

New SMQ Request Questions

When requesting new SMQs, please include answers to these questions in the justification field of the SMQ form

1. What is the scientific/pharmacovigilance question that led to the request for this SMQ?
2. Is the current MedDRA hierarchy (e.g., HLTs, PTs) or any existing SMQ suitable to address the question? If not, what are the deficiencies in the hierarchy or existing SMQs that should be addressed?
3. Would your organization be able to address this question without this new SMQ, and if so, how? (That is, what would be the strategy and terms used?)
4. Which SMQ structure (i.e., broad/narrow, hierarchical, algorithm) do you think would best address the question?
5. How often would your organization need this SMQ (e.g., only once to address a very specific emerging issue or regularly/routinely)?

Submitters are encouraged to include a list of PTs for the proposed SMQ