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Personalised approaches of the Portuguese Adverse Drug Reaction System

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Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. (WHO)

Before a medicine is placed on the market, the only safety information is provided by clinical trials, that includes a very limited and homogenous population (e.g., it normaly excludes children, elderly and pregnant women). It is only after the market authorization, and after it is being used by the destined population for a longer period of time that we get the fuller safety profile of a medicine.

“It is therefore essential that the **safety of all medicines is monitored throughout their use** in healthcare practice.” (EMA)

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The 3rd adverse drug reaction (ADR) awareness week campaign: 19-23 November 2018

Reporting side effects helps the safe use of medicines for babies, children and pregnant women #medsafetyweek

Campaign guide for stakeholders and partners

Medicines & Healthcare products Regulatory Agency

World Health Organization

Uppsala Monitoring Centre

HMA Heads of Medicines Agencies

ICMRA

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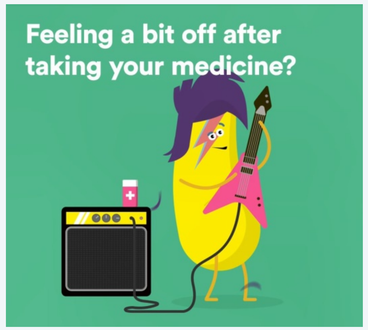
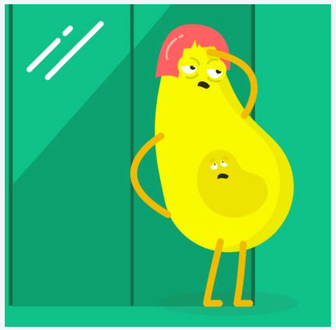
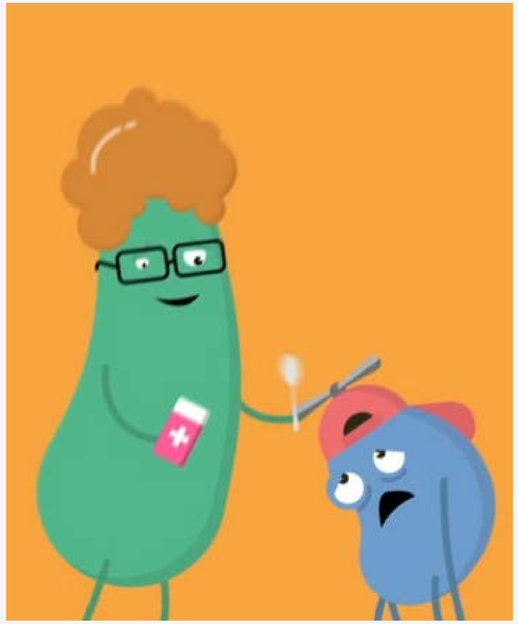
The 3rd adverse drug reaction (ADR) awareness week campaign: 19-23 November 2018







