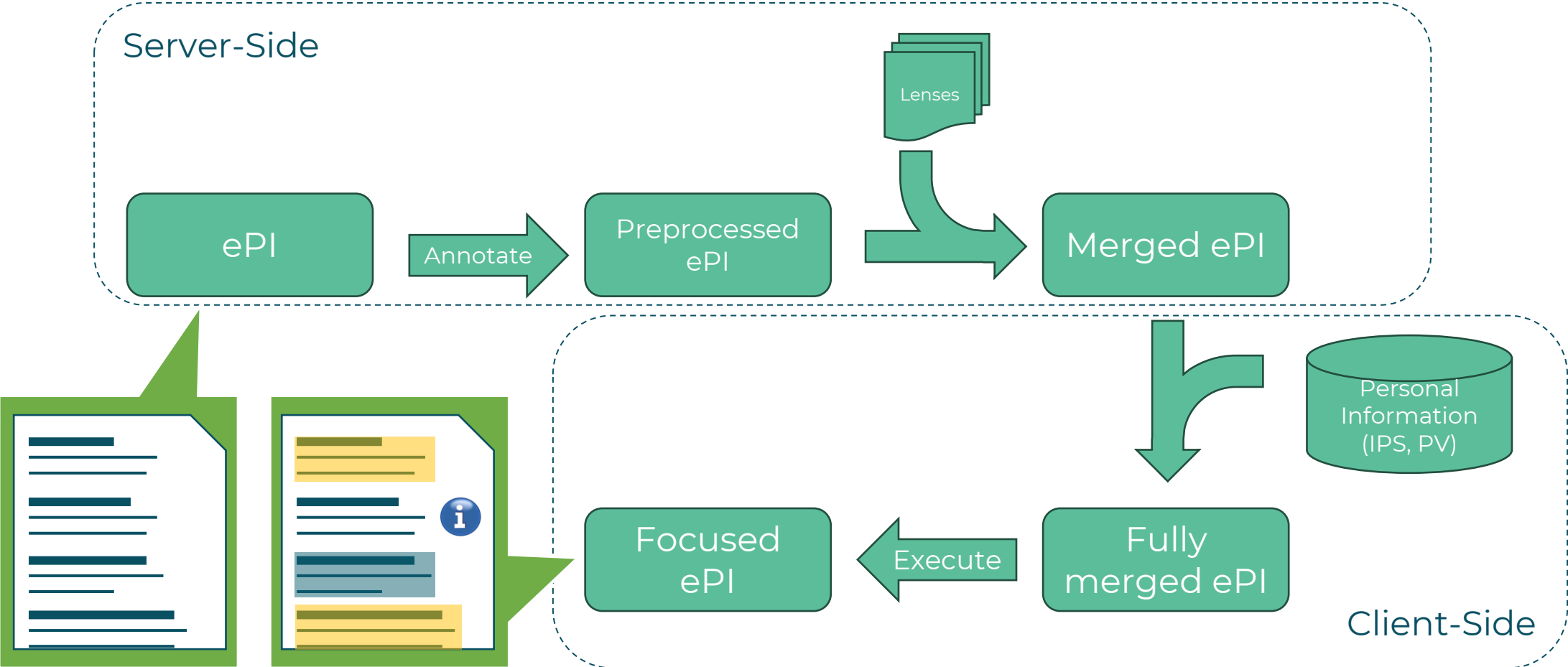


# Problem: Focusing

Focusing: adapting information to the context and preferences of the end user for effective and optimal understanding of the information.



