

The soft power or improvement of the regulatory and cultural environment

KickCancer’s second line of action to improve treatments available to children with cancer is to connect with all the players in the field (doctors, researchers, regulatory authorities, pharmaceutical industry).

Understanding and listing the players’ constraints is crucial to create a more favourable regulatory and cultural environment for a swifter access to innovation for children with cancer. Our goal is to make the system more efficient and not to blame anyone. Our basic assumption is that if it was easy to align everyone to cure paediatric cancers better... it would have happened a long time ago!

Signifiant presence on the European scene to improve regulation

At the European level, KickCancer, within Unite2Cure, actively contributed to the audit process of the European Regulation on Paediatric Medicines (consortium of patient associations from several European countries).

Although this may sound counter-intuitive, the final audit report of the Regulation on Paediatric Medicines left us unsatisfied but also very proud... indeed, even if the amendments of the Regulation we were calling for have not (yet) been enacted, the European Commission, thanks to our significant contribution to the audit, analysed and recognised the specific problems encountered in paediatric oncology. This result is also considered as a huge success by the “specialists” of the sector.

In the wake of this audit report, the European Commission has issued a roadmap with a view to improve the implementation of the Regulation on paediatric medicines as well as to audit a similar regulation, the Orphan Drugs Regulation, in order to understand why there are so few investments in some fields of paediatrics, including oncology. KickCancer and Unite2Cure participate in this new audit.

Thanks to our active contribution to those debates, KickCancer has built a strong credibility as a patient association with the European institutions and pharmaceutical companies. These discussions also allow us to promote cultural changes in the industry’s practices – faster and easier to implement than regulatory changes.

First steps on the Belgian scene

KickCancer is working on several projects in Belgium to make life easier for clinical oncologists and to raise awareness on paediatric cancers.

The first project is linked to what they call in the medicine jargon “off-label” drugs.

When a drug is authorised, this authorisation relates to a specific use: a given disease, a specific formulation (pill, syrup, etc.) and a determined dosage (“on-label”). When a medicine is used outside this specific formulation (for example: according to different dosage or for another disease), the medicine is then used “off-label”. In paediatric oncology, many drugs given to children are prescribed off-label. Their use has been tested through valid clinical trials, and the safety and effectivity of these drugs are demonstrated. Nevertheless, the company that produces those medicines did not ask for an official authorisation for this new indication.

These medicines used off-label however are included in international protocols and are regarded as the “standard of care”: the best care to date for a given type of cancer. A medicine prescribed off-label is not necessarily reimbursed in Belgium. As a result, several drugs listed in paediatric oncology protocols are not reimbursed by the RIZIF/INAMI. Parents must commit to the hospital to pay for these drugs: the stress of finding funds for their child’s treatment adds to the anxiety caused by the disease. This leads to administrative work overload for doctors, social services and the pharmacy of Belgian hospitals, which has no added value for the quality of care for the patients while philanthropic organisations end up dedicating funds to medicine bills to the detriment of other activities.

Unlike Belgium, our neighbouring countries (and several other European countries) reimburse off-label drugs in paediatric oncology.

KickCancer co-wrote an article with the Association of Belgian Paediatric Oncologists, asking for a structural change of regulation in Belgium to allow for the reimbursements of off-label drugs when they are included in an international protocol. First meetings with the cabinet of the Minister of Health already took place. To be continued...

First edition of our RUN TO KICK race – a kicking succes!

On September 30th, 2018, KickCancer organised the first edition of RUN TO KICK, a family charity race. We have gathered 680 runners who collected, all together, nearly 330.000 euros (328.928 euros to be accurate).

It was a beautiful day, the participants ran with a smile on their faces and their joy was as palpable as their emotion. Feeling the presence and commitment of their friends, family and sometimes even colleagues was an unforgettable experience for families who had a child with cancer.

We will organise RUN TO KICK every year... We already have a date for 2019: Sunday September 29th. Cancel your swimming lessons and your brunch with your great-aunt to come and run with us!



KickCancer is growing!

Two stars simultaneously joined our team in June 2018!

Céline Ghins, new administrator. She looks after KickCancer’s journey, for example, by finding suppliers who offer unbeatable prices or by organising a smashing Kids Corner for the RUN TO KICK race. Truth be told, she also manages countless number of tasks for us.

