

Universität  
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Basel



## Interim Annual Report



FONDS NATIONAL SUISSE  
SCHWEIZERISCHER NATIONALFONDS  
FONDO NAZIONALE SVIZZERO  
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FONDATION ETUDE SUISSE DE COHORTE HEPATITE C

abbvie



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On behalf of the  
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Data as of January 26, 2021

# Contents

- 1 Patient recruitment, follow-up and drop-outs 3**
  - 1.1 Recruitment . . . . . 3
  - 1.2 Visits and follow-up . . . . . 4
  - 1.3 Drop-outs and death . . . . . 6
  
- 2 Overall demographics 7**
  - 2.1 Age and gender distribution . . . . . 7
  - 2.2 Origin . . . . . 8
  - 2.3 Education . . . . . 9
  
- 3 Clinical features at baseline 10**
  - 3.1 History of infection . . . . . 10
  - 3.2 Alcohol consumption . . . . . 11
  - 3.3 Parameters of liver disease progression . . . . . 12
  - 3.4 Risk factors . . . . . 13
  - 3.5 Other anamnestic information . . . . . 14
  - 3.6 Treatment prior to inclusion . . . . . 15
  
- 4 Clinical features during follow-up 17**
  - 4.1 Complications and comorbidities . . . . . 17
  - 4.2 Liver biopsy, Fibroscan and Metavir . . . . . 18
  - 4.3 Laboratory tests and genotype . . . . . 20
  
- 5 Biobanking 22**
  
- 6 Treatment 23**
  - 6.1 Most recent and ongoing treatments . . . . . 24
  - 6.2 Treatments with DAAs . . . . . 26

# 1 Patient recruitment, follow-up and drop-outs

## 1.1 Recruitment

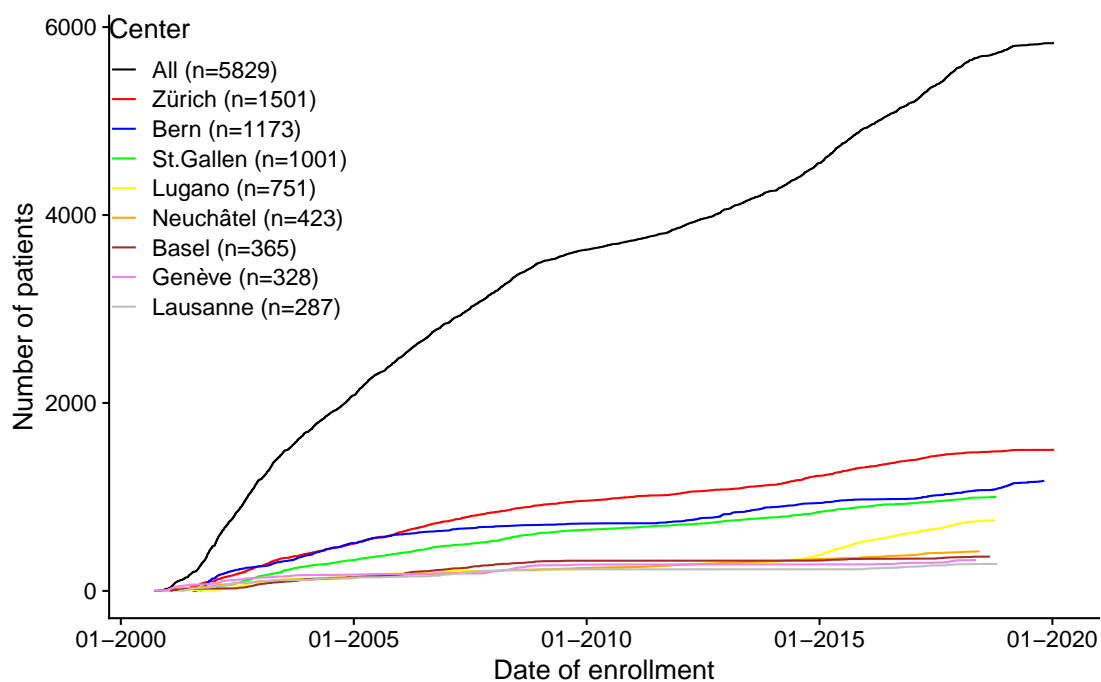


Figure 1: Patient recruitment for SCCS (first patient in: 2000-09-18).

Table 1: Patient recruitment by center and sex.

