



corneo

E2E Live Showcase

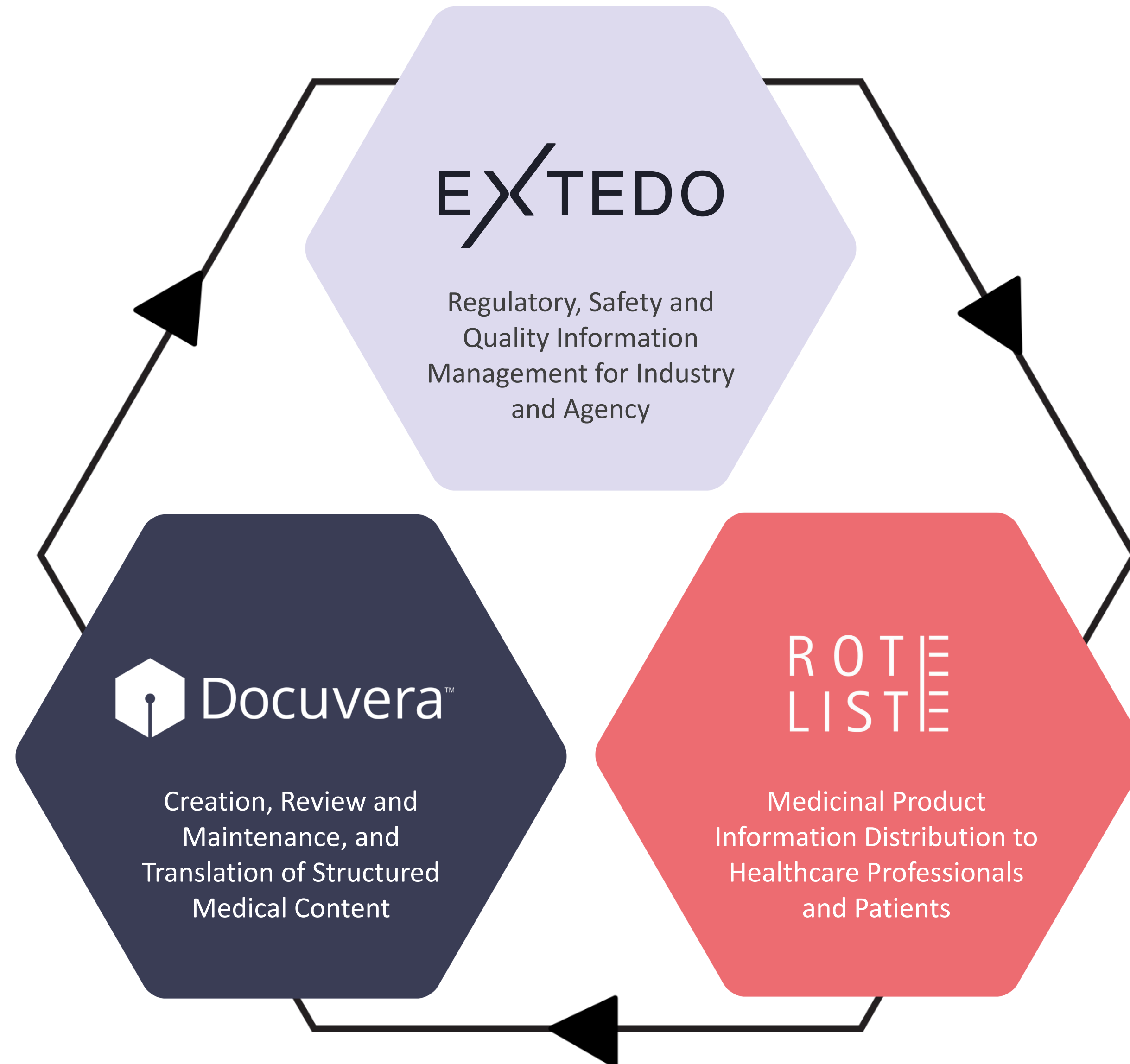
Bridging Industry, Agencies & Patients through ePI

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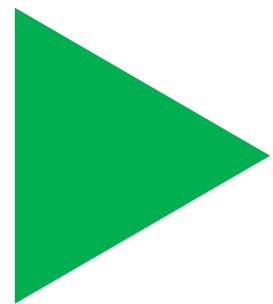
Director Strategic Projects



Together, we build the trusted bridge between industry, authorities and healthcare professionals facilitating innovative and compliant exchange of regulated information in life sciences to improve patient health.

The E2E Showcase Scenario

-  Authorized product Transformium 
-  New contra indication for pregnancy  discovered
-  Variation initiated and submitted as  **FHIR** ePI to the agency



We start our showcase with the agency review...

