



Swiss Research Network of  
Clinical Pediatric Hubs



# Annual Report 7 2019

**SwissPedNet**

c/o Swiss Clinical Trial Organisation

Effingerstrasse 35, 3008 Bern

T: 031 307 10 45

[www.swisspednet.ch](http://www.swisspednet.ch) | [info@swisspednet.ch](mailto:info@swisspednet.ch)

## Table of Contents

<b>Editorial.....</b>	<b>2</b>
<b>SwissPedNet Activities in 2019.....</b>	<b>3</b>
Increasing quality of pediatric healthcare in Switzerland by research and Improving children’s health through research.....	3
Connecting within Switzerland and abroad to facilitate conduct of pediatric clinical studies.....	3
Anticipating future development and innovation in clinical science.....	4
Providing training opportunities for young pediatric investigators and researchers, fostering continuous learning and adaptation.....	4
<b>SwissPedNet Projects in 2019.....</b>	<b>4</b>
Minimal requirements for local SOPs.....	4
Recommendations relating to inclusions of adolescents of child-bearing potential (CBP) in clinical trials.....	5
<b>Beneficiary of the funding period 2017 to 2020 .....</b>	<b>5</b>
<b>General Assembly 2019.....</b>	<b>5</b>
Changes in the composition of the SwissPedNet Board .....	5
New Auditors .....	5
<b>Acknowledgment .....</b>	<b>5</b>
<b>Outlook and next steps .....</b>	<b>6</b>
<b>Annual Financial Statement .....</b>	<b>7</b>
<b>People of SwissPedNet.....</b>	<b>8</b>
Members of the Board .....	8
Auditors .....	8
Member institutions and their representatives .....	8
Coordinator SwissPedNet.....	8
SwissPedNet Advisory Board .....	8

## Editorial

Dear reader,

The seventh year is over, and SwissPedNet, our network of clinical pediatric hubs and two service platforms for registries and clinical pharmacology is still harmoniously united. We could even strengthen and consolidate our activities during the past year.

The SwissPedNet Board of Directors has been working intensively on where SwissPedNet's journey should take it. What is the future picture that describes SwissPedNet? We decided for the following vision:

*All children and families benefit from high-quality research regardless of their age, pathology and place of residence.*

And we would like to achieve this by

*Increasing quality of pediatric healthcare in Switzerland by research;*

*Improving children's health through research;*

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

*Anticipating future development and innovation in clinical science;*

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

Please see for yourself in this report how we pursued and fulfilled our set goals.

Enjoy the reading!



Prof. Klara Posfay Barbe  
President SwissPedNet

## SwissPedNet Activities in 2019

Our activities followed our revised vision and the statements made in our mission.

We work to continuously implement the tasks described as our personal mission. When we look back to 2019, we are on the right track.

### 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 projects<sup>1</sup>.

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

Good cooperation within the individual locations and members works best when people know each other personally. SwissPedNet has launched several "field trips" for this purpose, the first invitation came from Geneva in 2018. In April 2019, the UKBB invited all the employees of our hubs to join them. In November, following our General Assembly, there was another meeting with all hub staff where newly developed quality standards could be presented. And for the third time this meeting took place in January 2020 at the Children's Hospital in Zurich.

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)<sup>2</sup>.

### ***c4c – conect4children – COllaborative Network for European Clinical Trials For Children***

SwissPedNet is part of the consortium of the pan-European research network c4c. The c4c research network brings together pharmaceutical companies, national pediatric research networks, multi-national indication-specific networks, patient associations, pediatric hospitals and other public research institutions from all over Europe.

Through c4c, three international studies now receive Swiss participation:

- TREOCAPA - Prophylactic treatment of the ductus arteriosus in preterm infants by acetaminophen – will be conducted in Geneva, Lausanne and Zurich.
- cASPerCF - Prospective validation and clinical evaluation of a new posaconazole dosing regimen for children and adolescents with cystic fibrosis and Aspergillus infection – has a trial site at the University Children's Hospital Zurich.
- KD-CAAP - Multi-centre, randomised, open-label, blinded endpoint assessed, trial of corticosteroids plus intravenous immunoglobulin (IVIG) and aspirin, versus IVIG and aspirin for prevention of coronary artery aneurysms in Kawasaki disease – will be opened in Basel, St. Gallen and Ticino in a later recruitment round.

<sup>1</sup> Multicenter studies that are open at several centers are named by each participating center.

<sup>2</sup> 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

## Anticipating future development and innovation in clinical science

The national initiative Swiss Personalised Health Network (SPHN) has the declared goal to promote the development of personalized medicine and personalized health in Switzerland.

SwissPedNet has been awarded two projects following a call for proposals by the SPHN:

- Harmonizing health related data and biospecimens across pediatric hospitals
- Optimizing pediatric dosing regimens based on a clinical data warehouse SwissPKcdw

The first is under the leadership of Claudia Kühni (Institute for Social and Preventive Medicine, ISPM Bern and SwissPedRegistry) and lays the foundation for collecting the routine data produced in pediatric clinics during daily work in such a way that a standardized data set is created, which can be used for clinical research in good quality. The project and its results were presented to a broad audience during a two-day symposium in December 2019.

The SwissPKcdw (Swiss Pharmacokinetics clinical datawarehouse) will develop and provide 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.

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

The **SwissPedNet Translational and Clinical Research Session** is already well established; in 2019, its seventh edition was held in Bellinzona. Here our young researchers learn to present their research projects and to answer questions from an interested audience.

The prizes were awarded to Carmen de Jong from the Institute for Social and Preventive Medicine at the University of Bern for her research project "Diagnosing asthma accurately in school-aged children suspected to have asthma" and to Patrick Meyer Sauteur from the University Children's Hospital Zurich for his work "Diagnosis of Mycoplasma pneumoniae pneumonia with measurement of specific antibody-secreting cells".

