

Outcome of collaboration and modernization: Transforming supply chain into a patient-centric approach

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Format: 30-minute presentation; 5-minute facilitated discussion

The power of digital

According to the International Telecommunications Union (ITU), there are now more mobile phone subscriptions than there are people on the planet.

Capabilities and Benefits We Hope to Realize



Digital Transformation



Patient Safety

The evolution of digital technologies, emerging data standards, and better healthcare for patient are the key drivers behind the development of personalised health-related information.

Transformation in Supply Chain to serve patients in personalized healthcare setting

Rare diseases: Vision

Imagine a world where...

The patient has easy and efficient access to treatment (at the right time and right place) and is enabled to adhere to the required regimen



Patients have streamlined access to different tools, information (awareness, training, diagnoses,...) and, support services required to improve quality of daily life of patients and caregivers

The patient and their caregivers and family are enabled to live as fulfilling a life as possible

Awareness

Diagnosis

Infra / Reach

Capability & Capacity

Fulfillment / Affordability

Adherence

1

Telemedicine, digital biomarkers and monitoring applications in place to support **access to healthcare specialists**. Avoiding the need for travelling to visit hospitals or clinics



2

Medication delivered to the patient's **home for the patients to take**
Or for HCP to administer – **Travelling Nurse available**



3

Training to patient, carer, HCP or hospital to deliver medication.



Product quality assured by zero touch release and last mile traceability
Product information assured by **e-Labeling**

11

E2E Data Capture

Patient outcomes and experience data is captured and used to holistically improve overall efficiency, supply chain developments and funding reimbursement decisions



9

Patients can expect **continuous improvements to products** as feedback mechanisms integrated as part of reviews



10

Access to **research trials**



8

Patients, families, caregivers, HCPs are **connected** to relevant networks for sharing experience, learning. Access to empathetic, psychological counselling services



7

Digital access to Clinic and Specialist HCP's to support the patient and family, (physio, occupational therapist, speech therapist, counsellor etc), visit scheduling via a single central portal



5

Prescription **automatically titrated** based on digital monitoring

6

Patient, families can find **Information** about and also access assistive technologies, tools and other necessities at a central place



4

Best outcome is achieved as patient is supported to **adhere** to treatment. Innovative ways in supporting patients - digitally monitored and shared with HCP's and health authorities for hurdle-free reimbursement or HTA requirements



Patients and Carers benefit from continuously improving outcomes and positive experiences

Phased approach of patient-centric approach in supply chain

We identified three areas to begin our transformation journey to meet patients needs:

1. Medications delivered to the patient's home (home delivery)
2. Zero touch release and last mile traceability to ensure product quality (tracking at unit level)
3. Electronic patients leaflets (e-labeling) to ensure timely product information (ePI)



Towards a Patient-centric approach

1. Medications delivered to the patient's home (Home Delivery)

Imagine a world where...

Patient Centric Transformation is Needed

Imagining new capabilities in service of patient needs

The patient has easy and efficient access to treatment (at the right time and right place) and is enabled to adhere to the required regimen



Patients have streamlined access to different tools, information (awareness, training, diagnoses,...) and, support services required to improve quality of daily life of patients and caregivers



The patient and their caregivers and family are enabled to live as fulfilling a life as possible

Where to start...

We believe home delivery of treatment to a patient's door is a critical component of this vision, and we're currently working experimenting with ways to enable this capability in a number of markets. From our early work we've found that:

Across markets patients and caretakers have expressed significant desire for a home delivery option, with many seeing a variety of benefits stemming from this capability.

Beyond patients and caretakers in early feedback the healthcare ecosystem has been receptive to these solutions to provide new mechanisms for care, and decrease appointment burden on clinics