Elevating Industry-Agency Collaboration

EXTEDO
PULSE
Industry



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1

change
request

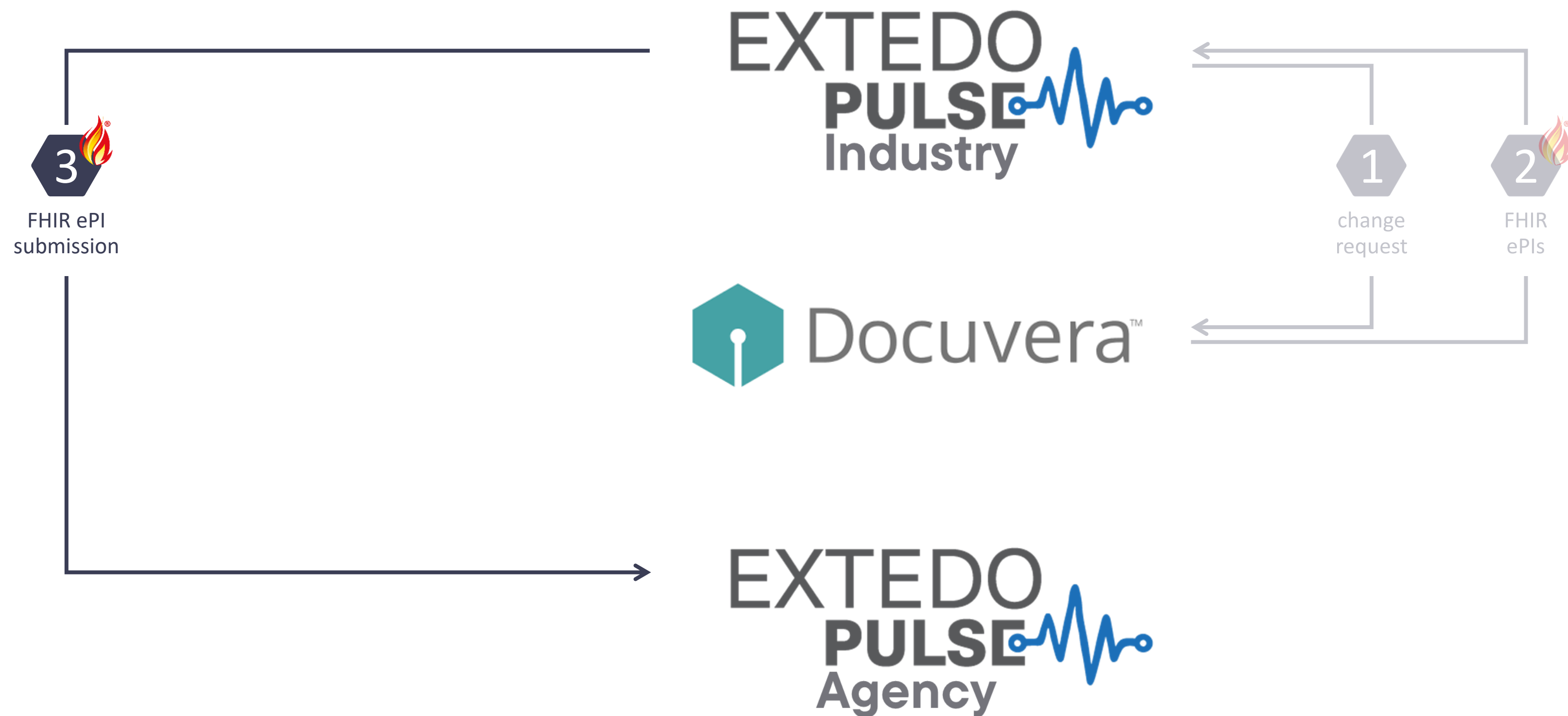
1

Situation: Contraindication is identified and reported via Pharmacovigilance system. Impacted content is assessed and regulatory activity is created. A change request is triggered to update the impacted product information accordingly.



2

After updating the relevant product information, the new versions are synchronized with the regulatory document management system via FHIR ePl.



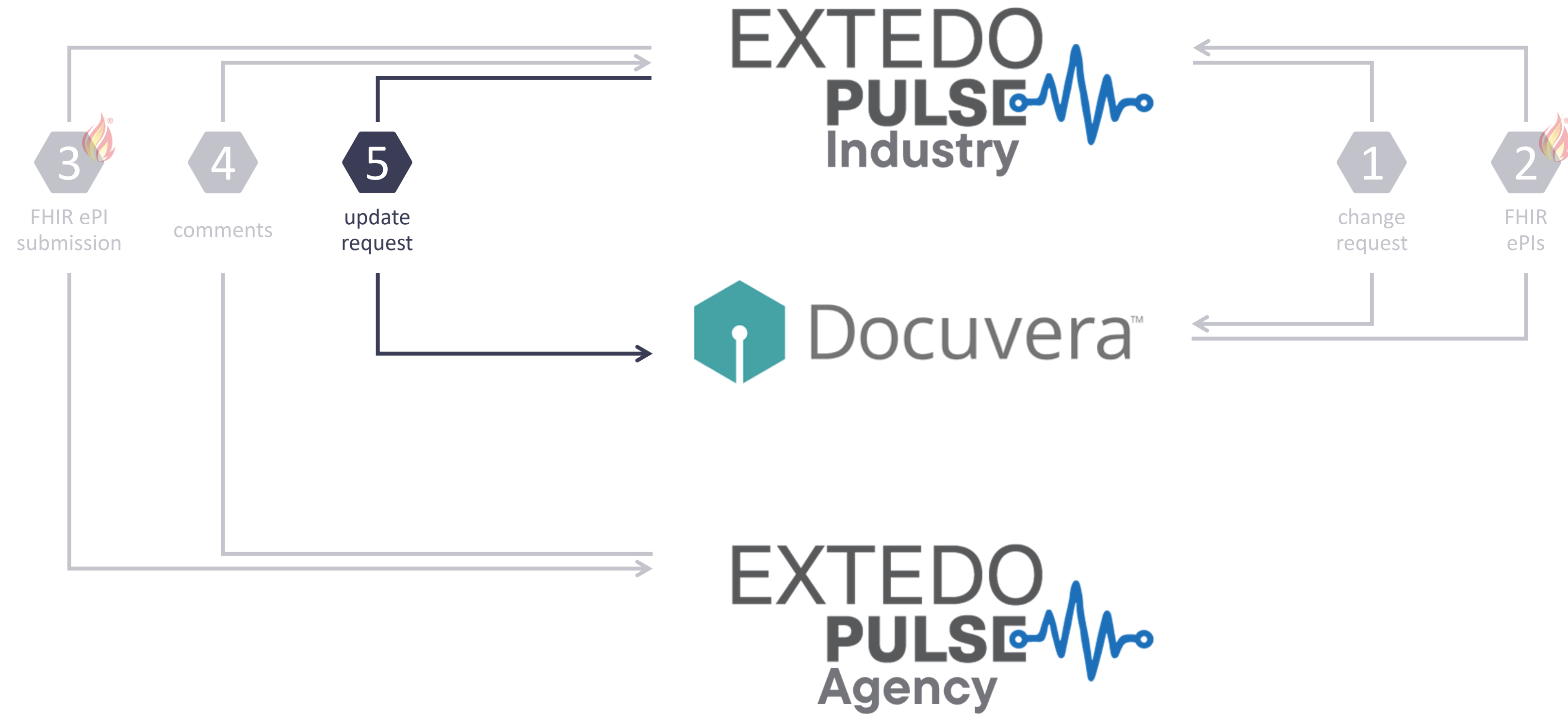
3

Updated product information is uploaded to the agency portal as FHIR ePIs. The agency portal automatically performs a technical validation, imports the submission into the case management system, and notifies assessors of the incoming submission.



