PEPFAR-Funded Evaluations

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Scientific Advisory Board Meeting
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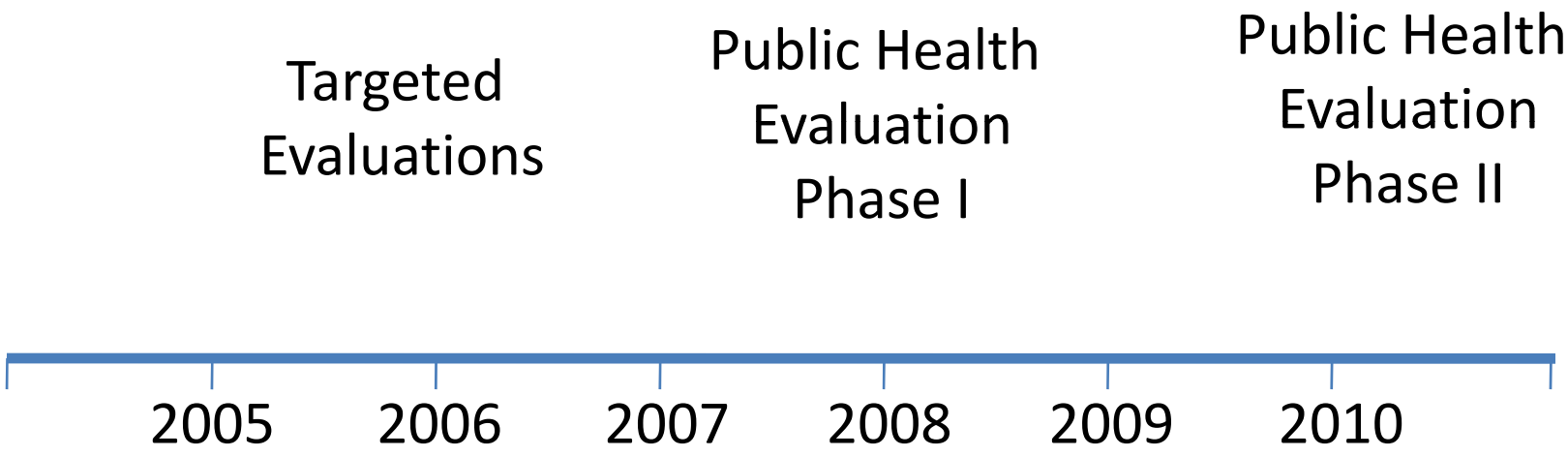
Overview

- Evaluation and research
- Priorities
- Current portfolio
- Challenges
- Future directions

PEPFAR Evaluation Timeline



Targeted Evaluation FY05-06

"Studies that provide rapid answers to specific, measurable, and focused questions about health program implementation to improve services and identify best practices."

- Legislative sensitivities on use of PEPFAR funds for "research" require careful selection of terminology and study design (no randomization)
- Little control at HQ level (concept approval and reporting are formalities)

Targeted Evaluation FY07

- Produce generalizable results and contribute to sustainability of programs
- Provide rigorous assessment usually including pre- and post-test results of a group with a comparison or control
- Not randomized trials, but leverage quasi-experimental designs
- Answer specific questions about overall efficacy and best practice

Public Health Evaluation FY08

- Includes and expands on TE, shifting the focus from individuals to communities and populations
- Studies of program activities, characteristics, outcomes and impact, to determine effectiveness of a program, compare program models, answer operational questions for implementation
- Sound scientific practices, including systematic sampling, comparison groups, and randomization when appropriate
- Increasingly result in data that can be aggregated across projects and countries
- Multi-country protocols to answer priority questions are encouraged, and may be generated at country, central, or evaluation team levels

Public Health Evaluation FY09

- Questions of global significance, allowing for some country-priority studies
- Effectiveness and impact of programs at community or population level
- Comparative evaluations of interventions or program models
- Operational questions related to implementation
- In-depth studies beyond routine program evaluation
- Utilizes rigorous, scientifically sound research methodology of varying complexity, and may include control groups, randomization, modeling or advanced statistical techniques

