EURACAN REGISTRY GOVERNANCE

The EURACAN Registry provides for a prospective collection of clinical data on rare adult solid cancers with the following objectives:

1. to help describe the natural history of rare adult solid cancers (how rare cancers develop, progress, possible association with other diseases etc.);
2. to evaluate factors that influence prognosis (e.g. mortality, survival, progression-free survival, quality of life - QoL) and treatment response;
3. to evaluate treatment effectiveness (systemic therapy, radiotherapy, surgery, targeted therapy, immunotherapy and possible combination therapies);
4. to evaluate indicators of quality of care (diagnostic and staging procedures, treatment strategies, follow-up etc.).

The EURACAN Registry is a collaboration of EURACAN health care providers (HCPs) and non-EURACAN expert centres or available national registries collecting clinical data on rare adult solid cancers.

STEERING COMMITTEE

In order to ensure the appropriate access and use of the data, the registry will be supervised by a **Steering Committee (SC)**:

COMPOSITION

- EURACAN domain and sub-domain leaders
- Work Package (WP) leaders
- European-Patient Advocacy Group leaders (e-PAGs) from each of the ten domains
- Representatives of national registries contributing data to the EURACAN registry
- EURACAN Registry coordinator (Fondazione IRCCS Istituto Nazionale dei Tumori).

The SC will include every domain leader and ePAG (1 domain leader and 1 ePAG per each domain). One alternate should be identified per domain leader and ePAG. Additional expertise may be brought into the Steering Committee as required.

FUNCTIONS

- To launch, plan, supervise and approve studies and publications based on the registry data
- To ensure adherence to the publication policy and to the guidelines for accessing the registry data
- To plan and endorse modifications of the registry structure (e.g., pathologic classification or staging changes etc.)
- Deliberate on requests of enrollment into the EURACAN Registry from non EURACAN centres or networks linked to it
- Once the registry is fully functioning, to promote the use of the registry data also for international collaborative studies (e.g. with US, Rare Cancers Asia, etc.), in other words ensure that the EURACAN Registry will be **FAIR** (findable, accessible, interoperable, reusable)
- To review the EURACAN registry governance
- To identify opportunities for financial support to maintain the registry.

The SC is chaired by the Registry Coordinator (Annalisa Trama, Fondazione IRCCS Istituto Nazionale dei Tumori [INT]) assisted by a Co-coordinator (Jean-Yves Blay, Centre Léon Bérard [CLB], as EURACAN Coordinator). The SC will meet once a year back-to-back with the EURACAN SC meeting.

The SC is supported in its activities by a dedicated scientific secretariat based at INT (contact: EURACANregistry@istitutotumori.mi.it; +39 02 2390 2901).

DATA ACCESS RULES

1. data remain the property of the contributing HCPs or registries
2. **each HCP or national registry is free to access and use its own data for research purposes**
3. each HCP or national registry including data in the EURACAN Registry can request access to the EURACAN Registry federated database **upon the presentation of a study protocol** that has to be approved by the SC

4. **third parties** (e.g., pharmaceutical companies, patient organisations, competent authorities etc.) can request use of the registry data. However, data should be used for projects that include EURACAN members. Thus, **third parties proposing a research question, should work with a EURACAN Principal Investigator (PI)** and should present **a study protocol** to be reviewed by the SC. If the research question is relevant but does not require a study protocol, a quick review will be provided by the SC and a written report including results of data analyses will be shared with the third party

5. **Commercial companies, depending on the study, may be asked to contribute funding**. **Data do not move from the HCPs or national registries and the commercial companies will not access the EURACAN registry federated database**. Funding will be used to support the registry maintenance and/or specific studies proposed by the EURACAN members and based on the registry data

6. each EURACAN domain will define a domain registry working group (RWG), made up of 3 to 5 members including an ePAG, to review the study protocols presented for the domain. Additional expertise may be brought in as required. The domain leader will chair this RWG and will report to the SC the results of the revision to inform and get SC approval

7. once a study on a specific domain is approved by the SC, the scientific secretariat will inform the relevant HCP or national registry by email requesting to express its willingness to share its data for the approved study. **If an HCP or national registry does not wish to share its data for the approved study, it can opt out from the study. In case, it is expected that it will provide explicit reason.** The HCP or national registry should inform the scientific secretariat within 2 weeks. In the event the HCP or national registry does not confirm whether it wishes to share its data within 2 weeks from the scientific secretariat request**, its data will not be used for the study**

8. the scientific secretariat will contact the national registry coordinator, not each centre contributing to the national registry (e.g. NETSARC, etc). This is in line

with the vision of EURACAN being a network of networks and therefore also a registry network

9. the scientific secretariat will inform the principal investigator (PI) of the proposed study about the SC decision
10. **the PI of the proposed study will be responsible for arranging a preliminary ethical review that will be shared with the participating centres**. The participating centres should provide their institutional ethical review response to the PI within 60 days
11. **the engagement of the EURACAN Registry in international collaborative efforts is highly supported. In this context, the SC is asked to deliberate on collaborative projects** involving the registry. Also, in this case HCPs and national registries will be informed and will be asked to agree or to opt-out of such engagement.

