



Implementing AI in RA

A real-life example

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Our experiences



Who is involved with implementing AI in your organization?

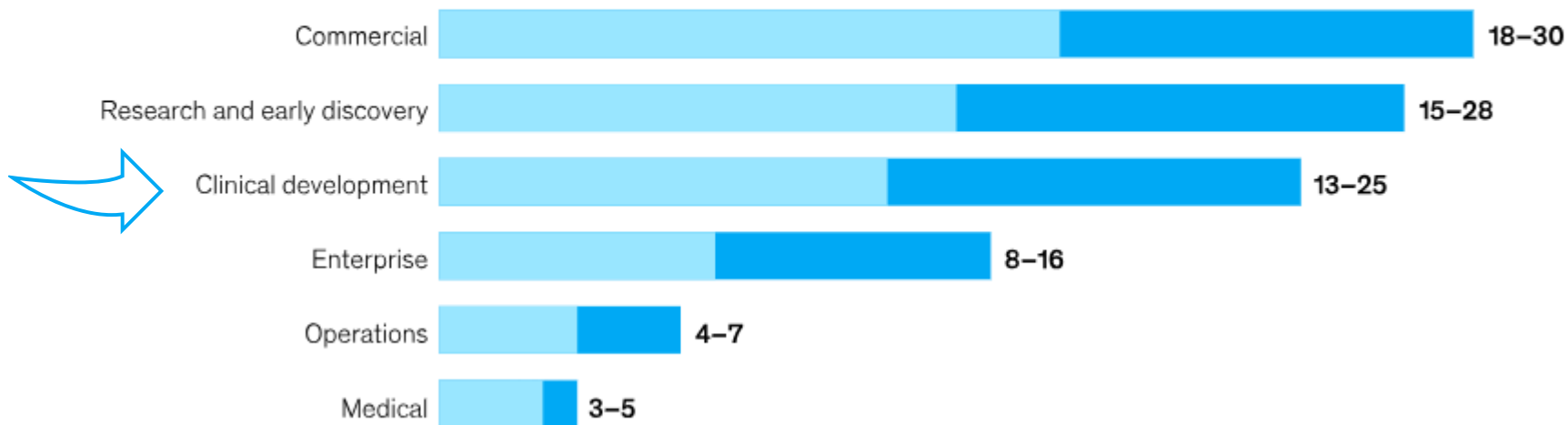




GenAI is transforming the pharma industry

Generative AI is expected to produce \$60 billion to \$110 billion in annual value across the pharmaceutical industry value chain.

Expected value annually, \$ billion



Including value for Regulatory Affairs

Source: McKinsey analysis

[McKinsey: Generative AI in the pharmaceutical industry: Moving from hype to reality, Jan. 2024](#)



Three Value Pillars

RA workstream for genAI

- // Internal Bayer Regulatory Affairs (RA) team
- // Established in 2023
- // Gathering colleagues across the whole RA organization
- // Mission: *“Leading the way in integrating AI into RA processes”*



