



Swiss Research Network of
Clinical Pediatric Hubs



Annual Report 3 2015

SwissPedNet

c/o Swiss Clinical Trial Organisation
Petersplatz 13, 4051 Basel

T: 061 260 10 45 | F: 061 260 10 49

www.swisspednet.ch | info@swisspednet.ch

Table of Contents

Editorial	2
SwissPedNet milestones according to the application to the SNSF in 2012	3
SwissPedNet Activities and Highlights 2015	3
Establishment of an International Advisory Board	3
Enpr-EMA	4
European Paediatric Clinical Trials Research Infrastructure EPCTRI	4
Swiss Research Infrastructures Roadmap - SwissPedNet application.....	4
SwissPedNet Clinical Research Session	5
SwissPedNet and Interpharma.....	6
Clinical Pediatric Hubs.....	6
Platform for (pediatric) study nurses and study coordinators.....	6
SwissPedNet General Assembly 2015	6
Composition of the Advisory Board as of November 20, 2015	7
Public awareness.....	7
Newspapers	7
Acknowledgment	8
Next steps	8
Annual Financial Statement.....	9
People of SwissPedNet.....	10
Members of the Board.....	10
Auditors.....	10
Member institutions and their representatives.....	10
Coordinator SwissPedNet	10

Editorial

The research infrastructure SwissPedNet matches an unmet and urgent need for pediatric translational and clinical studies. A major highlight in 2015 was the recognition of this fact by federal bodies and their integration of SwissPedNet on the Swiss Research Infrastructures Roadmap in 2015. SwissPedNet is now an integral part of the Swiss Clinical Trial Organisation SCTO and has a seat in its Steering Board, for the time being, however, with an observer status.

Early in 2015 SwissPedNet set up an Advisory Board. So far, four experts from international networks, with high expertise and reputation in pediatric research, plus a representative from pharmaceutical industry have agreed to become members of this board and to take the task. The first meeting of the Advisory Board took place on November 19, 2015 and all members were invited to attend the annual General Assembly of SwissPedNet.

The SwissPedNet Clinical Research Session has been effected for the third consecutive time during the annual SPG/SSP congress, which this year was held in Interlaken on June 12, 2015. The clinical pediatric research in Switzerland is a lively and innovative place. A large and interested audience could listen to ten most stimulating presentations from young researchers. The topics of research covered disciplines from hematology to chronobiology, nutrition and metabolic processes up to treatment of pain. Each presentation was followed by adjacent lively discussions with senior scientists.

The pediatric hub Basel, PedNet Basel or “Ambulantes Studienzentrum am UKBB”, celebrated its opening on October 27, 2015. We congratulate the Basel colleagues to this milestone in our endeavors. After PedNet Bern, the Clinical Research Center in Zurich and the “plateforme de recherche pédiatrique” in Geneva we have now already four established hubs from own initiatives and funds.

On a European level SwissPedNet became part of a new initiative, the European Paediatric Clinical Trials Research Infrastructure EPCTRI. SwissPedNet is the Swiss partner of a newly proposed research infrastructure of pan-European interest.

Outlook 2016: We prepare for the new and exciting era with motivating federal funding and the proper installment of the clinical pediatric hubs at each (university) children’s hospital, the pediatric registry center and SwissPedPha.

A warm thank you goes to all who help to make SwissPedNet a success.



Prof David Nadal
President SwissPedNet

SwissPedNet milestones according to the application to the SNSF in 2012

SwissPedNet follows up on the milestones as described in the original application to the SNSF in 2012. The third year of existence included the following activities:

- Involvement in first international multi-center trial
- Initiation of 2 to 3 national multi-center trials
- Proceed to become a fully established network
- Quality (self) assessment and reporting to SNSF, business plan
- (International) auditing of SwissPedNet

The survey we made in 2014 showed a high activity of multi-center studies within the pediatric hospitals in Switzerland. According to the data received as per December 23, 2014 85 pediatric multi-center studies/projects were open and running in Switzerland. Details were published in the annual report 2014.

