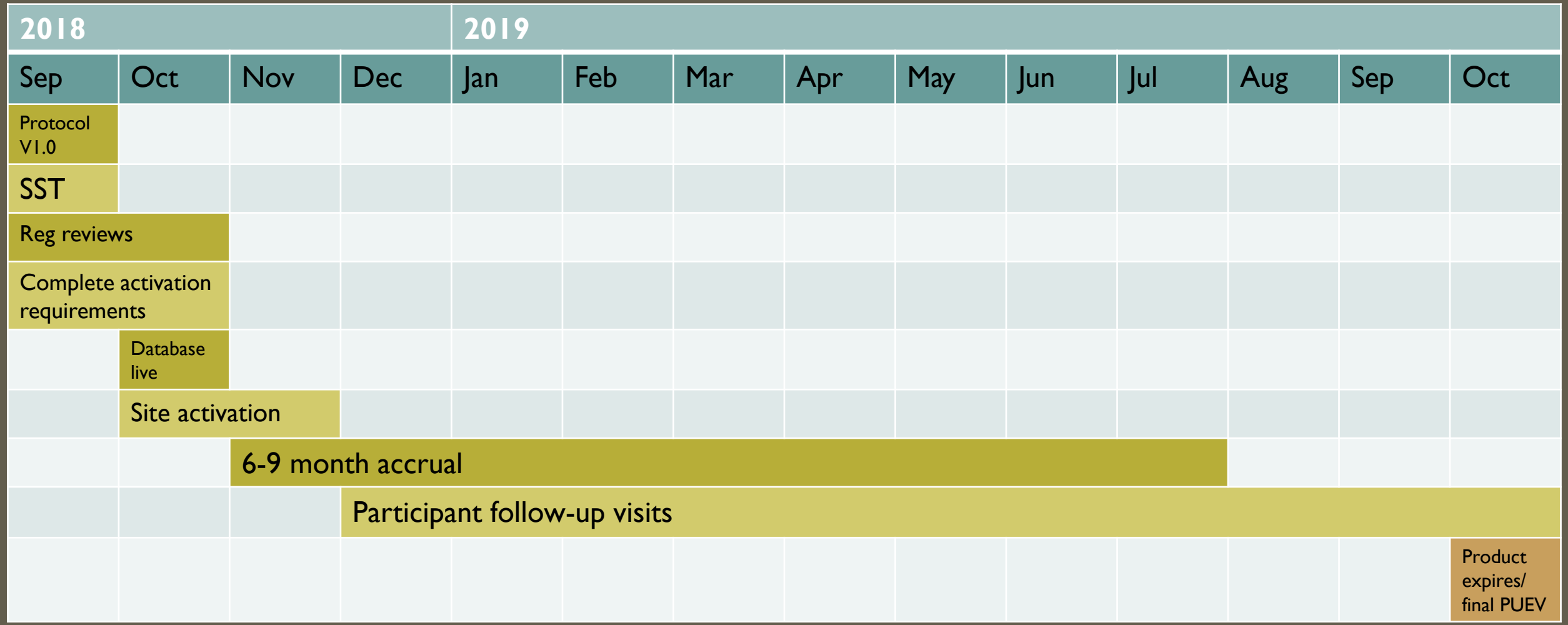
ACTIVATION AND STUDY TIMELINE

MTN-038 Study Specific Training

11 September 2018



NOTE: All VRs must be inserted by 31 July 2019
to allow for 13 weeks of product use before expiration on 31 October 2019.

Study Activation Checklist

MTN-038: A Phase 1, Randomized Pharmacokinetic and Safety Study of a 90 Day Intravaginal Ring Containing Tenofovir

Site Name		**Site Location**	
Site Investigator of Record		**Site Number**	

	Study Activation Requirement	Approval Date	Comments
Regulatory Requirements			
1.	Study protocol and site specific ICFs approved by [*local IRB*]		
2.	Supplemental study materials approved by [*local IRB*] (e.g. CASI, CRFs, Study Product Information/Instructions, Site-Specific Recruitment Materials/Plans)		
3.	All regulatory documentation submitted to MTN Regulatory (as requested)		*e.g. FDA 1572 signed and dated by the Site IoR, Financial Disclosure by all individuals listed on the FDA Form 1572 (date should precede or be the same as the date on the 1572), CVs (signed and dated), Investigator Signature Page, IRB/EC rosters, etc.*
4.	Transfer of Regulatory Obligations completed and signed	7JUN2018	
5.	Protocol submitted to the FDA by Sponsor (CONRAD)		*Documentation that CONRAD has submitted to FDA can be obtained from DAIDS*
6.	Protocol registration approval notice received from the DAIDS RSC Protocol Registration Office		
Pharmacy Requirements			
7.	Approved DAIDS PAB Pharmacy Establishment Plan (PEP) or an MTN Protocol-Specific Pharmacy Establishment Plan		
8.	Adequate pharmacy staffing in place for study implementation		
9.	Completion of pharmacy staff training as deemed required by MTN Pharmacist		