



Dept. Klinische Forschung
Clinical Trial Unit

Public Annual Report

Swiss Hepatitis C Cohort Study (SCCS)



FONDS NATIONAL SUISSE
SCHWEIZERISCHER NATIONALFONDS
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SWISS NATIONAL SCIENCE FOUNDATION

FONDATION ETUDE SUISSE DE COHORTE HEPATITE C



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On behalf of the
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Data as of February 16, 2017

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1 Patient recruitment, follow-up and drop-outs

1.1 Recruitment

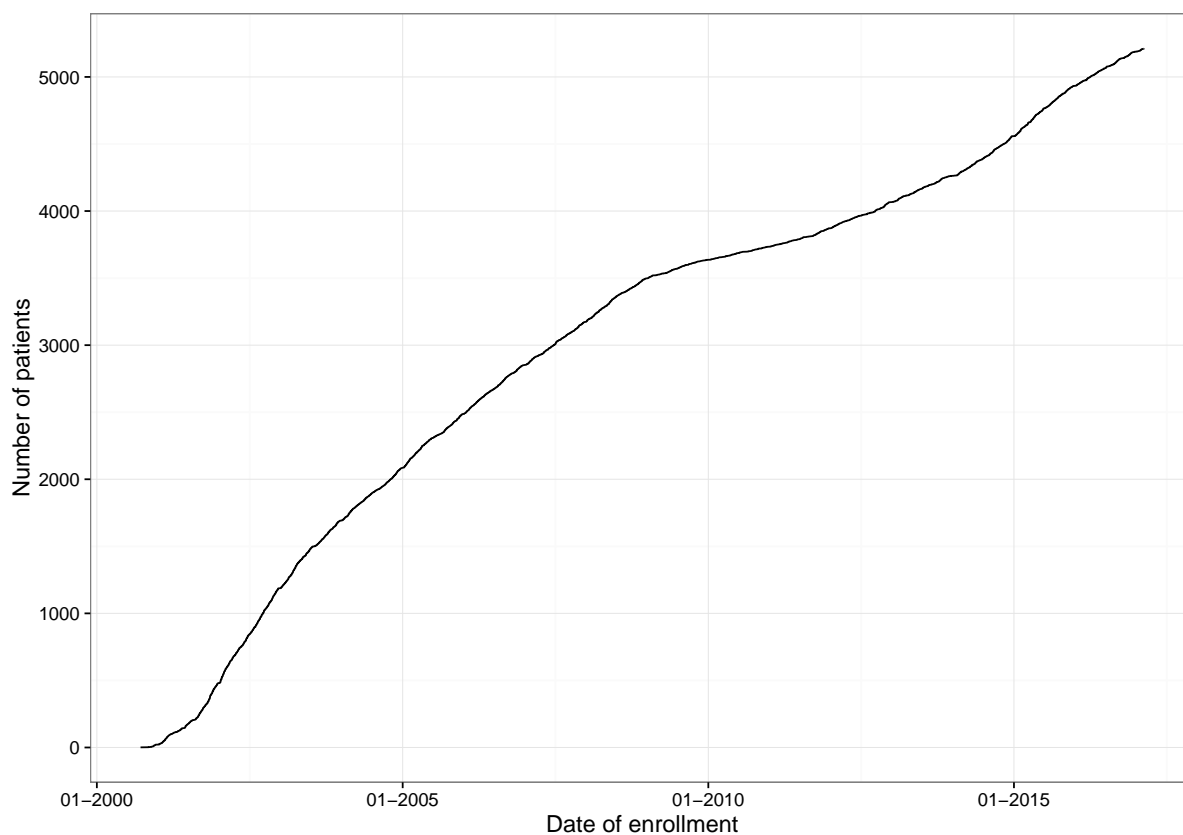


Figure 1: Patient recruitment for SCCS (first patient in: 2000-09-18).

1.2 Visits and follow-up

Table 1: Number of visits by visit type.

