Visit date	Study number	Patient initials	
□□/□□□/□□□□ (dd/mon/yyyy)	1510-□□□□□-□□	□□□□ E.g. Smith John SMJO	DARLO-C

DARLO-C
SELECTION CRITERIA CHECKLIST

Inclusion Criteria:	Yes/No (please tick)
1. Participants have voluntarily signed the informed consent form.	Yes ☐ No ☐ N/A ☐
2. 18 years of age or older.	Yes ☐ No ☐ N/A ☐
3. Have chronic HCV genotype 1 or 4 infection (defined as detectable HCV RNA)	Yes ☐ No ☐ N/A ☐
4. Recent injecting drug use (previous 6 months)	Yes ☐ No ☐ N/A ☐
5. HIV-1 infected subjects if they meet the following criteria: a) Have HIV infection documented by any licensed rapid HIV test or HIV enzyme or chemiluminescence immunoassay (E/CIA) test kit at any time prior to study entry (Baseline) and confirmed by a licensed Western blot or a second antibody test by a method other than the initial rapid HIV and/or E/CIA, or by HIV-1 p24 antigen, or plasma HIV-1 RNA viral load. b) Be on HIV Antiretroviral Therapy (ART) for at least 4 weeks prior to study entry using an ART regimen that is allowable with the intended DAA regimen as determined by the current PI and the Liverpool drug interaction website (http://www.hiv-druginteractions.org/) or current prescribing guidelines for elbasvir/grazoprevir OR be naive to treatment with any antiretroviral therapy (ART) with a baseline CD4 count of >200 and have no plans to initiate ART treatment while participating in this study and through to at least Follow-up Week 4.	Yes ☐ No ☐ N/A ☐
c) Negative pregnancy test at baseline (females of childbearing potential only)	Yes ☐ No ☐ N/A ☐
d) All fertile males and females must be using effective contraception during treatment and during 14 days after treatment end.	Yes ☐ No ☐ N/A ☐
Exclusion Criteria:	**Yes/No (please tick)**
1. Is taking or plans to take any prohibited medications as per DAA Product Information or herbal supplements, including but not limited to St. John's Wort (Hypericum perforatum) within 2 weeks of Baseline.	Yes ☐ No ☐ N/A ☐

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2. Is currently using or intends to use barbiturates	Yes ☐ No ☐ N/A ☐
3. Is a female and is pregnant or breast-feeding, or expecting to conceive or donate eggs from Baseline and continue throughout treatment, and after the last dose of study medication (as per the regimen requirements), or longer if dictated by local regulations	Yes ☐ No ☐ N/A ☐
4. Has any condition or pre-study laboratory abnormality, ECG abnormality or history of any illness, which, in the opinion of the investigator, might confound the results of the study or pose additional risk in administering the study drugs to the subject.	Yes ☐ No ☐ N/A ☐
5. Had a life-threatening SAE during the screening period.	Yes ☐ No ☐ N/A ☐
6. Has exclusionary laboratory values as listed below:	Yes ☐ No ☐ N/A ☐
7. Patients with Child Pugh-B or C decompensated cirrhosis.	Yes ☐ No ☐ N/A ☐
8. Previous HCV treatment-experience.	Yes ☐ No ☐ N/A ☐
9. Ongoing severe psychiatric disease as judged by the treating physician.	Yes ☐ No ☐ N/A ☐
10. Frequent injecting drug use that is judged by the treating physician to compromise treatment safety.	Yes ☐ No ☐ N/A ☐
11. Has one of the following hepatitis C resistance-associated NS5A substitutions M28L/T/V, Q30H/L/R, L31M, or Y93C/H/N/S • **Genotype 1a patients with any of the above substitutions are excluded from DARLO-C**	Yes ☐ No ☐ N/A ☐
12. Inability or unwillingness to provide informed consent or abide by the requirements of the study.	Yes ☐ No ☐ N/A ☐

Laboratory Assessment	**Value**
Haemoglobin	< 9.5 g/dL for both males and females
Platelets	< 75 x 10^3 /µL
Serum albumin	< 3.0 g/dL

Investigator Name: _____

Investigator Signature: _____

Date: _____

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