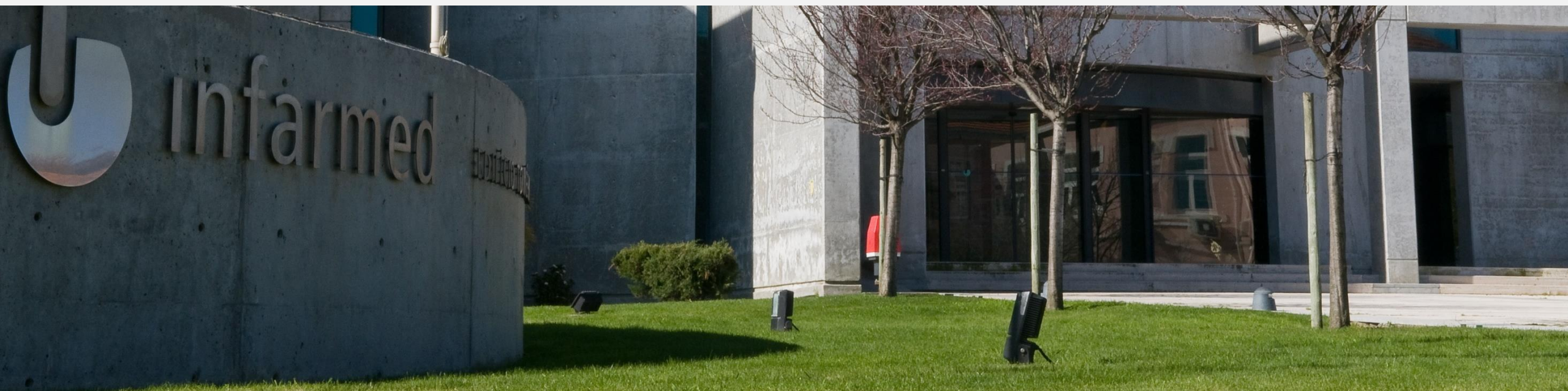


PROJETO INCLUIR

PATIENT INVOLVEMENT IN HEALTH TECHNOLOGY ASSESSMENT IN PORTUGAL

MARGARIDA OLIVEIRA

AMSTERDAM, 19.06.2019



INFARMED - National Authority of Medicines and Health Products, I.P.

Infarmed is the Portuguese Medicines Agency, that is responsible for the evaluation, authorization, regulation and control for human medicines as well as health products (medical devices and cosmetics) in the highest standards of public health protection.

This includes the complete Medicine Lifecycle, from development and regulatory steps, to price and reimbursement activities (**H**ealth **T**echnologies **A**ssessment).

PATIENT INVOLVEMENT IN HTA ACTIVITIES

2015 - 2016

New framework of the National System for Health Technology Assessment

INFARMED & Stakeholders Recommendation paper on patients involvement in HTA (Forum SiNATS)

2017

INCLUIR Project kick off
Patient associations registration at INFARMED
1st meeting within the scope of the national HTA Commission (CATS)



2018

Internal procedures and timetables development
Patient associations specific training on medicines lifecycle and HTA aspects

2019

HTA submission template development
Patient associations inputs on HTA for new medicines