Public Health Evaluation FY10

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- Effectiveness and impact of programs at community or population level
- Comparative evaluations of interventions or program models
- Operational questions related to implementation
- In-depth studies beyond routine program evaluation
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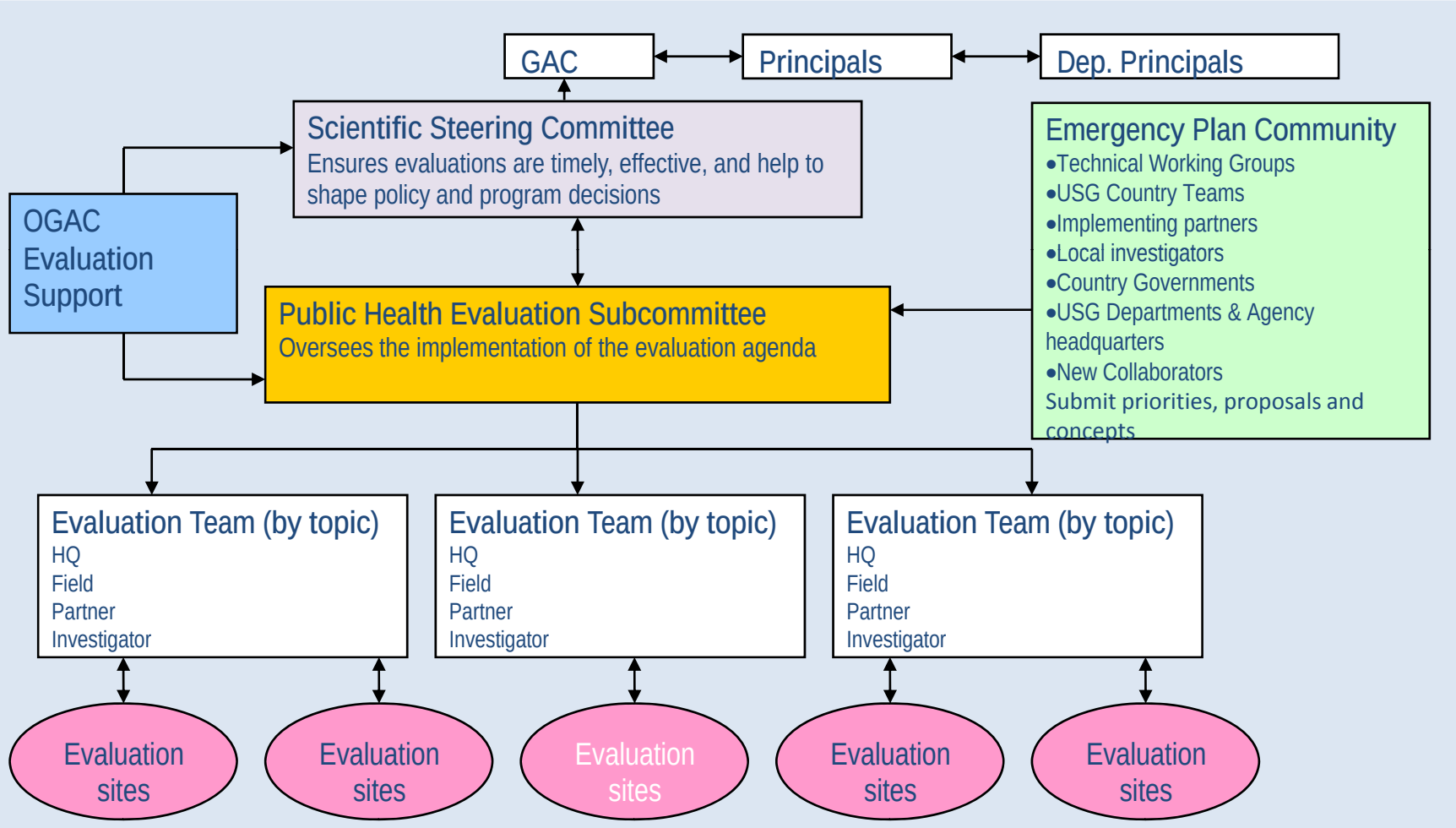
PHE Structure within PEPFAR