Center	First patient in	Sex		All	%
		Female	Male		
Zürich	2000-12-05	549	952	1501	25.8
Bern	2001-07-17	439	734	1173	20.1
St.Gallen	2001-09-04	325	675	1001	17.2
Lugano	2001-02-23	351	400	751	12.9
Neuchâtel	2000-11-06	159	264	423	7.3
Basel	2001-01-22	145	220	365	6.3
Genève	2000-09-18	130	198	328	5.6
Lausanne	2001-03-28	118	169	287	4.9
All	2000-09-18	2216	3612	5829	100.0

## 1.2 Visits and follow-up

Table 2: Number of visits by visit type and center.

Center	Visit type				All	%
	Baseline		Follow-up			
	n	%	n	%		
Zürich	1501	17.2	7237	82.8	8738	25.4
St.Gallen	1001	13.9	6207	86.1	7208	20.9
Bern	1173	20.4	4589	79.6	5762	16.7
Lugano	751	24.2	2356	75.8	3107	9.0
Neuchâtel	423	15.9	2232	84.1	2655	7.7
Lausanne	287	11.2	2270	88.8	2557	7.4
Basel	365	15.0	2069	85.0	2434	7.1
Genève	328	16.5	1662	83.5	1990	5.8
All	5829	16.9	28622	83.1	34451	100.0

Table 3: Follow-up time in years from baseline to most recent visit by center.

Center	n	Follow-up time [years]	
		Median	IQR
Zürich	1501	5.04	[ 1.92, 11.40]
Bern	1173	4.68	[ 1.02, 12.00]
St.Gallen	1001	5.70	[ 1.94, 11.76]
Lugano	751	3.06	[ 0.93, 6.94]
Neuchâtel	423	5.54	[ 2.37, 12.62]
Basel	365	7.26	[ 1.96, 12.91]
Genève	328	8.85	[ 2.82, 14.51]
Lausanne	287	8.22	[ 2.69, 15.16]
All	5829	5.01	[ 1.70, 11.93]

Total patient years: 39529.1

Table 4: Number of visits per patient, by center.

Center	n	Number of visits per patient										
		1	2	3	4	5	6	7	8	9	10	>=11
Zürich	1502	175	195	157	174	153	141	107	60	60	60	220
St.Gallen	1001	124	103	93	94	77	64	53	55	30	39	269
Bern	1173	233	173	127	119	122	80	61	47	41	46	124
Lugano	753	155	158	120	75	61	47	26	29	17	19	46
Neuchâtel	423	31	52	65	46	43	25	39	22	17	12	71
Lausanne	287	15	24	40	35	14	7	11	3	8	10	120
Basel	365	45	44	33	32	28	28	18	6	26	19	86
Genève	328	23	58	36	34	26	22	26	20	19	12	52
All	5832	801	807	671	609	524	414	341	242	218	217	988

### 1.3 Drop-outs and death

Table 5: Overview on drop-outs and patients lost to follow-up.

	<b>n</b>	<b>%</b>
All patients	5829	100.0
Patients with entry in stop-form	2325	39.9
Patient died	766	13.1
Patient wanted to discontinue	578	9.9
Patient did not respond to written invitations	285	4.9
Patient moved to foreign country	222	3.8
Other	244	4.2
In care by non-SCCS center	129	2.2
Patient changed address without notice	101	1.7

## 2 Overall demographics

### 2.1 Age and gender distribution

Table 6: Distribution of age at baseline visit by gender.

Sex	n	%	Age			
			Mean	Sd	Median	IQR
Female	2216	38	47.8	13.7	46.4	[38.2, 56.8]
Male	3612	62	46.0	11.7	45.4	[37.8, 53.2]
All	5829	100	46.7	12.5	45.8	[37.9, 54.4]

