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

Instructions: Email completed form to rdc27@pitt.edu, kbunge@mail.magee.edu and nancycsc@gmail.com.

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

Site: Query Date (dd-MMM-yy):
Completed by: Email address:
PTID: Participant Age (in years):
Enrollment Date (dd-MMM-yy):

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: Current study gel administration:
□ Definitely related □ No change
□ Probably related □ On hold
□ Possibly related □ Permanently discontinued
□ Probably not related □ Not applicable
□ Definitely not related

Has this AE been reported on a SCHARP AE Log form?
□ Yes
□ No

Has this AE been reported as an EAE? Has this AE been assessed more than once?
□ Yes
□ No
□ 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
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, kbunge@mail.magee.edu and nancysc@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, or llevy@fhi.org) for assistance.

FOR PSRT USE ONLY — PROVIDE RESPONSE TO QUERY HERE

PSRT Responding Member:
PSRT Response Date (dd-MMM-yyyy):

Query Outcome:
☑ Approved
☑ Not approved
☐ Not applicable

PSRT Comments: