

Exercise #2 Risk Evaluation Using a Quantitative Scale

Instructions:

Using three (3) risks identified in Exercise 1, assess the impact, likelihood, and detectability using a quantitative scale for 3 risks identified from the protocol summary.

Materials needed:

- Responses from Exercise 1
- Scale for likelihood
- Scale for detectability
- Scale for impact

Output: Rating of each risk for likelihood, detectability and impact.

1. BASIC RISK INFORMATION		2. RISK ASSESSMENT INFORMATION			
Risk Number	Risk Description	Impact 1 to 5	Likelihood 1 to 5	Detectability 1 to 5	RPN
R 1					
R 2					
R 3					

Likelihood

Score	Frequency
1	This will probably never happen/recur.
2	Do not expect it to happen/recur but it is possible it may do so.
3	Might happen or recur occasionally.
4	Will probably happen/recur, but it is not a persisting issue/circumstances.
5	Will undoubtedly happen/recur, possibly frequently.

Detectability

Score	Criteria
1	Very high chance of detection.
2	High chance of detection.
3	Medium chance of detection.
4	Low chance of detection.
5	Very low chance of detection.

Impact

Score	Criteria
1	The event <i>has a very low likelihood of impact</i> on HSP, product quality and/or reliability of the trial results.
2	The event <i>has a low likelihood of impact</i> on HSP, product quality and/or reliability of the trial results.
3	The event <i>most likely will impact</i> HSP, product quality and/or reliability of the trial results.
4	The event <i>has a high likelihood of impact</i> on HSP, product quality and/or reliability of the trial results.
5	The event <i>has a very high likelihood of impact</i> on HSP, product quality and/or reliability of the trial results.