Grand Challenges in Global Health

Examples of Objectives and Activities Tables

The following are hypothetical examples that illustrate the general approach to completing the tables, and should not be interpreted as literal examples.

It is highly likely that individual proposals will be at different phases of development than the examples presented below, and many proposals will include research for which proof-of-concept still needs to be demonstrated. It is critical that the objectives and outcome indicators in the table be as quantitative and measurable as possible, depending on the nature of the research, and be linked to your timelines and milestones.

Complex projects should have enough discreet, measurable, objectives to document the logic of the steps that will be taken along the proposed critical path to a solution, and to justify the scope and scale of the project.

The two examples below are in quite different areas of research, but by no means encompass all the possible variations that will be represented by GCGH applications. However, it is hoped that the examples will give applicants a better understanding of what is expected.

Example 1

Goal: To develop a sensitive, specific and quantitative immunochromatographic strip test for Disease X that can be used at the point-of-care in low-resource settings.

Objectives and Outcomes

Objective	Outcome Indicator	Baseline	Expected Outcome
1. Define assay and instrument product specifications in terms of assay sensitivity, specificity, speed of result and sample type.	Creation of product definition document that will be used to direct assay and instrument development decisions.	Existing diagnostic tests are not reaching the target population or the costs of the current tests are prohibitive for use in resource poor settings.	Evidence based performance specifications for assay and instrument development.
2. Development and optimization of the sample preparation step.	Simple and efficient one-step sample processing procedure.	Existing laboratory sample procedures are too complex for use at the point-of-care.	Simple and efficient one-step sample processing method that enables sample processing with 5 minutes, thereby meeting the defined product specifications.
3. Assay optimization.	Optimized assay that meets defined product specifications.	Existing immunochromatographic strip test platform. Existing antibody reagents with sufficient avidity and affinity for disease X target.	Specific detection of N µg of target protein. Data report on the analytical performance of the optimized assay.
4. Development of a simple instrument and software for measuring and interpreting assay results.	Development of first prototype device that meets defined product specifications.	Proof-of-concept qualitative immunochromatographic strip test with visual detection and interpretation of test results.	Quantitative measurement of immunochromatographic strip test results. Rapid data processing to provide a binary interpretation of quantitative data.

Objective	Outcome Indicator	Baseline	Expected Outcome
5. Pilot clinical evaluation of the integrated quantitative immunochromatographic strip test.	Sensitivity and specificity of the fully integrated diagnostic test with a small number of existing clinical samples.	Clinically unvalidated quantitative immunochromatographic strip test that meets the desired analytical performance characteristics.	Preliminary data with clinical samples to indicate that the integrated diagnostic test meets the desired clinical sensitivity and specificity of 95% and 99%, respectively.

Major Activities and Outputs

Activity/Output (indicate objective #)	Output Indicator	Baseline	Expected Target Output(s)
1.1 Convene meeting with disease X and field experts to determine the desired product attributes for the new diagnostic test.	Clearly articulated and agreed upon test performance specifications. Creation of a product definition document.	Documented need for a new diagnostic test for disease X. Currently available tests are not reaching the target population or are cost-prohibitive for use in these target populations.	Consensus on the required product attributes to meet the defined need. Clearly defined product definition document.
1.2 Comprehensive survey of published and web-based literature.	Clear understanding of the need to diagnose disease X and the pros and cons of existing diagnostic tools.	Feedback from field program staff regarding the need for a new diagnostic test.	Understanding of the potential programmatic benefit of the new diagnostic test.
2.1 Evaluation and optimization of sample processing buffer(s). 2.2 Assessment of the efficiency of the sample-processing step.	Simple and rapid sample processing protocol that meets defined product specifications.	Existing laboratory sample procedures are too complex for use at the point-of-care. Existing sample buffers that could be optimized for use in the immunochromatographic strip test assay.	Simple and efficient one-step sample processing method that enables sample processing within 5 minutes, and that meets the defined product specifications. Sample processing protocol.
3.1 Update intellectual property search (performed as part of proposal development) to ensure that there are no changes in prior art that would effect current assay development.	Assurance that proposed assay development does not infringe upon existing intellectual property.	Known patent and intellectual property landscape for immunochromatographic strip tests and key reagents.	Current intellectual property position document and freedom to practice assurance.

