dcvmn

Developing Countries Vaccine Manufacturers Network

2020 Annual Report

Contents

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Message from the President

Dear DCVMN members,

I would like to take this opportunity to thank all members for entrusting me the with the responsibility to lead DCVMN during my tenure as President of the Executive Committee (EC) of DCVMN [1]. During these uncertain times of the COVID Pandemic I can say with confidence that, along with the members of the EC, I can elevate the impact that network will have in the vaccine industry.

The pandemic, declared by WHO on 11 March 2021, has presented the industry with a new challenge. Thanks to the combined efforts of vaccine developers, various institutional stakeholders, and regulators around the world, we have seen vaccines being developed at a pace never seen before.

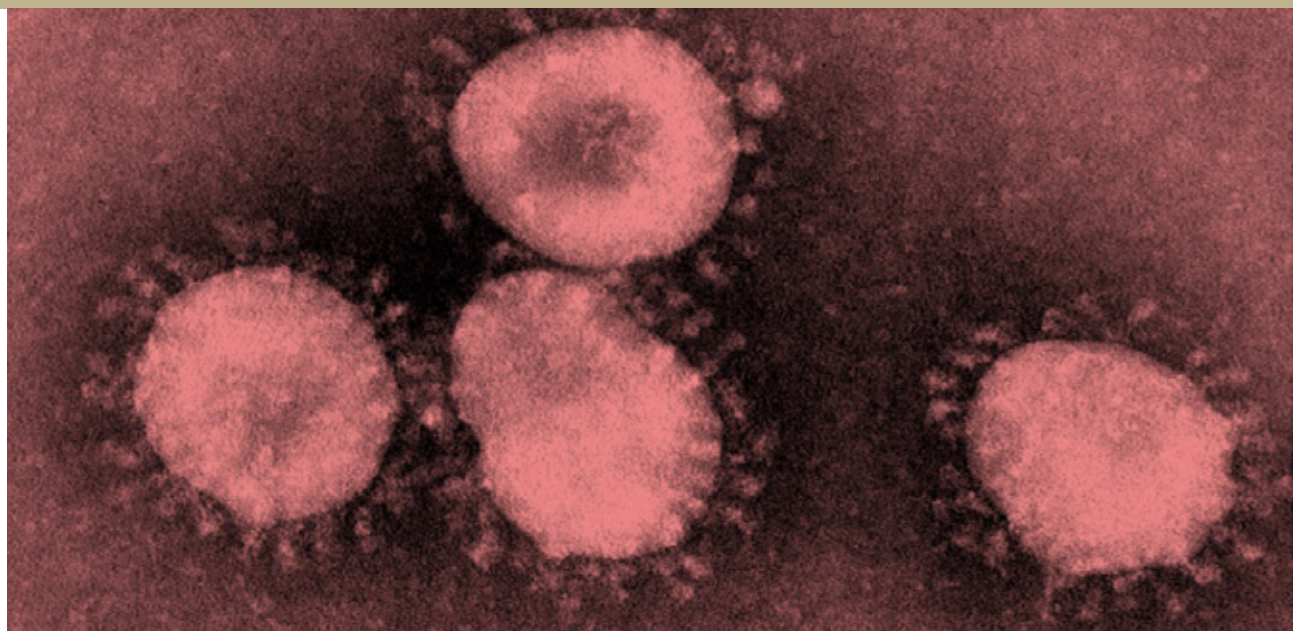
Being a Network that represents manufacturers that distribute annually over 3.5 billion doses of essential vaccines, now more than ever we have the ability to play a vital role in helping the world combat this pandemic. I, along with the EC members, believe that in order to maximize our impact, we need a stronger voice in decisions being made that affect the growth of the industry. All members are encouraged to put themselves in a position where the can provide the perspective of a DCVM, whether be in relation to product development, clinical development, quality control, regulatory affairs or business development.

I encourage all members to participate in activities, to formulate new ideas, foster new partnerships and to increase the impact of the Network.

Sai D. Prasad
DCVMN President

[1] *After 02nd June 2021, with the written approval of the new Statutes and Bylaws by over 75% of all eligible members, the Executive Committee has been renamed DCVMN Board, and the President has been renamed Chair of the Board.*

The COVID-19 pandemic



On 11th March 2020, the World Health Organization's Director-General, Dr. Tedros Adhanom Ghebreyesus, declared that the COVID-19 disease can be characterized as a global pandemic[2]. "This is due to the rapid increase in the number of cases outside China over the past 2 weeks that has affected a growing number of countries", he added.

The SARS-CoV-2 virus, a new strain of coronavirus that has not been previously identified in humans, first emerged in the Chinese city of Wuhan, in December 2019. Throughout January 2020, the number of cases in China increased significantly. After reaching other countries and based on its confirmed human-to-human transmission, the WHO declared the coronavirus spread a public health emergency of international concern on 30 January 2020. On March 7th, the number of confirmed cases of COVID-19 surpassed 100'000, affecting over 100 countries. Given escalating outbreaks and sharp increases in other countries, the WHO declared COVID-19 a pandemic on March 11th. Since, measures of containment have been taken around the globe to decrease and delay viral transmission so that healthcare systems can cope with the surge needs of patients.

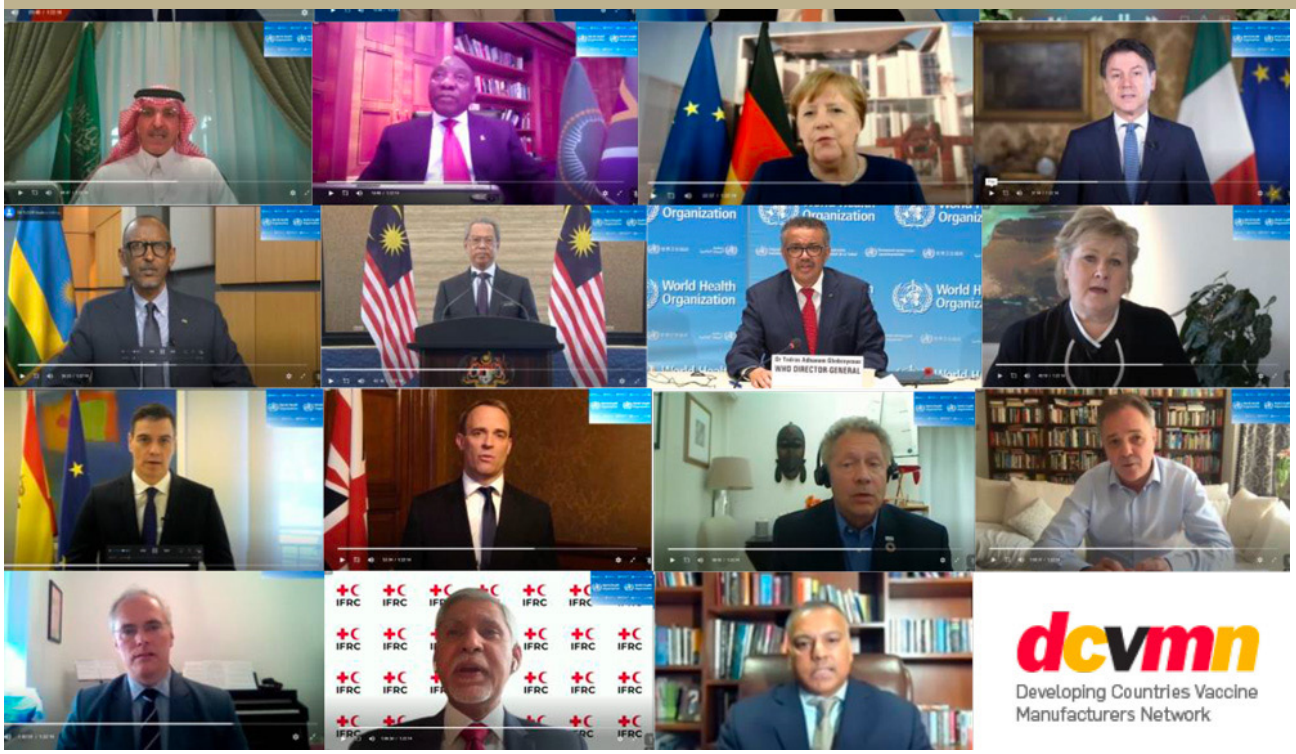
The vaccine industry is fully committed to accelerate efforts in research and development to respond as quickly as possible to the needs of populations everywhere. During this global emergency it is important to ensure that all vaccines for routine immunization are supplied and administered without any delays consequence of border control, travel and transportation restrictions.

The Network is committed to helping governments around the world to build strong healthcare systems based on disease prevention and to enable care for the most vulnerable in society. Several companies affiliated to the Network[3] are on the forefront of the research on vaccines against COVID-19 and have initiated programs to develop COVID-19 vaccines; the results of these development programs will be available in the months to come.