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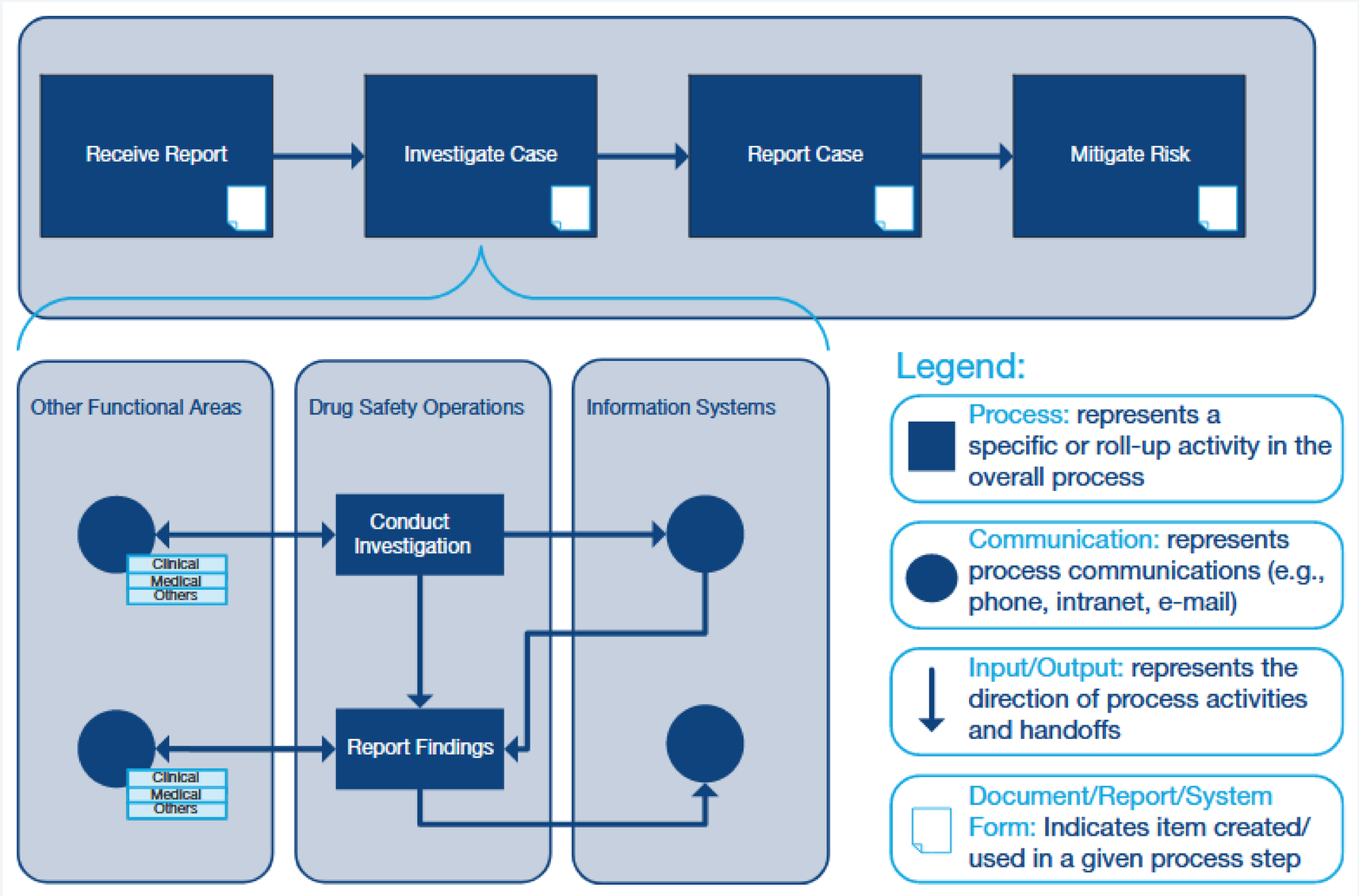
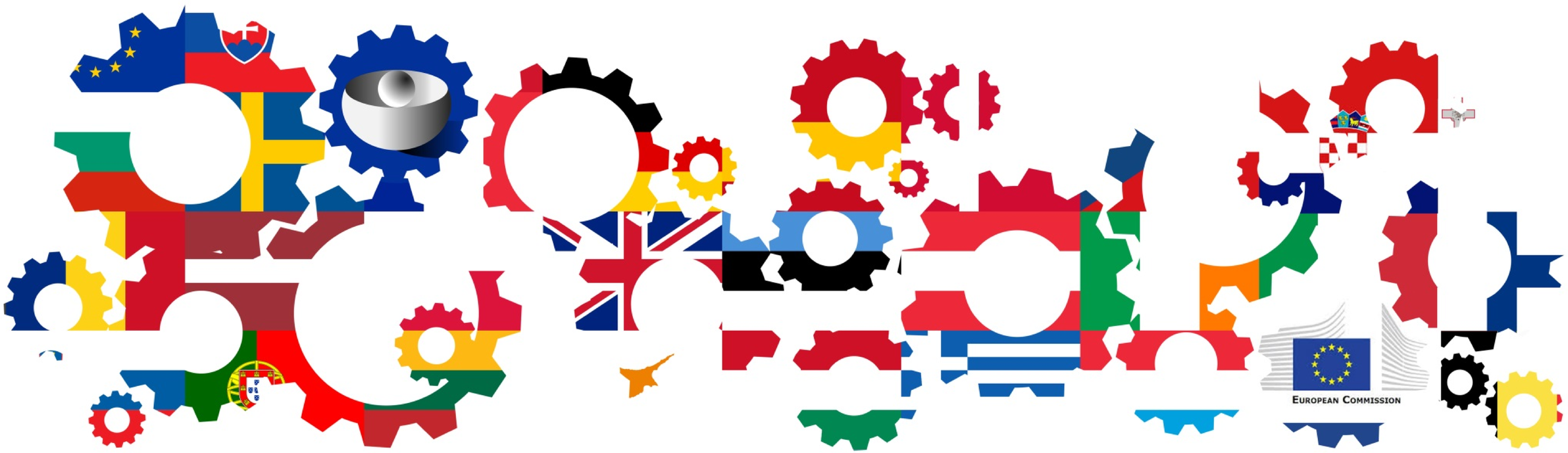
Spountaneous Reporting System