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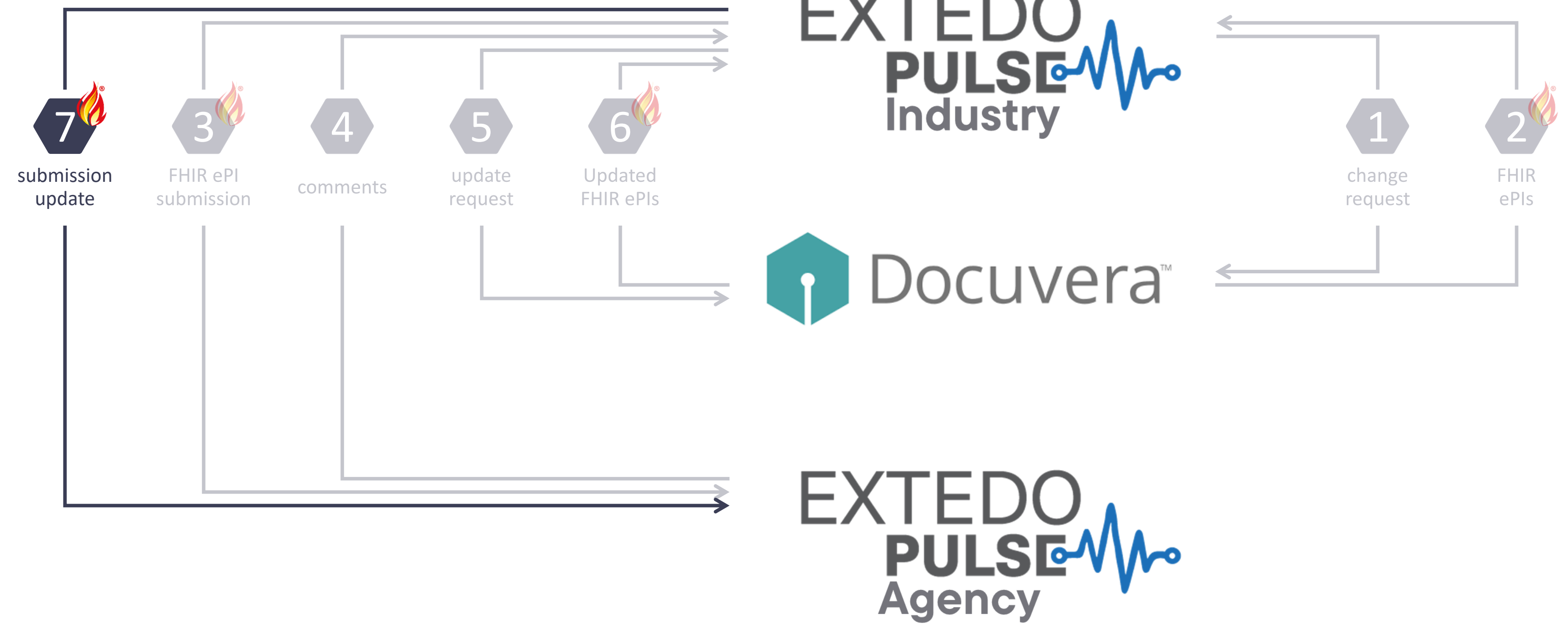
The agency assessor team reviews the updated product information and forwards comments and annotations on component level directly to industry via gateway.

