COPCOV Study Subject
eDiary User Guide

This User Guide details everything you need to know for entering your eDiary information.
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Overview: TRACKING YOUR SYMPTOMS – DAILY DIARY

In order for your study team to assess your symptoms in this study, you must complete 2 Diary entries every day until you finish your treatment. It is important that each Diary is fully completed and accurately reflects your symptoms. The application will remind you to complete your Diary twice daily.

The Diary must be filled out twice daily. Each entry must be at least 8 hours apart. You will be permitted to enter diary data for the previous 8 - 48 hours.

For each Diary you will be asked to provide the following information:

- Is this report for today?
  - If no, you will be asked to enter the Date and Time
- How do you feel?
  - If Unwell, you will be asked to choose from the listed symptoms.
    - If Shortness of breath, you will be asked to choose at rest or on exertion
    - If Other, you will be asked to specify symptoms: Itching, Skin rash, Headache, etc.
      - If Other symptom, you will be asked to specify.
- Temperature:
- Did or will you go to work today?
  - If No, you will be asked the question Reason for not going to work
- Did you take the drug for the day you are submitting this report for?
  - If no, you will be asked the question Reason for not taking the drug
    - If Other, you will be asked to specify

Please contact your study team if you have any questions or doubts on how to complete your eDiary.

The following pages contain detailed instructions on completing your diary with examples of data entry.
Downloading the Application:

*Please follow the steps below -*

1. Open the applicable store for your device
   
   a. iPhone: Apple App Store
   
   b. Android: Google Play Store

2. Search Fusion ePRO

3. Click on the Fusion ePRO App

4. Click Install / Get

5. Once downloaded to your device, click the icon to open it and follow the steps for **Logging into Fusion Mobile ePRO App**, below.
Logging into Fusion Mobile ePRO App:

Once the ePRO Mobile Diary Application has been downloaded and opened, you may proceed with logging in.

1. Click on the Fusion ePRO App.
2. Select your preferred language.
3. Enter the Study PIN, Subject Number and the Permanent Password you created and noted on your Subject Card.
4. Select the **Remember Me** option to save your login credentials for future use (See Figure 1.)
5. If you are unable to login, please reach out to the Study Team as per the information on your Study Card.
6. Once logged in, the Home Screen will display.

**Figure 1:**
Adding Diary Entries:

1. Select the *Add Entry* button in the bottom right of the screen (*See Figure 2*).

   **Figure 2:**

   ![Add Entry button](image)

2. The first question will display
   - *Is this report for today?*

3. If you are entering a current diary entry, please select *Yes* and the current Date and Time will automatically populate for you.
4. If you are completing a diary entry for the previous 8-48 hours, you can select No and enter the applicable Date and Time (See Figure 3). You cannot enter diaries from < 8 hours ago or for > 48 hours ago.

*Figure 3:*

5. Once answered, select the Next button to proceed to the next question.
6. The next question will appear on screen (See Figure 4).
   • How do you feel?

   **Figure 4:**

   ![Figure 4:](image)

7. Once you have selected your response, you may proceed to the next question by selecting the **Next** button (See Figure 4).
8. If **Unwell** is selected, you will be asked the following question (See Figure 5):
   - **If unwell (choose all that apply)**

### Figure 5:

![Diary entry for unwell symptoms](image-url)
9. If **Shortness of breath** is selected, the next question will appear on screen (See Figure 6).

- **Shortness of breath**

*Figure 6:*
10. If **Other** is selected, the next question will appear on screen (*See Figure 7*).

- **Other (choose all that apply)**

*Figure 7:*

![Image of eDiary interface showing Other (choose all that apply) options]
11. If **Other symptom** is selected, the next question will appear on screen (See Figure 8).

   - **Other symptom**
     
     i. Click on the ‘Other symptom’ text that is greyed out in order to type your response.

   **Figure 8:**
12. Next, you will be asked following question. (See Figure 9).

- **Temperature:**
  
  i. Click on the ‘Celsius’ text that is greyed out in order to type your response.

*Figure 9.1:*
• If the temperature is less than 34 or greater than 41, the following message will display. (See Figure 9.2).
  
  i. The temperature value you entered seems incorrect. Please confirm the reading on the thermometer.
• To proceed, please enter a temperature within the range of 34 – 41 and select Next

**Figure 9.2:**
If the temperature does not match the format, 2 digits and/or 1 decimal, the following message will display. (See Figure 9.3).

i. The format you have entered is incorrect. Please revise and ensure it meets the following format: numeric with up to 2 digits and 1 decimal. (Example: 36.4). If unable to take temperature, please enter ND for Not Done.

To proceed, please enter a temperature with the format 2 digits and 1 decimal or ND and select Next.

**Figure 9.3:**
13. Next, you will be asked the following question (See Figure 10):

- **Did or will you go to work today?**

*Figure 10:*
14. If No was selected for Did or will you go to work today? The following question will appear on screen (See Figure 11).

- Reason for not going to work (choose all that apply)

Figure 11:
15. Next, you will be asked the following question (See Figure 12):

- Did you take your drug for the day you are submitting this report for?

Figure 12:
16. If No was selected for Did you take your drug on the day you are entering this report for? The following question will appear on screen (See Figure 13).

- Reason for not taking the drug?

**Figure 13:**
17. If Other was selected for *Reason for not taking the drug*, the following question will appear on screen (See Figure 14).

