

# Applying Tags via Forms

Tags reflect the qualitative content of underlying studies and provide method for attaching text or images from these studies. After tags have been [configured](#), and so long as at least one study has been included, you can begin applying tags. Once a tag is applied, it is immediately viewable on [Qualitative Synthesis](#).

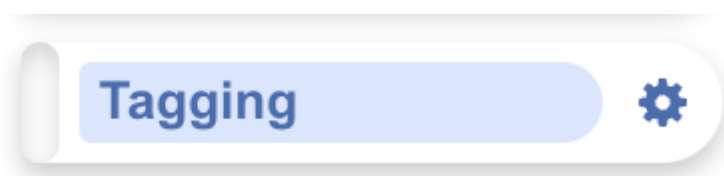
If you are in Standard Tagging mode, see [our instructions on how to apply standard tags](#).

## Steps for Tagging in Form-based Mode:

### 1. Navigate to Tagging

Click the “Tagging” button on the left-hand side, in the Nest Menu.

This will enable you to apply tags to records sequentially. If you would prefer to search and find records to tag, or to view records that have already been tagged, use [Study Inspector](#).



### 2. View the Full Text

Click on the “Full Text” toggle in the upper left to view the full-text PDF.

If no full text has yet been imported, learn how to upload it both individually and in bulk [here](#).

The screenshot displays the Autolit interface for a clinical trial article. The main content area shows the title "Intercalated combination of chemotherapy and erlotinib for patients with advanced stage non-small-cell lung cancer (FASTACT-2): a randomised, double-blind trial" and a summary of the study. The sidebar on the left contains navigation options such as "Nest Home", "Literature Search", "Abstract Screening", "Full Text Screening", "Tagging", "Study Inspector", and "Synthesis". The right sidebar shows a "Navigation" panel with a "Questions (24/37)" section, a "Full Text Tag Recs" section, and a "Tagging" section. The "Questions" section is highlighted with a red box, indicating the area for answering questions.

### 3. Answering Questions

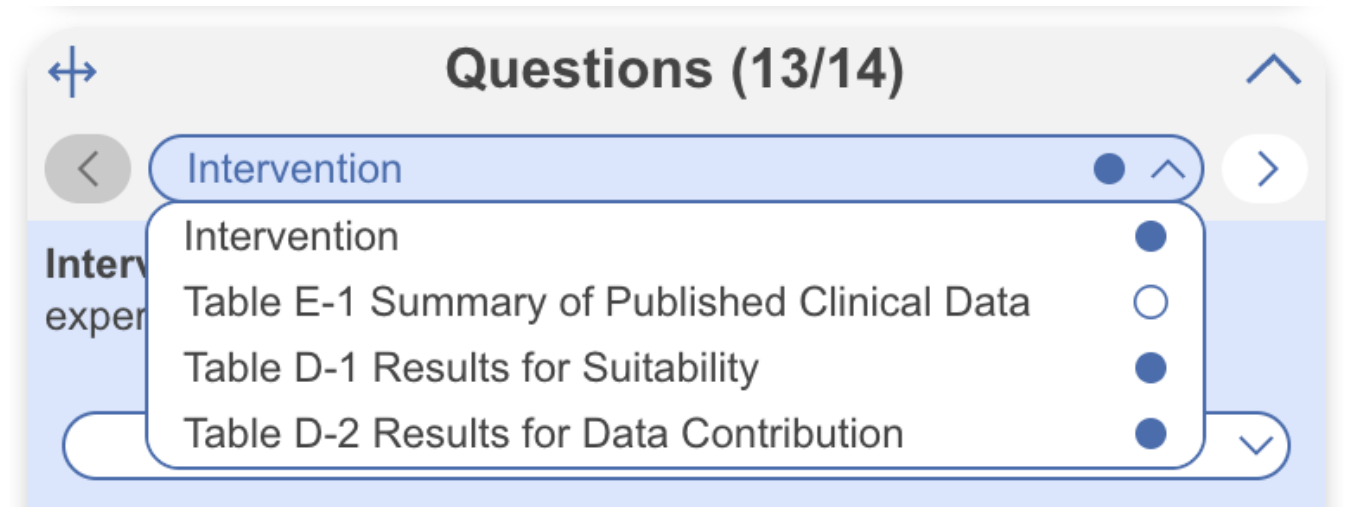
Form-based tagging is designed to show the questions you configured side-by-side with the Full Text for ease of data extraction. Questions will be available for answer in the right panel (red box); the Question under review has a **light blue background**, and all Questions should either be answered or marked "Not Relevant".

