

Using Form-based Tagging

If **Form-based mode is enabled**, the Questions will be available for answer in the right panel (red box); the Question under review has a **light blue background**, and all Questions should either be answered or marked “Not Relevant”.

The screenshot displays the Form-based Tagging interface. On the left is a sidebar with navigation options: Nest Home, Literature Search, Screening, Tagging, Extraction, Study Inspector, and Synthesis. The main area shows a research article titled "5-Fluorouracil, leucovorin, and oxaliplatin (mFOLFOX6) plus sunitinib or bevacizumab as first-line treatment for metastatic colorectal cancer: a randomized Phase IIb study". The right-hand panel, titled "Questions (3/11)", contains a question about study conclusions, an "Annotate or Enter Text" field, and "Not Relevant" and "Apply" buttons. Below the question is a section for "Inclusion/Exclusion Criteria" with a "Select Tag" dropdown and an "Age" field. At the bottom of the right panel are expandable sections for "Tagging", "Comments (0)", and "History". A red arrow points to the "Tagging" section.

All tags can still be added to the study using Standard Tagging by expanding the Tagging panel (red arrow above).

Answering Questions

By adding Answers, you are applying the underlying tag, with the tag content serving as the evidence that the correct Answer(s) have been added. The method of Answering depends on the type of Question, but for all Question types, the tags applied will populate the [Qualitative Synthesis](#) in the same manner as Standard Tagging.

Note: Tag Recommendations are not available for Form-based Tagging mode.

Question Type-specific Answers

For each Question in the list, complete the following actions based on the type of Question:

- **Single Select:** Apply one child tag that answers the pre-configured questions. To do so, select one of the tags from the drop-down, and then highlight or select an Excerpt.

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cancer: a randomized Phase IIb study

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Background: Sunitinib is an oral inhibitor of tyrosine kinase receptors implicated in tumor proliferation, angiogenesis, and metastasis. In this randomized, multicenter, open-label Phase IIb study, sunitinib plus mFOLFOX6 (oxaliplatin plus leucovorin plus 5-fluorouracil) was compared with bevacizumab plus mFOLFOX6 as first-line therapy in patients with metastatic colorectal cancer.

Methods: Patients were stratified by performance status, baseline lactate dehydrogenase level, and prior adjuvant treatment, and randomized 1:1 to receive sunitinib 37.5 mg/day for 4 weeks on and 2 weeks off plus mFOLFOX6 every 2 weeks or bevacizumab 5 mg/kg every 2 weeks plus mFOLFOX6 every 2 weeks. The primary endpoint was progression-free survival. Secondary endpoints included objective response rate, overall survival, safety, and quality of life.

Results: Enrollment was closed early following accrual of 191 patients, based on an interim analysis showing an inferior trend in the primary progression-free survival efficacy endpoint for sunitinib. Ninety-six patients were randomized to sunitinib plus mFOLFOX6 and 95 to bevacizumab plus mFOLFOX6. Median progression-free survival was 9.3 months and 15.4 months, respectively, but the objective response rate was similar between the study arms. Median overall survival was 23.7 months and 34.1 months, respectively. Dose reductions and interruptions were more common with sunitinib. Hematologic toxicity was more common in the sunitinib arm.

Conclusion: While the results of the sunitinib arm are comparable with those of previously reported FOLFOX combinations, the sunitinib-based combination was associated with more toxicity than that observed with bevacizumab and mFOLFOX6. The bevacizumab arm had an unexpectedly good outcome, and was much better than that seen in the Phase III trials.

Navigation

Back Skip Complete

Questions (4/11)

Study Type: What was the study type?

Enter Text

Not Relevant Not Relevant Apply

Study Objective: What was the study objective?

Tagging

Comments (0)

History

- **Multi-Select:** Any of the child tags can be an answer, so you can apply as many tags from the drop-down as are applicable to the study. When all relevant child tags are added, select “Next” to mark the Question complete.

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PATIENTS

Patients eligible for inclusion were at least 18 years of age, and had: histologically or cytologically confirmed adenocarcinoma of the colon or rectum with documented metastatic disease; Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; evidence of measurable disease according to Response Evaluation Criteria in Solid Tumors;⁹ and resolution of all acute toxic effects of prior therapy (except for alopecia) or surgical procedure to grade ≤1. Prior adjuvant therapy was permitted if more than 6 months had elapsed from completion of therapy and diagnosis of metastatic disease. The study was conducted in accordance with the Declaration of Helsinki and the International Conference on Harmonization guidelines on Good Clinical Practice, and applicable local regulatory requirements and laws. Written informed consent was obtained from all patients.