[2] *https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020*

[3] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7287474/*

DCVMN joined global leaders call for a new collaboration to accelerate equitable access to COVID-19 health technologies



Recognizing the April 20th United Nations General Assembly resolution[4], calling for rapid development, scale-up, manufacturing and supply of vaccines to confront the pandemic, the Developing Countries Vaccine Manufacturers Network (DCVMN) stands ready to fully collaborate with the Access to COVID Tools (ACT) Accelerator initiative, launched on 24th April 2020.

As the world's largest alliance of public and private vaccine manufacturing companies, from fourteen emerging countries, engaged in supply of vaccines for local and international use, DCVMN members collectively supply annually nearly four billion vaccine doses to 170 countries, and are ready to increase these efforts as needed. The Network is able to stimulate early cooperation between vaccine developers and suppliers towards rollout of vaccination, enabling equitable access to COVID-19 vaccines.

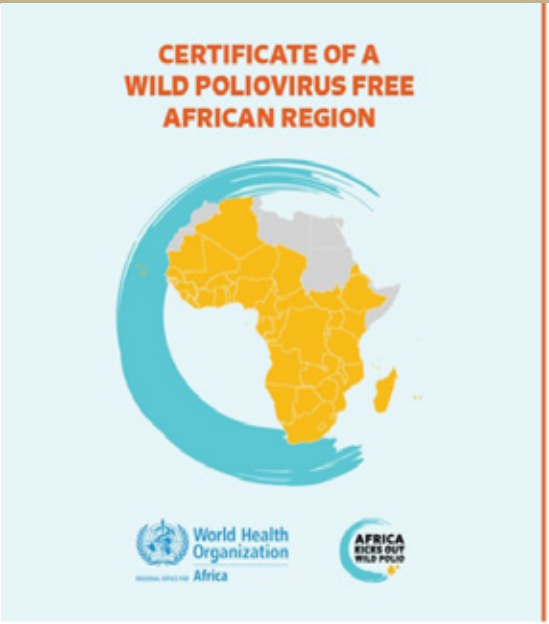
At least thirteen companies affiliated to the Network are involved in development of COVID-19 vaccine candidates across various platforms[5]. Once safe and efficacious vaccines have been developed, enormous manufacturing capacity will be required rapidly to meet the demand to protect the global population[6]. The COVID-19 pandemic requires a strong united front to turn the tide of this global public health burden. DCVMN members, with vaccine manufacturing, filling, packaging and distribution capabilities, supported this call, to ensure vaccines reach populations in every corner of the world without undue delay.

[4] https://www.un.org/pga/74/wp-content/uploads/sites/99/2020/04/Letter-to-Member-States-for-20-April-on-COVID19-Silence-Procedure-resolution-re-L.56-Final.pdf

[5] https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

[6] https://covid19.who.int/?adgroupsurvey={adgroupsurvey}&gclid=EAIaIQobChMI5ezDtPTw7QIVzeJ3ChOb2AqZEAAYASACEgJnHfD_BwE

DCVMN Congratulates WHO African Region for Wild Polio-Free Certification




We, the members of the Africa Regional Commission for Certification of Poliomyelitis Eradication, conclude today, Tuesday, 25 August 2020, that the transmission of indigenous wild poliovirus has been interrupted in all 47 countries of the WHO African Region.

On 25th August 2020, the Africa Regional Certification Commission certified the WHO African Region as wild polio-free after four years without a case. With this historic milestone, five of the six WHO regions – representing over 90% of the world's population – are now free of the wild poliovirus, moving the world closer to achieving global polio eradication.

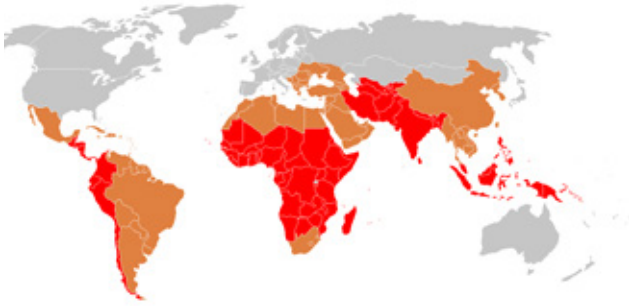
Polio is a virus which spreads from person to person, usually through contaminated water. It can lead to paralysis by attacking the nervous system. The poliovirus is transmitted from person to person, mainly through a recto-oral route or, less frequently, through contaminated water or food, and multiplies inside the intestines. While there is no cure for polio, the disease can be prevented through the administration of a simple and effective vaccine. Two out of three strains of wild polio virus have been eradicated worldwide. Efforts are underway across every country to rapidly boost immunity levels in children and protect them from polio paralysis. "Ending wild polio virus in Africa is one of the greatest public health achievements of our time and provides powerful inspiration for all of us to finish the job of eradicating polio globally," said WHO Director-General Dr Tedros Adhanom Ghebreyesus.

DCVMN company members are proud of contributing towards eradication with supply of polio vaccines to the African continent.

Despite a challenging year for global health, the certification of the African region as wild poliovirus-free is a sign of hope and progress. The resources and expertise used to eliminate wild polio have significantly contributed to Africa's public health and outbreak response systems. The polio programme provides health benefits to local communities, from supporting the African region's response to COVID-19 to bolstering routine immunization against other vaccine-preventable diseases.

More information at:
apps.who.int/iris/bitstream/handle/10665/272756/9789241513838-eng.pdf?ua=1 ; or https://www.who.int/en/news-room/fact-sheets/detail/rabies vac-green-light-to-manufacture-vaccines/

DCVMN members' engagements in vaccines' development and supply



Geographical Incidence of typhoid fever: Strongly endemic ; Endemic ; Sporadic cases. *Photo © Wikipedia*

First Ever Vaccine Under WHO Emergency Use Listing

Geneva, 13th November 2020 – WHO listed the nOPV2 vaccine (Bio Farma, Indonesia) for emergency use to address the rising cases of a vaccine-derived polio strain in a number of African and East Mediterranean countries. Countries in WHO's Western Pacific and South-East Asia regions are also affected by these outbreaks. The emergency use listing, or EUL, is the first of its kind for a vaccine and paves the way for potential listing of COVID-19 vaccines. The world has made incredible progress toward polio eradication, reducing polio cases by 99.9% in the last 30 years. But the last steps to ending this disease are proving the most difficult, particularly with continuing outbreaks of circulating vaccine-derived polio viruses (cVDPVs).

cVDPVs are rare and occur if the weakened strain of the poliovirus contained in the oral polio vaccine (OPV) circulates among under-immunized populations for a long time. If not enough children are immunized against polio, the weakened virus can pass between individuals and over time genetically revert to a form that can cause paralysis. Type 2 cVDPVs are currently the most prevalent form of the vaccine-derived virus.

More information at:
https://www.who.int/news/item/13-11-2020-first-ever-vaccine-listed-under-who-emergency-use

https://www.world-today-news.com/who-approves-indonesian-polio-vaccine-for-emergency-use/

THYPHIBEV achieved WHO Prequalification to contribute to fighting typhoid fever

Geneva, 04th December 2020 – WHO has granted today the prequalification status to TYPHIBEV, the thyphoid conjugated vaccine (TCV) manufactured by Biological E (BE), one of two suppliers of TCV to the UN agencies. The vaccine was developed in collaboration with the GSK Vaccines Institute for Global Health (GVGH), based in Italy, which first developed the vaccine strain and transferred the technology to BE in 2013. BE has further developed the vaccine, including manufacturing process optimization and scale up, pre-clinical studies and comprehensive clinical trials for Phase I, II/III in India. Today, this vaccine is being manufactured in BE's GMP manufacturing facilities in Hyderabad, India.

Typhoid fever is a systemic disease caused by a bacterial infection through the pathogen Salmonella enterica serovar Typhi (S. Typhi), a specific type of rod-shaped, flagellated, aerobic, Gram-negative bacterium, causing enteric symptoms. Infants, children, and adolescents in South-central and Southeast Asia experience the greatest burden of illness. Outbreaks of typhoid fever are also reported from sub-Saharan Africa and some areas in Latin America. To combat and to reduce the morbidity and mortality caused by typhoid fever, preventive measures and strategies have been employed, the most important being vaccination. With a recent commitment from Gavi, The Vaccine Alliance, to support the

introduction of TCV in eligible countries and increased funding from several stakeholders, momentum appears to be in favor of wider TCV use.

More information at:
https://extranet.who.int/pqvdata/PreviewVaccine.aspx?nav=0&ID=390 ; https://doi.org/10.1093/cid/ciaa504

More information at: https://polioeradication.org/wp-content/uploads/2019/06/english-polio-endgame-strategy.pdf ; https://www.precisionvaccinations.com/low-cost-sabin-inactivated-polio-vaccine-gains-development-momentum ; https://extranet.who.int/pqvdata/PreviewVaccine.aspx?nav=0&ID=390

First Sabin Inactivated Poliovirus Vaccine (sIPV) Achieved WHO Prequalification

Geneva, 2nd December 2020 – In 1988, the World Health Assembly adopted a goal of eradicating poliovirus globally. Since then, polio incidence has decreased by more than 99%, using oral polio vaccine (OPV, Sabin vaccines) and IPV (Salk vaccine) key in interrupting transmission. OPV has the benefits of lower cost compared with IPV and better induction of intestinal/mucosal immunity. However, it is also related to vaccine-derived poliovirus infections, and vaccine-associated paralytic polio, which have in recent years outnumbered wild-type polio infections in few countries, where polio vaccine coverage is limited. The Sabin Inactivated Poliovirus Vaccine is indicated to prevent the Wild Polio Virus in the hope of completely eradicating the disease, and can be manufacturered in emerging countries facilities - as opposed to the Salk strain - providing a cost-benefit to the populations in need.