PHE Evaluation Teams

- Multi-agency representation (CDC, DOD, HRSA, NIH, USAID)
- Provide technical review of all protocols funded under PEPFAR
  - Complements, does not replace, IRB review
  - TA resource to study team
- Evaluation Team focus areas:
  - Sexual Transmission
  - Care and Treatment
  - PMTCT/Pediatric
  - Counseling and Testing
- Pre-Teams
  - Male Circumcision
  - Human Resources for Health
  - Food and Nutrition
  - OVC

PHE Process

- Concept submission
  - Concept review
- Protocol submission
  - Protocol review
- Study initiation
  - Annual progress reports

PHE Priorities

Priorities FY05-06

- FY05-06
  - Country-driven
- FY07
  - TWG-driven, 41 priority areas/questions

Priorities FY08-09

1. What are the effects of available interventions (e.g., ART, male circumcision, behavior change communications) on incidence in serodiscordant couples?
2. What interventions reduce early mortality in patients initiating ART?
3. What are the effects of task-shifting for prevention, care, and treatment service delivery on quality, outcomes, cost effectiveness, etc?
4. How can barriers to national scale-up of PMTCT programs be overcome to maximize program impact while maintaining or improving overall maternal and child health?
5. Which models of provider-initiated HIV counseling and testing in clinical settings result in more people tested, higher percentage of HIV infected persons identified and linked to care, and a reduction in risk behaviors?
6. What are the optimal approaches to infant feeding and nutrition (e.g., feeding method, weaning strategy, ART and ARV prophylaxis for mother and child) among HIV-exposed children to maximize PMTCT and HIV-free survival?

Priorities FY08-09 (cont'd)

