



## FAQ ELSI rubric

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### What is pharmacogenomics?

Pharmacogenomics (PGx) refers to the study of individual's genetic information to predict the response (toxicity or efficacy) to a drug. Depending on this genetic information, a drug may be more or less effective and/or more or less toxic to a patient. Drugs can be more convenient for an individual than for another one and/or could induce more or fewer side effects for an individual than for another one. Pharmacogenomics can also help you to improve your treatment.

### How do I perform a PGx test?

In order to perform a PGx test, your medical doctor has to prescribe it. In general, a genetic test requires only a blood sample but it takes time to get the test results.

### What are my rights?

Before the prescription, the medical doctor must explain the procedure of a genetic analysis (details and consequences): this is called “enlightened information”. Before performing the PGx test, you will have to sign a consent that will be attached to the prescription. The signature of this document must be free and delivered without any constraints. You have the right to have access to all the necessary information to make your decision and you are free not to sign it. You have also the right not to know your test results.

### How can I have access to a PGx test?

Access to a PGx test is depending on your health condition and on the health system in your country. Indeed, PGx tests are used in routine care for only some health problems and for some drugs. There is a diversity of healthcare systems across Europe that do not all perform PGx tests in routine care. Check with your health system (public and/or private) to find out the reimbursement possibilities of the test and of the drug. Some countries have built lists of pharmacogenetics tests and drugs prescribed by any medical doctor that are reimbursed by the health insurance funds. These lists are updated and are based on the most recent scientific literature and associated clinical evidence. Sometimes, some gene-drug pairs require the prescription of a doctor with a title in clinical pharmacology and toxicology in order to be reimbursed.



How will the test results be transmitted to me?

Unlike other biological analysis, it is not the laboratory that will give you the results but your prescribing medical doctor unless you have declared that you expressed at the time of the prescription your right not to know. You can ask to be supported at the time of the transmission of the results. It is the duty of the medical doctor to provide you with all information and advice, not only at the time of the results but throughout the duration of the treatment.

How will PGx test results be used for my care?

Medical doctors are starting to use pharmacogenomics information to prescribe drugs, but these tests are only systematic for some health problems and some drugs. Depending on your PGx test results, a drug and/or drug doses will be chosen to likely work best for you.

Can PGx tests also be used for testing diseases?

No, PGx tests are not diagnostic tests and are not prescribed in order to predict the probability to develop others diseases. The genetic characteristics analysed by a PGx test are not necessarily related to the health problem of the patient: they simply play a role in the metabolism of the drug.

Can PGx test provide other information about my health?

PGx test can only give you information about how you will respond to several drugs. However, in case of further research programs, it is possible that the previous PGx test performed by new generation sequencings provides unexpected information, called incidental findings, which could give information about a particular disease or condition. In this case, you will be informed of these research programs and the informed consent form you signed before PGx testing should give information about the possibility of further research. In this particular case, you will have to give your consent and you will have the right to know or not to know about these particular results.

How PGx test results will be protected?

PGx test results are data qualified as personal data. There is a current law in Europe that protects personal data, called the General Data Protection Regulation (GDPR). Professionals



who perform the test and process the results must respect this legislation. According to this regulation, privacy is considered as a core individual right; as a result, data collection, storage and use should ensure that all the necessary measures to protection the confidentiality of health data are in place.

What is the European normative framework governing PGx?

PGx tests can be qualified as products and as such are falling under the *in vitro* diagnostic medical devices Regulation. This framework is covering the manufacturing of PGx tests and only concerns manufacturers who produce and market these tests.

PGx test results are considered as personal data. As such, they are falling under the GDPR, which protects these results with regards to privacy. The Regulation is applicable since May 25, 2018 in all European Union countries. It applies to all companies, administrations and associations that process personal data, including those related to health. For more information: [https://ec.europa.eu/info/law/law-topic/data-protection/reform/rights-citizens\\_en](https://ec.europa.eu/info/law/law-topic/data-protection/reform/rights-citizens_en)

Could I suffer from discrimination based on my PGx test results?

Many people are afraid about the use of genetic information by third parties for non-medical purposes. PGx test results that are collected and processed in the routine care can only be used for the purpose to give you the right drug and/or the right drug dose. According to the confidentiality and professional secrecy principles, no one have the possibility to share your results with third parties such as your employer or your insurance company.

In the context of a participation in a clinical trial, PGx test results can only be used for the purpose described in the informed consent form you signed before your inclusion.

Is PGx enough for personalized treatment?

Genetic factors are not the only ones influencing the response to treatments; biological characteristics such as gender, overweight, age or smoking could also influence the effectiveness of a drug. The conditions and lifestyle of the patient are also important factors, especially regarding the degree of adherence to treatment. Thus, medical doctors must closely monitor patients and assess adherence at all times.