The Sabin Inactivated Polio Vaccine (sIPV) produced by LG Chem is the first Sabin trivalent innactivated vaccine prequalified by WHO. It contains poliovirus type 1, type 2 and type 3 (Sabin strains) produced on Vero-cells, concentrated, purified and inactivated. Each dose contains 5 D-antigen units of type 1, 8 D-antigen units of type 2, and 16 D-antigen units of type 3. The sIPV is noninferior compared with IPV and can be used for primary vaccination against poliomyelitis.

CNBG receives first COVID-19 vaccine conditional approval from China regulators

Beijing, 31st December 2020 – China's health authorities have approved a COVID-19 vaccine from state-owned Sinopharm for general use on the population, the government has announced. The vaccine was developed by an affiliate of state-owned pharmaceutical giant Sinopharm, Beijing Biological Products Institute, a subsidiary of China National Biotec Group (CNBG). The vaccine was said to be 79.34% effective in preventing people from developing the disease based on interim data. The approval, announced by the National Medical Products Administration, comes after the United Arab Emirates this month became the first country to roll out the vaccine to the public, and as Pakistan announced a 1.2 million dose purchase from Sinopharm. China launched an emergency use programme in July aimed at essential workers and others at high risk of infection, and had administered more than 4.5 million doses as of 15th December, using at least three different products - two developed by CNBG and one by Sinovac Biotech, pointing to progress China has made in the global efforts to develop effective COVID-19 vaccines.

More information at:
https://www.reuters.com/article/us-health-coronavirus-vaccine-china-idUSKBN295O5P

Global Efforts to Stop COVID

DCVMN with world leaders to support the COVAX FACILITY

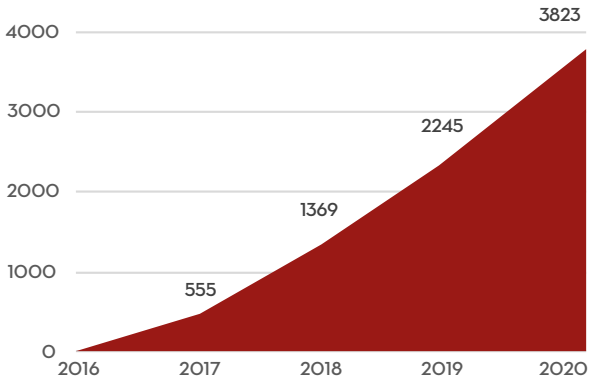
In the face of the current pandemic, Gavi, the vaccine alliance, is well placed to lead the charge in ensuring availability of COVID-19 vaccines for GAVI eligible countries and high-risk populations worldwide. “The COVID-19 AMC is an example of the progressive and decisive actions GAVI has taken to provide an initial framework to tackle this pandemic. The DCVMN constituency supports the COVID-19 Advance Market Commitment (AMC) and calls for equal participation of innovators and manufacturers”, said Sai D. Prasad, DCVMN President, at the Global Vaccine Summit, hosted by United Kingdom Prime Minister, Boris Johnson, gathering over 70 speakers. The livestreamed virtual event saw participation from over 30 heads of state and government, as well as leaders from business, civil society and international organizations. The event resulted in the raising of a remarkable US$ 8.8 billion towards the replenishment of Gavi, which the DCVMN commends. Representing a network of manufacturers that have collective experience in supplying nearly 4 billion doses annually to 170 countries, DCVMN members strive to be reliable partners, ready and available to support the Alliance in its response to COVID-19. The DCVMN members’ response to COVID-19 has been rapid and comprehensive: member companies initiated vaccine development, based on various technology platforms, enabling capabilities for large scale manufacturing, to supplying vaccines globally.

More information at:
https://www.gavi.org/news/media-room/world-leaders-make-historic-commitments-provide-equal-access-vaccines-all
https://www.gavi.org/news/media-room/gavi-launches-innovative-financing-mechanism-access-covid-19-vaccines

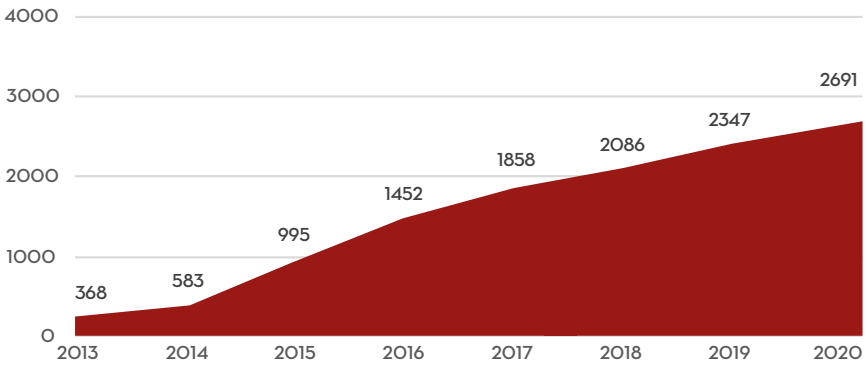
Training opportunities to Think ahead

In 2020, DCVMN continued to offer its members scientific and technical learning opportunities and professional training workshops transitioning to a fully virtual format, based on individual e-learning courses and e-workshops.

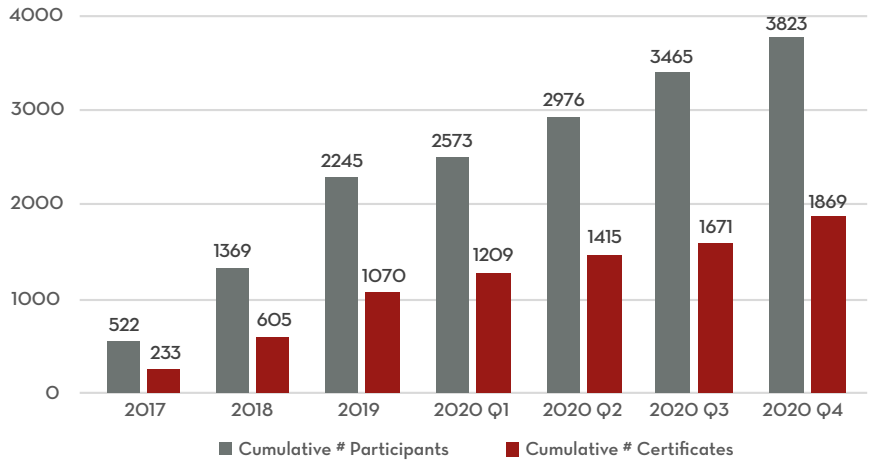
DCVMN launched its e-learning platform in December 2016, offering flexible, self-paced learning to strengthen vaccine manufacturers' knowledge to produce safe, effective, and affordable vaccines for all people. Participants can follow the e-learning courses from anywhere in the world, at any time. At the end of each course, participants that score at least 80% in the quiz can download a customized certificate of achievement. As of December 2020, the DCVMN e-learning platform offered 22 courses to its members. With ten new e-learning courses added to the platform in 2020, we denote an 83% increase in the number of courses compared to 2019. Since 2016, 3823 participants have enrolled in the e-learning courses, of which 1869 achieved certificates (see figure below). In 2020, we observed 1578 participants in the DCVMN e-learning courses and a total of 799 earned certificates. In 2021, DCVMN plans to develop Virtual Reality (VR) training courses for all DCVMN members. Efforts are currently underway to create a VR training course for a new in-vitro laboratory assay.



Cumulative # of e-learning participants



Cumulative #of training workshop's participants, 2013-2020



DCVMN e-learning platform available at https://moodle.dcvmn.net

In 2020, DCVMN workshops were held in an interactive virtual format. DCVMN and its partners organized seven e-workshops focused on topics related to regulatory affairs, pharmacovigilance, supply chain, and other essential subjects of interest to vaccine manufacturers. A total of 344 participants, from 39 companies and 15 countries. Attended the e-workshops in 2020. As preparation for the e-workshops, participants were asked to complete a relevant e-learning course, which improved the interactions between participants. The 2020 e-workshops topics and attendance are shown in the table below.

