

APAC e-Labeling Session

Craig Anderson

Co-lead HL7 VULCAN Electronic Product Information Project

Director, R&D Labeling Lead, International Labeling,
Pfizer R&D

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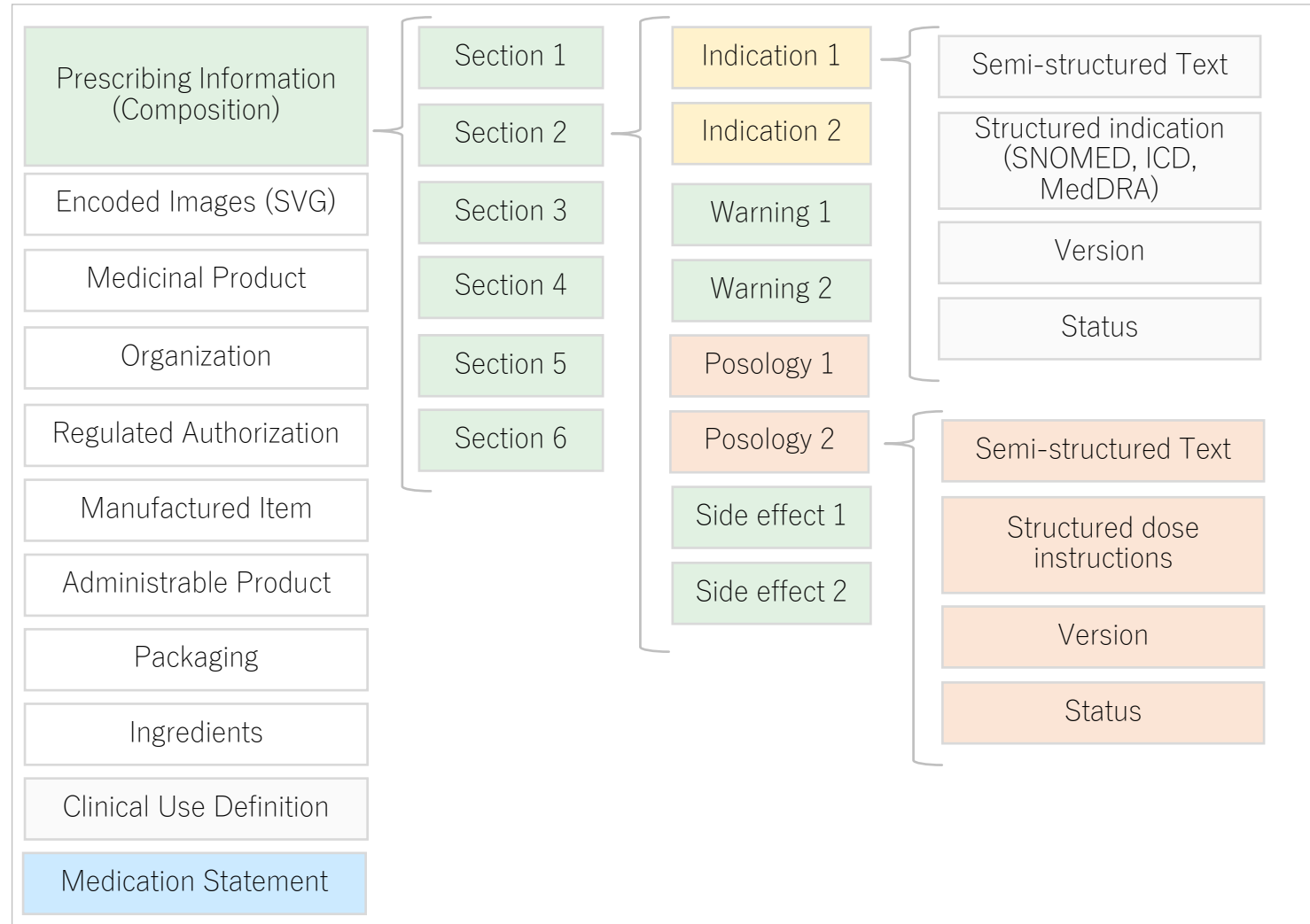
Potential ePI Use Cases

- **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.

Un-structured vs. Structured



Prescribing,
Safety, and
Product Details



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

Use case: Easier to read web style content

Virkestoff

Produkt	Virkestoff og styrke(r)
Brakelyx 100 mg tabletter	Brakelypten 100 mg
Brakelyx 250 mg tabletter	Brakelypten 250 mg

MT-numre

Pakning (Vnr)	MT-nummer	Region
123456	01-1234	Norge
234567	01-2345	Norge

Pakningsvedlegg: Informasjon til pasienten

Brakelyx 100 mg tabletter

Brakelyx 250 mg tabletter

Brakelypten

Instruksjonsfilmer

Les nøye gjennom dette pakningsvedlegget før du begynner å bruke dette legemidlet. Det inneholder informasjon som er viktig for deg.

