# RELIVE

International registry for patients with a relapsed or refractory hepatoblastoma or hepatocellular carcinoma

## RELIVE *flash*

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### RELIVE presentation during virtual SIOPEL Annual Meeting

The Geneva team presented and reviewed the current status of the RELIVE registry during the virtual SIOPEL Annual Meeting on March 18.

Here is where we are in a nutshell: The registry has been activated in Japan, the Netherlands, Poland, Spain, Switzerland, and data of the first 47 patients have been entered into the database. The activation is under way in Australia/New Zealand, Austria, Belgium, Canada, France, Germany, Italy, UK and the US.

During this meeting we also had the pleasure to welcome a representative from the University of Hong Kong who are very interested to join us in this adventure.

Currently, our highest priority is to activate the remaining groups and sites as fast as possible, and to document ~200 HB and ~100 HCC / HC NOS patients. The development of a treatment protocol for relapsed or refractory patients within PHITT 2 remains our ultimate goal.

We are very fortunate to have recruited for the RELIVE registry Dr. Aurore Britan, PhD, at the CANSEARCH research platform in paediatric oncology and haematology of the Geneva University Hospital (HUG). She has developed the REDCap database for RELIVE. Aurore worked for several years in fundamental research at the Faculty of Medicine of the University of Geneva and joined in 2011 the Swiss Institute of Bioinformatics, where she gained expertise in bioinformatics, biocuration and databases of human proteins. After obtaining the Diploma of Continuing Education in Management of Clinical Trials at the University of Geneva, Aurore joined the Clinical Research Centre of HUG in November 2018 as a scientific collaborator, where she was involved in coordinating the deployment of the General Consent for Research within the HUG and its follow-up and in managing clinical studies. She was also part of the Data Management team.

### RELIVE people

#### Dr. Guiomar Gutiérrez Schiaffino, Málaga Regional University Hospital, Spain

I have been a pediatric oncologist at the pediatric oncology unit for the past seven years. In this unit I am one of those responsible for the treatment of pediatric liver tumors, and I am proud to coordinate the RELIVE registry project in our center. I think it is a fantastic way to develop the best treatment of patients with refractory or relapsed disease. Only by working as a team can we find the best treatments for this rare but important disease.

In our center it is my task to coordinate and manage all the information related to such patients. We have been able to identify four patients who fulfill the eligibility criteria, and have successfully entered them into the REDCap database. I appreciate the collaboration.

## Retrospective or prospective data collection?

RELIVE aims to document the success or failure of therapy administered to patients with relapsed or refractory tumours. The success of such treatment can only be judged at a minimum follow-up of one to two years after administration, if the patient is still alive with no evidence of disease (ANED). If the treatment ultimately fails, this can be determined within a few months in case of refractory disease, or at the time point of relapse. In any of these cases, the facts are asserted *retrospectively*.

For patients who are alive as of today, we would also like to know about their status in the near future, say in one to two years. There may also be patients who have an event after activation of the study and may newly qualify for RELIVE. This is a *prospective* point of view.

The issue has implications with respect to the anonymisation of the data. A purely retrospective documentation can be done in a *completely anonymised* fashion. The RELIVE protocol instead plans also a *prospective update* of the data, which means that the patient has to remain identifiable at the local site through the patient identification number (Record ID) issued by the database. This amounts to a *pseudonymisation* of the patient record in the database, meaning that the database does not contain any information which would allow the identification of the patient. The local site however keeps a list of Record IDs and local patient numbers, and can thus make the link between updated information in the local hospital record and the Record ID in the database.

The Ethics Committee in charge of the study may distinguish between the two situations and in one country has actually limited the eligibility to a retrospective data collection. This is not the intent of the protocol, but still allows to register a substantial part of the population with a relapsed or refractory disease.

**Please do not hesitate to get in touch with us if you would like to share your Relive experience or how you are involved in the project.**