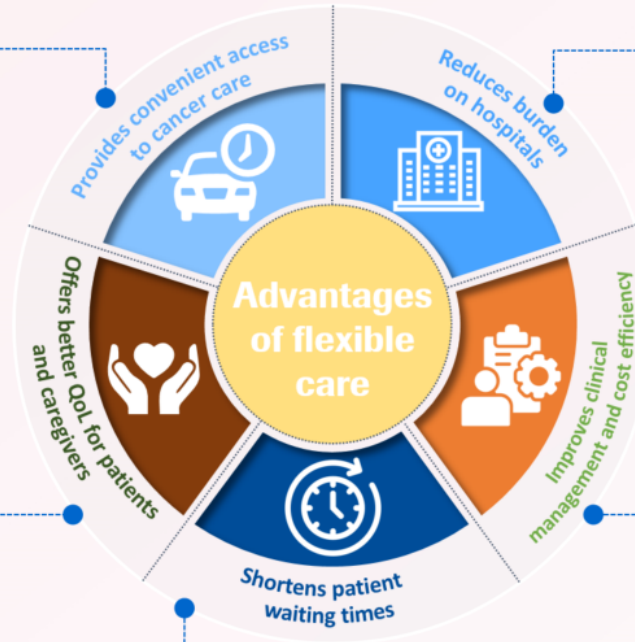
Flexible care offers many advantages for patients, caregivers and HCPs

PROVIDES CONVENIENT ACCESS TO CANCER CARE

Some patients have limited choice of treatment locations, requiring significant travel time¹⁻³

OFFERS BETTER QoL FOR PATIENTS AND CAREGIVERS^{4,5}

Patients maintain their usual lifestyle/timetable when receiving treatment at home. Caregivers benefit from reduced hospital visits and time off work



REDUCES BURDEN ON HOSPITALS

Treatment of patients at home/local centres increases capacity and patient throughput in cancer centres' outpatient chemotherapy suites^{2,6}