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

By default, questions are grouped by root tag (highest tag in tag hierarchy) allowing you to select specific groups of questions to answer at a time (blue box). Either select from the drop down or use the arrows to toggle between groups of questions. This is especially helpful if you have a large tag hierarchy and therefore, a single, long form of questions.

The screenshot displays the Autolit interface for a research article. The main content area shows the title "The effect of a surgical smoke evacuation system on surgical site infections of the spine" and an abstract. The sidebar on the left contains navigation options such as "Nest Home", "Literature Search", "Abstract Screening", "Full Text Screening", "Tagging", "MA Extraction", "Critical Appraisal", "Study Inspector", and "Synthesis". The right sidebar shows a "Navigation" panel with a "Questions (13/14)" section, a "Full Text Tag Recs" section, and a "Tagging" section. The "Questions" section is highlighted with a red box, indicating the area for answering questions. A red arrow points to the "Tagging" section, indicating the area for adding tags.

The root tags/groups follow a key to indicate completion of the corresponding group of questions. No circle indicates questions are incomplete, a hollow circle indicates partial completion, and a full circle indicates full completion.



However, if you prefer a single form you can change this in Settings:

### Tagging

In Standard tagging, the entire tagging hierarchy is made available as an open-ended list.

In Form-based tagging, tags can be turned into questions to be posed to the reviewer. There are three types of questions: Single Apply questions apply the tag selected, Single Select questions allow for only one of the child tags to be applied and Multiple Select questions allow for multiple child tags to be applied. All tags may have text text content. Questions can be shown in a single form, or in multiple forms grouped by their root tags.

Switching between these modes results in no loss of data.

Choose mode:

☐ Standard

☒ Form-based

Choose Form Group mode:

☐ Single Form

☒ Multiple Forms by Root

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.

### 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.

Nest Home

Activity

Settings

Literature Search

Other Sources

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Search Exploration

Abstract Screening

Adjudicate Screening

Full Text Screening

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Study Inspector

Synthesis

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Abstract Editor

Export

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Abstract Full Text Supplements Related Reports

PubMed

Articles

### Intercalated combination of chemotherapy and erlotinib for patients with advanced stage non-small-cell lung cancer (FASTACT-2): a randomised, double-blind trial

Yi-Lang Wu, Jin Sao Lee, Sumitra Thongprasert, Chong-Jen Yu, Li Zhang, Guis Ladrera, Vichien Srimuninnimit, Virate Sriuranpong, Jennifer Sandoval-Tan, Yunzhong Zhu, Meilin Liao, Caicun Zhou, Hongming Pan, Victor Lee, Yuh-Min Chen, Yan Sun, Benjamin Margono, Fatima Fuerte, Gee-Chen Chang, Kasan Seetalarom, Jie Wang, Ashley Cheng, Elina Syahruddin, Xiaoping Qian, James Ho, Johan Kurnianda, Hsingjin Eugene Liu, Kate Jin, Matt Truman, Ilze Bara, Tony Mok

**Summary**  
**Background** The results of FASTACT, a randomised, placebo-controlled, phase 2 study, showed that intercalated chemotherapy and erlotinib significantly prolonged progression-free survival (PFS) in patients with advanced non-small-cell lung cancer. We undertook FASTACT-2, a phase 3 study in a similar patient population.