	Visit type					
	Baseline		Follow-up		All	%
	n	%	n	%		
Total	5212	19.3	21735	80.7	26947	100.0

Table 2: Number of visits per patient.

n	Number of visits per patient											
	1	2	3	4	5	6	7	8	9	10	≥11	
Total	5216	973	797	654	492	378	299	270	256	235	206	656

Table 3: Number of recent visits by visit type, comparison to same period in previous year.

	Visit type			
	Baseline		Follow-up	
	2016 Q3+Q4	2015 Q3+Q4	2016 Q3+Q4	2015 Q3+Q4
	Total	123	169	973

1.3 Drop-outs and death

Table 4: Overview on drop-outs and patients lost to follow-up.

	n	%
All patients	5212	100.0
Patients with entry in stop-form	2029	38.9
Patient died	597	11.5
Patient wanted to discontinue	493	9.5
Patient did not respond to written invitations	257	4.9
Other	295	5.7
Patient moved to foreign country	167	3.2
In care by non-SCCS center	133	2.6
Patient changed address without notice	87	1.7

2 Overall demographics

2.1 Age and gender distribution

Table 5: Distribution of age at baseline visit by gender.

Sex	n	%	Age			
			Mean	Sd	Median	IQR
Female	1955	37.5	47.0	13.5	45.6	37.6 - 55.9
Male	3257	62.5	45.3	11.4	44.5	37.3 - 52.2
All	5212	100.0	45.9	12.2	45.0	37.4 - 53.3

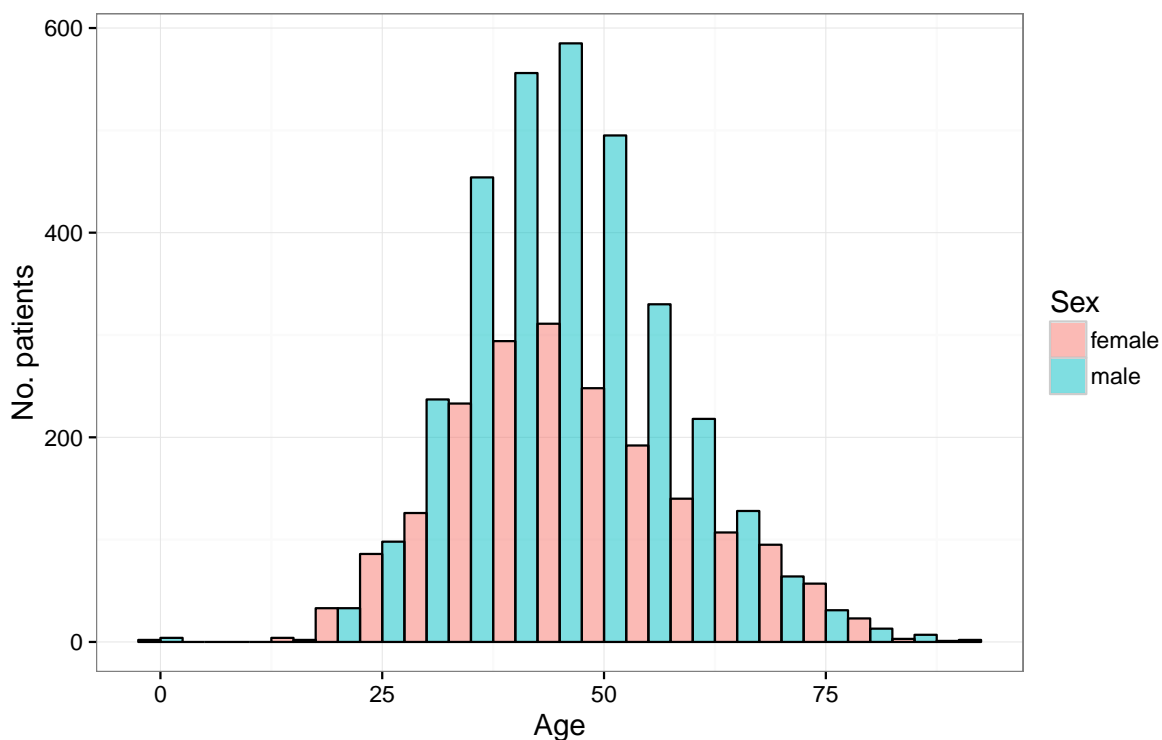


Figure 2: Age distribution at baseline visit by sex.