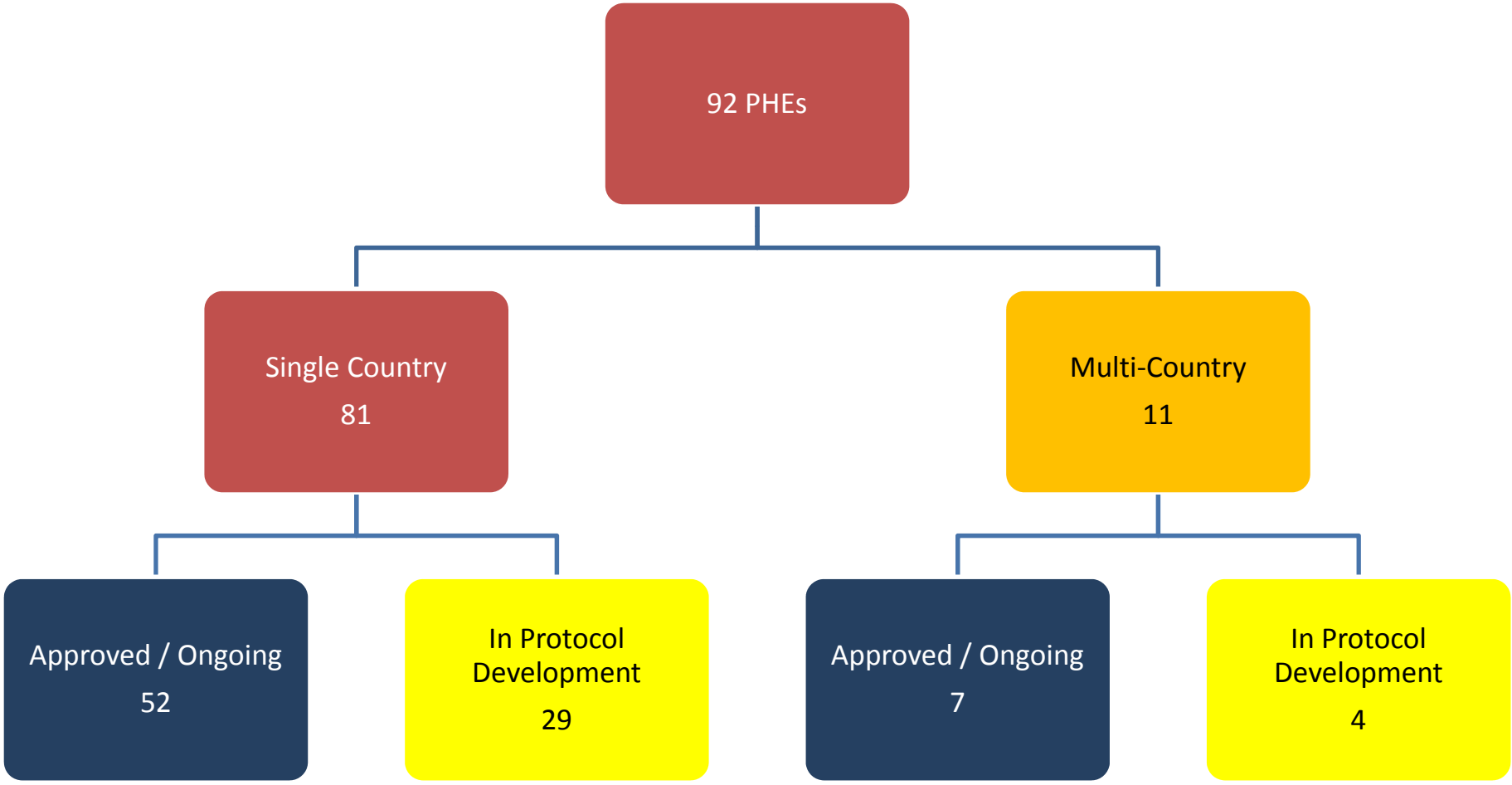
7. Can intensified behavioral interventions reduce HIV incidence among high-risk HIV-negative clients attending counseling and testing sites?
8. What are the most effective service delivery models to improve outcomes (e.g., retention in pre-ART, time to initiation of ART) among those receiving comprehensive pre-ART care?
9. What are the effective individual and mass behavioral change communication models to reduce concurrent partnerships?
10. What is the impact of provision of HIV-related services on the broader health system in a country (*e.g.*, on healthcare personnel, services in non-HIV facilities, healthcare infrastructure, national health funding, etc)?
11. What is the impact of wide-spread ART on prevalence/incidence on a population basis?