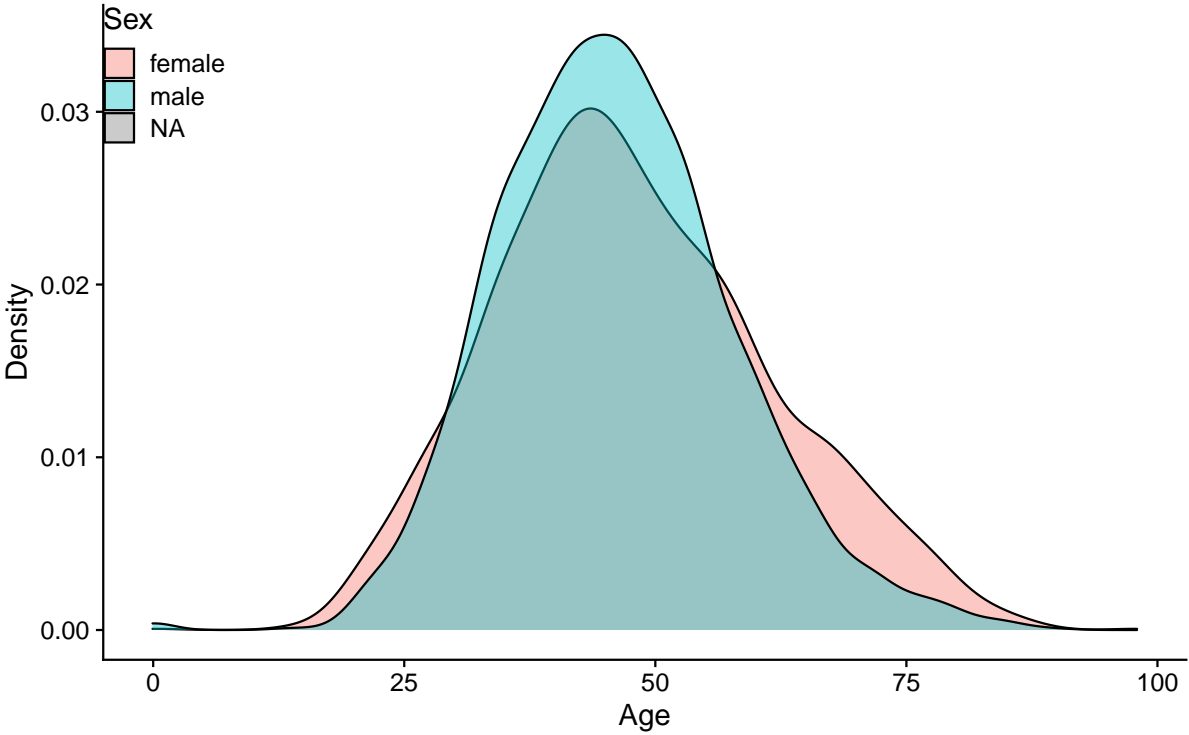


Figure 2: Age distribution at baseline visit by sex.

## 2.2 Origin

Table 7: Patient origin.

<b>Region</b>	<b>n</b>	<b>%</b>
North-western Europe	4239	72.7
Southern Europe	825	14.2
Eastern Europe and Central Asia	252	4.3
Sub-Saharan Africa	113	1.9
South- and East Asia	103	1.8
North Africa and Middle East	101	1.7
Latin America	74	1.3
USA and Canada	21	0.4
Caribbean	12	0.2
Australia and New Zealand	3	0.1
others	2	0.0
unknown	32	0.5
All	5829	100.0

Table 8: Ethnic origin of the patients.

<b>Ethnicity</b>	<b>n</b>	<b>%</b>
white	5438	93.3
black	125	2.1
Asian	108	1.9
Hispano-American	50	0.9
other	44	0.8
unknown	42	0.7
All	5829	100.0



## 2.3 Education

Table 9: Highest completed educational degree.

<b>Education</b>	<b>n</b>	<b>%</b>
None	1245	21.4
Apprenticeship (< 3 years)	682	11.7
Fulltime apprenticeship	2490	42.7
Secondary schools, vocational high school	259	4.4
Higher education and professional training	390	6.7
Institute of higher vocational education	301	5.2
University, higher education institution	351	6.0
Other	24	0.4
Unknown	83	1.4
All	5829	100.0

### 3 Clinical features at baseline

#### 3.1 History of infection

Table 10: Time between first positive documented anti-HCV test and baseline visit.

<b>Time since documented HCV [years]</b>	<b>n</b>	<b>%</b>
0-5	3126	53.6
5-10	1200	20.6
10-15	706	12.1
15-20	288	4.9
>20	289	5.0
Unknown	144	2.5

Table 11: Time between patient knows being HCV positive and baseline visit.

<b>Time since patient knows HCV+ [years]</b>	<b>n</b>	<b>%</b>
0-5	947	16.2
5-10	469	8.0
10-15	460	7.9
15-20	469	8.0
>20	608	10.4
Unknown	2872	49.3

## 3.2 Alcohol consumption

Table 12: Alcohol consumption at baseline.

