



93 NEWMAN STREET
LONDON
W1T 3EZ
T 020 7612 0370
F 020 7612 0371
www.teenagecancertrust.org

**Response to European Commission Concept Paper
on Commission Guidelines on the format and
content of applications for paediatric investigation
plans**

Contact: Sasha Daly, Head of Policy, Teenage Cancer
Trust, sasha.daly@teenagecancertrust.org

Introduction

Teenage Cancer Trust believes young people's lives shouldn't stop because they have cancer, so we treat them as young people first, cancer patients second.

We exist to improve the quality of life and chances of survival for the six young people aged between 13 and 24 diagnosed with cancer every day in the UK. We want to make sure every one of them has access to the best possible care and professional support from the point of diagnosis.

We fund and develop specialist units within UK NHS hospitals that bring young people together to be treated by teenage cancer experts in an environment tailored to meet their needs. Through education of young people about cancer and working with health professionals to improve their knowledge, we work to significantly improve their diagnosis experience. And through our own research and working with our partners in the NHS, across the UK governments and organisations both nationally and internationally, we strive to improve survival rates.

Accessing clinical trials for teenagers and young adults with cancer

Effective treatment for teenagers and young adults may differ from what works best for children or adults because of the different cancer biology, different treatment protocols and different response to treatment. This is why it's important that research is developed that will apply and trialled with the cancers common in young people.

Less than 20% of cancer patients aged 15-24 are currently getting access to clinical trials in the UK, compared with around 50-70% of children, and which may explain some of the difference in comparative five year survival.¹

There is also a substantial fall in accrual to clinical trials from age 14 onwards, and in a test period from 2005 – 2007 clinical trials didn't exist for some of the commonest cancers in this age group; for example there were no clinical trials for patients aged 0-17 with Hodgkin's Lymphoma.

Accrual rates are also particularly low in bone cancers and CNS tumours², which are also two of the cancer types where five year survival rates have the biggest proportional impact on teenagers and young adults.

In a set of meetings we've helped to host in the UK it has been agreed that there are often arbitrary age barriers set on clinical trials which restrict access to young people with cancer under the age of 18. However, if new drug trials were considered on the basis of their mechanism of action it would be possible for more trials to be opened to young people with cancer.

Changes to paediatric investigation plans

It has been identified that waivers allowed in the system of paediatric investigation plans (PIPs) means that drugs being developed for specified adult cancers are not opened to be trialled on cancers in young people because of waivers in these cases.

Vassal, G. et al, paper (2013) 'Is the European paediatric medicine regulation working for children and adolescents with cancer?' found that out of 26 new oncology drugs potentially relevant for paediatric malignancies, 14 were waived because the adult condition does not occur in children. We fully support the position of the Institute of Cancer Research who are leading this work.

It is unacceptable that potentially new life saving treatments are being blocked in a system which should be helping to improve paediatric research development. We call on the European Commission to take action swiftly to address this loop hole in the system which is letting down young people with cancer.

¹ Cancer Research UK (2013), *Cancer Stats Report: Teenage and young adult cancer*

² Whelan and Fern, Poor rates of accrual of teenagers and young adults into clinical trials in the UK, *Lancet Oncology* (2008) 9 (4), 306-307