Gravitate-Health:
putting ePI to work in the patient journey to drive better use of medicines

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ADVANCING HEALTH PRIORITIES

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Catherine Chronaki, HL7 Europe

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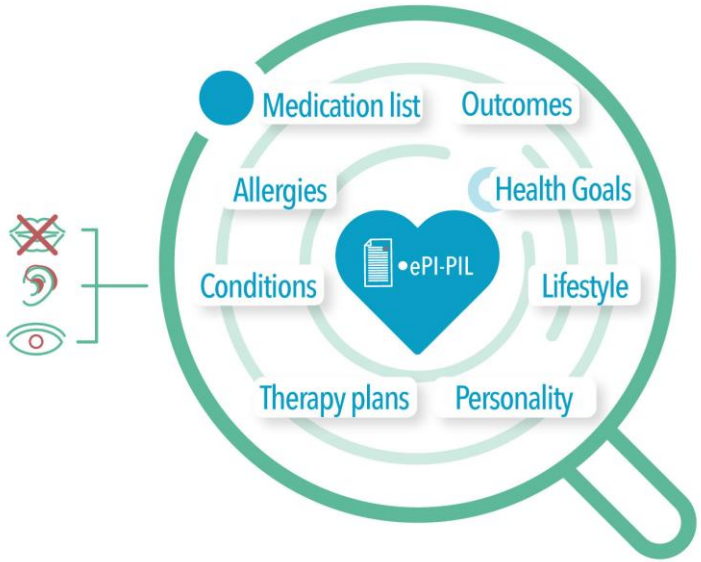
Gravitate-Health

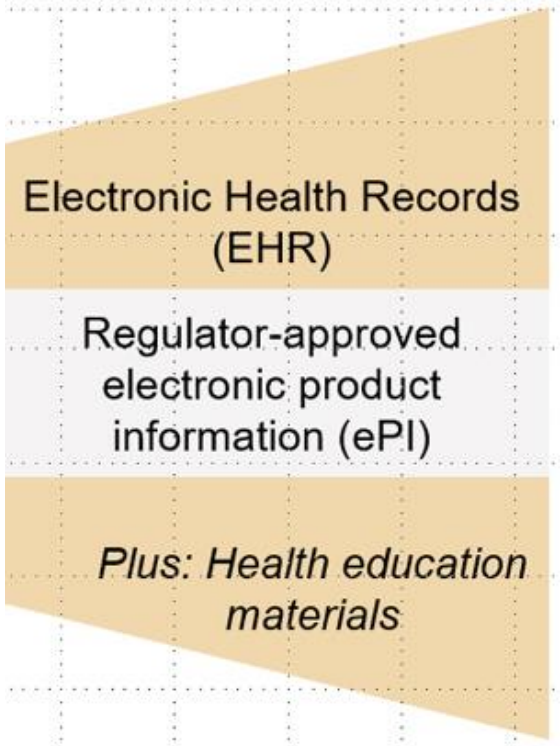
Role of standards in Delivering ePI

Catherine Chronaki, HL7 Europe

Agenda

- The standards we need:
  - Interoperability
  - Accessibility
  - Outcome Measures
- The standards we use:
  - HL7 FHIR®
  - W3C Accessibility standards
  - PREMs, PROMs, ICHOM

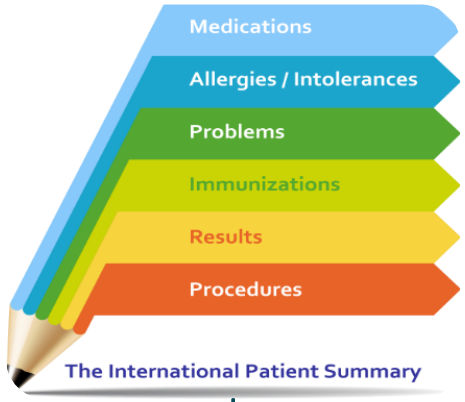




- So how can we use standards to make the G-lens reveal the power of ePI for understanding and adherence to treatment?