Date	Topic	Number of participants	Number of companies
16-18 March 2020	Vaccine Safety Monitoring and Pharmacovigilance Tools	67	14
27-29 April 2020	Regulatory Pathways and Changes in Vaccine Testing	68	22
12-14 May 2020	Health Technology Assessment	53	14
16-17 June 2020	Supply Chain Traceability	55	17
30 Sept-1 Oct 2020	Regulatory Pathways Part II	60	19
22 October 2020	PSPT 1st Technical Workshop	18	12
10 December 2020	PSPT 2nd Technical Workshop	23	12
TOTAL	**7**	**344**	**Average: 16**

DCVMN contributing to build regulatory excellence through professional graduate programme for its members at the National University Singapore

Following a DCVMN training workshop to **Fostering Regulatory Convergence Dialogue in Asia**, held on 25th March 2019, in Singapore[7], DCVMN Secretariat sought to understand about the scope of the Center of Regulatory Excellence (CoRE) at the National University of Singapore (NUS) and identify areas for collaboration.

CoRE provides a platform to develop programmes that build leadership capability among senior staff and executives, promote regulatory leadership and encourage policy innovation across the Asia-Pacific area. Launched in 2014, the Centre of Regulatory Excellence (CoRE) at Duke-NUS Medical School, is the first dedicated Asian centre targeted at the needs of national health regulators, the biomedical industry, and pharmaceutical and medical device companies. CoRE responded to a need for the creation of a neutral platform to help regulatory growth take shape and create an environment in which regulatory policy can be developed to create measurable results through improved health outcomes; preventing deaths and illnesses and enhancing the quality of life.

The DCVMN secretariat proposed to join the efforts towards development of regulatory talent, promote regulatory policy innovation and support regulatory networking to support public and private bodies in their development of strong regulatory capabilities, and encourage innovation through thought leadership and best practices.

As a consequence, in April 2020 the DCVMN Secretariat and the NUS signed an agreement where by DCVMN will support the talent development through training programmes for employees of DCVMN member companies to follow at NUS, providing the opportunity for many to receive academic highly recognized certificates of professional education, which are valued by regulatory inspectors and auditors. The aim of DCVMN-NUS training is to create an inspiring collaborative environment in which new healthcare products and vaccines can be developed, registered and delivered to populations in many emerging countries with ensured efficacy and safety profiles.

Over 2020 DCVMN sponsored the training fees for 12 employees of members (Biomanguinhos, Bravovax, CNBG, LG Chem, Panacea, Polyvac, Walvax, Zydus Cadila) who voluntarily participated in trainings on Pharmaceutical Regulation, Biosimilars & Biotherapeutics, Clinical and Medical Affairs. Congratulations to all!

More information at:
https://www.duke-nus.edu.sg/core/about

[7] *https://www.dcvmn.org/Workshop-Fostering-Regulatory-Convergence-Dialogue-in-Asia*

Best-practices supply chain working group

Based on the analyses of needs, agreed priorities, and previous discussions of the Supply Chain Working Group, a peer-reviewed paper was accepted by the Vaccine Journal, providing members' views to a wide audience in the global immunization community.

Two priorities were the main focus of the working group during 2020. The first related to the engagement of members in the research and development of COVID-19 vaccines given the growing pandemic. The monitoring of members' engagement showed a number of initiatives being pursued, both in terms of research and development, as well as collaborations across members, in carrying out the clinical trials necessary for assessing the safety and effectiveness of vaccines, and addressing regulatory approval. The second priority was on traceability. BioFarma updated the supply working group on its experience in the barcoding of primary packaging and this raised significant interest from members. Two developments were notable in this regard. First, Gavi and UNICEF indicated that they would require barcoding on secondary and tertiary packaging by end-2021 for vaccines procured by UNICEF. Second, the Vaccine Innovation Prioritization Strategy (VIPS) – an alliance of Gavi, WHO, UNICEF, PATH and the Bill and Melinda Gates Foundation – indicated the barcoding of primary packaging as a priority for the future. Collecting data allowed for a second peer-reviewed paper to be published:

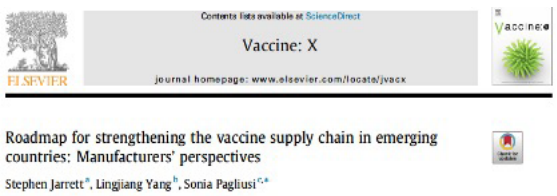

VACCINE

ELSEVIER FREE Full-Text Article

Vaccine. 2020 Jul 22; 38(34): 5418–5423. PMCID: PMC7287474
doi: 10.1016/j.vaccine.2020.06.022 10.1016/j.vaccine.2020.06.022 PMID: 32600808

Emerging manufacturers engagements in the COVID –19 vaccine research, development and supply

Sonia Pagliusi,[a,*] Stephen Jarrett,[b] Benoit Hayman,[c] Ulrike Kreysa,[d] Sai D. Prasad,[e] Martin Reers,[f] Pham Hong Thai,[g] Ke Wu,[h] Youn Tao Zhang,[i] Yeong Ok Baek,[j] Anand Kumar,[k] Anatoly Evtushenko,[l] Suresh Jadhav,[m] Weining Meng,[n] Do Tuan Dat,[o] Weidan Huang,[p] and Samir Desai[q]


Contents lists available at ScienceDirect

Vaccine: X

journal homepage: www.elsevier.com/locate/jvacx

Roadmap for strengthening the vaccine supply chain in emerging countries: Manufacturers' perspectives

Stephen Jarrett[a], Lingjiang Yang[b], Sonia Pagliusi[c,*]


VACCINE

ELSEVIER FREE Full-Text Article

Vaccine. 2020 Dec 14; 38(52): 8318–8325. PMCID: PMC7727743
doi: 10.1016/j.vaccine.2020.11.011: 10.1016/j.vaccine.2020.11.011 PMID: 33198075

The role of manufacturers in the implementation of global traceability standards in the supply chain to combat vaccine counterfeiting and enhance safety monitoring

Stephen Jarrett,[a] Taufik Wilmansyah,[b] Yudha Bramanti,[b] Hikmat Alifiamsar,[b] Drajat Alamsyah,[b] Komarapuram R. Krishnamurthy,[c] Lingjiang Yang,[d] and Sonia Pagliusi[e,*]

Working closely with Bio Farma, their experience on the barcoding of primary packaging was disseminated through a third peer-reviewed paper.

Bio Farma presented its experience at the virtual Annual General Meeting of the DCVMN. Given the rapidly increasing interest on barcoding and the availability of funding due to the halting of in-person meetings and activities due to the pandemic, the go-ahead was given for the DCVMN Secretariat to support additional pilots in the barcoding of primary packaging.

A call for expressions of interest was sent to DCVMN members with six companies initially expressing interest and four applications for support received by the deadline that had been set. These applications were due to be assessed by an independent review group early in the New Year.

DCVMN manufacturers trigger successful Collaborative Registration Procedure (CRP) for Accelerated Registration of WHO Prequalified Vaccines in Developing Countries

Encouraged by open dialogue between WHO and DCVMN, vaccine industry is actively pursuing the WHO Collaborative Registration Procedure: three DCVMN member companies - Biological E Ldt., Bharat Biotech International Ltd. and Serum Institute of India Pvt. Ltd.- were successful in registering their respective new WHO pre-qualified vaccines in eight developing countries: Democratic Republic of Congo, Eritrea, Ghana, Malaysia, Malawi, Nigeria, Sierra Leone, and Zambia. The Collaborative Registration Procedure (CRP) was launched in 2013 to facilitate and accelerate the registration process for WHO-prequalified medicines and vaccines in 43 CRP-adopting countries[8]. It is based on information sharing between WHO prequalification services and National Regulatory Authorities (NRAs) by leveraging assessment and inspection reports of WHO prequalification, and thereby eliminating duplicative regulatory tasks, for in-country registration of quality-assured products, contributing to their wider availability. This procedure helps harmonize submissions and streamline the licensure process in many developing countries. There has been a positive change in the registration process for WHO Prequalified vaccines during past few months[9]. The overall process has proceeded well within the stipulated 90 days period, likely due to the active consultation between NRA's and WHO-CRP team, although the greater success of achieving maximum registrations through CRP is yet to come. DCVMN calls for further support from governments to increase the value of WHO-Prequalification of vaccines towards accelerated global access goals.

[8] https://extranet.who.int/pqweb/medicines/collaborative-registration-faster-registration

[9] https://www.who.int/pq-vector-control/resources/orient_crp.pdf?ua=1

DCVMN established an international consortium of laboratories to study novel in vitro assay for childhood vaccines

With the support of a grant awarded by the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), DCVMN has established an international consortium of laboratories, to advance the in-house validation of a serological potency test for whole-cell pertussis-containing childhood vaccines. Pertussis, commonly known as whooping cough, is a severe disease caused by the Bordetella pertussis bacterium. A cornerstone of routine childhood immunization programs around the world, pertussis-containing vaccines, such as the pentavalent DTPHepBHib, save hundreds of thousands of lives annually.

The project, budgeted at 750 thousand US dollars, aims to support the in-house assessment of a serological assay (Pertussis Serological Potency Test - PSPT) to replace the Kendrick Test currently used for Pertussis potency testing. The PSPT benefits from increased reliability and reproducibility, sparing countless laboratory animals from the distress implied in the current test, while ultimately reducing the cost of a single vaccine dose.

