



MTN-041 Operational Guidance #01: Demographic CRF Completion

The purpose of this guidance document is to provide information regarding the process of completing question #17 on the Demographic Information Form (DEM) for MTN-041.

1) Demographic CRF: Question #17

- a. ALL MTN-041 participants must respond to items in Column 17i. ('*EVER heard of*').
- b. Column 17ii. ('*EVER used*') is only to be completed for pregnant and breastfeeding women (PBF) or male partners (MP) ONLY for items where the participant has responded 'yes' in column 17i ('*EVER heard of*').
 - i. Male partners **should not** be asked '*EVER used*' for items 17iic (vaginal gel) or 17iid (vaginal ring). If a male partner has responded 'yes' ('*EVER heard of*') to either item 17ic or 17id, then select 'Not Applicable' for 17iic and/or 17iid ('*Ever used*').

HIV PREVENTION PRODUCTS			
17i. [For ALL participants] What HIV prevention product(s) has the participant ever heard of before today? These could be products that are being studied, or products that are publicly/commercially available now.			
17ii. [For pregnant/ breastfeeding women or male partners ONLY] What HIV prevention product(s) has the participant ever used?			
17.		<i>[Only 'Go to 17ii' for MP or PBF if 'Yes']</i>	<i>[For pregnant/ breastfeeding women or male partners]</i>
		<i>i. EVER heard of</i>	<i>ii. EVER used</i>
	a. Male condom	<input type="checkbox"/> 1 Yes → Go to 17ii <input type="checkbox"/> 0 No	<input type="checkbox"/> 1 Yes <input type="checkbox"/> 0 No
	b. Female condom	<input type="checkbox"/> 1 Yes → Go to 17ii <input type="checkbox"/> 0 No	<input type="checkbox"/> 1 Yes <input type="checkbox"/> 0 No
	c. Vaginal gel	<input type="checkbox"/> 1 Yes → Go to 17ii <input type="checkbox"/> 0 No	<input type="checkbox"/> 1 Yes <input type="checkbox"/> 0 No <input type="checkbox"/> 99 Not Applicable
	d. Vaginal ring	<input type="checkbox"/> 1 Yes Go to 17ii <input type="checkbox"/> 0 No	<input type="checkbox"/> 1 Yes <input type="checkbox"/> 0 No <input type="checkbox"/> 99 Not Applicable
	e. Tablets/Oral PrEP	<input type="checkbox"/> 1 Yes → Go to 17ii <input type="checkbox"/> 0 No	<input type="checkbox"/> 1 Yes <input type="checkbox"/> 0 No
	f. Other (specify): _____	<input type="checkbox"/> 1 Yes → Go to 17ii <input type="checkbox"/> 0 No	<input type="checkbox"/> 1 Yes <input type="checkbox"/> 0 No

All Operational Guidance documents must be printed and filed with regulatory documentation.

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Julia Ryan

Signature

7/11/2018

Date