CoroPrevention script for case nurses (release 2.0)

This script describes the first steps when getting started with the Caregiver dashboard, which is the part of the CoroPrevention Tool Suite that is administer by study nurse and investigator.
For detailed instruction on the Tool Suite and eCRF, please refer to the applicable guidelines (e.g., Caregiver dashboard user guide, Patient general user manual, frequently asked questions, Troubleshooting list and eCRF completion guidelines).
Currently, you are using Release 2.0 of the Tool Suite, which includes the following modules:

- Parameter monitoring
- Increase your knowledge (i.e. education)
- Medication adherence (including the medication decision support)
- Start moving (including the EXPERT tool for exercise prescription)

In the next releases, the following modules will be added:

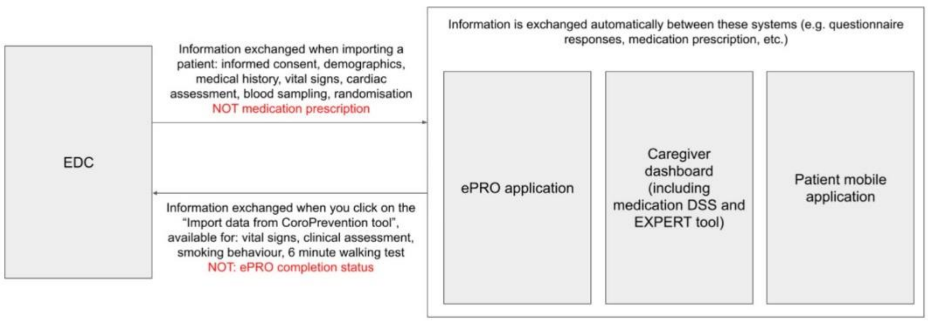
- Healthy nutrition
- Smoke-free living
- Stress relief

Visit 2

Visit 2 is the first visit after randomization, and thus the first visit that will make use of the CoroPrevention Tool Suite.

In preparation for Visit 2

- EDC entry should be completed (see EDC-specific training) after visit 1.
- Open the caregiver dashboard and log in to your account.
- Import the subject from the EDC to the Tool Suite by creating a patient record in the Tool Suite.
    - The graphic below shows which information is shared between the EDC and the Tool Suite (ePRO application, caregiver dashboard and patient mobile app).



<u>It is possible to complete the following information before Visit 2 (but not obligatory):</u>

- Click on the Open patient record button and thereafter select "Follow-up patient".
- Insert current medication prescription in the caregiver dashboard (as this is not automatically imported from the EDC).

    - If the medication prescription is completed prior to the visit, the patient can view the prescription in the medication prescription questionnaire on the tablet.
- Make an exercise prescription (i.e. weekly sports goal) using the EXPERT tool.
- Close the patient record when you are complete.

When the patient arrives

- Open the caregiver dashboard and log in to your account.
- Look up the patient's record using the subject ID.
- Use the tablet to scan the QR-code generated in the caregiver dashboard. Automatically, the correct set of questionnaires will be shown for the patient.
  Hand the tablet to the patient in order to let the patient complete the questionnaires.

- NOTE: A 6-minute walking test should be conducted, and vital signs should be measured before you start the consultation session utilising the caregiver dashboard.

In the consultation room

- Let patient sit down, ask if everything went well with completing the questionnaires.
- If patient needs support, complete the questionnaires together on the tablet.
- Explain today's visit.
- Then it is time for the following steps in the caregiver dashboard:
    - Opening the patient record for a visit.
      If the questionnaires were not completed by the patient, you will see a message saying: "There is no information from the questionnaires!"
    - Inserting vital signs, 6MWT results, clinical assessment and medication DSS-related information.
- Click the button to start the visit.

- NOTE: From this moment on, the **screen will be shared** with the patient, and the patient is invited to follow everything you will do on the screen.

<u>General</u>

- Start by discussing the risk profile bar at the top of the screen.
    - Especially pay attention if there is an exclamation mark for the stress relief icon as this indicates elevated anxiety, depression and stress based on the answers to the ePRO questionnaires.

<u>Journey</u>

- Start by discussing the patient's journey.
    - The "Be healthy" graph will depict the current status of the patient.
- Go to "Goal setting"
    - Discuss the current status and motivation. This information is available in the dashboard based on the questionnaires that the patient has completed.

    - NOTE: The right side of the screen can be used to change the "level of guidance". This can done after each module or at the end of the consultation for all modules at once.