**Methods** In this phase 3 trial, patients with untreated stage IIIB/IV non-small-cell lung cancer were randomly assigned in a 1:1 ratio by use of an interactive internet response system with minimisation algorithm (stratified by disease stage, tumour histology, smoking status, and chemotherapy regimen) to receive six cycles of gemcitabine (1250 mg/m<sup>2</sup> on days 1 and 8, intravenously) plus platinum (carboplatin 5 x area under the curve or cisplatin 75 mg/m<sup>2</sup> on day 1, intravenously) with intercalated erlotinib (150 mg/day on days 15–28, orally; chemotherapy plus erlotinib) or placebo orally (chemotherapy plus placebo) every 4 weeks. With the exception of an independent group responsible for monitoring data and safety monitoring board, everyone outside the interactive internet response system company was masked to treatment allocation. Patients continued to receive erlotinib or placebo until progression or unacceptable toxicity or death, and all patients in the placebo group were offered second-line erlotinib at the time of progression. The primary endpoint was PFS in the intention-to-treat population. This trial is registered with ClinicalTrials.gov, number NCT00883779.

**Findings** From April 29, 2009, to Sept 9, 2010, 451 patients were randomly assigned to chemotherapy plus erlotinib (n=226) or chemotherapy plus placebo (n=225). PFS was significantly prolonged with chemotherapy plus erlotinib versus chemotherapy plus placebo (median PFS 7.6 months [95% CI 7.3–8.3] vs 6.0 months [5.6–7.1], based on

Navigation

Back Skip Complete

Questions (24/37)

Relevant Evidence

Study Design: What is the study design? Include details of randomisation.

RCT

Observational

Active Trial

Enter Text

Next Answered Apply

Population: What is the population studied?

patients with stage IIIB/IV non-small-cell lung cancer.

Full Text Tag Recs

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.

Nest Home

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Navigation

Back Skip Complete

Questions (24/37)

Relevant Evidence

Not Relevant Not Relevant Apply

Baseline Characteristics: Provide a summary of the baseline characteristics of trial participants.

Select Tag

Age

Sex

Enter Text

Next Answered Apply

All questions in this form complete!

Full Text Tag Recs

Tagging

Comments (0)

History

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



Nest Home

Activity

Settings

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Navigation

Questions (24/37)

Relevant Evidence

Not Relevant Answered Update

Marketing Authorisation: Does the trial support application for marketing authorisation?

Annotate or Enter Text

Not Relevant Not Relevant Apply

Economic Model: Is this trial used in the economic model?

Annotate or Enter Text

Not Relevant Not Relevant Apply

Rationale for Economic Model: What is the rationale for use/non-use in the economic model?

Full Text Tag Recs

Tagging

Comments (0)

History

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

## Tag Recommendations

Tag Recommendations is displayed in the right-hand menu tab and searches the study full text, highlighting specific text that may be applicable to the tags in your hierarchy.

Standard Tag Recommendations (available to all users) perform a key word search of the tag name (and any applicable child tags), while Smart Tag Recommendations (only available to enterprise users) utilize OpenAI GPT 3.5/4 to perform a smart search of the tag data.

Standard tags are automatic, while Smart Tags can be switched on in Settings and used to generate recommendations for Abstracts as well as Full Texts.

If a recommendation is available for the selected question, it will be displayed. When clicked on, it will auto-scroll to the excerpt within the full text, auto-populate in the tag text box to be applied or removed. Learn more about how to use [Tag Recommendations](#).

## 4. Add an Annotation

To associate text content with a tag, identify this text either before or after selecting the tag from the drop-down. You have three options for how to identify the text excerpt that will be associated with that tag:

- **Highlighting (Text Annotation):** A traceable, exact quote from the text of the article.
- **Selection (Area Annotation):** A traceable, exact image extraction from a table, figure, or other area of the article.
- **Manual entry (No Annotation):** A non-traceable excerpt (that is, an excerpt that is not connected to a specific part of the article) that you type into the Tag Text box.

## 4a. Use the Highlighting Tool:

The default Tag Text method is Highlighting. You can also manually select the Highlighting icon, if you need to toggle back to this option.

Click and drag over the text you would like to Highlight. Highlighting will extract an exact text excerpt that is shown in light blue, and the text will be automatically populated to the Tag Text box.