# The Focusing process



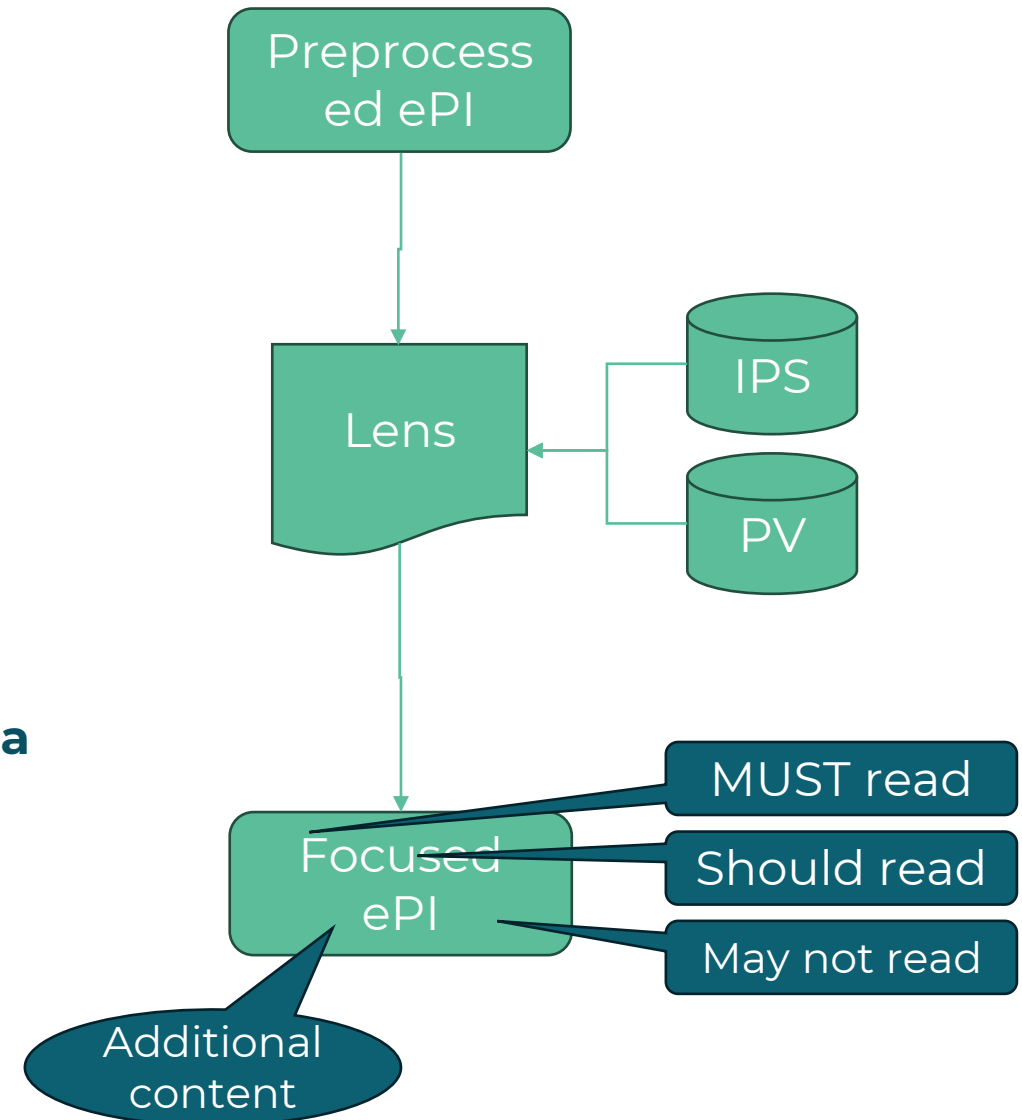
# The Lens

A Lens is a piece of code which encodes certain knowledge required to make **automatic decisions** on **how to better adapt the content**.

Within the Lens Execution Environment, the lens will have access to:

- **semantically annotated content** (with terminologies like SNOMED-CT, ICPC2, or ICD 10) , i.e. the preprocessed ePI,
- All the relevant information to the patient's health (**International Patient Summary**: IPS)
- The patient's current context and preferences (**Persona Vector**: PV).

The Lens can effectuate changes on the content, these changes are categorised in 2 types: attention detail modification (3 levels), addition of supplementary information.



# Focusing Operations

## Annotation using Standard Vocabularies

- ICD 10/11
- ICPC – 2 (International Classification of Primary Care)
- SNOMED-CT
- UMLS
- CDISC
- LOINC
- OMOP
- ...