Partnership



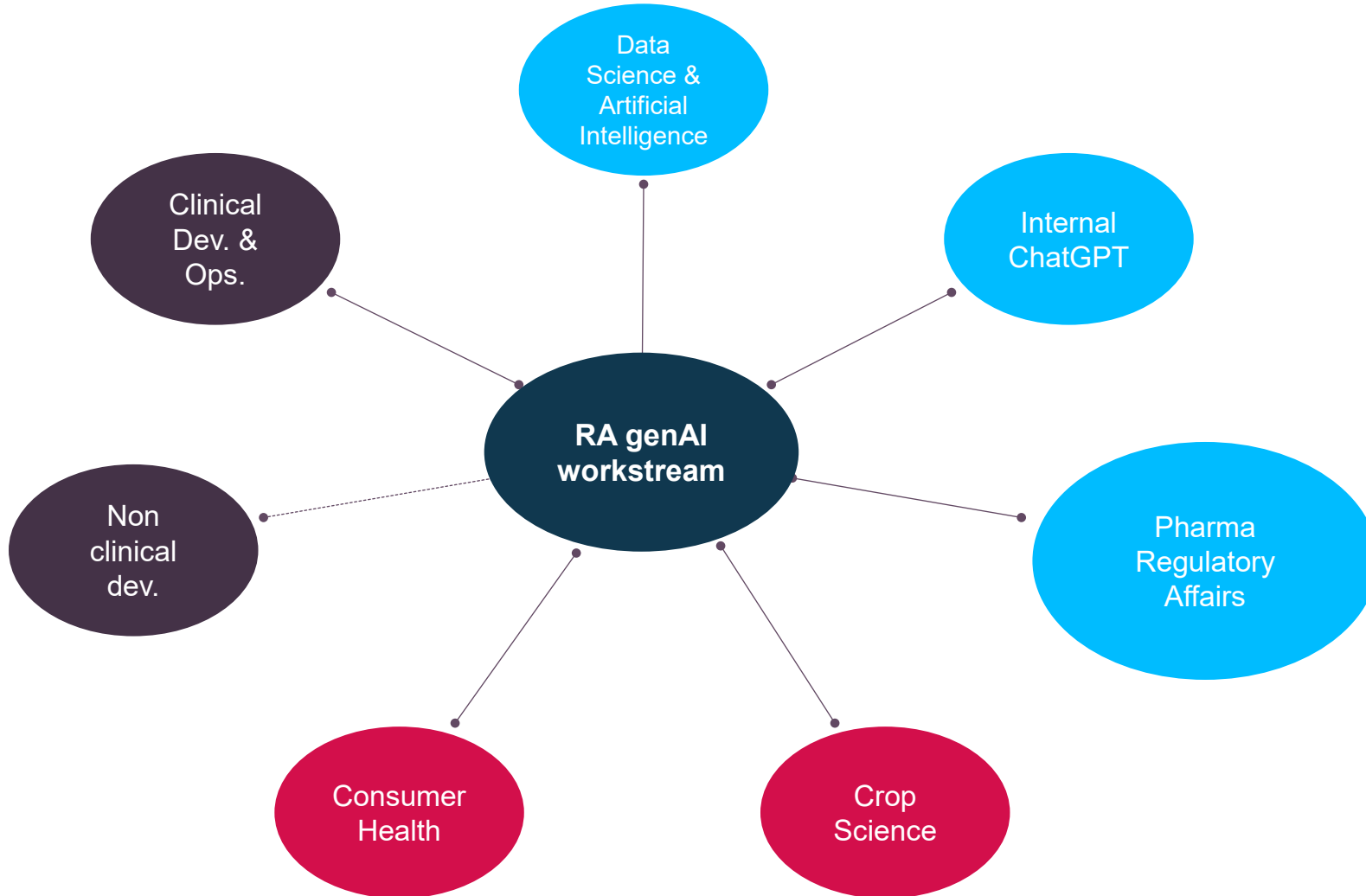
Tools & pilots



Communication & Training



Partnering with Key Stakeholders



Through internal and external partnership, we **identify synergies and collaboration opportunities**, aiming to achieve **efficiency gains across RA businesses and improved pilot results**.



AI implementation in RA - where did we start?



Submission authorship, creation and maintenance



Drafting templates for Authority Notification letters



Labeling & Translations support



Regulatory intelligence and policy



Generating summaries, monitoring



Regulatory strategy



40+ Use cases evaluated & prioritized based on:

- // Benefits / value
- // Estimated resource needs (funding/FTEs)
- // Technical feasibility
- // Potential use for other applications (“umbrella use cases”)



Our key use cases



Developing Responses to Health Authorities (HA) Request for Information (Rfi)

How to use genAI to leverage past HA interactions to retrieve previous similar RFI and draft answer?



Translating NDA Dossier

How to use genAI to translate parts of NDA dossiers, from English to local language?



