

Using Form-based Extraction

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 Extraction interface. On the left is a sidebar with navigation options: Nest Home, Literature Search, Screening (4/4), Tagging (0/4), Extraction (0/4), 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 article is from Cancer Management and Research, Dovepress, published 15 June 2015. The right sidebar contains a "Questions (3/11)" panel, which is highlighted with a red box. This panel includes a "Study Conclusion" question, an "Annotate or Enter Text" field, and buttons for "Not Relevant" and "Apply". Below this is an "Inclusion/Exclusion Criteria" section with a "Select Tag" dropdown and an "Age" field. A red arrow points to the "Tagging" section below the questions panel.

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

Answering Questions

By adding Answers, you are applying the underlying tag, with the Tag Excerpt 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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PMc

cancer: a randomized Phase IIb study

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J Randolph Hecht¹
Edith P Mitchell²
Takayuki Yoshino³
Manfred Welslau⁴
Xun Lin⁵
Edna Chow Maneval⁶
Jolanda Paolini⁷
Maria Jose Lechuga⁷
Albrecht Kretzschmar⁸

¹David Geffen School of Medicine at UCLA, Santa Monica, CA,
²Kimmel Cancer Center of Thomas Jefferson University, Philadelphia, PA, USA; ³National Cancer Center Hospital East, Chiba, Japan;
⁴Onkologische Praxis Klausmann/Welslau, Aschaffenburg, Germany;
⁵Pfizer Oncology, La Jolla; ⁶Seragon Pharmaceuticals, San Diego, CA, USA; ⁷Pfizer Oncology, Milan, Italy;
⁸Klinikum St Georg, Leipzig, Germany

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 FOLFOLX 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?

☒ RCT

Prospective Observational

Enter Text

Not Relevant Not Relevant Apply

Study Objective: What was the study objective?

[Selection]

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 design

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

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 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)¹⁰ and

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?

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

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Screening 4 / 4

Configure Screening

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¹David Geffen School of Medicine at UCLA, Santa Monica, CA;
²Kimmel Cancer Center of Thomas Jefferson University, Philadelphia, PA, USA; ³National Cancer Center Hospital East, Chiba, Japan; ⁴Onkologische Praxis Klausmann/Welslau, Aschaffenburg, Germany; ⁵Pfizer Oncology La Jolla, *Seragon Pharmaceuticals, San Diego, CA, USA; ⁶Pfizer Oncology Milan, Italy; ⁷Klinikum St Georg, Leipzig, Germany

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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?

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.

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