

# Pharmacogenomics (PGx) as a new special interest group (SIG) at ISoP

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## Background

The risk of certain adverse drug reactions (ADRs) is known to be associated with variation in so-called pharmacogenes<sup>1</sup>. Pharmacogenomic information has been included in the labels of a number of medicines to provide guidance on appropriate dose or to advise patients carrying risk alleles to carefully monitor for ADR symptoms or to not take the medicine<sup>2</sup>.

Pharmacogenomic information in the product label takes into consideration the overall benefit-risk balance, magnitude of the genomic biomarker effect, strength of evidence as well as other aspects such as seriousness of the ADRs, underlying diseases, therapeutic alternatives, and interactions with other medicines. The label regarding pharmacogenomic testing may be classified into three categories as mandatory, recommended, or for information<sup>3</sup>.

## Objective

The International Society of Pharmacovigilance (ISoP) established a global special interest group (SIG) in 2020 to provide an opportunity for members interested in pharmacogenomics to expand knowledge of how medicines cause ADRs in genomic subpopulations; and to support pharmacovigilance relevant to medicines with pharmacogenomic associations.

## Methods

**The SIG is open to all ISoP members** and is made up of clinical and academic members from medicines regulatory bodies, nongovernmental organisations and the pharmaceutical industry. **SIG members regularly share news and exchange experiences** to support coordination, evaluation and training on pharmacogenomics in pharmacovigilance, with the purpose of improving knowledge and contributing to the safety of those patients who must use medications.

## Results

**Examples of SIG activities:** to exchange experiences and provide support to healthcare professionals/organisations; to create networking opportunities for those researching and investigating pharmacogenomics; to support training and increase understanding and awareness of pharmacogenomics in pharmacovigilance.



### SWEDEGENE

Aims: to identify genetic risk factors for serious ADRs

- Led by Dr Pär Hallberg & Prof. Mia Wadelius, Uppsala University in collaboration with Karolinska Institutet; and the Swedish Medical Products Agency
- National collection of ADR cases – 4,000 collected so far
- Current focus on rare reactions to COVID-19 vaccines
- Seeking international collaborators