IMPROVES CLINICAL MANAGEMENT EFFICIENCY

Reduced HCP active time, dosing errors and drug wastage⁷

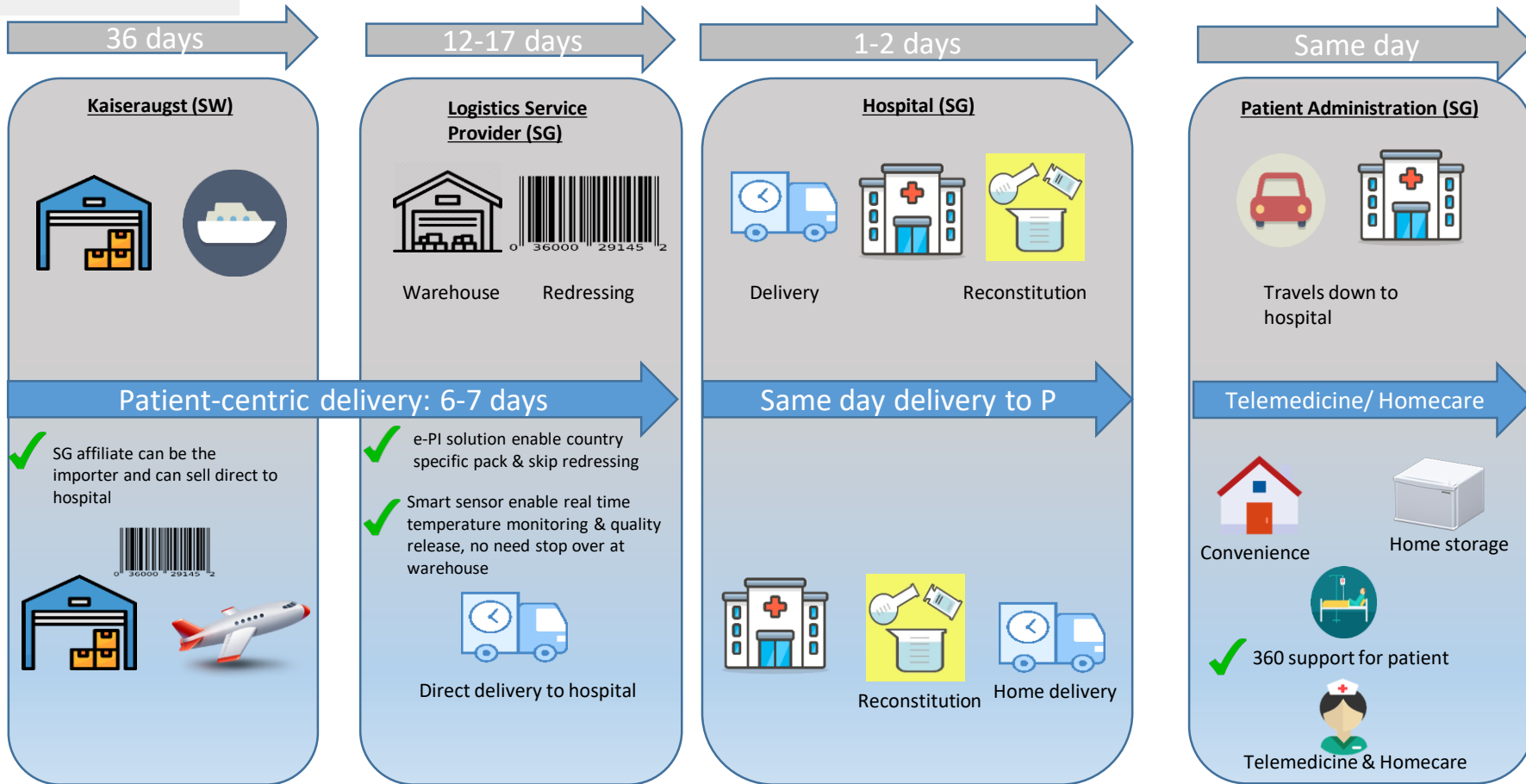
SHORTENS PATIENT WAITING TIMES

Significant time-savings for patients: no queues, shorter administration time⁶

1. Stevenson L, et al. *Br J Cancer* 2003;
2. LCA. Care closer to home and medicines optimisation. Pilot service evaluation report 2015;
3. Bordonaro S, et al. *Patient Prefer Adherence* 2014; 4. Denys H, et al. *Breast Cancer Res Treat* 2020;
5. Bordonaro S, et al. *J Multidiscip Healthc* 2012; 6. De Cock E, et al. *Cancer Med* 2016;
7. De Cock E, et al. EBCC 2014 (Abstract 42 and poster 033).

Home Delivery: How does it look like to supply based on patient's need

Current limitations

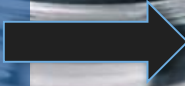


Towards a Patient-centric approach

2. Product quality preserved throughout E2E supply with Zero touch release and last mile traceability

The Challenge

Enable last mile product tracking and visibility from manufacture to patient



Data Elements

- Geo-location
- Temperature/condition
- Date / time

Project Purpose

With our focus on the patient we hope to achieve “last mile” visibility to our product **at unit level for temperature and location** and address the following challenges with the extended supply chain

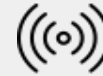
- Visibility to temperature excursions
- Mitigation of counterfeit risk
- Identification of mis-directed product
- Improved patient safety
- Improved patient access

Tracking at the unit level



- We set out to solve visibility challenges e.g.
 - Product inventory status
 - Vial Condition / Location
- Each challenge required a unique solution
- “Proof of Concept” phase

