



Annual Report 2016

Brighton Collaboration Foundation

Editorial

On behalf of the Brighton Collaboration Foundation we are pleased to introduce you to our annual report 2016.

Since 2003, the Foundation has supported the Partners of the Brighton Collaboration with program management, coordination and administration. The Brighton Collaboration started by establishing case definitions and has since developed a large portfolio of activities structured in 5 strategic focus areas.

In 2016, the Collaboration raised the bar with its fruitful scientific engagement. In a broad range of international projects, initiatives and volunteer working groups, Brighton Collaboration partners have developed standards and tools and conducted studies to improve the quality of vaccine safety data, a cornerstone of building trust in the safety of vaccines. A lot of this was made possible through the Collaboration's involvement in projects like Global Alignment of Immunisation Safety Assessment in Pregnancy (GAIA), funded by the Bill and Melinda Gates Foundation, or Global Research in Paediatrics (GRIP), funded by the European Commission Research Framework Program 7. The aim of GAIA is to improve data to strengthen immunisation programs involving pregnant women by harmonizing maternal, foetal, and neonatal health outcome assessments, with a specific focus on low and middle income Countries (LMIC). Our involvement in the GRIP project gave us the opportunity to develop a complete online learning module about vaccines and vaccine safety.

In 2017, we will continue to support and to contribute to the Brighton Collaboration's mission and vision. Besides our standard services for Collaboration Partners, our focus for 2017 lies primarily on the continuation of the GAIA project and on initiating a number of other vaccine safety projects. We are excited to continue our engagement.

Your executive management

Simone Casagrande Valli and Jorgen Bauwens

Technical Part of the Annual Report 2016

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ORGANISATIONAL FRAMEWORK

The Brighton Collaboration is an international network, stimulating both research and the distribution of sound information in the area of vaccine safety, with its headquarters in Basel. The Brighton Collaboration was founded in 1999 by a group of vaccine specialists in the English city of Brighton during an international medical congress. The reason for this was the urgent need for better data on vaccine safety as well as the need for global collaboration in this area. The Brighton Collaboration Foundation (The Foundation) was founded in 2003 by Prof. Dr Ulrich Heininger and Dr Jan Bonhoeffer, physicians for infectious diseases and vaccinations at the University Children's Hospital Basel (UKBB), with support of the UKBB. The Foundation operates as office, legal representative and point of contact for the global research network. For the last 12 years, funds deriving from donations and research grants as well as large international projects have been and continue to be reliably and transparently managed by the Foundation.

SCIENTIFIC FOCUS AREAS

SETTING STANDARDS:

Highly variable methodology in previous vaccine studies made valid comparison of vaccine safety profiles difficult, if not impossible. Researchers often used differing definitions for adverse events following immunisation (AEFI) such as «fever» or «encephalitis». Thus, the significance of reported higher or lower AEFI rates after different vaccines or between trials of the same vaccine conducted at different research centres were difficult to interpret. Variable case definitions of AEFI also made valid quantification of rare but serious AEFI nearly impossible.

The Brighton Collaboration has addressed these issues by using its expert network, via web platforms and teleconferences, to develop standardized and validated AEFI case definitions. These are published on the web and in the journal Vaccine. In addition to this ongoing effort, working groups have developed standardized protocols for safety aspects of vaccine clinical trials and/or post-marketing surveillance. Further, a web tool has been developed which facilitates accurate, rapid and standardized reporting and classification of AEFI according to the standardized case definitions. This requires only a few minutes to complete per case and thus promotes efficiency for reporters and investigators. Protocols for data analysis and reporting have also been developed.

CLINICAL ASSESSMENT:

For individuals with AEFI, thorough assessment of their condition is paramount, not only for the management of the respective event but also to ascertain whether the event was related causally to immunisation or not. Where such a causal relationship exists, it is increasingly important to advance the science of understanding the mechanism of such reactions. The Brighton Collaboration leverages a network of international experts to assist globally in exchanging information on such events and to help advance vaccine safety science and identify potentially causally related versus merely temporally related AEFI.

DATA SHARING:

Serious AEFI causally related to licensed vaccines are usually very rare (<1:10,000). However, they become relatively prominent when millions of healthy people are vaccinated, and the target disease disappears. Their reliable detection and evaluation are 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. VACCINE.GRID was established to do such activities.

