

Importância da Farmacovigilância na Prática Clínica

**How relevant is Pharmacovigilance to Clinical
practice**

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Dol

- Mário Miguel Rosa
 - Public Declaration of Interests and Confidentiality Undertaking:
 - https://www.ema.europa.eu/sites/default/files/ContactsAndExperts_CVs_and_DOIs/mrosa1_DI_en.pdf

What's the use of PhV?

- Ethics Principles
 - Beneficence / **Non maleficence**
 - Autonomy
 - Equity
 - Confidence
 - ...

What's the use of PhV?

- *Primum non nocere*

- Medical practice is all about *Risk Management*
 - Informative interview
 - Detailed observation
 - Proper diagnosis
 - The best and safer treatmentincluding patient's informed consent!

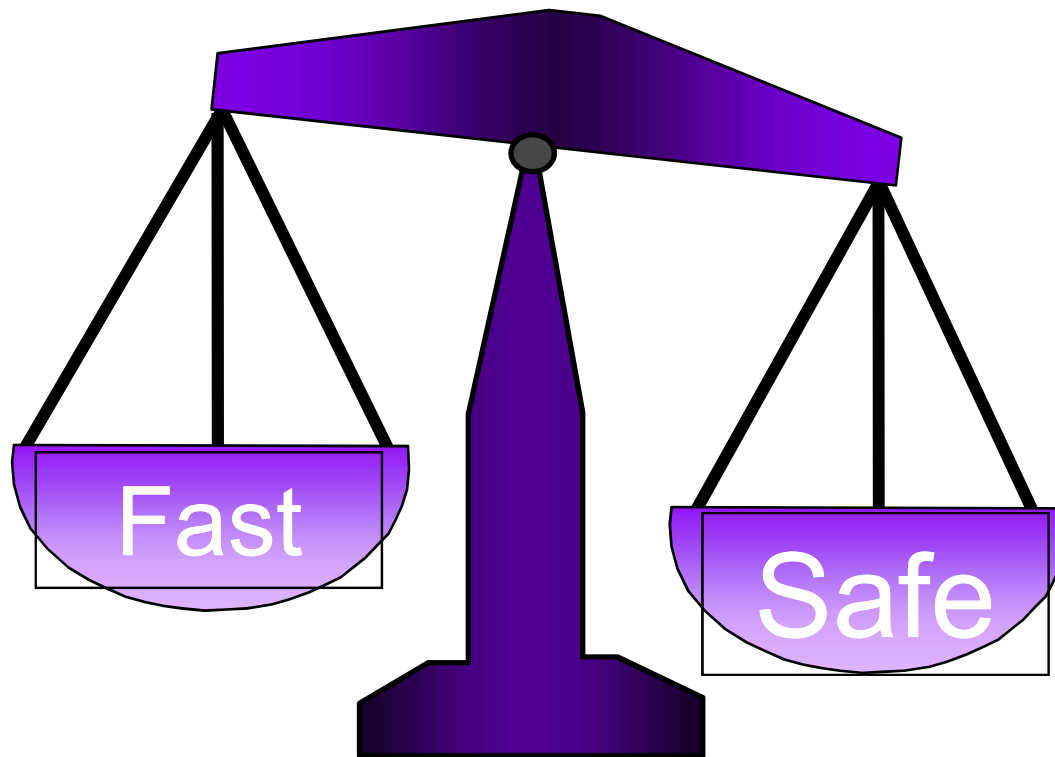
Safety

- Animal – Human translation



Drug Development: the «fast/safe» imbalance

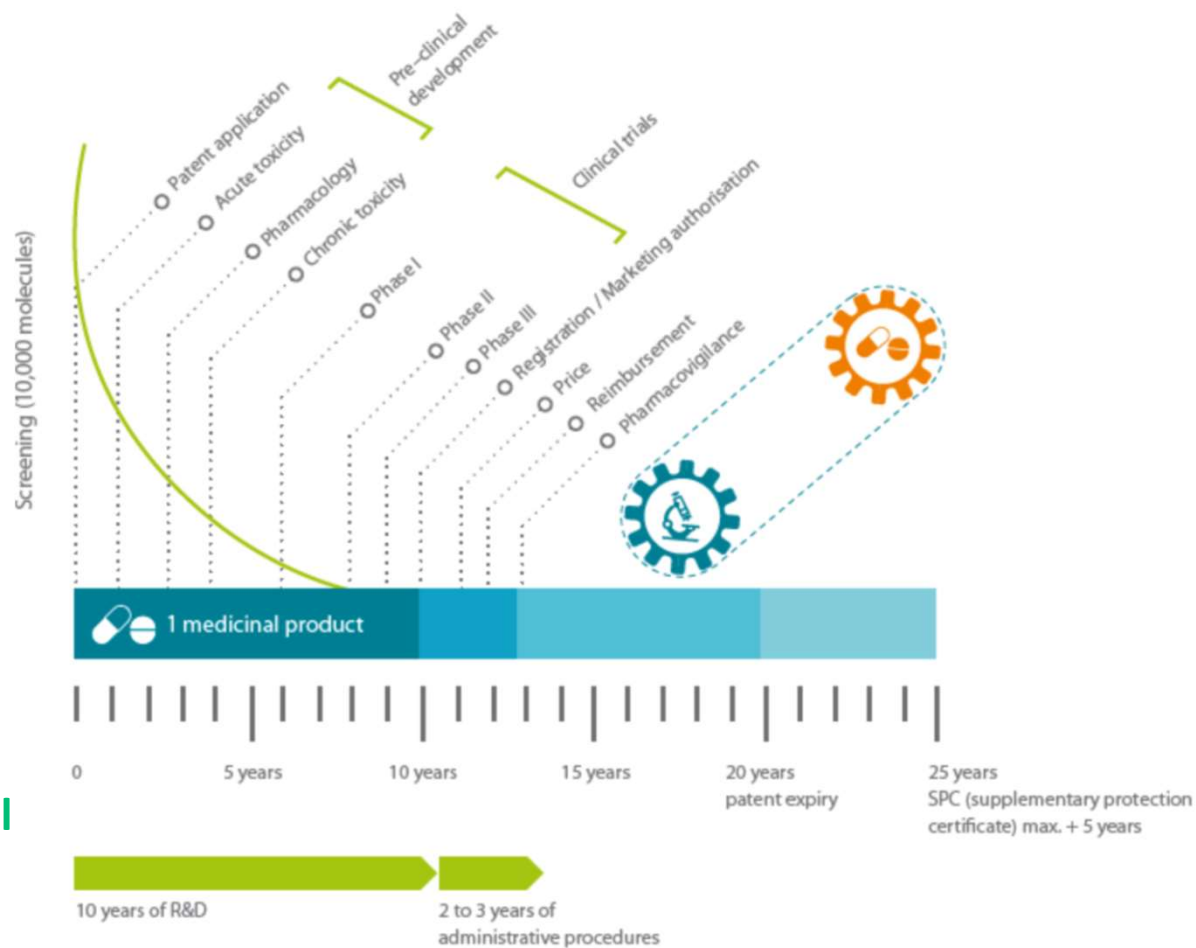
(ICH M3 guideline)



Simultaneous non-clinical
& clinical development

Drug Development

PHASES OF THE RESEARCH AND DEVELOPMENT PROCESS



EFPIA

The Pharmaceutical
Industry in Figures

Key Data 2022

Patient Risk Minimization in clinical practice

- 57 YO woman, taking letrozole as for the treatment in postmenopausal women with hormone-dependent advanced breast cancer
- Carotid territory TIA
- Past hx of gastritis

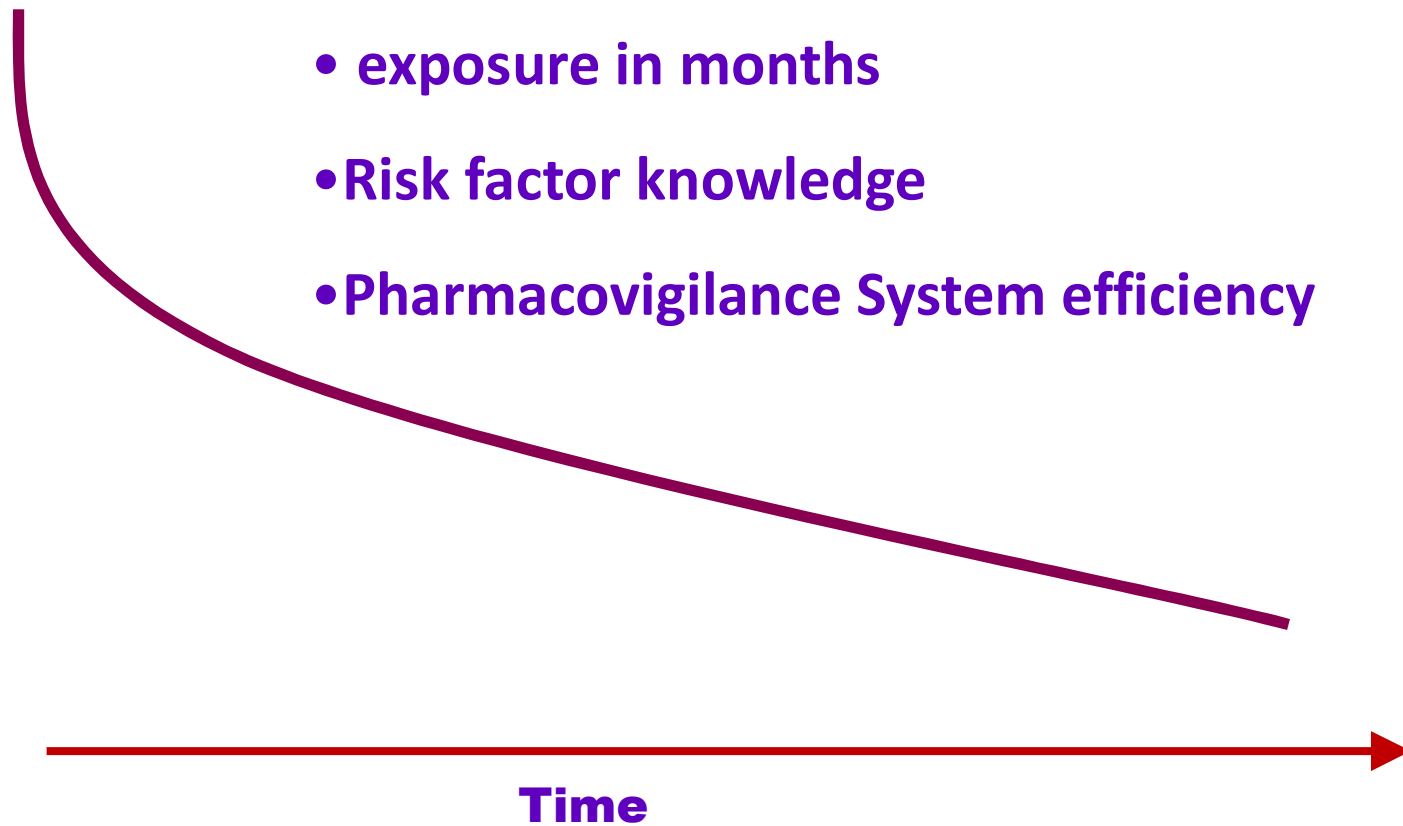
Patient Risk Minimization in clinical practice