The screenshot displays the Wiki.Nested-Knowledge interface. The main article, 'Intercalated combination of chemotherapy and erlotinib for patients with advanced stage non-small-cell lung cancer (FASTACT-2): a randomised, double-blind trial', is shown. The 'Tagging' sidebar on the left is active, and the 'Navigation' panel on the right shows 'Questions (24/37)' with 'Relevant Evidence' selected. The 'Full Text Tag Recs' section is also visible.

## 4b. Use the Select Tool:

To switch from the default Highlighting tool to the Select tool (middle icon above)

Create a box across the area you'd like to select for the tag. Click in the left-hand corner of your area of interest and drag across the text or table. This selection will be automatically saved in the tag text box.

Selection / Area Annotation is best used on tables, figures, and images that are not amenable to exact text quotation.

The screenshot displays the PubMed interface for a clinical trial article. The article title is "FASTACT-2: A multicentre, randomised, placebo-controlled, double-blind, phase study of intercalated erlotinib or placebo with gemcitabine and carboplatin or cisplatin followed by maintained erlotinib or placebo in patients with stage IIIB/IV non-small-cell lung cancer." The article is published in the *Journal of Clinical Oncology*, 2013, 31(17):2045-2054. The article is divided into sections: Abstract, Full Text, Supplements, and Related Reports. The Full Text section is currently selected, showing the Methods, Randomisation and masking, and Procedures sections. The Methods section describes the study design and population, while the Randomisation and masking section describes the randomisation process. The Procedures section describes the treatment regimen. The article includes a flowchart (Figure 1) showing the patient flow through the trial. The flowchart starts with 451 patients randomly assigned, who are then allocated to two groups: 225 allocated to chemotherapy plus placebo and 225 allocated to chemotherapy plus erlotinib. The flowchart details the number of patients who did not receive allocated treatment, the number of patients who received the allocated treatment, the number of patients who were withdrawn, and the number of patients who received placebo or erlotinib maintenance. The flowchart also shows the number of patients who did not receive or were not eligible to receive placebo or erlotinib maintenance. The flowchart ends with 112 received placebo maintenance and 135 received erlotinib maintenance. The flowchart is titled "Figure 1: Total profile. Chemotherapy+gemcitabine plus carboplatin or cisplatin."

The sidebar on the right contains a "Navigation" section with a "Skip" button and a "Complete" button. Below this is a "Questions (24/37)" section with a "Relevant Evidence" dropdown. The "Economic Model" question is currently selected, asking "Is this trial used in the economic model?". The "Rationale for Economic Model" question is also present, asking "What is the rationale for use/non-use in the economic model?". The "Methodology of RCTs and other evidence" question is also present, asking "Provide details of the methodology of the RCTs and non-randomised and non-controlled evidence identified." The sidebar also includes a "Full Text Tag Recs" section with a dropdown menu for "Tagging", "Comments (0)", and "History".

#### 4c. Manually type out in Tag text box:

If you prefer to manually type the information from the text, you can do this by clicking your cursor in the tag text box and type what you'd like.

Manual text entry should be used whenever you want to associate customized text rather than quotation from the underlying article. **Warning:** manual entry will not maintain an exact location in the full text, so it may be difficult to find the exact contents of the article that support manually entered text excerpts.

To select text manually (without highlight) select the right-most cursor icon (circled in below screenshot in blue).

#### Clear Annotations

If you need to redo your tag text annotation, you can either simply redo the action (Highlighting, Selecting, or Manually typing), or select "Clear Annotation" from the top of the Full Text (left-most x icon).

This will remove all tag text; next, choose the tag text type you would like to use, and redo the relevant Highlight, Selection, or Manual text entry.