- Ta vare på dette pakningsvedlegget. Du kan få behov for å lese det igjen.
- Spør lege eller apotek hvis du har flere spørsmål eller trenger mer informasjon.
- Dette legemidlet er skrevet ut kun til deg. Ikke gi det videre til andre. Det kan skade dem, selv om de har symptomer på sykdom som ligner dine.
- Kontakt lege eller apotek dersom du opplever bivirkninger. Dette gjelder også bivirkninger som ikke er nevnt i pakningsvedlegget. Se avsnitt 4.

I dette pakningsvedlegget finner du informasjon om:

1. Hva Brakelyx er og hva det brukes mot
2. Hva du må vite før du bruker Brakelyx
3. Hvordan du bruker Brakelyx
4. Mulige bivirkninger
5. Hvordan du oppbevarer Brakelyx
6. Innholdet i pakningen og ytterligere informasjon

1. Hva Brakelyx er og hva det brukes mot

>Lorem ipsum dolor sit amet, consectetur adipiscing elit. Integer cursus pulvinar nisi vitae lobortis. Nam auctor dolor at ante varius, et pellentesque nisl luctus. Phasellus a tellus elit. Vestibulum vitae consectetur nibh, non imperdiet augue. Fusce erat justo, mollis at porttitor cursus, sollicitudin in ex.

Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas. Ut eu luctus diam. Quisque blandit rhoncus felis, ex gravida ex egestas non.

Vivamus vitae turpis nec eros luctus tempus. Proin iaculis condimentum urna et laoreet. Nunc varius, sem in accumsan pellentesque, erat nunc rutrum sapien, et lobortis dui eros a ex. Aenean scelerisque, velit eget luctus auctor, lectus ipsum pharetra tortor, vitae laoreet sapien ligula ac diam.

3. Hvordan du bruker Brakelyx

In aliquam sem fringilla ut morbi tincidunt. In dictum non consectetur a erat nam. Nunc rhoncus viverra velit, nec eleifend enim mollis in. Sed ullamcorper vel turpis varius fringilla. Mauris gravida quam vel libero iaculis accumsan.



Duis sit amet diam erat. Aliquam sagittis accumsan est sed aliquam. Mauris mollis maximus nisl, nec ultricies nulla porttitor sed. Phasellus lobortis elit ut est condimentum, vel sagittis augue congue. Suspendisse fermentum quam non tincidunt dignissim. Pellentesque velit turpis, hendrerit at felis maximus, placerat venenatis tortor. Pellentesque tellus orci, viverra id eleifend id, molestie quis felis. Nulla facilisi.

Dersom du tar for mye av Brakelyx

Nulla porttitor massa id neque aliquam vestibulum. Nulla pharetra diam sit amet nisl suscipit. Faucibus in ornare quam viverra orci.

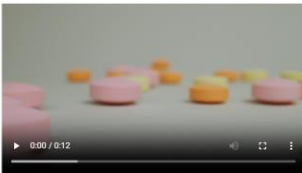
Dersom du har glemt å ta Brakelyx

Faucibus nisl tincidunt eget nullam non nisi est sit. Eget nulla facilisi etiam dignissim diam quis.

Dersom du avbryter behandling med Brakelyx

Turpis egestas sed tempus urna et pharetra pharetra. At tellus at urna condimentum mattis.

Instruksjonsfilmer



4. Mulige bivirkninger

Ultrices eros in cursus turpis massa tincidunt dui ut ornare. Mi ipsum faucibus vitae aliquet nec ullamcorper sit. Elit sed vulputate mi sit. Etiam dignissim diam quis enim. Vitae et leo dui ut.

Melding av bivirkninger

Kontakt lege, apotek eller sykepleier dersom du opplever bivirkninger. Dette gjelder også bivirkninger som ikke er nevnt i pakningsvedlegget. Du kan også melde fra om bivirkninger direkte via meldeskjema som finnes på nettsiden til Statens legemiddelverk: www.legemiddelverket.no/pasientmelding. Ved å melde fra om bivirkninger bidrar du med informasjon om sikkerheten ved bruk av dette legemidlet.

5. Hvordan du oppbevarer Brakelyx

Proin sagittis nisl rhoncus mattis rhoncus. Mattis ullamcorper velit sed ullamcorper morbi tincidunt ornare massa.