REGISTRY DATA MANAGEMENT AND ANALYSES

Supportive scientific and technical function (**to be identified discussing with domain leaders: each domain should identify at least a statistician to involve and train)?**

Supportive function for ethical and legal aspects: to be confirmed

Data analyses can be carried out by any HCP or national registry contributing to the EURACAN Registry. In the case of studies requested by third parties, a EURACAN member will contribute to oversee the analyses and to interpret the results. The federated database will not be shared with third parties.

FORMAT OF THE STUDY PROTOCOL

The study protocol must include the **names** and affiliations of all the individual **scientists and patients advocates** (*Addario et al. Patient value: Perspectives from the advocacy community. Health Expect 2018; 21(1): 57–63*) **who will be responsible for the study, the analysis and**

interpretation of the data, and who will expect to author any articles derived from the analysis; and a short protocol (1-2 pages), setting out:

1. the rationale for the study
2. the aims of the study
3. the methods of the proposed analysis
4. a detailed description of the registry data items necessary
5. the proposed time schedule for the study
6. the potential target journal
7. type of evidence the study will contribute too

In addition, those responsible for the study are also responsible for including the study in clinicaltrials.gov and the EU clinical trial registry https://www.clinicaltrialsregister.eu/ctr-search/search.

ACCESS TO THE EURACAN REGISTRY PUBLICATIONS

Journal publications based on the EURACAN Registry data must be fully open access. i.e., files of those publications will also be included on the EURACAN registry website in a suitable format. Furthermore, access to publications based on the EURACAN Registry data which are published on the journal website will be fully and freely available to anyone, regardless of whether they have a subscription to that journal or not.

All publications must reference the EURACAN Registry. For EU funding, the sentence to be inserted is the following:"This [insert appropriate description: e.g. report, publication, conference, …] was funded by the European Union's Health Programme (2014 – 2020). GA number 947604"

PUBLICATIONS RULES

Co-authorships on scientific publications emerging from registry data will generally be granted based on the ICMJE criteria (www.icmje.org):

- Substantial contributions to the conception or design of the work; or the acquisition,
- Analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND

- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

"Substantial contributions" by "acquisition of data for the work" will be commensurate to patient enrolment.

For the first 4 publications, the following rule will be followed:

Enrolment activity	Authorship inclusion
>50 % of local rare cancer population OR at least XX patients	in all publications
25-50 % of local rare cancer population OR at least XX patients	in 3 of 4 consecutive publications
10-25 % of local rare cancer population OR at least XX patients	in 2 of 4 consecutive publications
< 10 % of local rare cancer population BUT at least XX patients	in 1 of 4 consecutive publications

These criteria will be applied dynamically according to the number of patients entered at the time of manuscript submission. In addition, the authorship policy document including these criteria will be updated annually, with figures adapted according to the overall enrolment status.

Only one co-authorship per centre will be listed on each publication. It will be the responsibility of the centre to name the contributing scientist that shall be listed as a co-author. The affiliation listed should be the one where the work was carried out at the time of submission article.

Two co-authorships will be accepted from the investigating center which submitted the research request. In addition, any co-worker who has substantial impact on the execution of the study will be considered separately (e.g. statistician, technician, etc.). Patient advocates

(Addario et al. Patient value: Perspectives from the advocacy community. Health Expect 2018; 21(1): 57–63) should also be listed as authors, provided they meet the above criteria.

The PI should be appointed as the first author. The remaining authorship positions will be determined case by case. The sequence of listing of the co-authors will follow the number of all patients entered in the EURACAN Registry.

The chairman of the SC shall refrain from being systematically cited as last author.

The article will be circulated to the SC and centres involved before submission.

GOVERNANCE REVIEW

This document will be reviewed every 3 years and may be subject to change.

VOTING

For the SC decision, any voting will be based on a simple majority provided 50% of the eligible members of the SC are present. In the event of a tie, the Chair of the SC will cast the deciding vote

To amend this EURACAN Registry governance document requires a simple majority agreement of 50% of all the EURACAN Registry members. In the event of a tie, the Chair of the SC will cast the deciding vote.