CAPACITY BUILDING:

Expertise, state of the art scientific methods and competent infrastructures have to be developed in order to meet global needs, particularly in the developing world. This requires training in vaccine safety monitoring, methodology, data management and public communication. Brighton Collaboration partners have developed training material for the Global Research in Paediatrics (GRIP) Master of Science in Paediatric Medicines Development and Evaluation e-learning module on vaccinology and implemented programmes and courses.

PUBLIC CONFIDENCE:

The importance of public confidence in vaccines is well established. Vaccine «scares» prompted by rumours, 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 immunisation (AEFI) minimizes public anxiety.

The Brighton Collaboration, together with the London School of Hygiene and Tropical Medicine's Vaccine Confidence Project, is promoting research on the determinants of trust in vaccines, generally, as well as on the drivers of vaccine hesitancy, the manner in which they develop and spread, and effective strategies to best address vaccine safety concerns.

WHAT WE DO

NETWORK INFRASTRUCTURE:

In order to bring together committed stakeholders and to facilitate efficient collaboration, as well as knowledge transfer across different sectors, locations and professions, the Foundation establishes, provides and maintains an online collaborative working environment with access to its products, tools and services.

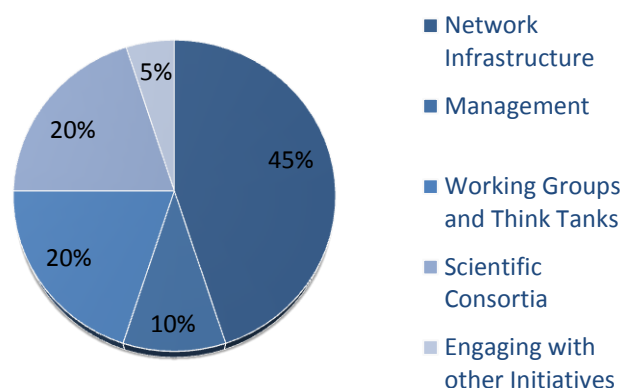


Figure 1: Foundation engagement by type of activity

MANAGEMENT:

The Foundation implements the Brighton Collaboration's strategic plans and maintains its organizational framework. Additionally, the Foundation develops marketing strategies, conducts fundraising activities and provides support to the Science Board (Scientific Advisory Committee) of the Collaboration.

WORKING GROUPS AND THINK TANKS:

The Foundation ensures concerted action within the global network. It supports the establishment of voluntary working groups and think tanks and provides them with coordinators.

SCIENTIFIC CONSORTIA:

The Foundation supports the acquisition of mandates for new projects in the area of vaccine benefit-risk evaluation in which it participates as managing entity, scientific partner or consultant.

ENGAGING WITH OTHER INITIATIVES:

To foster scientific innovation and leverage synergies among institutions in the field, the Foundation engages with other organizations and initiatives to achieve the shared vision of the Collaboration.

ACTIVITY REPORT 2016

NETWORK SERVICES

VSQ: VACCINE SAFETY QUARTERLY NEWSLETTER

The VSQ is the newsletter of the Brighton Collaboration and provides scientific information about current activities in the field of vaccine safety. The aim is to facilitate knowledge transfer among network partners and other visitors of our website, comprising vaccinologists, infectious disease specialists, epidemiologists, and health care providers as well as other professionals concerned with vaccine safety from academia, regulatory bodies, public health institutions, and industry. The VSQ is distributed within the BC network and additionally through Elsevier's Joint Vaccine Education Resource Center website: <http://vaccinesafetyresource.elsevier.com>

Each issue of the newsletter includes:

- I. Featured Article(s) focusing on a special topic
- II. Views and Perspectives giving space to controversial contributions on current topics
- III. Scientific News and Updates allowing scientific information exchange between network partners
- IV. Products and services provided by the Brighton Collaboration Foundation

Key accomplishments 2016:

- Two editions of the VSQ were published instead of four due to a lack of resources: one focussing on the Brighton Collaboration and one focussing on Viral Vectors.

CAFE: CLINICAL ADVISORY FORUM OF EXPERTS

The CLINICAL ADVISORY FORUM OF EXPERTS (CAFE) is a mailing list and online forum with the aim to discuss diagnosis and management of specific adverse events following immunisation (AEFI) and related vaccine safety questions among experts. CAFE is moderated by the Foundation's program manager, for timely and targeted coordination of discussions. All mailing list discussions are archived and can be reviewed and continued at the dedicated online forum of the BCF website: <https://brightoncollaboration.org/platform/forum.html>. All participants of CAFE are partners of the Brighton Collaboration. CAFE promotes knowledge transfer and harmonizes diagnostic and management approaches of the institutions involved by offering a platform for clinical and scientific exchange. Open exchange will balance less rigorous contributions with state of the art information and thus help knowledge exchange and capacity building over time.

