THE FRENCH NATIONWIDE SYSTEM FOR ADVERSE EVENT REPORTING BY PUBLIC, PATIENTS AND HEALTHCARE PROFESSIONNALS

From a hospital-based reporting of health-care-associated infection to a universal reporting system for adverse events
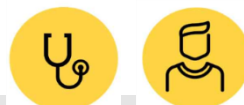
Félix FAUCON
General Inspector
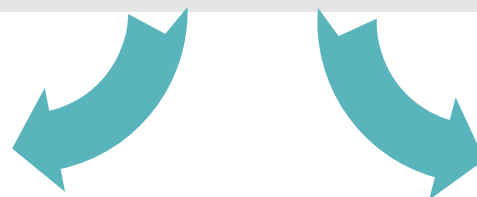General Inspectorate for social affairs and health

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

MINISTÈRE
DES AFFAIRES SOCIALES
ET DE LA SANTÉ

AN EXTENDED REPORTING SYSTEM

Unique portal for reporting any adverse event within all and every field of regulated vigilances and HCAE

Associated with the use of a drug, product or device

- Medication
- Material (instrument, implanted medical device, dressings, prosthesis…)
- Blood derived product (transfusion)
- Food additive
- Addictive substance
- Cosmetics
- Tattoo product
- Other products …

Healthcare-associated

- **Healthcare-associated infection**
- **Serious adverse event (associated with death, disability, or other public health threat)**

programme national pour la sécurité des patients 2013 / 2017

THE CONSTRUCTION PROCESS

A CO-CONSTRUCTION WITH REPRESENTATIVES OF ALL STAKEHOLDERS: REGISTRANTS AND ASSESSORS

- PATIENT ASSOCIATIONS
- HOSPITAL AND IN-TOWN HCP
- REGIONAL ENTITIES FOR VIGILANCE AND SUPPORT
- NATIONAL AGENCIES, REGIONAL HEALTH AGENCIES
- MINISTRY OF HEALTH

A PERMANENT DIALOGUE AND CONCERTATION

- 20 COLLABORATIVE WORKSHOPS
- MODEL CONSTRUCTION, PROTOTYPES AND TESTS
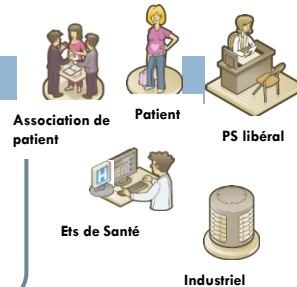- JOINT CONTENT DEVELOPMENT
- FOCUS GROUPS AND INDIVIDUAL FEED BACK

A single window for all types of registrants

- Web portal offers an ergonomical and simple access for all kinds of vigilance

Association de patient **Patient** **PS libéral**

Ets de Santé **Industriel**

Facilitating Serious Adverse Events notification

- **Directing registrant through a guidance module aiming the identification of the relevant type of vigilance**
- Orienting automatically to the existing notification tools, or enabling the online filling for non equipped types of vigilance

