The PDP Reach: How Far Should PDPs Extend?

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Current Role of Access within PDPs

• Access imbedded in work of organization
  • R&D, BD, Executive follow access principles
  • Focus of the Access Teams

• Access informs product development
  • How access considerations are incorporated into development of new product
  • How access informs target product profiles (TPP)
  • Consider: Mechanisms for mapping user requirements & Timing – before Phase 3, know the market

• Access facilitates timely uptake
  • Think through all the needs and facilitate potential roadblocks: fewer surprises
  • Catalyze/Leverage other partners
  • Fill gaps
**PDP Role in Post-Licensure**

- **Prioritize activities at country level**
  - Financing - the biggest hurdle?
  - Regulatory
  - Policy change
  - Pricing
  - Distribution/sales
  - Patient/provider education

- **Define Objectives: How far should we go?**
Partners

• Are the partners in place to take the rest on?
  • Partners with offices: e.g. MVI has PATH, others have...?
  • Manufacturers: relationships with regulatory, distribution, sometimes govt relations
  • Technical assistance providers in disease areas, supply chain management
  • WHO
  • National programs

• Are these sufficient or are there gaps?

• Input from countries and WHO needed!
Defining Our Mandate:
What is appropriate PDP Role Post-Licensure?

• Do we have the expertise?
  • Better to highlight the relevant gaps and advocate for others to take action?

• What successful balancing is currently happening?
  • Lessons learned from those on the market now

• How can we be clearer about what we are doing?
  • Is any of us covering the last mile?
  • If the worry is about cost, perhaps we need to define what costs we expect to have at implementation stage
  • Input from donors needed!