



1. WZ2019 – 2024 medicamentos innovadores asequibles para niños con cáncer y otras enfermedades que amenazan la vida.

La falta de innovación terapéutica es una de las razones principales del fracaso para mejorar las tasas de curación de los cánceres infantiles difíciles de tratar y continúa provocando efectos secundarios adversos a largo plazo en supervivientes. El Reglamento Pediátrico^v y el de Medicamentos Huérfanos^{vi} de la UE no han sido eficaces para impulsar el desarrollo de nuevos fármacos anticancerosos para niños.

La evaluación de los pocos medicamentos nuevos contra el cáncer en el mercado sigue el mismo proceso para los niños que para los adultos. El Parlamento Europeo votó una resolución sobre el Reglamento Pediátrico de la UE en diciembre de 2016^{vii}. A partir de 2019, la Comisión Europea considerará un curso de acción basado en la evaluación de los Reglamentos Pediátrico y de Medicamentos Huérfanos, así como los mecanismos de incentivos actualmente en vigor.

Acción: Los MPE deben solicitar los cambios normativos necesarios en referencia a la Resolución del Parlamento Europeo de dic. 2016 y la evidencia reciente proporcionada por las plataformas cooperativas de las partes interesadas en el desarrollo de medicamentos en oncología pediátrica^{viii}.



2. Foster allocation of resources to childhood cancer research with focus on big data and deep learning tools

The vast majority of innovative therapies in paediatric oncology have been developed in cross-border academic-driven research. In the face of rapid developments in immunotherapy and precision medicine, the focus is increasingly on big data. Improving researchers' access to and the sharing of biological, pathological and clinical data becomes urgent to foster further therapeutic innovation for childhood cancer. Public funding is needed to generate, make available and enable the analysis of big data in paediatric oncology, such as by using artificial intelligence.

Action: MEPs to call for the EU Programme for research and innovation to enable stable and sustainable international research platforms, including for digital research, which can lead to a visionary change for children and adolescents with cancer and contribute to significant knowledge advancement in basic science.



3. Ensure sustainability of the European Reference Networks (ERNs), of which ERN PaedCan is dedicated to paediatric cancer, in particular to combat inequalities in access to the best available treatment and expertise for children across Europe

The quality and availability of paediatric cancer care varies across Europe: an estimated 10% to 20% of cancer-related deaths occur due to lack of access to the specialist care or expertise that children with cancer require. Stemming from the EU Cross-Border Healthcare Directive, the European Reference Network for Paediatric Oncology (ERN PaedCan) has been established to reduce inequalities in childhood cancer survival by providing high-quality, accessible and cost-effective cross-border healthcare.

Action: MEPs to call for allocation of non-competitive funding to secure sustainability of the ERN model, including twinning, EU Clinical Patient Management System (CPMS), cross-border virtual advice, clinical guideline development, and continued parent/survivor involvement in building/improving the ERN Network.



4. Support collaborative efforts on the development and implementation of appropriate surveillance guidelines and long-term models of care for survivors of childhood cancer

There are currently approximately 300,000 - 500,000 long-term survivors of childhood cancer in Europe and this number increases over time. At least two-thirds of this population experience long-term physical and mental health problems as well as psychosocial difficulties that hinder their well-being and participation in society and the economy. The relative rarity of individual paediatric cancer types and their associated long-term side effects magnifies the critical importance of the European dimension to enable a smooth transition for childhood cancer survivors into a productive and healthier adulthood.

Action: Call for EU support to collaborative approaches to further define, disseminate and enable:

- Standardised surveillance guidelines for late-occurring side effects of childhood cancers
- Organised health care transition (paediatric to adult) as a standard of care across Europe
- Survivorship follow-up care plans & inter-operable IT tools to apply them cross-border



5. Support initiatives on interoperability, harmonisation and security of eHealth platforms to foster cross-border research and knowledge transfer for the benefit of childhood cancer patients and survivors

Fostering interconnection in Europe is the only way to arrive at a sustainable base for future joint data analysis and research in childhood cancers as well as to enable the travel of expertise to all parts of Europe. Many areas of health ICT innovation require greater capacity – both trained workforce and analytical platforms. Successful approaches are about taking into account all perspectives via a reinforced collaboration among stakeholders in order to successfully balance individual data privacy and the need for progress in research and care.

Action: Support the vision on Digital Transformation of Health and Care in the Digital Single Market across its three priorities: Citizens' secure access to their health data, including across borders, precision medicine through shared European data infrastructure and citizen empowerment with digital tools for user feedback and person-centred care.



6. Support initiatives that foster and promote patient advocacy and empowerment in research, healthcare, and socio-economic areas.

