

## ➔ From Research to Rollout: Evaluations that move a product to the "real world"

### Post-trial access

- Intervention provided to trial participants and, sometimes, their communities, after the trial is over and before a product is available for widespread use.

### Open label extensions

- Intervention made available, often for a specific time frame, in the context of a follow-on study protocol in which participants from the previous randomized controlled trial (RCT) know that they are receiving the active intervention.
- Gather information about how a product works in people who are now aware of the potential benefit.

### Open label / implementation studies

- Research protocols similar to above but enrolling new participants—e.g., those who were not previously enrolled in the RCTs and who might be in open label extensions (OLEs).

### Demonstration projects

- "Road test" use of new option in real-world settings—not in trial site.
- Can address both infrastructure needs to deliver intervention and ways individuals integrate it into daily activities and decision making.
- Can help answer core questions about which populations will gain greatest benefit from new interventions, how best to provide those tools and ensure that people use them as directed, and how to integrate new tools with existing methods and health systems.

### Product introduction

- Complex process of formally making new options widely available. Can include:
  - Meeting complex regulatory requirements, prequalification by WHO, and various country-specific requirements.
  - Overcoming logistical challenges, such as production scale-up, supply and logistics issues that come with manufacturing and introducing a new product.
  - Building awareness of and demand for new prevention methods in relevant communities through education, marketing, promotion and other activities.
  - Working with health ministries, funding agencies and implementing partners to ensure that new interventions are integrated with other proven strategies and health systems.

### Scale-up

- Process of ramping up access to new options for all who need them. Scale-up requires mobilization of sufficient resources for procurement, distribution, delivery, worker training and other costs associated with rollout; quick identification and resolution of potential bottlenecks; and engagement with at-risk communities to ensure a sense of ownership over the scale-up.