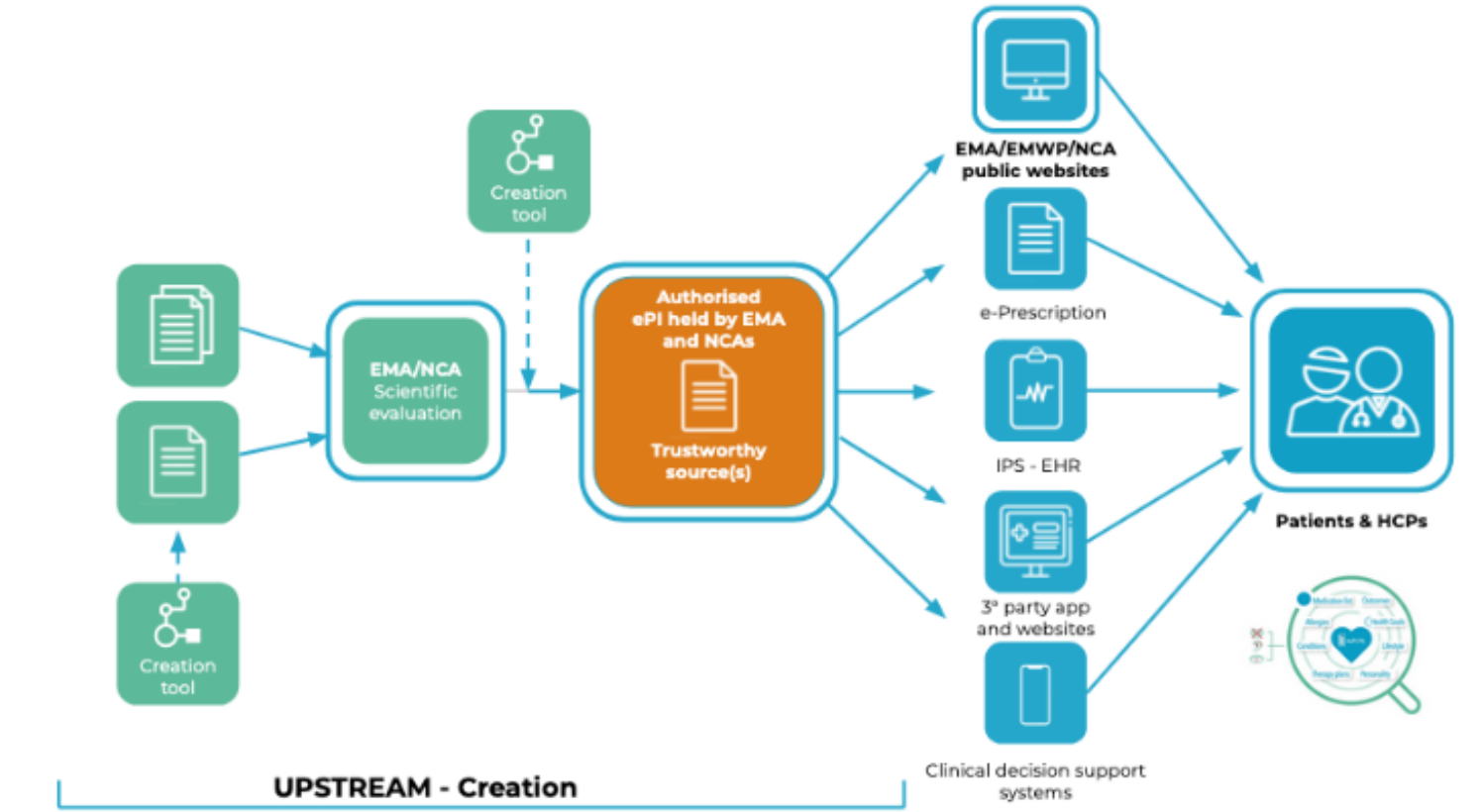
The International Patient Summary

A *document* composed by reusable profiles



The IPS "library" of profiles

W3C Accessibility Guidelines



Modified from the proposed model for ePI production, according to EMA ePI Key principles
https://www.ema.europa.eu/en/news/public-consultation-key-principles-electronic-product-information-eu-medicines