Engagement with patients' associations in case by case decisions

PATIENT INVOLVEMENT IN HTA

A PART OF THE **incluir** PROJECT

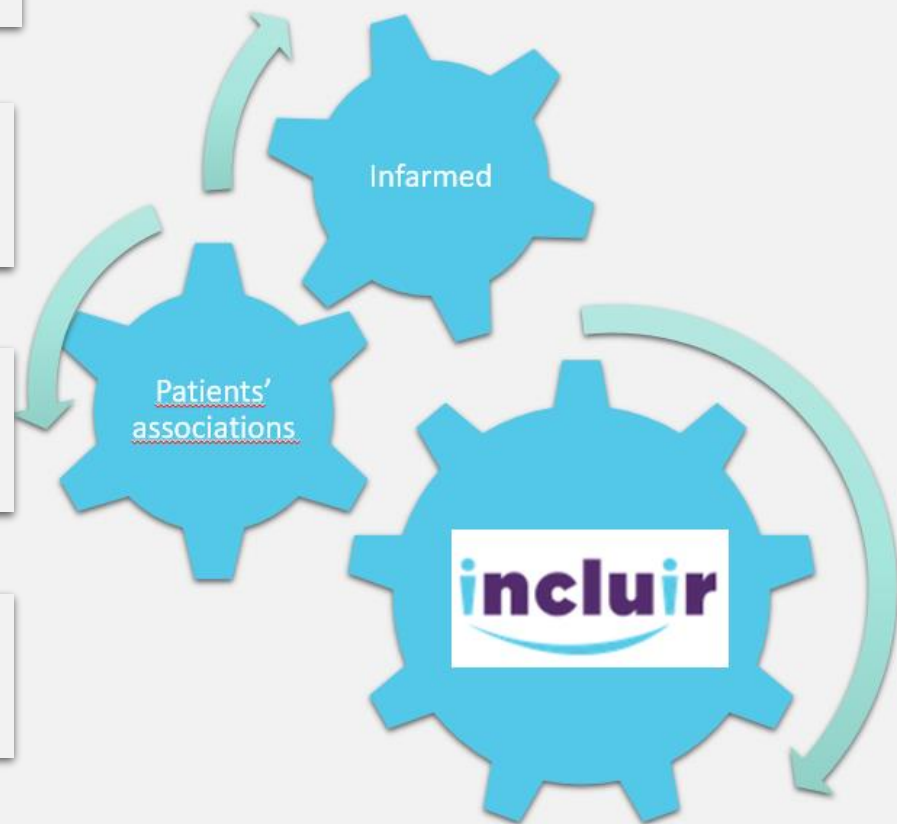
Other Goals

Increase proximity with patients and patients' associations

Change the relationship with patients and patients' associations in order to make it a regular practice with benefits for both parties

Make it possible for patients and patients' associations to build more informed positions about the processes where Infarmed has a direct role

Take the feedback and experience from HTA participation and evolve to engagement in other processes



HEALTH TECHNOLOGY ASSESSMENT

When?



Regulatory submission



Marketing Authorisation



P&R submission



Assessment



P&R decision



Reimbursement



HEALTH TECHNOLOGY ASSESSMENT

How we do it?



HTA Pharmacotherapeutic & Pharmacoeconomic assessment



**Initial proposal
PICO**



**Assessment of
added benefit**



**HTA Commission
Recommendation**

HEALTH TECHNOLOGY ASSESSMENT

Who does it?



HTA Pharmacotherapeutic & Pharmacoeconomic assessment



**Initial proposal
PICO**

Experts

Marketing
authorization
Holder

Patients



**Assessment of
added benefit**

Experts



**HTA Commission
Recommendation**

Experts

HEALTH TECHNOLOGY ASSESSMENT

PICO – What is it?



Initial proposal **PICO**

Experts
Marketing
authorization
Holder
Patients

Population or populations within the therapeutic indications under HTA
There are Groups or subgroups of people in whom the technology is expected to be more clinically effective? there are specific characteristics that should be examined separately?

Intervention
Medicinal Product (or device) in analysis

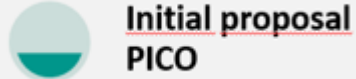
Comparators
What is the most appropriate comparator for the technology? Which is the actual clinical practice (in Portugal)?

