FRA: Global Regulatory Strategy Sample Questions

1. **What is the one key item you would expect to find in a Global Regulatory Strategy Document?**
    A. A patient diary from a Phase 3 trial
    B. A summary of nonclinical studies and approval pathways
    C. A list of all current clinical trials worldwide

Correct B

2. **Why should you consider regional medical practices in a global trial?**
    A. To ensure that different regions in the trial have the same standards of care
    B. To ensure that trial design, safety monitoring, and patient access are consistent with regional practices
    C. To ensure the intellectual property is protected

Correct B

3. **What was a key reason for the passage of the initial Prescription Drug User Fee Act?**
    A. To allow direct to consumer drug advertising
    B. To reduce review time
    C. To ensure drug safety

Correct B