

Guideline:	<i>Standard operating procedure for minimal data exchange for the Cancer Registry Naples 3 South.</i>
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Dataset Name (acronym):	Cancer Registry Naples 3 South (NA3CR)
Description of the Dataset:	The NA3CR collects clinical data from all individuals newly diagnosed with cancer in their own geographical area of reference. The data in the NA3CR is recorded from the initial diagnosis until healing or death of the patient with biennial follow-ups; (see ENCR recommendation https://encr.eu/sites/default/files/Recommendations/ENC R-Recommendation-standard-dataset_Mar2023.pdf)
Data Type(s):	Registry
EOSC4Cancer Use Case:	T4.1
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A. Purpose

This SOP describes the steps required for cancer registry data from NA3CR to be accessed and used by researchers in the context of the EOSC4Cancer project and beyond. Based on this information, we will define and suggest broader guidelines for data exchange within and beyond the EOSC4Cancer project. Below you will find an overview of the data models, ontology, vocabulary and dictionaries used by the dataset. Furthermore, data access procedures are described step-by-step.

B. List of definitions and abbreviations

Definitions	
CRC	Colorectal cancer
LC	Lung cancer

C. Data Models and ontology, vocabulary, dictionaries

Cancer Registry	Name	Description	References	Is this a standard?	Available conversions for harmonization
Data Models	ICDO-3	<p>DATA SET NA3CR:</p> <ul style="list-style-type: none"> · Gender · Date of birth · Date of death · Postal code · Patient data · Age at diagnosis · Gender · Vital status <p>TUMOR:</p> <ul style="list-style-type: none"> · data incidence: year and month · Basis for diagnosis · Topography · Morphology · Behavior · Stage · TNM - Localisation including sublocalisation metastases <p>Addition in lung tumours*</p> <ul style="list-style-type: none"> · Tumour size · Multifocality · Cytogenetic or molecular abnormalities in the tumour · PDL-1 result <p>Addition in colorectal tumours*</p> <ul style="list-style-type: none"> · Multifocal tumour - Molecular diagnostics (BRAF, RAS, MSI) 	<p>it is possible to consult aggregate data from the cancer register by consulting the site:</p> <p>www.registrotumorinapolisud.it</p>	Yes	
Vocabularies/ Ontology	ICDO-3 Third edition				

Dictionaries/Codebooks	ICDO-3 Third edition				
Formats	csv	Contains parameters that were requested			

D. Description of the data exchange process

Step	Action	Responsible (Name, email)	Link	Estimated time
The data exchange process is guided in Italy by the GDPR - EU- 2016/679 and by the Ministry of Health Decree 1st August 2023 "National Cancer Registry". The entire and complex procedure will make it very difficult to initiate an exchange of non-aggregated data making it impossible to analyze the data outside the Cancer Registry. At the moment the process of transmitting non-aggregated data from the register, but from individual records, is structured in different phases:				
1	Authorization requested from the General Director of the NA3CR for the transmission of data	Researcher		it is not possible to define the times of the entire authorization and data transmission process.
2	Preliminary assessment and authorization by the Data Protection Officer (DPO)	DPO		
3	Subsequent authorization by the General Director and.	Mario Fusco (mariofusco2@virgilio.it)		
4	Stipulation of an ad hoc operational protocol between the General Director of the ASL and the person in charge of the study project in which one is participating	Mario Fusco (mariofusco2@virgilio.it)		

E. Related documents and links

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