RELIVE

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

RELIVE *flash* No.2 - August 2021

Challenges

The RELIVE project is ambitious and poses several challenges to us all. In this edition of the *flash* we address two issues:

1. the definition of the event which leads to the inclusion of a patient into the study, and
2. the correct histological classification.

These issues were raised and discussed in the last conference call of the Steering Committee, who agreed to observe them closely as the study progresses. Thanks to the dedicated work of all involved, the activation of the project in the various countries proceeds steadily.

RELIVE people: Fabienne Toutain

Dear friends,

For several months, I have had the pleasure of being able to exchange by email with you concerning the RELIVE project. I would like to take advantage of this Newsletter to briefly introduce myself to you.

I have been a pediatric hematologist/oncologist for about twenty years, practicing first in France and then in Switzerland at the Geneva University Hospitals in the service headed by Marc Ansari. In this RELIVE registry project, I am the project manager. I am here to help you open the registry on your site and then accompany you throughout the process of registering the data of your patients with a relapsed or refractory hepatoblastoma or hepatocellular carcinoma. Please do not hesitate to contact me if needed at relive@cansearch.ch or fabienne.toutain@hcuge.ch

I hope to meet you in person once this will be possible again, and look forward to collaborate with you on this great project.
Fabienne

Status of activation

The study has now been activated in Cordoba, Spain, and two other sites in the region of Andalusia will join soon. Princes Maxima Centrum in the Netherlands is almost ready, as well as Italy, Poland and France. Preparations are ongoing in Germany, Japan, Belgium, Ireland, Australia/New Zealand and Poland. In the US, a network of sites is being set up around Cincinnati Children's Hospital Medical Center for hepatoblastoma and Dana Farber Cancer Institute for hepatocellular carcinoma. The team in Geneva is actively supporting the preparations in all these countries.

The Steering Committee states...

- **The RELIVE registry aims to include patients with relapsed or progressing disease, but also those with "refractory disease".**

This latter term may seem less obvious because it is not usually used in treatment trials, whereas relapse or PD are commonly used. Section 3.3 of the protocol gives the applicable definition: "In some patients, the tumour may not be eradicated completely by first-line treatment. Patients in this circumstance are considered to have treatment-refractory disease". The point to be taken is that the start of a new line of treatment due to the diagnosis of refractoryness leads to the addition of a new event and the treatment administered.

- **Patients with low AFP are sometimes difficult to classify (HB vs HCC vs HC NOS vs some other histology like rhabdoid tumor) and may need a central review.**

Central collection of histological material in the RELIVE registry is not foreseen in our study because it would add an unnecessary level of complexity. However, the Steering Committee recommends to national PIs/coordinators to make sure that biomaterial from difficult cases should be reviewed on a national level, including in appropriate cases more recent investigations like INI mutation to avoid rhabdoid tumors to be included.