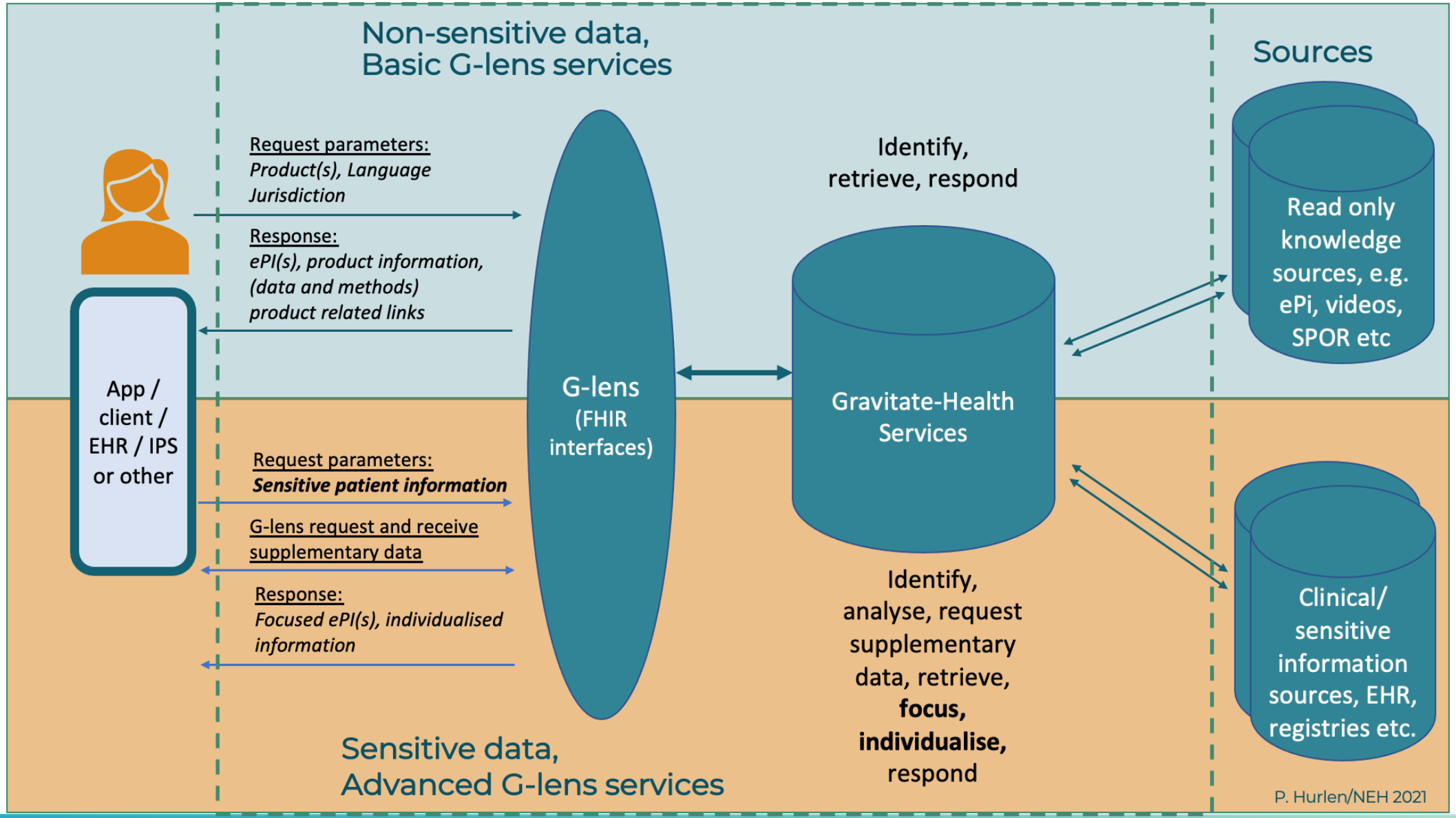
WCAG2.1 Success Criterion	Level	Target	Explanation
Orientation	AA	Mobile users Mobility impairment Low vision	Content and functionality should be available irrespective of user's device orientation.
Identify input purpose	AA	Cognitive & learning impairments Motor impairments	Forms that collect user data should define the purpose of input fields programmatically.
Reflow	AA	Low vision to read and mobile device users.	All the page content and functionality should be available without requiring 2-D scrolling
Non text contrast:	AA	Low vision users	A contrast of 3:1 against the adjacent colors should be present for user interface control state (i.e. hover, focus etc.) and key images **Note**: WCAG 2.0 contrast requirement was present for text and in WCAG 2.1 it has been extended to include non-text content as well.
Text spacing:		low vision users, dyslexic users, and users with cognitive impairments	Content and functionality should not be lost when text spacing styles are applied.
Content on Hover or Focus:	AA	Low vision users Learning impairments	Content that becomes available on hover or focus should be 1) **Dismissible** 2) **Hoverable and focusable** 3) **Persistent**
Character key shortcuts:	A	Low vision Dexterity impairments	Web pages should not include single character key shortcuts for carrying out different tasks
Pointer gestures:	A	Motor impairments Cognitive, learning impairments	All the functionality of a web page that involves multipoint gestures or path-based gestures should provide users with alternate means to carry out the task using single point activation controls.
Pointer cancellation:	A	Visual, Motor, Learning impairments	All page functionality should be executed on the Up event and not on Down event. If any functionality is executed on Down event, provide users with a mechanism to cancel it.
Label in Name:	A	Speech input users	Accessible name of a user interface control contains text that is present in the visual label.
Motion actuation:	A	Motor impairments	All the web page functionality that can be activated with device or user motion be also activated with user interface control.
Status messages:	AA	users of screen	Status messages can be defined