Adeline Godefroid, wonder collaborator. Adeline has supervised the organisation of RUN TO KICK with an outstanding talent without forgetting a single detail so that everything seemed naturally perfect. She also manages the administration of the foundation and participates in our communication activities. How did we manage before her arrival?

We still want to find one young talent to join our team and work on all our political and legal soft power projects – preferably a Dutch-speaking lawyer. If you have a nephew, a cousin or a friend who matches with this profile... contact us and we will send you the job description!

If you no longer wish to receive our newsletter, please let us know at info@kickcancer.org

kick cancer

Winter News



kickcancer.org

Help us to kick and make a difference for kids with cancer by making a donation and amplifying our voice on social media.

To make a donation

Fondation King Baudouin — KiCa Fund
BE10 0000 0000 0404
Communication: 016/1960/00070

All donations from 40 € or more are tax derivable in Belgium.

The Foundation accepts dual legacies and can help you put them in place. More than 85% of your donations will directly fund research or will go to our activities to defend children with cancer, less than 15% will be used for our communication, fundraising, administration and soft power.

Contact us: info@kickcancer.org
www.kickcancer.org

Hello!

KickCancer will soon celebrate its second birthday, Our foundation has firmly settled its activities in the Belgian and European landscapes... The time has come now to share our greatest achievements and plans with you! After all, we are in December, aren’t we? Let’s take this opportunity to send you our season’s greetings and wish you a kicking New Year 2019! Here at KickCancer, no one suffers from the vitamin D deficiency syndrome in the winter: We are hitting the ground until the end of 2018 and we are off to a flying start for 2019. Thank you for giving us wings and we hope that we can count on your support again next year!

A few key metrics

More than 1.5 million euros raised over two years

5 research projects financed for 743.000 euros and a 6th one currently being finalised for 100.000 euros

680 registered runners at RUN TO KICK, who requested the generosity of nearly 4.000 donators

12 articles in the print media, 4 radio broadcasts and 3 television appearances

7 people who contribute as employees, freelances or volunteers to the success of KickCancer (and soon some new recruits)...

Participation in 12 international conferences on research or improvement of access to treatments

KickCancer is pursuing its two-lines strategy in order to improve available treatments for children with cancer: the **financing of research projects** and **soft power** or the creation of dialogue channels with all the players likely to contribute to the improvement of these treatments.

Our research projects

Our first line of actions is to improve treatments for children with cancer by funding research projects. Here is a status update on the progress of 6 projects financed by KickCancer. You can consult the “Projects” tab on our website for more information on each of these.

Data manager: 93.000 euros over 3 years

The data manager allows the EPSSG, the European association of paediatric oncologists specialised in soft tissue sarcoma, to analyse data from a completed clinical trial from new angles and to render the data interoperable with similar US databases. The goal is to validate a new international classification method with uniform risk groups in order to refine and improve patient treatments on the basis of their risk group.

First results: two subgroups of patients have already changed risk category. Specifically, in the new treatment protocol, a first category of children was transferred from the “high risk” to the “standard” risk group, which justifies the use of lighter treatments in the hope of reducing the long-term side effects caused by the treatments. On the other hand, a second category of patients was transferred to a higher risk group and will receive a heavier treatment in the hope of improving their survival chances.

Status and next steps: there will be two interim reports published in April 2019 and 2020; a final report on the projects is expected in the Spring of 2021.

A clinical trial for solid refractory or relapsed tumours: 150.000 euros over 3 years

This innovative clinical trial will test the combination of three classical metronomic chemotherapies with a “PD-1 checkpoint inhibitor” or Nivolumab®. This trial allows children to benefit from immunotherapy.

The clinical trial will take place in six French hospitals and in Belgium, in the university hospital of Ghent; it will be open to patients with a solid tumour who do not respond to standard treatments or who are in relapse.

Latest developments: The project has been approved by the French ethics committee and will start recruiting patients in the French centres before the end of 2018. The trial in Belgium will open in the course of 2019.

Next steps: The trial is structured in two phases; the first one will bring a first batch of results and will end in late 2019- early 2020. A first report will be drafted at the end of this first phase (December 2019 – January 2020) and afterwards, annually. The final results of the trial will be available during the first quarter of 2024, or five years after the opening of the study, which allows for a two whole years of follow-up of the last patient included in the study.

A project to improve our understanding of the resistance mechanisms of high-risks cancers: 200.000 euros over 4 years

In the event of inefficacy of so-called “first-line” standard treatment, the orientation towards new therapeutic approaches and the understanding of the resistance mechanisms must be based on an in-depth analysis of the biological characteristics of the tumour and the analysis of the interactions between the tumour and the patient.