During the last three years pharmaceutical companies have asked SwissPedNet for feasibility checks and further participation in 12 international pediatric clinical studies. In most cases inclusion criteria did not allow finding suitable patients in the hospitals of SwissPedNet. For three studies, clinical investigators showed interest and study patients would have been available, but then the pharmaceutical companies decided to refrain from opening Swiss study sites.

An audit of SwissPedNet activities is planned once all pediatric hubs are established.

SwissPedNet Activities and Highlights 2015

Establishment of an International Advisory Board

The General Assembly in 2014 decided to install an international scientific advisory board.

The following experts could be committed to become members of the SwissPedNet Advisory Board by February 1, 2015:

- Dr Saskia de Wildt, Erasmus MC Sophia Children's Hospital, Rotterdam, the Netherlands
Director Medicines for Children Research Network, the Netherlands
- Prof Martin Offringa, Child Health Evaluative Sciences, The Hospital for Sick Children, Toronto, Canada, President of StaR Child Health
- Dr Simon Rotzler, Interpharma Switzerland
Head of Clinical Operations Bayer (Schweiz) AG, Liaison to Pharmaceutical Industry
- Dr Mark Turner, Institute of translational medicine, University of Liverpool, UK
Director Medicines for Children Research Network, UK and Chair of the Enpr-EMA coordinating group
- Prof Johannes van den Anker, Chair paediatric clinical pharmacology, University of Basel and University children's hospital Basel, Switzerland

Rules of internal procedures for the Advisory Board were approved by the General Assembly by E-mail voting in February 2015. The duties have been defined to review the annual report and provide pointed and critical remarks and to explore synergies between SwissPedNet and the represented

institution or organization. The first meeting of the Advisory Board and the SwissPedNet Board took place on November 19, 2015.

Enpr-EMA

In the first quarter of 2015, SwissPedNet updated its self-assessment form and sent it for re-evaluation to the coordinating group. An upgrade to category 2 membership cannot be approached, as SwissPedNet lacks criteria 6 “public involvement”. SwissPedNet now seeks for collaboration with the Swiss EUPATI team in 2016 to become more active with patient and parent involvement.

SwissPedNet participated at the 7th Enpr-EMA workshop held in June 2015. A lively exchange of experience and expectations of pediatric research networks took place. Individual working groups presented their reports and updates, details are published on the EMA website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2015/04/event_detail_001143.jsp&mid=WC0b01ac058004d5c3

European Paediatric Clinical Trials Research Infrastructure EPCTRI

The European Strategy Forum on Research Infrastructures (ESFRI) Roadmap identifies new Research Infrastructures of pan-European interest corresponding to the long-term needs of the European research communities, covering all scientific areas, regardless of possible location. ESFRI opened a call for new RIs early 2015 to become part of the updated Roadmap.

Dr Mark Turner and colleagues applied for EPCTRI, and SwissPedNet is the Swiss partner of the EPCTRI. Both the SERI and the SNSF endorse the SwissPedNet participation with a letter of intent for collaborating in setting up EPCTRI and expressing interest to provide political support for that process. On September 17, 2015 Mark Turner and collaborators presented EPCTRI to the ESFRI selection panel in Brussels. In December 2015 EPCTRI received the good news from ESFRI that the European Commission and ESFRI recognized the need for infrastructure at site level for pediatric research. The scientific case was highly rated. But the level of collaboration as presented in the application is not currently mature enough to be classified as a strong Research Infrastructure.

