Interview Slide Deck

Product Development Partnership
Access Timelines Project

Laura Frost and Sybil Eng

Agenda

- Background on PDP Access Timelines Project
- Guiding questions for this interview
- Categories of access activities
- Access activities Gantt chart
- Main access lessons learned from PDP projects
- Next steps

Background on PDP Access Steering Committee and Current Access Timelines Project

- PDP Access Steering Committee formed in 2008 to collaborate in improving PDP effectiveness in critical access areas
- Current project commissioned in 1Q11 to accomplish the following:
  - Study access timelines for drugs and vaccines developed for low-andmiddle-income (LMIC) settings
  - Create a series of generic access timelines for drugs and vaccines
  - Describe and explain rationale for approaches and best practices that accelerate access to new products
- Data for project will be gathered via interviews with staff from PDPs, donors, and pharmaceutical companies with experience bringing products to LMICs

PDPs may use project deliverables to ensure optimal uptake and accelerated introduction of their products in developing countries

Guiding Questions for this Interview

- Does the list and sequence of activities within each category (on subsequent slides) reflect what you know to be happening now, in the projects with which you are familiar?
- Which of the activities on the list do you view as more time sensitive? Less time sensitive? Why?
- What access activities tend to be/have been left until too late? Or implemented too early? Why? What have been the consequences of getting timing and sequencing wrong?
- Where and how can access timelines be compressed?
- Is the timing of any of the activities, or the transitions between them, unduly optimistic or unrealistic? Which ones and why?

Strategy and Planning

- Create internal PDP working group on access, if not already existing, and establish TPP
- Assess burden of disease, unmet need, and stakeholder feedback, and revise TPP
- Define regulatory strategy (i.e., sequence of regulatory filings)
- Define pricing and financing strategy (e.g. tiered or not; price ceiling)
- Assess financing landscape and define and present investment case
- Define product introduction and rollout strategy (priority countries, individual country challenges, partners)

Intellectual Property Management

- Negotiate and finalize production agreements with manufacturers (including pricing agreements)

Process Development, Manufacturing, and Supply

- Conduct market study, assess possible manufacturing, assess range of possible manufacturing partners and feasibility of technology transfer (if relevant to the project)
- Develop strategic demand forecast for global supply
- ***Select and finalize agreement with manufacturing partners for technology transfer (if relevant)****
- Conduct stress and stability tests
- Conduct follow-on process development and packaging activities, e.g.:
  - Optimize API synthesis routes and formulation
  - Scale up manufacturing
  - Review range of inner packaging, conduct stability testing in inner packaging
  - Integrate global supply chain and demand forecasts to ensure sufficient global supply
  - Finalize outer product packaging and labeling with manufacturing partner
  - Manufacture product
- ***Product ready for shipment****

* ***Boldface and italicized type*** indicates a milestone

Regulatory

- Prepare and file SRA or twinned regulatory filing for product approval
- ***SRA or twinned marketing authorization received****
- Prepare and file WHO prequalification dossiers and country-specific dossiers
- Develop plan for post-marketing safety surveillance

*__Boldface and italicized type__ indicates a milestone

Communications and Advocacy

- Identify experts and product champions, develop publication plan, and conduct product awareness activities
- Develop a standard evidence package for global and country decision-makers and donors
- Communicate information and results (i.e., incidence/prevalence data, Phase 3 results, pilot/demonstration projects) to generate interest in introducing the product

Economics and Financing

- Engage in policy discussions, knowledge building, and advocacy activities with key global financing bodies
- Commission economics and financing studies (i.e., cost-effectiveness analyses, studies of broader economic and social impact, etc.)
- ***Public and private sector prices defined for all countries****
- Conduct funding discussions with donors and national governments
- ***Financing decisions made by donors and national governments****

**Boldface and italicized type* indicates a milestone

Global Policy

- Consult with WHO (and other global agencies, as appropriate) on what information should be submitted to its expert committee
- Submit evidence to WHO/expert committee for endorsement
- ***WHO/expert committee recommendation of product****
- Apply for inclusion on global Essential Medicines List

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Country Decision Support

- Define key issues for and against introduction in particular countries
- Engage in direct, intensive, and country-specific one-on-one communication with key decision-makers, including national program managers, regulatory authorities, WHO, country office staff, and local researchers
- Plan for pilot/demonstration studies
- ***Ministries of Health decide to support and participate in pilot/demonstration projects****

