DEPENDENCY TABLE APPENDIX

PDP Access Timelines Project, August 2011

Activity Number	Activity	Dependencies	Rationale
2.0 STRATEGY & PLANNING			
2.1	Assess burden (incidence and prevalence) of disease and unmet need	*Follow-on activities*: 2.2: Revise TPP and obtain stakeholder feedback (iterative activity) 4.1: Develop strategic demand forecast for global supply (iterative activity) 7.4V: Present investment case and conduct funding discussions with GAVI (if applicable)	2.2: TPP requires information on epidemiology of disease to show that there is a public health rationale for the product 4.1: Strategic demand forecast for product needs to take into account unmet medical need and current burden of disease 7.4V: Investment case for vaccine requires information on lives potentially saved by vaccine, so burden of disease information is needed
2.2	Revise TPP and obtain stakeholder feedback (iterative activity)	*Prerequisite activities*: 2.1: Assess burden (incidence and prevalence) of disease and unmet need 6.1: Identify global medical and scientific KOLs to serve on product expert/platform groups	2.1: Presented above 6.1: Global medical and scientific KOLs will provide crucial input into the TPP, so the expert/platform groups need to be in place before TPP can be revised
		Follow-on activities: 2.3V: Assess impact of potential formulation constraints on demand 7.4V: Present investment case and conduct funding discussions with GAVI (if applicable)	2.3V: TPP for a vaccine will include information on vaccine formulation, which may have impacts on demand 7.4V: Investment case for a vaccine includes an early demand forecast, which will be impacted by formulation as specified in the TPP
2.3V	Assess impact of potential formulation constraints on demand	*Prerequisite activity:* 2.2: Revise TPP and obtain stakeholder feedback (iterative activity)	2.2: Presented above, in 2.2
		Follow-on activity:	

Activity Number	Activity	Dependencies	Rationale
		4.2: Assess possible manufacturing processes (including need for any capital expenses), assess range of possible manufacturing partners and feasibility of technology transfer (if relevant)	4.2: The determination of manufacturing processes as well as assessment of possible manufacturing partners and feasibility of technology transfer will depend on the intended formulation for the product and how complex this is.
2.4	Define regulatory strategy (iterative activity)	*Prerequisite activities:* 2.7: Define product rollout strategy 4.1: Develop strategic demand forecast for global supply (iterative activity) 5.1: Confer with regulatory agencies regarding manufacturing expectations, clinical trial design, appropriate cohorts to study, safety issues of potential concern, and regulatory submission requirements (iterative activity)	2.7, 4.1: Information from the strategic demand forecast can be used to develop the product rollout strategy, dictating sequence of countries where product will be rolled out; this sequence feeds into the regulatory strategy 5.1: Ongoing dialogue that begins pre-Phase 2 with regulators will inform regarding these necessary components (development program, safety, submission requirements) of regulatory strategy
		Follow-on activities: 2.6: Assess financing, pricing, and policy landscape and strategy (iterative activity) 4.2: Assess possible manufacturing processes (including need for any capital expenses), assess range of possible manufacturing partners and feasibility of technology transfer (if relevant)	2.6: Regulatory strategy, especially planned country rollout sequence, will dictate pricing (tiered or not) 4.2: Planned sequence of filings and approvals will dictate where the product needs to manufactured (e.g. filing with FDA will require working with certain plants for manufacture vs. filing with EMA or country-level regulatory agencies)
2.5	Establish likely market demand and market landscape at time of product launch (iterative activity)	*Follow-on activity:* 2.7: Define product rollout strategy	2.7: Method in which product can be rolled out postlaunch will depend on whether it is first-in-class, in which case it may need to be rolled out in a stepwise fashion, or a follow-on product, which could be rolled out more rapidly
2.6	Assess financing, pricing, and policy landscape and	*Prerequisite activities:* 2.4: Define regulatory strategy	2.4: Presented above