Priorities FY10

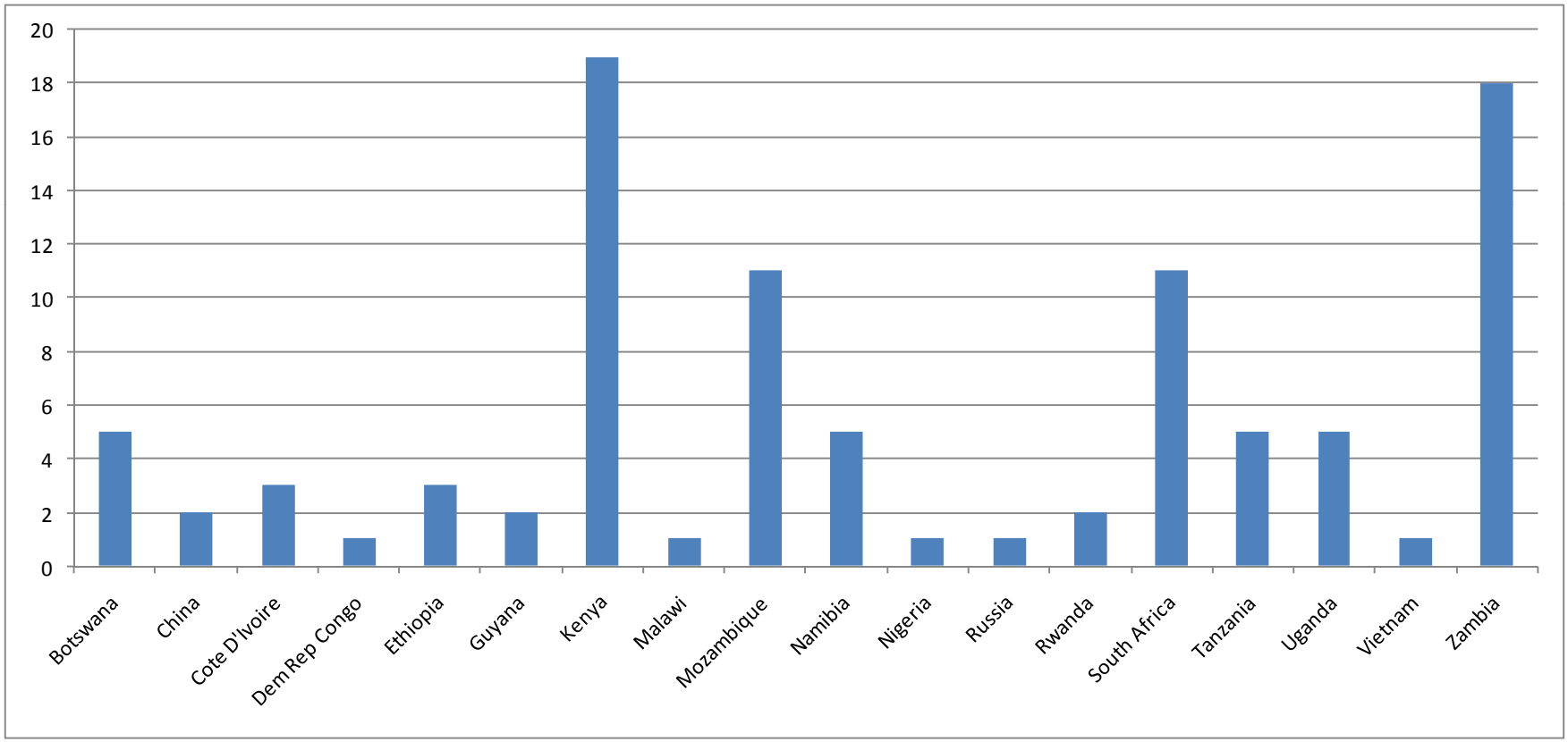
- Country-driven concepts that answer questions of specific interest and priority to the country
- Concepts based on country needs, particularly as identified and proposed by MOH
- May align with priorities in FY09

Current Portfolio

Current PHE Studies



PHE Studies by Country



PHE Study Topics

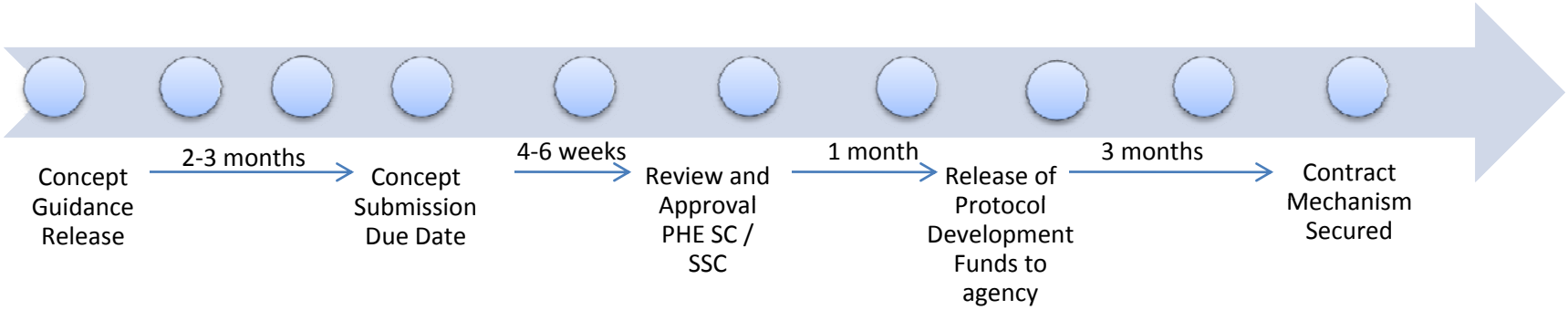
- Care and Treatment (45)
  - HIV/TB
  - HSS/HRH
  - Costing
- PMTCT / Pediatrics (23)
  - OVC
- Sexual Transmissions/Prevention (19)
  - Male Circumcision
- Counseling and Testing (5)