***Boldface and italicized type** indicates a milestone

Country Implementation

- Conduct, support, or advise pilot/demonstration projects
- Provide support for country policy review
- ***Ministries of Health adopt the product based on WHO recommendation and product evidence (scenario 1)****
- Ministries of Health roll out the drug (scenario 1)
- ***Ministries of Health adopt the product after reviewing evidence from pilot/demonstration projects and other country evidence (scenario 2)****
- Ministries of health roll out the drug (scenario 2)

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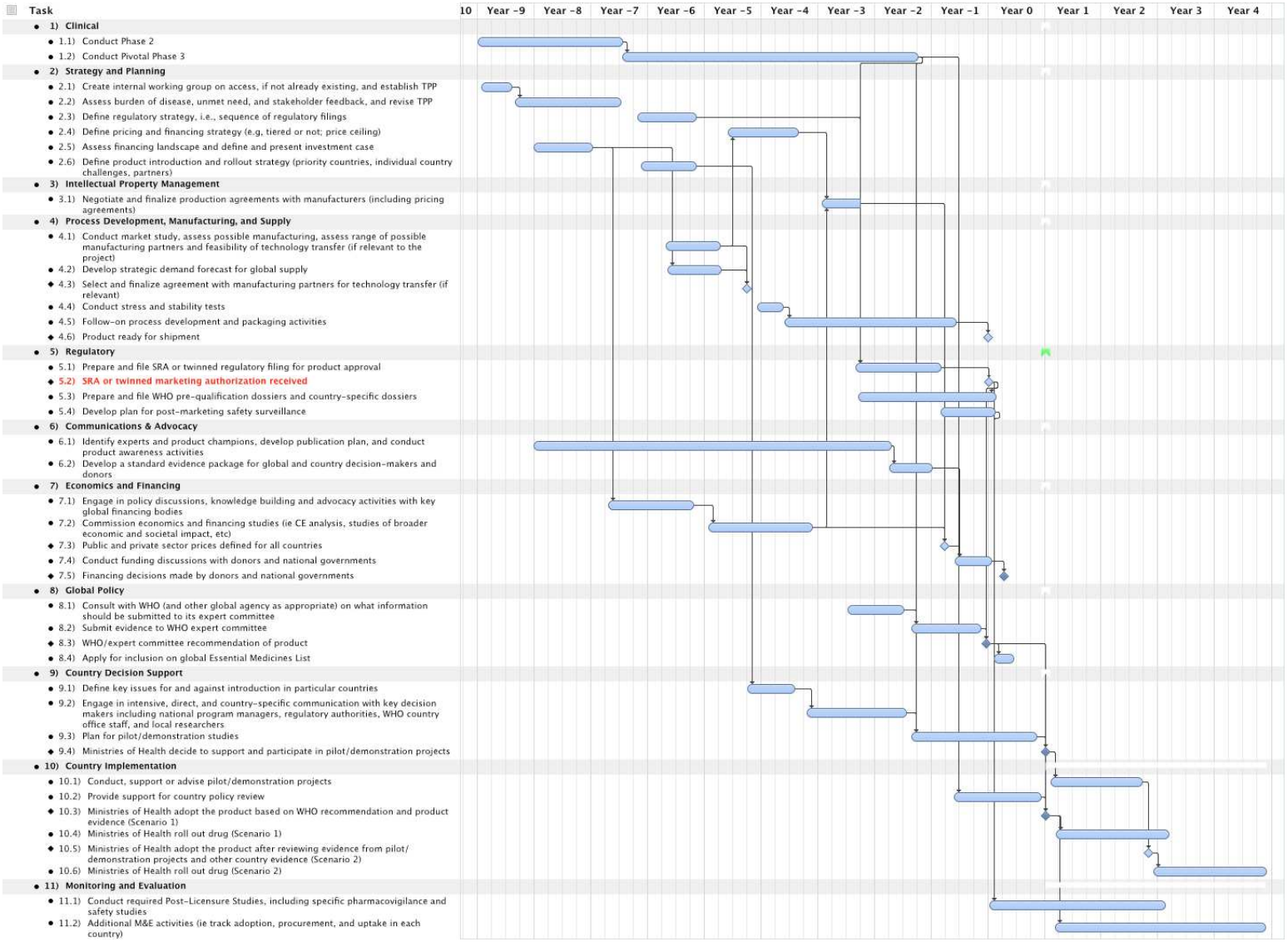
Monitoring and Evaluation

- Conduct required post-licensure studies, including specific pharmacovigilance and safety studies
- Conduct additional monitoring and evaluation activities:
  - Track procurement in each country
  - Track uptake in each country

PDP Access Activity Gantt Chart



Main Access Lessons Learned from Projects

- What are the five key access-related learnings from your project experience? Please consider:
  - Activities and decision points that were triggers for unusual activity, e.g. a capital expenditure on a manufacturing plant
  - Specific planning steps or activities carried out earlier in the project that saved substantial amounts of time downstream
  - Unanticipated activities that substantially delayed market access for a product
- What activities or studies did you need to do before you could establish your key strategies (e.g. regulatory, pricing, product financing, roll-out strategy, etc.)?
- What major, strategic, non-clinical activities are missing from this Gantt chart?

