



Swiss Research Network of
Clinical Pediatric Hubs



Annual Report September 2013 to December 2014

SwissPedNet

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Editorial

SwissPedNet already celebrated its 2nd anniversary. In 2012 pediatricians of the five university children's hospitals (Basel, Bern, Geneva, Lausanne and Zurich) and of the three children's hospitals of Aarau, Luzern and St. Gallen created enthusiastically SwissPedNet, the Swiss research network of clinical pediatric hubs.

The task of the network is to promote, facilitate, coordinate, and conduct clinical trials devoted to children ranging from newborns to adolescents, in all pediatric disciplines. The ultimate goal is to enhance clinical research in pediatrics both by supporting pediatric clinician scientists to foster their commitment to high-quality clinical research and by encouraging an overall increased acceptance in the community of trials in children.

A key issue during this 2nd year of existence was seeking funding for the research infrastructure for pediatrics. Properly staffed clinical pediatric hubs will guarantee the quality aspects of research in children through age-adequate infrastructures, pediatrics-trained personnel, and a joining Quality Management System (QMS), i.e. same pediatric-specific guidance documents (SOPs) to facilitate the conduct of multi-center studies and communication between the individual hubs. The possibilities to receive basic financing with the coming funding period (2017 to 2020) have been exploited. SwissPedNet is hopefully on its way to become part of the *Swiss Research Infrastructures Roadmap*.

A notable contribution in our endeavors came from Bern: the clinical pediatric hub at the university children's hospital Bern established PedNet Bern. With funds from their home institution they started with a study doctor and a study nurse with beginning of 2014. Bern now joins former own initiatives like in Geneva (*Plateforme de Recherche Clinique*) and in Zurich (*Forschungszentrum für das Kind*). We hope PedNet Bern motivates the other hubs in proceeding creating research infrastructures, as all these efforts will help the pediatric investigators in Switzerland to conduct their studies state of the art and with support of study nurses.

However, there is a remarkable pediatric research activity in Switzerland and the collaboration between the clinical pediatric hubs is carried out. The 2nd edition of the SwissPedNet Clinical Research Session gave an interesting insight in current studies and projects conducted in our Swiss (university) children's hospitals.

The future will bring us even more research projects and pediatric clinical drug trials. Indeed, Johannes van den Anker joined the university children's hospital Basel appointed for the position of the *Eckenstein-Geigy* professorship for pediatric pharmacology. The chair in pediatric pharmacology at the University of Basel is unique in Switzerland and rare in Europe, it fulfills a pioneer task in Switzerland and large part of Europe. SwissPedNet is the ideal partner to succeed with the intended close collaboration of all Swiss universities and bring together all pediatric clinics. We are highly motivated to participate and collaborate in pediatric pharmacology and have the pediatric research infrastructure in place for all these coming clinical studies. This is also witnessed by the application SwissPedPhaTec to the *Swiss Research Infrastructures Roadmap*. SwissPedPhaTec is a joint effort of the university children's hospitals of Basel and Zurich, the University Hospital of Basel and the Kinder- und Jugendpsychiatrischer Dienst Zürich in creating a platform for innovative pediatric pharmacology technology.

Networks are essential to cope with the challenges in pediatric research. SwissPedNet fills in the gap within Switzerland and has already established international collaborations, as the pediatric

population with their rare diseases is small. Proper research infrastructure within the children's hospitals is crucial for competitive and reliable study conduct in and with children. In Switzerland, the initiators of SwissPedNet set the course for the future nationally and internationally.

I thank all contributors for their collaboration and support in our efforts to reach the aim of evidence-based medicine also for our children.



Prof David Nadal
President SwissPedNet

SwissPedNet milestones according to the application to the SNSF in 2012

The milestones have been defined under the assumption, that the clinical pediatric hubs receive basic financing from the universities. As only the Swiss National Science Foundation SNSF granted the position of a national coordinator and the hubs could not be appropriately established, some of the milestones remain unaccomplished or are still ongoing:

