Research trends for early cancer biomarker detection in Italy: an Integrated Program in Oncology (PIO) survey

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ABSTRACT

Aims and background. In 2007, an Italian Research Network proposed to the Ministry of Health a concerted action aimed at developing a specific pathway for the analytical and clinical validation of new biomarkers for early cancer diagnosis. The action, funded by the Italian Ministry of Health within the Integrated Program in Oncology (PIO) and coordinated by the National Cancer Institute of Bari, started in 2008 involving 37 national research teams.

Methods. To monitor the methodological and analytical needs of the studies proposed by the research teams of PIO as well as to explore the plausibility of planning external quality assessment programs for early cancer biomarker detection, the coordinating team developed an ad hoc questionnaire that was submitted to each research team.

Results. From the collected data it emerged that about 70% of the biomarkers under investigation were analyzed according to nonroutine laboratory practices. The biological material utilized for biomarker assessment consisted of solid tissue (normal or pathological) in 31% of studies, serum in 21%, urine in 15%, plasma in 15%, and whole blood in 11%. Specific training of personnel directly involved in the program was reported by 18% of the teams. In 2008, only 6% of laboratories involved in PIO participated in both external quality assessment and internal quality control schemes specifically designed for the biomarkers under consideration. Standard operating procedures for the determination of about half (52%) of the biomarkers proved to be lacking in at least one phase of the biomarker assessment process.

Conclusions. On the basis of these results, we decided to give priority to the application of a four-phase process for the analytical validation of new potential biomarkers by setting up and applying standard operating procedures and developing external quality assessment and internal quality control schemes as specific steps of the workflow. Free full text available at www.tumorionline.it

Key words: cancer biomarker, Italy, survey.

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