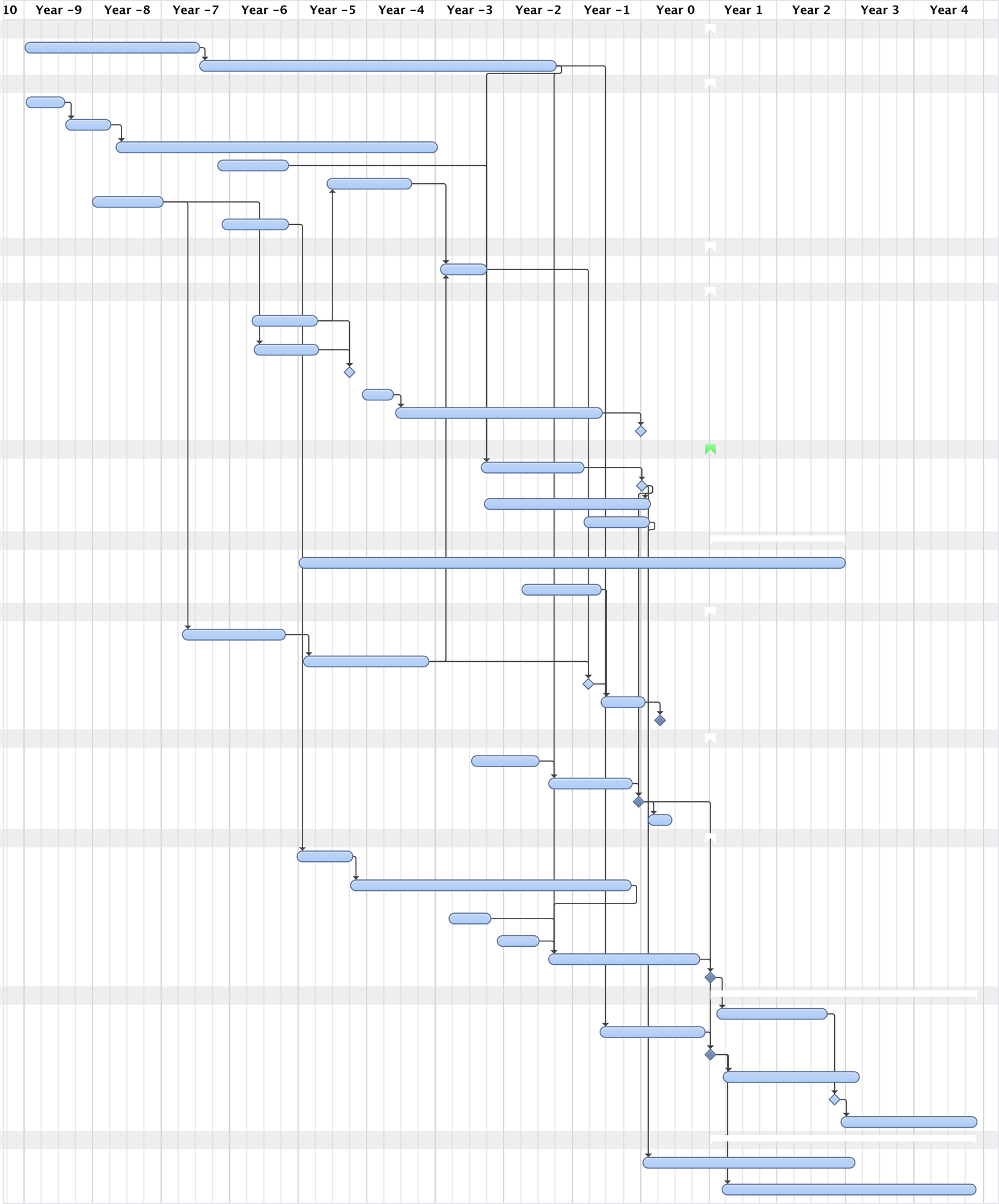
Next Steps

- The project consultants will compile a transcript of this interview and send it to you within two weeks for your review
- During your transcript review you may:
  - Correct any errors and/or add information
  - Specify whether information can be used freely, may only be used as context or background, or may not be used at all
- It has been standard practice in PDP SC projects to include a list of all project interviewees and their affiliations within the final project paper, but your name and affiliation will only be included with your permission
- You will have the opportunity to comment on draft copies of all project deliverables when they are prepared and will receive final copies of these for your files (expected end 2Q11)