1st year

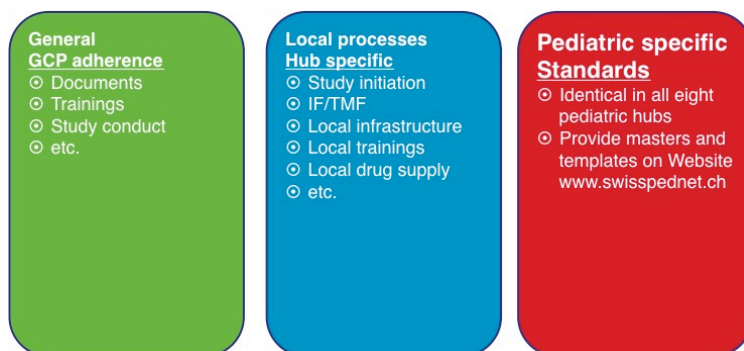
- Establishment of pediatric SOPs according to Swiss Clinical Trial Organisation (SCTO) guidelines
- ✓ Establishment of communication and network structures, branding
- ✓ Establishing meetings and a coordinated central trial registration tool
- ✓ Crosslink to Enpr-EMA and Swissmedic, relevant stake holders
- Adaptation of quality guidelines according to final HFG
- Establishment of an international scientific advisory board
- ✓ Establishment of first pediatric-specific GCP course

2nd year

- ✓ Validation of structures based on running a small multi-center trial
- ✓ Optimization of the structures and processes
- Adaptation of quality guidelines according to final HFG
- Establishment of specific work groups (ethics, registries etc.)
- ✓ Forums, public relations, international contacts for future trials
- Initiation of first national multi-center trial
- ✓ Coordinate (Hub) pediatric experts for pediatric clinical trials
- Develop a clear financial structure and calculation tools for external /industrial trials

Quality Management System QMS

The concept of the Clinical Pediatric Hubs' QMS is defined: we envisage a three pillar QMS.



For general GCP adherence we seek for a collaboration agreement between the local CTUs and the pediatric hubs.

SwissPedNet actively works on pillar 2 and 3, still in collaboration with the SCTO Quality Assurance Working Group.

International Advisory Board

The SwissPedNet Board considered the establishment of an international (scientific) advisory board. Depending on the development of SwissPedNet it has to be clarified, if SwissPedNet needs a "scientific board", who will review the study activity, give advise for study programs, etc. or if a board observing the structure and processes of SwissPedNet would be more adequate.

SwissPedNet strives to become the facilitator of pediatric clinical research, but will not become responsible for the research focus. SwissPedNet might also consider having people from patient/parent organizations in the board. However, tasks and duties of the advisory board must be defined prior to look for potential members.

The General Assembly decided to install an international / national advisory board (see below).

Establishment of specific work groups (ethics, registries etc.)

SwissPedNet decided to initiate an ethics research project under the lead of ethicists and with patients and parents from the children's hospitals. It will be a joint project of ethicists from the five universities under the lead of Prof Brigitte Tag from the "Kompetenzzentrum Medizin - Ethik - Recht Helvetiae" from the University Zurich (<http://www.merh.uzh.ch/index.html>). It is scheduled for 2015.

The study will create a solid base for the understanding "what means ethic" and provide standards to e.g. ethics committees, how to evaluate pediatric studies.

According to the application submitted on January 23, 2014 to the SNSF and SERI (see below), the research infrastructure for pediatrics will include a central infrastructure for registries at the ISPM Bern. The Child and Adolescent Health Research Group at the ISPM Bern already coordinates, together with the relevant organ specialists, several national pediatric registries and cohort studies. This includes the Swiss Childhood Cancer Registry (with Pediatric Oncologists), the Swiss Growth Registry (with Pediatric Endocrinologists), the Swiss Pediatric Renal Registry (with Pediatric Nephrologists), the Swiss Primary Ciliary Dyskinesia Registry (with Pediatric Pulmonologists), the Swiss Congenital Heart Disease Cohort (with Pediatric Cardiologists) and the Swiss Registry for Rare Diseases (with several pediatric subspecialties).

Initiation of first national multi-center trial and study activity in Switzerland

SwissPedNet provides the framework for study conduct in Switzerland. Sponsor responsibility remains always with the investigator and his / her home institution.