		Sex					
		Female		Male		All	
		n	%	n	%	n	%
Ever used to drink > 20g/day	Yes	755	34.1	1980	54.8	2736	46.9
	No	1445	65.2	1597	44.2	3042	52.2
	Unknown	12	0.5	28	0.8	40	0.7
Drinking habits at baseline	Heavy drinker (>40g / day)	135	6.1	543	15.0	678	11.6
	Moderate drinker (20-40g / day)	289	13.0	678	18.8	967	16.6
	Not drinking	1445	65.2	1596	44.2	3041	52.2
	Unknown	347	15.7	795	22.0	1143	19.6

### 3.3 Parameters of liver disease progression

Table 13: Parameters of liver disease progression at baseline.

		n	%
Cirrhotic	Yes	938	16.1
	No	4836	83.0
	Unknown	55	0.9
Gastrointestinal haemorrhage	Yes	90	1.5
	No	3350	57.5
	Unknown	2389	41.0
Jaundice	Yes	109	1.9
	No	3322	57.0
	Unknown	2398	41.1
Porto-systemic encephalopathy	Yes	42	0.7
	No	3390	58.2
	Unknown	2397	41.1
Ascites	Yes	131	2.2
	No	3305	56.7
	Unknown	2393	41.1
Primary liver cancer	Yes	65	1.1
	No	3380	58.0
	Unknown	2384	40.9

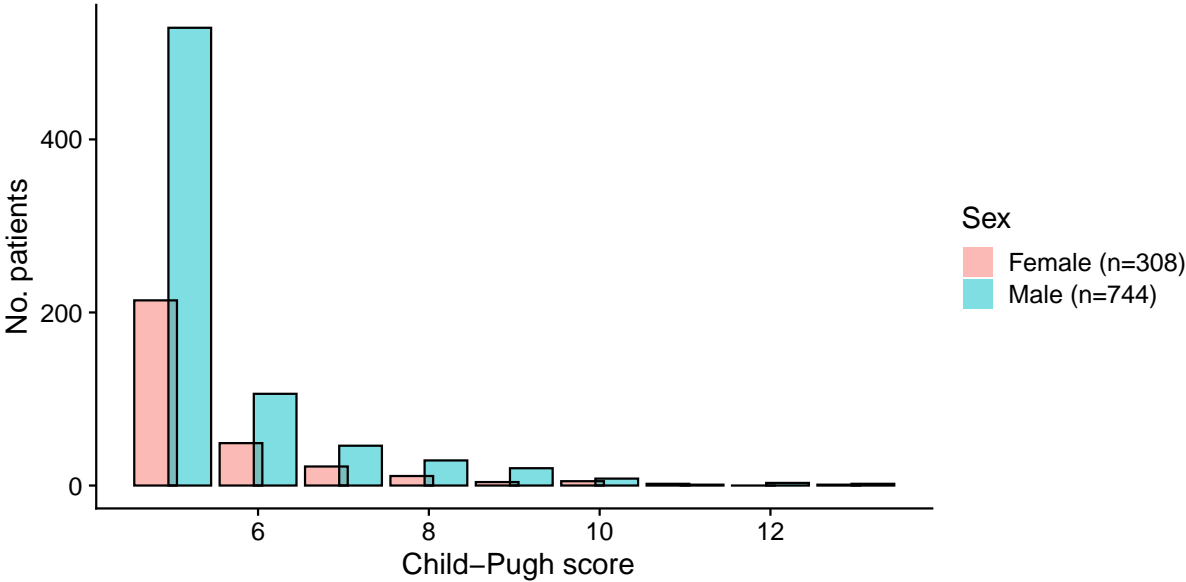


Figure 3: Distribution of Child-Pugh score.

### 3.4 Risk factors

Table 14: Risk factor at baseline.