PWC, 2006

The European medicines regulatory network



~ 50 national regulatory authorities European Commission European Medicines Agency

What are the major challenges for the future of PhV?

Technology

- **Big Data**
- **Real World Evidence (RWE)**
- **Clinical registries and electronic health records (EHR)**
- **Social Media**

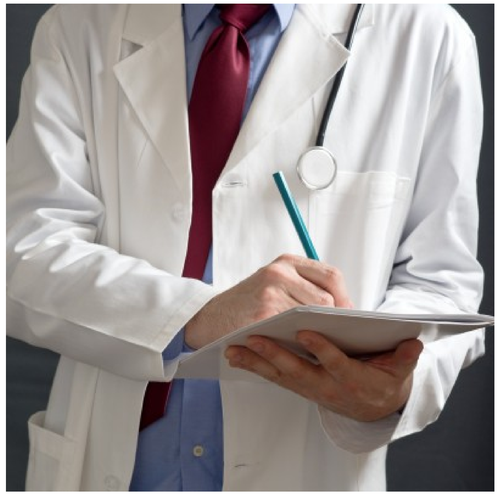
“Information => Action”

People

- **Greater involvement from healthcare professional**
- **Greater involvement of patients and users**

Canedo, 25 years of Pharmacovigilance in Portugal, 2018

What is the strategy?



“Personalised” approach:

- To help us communicate better;
- To stimulate HCP to report ADR;
- To get more expertise to the system;
- To get more research to the system;
- To get the more involved in the Benefit-Risk analysis;
- (...)