Activity Number	Activity	Dependencies	Rationale
2.6	strategy (iterative activity)	2.5: Establish likely market demand and market landscape at time of product launch (iterative activity)	2.5: Presented above
		Follow-on activities: 4.1: Develop strategic demand forecast for global supply (iterative activity) 7.1: Engage in policy discussions, knowledge building and advocacy activities with key global financing bodies 7.4V: Present investment case and conduct funding discussions with GAVI (if applicable) 8.1: Consult with WHO (and other global agency as appropriate) on what information should be submitted to its expert committee (SAGE/STAG)	4.1: Strategic demand forecast needs to take into consideration what the financing and pricing situations for the product are likely to be and also whether policy changes (e.g. changes to GAVI's copayment policies) will impact the product 7.1: Knowledge about the changing financing, pricing, and policy landscapes will feed into these discussions with global financing bodies 7.4V: The vaccine investment case includes an estimate of likely costs for procurement of the vaccine, which will be informed by ongoing landscaping of financing, pricing, and policy 8.1: The policy aspect of this landscaping exercise that will have identified evidence needed for global, regional, and national adoption of the product will inform consultations with WHO (and other global agencies as appropriate) regarding evidence needed for the expert committee.
2.7	Define product rollout strategy	*Prerequisite activities:* 2.4: Define regulatory strategy (iterative activity) 2.5: Establish likely market demand and market landscape at time of product launch (iterative activity)	2.4: Presented above 2.5: Presented above
		Follow-on activity: 9.1: Define key issues for and against introduction in particular countries	

Activity Number	Activity	Dependencies	Rationale
3.0 INTELLECTUAL PROPERTY MANAGEMENT			
3.1	Develop an IP map and ensure IP clearance from patent holders	*Follow-on activities*: 4.3: Negotiate and finalize production agreements with manufacturers	4.3: The map determines potential IP barriers and allows IP negotiations to be built into initial agreements with partners.
4.0 PROCESS DEVELOPMENT & MANUFACTURING			
4.1	Develop strategic demand forecast for global supply (iterative activity)	*Prerequisite activities:* 2.1: Assess burden (incidence and prevalence) of disease and unmet need 2.6: Assess financing, pricing, and policy landscape and strategy (iterative activity)	2.1: Strategic demand forecast for product needs to take into account unmet medical need and current burden of disease 2.6: Strategic demand forecast needs to take into consideration what the financing and pricing situations for the product are likely to be and also whether policy changes (e.g. changes to GAVI's copayment policies) will impact the product
		Follow-on activities: 4.2: Assess possible manufacturing (including need for any capital expenses), assess range of possible manufacturing partners, and feasibility of technology transfer (if relevant) 7.4V: Present investment case and conduct funding discussions with GAVI (if applicable)	4.2: The strategic demand forecast will dictate the amount of product that needs to be manufactured, which will in turn determine the type of manufacturing process that needs to be considered for the product 7.4V: The investment case for a vaccine needs to include at least a preliminary estimate of the strategic demand forecast, so that the scale of product need can be considered
4.2	Assess possible manufacturing processes (including	*Prerequisite activities*: 2.3V: Assess impact of potential formulation on demand	2.3V: The determination of manufacturing processes as well as assessment of possible manufacturing partners and feasibility of

Activity Number	Activity	Dependencies	Rationale
4.2	need for any capital expenses), assess range of possible manufacturing partners, and feasibility of technology transfer (if relevant)	2.4: Define regulatory strategy (iterative activity) 4.1: Develop strategic demand forecast for global supply (iterative activity)	technology transfer will depend on the intended formulation for the product and how complex this is. 2.4: Planned sequence of filings and approvals will dictate where the product needs to manufactured (e.g. filing with FDA will require working with certain plants for manufacture vs. filing with EMA or country-level regulatory agencies) 4.1: Presented above
		Follow-on activity: 4.3: Select and finalize agreement with manufacturing partners for technology transfer (if relevant)	4.3: Selection and finalization of agreement with manufacturing partner(s) is predicated by a consideration of manufacturing processes, range of partners, and technology transfer
4.3	Select and finalize agreement with manufacturing partners for technology transfer (if relevant)	*Prerequisite activities:* 4.2: Assess possible manufacturing processes (including need for any capital expenses), assess range of possible manufacturing partners, and feasibility of technology transfer (if relevant)	4.2: Presented above
4.4	Support partner's conduct of necessary product tests and ensure manufacture of product is done in compliance with Good Manufacturing Processes	*Follow-on activity*: 4.5: Support partner's implementation of follow-on process development and packaging	4.5: Partner's ability to conduct follow-on process development and packaging is dependent on its ability to make a product that passes necessary tests and is produced in compliance with GMP
4.5	Support partner's implementation of follow-on process	*Prerequisite activity:* 4.4: Support partner's conduct of necessary product	4.4: Presented above