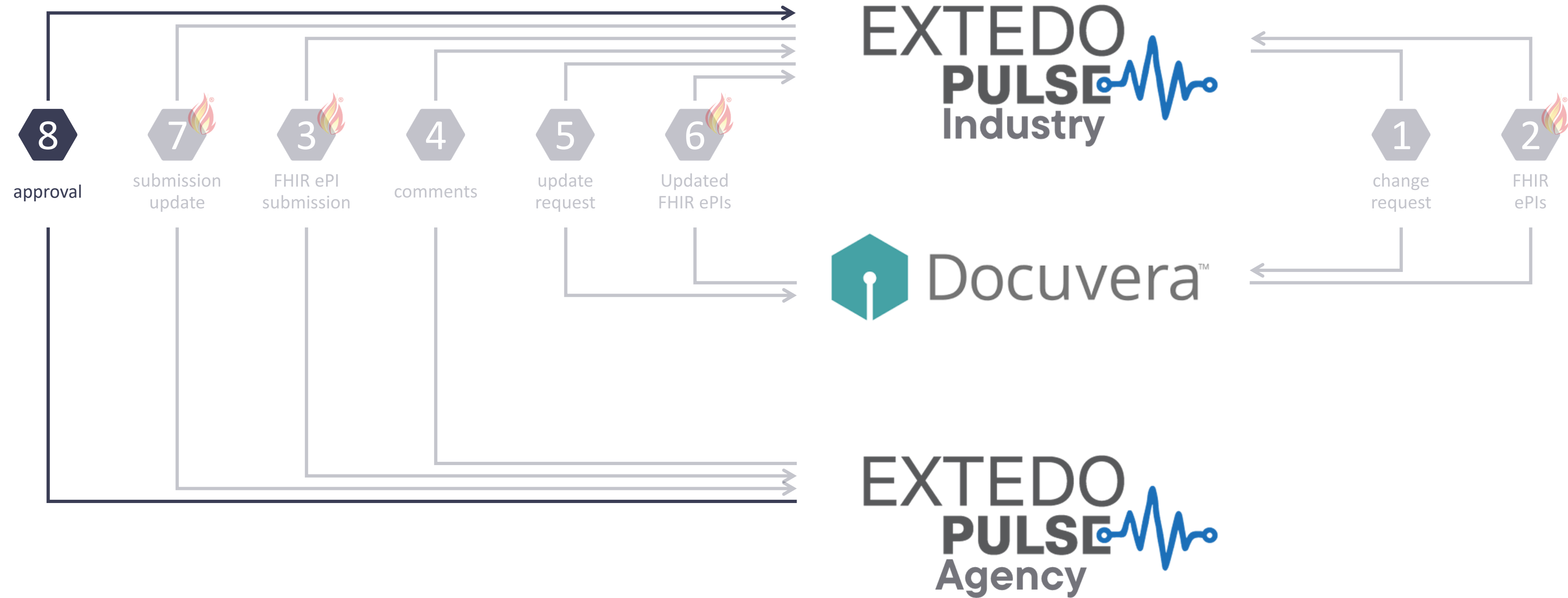


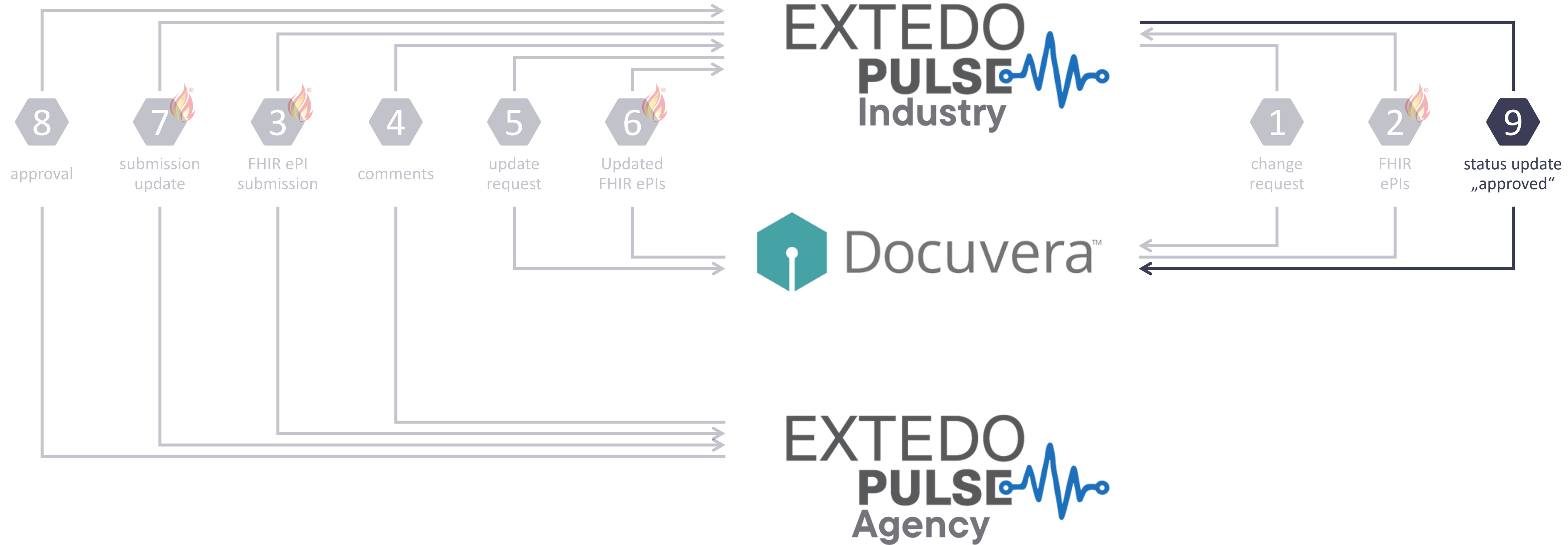
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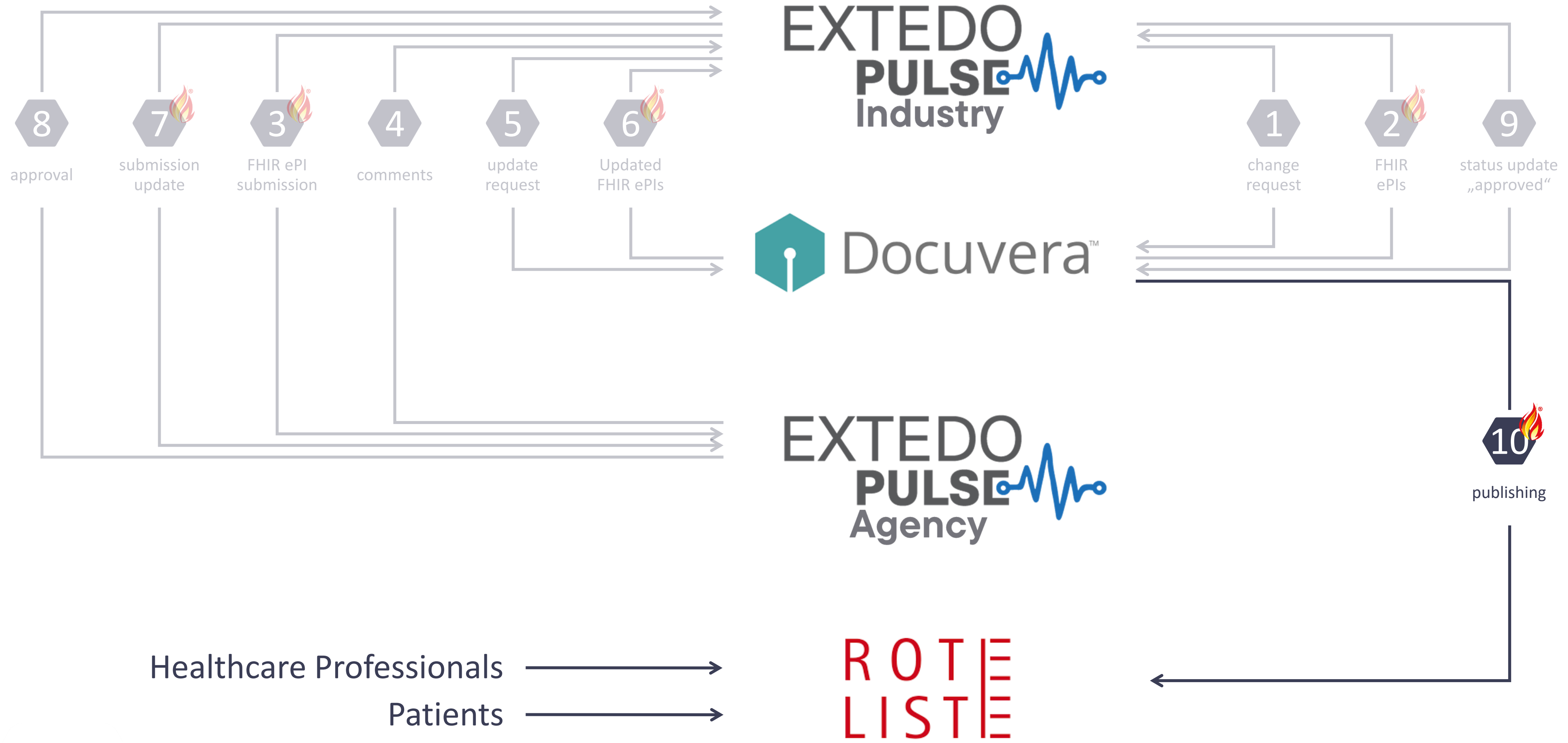
Regulatory Management reviews the agency comments and, if agreed, forwards the update requests directly at component level to the authoring team.