STUDY OBJECTIVES

The primary objective was to compare the efficacy of sunitinib and mFOLFOX6 with bevacizumab and mFOLFOX6 in terms of progression-free survival. Secondary objectives included measures of objective response rate, overall survival, safety, and tolerability, including patient-reported outcomes.

Study design

Patients were randomized 1:1 to receive mFOLFOX6 (oxaliplatin 85 mg/m² and leucovorin 400 mg/m²)

Navigation

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Questions (3/11)

Not Relevant Apply

Inclusion/Exclusion Criteria: What were the inclusion and exclusion criteria?

Select Tag

- Pregnancy
- Age

Enter Text

Next Answered Apply

Study Location: What was the study location?

28 days after the last dose of study drug for adverse events, and were followed for overall survival until the study was terminated in May 2011.

Study objectives

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Study assessments

Tumor assessments were performed every 8 weeks. Efficacy evaluation was based on investigator's assessment using Response Evaluation Criteria in Solid Tumors 1.0 criteria. Adverse events were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events version 3.0, and patient-reported outcomes on the Functional Assessment of Cancer Treatment-Colorectal (FACT-C_x) and

- **Single Apply:** The tag under review is either applied to the study (select “Apply”) or marked irrelevant. No child tags are added!

Next Home

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PMC

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cancer: a randomized Phase IIb study

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Navigation

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Questions (4/11)

Study Objective: What was the study objective?

[Selection]

[Not Relevant](#) [Answered](#) [Update](#)

Study Conclusion: What were the study conclusions?

the sunitinib-based combination was associated with more toxicity than that observed with bevacizumab and mFOLFOX6.

[Not Relevant](#) [Answered](#) [Update](#)

Inclusion/Exclusion Criteria: What were the inclusion and exclusion criteria?

[Tagging](#)

[Comments \(0\)](#)

[History](#)

Whenever a Question has no relevant answers, select “Not Relevant” to move to the next Question.