2.2 Origin

Table 6: Patient origin.

Region	n	%
North-western Europe	3807	73.0
Southern Europe	727	13.9
Eastern Europe and Central Asia	215	4.1
North Africa and Middle East	99	1.9
Sub-Saharan Africa	97	1.9
South- and East Asia	87	1.7
Latin America	68	1.3
USA and Canada	19	0.4
Caribbean	11	0.2
Australia and New Zealand	2	0.0
others	0	0.0
unknown	30	0.6
All	5212	100.0

Table 7: Ethnic origin of the patients.

Ethnicity	n	%
white	4866	93.4
black	107	2.1
Asian	89	1.7
Hispano-American	46	0.9
other	46	0.9
unknown	41	0.8
All	5212	100.0

2.3 Education

Table 8: Highest completed educational degree.

Education	n	%
None	1110	21.3
Apprenticeship (< 3 years)	606	11.6
Fulltime apprenticeship	2252	43.2
Secondary schools, vocational high school	234	4.5
Higher education and professional training	333	6.4
Institute of higher vocational education	278	5.3
University, higher education institution	304	5.8
Other	20	0.4
Unknown	70	1.3
All	5212	100.0

3 Clinical features at baseline

3.1 History of infection

Table 9: Time between first positive documented anti-HCV test and baseline visit.

Time since documented HCV [years]	n	%
0-5	2884	55.3
5-10	1128	21.6
10-15	630	12.1
15-20	211	4.0
>20	157	3.0
Unknown	130	2.5

Table 10: Time between patient knows being HCV positive and baseline visit.

Time since patient knows HCV+ [years]	n	%
0-5	767	14.7
5-10	405	7.8
10-15	394	7.6
15-20	384	7.4
>20	412	7.9
Unknown	2847	54.6

3.2 Alcohol consumption

Table 11: Alcohol consumption at baseline.

		Sex					
		Female		Male		All	
		n	%	n	%	n	%
Ever used to drink > 20g/day	Yes	656	33.6	1777	54.6	2433	46.7
	No	1290	66.0	1453	44.6	2743	52.6
	Unknown	6	0.3	20	0.6	26	0.5
Drinking habits at baseline	Heavy drinker (>40g / day)	46	2.4	190	5.8	236	4.5
	Moderate drinker (20-40g / day)	149	7.6	375	11.5	524	10.1
	Not drinking	1290	66.0	1452	44.6	2742	52.6
	Unknown	470	24.0	1240	38.1	1710	32.8

3.3 Parameters of liver disease progression

Table 12: Parameters of liver disease progression at baseline.

		n	%
Cirrhotic	Yes	851	16.3
	No	4309	82.7
	Unknown	52	1.0
Gastrointestinal haemorrhage	Yes	88	1.7
	No	3203	61.5
	Unknown	1921	36.9
Jaundice	Yes	103	2.0
	No	3180	61.0
	Unknown	1929	37.0
Porto-systemic encephalopathy	Yes	41	0.8
	No	3244	62.2
	Unknown	1927	37.0
Ascites	Yes	123	2.4
	No	3166	60.7
	Unknown	1923	36.9
Primary liver cancer	Yes	56	1.1
	No	3241	62.2
	Unknown	1915	36.7