Unit Level Visibility



Visibility Beyond our Own Supply Chain



Internal Supply Chain

Distributors /
Wholesalers



Hospital
Networks

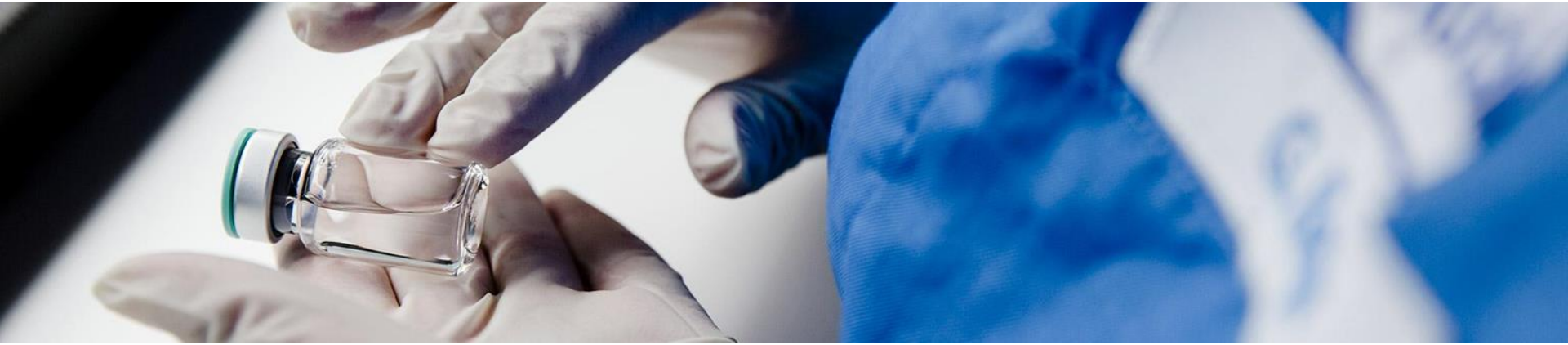


Patient



Scope: Extended Supply Chain

Solution Requirements



Frictionless *Autonomous*

No reliance upon human intervention

Cannot change or disrupt current supply chain process

Power *Efficient*

Power efficiency aligned with product lifecycle - 2-3 years

Cost *Effective*

Low to zero expectation of device return

Phased approach of patient-centric approach in supply chain

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Towards a patient-centered approach

3. Electronic Patient Leaflet (e-labeling)

Information Access in the Digital Age (patient-centric)



Characteristics (patient-centric)

- Instantly accessible
- Available where you need it
- Connected across devices
- In the format you want

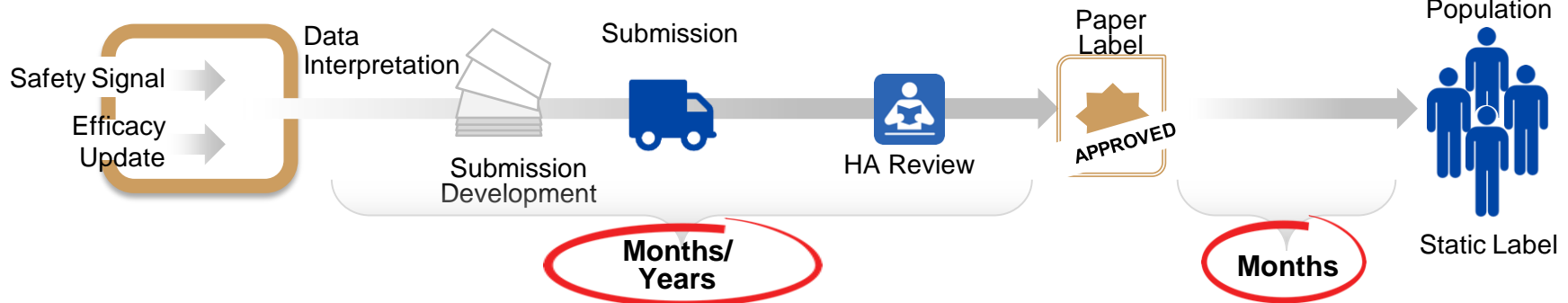
Patient Access to Product Information (PI) today

- Printed materials
- Slow to update
- Static / inflexible
- Not personalised

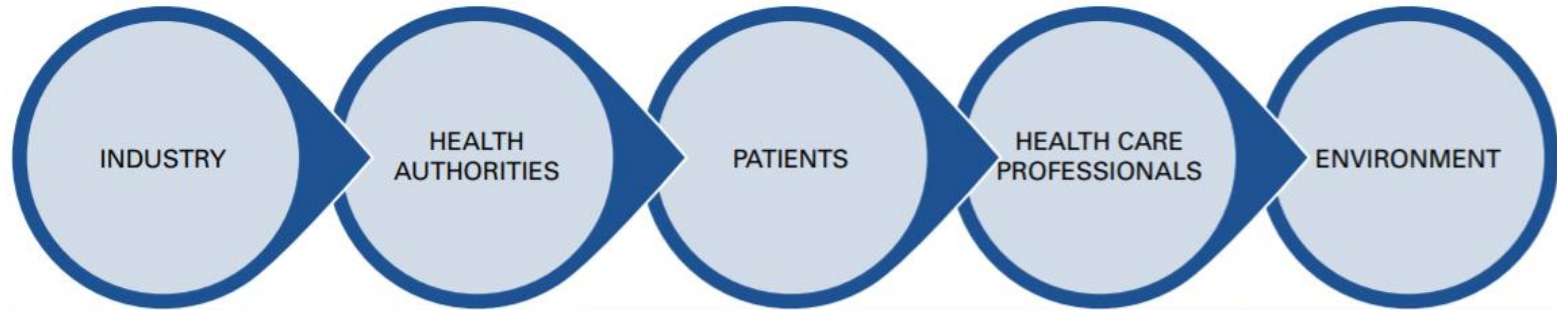
> The Challenge

The regulation of product information doesn't reflect the future healthcare ecosystem

