



## **MEDIA RELEASE: Three clinical trials awarded STAMP for inclusive approach**

Three clinical trials in oncology have been awarded the FAIR for AYA STAMP, a new accolade that credits medical research which actively avoids unnecessary barriers based on age. It is hoped that the STAMP will encourage other researchers to follow the lead set by these three research teams in offering opportunities for adolescents and young adults to participate in trials

The three laureates are:

- ELI LILLY/LOXO ONCOLOGY: LIBRETTO-001 (Phase I –II): ‘A Phase 1/2 Study of Oral LOXO-292 in Patients with Advanced Solid Tumors, Including RET Fusion-Positive Solid Tumors, Medullary Thyroid Cancer, and Other Tumors with RET Activation (LIBRETTO-001)’
- ELI LILLY AND COMPANY: LIBRETTO-531 (Phase III): ‘A Multicenter, Randomized, Open-label, Phase 3 Trial Comparing Selpercatinib to Physicians Choice of Cabozantinib or Vandetanib in Patients with Progressive, Advanced, Kinase Inhibitor Naïve, RET-Mutant Medullary Thyroid Cancer (LIBRETTO-531)’
- ROCHE: TAPISTRY (Phase II): ‘Tumor-agnostic precision immuno-oncology and somatic targeting rational for you (TAPISTRY) phase II platform trial’

The awards were announced at the 2021 ACCELERATE Paediatric Oncology Conference, where all three trials were acknowledged as excellent examples of how young people can be included in research, both to their benefit and that of the overall trial process.

Applications are now open for the next round of awards and details of how to take part can be found here:

<https://www.accelerate-platform.org/fair-trials/fair-trials-resources/fair-aya-stamp/>

## Benefits

The full title of the award is the *Fostering Age Inclusive Research for Adolescents and Young Adults STAMP* and it can be used to publicise excellence in a number of ways. The award can feature on trial protocols, clinical trial applications or other associated documents, as well as academic publications. Trials which have received the STAMP will appear on the ACCELERATE website and may be used in other ACCELERATE media as exemplars for the research community.

## Limitations

The scheme does not provide an overall scientific review of the trial. It only evaluates the study design elements that relate to age inclusivity. It refers specifically to a particular trial, not the organisations or individuals involved or any other activities in which they are engaged.

**Chris Copland, parent representative,** says: *“Clinical trials offer hope that one day we may save the thousands of young lives we lose to cancer every year in Europe alone. However, many trials currently exclude patients under eighteen, though this age limit bears little relation to science, safety or compassion.*

*“We must change this situation as fast as we can. Our FAIR Trials Initiative is a major step in the right direction.”*

**Dr Nathalie Gaspar, a paediatric oncologist from the Gustave Roussy in Paris,** says: *“My main fear is missing an opportunity to cure a young person, or at the very least being able to extend their young lives. It is utterly unbearable to tell a teenager, just because they are under 18, that they cannot access a trial, which may offer their last bit of hope.*

*“The industry is united in recognising that this 18-year age limit is an artificial one and with no clinical evidence behind it. We now have to work hard to ensure that the practice is changed.”*

**Professor Pamela Kearns,** (University of Birmingham, Cancer Research UK Clinical Trials Unit in the United Kingdom) and SIOE Europe President, says: ‘It is my hope that age limits won’t be the barrier in the future. It’s about the biology of the drug and the needs of the patient, that’s where the future of clinical trials needs to be.’

Paediatric oncologists and parents are available for press/broadcast interviews to provide further details on this issue. Please contact: [Carole.Lecinse@gustaveroussy.fr](mailto:Carole.Lecinse@gustaveroussy.fr)

### 'Fostering Age Inclusive Research' (FAIR) Trials Initiative Group

Research into teenage and young adults’ cancer has made slower progress than for any other age group. One reason is that many clinical trials exclude patients under 18, without medical justification. To confront this problem, 'Fostering Age Inclusive Research' (FAIR) Trials Initiative Group was established in 2017 by the ACCELERATE platform. Made up of 15 experts

from Academia, Industry and Patients/Parents advocacy, the group aims to raise awareness and promote changes. You can find out about the group's work and what you can do to help [here](#).

[www.accelerate-platform.org/fair-trials](http://www.accelerate-platform.org/fair-trials) | [contact@accelerate-platform.org](mailto:contact@accelerate-platform.org) | T: +32 2 880 62

85

**Twitter:** @ACCELERATE\_cure | #FAIRtrials / #ACCELERATEcure

#### NOTE TO EDITORS

- In Europe and North America respectively, more than 46 000 and 29 000 adolescents and young people (aged 15 to 24) are diagnosed with cancer every year [\[1\]](#)
- In Europe and North America respectively, more than 6 000 and 3 000 adolescents and young people (aged 15 to 24) die of cancer each year [1](#)
- Several cancers in adolescents and young adults have dismal prognosis (metastatic form and some histological types) with few chances of cure and improvement over the years [\[2\]](#)
- 80% are disease-free after 5 years from diagnosis, thanks to currently available multidisciplinary treatments and good histology cancer incidence in adolescents and young adults [\[3\]](#)
- Two-thirds of survivors experience long-term side effects of treatment, which are severe and impact on the daily life of half of those affected [3](#)
- Beyond 5 years from diagnosis, disease-free survivors of a cancer occurring at adolescence and young adulthood have higher mortality rates than their non-affected peers [\[4\]](#)

---

[\[1\]](#) Global Cancer Observatory, Globocan 2018 (<http://gco.iarc.fr>)

[\[2\]](#) Survival of European adolescents and young adults diagnosed with cancer in 2000–07: population-based data from EURO CARE-5. Annalisa Trama, Laura Botta, Roberto Foschi, Andrea Ferrari, Charles Stiller, Emmanuel Desandes, Milena Maria Maule, Franco Merletti, Gemma Gatta, and the EURO CARE-5 Working Group\*. DOI:10.1016/S1470-2045(16)00162-5

[3] Late Morbidity Leading to Hospitalization Among 5-year Survivors of Young Adult Cancer: A Report of the Childhood, Adolescent and Young Adult Cancer Survivors Research Program. Zhang et al. *International Journal of Cancer*, 2014

[4] Robison, et al. *Nature review cancer*, 2014