Regulatory & Labeling Intelligence

How to use genAI to efficiently and quickly search across internal and external labels, assessment reports and guidelines?



RA Community Engagement

Monthly coffee chat
monthly short interactive online sessions



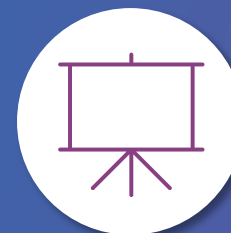
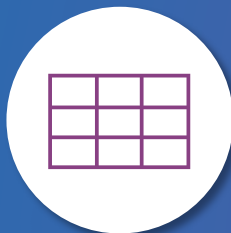
SharePoint
Information source on the workstream

Newsletters
Publication of articles related to the workstream updates and AI in general



Regulatory channel in genAI community
Knowledge sharing, networking (also with other colleagues beyond RA)

Prompt repository
Platform to share RA relevant prompts and assistants



Roadshow
Visit RA teams to introduce genAI and the workstream



Projects that did not work but provided valuable learnings

Labeling translations via GPT (internal) - 2024

- Existing machine translation tools superior for many languages
- Redirected towards NDA dossier translations

Analyzing guidelines via GPT (internal) - 2024

- Required resources not (yet) connected to the platform
- Prompt developed for summarizing manually uploaded guidelines

Writing assistant to re-use existing text in template - 2024

- User interface did not match user needs
- Developed into Word plugin



Getting started



Who knows how to prompt?





Types of use cases

Quick Wins

- Simple use cases supporting our daily work, e.g. write email, summarize document
- Prompting training usually sufficient

Low complexity

- Can usually be resolved using ChatGPT-like platforms
- May involve upload of documents or information retrieval from external websites / services
- Support for more complex prompts often needed (iterative prompt development)

Medium to high complexity

- Resources & funding needed
- Use case evaluation & monitoring process in needed
- Collaboration with data scientists and IT experts needed



Quick wins - what can we already use AI for today?

- ▶ Meeting minutes
- ▶ Summarizing and analyzing documents
- ▶ Writing support (e.g. emails)
- ▶ Finetuning formatting
- ▶ Enhancing readability
- ▶ Converting HCP label wording into patient-friendly wording



Prompt Structure Cheat Sheet

- ▶ A basic framework for building good prompts is the **Role, Task, Format, Context** framework. It helps you to cover the most important aspects to get qualitative answers.

Role:

- Project Leader
- Stakeholder
- Manager
- Customer
- Provider
- Training participant
- ...

Task:

- Create content
- Create a Stakeholder list
- Summarize a document
- Write a draft meeting agenda
- Translate content
- Plan project tasks
- Compare information
- ...

Format:

- Table
- Text
- Chart
- Slides
- Video Script
- Audio Script
- Translation
- ...

Context:

- Additional descriptions
- What you don't want
- Examples
- Additional sources like data sources, PDF, ...
- ...



Use information about yourself, your own role, and examples of your own writing to get answers that sound more like your own



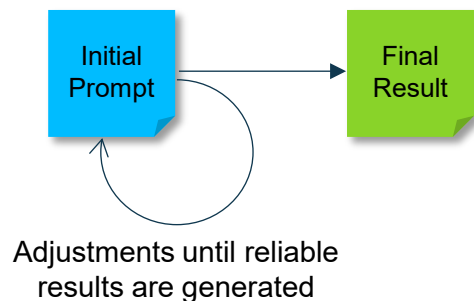
One-time searches vs. iterative prompt development

Conversational Prompts



For simple, one-time use cases, conversational prompts usually work well. However, for re-usable prompts, a conversation chain would not work well.

Iterative Prompt Design



With iterative prompt design you change the initial prompt until it provides the expected final output reliably. These prompts can then be re-used for the same task.