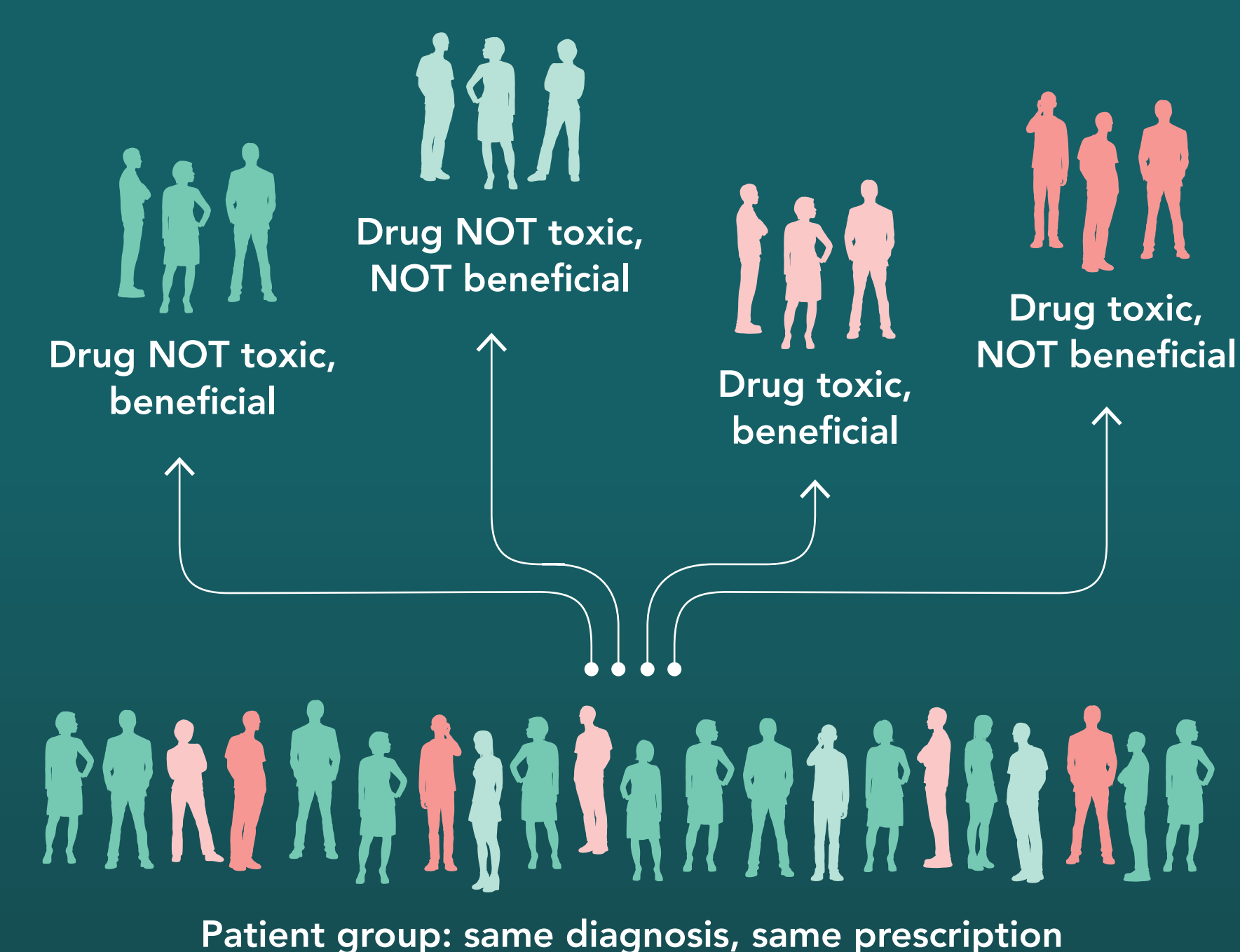


### PROF. AFAF LAMZOURI

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- Professor at Faculty of Medicine and Pharmacy of Tangier, Abdelmalek Essaadi University
- Head of Department of Medical Genetics (Genetic diseases/Oncogenetics/Pharmacogenetics), Tangier Tetouan Al Hoceima University Hospital, Morocco
- Member of the ISoP Pharmacogenomics Special Interest Group
- Areas of interest in pharmacogenetics:
  - Pathologies revealed by an abnormal response to drugs: Ex. G6PD deficiency; malignant hyperthermia and Gilbert's syndrome
  - Clinical applications of pharmacogenetics:
    - In psychiatry: Antidepressants and CYP2D6
    - In cardiology: Clopidogrel and CYP2C19
    - In infectious pathology: Ex. Tuberculosis++: Isoniazid and NAT2 / CYP2E1
    - Tacrolimus in kidney transplant patients and CYP3A5
    - In oncology:
      - Targeted therapy+++; Ex. Efficacy of PARP inhibitors in cancers with BRCA mutation
      - Fluoropyrimidine toxicity and DPYD

- 1 Regular SIG member meetings every 1–2 months.
- 2 Presentation at ISoP Patient Safety Day “Pharmacogenomics in Pharmacovigilance” (Sept 2020).
- 3 Uppsala Reports (issue 83) “Pharmacogenomics” in focus (Nov 2020).
- 4 Editorial in Drug Safety, “The International Society of Pharmacovigilance (ISoP) Pharmacogenomic (PGx) Special Interest Group (SIG): Pharmacogenomics in Pharmacovigilance”<sup>4</sup> (May 2021).
- 5 Drug Safety Matters podcast produced by UMC (Episode #10 on Pharmacogenomics) – “Tailoring drug therapy to your genes – Qun-Ying Yue” [www.drugsafetymatterspod.org/618871/8795485](http://www.drugsafetymatterspod.org/618871/8795485) (July 2021)
- 6 Presentations at North American Society of Pharmacovigilance (NASoP) Oct 2021 and EUPV CONGRESS Dec 2021.



## Conclusion

The pharmacogenomics SIG at ISoP will contribute to the goal of identifying patients at risk and to improve the benefit/risk balance of drug treatment in genomic subpopulations.

## References:

- <sup>1</sup> Carr DF, Pirmohamed M. Biomarkers of adverse drug reactions. *Exp Biol Med* (Maywood) 2018; 243: 291–299.
- <sup>2</sup> Drug Label Annotations. PharmGKB, <https://www.pharmgkb.org/labelAnnotations> (accessed 28 April 2022).
- <sup>3</sup> Guideline on key aspects for the use of pharmacogenomics in the pharmacovigilance of medicinal products. 19.
- <sup>4</sup> Yue Q-Y. The International Society of Pharmacovigilance (ISoP) Pharmacogenomic Special Interest Group: Pharmacogenomics in Pharmacovigilance. *Drug Saf* 2021; 44: 615–617.