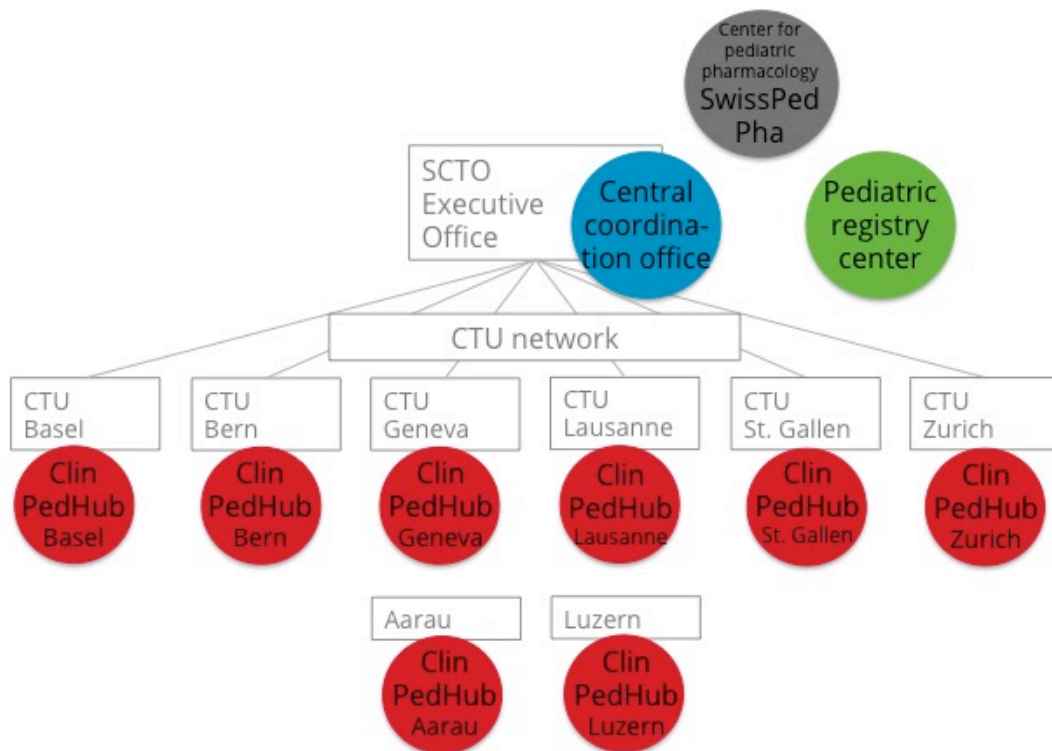
In its evaluation ESFRI recognized that more work needs to be done on governance, planning, human resources, relationships with governments and industry. Experience shows that this work requires resources. While the scientific need is high, the EPCTRI is not currently mature enough to enter the 2016 ESFRI roadmap. The organizers of EPCTRI will work on the findings and we will support them as far as we can.

Swiss Research Infrastructures Roadmap - SwissPedNet application

According to the Swiss Research Infrastructures Roadmap SwissPedNet sent its application to receive federal funds for the period 2017 to 2020. The application was submitted to the SERI within the application of the SCTO on June 30, 2015.

SwissPedPha was added to our application on May 18, 2015, as the SERI supports pediatric research only via SwissPedNet and thus could not support the application of SwissPedPha to SERI.

SwissPedNet applied for the following nation-wide research organization:



Graph 1: SwissPedNet – nation-wide research organization

The research infrastructure SwissPedNet consists of eight clinical pediatric hubs, a central coordination office within the executive office of the SCTO, the pediatric registry center SwissPedRegistry at the ISPM Bern, available to all pediatricians, and SwissPedPha, the RI at the university children’s hospital Basel and the universities of Geneva, Lausanne and Zurich providing services in pediatric pharmacology for all pediatric hubs and beyond.

The clinical pediatric hubs collaborate closely with the CTUs. Contracts between each hub and a corresponding CTU will be elaborated during 2016.

SwissPedNet Clinical Research Session

SwissPedNet organized the 3rd edition of the SwissPedNet Clinical Research Session on June 12, 2015 during the SGP/SSP congress in Interlaken. 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.

Winners of the SwissPedNet Clinical Research Award 2015 are

Dr. Chafika Kies, University Children's Hospital Lausanne CHUV for her research project "New guidelines for the diagnosis of high-grade vesico-ureteral reflux in children under three months with first febrile urinary tract infection?"

and

Dr. Caroline Guyer, University Children's Hospital Zurich for her research project "Very preterm infants show earlier emergence of 24-hour sleep-wake rhythms compared to term infants".

Pfizer sponsored the SwissPedNet Clinical Research Award of total CHF 3000.-. For more details see also [Paediatrica publication](#).