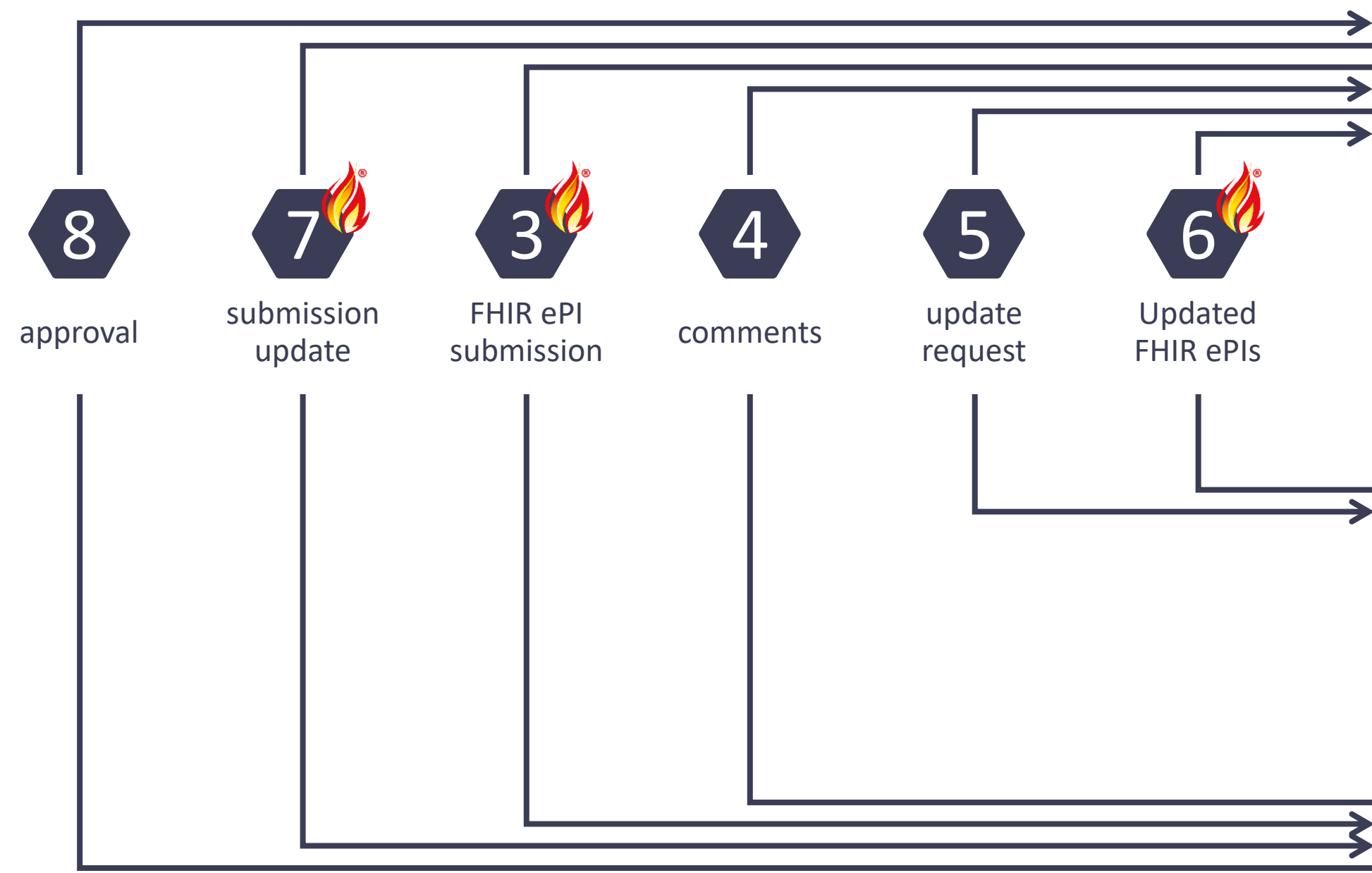








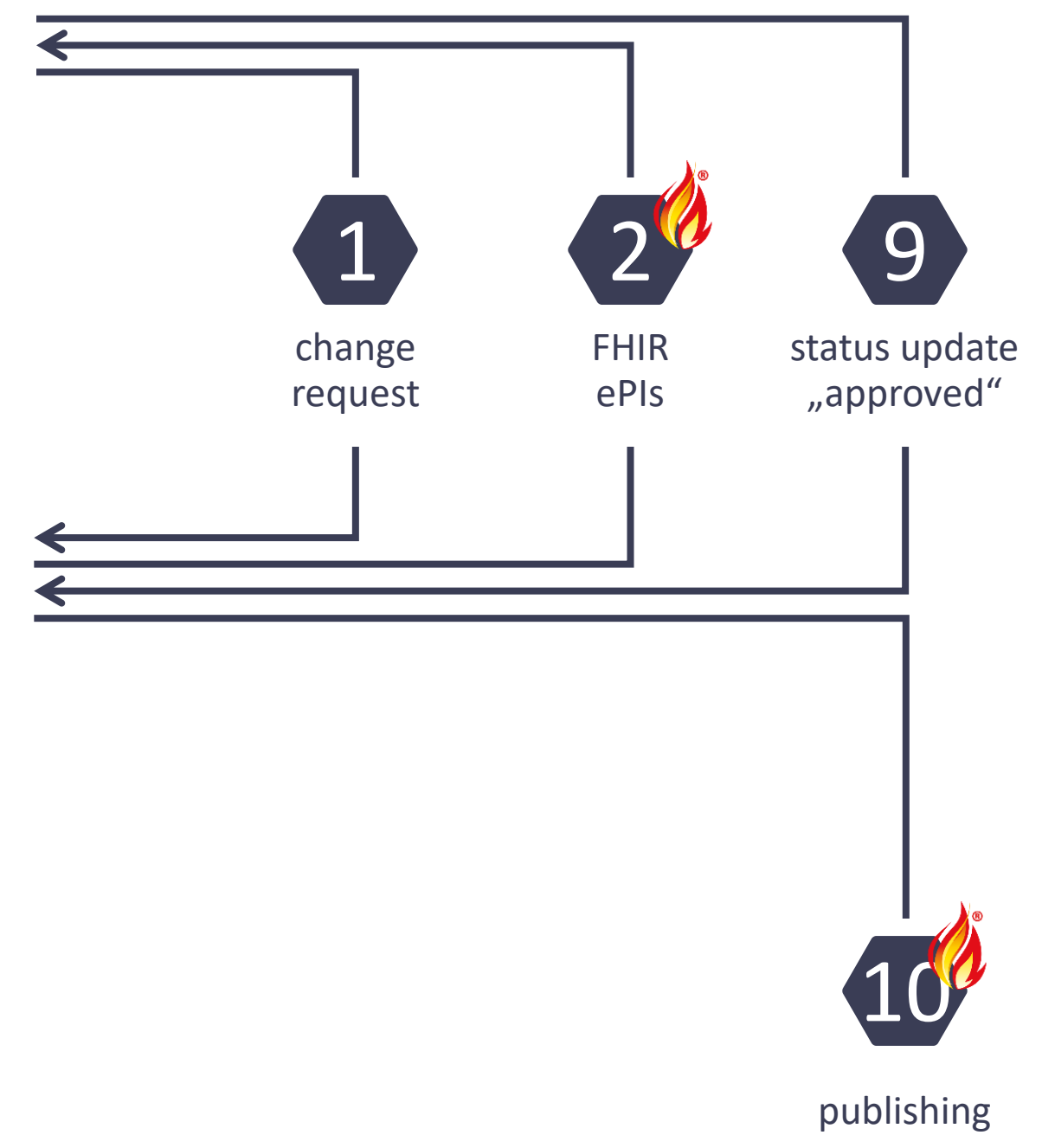




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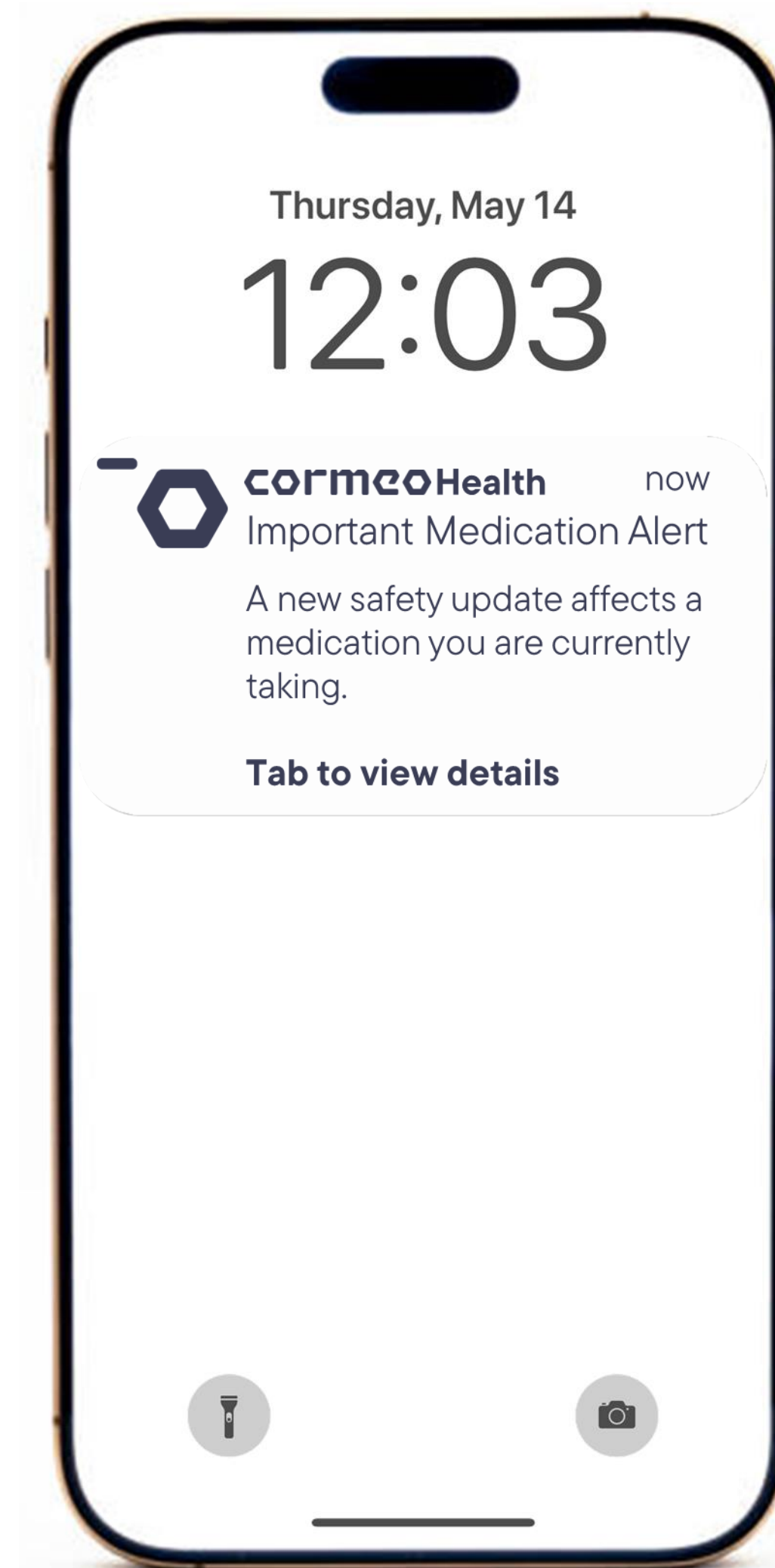
Healthcare Professionals →
Patients →

ROTE
LISTE



Leveraging FHIR-based ePIs across our systems streamlines the process and enhances collaboration—enabling faster and more efficient delivery of information to healthcare professionals and patients