New Vulcan Projects: Electronic Product Information (ePI or e-Labeling)

Topic (Proposed)	Notes / Discussion
Initiator	• Gravitate-Health Consortium, part of the Innovative Medicines Initiative (IMI)  39 partners in Europe and USA European start Global Outreach *How can we apply an open access digital platform with trusted Digital health Information to transform the way patients access and understand health information, and apply this in personal health for adherence to treatment, risk minimization and quality of life ?*
Use Case	• Structured format for authorized product and prescribing information • Enables/relates to: International Patient Summary (IPS); ePrescribing; Product identification (IDMP); pharmacovigilance; patient compliance and empowerment; clinical trial eligibility and enrolment
Rationale for Use Case	• Topic of interest in many geographical regions; growing need for a harmonized global approach • Following Vulcan guiding principles to strategically connect and maximize resources to develop a single pathway for interoperable exchange of data
Initial Plans	• Connectathon in September and subsequent connectathons • Partnership with EMA • Roundtable in October

VULCAN

Work in progress – G-lens



Same content, two implementation models (EMA ePI and Vulcan ePI)

	EMA Profile - FHIR Resource Names[1]
1	List
2	Bundle
3	Composition
4	Binary
5	Organization
6	RegulatedAuthorization
7	MedicinalProductDefinition
8	PackagedProductDefinition
9	AdministrableProductDefinition
10	ManufacturedItemDefinition
11	Ingredient
12	ClinicalUseDefinition

[1] Rows 1 to 4 make up the ePI. ePI cross references out to SPOR which is made up of rows 5 to 11.

	Vulcan Profile - FHIR Resource Names[2]
1	List
2	Bundle
3	Composition
4	Binary
5	Organization
6	RegulatedAuthorization
7	MedicinalProductDefinition
8	PackagedProductDefinition
9	AdministrableProductDefinition
10	ManufacturedItemDefinition
11	Ingredient
12	ClinicalUseDefinition

[2] Vulcan ePI managed as a single self-contained document.
[3] Devices in packaging (e.g., syringe)

Looking forward to Connectathon 30: Why don't you join?

- Streamline the creation of ePIs
- Test Rules for G-lens rules
- Dive into accessibility and digital health literacy

Gravitate Health

- ePI Track details
- Github repository
  - (FSH instances of the 4 prototypes)
- Implementation Guide
- ClinFHIR example instances
  - Graph of Humalog ePI prototype
  - Graph of Skilarence ePI prototype

The Gravitate-Health project has received funding from the Innovative Medicines Initiative Joint Undertaking under grant agreement No 945334.

Thank you!

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