Activity/Output (indicate objective #)	Output Indicator	Baseline	Expected Target Output(s)
3.2 Identify vendors and procure required reagents. 3.3 Test raw materials using proof-of-concept assay prototype. 3.4 Optimize proof-of concept assay conditions. 3.5 Compare performance of optimized assay with reference standard. 3.6 Define assay variance, reproducibility & correlation characteristics. 3.7 Determine cross-reactive or inhibitory substances. 3.8 Determine reagent and analyte stability. 3.9 Produce immunochromatographic strip test prototypes according to standard operating procedures.	*Additional indicators should be provided for activities 3.2-3.9.*		Reagents procured at reasonable cost. Acceptable performance of raw materials in the assay format. Acceptable assay analytical performance. Acceptable levels of assay variance. No uncontrollable interference. Accelerated and real-time assay stability that meets defined product specifications. Sufficient number of prototype tests to perform retrospective evaluation with clinical specimens.
4.1 Update intellectual property search (performed as part of proposal development) to ensure that there are no changes in prior art that would	Assurance that development of the proposed instrument does not infringe upon existing intellectual property.	Known patent and intellectual property landscape for the proposed instrument.	Current intellectual property position document and freedom to practice assurance.

Activity/Output (indicate objective #)	Output Indicator	Baseline	Expected Target Output(s)
effect current instrument development.			
4.2 Identify vendors, specify and procure required instrument components and software.	*Additional indicators should be provided to match activities 4.2-4.7.*		Components procured at a reasonable cost.
4.3 Develop test plan for instrument prototype #1.			Comprehensive test plan.
4.4 Assemble and test hardware for instrument prototype #1.			Instrument hardware and software meet desired performance specifications
4.5 Assemble and test software for instrument prototype #1.			
4.6 Create drawings of prototype #1.			Completed drawings
4.7 Build instrument prototype according to standard operating procedures.			Prototype instrument for assessing the clinical performance of assay prototypes.
5.1 Development of a clinical research protocol for evaluation of the integrated test with existing clinical samples. Obtain all necessary ethical clearances.	Ethical clearance for use of existing clinical samples in the assessment of the integrated test.	Existing clinical samples	Detailed research protocol and all necessary ethical clearances.
5.2 Assessment of the performance of the integrated assay compared to the recognized gold standard.	Initial data on the clinical performance of the integrated test in terms of sensitivity and specificity of the test compared to the reference standard.	Analytical performance of the prototype test meets the desired product specifications.	Preliminary data with clinical samples to indicate that the integrated diagnostic test meets the desired clinical sensitivity and specificity of 95% and 99%, respectively.

Example 2

Goal: To understand which immunological responses are protective against TB.

This hypothetical example illustrates how the table might be completed for a project that has less concrete outcomes than example #1.

Objectives and Outcomes

Objective	Outcome indicator	Baseline	Expected Outcome
1. Define the requirements of a whole genome microarray that can identify host and mycobacterial gene activity	A description of the desirable parameters of such a microarray, including identification of the source of the starting materials.	No microarrays suitable for this purpose have been developed	Outline of steps by which the microarrays can be made.
2. Develop and optimize the microarrays	Various parameters are optimized	Technology for doing this is well established	Microarrays can be produced reliably and reproducibly
3. Produce the microarrays, perform QC, and test with known gene expression systems	Microarrays produced and tested	Technology for producing microarrays is well understood	Micorarrays reliably and reproducibly meet QC standards and give the expected results for known genes
4. Develop study design to show that differences in gene expression can be detected using microarrays	Analysis has been performed to determine optimal study design	The disease states and appropriate controls are known	A study has been designed that can provide definitive and interpretable results
5. Identify criteria and sources for population samples needed to perform study designed in 4.	Documentation of existing samples that meet the criteria	The characteristics of suitable samples are known	A source of samples is identified and agreements are in place, including appropriate ethical clearances
6. Use samples to determine whether the microarrays can pick up any differences	Testing of samples has been completed per protocal	No systematic survey of differences in gene expression have been carried out to date	Tests show differences in gene activity between individuals who are uninfected, immune, or have active infection

Major Activities and Outputs

The Activities and Outputs table can be derived from the Objectives and Outcomes table by analogy with example #1.