Example prompt: patient-friendly language

Role + context	You will act as a medical writer to simplify a medical text while keeping the same content. The purpose of the text is to provide a version of a pharmaceutical product's label that is easy for any patient to understand. The original text will be provided in medical terminology, and the output will need to contain only commonly used words.
Task	The goal is to transform the medical text to be patient-friendly with a maximum reading level of B1 based on the European Common Framework of Reference, or a Flesh-Kincaid score of 6-8.
Format	You will keep sentences short and clear and use bulleted lists where possible. In case the source text provides instructions for the healthcare professional, revise these so they match the point of view of the patient.
Additional instruction	Ask me about the text in the response.



Patient-friendly language prompt: output

Approved section 4.4 Warnings and precautions

Immunocompromised individuals

The safety and efficacy of VIMKUNYA has not been assessed in patients with immunodeficiency and patients using systemic immunosuppressive therapies. It is not known whether individuals with impaired immune responsiveness, including individuals receiving immunosuppressive therapy, will elicit the same response as immunocompetent individuals to the vaccine regimen.

Anxiety-related reactions

As with all injectable vaccines, anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.

Concurrent illness

Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination

Output plain language prompt

Weakened Immune System

- VIMKUNYA has not been tested in people with a weak immune system or those taking strong medicines that lower immunity.
- We do not know if people with a weak immune system will respond the same way to the vaccine as those with a healthy immune system.

Anxiety Reactions

- Some people may feel anxious when getting a shot. This can cause:
 - Fainting (vasovagal reaction)
 - Rapid breathing (hyperventilation)
- It's important to take steps to prevent injuries if someone faints.

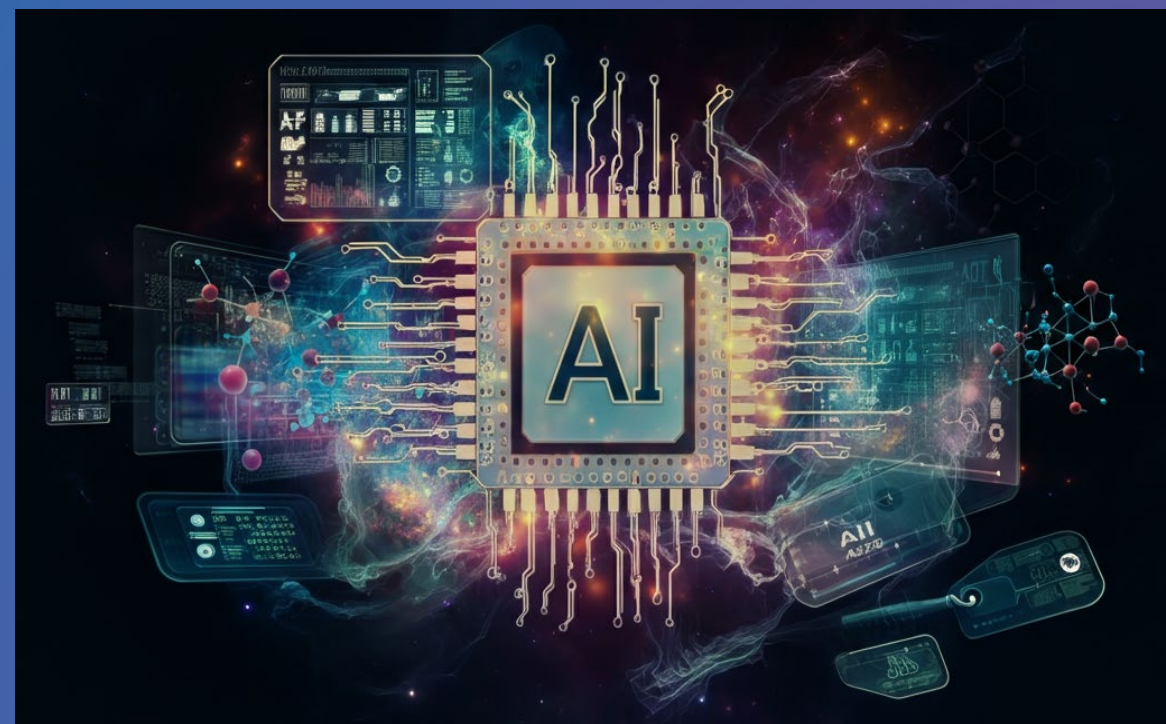
Sickness Before Vaccination

- If you are very sick with a high fever or serious infection, wait to get vaccinated.
- If you have a minor illness or a low fever, you can still get the vaccine.



