

Brighton Collaboration Foundation Basel

Report of the statutory auditors to the Board on the financial statements 2013



Report of the statutory auditors on the limited statutory examination to the Board of Brighton Collaboration Foundation Basel

As statutory auditors, we have examined the financial statements of Brighton Collaboration Foundation, which comprise the income statement, balance sheet, statement of changes in equity, cash flow statement and notes (pages 16 to 23), for the year ended 31 December 2013. As permitted by Swiss GAAP FER 21 the information in the performance report (pages 1 to 15) is not required to be subject to the statutory auditors' examination.

These financial statements in accordance with Swiss GAAP FER 21 are the responsibility of the Board. Our responsibility is to perform a limited statutory examination on these financial statements. We confirm that we meet the licensing and independence requirements as stipulated by Swiss law.

We conducted our examination in accordance with the Swiss Standard on Limited Statutory Examination. This standard requires that we plan and perform a limited statutory examination to identify material misstatements in the financial statements. A limited statutory examination consists primarily of inquiries of foundation personnel and analytical procedures as well as detailed tests of foundation documents as considered appropriate in the circumstances. However, the testing of the operational processes and the internal control system, as well as inquiries and further testing procedures to detect fraud or other legal violations, are not within the scope of this examination.

Based on our limited statutory examination, nothing has come to our attention that causes us to believe that the financial statements do not give a true and fair view of the financial position, the results of operations and the cash flows in accordance with Swiss GAAP FER 21. Furthermore, nothing has come to our attention that causes us to believe that the financial statements do not comply with Swiss law and the foundation's deed.



PricewaterhouseCoopers AG

Dr. Rodolfo Gerber

Sandro Hirzel

Audit expert Auditor in charge

Münchenstein, 21 March 2014

Enclosure:

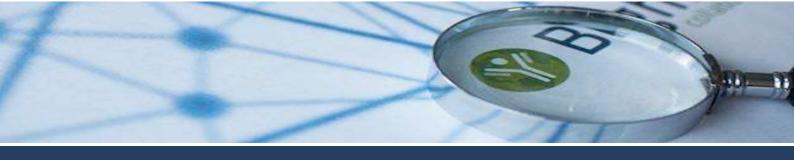
 Financial statements (income statement, balance sheet, statement of changes in equity, cash flow statement and notes)



Annual Report 2013 SWISS GAAP FER



Of the Brighton Collaboration Foundation



A WORD FROM THE PRESIDENT



The Brighton Collaboration is about building trust in the safety of vaccines through rigorous science. As immunization programs mature globally and the investigation of vaccine safety concerns requires globally concerted analysis and response, the need for collaborative approaches, international standards and guidance, and shared infrastructure have never been greater. This is what Brighton Collaboration partners are committed to address and what the Foundation has been dedicated to support for over a decade now.

Scientific innovations for building trust in the safety of vaccines have characterized 2013 more than anything. For example, Brighton Collaboration partners focused on developing novel

research standards including template safety elements for clinical trial protocols and a reference set of positive and negative vaccine-adverse event associations for performance testing of signal detection methods and functional evaluation of active and passive surveillance systems. Further, new methodological approaches to ascertain vaccine exposure and verify cases of adverse events during immunization campaigns in low and medium income countries (LMIC) were developed to enable large population based studies in these settings. Brighton Collaboration partners piloted an international collaborative feasibility study in LMIC based on a shared protocol and common web-based research infrastructure in Ghana, Kenya, and Mozambique and demonstrated promising interim results. Moreover, new strategies for monitoring public confidence in vaccines administered in LMIC were created. An approach to utilizing social media in this setting was created and methods for automated public confidence monitoring of electronic media monitoring based on text mining and computer learning algorithms are being established.

At the Foundation we also continued to build analytic capacity by widening the global network of health care databases useful for observational studies and by offering structured training. Certainly a highlight was the launch of CAFÉ, the Clinical Advisory Forum of Experts and an information exchange mechanism for Brighton Collaboration partners for real time discussion of cases with adverse events and related vaccine safety questions. This enables rapid global support for local safety questions and stimulates collaborative approaches. The Vaccine Safety Journal Club is another mechanism allowing for collaborative scientific exchange on vaccine safety hot topics, which was provided in collaboration with Elsevier at its online platform VaccineOrb.

Unwarranted and legitimate emerging vaccine safety concerns alike are best addressed with scientifically valid systems in place to define, detect, analyze and communicate accurate information on adverse events following immunization (AEFI). This is where the Brighton Collaboration comes in. The Brighton Collaboration is the world's largest network of vaccine safety professionals and is unique in its capacity to leverage highly specific expertise and large data sources focusing on the investigation of vaccine safety concerns in developed countries as well as LMIC. I wish to express my heartfelt gratitude to all generous donors sharing the vision of the many scientists globally and supporting health and wellbeing of current and future populations. While the global safety requirements and challenges are increasing, inadequate funding prevents us from fully utilizing the Collaboration's capacity to coordinate our largely voluntary work and world-renowned technical resources to rapidly address unpredicted safety concerns requiring immediate investigation to maintain public confidence in vaccines with a favorable benefit-risk profile. To this end, the Foundation will focus on fundraising campaigns building the Global Immunization and Vaccine-Safety Endowment (GIVE) in 2014.

Telpho Z. Z

Jan Bonhoeffer, President
Brighton Collaboration Foundation



GLOSSARY

AEFI Adverse Event Following Immunization

BC Brighton Collaboration

CDC Centers for Disease Control and Prevention

EMIF European Medical Information Framework

EVI European Vaccine Initiative

FDA Food and Drug Administration

GBS Guillain-Barre Syndrome

GRiP Global Research in Pediatrics

GVSI Global Vaccine Safety Initiative

IMI Innovative Medicines Initiative

LMIC Low and Middle Income Countries

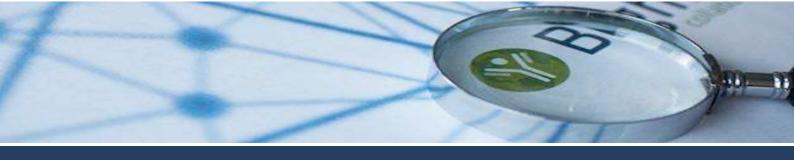
PREVENT Program Enhancing Vaccine Epidemiology Networks and Training

SOMNIA Systematic Observational Method for Narcolepsy and Influenza Immunization Assessment

VAERS Vaccine Adverse Event Reporting System

VAESCO Vaccine Adverse Event Surveillance and Communication

WHO World Health Organization



ORGANIZATIONAL FRAMEWORK

Our mission is to enhance the science of vaccine research by providing standardized, validated objective methods for monitoring safety profiles and benefit-risk ratios of vaccines.

