



Edoardo Crimini^{1,2}, Angela Esposito¹, Carmen Belli¹, Roberta Scafetta^{1,3}, Raimondo Scalia^{1,4}, Grazia Castellano^{1,2}, Elisa Giordano^{1,2}, Jalissa Katrini^{1,2}, Liliana Ascione^{1,2}, Matteo Repetto^{1,2}, Luca Boscolo Bielo^{1,2}, Antonio Marra¹, Dario Trapani^{1,2}, Teresa Profeta¹, Gianluca Varano⁵, Daniele Maiettini⁵, Paolo Della Vigna⁵, Franco Orsi⁵, Carmen Criscitiello^{1,2}, Giuseppe Curigliano^{1,2}

1 Division of Early Drug Development, European Institute of Oncology, IRCCS, 20141 Milan, Italy. 2 Department of Oncology and Hemato-oncology, University of Milan, 20122 Milan, Italy. 3 Department of Medical Oncology, Campus Bio-Medico University of Rome, Rome, Italy. 4 Department of Surgical, Oncological and Oral Sciences, University of Palermo, 90127, Palermo, Italy. 5 Division of Interventional Radiology, European Institute of Oncology, IRCCS, 20141 Milan, Italy.

INTRODUCTION

Some early-phase clinical trials demand newly-collected tumor tissue, requiring patients to undergo new biopsies. Some trials prescreening by nextrequire a generation sequencing (NGS), but the test can fail. Biopsies may have complications.

METHODS

Retrospective study on the patients of the Early Drug Development (EDD) Unit of European Institute of Oncology, who performed fresh biopsies for research purpose. Aims: safety of the biopsies and adequacy of the tumor tissue for NGS testing.

	Number of patients (%)
Gender	
Female	280 (79%)
Male	75 (21%)
Median age	56 years
Tumor types	
Breast cancer	142 (40.0%)
Lung adenocarcinoma	22 (6.2%)
Cholangiocarcinoma	21 (5.8%)
Carcinoma of unknown primary	21 (5.8%)
Others	149 (42.0%)
Total patients	355

Table 1. Characteristics of patients undergoing new biopsies at trial entry

EC has no conflicts of interest to declare

710P A retrospective study on the safety and adequacy of fresh biopsies for Next Generation Sequencing in early-phase clinical trials

MOST COMMON BIOPSY SITES





RESULTS
 731 patients referred to the EDD Unit from January 2014 to December 2022. 355 patients (48.6%) underwent a biopsy. Liver, lymph nodes, skin and breast the most frequent sites of biopsy. Median time from trial's informed consent to biopsy: 3 days (R 0-83). Tumor tissue was adequate for histological diagnosis in 98%.; NGS testing was successful in 88.4% of cases. 9 out of the 16 unsuccessful NGS were performed on liver tissue. 11 patients (3.1%) had procedural complications, but none required hospitalization nor led to sequelae.
CONCLUSION
Half of the patients performed a fresh biopsy. Only a minority of patients had non serious complications. 10% of NGS failed due to poor sample quality or quantity, highlighting the importance to implement specific guidance and Standard Operating Procedure for samples intended for NGS.