



Swiss Research Network of
Clinical Pediatric Hubs



SNSF enactment 33CI30-121135/8 and 33FI30-147499/3

Annual Report September 2012 to August 2013

SwissPedNet

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Table of Contents

Introductory remarks	2
Organization of SwissPedNet	3
National Level	3
Local Level	4
Financing	4
National Level	4
Local Level	5
Milestones	6
Quality Management System QMS	6
Collaboration with network of CTUs	6
Contact point for industry	7
Enpr-EMA	7
SwissPedNet Clinical Trials Session	7
Website	8
Consultations	8
Implementation of the new law on human research	8
Funding period 2017ff	8
Public awareness	9
Next steps	9
Budget 2014 to 2016	10
Gratitude and Outlook	11
People of SwissPedNet	12
Members of the Board	12
Auditors	12
National Coordinator PedNet	12
The contact persons for SwissPedNet within the pediatric hospitals or clinics	12

Introductory remarks

On February 24, 2012 the Swiss National Science Foundation (SNSF) issued the enactment 33CI30-121135/8 and granted additional money to the "National Collaborative Center (NCC)". The amount was spoken as seed money to cover the salary of a national coordinator SwissPedNet to integrate pediatric clinical research into the national network of CTUs. On July 1, 2013, the enactment 33FI30-147499/3 granted the extrapolation of this first year grant until end of 2013.

On August 13, 2012 the newly appointed national coordinator PedNet started her position within the Swiss Clinical Trial Organisation SCTO (www.scto.ch).

The present annual report records the development of SwissPedNet within its very first year of existence. An additional report will be incorporated into the SCTO annual report by the end of 2013, as SwissPedNet will go into the calendar year reporting period in the future.

The SwissPedNet coordination office has been located at the SCTO executive office. Consequently, the coordinator SwissPedNet could concentrate on the essentials and benefit from the SCTO colleagues and their experience with establishing and maintaining a network. SCTO shared knowledge, made contacts with interested people and associations, and offered contribution with already established communication tools, e.g., sending out promotional e-mails to all stakeholders within academic research, participating at the Forum Clinical Research, etc. Regarding administrative tasks the SwissPedNet coordination office is established within a well-equipped office, the SCTO accountant takes over terms of employment, wage payments, the SwissPedNet bookkeeping, and with all colleagues there is always a contact person or deputy to answer calls and forward inquiries. This is a comfortable situation for a start-up organization.

SwissPedNet is a young initiative of the eight pediatric Class A hospitals of Switzerland. Although SwissPedNet is still in a start-up phase, it is now ready for all collaborations of interest and keen to work together with all stakeholders on the medical progress and the improvement of pediatric clinical research in order to implement evidence-based medicine also for our children.



Pascale Wenger

National coordinator SwissPedNet
on behalf of the SwissPedNet Board

Organization of SwissPedNet

SwissPedNet, initiated by pediatricians of the five university children's hospitals and the three class A children's hospitals, has been founded as an association according to the Swiss civil code §§ 66 to 79 on February 28, 2013 by adopting the SwissPedNet bylaws. (see <http://www.swisspednet.ch/about-us/organization/> → Bylaws of SwissPedNet)

The eight children's hospitals or pediatric clinics are founding members and, hence, ordinary members of this research network of clinical pediatric hubs, which aims to promote, facilitate, coordinate and conduct clinical trials devoted to children.

SwissPedNet elected a board consisting of five members. The board conducts the business of the SwissPedNet.

For ordinary members a membership fee of CHF 500.- has been decided on. These membership fees will help us to initiate research funding and cover some of our expenses, e.g. the recurring costs for our website www.swisspednet.ch and general expenses for meetings. Members have access to the book keeping of SwissPedNet, which has appointed auditors. The balance sheet will be presented at the general assembly, which is scheduled once per year in the 4th quarter, and all members will receive a copy of the meeting minutes.

SwissPedNet is on its way to conduct multi-center clinical studies - in all pediatric disciplines and ranging from newborns to adolescents - in the clinical pediatric hubs. SwissPedNet joins clinical researchers with the aim to conduct multi-center studies in the eight pediatric hubs. SwissPedNet does not act as Sponsor of clinical studies; Sponsor responsibility always remains with the principal investigator or industry.