Contact Details for Project Consultants

- Please feel free to contact us with any questions you may have:
  - Laura Frost, ScD – Partner, Global Health Insights
    laurajfrost@glohi.org +1 973 699 4211
  - Sybil Eng, PhD – Consultant, Global Health Insights
    sybil.eng@gmail.com +1 917 355 4838
- Thank you for contributing your time and insights!

Task
1) Clinical
1.1) Conduct Phase 2
1.2) Conduct Pivotal Phase 3
2) Strategy and Planning
2.1) Create internal working group on access, if not already existing, and establish TPP
2.2) Assess impact of potential formulation constraints on demand (e.g. if product requires multiple doses, isn't ready to use, requires special storage)
2.3) Assess burden of disease, unmet need, and stakeholder feedback, and revise TPP
2.4) Define regulatory strategy, i.e., sequence of regulatory filings
2.5) Define pricing and financing strategy (e.g, tiered or not; price ceiling)
2.6) Assess financing landscape and define and present investment case
2.7) Define product introduction and rollout strategy (priority countries, individual country challenges, partners)
3) Intellectual Property Management
3.1) Negotiate and finalize production agreements with manufacturers (including pricing agreements)
4) Process Development, Manufacturing, and Supply
4.1) Conduct market study, assess possible manufacturing, assess range of possible manufacturing partners and feasibility of technology transfer (if relevant to the project)
4.2) Develop strategic demand forecast for global supply
◆ 4.3) Select and finalize agreement with manufacturing partners for technology transfer (if relevant)
4.4) Conduct stress and stability tests
4.5) Follow-on process development and packaging activities
◆ 4.6) Product ready for shipment
5) Regulatory
5.1) Prepare and file SRA or twinned regulatory filing for product approval
◆ **5.2) SRA or twinned marketing authorization received**
5.3) Prepare and file WHO pre-qualification dossiers and country-specific dossiers
5.4) Develop plan for post-marketing safety surveillance
6) Communications & Advocacy
6.1) Identify experts and product champions, develop publication plan, and conduct product awareness activities
6.2) Develop a standard evidence package for global and country decision-makers and donors
7) Economics and Financing
7.1) Engage in policy discussions, knowledge building and advocacy activities with key global financing bodies
7.2) Commission economics and financing studies (ie CE analysis, studies of broader economic and societal impact, etc)
◆ 7.3) Public and private sector prices defined for all countries
7.4) Conduct funding discussions with donors and national governments
◆ 7.5) Financing decisions made by donors and national governments
8) Global Policy
8.1) Consult with WHO (and other global agency as appropriate) on what information should be submitted to its expert committee
8.2) Submit evidence to WHO expert committee
◆ 8.3) WHO/expert committee recommendation of product
8.4) Apply for inclusion on global Essential Medicines List
9) Country Decision Support
9.1) Define key issues for and against introduction in particular countries
9.2) Engage in intensive, direct, and country-specific communication with key decision makers including national program managers, regulatory authorities, WHO country office staff, and local researchers
9.3) Conduct regional workshops to share information and best practices, and plan for introduction
9.4) Conduct workshops to apply for financing (in GAVI eligible countries)
9.5) Plan for pilot/demonstration studies
◆ 9.6) Ministries of Health decide to support and participate in pilot/demonstration projects
10) Country Implementation
10.1) Conduct, support or advise pilot/demonstration projects
10.2) Provide support for country policy review
◆ 10.3) Ministries of Health adopt the product based on WHO recommendation and product evidence (Scenario 1)
10.4) Ministries of Health roll out drug (Scenario 1)
◆ 10.5) Ministries of Health adopt the product after reviewing evidence from pilot/ demonstration projects and other country evidence (Scenario 2)
10.6) Ministries of Health roll out drug (Scenario 2)
11) Monitoring and Evaluation
11.1) Conduct required Post-Licensure Studies, including specific pharmacovigilance and safety studies
11.2) Additional M&E activities (ie track adoption, procurement, and uptake in each country)



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