ADD OR CHANGE A SUBJECT'S TREATMENT ARM

Description: Many studies are designed to have multiple treatment arms. Subjects must be assigned to the appropriate study arm in OnCore to facilitate subject visit tracking, sponsor invoicing, and enrollment reporting. As the subject progresses through the study, the subject's arm status must be updated as applicable.

PLACE A SUBJECT ON A TREATMENT ARM



Before you can change the subject status to "On Treatment", the subject must have already been placed <u>On Study</u>.

- 1. If you are not already in the subject's record,
 - Navigate to Menu > Subjects > CRA Console
 - Select your protocol
 - Click on the blue hyperlink <u>MRN</u> of your subject.
- 2. Click on the **Treatment** vertical tab. *Click* [Update] if needed.
- 3. Select the arm from the Arm drop-down box and enter the On Arm Date.
- 4. If applicable, you can also enter the **On Treatment Date**.
- 5. Click the teeny tiny blue <u>Save</u> hyperlink.
- 6. Note: Assigning a subject to a study arm will not change the **Subject Status** in the upper right of the page. However, if you added an **On Treatment Date** along with the **On Arm Date**, the status will change to **ON TREATMENT**.
- 7. If this study has an OnCore calendar segment triggered by "On Arm", this part of the subject's calendar is now available for visit check in and subsequent sponsor invoicing activity.



WARNING: When registering a subject or updating a subject status in OnCore, make sure that you do <u>NOT</u> have the corresponding study or patient record open in Epic.

If the Epic record is open, the subject status will <u>NOT</u> update from OnCore.

TAKE A SUBJECT OFF OF A TREATMENT ARM

- 1. Find Your Subject.
- 2. Click on the **Treatment** vertical tab.
- 3. Find the line in the **Subject Treatment** section that corresponds to the Arm the subject is coming off and click the tiny blue **Edit** hyperlink.
- 4. Enter the Off Arm Date.
- 5. Click the teeny tiny blue <u>Save</u> hyperlink.
- 6. Note: Removing a subject from a study arm will not change the **Subject Status** in the upper right of the page.
- 7. If this study has an OnCore calendar segment triggered by "Off Arm", this part of the subject's calendar is now available for visit check in and subsequent sponsor invoicing activity.



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If the Epic record is open, the subject status will <u>NOT</u> update from OnCore.

ADD OR CHANGE A SUBJECT'S TREATMENT ARM

CHANGE A SUBJECT'S TREATMENT ARM

- 1. Find Your Subject.
- 2. Click on the **Treatment** vertical tab.
- 3. Find the line in the **Subject Treatment** section that corresponds to the Arm the subject is coming off and click the tiny blue **Edit** hyperlink.
- 4. Enter the Off Arm Date.
- 5. Click the teeny tiny blue <u>Save</u> hyperlink.
- 6. Click the **[Add]** button.
- 7. Select the arm you are switching the subject to from the Arm drop-down box and enter the On Arm Date.
- 8. If applicable, you can also enter an **On Treatment Date** from this screen.
- 9. Click the teeny tiny blue Save.
- 10. Note: Assigning a subject to a study arm will not change the **Subject Status** in the upper right of the page. However, if you added an **On Treatment Date** along with the **On Arm Date**, the status will now be **ON TREATMENT**. To take a subject "Off Treatment", see <u>Take a Subject Off Treatment</u>.
- 11. If this study has any OnCore calendar segments triggered by "On Arm" or "Off Arm", these parts of the subject's calendar are now available for visit check in and subsequent sponsor invoicing activity.



WARNING: When registering a subject or updating a subject status in OnCore, make sure that you do <u>NOT</u> have the corresponding study or patient record open in Epic.

If the Epic record is open, the subject status will <u>NOT</u> update from OnCore.