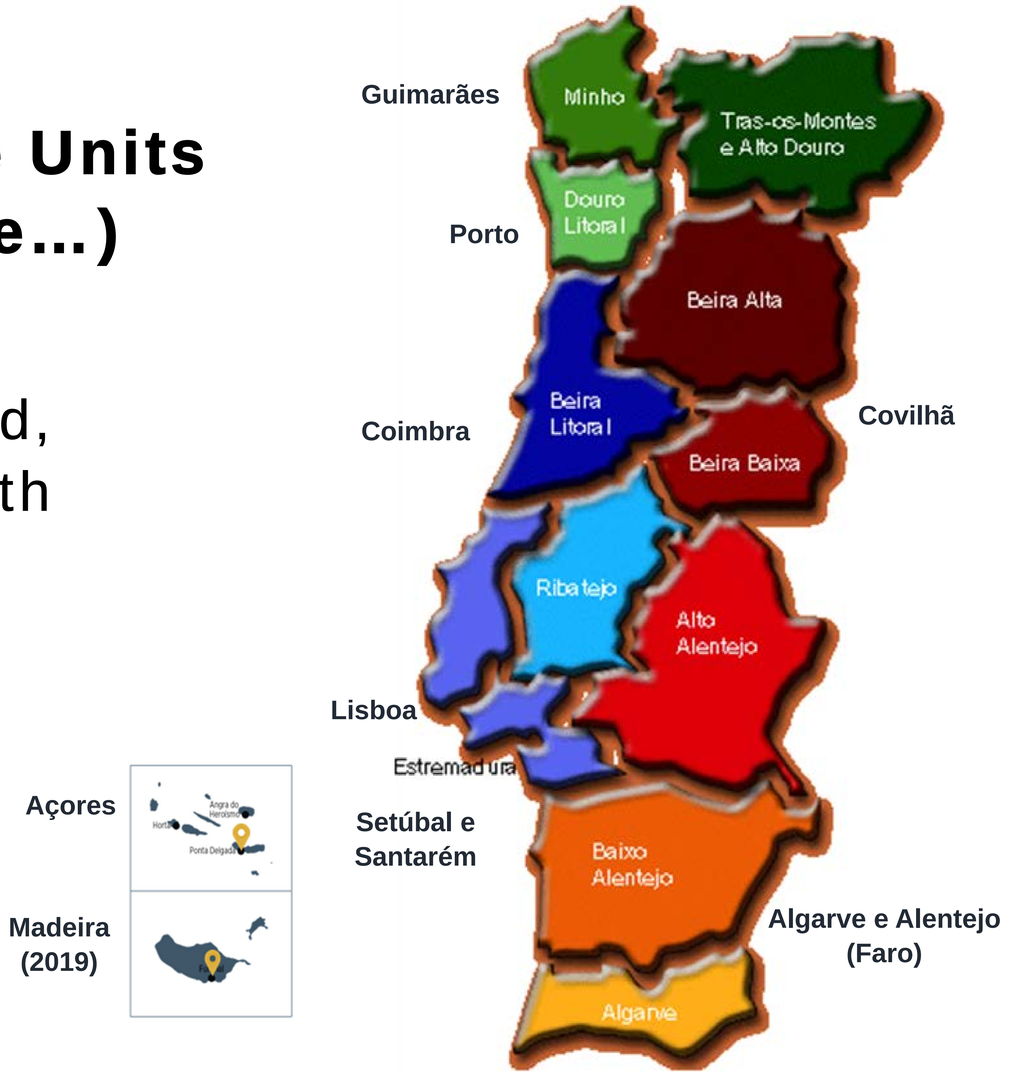
“Personalised” approach:

- To help us communicate better;
- To get more feed back from patients;
- To get the more involved in the Benefit-Risk analysis;
- (...)

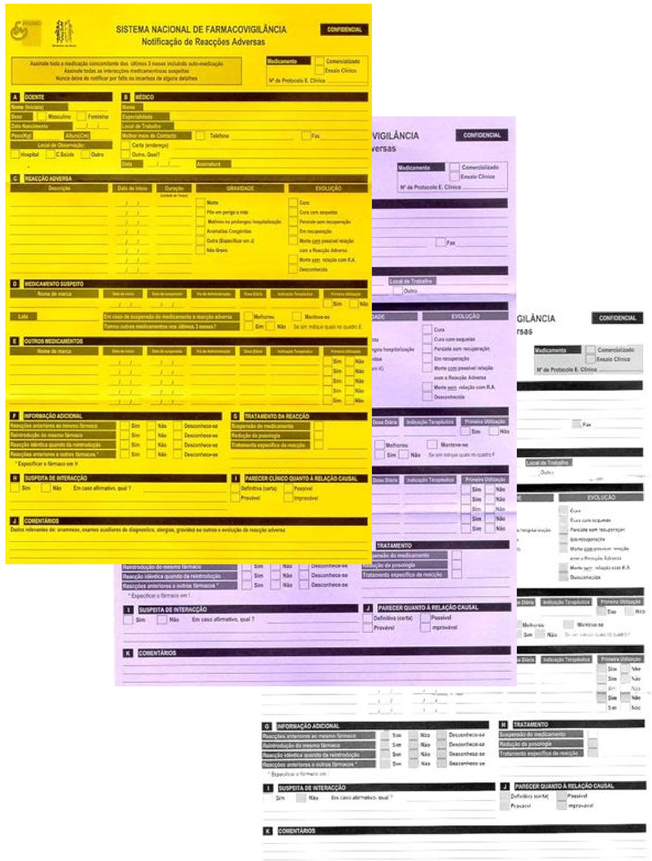
Make it closer to people (make it more “personal”)

8 Pharmacovigilance Units (and more to come…)

- Get more professionals involved, from different areas and with different backgrounds.