- Stroke prophylaxis
 - ASA?
 - Clopidogrel?

Patient Risk Minimization in clinical practice

- Stroke prophylaxis
 - ASA – GI upset; pt takes 20 mg omeprazole PRN
 - Clopidogrel decreased effect due to cytochrome P450-isoenzyme 2C19 inhibition
 - Double risk of antiplatelet action failure (letrozole + omeprazole)

Maleficent potential of a drug



Post-marketing safety

- Key contribution of HCPs to improve drug safety
 - Spontaneous reporting of adverse events



Post-marketing safety

- Spontaneous reporting of adverse events
- Key contribution of HCPs to improve drug safety
 - Rare events
 - Drug-drug interactions
- Empowers prescribers and end-users

B/R balance



Patient-doctor relation

- Reaching the patient
 - Discussion on possible benefits and risks AND its risk frequency
 - Lay language
 - Adequate documentation
- Accommodating patient decision and monitoring

Patient-doctor relationship

- Reaching the patient
 - Adequate documentation
 - SmPC / Patient Leaflet pdf!



A Infomed é a base de dados nacional de medicamentos de uso humano e destina-se a todos os cidadãos. Para que esta base de dados seja para todos, é fundamental a sua constante evolução. Envie-nos as suas sugestões.



Resultados:

MG: Medicamento Genérico; MB: Medicamento Biossimilar; MP: Medicamento Pediátrico

Nome do Medicamento	Substância Ativa/DCI	Forma Farmacêutica	Dosagem	Titular de AIM	Comercialização	Documentos
● Femara	Letrozol	Comprimido revestido por película	2.5 mg	Novartis Farma - Produtos Farmacêuticos, S.A.		
● Letrozol Accord MG	Letrozol	Comprimido revestido por película	2.5 mg	Accord Healthcare, S.L.U.		
● Letrozol Alter MG	Letrozol	Comprimido revestido por película	2.5 mg	Alter, S.A.		
● Letrozol Azevedos MG	Letrozol	Comprimido revestido por película	2.5 mg	Laboratórios Azevedos - Indústria Farmacêutica, S.A.		
● Letrozol Ebrocite MG	Letrozol	Comprimido revestido por película	2.5 mg	Laboratórios Azevedos - Indústria Farmacêutica, S.A.		
● Letrozol Farmoz MG	Letrozol	Comprimido revestido por película	2.5 mg	Farmoz - Sociedade Técnico Medicinal, S.A.		
● Letrozol Genthon MG	Letrozol	Comprimido revestido por película	2.5 mg	Genthon, B.V.		

Patient-doctor relation

- Accommodating patient decision and monitoring
 - Literature + Regulator data

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Substâncias Ativas/DCI
2977

Medicamentos
37395

Apresentações
106916

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11/12/2022

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How relevant is Pharmacovigilance to Clinical practice

- Improves post marketing safety knowledge \Rightarrow Improvement on B/R
- Empowers product end-users (Patients + HCPs)
- Key tool to master communication with patient

Thank You!