NEED

The widespread elimination of formerly epidemic diseases has led to reduced concern about the threat of epidemics and heightened public concern about vaccine safety issues. Maintaining public confidence in vaccines requires provision of the best possible documentation of vaccine safety profiles and benefit-risk ratios and addressing the drivers of public distrust. Unwarranted and legitimate emerging vaccine safety concerns alike are best addressed with scientifically valid systems in place to rapidly detect, analyze and communicate accurate information on adverse events following immunization (AEFI) by identifying real safety issues and dispelling unwarranted concerns. The success of vaccines brings the responsibility to ensure that immunizations remain as safe as possible, particularly since they are given to healthy individuals.

THE BC FOUNDATION

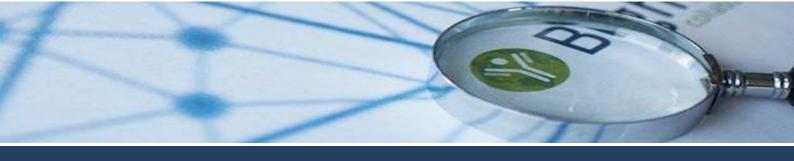
The Brighton Collaboration Foundation ("the Foundation") is an international non-profit organization addressing this need. It was founded by the University Children's Hospital Basel, Switzerland in November 2003 and is registered at the commercial register of the Kanton Basel City (CH- 270.7.002.873-2) as a tax-exempt public charity. The Foundation is governed by its Board of Directors and advised by its Scientific Advisory Committee. The Foundation does not advocate for specific vaccines and does not receive funding from individual manufacturers.

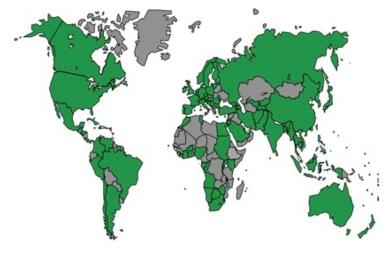
The Foundation's activities focus on its role within the Brighton Collaboration (BC) of which it is a constitutional partner and for which it serves as focal point, legal representative and administrative body. The Foundation provides and supervises the Management Team performing the day-to-day coordination of the BC and supporting the BC's Science Board. On the scientific level, the Management Team coordinates the voluntary activities of the BC. In addition, it negotiates grant agreements and service contracts on behalf of the BC and is directly involved in conduct and coordination of scientific projects.

THE NETWORK

The BC is the world's largest network of vaccine safety professionals. It is unique in its capacity to leverage highly specific expertise and large data sources focusing on the investigation of vaccine safety concerns. The BC includes professional individuals and legal entities from the following sectors:

- Regulatory authorities
- Public health service organizations
- Academic institutions
- Health care providers
- Vaccine manufacturers





The BC is a scientifically independent partnership. It comprises professional volunteers and organizational partners around the globe working towards the BC vision and mission. It is governed by its Science Board, administrated by the Foundation and advised by its Observers.

The Science Board sets research priorities, oversees the scientific progress, advises the Foundation, the participants, and promotes scientific rigor. Each member primarily advises on one of the following areas: Setting Standards, Clinical Assessment, Data Linkage, Capacity Building, and Public Confidence. For more than 10 years the BC and its Foundation has brought

together vaccine safety professionals and committed organizations from all over the world. The Science Board serves as the Foundation's Advisory Committee

REGIONAL CHAPTERS

BC projects have global scope. To reflect its success on an organizational level, a network of associated organizations is being built. The first associated organization is the Brighton Foundation US, Inc. The Foundation is registered in Newton Massachusetts, USA (EIN 45-3200301 and DUNS 8303 27321). The Brighton Foundation US, Inc. is a tax exempt charitable organization under section 501(c) (3) of the Internal Revenue Code, USA, established in August 2011.

The aim is to establish further regional foundations. They are to be self-dependent organizations that share the vision, mission and objectives of the BC and support them within a specified geographical region. They support the BC network in different ways — by collecting donations, organizing local events or projects and sharing high quality vaccine safety information. They also provide the volunteer community and potential partners and supporters with a point of contact capable of fulfilling specific local needs.

PARTNERING ORGANIZATIONS 2013

The Foundation has begun to establish organizational partnerships to leverage organizational synergies, by adding a network of organizations to the existing BC network. Memoranda of Understanding were concluded with the following organizations:

- Brighton Foundation US, Inc. Boston, USA
- Centers for Disease Control and Prevention (CDC), Atlanta, USA
- European Vaccine Initiative (EVI), Heidelberg, GER
- International Alliance for Biological Standardization (IABS), Geneva, Switzerland
- P95 Pharmacovigilance and Outcomes Research, Leuven, BEL
- VACCINE.GRID, Quantifying Vaccine Outcomes, Basel, CH



MAJOR COMPETITIVE GRANT RESEARCH PROJECTS 2013

GVSI: Global Vaccine Safety Initiative



This vaccine safety initiative of the World Health Organization (WHO) is implementing the Global Vaccine Safety Blueprint, the vaccine safety strategy of the Global Vaccine Action Plan (GVAP). The Foundation was instrumental in developing the Blueprint and is contributing to the implementation of the GVSI project portfolio.

GRIP: Global Research in Pediatrics





The Foundation is the partner promoting vaccine research in this European Commission Network of Excellence project. The Foundation is committed to improving medicines for children including vaccines by providing training and establishing global data networks for investigation for the safety and effectiveness of medicines for children.

EMIF: European Medical Information Framework



The Foundation is a partner in this project of the Innovative Medicines Initiative (IMI) establishing a European Medical Informatics Framework that will allow for secondary use of electronic health records and other data sources for medical research on cohorts. The Foundation is committed to promote utility of the platform for observational vaccine safety studies and creating synergies with other projects.

ADVANCE: Accelerated development of vaccine benefit-risk collaboration in Europe



The Foundation was instrumental in establishing the consortium and conceptualizing this project of the Innovative Medicines Initiative (IMI). As ADVANCE associate partner, the Foundation is committed to contributing to the development of shared research standards and resources for utilizing electronic health record data in Europe for the assessment of vaccine benefit/risk ratios.