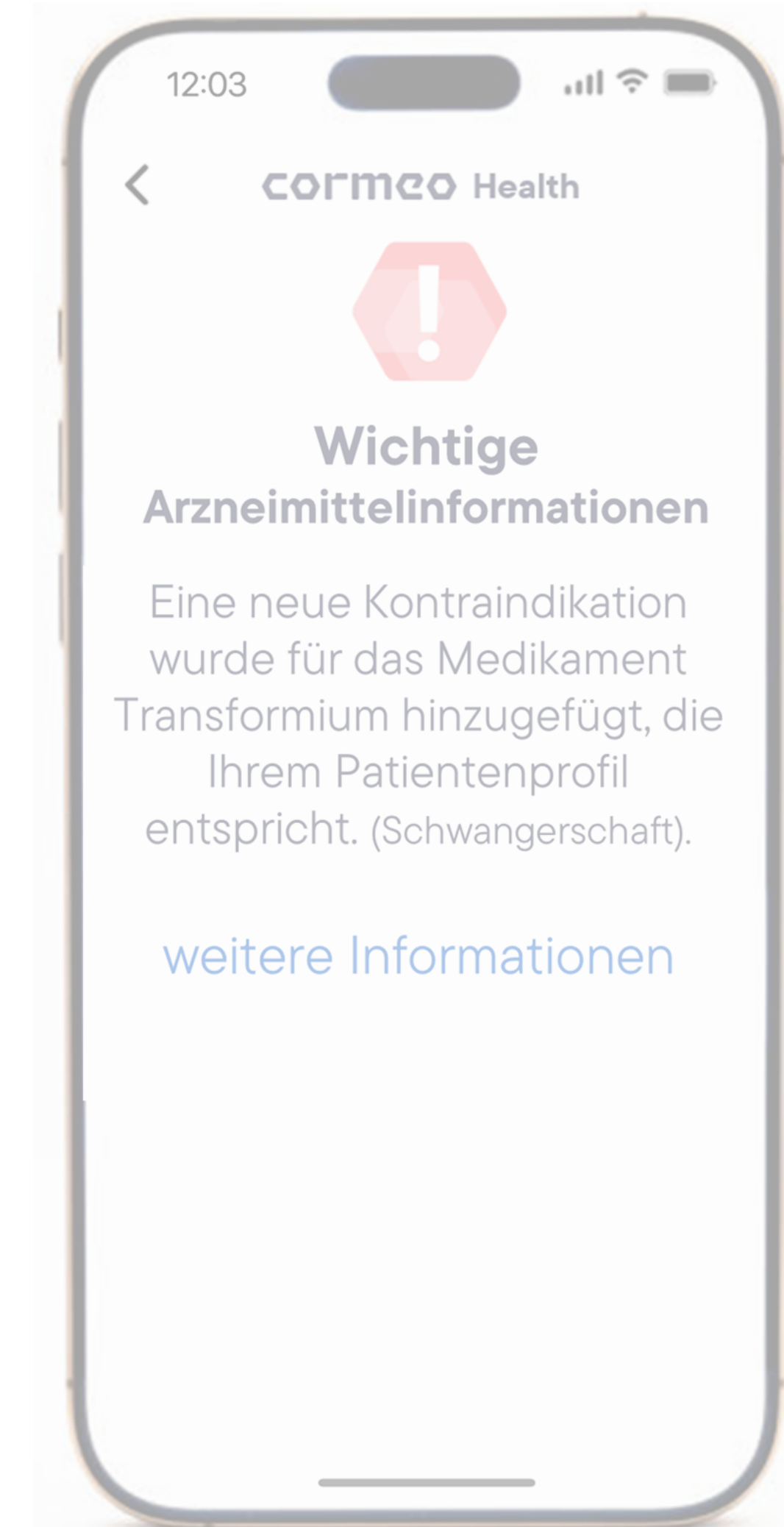
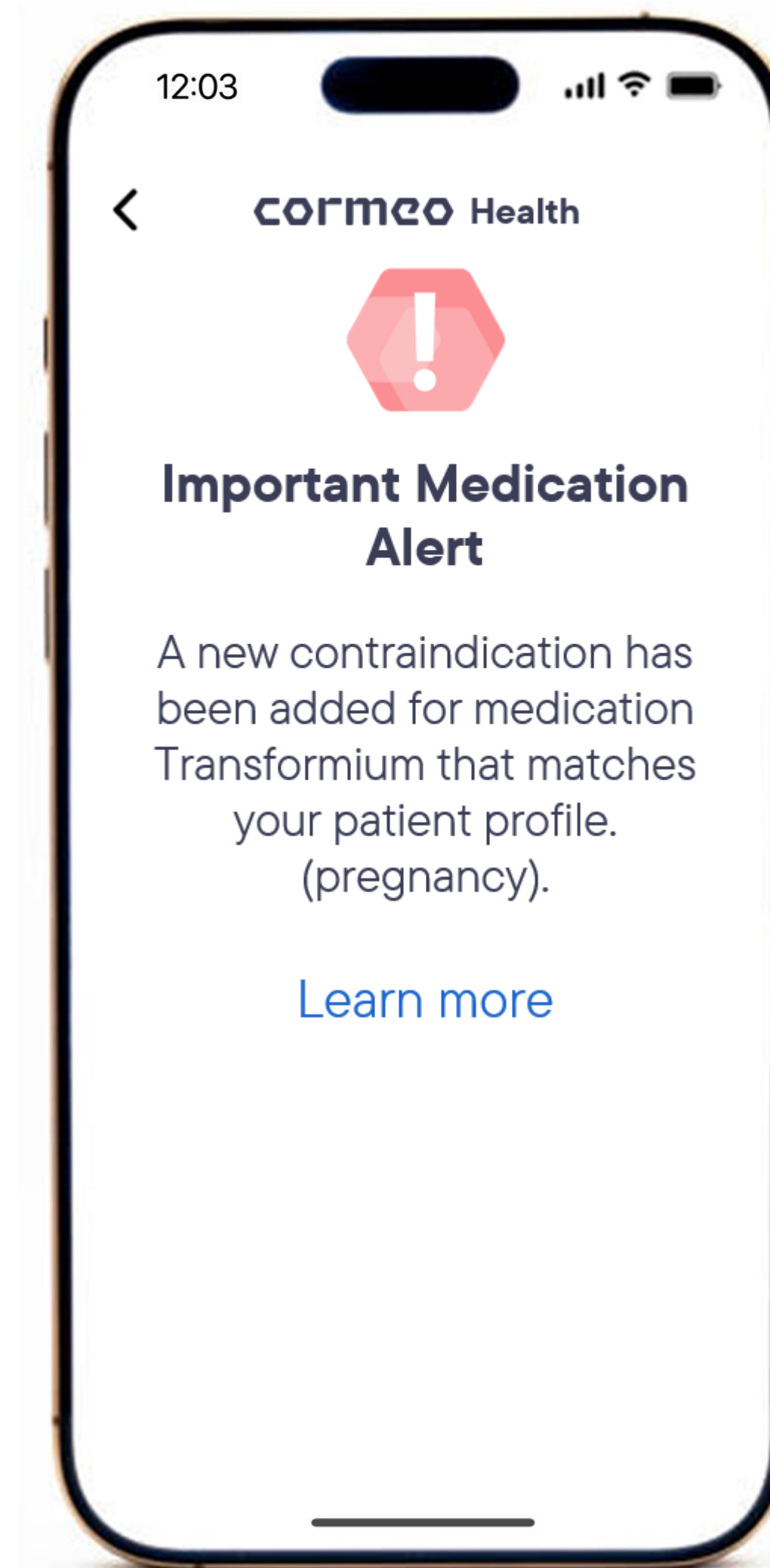
A Patient's View



