

Routine molecular screening of advanced refractory cancer patients: An analysis of the first 2490 patients of the ProfILER Study.

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[Tumor-Based Biomarkers](#)

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[Abstract Disclosures](#)

Abstract:

Background: ProfILER (NCT01774409) is a molecular profiling clinical trial exploring cancer cell genomic alterations in pts with advanced disease to guide treatment. **Methods:** Pts with confirmed diagnosis of advanced cancers are eligible. DNA extracted from either archival or fresh collected tumor samples was analyzed by targeted exon sequencing of 60 cancer related genes and whole genome array comparative genomic hybridization (CGH). A multidisciplinary molecular board analyzes genomic data and recommends molecular targeted therapies (MTT) when actionable alterations are found. **Results:** As of Jan 2017, 2490 pts (55% female, median age 59, range 1-90) were consented; 1826 (73.3%) tumors were analyzed, 301 (12%) are ongoing (not done in 363 pts (14.6%) for technical issues). Tumor types were colorectal (10.3%), gyneco (9.5%), breast (8.8%), head & neck (7.1%) carcinomas, sarcomas (7.1%) and brain tumors (6.5%). 940/1826 pts (51.5%) had at least 1 actionable mutation (AM): 579 pts with only one AM, while 358 with 2 or more AM (up to 6). Mutations (including substitutions and small indels), amplifications and homozygous deletions (HD) were observed respectively in 55.3%, 42.1% and 25.5% of tumor samples. The most common AM were on *KRAS* (n = 156; 8.5%), *PIK3CA* (n = 150; 8.2%), *CDKN2A HD* (n = 174; 9.5%), *PTEN HD* (n = 49, 2.7%), *CCND1* (n = 97; 5.3%), *FGFR1* (n = 56; 3.1%), *MDM2* (n = 53; 2.9%), *HER2* (n = 42; 2.3%) and *HER1* (n = 41; 2.2%). MTT were recommended in 644 pts. Among them, 101 (gyn [28%], GI [18%], breast [12%]) initiated a recommended MTT. Collection of treatment data is ongoing for 202 pts. MTT received were mTOR inhibitors (39%), anti-angiogenic TKI (21%), EGFR TKI (9.8%), inhibitors of cell cycle (6.9%). Best responses were CR (n = 2, 2.3%), PR (n = 13, 15.1%), SD (n = 29, 33.7%), PD (n = 42, 48.8%), with a median PFS of 2.8 months (95% IC: 2.2-3.5). 24% are alive progression free at 6 months. Updated data will be presented at the meeting. **Conclusions:** In this series of 2490 cancer pts, CGH and NGS identified actionable alterations on 51% of pts, with treatment recommendation in 35%. Most patients treated derived benefit from the recommended MTT, but these represent a minority of the whole population screened. Clinical trial information: [NCT01774409](#)