**Weekly COVID-19 follow-up Questionnaire**

**Participants data:**

* Protocol:
* Names and surnames:
* Age:
* Telephone contact:
* Current address:
* Study phase (double blind / open extension):
* Randomization date:
* Date of the last on-site visit:

PHONECALL DATE:

1. **Demographic data:**
2. Who answers the call (name, surname and relationship)?
3. Who do you live with?:
   1. Couple:
   2. Children:
   3. Carer:
   4. Others:
4. Is this your usual residence? (YES / NO):
5. Are you alone? (YES / NO):
6. IF YES: do have a family member to supervise you? (YES / NO)
7. IF YES: Who:
8. IF NO: Do you have social support? (YES / NO)
9. IF NO: notify social work.

**2. Ad-hoc COVID-19 questionnaire**

1. Confinement start date:
2. Have **YOU** experienced any of the following symptoms? (YES / NO):
3. Dry cough:
4. Fever (record temperature):
5. Sneezing:
6. Difficulty breathing:
7. Fatigue:
8. Diarrhea:
9. Anosmia / ageusia:
10. Others:
11. Classify the case (report date in case of PCR performed):
12. Confirmed case (positive PCR):
13. Probable case (inconclusive PCR):
14. Case dismissed (negative PCR):
15. Possible case (mild acute respiratory infection without PCR criteria):
16. None of the above:
17. In case of confirmed, probable or possible case:
18. Current situation:
19. Isolation (YES / NO, date):
20. Hospitalization (YES / NO, date):
21. Treatment (start date):
22. Has **ANY FAMILY MEMBER** experienced any of the following symptoms? (YES / NO):
23. Dry cough:
24. Fever (record temperature):
25. Sneezing:
26. Difficulty breathing:
27. Fatigue:
28. Diarrhea:
29. Anosmia / ageusia:
30. Others:
31. Classify the case (report date in case of PCR):
32. Confirmed case (positive PCR):
33. Probable case (inconclusive PCR):
34. Case dismissed (negative PCR):
35. Possible case (mild acute respiratory infection without PCR criteria):
36. None of the above:
37. In case of confirmed, probable or possible case:
38. Current situation:
39. Isolation (YES / NO, date):
40. Hospitalization (YES / NO, date):
41. Treatment (start date):
42. Confinement Compliance:
    1. Patient:
       1. Leaves the house (YES / NO):
          1. IF YES: Frequency:
          2. IF YES: Reasons:
    2. Family member who lives with the patient:
       1. Leaves the house (YES / NO):
          1. IF YES: Frequency:
          2. IF YES: Reasons:
    3. Who buys the food?
       1. Frequency:

**3. Safety data for clinical trials**

1. Have you had symptoms other than those of a common cold? (YES / NO):
   * 1. IF YES: Which one(s), duration, course:
2. Any recent changes in your prescribed medication? (YES / NO):
   * 1. IF YES: Name of the drug, dose, interval of administration:
3. Adverse effect (YES / NO):
   * 1. Mild: The event is easily tolerated and does not interfere with activities of daily living.
     2. Moderate: The event interferes with activities of daily life.
     3. Severe: incapacity to carry out activities of daily life, disabling, requires medical intervention. See SAE criteria.
4. Relationship to study medication:
   * 1. Definitive: there is a temporal relationship between the start of the event and the administration of the study medication. It is a known reaction of the drug, its chemical group or is predictable by its pharmacology. The event cannot be explained by the patient's clinical condition or by other factors.
     2. Probable: There is a reasonable time relationship between the start of the event and the administration of the study medication. It cannot be explained by the patient's clinical condition, intercurrent pathology, or concomitant treatment. In case of discontinuation of the study medication, the event revolves or decreases in intensity, reappearing with its new introduction. The adverse effect is possibly known as a reaction of the drug, its chemical group or is predictable by its pharmacology.
     3. Possible: There is a reasonable time relationship between the start of the event and the administration of the study medication. The event can be explained by the patient's clinical condition, an intercurrent pathology or concomitant treatment. In case of discontinuation of the study medication, the event revolves or decreases in intensity, reappearing with its new introduction.
     4. Unlikely: There is no good temporal relationship between the start of the event and the administration of the study medication. The event can be easily explained by the patient's clinical condition, intercurrent pathologies, or concomitant treatment.
     5. Not related:

**4. Do you need us to contact someone? (YES / NO):**

**NOTES:**

The following points are discussed:

* The sponsor gives the possibility to continue with the study medication.
* We will carry out a weekly telephone follow-up to detect eventualities.
* In case of an adverse event requiring urgent care reported by you or a family member, you will be referred and evaluated at Corachán Clinic Emergency Room accompanied by a Fundació ACE doctor.
* A courier service will deliver the medication to your home, if required to continue the study.
* Agreement to receive the IP on site when the lockdown ends.

Given the above, the participant determines to continue the study

**- YES /ACCEPT**

**- NO/REJECT**