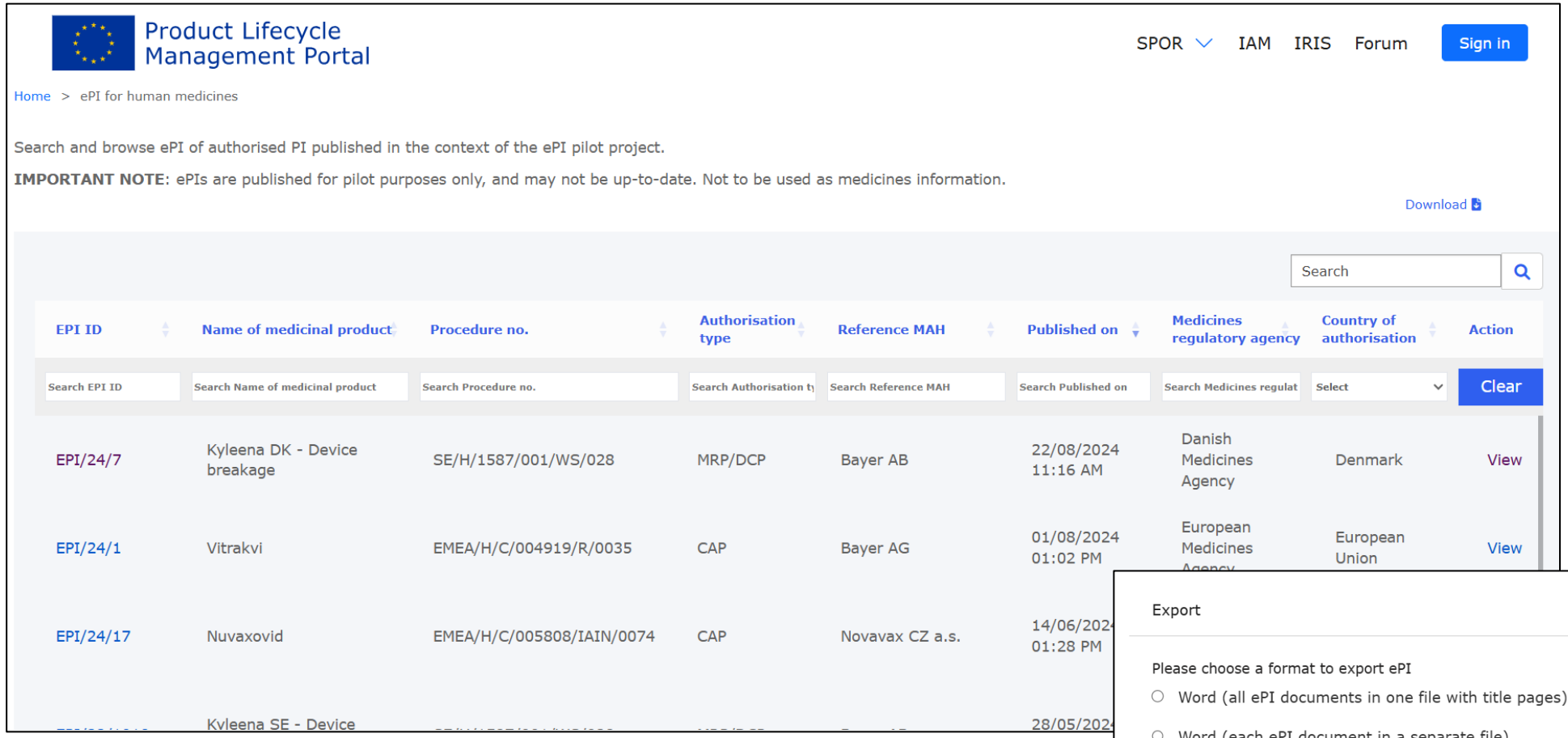
[Felleskatalogen (Norwegian national drug compendia) ePI Style sheet: nordic-epi-ig/docker at epi-styling · felleskatalogen/nordic-epi-ig]

