



Swiss Research Network of  
Clinical Pediatric Hubs



# Annual Report 4 2016

## **SwissPedNet**

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## Editorial

The major highlight in 2015 – the recognition that SwissPedNet matches an unmet and urgent need for pediatric translational and clinical studies and its integration on the Swiss Research Infrastructures Roadmap – was the main driver for our activities in 2016. We aimed to be ready for the funding period 2017 to 2020 when we hope to properly install and consolidate our pediatric hubs.

Our actions aimed to harmonize the characteristics of our individual hubs, to implement the network with the conduct of a multi-center trial and coordinate interactions between the trial and the hubs and finally to develop and deliver clear messages about the value of SwissPedNet. We made remarkable good progress, and slowly but steadily we establish networking in pediatric clinical research in Switzerland.

Early in the year, we have been informed by the SERI that we should rethink the distribution of applied funds and develop a plan B with only 50% of the budget, as the economic development asked for austerity programs and the available amount for all funded applicants decreased since the beginning of the planning.

On the European level, SwissPedNet is closer linked to ECRIN. ECRIN received a positive funding decision from the European Commission's Horizon 2020 program for the creation of a Pediatric Clinical Research Infrastructure Network (PedCRIN). The network will bring together ECRIN and the European Pediatric Clinical Trial Research Infrastructure (EPCTRI), which is comprised of more than 20 national and specialty networks. SwissPedNet is the Swiss hub in the PedCRIN project and the EPCTRI. We hope with this liaison that we will gather interesting international study projects to be conducted also in Switzerland.

Outlook 2017: We are eager to install the clinical pediatric hubs at each (university) children's hospital with the federal funding for the current funding period 2017 to 2020. The funding is lower than expected and we have to consider thoroughly what can be done now and what has to wait.

We very much look forward to an exiting future where we work on our vision to become the leading (virtual) pediatric research hospital in Switzerland.



Prof David Nadal  
President SwissPedNet

## SwissPedNet milestones according to the application to the SNSF in 2012

Regarding the milestones as described in the SNSF application in 2012 we may say that we reached them all according to our resources. We had limited funds, only the coordination office could be installed, there was no money for the clinical pediatric hubs. All activities in the hubs were based on the initiative of single individuals and on institutional funds. Taking this into consideration, we are proud on what we achieved regarding pediatric clinical research in Switzerland since 2012.

The fourth and fifth year of SwissPedNet foresees further trials, consolidation phase and future goals according to business plan (including financing concept and applications).

Regarding further trials and SwissPedNet consolidation phase we are making good progress. And our future goals are set and crystal clear: we want to become the (virtual) leading pediatric research hospital of Switzerland.

With the end of 2016, we leave the auspices of the SNSF and enter a new aera of direct federal funding by the SERI according to RIPA art. 15.

## SwissPedNet Highlights 2016

### SwissPedNet's multi-center study activity

The coordination office of SwissPedNet is recognized as point of contact for the pharmaceutical industry. In 2016 four requests for feasibility assessment reached the coordination office and in two of them potential study sites for these international trials have been identified.

Within academia SwissPedNet supports the Swiss coordinating investigator in the initiation of the international Penta17/Smile study in HIV infection. Penta foundation Italy acts as Sponsor and we have four study sites in Switzerland. The corresponding CTU took over the regulatory tasks and prepared the applications to the lead ethic's committee and Swissmedic in close collaboration with the coordinating investigator of the children's hospital.

On a national level SwissPedNet is involved in two multi-center investigator-initiated studies:

The *CITRUS study* is a multi-center Tb diagnostic study with 11 study sites in Switzerland. All nine SwissPedNet hubs participate in this study. The CTU involvement regarding regulatory affairs and study coordination for CITRUS was only limited, as protocol development has been supported by a PhD candidate and study coordination is done by local staff dedicated for this project.

The *GSI study* on primary immunodeficiencies originally has been designed as a single-center study. SwissPedNet supported the investigator to find additional study sites or recruiting sites, where the patients would be transferred to the main site. Now this study has three sites for study recruitment and study conduct.

### SwissPedNet Vision

During the SwissPedNet retreat on August 18, 2016 the participants decided to think different - be more than just a network, act like a leading research hospital. SwissPedNet should be perceived as

one big hospital with a catchment area of 8 millions residents: SwissPedNet – the (virtual) leading pediatric research hospital of Switzerland.

This thought led us to the vision of SwissPedNet, where the ideal situation of pediatric clinical research in Switzerland is described: all children in Switzerland have access to research of high quality and in well-installed research infrastructure, independent of their age, their pathology and their place of residence. The inclusion of pediatric surgery, pediatric anesthesia, and pediatric psychiatry needs to be considered.