Key takeaways

- ▶ AI can already support your daily work now
- ▶ Learning how to prompt is essential
- ▶ Change management plays a large role in the adoption of AI
- ▶ For more complex use cases, get started by evaluating your internal AI landscape (available tools and data scientist / AI / IT support)



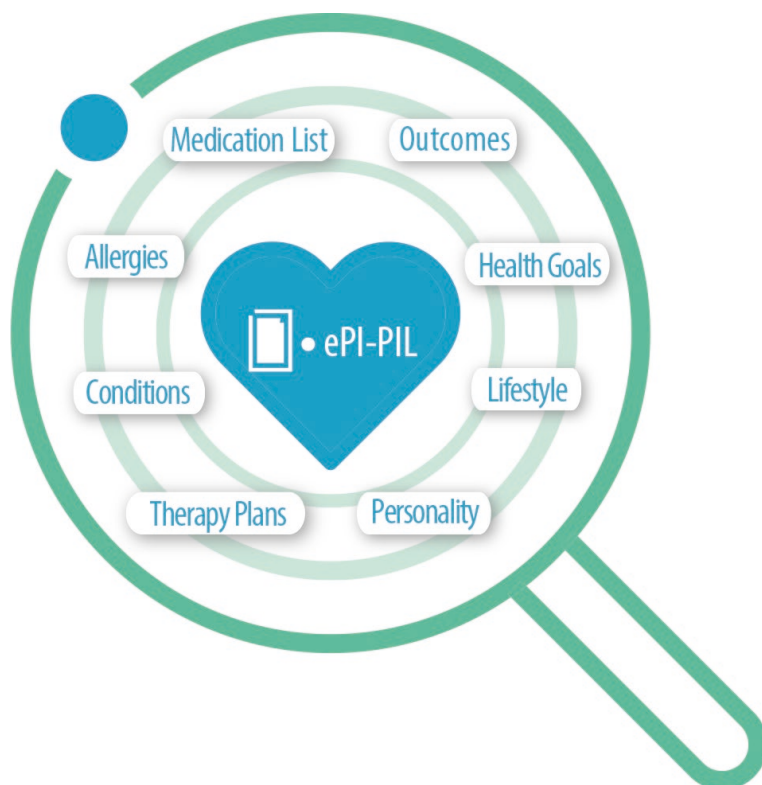


External projects



IMI Gravitare Health

www.gravitatehealth.eu



What it is

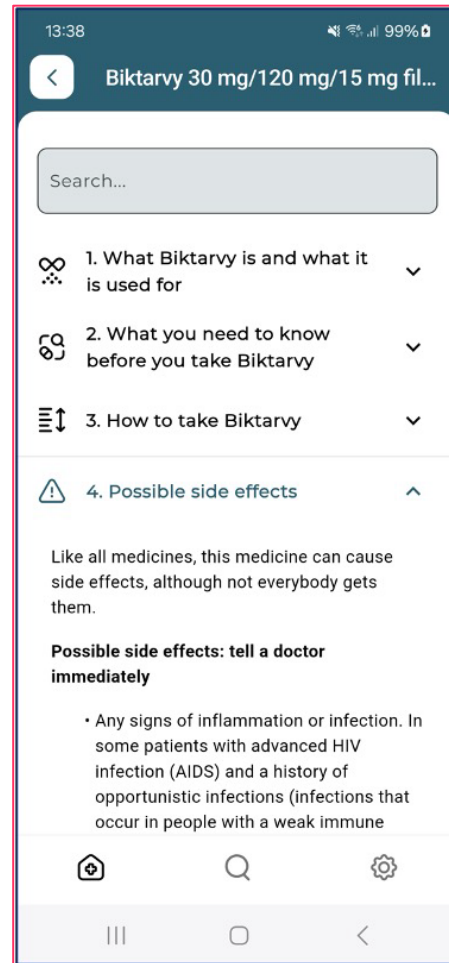
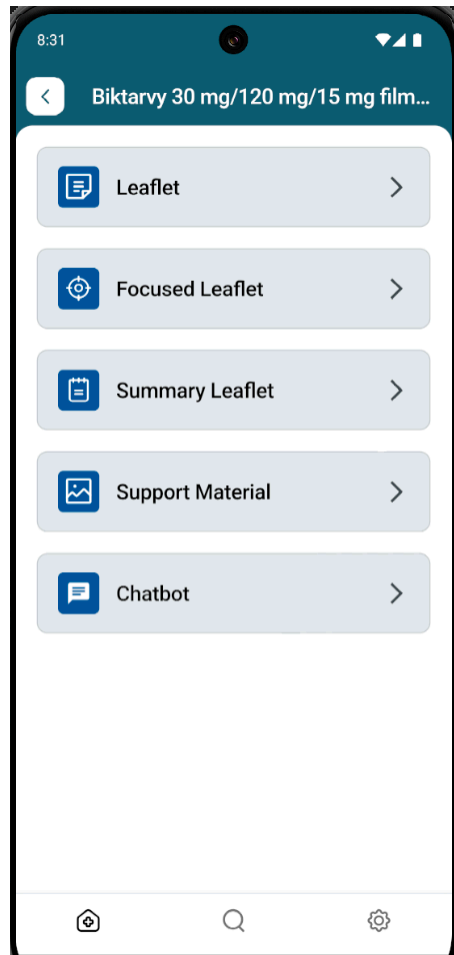
A public-private digital health information project that is developing an open-source digital platform with services to improve patients' access to more relevant and understandable information about medicines from trusted sources, delivered via the G-lens[®] service.