The **Next Generation Research Day** is the other main pillar of our training program: In November 2019, this all-day workshop was held for the second time to prepare young clinical researchers for the challenges of a research project. The event is very popular, that is why we decided to hold the NextGen RD for the third time on November 20, 2020.

## SwissPedNet Projects in 2019

### Minimal requirements for local SOPs

A working group of research nurses and study coordinators of our clinical research hubs elaborated minimal requirements for SOPs for the following topics:

- Sponsor and investigator responsibilities in clinical trials performed under Clinical Trials Ordinance (KlinV/OClin)
- Informed consent process
- Qualification and training of research team members
- Safety reporting in clinical studies with medical devices

## **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.

These recommendations are now in review at different stakeholders. Once they are final they will provide a concrete guidance as how to respond to the situation of minor adolescents of child bearing potential who may be enrolled in a clinical trial and/ or need to receive potentially teratogenic medication. It advises on how to deal with the issue of adolescents of CBP in regards to the prescription and maintenance of contraceptives as well as the use of pregnancy test. It gives suggestions as how to react to the adolescent who claims/ needs confidentiality. It offers a tool on how to assess an adolescent's functioning and lifestyles.

## **Beneficiary of the funding period 2017 to 2020**

We are now in the last year of the current funding period.

The application for future funding has been submitted within the application of the Swiss Clinical Trial Organisation. The employment of 0.5 to 0.7 FTE research staff for our pediatric research hubs, SwissPedPha and SwissPedRegistry gave the impetus to proceed with the establishment of our nation-wide research infrastructure for pediatrics. To face all research projects that could be conducted, an increase to 0.8 to 1 FTE would be highly appreciated.

## **General Assembly 2019**

The 7<sup>th</sup> SwissPedNet General Assembly has been held on November 22, 2019.

### **Changes in the composition of the SwissPedNet Board**

PD Dr Sandra Bigi left the board in August 2019 as she handed over the responsibility for the hub Bern. The board remains with six board members as elected in 2018.

### **New Auditors**

The General Assembly thankfully agrees to two new auditors:

PD Dr Florian Singer from the University children's hospital Bern and PD Dr Barbara Goeggel Simonetti from the EOC Ticino.

## **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 2020 we still profit from the federal funds contributing to our activities. We look forward to an increased international study activity with our participation in the c4c project.

Regarding our teaching activities we will introduce an additional module to our NextGen Research Day. Stay informed on our website.

Our application for further funding in the funding period to come (2021 to 2024) has been submitted within the application of the SCTO and we are confident that funding will be continued in 2021.

## Annual Financial Statement

Accounts 1.10.2018 to 30.9.2019 and Balance sheet as per 30.9.2019

	2017	2018	2019
	CHF	CHF	CHF
<b>1. Income</b>			
Membership fees	5'500.00	11'000.00	11'000.00
Educational Grant Pfizer	4'431.50	5'037.39	4'729.70
Sponsoring (sgp/ssp)	3'000.00	3'000.00	6'000.00
Transfer from deferred charges to expenses "SwissPedNet Travel Award"	0.00	0.00	2'459.00
<b>Total income:</b>	<b>12'931.50</b>	<b>19'037.39</b>	<b>24'188.70</b>
<b>2. Expenses</b>			
General Assembly	3'458.39	3'556.00	2'222.70
Website Hosting	648.00	646.20	597.74
Website Development and Support		10'477.85	2'841.99
Website domain name	186.10	83.50	68.00
Award SwissPedNet Clinical Research Session	3'000.00	3'000.00	6'000.00
Study Project in Pediatric Health Services Research		60'000.00	0.00
SwissPedNet NextGen Research Day	0.00	0.00	1'719.00
SwissPedNet Retreat	490.95	148.00	328.00
SwissPedNet (general costs & expenses)	684.40	698.00	1'113.25
Postfinance account management	60.00	105.00	60.00
<b>Total expenses:</b>	<b>8'527.84</b>	<b>78'714.55</b>	<b>14'950.68</b>
Total income:	12'931.50	19'037.39	24'188.70
Total expenses:	8'527.84	78'714.55	14'950.68
<b>Total profit margin/loss of profits:</b>	<b>4'403.66</b>	<b>-59'677.16</b>	<b>9'238.02</b>

<b>3. Balance as per 30.9.2019</b>	<b>Liabilities</b>	
Account balance PC 60-488628-5	70'716.04	
Deferred charges to income	0.00	
Deferred charges to expenses		0.00
Capital of the association		70'716.04
	<b>70'716.04</b>	<b>70'716.04</b>

<b>4. Association assets</b>	<b>CHF</b>
Asset as per 30.09.2018	61'478.02
Asset as per 30.09.2019	70'716.04
<b>profit margin:</b>	<b>9'238.02</b>



## 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 and PD Dr Florian Singer  
University Children's Hospital Geneva, Prof. Klara Posfay Barbe and Prof. Claire-Anne Siegrist-Juillard  
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, Prof. Marc Pfister and Prof. Johannes van den Anker

### Coordinator SwissPedNet

Pascale Wenger, Swiss Clinical Trial Organisation SCTO

### SwissPedNet Advisory Board

Prof. Saskia de Wildt, Radboud University, Nijmegen, the Netherlands  
Prof. Evelyne Jacqz-Aigrin, CHU Paris - Hôpital Robert Debré, France  
Prof. Christian Kind, Pediatrician, President Central Ethics Commission of the Swiss Academy of Medical Sciences  
Mrs Pirkko Lepola, Executive Secretary FinPedMed, General Secretary NordicPedMed, HUS Helsinki University Hospital, Finland  
Dr Simon Rotzler, Interpharma Switzerland