

FIRST LINE Day 0 (Form 04 –Enrolment CRF) (1)



PID# \_\_\_\_\_ Date of Visit \_\_\_\_\_

Medical History

- Alcoholism: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
Substance use: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
Depression: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
Cerebrovascular: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
Malignancy: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
P Neuropathy: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
Cryoglobulinemic vasculitis: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
Renal insufficiency: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
HCV immune complex-related nephropathy: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
Diabetes: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
Hyper-cholesterolaemia: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
Syncope: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
Hypertension: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
Heart failure: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
Angina: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
MI: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
Artery bypass: Y [ ] N [ ] Current [ ] Recent [ ] Historic [ ]
Smoking Status: [ ] Non Smoker [ ] Past Smoker [ ] Current Smoker

Previous HCV treatment

- Spontaneously cleared infection? Y [ ] N [ ]
Previous successful treatment? Y [ ] N [ ]
Previous unsuccessful treatment? Y [ ] N [ ]

FIRST LINE Day 0 (Form 04 –Enrolment CRF) (3)



PID# \_\_\_\_\_ Date of Visit \_\_\_\_\_

Concomitant Medications

- Any other meds: Y [ ] N [ ]
Medications: \_\_\_\_\_

Pregnancy

- Woman of Childbearing potential? Y [ ] N [ ]
Date of pregnancy test: [ ]-[ ]-[ ]-[ ]-[ ]-[ ]
Result: Positive [ ] Negative [ ]

IL28 test

- Test preformed? Y [ ] N [ ] N/A [ ]
Result: IL28 CC [ ] IL28 CT [ ] IL28 TT [ ] No result [ ]
No result why: \_\_\_\_\_

Next visit

- Day 3 [ ]-[ ]-[ ]-[ ]-[ ]-[ ]
Day 7 [ ]-[ ]-[ ]-[ ]-[ ]-[ ]
Day 14 [ ]-[ ]-[ ]-[ ]-[ ]-[ ]

Questionnaires

- Form 05 –EQ-5D [ ]
Form 06 – MOSCOG [ ]
Form 07 – SF-12 [ ]

Lab results required- tick if collected

- HCV VL [ ] Haematology [ ]
Biochemistry [ ]

Sign: \_\_\_\_\_ Date: \_\_\_\_\_

FIRST LINE Day 0 (Form 04 –Enrolment CRF) (2)



PID# \_\_\_\_\_ Date of Visit \_\_\_\_\_

Previous HCV treatment cont.

- If unsuccessful was the participant : an intolerant relapser? Y [ ] N [ ]
a relapser after full treatment? Y [ ] N [ ]
a non-responder ? Y [ ] N [ ]
breakthrough on treatment ? Y [ ] N [ ]

Treatment dates: Interferon

From [ ]-[ ]-[ ]-[ ]-[ ]-[ ]
To [ ]-[ ]-[ ]-[ ]-[ ]-[ ]

Treatment dates: Ribavirin

From [ ]-[ ]-[ ]-[ ]-[ ]-[ ]
To [ ]-[ ]-[ ]-[ ]-[ ]-[ ]

Treatment dates: DAA please specify which DAA's: \_\_\_\_\_

From [ ]-[ ]-[ ]-[ ]-[ ]-[ ]
To [ ]-[ ]-[ ]-[ ]-[ ]-[ ]

Stored samples

20 ml EDTA (required)

- Size of tubes: [ ]-[ ]ml
No tubes collected: [ ]
Date of specimen: [ ]-[ ]-[ ]-[ ]-[ ]-[ ]
Time of collection: [ ]:[ ]

Optional 2.5ml whole blood PAXgene RNA

- Size of tubes: [ ]-[ ]ml No tubes collected: [ ]
Date of specimen: [ ]-[ ]-[ ]-[ ]-[ ]-[ ]
Time of collection: [ ]:[ ]

Optional 2.5ml whole blood for EDTA DNA

- Size of tubes: [ ]-[ ]ml No tubes collected: [ ]
Date of specimen: [ ]-[ ]-[ ]-[ ]-[ ]-[ ]
Time of collection: [ ]:[ ]