

The AIR study: an Italian Head and Neck Cancer registry

On behalf of AIOCC board:

L.Licitra¹, G. Almadori², E. Cavalera³, D. Galizia⁴, G Gregorc⁴, L. Livi⁵, L. Locati⁶, G. Molteni⁷ E. Orlandi^{8*}

*lead presenter

¹Head and Neck Cancer Medical Oncology Department, Fondazione IRCCS Istituto Nazionale dei Tumori and University of Milan, Milan

² Department of Clinical, Surgical, Diagnostic, and Pediatric Sciences, University of Pavia, Pavia

³ Department Oncological Radiotherapy, "Vito Fazzi" Hospital, Lecce, Italy

⁴ Department of Medical Oncology Candiolo Cancer Institute, FPO-IRCCS, Candiolo (TO)

⁵ Department of Experimental and Clinical Biomedical Sciences "M Serio", University of Florence, Florence, Italy; Radiation Oncology Unit, Oncology Department, Azienda Ospedaliero Universitaria Careggi, Florence, Italy.

⁶ Department of Internal Medicine and Therapeutics, University of Pavia; Medical Oncology Unit, Istituti Clinici Scientifici Maugeri IRCCS, Pavia

⁷ Department of Otolaryngology - Head and Neck Surgery, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy; Department of Medical and Surgical Sciences, Alma Mater Studiorum - University of Bologna

⁸ Chief of Clinical Department, National Center for Oncological Hadrontherapy (Fondazione CNAO), Pavia, Italy; Department of Clinical, Surgical, Diagnostic, and Pediatric Sciences, University of Pavia, Pavia, Italy

Objective: The AIR study (Clinicaltrial.gov ID: NCT06248944) aims to establish an Italian clinical registry for H&N cancer, documenting diagnostic and therapeutic patterns across all disease stages through a multicenter prospective-retrospective approach.

Methods: The registry collects H&N carcinoma data from patients treated in Italy. A privacy preserving federated learning infrastructure is implemented. This allows privacy preserving data linking across registries to ensure combined analysis of Italian data with other European and potentially global cohorts. The data collection requires the completion of 16 forms (if all applicable) with approximately 500 variables.

Results: Nine sites have been activated since July 2022, listed with the number of patients enrolled: INT Milano 221; Fondazione CNAO 187; P.O. Vito Fazzi` 65; Fondazione del Piemonte per l'Oncologia 34; ICS Maugeri 29; AOU Careggi 11, Fondazione Agostino Gemelli 10; AOUI Verona 6; Policlinico Umberto I 0. Two more sites will be activated in the next few months: Don Bosco Torino and AOU Padova. We plan to add more sites pending adequate funding.

A sample size is not planned. An average of 200 patients/site/year was planned. Five hundred and sixty-three patients have been enrolled to date. 360 (63,9%) patients are male, 202 (35,9%) are female, for 1 patient (0,2%) gender is missing. 34 (6,0%) are aged between 18-35; 151 (26,8%) between 36-55; 304 (54,0%) between 56-75; 72 (12,8%) between 76-90. For 2 patients (0,4%) age is missing. The patients have the following year of diagnosis: 2022

(121); 2023 (78); 2021 (68); 2020 (53); 2019 (29); 2018 (18). A hundred and fifty patients were enrolled in the prospective cohort. Two hundred twenty four patients were enrolled in the retrospective cohort.

The first contact at the site was for 222 (39,4%) patients at diagnosis; 276 (49,0%) at treatment of the primary tumor; 50 (8,9%) at recurrence; 14 (2,5%) during metastatic disease; 1 (0,2) at follow-up stage.

The histotypes are as follows: squamous cell carcinoma 296 (52,6%), adenocarcinoma 152 (27,0%), carcinoma (not specified) /carcinoma undifferentiated 66 (11,8%). Other histologies in 9% .

Conclusion: We are a long way from the number of patients declared as potentially enrollable at the feasibility analysis: about one year after all sites were activated almost 1500 patients were expected to be enrolled, but only one third have been enrolled so far. In addition more than half of the report forms are incomplete. AIOCC aims at further supporting AIR to improve data quality and subject's registration.