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Settings

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Adjudicate Screening

**Tagging** ⚙️

**Study Inspector**

**Synthesis**  
Dashboard Editor  
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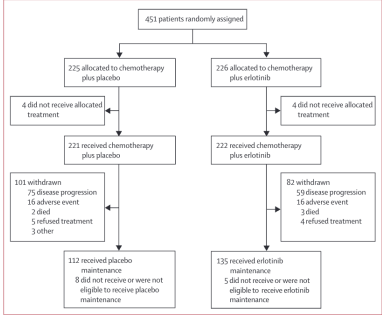
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**Methods**  
**Study design and population**  
FASTACT-2 was a multicentre, randomised, placebo-controlled, double-blind, phase study of intercalated erlotinib or placebo with gemcitabine and carboplatin or cisplatin followed by maintained erlotinib or placebo in patients with stage IIIB/IV non-small-cell lung cancer. The study was undertaken in 28 centres in China (nine), Hong Kong (four), Indonesia (three).

**Randomisation and masking**  
Patients were randomly assigned in a 1:1 ratio by use of a central randomisation programme with a minimisation algorithm. The aim of minimisation was to reduce imbalance between treatment groups within each strata by allocation of patients (using a fairly high probability) to the treatment group that minimised this imbalance. Central randomisation and drug-pack allocation were assigned by use of an interactive internet response system. Everyone outside the company responsible for the interactive internet response system was masked to treatment allocation with the exception of a small independent group that was responsible for monitoring data and safety early in the trial. Patients were stratified by disease stage (IIIB, IV), tumour histology (adenocarcinoma, other), smoking status (current, former, never), and chemotherapy regimen (gemcitabine plus carboplatin, gemcitabine plus cisplatin).

**Procedures**  
Patients were randomly assigned to receive six cycles of gemcitabine (1250 mg/m<sup>2</sup> on days 1 and 8 of a 4 week cycle, intravenously) plus platinum (carboplatin 5×area under the curve, intravenously, or cisplatin 75 mg/m<sup>2</sup> on day 1 of a 4 week cycle, intravenously) with either sequential erlotinib (150 mg/day, chemotherapy plus erlotinib group) or placebo (chemotherapy plus placebo group) on days 15–28 of each cycle. Patients who did not



**Figure 1: Trial profile**  
Chemotherapy+gemcitabine plus carboplatin or cisplatin.

www.thelancet.com/oncology Published online June 17, 2013 http://dx.doi.org/10.1016/S1470-2045(13)70254-7

**Navigation**

Back Skip Complete

**Questions (24/37)**

Relevant Evidence

**Economic Model:** Is this trial used in the economic model?

Annotate or Enter Text

Not Relevant Not Relevant Apply

**Rationale for Economic Model:** What is the rationale for use/non-use in the economic model?

Randomisation and maskingPatients were randomly assigned in a 1:1 ratio by use of a central randomisation programme with a minimisation algorithm.

Not Relevant Not Relevant Apply

**Methodology of RCTs and other evidence:** Provide details of the methodology of the RCTs and non-randomised and non-controlled evidence identified.

Non-randomised Non-controlled

**Full Text Tag Recs**

Tagging

Comments (0)

History

Q: Why not leave the annotation / tag text blank?

A: It is possible to apply tags without filling in the tag text. However, doing so will mean that the only evidence that the tag is applicable to that specific study will be the fact that it was applied, and those who view your Qualitative Synthesis will have no context. If you fill in text content, you provide specific evidence of that tag's applicability as well as presenting the specific information from that study to viewers of Qualitative Synthesis.

## 5. Click "Apply Tag"

Once you have the content of interest into the tag text box, make sure that you have selected the relevant tag from the drop-down menu (red box). Once you have confirmed that both the Tag and the Tag Text Content are correct, click "Apply Tag."

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451 patients randomly assigned

225 allocated to chemotherapy plus placebo

225 allocated to chemotherapy plus erlotinib

4 did not receive allocated treatment

221 received chemotherapy plus placebo

221 received chemotherapy plus erlotinib

101 withdrawn

75 disease progression

16 adverse event

2 died

5 refused treatment

3 other

82 withdrawn

59 disease progression

16 adverse event

3 died

4 refused treatment

112 received placebo maintenance

8 did not receive or were not eligible to receive placebo maintenance

135 received erlotinib maintenance

5 did not receive or were not eligible to receive erlotinib maintenance

Figure 1: Trial profile

Chemotherapy-gemcitabine plus carboplatin or cisplatin.