Patient, parent and survivor empowerment should go hand in hand with actions to improve cooperation on research and healthcare across Europe. For this, patient advocates should be encouraged to participate in these initiatives and helped to acquire the tools and skills to become educated and informed. Patient empowerment also calls for socio-economic provisions such as extended paid leave for parents when taking care of a sick child and equal rights in access to financial services for survivors of childhood cancer.

Action: Support the vision of collaboration with all stakeholders on initiatives in research and healthcare by promoting patient, parent and survivor empowerment, with consideration for the socio-economic dimension.

THROUGHOUT

Proactively monitor EU legislative processes to integrate the health, research and socio-economic needs of the paediatric haematology oncology community into new initiatives.

Individual types of cancer in children and adolescents are rare, but taken together they represent a leading public health and socio-economic issue in Europe. Patients and affected families stand to gain considerably from pan-European cooperation on research and healthcare as a result of the disease's rarity at the national level combined with its important shared burden across Europe. Ensuring equal rights and adequate social protection for parents, patients and survivors is an important underlying priority.

**THE EUROPEAN PAEDIATRIC ONCOLOGY COMMUNITY COUNTS ON YOU
TO BEAT CHILDHOOD CANCER AND ACHIEVE MORE AND BETTER CURES,
TOWARDS ZERO DEATHS & ZERO LATE EFFECTS**

Embargoed until 06.05.19

About SIOP Europe



The European Society for Paediatric Oncology (SIOP Europe or SIOPE) is the only pan-European organisation representing all professionals working in the field of childhood cancers. With more than 1,850 members across 35 countries, SIOP Europe is leading the way to ensure the best possible care and outcomes for all children and adolescents with cancer in Europe. The SIOPE Strategic Plan 'A European Cancer Plan for Children and Adolescents' includes specific objectives and implementation platforms to achieve this mission. Learn more: www.siope.eu and follow us on [Twitter](#), [LinkedIn](#) & [Facebook](#).

About Childhood Cancer International – Europe



Childhood Cancer International - Europe (CCI-E) represents childhood cancer parents' and survivors' groups as well as other childhood cancer organisations in Europe. More precisely, 67 organizations in 33 European countries are members of CCI. CCI Europe works together with all relevant stakeholders for the same aim, namely to help children and adolescents with cancer to be cured, with no - or as few as possible - long term health problems / late effects. Therefore CCI Europe is engaging in advocacy for affordable drugs, better treatment modalities and financial / psychosocial support of the patients and their families, providing numerous opportunities for members to meet and share information, experiences and knowledge with other members, raising awareness about childhood cancer in the public for better support of children and adolescents with cancer and survivors, providing education and information about the disease, its treatment and survivorship, understanding the causes of paediatric cancer and promoting prevention attitudes and health lifestyle wherever possible as well as providing assistance and guidance in establishing new childhood cancer groups in Europe.

ⁱ Globocan 2018 (<http://gco.iarc.fr>)

ⁱⁱ idem source ⁱ

ⁱⁱⁱ Hjorth, L, Haupt L, Skinner R, et al. Survivorship after childhood cancer: PanCare: A European Network to promote optimal long-term care. European Journal of Cancer 2015, Volume 51, Issue 10, 1203 – 1211 <https://www.sciencedirect.com/science/article/pii/S0959804915003068>

^{iv} Gatta G, Botta L, Rossi S, et al. EURO CARE Working Group. Childhood cancer survival in Europe 1999-2007: results of EURO CARE-5--a population-based study. Lancet Oncol. 2014 Jan;15(1):35-47. Erratum in: Lancet Oncol. 2014 Feb;15(2): e52 [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(13\)70548-5/fulltext](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(13)70548-5/fulltext)

^v Position statement: Paediatric Cancer Medicines - Urgent need to speed up life-saving innovation: https://www.siope.eu/wp-content/uploads/2013/06/1.-Paediatric_Reg_Position_paper.pdf

^{vi} Vassal, Gilles et al. Orphan Drug Regulation: A missed opportunity for children and adolescents with cancer, European Journal of Cancer , Volume 84 , 149 – 158

^{vii} European Parliament resolution of 15 December 2016 on the regulation on paediatric medicines (2016/2902(RSP))

^{viii} ACCELERATE Platform: <https://www.accelerate-platform.eu>

Vassal Gilles et al. Creating a unique, multi-stakeholder Paediatric Oncology Platform to improve drug development for children and adolescents with cancer. Eur J Cancer. 2015 Jan; 51: 218-224. <https://www.ejancer.com/article/S0959-8049%2814%2901065-X/fulltext?code=ejc-site>