Key accomplishments 2016:

- 16 vaccine safety concerns were raised and followed by email discussion facilitated through CAFE.

ONLINE PLATFORM

The online work environment is a unique platform for innovation; information exchange and knowledge transfer, featuring various tools, and archives for vaccine safety monitoring and research. Both, the

Collaboration's progress and technological developments, warrant a relaunch of the online platform to serve the Collaboration's partners better and to build capacity for improved knowledge management.

Key accomplishments 2016:

- Technical upgrade of the online platform was realised in 2016 for public relaunch in 2017.
- The public website structure was simplified. Fewer subpages and a clear hierarchy and navigation structure will improve the user experience.
- The public website content was restructured to highlight key information and facilitate browsing. Detailed information is available as downloadable PDF documents, providing deeper and transparent insight into our structure and work for the further interested readers.
- Preparations to replace the proprietary online platform by a Google Apps based platform integrated with our existing content management system Magnolia. This will facilitate implementation and decrease cost of future platform maintenance.
- The public website was made structurally "service ready". This implies the capacity to host larger structured download areas and a better integration of the increasing number of available and emerging online tools as services for Brighton Collaboration partners.
- The platform format was adjusted to meet the WHO Vaccine Safety Net (VSN) guidelines.

WORKING GROUPS AND THINK TANKS

VASCULITIS WORKING GROUP

The second phase of the VASCULITIS WORKING GROUP was coordinated by the Foundation in collaboration with the Italian regulatory authority (AIFA), under a research contract with the latter. The aim was to develop case definitions for vasculitis.

Key accomplishments 2016:

- Systematic review on vasculitis and immunisation published (Vaccine (2016), 134(51), pp. 6641-6651).
- Analysis of spontaneous reports of international vasculitis databases published (Vaccine (2016), 134(51), pp. 6634-6640).
- Case definitions and guidelines for data collection, analysis and presentation for Kawasaki Disease, Systemic Lupus Erythematosus, Single Organ Cutaneous Vasculitis as AEFI published (Vaccine (2016), 134(51), pp. 6561-6596).
- Case definitions and guidelines for data collection, analysis and presentation for IgA Vasculitis (Henoch-Schönlein) as AEFI submitted for publication.
- Manuscript "Kawasaki Disease and Immunisation: A Systematic Review" submitted for publication.

VIRAL VECTOR VACCINE SAFETY WORKING GROUP

The VIRAL VECTOR VACCINE SAFETY WORKING GROUP (VVS-WG), coordinated by the US Centers for Disease Control and Prevention (CDC), provides templates standardizing the collection, analysis and dissemination of safety data on emerging viral vector vaccines against HIV malaria, and TB in both pre- and post-licensure settings.

Key accomplishments 2016:

- "Unique Safety Issues Associated with Virus-Vectored Vaccines: Potential for and Theoretical Consequences of Recombination with Wild Type Virus" published (Vaccine (2016), 34(51), pp. 6610–6616).
- "Adventitious Agents and Live Viral Vectored Vaccines: Considerations for Archiving Samples of Biological Materials for Retrospective Analysis" published (Vaccine (2016), 34(51), pp. 6617–6625).
- "Live Virus Vaccines Based on a Vesicular Stomatitis Vaccine (VSV) Backbone: Standardized Template with Key Considerations for a Risk/Benefit Assessment" published (Vaccine (2016), 34(51), pp. 6597–6609).

WHEEZE WORKING GROUP

The WHEEZE WORKING GROUP was coordinated by the Foundation in collaboration with the World Health Organization (WHO). The aim was to develop a case definition for wheezing. In 2015, a systematic review on wheezing took place, followed by the development of a manuscript for a standardized case definition.

Key accomplishments 2016:

- Case definition and guideline for data collection, analysis and presentation for wheeze as an AEFI submitted for publication.

ARTHRITIS WORKING GROUP

The ARTHRITIS WORKING GROUP was coordinated by the Foundation under a research contract with the World Health Organization (WHO). The aim was to develop a case definition for arthritis. In 2015, a systematic review of aseptic arthritis took place, followed by the development of a manuscript for a standardized case definition.