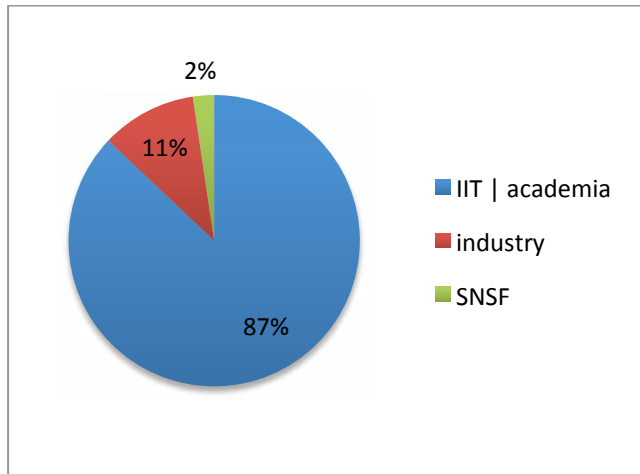
SwissPedNet made a survey within the clinical pediatric hubs to collect the on-going pediatric multi-center studies in Switzerland. The data has been collected during August to December 2014.

Completeness of the data is not guaranteed.

Studies from the Swiss Paediatric Oncology Group SPOG are not part of this survey as SPOG has a well-organized study activity and receives core-funding. The SPOG studies are reported in the annual report of SPOG.

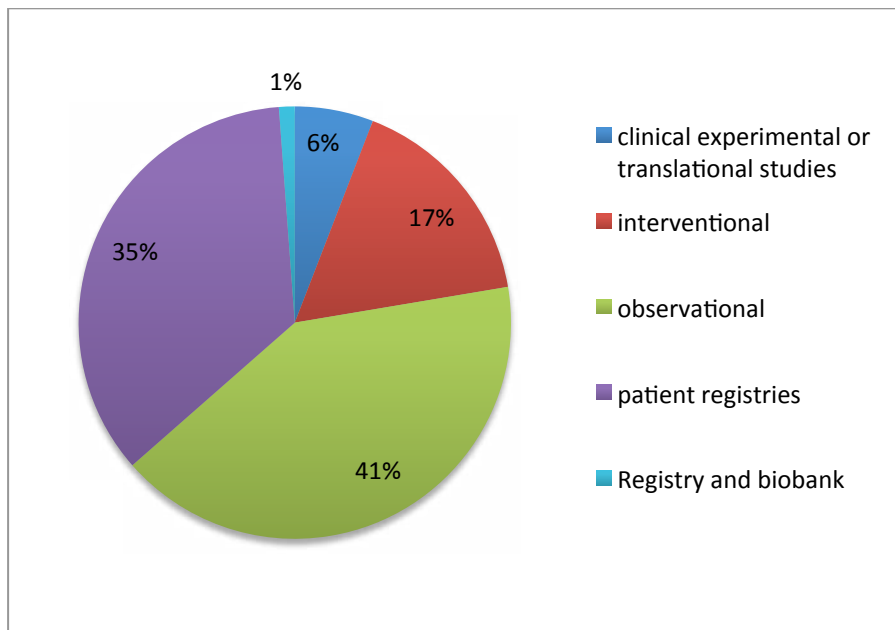
As per 23.12.2014 85 pediatric multi-center studies are open in Switzerland¹. The following figures show type of sponsor, study type, and the pediatric specialties with open studies.

Type of sponsor: Industry study versus investigator initiated trials (IITs | academia) (n=85)



