

# Country Decision Making

William Wells\* and Alan Brooks#

\*Global Alliance for TB Drug Development, New York, NY USA

#PATH Malaria Vaccine Initiative, France

July 27, 2010

PDP Access Meeting, Divonne les Bains



**TB ALLIANCE**

GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

# Country Decision Making is By and For the Country [but others can assist]

- It is the country that reaches the decision
- With so many activities at country level, however, the consideration of new products may get lost
- Globally, PDPs can help multilateral agencies to work through the necessary issues in a harmonized manner
- Locally, PDPs, WHO, pharma and other actors can assist in the generation of a public health case for and against adoption
- Depending on the product and disease, there may also be need for:
  - definition of disease burden;
  - establishment of new decision-making bodies;
  - support for local advocacy;
  - and Phase IV studies.



# What is the pathway from engaging one country to adoption by many?

- Trials are the starting point: Country involvement in Phase III and/or IV studies builds local momentum towards adoption
  - iOWH Phase IV trials
  - DNDi disease platforms
  - IVCC M&E of vector control programmes
- But then regional meetings allow further buy-in and cross-fertilization between more- and less-involved countries
  - PneumoADIP/IVAC regional meetings
  - MVI decision-making framework meetings
- WHO's network (country offices to regional to global) can:
  - Keep the process moving
  - Monitor progress towards decision-making



# How PDPs prioritize countries for engagement and establish a local presence

- Countries are prioritized with two (sometimes overlapping) goals in mind:
  - Identify early adopters
  - Maximize final public health impact
- Strategies for establishing a local presence include:
  - Country offices (usually driven by R&D needs)
  - Consultants on partial retainer
  - Sustained engagement with existing or newly formed committees
  - Strengthened engagement with local researchers
  - Ad hoc engagement with local committees



# Division of labor

- Coordination of access activities often requires the input of an organization dedicated to this process.
- But PDPs cannot reach every country; partnership is necessary.
- Other partners who can support country decision making:

<u>Partner</u>	<u>Advantages</u>	<u>Disadvantages</u>
Multilaterals such as WHO	Extensive reach and impartiality	Typically cautious about new interventions; May be overwhelmed by other initiatives and thus lack time and resources to devote to new product introduction
Local academia, researchers and/or professional organizations	Close to in-country processes, needs and data; Credible with local policy-makers	May not have a broad view of a problem; May be influenced by personal research interests
NGOs	Some have specific expertise in new product introduction	Require funding specific to the new product to drive their activities
Pharma and/or manufacturing partners	Product-specific expertise, and in some cases extensive sales networks in some markets	May be seen as a biased source of decision making information; may lack experience in the disease and/or in low income settings



# The session today

- Role of PDPs and division of labor (Philip Anum, MoH, Ghana)
- DNDi's approach (Florence Camus-Bablon, DNDi)
- IVAC's (and its predecessors') approach with multilaterals (Lois Privor-Dumm, IVAC)
  
- Moderated panel: 3 speakers + Alan Brooks, MVI
  - Number of new products vs. absorptive capacity
  - Extent of involvement of PDPs (# countries with direct interaction; depth of interaction)
  - Choice of partner for country engagement (multilaterals, local researchers, NGOs, pharma)