Use case: EMA's online ePI Portal



https://plm-portal.ema.europa.eu/ePIAll/

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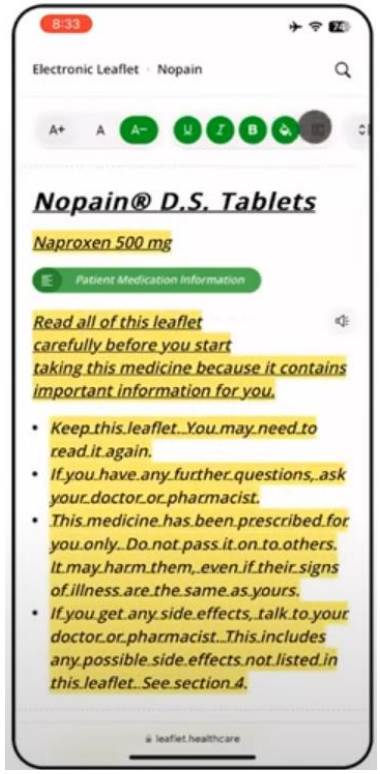
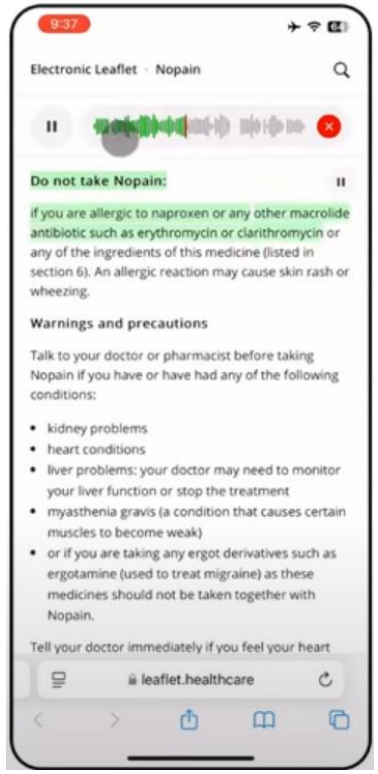
Use case: Jordan FDA's App with accessibility features

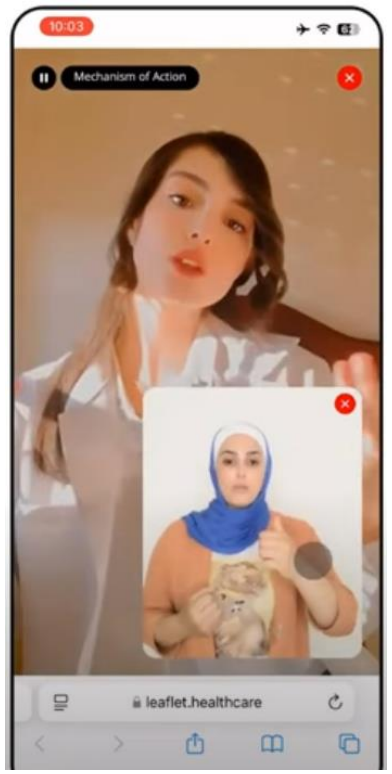
Control text size, dark mode, appearance



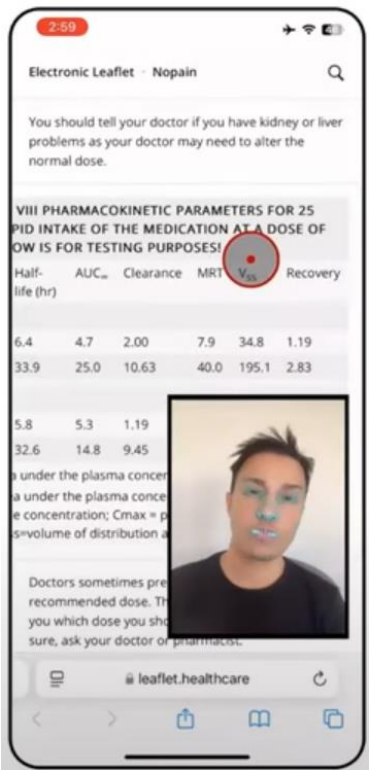
Text to speech



Sign language



Face navigation



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21.10.2024 | ePI on FHIR: Shaping the Future of Global Healthcare - Gravitate Health