## Personal User Data

- IPS (BE,FE,Both or neither)
- User Profile (BE or FE)
- Temporary Profile (a.k.a “lambda profile”) (only FE)
- User Preferences (FE)

## Standard Lens operations

### Add CSS class:

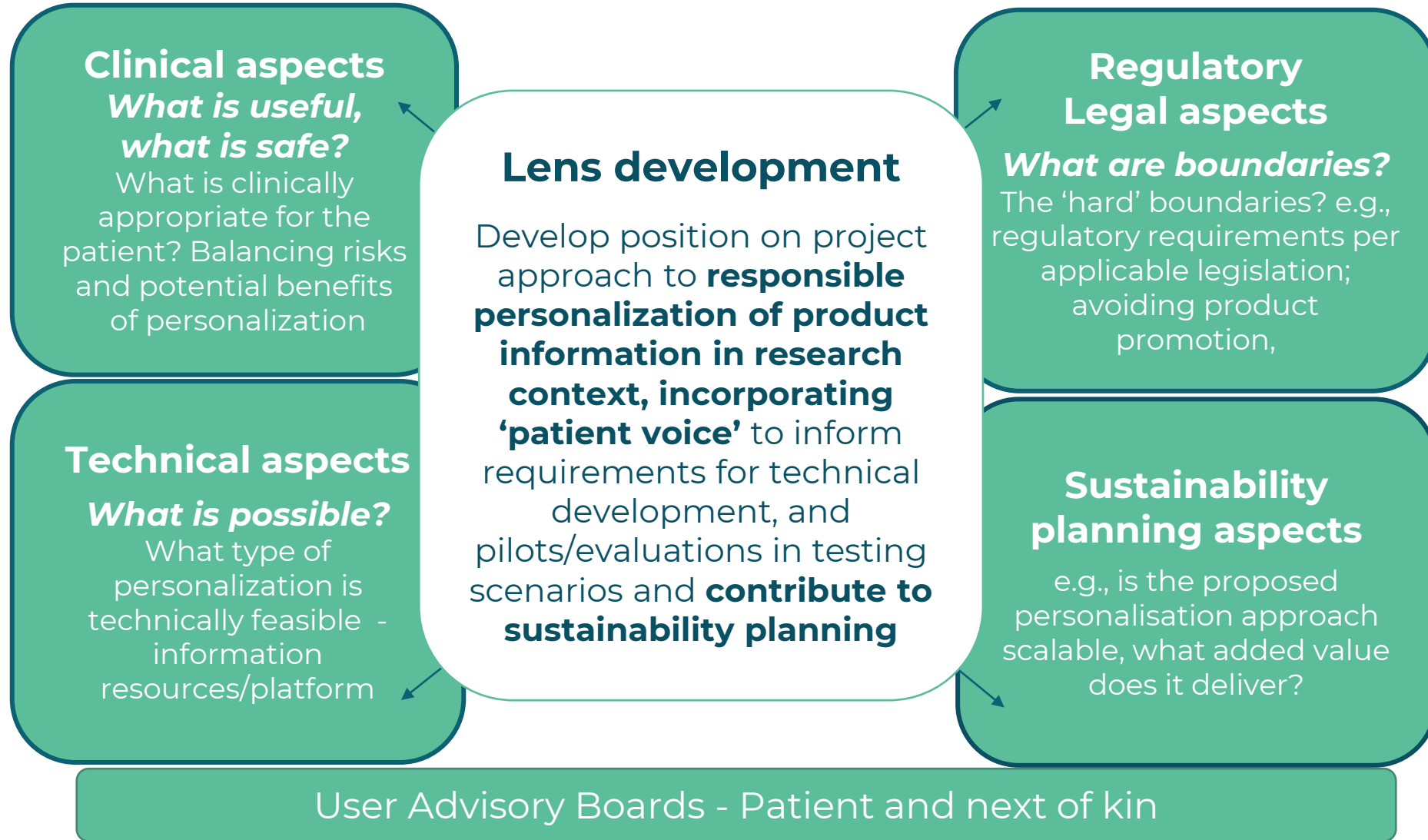
- Highlighting
- Collapsing

### Add HTML tag:

- Adding links
- Adding images / videos
- Adding forms
- Adding “Hovering”
- Adding explanation

# Focusing of information

– defining the approach to focusing



## Pregnancy

- **FOR ALL** <pregnancy precautions>  
*IF patient is Pregnant THEN add Highlight CSS class*
- **FOR ALL** <pregnancy precautions>  
*IF patient is cis-male OR patient is over 60 OR patient is under 12 THEN add Collapse CSS class*
- ...

## Diabetes

- **FOR ALL** <hiperglucemia>  
*IF patient's IPS contains <diabetes> THEN add Highlight CSS Class*
- **FOR ALL** <hiperglucemia>  
*IF patient.literacy is not high THEN add hyperlink to glossary*
- ...