### **Research organization in pediatrics**

The Swiss Society of Paediatrics (SGP/SSP) considers designating SwissPedNet as the official research organization of the SGP/SSP. Via the SGP/SSP SwissPedNet also has a solid link to the primary care professionals.

### **SwissPedNet part of Horizon 2020 funded PedCRIN project**

ECRIN-ERIC ([www.ecrin.org](http://www.ecrin.org)) is a generic infrastructure for multinational trial management, in any disease area, but with the exception of pediatric competences and infrastructure. To correct this, ECRIN-ERIC applied for an upgrade of ECRIN to develop a common infrastructure for pediatric trial management PedCRIN through cooperation with the European Pediatric Clinical Trial Research Infrastructure (EPCTRI).

ECRIN persuaded with its application and receives now Horizon 2020 funding for PedCRIN.

The SCTO respectively SwissPedNet is the Swiss partner of this network.

## **Activities and Projects in 2016**

### **Platform for (pediatric) study nurses and study coordinators**

As done in 2015, SwissPedNet together with the SCTO supported also the 2<sup>nd</sup> edition of the national study nurse/study coordinator meeting on April 22, 2016 with a monetary contribution. The event was a most motivating and rewarding success; over 100 persons joined this 2<sup>nd</sup> meeting.

These two meetings helped the group of study nurses and study coordinators to build up a network.

### **SwissPedNet Clinical Research Session**

SwissPedNet organized the 4<sup>th</sup> edition of the SwissPedNet Clinical Research Session on June 9, 2016 during the SGP/SSP congress in Bern. After submitting their studies and research projects to the judging panel, 10 young researchers received the opportunity to present their work during 10 minutes talk and adjacent explanations and dialogue with the audience. The research projects covered all disciplines of pediatrics; beside clinical and epidemiological questions also studies in basic research have been presented. Along with the content itself, the judging panel evaluated the performance and the following discussion of the young researchers.

We congratulate the winners of the SwissPedNet Translational & Clinical Research Award 2016:

*Flavia Wehrle, University Children's Hospital Zurich* for her research project "EEG sleep slow wave activity as a marker of load-dependent executive function deficits in very preterm children." (SPN6)

and

*Dr. Insa Korten, University Children's Hospital Bern* for her research project "Respiratory viruses in healthy infants and infants with Cystic Fibrosis. A prospective cohort study." (SPN10)

AbbVie, Bayer, Bristol-Myers Squibb, Celgene and Pfizer jointly offered the award of CHF 3000. –.

A summary of the research session has been published in *Paediatrica* Vol 27 (4/2016).

### **SwissPedNet Travel Award**

Receiving sponsoring from AbbVie, Bayer, Bristol-Myers Squibb, Celgene and Pfizer for our young researchers, SwissPedNet offers travel awards for up to CHF 1,000 to young researchers who travel for short research trainings or research stays in 2016/2017.

The call for travel awards is still open and we may still fund three to four travels.

### **Ethic Standards for Pediatrics**

A working group consisting of mainly people from the clinical hub Zurich and representatives from ethic's committee and swissethics elaborates standards for pediatric clinical research. Once the standards are finalized SwissPedNet will centrally manage them.

The topics, where standards would be a helpful tool for researchers and ethic's committees, include the development of a new and concise patient information template for children and adolescents, a definition for blood sample quantities allowed in research projects, the general consent for the use of samples and data, the involvement of healthy volunteers in pediatrics and how we deal with research projects without benefit for the patient, i.e. according to HRA art. 22 (2) and (4).

The working groups aims to finalize the standards by summer 2017. The standards will be subjected to a thorough review process with interested researchers in all SwissPedNet hubs during Q1 /Q2 2017.

### **SwissPedRegistry**

There are plans in establishing a Swiss registry for rare diseases. Discussions and negotiations are ongoing; SwissPedRegistry installed the pilot project and collaborates closely with the SwissPedNet hubs to spread the registry and its data collection on a national level.

### **SwissPedPha**

During 2016 no project could be realized between SwissPedPha and SwissPedNet. Pharmacological and data modeling projects are not yet brought into the clinical pediatric hubs.

With the limited funds received for the coming funding period it is not yet clear how this collaboration can be moved forward.

## SwissPedNet's Network

### Enpr-EMA

SwissPedNet is member of the European Network of Pediatric Research at the European Medicines Agency (Enpr-EMA). Still a category 3 member, as SwissPedNet cannot prove adequate public involvement according to the recognition criteria defined by Enpr-EMA.

However, SwissPedNet is in the loop of all shared information by and via Enpr-EMA and we are invited to the annual workshop with and for Enpr-EMA members.

The coordinator of SwissPedNet joins a working group of Enpr-EMA to establish a survey for all Enpr-EMA members with the aim to uncover the following shortcomings of the currently available information such as the core business of each network, the organization of each network, the type / nature of network (network of sites and/or network of researchers), the availability of dedicated staff / research infrastructure, and the collaboration of each network with other existing organizations, service providers, networks.