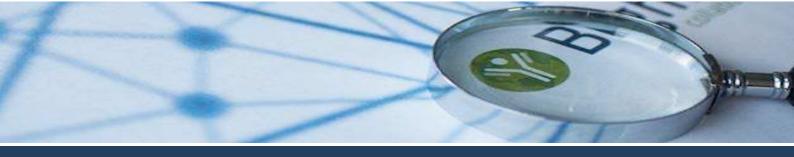
SOMNIA: Enhanced Evaluation of Risk of Narcolepsy Associated with Pandemrix™ and Arepanrix™



The Foundation responsed to the public consultation by the Center of Disease Control to quantify the risk of Narcolepsy following ASO3 and MF59 adjuvanted pandemic influenza vaccines (H1N1pdm09). Together with the University Cincinnati and Erasmus Medical Center a global research consortium, a unified research infrastructure and a shared protocol were established.

DONORS AND CONTRIBUTORS

In addition to our grant support, we receive contributions from donors including the Children's Hospital Basel, Switzerland and private donors. Donations become part of the the Foundation Global Vaccine Safety Fund, are used exclusively for the purpose of the Foundation and leverage the experience and capacity of professionals in the dynamic scientific community we serve.



SERVICES FOR A DYNAMIC SCIENTIFIC COMMUNITY

The Foundation maintains and supervises the BC's Management Team. As the field of vaccine safety research has grown, so has the BC and its Management Team.



Since 2003 the Management Team has been able to bring together vaccine safety professionals and committed organizations from all over the world. The Management Team works to attain the BC's mission and vision. It enhances the strategies of the Science Board by connecting outside partners and resources with BC scientists. The BC's Management Team is responsible for the operational implementation of the BC strategic plan. It provides services in the following three different areas to support the BC network and to achieve its mission:

- Effective and efficient Network
- Modern infrastructure and tools
- System resource and marketing management

EFFECTIVE AND EFFICIENT NETWORK

To facilitate knowledge transfer across different sectors, locations and professions, the Management Team supports the network by promoting coordination, disseminating information, providing training and supporting networking and acquisition of new projects in the area of vaccine benefit-risk evaluation.

KEY SERVICES AND PRODUCTS

- BC newsletter Vaccine Safety Quarterly (VSQ)
- BC literature forum Vaccine Safety Journal Club
- BC clinical forum Clinical Advisory Forum of Experts (CAFÉ)
- BC research forum Topic specific webinars, teleconferences
- BC training forum Workshops and fellowships
- BC investigator forum Consortium formation, grant writing, project coordination



MODERN INFRASTRUCTURE AND TOOLS

To bring together committed BC stakeholders and to facilitate efficient work together, the Management Team maintains the Foundation's online collaborative working environment with access to the products and services of the Collaboration.

KEY SERVICES AND PRODUCTS

PUBLIC INFORMATION AREA

- Information about the network and its Foundation
- Information about the products and services
- Access to tools and services to facilitate vaccine safety activities
- Registration as Partner of the Collaboration

ONLINE RESOURCE AREA

- Standardized case definitions of adverse events following immunization
- Guidelines for collection, analysis, and presentation of vaccine safety data
- Automatic Case Classification Tool (ABC tool)
- Template protocols for vaccine safety research
- Library of vaccine safety publications
- Links to high quality vaccine safety resources
- Vaccine Safety Quarterly newsletter

VIRTUAL WORKING AREA

- Opportunity to establish new work groups or participate in current ones
- Document sharing within a safe environment
- Access to "WHO's WHO" (Address database with more than 3000 participants, partners and associated stakeholders, in the area of vaccine safety research)

SYSTEM, RESOURCES AND MARKETING MANAGEMENT

The Management Team implements the BC's strategic priorities and maintains the organizational framework of the Collaboration and its Foundation. In addition, the Management Team assists the Foundation in establishing marketing strategies in general and fundraising activities in particular.



KEY SERVICES AND PRODUCTS

- Development and implementation of policies, procedures, and strategic plans
- Coordination and maintenance of the daily administrative work of the BC
- Support of the BC Boards to fulfill their respective functions
- Marketing and fundraising

ACCOMPLISHMENTS 2013

- The Foundation and the Management Team administer the involvement of the BC Foundation in 5 larger competitive grant projects as coordinator or contractual partner. This is a rewarding experience and allows the BCF and its partners to contribute directly to improving the science in the field.
- The Services provided by the BC Management Team were redefined and structured as outlined above to enhance the effectiveness and efficiency of collaborative action in the BC, to promote creation of innovative infrastructures and tools, and to optimize non-profit system resource and marketing management.
- The recent economic recession greatly diminished the availability of grant and charitable funding for most non-profits and NGOs across the globe. After experiencing a fiscal gap in grant funding sources ourselves we found it necessary to reduce the Management Team by 50%, but in 2013 we were able to partially re-stabilize the team with 3 part time positions bringing us up to 70% of our previous capacity. Admirably, our remaining Management Team was deeply dedicated to our mission and provided many volunteer hours to compensate for the constrained human resources.
- The Science Board Elections 2013 were held successfully. Four outstanding new members were elected into the Board (Kathy Edwards, Mike Gold, Barbara Law, Dan Salmon) and one was re-elected (Hector Izurieta).
- Several new tools to leverage network capacity and to create synergies between BC partners were developed and implemented. This includes the launch of CAFÉ, and the BC Journal Club on Elsevier's VaccineOrb.

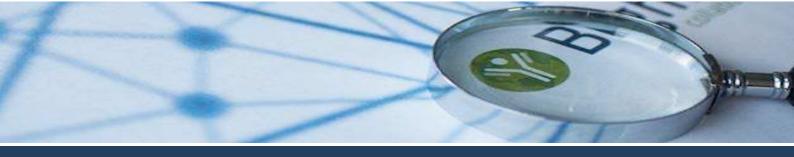
MAIN TARGETS 2014

Corporate fundraising with our associated US Foundation:

• The main managerial focus will be on building up the Global Vaccine Safety Fund comprised of two main elements. A reserve fund to ensure continuity of core staff funding for one year in the event of future fiscal gaps in grant fund sources. Second, the launch of an endowment fundraising campaign is launched to ensure sustained core management funding, including core staff salaries, equipment, supplies, transportation, and communication cost. This will ensure a sustainable, vigorous and excellent program of research based on competitive grants.

Expansion of the team of scientific coordinators

In the stabilized financial situation and the enlargement of the current project portfolio, we will be able to further stabilize and expand capacity of the Management Team to cover again the essential areas and ensure the advancement of the largely voluntary network and its mission. In a first step we aim to hire a second full time scientific research coordinator in the first quarter of the year.



Expansion of the Foundation Board

• We plan to expand our Board of Directors with specific expertise in marketing and fundraising in the first quarter of 2014.