1

cormeo health is a fictitious health insurance app to demonstrate information distribution towards patients.

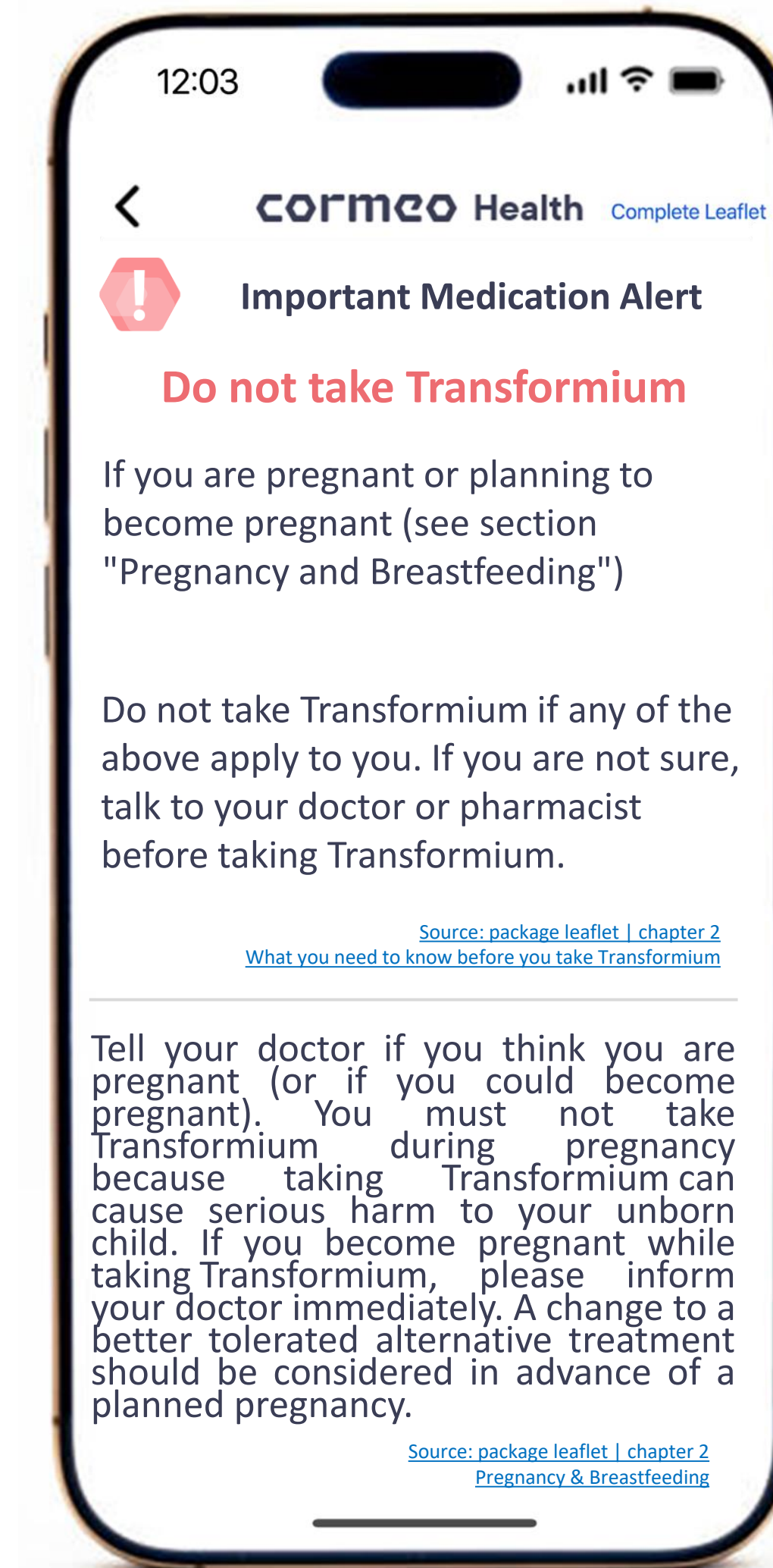
Upon event, cormeo health insurance App will inform patients about relevant updates based on their individual electronical patient profile.



corneo health is a fictitious health insurance app to demonstrate information distribution towards patients.

2

Entering corneo Health, further information will be revealed concerning the notification. In the patient's preferred language...



Alert details are revealed matching the patients profile & the IDMP based component metadata.

3

corneo health show relevant information and highlight the potential impact based on the individual patient's profile.

corneo health is a fictitious health insurance app to demonstrate information distribution towards patients.

- **Elevating Industry-Agency Interaction and Exchange**
- **Transforming data into information shared in time**
- **Facilitates content-level data exchange**
- **Promotes interactive collaboration between industry & agency**
- **Accelerates time to market with rolling submissions**
- **Direct agency interaction on content level**



Q&A

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