

Product Use Management

MTN Annual Meeting 16 March 2010

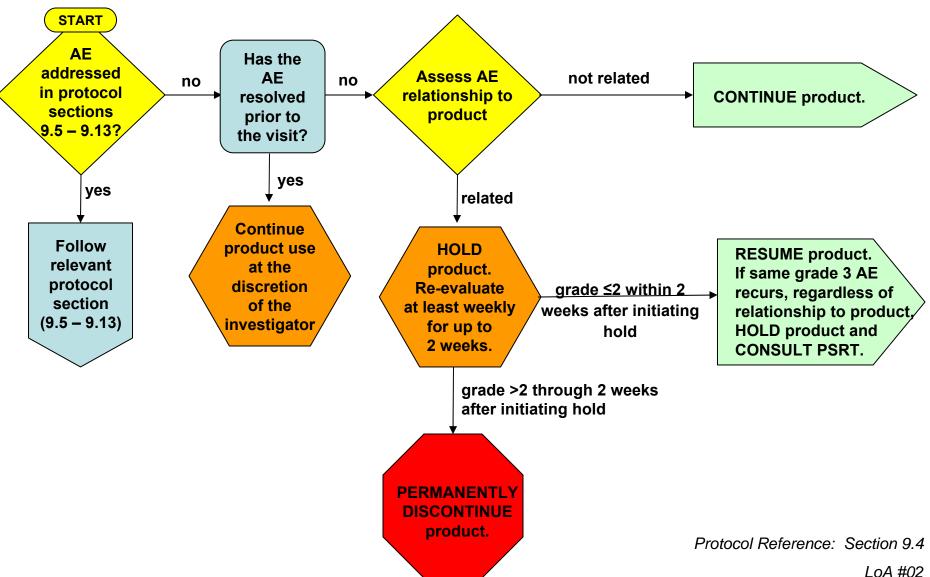




VOICE Product Use Management: Grade 3 Adverse Events

ORAL and VAGINAL Study Product

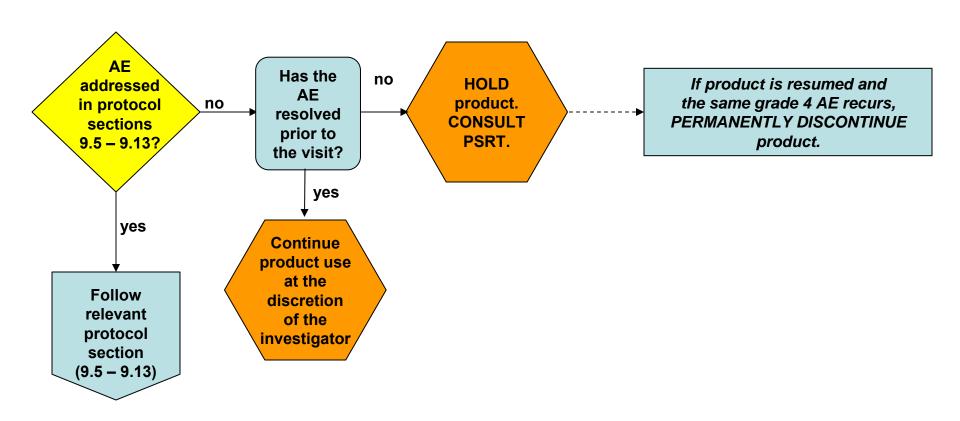
Under Letter of Amendment #02



VOICE Product Use Management: Grade 4 Adverse Events

ORAL and VAGINAL Study Product

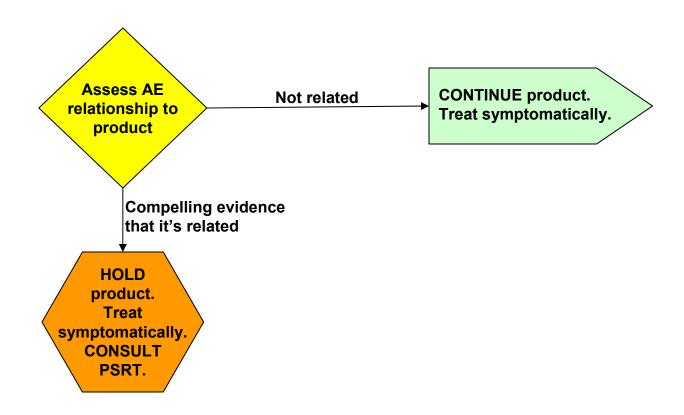
Under Letter of Amendment #02



Protocol Reference: Section 9.4

VOICE Product Use Management: Nausea, Vomiting, and/or Diarrhea VAGINAL Study Product

