

MTN 004 Protocol Safety Review Team Query Form, page 1 of 2

Instructions: Email completed form to [rdc27@pitt.edu](mailto:rdc27@pitt.edu), [kbunge@mail.magee.edu](mailto:kbunge@mail.magee.edu) and [nancycsc@gmail.com](mailto:nancycsc@gmail.com).

**IMPORTANT:** Complete all required fields so the PSRT has all information needed to respond to your query.

**Site:**  
**Completed by:**

**Query Date (dd-MMM-yy):**  
**Email address:**

**PTID:**  
**Enrollment Date (dd-MMM-yy):**

**Participant Age (in years):**

- Reason for query:**
- Product use consultation:
    - Should use of study gel be temporarily discontinued (held)?
    - Should use of study gel be permanently discontinued (held)?
    - Should use of study gel be resumed?
  - Request for consultation on AE management
  - Request to withdraw participant from the study
  - Request to unblind participant's gel assignment
  - Other, specify:

**Is this query a request for the PSRT to consult on an adverse event (AE)?**

- Yes → continue completing this page
- No → skip to Comments on page 2

**Primary AE of concern:**

**AE onset date (dd-MMM-yy):**

**AE severity grade at onset:**

**Relatedness to study gel:**

- Definitely related
- Probably related
- Possibly related
- Probably not related
- Definitely not related

**Current study gel administration:**

- No change
- On hold
- Permanently discontinued
- Not applicable

**Has this AE been reported on a SCHARP AE Log form?**

- Yes
- No

**Has this AE been reported as an EAE?**

- Yes
- No

**Has this AE been assessed more than once?**

- Yes
- No → skip to Comments on page 2

**Date of most recent assessment (dd-MMM-yy):**

**Status of AE at most recent assessment:**

- Continuing, stabilized (severity grade unchanged)
- Continuing, improving → severity grade decreased to
- Continuing, worsening → severity grade increased to
- Resolved

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Comments: Provide additional details relevant to this query. If gel use has been held, include date of last reported gel application prior to the hold (per participant report).

End of Form for Site Staff. Email completed form to the MTN 004 MTN Protocol Safety Physicians [rdc27@pitt.edu](mailto:rdc27@pitt.edu), [kbunge@mail.magee.edu](mailto:kbunge@mail.magee.edu) and [nancycsc@gmail.com](mailto:nancycsc@gmail.com). If an email response is not received from the PSRT within 3 business days, re-contact the MTN Protocol Safety Physicians and/or the MTN CORE ([kgomez@fhi.org](mailto:kgomez@fhi.org), or [llevy@fhi.org](mailto:llevy@fhi.org)) for assistance.

FOR PSRT USE ONLY — PROVIDE RESPONSE TO QUERY HERE

**PSRT Responding Member:**

**PSRT Response Date (dd-MMM-yy):**

**Query Outcome:**

- Approved
- Not approved
- Not applicable

**PSRT Comments:**