

PANEL QUESTIONS

Question 1.

What ulcer rate does the panel think we should use as the “maximum acceptable risk” (for statistical testing)?

- 60/10,000 ulcers/patient-year (~3X the 7-day EW rate);
- 48/10,000 ulcers/patient-year (~2.4X the 7-day EW rate);
- other?

Question 2.

Does the panel feel there would be difficulty in getting enough Extended Wear ulcer cases for an effective case-control study?

Question 3.

What Statistical Power would the panel recommend to ensure confidence in the result?

Question 4.

(If a case-control study is being done)

In order to achieve greater sensitivity and power would the panel recommend one or both of the following?

- Waiting until 30% market penetration is achieved.
- Accumulating cases over a 2-year period.

Question 5.

What type of clinical setting would the panel recommend for implementation of a post-approval cohort study?

- private practitioners?
- commercial chains?
- HMOs?
- all of the above?
- sponsor’s discretion?

Question 6.

What type of study would the panel recommend?

- a case-control study?
- a cohort study?
- both?

Question 7.

How would the panel define the endpoints that we are interested in for the study?

- Patients with presumed infectious ulcers;
- Patients with any type of ulcers;
- Patients with central or para-central scars (not present at pre-fit);
- Patients with reduction in acuity associated with scarring;
- Other?