



Swiss Research Network of
Clinical Pediatric Hubs



Annual Report 8 2020

SwissPedNet

c/o Swiss Clinical Trial Organisation

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Editorial

Dear reader,

The eighth year of SwissPedNet, our network of clinical pediatric hubs and two service platforms for registries and clinical pharmacology, was of course marked by the pandemic and the resulting cancellation of many meetings and events. But SwissPedNet can also be virtual, we learn and improve.

With the last's year newly formulated vision "All children and families benefit from high-quality research regardless of their age, pathology and place of residence" we followed up on our mission to achieve it.

The year was very busy dealing with SARS-CoV-2 and most of our physicians, study coordinators and nurses had to submit to the regime in the institutions. Nevertheless, we were able to continue with our studies in our clinical pediatric hubs.

Please see for yourself in this report what we achieved in this very special year 2020.

Enjoy the reading!



Prof. Klara Posfay Barbe
President SwissPedNet

SwissPedNet Activities in 2020

Increasing quality of pediatric healthcare in Switzerland by research and Improving children's health through research

These are long-term goals. What we can say with certainty is that our pediatric hubs are actively doing research. A summary of ongoing clinical and epidemiological studies can be found on our website (<https://www.swisspednet.ch/de/studies/>) In total, our eleven member institutions are involved in over 300 studies or research projects¹.

Connecting within Switzerland and abroad to facilitate conduct of pediatric clinical studies

SwissPedNet has launched several "**field trips**" to increase good cooperation within the individual locations and members, to get SwissPedNet contributors to get to know each other personally.

For the third time this meeting took place in January 2020 at the Children's Hospital in Zurich. Interesting presentations and lively discussions made the third field trip an appreciated experience.

SwissPedNet is in the consortium of **c4c (conect4children)**, the large collaborative European network that aims to facilitate the development of new drugs and other therapies for the entire pediatric population. c4c is a pioneering opportunity to build capacity for the implementation of multinational pediatric clinical trials whilst ensuring the needs of babies, children, young people and their families are met.

Due to our participation in this network, two interesting investigator-initiated trials came to Switzerland:

TREOCAPA - prophylactic treatment of the ductus arteriosus in preterm infants by paracetamol. This study will assess the effectiveness of paracetamol on the closure of the ductus arteriosus and the increase in surviving without severe morbidity in extremely premature infants. The study aims to recruit around 800 babies in 17 European countries.

Switzerland contributes to this multinational clinical trial through combined forces: The recruitment is being done by the SwissPedNet hubs Zurich, Geneva and Lausanne. In addition, regulatory support and monitoring is provided by the ECRIN partners, the Clinical Trial Units in Zurich, Geneva and Lausanne. Zurich was the first center that recruited the first (!) four babies in this study.

cASPerCF - Prospective validation and clinical evaluation of a new posaconazole dosing regimen for children and adolescents with cystic fibrosis and Aspergillus. The study will assess the dose of posaconazole in children and young people with Cystic Fibrosis and Aspergillus infection and aims to recruit 135 children as part of the study. In Switzerland, the University Children's Hospital Zurich participates in this study.

In January the c4c leaders visited contributors of SwissPedNet to assess the processes and quality management systems in our clinical study sites. We have been assessed as being a well-functioning network providing services according to their objectives.

¹ Multicenter studies that are open at several centers are named by each participating center.

Since 2012, SwissPedNet has been a member of **Enpr-EMA**, the European Network of Paediatric Research at the European Medicines Agency. This network aims in particular to facilitate the conduct of studies in pediatrics in order to increase the availability of approved medicines for children. This network is used mainly by the pharmaceutical industry when it is looking for study centers in Europe for its Pediatric Investigation Plans (PIP)².

Anticipating future development and innovation in clinical science

Harmonizing health related data and biospecimens across pediatric hospitals: The project under the leadership of Claudia Kühni (Institute for Social and Preventive Medicine, ISPM Bern and SwissPedRegistry) laid the foundation for collecting the routine data produced in pediatric clinics during daily work. A standardized data set has been created, which can be used for clinical research in good quality. For the time being we aim to get the institutions to implement the new structures.

Optimizing pediatric dosing regimens based on a clinical data warehouse SwissPKcdw: The SwissPKcdw (Swiss Pharmacokinetics clinical datawarehouse) develops and provides tools for pharmacokinetic modelling. These tools should then be able to predict dosing regimens for pediatric patients based on the data in the Clinical Data Warehouse. This project is still running.