Promoting sanitary safety monitoring and notification initiatives

- Through a simplified information
- And a feed back to the registrant issuing an acknowledgement of receipt for every notification
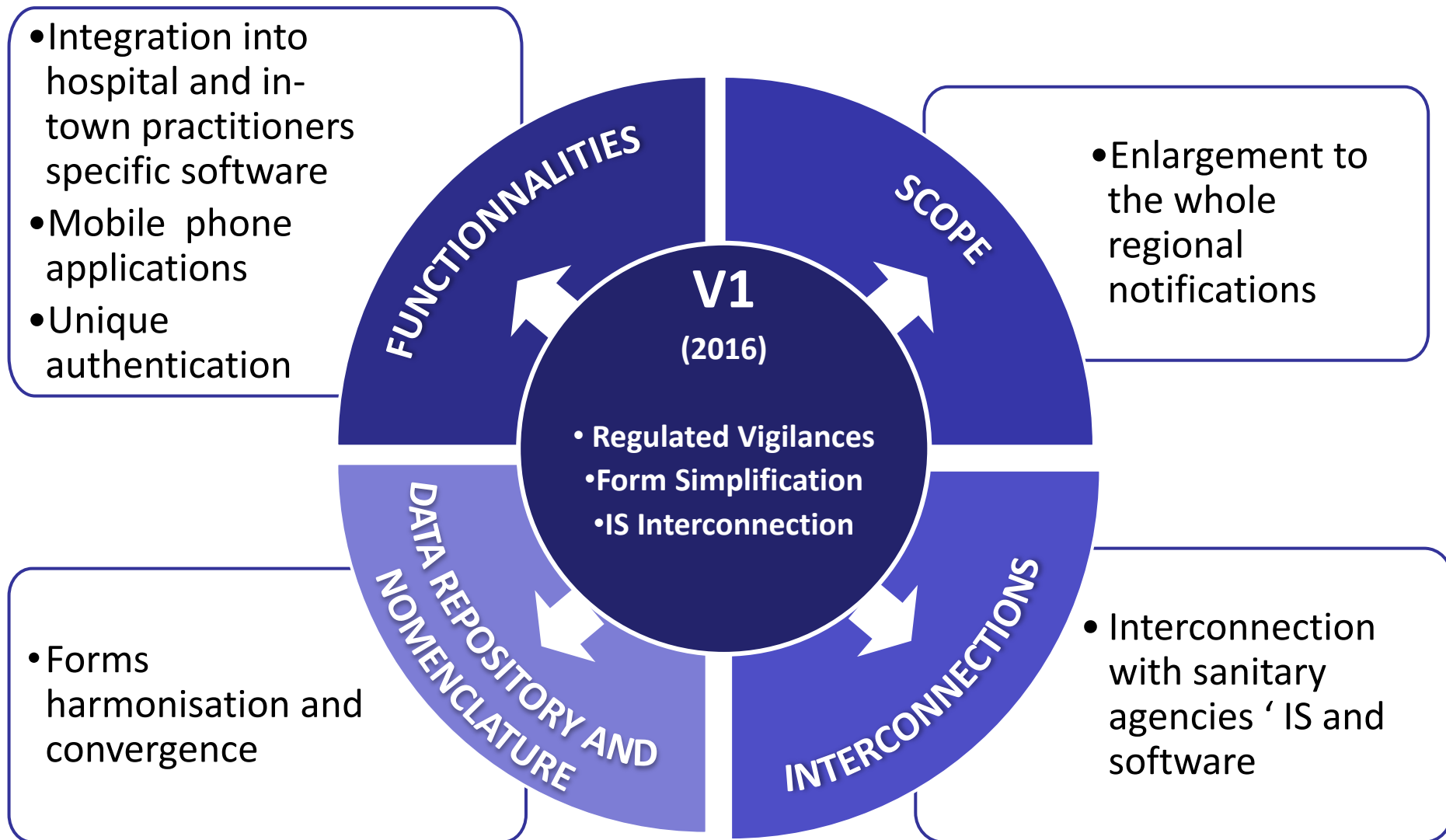
Facilitating the transmission of information to the assessors

- **Addressing automatically and immediately the notification to the relevant assessors**
- Using email or interconnected messaging

A FIRST VERSION DELIVERED IN 2016 PROGRESSIVELY ENRICHED BY FURTHER DEVELOPMENTS

- Integration into hospital and in-town practitioners specific software
- Mobile phone applications
- Unique authentication

FUNCTIONNALITIES

SCOPE

- Enlargement to the whole regional notifications

V1
(2016)

- Regulated Vigilances
- Form Simplification
- IS Interconnection

DATA REPOSITORY AND NOMENCLATURE

INTERCONNECTIONS

- Forms harmonisation and convergence

- Interconnection with sanitary agencies ' IS and software

A GUIDE THROUGH REPORTING

Directs the reporter to the alert system corresponding to his/her context

- **Simple, non-technical questions**
- **Directed** to the relevant alert system
- **web-based reporting** via online forms
- Does not substitute existing tools

3 possible pathways for reporting:

Direct reporting

Via an HCP

Existing on-line system

THE ONLINE FORM

From an historical stratification…

TO A TWO STEP MONITORING AND FEEDBACK PROCESS

Medicines agency

Health Authority

Public Health

CEIP
CRPV
CRH
CRMV (exp)

Adverse Drug Events

OMEDIT

Drug use monitoring

SRA

HC Safety & Quality

SAE & HCAI

CPIAS

Infection Prevention & Control and AMR

CIRE

Epidemiology

Regional Health Agency

Regional subsidiaries of health agencies providing expertise and support to HCP and ARS

DIV
ASN

Biomedicine agency

Nuclear medicine

CAPTV

Poison Control Centre

Food & environment

FOCUS ON PHARMACOVIGILANCE NOTIFICATION

Notification

INDIVIDUAL

HEALTH CARE PROVIDER

- Notification of a drug adverse event

Sending

- Either downloaded or email notification
- Or using the specific HCP secure messaging

Assessment

- Reception by the concerned regional centre of pharmacovigilance (CRPV)

PHARMACOVIGILANCE

The web portal doesn't substitute for existing tools, such as notification websites yet used by some CRPV, or hospitals.