- Other reason

*Figure 14:*

![Image of the eDiary interface showing the Other reason section.](image-url)
18. Once all questions have been answered, the following Confirm Entry Summary screen will appear. (See Figure 15).

- Click OK if you would like to submit your entry
- Click CANCEL if you would like to revise any of your answers
  
i. You will be brought to the previous screen where you can select the Previous button to scroll through your previous question answers

*Figure 15:*

<table>
<thead>
<tr>
<th>Confirm Entry Summary</th>
<th>OK</th>
<th>CANCEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is this report for today?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>15/Apr/2020</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>15:08</td>
<td></td>
</tr>
<tr>
<td>How do you feel?</td>
<td>Unwell</td>
<td></td>
</tr>
<tr>
<td>If unwell (choose all that apply)</td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Other (choose all that apply)</td>
<td>Other symptom</td>
<td></td>
</tr>
<tr>
<td>Other symptom</td>
<td>H</td>
<td></td>
</tr>
<tr>
<td>Temperature:</td>
<td>ND</td>
<td></td>
</tr>
<tr>
<td>Did or will you go to work today?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Reason for not going to work (choose all that apply)</td>
<td>Not scheduled to work</td>
<td></td>
</tr>
<tr>
<td>Did you take the drug for the day you are submitting this report?</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
Viewing Diary Entries

1. Select the View Entry button in the bottom right of the screen (See Figure 16).

   **Figure 16:**

   ![View Entry Button](image)

2. A list of diary entries made will display (See Figure 17).

   a. Click on the entry, if you would like to view the answers provided

   **Figure 17:**

   ![Diary Entry](image)
Updating Diary Entries

If you previously submitted a report that requires updates, please contact your Study Team in order to make the changes on your behalf.
Notifications

Fusion ePRO is configured with notifications to remind participants to fill in their eDiary.

Following a 12-hour period from last diary entry, a participant will receive the following reminder (See Figure 18) –

- Please remember to fill out your Report!
  - Users can swipe right on the notification banner to dismiss the reminder notification.

Figure 18:
Fusion ePRO will also remind participants of the next scheduled visit (Figure 19).

- Your follow-up visit is scheduled for 3 days from now. Please plan to visit the study site.

*Figure 19:*
Installing Fusion ePRO App Updates:

During the Study you may need to install updates to the Fusion ePRO Application.

To do so, please follow the steps below:

**iOS Device (iPhone / iPad)**

1. Click on the App Store icon to access the App Store
2. At the bottom, click on the Updates icon at the bottom of the screen
3. The Fusion ePRO App will display with a button that says **UPDATE**
4. Click the **UPDATE** button
   a. When the updates are completed, the UPDATE button will display as **OPEN**
**Android Device**

1. Click on the icon to access the Play Store

2. **To Update Android apps automatically:**
   a. At the top left, click on the Menu Icon
   b. Scroll down in the Menu bar and select Settings
   c. Click on Auto-update apps and select one of the two options:
      i. Auto-update apps at any time. Data charges may apply, or
      ii. Auto-update apps over Wi-Fi only

3. **To Update Android apps manually:**
   a. At the top left, click on the Menu Icon
   b. Click on My apps & games
   c. The Fusion ePRO App will display with a button that says **UPDATE**
   d. Click the **UPDATE** button
      i. When the updates are completed, the **UPDATE** button will display as **OPEN**
Frequently Asked Questions

1. Initial Log In
   a. Temporary Password, Study PIN, Username
      i. These details will be available on the Study Card provided by your Study Team.
         1. If you do not have a Study Card, please contact your Study Team.
   b. Language Selection
      i. Please select from the list of available languages to display questions in your preferred language
         1. Note: Additional language options will be released as they become available. Please see Pages 26 – 27 to set auto-updates for the ePRO App to ensure the latest updates are always available

2. Passwords
   a. Forgotten Password
      i. Please contact your Study Team for assistance in resetting your password.
   b. Password Entry Requirements
      i. When choosing your permanent password, a 5 digit numeric password is recommended
      ii. Check the box beside Remember Me to save your login credentials for future use

3. Adding, Storing, Syncing and Viewing Entries
   a. The Add Entry button is located at the bottom-right after initial log in
   b. The View Entries button is located at the bottom-middle after initial log in
   c. Storing Entries
      i. Entries will be stored locally on the device and will be viewable within the View Entries Tab until user is logged out of the app
   d. Syncing Entries
      i. Online Entries
         1. Entries will sync automatically if device is connected through data or Wifi
      ii. Offline Entries
         1. If the device does not have internet connection, OFFLINE will display in the bottom-right corner of the View Entries Tab
         2. The total number of entries pending to sync will display on the Home Tab
         3. Entries will not be deleted from the device until synced, even if the User logs out of the app
4. Cancelled Entries
   a. Cancel an Entry without saving the data
      i. Cancel from the First Page
         1. Press previous to return to first page if entry has been started
         2. Press the red Cancel button on the first page
         OR
      ii. Cancel from the Last Page (Confirm Entry Summary)
         1. If an entry has been completed but not yet saved, complete data entry up to the last page
            a. Click cancel from the top-right of the Confirm Entry Summary Page

   b. Confirming a cancelled Entry
      i. Select the View Entries Tab (bottom-middle of Home Page) to confirm that the entry did not save to the app
         1. If an entry was saved to the app unintentionally, contact your Study Team to make the updates on your behalf
If you ever need help while using Fusion ePRO Mobile Application configured for the COPCOV Study, please contact your Study Team.