Outcomes
Which outcomes should be considered: mortality, morbidity, health-related quality of life, adverse events

P I C O

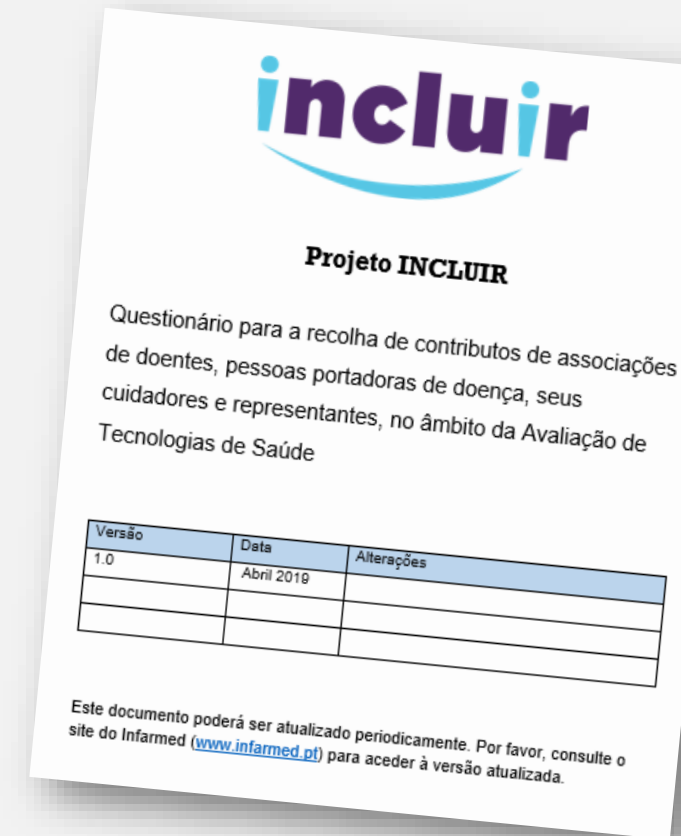
PATIENT INVOLVEMENT IN HTA ACTIVITIES

How we do it?



Dedicated form, that is pre-filled with specific product information, and sent to the patient association that represents condition or disease for which the medicine is being assessed

- Current experience from patients, their caregivers and family members
- Perceptions of patients, their caregivers and family members about the medicinal product under HTA
- Declaration of interests



Versão	Data	Alterações
1.0	Abril 2019	

Este documento poderá ser atualizado periodicamente. Por favor, consulte o site do Infarmed (www.infarmed.pt) para aceder à versão atualizada.

PATIENT INVOLVEMENT IN HTA ACTIVITIES

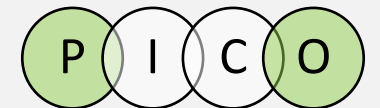
Submission form



Current experience from patients, their caregivers and family members

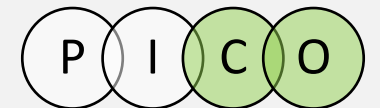
How does the condition or disease for which the medicine is being assessed, affect patients' everyday life (and also their caregivers and family members) ?

- *Everyday life activities that patients find difficult or are unable to do (and may demand support from caregivers/family)*
- *Types of patients that are most affected by the condition (e.g. men/women, children, ethnic groups).*
- *Aspects of the condition that are the most important to control*



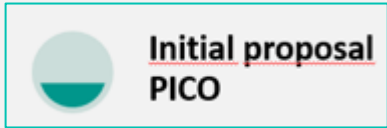
Experience with current therapies

- *Main therapies currently used by patients for this condition and how they are given*
- *Extent to which current therapies control or reduce the most challenging aspects of the condition.*
- *The most important benefits of current therapies.*



PATIENT INVOLVEMENT IN HTA ACTIVITIES

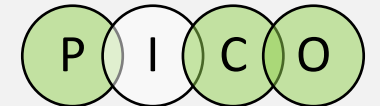
Submission form



Perceptions of patients, their caregivers and family members about the medicinal product under HTA

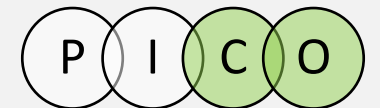
For those without experience using the new medicine: what are the expectations/limitations of it in relation to currently available treatments?

- *Expectation for advantages and disadvantages of the new medicine*
- *Level of improvement patients would like to see / impact the new medicine might have on quality of life*
- *Groups of patients who might particularly benefit or who might benefit less from the new medicine than others*



For those with experience using the new medicine, what difference did it make to their lives

- *Expectation for advantages and disadvantages of the new medicine*
- *Ease of use*
- *Symptoms that were improved with the new medicine and impact on quality of life*



PATIENT INVOLVEMENT IN HTA ACTIVITIES

How we do it?