New products FORUM and GUARD

- Thanks to a contribution of the Swiss Foundation "Irma Wigert Stiftung", Küsnacht ZH, Switzerland we have the opportunity to extend our platform with new tools FORUM and GUARD.
- The new electronic tool FORUM is primarily intended to complement the mailing list established for CAFÉ. With the generous contribution of the aforesaid foundation we are able to offer an extended web based tool on our Website which enables online discussion, archiving and summaries of worldwide inputs and information on adverse events following immunization (AEFI).
- With GUARD, a Global Unified Adverse Event Reference Database, we aim to establish a centralized, web-based information portal. It is intended to become a globally unique database that can be collaboratively maintained and used by specialists, doctors, and health authorities. Besides literature and publications, we will also provide output and outcome of our new tool FORUM.

THE BC'S SCIENTIFIC STRATEGIC PRIORITIES

A scientifically valid vaccine safety profile depends on high quality information. The entire process, from vaccine development to the actual administering of the vaccine, depends on best possible vaccine information. Everything the BC and its Foundation do is for the purpose of providing vaccine stakeholders with the best possible information so they can make the best possible decisions. The BC focuses on 5 Strategic Priorities:

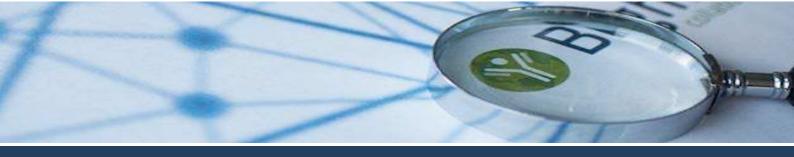


1. SETTING STANDARDS

Scientific Advisors:

Jim Buttery, Murdoch Children's Research Institute, Melbourne, AUS Barbara J. Law, Public Health Agency of Canada, Ottawa, Ontario, CAN (new since Nov. 2013)

Highly variable methodology in previous vaccine studies made valid comparison of vaccines' safety profiles difficult if not impossible. The BC addresses these issues with its expert network, to develop standardized and validated AEFI case definitions, guidance documents as well as template protocols for safety aspects of vaccine clinical trials and observational studies. Further, BC partners develop web tools making possible accurate, rapid and standardized classification of AEFI according to the standardized case definitions.



Accomplishments of BC Partners in 2013

- The case definition of Narcolepsy as an AEFI was published together with guidelines for data collection, analysis and publication.
- Evaluation studies of BC case definitions demonstrate their applicability in mature active and passive surveillance systems and provide an evidence base informing their cyclical revision.
- A template protocol for clinical trials investigating vaccines with focus on safety elements was published.
- A reference set of positive and negative associations between vaccines and adverse events was established for performance testing of signal detection methods
- Three viral vector vaccine templates are ready for review (Yellow Fever vaccine, Sendai and vesicular stomatitis vector

New Targets 2014

- Vasculitis case definition
- Online commenting and revision tool of case definitions and other harmonization documents
- Global Unified AEFI Reference Database (GUARD). A matrix of updated information about vaccines, AEFI and their associations.
- Assessment of current practice of signal work up
- Evaluation of case definitions in spontaneous reporting systems

2. CLINICAL ASSESSMENT

Scientific Advisors:

Paul Heath (rotated off), Najwa Khuri Bulos (rotated off)

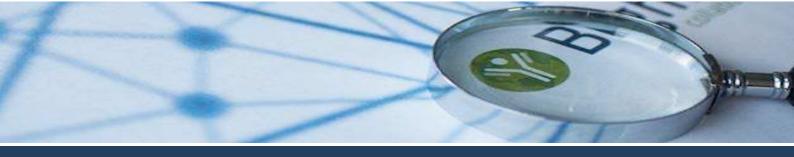
Kathryn M. Edwards, Vanderbilt University School of Medicine, Nashville, Tennessee, USA (new since Nov. 2013)

Michael S. Gold, Women's and Children's Health Network, Adelaide, AUS (new since Nov. 2013)

For individuals with AEFI, thorough assessment of their condition is paramount, not only for the management of the respective event, but also to advance the science of vaccine safety. At the BC we leverage a network of international experts to assist globally in exchanging information on such events and to help advance vaccine safety science.

Accomplishments of BC Partners in 2013

- The Clinical Advisory Forum of Experts (CAFÉ) was launched to enable real time discussion of individual cases with AEFI and related questions with the global network of partners.
- A pilot project demonstrated that algorithms for clinical work up of patients with AEFI can be developed based on the case definitions and facilitates their implementation



New Targets 2014

- Expansion of CAFÉ and creation of related online discussion forum
- Creation of additional clinical algorithms based on established process (e.g. encephalitis/myelitis/ADEM, aseptic meningitis) and review by the Brighton Collaboration partners
- Launch (global) network of immunization clinics using and evaluating Brighton case definitions.

3. DATA LINKAGE

Scientific Advisors:

Steve Black, Cincinnati Children's Hospital Medical Center, Cincinnati, USA Miriam Sturkenboom, Erasmus University Medical Center Rotterdam, Rotterdam, NED

Serious AEFI causally related to licensed vaccines are usually rare (<1:100,000). However, they become relatively prominent when millions of healthy persons are vaccinated and the target disease disappears. Their reliable detection and evaluation is important to provide the best care. The rarity of such events makes detection and analysis possible only through linkage of large digital databases across countries. BC partners have made this a working reality.

Accomplishments of BC Partners in 2013

- Results of narcolepsy incidence rates in Europe (VAESCO) and Global H1N1-GBS study published
- Global H1N1-Narcolepsy case control study (SOMNIA) expanded to include ASO3 and MF59 adjuvanted H1N1
- First results from technical pilot study in Africa (PREVENT) demonstrate feasibility and challenges
- Draft of global map of healthcare databases for monitoring drugs and vaccines for children

New Targets 2014

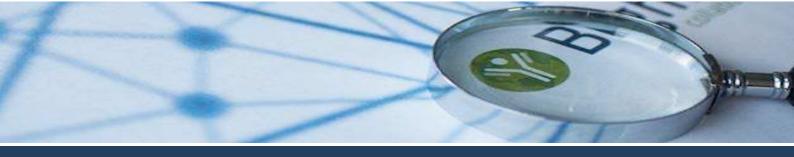
- Facilitate and support development of global collaborative investigations (GVSI, GRIP, PREVENT, PAHO)
- Provide Technical Advisory Groups for observational studies of AEFI of international interest and potential impact

4. CAPACITY BUILDING

Scientific Advisors:

Hector Izurieta, US Food and Drug Administration, Rockville, USA (re-elected)
Egeruan Babatunde Imoukhuede, Jenner Vaccine Institute, University of Oxford, Oxford UK

Expertise, state of the art scientific methods and competent infrastructures need to be developed to meet global needs, particularly in the developing world. This requires training in vaccine safety monitoring, methodology, data management, and public communications. Brighton is developing such material for use in the developing world.



