“SINOPSYS”
Epidemiology of COVID-19 infection in patients with hematological malignancies: A European Haematology Association Survey

Promotor
Prof Livio Pagano, Fondazione Policlinico Universitario A. Gemelli – IRCCS - Università Cattolica del Sacro Cuore, Roma, Italia

Steering Committee
Prof Nikolai Klimko, University of Saint Petersburg, Russia
Prof Anthony Pagliuca, King’s College Hospital London
Prof Martin Hoenigl, University of Graz, Austria
Prof Paolo Corradini, University of Milano, Italia
Dr Alessandro Busca, Ospedale San Giovanni Battista, Torino, Italia
Prof Francesco Passamonti, University of Insubria, Varese, Italia
Dr Philipp Köhler, University Hospital Cologne, Germany
Prof Oliver Cornely, University Hospital Cologne, Germany
To the best of our knowledge, no data are available at present on SARS-CoV-2 infection in patients with HM. However, the COVID-19 pandemic has presented unique challenges and learning opportunities on hematological malignancies. The future trajectory of this pandemic seems to be still uncertain, and hematological communities must continue to prepare for its widespread impact.

In this project, we will implement a cooperation between all hematology department members of EHA in order to assess epidemiological data on incidence and outcome of HM patients infected by SARS-CoV-2. We will provide useful information to inform individualized plan for HM patients.

1. **Primary objective**
   - To assess the epidemiology and outcomes of patients with HM infected of COVID-19 disease

2. **Secondary objectives**
   - To estimate the incidence and type of COVID-19 disease (i.e. symptomatic, asymptomatic).
   - To evaluate admission to ICU
   - To estimate the frequency of pre-existing co-morbidities.
   - To evaluate acute mortality rate (within 30 days from diagnosis of COVID-19)
   - To estimate the rate of overall case-fatality rate.
   - To assess the spatial-geographical patterns of disease.
   - To stratify patients per off-therapy/on-therapy, per type of therapy (chemo, immunotherapy, cell therapy, stem cell transplant)

3. **Overall design**
   This is a multicenter retrospective/prospective, cohort, non-interventional observational study. Researchers from different European countries will be invited to participate in the study. In the retrospective phase of the study, the participating centres will retrospectively review all episodes of COVID-19 disease occurring in HMs identified at their institutions since February 2020. In the prospective phase of the study, investigators will include episodes of COVID-19 disease occurring since the study start up until 31 December 2020.

   The study population will must be older than 18 years of age with HM and SARS-CoV-2 infection. All patients with documented SARS-CoV-2 infection (COVID) and history or active hematological malignancies, who refer to any Hematological Unit will be included.

   Hospitals members of the European Haematology Association (EHA) will be invited to participate.

4. **Inclusion criteria**
   - Age equal to or greater than 18 years of age.
- History of hematological malignancies (acute leukemias, myelodysplastic syndromes, myeloproliferative neoplasms, lymphomas, myeloma, chronic myeloproliferative disorders) at any stage/status.
- Active hematological malignancies at any stage/status.
- Diagnosis of hematological malignancy (acute leukemias, myelodysplastic syndromes, myeloproliferative neoplasms, lymphomas, myeloma, chronic myeloproliferative disorders) at any stage/status.
- SARS-CoV-2 positive test (nasopharyngeal, BAL, fecal), documented by Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panels.

Exclusion criteria

- Hematological diseases, other than hematological malignancies.
- Not tested positive for SARS-CoV-2
- Patients “off therapy” for more than 5 years

5. Data collection
An Electronic-based database with anonymization has been built and available to collect all useful information with single access for each participating Institution. Data collected will be demographics, epidemiological factors, admission information, severity of COVID-19 disease, hematological malignancies history, disease status with past/ongoing treatments, and outcome at 30 days from diagnosis.

6. REFERENCES