Future use case: ePI Type 3 / 4 - Personalized Undesirable Effects

- Rather than a “regular” Word table, the table is generated from structured data components. This will allow us to create personalized undesirable effect tables.

```
<undesirableEffect>
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```

```
<undesirableEffect>
    <classification>
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    <frequency value="≥10%"/>
```

Structured data styled into a table

Table 4. Adverse Reactions (≥10%) in PALOMA-2

	IBRANCE plus Letrozole (N=444)			Placebo plus Letrozole (N=222)		
Adverse Reaction	All Grades %	Grade 3 %	Grade 4 %	All Grades %	Grade 3 %	Grade 4 %
Infections and infestations						
Infections*	60‡	6	1	42	3	0
Blood and lymphatic system disorders						
Neutropenia	80	56	10	6	1	1
Leukopenia	39	24	1	2	0	0
Anemia	24	5	<1	9	2	0
Thrombocytopenia	16	1	<1	1	0	0

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Future use case: ePI Type 3 / 4 - Structured Dose Syntax

Adults

Condition	Dose
To treat cryptococcal meningitis	400 mg on the first day then 200 mg to 400 mg once daily for 6 to 8 weeks or longer if needed. Sometimes doses are increased up to 800 mg
To stop cryptococcal meningitis from coming back	200 mg once daily until you are told to stop
To treat coccidioidomycosis	200 mg to 400 mg once daily from 11 months for up to 24 months or longer if needed. Sometimes doses are increased up to 800 mg
To treat internal fungal infections caused by *Candida*	800 mg on the first day then 400 mg once daily until you are told to stop
To treat mucosal infections affecting the lining of mouth, throat and denture sore mouth	200 mg to 400 mg on the first day then 100 mg to 200 mg once daily until you are told to stop
To treat mucosal thrush – dose depends on where the infection is located	50 mg to 400 mg once daily for 7 to 30 days until you are told to stop
To stop mucosal infections affecting the lining of mouth, throat from coming back	100 mg to 200 mg once daily, or 200 mg 3 times a week, while you are at risk of getting an infection
To treat genital thrush	150 mg as a single dose
To reduce recurrence of vaginal thrush	150 mg every third day for a total of 3 doses (day 1, 4 and 7) and then once a week for 6 months while you are at risk of getting an infection
To treat fungal skin and nail infections	Depending on the site of the infection 50 mg once daily, 150 mg once weekly, 300 to 400 mg once weekly for 1 to 4 weeks (Athlete's foot may be up to 6 weeks, for nail infection treatment until infected nail is replaced)
To stop you from getting an infection caused by *Candida* (if your immune system is weak and not working properly)	200 mg to 400 mg once daily while you are at risk of getting an infection

To treat internal fungal infections caused by *Candida*	800 mg on the first day then 400 mg once daily until you are told to stop

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<dosageInstruction>
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```

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      </coding>
    </type>
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      <unit value="TAB"/>
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      <code value="TAB"/>
    </doseQuantity>
  </doseAndRate>
</dosageInstruction>
```

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[UK's NHS FHIR Dose Syntax Implementation Guidance | Dose Syntax Implementation for FHIR]

Lessons Learned: EMA/FDA pilots and Gravitate Health/Vulcan project work

- Recommend starting with ePI Type 2
- Remain harmonized with EMA and Vulcan Implementation Guides where possible
- Recommended roadmap:
  - Phase 1: Create a prototype ePI as a gold standard
  - Phase 2: Technical pilot
  - Phase 3: Production Pilot (Voluntary)
  - Phase 4: Production (Voluntary)
  - Phase 5: Production (Mandatory)
- Aim for a two-year timeframe to go from Phase 1 to Phase 4. Allow grace period between Phase 4 and 5 to allow industry time to get ready.