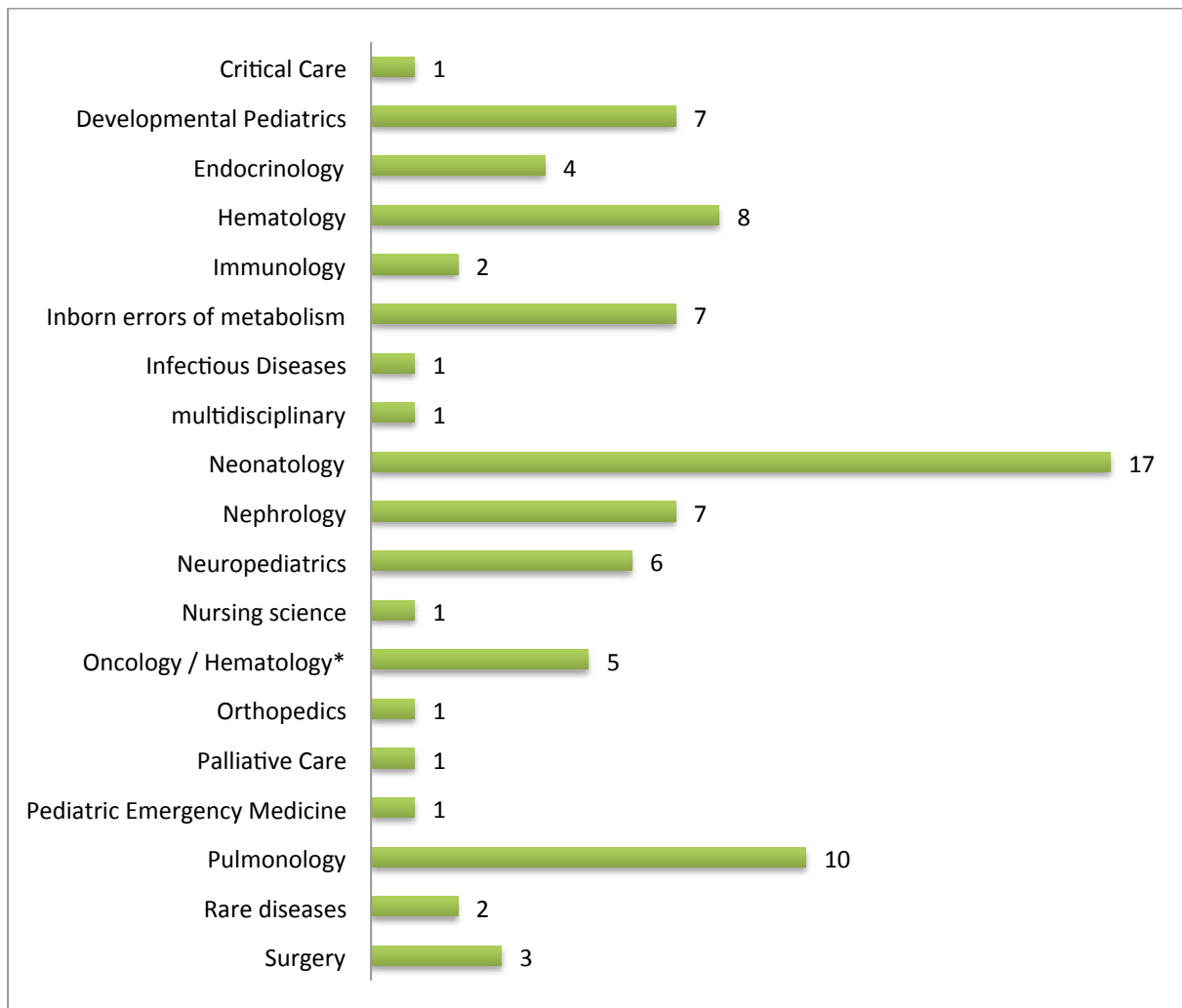
The 2% SNSF studies are also IITs, but the source of funding has been declared as “SNSF study”. Probably more IITs listed here are funded by the SNSF.

The following study types can be distinguished between the multi-center studies (n=85):



¹ Collection of all open Swiss pediatric studies with > 1 study site. SwissPedNet, 23.12.2014, data on file.

Pediatric specialties performing multi-center studies (n=85):



* without studies from the Swiss Paediatric Oncology Group SPOG

The main part of the research activity of the Swiss pediatricians lies within the realm of non-interventional epidemiological studies and the establishment of registries. To increase the number of interventional studies and studies with IMPs a proper research infrastructure as applied for is highly needed.

SwissPedNet Activities and Highlights 2014

General Assembly 2013

The open part of the first general assembly was dedicated to networking, finding synergies with existing research groups in Switzerland and abroad and with the pharmaceutical industry.

The SwissPedNet guests, the Swiss Society of Neonatology / Swiss Neonet, Prof Hans Ulrich Bucher, president, Dr Mark Adams, research fellow, the Swiss Paediatric Oncology Group SPOG, Prof Felix Niggli, president and the Medicine for children Research Network, Netherland (MCRN NL), Saskia De Wildt, MD, PhD and Managing Director, and Dr Daniela Gunz from MSD, gave very interesting insights into their work.

