



CTA Meeting on Pediatric ARVs: Critical Discussion of the Proposed Global Accelerator for Pediatric Formulations

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STAGE 1 (1-2 years)

- Continue the current mechanism with the present structure
- No/negligible funding required
- Specific activities described in Stage 1 will make impact and progress towards the goal
- Key activities will be extended to TB and hepatitis where appropriate and feasible
- Deliverables:
 - Regulatory efficiencies in place
 - Revised PADO priority list



End of Stage 1 review

- Impact of Stage 1 activities
- Future product portfolio to develop



STAGE 2 (~3 years, many activities in parallel to Stage 1)

- Create a core group of experts to be members of the Global Accelerator
- Funding required for activities such as PK studies, additional clinical studies and administrative support to manage the activities
- To be hosted by another organization with matching strategic objectives
- Current grants in paediatric HIV space to inform additional activities
- Scope will have major focus on ARVs, but also include other diseases
- Moderate exit cost
- Deliverables:
 - Completion and implementation of PADO formulations currently under development
 - Synergies with other disease areas identified
 - Moderate Exit Cost



End of Stage 2 review

- Impact of Stage 2 activities
- Future product portfolio to develop
- Assessment of market need



STAGE 3

- Expansion of scope and mission (potential creation of an independent entity or inclusion in an existing PPP)
- Develop Global Accelerator Advisory Board and funding activities
- Possibility to expand to other disease areas beyond HIV
- Very high exit cost

Today we would like your endorsement on the key activities of stage 1

Input for refinement of stage 2

Vision for Stage 3

Stage 1 Actions

1. FDA/EMA initiative to impact faster pediatric studies – WHO, in collaboration with other relevant CTA partners to set up meetings with the FDA Division of Antiviral Products and the EMA PDCO to discuss and agree on ***three to five key recommendations*** to innovators
 - Include adolescents in initial registrational adult efficacy trials or in parallel with adult studies
 - Engage with WHO PAWG and engage pediatric HIV clinical trials networks to develop simplified, efficient pediatric trials.
 - Use WHO weight bands and use weight-based dosing (rather than age-based dosing) in designing pediatric PK and safety studies
 - Enroll all other ages/weight bands concurrently and not as sequential cohorts for the remaining (pre-adolescent) paediatric population
 - Begin formulation development appropriate for clinical trials for pediatric populations as soon as evidence of potential public health benefit to pediatric patients is evident
 - Ensure acceptability and palatability data is also provided

Stage 1 Actions (cont'd)

1. FDA/EMA initiative to impact faster pediatric studies – ...to discuss and agree on *three to five key recommendations* to innovators
2. FDA/EMA should guide the innovators to simplify and harmonise the PSP/PIP document
 - simplified, efficient pediatric trials
3. Develop a "master protocol" for pediatric clinical trials of ARVs designed to collect similar (required) PK and safety data for any desired pediatric product
4. WHO will further engage with strengthening the paediatric regulatory network and to promote a more coordinated approach to in-country drug registration
5. Explore the possibility of including additional incentives for pediatric formulation development when granting license for novel drugs.
6. Improve assessment of market needs and the staging/duration of each PADO priority product in the marketplace.

STAGE 2

1. Create a core group of experts to be members of the Global Accelerator
2. Funding required for activities such as PK studies, additional clinical studies and administrative support to manage the activities
3. To be hosted by another organization with matching strategic objectives
4. Current grants in paediatric HIV space to inform additional activities
5. Scope will have major focus on ARVs, but also include other diseases
6. Moderate exit cost
7. Deliverables:
 1. Completion and implementation of PADO formulations currently under development
 2. Synergies with other disease areas identified

STAGE 3

- Expansion of scope and mission
 - Potential creation of an independent entity or inclusion in an existing PPP
- Develop Global Accelerator Advisory Board and funding activities
- Possibility to expand to other disease areas beyond HIV
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Thank you!

- Time for a break...

BREAK TIME



It's Time For A Break