## Intake

- **FOR ALL** <injectable>  
*add multimedia video*
- **FOR ALL** <oral intake>  
*IF patient.literacy is not high THEN add hover overlay with oral intake advice*
- **FOR ALL** < injectable >  
*IF patient.literacy is low THEN add icon*
- **FOR ALL** <oral intake>  
*IF patient.literacy is low THEN add icon*

# Taxonomy of Lenses (draft)

- Generic Medicine knowledge (e.g. General recommendations, processes)
- Personal Preferences (e.g. pictograms, terminology)
- Condition (e.g. Pregnancy, smoker, allergies, Socio demographic...)
- (Chronic)(Specific) Disease (e.g. Diabetes)
- Health Literacy (e.g. glossary, questionnaire)
- Side effects (when user reports side effects; Where are side effects reported?)
- Patient Safety
- Health Care Professional (e.g. Specific HCP recommendations)
- Online communities (e.g. knowledge and connection to online communities)
- Local Social/Wellbeing services (e.g. antipoison centers nearby, call this number in case of emergency)
  - location based services
  - Services to connect with HCP, or Pharmacists
- Additional material (e.g. pdf, online resources)
- Web enhancement (e.g. Linking between ePIs)
- Accessibility
- Trial recruitment and execution
- Interactions
  - Informative (highlight possible interactions)
  - Monitoring (highlight adverse effects)
- Open Data (e.g. allergy medication + pollen count in the zone)
- Wearable and Medical device connected
- Crowd-sourced, Machine Learning, Federated trained self-personalization service





## Mockup ePI from Spain

- Overview
- Examples of focused ePIs





## 2 personas: Pedro and Alicia



### Health Conditions

- HIV (diagnosed with 38 years)
- Depression

### Medication and Therapies

#### Prescribed by Doctor

- DOVATO ->Dolutegravir/Lamivudina
- Calcium/Vit D

#### Additional (non prescribed)

- Magnesium supplements
- Protein supplements
- Flu vaccine



### Health Conditions

- HIV (diagnosed with 25 years)
- Overweight
- Trying to get pregnant

### Medication and Therapies

#### Prescribed by Doctor

- BIKTARVY->Bictegravir/Emtricitabine/Tenofovir  
Alafenamide
- Calcium/Vit D

#### Additional (non prescribed)

- St. John's Wort (HIPÉRICO ARKOPHARMA cápsulas duras, Hypericum perforatum L.)
- Magnesium supplements
- Flu vaccine

## Persona Vector

- Gender
- Age
- Weight
- Height
- Medication list
- Problems – conditions
- Allergies (\*)
- Intollerances (\*)
- History of pregnancy
- Breastfeeding

Health problem	ICPC-2
HIV-infection/AIDS	B90 HIV-infection/AIDS
Influenza	R80 Influenza
Pneumonia	R81 Pneumonia
Anxiety disorder	P74 Anxiety disorder/anxiety state
Pregnancy	W78 Pregnancy
Pregnancy	W27 Fear of complications of pregnancy
Drug abuse	P19 Drug abuse
Fear of medical treatment	A13 Concern/fear medical treatment
Depression disorder	P03 Feeling depressed
Medication abuse	P18 Medication abuse
Immunodeficiency	B99 Blood/lymph/spleen disease other
Liver disease	D97 Liver disease NOS
Hepatitis C	B18.2: Chronic viral hepatitis C
Hepatitis B	B18.1: Chronic viral hepatitis B without delta-agent
Urethritis	U72 Urethritis
Dyspepsia/indigestion	D07 Dyspepsia/indigestion
Poisoning	A84 Poisoning by medical agent
Infectious disease other	A78 Infectious disease other/NOS

# Example 1: condition

## Original ePI

### 1. What Dovato 50 mg/300 mg film-coated tablets is and what it is used for

Dovato is a medicine that contains two active ingredients used to treat human immunodeficiency virus (HIV) infection: dolutegravir and lamivudine. Dolutegravir belongs to a group of anti-retroviral medicines called integrase inhibitors (INIs), and lamivudine belongs to a group of anti-retroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

Dovato is used to treat HIV in adults and adolescents over 12 years old who weigh at least 40 kg.

Dovato does not cure HIV infection; it keeps the amount of virus in your body at a low level. This helps maintain the number of CD4 cells in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.