		n	%
I.V. drug use	Yes	3195	54.8
	No	2581	44.3
	Unknown	53	0.9
Blood transfusion(s) or derivates	Yes	1321	22.7
	No	4159	71.4
	Unknown	349	6.0
Anti-HCV positive sexual partner	Yes	828	14.2
	No	3441	59.0
	Unknown	1560	26.8
High risk sexual behaviour	Yes	780	13.4
	No	4587	78.7
	Unknown	462	7.9
Accidental needle-prick	Yes	594	10.2
	No	4937	84.7
	Unknown	298	5.1
Invasive medical procedures	Yes	2350	40.3
	No	3367	57.8
	Unknown	112	1.9
Profession in contact with blood	Yes	465	8.0
	No	5280	90.6
	Unknown	84	1.4
Anti-HCV-positive household (not sexual)	Yes	397	6.8
	No	4790	82.2
	Unknown	642	11.0
Intranasal drugs	Yes	2081	35.7
	No	2394	41.1
	Unknown	1354	23.2
Tattoo	Yes	1631	28.0
	No	2807	48.2
	Unknown	1391	23.9
Body piercing	Yes	1091	18.7
	No	3303	56.7
	Unknown	1435	24.6

### 3.5 Other anamnestic information

Table 15: Other anamnestic information at baseline.

		n	%
Pregnancy	Yes	1427	24.5
	No	4355	74.7
	Unknown	47	0.8
Delivery	Yes	1264	21.7
	No	4515	77.5
	Unknown	50	0.9
Treatment for depression (incl. psychotherapy)	Yes	1709	29.3
	No	4070	69.8
	Unknown	50	0.9
Psychiatric treatment (other than depression)	Yes	1120	19.2
	No	4656	79.9
	Unknown	53	0.9
Imprisonment	Yes	1350	23.2
	No	4412	75.7
	Unknown	67	1.1
Drug substitution program (e.g. methadone)	Yes	1887	32.4
	No	3908	67.0
	Unknown	34	0.6
Illicit i.v. drugs	Yes	2188	37.5
	No	3600	61.8
	Unknown	41	0.7
Intranasal drugs	Yes	1892	32.5
	No	3875	66.5
	Unknown	62	1.1
Organ transplantation	Yes	114	2.0
	No	5686	97.5
	Unknown	29	0.5
Diabetes	Yes	297	5.1
	No	5491	94.2
	Unknown	41	0.7

### 3.6 Treatment prior to inclusion

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

<b>Therapy before baseline</b>	<b>n</b>	<b>%</b>
Yes	3696	63.4
No	2133	36.6
All	5829	100.0

Table 17: Frequency of drug combinations in therapies before baseline (multiple therapies per patient possible). Therapies with n<10 are grouped to the category 'Others'.

<b>Drug / drug combination</b>	<b>n</b>	<b>%</b>
pegINF alpha-2a, Ribavirin	648	30.1
pegINF alpha-2b, Ribavirin	308	14.3
Recombinant alpha-interferon	270	12.6
Recombinant alpha-interferon, Ribavirin	266	12.4
Ledipasvir, Sofosbuvir	103	4.8
Grazoprevir/Elbasvir	72	3.3
Interferon N/S, Ribavirin	45	2.1
Sofosbuvir/Velpatasvir	43	2.0
Ribavirin, Sofosbuvir	40	1.9
Daclatasvir, Sofosbuvir	27	1.3
pegINF alpha-2a	22	1.0
Interferon N/S	21	1.0
Natural alpha-interferon-n1	20	0.9
pegINF alpha-2a, Ribavirin, Telaprevir	20	0.9
Ribavirin, Dasabuvir, Ombitasvir, Paritaprevir	18	0.8
Glecaprevir/Pibrentasvir	18	0.8
Recombinant alpha-interferon, Amantadine	17	0.8
Ribavirin, Ledipasvir, Sofosbuvir	17	0.8
Natural alpha-interferon-n1, Ribavirin	17	0.8
Dasabuvir, Ombitasvir, Paritaprevir	16	0.7
Recombinant alpha-interferon, Amantadine, Ribavirin	15	0.7
Ribavirin, Daclatasvir, Sofosbuvir	13	0.6
pegINF alpha-2a, Ribavirin, Sofosbuvir	12	0.6
Ribavirin	11	0.5
pegINF alpha-2b	10	0.5
Other	81	3.8
All	2150	100.0



## 4 Clinical features during follow-up

### 4.1 Complications and comorbidities

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

	<b>nYes</b>	<b>%</b>
Cirrhotic ever	1495	25.6
Primary liver cancer ever	282	4.8
Diabetes ever	577	9.9
Transplantation ever	250	4.3

## 4.2 Liver biopsy, Fibroscan and Metavir

Table 19: Availability of fibrosis information.

	nYes	%
Biopsy information available	3080	52.8
Fibroscan information available	3573	61.3

Table 20: Metavir F at most recent biopsy.