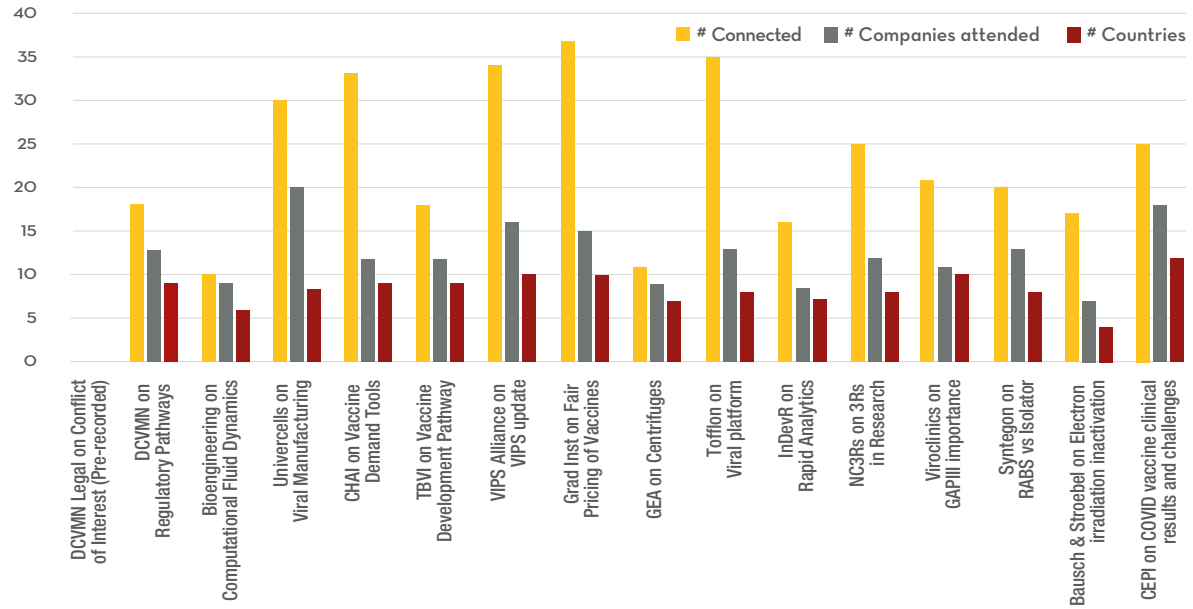
The DCVMN-led international consortium of twelve laboratories was launched on 29th September 2020, and includes vaccine manufacturers and national control laboratories, joining forces for the 18-month study. The Senior Scientific Adviser and PSPT Steering Committee Chairperson, Dr. Christina von Hunolstein, at the Istituto Superiori di Sanità, noted that "strong scientific evidence will be crucial to adopt state-of-the-art testing and shaping future requirements for testing pertussis-containing vaccines. This requires a concerted effort among vaccine manufacturers and expert control laboratories." Data and scientific evidence derived from the study will allow an open dialogue on the broader use of the in vitro testing.

More information at:
https://www.dcvmn.org/-PSPT-consortium-57-
https://niimbl.force.com/s/pc31-302

Increasing access to expertise and technical capabilities

DCVMN continued its efforts to promote open and equitable access to information in 2020 by means of webinars and the Technical Portal databases on the website. The well-established webinar platform allowed DCVMN to pivot rapidly in early 2020 from face-to-face to virtual events during the pandemic, offering additional webinars. The primary goal of the webinar program is to share information on current technical and industry topics. Regular contact and communication also helps to strengthen DCVMN community ties and develop continuity.

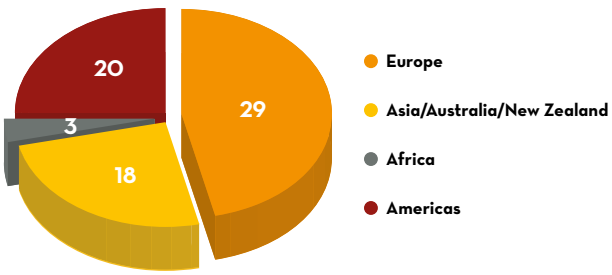
Sixteen webinars were presented in 2020 by resource member or partner organizations on product development (1), manufacturing technologies (7), clinical and regulatory processes (2), planning and pricing models (2) and specialist topics (3Rs, GAP III and governance). Past webinar slides and recordings are made available on the DCVMN website as an open information resource. Use of this resource has increased steadily. Cf. https://www.dcvmn.org/-Webinar-materials-13-



The DCVMN Portal includes two databases: Consultants and Technical Collaborations. In the first, consultants with aregional or international experience, who are available to provide services to DCVMN Secretariat or directly to members, list themselves on this database via a website form. The database established in 2016, was updated in 2019. At the end of 2020, 70 consultants from 20 countries were listed.

The technical collaborations database launched in early 2020, allows member companies to voluntarily list their technical capabilities and spare capacities to expand collaboration opportunities. The COVID-19 pandemic has subsequently resulted in significant global effort to gather market intelligence on global vaccine production capacities and has prompted many new international collaborations to meet anticipated COVID vaccine demand. Cf. https://www.dcvmn.org/spip.php?page=partnerships

Regional distribution of consultants available on the Portal



Strengthening Pharmacovigilance

The DCVMN activities to increase and strengthen PV capacities for sustainable and stable supply and to enhance vaccine safety monitoring by using best practices, which started in March 2019, was continued in 2020 by providing various supporting tools.

In January 2020 the Vaccine Pharmacovigilance e-learning course went live. The course provides a shared understanding to continuous vaccine safety surveillance in the peri- and post-licensure setting. The course aims to equip the participants with up-to-date knowledge to structure and update their pharmacovigilance systems and implement best practices, in compliance with the requirements of the relevant regulatory authorities.

A PV audit checklist for facilitating internal PV system gap analyses was presented and discussed for implementation, examples for performing Health Hazard Evaluations for potential safety concerns following product quality issues were addressed, and a proposal for a PV SOP master-list was presented.

Four DCVMN PV Working Group meetings were held to discuss PV topics, also in the context of COVID-19 vaccine development and safety surveillance. Initiatives to support DCVMs include vaccine safety monitoring in the pre-, peri- and post-licensure phases of COVID-19 vaccine life cycle, within the frame of the COVAX facility, were in the planning phase.

From March 16 – 18 an advanced pharmacovigilance workshop was held virtually, covering training on best practices in core PV activities: AEFI case management and aggregate reporting (PSURs), signal- and risk management, and PV Quality Management Systems were provided.

To understand the specific needs of DCVMN member companies involved in COVID-19 vaccine development, a questionnaire was circulated to the DCVMN PV WG members. The Questionnaire specifically addressed the companies' needs for signal and risk management in the pre-, peri- and post-licensure setting, preparation of RMPs, as well as benefit / risk assessment for aggregate reporting (e.g., monthly reports following COVID-19 vaccine introduction, PSURs, a.o.).

21st Annual General Meeting:
Vaccines for a healthy future

The Developing Countries' Vaccine Manufacturers Network (DCVMN) held its 21st Annual General Meeting from 3rd to 5th November 2020, the first being held on a virtual platform, due to the pandemic declared on by the World Health Organization (WHO) on 11th March 2020[10]. The discussions focused on vaccines against SARS-CoV-2 virus to prevent the COVID-19 disease. Over 380 participants from 36 countries, including leaders from industry, research institutions and global health organizations, joined the online deliberations and agreed on the importance of vaccine developers and manufacturers in rapidly bringing to the world safe and effective vaccines to end the COVID-19 pandemic. The pandemic is expanding rapidly which makes the global availability and equitable access to safe and effective COVID-19 vaccines critical. Strategies put in place include the establishment of the ACT-A within which the COVAX facility aims to distribute 2 billion COVID-19 vaccine doses by the end of 2021 with procurement mechanisms established. At the same time, regulatory authorities have emergency use authorizations aimed at the rapid approval of safe and effective vaccines, and harmonization in regulatory approaches being advocated.

Vaccine industry has moved with unprecedented speed thanks to thousands of volunteers in many countries who participated in clinical studies. In total there were more than 200 candidate vaccines reported, and about ten have reached phase 3 trials, including two mRNA candidates by Pfizer/BioNTech, and Moderna. Another technology was developed by Oxford University and AstraZeneca, in collaboration with emerging manufacturers in Argentina, Brazil, China, Korea, India, and Mexico. Other candidates include inactivated virus vaccines from Sinovac Biotech, in collaboration with Butantan, two vaccines from Sinopharm and one from Bharat Biotech which is in phase 3 trials in India. CanSino Biologics is well advanced with its vaccine development as is Novavax and Johnson & Johnson, in collaboration with Biological E. A vaccine produced in Russia was also advancing.