6. Innholdet i pakningen og ytterligere informasjon

Sammensetning av Brakelyx

Quisque sagittis purus sit amet. Massa placerat dui ultricies lacus sed turpis tincidunt.

Hvordan Brakelyx ser ut og innholdet i pakningen

At imperdiet dui accumsan sit amet nulla facilisi morbi. Interdum posuere lorem ipsum dolor sit amet.

Pakningsfoto



Brakelyx 100 mg tabletter



Brakelyx 250 mg tabletter

Innehaver av markedsføringstillatelsen

Eget nunc lobortis mattis aliquam faucibus purus in.

Tilvirker

Eu augue ut lectus arcu bibendum at varius.

Dette pakningsvedlegget ble sist oppdatert 26.03.2023



APAC

Asia Partnership Conference
of Pharmaceutical Associations

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

5

Use case: EMA's online ePI Portal

**Product Lifecycle Management Portal**

SPOR  IAM IRIS Forum [Sign in](#)

[Home](#) > [ePI for human medicines](#)

Search and browse ePI of authorised PI published in the context of the ePI pilot project.

IMPORTANT NOTE: ePIs are published for pilot purposes only, and may not be up-to-date. Not to be used as medicines information.

Download 

Search 

EPI ID	Name of medicinal product	Procedure no.	Authorisation type	Reference MAH	Published on	Medicines regulatory agency	Country of authorisation	Action
EPI/24/7	Kyleena DK - Device breakage	SE/H/1587/001/WS/028	MRP/DCP	Bayer AB	22/08/2024 11:16 AM	Danish Medicines Agency	Denmark	View
EPI/24/1	Vitrakvi	EMA/H/C/004919/R/0035	CAP	Bayer AG	01/08/2024 01:02 PM	European Medicines Agency	European Union	View
EPI/24/17	Nuvaxovid	EMA/H/C/005808/IAIN/0074	CAP	Novavax CZ a.s.	14/06/2024 01:28 PM			
EPI/24/18	Kyleena SE - Device	SE/H/1587/001/WS/028	MRP/DCP	Bayer AB	28/05/2024			

Export 

Please choose a format to export ePI

☐

 Word (all ePI documents in one file with title pages)

☐

 Word (each ePI document in a separate file)

☒

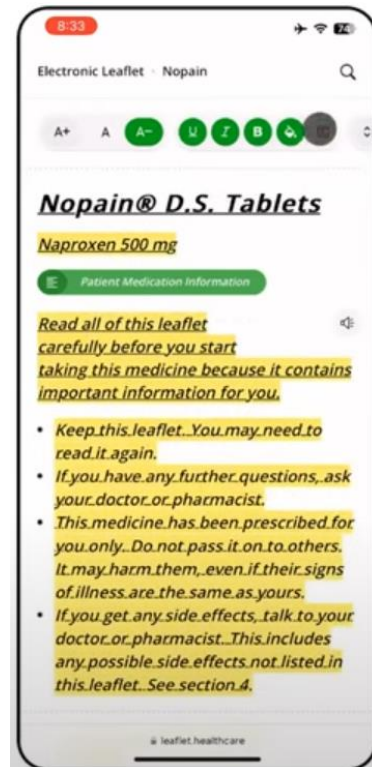
 FHIR

Export

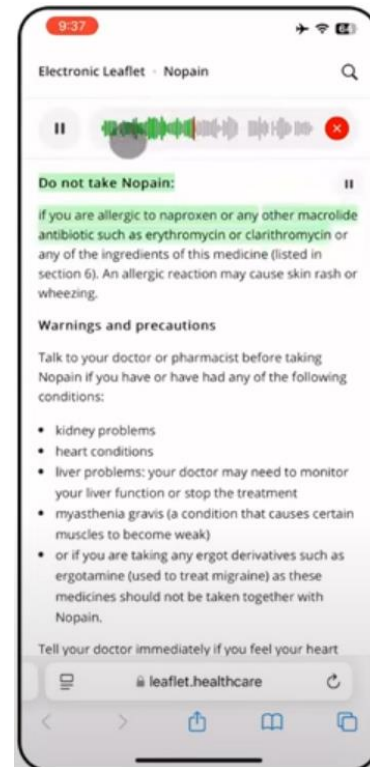
Cancel

Use case: Jordan FDA's App with accessibility features

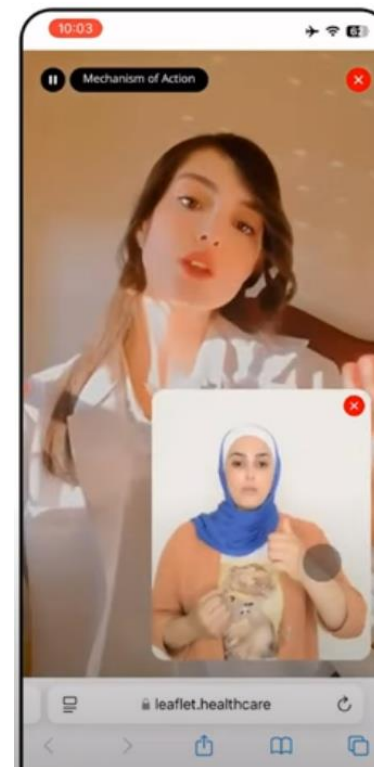
Control text size, dark mode, appearance