Metavir F	n	%
0	292	5.0
1	890	15.3
2	805	13.8
3	397	6.8
4	549	9.4
Unknown	2896	49.7

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

Activity of chronic hepatitis	n	%
None	106	1.8
Minimal	981	16.8
Mild	947	16.2
Moderate	415	7.1
Severe	65	1.1
Unknown	3315	56.9

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

		<b>n</b>	<b>%</b>
Bile duct lesion	Yes	326	5.6
	No	1148	19.7
	Unknown	4355	74.7
Siderosis	Yes	318	5.5
	No	1902	32.6
	Unknown	3609	61.9
Steatosis	Yes	1641	28.2
	No	768	13.2
	Unknown	3420	58.7
Lymphoid follicles	Yes	705	12.1
	No	897	15.4
	Unknown	4227	72.5
Eosinophils	Yes	479	8.2
	No	665	11.4
	Unknown	4685	80.4
Neutrophils	Yes	171	2.9
	No	844	14.5
	Unknown	4814	82.6
Mallory bodies	Yes	138	2.4
	No	1127	19.3
	Unknown	4564	78.3
Granulomata	Yes	84	1.4
	No	929	15.9
	Unknown	4816	82.6

### 4.3 Laboratory tests and genotype

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

		n	%
HCV RNA	Positive	2137	36.7
	Negative	3500	60.0
	No test available	192	3.3
anti-HIV	Positive	319	5.5
	Negative	3809	65.3
	No test available	1701	29.2
anti-HBc	Positive	1987	34.1
	Negative	2697	46.3
	No test available	1145	19.6
anti-HBs	Positive	2042	35.0
	Negative	2322	39.8
	No test available	1465	25.1
HBs-Ag	Positive	93	1.6
	Negative	4350	74.6
	No test available	1386	23.8

Table 24: Frequency of HCV genotypes.

<b>Genotype</b>	<b>n</b>	<b>%</b>
1, subtype not specified	887	15.2
1A	887	15.2
1B	801	13.7
2, subtype not specified	321	5.5
2A	53	0.9
2B	25	0.4
2C	22	0.4
3, subtype not specified	652	11.2
3A	724	12.4
3B	1	0.0
3H	1	0.0
4, subtype not specified	396	6.8
4A	46	0.8
4B	2	0.0
4C	21	0.4
4D	27	0.5
4E	6	0.1
4F	9	0.2
4H	13	0.2
4N	1	0.0
4R	1	0.0
5, subtype not specified	2	0.0
5A	6	0.1
6, subtype not specified	5	0.1
6A	1	0.0
6N	1	0.0
Unknown	918	15.7
All	5829	100.0

## 5 Biobanking

Table 25: Number of biobanking events and biobanked aliquots by center.

Center	Sample type					
	Plasma		DNA cell pellet		Viable cells	
	n <sub>samples</sub>	Σ aliquots	n <sub>samples</sub>	Σ aliquots	n <sub>samples</sub>	Σ aliquots
Basel	1672	5032	5	5	1472	4014
Bern	3763	16983	1252	1264	756	2083
Genève	1484	4467	6	18	1033	3091
Lausanne	2037	9803	26	27	777	2178
Lugano	4268	14416	1229	3618	630	1878
Neuchâtel	1603	7451	265	715	653	1788
St.Gallen	5270	16347	1384	2948	1780	5251
Zürich	8469	25331	4823	4851	31	68
All	28566	99830	8990	13446	7132	20351

Table 26: Number of biobanking events (unique time points) per patient.

Nr. sampling days	n	%
0	336	5.8
1	980	16.8
2	766	13.1
3	643	11.0
4	545	9.3
5	471	8.1
6	377	6.5
7	334	5.7
8	310	5.3
9	227	3.9
>=10	840	14.4
All	5829	100.0

## 6 Treatment

Table 27: Number of reported therapies per patient, mean follow-up time and fraction of patients with a stop entry.

<b>Number of therapies</b>	<b>n</b>	<b>%</b>	<b>Mean FU time [y]</b>	<b>%<sub>stop</sub></b>
0	2133	36.6	4.8	52.2
1	2826	48.5	7.1	34.1
2	667	11.4	10.2	29.1
3	155	2.7	11.0	29.0
4	39	0.7	12.7	23.1
5	8	0.1	13.2	12.5
6	1	0.0	18.9	0.0
All	5829	100.0	6.8	39.9

## 6.1 Most recent and ongoing treatments

Table 28: Frequency of drug combinations in **most recent therapy** including information on therapy duration.