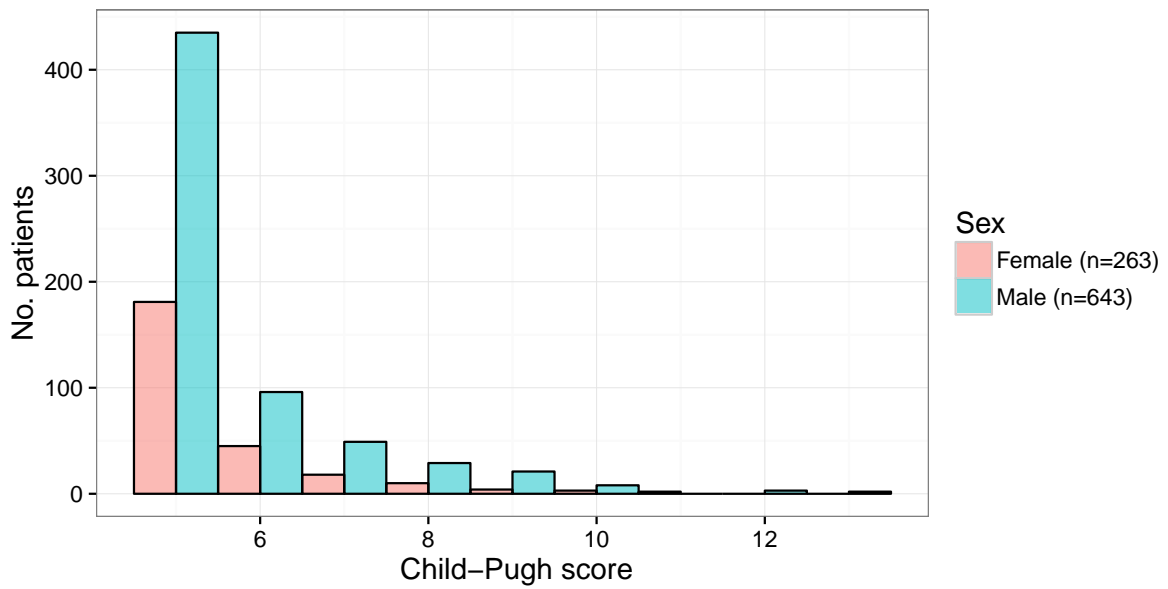


Figure 3: Distribution of Child-Pugh score.

3.4 Risk factors

Table 13: Risk factor at baseline.

		n	%
I.V. drug use	Yes	2869	55.0
	No	2294	44.0
	Unknown	49	0.9
Blood transfusion(s) or derivates	Yes	1164	22.3
	No	3733	71.6
	Unknown	315	6.0
Anti-HCV positive sexual partner	Yes	720	13.8
	No	3066	58.8
	Unknown	1426	27.4
High risk sexual behaviour	Yes	708	13.6
	No	4115	79.0
	Unknown	389	7.5
Accidental needle-prick	Yes	525	10.1
	No	4433	85.1
	Unknown	254	4.9
Invasive medical procedures	Yes	2065	39.6
	No	3056	58.6
	Unknown	91	1.7
Profession in contact with blood	Yes	413	7.9
	No	4725	90.7
	Unknown	74	1.4
Anti-HCV-positive household (not sexual)	Yes	342	6.6
	No	4288	82.3
	Unknown	582	11.2
Intranasal drugs	Yes	1793	34.4
	No	2044	39.2
	Unknown	1375	26.4
Tattoo	Yes	1369	26.3
	No	2441	46.8
	Unknown	1402	26.9
Body piercing	Yes	917	17.6
	No	2858	54.8
	Unknown	1437	27.6

3.5 Other anamnestic information

Table 14: Other anamnestic information at baseline.