Key accomplishments 2016:

- Finalization and peer-review of systematic review on aseptic arthritis and immunisation.
- Case definition and guideline for data collection, analysis and presentation of acute aseptic arthritis as an AEFI finalized.

SCIENTIFIC CONSORTIA

GAIA: GLOBAL ALIGNMENT OF IMMUNISATION SAFETY ASSESSMENT IN PREGNANCY

The GAIA project is coordinated by the Brighton Collaboration Foundation under a research contract with the Bill and Melinda Gates Foundation. The aim of GAIA is to improve data generated for strengthening programs of immunisation in pregnancy by harmonizing maternal, pregnancy, foetal, and neonatal health outcome assessments with a specific focus on low and middle income Countries (LMIC).

Key accomplishments 2016:

- Development of guidelines for harmonized collection, analysis and presentation of safety data in clinical trials immunising pregnant women.
- Creation of a matrix for the collection of a core set of safety data in clinical trials immunising pregnant women.
- Publication of a special issue of the journal Vaccine (Vaccine (2016), 34(49), pp. 5991-6109). Focus immunisation in pregnancy, including the above guidelines and matrix as well as the following 10

case definitions established in 2015: maternal death, foetal distress, post-partum haemorrhage, premature labour, pre-eclampsia, stillbirth, neonatal death, preterm birth, congenital anomalies, neonatal sepsis.

- Development of 11 additional case definitions for neonatal and obstetric safety outcomes:
- acute neonatal encephalopathy, congenital microcephaly, low birth weight, respiratory distress in the neonate, small for gestational age, failure to thrive, abortion and ectopic pregnancy, antenatal bleeding, dysfunctional labour, foetal growth restriction, gestational diabetes mellitus.
- Creation of a glossary and ontology of terms and concepts for harmonized safety assessment of immunisation during pregnancy.
- Establishment of a dedicated stakeholder network of more than 600 professionals in over 60 countries.

GRIP: GLOBAL RESEARCH IN PAEDIATRICS

GRIP is a network of excellence stimulating and facilitating the development and safe use of medicines in children, funded by the European Commission Research Framework Program 7. The Brighton Collaboration Foundation is a GRIP consortium partner.

Key accomplishments 2016:

- Development and implementation of the Vaccine Module in the GRIP International Masters in Paediatric Drug Evaluation and Research.

SOMNIA: SYSTEMATIC OBSERVATIONAL METHOD FOR NARCOLEPSY AND INFLUENZA IMMUNISATION ASSESSMENT

Coordinated by Cincinnati Children's Hospital and Erasmus University Medical Center, the partners of the SOMNIA consortium, funded by the Centers of Disease Control and Prevention (CDC), are investigating the epidemiology of narcolepsy and its potential association with influenza vaccines in 10 countries on four continents. The Brighton Collaboration Foundation was the CDC's contractual partner, managing the project and providing strategic and scientific input.

Key accomplishments 2016:

- Final report submitted to CDC.
- Preparing publication of the study results, including incidence rates and international case controlling finalisation.

PRIMED: GLOBAL NETWORK OF CLINICS PILOT

PRIMED (PRecision Immunity in MEDicine) is a pilot project with the aim to form a global network of immunisation clinics investigating inter-individual variations in immune responses to vaccines leading to adverse events. In 2016 the pilot was successfully launched with the support provided by the University of Basel's Children's Hospital (UKBB), the Irma Wigert Stiftung (a Swiss foundation) and private philanthropic donations.

Key accomplishments 2016:

- The online platform tool was made ready to register clinics and start building information exchange.

OPERATING REVIEW

GOVERNANCE FRAMEWORK

The Brighton Collaboration 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 bylaws. The first Board was appointed by the Founder to constitute then and complete itself.

The Board of Directors currently consists of 4 members with voting rights. The Board elects a President, a Vice-President, and a Treasurer amongst 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 in line with Swiss GAAP FEER 21 requirements. PricewaterhouseCoopers was re-elected as the external auditor.

