

Protocol for updating the cancer registry-based European High Resolution Project

SUMMARY

Background

European High resolution (HR) studies on breast, colorectal, prostate, testis and stomach cancer carried out during the past years demonstrated that at least some European Cancer Registries (CRs) are able to collect clinical information on stage, diagnostic exams, treatment and follow-up, additionally to the routinely collected CR data.

Aims

The **GENERAL AIM of the present HR study**, as in the past, is **to help interpreting differences in cancer outcome and survival** across European populations, using more detailed data on diagnosis, treatment and follow-up than those usually available in the routine activity of cancer registries. Short and medium or long term aims can be envisaged:

Short term aims:

- to analyse patterns of care and adherence to clinical recommendations and internationally agreed guidelines for diagnosis and treatment across countries, regions, or groups of patients.
- to investigate disease-free and short term survival
- to increase the quality of data collected by CRs on stage and morphology, and to better characterize cancers, by means of validated biomarkers
- to test the feasibility of collecting data on co-morbidity potentially influencing cancer prognosis.

Medium and long term aims:

- to update follow-up for life status and relapse, after an adequate length of time since diagnosis. For this purpose, in addition to the usual procedures adopted by CRs to update life status and relapse, the linkage of the HR records with those included in the EUROCARE basic database will be carried out.

Study design and inclusion criteria

In the present HR study, a **“prospective” data collection** is adopted, meaning that cancer cases diagnosed in the latest or current year of registration will be included in the study, in order to facilitate the acquisition of information on care items to the variables usually recorded by cancer registries.

Data collection will **start in January, 2014** and will include the year of incidence the registries are registering in 2014, which for most registries regards **cases diagnosed in one year during 2011-2013**. However, cases incident one or two years before 2011 or incident in 2014 are also suitable.

BREAST, COLORECTAL, and LUNG cancers, SKIN MELANOMA and Non-Hodgkin (follicular and diffuse large B-cell) LYMPHOMA will be included in this study.

In particular, it is required to collect:

Breast: a minimum of **500 adult** (≥ 15 years) **women per registry** diagnosed with in situ (/2) or malignant (/3) breast cancer (ICD-O-3 topography code: C50)

Colorectum: a minimum of **500 adult** (≥ 15 years) cases **per registry** diagnosed with malignant (/3) colon (C18), rectum (C20), rectosigmoid junction (C19) and anus and anal canal (C21) cancers

Lung: a minimum of **500 adult** (≥ 15 years) cases **per registry** diagnosed with malignant (/3) lung (C34) cancer

Skin melanoma: a minimum of **300 adult** (≥ 15 years) cases **per registry** diagnosed with malignant (/3) skin melanoma (C44)

Lymphoid malignancies: a minimum of **200 adult** (≥ 15 years) cases **per registry** diagnosed with follicular (ICD-O-3 morphology codes: 9690-9691, 9695, 9698) and diffuse large B-cell (9678-9680, 9684) lymphoma

among those incident in the chosen year and/or area.

If the minimum number of cases is not recorded during the selected incidence year, the CR should extend its sampling forward/backward in time. However, for diffuse and follicular lymphomas, taking into account cases incident in some small areas covered by cancer registration (< 50 cases/year), at least two complete years of incidence are required.

Variables

Besides **classical HR** data on diagnostic investigations, clinical and pathological stage, bio-molecular tumour characterisation, and type of treatments (including chemotherapy, radiotherapy, targeted therapy and surgery), the feasibility of studying **further factors** potentially influencing prognosis (co-morbidity at diagnosis, body weight, height, body mass index, smoking habits, and performance status) will be also investigated.

The list of cancer specific variables is included in the detailed protocol, divided in mandatory and optional.

Coordination, storage, and confidentiality

The study is **coordinated** by the **Analytical Epidemiology and Health Impact Unit (Dr. Milena Sant)**, by the **Fondazione IRCCS Istituto Nazionale dei Tumori**.

Data will be stored individually and anonymously (individual case identification code – alphanumeric code – will be assigned by each cancer registry, not allowing patient identification by the coordinating centre) in a dedicated server hosted by the Fondazione IRCCS Istituto Nazionale dei Tumori.

Funding

The presently available funds at the Fondazione IRCCS Istituto Nazionale dei Tumori support coordination, quality checks and basic data analyses. At the moment, the considerable amount of work done by the local registries should rely on local national support. However, the possibility of obtaining funds for HR data collection by cancer registry will be also searched for and applications prepared by the coordinating centre in cooperation with cancer registries.

Within the EPAAC project a collaboration has been established between WP8 (optimizing EU research funding) and WP9 (cancer information and data). The HR studies will represent a specific task of a draft pilot project on “outcome research”, to be further developed and submitted to the EU, in the perspective of future funding.