- Total PHEs: 92 *(includes multi-country PHEs)*

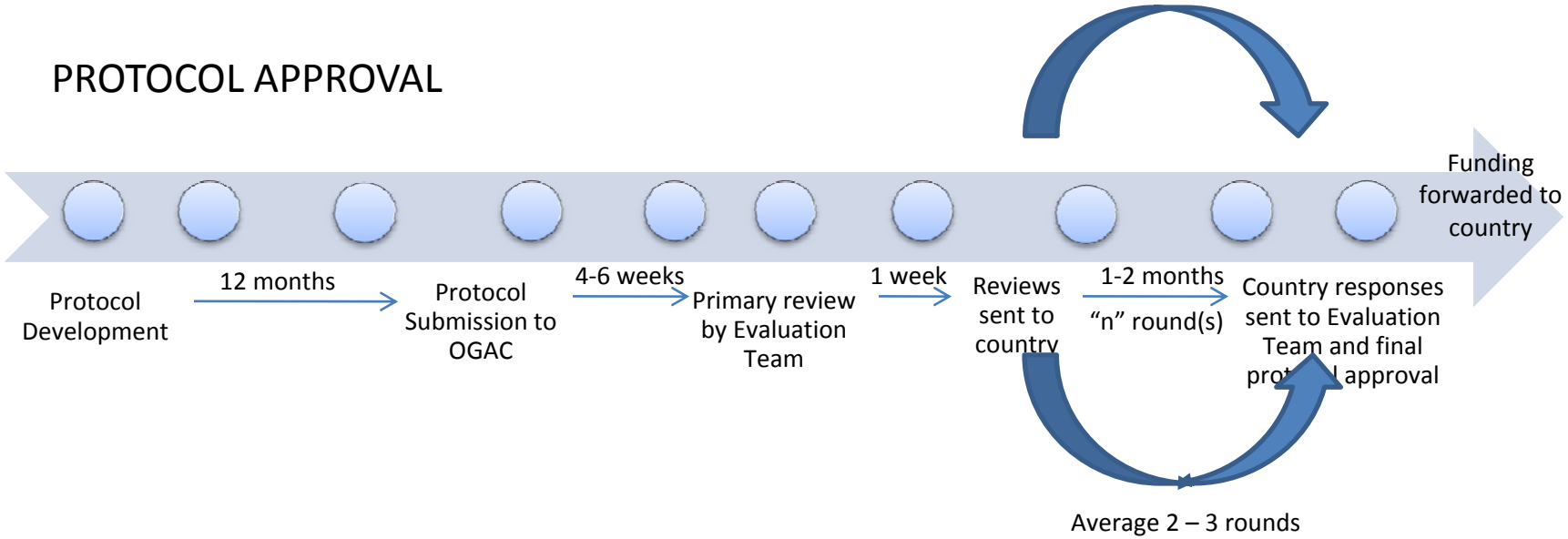
Challenges

PEPFAR Submission and Approvals Timeline

CONCEPT SUBMISSION



PROTOCOL APPROVAL



PHE Implementation Challenges

- Many concepts not approved after technical review
  - Unclear methodologies, sample size and statistical power issues
- Slow progress on many studies
  - Transition from concept to protocol is problematic
  - Protocol review often takes multiple iterations
  - Multi-country studies slowed by many “moving parts”
  - Long delays result in irrelevance of original concept
- Country Teams are reluctant to engage in PHE process
- Ensuring the appropriate balance between quality PHE and timeliness of execution