Medication adherence

- Go to the medication adherence module.
    - The current status will be shown and can be discussed with the patient (high or low adherence, barriers to the patient, etc.)
- In "prescription" you can see the current prescription for the patient. Tell the patient that potential recommendation for medication and dose adjustments are further discussed during the consultation with the investigator.
- After discussing medication adherence, go back to Journey -> Goal setting and decide together with the patient if you want to change the level of guidance for "Medication adherence".

Start moving

- Go to the start moving module.
- Status:
    - The current status will be shown and can be discussed with the patient (current physical activity status of the patient).
- Go to Goal setting -> Weekly sports goal.
    - Click on "Edit sports goal" to set the weekly sports goal using the EXPERT tool (if this was not done in advance).
        - Complete primary indication, key risk factors, exercise modifiers, anomalies and medication and accept the recommendation.
        - If you think the recommendation is not suitable for the patient, you can modify the exercise prescription and save it.
        - Briefly review safety precautions with the patient and explain these to the patient if applicable.
    - Discuss the goal (flags for kilocalories and intensity, sessions, duration, strength training) together with the patient-provided information (physical complaints, favourite activities, favourite activities from childhood).
- Next go to "Daily activity goal".
    - Discuss current level and, if needed, decide together with the patient upon a suitable daily activity goal.
- After discussing start moving, go back to Journey -> Goal setting and decide together with the patient if you want to change the level of guidance for "Start moving".

- **Note: remember to discuss with the patient to go into "Monitored action" in the Journey to make sure the recommendations are visible to the patient**.

Modules made available later during the course of the trial: healthy nutrition, smoke-free living, stress relief

- Other modules are made available at a later stage of the trial.
- Make sure to discuss the Risk profile bar, and to motivate the patient to already change or improve their behaviour if needed for these risk factors. If needed, refer to professional help (dietician, psychologist, tobaccologist).

Education – Increase your knowledge

- Go to the "Increase your knowledge" module.

- Discuss with the patient what topics could be interesting for him/her and mark them as favourites. The patient will see that the nurse has suggested these topics to him/her (appearing in the favourites in the mobile app).

End of Case Nurse Visit

- You can close the patient record. Please note that if you close the record, the investigator will need to click on “re-open visit” when logging in to Caregiver dashboard with their user ID.

OR

- You can leave the visit open and log-out of Caregiver dashboard. Investigator needs to close the visit once the medication DSS consultation is completed.

- If the subject uses an Android smartphone: Please make sure Google Fit (Android) is installed and step tracking is activated before installing the CoroPrevention mobile app.
- If the subject uses an iPhone: Please make sure that step tracking is enabled for the Apple Health App.
- Support the patient with installing the CoroPrevention application on their smartphone from the applicable App store (Google Play Store or Apple App Store).
- Print the QR code from Caregiver Dashboard for the patient to login.
- Complete the “Welcome” reminder on the smartphone together with the patient.

- NOTE: Refer to help sources: FAQ, CoroPrevention website and the patient general user manual. Patients can request a printed copy if they want.

Doctor Visit – Visit 2 (similar for Visit 6)

- After seeing the case nurse, the patient should see the doctor (cardiologist/internist/other) to make sure that the cardiac medication prescription is reviewed and if needed, adjusted, to align with ESC guidelines.
- Log in to the caregiver dashboard with an investigator’s account.
- Open the patient record.
    - Note: preferably the patient record is still open for visit 2/6. If this is not the case, you need to reopen the visit from the timeline.
- Click on “Open Medication Decision Support” in the top right corner.
- Review the current medication at the top.
- Scroll down to “Recommendation”.
    - Certain medication classes will be recommended
    - Evaluate if you agree with the medication recommendation and if no contra-indications exist. Select "Accept prescription” (line by line).
    - Prescribe a medication of your choice within this class to the patient.
        - Add the name, dose, frequency and moment(s) of intake.
        - Click on “Save” on the right side of the screen.
        - Make sure to give the prescriptions for the pharmacy to the patient.
    - If you do not agree with the recommendation, please reject the recommendation by clicking on the “trash” symbol and indicate why you do not agree with the recommendation.
- Close the patient record.

- CoroPrevention Tool Suite, Caregiver dashboard web address: https://dashboard.coroprevention.eu/login

- CoroPrevention EDC web address: https://edc.coroprevention.eu/login