BOARD OF DIRECTORS

PD Dr Jan Bonhoeffer, Basel, CH, President; Dr Thomas Mayer, Basel, CH, Legal Counsel; Kaspar Sutter, Basel, CH, Treasurer; Caroline Cron, Basel, CH, Legal Counsel and Swiss Partnerships

SCIENTIFIC ADVISORY BOARD (SCIENCE BOARD)

Prof. Dr. Steven Black, Cincinnati Children's Hospital, Cincinnati USA; Prof. Dr. Jim Buttery, Monash Children's Hospital, Melbourne, AUS; Prof. Dr. Kathryn M. Edwards, M.D., Vanderbilt University School of Medicine, Nashville, Tennessee, USA; Prof. Dr. Michael S. Gold, Women's and Children's Health Network, Adelaide, AUS; Dr. Egeruan Babatunde Imoukhuede († 19 July 2016), Jenner Institute, University of Oxford, Oxford, UK; Dr. Hector Izurieta, EPI, World Health Organization, Geneva, CH; Dr. Barbara J. Law, Centre for Immunization and Respiratory Infectious Diseases, Public Health Agency of Canada, Ottawa, CAN (retired June 2015); Dr. Heidi Larson, London School of Hygiene & Tropical Medicine, London, UK; Prof. Dr. Daniel Salmon BA, MPH, PhD, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA; Prof. Dr. Miriam Sturkenboom, Erasmus University Medical Center, Rotterdam, NED.

SECRETARIAT (MANAGEMENT TEAM)

Simone Casagrande Valli, MBA, Foundation-Manager; Viviane Seeger, Management Assistant; Jorgen Bauwens, MSc, MPH, Scientific Coordinator and Programme Manager; Jan Bonhoeffer, MD, Senior Scientist.

Financial Statement / Jahresrechnung 2016

SWISS GAAP FER 21

Brighton Collaboration Foundation

Overview: The following financial statements of the Foundation have been prepared using Swiss Generally Accepted Accounting Principles (SWISS GAAP FER 21). These Swiss GAAP FER financial statements also comply with the requirements of Swiss law. During the financial year 2016, the Foundation managed a contract portfolio equivalent to CHF 4'515'400. This portfolio consists of cost reimbursement contracts and grants. In 2016, CHF 1'343'082 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 47'301. This amount will be credited to the Foundation's existing accumulated net assets. The contributions from 318 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 2016 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.

Übersicht: Die folgende Jahresrechnung der Stiftung wurde nach SWISS GAAP FER 21 erstellt. Diese Jahresrechnung geht einher mit Schweizer Recht. Im Jahr 2016 umfasste das Projektportfolio der Stiftung CHF 4'515'400. Im 2016 wurden aus diesem Portfolio Projektleistungserträge von CHF 1'343'082 realisiert. Erträge wurden im Zusammenhang mit den dafür erbrachten Leistungen realisiert. Das Stiftungskapital hat um CHF 47'301 zugenommen, welches dem bestehenden Kapital angerechnet wird. Die Beiträge der 318 unentgeltlich, freiwillig arbeitenden Fachexperten findet keine Abbildung in der Jahresrechnung, da der Stundenaufwand nicht erfasst bzw. rapportiert wird. Das Management der Stiftung definiert die Finanzstruktur im 2016 als solide. Das Management richtet seinen Fokus weiterhin auf neue, zusätzliche finanzielle Quellen, um sich weltweit im Bereich sichere Impfstoffe etablieren zu können.

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FINANCIAL STATEMENTS / JAHRESRECHNUNG 2016
SWISS GAAP FER 21

Balance Sheet and Statement of Changes in Equity in CHF

As per December 31st, 2016 and 2015

Bilanz und Eigenkapitalnachweis in CHF

Dezember 31.12.2016 sowie 2015

	31.12.2016	31.12.2015
ASSETS / Aktiven		
Current Assets / Umlaufvermögen		
Cash & Cash Equivalents / Umlaufvermögen	685'811.95 CHF	695'714.19 CHF
Accounts Receivable / Forderungen aus Lieferungen + Leistungen	6'357.45 CHF	2'286.35 CHF
Value Added Tax & Withholding Tax / Steuerforderungen (MwSt)	10'898.55 CHF	6'898.33 CHF
Accrued Revenues / Aktive Rechnungsabgrenzungen	- CHF	133'492.00 CHF
Total Current Assets / Total Umlaufvermögen	703'067.95 CHF	838'390.87 CHF
Non-Current Assets / Anlagevermögen		
Fixed Assets/Investments / Anlagen	- CHF	- CHF
Total Non-Current Assets / Total Anlagevermögen	- CHF	- CHF
Total Assets / Total Aktiven	703'067.95 CHF	838'390.87 CHF