Activity Number	Activity	Dependencies	Rationale
	development and packaging	tests and ensure manufacture of product is done in compliance with Good Manufacturing Processes	
5.0 REGULATORY			
5.1	Confer with regulatory agencies regarding manufacturing expectations, clinical trial design, appropriate cohorts to study, safety issues of potential concern, and regulatory submission requirements (iterative activity)	*Follow-on activities:* 2.4: Define regulatory strategy (iterative activity) 5.2: Develop plan for postmarket safety surveillance, including acquisition of necessary data for contextualization of potential product safety signals (iterative activity) 5.3: Prepare and file SRA or twinned regulatory filing, including safety-related documentation and plans, for product approval 11.1: Support conduct of required post-licensure safety studies, routine pharmacovigilance, and safety reporting	2.4: Ongoing dialogue that begins pre-Phase 2 with regulators will inform regarding these necessary components (development program, safety, submission requirements) of regulatory strategy 5.2: Dialogue with regulators will allow PDPs and regulatory agencies to agree on those safety issues that need further follow-up via postmarketing safety surveillance and studies 5.3: Discussions about regulatory submission requirements with regulatory agencies will allow PDPs to assemble a filing that is more likely to gain product approval by agencies than a filing put together without information gleaned from regulatory discussions 11.1: Dialogue with regulators will allow PDPs and regulatory agencies to agree on those safety issues that need further follow-up via postmarketing safety surveillance and studies
5.2	Develop plan for postmarket safety surveillance, including acquisition of necessary data for contextualization of potential product safety signals (iterative activity)	*Prerequisite activities*: 5.1: Confer with regulatory agencies regarding manufacturing expectations, clinical trial design, appropriate cohorts to study, safety issues of potential concern, and regulatory submission requirements (iterative activity)	5.1: Presented above
		Follow-on activity: 11.1: Support conduct of required post-licensure safety studies, routine pharmacovigilance, and safety reporting	11.1: Conduct of required post-licensure safety activities will be need to follow closely the plan devised by PDPs in conjunctions with regulators for postmarketing safety surveillance

Activity Number	Activity	Dependencies	Rationale
5.3	Prepare and file SRA or twinned regulatory filing, including safety-related documentation and plans, for product approval	*Prerequisite activities:* 5.1: Confer with regulatory agencies regarding manufacturing expectations, clinical trial design, appropriate cohorts to study, safety issues of potential concern, and regulatory submission requirements (iterative activity)	5.1: Presented above
		Follow-on activities: 5.4: SRA or twinned marketing authorization received	5.4: Marketing authorization approval is dependent on submission of a high-quality regulatory filing
5.4	SRA or twinned marketing authorization received	*Prerequisite activity:* 5.3: Prepare and file SRA or twinned regulatory filing, including safety-related documentation and plans, for product approval	5.3: Presented above
		Follow-on activities: 5.5: File WHO pre-qualification dossiers (if relevant), including safety-related documentation and plans 5.7: File endemic country dossiers, including safety-related documentation and plans 7.4: Conduct funding discussions with other donors, national governments, and innovative financing bodies 11.1: Support conduct of required post-licensure safety studies, routine pharmacovigilance, and safety reporting	5.5: Marketing authorization approval by a SRA will expedite WHO prequalification status, since the former have the necessary expertise and resources to conduct comprehensive, quality evaluations of dossiers 5.7: Marketing authorization approval by a SRA may expedite national RA approval, since the former have the necessary expertise and resources to conduct comprehensive, quality evaluations of dossiers 7.4: Many funding organizations will not fund procurement of a product unless a SRA has approved the product. 11.1: The starting point of post-licensure study commitments is once the product gains its first marketing authorization approval
5.5	File WHO prequalification	*Prerequisite activity:*	5.4: Presented above