[10] *https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020*

Governance statements

The Executive Committee established in January 2020, brings together a range of skills and experiences to represent corporate members around the globe, in governing an organization, sharing the commitment to contribute to improving vaccination for all people, through their involvement amidst meetings, events, committees, activities, and global efforts. All EC members act on a voluntary, non-remunerated basis. The President to the Committee for the coming period of 2020-23, is Mr. Sai Prasad and new EC members include Tiago Rocca, Adriansjah Azhari and Wendy Huang. The Committee held its formal governance virtual meetings on the following dates: April 6, May 8, May 14, May 15, June 11, July 13, August 26, September 23, October 21, October 26, November 27, December 17 2020, as listed on the table below, with pre-set agenda and relevant documents circulated in advance to facilitate informed decisions, and minutes to the formal virtual meetings are accessible to all members to consult at https://www.dcvmn.org/Meeting-minutes.

Role	Name	Company	Attendance out of 12 virtual meetings in 2020
President	Mr. Sai Prasad	Bharat Biotech	11
Vice-President	Mr. Patrick Tippoo	Biovac	11
Treasurer	Mr. Fernando Lobos	Sinergium	9
Member	Ms. Lingjang Yang	CNBG-Sinopharm	10
Member	Mr. Adriansjah Azhari	BioFarma	8
Member	Mr. Tiago Rocca	Butantan	11
Member	Ms. Wendy Huang	Innovax	10
Senior Adviser	Dr. Suresh Jadhav	Serum Institute of India	1
Executive Secretary (non-voting)	Dr. Sonia Pagliusi	DCVMN International	12

In addition, DCVMN Secretariat regularly supports the Donors Advisory Committee (DAC) meetings, formed by advisers from FVMRH/Imperial College London, PATH, and NIIMBL, who are supporting and guiding the Network technical and scientific activities for members manufacturers. The Advisory Committee held 4 virtual meetings in 2020 (03 April, 25 June, 02 September, 02 December). Furthermore, expert Working Groups (WGs) formed by DCVMN members manufacturers around strategic areas (supply chain, regulatory affairs, 3Rs and vaccine safety/pharmacovigilance) foster dialogue on non-competitive topics and implementation of innovations. WG meetings are held regularly, to advance the sharing of best-practices and projects of common interest to most members.

The Working Group activities are currently supported by independent senior expert consultants, funded with donors' funds, who help develop and analyse surveys, draft white papers and presentations, training & communication materials. DAC and WG members act on a voluntary non-remunerated basis, similar to EC members. This new structure empowers the members to be directly involved in leading and directing the working groups and related Network activities.

Financial statements

The accounts of 31st December 2020 showed liquidities of 3'978'318.58 USD available to DCVMN International at the bank in Switzerland, and increase of 27% compared to 2019. It is noted that the funds from donors are kept in separate accounts and are dedicated for use only for purposes/activities agreed by the donors in accordance with signed agreements, and not used to support unrelated activities or staff benefits. Membership/partnership funds are used for secretariat operations and maintenance costs that may include staff salaries, fringe benefits, insurances and administrative supplies/support, as well as for the organization of the AGM and complement some training activities. Secretariat expenses are aligned with the 5-year strategic plan. Membership status as of December 2020 indicated that there were 41 members, of which 13 were full members (with WHO PQed vaccines). In 2020, all members settled membership contributions.

BALANCE SHEET AS AT 31 DECEMBER

	31.12.2020		31.12.2019	
ASSETS	**CHF**	**USD**	**CHF**	**USD**
Current assets				
Liquidities	3'516'435.79	3'978'318.58	3'029'699.33	3'128'561.88
Advance deposit for expenses	4'419.50	5'000.00	4'842.00	5'000.00
Members contribution to receive	0.00	0.00	49'388.40	51'000.00
Provision for loss on members contributions	0.00	0.00	-37'767.60	-39'000.00
Regus deposit	58.00	65.62	58.00	59.89
Prepaid expenses	8'468.49	9'580.82	5'164.63	5'333.16
Total current assets	**3'529'381.78**	**3'992'965.02**	**3'051'384.76**	**3'150'954.93**
TOTAL ASSETS	**3'529'381.78**	**3'992'965.02**	**3'051'384.76**	**3'150'954.93**
LIABILITIES	**CHF**	**USD**	**CHF**	**USD**
Short-term liabilities				
Payables	0.00	0.00	31'236.61	32'255.91
Donations carryover	909'262.85	1'028'694.25	448'605.49	463'244.00
Accrued expenses	121'980.89	138'003.04	278'915.63	288'016.97
Total short-term liabilities	**1'031'243.74**	**1'166'697.29**	**758'757.73**	**783'516.88**
Unrestricted reserves				
Capital	2'292'627.03	2'362'205.63	1'923'729.08	2'031'975.60
Translation adjustment USD/CHF		10'460.85		5'232.42
Net result for the year	205'511.01	453'601.25	368'897.95	330'230.03
Total unrestricted reserves	**2'498'138.04**	**2'826'267.73**	**2'292'627.03**	**2'367'438.05**
TOTAL LIABILITIES	**3'529'381.78**	**3'992'965.02**	**3'051'384.76**	**3'150'954.93**

INCOME AND EXPENSES STATEMENT FOR THE YEAR ENDED 31 DECEMBER

	2020		2019	
Income	**CHF**	**USD**	**CHF**	**USD**
Members contributions	509'425.50	519'000.00	562'531.75	561'000.00
Provision for loss on members contributions	0.00	0.00	-37'767.60	-39'000.00
Reversal provision for loss on members contributions	37'767.60	39'000.00	29'574.00	30'000.00
Loss on members contributions	-37'767.60	-39'000.00	-29'574.00	-30'000.00
Donations received	1'076'092.66	1'148'884.15	1'331'092.30	1'324'915.86
Donations carryover from previous year	448'605.49	463'244.00	0.00	0.00
Donations carryover	-909'262.85	-1'028'694.25	-448'605.49	-463'244.00
Annual meeting participants' contribution	1'800.82	1'890.00	32'875.55	32'820.00
Total income before financial income	**1'126'661.62**	**1'104'323.90**	**1'440'126.51**	**1'416'491.86**
Other financial income				
Gain on investments	0.00	0.00	16'005.18	16'048.51
Total other financial income	**16'005.18**	**16'048.51**	**16'005.18**	**16'048.51**
TOTAL INCOME	**1'126'661.62**	**1'104'323.90**	**1'456'131.69**	**1'432'540.37**
Operating expenses				
Best practice supply WG	-27'904.80	-30'000	-46'660.10	-46'884.78
Training Initiative	-93'244.94	-98'274.68	-157'243.45	-156'927.33
Regulatory Forum Initiative	-122'747.84	-131'356.05	-52'778.52	-52'612.59
Consulting Databases Initiative	-15'839.88	-17'004.75	-12'349.39	-12'410'41
Pharmacovigilance Initiative	-13'173.88	-13'750.00	-30'437.33	-30'558.99
Annual General Meeting	-73'336.60	-80'008.30	-69'147.22	-68'489.34
Total operating expenses	**-346'247.94**	**-370'393.78**	**-368'556.01**	**-367'883.44**
Staff costs				
Salaries	-253'610.50	-264'700.15	-177'224.00	-176'573.77
Social contributions AVS/AI/APG/AC/PCFam	-23'341.70	-24'837.93	-16'025.80	-15'915.54
Social and accident insurances	-5'144.60	-5'575.16	-3'592.30	-3'637.94
LPP contribution	-17'129.25	-18'107.82	-13'781.80	-13'815.80
Total staff costs	**-299'226.05**	**-313'221.26**	**-210'623.90**	**-209'943.05**
Other operating expenses				
Office rental	-7'427.06	-7'719.59	-7'211.63	-7'190.24
Office insurance	-389.15	-401.85	-350.25	-355.30
Office supplies	-2'567.43	-2'743.39	-4'012.20	-4'009.21
Accounting services	-14'894.90	-16'375.63	-12'153.95	-12'274.80
Legal consulting	-70'813.75	-79'976.93	-30'739.95	-31'726.09
HR and payroll services	-28'171.10	-30'932.47	-11'728.00	-11'665.17
Technical support by FVMR Hub	-23'626.33	-25'000.00	-54'913.58	-54'567.71
Financial audit	-10'770.00	-12'760.82	-10'433.00	-10'749.61
Publications	-7'838.26	-8'143.48	-2'584.80	-2'555.41
Travel and foreign expenses secretariat	0.00	0.00	-22'416.59	-22'361.13
Management expenses	-1'322.95	-1'401.73	-3'533.32	-3'519.32
Executive Committee Meetings	0.00	0.00	-1.720.00	-1'751.28
Miscellaneous	-1'058.57	-1'103.50	0.00	0.00
Total other operating expenses	**-168'879.50**	**-186'559.39**	**-161'797.27**	**-162'725.27**
EARNING BEFORE INTEREST AND TAXES	**312'308.13**	**234'149.47**	**715'154.51**	**691'988.61**
Financial expenses				
Interest paid	0.00	0.00	-1.30	-1.34
Bank and PayPal charges	-1'692.80	-1'775.26	-3'391.62	-3'397.86
Foreign exchange loss	-333'225.29	-12'536.81	-82'402.97	-89'659.15
Total financial expenses	**-334'918.09**	**-14'312.07**	**-85'795.89**	**-93'058.35**
EARNING BEFORE TAXES	**-22'609.96**	**219'837.40**	**629'358.62**	**598'930.26**
Prior-period income and expenses				
Prior year grant adjustment	0.00	0.00	-244'987.77	-252'982.00
Extraordinary income	244'987.77	252'982.00	0.00	0.00
Other incomes	822.00	849.17	0.00	0.00
Taxes on previous year	60.40	-1'002.00	333.90	204.54
Total prior-period income and expenses	**245'870.17**	**252'829.17**	**-244'653.87**	**-252'777.46**
RESULT BEFORE TAXES	**223'260.21**	**472'666.57**	**384'704.75**	**346'152.80**
Taxes	-17'749.20	-19'065.32	-15'806.80	-15'922.77
NET RESULT FOR THE YEAR	**205'511.01**	**453'601.25**	**368'897.95**	**330'230.03**

Notes to the financial statements

1. Overview

Purpose of the association

DCVMN is a public health driven, international alliance of manufacturers, working to strengthen vaccine manufacturers through the provision of information and professional training programs, technology improvements, innovative vaccine research and development, encouraging technology transfer initiatives, and educating the public about the availability of safe, effective and affordable vaccines for all people.