	31.12.2016	31.12.2015
LIABILITIES AND NET ASSETS / Passiven		
Current Liabilities / Kurzfristiges Fremdkapital		
Accounts Payable / Kreditoren	295.65 CHF	5'782.35 CHF
Social Security Balances Payable / Rückstellungen für Sozialversicherungen	- CHF	- CHF
Accrued Salaries (Balance Flexitime) / Rückstellungen für Löhne (Gleitzeit)	10'840.00 CHF	15'250.00 CHF
Accrued Expenses / Passive Rechnungsabgrenzungen	18'600.00 CHF	19'500.00 CHF
Deferred Revenue / Passive Umsatzerlösabgrenzungen	434'000.00 CHF	605'827.00 CHF
Total Liabilities / Total Passiven	463'735.65 CHF	646'359.35 CHF
Net Assets / Netto Vermögen		
Unrestricted net Assets / Freies Stiftungskapital	239'332.30 CHF	192'031.52 CHF
Total Net Assets / Total Vermögen	239'332.30 CHF	192'031.52 CHF
Total Liabilities and Net Assets / Total Passiven	703'067.95 CHF	838'390.87 CHF

STATEMENT OF CHANGES IN EQUITY / EIGENKAPITALNACHWEIS

Previous Net Assets /
Organisationskapital

Revenues (external) /
Rechnungsabgrenzungen

Current Net Assets /
Netto Vermögen

Net Assets / Netto Vermögen

Unrestricted / Freies Fondkapital

Total Net Assets / Total Vermögen

192'031.52 CHF	47'300.78 CHF	239'332.30 CHF
192'031.52 CHF	47'300.78 CHF	239'332.30 CHF

FINANCIAL STATEMENTS / JAHRESRECHNUNG 2016
SWISS GAAP FER 21

Income Statement in CHF
Year Ended December 31, 2016 and 2015
Betriebsrechnung in CHF
31.12.2016 und 2015

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.

Der folgende Finanzbericht der Stiftung wurde nach SWISS GAAP FER erstellt. Dieser Finanzbericht geht einher mit Schweizer Recht.

	2016 Total	2015 Total
Operating Revenues & Other support / Ertrag aus Aktivitäten und Leistungen brutto		
Research Contracts / Erträge aus Forschungsverträge	1'343'081.56 CHF	1'183'463.80 CHF
Unrestricted Donations / Zweckunbestimmte Spenden	33'879.00 CHF	12'550.00 CHF
Total Operating Revenues & Other support / Ertrag aus Aktivitäten und Leistungen	<u>1'376'960.56 CHF</u>	<u>1'196'013.80 CHF</u>
Direct Costs of Operating Revenue / Direkte Kosten aus Forschungstätigkeit		
Travel, Subcontractor, 3rd. Parties / Aufwand Reisen, Vertragspartner	970'299.81 CHF	746'515.85 CHF
Direct Cost for service providers / Direkte Kosten für Dienstleister	73'010.45 CHF	33'600.00 CHF
Total Direct Costs of Operating Revenue / Direkter Projektaufwand	<u>1'043'310.26 CHF</u>	<u>780'115.85 CHF</u>
Total Unrestricted Net Earnings / Ertrag aus Aktivitäten und Leistungen netto	<u>333'650.30 CHF</u>	<u>415'897.95 CHF</u>
Operating Expense / Betriebsaufwand		
Personnel Expenses / Personalaufwand		
Salary Expenses / Personalkosten	200'591.30 CHF	283'829.85 CHF
Employee Insurance & Other Expenses / Übriger Personalaufwand	27'701.05 CHF	40'618.13 CHF
Coordinating Expenses / Abgaben, Gebühren, Verwaltung		
Aquisition & Teleph. & Office Expenses / Akquisitions- & Verwaltungskosten	13'824.90 CHF	9'098.85 CHF
Governmental Charges / Gebühren	796.00 CHF	722.00 CHF
Auditor & Consulting Fees / Revision & Buchhaltungs-/Controllingaufwand	41'045.00 CHF	43'850.00 CHF
Information Technology / Informatikaufwand	3'668.00 CHF	5'353.80 CHF
Marketing Expenses / Werbeaufwand		
Advertising & Advertising Materials / Werbeinserate, Werbematerial	269.80 CHF	309.15 CHF
Marketing, Communication Consulting & Services / Marketing, Werbeberatung	4'630.45 CHF	8'324.15 CHF
Total Operating Expenses / Betriebsaufwand	<u>292'526.50 CHF</u>	<u>392'105.93 CHF</u>
Operating Income before interest / Betriebsergebnis vor Finanzerfolg	<u>41'123.80 CHF</u>	<u>23'792.02 CHF</u>
Financial Result / Finanzergebnis		
Bank Charges & Fees / Bankspesen	-	228.08 CHF
Interest Income / Finanzertrag	-	0.79 CHF
Exchange rate gains (+) & losses (-) / Wechselkurs Gewinn (+) und Verluste (-)	6'192.18 CHF	11'116.00 CHF
Total Financial Result / Total Finanzergebnis	<u>6'176.98 CHF</u>	<u>11'343.29 CHF</u>
Operating Income / Betriebsergebnis nach Finanzerfolg	<u>47'300.78 CHF</u>	<u>12'448.73 CHF</u>
- Decrease / + Increase in Unrestricted Net Assets / - Abnahme / + Zunahme Stiftungskapital	<u>47'300.78 CHF</u>	<u>12'448.73 CHF</u>