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www.thelancet.com/oncology Published online June 17, 2013 http://dx.doi.org/10.1016/S1470-2045(13)70254-7

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Back Skip Complete

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Methodology of RCTs and other evidence: Provide details of the methodology of the RCTs and non-randomised and non-controlled evidence identified.

Non-randomised Non-controlled

Full Text Tag Recs

Tagging

Comments (0)

History

## Tags with Table Contents

By default, all tags to be applied are accompanied by text contents unless table contents are configured. When these tags are encountered within the form, the table you created will be shown and you can input text into any of the rows. When you are satisfied, click “Apply Tag.”

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Articles

Intercalated combination of chemotherapy and erlotinib for patients with advanced stage non-small-cell lung cancer (FASTACT-2): a randomised, double-blind trial

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Published Online June 17, 2013 http://dx.doi.org/10.1016/S1470-2045(13)70254-7 See Online/Comment http://dx.doi.org/10.1016/S1470-2045(13)70281-X Guangdong Lung Cancer Institute, Guangdong General Hospital, Guangdong Academy of Medical Sciences, Guangzhou, China (Prof Y-L Wu MD); Beijing Chest Hospital, Beijing, China (Prof Y-L Zhu MD); Shanghai Lung Tumor Clinical Medical Centre, Shanghai Chest Hospital, Shanghai, China (Prof M-Liao MD); Shanghai Pulmonary Hospital, Shanghai, China (C Zhou MD); Sir Run Run Shaw Hospital, Hangzhou, China (J Ho MD);

Navigation

Back Skip Complete

Questions (24/37)

Relevant Evidence

Methodology of RCTs and other evidence: Provide details of the methodology of the RCTs and non-randomised and non-controlled evidence identified.

RCT Methods Non-randomised methods Non-controlled methods

Not Relevant Not Relevant Apply

Additional and Supporting Evidence: Provide a description of the methods used for expert elicitation or expert opinion.

Method Type Description

Full Text Tag Recs

Tagging

Comments (0)

History

Highlighting pdfs does not automatically input the text into the box unlike tags with text contents only. However, it will remember any text highlighted or selected in the pdf and auto-scroll to it when the tag is selected again.

Note: If you are entering numerical data into tables, no automated statistics are generated. This is only done in the Meta-Analytical Extraction module.

To alter the columns in the table for this tag, either click on the column header in the Tagging module

itself, or head back to Configure Tagging. [Learn more about tag tables here.](#)

## 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.

The screenshot displays the Nesting Knowledge interface. On the left, a sidebar contains navigation options: Nest Home, Activity, Settings, Literature Search, Other Sources, Duplicate Review, Search Exploration, Abstract Screening, Adjudicate Screening, Full Text Screening, Adjudicate Screening, Tagging (highlighted), Study Inspector, and Synthesis. The main area shows a document titled '78 Wu, 2013' with tabs for Abstract, Full Text, Supplements (highlighted), and Related Reports. The document content includes sections for Results, Conclusions, Limitations, Future work, Study registration, and Funding. On the right, a 'Navigation' panel shows 'Questions (24/37)' with a dropdown for 'Analyses' and buttons for 'Not Relevant', 'Apply', and 'Complete'. Below this, there are sections for 'Tagging', 'Comments (0)', and 'History'.

## 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.

## Tagging Supplemental Materials

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AbstractFull TextSupplementsRelated Reports

CT.gov

Navigation

BackSkipComplete

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

Author Manuscript

HHS Public Access

Author manuscript

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

Published in final edited form as:

Indian J Pediatr. 2012 August ; 79(8): 1062–1068. doi:10.1007/s12098-012-0765-1.

Vitamin D in Chronic Kidney Disease

Yahn-Yir Chau and

Taipei Cathay General Hospital, Taipei, Taiwan

Juhi Kumar

Weill Cornell Medical College, New York, NY, USA

505 East 70th Street, Helmsley Towers 3, New York, NY 10021, USA

Juhi Kumar: juk2013@med.cornell.edu

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

## Add New Tags on the Fly

If you encounter a single or multiple select question where the answer is not one of your pre-configured tags, you can either add it to your hierarchy on the Configure Tagging page, or add it 'on the fly' without leaving the page.

