

FAIR Trials

Fostering **A**ge **I**nclusive **R**esearch

Chris Copland



**Sarcoma
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ACCELERATE

INNOVATION FOR CHILDREN AND ADOLESCENTS WITH CANCER



Chloe's story

Cancer's lost generation: the teens and young adults 'forgotten in the middle'
While overall cancer survival rates have improved, young people fare less well – and their symptoms are often dismissed

Hannah Partos
The Guardian, Sunday 15 December 2013 20.00 GMT
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Mother of 18-year-old cancer victim says drug trials must admit more teenagers
11 July 2013



[Recall](#)

Patient to have clean

Cyclist London segre

Cyclist £100,000 road injury

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Ability makes patient enjoy

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THE BIGGER PICTURE

Many more young people are excluded from clinical trials - without medical justification.

“ Only six of 49 studies of cancers common in teenagers and young adults had age eligibility criteria... appropriate for the biological age range of the diseases.”

(Fern and Whelan, 2014)



Hodgkin's lymphoma occurs in children, teenagers and young adults.

A new drug* was approved *for adults* in 2012 in Europe.

The paediatric trial (i.e. for those ≤ 18 years) was still on-going in 2016 .

***Brentuximab vedotin**

GHOST trials

A new drug* for the treatment of melanoma, was approved for adults in 2012.

The trial for patients aged 12- 18 opened in 2011 in 10 countries and 4 continents.

As of December 2015, only 6 patients had been recruited.

***Vemurafenib**

ACCELERATE proposals

INNOVATION FOR CHILDREN AND ADOLESCENTS WITH CANCER

- Age of trial entry reduced to 12 yrs. in adult early phase studies (where medically justified)
- Adolescents treated in an age-appropriate setting

Still included in paediatric or TYA trials where relevant.



proposals

Gaspar has demonstrated that these are:

- safe
 - toxicity and dosing manageable
- compatible with law and regulation
- *and* do not delay or jeopardise adult trials



Dogma -

Widespread belief within the profession that lowering age of entry risks all of the above.

Problem is not one of regulation
but of *culture*.

Goals:

raise awareness

challenge dogma

call for changes to standard procedures

Tactics

Identify well-designed, inclusive trials

Take the case

- to umbrella organisations (eg. ESMO)
- to Pharma
- to ethics committees
- to the wider children's cancer community

Online Resources



ONLINE SURVEY

Core group:

- clinicians and researchers
- pharma / biotechs
- parents /survivors

Wider circle:

to consult and offer support



Welcome interaction with wider health community

It takes a continent...



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References

Gaspar, N. et al., 2018. Joint Adolescent-Adult Early Phase Clinical Trials to Improve Access to New Drugs for Adolescents with Cancer: Proposals from the Multi-stakeholder Platform-ACCELERATE. *Annals of oncology: official journal of the European Society for Medical Oncology / ESMO*. 43, pp 38-49. Available from:

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Fern, L., Lewandowski, J., Coxon. & Whelan, J. (2014) Accessible, aware, appropriate, and acceptable: a strategy to improve participation of teenagers and young adults in cancer trials. *The Lancet Oncology*, 15 (8). Available from:

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chris.copland@york.ac.uk

www.accelerate-platform.org/fair-trials/