The survey should inform us how we can best work together and find suitable partners, how we can optimally exchange our expertise and share experience more effectively and to present precise and clear information to all stakeholders about the networks services, functions and competencies.

The results of this survey will be available in March 2017; a publication is planned.

### PedCRIN – the Pediatric Clinical Research Infrastructure Network in Europe

As Swiss partner of the PedCRIN project SwissPedNet will be involved in the work packages to establish European-wide research infrastructure in pediatrics.

The five work packages (WPs) of PedCRIN:

- WP1: Project coordination and implementation of management decisions
- WP2: Definition of the PedCRIN business strategy and governance structure
- WP3: Development of tools specific for pediatric and neonatal trials (trial methodology and outcome measures, adverse event reporting bio-sample management, ethical and regulatory database, monitoring, quality and certification)
- WP4: Provision of operational support to select pilot trials, which will be coordinated by ECRIN with the support of national pediatric coordinators hosted by pediatric networks (that currently exist or are being set-up)
- WP5: Communication targeting user communities (including industry partners) and policymakers, and aiming to empower patients and parents

The collaboration puts SwissPedNet on the European landscape and gives us a very welcome visibility. It will support us attracting new drugs and therapies for Switzerland.

### Swiss Clinical Trial Organisation SCTO

SwissPedNet is an independent organization but closely linked to the SCTO. The clinical pediatric hubs rely on the existing infrastructure of the SCTO network of CTUs. The president of SwissPedNet has a seat in the SCTO Steering Board.

The collaboration between SCTO and SwissPedNet is based on the guiding principle to not duplicate any infrastructure already available. It may be seen as pilot project for coming collaborations with other research networks or clinical research organizations.

SwissPedNet enjoys being part of the SCTO; the synergies arising out of this close collaboration are very beneficial for SwissPedNet.

### **Swiss Paediatric Oncology Group SPOG**

SPOG has a long tradition in conducting clinical studies in children. While SPOG acts as Sponsor and attends clinical study projects in Switzerland, SwissPedNet provides decentralized research infrastructure in its pediatric hubs. With the federal funds in 2017 SwissPedNet will become a service provider for sponsors of any discipline or pathology.

Together with SPOG we formulated a vision about the entire pediatric research in Switzerland, broadly speaking the ideal setting that all children have access to research on a high quality independent of their age or pathology or place of residence.

This will be reached with an interdisciplinary network. All subspecialties of pediatrics, pediatric surgery, pediatric anesthesia, and pediatric psychiatry benefit from synergies without losing their identity. The network will provide an attractive platform for translational research and the investigation of new diagnostics, substances and other therapies.

Together with the SPOG the pediatric vision has been formulated and discussed with the SERI. This gives us the fundament to further develop this vision and find new strategies for collaboration with all pediatric disciplines and pathology specific research groups.

We look forward to further developing this vision and implementing a national pediatric research network for all pathologies and disciplines in Switzerland during the coming years.

### **SwissPedNet and the Pharmaceutical Industry**

Two meetings took place to discuss the possibilities for industry when addressing SwissPedNet for the conduct of their studies and more generally to exchange expertise between industry and pediatric clinical researchers.

As evidence-based pediatric medicine is still neglected, the environment is continuously changing and pediatric needs are increasing, so there is a need to evolve and to address arising challenges. Pfizer addresses this issue and established the Pediatric Center of Excellence (Ped CoE), which is to improve the health and well-being of children by applying science, driving operational excellence, aligning resources and providing a unified voice for the needs of children. Advantages to bring Pfizer studies to Switzerland are recognized, i.e. the quality of data generated among SwissPedNet hospitals is considered good, follow ups with patients and parents are optimal, patient-doctor-parents relationships are maintained well and pediatricians know each other and collaborate. Pfizer confirm interest in collaborating with all countries, preferably organized in clinical trial networks, on a local, regional and global level.

We look forward to being addressed by Pfizer for developing and conducting their pediatric clinical trials also in Switzerland.



## General Assembly 2016

The first term of the SwissPedNet board expired in 2016 and we had new elections during the General Assembly on November 18, 2016.

The General Assembly elected David Nadal for an additional year as president. He brought SwissPedNet forward to the well-recognized organization it is today and he should be on board when we may start with proper funding of the clinical pediatric hubs. As he will retire in 2017 he cannot preside SwissPedNet for the entire term.

Klara Posfay Barbe is willing to take over from David Nadal in 2018. The General Assembly elected her as president-elect. She will now join the board and attend the president's activities together with David Nadal in 2017.

As vice-president Urs Frey has been re-elected for the coming two years. He will resign in 2019.