Activity Number	Activity	Dependencies	Rationale
5.5	dossiers (if relevant), including safety-related documentation and plans	5.4: SRA or twinned marketing authorization received	5.4: Presented above
		Follow-on activities: 5.6: WHO prequalification approval received (if relevant)	5.6: WHO prequalification of products requires submission of a comprehensive dossier containing product data and information, which will be evaluated with manufacturing and clinical site information when determining whether to prequalify the product
5.6	WHO pre-qualification approval received (if relevant)	*Prerequisite activity:* 5.5: File WHO pre-qualification dossiers (if relevant), including safety-related documentation and plans	5.5: Presented above
		Follow-on activity: 5.7: Prepare and file endemic country dossiers, including safety related documentation and plans	5.7: WHO prequalification of product may expedite individual country RA approval of product
5.7	File endemic country dossiers, including safety related documentation and plans	*Prerequisite activity:* 5.4: SRA or twinned marketing authorization received 5.6: WHO pre-qualification approval received (if relevant) 10.2D: Conduct country studies on the target market's providers and end-users, for use in product packaging and informational materials (if applicable)	5.4: Presented above 5.6: Presented above 10.2D: Information on market's healthcare providers and end-users will allow for creation of product packaging and informational materials that take into consideration any unique characteristics (e.g. lower literacy rates necessitating greater use of pictographs) of these individuals for inclusion in country-specific dossier
		Follow-on activities: 10.3: Ministries of Health adopt the product based on WHO recommendation and product evidence (scenario 1)	10.3: Country Ministries of Health need a robust country-specific evidence package to review in order to make approval decisions

Activity Number	Activity	Dependencies	Rationale
		10.5: Ministries of Health adopt the product after reviewing evidence from pilot/demonstration projects and other country evidence (Scenario 2)	10.5: Country Ministries of Health need a robust country-specific evidence package to review in order to make approval decisions
6.0 COMMUNICATION & ADVOCACY			
6.1	Identify global medical and scientific KOLs to serve on product expert/platform groups	*Follow-on activities:* 2.2: Revise TPP and obtain stakeholder feedback (iterative activity) 6.4: Carry-out coalition building activities at the country, regional, and/or global levels 7.1: Engage in policy discussions, knowledge building, and advocacy activities with key global financing bodies 8.1: Consult with WHO (and other global agency as appropriate) on what information should be submitted to its expert committee 9.2: Engage in intensive, direct, and country-specific communication with key decision makers including national program managers, regulatory authorities, WHO country office staff, Ministry of Finance officials, and local researchers and academics	2.2: KOL group will provide necessary feedback to revised TPP 6.4: Scientific and medical expert group may participate in coalition building activities, advocating for the disease area and product 7.1: KOL group can add essential scientific and medical input to discussions with global financing bodies, making public health case for product 8.1: Scientific and medical expert group may liaise with WHO and other global agency expert committees to assist these individuals in understanding clinical development data as well as policy around product 9.2: KOL group can be influential in conversations with local stakeholders in priority countries, especially if they have been carefully selected for their expertise in these regions
6.2	Develop publication plan, identify additional champions, and conduct product awareness and demand generation activities	*Follow-on activity*: 6.4: Carry-out coalition building activities at the country, regional, and/or global levels	6.4: Coalition building activities will rely on all of the components of Activity 6.2 for developing the public health rationale for the product and generating product support among global and local healthcare providers and advocates

Activity Number	Activity	Dependencies	Rationale
6.3	Develop standard evidence package for global and country decision-makers and donors	*Prerequisite activities:* 5.1: Confer with regulatory agencies regarding manufacturing expectations, clinical trial design, appropriate cohorts to study, safety issues of potential concern, and regulatory submission requirements (iterative activity) 6.1: Identify global medical and scientific KOLs to serve on product expert/platform groups 9.2: Engage in intensive, direct, and country-specific communication with key decision makers including national program managers, regulatory authorities, WHO country office staff, Ministry of Finance officials, and local researchers and academics	5.1: Ongoing conversations and formal meetings with regulators will inform PDPs as to those data (from clinical trials, manufacturing processes, and other aspects of the development program) that are important to include in a standard evidence package for a country 6.1: KOLs, particularly those with expertise in a specific country or region, may be able to assist PDPs in developing standard evidence packages since they will understand the types of data that are most compelling for that country/region 9.2: These interactions with individuals working on the national level will further inform PDPs with respect to critical data to include in a standard evidence package
		Follow-on activities: 5.3: Prepare and file SRA or twinned regulatory filing, including safety-related documentation and plans, for product approval 5.5: File WHO pre-qualification dossiers (if relevant) 5.7: File endemic country dossiers, including safety related documentation and plans 10.3: Ministries of Health adopt the product based on WHO recommendation and product evidence (scenario 1) 10.5: Ministries of Health adopt the product after reviewing evidence from pilot/demonstration projects and other country evidence (Scenario 2)	5.3: The standard evidence package will be an essential component of the SRA or twinned regulatory filing 5.5: The WHO prequalification dossier should include product data and information and the standard evidence package will be a necessary part of these data 5.7: The standard evidence package will be included in country-specific dossiers 10.3: A strong standard evidence package will assist in assuring the Ministries of Health that the product is safe, efficacious, and approvable for use in country. 10.5: Same rationale as for 10.3 (vaccine), 10.4 (drug)
6.4	Carry-out coalition building activities at the country,	*Prerequisite activities:* 6.1: Identify global medical and scientific KOLs to serve	6.1: Presented above

