Exercise #1 Risk Identification at the Protocol Level

Instructions:
Using the protocol summary document provided, identify three (3) to five (5) potential risks for further evaluation at the protocol level.

Materials needed:

- Protocol Summary
- Lists of risks to consider

Output: 3 to 5 potential risks at the protocol level

1	
2	
3	
4	
5	

Lists of areas at the protocol level to consider:

- Investigational drug product
  - Manufacturing
  - Properties of the product
  - Labelling
  - Packaging
- Trial design and protocol specific requirements
  - Complexity of trial design
  - Trial population
  - Therapeutic area
  - Sample size calculation
  - Eligibility criteria
- Operational
  - Study budget
  - Development deadlines
  - Staffing
  - Study specific training
  - Study management
  - Clinical trial site selection and management
  - Contract research organization involvement
  - Clinical trial supply processes and management
  - Clinical site setup and infrastructure
  - Laboratory setup
  - Setup of trial databases
  - Site monitoring
  - Clinical data management
  - Reporting/communication lines