Specific input on Outcomes scoring

- Together with clinical experts input => final score by outcome
- To be considered for both comparator and innovator
- May be crucial to HTA recommendation

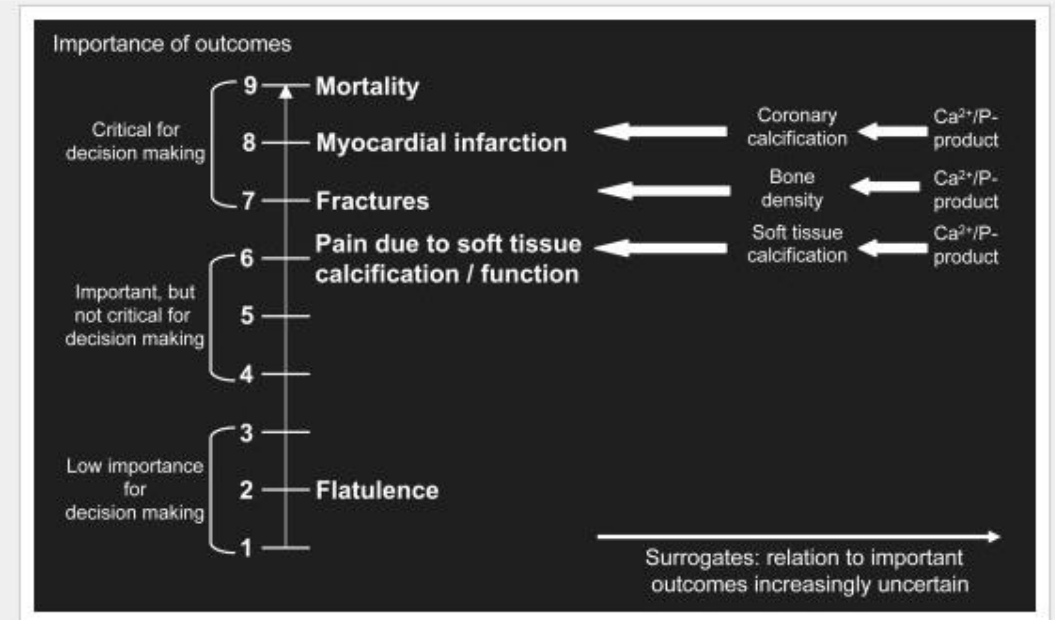


Fig. 1

Hierarchy of outcomes according to their importance to assess the effect of phosphate-lowering drugs in patients with renal failure and hyperphosphatemia.

HEALTH TECHNOLOGY ASSESSMENT

Who does it?



HTA Pharmacotherapeutic & Pharmacoeconomic assessment



**Initial proposal
PICO**

Experts

Marketing
authorization
Holder

Patients



**Assessment of
added benefit**

Experts



**HTA Commission
Recommendation**

Experts

includes mention
of patient
involvement



Taking into account patient involvement at PICO
(if need face to face meeting may be organized)

PATIENT INVOLVEMENT IN HTA ACTIVITIES

Patient association eligible for consultation

Oncology



ACREDITAR - Associação de Pais e Amigos de Crianças com Cancro	<u>Pediatric oncology</u>
AMPM - Associação de Mulheres com Patologia Mamária	<u>Breast cancer</u>
APCL - Associação Portuguesa Contra a Leucemia	<u>Hematooncology</u>
<u>Europacolon Portugal</u>	<u>Gastric cancer</u>
EVITA - Associação de Apoio a Portadores de Alterações nos Genes Relacionados com Cancro Hereditário	<u>Hereditary cancer</u>

incluir

The logo consists of the word "incluir" in a bold, sans-serif font. The letters 'i', 'u', and 'i' are light blue, while 'n', 'c', 'l', 'u', and 'r' are dark purple. Below the text is a thick, light blue curved line that resembles a smile.

Obrigada pela Atenção!