How it works

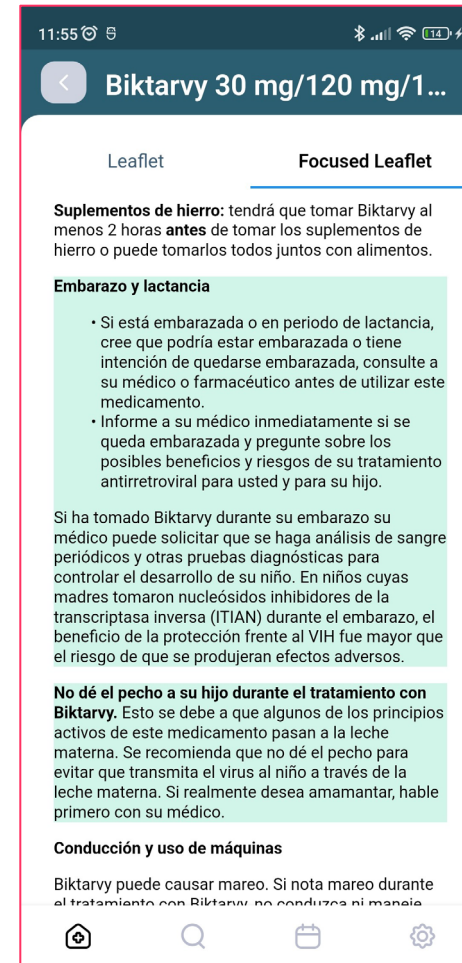
- Gravitare-Health uses trusted information in a focused way using the electronic product information.
- For focusing, a subset of health record data (International Patient Summary) is used.
- The platform presents users with information that is relevant to them, based on their conditions and preferences.
- Additional trusted health information can be incorporated to enhance understanding and ensure safer use of medicines.
- The G-lens[®] service considers medication list, allergies, conditions, therapy plan, health goals, personality, lifestyle, etc.