Activity Number	Activity	Dependencies	Rationale
	regional, and/or global levels	on product expert/platform groups 6.2: Develop publication plan, identify additional champions, and conduct product awareness and demand generation activities 7.3: Commission economics and financing studies (i.e. CE analysis, studies of broader economic and societal impact, etc.)	6.2: Presented above 7.3: Studies showing that there is a strong economic and societal case for the product will provide necessary data for use in country, regional, and global coalition building activities
7.0 ECONOMICS & FINANCING			
7.1	Engage in policy discussions, knowledge building, and advocacy activities with key global financing bodies	*Prerequisite activities:* 2.6: Assess financing, pricing, and policy landscape and strategy (iterative activity) 6.1: Identify global medical and scientific KOLs to serve on product expert/platform groups	2.6: In order to conduct these discussions with key global financing bodies, PDPs will also want to have a clear sense of financing options and strategies that may be available for the product and which key organization to target in discussions. 6.1: Medical and scientific KOLs who are familiar with the product can play a key role as advocates, lending their perspectives on why the product deserves to be financed
		Follow-on activity: 7.3: Commission economics and financing studies (i.e. CE analysis, studies of broader economic and societal impact, etc.) 7.4: Conduct funding discussions with other donors, national governments, and innovative financing bodies	7.3: Economics and financing studies carried out in support of the product will be informed by any gaps in evidence identified in policy discussions, knowledge building, and advocacy activities. 7.4: Policy discussions, knowledge building, and advocacy activities will provide a foundation for subsequent concrete funding discussions with donors, national governments, and innovative financing bodies.

Activity Number	Activity	Dependencies	Rationale
7.2	Conduct funding discussions for innovative financing	*Prerequisite activity*: 4.2: Evaluate possible manufacturing processes (including need for any capital expenses), assess range of possible manufacturing partners and feasibility of technology transfer (if relevant)	4.2: Manufacturing processes will often comprise a large proportion of the cost of bringing a drug to market and any capital expenses within this category should be fully understood prior to funding discussions.
7.3	Commission economics and financing studies (i.e. CE analysis, studies of broader economic and societal impact, etc.)	*Prerequisite activity:* 7.1: Engage in policy discussions, knowledge building, and advocacy activities with key global financing bodies *Follow-on activities:* 6.4: Carry out coalition building activities at the country, regional, and/or global levels 7.4: Conduct funding discussions with other donors, national governments, and innovative financing bodies	7.1: Economics and financing studies carried out in support of the product will be informed by any gaps in evidence identified in policy discussions, knowledge building, and advocacy activities. 6.4: Studies showing that there is a strong economic and societal case for the product will provide necessary data for use in country, regional, and global coalition building activities 7.4: Economics and financing studies will provide supporting tools in funding discussions with donors, national governments, and innovative financing bodies.
7.4	Conduct funding discussions with donors and national governments	*Prerequisite activities:* 1.1: Conduct Phase 2b 7.1: Engage in policy discussions, knowledge building, and advocacy activities with key global financing bodies 7.3: Commission economics and financing studies (i.e. CE analysis, studies of broader economic and societal impact, etc.)	1.1: Promising results from Phase 2 trials can provide compelling evidence in favor of funding the product 7.1: Policy discussions, knowledge building, and advocacy activities will provide a foundation for subsequent concrete funding discussions with donors, national governments, and innovative financing bodies. 7.3: Economics and financing studies will provide supporting tools in funding discussions with donors, national governments, and innovative financing bodies.

