Milestones: NeoSyp: Low Cost Mechanical Syringe Pump to Regulate IV-Fluid Delivery in Low-Resource Settings

Milestone	Estimated Completion Day	Deliverable
1	Award date + 14 days	This milestone requirement is considered fulfilled when the following actions have occurred and the deliverables and/or associated narrative have been submitted to the AOR for review/concurrence: • Updated project implementation plan depicted in a Gantt chart.
2	Award date + 4 months	This milestone requirement is considered fulfilled when the following actions have occurred and the deliverables and/or associated narrative have been submitted to the AOR for review/concurrence: • Confirmation of Institutional Review Board submission from Rice University and the University of Malawi, College of Medicine to conduct the clinical evaluation of AutoSyp. • Design and training programs to enable use of the AutoSyp in district hospitals. Deliverable is a written summary of the process to design training program, and materials that will be used in the training.
3	Award date + 9 months	This milestone requirement is considered fulfilled when the following actions have occurred and the deliverables and/or associated narrative have been submitted to the AOR for review/concurrence: • Complete final user interface for AutoSyP. Deliverables will include a diagram of the AutoSyP user interface and written summary that outlines the changes made including justification. • Present prototype device to intended users in Malawi and obtain feedback on ease of use. Deliverable will include a written summary of feedback from nurses, doctors and other intended users to be obtained at a site visit to Queen Elizabeth Central Hospital in Blantyre, Malawi. • Product Requirements Specification (PRS) for AutoSyp that details needs of users, performance requirements, and the cost of goods for AutoSyp in order to create a successful market entry product.
4	Award date + 1 year	This milestone requirement is considered fulfilled when the following actions have occurred and the deliverables and/or associated narrative have been submitted to the AOR for review/concurrence: • Test training programs to enable use of the AutoSyp in district hospitals. Deliverable is a written summary of the pilot test the training program, post-test results, summary of adjustments made to training based on test results and/or user feedback. The expectation is that students will score 80% or better on the post-test which includes mock procedures to be considered competent. • Initiate Clinical Trial. Deliverable is a summary of the trial to date including number of subjects and preliminary data, • Final results from the clinical evaluation of AutoSyp (Generation 2 pump, or another improved version approved by USAID) to assess the potential impact of the device to improve treatment for neonates and pediatric patients who require parenteral fluid

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		and/or IV medication. • The report must include the following data: ○ *indications for use, medication delivered with AutoSyp, whether or not it was successfully delivered, if there were any complications during delivery, what the alternative for delivery would have been, complications associated with usage of the device, and any other challenges that arise in using the device. • Confirmation that all medical staff demonstrated competence through testing and trainer observation of mock procedures prior to use of AutoSyp. *Note that DIV may request full data sets at a later date.

5	Award date + 1 year, 3 months	This milestone requirement is considered fulfilled when the following actions have occurred and the deliverables and/or associated narrative have been submitted to the AOR for review/concurrence:
		• Final report to include the following (more specific guidance on the format and content of the final report may be provided by the AOR at a later date)
		• Report on next steps that will be required to achieve the intended scale up plans, including noting potential partners that are interested and/or commitments made by stakeholders. This must include:
		  ○ Summary of the stakeholders meeting, including a description of the role of the Malawi MOH, to develop a sustainable, country-wide implementation plan to deploy AutoSyp at district hospitals
		  ○ Additional steps required (i.e., FDA approval, Malawi regulatory approval, further training, additional product modifications, etc) that are required before country-wide scale up is feasible. Also include thoughts about possibilities for expansion beyond Malawi.
		  ○ Financial requirements to support a country-wide scale up plan and how Rice University or other partners plan to pursue securing the necessary funds
		  ○ Partnerships (non-financial) that will be required to implement the country-wide scale up plan and how Rice University or others will pursue solidifying these partnerships
		  ○ In the event that the trial and related project activities are not successful (including stakeholder engagement), please discuss lessons learned about this effort that could inform similar undertakings by other groups.