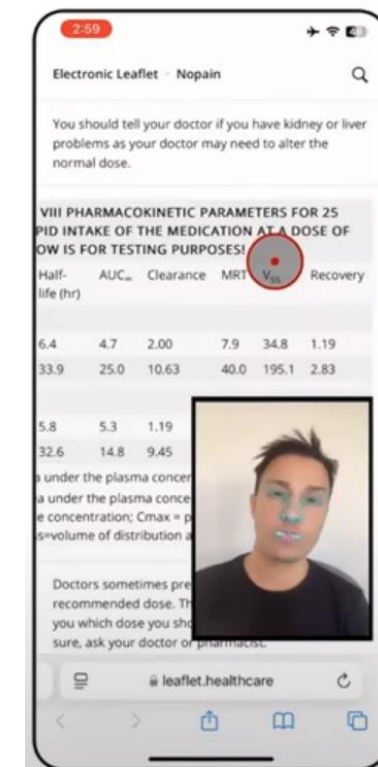
Text to speech



Sign language



Face navigation



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>
  <classification>
    <coding>
      <system value="http://snomed.info/sct"/>
      <code value="36225005"/>
      <display value="Blood and lymphatic system disorders"/>
    </coding>
  </classification>
  <symptomConditionEffect>
    <coding>
      <system value="http://snomed.info/sct"/>
      <code value="703938007"/>
      <display value="Neutropenia"/>
    </coding>
  </symptomConditionEffect>
  <frequency value="≥10%"/>
</undesirableEffect>
```

```
<undesirableEffect>
  <classification>
    <coding>
      <system value="http://snomed.info/sct"/>
      <code value="36225005"/>
      <display value="Blood and lymphatic system disorders"/>
    </coding>
  </classification>
  <symptomConditionEffect>
    <coding>
      <system value="http://snomed.info/sct"/>
      <code value="702760002"/>
      <display value="Leukopenia"/>
    </coding>
  </symptomConditionEffect>
  <frequency value="≥10%"/>
</undesirableEffect>
```

Structured data
styled into a
table

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

Adverse Reaction	IBRANCE plus Letrozole (N=444)			Placebo plus Letrozole (N=222)		
	All Grades %	Grade 3 %	Grade 4 %	All Grades %	Grade 3 %	Grade 4 %
Infections and infestations						
Infections ^a	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

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 <i>Candida</i>	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 <i>Candida</i> (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

```
<dosageInstruction>
  <sequence value="1"/>
  <text value="800 mg on the first day"/>
  <additionalInstruction>
    <coding>
      <system value="http://snomed.info/sct"/>
      <code value="311504000"/>
      <display value="With or after food"/>
    </coding>
  </additionalInstruction>
  <timing>
    <repeat>
      <frequency value="1"/>
      <period value="1"/>
      <periodUnit value="d"/>
    </repeat>
  </timing>
  <route>
    <coding>
      <system value="http://snomed.info/sct"/>
      <code value="26643006"/>
      <display value="Oral Route"/>
    </coding>
  </route>
</dosageInstruction>
```

```
</route>
<method>
  <coding>
    <system value="http://snomed.info/sct"/>
    <code value="738995006"/>
    <display value="Swallow (adminis..."/>
  </coding>
</method>
<doseAndRate>
  <type>
    <coding>
      <system value="http://terminology.hl7.org/CodeSystem/dose-and-rate-type"/>
      <code value="ordered"/>
      <display value="Ordered"/>
    </coding>
  </type>
  <doseQuantity>
    <value value="4"/>
    <unit value="TAB"/>
    <system value="http://terminology.hl7.org/CodeSystem/dose-and-rate-unit"/>
    <code value="TAB"/>
  </doseQuantity>
</doseAndRate>
</dosageInstruction>
```

To treat internal fungal infections caused by <i>Candida</i>	800 mg on the first day then 400 mg once daily until you are told to stop
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Lessons Learned: EMA/FDA pilots and Gravitare 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.