Future Directions

Transitioning PHE

- Reframe in context of Implementation Science
- Align directly with each country's national research priorities
  - With country government, develop a national HIV/AIDS research-needs assessment and plan, a plan for research-capacity building, and a plan for utilizing research to better inform policies and programs
- Capacity building necessary to enable in-country investigators and institutions to lead studies

FY10 Transition

- Introduction of Implementation Science concept
- Financial support external to PEPFAR mechanisms
  - NIH Supplement

FY10 NIH Supplement

PEPFAR NIH Supplement Award Summary

- Total # of applications submitted: 141
- Number awarded: 35
  - Care and Treatment: 19 (54%)
  - PMTCT/Pediatrics: 11 (31%)
  - Prevention: 5 (14%)
- Number of PEPFAR countries represented: 18

FY10 NIH Supplement

Specific Research Areas

- Nutrition
- OVC
- PMTCT
- Retention of HIV+ patients in care and treatment
- Integration of services into 1^{o} care & co-morbidities
- HIV prevention interventions
- HSS / HRH
- Gender
- MARPs (including MSM and IDUs)

FY11 Transition

- RFAs directed towards evaluation of priority objectives for PEPFAR writ large
  - Determined in consultation with Scientific Advisory Board
- Focus on country-level capacity building and strengthening research skills
  - Support for local-researcher projects
- Combination prevention
  - Evaluation should focus on the *entire* package
  - ARV-based prevention will be a critical component

Implementation Science

From: *Padian, Holmes, McCoy, Lyerla, Bouey and Goosby: JAIDS, 2011*

What is Implementation Science?

- Methods to improve the uptake, implementation, and translation of research findings into routine and common practices.
- Less focus on what works and more on ***how*** we :
  - Deliver interventions efficiently and effectively
  - Transfer and adapt interventions from one setting or population to another
  - Make informed, evidence-based choices between competing:
    - ➢ interventions
    - ➢ components within a combination strategy
    - ➢ strategies for delivery

Outcomes of IS

- Effectiveness at a community level
- Optimal delivery of services (value for the money; efficiency)
  - Cost effectiveness
  - Most efficient strategies for implementation

Major Components of IS

- Monitoring and evaluation (inputs/outputs)
- Operations research (simulation, mathematical optimization, decision science)
- Impact evaluation (methods that permit causal attribution of outcomes to programs delivered at scale)

IS Example Questions

- What are the best ways to optimize service delivery?
  - Balance of fixed and mobile clinics
  - Most efficient and effective methods to accelerative task shifting
  - Effectiveness and efficiency of vertical versus integrated services

- How can we improve access to programs?
  - Whom to target (optimal time) to begin treatment for HIV and TB to maximize clinical ***and*** public health benefits
  - Best methods to
    - Identify those who are eligible (on-going screening)
    - Decentralize quality care
    - Increase long-term retention

IS Example Questions (cont'd)

- What are the most robust methods to optimize or amplify the impact of prevention?
  - Incentives or economic opportunities
  - Innovative methods to increase adherence
  - Optimal combination of strategies to enhance ARV-based prevention

- How can we adapt the health platform PEPFAR helped develop to strengthen delivery system for other health outcomes
  - TB
  - MCH, Reproductive health

Overall Goals of an IS agenda

- Choosing interventions strategically
- Focusing them where they will have maximum benefit
- Improve implementation efficiency
  - Better management
  - Strategic integration with other services
- Maximize long-term benefit, not results for the annual report

What Does IS Mean for PEPFAR?

- Provides a single framework for the entire spectrum of PEPFAR programs and evaluations from M & E →OR →IE
- Provides a uniform strategy for the collection and use of information across the entire IS spectrum
- Strengthens standards of evidence that underlie PEPFAR activities
- Focuses resources on critical questions and casual evidence

IS Capacity Building

- Assess existing programs and opportunities for training in research and methods of evaluation
- Work with countries to develop programs and TA where needed
- Focus on long-term impact: shift the focus from numbers trained to numbers shaping and driving the research agenda