Accomplishments of BC Partners in 2013

- Roadmap for the international collaborative epidemiologic monitoring of safety and effectiveness of new high priority vaccines published
- Development of training modules for vaccine pharmacoepdemiology launched
- Global inventory of electronic health care databases with pediatric data is launched
- Participation and contribution to strategic planning by the Global Vaccine Safety Initiative (GVSI) of the World Health Organization
- The Vaccine Safety Quarterly (VSQ) is established as an instrument for structured information sharing on developments in the field and awareness raising about partner projects?
- The Vaccine Safety Journal Club is inviting critical review and discussion of vaccine safety hot topics on Elsevier's VaccineOrb

New Targets 2014

- Create e-learning training materials and repository for virtual training modules
- Start structured translation program of case definitions

5. PUBLIC CONFIDENCE

Scientific Advisors:

Heidi Larson, The Vaccine Confidence Project London School of Hygiene and Tropical Medicine, London, UK Daniel Salmon, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA (new since Nov. 2013)

The importance of public confidence in vaccines is well established. Vaccine «scares» prompted by rumors, sensationalized media reports or flawed studies published in the scientific literature, have demonstrated that public mistrust of vaccine safety can seriously derail effective vaccination programs. Prompt investigation and management of adverse events following immunization (AEFI) has also shown to be critical to minimize public anxiety.

The BC is promoting research on the determinants of trust and distrust in vaccines generally as well as on the drivers of vaccine «scares», the manner in which they develop and spread, and effective strategies to best address vaccine safety concerns.

Accomplishments of BC Partners in 2013

 Study investigating the drivers of public concern around Pentavalent Vaccine and SIDS in Southern India is launched.

New Targets 2014

- Evaluate usefulness of different approaches to media surveillance in LMIC
- Support development of automated signal detection routines in media surveillance system
- Establish framework for measuring the impact of public concern on immunization programs



OPERATING REVIEW

GOVERNANCE FRAMEWORK

The BC Foundation is subject to the laws of Switzerland. It is directly supervised by the section of the Swiss Government assigned to Not-For-Profit Organizations. All powers of the Foundation are exercised by or under the authority of the Board of Directors. The Board is in charge of all powers not conferred to other executive bodies of the Foundation by its articles and by-laws. The first Board was appointed by the Founder to then constitute and complete itself. The Board of Directors currently consists of 6 members with voting rights. It elects a President, a Vice-President, and a Treasurer among its members as well as the other executive bodies: the Auditor and the Scientific Advisory Committee. The Board stands for the independence of the Foundation to promote high quality vaccine research, independent of vested interests. The Board works entirely voluntarily. The Scientific Advisory Committee advises the Board to realize the purpose of the Foundation. The external auditor reviews the financial reports of the organization and ensures compliance with Swiss legal requirements. Price Waterhouse Coopers was re-elected as the external auditor.

BOARD OF DIRECTORS

We thank Norbert Sommerfeld for his valued contributions to the Foundation Board until 2013. As per December 31, the Foundation Board comprised the following members:

Dr. Jan Bonhoeffer, University Children's Hospital Basel (UKBB), Switzerland, President

Dr. Thomas Mayer, Attorney, Basel, Switzerland, Vice-President

Prof. Ray Spier, Editor: Vaccine, London, England

MANAGEMENT TEAM

Dr. Jan Bonhoeffer, Executive Director

Dr. Yolanda Brauchli Pernus, Scientific Coordinator

Simone Casagrande Valli, MBA, Foundation Manager

Zizi Camarda, Finance and Project Assistant

SCIENTIFIC ADVISORY COMMITTEE

We thank Prof. Paul Heath, St. George's Vaccine Institute, University of London, London, UK and Prof. Najwa Khuri-Bulos, Jordan University Hospital, Amman, Jordan for their valued guidance until 2013. As per December 31.12.2013 the Committee comprised the following members:

Dr. Jim Buttery, Associate Professor, Monash Children's Hospital, Melbourne, AUS

Dr. Barbara J. Law, Public Health Agency of Canada, Ottawa, Ontario, CAN (new)

Dr. Kathryn M. Edwards, Vanderbilt University School of Medicine, Nashville, Tennessee, USA (new)

Dr. Michael S. Gold, Associate Professor, Women's and Children's Health Network, Adelaide, AUS (new)

Prof. Steve Black, Cincinnati Children's Hospital, Cincinnati USA

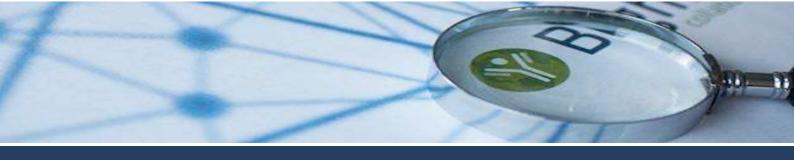
Prof. Miriam Sturkenboom, Erasmus Medical Center, Rotterdam, NED

Dr. Egeruan Babatunde Imoukhuede, Jenner Institute, University of Oxford, Oxford, UK

Dr. Hector Izurieta, Food and Drug Administration, Rockville, USA

Dr. Heidi Larson, London School of Hygiene & Tropical Medicine, London, UK

Dr. Daniel Salmon, Associate Professor, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA (new)



FINANCIAL REVIEW SWISS GAAP FER

OVERVIEW

The following financial statements of the Foundation have been prepared using Swiss Generally Accepted Accounting Principles (SWISS GAAP FER). These Swiss GAAP FER financial statements also comply with the requirements of Swiss law.

During the past financial year, the Foundation managed a contract portfolio equivalent to CHF 3'164'000. This portfolio consists of cost reimbursement contracts and grants. In 2013, CHF 707'394 of this portfolio was recognized as operating revenue to the extent of the project expenses incurred. No revenue was recognized before reimbursable activities had been conducted.

The Unrestricted Net Assets of the Foundation have increased by CHF 1'775. This amount will be credited to the foundation's existing accumulated net assets.

The contributions from 310 volunteering professionals were not recognized in the financial statements, because the hours worked by these professionals were not recorded or tracked.