The G-Lens in action

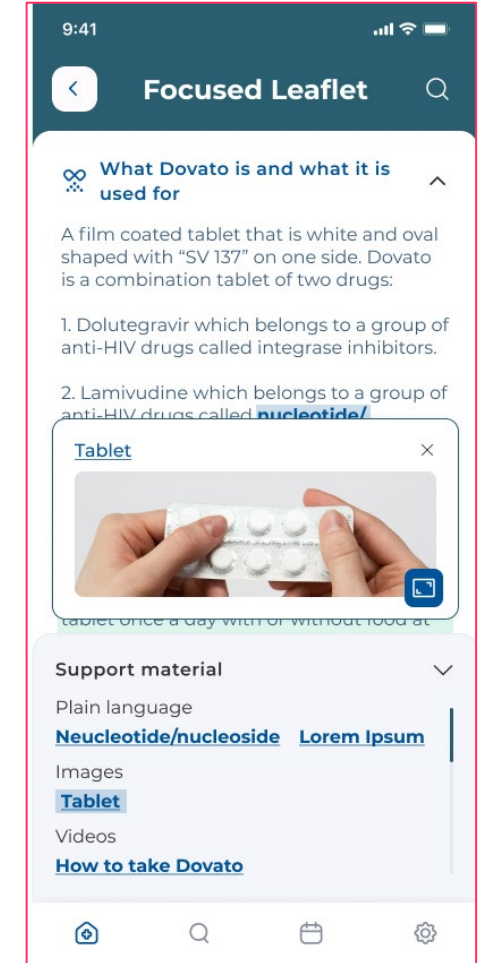
ePI - Leaflet



ePI - focused



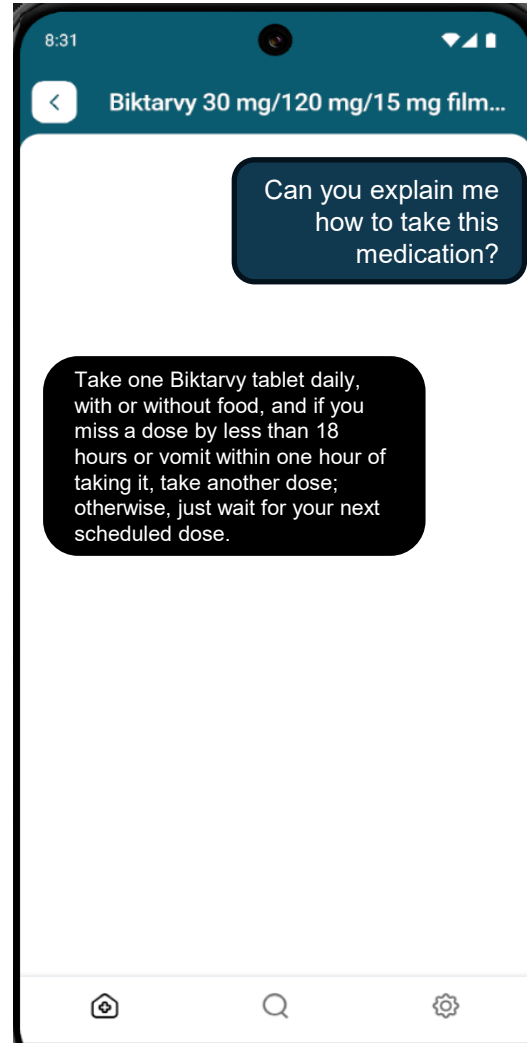
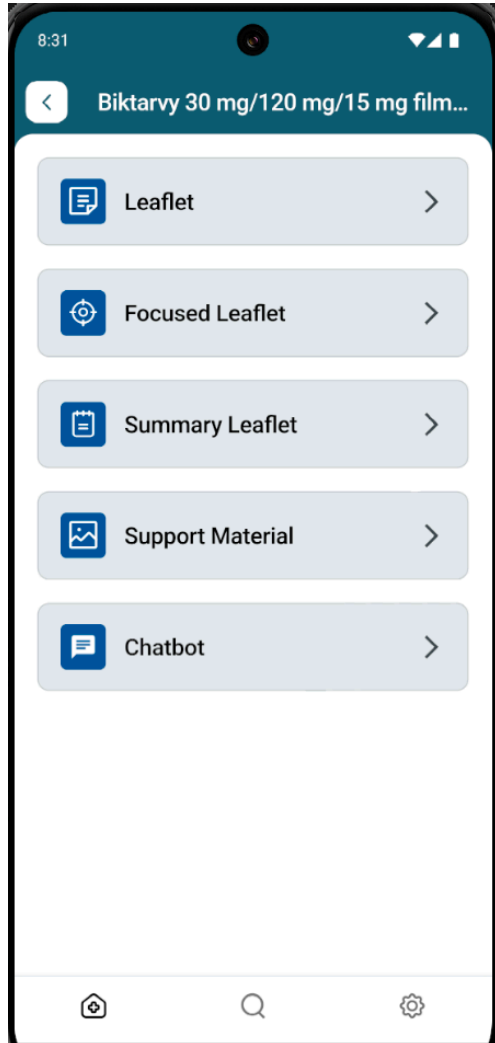
ePI - focused