2. Accounting principles applied in the preparation of the financial statements

These financial statements have been prepared in accordance with the statutes and the provisions of commercial accounting as set out in the Swiss Code of Obligations (Art. 957 to 963b CO).

Foreign currency translation

Assets and liabilities in foreign currencies are translated into Swiss francs at the exchange rate in effect at the balance sheet date. Transactions in foreign currencies are translated into Swiss francs at the rate in effect at the average monthly rate.

Liquidities

Cash and cash equivalents are carried in the balance sheet at their nominal value.

Investments

Investments are valued at market price, if any.

Contributions receivables

Members contributions to receive are carried at their nominal value. Charges are calculated for these assets on an individual basis.

Payables

Payables are recorded in the balance sheet at their nominal value on the basis of invoices corresponding to services made on the date of closing.

Recognition of revenues and expenses

Revenues are recorded on the principle of periodicity, i.e., when revenue-generating transactions or events occur rather than on the basis of cash flows.

Expenses are recorded according to the principle of periodic delimitation, i.e. when the operations or events generating expenses occur and not according to cash flows.

3. Details, analyses and explanations to the financial statements

Number of full-time

The number of full-time employee equivalents did not exceed 10 on an annual average basis.

Pension liabilities

On 31 December 2020 the liability to the pension scheme amounted to CHF 4'234.45 / USD 4'790.64 (31 December 2019: CHF 4'383.10 / USD 4'526.13).

Explanations of extraordinary, non-recurring or prior-period items in the income and expenditure statement

• Donations carryover

The amount of CHF 909'262.85 / USD 1'028'694.25 was unused by 31st December 2020 and therefore deferred as carryover to be disbursed in 2021, with agreement of the donor. Carryover is the process by which unobligated funds remaining at the end of a budget period may be carried forward to the next budget period to cover allowable costs in that budget period. The carryover of funds enables grantees to use unexpended prior year grant funds in the next budget period.

• Legal consulting

In 2020 DCVMN engaged an extemal legal services firm to draft the new statutes and bylaws for the association.

• HR and payroll services

In 2020 DCVMN contracted the services of an Executive Recruiting Agency to engage the new CEO.

• Travel expenses

In 2020 due to the pandemic and international health security regulations ail travel was cancelled.

• Extraordinary income

A negative adjustment in a philanthropie pledge resulted in a reduction of CHF 244'987.77 / USD 252'982.- was in the 2019 financial statements (prior year grant adjustment). This amount has not been repaid in 2020 and is no longer to be repaid, which is why it has been booked as extraordinary income

4. General comments

1. DCVMN annual revenue from memberships, donations and financial gains in 2020 decreased by 18%, to CHF 1'587'318.98 (USD 1'669'774.15) before carryover, and before the variation on the provision on members contributions, from CHF 1'942'504.78 (USD 1'934'784.37), in 2019. This is mainly related to decrease partnerships and donations, as compared to 20 19.

2. Membership status as of December 2020 indicated that there were 41 members, of which 13 were full members (with WHO PQed vaccines). In 2020 there were no members that left the network and all members settled membership contributions.

3. The Network's activities and interim financial statements (up to Q3 2020) were presented by the Treasurer, on behalf of the Executive Committee, to the General Assembly of members on 3rd November 2020, at a virtual meeting, due to COVID-19 pandemic.

4. The Executive Committee's proposed budget for 2021 approved by the members assembly is targeted at 1'565'000 USD income and ca. $1'450'000 USD for expenses, which includes carryover funds from donors.

5. The budget income for 2021, was based on the assumptions below:

a) a philanthropic pledge of 758'289 USD, allocated for training and regulatory related activities in 2020.

b) a pledge of ca. 300'000 GBP, allocated for QC, GMP and technology support in 2021.

c) the membership contributions expected to remain similar to 2020estimated at slightly over 520'000.- USD. The funds received from members are dedicated to administrative operations including secretariat, rental, IT, supplies communication and staff salaries.

d) continuous corporate partnership contributions estimated at ca. 200'000 USD, for workshops and AGM.

Note that exchange rate volatility may influence the budget slightly up/downwards.

6. The approved budget for 2021 will have an approved carryover amount of CHF 222'039.86 / USD 251'204.73 (Bill & Melinda Gates Foundation - OPPI 204376), CHF 255'359.84 / USD 288'901.28 (NJTMBL), CHF 352'105.67 / USD 398'354.64 (PATH) and CHF 26'517.-/ USD 30'000.- (ESCO) corresponding to activities funded by respective donors.

7. All income and disbursements are handled exclusively by bank transfers, providing traceable, independent and accurate accoun-

ting records, complying with international accounting and business practices. All disbursements are subject to a two-signature system approval, prepared by the Secretariat and approved by the Treasurer, with two witnesses, an external comptroller and a DCVMN member. All disbursements correspond to bank transaction records and invoices corresponding to services. Accounts are available to corporate members, nominated by the Executive Committee, as well as by donors and local authorities, for financial review and assessment.

8. Of note, in 2020 the USD/CHF exchange rate contributed to foreign exchange loss of CHF 333'225.29 / USD 12'536.81, that reflected the value of the dollar on 31 December 2020 against local currency (CHF) as compared to the average exchange rate of the dollar over the calendar year. The indicated gains/losses and surplus are declared to the local fiscal authorities.

9. DCVMN has decided to divest in financial products since 2019, due to the volatility of global economy.

The unaudited financial statements were prepared by Multifiduciaire Genève S.A., (www.multigeneve.ch), under the oversight and responsibility of DCVMN Executive Committee.

DCVMN International
Developing Countries Vaccine Manufacturers Network
CH-1260 Nyon

BALANCE SHEET AS AT 31 DECEMBER

	Notes	31.12.2020 CHF		31.12.2020 USD	31.12.2019 CHF		31.12.2019 USD
ASSETS							
Current assets							
Liquidities		3'516'435.79	0.8839	3'978'318.58	3'029'699.33	0.9644	3'128'561.88
Advance deposit for expenses		4'419.50	0.8839	5'000.00	4'842.00	0.9644	5'000.00
Members contributions to receive		0.00	0.8000	0.00	49'388.40	0.9644	51'000.00
Provision for loss on members contributions		0.00	0.8000	0.00	-37'767.60	0.9644	-39'000.00
Regus deposit		58.00	0.8839	65.62	58.00	0.9644	59.89
Prepaid expenses		8'468.49	0.8839	9'580.82	5'164.63	0.9644	5'333.16
Total current assets		**3'529'381.78**		**3'992'965.02**	**3'051'384.76**		**3'150'954.93**
TOTAL ASSETS		**3'529'381.78**		**3'992'965.02**	**3'051'384.76**		**3'150'954.93**
LIABILITIES							
Short-term liabilities							
Payables		0.00	0.8000	0.00	31'236.61	0.9644	32'255.91
Donations carryover	3.1	909'262.85	0.8839	1'028'694.25	448'605.49	0.8000	463'244.00
Accrued expenses		121'980.89	0.8839	138'003.04	278'915.63	0.9644	288'016.97
Total short-term liabilities		**1'031'243.74**		**1'166'697.29**	**758'757.73**		**783'516.88**
Unrestricted reserves							
Capital		2'292'627.03		2'362'205.63	1'923'729.08		2'031'975.60
Translation adjustment USD/CHF				10'460.85			5'232.42
Net result for the year		205'511.01		453'601.25	368'897.95		330'230.03
Total unrestricted reserves		**2'498'138.04**		**2'826'267.73**	**2'292'627.03**		**2'367'438.05**
TOTAL LIABILITIES AND RESERVES		**3'529'381.78**		**3'992'965.02**	**3'051'384.76**		**3'150'954.93**

DCVMN International
Developing Countries Vaccine Manufacturers Network
CH-1260 Nyon

