

Gravitate Health

Hackathon #1
17th – 19th Jan, 2023

indegeneTM

Indegene operates at the intersection of healthcare expertise and technology

19 of the world's top 20 biopharma companies trust us

25 Years

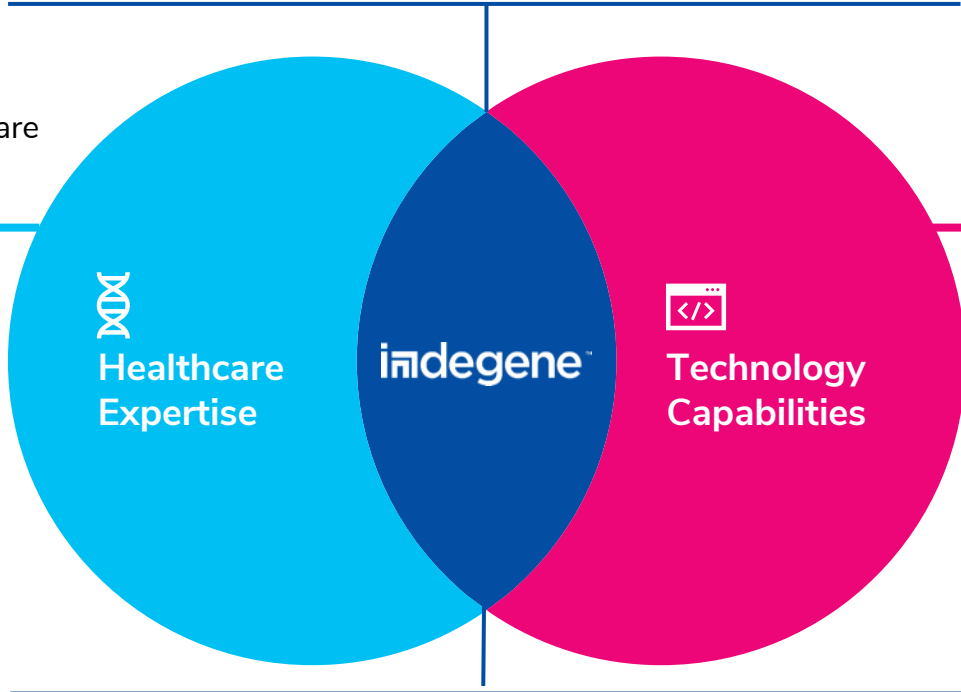
Healthcare Domain Expertise

22%

Employees With Healthcare Background

600+

Dedicated Team For Innovative Technologies



- Practitioner knowledge
- Regulatory understanding
- Medical content know-how

- Digital-first approach
- Proprietary tools, platforms
- Advanced data and analytics

Solutions across the life sciences commercialization value chain

Clinical ▶ Regulatory Affairs ▶ Medical Affairs ▶ Market Access ▶ Sales and Marketing ▶ Patient Support ▶ Pharmacovigilance

Industry recognition

A row of seven award logos: Great Place To Work, Peak Matrix (Life Sciences Commercial Services Specialists), Avtar (Best Companies For Women), FT Financial Times (High-Growth Companies Asia-Pacific 2022), Statista, Best Brands, and CMO Asia.