National Level

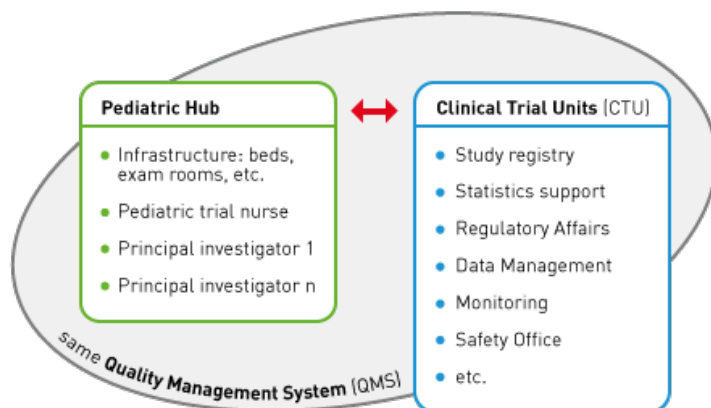
The SwissPedNet coordination office is established within the Swiss Clinical Trial Organisation (SCTO). The national coordinator PedNet is a 0.7 FTE position with the following allocated tasks:

- a. The practical implementation of the association's purpose,
- b. Effective organizing services for the clinical pediatric hubs,
- c. Coordinating national multi-center trials, particularly in rare diseases and in longitudinal settings,
- d. Linking to neighboring networks on a national and international level,
- e. Acting as a coordination and representation body for European pediatric clinical trial networks and industry,
- f. Helping to raise political awareness for the need for research in pediatrics,
- g. Supporting to receive grants and donations,
- h. Organizing symposia,
- i. In collaboration with the CTU-Network establishing a Quality Management System for the clinical pediatric hubs,
- j. Writing and distributing minutes of the board meetings and general assemblies,
- k. Maintaining the SwissPedNet website,
- l. Maintaining close links with the SCTO and its CTU-Network.

The achievements of the national coordination office reached so far are listed under "Milestones".

Local Level

Clinical Pediatric Hubs are or will be established within the children’s hospitals or clinics. The hubs will be closely linked to the existing CTUs; only pediatric specific tasks must be created and maintained.



Some of the pediatric hubs still lack appropriate local funding. The network strives toward an improvement of this situation wherever possible to establish proper infrastructure in all pediatric hubs.

Financing

National Level

The SNSF funds the national coordination office of SwissPedNet. Notably, the SNSF funds are given with the condition to use the existing infrastructure of the CTUs and not to duplicate available services provided by them. Hence, SwissPedNet will strictly adhere to use existing infrastructures and services for the development and conduct of their studies, except where pediatric-specific needs exist.

In August 2012, the national coordinator PedNet started her work in the offices of the SCTO. The following table gives an overview of the expenses raised by the coordination office and the income of SwissPedNet within the reporting period 1.9.2012 to 31.8.2013:

Expenses	CHF
National Coordinator PedNet	98'000.00
PedNet coordinator Infrastructure costs (Overheads, Rooms, IT)	16'000.00
Allowable expenses (e.g. travels)	1'395.00
SwissPedNet Logo and Web design	7'311.60
SwissPedNet Website	10'110.45
Recurring costs Website (hosting April to September)	449.30
Total Costs	133'266.35

Income	CHF
SNSF Grant 33CI30-121135/8 (24.2.2012 to SAMW)	136'000.00
Educational Grant	19'180.00
Membership fees	4'000.00
Total Income	159'180.00

Local Level

To install and operate the clinical pediatric hubs within the eight class A children's hospitals or clinics an application was submitted to the SUK / CUS "*Projektgebundene Beiträge 2013 – 2016, Antrag auf ein Kooperations und Innovationsprojekt (KIP)*" on May 31, 2012. In November 2012 SwissPedNet was informed that the investment for clinical research would be granted via Swiss TransMed (KIP18) and that SwissPedNet was invited to submit pediatric projects, but funding of infrastructure was not part of Swiss TransMed. Moreover, SwissPedNet was informed that the money of SwissTransMed is earmarked for projects that must involve ETHZ or EPFL. Thus, pediatric clinical projects would only be eligible, if ETHZ or EPFL would be co-applicants in the research proposal.

Therefore, SwissPedNet sent applications to the Swiss Academy of Medical Sciences (SAMS) and the State Secretariat for Education, Research and Innovation (SERI) to receive seed money for the clinical pediatric hubs.

SAMS granted an amount of CHF 100'000.- for 2014, if SwissPedNet would succeed in receiving at least further CHF 400'000.-.

SERI informed SwissPedNet that within a running funding period, there was no possibility to grant further amounts. As a consequence and to guarantee correct national clinical research planning in the future, SwissPedNet was invited to join the new SERI project "Organization of federally funded clinical research as from 2017 onwards".