- The approval process for label updates involves a step-wise, sequential approach to accumulating, compiling, submitting, reviewing, approving and communicating validated product information guidance
- Regulatory updates to product labeling typically require up to 1.5 years from data availability to approval and availability in patient-accessible labels



ePI: Drivers and benefits for all stakeholders



- Mitigation of shortages
- Efficiency gains for regulatory systems and facilitating decision-making
- Enhancing knowledge of trends in medicines and their evolution

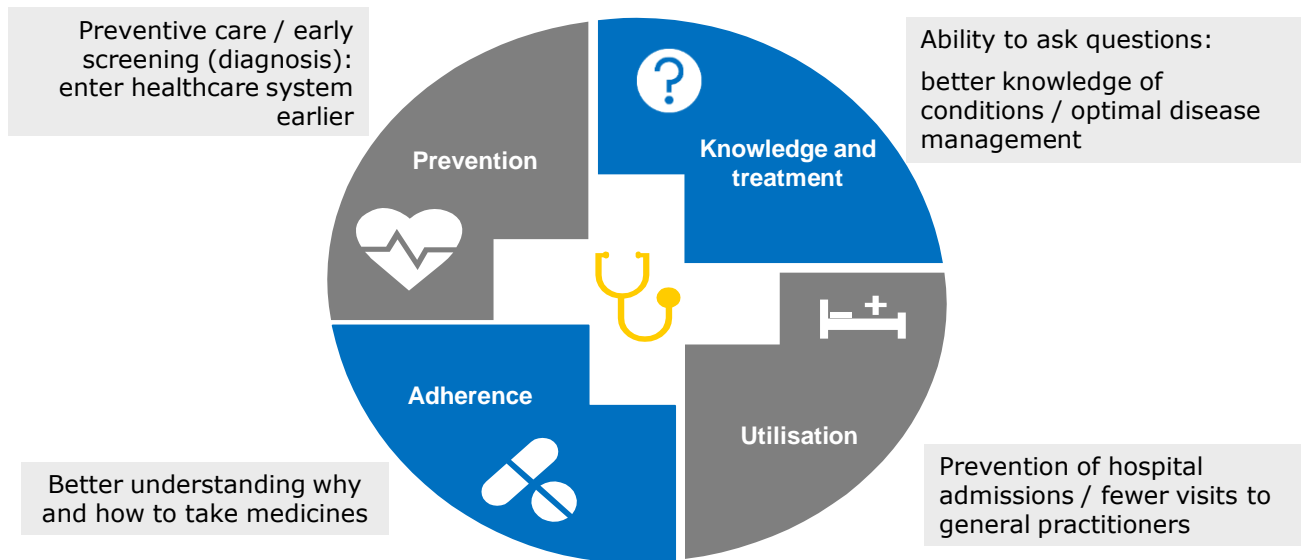
- Improved access to tailored information on end-user needs
- Accessibility to user with diverse abilities
- Advance health literacy
- Provision of the latest information on a medicine's safety, benefits and conditions of use
- Informed decision-making by patient/consumer and HCPs
- Multi-linguale ePI

- Less waste of paper leaflet

Reference: IATF paper, <https://www.efpia.eu/media/589587/electronic-product-information-from-principles-to-actions.pdf>