FOCUS ON A NOTIFICATION ORIENTED TO A REGIONAL HEALTH AGENCY

Notification

INDIVIDUAL

- Health care adverse event

HEALTH CARE PROVIDER

- Severe Adverse Event notification
- Outpatient health care associated infection
- Health care adverse event

Sending

- Automatically interconnection with the regional vigilance and sanitary safety IS

Assessment

- Receipt by the regional agency team (regional focal point)

ars
Agence Régionale de Santé

FOCUS ON TOXICOVIGILANCE

INDIVIDUAL

HEALTH CARE PROVIDER

Notification

- Notification of a Poisoning resulting from an everyday life product

Sending

- Either downloaded or email notification
- Or using the specific HCP secure messaging

The individual is notified that:

- *In an emergency or a need of medical assistance, he has to contact the poison control centre or the medical emergency services*

- *In the case of calling a poison control centre, it is not necessary to notify the adverse event, because the poison control centre systematically carries out the notification*
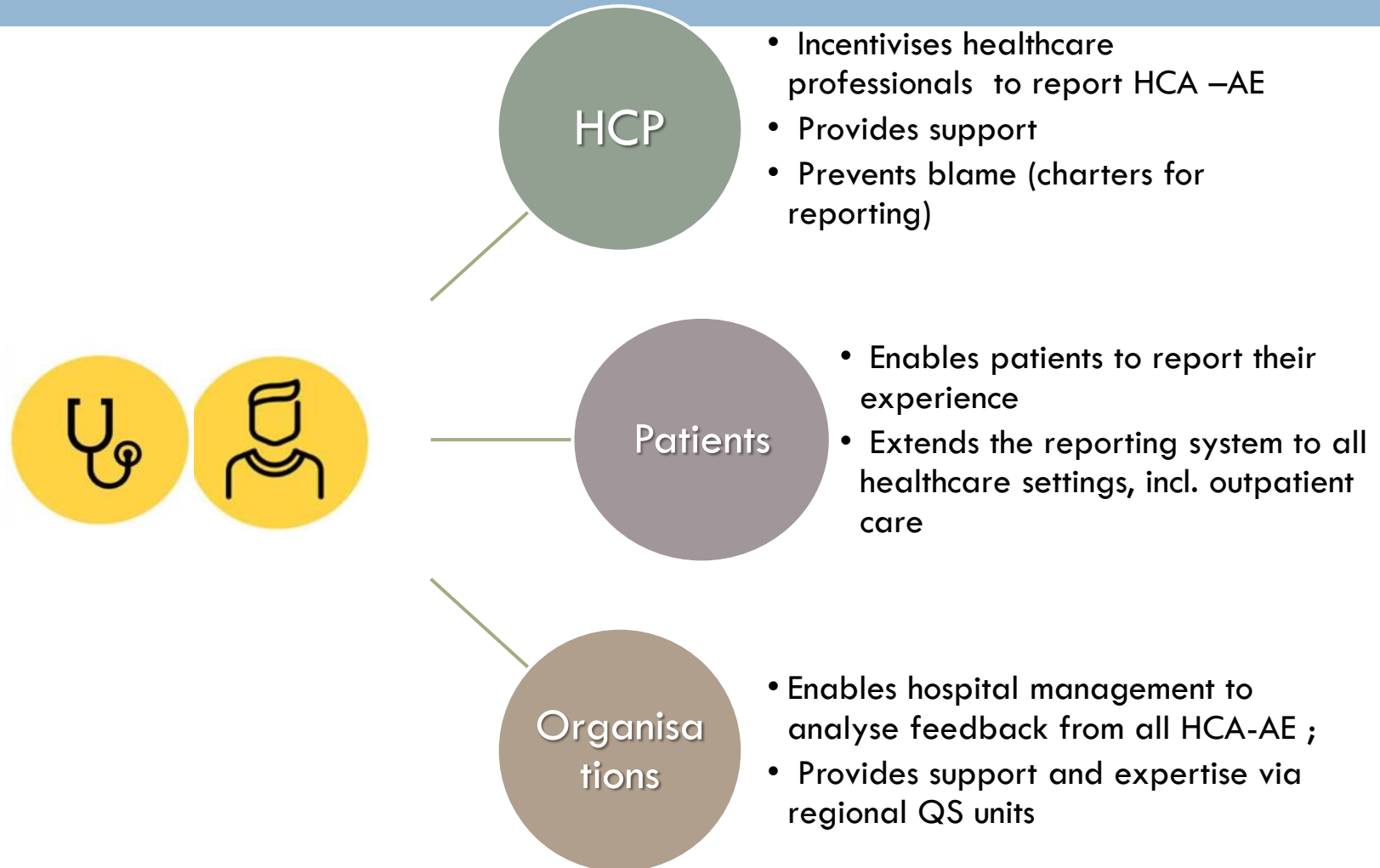
Assessment