The clinical pediatric hubs acted locally to receive support from their home institutions, universities and cantons, with the following success:

In-kind contribution for 2014		CHF
Clinical Pediatric Hub Basel	Distribution of staff to be defined	150'000.00
Clinical Pediatric Hub Bern	Research Clinician MD (1 FTE), trial nurse (0.5 FTE)	200'000.00
Clinical Pediatric Hub Geneva	no contribution	0.00
Clinical Pediatric Hub Lausanne	Trial nurse (0.4 FTE)	40'000.00
Clinical Pediatric Hub St. Gallen*	Trial nurse (0.5 FTE)	50'000.00
Clinical Pediatric Hub Zurich	Scientist (1.5 FTE), Secretariat (0.5 FTE)	231'000.00
Overall		671'000.00

*Request submitted to hospital management, to be decided in October 2013.

Milestones

Quality Management System QMS

At the founding meeting of SwissPedNet on February 28, 2013, SwissPedNet adopted a Quality Policy compulsory for all Clinical Pediatric Hubs. (see <http://www.swisspednet.ch/about-us/organization/> → Quality Policy of SwissPedNet)

During a meeting with the CTUs' Quality Assurance (QA) Working Group on May 16, 2013, the concept for the Clinical Pediatric Hubs' QMS was presented and discussed and the valuable input from the QA specialists incorporated into the SwissPedNet QMS concept.

The SwissPedNet concept envisages a three-pillar QMS:

Pillar 1: General GCP adherence

General GCP adherence is covered by the existing QMS of the CTUs. To rely on the CTU's QMS a collaboration agreement between the Pediatric Hubs and the local CTU must be issued.

Pillar 2: Local processes

Pillar 2 will be hub-specific. SwissPedNet provides a checklist with all documents required for local processes within a clinical pediatric hub to conduct clinical studies according to current GCP standards.

Pillar 3: Pediatric-specific standards

SwissPedNet wants to implement the same pediatric-specific guidance documents (i.e. guidelines, SOPs and working instructions) in all eight pediatric hubs. This will facilitate the conduct of multi-center studies and communication between all trial sites.

For the pediatric-specific standards SwissPedNet actively searched and agreed on the collaboration with StaR Child Health. StaR Child Health is an international initiative that seeks to improve the quality of design, conduct, and reporting of pediatric clinical research by promoting the use of modern research standards. <http://ifsrc.org/home/standards/>

SwissPedNet will provide templates and matrices for SOPs according to the topics published by StaR to all clinical pediatric hubs for local adoption.

Collaboration with network of CTUs

The CTUs' QA Working Group and SwissPedNet collaborate to implement the SwissPedNet QMS in the clinical pediatric hubs (see above).

The Swiss Pediatric Sepsis Study – a national prospective cohort study to assess epidemiology, novel immunodeficiencies and the impact of genetic variation on susceptibility to sepsis in children started in September 2011 in all eight clinical pediatric hubs plus the neonatology of the University Hospital Zurich. The study will run for at least further two years to reach target patient number of 600. With the involvement of SwissPedNet a successful outsourcing of data entry and monitoring tasks to the CTU Zurich for the German speaking hubs and to the CTU Lausanne for the French speaking hubs was installed.

There are four study proposals, where collaboration with the CTUs will be envisaged once the proposals are more advanced and CTU involvement will be needed.

No.	Date	Title	Indication	Principal_Investigator	Clinical Hub	Participating_Hubs	Study_Status
1	13.08.2012	Swiss Pediatric Sepsis Study	Sepsis	Luregn Schlapbach	Bern	all, plus ZHNeonat	open
2	04.04.2013	CF Transition	Cystic Fibrosis	Alexander Möller	Zurich	all	proposal
4	06.03.2013	Effects of high doses Ibuprofen on polyposis and chronic rhinosinusitis in children with cystic fibrosis	Cystic Fibrosis	Yann Kernen	Lausanne	BE, ZH	proposal
5	16.07.2013	Find surrogate marker in MRI with new scanner of USB	Spinal muscular atrophy (SMA)	Ulrike Bonati	Basel	Basel, UKBB and Radiology of USB	proposal
7	16.07.2013	JIR cohort		Manuel Diezi	Lausanne	all, plus Winterthur, Begium, France	proposal

Table 1: List of multi-center studies requesting collaboration with SwissPedNet and CTU network.

Contact point for industry

Despite the still limited awareness of the existence of SwissPedNet already two requests were submitted by industry for the conduct of their pediatric trials.

