# The childhood cancer community calls for a pragmatic approach to trial governance in Europe

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We call for:

- **FAIR and proportionate risk categorisation of childhood cancer trials**
- **FAIR insurance for academic trials treating children with rare diseases**
- **FAIR and proportionate transparency measures**

**SIOP Europe**, the **European Society for Paediatric Oncology (SIOPE),** representing the paediatric and adolescent oncological clinical research community across Europe, welcomes the proposal by the European Commission for an **EU Clinical Trials Regulation**, which encapsulates changes that will address many of the limitations of the EU Clinical Trials Directive (2001/20/EC).
**Clinical trials have been instrumental in improving cure rates for young patients with cancer**. Now, **80%** of childhood cancer patients survive this life-threatening disease. Cure rates have increased dramatically since the 1960s, when only about 10-20% of patients survived.
This was possible thanks to the **successful collaboration** between scientific experts and by harmonising the treatment patients receive when participating to **academic clinical trials.**

The most successful way to cure children with cancer is **optimising treatments based on existing, well-established, standard chemotherapy drugs**. These drugs are **'off-label'**, in other words only manufactured for adults. Off-label drugs have been tried and tested for many years as standard practice, and have been proved to **save the lives of children and adolescents with cancer**.

Even though off-label drugs have been used successfully for over **forty years**, there is a **hugely burdensome, unjustified** level of regulation inflicted on the academic community entertaining clinical trials. If all drugs were licensed to be used for paediatric cancer, **this intense level of reporting could change**.

**Academic clinical trials have so far provided reliable, successful solutions to save children lives.**

***The EU Clinical Trials Regulation offers an opportunity for the policy makers to support the academic community to streamlining clinical trials development, ensuring less red tape faces researchers. This will lead to an increase in the time spent on optimising treatments and care of children and adolescents with cancer and therefore improving their quality-of-life.***


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