Management views the current financial structure and financial position of the Foundation throughout 2014 as solid. Management will continue to enlarge its international scope with the view of achieving additional funding sources and research opportunities for the purpose of furthering world-wide vaccine safety.

Income Statement in CHF

Year Ended December 31, 2013 and 2012

<u>-</u>				Fi	unctional Expenses						
Changes in Unrestricted Net Assets:	Innovation & Development: Case Definitions& Protocols	Innovation & Development: New Methodologies	Innovation & Development: New Technologies	Data Production: Collaborative Studies:	Capacity Building: External, Linked Databases	Capacity Building: External, Other	Capacity Building: External, Training & Knowledge Transfer	Capacity Building: Internal, Organizational Infrastructure Development	Central Coordination:	2013 Total	2012 Total
Operating Revenues & Other support Research Contracts Unrestricted Donations Contributions in-Kind Speaker Fees & Awards Other Income Total Operating Revenues & Other support										707'394.41 CHF 65'542.68 CHF - CHF - CHF - CHF 772'937.09 CHF	294'780.45 CHF 150'475.00 CHF - CHF - CHF 46'134.17 CHF 491'389.62 CHF
Direct Costs of Operating Revenue Travel & 3rd Party Research Contracts Total Direct Costs of Operating Revenue										352'395.68 CHF 352'395.68 CHF	182'967.42 CHF 182'967.42 CHF
Net Assets Released from Restrictions: Satisfaction of Restricted Donations Total Assets Released from Restrictions										- CHF - CHF	- CHF
Total Unrestricted Net Earnings	41'707.60 CHF	54'742.07 CHF	- CHF	206'568.99 CHF	116'191.09 CHF	- CHF	1'331.66 CHF	- CHF		420'541.41 CHF	308'422.20 CHF
Operating Expenses: Personnel Expenses Salary Expenses Employee Insurance & Other Expenses Coordinating Expenses	25'544.18 CHF 4'138.77 CHF	33'527.25 CHF 5'432.21 CHF	- CHF - CHF	126'514.95 CHF 20'498.44 CHF	71'162.23 CHF 11'529.98 CHF	- CHF - CHF	815.59 CHF 132.14 CHF	- CHF - CHF		257'564.20 CHF 41'731.54 CHF	111'211.02 CHF 16'675.22 CHF
Office Expenses Governmental Charges Auditor & Consulting Fees Information Technology Marketing Expenses									5'974.10 CHF 564.70 CHF 72'318.15 CHF 37'763.25 CHF	5'974.10 CHF 564.70 CHF 72'318.15 CHF 37'763.25 CHF	9'007.85 CHF 1'550.00 CHF 80'122.75 CHF 16'639.63 CHF
Advertising & Advertising Materials Marketing, Communication Consulting & S Other Operating Expenses Donations & Contributions (Vaccine-Grid F		ollahoration Fundatio	nlis lisa)						1'315.00 CHF - CHF	1'315.00 CHF - CHF	1'464.75 CHF 3'396.10 CHF 66'382.60 CHF
Accumulated VAT & Interest Penalties	canadion, Brighton C								- CHF	- CHF	- CHF
Total Operating Expenses										417'230.94 CHF	306'449.92 CHF
Financial Result: Bank Charqes & Fees Interest Income Exchange rate gains (+) & losses (-) Total Financial Result:									-	743.35 CHF - 42.22 CHF - 834.18 CHF - 1'535.31 CHF -	439.70 CHF 13.85 CHF 9'182.90 CHF 9'636.45 CHF
Total Direct Costs & Expenses										771'161.93 CHF	499'053.79 CHF
- Decrease / + Increase in Unrestricted Net Asset	ts								_	1'775.16 CHF -	7'664.17 CHF

Balance Sheet and Statement of Changes in Equity in CHF As per December 31st, 2013 and 2012

		Ва	alance Sheet			
	31.12.2013	31.12.2012			31.12.2013	31.12.2012
ASSETS			LI	ABILITIES AND NET ASSETS		
Current Assets				Current Liabilities		
Cash & Cash Equivalents	309'923.30 CHF	41'402.55 CHF		Accounts Payable	385.50 CHF	32'194.61 CHF
Accounts Receivable	- CHF	44'907.40 CHF		Social Security Balances Payable	25'733.55 CHF	3'410.09 CHF
Accounts Receivable Founder		- CHF		Accrued Salaries (Balance Flexitime)	8'600.00 CHF	- CHF
Value Added Tax & Withholding Tax	4'261.40 CHF	10'766.60 CHF		Accrued Expenses	7'100.00 CHF	7'300.00 CHF
Accrued Revenues	46'930.00 CHF	92'756.00 CHF		Deferred Revenue	185'060.00 CHF	12'260.06 CHF
Prepaid Expenses	- CHF	- CHF		Accrued VAT & Interest Penalty Liability	- CHF	2'207.30 CHF
Total Current Assets	361'114.70 CHF	189'832.55 CHF		Non-Current Liabilities		
				Bank Loans/Contingencies	- CHF	- CHF
Non-Current Assets				Total Liabilities	226'879.05 CHF	57'372.06 CHF
Fixed Assets/Investments	- CHF	- CHF		Net Assets		
Total Non-Current Assets			Unrestricted	134'235.65 CHF	132'460.49 CHF	
				Temporarily Restricted	- CHF	- CHF
				Permanently Restricted	- CHF	- CHF
				Total Net Assets	134'235.65 CHF	132'460.49 CHF
Total Assets	361'114.70 CHF	189'832.55 CHF	To	etal Liabilities and Net Assets	361'114.70 CHF	189'832.55 CHF
				-		
STATEMENT OF CHANGES IN EQUITY						
	Previous Net	Revenues	Revenues			
	Assets	(internal)	(external)	Current Net Assets		
Net Assets		, ,	, , ,			
Unrestricted	132'460.49 CHF	- CHF CHF	1'775.16	134'235.65 CHF		
Temporarily Restricted	- CHF	- CHF	- CHF	- CHF		
Permanently Restricted	- CHF	- CHF	- CHF	- CHF		
Total Net Assets	132'460.49 CHF	- CHF CHF	1'775.16	134'235.65 CHF		
10tal 140t / 1330t3	132 400.43 CIII	Ciii Ciii	1 // 3.10	13-7 233.03 CITI		