## Focused ePI

### 1. What Dovato 50 mg/300 mg film-coated tablets is and what it is used for

Dovato is a medicine that contains two active ingredients used to treat human immunodeficiency virus (HIV) infection: dolutegravir and lamivudine. Dolutegravir belongs to a group of anti-retroviral medicines called integrase inhibitors (INIs), and lamivudine belongs to a group of anti-retroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

Dovato is used to treat HIV in adults and adolescents over 12 years old who weigh at least 40 kg.

Dovato does not cure HIV infection; it keeps the amount of virus in your body at a low level. This helps maintain the number of CD4 cells in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

User: Pedro Problem-condition: HIV

Medication: Dovato

## Example II: age

### Original ePI

#### 2. What you need to know before you take Dovato 50 mg/300 mg film-coated tablets

[...]

#### Children

This medicine is not for use in children under 12 years of age, because it has not been studied in these patients.

[...]



### Focused ePI

#### 2. What you need to know before you take Dovato 50 mg/300 mg film-coated tablets

[...]

#### Children

This medicine is not for use in children under 12 years of age, because it has not been studied in these patients.

[...]

# Example III: gender

## Original ePI

### 2. What you need to know before you take Dovato 50 mg/300 mg film-coated tablets

[...]

#### **Pregnancy**

If you are pregnant, think you may be pregnant, or if you are planning to have a baby:

Talk to your doctor about the risks and benefits of taking Dovato.

Taking Dovato at the time of becoming pregnant or during the first six weeks of pregnancy, may increase the risk of a birth defect, called neural tube defect, such as spina bifida (malformed spinal cord).

If you could get pregnant while taking Dovato:

Talk to your doctor and discuss whether there is a need for contraception, such as condom or Pills.

Tell your doctor immediately if you become pregnant or are planning to become pregnant. Your doctor will review your treatment. Do not stop taking Dovato without consulting your doctor, as this may harm you and your unborn child.

#### **Breast-feeding**

Breast-feeding is not recommended in women living with HIV because HIV infection can be passed on to the baby in breast milk.

A small amount of the ingredients in Dovato can also pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding, you should discuss it with your doctor as soon as possible.

[...]



## Focused ePI

### 2. What you need to know before you take Dovato 50 mg/300 mg film-coated tablets

[...]

#### **Pregnancy**

If you are pregnant, think you may be pregnant, or if you are planning to have a baby:

Talk to your doctor about the risks and benefits of taking Dovato.

Taking Dovato at the time of becoming pregnant or during the first six weeks of pregnancy, may increase the risk of a birth defect, called neural tube defect, such as spina bifida (malformed spinal cord).

If you could get pregnant while taking Dovato:

Talk to your doctor and discuss whether there is a need for contraception, such as condom or Pills.

Tell your doctor immediately if you become pregnant or are planning to become pregnant. Your doctor will review your treatment. Do not stop taking Dovato without consulting your doctor, as this may harm you and your unborn child.

#### **Breast-feeding**

Breast-feeding is not recommended in women living with HIV because HIV infection can be passed on to the baby in breast milk.

A small amount of the ingredients in Dovato can also pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding, you should discuss it with your doctor as soon as possible.

[...]

## Example IV: interaction 1

### Original ePI

#### 2. What you need to know before you take Biktarvy 50 mg/200 mg/25 mg film-coated tablets

##### Do not take Biktarvy

If you are allergic to bicitgravir, emtricitabine, tenofovir alafenamide or any of the other ingredients of this medicine (listed in section 6).

rifampicin used to treat some bacterial infections such as tuberculosis

St. John's wort (*Hypericum perforatum*), a herbal remedy used for depression and anxiety, or products that contain it.

If any of these apply to you, **do not take Biktarvy and tell your doctor immediately.**

[...]



### Focused ePI

#### 2. 2. What you need to know before you take Biktarvy 50 mg/200 mg/25 mg film-coated tablets

##### Do not take Biktarvy

If you are allergic to bicitgravir, emtricitabine, tenofovir alafenamide or any of the other ingredients of this medicine (listed in section 6).

rifampicin used to treat some bacterial infections such as tuberculosis

St. John's wort (*Hypericum perforatum*), a herbal remedy used for depression and anxiety, or products that contain it.

If any of these apply to you, **do not take Biktarvy and tell your doctor immediately.**

[...]

# Example V: interaction 2

## Original ePI

### 2. What you need to know before you take Dovato 50 mg/300 mg film-coated tablets

[...]