To add a tag on the fly, type the title of your new tag answer into the “Select Tag” box, and click “Add Option” that appears at the top of the drop-down list of tags.

Nest Home

Activity

Settings

Literature Search

Other Sources

Duplicate Review

Search Exploration

Abstract Screening

Adjudicate Screening

Full Text Screening

Adjudicate Screening

Tagging

Study Inspector

Synthesis

Dashboard Editor

Abstract Editor

Export

78 Wu, 2013

AbstractFull TextSupplementsRelated Reports

PubMed

Navigation

BackSkipComplete

Questions (24/37)

Relevant Evidence

Study Design: What is the study design? Include details of randomisation.

Prospective Cohort Study

Add Option: Prospective Cohort Study

Observational

Active Trial

Enter Text

NextAnsweredApply

Population: What is the population studied?

patients with stage IIIB/IV non-small-cell lung cancer.

Full Text Tag Recs

Tagging

Comments (0)

History

Articles

Intercalated combination of chemotherapy and erlotinib for patients with advanced stage non-small-cell lung cancer (FASTACT-2): a randomised, double-blind trial

Yi-Lang Wu, Jin-Soo Lee, Sunetra Thongprasert, Chong-Jen Yu, Li Zhang, Guile Lahera, Vichien Simunjanimit, Vinote Sriwongang, Jennifer Sandoval-Tan, Yunzhong Zhu, Meilin Liao, Caican Zhou, Hongming Pan, Victor Lee, Yuh-Min Chen, Yan Sun, Benjamin Margono, Fatima Fuerte, Gee-Chen Chang, Kasan Seetalarom, Jie Wang, Ashley Cheng, Elsona Syahrudin, Xiaoping Qian, James Ho, Johan Kurniandito, Hainjin Eugene Liu, Kate Jin, Matt Truman, Ilze Bara, Tony Mok

Summary

Background The results of FASTACT, a randomised, placebo-controlled, phase 2 study, showed that intercalated chemotherapy and erlotinib significantly prolonged progression-free survival (PFS) in patients with advanced non-small-cell lung cancer. We undertook FASTACT-2, a phase 3 study in a similar patient population.

Methods In this phase 3 trial, patients with untreated stage IIIB/IV non-small-cell lung cancer were randomly assigned in a 1:1 ratio by use of an interactive internet response system with minimisation algorithm (stratified by disease stage, tumour histology, smoking status, and chemotherapy regimen) to receive six cycles of gemcitabine (1250 mg/m<sup>2</sup> on days 1 and 8, intravenously) plus platinum (carboplatin 5x area under the curve or cisplatin 75 mg/m<sup>2</sup> on day 1, intravenously) with intercalated erlotinib (150 mg/day on days 15–28, orally; chemotherapy plus erlotinib) or placebo orally (chemotherapy plus placebo) every 4 weeks. With the exception of an independent group responsible for monitoring data and safety monitoring board, everyone outside the interactive internet response system company was masked to treatment allocation. Patients continued to receive erlotinib or placebo until progression or unacceptable toxicity or death, and all patients in the placebo group were offered second-line erlotinib at the time of progression. The primary endpoint was PFS in the intention-to-treat population. This trial is registered with ClinicalTrials.gov, number NCT00883779.

Findings From April 29, 2009, to Sept 9, 2010, 451 patients were randomly assigned to chemotherapy plus erlotinib (n=226) or chemotherapy plus placebo (n=225). PFS was significantly prolonged with chemotherapy plus erlotinib versus chemotherapy plus placebo (median PFS 7.6 months [95% CI 7.3–7.9] vs 6.0 months [95% CI 5.6–6.4], hazard ratio

In the modal that appears, confirm the tag name, add a description (optional), and the parent tag will already be pre-populated. Once created, you will now be able to find the new Tag on the drop-down list.

Note: Only tags with text contents can be created on the fly. To toggle on table contents, edit the tag in Configure Tagging.

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Last update: **2023/12/06 21:58**