

QTDP Reviewer Response Sheet (Revised 8/3/2010)

NR (*the applicant did not provide a response*)

NO (*the applicant answered NO*)

CONCUR (*the applicant answered YES- reviewer CONCURS*)

REJECT (*the applicant answered YES- reviewer does not CONCUR*)

Question 1. -NR -NO -Concur -REJECT Reject Code ____

Question 2. -NR -NO -Concur -REJECT Reject Code ____

Question 3. -NR -NO -Concur -REJECT Reject Code ____

Question 4. -NR -NO -Concur -REJECT Reject Code ____

Further evaluation is not needed if the reviewer does not concur with at least one "Yes" response to questions 1-4.

Question 5. -NR -NO -Concur -REJECT Reject Code ____

Question 6a. -NR -NO -Concur -REJECT Reject Code ____

Question 6b. -NR -NO -Concur -REJECT Reject Code ____

Question 7. -NR -NO -Concur -REJECT Reject Code ____

Question 8. -NR -NO -Concur -REJECT Reject Code ____

Further evaluation is not needed if the reviewer does not concur with at least one "Yes" response to:

- *Questions (5 and 6a)*
- *Or Questions (5 and 6b)*
- *Or Question 7*
- *Or Question 8.*

Question 9. Has the applicant demonstrated a credible scientific basis to establish that the project has a reasonable potential to achieve its stated goals? Based on the applicant's response to question 9 and using the decision support material provided, assign a score of 1(best) through 5 (worst) [integers only].
Enter Score ____

Question 10 Considering the stage of development of the project, the research and development strategy, and the extent of progress, is there a reasonable potential that the project will achieve its goals? Based on the applicant's response to question 10 and using the decision support material provided, assign a score of 1(best) through 5 (worst) [integers only].
Enter Score ____

Question 11. Has the applicant demonstrated the resources, management experience, and organizational capacity to support a reasonable potential for the successful completion of the project? Based on the applicant's response to question 11 and using the decision support material provided, assign a score of 1(best) through 5 (worst) [integers only].
Enter Score ____

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Decision Support Codes for Questions 1-8

1. Choose “Reject” if:
 - a) Project is not designed to develop a product OR not intended to treat or prevent a disease or condition.
 - b) Project does not involve conducting pre-clinical activities, clinical trials, or clinical studies, or carrying out research protocols.
 - c) Activities are not for the purpose of securing approval from FDA of a new drug application or a biologic license application.
 - d) Project is for the purpose of developing a product to be approved as a generic drug under an abbreviated new drug application OR a biosimilar license application.
 - e) Project is for the purpose of developing a medical device that will not be approved under a biologic license application.
 - f) A supporting narrative was not provided or insufficient information was provided to determine whether or not the “yes” response is justified.

2. Choose “Reject” if:
 - a) Project is not designed to diagnose a disease or condition.
 - b) A supporting narrative was not provided or insufficient information was provided to determine whether or not the “yes” response is justified.

3. Choose “Reject” if:
 - a) Project is not designed to determine molecular factors related to diseases or conditions.
 - b) Project is not designed to develop molecular diagnostics.
 - c) Molecular diagnostics to be developed are not designed to guide therapeutic decisions.
 - d) A supporting narrative was not provided or insufficient information was provided to determine whether or not the “yes” response is justified.

4. Choose “Reject” if:
 - a) Project is not designed to develop a product, process, or technology.
 - b) Product, process, or technology is not intended to further the *delivery or administration* of a drug or of a medical device.
 - c) A supporting narrative was not provided or insufficient information was provided to determine whether or not the “yes” response is justified.

5. Choose “Reject” if:
 - a) Project is not intended to result in one or more therapies (defined as projects that prevent, detect, diagnose or treat a disease or condition).
 - b) Project is intended to result in a therapy but applicant does not establish (in the response or in the introductory statement) that the therapy will *significantly differ* from currently available therapies.
 - c) Project is designed to result in a therapy that is in the same class as existing therapies, without any significant enhancement in safety or effectiveness or any significant change in intended use.

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- d) A supporting narrative was not provided or insufficient information was provided to determine whether or not the “yes” response is justified.

6.a. Choose “Reject” if:

- a) Applicant does not identify any medical need that will be addressed by its therapy.
- b) The need identified by the project is met by currently available therapies.
- c) A supporting narrative was not provided or insufficient information was provided to determine whether or not the “yes” response is justified.

6.b. Choose “Reject” if:

- a) Applicant does not identify any chronic or acute disease or condition to be prevented, detected, or treated by the proposed therapy.
- b) Applicant does not provide any credible basis to conclude that its product, if developed, would prevent, detect, or treat a chronic or acute disease or condition.
- c) A supporting narrative was not provided or insufficient information was provided to determine whether or not the “yes” response is justified.

7. Choose “Reject” if:

- a) Applicant does not provide any credible basis to conclude that its project will reduce long-term health care costs in the United States.
- b) Applicant does not demonstrate that project will lead to actual cost reductions rather just substituting one cost for another.
- c) A supporting narrative was not provided or insufficient information was provided to determine whether or not the “yes” response is justified.

8. Choose “Reject” if:

- a) Applicant does not provide a credible basis to conclude that the project will significantly advance the goal of curing cancer within the next 30 years.
- b) A supporting narrative was not provided or insufficient information was provided to determine whether or not the “yes” response is justified.

Decision Support for Questions 9-11

Question 9:

Has applicant demonstrated a credible scientific basis to establish that the project has a reasonable potential to achieve its stated goals?

- The information provided suggests that it is highly likely that the project will achieve its stated goals based on a well-established scientific basis and extensive scientific evidence (1).
- The information provided suggests that it is likely that the project will achieve its stated goals based on a well-established scientific basis and sufficient scientific evidence (2).

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- The information provided suggests a plausible scientific theory to support the project, but there is today limited evidence to support that theory. (3).
- The information provided does not suggest a plausible scientific theory to support the project, but potential success remains a possibility (4).
- Insufficient information was provided or the information provided does not suggest a plausible scientific theory to support the project and the available scientific evidence makes success unlikely (5).

Question 10:

Considering the stage of development of the project, progress described, and the planned research and development strategy, is there a reasonable potential that the project will achieve its stated goals?

- The planned research and development strategy is reasonable, progress has been good, and the project is very likely to be completed within a reasonable timeframe (1).
- The planned research and development strategy is reasonable although progress has been limited but the project is likely to be completed within a reasonable timeframe (2).
- The planned research and development strategy is somewhat risky but progress has been made and the project may be completed within a reasonable timeframe (3).
- The planned research and development strategy is risky and little progress has been made. Completion of the project within a reasonable timeframe is not very likely but is possible (4).
- Information provided by the applicant concerning the stage of development of the project was not sufficient to make an assessment of the likelihood of the stated goals being achieved (5).

Question 11:

Will the resources, management experience, and organizational capacity of the applicant support successful completion of the project?

- Resources, management experience and organizational capacity are likely to support successful completion of the project (1).
- While management experience and organizational capacity are adequate, funding to support completion of the project, even with a tax credit or grant, seems uncertain (2).
- The project appears to be reasonably well-funded, but applicant does not at this time demonstrate adequate management experience and organizational capacity to anticipate completion of the project (3).
- Based on the information submitted, there are significant questions about whether the applicant has the resources, management experience, or organizational capacity to support completion of the project OR work on the project has been suspended temporarily or permanently for financial reasons. (4).
- Insufficient information has been provided to support an assessment that the applicant has the resources, management experience, or organizational capacity to support completion

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of the project or work on the project has been abandoned for reasons other than lack of financial resources (5).