Group	Drug / drug combination	n	%	Duration [weeks]		
				Median	IQR	
INF +/- RBV	pegINF alpha-2a, Ribavirin	988	26.7	28	[24, 48]	
	pegINF alpha-2b, Ribavirin	425	11.5	26	[24, 48]	
	Recomb. alpha-interferon, Ribavirin	135	3.6	49	[22, 52]	
	Recomb. alpha-interferon	72	1.9	26	[13, 49]	
	Interferon N/S, Ribavirin	41	1.1	26	[22, 48]	
	pegINF alpha-2a	15	0.4	24	[14, 38]	
	pegINF alpha-2b	10	0.3	29	[20, 48]	
	Natural alpha-interferon-n1, Ribavirin	9	0.2	26	[22, 30]	
	Recomb. alpha-interferon, Amantadine, Ribavirin	7	0.2	51	[42, 52]	
	Other	22	0.6	36	[16, 52]	
	All	1724	46.6	27	[24, 48]	
DAA + INF +/- RBV	pegINF alpha-2a, Ribavirin, Telaprevir	67	1.8	48	[24, 48]	
	pegINF alpha-2a, Ribavirin, Sofosbuvir	40	1.1	12	[12, 12]	
	pegINF alpha-2b, Ribavirin, Sofosbuvir	13	0.4	12	[12, 12]	
	pegINF alpha-2a, Ribavirin, Boceprevir	11	0.3	43	[32, 48]	
	pegINF alpha-2b, Ribavirin, Telaprevir	10	0.3	40	[24, 48]	
	Interferon N/S, Ribavirin, Sofosbuvir	5	0.1	13	[12, 13]	
	Interferon N/S, Ribavirin, Telaprevir	5	0.1	48	[38, 48]	
	Other	18	0.5	45	[24, 48]	
	All	169	4.6	24	[12, 48]	
	DAA w/o INF	Ledipasvir, Sofosbuvir	522	14.1	12	[12, 12]
Sofosbuvir/Velpatasvir		242	6.5	12	[12, 12]	
Grazoprevir/Elbasvir		234	6.3	12	[12, 12]	
Ribavirin, Sofosbuvir		120	3.2	22	[12, 24]	
Daclatasvir, Sofosbuvir		118	3.2	12	[12, 24]	
Glecaprevir/Pibrentasvir		107	2.9	8	[ 8, 9]	
Dasabuvir, Ombitasvir, Paritaprevir		87	2.4	12	[12, 12]	
Ribavirin, Ledipasvir, Sofosbuvir		71	1.9	12	[12, 14]	
Ribavirin, Dasabuvir, Ombitasvir, Paritaprevir		61	1.6	12	[12, 12]	
Ribavirin, Daclatasvir, Sofosbuvir		59	1.6	24	[24, 24]	
Ribavirin, Sofosbuvir/Velpatasvir		27	0.7	12	[12, 12]	
Ribavirin, Simeprevir, Sofosbuvir		16	0.4	12	[12, 12]	
Sofosbuvir/Velpatasvir/Voxilaprevir		16	0.4	12	[12, 12]	
Sofosbuvir		12	0.3	12	[12, 14]	
Ribavirin, Dasabuvir, Ombitasvir		10	0.3	12	[12, 12]	
Ribavirin, Ombitasvir, Paritaprevir		10	0.3	12	[12, 13]	
Ribavirin, Grazoprevir/Elbasvir		8	0.2	16	[16, 16]	
Simeprevir, Sofosbuvir		7	0.2	24	[12, 24]	
Ribavirin, Faldaprevir, BI207127		5	0.1	24	[20, 40]	
Other		36	1.0	21	[12, 25]	
All		1768	47.8	12	[12, 13]	
Total			3700	100.0	22	[12, 29]

INF +/- RBV: treated with IFN alone, IFN + ribavirin, peg-IFN + ribavirin; DAA + INF +/- RBV: additionally with DAA; DAA w/o INF: DAA without INF.



Table 29: Frequency of drug combinations in **ongoing therapies**, i.e. therapies with start date within last 72 weeks and no reported stop date.

