Use this worksheet to guide and document protocol counseling, which encompasses protocol adherence and study product and study product use counseling. At Visits 1-7, protocol adherence counseling must be provided but may be abbreviated and tailored to participant needs. Staff should review the participant’s Protocol Counseling Worksheet from the previous visit to determine the level of counseling needed and any issues to revisit.

**Protocol Adherence Counseling:**

* **At Visits 1-7, provide guidance on study requirements, including prohibited practices, products and/or medications**
* Present to study visits as scheduled
* Respond to brief, weekly SMS assessments about product use and RAI behaviors
* Refrain from using non-study rectally-administered medications/products, including lubricants containing nonoxynol-9 (N-9)
* Inform study staff of all medications taken during study participation
* Do not take part in other research studies involving drugs, medical devices, vaccines, or genital or rectal products for the duration of study participation
* Contact study staff with any questions and/or to report any issues with study products

**Study Product/Study Product Use Counseling:**

* **At Visit 2 (Enrollment) and Visits 4 and 6 (Product Switch Visits), provide study product and study product use counseling, in accordance with participant’s randomization sequence**
* **N/A**
* Provide an overview of the study product
* Explain that the first dose will be self-administered in-clinic
* Review study product use instructions and provide a copy of study product instructions sheet
* Provide product for participant self-administration
* Encourage the participant to ask any questions about the study product and/or its administration, and to inform staff of any issues with self-administration
* Instruct participant to return any unused study product (unused suppositories, inserts and empty enema bottles) at their next scheduled visit

**Any counseling issues/questions/concerns discussed at this visit?**

None reported

Yes. Document discussion, counseling provided, and issues to follow up on at next visit:

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