

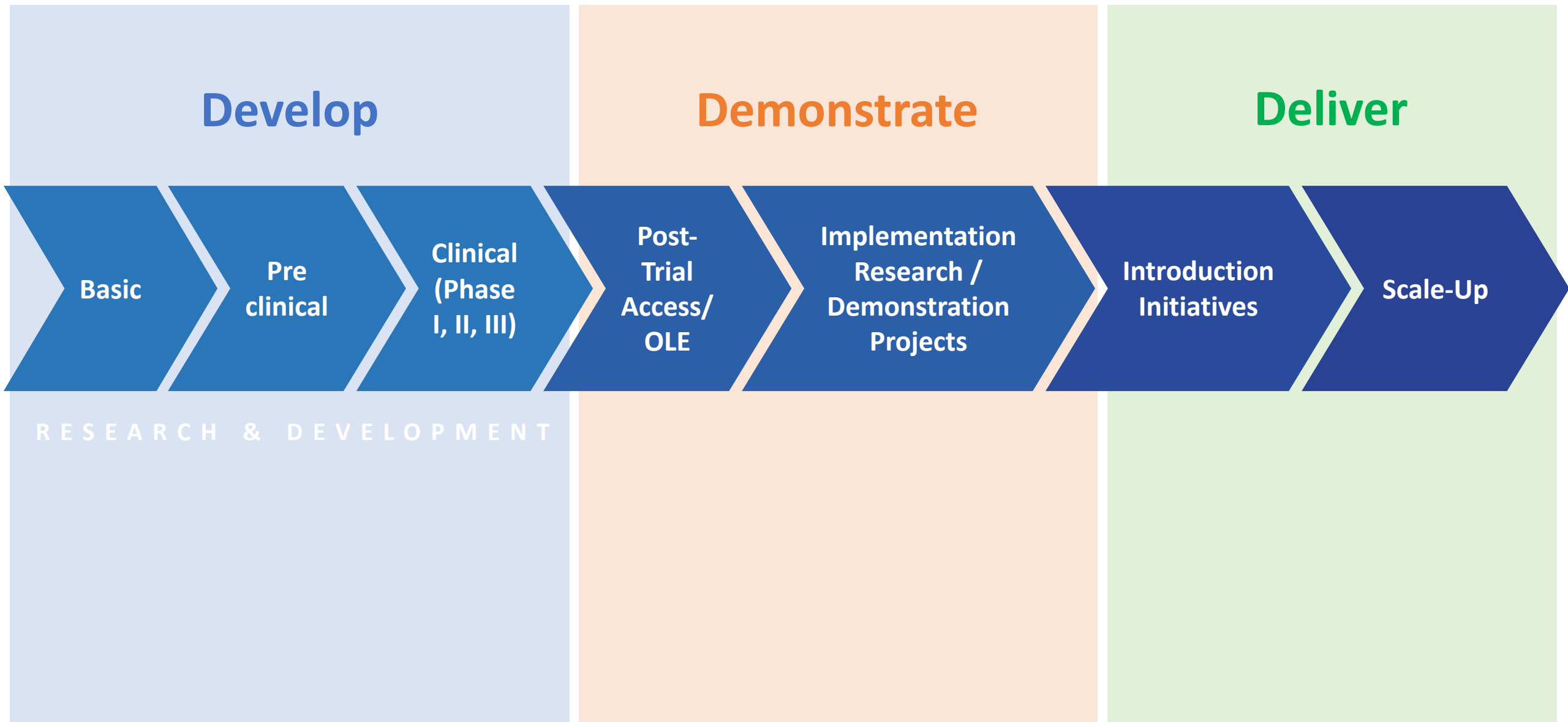
AVAC

Global Advocacy for HIV Prevention

From Research to Rollout: Comparing oral PrEP and the dapivirine ring

AVAC
March 2018

Product Introduction Process: Research to rollout



Product Introduction Process: Moving a product to the “real world”

Post-trial access

After trial ends, intervention provided to participants, and sometimes their communities

Open label extensions (OLE)

Follow-on study, intervention available for specific time to participants from randomized controlled trial who know they are receiving active intervention/potential benefit

Implementation research

Research protocol enrolling new participants (not previously in trials/OLE), aiming to assess intervention in a more “real world” setting

Demonstration projects

Offer use of new intervention outside of clinical trial site; can address delivery infrastructure needs and ways individuals integrate it into daily activities & decision making

Introduction initiatives

Large-scale provision of an intervention, sometimes part of country rollout, aiming to learn and apply lessons from introducing an intervention at scale

Scale-up

Complex process of making new intervention widely available, includes mobilization of sufficient resources for procurement, distribution, delivery, worker training, etc.

Product Introduction Process: Comparing oral PrEP and Dapi Ring

Phase III Efficacy	44% <i>(iPrEx, 2010)</i>	27% & 31% <i>(ASPIRE & Ring Study, 2016)</i>
Open label extensions (OLE)	50% <i>(iPrEx OLE, 2014)</i>	54% & 54% <i>(HOPE & DREAM OLE, 2018)</i>
Implementation research	86% <i>(PROUD, 2015)</i>	
Demonstration projects	62 distinct post-approval projects; 47 different organizations; projects ongoing, planned and completed in 30 different countries <i>(As of Jan 2018)</i>	??? <i>(design and funding pending)</i>
Introduction initiatives		
Scale-up		

Product Introduction Process: Comparing oral PrEP and Dapi Ring

	Oral PrEP (MSM)	Oral PrEP (Heterosexual Men & Women)	Dapivirine Ring
Phase III Efficacy	44% <i>(iPrEx, 2010)</i>	75% <i>(Partners, 2011)</i>	27% & 31% <i>(ASPIRE & Ring Study, 2016)</i>
Open label extensions (OLE)	50% <i>(iPrEx OLE, 2014)</i>	90% <i>(Partners, 2014)</i>	54% & 54% <i>(HOPE & DREAM OLE, 2018)</i>
Implementation research/ Demo Projects	86% <i>(PROUD, 2015)</i>	96% <i>(Partners Demo, 2015)</i>	???
Introduction initiatives	62 post-approval projects; ongoing, planned & completed in 30 countries with 47 different orgs <i>(As of Jan 2018)</i>		<i>(design & funding pending)</i>