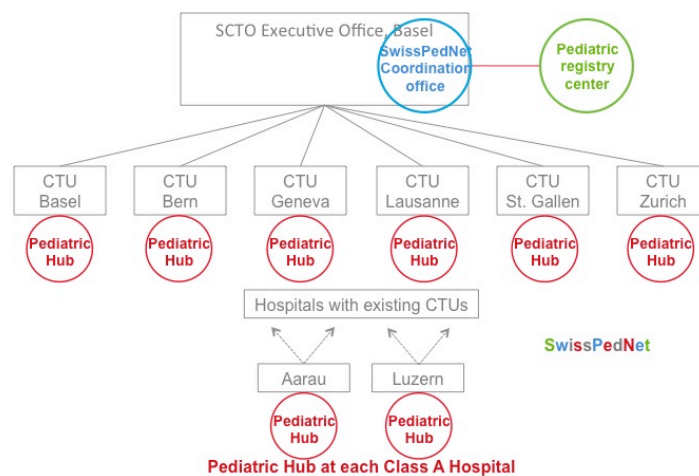
During lively discussions synergies and potential collaborations between these associations, pharmaceutical industry and SwissPedNet have been raised and will be followed.

Call for applications for new research infrastructures (RI) of national relevance (SERI/SNSF)

Aim of the call: Update and renewal of the Swiss roadmap for research infrastructures of national relevance for 2017 – 2020.

SwissPedNet meets the criteria of particular importance and applied and introduced the clinical pediatric hubs as new RI within the Swiss roadmap for RIs of national relevance.

The application submitted applied for the following RI “SwissPedNet”:



Applicant: Consortium of all 5 universities, co-applicants: the 3 cantonal children’s hospitals.

On a national level, there is the SwissPedNet coordination office established within the executive office of the SCTO and the central infrastructure for registries at the ISPM Bern.

On a local level, there will be Clinical Pediatric Hubs within the children’s hospitals or clinics. These hubs will be closely linked to the existing CTUs; only pediatric-specific tasks are developed and maintained. Research staff, i.e. a study coordinator and pediatric study nurse will be employed by the children’s hospitals.

The application’s content has also been transferred into the mandate the State Secretariat for Education, Research and Innovation (SERI) issued to the SCTO and SwissPedNet.

The SNSF evaluated SwissPedNet as a network, which extensively collaborates with and is coordinated by the SCTO and its CTU network. The SNSF strongly supports this nation-wide platform with a truly science enabling and cross-disciplinary approach. SwissPedNet being an integral part of the SCTO/CTU structure will benefit from SERI funds directly.

Clinical Pediatric Hubs



PEDNET BERN is the new service platform for clinical research in children and for children within the university children’s hospital Bern. It is part of SwissPedNet, one of the eight clinical pediatric hubs. On May 21, 2014 PedNet Bern celebrated its opening after start up in January 2014 with their kick off meeting.

A study doctor and a study nurse care for the research projects within the children's hospital. PedNet Bern is contact-point for all investigators and the coordinator SwissPedNet.

Collaboration with the Chair Pediatric Pharmacology at the University of Basel and SwissPaedPhaTec located at the University children's hospitals Basel and Zurich

SwissPedNet is the ideal partner for the Swiss chair of pediatric pharmacology located at the University of Basel to succeed with the intended close collaboration of all Swiss universities and bring together all pediatric clinics.

A first project has already been realized with the joint application to the *Gebert RUF* call on August 8, 2014 with the project proposal "Novel pharmacometric and omics-based approach to improve the care of children and adults with Fabry nephropathy".

SwissPedNet and scienceindustries

Two meetings took place between SwissPedNet and the clinical research group of scienceindustries. Discussions about best practice of collaboration and reimbursement for feasibility checks have been raised. Scienceindustries welcomes the contact-point for questions regarding pediatric trials. During 2014, SwissPedNet answered to seven feasibility assessments from pharmaceutical industry.

In close collaboration with SwissPedNet AbbVie has chosen three Swiss study sites for an international epidemiological study. The Swiss study sites contributed with 110 patients from a total of nearly 2000 patients. The cooperation was very productive and helpful for both sides.

SwissPedNet Clinical Research Session

SwissPedNet organized the 2nd edition of the SwissPedNet Clinical Research Session on June 12, 2014 during the fPmh congress in Basel. After submitting their studies and research projects to the judging panel, 14 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 (Henrik Köhler, Aarau; Claudia Kühni, Bern; Dagmar L'Allemand-Jander, St. Gallen; Christina Stadler, Basel; Andrea Superti-Furga, Lausanne) also evaluated the performance and the following discussion of the young researchers.