No.	Date	Title	Indication	Principal_Investigator	Clinical Hub	Participating_Hubs	Study_Status
3	25.03.2013	PONI	RSV LRTI	David Nadal	Zurich	Basel, Geneva, Zurich	proposal
6	02.07.2013	Phase II Pharmacokinetics, Efficacy, and Safety of Belatacept in Pediatric Renal Transplant Recipients	Kidney transplant	Guido Laube	Zurich	Zurich	proposal

Table 2: List of industry studies requesting collaboration with SwissPedNet.

Enpr-EMA

SwissPedNet is also linked via Enpr-EMA to internationally share high quality medical expertise and robust data from Switzerland.

SwissPedNet is member of Enpr-EMA, the European Network of Paediatric Research at the European Medicines Agency. This is a network of research networks and experts and beside others Enpr-EMA facilitates the pharmaceutical industry's access to pediatric clinical study centers and experts. They also include their members in consultations of new guidelines and lists of development programs for drugs used in children.

On February 26, 2013 the coordination group members of Enpr-EMA rapidly decided to allocate first-step membership (termed category 3) for SwissPedNet. The SwissPedNet self-assessment form is published on the Enpr-EMA website.

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/03/WC500140646.pdf

SwissPedNet Clinical Trials Session

At the SGP/ SSP (Swiss Society for Pediatrics) annual conference in Geneva on June 21, 2013 SwissPedNet took over the realization of the "Young Researchers Day" and launched a new platform called "SwissPedNet Clinical Trials Session".

Representatives from the pediatric hubs of SwissPedNet had elected the projects to be presented orally in advance from a plethora of applications. The young researchers presented their studies to the audience during 10-minutes talks, which were followed by questions from the floor that raised motivated discussions. The audience hosted many experienced and senior pediatric researchers, who challenged the young researchers with their expertise and targeted questions.

The SwissPedNet Clinical Trials Session had a rather impressive start and was highly well-received at the SGP / SSP annual conference. The organizers are confident, that this session will become a valuable platform for young researchers to present their research projects and receive input from experienced scientists. <http://www.swisspednet.ch/news-events/>

Website

SwissPedNet created an own website (www.swisspednet.ch). To finance the website's design and development, SwissPedNet approached pharmaceutical industry to obtain an educational grant. The website is accessible for the public since April 1, 2013.

The website is a tool to increase visibility and promotion of SwissPedNet to the public, interested stakeholders, and researchers. SwissPedNet regularly posts current information within its field of interest. Furthermore, it is also an essential platform to share information and documents. To complete all coordination tasks needed for the conduct of multi-center trials with all eight pediatric hubs the website provides a password protected extranet for members and trial staff. So far the website is in English only and we are currently looking for an additional grant to make it available also in German and French.

Consultations

SwissPedNet was officially asked and took the opportunity to constructively comment on the new legislation during the consultation phase. Thus, SwissPedNet submitted a carefully elaborated and comprehensive pediatric view regarding the ordinances of the "Humanforschungsgesetz" / "Loi relative à la recherche sur l'être humain" on October 31, 2012 and the "Krebsregistrierungsgesetz" / "Loi fédérale sur l'enregistrement des maladies oncologiques" on March 21, 2013.

Implementation of the new law on human research

Within the attempts for smooth implementation of the new law on human research and its corresponding ordinances, the Federal Office of Public Health commissioned the Ethics Committees to elaborate recommendations and revise existing leaflets and checklists.

SwissPedNet is involved with the working group 5, research with children and adolescents.

Funding period 2017ff

SwissPedNet is involved in the project of the State Secretariat for Education, Research and Innovation (SERI) called "Organization of Clinical Research financed by the Confederation as from 2017: measures concerning SCTO/CTU-network and SAKK/SPOG". The national coordinator PedNet is part of the project team and the president SwissPedNet is member of the project steering committee.

Public awareness

On April 2, 2013 we issued a press release “Research collaboration dedicated to children”.

<http://www.swisspednet.ch/news-events/>

There have been several contacts and meetings with interested stakeholders. On June 11, 2013 we presented SwissPedNet to the clinical research group of *scienceindustries*. On June 19, 2013 we established first contact with the *Swiss Biotech Association*, where we could publish an article in their NTN News Bulletin. ([News Bulletin](#))

Next steps

A continuous main task of SwissPedNet is and will be to assist the clinical pediatric hubs to setup and maintain appropriate infrastructure as well as implementing a well-working QMS. With the establishment of the clinical pediatric hubs the concept of the QMS will be implemented and thereby its practicability will be tested.

The communication tools so far installed need validation. We are confident that most study proposals requesting collaboration with SwissPedNet will be conducted and will help us to identify what kind of support and coordination is needed.