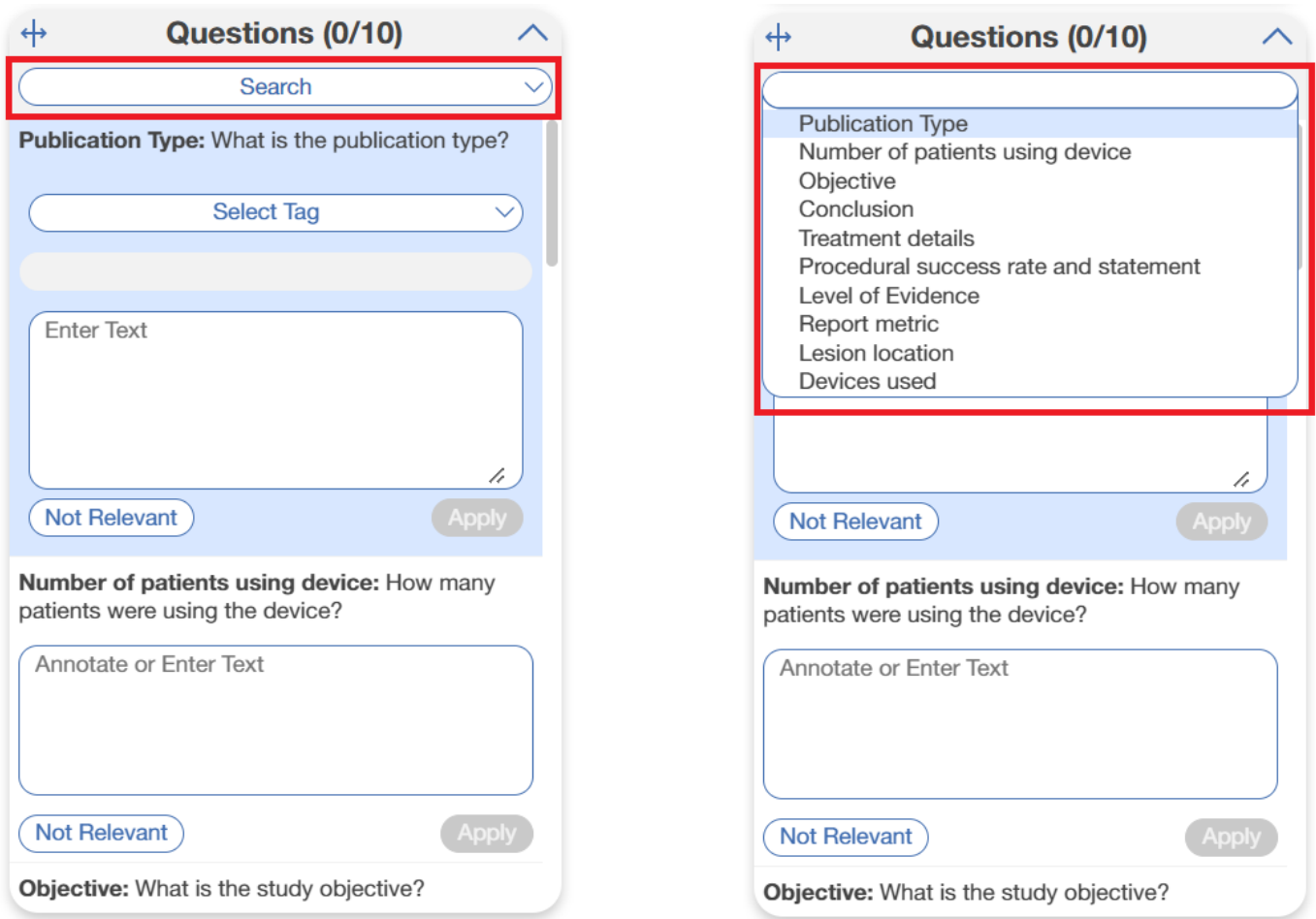
What Answering a Question does

When a Question is finished (Applied or, for Multi-Select, when you select “Next”), or when the Question is marked Not Relevant, the count of completed Questions at the top of the right panel will update.

When all Questions are finished, you can either add tags using the Standard method (by opening the Tagging panel), or you can move to the next study by selecting “Complete” in the upper right-hand corner.

Question Search and Answer Status

You can search for a specific tag and its associated question anytime using the search bar and dropdown. Clicking on your desired option will take you directly to that question.



Once you begin answering questions, the status of these answers will be displayed next to tags in this same dropdown.

Answer Status Key:

- No Circle = Question is unanswered

- Hollow Circle = Question assigned as “Not Relevant”
- Filled Circle = Question is answered with tag applied

In the below example, Publication Type was deemed not relevant, Number of patients using device was answered with tag applied, Objective (as well as the rest of the questions) were unanswered.

Questions (2/10)

☐ Publication Type

☒ Number of patients using device

☐ Objective

☐ Conclusion

☐ Treatment details

☐ Procedural success rate and statement

☐ Level of Evidence

☐ Report metric

☐ Lesion location

☐ Devices used

Conclusion: What are the study conclusions?

Annotate or Enter Text

Not Relevant

Apply

Treatment details: What are the treatment details?

Schedule	Drug Type	Administration

Tagging Supplemental Materials

If the study you are tagging has supplemental materials in pdf format, you may also apply tags to these texts. The functionality is the same as tagging full texts: automatic copy of text to clipboard and


text box, text highlighting and area selection allowing immediate direction to the excerpt when the tag is selected etc.

Note: Tag Recommendations are currently unavailable for supplemental pdfs.

AbstractFull TextSupplementsRelated Reports

CT.gov

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Author manuscript

Indian J Pediatr. Author manuscript; available in PMC 2016 June 01.

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Vitamin D in Chronic Kidney Disease

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Abstract

Vitamin D deficiency is widespread in both the pediatric and adult chronic kidney disease (CKD) population. CKD is characterized by dysregulation of vitamin D and mineral metabolism. Secondary hyperparathyroidism and its management puts patients with CKD at increased cardiovascular risk. Emergence of experimental and some clinical data suggesting beneficial effects of vitamin D on proteinuria, blood pressure, inflammation and cardiovascular outcomes has pushed it to the center stage of CKD research. Pediatric data on vitamin D dysregulation and its

Author Manuscript

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Questions (0/59)

Search

1. Decision Problem: Is there a clear statement of the decision problem? Answer Yes/No/Unclear/Not relevant

Annotate or Enter Text

Not RelevantApply

2. Objective: Is the objective of the model specified and consistent with the stated decision problem? Answer Yes/No/Unclear/Not relevant

Annotate or Enter Text

Not RelevantApply

3. Decision maker: Is the primary decision maker specified? Answer Yes/No/Unclear/Not relevant

Annotate or Enter Text

Tagging

History

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