Statement of Cash Flows in CHF

For the Year Ended December 31, 2013 and 2012

		31.12.2013	31.12.2012	
Cash Flows from Operating Activities:				
Change in Net Assets	CHF	1'775.16	CHF	(7'664.17)
Adjustments to Reconcile Change in Net Assets to Net Cash Provided by Operating Activities:				
(Increase) / Decrease in Accounts Receivable	CHF	51'412.60	CHF	69'092.33
(Increase) / Decrease in Accrued Revenues	CHF	45'826.00	CHF	(68'548.90)
(Increase) / Decrease in Prepaid expenses	CHF	-	CHF	2'175.31
Increase / (Decrease) in Deferred Revenues	CHF	172'799.94	CHF	(19'408.92)
Increase / (Decrease) in Accrued VAT & Interest Penalty Liability	CHF	(2'207.30)	CHF	(17'498.30)
Increase / (Decrease) in Acct's Payable & Accrued Expenses	CHF	(1'085.65)	CHF	(570'948.65)
Net Cash Provided by Operating Activities	CHF	268'520.75	CHF	(612'801.30)
Cash Flows from Investing Activities:				
Purchases of Property and Equipment	CHF	-	CHF	-
Net Cash Provided (Used) by Investing Activities	CHF	-	CHF	-
Cash Flows from Financing Activities:				
Decrease (Increase) in Loans Payable	CHF	-	CHF	-
Net Cash Provided (Used) by Financing Activities	CHF	-	CHF	-
Net Increase (Decrease) in Cash and Cash Equivalents	CHF	268'520.75	CHF	(612'801.30)
Cash and Cash Equivalents at beginning of Year	CHF	41'402.55	CHF	654'203.85
Cash and Cash Equivalents at End of Year	CHF	309'923.30	CHF	41'402.55
Non-Cash Related Activities:				
Contributions in-Kind	CHF	-	CHF	-

Notes to the Financial Statements of the Brighton Collaboration Foundation

1. ACCOUNTING STANDARDS AND LEGAL PLACE OF FULFILMENT

The Financial Statements of the Brighton Collaboration Foundation (the Foundation) comply with the Swiss Generally Accepted Accounting Principles for small non-profit organizations Swiss GAAP FER 21 and the applicable Swiss Laws for Non-Profit Organizations.

2 NATURE OF THE ORGANIZATION

The Foundation is a Not-For-Profit Organization which was established to protect and preserve public health by promoting a scientific basis for and quality of immunization safety assessment and monitoring. The Foundation promotes the development and availability of globally accepted, high quality scientific standards for research on and communication of data on immunization safety. The Foundation also conducts immunization safety research itself and supports such research projects. To achieve its goals the Foundation acquires contracts with renowned organizations who complete and monitor studies as applied for and assigned by international governing bodies within the health and welfare environment.

3. BASIS OF PRESENTATION

The accompanying income statement, statement of changes in equity, balance sheet and statement of cash flows of the Foundation are maintained on the accrual basis pursuant to the requirements of Swiss GAAP FER. Further to this, the Foundation reports information regarding its financial positions and activities according to three classes of equity: unrestricted equity, temporarily restricted equity, and permanently restricted equity. This approach is concurrent with that stipulated by Swiss GAAP FER 21, Accounting for Public and Social Not-For-Profit Organizations.

The Foundation considers unrestricted equity to be those assets or contributions donated without donor imposed restrictions or requirements as well as those with donor imposed restrictions where the funds are received and expended in the same year. This category also includes income generated by the Foundation through its operating activities, which is composed primarily of cost reimbursement research contracts and grants. Temporarily restricted and permanently restricted equity are those assets or contributions donated with donor imposed restrictions. Such restrictions could be, but are not limited to, designations for future periods and/or requirements of use only for specific purposes.

Current year operating revenues from grants and contracts are recognized according to the specific agreement. Generally the Foundation's operating activities result in an engagement in cost reimbursement contracts or grants. The revenues of such contracts or grants are recognized as operating revenue in the current year to the extent of the project expenses incurred. No revenue is recognized before reimbursable activities have been conducted. All current grants and contracts are subject to audit by the contracting party.

4. ACCOUNTING POLICIES

Significant accounting policies are comprised of the following:

- (a) **Cash and Cash Equivalents:** To this date this position only comprises current bank accounts as well as cash-on-hand. The Foundation however considers all highly liquid positions (excluding any positions related to restricted assets) with a maturity of three months or less when purchased to be cash equivalents.
- (b) **Accounts Receivable:** The receivables within the Foundations financial position do not include any allowance for uncollectible accounts. However, receivables are reviewed on a monthly basis. If it becomes evident that certain positions are uncollectable a provision for these positions would be recorded as an allowance for uncollectible accounts.
- (c) **Accrued Revenues:** Based on the accrual basis of accounting this position includes revenues against research projects for which management views the requirements of the contract as having been fulfilled, however the outstanding balance was not at the close of the financial statements yet forwarded to the Foundation.
- (d) **Fixed Assets:** The Foundation did not hold any such items at the close of the financial statements. Had the Foundation held such items it would depreciate these using a straight-line method at rates designed to amortize the cost of these assets over their estimated useful lives.
- (e) **Restricted & Temporarily Restricted Assets:** Note 3 defines the Foundation's understanding of restricted and temporarily restricted assets. At the close of the Financial Statements the Foundation did not hold any such assets.
- (f) **Accrued Expenses:** Based on the accrual basis of accounting this position includes expenses against research projects for which management views the requirements of the contract as having been fulfilled. However the bill for the outstanding balance was not at the close of the financial statements, yet received from the 3rd party.

5. MEASURE OF OPERATIONS

In the Foundation's Statement of Activities, all revenues, unrestricted donations and expenses that serve an integral part in achieving the Foundation's purpose are considered operating activities. Any contributions and donations to temporarily and permanently restricted net assets would be considered as non-operating support, gains and losses.

6. CONTRIBUTED SERVICES AND DONATIONS

Contributed services are reported in the financial statements as Contributions in-Kind. Such donations are only recognized when those services: (1) create or enhance non-financial assets; or (2) require specialized skills provided by individuals possessing those skills and are services that would be typically purchased if not provided by donation. The recognized contributions in-kind in the Foundation's statement of activities are documented by the research institutes involved in the Foundation's research contracts in each research institute's closing financial statements.

Financial Donations are recorded at the date of receipt. Such a donation is reflected in the Foundation's statement of activities. The current statement of activities does not record any revenue for donated materials. However, such materials would be recorded at fair value at the date of the gift. In the absence of any donor imposed restrictions the Foundation's statement of activities reports the current years donations as unrestricted revenue.