FINANCIAL STATEMENTS / JAHRESRECHNUNG 2016
SWISS GAAP FER 21

Statement of Cash Flows in CHF
For the Year Ended December 31, 2016 and 2015
Mittelflussrechnung per Dezember 31, 2016 und 2015

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.

Der folgende Finanzbericht der Stiftung wurde nach SWISS GAAP FER erstellt. Dieser Finanzbericht geht einher mit Schweizer Recht.

	31.12.2016	31.12.2015
Cash Flows from Operating Activities / Mittelfluss aus Ertragsrechnung		
Change in Net Assets / Veränderung des Fondvermögens	47'300.78 CHF	12'448.73 CHF
 Adjustments to Reconcile Change in Net Assets to Net Cash Provided by Operating Activities Veränderung des Nettovermögens aus laufender Geschäftstätigkeit		
(Increase) / Decrease in Accounts Receivable (Zunahme) / Abnahme Forderungen aus Lieferungen + Leistungen	- 8'071.32 CHF	6'005.44 CHF
(Increase) / Decrease in Accrued Revenues (Zunahme) / Abnahme Aktive Rechnungsabgrenzungen	133'492.00 CHF	- 107'682.00 CHF
Increase / (Decrease) in Deferred Revenues Zunahme / (Abnahme) Umsatzerlösabgrenzungen	- 171'827.00 CHF	387'267.00 CHF
Increase / (Decrease) in Acct's Payable & Accrued Expenses Zunahme / (Abnahme) Kreditoren, Passive Rechnungsabgrenzungen	- 10'796.70 CHF	- 2'985.10 CHF
 Net Cash Provided by Operating Activities / Cash-Flow aus laufender Geschäftstätigkeit	 - 9'902.24 CHF	 295'054.07 CHF
 Net Increase (- Decrease) in Cash and Cash Equivalents / Netto-Zunahme (- Abnahme) liquide Mittel	 - 9'902.24 CHF	 295'054.07 CHF
Cash and Cash Equivalents at beginning of Year Liquide Mittel am Anfang des Jahres	 695'714.19 CHF	 400'660.12 CHF
Cash and Cash Equivalents at End of Year Liquide Mittel am Ende des Jahres	 685'811.95 CHF	 695'714.19 CHF

