

Castor ePRO Site Guide: ePRO Symptom Diary Setup on Castor

Introduction

This guide is for recording the ePRO (electronic patient reported outcomes) symptom diary on the eCRF Castor for the ESCAPE trial. The diaries are set up on Castor called “surveys”. The survey notifications need to be activated on Castor from the date of randomisation. You should give the participant the choice to complete their symptom diary electronically (either via the Castor Connect app or by an email link), or on paper. The research team must complete the “Symptom Diary Setup” on Castor **on the date of visit 2** to record this preference.

Paper diary completion

If the participant chooses to complete their symptom diary on paper, the following question must be answered “no”. Please ensure the participant is provided with paper copies of the weekly symptom diary, with enough copies to complete until their next visit.

Visit 2 - Randomisation

20. Symptom diary setup

✓ 20.1 Has the participant provided their email address to receive the daily symptom diary? *

Yes No

Collect the completed copies of the weekly paper symptom diaries at each visit and provide the participant with a new paper diary pack to complete until their following visit. Paper symptom diaries will be transcribed into Castor by the site research team. To enter the weekly symptom diary on Castor:

- Go to the Castor “Participants” homepage
- Click on the participant ID
- On the left side of the Castor webpage, click on “Repeating data”
- At the top right of the Castor webpage, click on “Create”
- From the dropdown list, select “ESCAPE paper symptom diary”
- Enter the data on Castor as shown on the paper diary

You do not need to follow any further instructions within this guide.

Electronic diary completion

If the participant chooses to complete their symptom diary electronically, the following questions must be answered “**yes**” on Castor visit 2 under “**Symptom diary setup**” tab:

Visit 2 - Randomisation

21. Symptom diary setup

✓ 21.1 Has the participant provided their email address to receive the daily symptom diary? *

Yes No

✓ 21.1.1 Has the email address been recorded in Castor? *

Yes No

 Please provide the ESCAPE ePRO Participant Guide to the participant.

Electronic diary completion – App

If the participant chooses to complete their symptom diary electronically through the Castor Connect App, the following questions must be answered “**yes**” on Castor visit 2 under “**Symptom diary setup**” tab:

✓ 21.1.2 Would the participant prefer to install and use the Castor Connect mobile App to receive the daily symptom diary? *

Yes No

The data management team will activate the daily & monthly diaries for the participant to receive through the App. The participant should follow the instructions in **ESCAPE Castor ePRO Participant Guide** to download & set up the Castor Connect App.

Electronic diary completion – Email

If the participant chooses to complete their symptom diary electronically through the Castor Connect App, the following questions must be answered “no” on Castor visit 2 under “Symptom diary setup” tab:

✓ 21.1.2 Would the participant prefer to install and use the Castor Connect mobile App to receive the daily symptom diary? *

Yes No

The data management team will activate the daily & monthly diaries for the participant to receive through email. The participant should follow the instructions in **ESCAPE Castor ePRO Participant Guide** for email completion. Advise the participant to check their junk folder.

Adding participant email address to Castor


If the participant agrees to complete their symptom diary electronically, you must collect their email address and add this to Castor. This can be done when you create the participant ID, or you can add the email address after the participant ID has been created. **Their email address must be on Castor by visit 2**, in order to activate the symptom diary at the start of the trial.

Participants completing the electronic symptom diary will receive either an App notification or an email link daily for the duration of the trial (from visit 2 – end of trial).

Please ensure the participant receives the **ESCAPE Castor ePRO Participant Guide** for instructions on how to set up the Castor app or the email notifications.

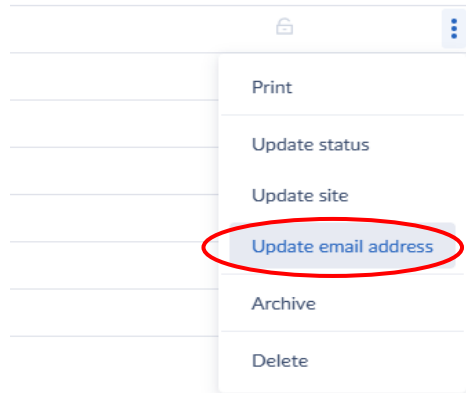
Adding a participant email when creating a new participant

Open Castor to view the ESCAPE participant overview page.

- Go to the Castor “Participants” homepage and click 
- The site information will be pre-populated
- Enter the participant ID (in the correct format of site number and participant number e.g. 0101)
- Add the participant email
- Click “Create”

Adding a participant email after a participant has been created

- The email address can also be added after the creation of the participant ID on Castor.
- Go to the Castor “Participants” homepage
- Click on the three vertical dots to the far right of the participant ID
- Select **Update email address**
- Enter your Castor password and click **Proceed**



Enter the email address of the participant and note a reason for this change. Then click “**Change participant email**”

Review of Symptom Diary Completion

For paper completion: at each in person visit, collect the weekly paper diary pack & reissue a new weekly pack for the following visit.

For ePRO completion: at visit 3 (phone call) and visit 4, 5 & 6 (in person), please confirm verbally with the participant if they are receiving the app or email notifications and whether they are completing the symptom diary.

Stopping ePRO notifications

For App: notify the participant that they should delete the App on their mobile or tablet device to stop all future notifications.

For email: contact the data management team to stop future email notifications.

Contact ESCAPE-DM@dundee.ac.uk if you have any questions.