Winners of the SwissPedNet Clinical Research Award 2014 are

- *Sophie Böttcher-Haberzeth* from the University children's hospital Zurich for her basic research project „Pigmented dermo-epidermal skin substitutes in a long-term in vivo assay“ and
- *Ines Mack* from the University children's hospital Basel for presenting her prospective study on the impact of biometric and environmental co-factors on human rhinovirus infections in healthy infants.

AbbVie, Bayer HealthCare and MSD have jointly sponsored the SwissPedNet Clinical Research Award of total CHF 3000.-.

Platform for (pediatric) study nurses and study coordinators

SwissPedNet supports the pediatric study nurses to have a platform for mutual exchange. Study nurses of the SwissPedNet member hospitals and clinics organize a national study nurse meeting, it is scheduled for first quarter of 2015 and will be located in Bern.

The SCTO supports this event as long as it will not remain population specific and all study nurses and study coordinators will be invited. The initiators, i.e. the pediatric study nurses will open their platform and spread all information available with all their colleagues.

Enpr-EMA

SwissPedNet is member of Enpr-EMA and participated at the 6th Enpr-EMA workshop held in June 2014.

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/2014/03/event_detail_000930.jsp&mid=WC0b01ac058004d5c3

SwissPedNet, so far, is not yet involved in a working group, but would volunteer when there comes a possibility to join in.

In first quarter of 2015, SwissPedNet will update the self-assessment form and send it for re-evaluation to the coordinating group. An upgrade to category 2 membership can be expected.

General Assembly 2014

The General Assembly (GA) was held on November 25, 2014.

The GA decided to build an international / national advisory board. For the time being, their main task will be evaluating the SwissPedNet annual report, judge about the activities, and support/advise the annual planning. The following persons will be contacted: Martin Offringa (CAN), Mark Turner (UK), Saskia de Wildt (NL), a representative of scienceindustries (CH), Johannes van den Anker (CH, pharmacologist).

Regarding the SwissPedNet "Survey of on-going multi-center studies in Switzerland" in 2014 the GA decided to prepare a publication for Swiss Medical Weekly.

Again SwissPedNet organized an open part of their General Assembly. The afternoon was dedicated to information exchange regarding Quality Management Systems and international connection, which are of interest also for our partner organizations like SPOG, Swiss Neonet, SwissPaedPhaTec.

Prof Martin Offringa, Toronto, was connected (web-based conference) and gave us insight to the activities of StaR Child Health (a group of methodologists, clinicians and policy makers who seek to enhance the quality, ethics and reliability of pediatric clinical research by promoting the use of evidence-based standards or guidance for clinical studies with children). His presentation was followed by a discussion of potential contribution of SwissPedNet / Swiss researchers (what can StaR Child Health do for SwissPedNet and what can SwissPedNet do for StaR Child Health).

Dr Mark Turner, University of Liverpool and chair of the coordinating group of Enpr-EMA (the European Network of Paediatric Research at the European Medicines Agency) was present in person. The attendees received first hand information about their work, an update about global pediatric clinical research networks, and the requirements to be fulfilled to become a full Enpr-EMA member. The presentation was followed by a discussion about Swiss contribution.

SwissPedNet - an integral part of the SCTO/CTU structure

As SwissPedNet being now an integral part of the SCTO/CTU structure, SwissPedNet has been invited to join the steering board of the SCTO. According to the current SCTO bylaws, the steering board comprises of exclusively representatives of the founding institutions, i.e. the Swiss Academy of Medical Sciences SAMS, the university hospitals Basel, Bern, Geneva, Lausanne and Zurich, the cantonal hospital St. Gallen and the Collège des Doyens. SwissPedNet will join the board as assessor from now on.

The GA assigned David Nadal as SwissPedNet representative, and as his deputy Andrea Superti-Furga.

Public awareness

Website

With the beginning of 2014, German and French translations of the SwissPedNet website have been made available online.

SwissPedNet Booth at the fPmh congress

During the fPmh congress in Basel on June 12 and 13, 2014 SwissPedNet presented itself with a booth to enhance its recognition among the pediatricians. It was a joint presence with Swiss Neonet and SPOG.

Publications in Paediatrica

SwissPedNet is in negotiations with Paediatrica to receive a constant column to spread their news.