Providing training opportunities for young pediatric investigators and researchers, fostering continuous learning and adaptation

In 2020, this part of our activities fell victim to Corona, we had to cancel our training events.

The **SwissPedNet Translational and Clinical Research Session** is already well established; it was planned in May, however its eighth edition had to be canceled. This event will now resume in June 2021, we will do it virtually during the sgp/ssp annual conference in June 2021.

The **Next Generation Research Day** is the other main pillar of our training program. Unfortunately, we had to cancel its third edition in November as well. This all-day workshop will now be in our program in 2021. Beside the NextGen Research Day STEP 1 (Development), we will also offer a STEP 2 program (leadership) and aim to have the participants of the former STEP 1 trainings in our STEP 2 program.

SwissPedNet Projects in 2020

Recommendations relating to inclusions of adolescents of child-bearing potential (CBP) in clinical trials

A working group of pediatric and adolescent clinicians, research coordinators, and people from ethics committees worked on a guidance document about including adolescents of child bearing potential (CBP) in clinical trials or exposure to prescription of teratogenic medication.

The review article: adolescents of childbearing potential in clinical trials has been published in Swiss Medical Weekly on 25.09.2020. DOI: <https://doi.org/10.4414/smw.2020.20333>.

² A development plan designed to ensure that the necessary data are generated through studies in children to ensure that a new medicinal product is also authorized for children

SNSF - IICT Call

Prof. Maja Steinlin's PASTA trial is one of five new clinical studies funded by the SNSF: PASTA investigates the question: "Does administering steroids in high doses help children suffering from stroke and a one-sided narrowing of brain arteries?" SwissPedNet committed support with our clinical pediatric hubs.

General Assembly 2020

The 8th SwissPedNet General Assembly has been held on November 20, 2020.

Final year of the federal funding period 2017 to 2020

Each hub, SwissPedPha and SwissPedRegistry presented (1) key achievements, (2) the factors that helped to establish/ enhance the hub, (3) challenges and opportunities, and (4) a short outlook to the new funding period 2021 to 2024.

In summary, infrastructure and governance were enhanced at all hubs. It was impressive to see how the federal funds boosted the activities within our clinical pediatric hubs and laid the ground for pediatric clinical research throughout Switzerland.

SwissPedPha enhanced their activities by innovations through collaboration. They realized partnership with a pharmaceutical technology center for novel patient-friendly formulations. Their clinical pharmacological research group cares for applied pediatric pharmacology.

SwissPedRegistry with their SPHN-funded project "Harmonizing health related data and biospecimens across pediatric hospitals" laid the cornerstone for a pediatric learning health system in Switzerland. The data catalogues (SwissPedData Version 1.0) - defined in a national Delphi process - are now on its way to implementation.

Election of the president and the board

The following board members have completed their three year's term and have been unanimously re-elected for a second term: Prof. Klara Posfay Barbe, president, Prof. Matthias Baumgartner, vice-president, Prof. Roger Lauener, assessor and Prof. Marc Pfister, assessor.

Together with Dr Julia Bielicki and Prof. Claudia Kuehni the board is complete with its six members.

Changes in the composition of the SwissPedNet Advisory Board

Prof. Saskia de Wildt and Prof. Christian Kind left our advisory board, and they are replaced with Prof. Michael Levin, Imperial College London, UK and Prof. Johan Vande Walle, Ghent University Hospital.

Acknowledgment

Our thanks go again to the SCTO and their continuous support for the pediatric research infrastructure and their support in collaboration with European projects.

The sgp/ssp granted the SwissPedNet translational and clinical research award, Pfizer offered an educational grant, Roche, Eli-Lilly and Bayer financed the NextGen Research Day.

These grants are highly appreciated.

Outlook and next steps

In 2021 we enter the new federal funding period 2021 to 2024 and may follow-up on all our activities, as our basic funding is guaranteed for the coming four years.

Our teaching activities will continue, and we look forward to the additional module to our NextGen Research Day. Stay informed on our website.

Patient and Public Involvement (PPI) in academic clinical research might bring a revolution to clinical research in the coming 10 years. Its implementation must be done locally, however, we aim to closer integrate PPI in our daily work and provide some guidance for our clinical pediatric hubs.