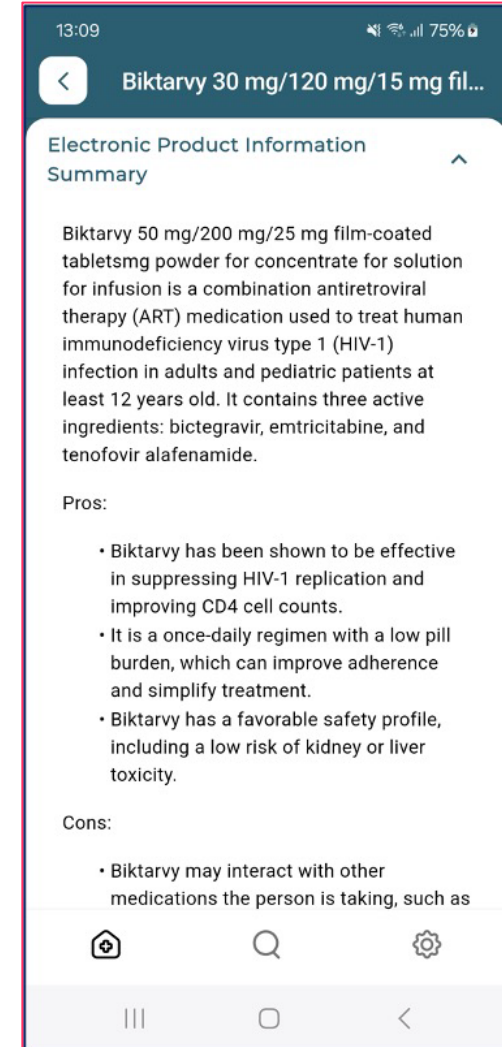


AI-augmentation of the G-Lens

Chatbot



ePI - summary





Foundation 29

www.foundation29.org

DxGPT: AI-Powered Medical Diagnosis

DxGPT is a pioneering experiment that uses large language models to create medical diagnostic support systems. This application explores how AI can assist in the accurate and rapid identification of medical conditions, improving the diagnostic process for patients.

AI that connects patients with clinical trials

Simplifying access to clinical research

Developed by Fundación 29, this tool simplifies the search for clinical trials, making the process more accessible for everyone.

AI that helps families with rare diseases

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Medical reports you can understand

Upload your hospital discharge report and get an adapted version in clear and understandable language for patients and families. Our AI analyzes the medical document and transforms it into easy-to-understand text, maintaining all important information but explaining it in an accessible way.

Agents for medical management

Your personal medical assistant for healthcare

Nav29 is a free application that allows patients and doctors to speed up the rare disease diagnosis process. We apply artificial intelligence to help patients and professionals identify symptoms and predict accurate diagnoses.

Health for all, Hunger for none



bayer.com