Project Overview / Projektübersicht 2016

Amounts in CHF
Beträge in CHF

Projekte	Ertrag Revenues 2016	Direkte Kosten Direct Costs 2016	Netto Ertrag Net Earnings 2016	Destinatäre Beneficiaries	Netto Ertrag Net Earnings 2017
World Health Organization (ARTHRITIS)	15'239	9'776	5'463	Andreas Woerner, Pediatric Rheumatology, University Children's Hospital Basel	-
Center for Disease Control & Prevention (SOMNIA)	772'727	673'478	99'249	Erasmus Medical Center, NL / Cincinnati Children's Hospital, Cincinnati, USA, plus 11 countries (e.g. Argentinien, Denmark, Taiwan, Canada)	-
Global Research in Paediatrics, FP7 (GRIP)	77'882	34'420	43'462	University Children's Hospital Basel	-
European Commission, FP7 (EMIF)	6'881	2'500	4'381	PriceWaterhouseCoopers (Projekt Audit)	-
Irma Wigert Stiftung (DISCOVERY, PRIMED)	80'000	73'010	6'990	Open Interactive GmbH, Oswald Siegfried Werbeagentur GmbH	85'000
Universitäts-Kinderspital beider Basel	28'839	-	28'839		
Agenzia Italiana del Farmaco (VASCULITIS II)	1'920	-	1'920	-	-
Bill and Melinda Gates Foundation (GAIA I)	359'594	224'717	134'877	Univ. of Washington, St. George's Univ. London, Baylor College Med., Global Healthc. (S. Kochhar), Synapse, IABS, Erasmus Med.C., Cincinnati Children's Hospital, Hudson Institut, WHO	60'000
EU2P (Data Surrey)	-	25'409	-25'409		
	1'343'082	1'043'310	299'771		145'000

BRIGHTON COLLABORATION FOUNDATION

DISCLOSURE: NOTES TO THE FINANCIAL STATEMENTS 2016

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.

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 year's 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

- 13 specialists working for the Science Board
- 4 specialists working for the Foundation Board (BCF)
- 5 specialists working for the Foundation Board (BFUS)
- 179 specialists working on the Immunization in pregnancy Task Forces and Working Groups (GAIA)
- 23 specialists working on the Viral Vector Working Group (V3S-WG)
- 32 specialists working on the Vasculitis Working Group
- 51 specialists working on the Clinical Advisory Forum of Experts (CAFE)
- 11 specialists working on the Vaccine Safety Quarterly (VSQ)

8. PAID UP CAPITAL

The founder, the University Children's Hospital Basel (UKBB), endowed the foundation with CHF 37'399.35.

9. USE OF ESTIMATES

The preparation of the financial statements in conformity with Swiss GAAP FER 21 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 Deferred Revenues equivalent to CHF 434'000 was the result of funds which had been collected from The European Commission, Brussels equivalent to CHF 39'000 (GRIP), the Irma Wigert Foundation equivalent to CHF 195'000, and the Bill and Melinda Gates Foundation equivalent to CHF 200'000 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 4'515 TCHF and represent 1'343 TCHF of the Foundation's current year's 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 its intensive current use and reliance on 3rd party service providers. The details to this research contract are as follows (T = Thousand):

CONTRACT PARTNER		TOTAL CONTRACT REVENUE	REVENUE TAKEN IN CURRENT YEAR	REVENUE TAKEN IN PRIOR YEARS	FUTURE REVENUES
(1) WORLD HEALTH ORGANIZATION (ARTHRITIS)	TCHF	36	15	21	-
(2) CENTER OF DISEASE CONTROL&PREVENTION (SOMNIA)	TCHF	2'499	773	1'726	-
(3) EUROPEAN COMMISSION, FP7 (GRIP)	TCHF	531	78	414	39
(4) EUROPEAN COMMISSION, FP7 (EMIF)	TCHF	84	7	77	-
(5) IRMA WIGERT STIFTUNG (DISCOVERY, PRIMED)	TCHF	282	80	7	195
(6) UNIVERSITÄTS-KINDERSPITAL BEIDER BASEL	TCHF	29	29	-	-
(7) AGENZIA ITALIANA DEL FARMACO (VASCULITIS II)	TCHF	11	2	9	-
(8) BILL AND MELINDA GATES FOUNDATION (GAIA I)	TCHF	1'043	360	484	200
TOTAL CONTRACT VALUE	TCHF	4'515	1'343	2'738	434

12. EXCHANGE RATES

All Balance sheet positions have been converted using the rates applicable on the 31.12.2016.

1.074136 CHF = 1.00 Euro

1.016500 CHF = 1.00 USD

Income Statement positions have been converted using daily rates applicable during 2016.

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 2016

During the year ended December 31st, 2016 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 31'200 CHF and was directly reimbursed by the Foundation for actual travel and subsistence costs equivalent to 331 CHF.

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

The increase in unrestricted equity equivalent to 47'301 CHF will be used for the Foundation's statutory purpose. The Foundation does not engage in trading activities.

17. EVENTS SUBSEQUENT TO THE DECEMBER 31, 2016 BALANCE SHEET DATE

No events occurred subsequent to December 31. 2016 which affect the value of the recorded assets and liabilities.