

1) What would potentially be some of the roles pharmaceutical companies could play and how can they partner with USAID?

Pharmaceutical companies could potentially collaborate with USAID and other interested parties in a number of ways. Illustrative examples include, but are not limited to: developing new and improved ARV regimens that are tailored to the needs of populations living in developing countries; collaborating on research related to how best to utilize these new ARVs in resource-limited settings to achieve maximum public health impact while also addressing the needs of vulnerable populations such as pregnant women and children; partnering to more rapidly scale up manufacturing of better ARV regimens that can be provided at a reduced cost to low-income countries; expediting efforts to register new ARVs in developing countries; and collaborating with others at the global and country levels to address policy and planning issues related to introduction of new and better ARV regimens. Pharmaceutical companies with demonstrated capacity in areas such as these are encouraged to express interest, and do not necessarily need to present a detailed specific solution, as long as there is a stated willingness to employ their proven capacities and collaborate with others to develop innovative solutions that will address the challenges stated in the BAA.

2) Are applicants allowed to include in their Expressions of Interest (EOIs) projects that we are already working on (e.g. -product development already underway), or is this BAA Addendum only for exploring “new” development not yet in the pipeline?

The EOI may include products currently under development if the organization believes that the target product would be useful to further simplify ART delivery from what is currently the norm in resource-limited settings. In the process of developing innovative solutions to ART simplification with other interested parties, new procedures or additional ideas for how to utilize a product under development may also arise. Organizations that have strong capacity to develop, test, and introduce new products are also encouraged to express interest, even if they do not have a specific product in mind, as long as they are willing to consider employing their expertise with others to develop solutions to simplify and improve ART.

3) What is the time period covered by this collaboration? Is it aligned to the PEPFAR 3.0 timeline through 2018? For example, if projects already in our pipeline are able to be included, should we focus on near-term ideas (eg -2016 time period) so launch and scale-up fit within PEPFAR 3.0, or can we also include those on a longer development timeline potentially beyond PEPFAR 3.0 (2017-2019)?

This collaboration will respond to the goals and objectives of PEPFAR 3.0, but will also respond to USAID-specific priorities, goals, and objectives which serve to advance improving outcomes for populations affected by HIV. Given this, the collaboration is not limited to the time period for PEPFAR 3.0.

4) In determining whether to submit one versus multiple EOIs, the Addendum indicates that “EOIs may address multiple solutions, or applicants can submit multiple EOIs that each respond to a unique solution”. This guidance pertains to how to address multiple solutions, not multiple approaches within a solution. As a manufacturer we will be addressing only solution #6 but may have many proposed approaches; should we try to keep all our approaches to one EOI since they will all address the same solution, or can multiple EOIs also respond to the same solution?

An organization may submit approaches in one EOI or multiple EOIs that address the same solution. It is up to the organization; however, please note that all EOIs must follow the EOI criteria outlined in the BAA Addendum #2, pages 6-7.

5) Should the approaches be country-specific, or will differentiated approaches to country context be discussed at a later date if the EOI is chosen to advance in the collaborative process?

It is up to the organization whether to propose country or region specific approaches or to propose broader ideas. All EOIs must follow the criteria outlined in the BAA Addendum #2, pages 6-7.

6) Please can you clarify if the BAA response team is expecting one submission per novel innovation; or one submission per group/consortium willing to work on the proposal listing a number of innovations?

It is expected that interested organizations will submit one Expression of Interest (EOI) in response to the collaboration announcement. As a function of the collaboration and project development process following EOI submissions, the project could potentially be implemented by a consortium of organizations.