		n	%
Pregnancy	Yes	1263	24.2
	No	3908	75.0
	Unknown	41	0.8
Delivery	Yes	1112	21.3
	No	4056	77.8
	Unknown	44	0.8
Treatment for depression (incl. psychotherapy)	Yes	1532	29.4
	No	3645	69.9
	Unknown	35	0.7
Psychiatric treatment (other than depression)	Yes	995	19.1
	No	4179	80.2
	Unknown	38	0.7
Imprisonment	Yes	1198	23.0
	No	3962	76.0
	Unknown	52	1.0
Drug substitution program (e.g. methadone)	Yes	1698	32.6
	No	3489	66.9
	Unknown	25	0.5
Illicit i.v. drugs	Yes	2101	40.3
	No	3079	59.1
	Unknown	32	0.6
Intranasal drugs	Yes	1777	34.1
	No	3383	64.9
	Unknown	52	1.0
Organ transplantation	Yes	105	2.0
	No	5086	97.6
	Unknown	21	0.4
Diabetes	Yes	264	5.1
	No	4917	94.3
	Unknown	31	0.6

3.6 Treatment pre-baseline

Table 15: Number of therapy courses prior inclusion to SCCS.

Number of therapies	n	%
0	3511	67.4
1	1442	27.7
2	220	4.2
3	37	0.7
4	2	0.0
All	5212	100.0

Table 16: Has the patient ever received treatment for his/her hepatitis C before entering the SCCS?

Therapy before baseline	n	%
Yes	2707	51.9
No	2505	48.1
All	5212	100.0

Table 17: Frequency of drug combinations in therapies before baseline (multiple therapies per patient possible). Therapies with n<3 are grouped to the category 'Others'.

Drug / drug combination	n	%
pegINF alpha-2a, Ribavirin	620	34.1
pegINF alpha-2b, Ribavirin	296	16.3
Recombinant alpha-interferon	268	14.7
Recombinant alpha-interferon, Ribavirin	266	14.6
Ledipasvir, Sofosbuvir	56	3.1
Interferon N/S, Ribavirin	32	1.8
Ribavirin, Sofosbuvir	22	1.2
Natural alpha-interferon-n1	20	1.1
Recombinant alpha-interferon, Amantadine	18	1.0
Interferon N/S	18	1.0
Natural alpha-interferon-n1, Ribavirin	17	0.9
pegINF alpha-2a	17	0.9
pegINF alpha-2a, Ribavirin, Telaprevir	17	0.9
Ribavirin, Dasabuvir, Ombitasvir, Paritaprevir	16	0.9
Recombinant alpha-interferon, Amantadine, Ribavirin	14	0.8
Ribavirin	12	0.7
Daclatasvir, Sofosbuvir	10	0.6
Ribavirin, Ledipasvir, Sofosbuvir	10	0.6
pegINF alpha-2a, Ribavirin, Sofosbuvir	10	0.6
Dasabuvir, Ombitasvir, Paritaprevir	9	0.5
pegINF alpha-2b	9	0.5
pegINF alpha-2a, Ribavirin, Boceprevir	6	0.3
Ribavirin, Daclatasvir, Sofosbuvir	5	0.3
pegINF alpha-2b, pegINF alpha-2a, Ribavirin	5	0.3
pegINF alpha-2a, Ribavirin, Faldaprevir	4	0.2
Consensus alpha-interferon	3	0.2
pegINF alpha-2b, Ribavirin, Sofosbuvir	3	0.2
Other	34	1.9
All	1817	100.0

4 Clinical features during follow-up

4.1 Complications and comorbidities

Table 18: Complications/comorbidities at baseline and during follow-up.

	n _{Yes}	%
Cirrhotic ever	1407	27.0
Primary liver cancer ever	226	4.3
Diabetes ever	489	9.4
Transplantation ever	220	4.2

4.2 Liver biopsy, Fibroscan and Metavir

Table 19: Availability of fibrosis information.

	nYes	%
Biopsy information available	2970	57.0
Fibroscan information available	2850	54.7

Table 20: Metavir F at most recent biopsy.

Metavir F	n	%
0	280	5.4
1	866	16.6
2	792	15.2
3	386	7.4
4	530	10.2
Unknown	2358	45.2

Table 21: Activity of chronic hepatitis at most recent biopsy.