For our first General Assembly scheduled for November 26, 2013 we have invited key representatives of existing Swiss pediatric networks (oncology and neonatology) to elaborate synergies and design common projects.

The Director from the Dutch Medicines for Children Research Network (<http://mcrn.nl>) confirmed participation and will present us, how the Netherlands succeeded in building up a successful network.

Establish a Conference / Congress “University Pediatrics with Focus on Research”. This research day will focus in a series of special sessions on the interdisciplinary research projects of the existing pediatric societies and cooperative groups. It would involve also laboratory research and most important, *from bench to bedside* and *from bedside to bench* projects.

Budget 2014 to 2016

To perform the tasks and to achieve the milestones as described in the primal application to the SNSF, SwissPedNet must set up proper infrastructure in its clinical pediatric hubs. SwissPednet aims to employ for all eight hubs research associates (3.5 FTE) and pediatric trial nurses (4.0 FTE) within a global budget. In-kind contributions of the home institutions, universities and/or cantons do not yet cover all costs budgeted so far. According to the current funding situation, our budget shows an expenses and income disparity.

Expenses	2014	2015	2016	<i>Total</i>
	CHF	CHF	CHF	CHF
Research associate (350%)*	490'000.00	490'000.00	490'000.00	1'470'000.00
Pediatric trial nurse (400%)*	400'000.00	400'000.00	400'000.00	1'200'000.00
National Coordinator PedNet (70%)	98'000.00	98'000.00	98'000.00	294'000.00
PedNet coordinator Infrastructure costs	16'000.00	16'000.00	16'000.00	48'000.00
Meetings, Symposia, Travel costs	2'000.00	2'000.00	2'000.00	2'000.00
Swiss PedNet Website (Hosting)	624.00	624.00	624.00	1'872.00
Overall expenses	1'006'624.00	1'006'624.00	1'006'624.00	3'019'872.00

Income	2014	2015	2016	<i>Total</i>
Membership fees	4'000.00	4'000.00	4'000.00	12'000.00
SAMW grant	100'000.00			100'000.00
Educational Grant	20'000.00	20'000.00	20'000.00	60'000.00
in-kind contribution hubs	671'000.00	671'000.00	671'000.00	2'013'000.00
Overall income	795'000.00	695'000.00	695'000.00	2'185'000.00

*Personnel for all eight pediatric hubs. Employed by e.g. a CTU, but dedicated for pediatric needs.

Gratitude and Outlook

SwissPedNet would like to underscore once more that it highly appreciates the courtesy of the SNSF's council in granting the position of a national coordinator PedNet. This decision has boosted SwissPedNet's dedication and efforts in establishing itself. SwissPedNet is, more than ever, convinced that pediatric clinical research needs a national platform to be successful and internationally competitive. The pediatric population ranging from premature babies to adolescents can neither be treated nor investigated within the adult medicine settings lacking specialized personnel and infrastructures. Moreover, it is globally recognized, that the pediatric population is a population with special legal and ethical needs. Indeed, the *Paediatric Regulation* came into force in the European Union in 2007. There is a specific ICH Guideline for clinical investigation of medicinal products in the pediatric population, and within national law, Art. 21 to 24 of the law on human research demand special requirements for research in children and adolescents. The fulfillment of these requirements is not yet accordingly established in Switzerland. Thus, to comply with above regulations, a pediatric-specific platform matching the research efforts in adult medicine is important.

A position to take over the coordinative role for the non-operative tasks within pediatric clinical research must be available. The tasks of this position include acting as a hub for the pediatric networks, facilitating the interactions with industry and cooperative groups, also from abroad, assisting pediatric-specific linking to neighboring networks on a national and international level, helping to raise political awareness for the need for research in pediatrics, organizing symposia, care for pediatric specific quality standards, etc. Thus, the activities of this coordinative position are essential to build up and maintain a functionally efficacious SwissPedNet.

SwissPedNet thanks the research council of the SNSF for supporting the efforts to substantially enhance clinical research in pediatrics in Switzerland and its quality and international recognition, both by supporting pediatric clinician scientists to foster their commitment to high-quality clinical research as well as by encouraging an overall increased acceptance of trials in children in the Swiss scientific and lay community.

Prof. Dr. med. David Nadal
President SwissPedNet

Prof. Dr. med. Urs Frey
Vice president SwissPedNet

People of SwissPedNet

Members of the Board

- President: Prof. Dr. med. David Nadal, University Children's Hospital Zurich
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- Assessors: Prof Dr. med. Christa Flück, University Children's Hospital Bern
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Auditors

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National Coordinator PedNet

Pascale Wenger, SCTO

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