

29 March 2019

All –

I am very pleased to re-connect and provide an update on activities that have transpired in follow-up to the European Forum for Good Clinical Practice (EFGCP) **'Facilitating Adolescent Inclusion in Adult Research' Kick-Off Meeting** held in October 2018.

On 18 February 2019, the EFGCP Board endorsed the following 'Position Statement' related to adolescent inclusion:

As part of the responsibility to provide better medicines for children, the EFGCP strongly recommends:

- *That researchers, regulators, and members of ethics committees weigh the totality of physiologic, pathologic, and other disease specific evidence to consider adolescent inclusion in adult research and vice versa – young adults as an extension population in paediatric/adolescent studies - when relevant as a trial methodology to facilitate earlier access to investigational and approved medicines for adolescent patients.*

It is our expectation that this statement can be of immediate use to you and the broader pediatric research community when engaging other researchers, regulators, and ethics committees.

In addition, the Children's Medicines Working Party (CMWP) of the EFGCP has completed an analysis of the feedback from the Kick-Off Meeting and has identified 4 priority projects intended to generate meaningful information to be used in further support of this position. The identified priorities include:

1. Meta-analysis for publication on the experience of hybrid trials (adult and adolescents), existing guidance in the EU, and impact on product registration(s)
2. Retrospective analysis of the executed EU paediatric investigation plans (PIPs) to analyze algorithms to identify scenarios where similar safety/efficacy data among adolescents and adults may be used as part of the development considerations for similar mechanisms of action
3. International alignment of approach to facilitate global acceptance of adolescent inclusion in adult research
4. Define pre-requisites/minimum requirements/key criteria for risk-benefit evaluation to support inclusion of adolescents in adult studies (general vs. indication-specific)

To facilitate discussion and accomplish these priorities, the CMWP respectfully requests your continued engagement. **If you or your organization would like to collaborate with us on these priorities, please reply to this communication by EOB (CET) Monday, 08 April 2019.** Upon receipt of affirmative replies, we will provide a Doodle poll of availability to schedule the first planning call.

Thank You for your continued commitment to children. On behalf of the EFGCP CMWP, we look forward to collaborating with you on these next steps!

Warm regards –

Christina Bucci-Rechtweg, MD (on behalf of the EFGCP CMWP)