Activity of chronic hepatitis	n	%
None	92	1.8
Minimal	933	17.9
Mild	914	17.5
Moderate	402	7.7
Severe	58	1.1
Unknown	2813	54.0

Table 22: Overview on other measures reported at most recent biopsy.

		n	%
Bile duct lesion	Yes	309	5.9
	No	1093	21.0
	Unknown	3810	73.1
Siderosis	Yes	307	5.9
	No	1826	35.0
	Unknown	3079	59.1
Steatosis	Yes	1567	30.1
	No	739	14.2
	Unknown	2906	55.8
Lymphoid follicles	Yes	675	13.0
	No	856	16.4
	Unknown	3681	70.6
Eosinophils	Yes	468	9.0
	No	622	11.9
	Unknown	4122	79.1
Neutrophils	Yes	165	3.2
	No	798	15.3
	Unknown	4249	81.5
Mallory bodies	Yes	129	2.5
	No	1069	20.5
	Unknown	4014	77.0
Granulomata	Yes	83	1.6
	No	872	16.7
	Unknown	4257	81.7

4.3 Laboratory tests and genotype

Table 23: Overview on all most recently reported test results.

		n	%
HCV RNA	Positive	2828	54.3
	Negative	2237	42.9
	No test available	147	2.8
anti-HIV	Positive	315	6.0
	Negative	3549	68.1
	No test available	1348	25.9
anti-HBc	Positive	1876	36.0
	Negative	2501	48.0
	No test available	835	16.0
anti-HBs	Positive	1859	35.7
	Negative	2163	41.5
	No test available	1190	22.8
HBs-Ag	Positive	90	1.7
	Negative	4004	76.8
	No test available	1118	21.5

Table 24: Frequency of HCV genotypes (sub-types for genotype 1, if specified).

Genotype	n	%
1, subtype not specified	910	17.5
1a	763	14.6
1b	724	13.9
2	394	7.6
3	1276	24.5
4	475	9.1
5	7	0.1
6	5	0.1
Not reported	658	12.6
All	5212	100.0

5 Treatment

Table 25: Number of reported therapies per patient, mean follow-up time and fraction of patients with a stop entry.

Number of therapies	n	%	Mean FU time [y]	% _{stop}
0	2505	48.1	4.5	42.0
1	2072	39.8	6.3	39.0
2	484	9.3	8.5	27.3
3	118	2.3	8.8	27.1
4	28	0.5	11.0	14.3
5	4	0.1	12.2	0.0
6	1	0.0	15.6	0.0
All	5212	100.0	5.7	38.9



5.1 Most recent and ongoing treatments

Table 26: Frequency of drug combinations in **most recent therapy** including information on therapy duration. Therapies with n<3 are grouped to the category 'Others'.