Christa Flück and Johannes Rischewski have been re-elected as assessors for the new term.

As Andrea Superti-Furga took over a new position in CHUV outside of pediatrics, he could not continue with his activity in the board. SwissPedNet thanks him for his support during the very important time of establishing SwissPedNet.

## Acknowledgment

The SNSF had trust in the endeavors of the pediatricians and granted the position of a coordinator for the period 2013 to 2016. This was the starting point to proceed with the Swiss pediatric research network and we wholeheartedly thank the SNSF for the continuous support during this very important time to establish SwissPedNet in the Swiss research landscape.

For the 4<sup>th</sup> time in series Pfizer AG awarded SwissPedNet with an educational grant, which is highly appreciated.

## Next steps

Off we go: we eventually may install the clinical pediatric hubs.

Now we have to think about performance measures to evaluate the impact of the infrastructure funded by the SERI. And we need projects and studies conducted in the SwissPedNet hubs.

The SGP/SSP together with Collège A will make a call for study projects in Pediatric Health Services Research to bring in study proposals. The topic should be relevant for ambulatory and outpatient care with a wide-ranging scope. Patient recruitment will be in all nine clinical pediatric hubs. It is planned to present the study during the SGP/SSP annual meeting on June 1, 2017 in St. Gallen.

## Annual Financial Statement

Accounts 1.10.2015 to 30.9.2016 and Balance sheet as per 30.9.2016

	2015	2016
	CHF	CHF
<b>1. Income</b>		
Membership fees	4'000.00	5'500.00
Educational Grant Pfizer	5'222.90	6'406.02
Sponsoring	0.00	7'500.00
EnprEMA workshop (allowance participation PW)	190.83	284.72
Postfinance credit interest	38.50	9.05
<i>Total income:</i>	<u>9'452.23</u>	<u>19'699.79</u>
<b>2. Expenses</b>		
	CHF	
General Assembly - Guest speaker / Advisory Board	1'321.86	2'456.27
Website Hosting	648.00	648.00
Website Maintenance/domain name	83.50	1'080.40
Public awareness (translations for Paediatrica)	702.00	1'123.20
Award SwissPedNet Clinical Research Session	3'000.00	3'000.00
SiwssPedNet Travel Award	0.00	5'500.00
National Study Nurse / Study Coordinator Meeting	3'020.38	910.45
SwissPedNet Retreat	310.50	515.40
SwissPedNet (general costs & expenses)	945.50	932.00
Postfinance account management	0.00	2.00
<i>Total expenses:</i>	<u>10'031.74</u>	<u>16'167.72</u>
Total income:	9'452.23	19'699.79
Total expenses:	10'031.74	16'167.72
<i>Total profit margin/loss of profits:</i>	<u>-579.51</u>	<u>3'532.07</u>
<b>3. Balance as per 30.9.2016</b>		
		Liabilities
Account balance PC 60-488628-5	120'751.52	
Deferred charges to income	500.00	
Deferred charges to expenses*		4'500.00
Capital of the association		116'751.52
	<u>121'251.52</u>	<u>121'251.52</u>
<b>4. Association assets</b>		
	CHF	
Asset as per 30.09.2015	113'219.45	
Asset as per 30.09.2016	116'751.52	
<i>profit of assets:</i>	<u>3'532.07</u>	

\*only CHF 1000.- for the travel award have been spent by 30.9.2016

## People of SwissPedNet

### Members of the Board

President in 2017: Prof. Dr. med. David Nadal, University Children's Hospital Zurich

President-elect: Prof. Dr. med. Klara Posfay-Barbe, University Children's Hospital Geneva

Vice-president: Prof. Dr. med. Urs Frey, University Children's Hospital Basel

Assessors: Prof Dr. med. Christa Flück, University Children's Hospital Bern

PD Dr. med. Johannes Rischewski, Children's Hospital Luzern

### Auditors

Dr. med. Manuel Diezi, University Children's Hospital Lausanne

Dr. med. Sara Bernhard-Stirnemann, Children's Hospital Aarau

### Member institutions and their representatives

University Children's Hospital Basel, Prof Urs Frey and Prof Ulrich Heininger

University Children's Hospital Bern, Prof Christoph Aebi and Prof Christa Flück

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 David Nadal

Children's Hospital Aarau, Prof Henrik Köhler

Children's Hospital Luzern, PD Dr Johannes Rischewski

Children's Hospital of Eastern Switzerland, St. Gallen, Prof Roger Lauener

Children's Hospital EOC Ticino, Bellinzona, Prof Giacomo Simonetti

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

Prof Martin Offringa, Child Health Evaluative Sciences, Toronto, Canada

Dr Simon Rotzler, Interpharma Switzerland

Dr Mark Turner, Institute of Translational Medicine, University of Liverpool, UK