Supplementary Material. Questionnaire on the implementation of pharmacogenomics distributed to and completed by the participating laboratories in the survey. The document includes all items exactly as presented to respondents, providing full transparency regarding the survey content and structure.

IMPLEMENTATION OF PHARMACOGENETICS IN ITALY

The Joint Working Group for the Implementation of Pharmacogenetics in Italy

**For these questions you can select more than one answer.*

	Information on the laboratory that performs pharmacogenetics services
1.	In which city is the laboratory that provides the services located? _____
2.	Does the laboratory operate in a public or private context? o public o private o other
3.	Indicate the name of the institution (both public and private) in which the **laboratory** is located _____
4.	If the **laboratory** is part of a public institution, how can it best be defined? o Hospital o Scientific Research and Treatment Institute (IRCCS) o University Hospital o University o ASL/ULS o other _____
5.	In the case of an entity belonging to the National Health System, how is the Structure hosting the **laboratory** defined and what is its name? o Simple Operating Structure _____ o Simple Departmental Operational Structure_____ o Complex Operational Structure_____ o other_____
6.	Which professional figure is the director/manager of your facility? o medical specialist in: _____ o pharmacist specialist in: _____ o biologist specialist in: _____ o Chemist specialized in: _____ o Other _____
	Information regarding the person **completing** the questionnaire
7.	What role do **you** have within the organization that hosts the laboratory? _____
8.	Do you have a college degree? If yes, which one? o no o yes _____

9. Do you have a clinical specialty diploma? If yes, which one?
   - yes _____
   - no

Information on germline pharmacogenetics **services** provided by the laboratory

10. What are the categories of patients for whom pharmacogenetic **services** are required?*
    - Outpatient
    - Inpatients
    - Patients with private access on the recommendation of the general practitioner
    - Patients in private access on the recommendation of a specialist doctor
    - Other _____

11. Where do requests for pharmacogenetic **services** come from? *
    - from the institution to which the laboratory belongs
    - from an entity other than the one to which the laboratory belongs but in the same geographical region
    - from an entity other than the one to which the laboratory belongs and from a different geographical region.
    - other _____

12. Which specialist prescribes PGx services more frequently? *
    _____

13. Is it expected that informed consent and/or privacy consent documents will be obtained before performing these **services**?
    - Yes, specific for pharmacogenetics
    - Yes, general for genetics
    - no

14. Are any incidental findings from pharmacogenetic analysis reported to the patient? (If yes, please report for which genes)
    - Yes_____
    - No

15. Which genes can be tested at the laboratory where you work?*
    For the most frequently analysed genes (up to a maximum of 5), please fill out a form in the appendix section found at the end of the document.

	Reported	Not reported
☐ **ABCB1**	☐	☐
☐ **ABCG2**	☐	☐
☐ **CYP2B6**	☐	☐
☐ **CYP2C9**	☐	☐
☐ **CYP2C19**	☐	☐
☐ **CYP2D6**	☐	☐
☐ **CYP3A4**	☐	☐
☐ **CYP3A5**	☐	☐
☐ **DPYD**	☐	☐
☐ **HLA**	☐	☐
☐ **NAT2**	☐	☐
☐ **NUDT15**	☐	☐
☐ **SLCO1B1**	☐	☐
☐ **TPMT**	☐	☐
☐ **UGT1A1**	☐	☐
☐ **VKORC1**	☐	☐
☐ **Other _____**		

Information on **reporting** of germline pharmacogenetic services provided by the laboratory

16. Following the technical and clinical validation of the report, which specialist signs the pharmacogenetics report?
    - Medical specialist in: _____
    - Pharmacist specialist in: _____
    - Biologist specialist in: _____
    - Chemist specialized in: _____
    - Other _____

17. Is there a **commentary** included with the test results in the pharmacogenetics report?
    - o yes
    - o no

18. If a **comment** is provided on the pharmacogenetic result, it states*:
    - o Interpretation of the genetically predicted phenotype
    - o Reporting a phenotype at risk of toxicity/inefficacy
    - o specific prescription indication on the dosage to be adopted in the specific patient (pharmacological consultancy)
    - o Redirection to the branch specialist
    - o other _____

19. Does the laboratory produce **pharmacology counseling** reports separately from the pharmacogenetics report?
    - o No
    - o yes, by reporting following a prescription signed by the specialist _____
    - o Yes, through informal documentation (email, telephone or verbal communication)
    - o other _____

20. Is a **pharmacological** counseling service provided for pharmacogenetic reports produced by other laboratories?
    - o no
    - o yes

Volumes and pharmacogenetic performance analysis **times**

21. In the last year, how **many patients** have had pharmacogenetic testing performed in the laboratory where you work?
    - o Less than 50 tests
    - o between 50 and 100 tests
    - o between 100 and 200 tests
    - o More than 200 tests

22. Please indicate the average **time** (working days) between the test request and:
    - o The issuance of the germline pharmacogenetics report _____
    - o The issuance of the pharmacological consultation (if reported separately) _____

Information on reimbursement for pharmacogenetic services

23. Are the costs of pharmacogenetic analysis **reimbursed** by the National Health System?
    - o yes, for all tests
    - o yes, only for some tests
    - o no

24. If you are aware, can you provide **the nomenclature entry** used to perform the pharmacogenetic analysis?

    _____

25. If your laboratory provides pharmacological consultation services, is this **reimbursed** by the National Health System? If so, can you provide **the nomenclature used** to provide this service?
    - o no
    - o yes _____

Suggestions and **expectations** on the “Joint Working Group”

26. Do you know of any other professionals/laboratories in your region who might be interested in completing this questionnaire? If so, where can we send it?
    - o no
    - o yes _____

27. Do you have any **suggestions** for activities that you think could be promoted by the Joint Working Group for the Implementation of Pharmacogenetics in Italy?

    _____

APPENDIX x5

Gene: _____

1: For which drug(s) is genotyping performed?
_____

2: In which of these scenarios could pharmacogenetic testing of this gene be considered in your laboratory?
- Test prescribed before administering a drug
- Test prescribed following a clinical event (toxicity and/or other)
- Preventive profiling: testing of a broad panel of genes without any immediate therapeutic need
- Semi-preventive profiling: testing prescribed before administering a drug, but extending the analysis to a broader panel of genes not related to immediate therapeutic need

3: List below the variants/haplotypes that are evaluated
_____

4. What criteria were used to select the panel of variants/haplotypes evaluated for this gene?*
- Literature review
- CPIC guidelines
- DPWG guidelines
- SIF-AIOM guidelines
- AMP recommendations
- Other _____

5. Does the laboratory where you work use CE-IVD kits for the gene in question? (If yes, specify the type of kit)
- No
- Yes_____

6: Is more than one method used to confirm the genotyping results?
- yes
- no

7: What methodology is used for genotyping?*
- Sanger sequencing
- Pyrosequencing
- Whole Exome Sequencing (WES)
- Whole Genome Sequencing (WGS)
- Targeted NGS
- MALDI-TOF mass spectrometry
- Allelic discrimination via qPCR
- SNP array
- Use of genetic data already available and collected for purposes other than pharmacogenetics
- other _____

8. Are bioinformatics software/tools used for genetic data analysis and/or haplotype processing? (If yes, please specify which ones)
- Yes_____
- No

9. Which guideline(s) is/are adopted to provide the clinical interpretation of the report for the specific drug-gene pair?*
- CPIC Guideline
- DPWG Guideline
- SIF-AIOM guideline
- other _____

Thank you for your support!

The Joint Working Group for the Implementation of Pharmacogenetics in Italy

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