Improve the technology to what the users want



Novo

Portal **RAM**

Notificação de Reações Adversas a Medicamentos

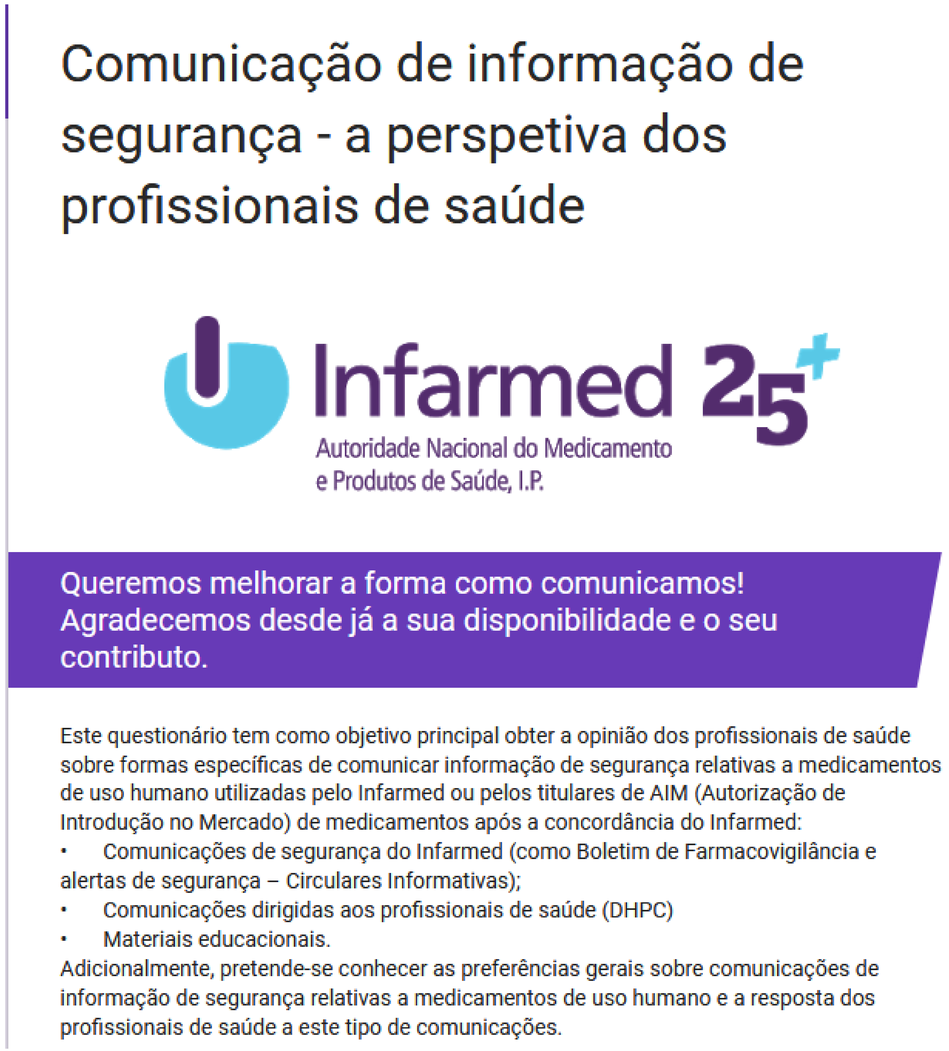
Improve the technology to what the users want

Using a cell phone to report

ADRs to Portal RAM

Use the means of communication they prefer

Use the means of communication they prefer



Comunicação de informação de segurança - a perspetiva dos profissionais de saúde

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Queremos melhorar a forma como comunicamos! Agradecemos desde já a sua disponibilidade e o seu contributo.

Este questionário tem como objetivo principal obter a opinião dos profissionais de saúde sobre formas específicas de comunicar informação de segurança relativas a medicamentos de uso humano utilizadas pelo Infarmed ou pelos titulares de AIM (Autorização de Introdução no Mercado) de medicamentos após a concordância do Infarmed:

- Comunicações de segurança do Infarmed (como Boletim de Farmacovigilância e alertas de segurança – Circulares Informativas);
- Comunicações dirigidas aos profissionais de saúde (DHPC)
- Materiais educacionais.