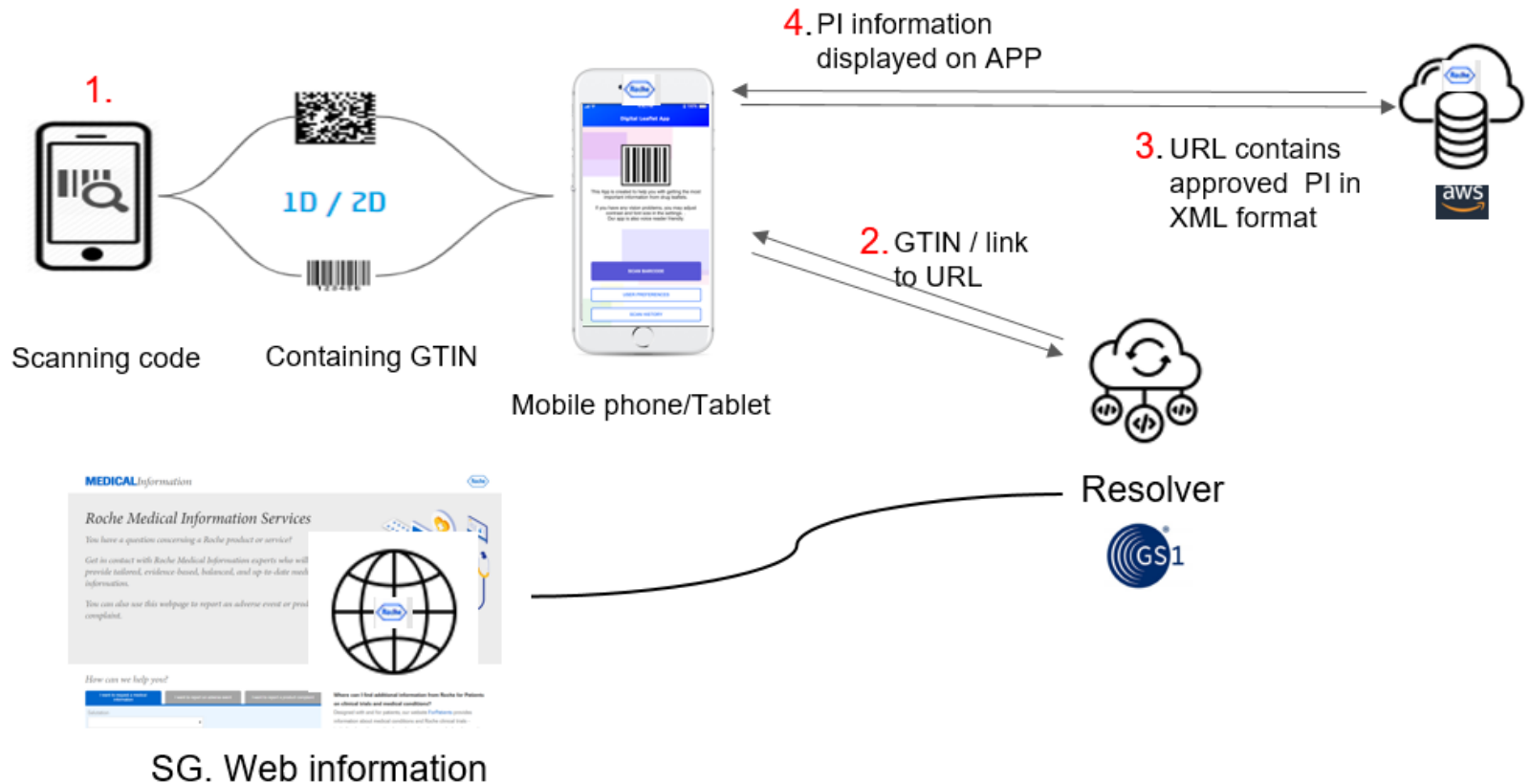
Health literacy principles

Supporting patient health behaviors and outcomes



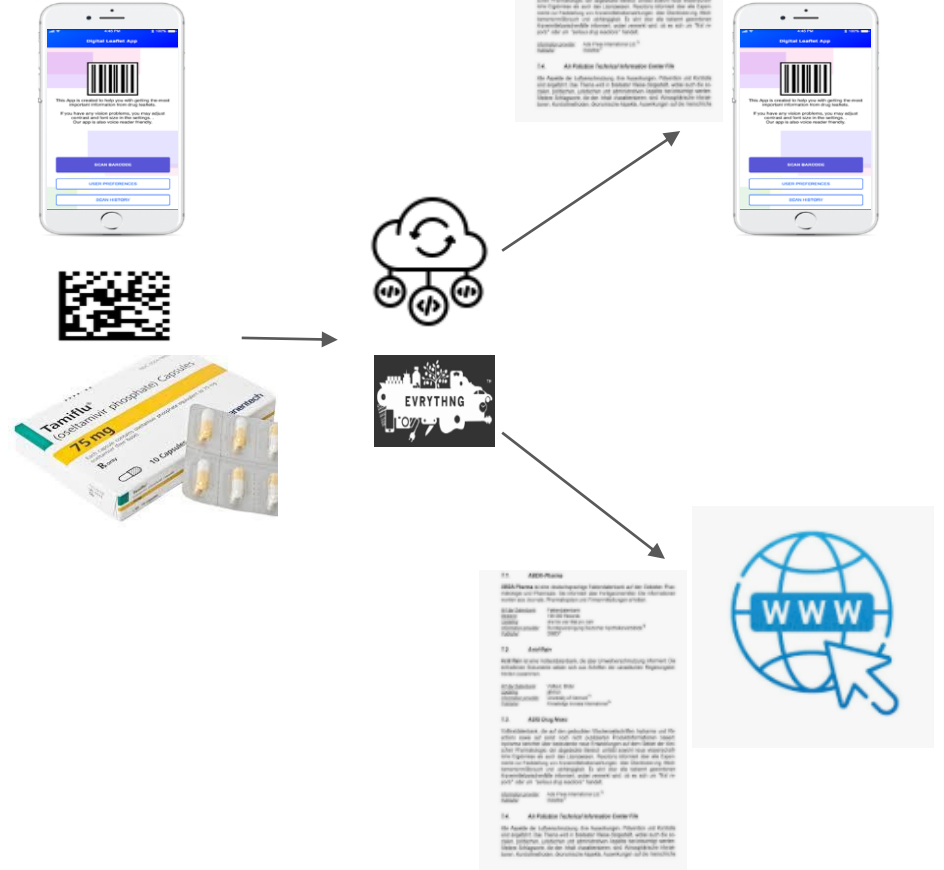
1. Nielsen-Bohman, L., Panzer, A. M., & Kindig, D. A. (Eds.). (2004). *Health literacy: A prescription to end confusion*. Washington, DC: National Academies Press.
2. Weiss BD. *Health Literacy: Health literacy and patient safety: Help patients understand*. The American Medical Association (AMA) Foundation and the AMA. May 2007.
3. Wilson IR, et al. "Physician-Patient Communication About Prescription Medication Nonadherence: A 50-State Study of America's Seniors." *JGIM*. January 2007;22(1):6-12.

Roche - Pilot digital leaflet system landscape



What are the benefits

1. Product Information availability – when and where you want, all languages
2. Publish e-Product information 1-3 weeks after HA approval
3. Most updated PI always available. (Versioning)
4. Increased usability. Videos text to speech, search
5. Business process to ensure compliance, version and content control prior ePI dissemination
6. Reduction of write offs
7. Reduction of cost for printed material and footprint
8. Established Eco system could enable further opportunities by routing digital content. e.g link user to MedInfo, Edme other platforms



Video demonstration



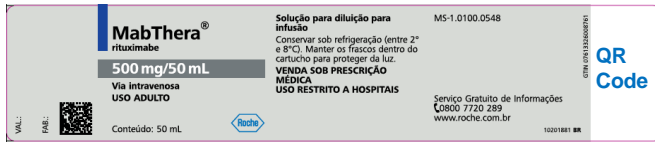
The screenshot displays a mobile application interface for Roche ePI. At the top, the status bar shows the time 16:56, signal strength, Wi-Fi, and battery icons. The app header is blue with a back arrow, the text "Roche ePI", and "Roche ePI". The main content area is white and features the product name "ROACCUTANE®" and the active ingredient "Isotretinoin". Below