Activity Number	Activity	Dependencies	Rationale
7.4V	Present investment case and conduct funding discussions with GAVI (if applicable)	*Prerequisite activities:* 2.1: Assess burden (incidence and prevalence) of disease and unmet need 2.2: Revise TPP and obtain stakeholder feedback (iterative activity) 2.6: Assess financing, pricing, and policy landscape and strategy (iterative activity) 4.1:Develop strategic demand forecast for global supply *Follow-on activities:* 9.3V: Conduct workshops to apply for funding in GAVI eligible countries	2.1: Investment case for a vaccine needs to include number of lives saved, which will rely on epidemiologic data on disease burden and fatality rate 2.2: The TPP is an important component of the vaccine investment case 2.6: PDP's knowledge of financing, pricing, and policy landscapes at the present time as well as when product is likely to be launched will facilitate more informed discussions about funding with GAVI 4.1: Investment cases for vaccines require at least an early estimate about what demand is likely to be 9.3V: GAVI must agree to provide funding before country workshops to apply for said funding can be held
8.0 GLOBAL POLICY			
8.1	Consult with WHO (and other global agency as appropriate) on what information should be submitted to its expert committee	*Prerequisite activities:* 2.6: Assess financing, pricing, and policy landscape and strategy (iterative activity) 6.1: Identify global medical and scientific KOLs to serve on product expert/platform groups	2.6: The policy aspect of this landscaping exercise that will have identified evidence needed for global, regional, and national adoption of the product will inform consultations with WHO (and other global agencies as appropriate) regarding evidence needed for the expert committee. 6.1: Scientific and medical expert group may liaise with WHO and other global agency expert committees to assist these individuals in understanding clinical development data as well as policy issues around product

Activity Number	Activity	Dependencies	Rationale
		Follow-on activity: 8.2: Submit evidence to WHO expert committee	8.2: Presubmission consultations with WHO and other global agencies will allow for a more informed package of evidence to be submitted to expert committee
8.2	Submit evidence to WHO expert committee	*Prerequisite activities:* 8.1: Consult with WHO (and other global agency as appropriate) on what information should be submitted to its expert committee	8.1: Presented above
		Follow-on activity: 8.3: WHO/expert committee recommendation of product	8.3: WHO/expert committee's recommendation of product is predicated on positive assessment of the product evidence submitted
8.3	8.3: WHO/expert committee's recommendation of product is predicated on positive assessment of the product evidence submitted	*Prerequisite activities:* 8.2: Submit evidence to WHO expert committee	8.2 Presented above
		Follow-on activities: 8.4: Apply for inclusion on global Essential Medicines List 10.3: Ministries of Health adopt the product based on WHO recommendation and product evidence (scenario 1)	8.4: EML lists those products that have received the recommendation of WHO Expert Committee on the Selection and Use of Medicines 10.3: Recommendation of a product by the WHO/expert committee may positively influence a country Ministry of Health's likelihood of adopting the product for use in that country
8.4	Apply for inclusion on global Essential Medicines List	*Prerequisite activity:* 8.3: WHO/expert committee recommendation of product	8.3: Presented above

Activity Number	Activity	Dependencies	Rationale
		Follow-on activity: 10.2: Provide support for country policy review	10.2: A country is more likely and in some cases will only adopt the product if its generic form is on the WHO EML
9.0 COUNTRY DECISION SUPPORT			
9.1	Define key issues for and against introduction in particular countries	*Prerequisite activities:* 2.2: Revise TPP and obtain stakeholder feedback 2.7: Define product rollout strategy	2.2: In the process of obtaining stakeholder feedback, the key issues for and against introduction in countries will first be discussed; Activity 9.1 will later build on these in a more in-depth, focused way. 2.7: The product rollout strategy will determine in which countries to focus the study of key issues for and against introduction.
		Follow-on activity: 9.2: Engage in intensive, direct, and country-specific communication with key decision makers including national program managers, regulatory authorities, WHO country office staff, Ministry of Finance officials, and local researchers and academics	9.2: Those PDPs that are able to approach country stakeholders with an assessment of the key issues for and against introduction will be equipped to present a more compelling case to MoHs and other national stakeholders.
9.2	Engage in intensive, direct, and country-specific communication with key decision makers including national program managers, regulatory authorities, WHO country office staff, Ministry of Finance	*Prerequisite activities:* 6.1: Identify global medical and scientific KOLs to serve on product expert/platform groups 9.1: Define key issues for and against introduction in particular countries 10.2D: Conduct country studies on target market's providers and end-users, for use in product packaging and informational materials (if applicable)	6.1: KOL group can be influential in conversations with local stakeholders in priority countries, especially if they have been carefully selected for their expertise in these regions 9.1: Presented above 10.2D: Presented above
		Follow-on activity:	