  - Reception by the concerned regional poison control centre

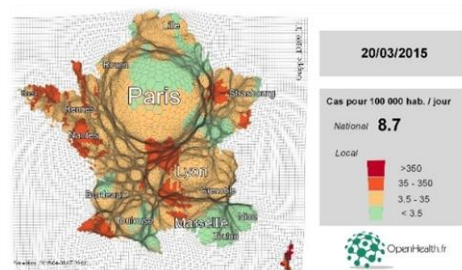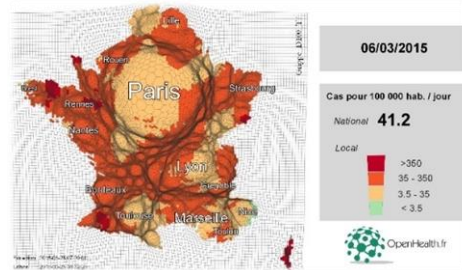**CapTv** — Association des Centres Antipoison et de Toxicovigilance

Expected benefits from the extended web-based reporting system: Promoting a safety culture

HCP
- Incentivises healthcare professionals to report HCA –AE
- Provides support
- Prevents blame (charters for reporting)

Patients
- Enables patients to report their experience
- Extends the reporting system to all healthcare settings, incl. outpatient care

Organisations
- Enables hospital management to analyse feedback from all HCA-AE ;
- Provides support and expertise via regional QS units

THANK YOU FOR YOUR ATTENTION

Real-time tracking of Flu vaccination campaign

Flu epidemiology tracking in 2015
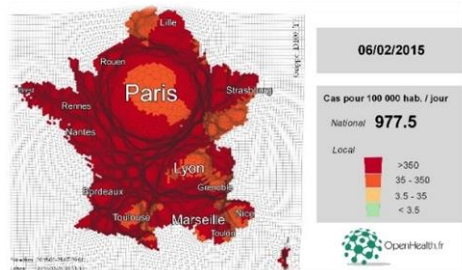
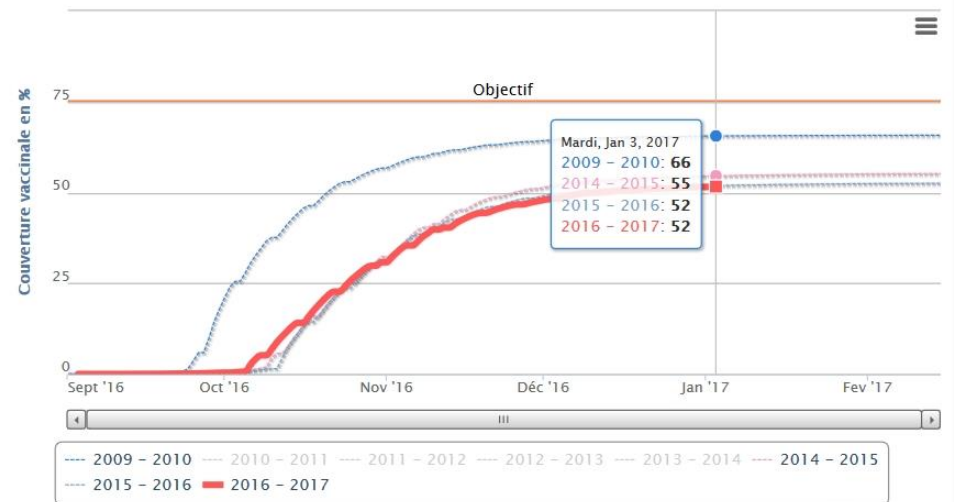**Public Health Indicators**

Longitudinal data for practices monitoring and real time

Sexe

Gender

Year of birth

Follow-up of the drugs deliveries for each patient (with all details)

Use Case - L'impact des mesures de sécurité

L'évolution des patients sous VALPROATE vers une thérapie alternative

Impact des mesures de sécurité

- Un recours aux traitements alternatifs **spécifique aux femmes …**

- mais **limité** avec seulement **12 %** de femmes concernées vs. 6 % d'hommes

n = 2 430 Femmes
15 – 49 ans