Challenges at a glance

❑ Challenge 1: IDENTIFY RULES TO ANNOTATE PATIENT INFORMATION

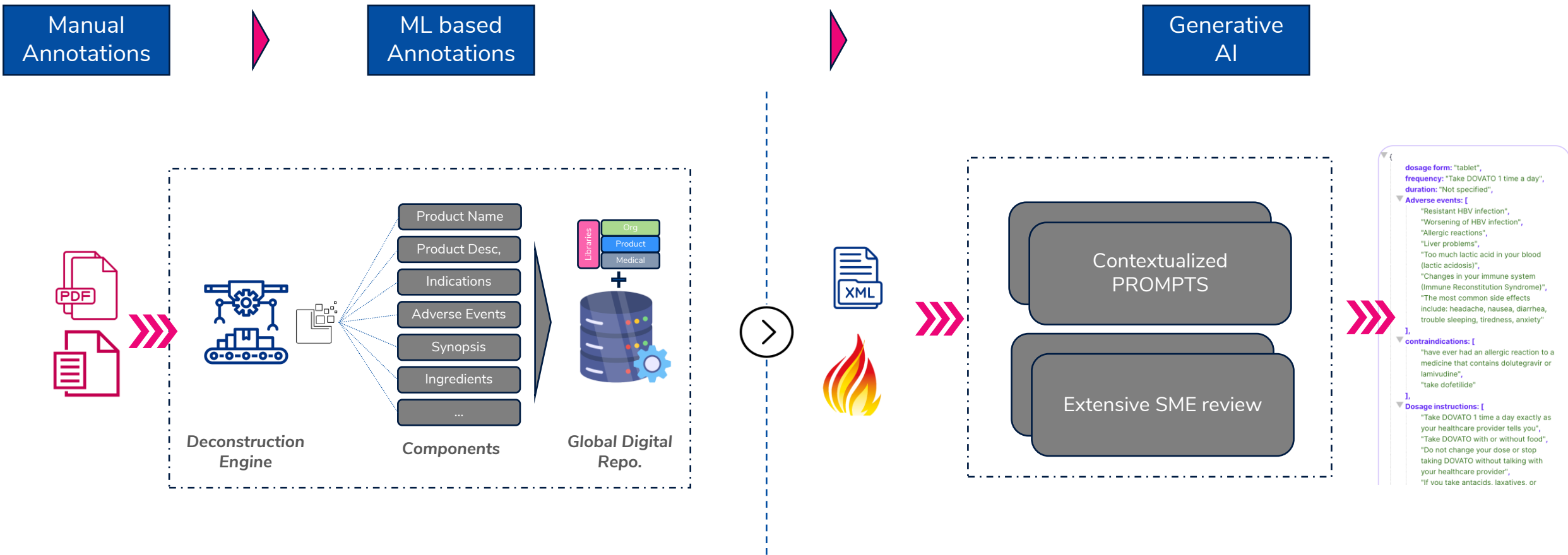
- To Create a structured representation of the information contained within the unstructured text of a product information digital leaflet
- To classify/annotate relevant content within the ePI to a standard set of library

❑ Challenge 2: DESIGN ALIGNED MEDICINE INFORMATION VISUALISATIONS FOR PATIENTS

- Develop G-lenses (a 'G-lens' is a piece of code which encodes certain knowledge required to better adapt the content of product information) using:
 1. ePIs with embedded semantic annotations (using standard terminologies such as SNOMED-CT, LOINC, ICD 10, iCPC-2),
 2. a persona vector i.e., the information relevant to the patient's health in an International Patient Summary-IPS, and
 3. the patient's current context and preferences ,create a lens that effectively and optimally adapts the content to preferences and context to provide the patient with relevant information about his/her medicines

Solution 1: Generative AI enabled annotations/classification

A paradigm shift for Patient information pre-processing and classification



Working Model

Existing

← Dovato LPD_only.docx

Search by Found, Undetected sections

Sections

- FULL PRESCRIBING INFORMATION
- 1 INDICATIONS AND USAGE
- 2 DOSAGE AND ADMINISTRATION
- 2.1 Testing Prior to or When Initiating Treatm...
- 2.2 Recommended Dosage
- 2.3 Recommended Dosage with Certain Coa...
- 2.4 Not Recommended in Patients with Seve...
- 3 DOSAGE FORMS AND STRENGTHS
- 4 CONTRAINDICATIONS
- 5 WARNINGS AND PRECAUTIONS
- 5.1 Patients Co-infected with HIV-1 and HB...
- HBV and the Risk of Posttreatment Exacerba...
- 5.2 Hypersensitivity Reactions
- 5.3 Hepatotoxicity
- 5.4 Embryo-Fetal Toxicity

2 DOSAGE AND ADMINISTRATION

2.1 Testing Prior to or When Initiating Treatment with DOVATO

Dosage and Method of Administration - Special Populations - Others - Testing Prior to or When Initiating Treatment with DOVATO

Prior to or when initiating DOVATO, test patients for HBV infection [see Warnings and Precautions (5.1)].

Dosage and Method of Administration - Special Populations - Others - Testing Prior to or When Initiating Treatment with DOVATO

Perform pregnancy testing before initiation of DOVATO in individuals of childbearing potential [see Warnings and Precautions (5.4), Use in Specific Populations (8.1, 8.3)].

2.2 Recommended Dosage

Dosage and Method of Administration - General - Regular Population - Recommended Dosage

DOVATO is a fixed-dose combination product containing 50 mg of dolutegravir and 300 mg of lamivudine. The recommended dosage regimen of DOVATO in adults is one tablet taken orally once daily with or without food [see Clinical Pharmacology (12.3)].

2.3 Recommended Dosage with Certain Coadministered Drugs

Dosage and Method of Administration - Special Populations - Others - Recommended Dosage with Certain Coadministered Drugs

The dolutegravir dose (50 mg) in DOVATO is insufficient when coadministered with drugs listed in Table 1 that may decrease dolutegravir concentrations; the following dolutegravir dosage regimen is recommended.