Activity Number	Activity	Dependencies	Rationale
	officials, and local researchers and academics	9.4: Plan for pilot/demonstration projects	9.4: Discussions with local stakeholders will help PDPs target the areas that should be the focus of national or regional pilot/demonstration projects
9.3	Conduct regional workshops to share information and best practices and plan for introduction	*Follow-on activities:* 9.4: Plan for pilot/demonstration projects 10.4: Ministries of Health roll out the product (Scenario 2)	9.4: Pilot/demonstration projects may take into consideration information gaps revealed by regional workshops and make these a focus of further studies. In addition, information and best practices shared at regional workshops provide justification for national-level pilots and demonstrations projects. 10.4: Roll out in early adopting countries (that have not conducted pilot studies), will take in consideration best practices in plans for rollout.
9.3V	Conduct workshops to apply for financing (in GAVI eligible countries)	*Prerequisite activity:* 7.4V: Present investment case and conduct funding discussions with GAVI (if applicable)	7.4V: If GAVI decides to fund the vaccine, it is often helpful to countries unfamiliar with the process to hold workshops on how to apply for GAVI financing
9.4	Plan for pilot/demonstration projects	*Prerequisite activities:* 9.2: Engage in intensive, direct, and country-specific communication with key decision makers including national program managers, regulatory authorities, WHO country office staff, Ministry of Finance officials, and local researchers and academics 9.3: Conduct regional workshops to share information and best practices and plan for introduction 9.3V: Conduct workshops to apply for financing (in GAVI eligible countries)	9.2: Presented above 9.3: Presented above 9.3V (vaccine): Presented above

Activity Number	Activity	Dependencies	Rationale
		Follow-on activities: 9.5: Ministries of Health decide to support and participate in pilot/demonstration projects	9.5: If enough external evidence is presented to Ministries of Health, then Ministries may request or agree upon a local pilot to support proof of concept at the national level, thereby creating a critical mass of evidence for adoption
9.5	Ministries of Health decide to support and participate in pilot/demonstration projects	*Prerequisite activity:* 9.4: Plan for pilot/demonstration projects	9.4: Presented above
		Follow-on activity: 10.1: Conduct, support, or advise pilot/demonstration projects	10.1: The ability for pilot/demonstration projects to move forward is dependent on the agreement of Ministries of Health to support and participate in them
10.0 COUNTRY IMPLEMENTATION			
10.1	Conduct, support, or advise pilot/demonstration projects	*Prerequisite activities:* 5.7: File endemic country dossiers, including safety related documentation and plans 9.5: Ministries of Health decide to support and participate in pilot/demonstration projects	5.7: National regulatory approval is required for pilot/demonstration studies in most countries. 9.5: The ability for pilot/demonstration projects to move forward is dependent on the agreement of Ministries of Health to support and participate in them
		Follow-on activities: 10.5: Ministries of Health adopt the product after reviewing evidence from pilot/demonstration projects and other country evidence (Scenario 2) 11.2: Carry out studies and activities to track product adoption and uptake and also to support the assessment of public health impact on disease incidence	10.5: Data from pilot/demonstration projects are needed to support product adoption by Ministries of Health 11.2: Data from pilot/demonstration projects can provide critical postlicensure evidence of product effectiveness

Activity Number	Activity	Dependencies	Rationale
10.2	Provide support for country policy review	*Prerequisite activities:* 8.4: Apply for inclusion on global Essential Medicines List	8.4: Country policy review is more likely to be in favor of the product if it has been included on the EML
		Follow-on activities: 10.3: Ministries of Health adopt the product based on WHO recommendation and product evidence (Scenario 1)	10.3: Ministries of Health often adopt products based on WHO recommendations and product evidence, since WHO is a trusted source of information and recommendations about products for most countries
10.2D	Conduct country studies on the target market's providers and end-users, for use in product packaging and informational materials (if applicable)	*Prerequisite activities:* 5.7: File endemic country dossiers, including safety related documentation and plans 2.7: Define product rollout strategy *Follow-on activities:* 9.2: Engage in intensive, direct, and country-specific communication with key decision makers including national program managers, regulatory authorities, WHO country office staff, Ministry of Finance officials, and local researchers and academics	5.7: Information on market's healthcare providers and end-users will allow for creation of product packaging and informational materials that take into consideration any unique characteristics (e.g. lower literacy rates necessitating greater use of pictographs) of these individuals for inclusion in country-specific dossier 2.7: The product rollout strategy will determine in which countries to focus Activity 9.1 in. 9.2: Those PDPs that are able to approach country stakeholders with an assessment of the market will be equipped to present a more compelling case to MoHs and other national stakeholders.
10.3	Ministries of Health adopt the product based on WHO recommendation and product evidence (Scenario 1)	*Prerequisite activities:* 5.7: File endemic country dossiers, including safety related documentation and plans 6.3 Develop standard evidence package for global and country decision-makers and donors 8.3: WHO/expert committee recommendation of product	5.7: Ministry of Health adoption requires prior registration by national regulatory authorities. 6.3: Ministries of Health need a robust country-specific evidence package to review in order to make approval decisions 8.3: Recommendation of a product by the WHO/expert committee will positively influence the likelihood of Ministries of Health in Scenario 1 in adopting the product for use in that country