INCOME AND EXPENSES STATEMENT FOR THE YEAR ENDED 31 DECEMBER

	Notes	2020 CHF	2020 USD	2019 CHF	2019 USD
Income					
Members contributions		509'425.50	519'000.00	562'531.75	561'000.00
Provision for loss on members contributions		0.00	0.00	-37'767.60	-39'000.00
Reversal provision for loss on members contributions for previsous year		37'767.60	39'000.00	29'574.00	30'000.00
Loss on members contributions		-37'767.60	-39'000.00	-29'574.00	-30'000.00
Donations received		1'076'092.66	1'148'884.15	1'331'092.30	1'324'915.86
Donations carryover from previous year		448'605.49	463'244.00	0.00	0.00
Donations carryover	3.1	-909'262.85	-1'028'694.25	-448'605.49	-463'244.00
Annual meeting contribution participants		1'800.82	1'890.00	32'875.55	32'820.00
Total income before financial income		**1'126'661.62**	**1'104'323.90**	**1'440'126.51**	**1'416'491.86**
Other financial income					
Gain on investments		0.00	0.00	16'005.18	16'048.51
Total other financial income		**0.00**	**0.00**	**16'005.18**	**16'048.51**
Total income		**1'126'661.62**	**1'104'323.90**	**1'456'131.69**	**1'432'540.37**
Operating expenses					
Best practice supply WG		-27'904.80	-30'000.00	-46'600.10	-46'884.78
Training Initiative		-93'244.94	-98'274.68	-157'243.45	-156'927.33
Regulatory Forum initiative		-122'747.84	-131'356.05	-52'778.52	-52'612.59
Knowledge exchange and databases initiative		-15'839.88	-17'004.75	-12'349.39	-12'410.41
Pharmacovigilance initiative		-13'173.88	-13'750.00	-30'437.33	-30'558.99
Annual General Meeting		-73'336.60	-80'008.30	-69'147.22	-68'489.34
Total operating expenses		**-346'247.94**	**-370'393.78**	**-368'556.01**	**-367'883.44**
Staff costs					
Salaries		-253'610.50	-264'700.15	-177'224.00	-176'573.77
Social contributions AVS/AI/APG/AC/PCFam		-23'341.70	-24'837.93	-16'025.80	-15'915.54
Social and accident insurances		-5'144.60	-5'575.36	-3'592.30	-3'637.94
LPP contribution		-17'129.25	-18'107.82	-13'781.80	-13'815.80
Total staff costs		**-299'226.05**	**-313'221.26**	**-210'623.90**	**-209'943.05**
Other operating expenses					
Office rental		-7'427.06	-7'719.59	-7'211.63	-7'190.24
Office insurance		-389.15	-401.85	-350.25	-355.30
Office supplies		-2'567.43	-2'743.39	-4'012.20	-4'009.21
Accounting services		-14'894.90	-16'375.63	-12'153.95	-12'274.80
Legal consulting	3.2	-70'813.75	-79'976.93	-30'739.95	-31'726.09
HR and payroll services	3.3	-28'171.10	-30'932.47	-11'728.00	-11'665.17
Technical support by FVMR Hub		-23'626.33	-25'000.00	-54'913.58	-54'567.71
Financial audit		-10'770.00	-12'760.82	-10'433.00	-10'749.61
Publications		-7'838.26	-8'143.48	-2'584.80	-2'555.41
Travel and foreign expenses secretariat	3.4	0.00	0.00	-22'416.59	-22'361.13
Management expenses		-1'322.95	-1'401.73	-3'533.32	-3'519.32
Executive Committee Meetings		0.00	0.00	-1'720.00	-1'751.28
Miscellaneous		-1'058.57	-1'103.50	0.00	0.00
Total other operating expenses		**-168'879.50**	**-186'559.39**	**-161'797.27**	**-162'725.27**
EARNINGS BEFORE INTEREST AND TAXES		**312'308.13**	**234'149.47**	**715'154.51**	**691'988.61**
Financial expenses					
Interests paid		0.00	0.00	-1.30	-1.34
Bank and PayPal charges		-1'692.80	-1'775.26	-3'391.62	-3'397.86
Foreign exchange loss		-333'225.29	-12'536.81	-82'402.97	-89'659.15
Total financial expenses		**-334'918.09**	**-14'312.07**	**-85'795.89**	**-93'058.35**
EARNINGS BEFORE TAXES		**-22'609.96**	**219'837.40**	**629'358.62**	**598'930.26**
Prior-period and extraordinary income and expenses					
Prior year grant adjustment		0.00	0.00	-244'987.77	-252'982.00
Extraordinary income	3.5	244'987.77	252'982.00	0.00	0.00
Others income		822.00	849.17	0.00	0.00
Taxes on previous year		60.40	-1'002.00	333.90	204.54
Total pior-period income and expenses		**245'870.17**	**252'829.17**	**-244'653.87**	**-252'777.46**
RESULT BEFORE TAXES		**223'260.21**	**472'666.57**	**384'704.75**	**346'152.80**
Local taxes		-17'749.20	-19'065.32	-15'806.80	-15'922.77
NET RESULT FOR THE YEAR		**205'511.01**	**453'601.25**	**368'897.95**	**330'230.03**

Acknowledgements

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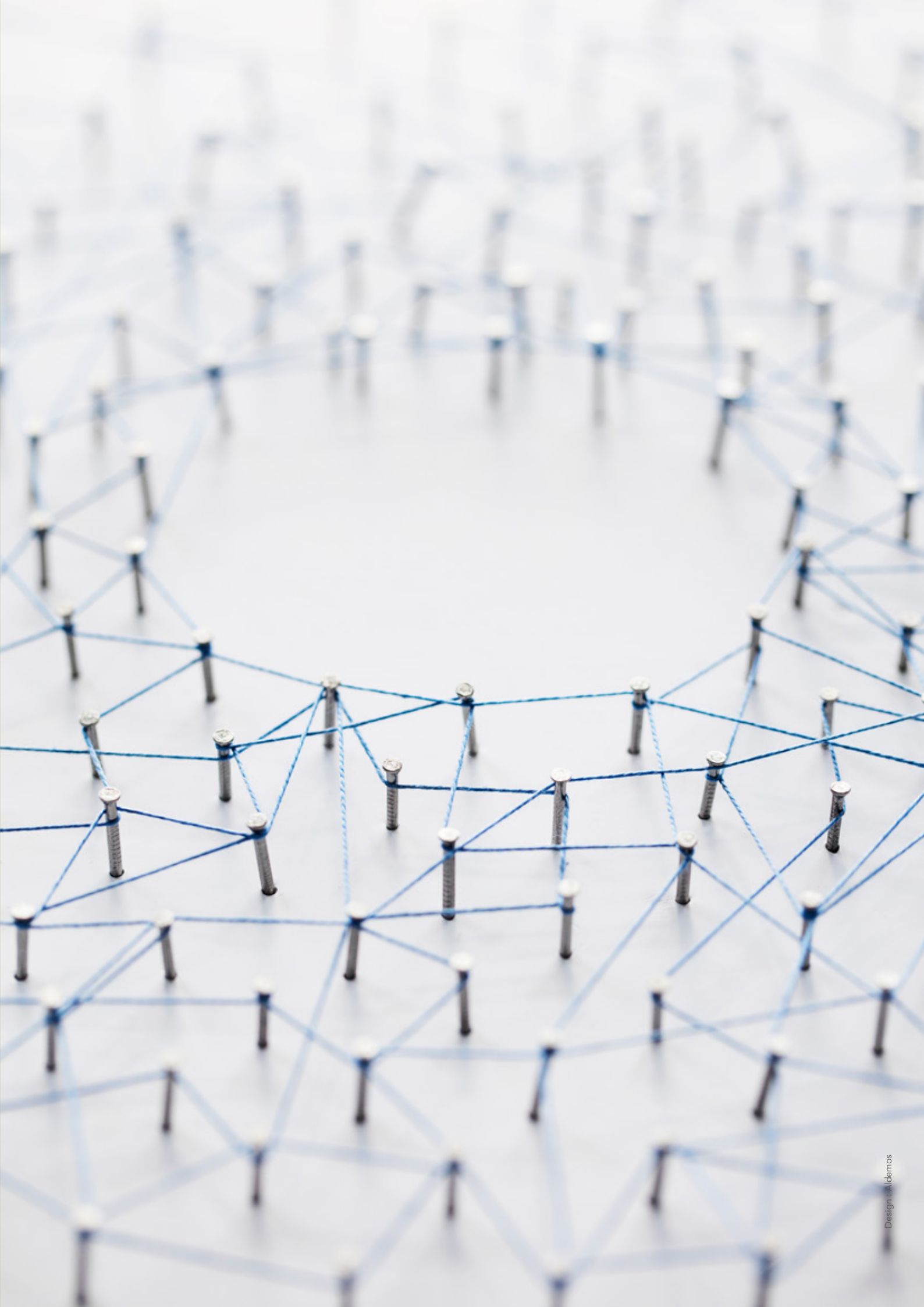
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