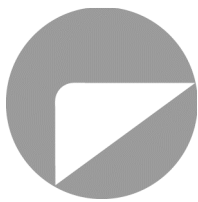
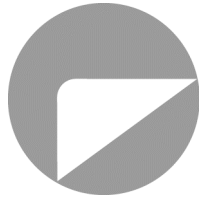
**SYNOPSIS**

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<b>Project Title:</b>	Swiss registry on primary biliary cholangitis
<b>Project Plan Version and Date:</b>	Version 1.2, 5.8.2016
<b>Trial registration:</b>	
<b>Risk categorisation:</b>	Risk category A
<b>Type of Research:</b>	Research project in which biological material is sampled and health-related medical data is collected. In addition, already existing health-related medical data are used for further research. Coded data are used.
<b>Project design:</b>	This is a retrospective and prospective registry with biobank.
<b>Background and Rationale:</b>	Primary biliary cholangitis (PBC) is a rare autoimmune cholestatic liver disease. No data about the disease exist from Switzerland. The only approved treatment is ursodeoxycholic acid, but response is inadequate or absent in about 30% of patients, with non-responders facing a 5-fold higher risk of death or need for liver transplantation than responders. In addition, little data are available on the long-term course of subjects with isolated anti-mitochondrial antibodies and/or isolated PBC-specific anti-nuclear antibodies.
<b>Objectives:</b>	To collect high quality prospective data on a rare disease in order to elucidate epidemiology, natural history, response to treatment and outcome. In addition, the biobank allows addressing specific scientific issues on a variety of open questions. The registry will provide a platform for carrying out scientific research projects on PBC. In addition, the registry will allow collaboration with reference networks on PBC abroad.
<b>Inclusion Exclusion criteria:</b>	Primary biliary cholangitis patients, diagnosed according to recognized criteria (1), are included. Subjects with isolated anti-mitochondrial antibodies and/or isolated PBC-specific anti-nuclear antibodies are also included. Patients/subjects aged at least 18 years and living in Switzerland are included.



## FONDAZIONE EPATOCENTRO TICINO

<b>Measurements and procedures:</b>	Enrolment visit and one follow-up visit at least once a year are planned. Whole blood is collected for biobanking once a year. Optionally, if available and collected during normal clinical procedures, liver fragments are obtained.
<b>Number of Participants:</b>	Number of subjects projected for the entire study (all sites combined): 500 (corresponding to 1/3 of the estimated global PBC population residing in Switzerland, assuming a disease prevalence of 20:100'000)
<b>Project Duration, schedule:</b>	The project will start by 1.1.2017. Estimated duration for the main investigational plan: at least 5 years.
<b>Project Centres:</b>	Multi-centre project, including 5 centres throughout Switzerland.
<b>Risk-Benefit statement:</b>	This project has no risk for participants, biosamples will only be collected concurrently with planned blood collection/liver biopsy for clinical purposes.



**SCHEDULE OF ASSESSMENTS**

Project Periods	enrollment						
Visit	1	2	3	4	5	...	...
Time (month)	0	12	24	36	48	...	...
Participant Information and Informed Consent	x						
Demographics	x						
Medical History	x	x	x	x	x		
Inclusion Criteria	x						
Physical examination	x	x	x	x	x		
Vital signs	x	x	x	x	x		
Treatment history	x	x	x	x	x		
Biochemistry	x	x	x	x	x		
Liver autoantibodies	x						
Sampling of biological material	x	X	x	x	x		