<b>Drug / drug combination</b>	<b>n</b>	<b>%</b>
Glecaprevir/Pibrentasvir	3	60.0
Sofosbuvir/Velpatasvir	2	40.0
All	5	100.0

## 6.2 Treatments with DAAs

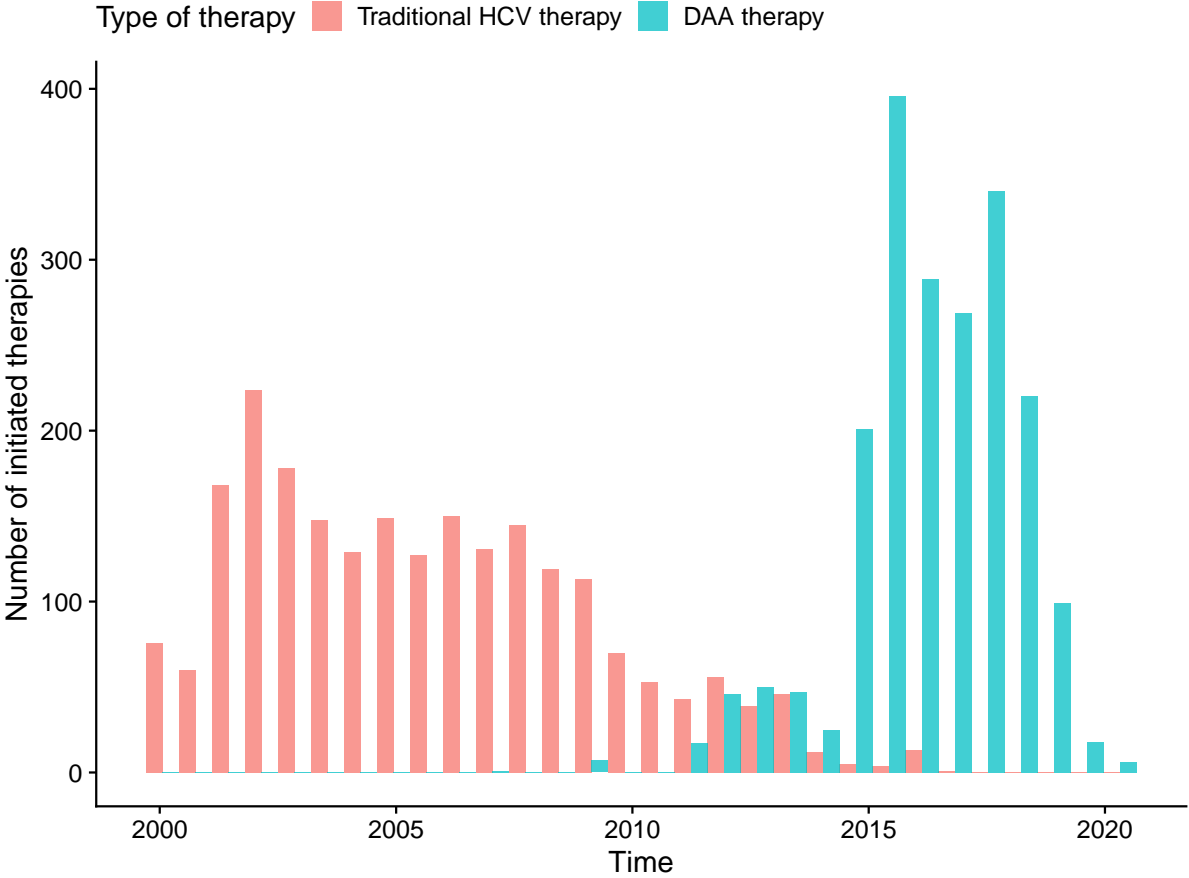


Figure 4: Number of initiated therapies per year since 2000 - by therapy type.

Table 30: Information on cirrhosis and genotype of patients with DAA therapy (at most recent DAA treatment).

		n	%
Cirrhotic ever	Yes	622	32.1
	No	1313	67.7
	Unknown	4	0.2
Genotype	1	1009	52.0
	2	76	3.9
	3	298	15.4
	4	184	9.5
	5	2	0.1
	6	2	0.1
	Unknown	364	18.8
	All	1939	100.0

Table 31: Availability of viral load information 1-12 months after most recent DAA therapy stop and HCV test result. HCV level for therapies stopped recently may have not been reported yet.

Viral load measured	All	HCV RNA test				Therapy start >= 2020-01-01	
		positive		negative		n	%
		n	%	n	%		
No	511	0	0.0	0	0.0	4	0.8
Yes	1428	67	4.7	1361	95.3	2	0.1