Drug / drug combination	n	%	Duration [days]		
			Mean	Sd	Median
pegINF alpha-2a, Ribavirin	1073	39.6	244.1	100.9	204.0
pegINF alpha-2b, Ribavirin	460	17.0	234.1	101.4	182.0
Ledipasvir, Sofosbuvir	273	10.1	98.9	42.1	84.0
Recombinant alpha-interferon, Ribavirin	153	5.6	254.5	125.3	335.0
Ribavirin, Sofosbuvir	99	3.7	143.9	51.1	167.0
Recombinant alpha-interferon	80	3.0	195.1	127.4	182.0
Daclatasvir, Sofosbuvir	62	2.3	115.6	41.1	85.0
pegINF alpha-2a, Ribavirin, Telaprevir	59	2.2	257.1	100.7	334.0
Dasabuvir, Ombitasvir, Paritaprevir	46	1.7	86.0	13.1	84.0
Ribavirin, Ledipasvir, Sofosbuvir	46	1.7	112.9	66.2	84.0
Ribavirin, Daclatasvir, Sofosbuvir	40	1.5	155.1	30.0	168.0
Ribavirin, Dasabuvir, Ombitasvir, Paritaprevir	40	1.5	101.2	38.8	84.0
pegINF alpha-2a, Ribavirin, Sofosbuvir	38	1.4	93.6	32.5	84.0
Interferon N/S, Ribavirin	24	0.9	211.0	107.7	175.0
pegINF alpha-2a	13	0.5	181.2	128.9	168.0
Trials for new HCV treatment	13	0.5	126.5	107.0	84.0
Ribavirin, Simeprevir, Sofosbuvir	12	0.4	98.1	32.0	84.0
Natural alpha-interferon-n1, Ribavirin	11	0.4	208.5	84.8	184.0
pegINF alpha-2b	11	0.4	214.8	122.2	183.0
pegINF alpha-2b, Ribavirin, Sofosbuvir	11	0.4	83.8	0.4	84.0
Ribavirin	10	0.4	189.5	97.0	172.0
pegINF alpha-2a, Ribavirin, Trials for new HCV treatment	9	0.3	308.4	79.7	335.0
Recombinant alpha-interferon, Amantadine, Ribavirin	8	0.3	311.9	89.5	346.0
Ribavirin, Dasabuvir, Ombitasvir	7	0.3	95.9	31.8	84.0
pegINF alpha-2b, Ribavirin, Telaprevir	7	0.3	226.4	79.1	175.0
pegINF alpha-2a, Ribavirin, Boceprevir	6	0.2	314.0	62.2	336.0
Ribavirin, Faldaprevir, BI207127	6	0.2	171.5	92.8	152.5
pegINF alpha-2b, pegINF alpha-2a, Ribavirin	6	0.2	268.2	141.3	197.5
Recombinant alpha-interferon, Amantadine	5	0.2	275.8	114.6	322.0
pegINF alpha-2b, Ribavirin, Boceprevir	5	0.2	342.6	38.0	336.0
Interferon N/S	5	0.2	127.2	134.1	62.0
Interferon N/S, Ribavirin, Telaprevir	5	0.2	290.2	67.6	334.0
Natural alpha-interferon-n1	5	0.2	221.6	132.7	153.0
Ribavirin, Ombitasvir, Paritaprevir	5	0.2	102.4	36.8	84.0
Ribavirin, Protease inhibitor N/S, Polymerase inhibitor N/S	5	0.2	162.4	64.3	194.0
Simeprevir, Sofosbuvir	5	0.2	168.8	61.2	168.0
Sofosbuvir	5	0.2	110.4	41.7	90.0
Faldaprevir, BI207127	3	0.1	196.3	3.8	198.0
pegINF alpha-2a, Ribavirin, Faldaprevir	3	0.1	242.7	157.5	326.0
Interferon N/S, Ribavirin, Sofosbuvir	3	0.1	89.3	4.6	92.0
Ribavirin, Trials for new HCV treatment	3	0.1	84.0	0.0	84.0
Other	30	1.1	229.6	144.7	172.5
All	2710	100.0	206.0	110.3	168.0

Table 27: Frequency of drug combinations in **ongoing therapies**, i.e. therapies with start date within last 72 weeks before the most recent visit and no stop date.

Drug / drug combination	n	%
Ledipasvir, Sofosbuvir	38	30.4
Daclatasvir, Sofosbuvir	23	18.4
Ribavirin, Sofosbuvir	13	10.4
Ribavirin, Daclatasvir, Sofosbuvir	11	8.8
Ribavirin, Ledipasvir, Sofosbuvir	8	6.4
Dasabuvir, Ombitasvir, Paritaprevir	7	5.6
Ribavirin, Dasabuvir, Ombitasvir, Paritaprevir	6	4.8
Sofosbuvir	5	4.0
Dasabuvir, Ombitasvir	4	3.2
Ribavirin, Ombitasvir, Paritaprevir	4	3.2
Ribavirin	2	1.6
Dasabuvir	1	0.8
Dasabuvir, Paritaprevir	1	0.8
Ombitasvir, Paritaprevir	1	0.8
Trials for new HCV treatment	1	0.8
All	125	100.0