RELIVE

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

RELIVE *flash*

No.3 - December 2021

RELIVE: the first year

One year ago we notified all of you that the RELIVE project was ready to be launched in Europe, Japan, Australia/New Zealand and North America. In the meantime, we have had extensive communications in our effort to go through the various steps of activation required by regulatory authorities, ethics committees and hospital administrations at your institutions. Many details had to be worked out, and mutual understanding and goodwill was essential to make progress. Sometimes unexpected obstacles turned up which required flexibility to reach a mutual understanding. Today we can say that the activation process is still ongoing in many sites, but that obstacles can be overcome. The project has been activated in four countries, and the first patient data have been recorded. We are confident that the next year will allow all interested sites to start their participation. During the SIOPEL meeting planned to be held on March 17/18 in Utrecht, we plan to organise an open RELIVE session bringing together all of you with the aim to meet, exchange and discuss experiences and to strengthen our spirit of collaboration.

In the meantime we encourage you to visit our website and to register if you have not already done so.

RELIVE Website

RELIVE status

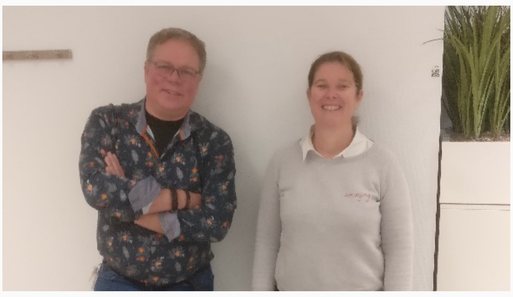
Great news: the first 41 patients have been entered into the database!

Country / site		number of registered patients
Netherlands	Utrecht	34
Spain	Málaga	4
	Sevilla	1
Switzerland	Geneva	1
	Zurich	1
TOTAL		41

The study has been activated in sites in the region of Andalucia, Spain, in The Netherlands, Poland and Switzerland. Sites in Belgium and Italy are almost ready. Activation steps are ongoing in Austria, Australia/New Zealand, France, Ireland, Italy, Japan, the UK, the US and Canada. The team in Geneva is actively supporting the preparations in all these countries.

RELIVE people

Princess Máxima Center, Utrecht, The Netherlands



Kathelijne Kraal

I have been working as a pediatric oncologist for the past 14 years, with a specific interest in neuroblastoma and liver tumor patients. Currently, I am the national PI for RELIVE in our center and my colleague J Zsiros is a member of the steering committee. I enjoy working in the field of liver tumors as a multidisciplinary approach is warranted and there are many challenges remaining, especially in refractory/ relapse patients. We work together with two other pediatric oncologists (J Zsiros and M van Grotel), along with our pathologists, surgeons and radiologists.

Jan Lieverst

I have been working on oncology data for almost 25 years, the last 16 in pediatric oncology. As Program Manager of the Clinical Data for the Máxima Trial and Data Center since 2019, I am responsible for the availability of historical data and data from the Electronic Patient Dossier for Research. Instead of entering data manually, we use the REDcap import facility to feed data from our existing database into the RELIVE database. Together with Kathelijne we curate and complete our data to make the dataset as complete as possible.

Data Protection

During the activation process questions were raised from several sites concerning the issue of correctly protecting data. This is a very sensitive topic and requires careful consideration. Sections 5.2. and 12.5. of the RELIVE protocol describe our data protection rules. A complete anonymisation of patient data is not possible since it would mean that a site cannot identify their patients individually. This is however necessary in case central datamanagement issues a query requiring the site to go back to the patient record, or if the site needs to update a certain patient record. Sites have a list of their patients on which they note the *"record ID"* issued by the electronic data capture system. Neither names nor birth dates nor hospital numbers can be recorded in the database. Accordingly, we call this pseudonymisation.

In addition, an ethics committee raised the question who has access to individual patient records. Section 5.1. of the protocol states that *"The Steering Committee will be able to view all data …"*. The meaning of this statement is that the members of the Steering Committee will receive reports from the statistician with aggregated data like a median, a survival curve, or a contingency table, but not individual patient records.

We take this opportunity to wish you Happy Holidays and a smooth start into 2022!