Adicionalmente, pretende-se conhecer as preferências gerais sobre comunicações de informação de segurança relativas a medicamentos de uso humano e a resposta dos profissionais de saúde a este tipo de comunicações.

Inquiry to HCP on their preferences for receiving medicine safety information (with the cooperation of the Professional Associations)

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Inovate

Algorithms can be your friends for a personalized approach strategy.

They help identify patients of interest and they save time for other tasks.

We are studying and testing algorithms and software to:

- Identify patients more at risk of experiencing an ADR;
- Help with MedDRA coding (“Natural Language Software”), improving the quality of the case coding;
- Using Bayesian networks (PhV Porto) to help causality assessment.

To predict and prevent ADR

- **Create awareness on the importance of getting a good clinical anamnesis in order to identify patients at risk of an ADR:**
  - Every risk communication to HCP by the Pharmacovigilance department clearly identifies the clinical conditions that putt the patient most at risk.

Circular Informativa

N.º 158/CD/550.20.001

Data: 12/11/2018

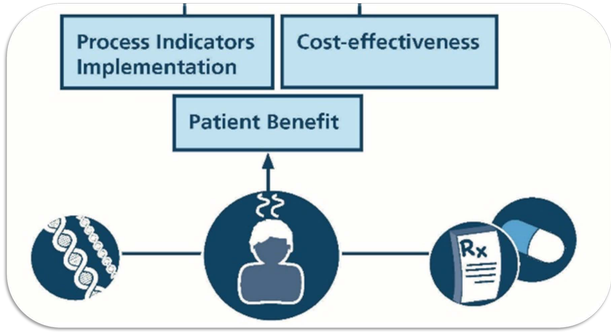
Assunto: **Metamizol e risco de agranulocitose**

Para: Divulgação geral

Estes medicamentos não devem ser utilizados em doentes com reações hematológicas prévias ao metamizol, em tratamento com imunossupressores ou outros medicamentos que possam causar agranulocitose. Deve ser tida particular atenção à prescrição destes medicamentos em doentes idosos.

- Patients that experienced previous hematological reactions to metamizol;
- Patients treated with immunosuppressants;
- Elderly patients

To predict and prevent ADR



PREPARE STUDY

(**PR**Eemptive Testing for **P**reventive **A**dverse **D**rug **Re**actions)

Objective:

To investigate a pre-emptive genotyping approach of a panel of PGx variants covering **13 important pharmacogenes** as a new model of personalized medicine.

Design:

Open randomized cross-over trial in **7 countries** including **8,000 patients**.

Outcomes:

Primary	Clinical outcome
Secondary	Process indicators for implementation
	Cost-effectiveness
	Patient reported outcomes

To predict and prevent ADR

Pilot project: RAM - predict - Methodology

Pharmacovigilance Department:
ADR assessment:
- Seriousness criteria
- Multiple ADR history
- “Clinically interesting for pharmacogenetic testing”

Medical doctor
- Clinical assessment of ADR

ADR Patient (adults)

Pharmacogenetics Medical Appointment: (imunologist/internal medicine/clinical pharmacology):
- Informed consent
- Structured clinical assessment
- Coded patient (“blinded”)
- Biological sample collection

INSA – Genetics Lab
- Sample processing;
- “Pharmacogenes” panel of clinical relevance for ADR
- Pharmacogenetics report;
- Data base.

INSA / INFARMED:
- Global analysis (including cost-benefit analysis)
- Recommendations for future actions

Take Home Messages

- In these new (and exciting) times of (massive) technology and science outbreaks, we need to design clever **strategies** that help us select efficient and effective ways of getting to each professional/patient.
- **New science outcomes and technologies** are welcomed for a more personalised pharmacovigilance system.
- However, not all in personalised medicine is about the “new”: sometimes it’s just about **tailoring an old suit to make it fit better**!

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Thank you for your attention.

Danke Schön

OBRIGADO!

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