SwissPedNet and Interpharma

On August 28, 2015 SwissPedNet presented the nation-wide research organization as applied for at the SERI to the Clinical Research Working Group of Interpharma. Together with Profs Johannes van den Anker and Marc Pfister from SwissPedPha SwissPedNet provided current information what is available and what is planned in the Swiss pediatric research community to representatives of the pharmaceutical industry. The delegates of the Clinical Research Working Group were highly interested and will share this information with their headquarters to receive more clinical studies to be conducted in Switzerland.

Clinical Pediatric Hubs



Swiss Research Network of
Clinical Pediatric Hubs

PEDNET BASEL ("Ambulantes Studienzentrum am UKBB") celebrated its opening on October 27, 2015. It is the fourth established clinical pediatric hub of SwissPedNet, still from own initiatives and funds. Together with Bern, Geneva, and Zurich dedicated staff care for the research projects within the children's hospitals and are contact points for the SwissPedNet coordinator.

Platform for (pediatric) study nurses and study coordinators

SwissPedNet together with the SCTO support the (pediatric) study nurses to have a platform for mutual exchange. Study nurses of the SwissPedNet member hospitals organized a national study nurse meeting on April 16, 2015. The event was open for all study nurses and coordinators, i.e., not only for pediatrics.

The event was a most motivating and rewarding success; over 100 persons joined this first meeting. The follow up event is planned for April 20, 2016 with the same organizing committee.

SwissPedNet General Assembly 2015

The General Assembly 2015 accepted the pediatric registry center SwissPedRegistry and SwissPedPha as new ordinary members of SwissPedNet. Service level agreements for these service providers will be elaborated during 2016.

In addition, the children's hospitals of the *Ente Ospedaliero Cantonale* in Ticino with its head Prof Giacomo Simonetti have been accepted as ninth clinical pediatric hub of SwissPedNet. It has to be decided, how Ticino will be integrated into the funding system, as so far we applied for only eight hubs.

A major topic during the General Assembly was the coming funding period 2017 to 2020, i.e. how do we shape the future of SwissPedNet. The SwissPedNet aim is to establish clinical hubs open for all specialties that all different groups can profit from the research infrastructure funded by the government. One specific goal is to set-up the hubs in each member hospital. We need consistent processes and local architecture. And we still aim for a "one stop shop".

Our Advisory Board members Saskia de Wildt and Mark Turner recommended implementing four action points to be performed immediately:

1. Harmonization of characteristics of individual hubs with the aim: Clear expectations of hubs (for trials, sponsors and for evaluation of the hubs)
2. Implementation of the network, i.e. conduct at least one multi-center trial and coordinate interactions between the trial and the hubs (define how this will be done and manage the interactions actively)
3. Public relations with the aim to develop and deliver clear messages about the value of SwissPedNet
4. How will hubs be judged? I.e. define metrics for whether funding will be continued at hub level and process for review (e.g. data collection, review by External Advisory Board, decision by SwissPedNet, input by SCTO)

These action points will be followed up during 2016 to be ready for the funds in 2017.

Composition of the Advisory Board as of November 20, 2015

With SwissPedPha as new ordinary member of SwissPedNet, Prof Johannes van den Anker will be replaced in the Advisory Board. The replacing expert is Prof Evelyne Jacqz-Aigrin, CHU Paris - Hôpital Robert Debré, France. She is pediatric pharmacologist with broad experience in clinical research. We appreciate very much her confirmation to take part in the SwissPedNet Advisory Board.

In addition, we asked Prof Christian Kind to become member of the advisory board. Prof Kind is an expert for ethical issues, has a broad knowledge of pediatric clinical research and knows the Swiss environment. Fortunately he also agreed to contribute and share his knowledge.

The current Advisory Board of SwissPedNet has the following composition:

- Dr Saskia de Wildt, Erasmus MC Sophia Children's Hospital, Rotterdam, 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, The Hospital for Sick Children, Toronto, Canada
- Dr Simon Rotzler, Interpharma Switzerland
- Dr Mark Turner, Institute of Translational Medicine, University of Liverpool, UK

Public awareness

Newspapers

The *NZZ am Sonntag* raised the question about effective and safe medication for children and published an article on June 14, 2015 about this topic. SwissPedNet was mentioned as one of the answers. Other journals took up the matter and SwissPedNet could enjoy some media exposure and hence raise public awareness for the need of research in children.