#### Other medicines and Dovato

[...]

Tell your doctor if you are taking any of the medicines in the following list:

- metformin, to treat diabetes
- medicines called antacids, to treat indigestion and heartburn. Do not take an antacid during the 6 hours before you take Dovato, or for at least 2 hours after you take it (see also section 3, 'How to take Dovato')
- supplements or multivitamins containing calcium, iron or magnesium. If you take Dovato with food, you can take supplements or multivitamins containing calcium, iron or magnesium at the same time as Dovato. If you do not take Dovato with food, do not take a supplement or multivitamin containing calcium, iron or magnesium during the 6 hours before you take Dovato, or for at least 2 hours after you take it (see also section 3, 'How to take Dovato')
- emtricitabine, etravirine, efavirenz, nevirapine or tipranavir/ritonavir, to treat HIV infection
- [...]



## Focused ePI

### 2. What you need to know before you take Dovato 50 mg/300 mg film-coated tablets

[...]

#### Other medicines and Dovato

[...]

Tell your doctor if you are taking any of the medicines in the following list:

- metformin, to treat diabetes
- medicines called antacids, to treat indigestion and heartburn. Do not take an antacid during the 6 hours before you take Dovato, or for at least 2 hours after you take it (see also section 3, 'How to take Dovato')
- supplements or multivitamins containing calcium, iron or magnesium. If you take Dovato with food, you can take supplements or multivitamins containing calcium, iron or magnesium at the same time as Dovato. If you do not take Dovato with food, do not take a supplement or multivitamin containing calcium, iron or magnesium during the 6 hours before you take Dovato, or for at least 2 hours after you take it (see also section 3, 'How to take Dovato')
- emtricitabine, etravirine, efavirenz, nevirapine or tipranavir/ritonavir, to treat HIV infection
- [...]









## Example VI: pictogram lens

### Original ePI

1. What Dovato 50 mg/300 mg film-coated tablets is and what it is used for
2. What you need to know before you take Dovato 50 mg/300 mg film-coated tablets
3. How to take Dovato 50 mg/300 mg film-coated tablets
4. Possible side effects
5. How to store Dovato 50 mg/300 mg film-coated tablets
6. Contents of the pack and other information

### Focused ePI (\*)

-  1. What Dovato 50 mg/300 mg film-coated tablets is and what it is used for
-  2. What you need to know before you take Dovato 50 mg/300 mg film-coated tablets
-  3. How to take Dovato 50 mg/300 mg film-coated tablets
-  4. Possible side effects
-  5. How to store Dovato 50 mg/300 mg film-coated tablets
-  6. Contents of the pack and other information

(\*) Examples of pictograms taken and adapted from WP4 wireframes for the sole purposes of illustrating the concept

# Example VII: glossary lens

## Original ePI

### 1. What Biktarvy 50 mg/200 mg/25 mg film-coated tablets is and what it is used for

Biktarvy contains three active substances:

- bicitgravir, an antiretroviral medicine known as an integrase strand transfer inhibitor (INSTI)
- emtricitabine, an antiretroviral medicine of a type known as a nucleoside reverse transcriptase inhibitor (NRTI)
- tenofovir alafenamide, an antiretroviral medicine of a type known as a nucleotide reverse transcriptase inhibitor (NtRTI)

[...]

## Focused ePI

### 1. What Biktarvy 50 mg/200 mg/25 mg film-coated tablets is and what it is used for

Biktarvy contains three active substances:

- bicitgravir, an antiretroviral medicine known as an integrase **strand transfer inhibitor (INSTI)**

Antiretroviral (ARV) HIV drug class. Integrase strand transfer inhibitors (INSTIs) block integrase (an HIV enzyme). HIV uses integrase to insert (integrate) its viral DNA into the DNA of the host CD4 cell. Blocking integrase prevents HIV from replicating (\*)

[...]

(\*) Clarification from <https://clinicalinfo.hiv.gov> for the purpose of illustrating the concept Clarifications TBD in Gravitate-Health

- ePIs
- IPS
- Mini-scenario
- Example preprocessor implementation
- Example Lens implementations
- FOSPS Source
  - <https://github.com/Gravitate-Health>
- FOSPS API
  - <https://fosps.gravitatehealth.eu/swagger-fosps/>



Thank You



innovative  
medicines  
initiative