this, there are five video thumbnails, each with a "Play" button. The thumbnails are: Video 1 (blue background with a person), Video 2 (red background with a person), Video 3 (blue background with two people), Video 4 (red background with two people), and Video 5 (green background with a person). A semi-transparent black box at the bottom of the screenshot contains the text: "Multimedia content available for enhanced user experience".

What we need to avoid

Good or bad?
When patients
see 3 or 4
codes on the
product box?

Why Roche uses the GS1 Pharmaceutical barcode and not the QR code?

Folding box



Which code should I scan to get the relevant information on a single item?

GS1
DataMatrix
Barcode

- confusion what code is for which purpose?
- small packs - limited space for multiple codes leading to inability to read codes properly?
- QR codes - maybe "cut and paste"?



- Roche and other pharmaceutical companies are following the pharmaceutical standard of GS1
- While regulatory bodies drive the implementation of GS1 DataMatrix for the fight against counterfeit healthcare products and for better control of the supply chain from the point of manufacture to the point of administration, ISO/IEC QR Code is at this time primarily found on packages as a link to marketing information about a product. However, the inclusion of more than one barcode symbol on the same package or label is not recommended by GS1 Healthcare and its global community. Both objectives, traceability as well as access to product information
- GS1 is finalising the Digital Link standard to enable mobile devices (i.e., smartphones) to scan the single barcode (i.e., linear or 2D) and access digital content about the product.