Acknowledgment

Already for the third time Pfizer AG awarded SwissPedNet with an educational grant. This grant allowed us to award the young researchers at the SwissPedNet Clinical Research Session, to hold a retreat, and to invite our Advisory Board members to the first meeting and the General Assembly.

Next steps

2016 will focus on preparing for the new era with federal funding of the clinical pediatric hubs, the pediatric registry center SwissPedRegistry, and SwissPedPha. See also action points 1 to 4.

SwissPedNet elaborates a framework agreement with the SCTO and each clinical pediatric hub individual agreements with their corresponding CTU offering population unspecific services for the hubs.

The individual pediatric hubs, the SwissPedRegistry and SwissPedPha will present a business plan on how to invest the federal funds. Rules for financial contributions, a distribution key and performance measures must be in place by end of 2016.

Patient and parent involvement is a key element to become a full member of the Enpr-EMA. SwissPedNet strives to implement strategies to collaborate closer with patient and parent organizations and have them involved in the activities of SwissPedNet.

The term of the president and board members expires with the next General Assembly. New potential board members will be addressed early to guarantee a seamless and smooth change over in November 2016.

Annual Financial Statement

Accounts 1.10.2014 to 30.9.2015 and Balance sheet as per 30.9.2015

	2014	2015
	CHF	CHF
1. Income		
Membership fees	4'000.00	4'000.00
SAMS seed money	100'000.00	0.00
Educational Grant Pfizer	10'800.00	5'222.90
Sponsoring	3'000.00	0.00
Coordination PONI study	1'540.00	0.00
EnprEMA workshop (allowance participation PW)		190.83
Postfinance credit interest	0.95	38.50
<i>Total income:</i>	<u>119'340.95</u>	<u>9'452.23</u>
2. Expenses		
General Assembly - Guest speaker / Advisory Board	690.09	1'321.86
Website Hosting	648.00	648.00
Website Maintenance/domain name	305.90	83.50
Logo SwissPedNet/Hubs	3'456.00	0.00
Public awareness*	529.47	702.00
Award SwissPedNet Clinical Research Session	3'000.00	3'000.00
National Study Nurse / Study Coordinator Meeting		3'020.38
SwissPedNet Retreat	315.00	310.50
SwissPedNet (general costs & expenses)		945.50
EnprEMA workshop - participation PW (flight/hotel)	375.83	0.00
Postfinance account management	40.00	0.00
<i>Total expenses:</i>	<u>9'360.29</u>	<u>10'031.74</u>
Total income:	119'340.95	9'452.23
Total expenses:	9'360.29	10'031.74
<i>Total profit margin/loss of profits:</i>	<u>109'980.66</u>	<u>-579.51</u>
3. Balance as per 30.9.2015	Assets	Liabilities
Account balance PC 60-488628-5	107'996.55	
Deferred charges	5'222.90	
Capital of the association		113'219.45
	<u>113'219.45</u>	<u>113'219.45</u>
4. Association assets	CHF	
Asset as per 30.09.2014	113'798.96	
Asset as per 30.09.2015	113'219.45	
<i>Loss in assets:</i>	<u>-579.51</u>	

People of SwissPedNet

Members of the Board

- President: Prof. Dr. med. David Nadal, University Children's Hospital Zurich
- 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
- Prof. Dr. med. Andrea Superti-Furga, University Children's Hospital Lausanne

Auditors

- Dr. med. Manuel Diezi, University Children's Hospital Lausanne
- Prof. Dr. med. Henrik Köhler, 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 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 Andrea Superti-Furga
- 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, PD Dr Jürg Barben
- Children's Hospital EOC Ticino, Bellinzona, Prof Giacomo Simonetti
- SwissPedRegistry, Pediatric Registry Center, ISPM, University of Bern, Prof Claudia Kühni
- SwissPedPha, Prof Marc Pfister

Coordinator SwissPedNet

- Pascale Wenger, Swiss Clinical Trial Organisation SCTO