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

Paolo Verderio[1], Anita Mangia[2], Claudio Orlando[3], Maurizio Belfiglio[4], Antonio Marchetti[5], Lucio Bertario[1], Gennaro Chiappetta[6], Massimo Gion[7], Gian Paolo Tonini[8], Franca Podo[9], Amina Vocaturo[10], Rosella Silvestrini[11], Claudio Lombardo[8], and Angelo Paradiso[2]

[1]Fondazione IRCCS Istituto Nazionale Tumori, Milano; [2]Istituto Tumori "Giovanni Paolo II", Bari; [3]Università di Firenze; [4]Consorzio Mario Negri Sud, Chieti; [5]Università di Chieti; [6]INT Fondazione Pascale-Napoli; [7]Centro Regionale Indicatori Biochimici di Tumore-IOV-IRCCS-Venezia; [8]IST Genova; [9]Istituto Superiore Sanità, Roma; [10]Istituto Tumori IRCCS "Regina Elena" Roma; [11]Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori, Forlì, Italy

Coauthors: Sara Pizzamiglio Istituto Nazionale Tumori, Milano; Massimo Romani Oncologia Sperimentale IST, Genova; Elena Belloni Campus IFOM-IEO, Milano; Delia Cavallo Dipartimento di Medicina Occupazionale ISPESL, Roma; Paola Ulivi Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori, Forlì; Stefania Tommasi IRCCS Istituto Tumori "Giovanni Paolo II", Bari; Agostino Steffan Unità di Patologia Oncologica INT-Aviano, Pordenone; Antonio Russo Oncologia Molecolare Università di Palermo, Palermo; Alessio Massimo Fondazione Centro San Raffaele Monte Tabor, Milano; Daniele Calistri Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori, Forlì; Paola Parrella Casa Sollievo della Sofferenza San Giovanni Rotondo, Foggia; Massimo Broggini Istituto di Ricerca Mario Negri-Milano; Antonio Giuseppe Naccarato Università di Pisa ed Azienda Ospedaliera Universitaria Pisana, Pisa; Fiamma Buttitta Dipartimento di Oncologia e Neuroscienze, Università di Chieti, Chieti; Gaetano Finocchiaro Istituto Nazionale Neurologico C. Besta, Milano; Giulia Veronesi Division of Thoracic Surgery-IEO, Milano; Lorena Landuzzi Istituti Ortopedici Rizzoli, Bologna; Maria Benevolo Dipartimento di Patologia IRCCS Istituto "Regina Elena", Roma; Luciano Mariani IRCCS Istituto "Regina Elena", Roma; Federico De Marco Laboratorio di Virologia IRCCS Istituto "Regina Elena", Roma; Aldo Venuti Laboratorio di Virologia IRCCS Istituto "Regina Elena", Roma; Gianluigi Giannelli Department of Internal Medicine, Immunology and Infectious Disease, University of Bari, Bari; Michele Quaranta Laboratorio Analisi IRCCS Istituto Tumori "Giovanni Paolo II", Bari; Vito Trojano Oncology Gynecology Division IRCCS Istituto Tumori "Giovanni Paolo II", Bari.

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