

Barriers to early clinical trial access for adolescents and young adults still exist

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Young cancer patients at the crossroads of childhood and adulthood seem to be stuck in a treatment impasse. A study to be presented at the ESMO 2018 Congress in Munich, has highlighted the existence of barriers to the inclusion of 12 to 25-year-olds in both adult and paediatric early phase clinical trials, suggesting a need for more tailored approaches to give this patient population better access to therapeutic innovation.

In Europe, the legal minimum age to participate in adult [clinical trials](#) is almost universally 18 years. "We know, however, that certain girls will develop genetically driven breast cancers very early in life: there are no paediatric trials for this disease, yet these [patients](#) are systematically barred from participating in the relevant adult trials. The situation is similar for some adolescents with lymphomas or sarcomas, whose tumours often resemble those of [adults](#) much more closely than those found in children," said study author Dr. Aurore Vozy, from Gustave Roussy Institut de Cancérologie in Villejuif, France.

In rare cases, adults in their early twenties are also diagnosed with tumours most commonly seen in children. Paediatric clinical trials, meanwhile, typically set an upper age limit of 18 or 21 years.

To assess the availability and accessibility of new treatments to young cancer patients, a review was conducted of all phase I and phase II trials opened at Gustave Roussy between 2012 and 2017 for solid tumours or lymphomas. Over a six-year period, 465 trials were open, but only 65 included teenagers between 12 and 17 years of age. "In other words, patients in this age group had access to less than 15% of all the early phase trials at our institute," Vozy noted.

Among the 389 trials that were not open to adolescents, it was found that 55% could have been relevant for underage patients—28 trials targeted tumour types that are particularly common

among teenagers. "This means that patients have been denied access to innovative medicines which were available at the very centre where they were being treated, and to which they may have had a better response than to conventional therapy," said Vozy.

Out of 62 paediatric trials open at the centre over the same period, over half did not recruit patients between 19 and 25 years old—even though 10 of these trials targeted cohorts of tumour types that also occur in this age group. "Raising the age bar in paediatric trials to 25 years would clearly make sense in certain cases," Vozy observed.

She argued, however, that the more pressing issue is the current age limit in adult trials: "We know that the diseases, toxicities and pharmacology seen in 12 to 17-year-olds are similar to what we find in adults, so it would be feasible to include these patients in adult trials at no additional risk to them." This has already been done successfully in the USA, where the minimum age for trial participation has been lowered to 12 years.

An additional measure to consider, Vozy underlined, is creating dedicated trial cohorts for adolescents within adult trials: "In a context where, today, most phase I trials in oncology are launched with multiple study populations for different tumour types, it would be easy to cater to the specific needs of adolescents by including them in cohorts of their own," she explained. "The main constraint is that trials which include underage patients should only be conducted in centres that also have paediatric services onsite: adolescents may be affected by disease similarly to adults, but they still need to be treated and followed up on by paediatric specialists."

Dr. Giannis Mountzios, ESMO Chair of the joint ESMO/SIOPE Working Group on Cancer in Adolescents and Young Adults (AYA), commented: "The report presented by this group of researchers

is a testament to their scientific rigour, providing objective data that was direly needed on this very critical issue. It shows that even at a highly specialised cancer centre like Gustave Roussy, these arbitrary age limits, which have no medical or scientific basis, are widely used and prevent young patients from accessing clinical trials that target their tumour type. The situation is certainly even worse in centres that don't have the same expertise and dedicated services for adolescents and young adults. This is why ESMO created the Cancer in AYA Working Group together with the European Society of Paediatric Oncology in 2016, through which we aim to raise awareness and influence authorities and stakeholders to stop imposing these barriers."

"I am happy to report that we are now starting to see clinical trials open for specific tumour types across several age groups: the recent approval, in both the USA and Europe, of CAR T-Cell therapy for leukaemia and certain types of lymphoma in children and young adults up to 25 years has been a big breakthrough in this regard. However, this is just the starting point of what should be a concerted effort to look at and devise appropriate care strategies for all the patient sub-groups—including women, the elderly and patients with particular medical conditions—that are chronically underrepresented in clinical [trials](#)," Mountzios stated.

More information: Abstract 424P_PR 'Inclusion of adolescents in adult early phase trials and young adults in paediatric early phase trials: a reality or a myth?' will be presented by Aurore Vozy during Poster Display Session on Monday, 22 October 2018, 12:45 to 13:45 (CEST) in the Poster Area Networking Hub - Hall A3. *Annals of Oncology*, Volume 29 Supplement 8 October 2018

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