7. UNRECORDED CONTRIBUTIONS

A significant amount of contributed services were received from individuals with specialized skills, which would have been purchased had they not been contributed. The value of these services has however not been reported within the Foundation's financial statements. Management has chosen not to report this value due to a lack of detailed documentation with respect to hours worked by these individuals. These unrecorded contributions were received from the following amount of individuals for the following tasks:

- (1) 10 specialists working for the Foundation's Scientific Advisory Committee
- (2) 12 specialists working on the PREVENT Working Group
- (3) 27 specialists working on the Viral Vector Working Group
- (4) 38 specialists working on the Bell's Palsy Work Group
- (5) 122 specialists working on the Clinical Advisory Forum of Experts
- (6) 101 specialists working on the Vaccine Safety Journal Club

8. FUNCTIONAL EXPENSES

In the Statement of Activities the Foundation reports operating expenses by natural and functional expense categories as per the requirements of Swiss GAAP applicable to voluntary health and welfare organizations. The functional expense categories reflect the internal reporting of the expense within the Foundation. It is based on the area of activity within of the Foundation's purpose that the respective expense was incurred for. The Statement of Activities provides a financial breakdown of the following functional expense categories. The definition of these categories is as follows:

- (a) Innovation and development case definitions and protocols: This comprises consensus formation and publication of standardized and globally accepted definitions of adverse events following immunization and the development of template protocols for pre-licensure clinical trials and post-licensure hypothesis testing studies.
- (b) Innovation and development new methodologies: This comprises the creation of novel approaches to scientific questions related to the safety of vaccines. For example collaborative epidemiologic studies involving databases from several countries or innovative data linkage methods in resource limited environments.
- (c) Innovation and development new technologies: This comprises the creation of tools and infrastructure for vaccine safety research. For example integrated data collection, transmission, and validation tools for epidemiologic studies based on a distributed data model.
- (d) Data Production collaborative studies: This comprises planning, conduct and publication of results from synchronized vaccine safety studies involving multiple study sites and based on shared protocols and infrastructure.
- (e) Capacity building external, linked databases: This comprises support for establishing the necessary infrastructure to link local or regional exposure and outcome databases.
- (f) Capacity building external, other: This comprises support for establishing external infrastructures other than linked databases. For example, online collaboration platforms provided for other research projects in the field.
- (g) Capacity building external, training and knowledge transfer: This comprises training activities and contributions to scientific meetings.
- (h) Capacity building internal, organizational infrastructure development: This comprises activities to render the Brighton Collaboration more productive and effective as a research network.
- (i) Central coordination: This comprises activities to coordinate and manage the interactions in the network across projects.

9. USE OF ESTIMATES

The preparation of the financial statements in conformity with Swiss GAAP require management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of any contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Key estimates include the accrued revenues and accrued expenses of the period.

10. DETAILS TO IMPORTANT BALANCE SHEET POSITIONS

The Accrued Revenues are based on funds owed to the foundation by the World Health Organization, Switzerland, equivalent to CHF 45'860. The accrual was based on project work for these organizations which had not yet been billed as per the 31.12.2013. The Deferred Revenues equivalent to CHF 185'060 was the result of funds which had been collected from the Centre for Disease Control, USA equivalent to CHF 39'000, The European Commission, Brussels equivalent to CHF 26'060 and the Irma Wiegert Foundation equivalent to CHF 120'000, which had not yet been earned at the close of the current financial year.

11. CONTRACTUAL ARRANGEMENTS, RISKS, AND RISK ASSESSMENT

Management and the Board of Directors assess the operative and strategic risks of the Foundation within their quarterly meetings. At these meetings, appropriate measures to address risks have been taken. A significant portion of the unrestricted revenues of the Foundation is provided under contractual research agreements. These research agreements accumulate to a total 3'164 T CHF and represent 707 T CHF of the Foundation's current years revenues. The Foundation currently complies with and is able to fulfil all aspects of these contracts. However, any significant reduction in the level of this support could have an effect on the Foundation's activities. Management would not however, expect this to effect the Foundation's financial position, due to it's intensive current use and reliance on 3rd party service providers. The details to these research contract are as follows (T = Thousand):

Contract Partner	Total Contract Revenue		Revenue taken in Current Year		Revenues taken in Prior Years		Futures Revenues	
(1) World Health Organization, Research Contracts	CHF T	187	CHF T	97	CHF T	-	CHF T	90
(2) Center for Disease Control & Prevention (SOMNIA)	CHF T	2'012	CHF T	398	CHF T	47	CHF T	1'567
(3) European Commission, FP7 (GRIP)	CHF T	654	CHF T	163	CHF T	216	CHF T	275
(4) European Commission, FP7 (EMIF)	CHF T	191	CHF T	49	CHF T	=	CHF T	142
(5) Irma Wiegert Stiftung (GUARD, CAFE)	CHF T	120	CHF T	-	CHF T	-	CHF T	120
Total Contract Value:	CHF T	3'164	CHF T	707	CHF T	263	CHF T	2'194

12. EXCHANGE RATES

All Balance sheet positions have been converted using the rates applicable on the 31.12.2013.

1.22568 CHF = 1.00 Euro

0.88985 CHF = 1.00 USD

Income Statement positions have been converted using average rates applicable during 2013.

13. INCOME TAXES

As a Not-For-Profit organization in the Canton of Basel-City, Switzerland the Foundation is not subject to Federal or Cantonal income tax. Written confirmation that the foundation complies with article 56 of paragraph 66 of the Swiss Tax law has been received from the Tax Authorities of the Canton of Basel-City, Switzerland.

14. BOARD MEMBER REMUNERATION

The Board is working on a voluntary basis. No Remuneration or honoraria were paid

15. TRANSACTIONS WITH RELATED PARTIES IN 2013

During the year ended December 31st, 2013 Dr. Bonhoeffer, the board president, who has also assumed the function of the acting CEO and lead research project coordinator of the Foundation received a salary equivalent to 62'400 CHF and was directly reimbursed by the Foundation for actual travel and subsistence costs equivalent to 956 CHF. During the year ended December 31st, 2013 an amount equivalent to 21'140 CHF was paid to N. Sommerfeld, treasurer of the board, who also assumed the role of CFO on the operational level until may 2013.

16. INTENDED ALLOCATION OF THE INCREASE IN UNRESTRICTED EQUITY / NET ASSETS

The increase in unrestricted equity equivalent to 1'775 CHF will be used for the Foundation's statutory pupose. The Foundation does not engage in trading activities.

17. EVENTS SUBSEQUENT TO THE DECEMBER 31, 2013 BALANCE SHEET DATE

No events occurred subsequent to December 31.2013 which effect the value of the recorded assets and liabilities.