Activity Number	Activity	Dependencies	Rationale
		10.2: Provide support for country policy review	10.2: Presented above
		Follow-on activities: 10.4: Ministries of Health rollout product (Scenario 1) 11.2: Carry out studies and activities to track product adoption and uptake and also to support the assessment of public health impact on disease incidence	10.4: Ministries of Health can only rollout a product once it has adopted it 11.2: Once the product has been adopted, activities can begin to track product adoption and uptake and to support a determination of the product's impact on public health
10.4	Ministries of Health rollout product (Scenario 1)	*Prerequisite activity:* 10.3: Ministries of Health adopt the product based on WHO recommendation and product evidence (Scenario 1)	10.3: Presented above
10.5	Ministries of Health adopt the product after reviewing evidence from pilot/demonstration projects and other country evidence (Scenario 2)	*Prerequisite activities:* 5.7: File endemic country dossiers, including safety related documentation and plans 6.3 Develop standard evidence package for global and country decision-makers and donors 10.1: Conduct, support, or advise pilot/demonstration projects	5.7: Ministry of Health adoption requires prior registration by national regulatory authorities. 6.3: Ministries of Health need a robust country-specific evidence package to review in order to make approval decisions 10.1: Presented above
		Follow-on activities: 10.6: Ministries of Health rollout the product (Scenario 2) 11.2: Carry out studies and activities to track product adoption and uptake and also to support the assessment of public health impact on disease incidence	10.6: Ministries of Health can only rollout a product once it has adopted it 11.2: Once the product has been adopted, activities can begin to track product adoption and uptake and to support a determination of the product's impact on public health

Activity Number	Activity	Dependencies	Rationale
10.6	Ministries of Health rollout the product (Scenario 2)	*Prerequisite activity:* 10.5: Ministries of Health adopt the product after reviewing evidence from pilot/demonstration projects and other country evidence (Scenario 2)	10.5: Presented above
11.0 MONITORING & EVALUATION			
11.1	Support conduct of required post-licensure safety studies, routine pharmacovigilance, and safety reporting	*Prerequisite activities:* 5.1: Confer with regulatory agencies regarding manufacturing expectations, clinical trial design, appropriate cohorts to study, safety issues of potential concern, and regulatory submission requirements 5.2: Develop plan for postmarket safety surveillance, including acquisition of necessary data for contextualization of potential product safety signals (iterative activity) 5.4: SRA or twinned marketing authorization received	5.1: Ongoing dialogue with regulators from early on (pre-Phase 2) in the project will allow PDPs to identify those safety issues of potential concern to agencies where longer-term follow-up via postmarketing safety studies or targeted pharmacovigilance is warranted. 5.2: Safety issues identified with regulators will dictate the data on background rates of safety events needed to place safety data post-licensure into context. 5.4: Market approval of product triggers start of postmarketing safety surveillance activities.
11.2	Carry out studies and activities to track product adoption and uptake and also to support the assessment of public health impact on disease incidence	*Prerequisite activities:* 10.1: Conduct, support, or advise pilot/demonstration projects 10.3: Ministries of Health adopt the product based on WHO recommendation and product evidence (Scenario 1) 10.5: Ministries of Health adopt the product after reviewing evidence from pilot/demonstration projects and other country evidence (Scenario 2)	10.1: Results from pilot/demonstration projects can provide information on product effectiveness in real world settings. 10.3: Activities to track adoption are necessarily dependent on countries approving and using the product 10.5`: Activities to track adoption are necessarily dependent on countries approving and using the product