

EU/ICH Guidelines Coordinator
Office of Medicines Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
euguidelines@tga.gov.au

4th February 2020

Dear Sir/Madam

Re: Proposal to adopt the Food and Drug Administration Guidance: Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials (March 2019)

Canteen wishes to respond to the invitation outlined on the Therapeutic Goods Administration (TGA) website on 18 December 2019 with the proposed adoption of the guideline named above dated March 2019. We thank the TGA for the opportunity to respond to this consultation. Our submission has been prepared with the support and endorsement of Canteen's Youth Cancer Service Clinical Trials Expert Advisory Group, comprising senior leaders in the Australian clinical trials sector (Appendix 1).

The principal activity of Canteen is the nation-wide support, development and empowerment of young people impacted by cancer aged between 12 and 25 years in Australia. A partnership with the Commonwealth and State Governments has allowed the delivery of a national network of state-wide youth cancer services which provide specialist treatment and support for young cancer patients across Australia. Approximately 75% of newly diagnosed patients requiring hospital care are seen by Youth Cancer Services.

Canteen strongly supports equity of access to clinical trials and novel therapeutics for the full spectrum of the Adolescent and Young Adult (AYA) population and therefore is strongly supportive of the TGA proposal in the adoption of these FDA guidelines. Clinical trials access is highly relevant as low levels of clinical trial participation in this age group has been a strong contributor to the lagging survival improvement identified. It should also be noted that the exclusion of adolescents from adult clinical trials in many instances has not been based on scientific evidence, rather an arbitrary decision by the pharmaceutical industry and other

research bodies. Adoption of these guidelines will provide stimulus to the pharmaceutical industry for the inclusion of adolescent patients aged under 18 in disease and target-appropriate adult oncology trials and enables equitable access to potentially lifesaving therapeutic options for this population.

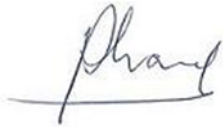
Promoting clinical trial participation for young Australians has been a long-standing aim of Canteen. Complementing the Youth Cancer Services program, Canteen has established the MRFF funded *Australian Young Cancer Patient Clinical Trials Initiative*. The key aim of this initiative is to stimulate and support clinical research activity and provide greater access to innovative clinical trials for AYAs with cancer, prioritising trials that address AYA cancers with low survival rates and strategies that will improve trial participation rates for young cancer patients across paediatric and adult settings. The funded trials are largely co-operative sponsored studies with industry in-kind support. Canteen is aware that industry funded clinical trials present additional barriers for AYA, largely around the strict age eligibility criteria and often does not align with incidence of particular cancers which transcend the age spectrum. Canteen sees a pressing need to address this barrier to enable equity of access for the full spectrum of AYA's including 12-17 year old patients in disease and target appropriate adult oncology industry funded trials.

The reasons behind the importance of improving clinical trial access for AYA cannot be overstated; around half of the cancer types that affect young people still have 5-year survival rates below 77%. In addition, patients enrolled in clinical trials tend to have better outcomes in terms of quality-of-life and survival,. In 2017, there were 306 AYA diagnosed with cancer in Victoria but only 27 were enrolled onto a clinical trial. While the proportion of AYA cancer patients enrolled in clinical trials is currently not known for Australia, we suspect that the situation is similar to the UK where enrolment of AYAs aged 15–29 years is lower than that of children aged under 15 years. Young people in the 15-25 age group are often caught between being too old to access paediatric trials, but too young for adult trials, even though that may be the best therapeutic option for their cancer treatment.

Canteen believes there is an urgent need to remove all barriers which are preventing AYA accessing clinical trials and ensure equity of access for the full AYA age spectrum. We strongly support the TGA adoption of the guidelines contained in the March 2019 FDA document *Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials* and believe that such an adoption will lead to life-saving treatments being offered to young Australians with cancer and promote vital treatment advances for this population.

Should you require any further comment from Canteen, please contact Dr Pandora Patterson, General Manager, Research and Youth Cancer Services on 0413 431 078 or Pandora.Patterson@canteen.org.au.

Yours sincerely,



Peter Orchard
Chief Executive Officer
CanTeen Australia

APPENDIX 1

Canteen Youth Cancer Service Clinical Trials Expert Advisory Group Membership

Prof David Thomas (Chair)

Prof Ian Olver

Prof John Simes

Dr Michael Osborn

Mr Joey Lynch

Mr Kieran Schneemann

Prof John Zalcborg

Canteen representation:

Mr Peter Orchard

A/Prof Pandora Patterson