Enhancement of using the GS1 pharmaceutical standard of the **existing** GS1 barcode: end users can use GS1 barcode to get the additional features

- **Linking** to verification as protection against counterfeiting
- **Linking** to information about the product (videos, audios, illustrations, texts...)
- **Linking** to electronic health records etc.
- **Hospital waste management**
- **Patient cards**
- **TE (Tamper Evidence) type**
- **Parallel or Illicit trading – eg this packs is intended for Switzerland only**
- **And many more**

There are ongoing pilots in Asia, Europe, Latam, Africa, Canada, and more.
Sharing here the feedback received from the pilot in Europe



Feedback from Belgium/Luxembourg ePI Pilot Project

Key Survey Outcomes (t=12 months)

- In the first 12 months, 69 249 units were sold with the absence of a paper leaflet
- Total of 4 questions were asked by HCPs:
 - 3 related to the presence of a blank leaflet added in the packaging to ensure the stability of the vial in the carton
 - 1 related to the pilot asking what was expected from the pharmacists in the project, and if the physicians (specialists) were also informed about the pilot
- In all cases, it was sufficient to provide general information about the pilot, and there has been **no request by HCPs to receive the paper patient leaflet**
- Based on the 12 month pilot period, 98% of responding hospital pharmacists agreed with removing the paper leaflet from all hospital-only medicines

What's next



- Roche has established a ePI plug and play solution which provides safe and fast access to digital PI content
- Pilots on-going in Europe, Latam, Asia, Africa, Canada, and more.
- It will allow the user to experience new digital technologies with the aim to receive customer and patient feedback without waiting for a global solution which haven't been established yet.
- Roche recommends to start with country specific pilots to receive fast feedback of end customer and patient. With this we all can learn and adapt technologies accordingly.

Capabilities and Benefits We Hope to Realize



Digital Transformation



Patient Safety

Fundamentally It's About the Patient



Enhanced partnerships with HCP's



Greater product level visibility



Improved patient access



Increased patient safety



Reimagine the patient journey for the ecosystems benefit

Piloting solutions to meet needs now and in the future



1

Reimagine the patient journey for the ecosystems benefit

*Across markets, Covid has revealed the need for new capabilities to enable home delivery and drive more patient centric approaches **enabling greater care and value for the entire ecosystem - from patients and caretakers to HCPs.***

2

Increased product convenience, reliability, and optionality for patients

*Home delivery provides health care providers new mechanisms and channels to treat their patients. Home delivery **can reduce the often high burden of travel, or risk of exposure for immunocompromised patients that need to receive treatment on an ongoing basis.***

3

Greater efficiency and control of the end-to-end value chain

*Home delivery solutions enable greater control of the quality and service-level provided through the end-to-end value chain, from Roche to the patient **ensuring the highest quality of service is provided in the most efficient manner from end to end.***

4

Establish capabilities that enable collaboration and spark innovation

*Home delivery can establish connections between distributed parties, and aggregate data across the end-to-end patient journey. The capabilities enabling this provide substantial opportunity for new value creation of collaboration through data, with **opportunity to draw better insights and partner with the broader ecosystem on new solutions***

Opportunities

Modernization 2: Tracking at unit level

Modernization 3: e-Labeling

- Tracking device at product's unit level - assurance of product quality and supply chain integrity throughout E2E supply
- e-PI will enable creation of PI that is accessible to everyone, including e.g. blind or visually-impaired, etc.
- e-PI will support the provision of the latest safety information. Improving convenience and integration of content, should increase patient understanding and engagement
- We need collaboration and partnership including regulators, Ministries, hospitals, to transform our supply chain approach that will be revolving around patients' needs.
- Next step – working together to initiate a pilot in e-labeling

*"I like working with people. I believe
change can only come through collaboration."*

**- Alain de Botton
Philosopher & Author**

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Centre for Innovation in Regulatory Science Virtual Workshop
Regulatory, HTA and Payer Interactions and Collaborations:
Optimising their Use and Outcome Success
10 & 11 March 2021

Doing now what patients need next