

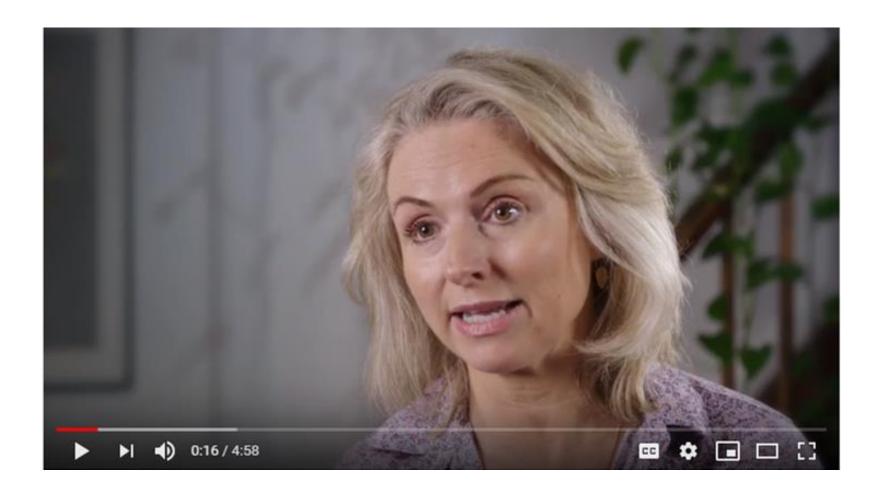
FAIR Trials

Fostering Age Inclusive Research

Chris Copland







Chloe's story



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



- 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.



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



working group

Online Resources





ONLINE SURVEY



working group

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...









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