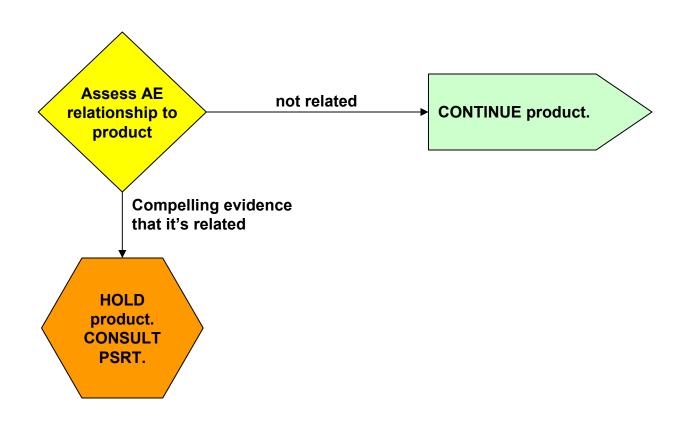
Under Letter of Amendment #02



Protocol Reference: Section 9.5.1

VOICE Product Use Management: AST or ALT Elevation VAGINAL Study Product

Under Letter of Amendment #02



Protocol Reference: Section 9.5.2

VOICE Product Use Management: Grade 4 AST or ALT Elevation ORAL Study Product

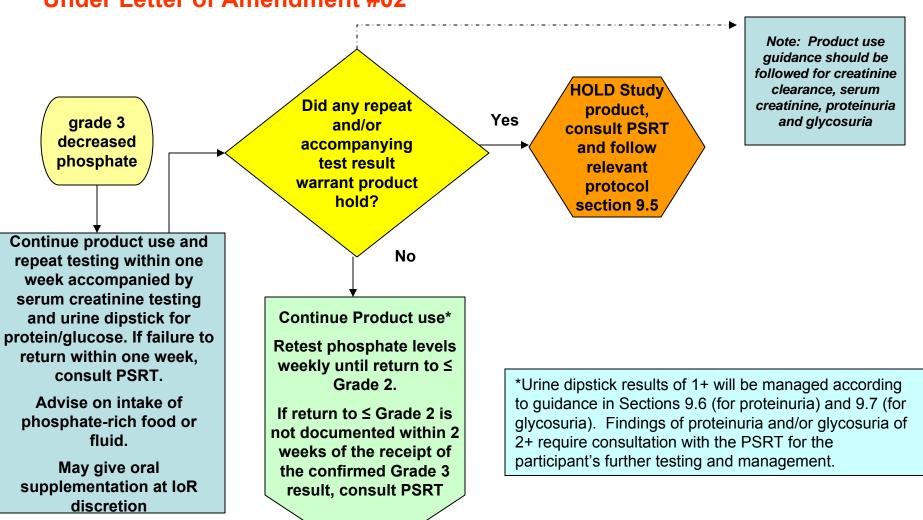
Under Letter of Amendment #02

PERMANENTLY
DISCONTINUE
product and consult
the PSRT.
Re-test at least
weekly until both
AST and ALT are
grade ≤1.

Protocol Reference: Section 9.5.2

VOICE Product Use Management: Grade 3 Hypophosphatemia ORAL Study Product

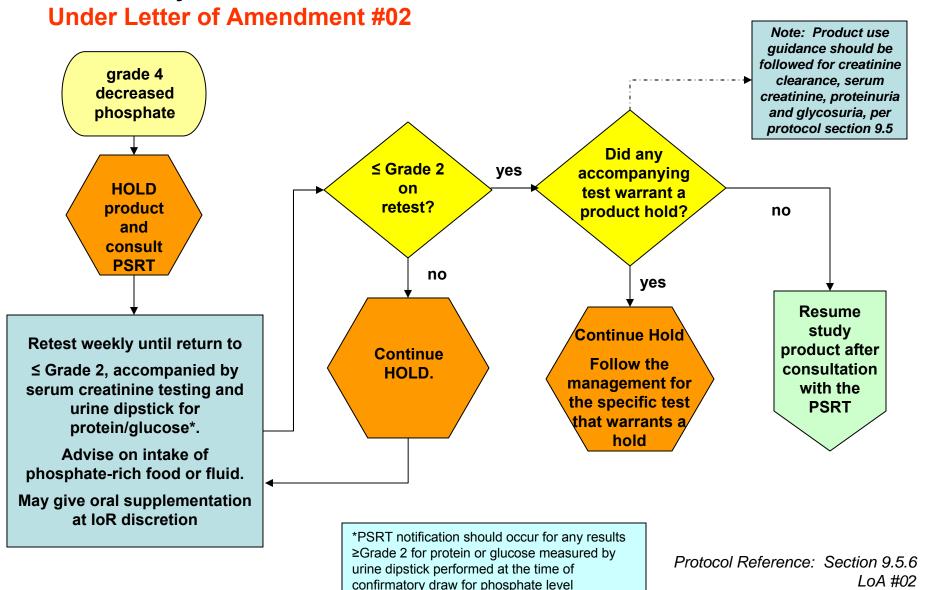
Under Letter of Amendment #02



Protocol Reference: Section 9.5.6

LoA #02

VOICE Product Use Management: Grade 4 Hypophosphatemia ORAL Study Product



got questions?