Dosage and Method of Administration - Special Populations - Others - Recommended Dosage with Certain Coadministered Drugs

Table 1. Dosing Recommendations for DOVATO with Coadministered Drugs

Coadministered Drug	Dosing Recommendation
Carbamazepine	An additional dolutegravir 50-mg tablet, separated by 12 hours from DOVATO, should be



Future Ready

Project Name: Gravitate Health Hackathon

Use Case: ePI Annotations

Run

Content

Formatted Raw Cost: \$ 0.0440 Tokens: 2773 (OpenAI GPT-4 Turbo Preview): complete

What is the most important information I should know about BIKTARVY? BIKTARVY can cause serious side effects, including:

- Worsening of hepatitis B virus (HBV) infection. Your healthcare provider will test you for HBV infection before or when you start treatment with BIKTARVY. If you have HBV infection and take BIKTARVY, your HBV may get worse (flare-up) if you stop taking BIKTARVY. A "flare-up" is when your HBV infection suddenly returns in a worse way than before.
 - Do not run out of BIKTARVY. Refill your prescription or talk to your healthcare provider before your BIKTARVY is all gone.
 - Do not stop taking BIKTARVY without first talking to your healthcare provider.
 - If you stop taking BIKTARVY, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver, and may give you a medicine to treat hepatitis B. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking BIKTARVY.
- For more information about side effects, see "What are the possible side effects of BIKTARVY?"

What is BIKTARVY?

- BIKTARVY is a prescription medicine that is used without other HIV-1 medicines to treat human immunodeficiency virus-1 (HIV-1) infection in adults and children who weigh at least 55 pounds (25 kg):
 - who have not received HIV-1 medicines in the past, or
 - to replace their current HIV-1 medicines for people whose healthcare provider determines that they meet certain requirements.
- HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).
- BIKTARVY contains the medicines bictegravir, emtricitabine, and tenofovir alafenamide.
- It is not known if BIKTARVY is safe and effective in children who weigh less than 55 pounds (25 kg).

Do not take BIKTARVY if you also take a medicine that contains:

- dofetilide
- rifampin

What should I tell my healthcare provider before taking BIKTARVY?

Before taking BIKTARVY, tell your healthcare provider about all your medical conditions, including if you:

- have liver problems, including HBV infection
- have kidney problems

dosage form: "BIKTARVY contains the medicines bictegravir, emtricitabine, and tenofovir alafenamide,"

frequency: "Take BIKTARVY 1 time each day with or without food,"

duration: "Not specified in the provided text."

Adverse events: [

- "Worsening of hepatitis B virus (HBV) infection",
- "Changes in your immune system (Immune Reconstitution Syndrome)",
- "New or worse kidney problems, including kidney failure",
- "Too much lactic acid in your blood (lactic acidosis)",
- "Severe liver problems",
- "The most common side effects of BIKTARVY are diarrhea, nausea, and headache"

].

contraindications: [

- "Do not take BIKTARVY if you also take a medicine that contains dofetilide,"
- "Do not take BIKTARVY if you also take a medicine that contains rifampin."

].

Dosage instructions: [

- "Take BIKTARVY exactly as your healthcare provider tells you to take it,"
- "Take BIKTARVY 1 time each day with or without food,"
- "If you are on dialysis, take your daily dose of BIKTARVY following dialysis,"
- "If you take antacids that contain aluminum or magnesium, take BIKTARVY at least 2 hours before or 6 hours after you take these antacids,"
- "If you take supplements or antacids that contain iron or calcium, take BIKTARVY with food at the same time that you take these supplements or antacids."

].

Solution 2: FOCUSed information for different personas



Alicia Gravitare

Gender : Female

Date of Birth : 1998-10-05

Medication :

- BIKTARVY Bictegravir /Emtricitabine/ Tenofovir Alafenamide 1 t QD
- Carbamazepine 1 t TID

Problem List :

- Depressive disorder
- Human immunodeficiency virus infection
- Trigeminal neuralgia
- Overweight

User Persona



Created by Gem Design from Noun Project

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{
  "dosage form": "The tablets are film-coated with a coating material containing iron oxide black, iron oxide red, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.",
  "frequency": "Take BIKTARVY 1 time each day with or without food.",
  "duration": "Not specified in the provided text.",
  "Adverse events": [ 6 items ],
  "contraindications": [ 2 items ],
  "Dosage instructions": [ 7 items ],
  "Warnings and precautions": [ 7 items ],
  "Indications": "BIKTARVY is a prescription medicine that is used without other HIV-1 medicines to treat human immunodeficiency virus-1 (HIV-1) infection in adults and children who weigh at least 55 pounds (25 kg).",
  "Storage instructions": [
    "Store BIKTARVY below 86°F (30°C).",
    "Keep BIKTARVY in its original container.",
    "Keep the container tightly closed.",
    "Keep BIKTARVY and all medicines out of reach of children."
  ]
}
```

Annotated ePI



```
{
  "Dosage frequency": "Take BIKTARVY 1 time each day with or without food.",
  "Dosage Instruction": [
    "Take BIKTARVY exactly as your healthcare provider tells you to take it.",
    "Take BIKTARVY 1 time each day with or without food.",
    "If you take supplements or antacids that contain iron or calcium, take BIKTARVY with food at the same time that you take these supplements or antacids."
  ],
  "Warnings and Precautions": [
    "Before taking BIKTARVY, tell your healthcare provider about all your medical conditions, including if you have liver problems, including HBV infection, have kidney problems, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.",
    "Do not start a new medicine without telling your healthcare provider."
  ],
  "Contraindications": [
    "Do not take BIKTARVY if you also take a medicine that contains dofetilide.",
    "Do not take BIKTARVY if you also take a medicine that contains rifampin."
  ]
}
```

FOCUSed ePI

Solution 2: Generative AI enabled personalized patient information

Existing

+

Patient Information
BIKTARVY® (bik-TAR-vee)
(bictegravir, emtricitabine, and tenofovir alafenamide)
tablets

Important: Ask your healthcare provider or pharmacist about medicines that should not be taken. For more information, see "What should I tell my healthcare provider before taking BIKTARVY?"

What is the most important information I should know about BIKTARVY?
BIKTARVY can cause serious side effects, including:

- Worsening of hepatitis B virus (HBV) infection. **Your healthcare provider will test you for HBV before or when you start treatment with BIKTARVY. If you have HBV infection and take BIKTARVY, you may get worse (flare-up) if you stop taking BIKTARVY. A "flare-up" is when your HBV infection returns in a worse way than before.**
 - Do not run out of BIKTARVY. Refill your prescription or talk to your healthcare provider before all gone.
 - Do not stop taking BIKTARVY without first talking to your healthcare provider.
 - If you stop taking BIKTARVY, your healthcare provider will need to check your health often and regularly for several months to check your liver, and may give you a medicine to treat hepatitis. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking BIKTARVY.

For more information about side effects, see "What are the possible side effects of BIKTARVY?"

What is BIKTARVY?
 BIKTARVY is a prescription medicine that is used without other HIV-1 medicines to treat human immunodeficiency virus (HIV-1) infection in adults and children who weigh at least 55 pounds (25 kg):

- who have not received HIV-1 medicines in the past, or
- to replace their current HIV-1 medicines for people whose healthcare provider determines that they meet the requirements.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).
 BIKTARVY contains the medicines bictegravir, emtricitabine, and tenofovir alafenamide. It is not known if BIKTARVY is safe and effective in children who weigh less than 55 pounds (25 kg).

Do not take BIKTARVY if you also take a medicine that contains:

- dofetilide
- rifampin

What should I tell my healthcare provider before taking BIKTARVY?
Before taking BIKTARVY, tell your healthcare provider about all your medical conditions, including:

- have liver problems, including HBV infection
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if BIKTARVY can harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with BIKTARVY.

Pregnancy Registry: There is a pregnancy registry for women who take BIKTARVY during pregnancy. This registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. Do not breastfeed if you take BIKTARVY.
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - At least one of the medicines in BIKTARVY can pass to your baby in your breast milk. It is not known if BIKTARVY can pass into your breast milk.

Talk with your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, antacids, laxatives, vitamins, and herbal supplements.
 Some medicines may interact with BIKTARVY. Keep a list of your medicines and show it to your healthcare provider when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with BIKTARVY.

Reference ID: 4742348

Future Ready

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{
  "Dosage frequency": "Take BIKTARVY 1 time each day with or without food.",
  "Dosage Instruction": [
    "Take BIKTARVY exactly as your healthcare provider tells you to take it.",
    "Take BIKTARVY 1 time each day with or without food.",
    "If you take supplements or antacids that contain iron or calcium, take BIKTARVY with food at the same time that you take these supplements or antacids."
  ],
  "Warnings and Precautions": [
    "Before taking BIKTARVY, tell your healthcare provider about all your medical conditions, including if you have liver problems, including HBV infection, have kidney problems, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.",
    "Do not start a new medicine without telling your healthcare provider."
  ],
  "Contraindications": [
    "Do not take BIKTARVY if you also take a medicine that contains dofetilide.",
    "Do not take BIKTARVY if you also take a medicine that contains rifampin."
  ]
}
```



Reference ID: 4742348

Thank You