Publication in Swiss Medical Weekly

Swiss Medical Weekly published a review article on 25.9.2014:

Research dedicated to children: SwissPedNet with its international links overcomes key barriers to proper research in paediatrics. ([Swiss Med Wkly. 2014;144:w14006](#)).

Acknowledgment

Thanks to the Swiss Academy of Medical Sciences SAMS SwissPedNet has a necessary solid financial basis at its disposal, as SAMS supported the endeavors of SwissPedNet with a significant amount of seed money in 2014.

Already for the second time Pfizer AG awarded SwissPedNet with a generous educational grant. This grant allowed us to hold a retreat and make some strategic decisions. To intensify our international liaison with Enpr-EMA the grant allowed us to participate at the 6th Enpr-EMA workshop held in

London in June 2014 and to invite Mark Turner, chair of the coordinating group of Enpr-EMA, as guest speakers to our GA. Beside this, we need the money for the hosting and maintenance of the website.

Next steps

SwissPedNet follows up on the milestones as described in the initial application to the SNSF in 2012. Coming into the third year of existence this will include 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

For collaborations with foreign sponsors Swiss law asks for a legal representative with seat in Switzerland. Universities and University hospitals do not take over this task with the result, that some studies could not be conducted in Switzerland. This problem is not typical for pediatrics, but it becomes a major concern, as pediatric research and its rare diseases and small population depend on multi-national research. Therefore, SwissPedNet will strive for a solution of this problem, but will also rely on the endeavors in this respect of the SCTO.

Annual Financial Statement

Accounts 1.10.2013 to 30.9.2014 and Balance sheet as per 30.9.2014

1. Income	CHF
Membership fees	4'000.00
SAMS seed money	100'000.00
Educational Grant Pfizer	10'800.00
Sponsoring	3'000.00
Coordination PONI study	1'540.00
Postfinance credit interest	0.95
<i>Total income:</i>	<u><u>119'340.95</u></u>

2. Expenses	CHF
GA 2013 - Guest speaker Saskia de Wildt	690.09
Website Hosting	648.00
Website Maintenance	305.90
Logo SwissPedNet/Hubs	3'456.00
Booth at the fPmh congress, 12./13.6.2014	529.47
Award SwissPedNet Clinical Research Session	3'000.00
SwissPedNet Strategy Meeting 2.7.14	315.00
6th EnprEMA workshop - participation PW (flight/hotel)	375.83
Postfinance account management	40.00
<i>Total expenses:</i>	<u><u>9'360.29</u></u>

Total income:	119'340.95
Total expenses:	<u>9'360.29</u>
<i>Total profit margin:</i>	<u><u>109'980.66</u></u>

3. Balance as per 30.9.2014	Assets	Liabilities
Account balance PC 60-488628-5	113'798.96	
Deferred charges	0.00	
Capital of the association		113'798.96
	<u>113'798.96</u>	<u>113'798.96</u>

4. Association assets	CHF
Asset as per 30.09.2013	3'818.30
Asset as per 30.09.2014	<u>113'798.96</u>
<i>Growth in assets:</i>	<u><u>109'980.66</u></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

Coordinator SwissPedNet

Pascale Wenger, Swiss Clinical Trial Organisation SCTO

The contact persons for SwissPedNet within the pediatric hospitals or clinics

- Prof Matthias Baumgartner, University Children's Hospital Zurich
- PD Dr Jürg Barben, Children's Hospital of Eastern Switzerland, St. Gallen
- Dr Manuel Diezi, University Children's Hospital Lausanne
- Prof Christa Flück, University Children's Hospital Bern
- Prof Urs Frey, University Children's Hospital Basel
- Prof Ulrich Heininger, University Children's Hospital Basel
- Prof Henrik Köhler, Children's Hospital Aarau
- Prof Claudia Kühni, ISPM, University of Bern
- Prof Dagmar L'Allemand-Jander, Children's Hospital of Eastern Switzerland, St. Gallen
- Prof David Nadal, University Children's Hospital Zurich
- PD Dr Klara Posfay Barbe, University Children's Hospital Geneva
- PD Dr Johannes Rischewski, Children's Hospital Luzern
- Prof Claire-Anne Siegrist-Juillard, University Children's Hospital Geneva
- Prof Andrea Superti-Furga, University Children's Hospital Lausanne