This project aims at allowing a full molecular analysis of the tumour upon diagnosis for the children and adolescents with a high-risk cancer, thanks to advanced technologies, including high-debit sequencing. By analysing blood samples (including the circulating DNA of the tumour cells) during the treatment and follow-up, researchers can then keep track of the modifications of those molecular profiles. The collected molecular information is compared with the clinical results of patients (response or lack of response to treatment) to refine our understanding of the response to treatment.

This project will allow for a better understanding of the avoidance and resistance mechanisms to the standard treatments. In conjunction with other ongoing projects (such as clinical trials), the results of this analysis will enable doctors to swiftly redirect patients towards the best therapeutic strategies.

Status update: The recruitment of the first patients started in April 2018 and to this day, 31 patients were admitted into this trial.

Next steps: A first activity report will be drafted by a team of researchers from the Marie Curie Institute in April 2019 and thereafter, annually. The project will end in 2022.

Two projects ITCC¹: 300.000 euros over 1 year

These two projects were selected in collaboration with the ITCC through an open call for projects.

Status update: both projects started in October 2018 and will last 12 months. The final activity report will be issued in December 2019.

Project on liquid biopsies

For children with rhabdomyosarcoma, assessing response to treatment and whether they remain in remission requires regular imaging such as MRI. In some types of cancer, but not rhabdomyosarcoma, it has been shown to be clinically useful to assess abnormal DNA released from a cancer into the bloodstream. This technique is called “liquid biopsy” and its purpose is to collect cancer cells in the blood as opposed to a sample taken by surgery.

This study aims to validate the usefulness of the concept of correlation between the amount of rhabdomyosarcoma specific DNA found in the blood and the quality of the response of said patients to their treatment. In practice, if the correlation is confirmed, patients could be followed with simple blood tests instead of MRIs (which requires anaesthesia for younger patients). Doctors will also be able to reorient the patient more quickly towards a new therapeutic strategy when those patients do not respond to treatment or relapse.

A better cure for an incurable brain tumour

Brain tumours are the main causes of mortality and morbidity of children, adolescents and young adults. Gliomas are the most frequent and the most fatal kind, among which the diffuse intrinsic pontic gliomas (or DIPG) represents the most severe form, universally incurable with hardly any patients surviving more than 2 years after the diagnosis.

This project will characterise these two sub-groups of DIPG by scrutinising their differences at the epigenetic level. Epigenetics study the expression or regulation of the genes: it focuses on the sequences of the gene and analyses which are activated, and which are not (this activation makes it possible to explain why cells provided with the same DNA fulfil different functions in our body). These results will allow to contemplate different targeted treatments for each sub-group, despite the fact that they present the same genetic mutation.

A coordination unit for clinical trials in Belgium: 100.000 euros per year

Most clinical trials² are coordinated at a European level in paediatric oncology; however, each participating country must have the clinical trial approved at its own national level and for so-called “academic” trials (which are not funded by a pharmaceutical company), seek its own funding.

The Belgian Paediatric Oncology Association (BSPHO³) currently does not have enough internal resources to sustainably support its efforts to participate in all European clinical trials. KickCancer is committed to allocating the first € 100.000 raised each year during the RUN TO KICK race to finance the first stones of this coordination cell.

The aim of this cell is to enable the Belgian centres to coordinate their research activities in order to make them more effective and improve the care provided to Belgian patients.

First steps: In conjunction with the King Baudouin Foundation, KickCancer will provide BSPHO with necessary resources to enable physicians to prepare their clinical trial files without encroaching on their clinical or research time.

Long-term development: In the longer run, KickCancer wants to convince other Belgian institutions to finance this coordination cell. The expansion will provide Belgian paediatric oncology centres with a structural and coordinated support for setting up and funding their clinical trials. The underlying vision, naturally, is to improve the therapeutic offer in Belgium for children with cancer.

¹ L’ITCC (Innovative Treatments for Children with Cancer) is a network of European hospitals with specialized services in pediatric oncology and equipped to set up clinical trials in the early phase with innovative molecules.

² All those organized in Belgium — only big countries such as France, Germany, etc. have sufficient own recruitment capacity to organize a clinical trial at a purely national level.

³ Belgian Association for Pediatric Haemato-Oncology