Annual Financial Statement

Accounts 1.10.2019 to 30.9.2020 and Balance sheet as per 30.9.2020

	2018	2019	2020
	CHF	CHF	CHF
1. Income			
Membership fees	11'000.00	11'000.00	11'000.00
Educational Grant Pfizer	5'037.39	4'729.70	4'129.70
Sponsoring (sgp/ssp) Research session	3'000.00	6'000.00	0.00
Sponsoring NextGen RD	0.00	0.00	7'700.00
Transfer from deferred charges to expenses "SwissPedNet Travel Award"	0.00	2'459.00	0.00
Total income:	19'037.39	24'188.70	22'829.70
2. Expenses			
General Assembly	3'556.00	2'222.70	3'300.73
Website Hosting	646.20	597.74	549.28
Website Development and Support	10'477.85	2'841.99	51.16
Website domain name	83.50	68.00	99.00
Award SwissPedNet Clinical Research Session	3'000.00	6'000.00	0.00
Study Project in Pediatric Health Services Research	60'000.00	0.00	0.00
SwissPedNet NextGen Research Day	0.00	1'719.00	4'616.50
SwissPedNet Retreat	148.00	328.00	117.90
SwissPedNet (general costs & expenses)	698.00	1'113.25	1'242.51
Postfinance account management	105.00	60.00	60.00
Total expenses:	78'714.55	14'950.68	10'037.08
Total income:	19'037.39	24'188.70	22'829.70
Total expenses:	78'714.55	14'950.68	10'037.08
Total profit margin/loss of profits:	-59'677.16	9'238.02	12'792.62

3. Balance as per 30.9.2020	Liabilities	
Account balance PC 60-488628-5	83'508.66	
Deferred charges to income	0.00	
Deferred charges to expenses		0.00
Capital of the association		83'508.66
	83'508.66	83'508.66

4. Association assets	CHF
Asset as per 30.09.2019	70'716.04
Asset as per 30.09.2020	83'508.66
profit margin:	12'792.62

People of SwissPedNet

Members of the Board

President:	Prof. Dr Klara Posfay-Barbe
Vice-president:	Prof. Dr Matthias Baumgartner
Assessors:	Dr Julia Bielicki
	Prof. Claudia Kühni
	Prof. Roger Lauener
	Prof. Marc Pfister

Auditors

PD Dr Barbara Goeggel Simonetti
PD Dr Florian Singer

Member institutions and their representatives

University Children's Hospital Basel, Dr Julia Bielicki and Prof. Ulrich Heininger
University Children's Hospital Bern, Prof. Christa Flück, PD Dr Florian Singer, PD Dr Philipp Agyeman
University Children's Hospital Geneva, Prof. Klara Posfay Barbe and Prof. Constance Barazzone
University Children's Hospital Lausanne, Dr Manuel Diezi and Prof. Umberto Simoeoni
University Children's Hospital Zurich, Prof. Matthias Baumgartner and Prof. Christoph Berger
Children's Hospital Aarau, Prof. Henrik Köhler and Dr Dominik Müller-Suter
Children's Hospital Luzern, Dr Michael Büttcher and Dr Franziska Righini
Children's Hospital of Eastern Switzerland, St. Gallen, Prof. Roger Lauener and Dr Christian Kahlert
Children's Hospital EOC Ticino, Bellinzona, Prof. Giacomo Simonetti and PD Dr Barbara Goeggel
SwissPedRegistry, Pediatric Registry Center, ISPM, University of Bern, Prof. Claudia Kühni
SwissPedPha, Pediatric Pharmacology and Pharmacometrics Research Center at the UKBB, Prof. Marc Pfister and Prof. Johannes van den Anker

Coordinator SwissPedNet

Pascale Wenger, Swiss Clinical Trial Organisation SCTO

SwissPedNet Advisory Board

Prof. Evelyne Jacqz-Aigrin, CHU Paris - Hôpital Robert Debré, France
Mrs Pirkko Lepola, Executive Secretary FinPedMed, General Secretary NordicPedMed, HUS Helsinki University Hospital, Finland
Prof. Michael Levin, Paediatrics and International Child Health, Imperial College London, UK
Dr Simon Rotzler, Interpharma Switzerland
Prof. Johan Vande Walle, Department of Internal Medicine and Pediatrics, Ghent University Hospital, Belgium