
Pandemic Influenza Preparedness Framework

ANNUAL PROGRESS REPORT

1 January – 31 December 2018



WHO/WHE/IHM/PIP/2019.1

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INTRODUCTION

The **Pandemic Influenza Preparedness (PIP) Framework** is an innovative public health instrument that brings together Member States, industry, other stakeholders and WHO to implement a global approach to pandemic influenza preparedness and response. The key goals include: to improve and strengthen the sharing of influenza viruses with human pandemic potential; and to increase the access of developing countries to vaccines and other pandemic response supplies.

The Framework includes a benefit-sharing mechanism called the Partnership Contribution (PC). The PC is collected as an annual cash contribution from influenza vaccine, diagnostic, and pharmaceutical manufacturers that use the WHO Global Influenza Surveillance and Response System (GISRS). Funds are allocated for: (a) pandemic preparedness capacity building; (b) response activities during the time of a pandemic; and (c) PIP Secretariat for the management and implementation of the Framework.

For pandemic preparedness capacity building, activities are implemented according to six outputs under one outcome in the High Level Implementation Plan (HLIP) II 2018-2023. The technical and financial investments of countries and other partners, including GISRS, play a critical role in advancing pandemic preparedness alongside PC investments. Collectively, resources are used to strengthen pandemic preparedness systems, knowledge and capacities. We thank countries and partners for their important role and contribution. The progress made and successes achieved are a result of joint collaboration on common objectives.

This report addresses the recommendation from the 2016 PIP Review that WHO develop a progress report that presents overall success metrics and infographics to illustrate progress in PIP Framework implementation. The report is published twice a year: once as a semi-annual report and once as an annual report. Technical and financial implementation for HLIP II and the PIP Secretariat are presented. Milestones are measured every six months and indicators are measured yearly. All data are presented cumulatively from 1 January 2018.

For financial implementation, progress is reported against biennial workplan allocations. Figures presented exclude WHO Programme Support Costs (PSC) unless otherwise stated. For the mid-year reports, income, expenditures and encumbrances are presented, and are based on WHO's financial tracking system (GSM). For annual reports, income and expenditures are presented, in line with the yearly WHO Interim Certified Financial Statement (ICFS).

Many staff across WHO Clusters and Departments in all Major Offices support the implementation of the PIP Framework. Without their work, dedication and collaboration, there would be no progress to report on. We extend our sincere thanks to these staff for their invaluable work.

The report is structured as a series of infographics as follows:

- **PIP Framework implementation overview (pages 6 - 7)**
- **Technical and financial implementation progress (pages 8 - 18)**
- **Financial report including ICFS - Annex A (reported annually only)**

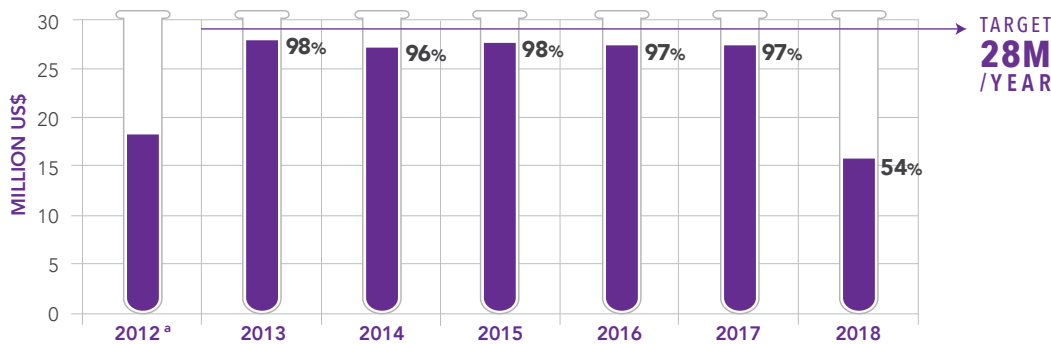
ACRONYMS & ABBREVIATIONS

AFR	WHO African Region	NITAG	National Immunization Technical Advisory Groups
AG	Advisory Group	NRA	National Regulatory Authority
AMR	WHO Region of the Americas	NVDP	National Vaccine Deployment Plan
BM	Biological Material	PC	Partnership Contribution
BOD	Burden of Disease	PCR	Polymerase Chain Reaction
CC	Collaborating Centre	PIP	Pandemic Influenza Preparedness
CRP	Collaborative Registration Procedure	PIRM	Pandemic Influenza Risk Management
CVV	Candidate Vaccine Virus	PISA	Pandemic Influenza Severity Assessment
DFID	Department for International Development (United Kingdom)	PQ	Prequalification
DG	Director-General	PSC	Programme Support Costs
EB	Executive Board	QMS	Quality Management Systems
EMR	WHO Eastern Mediterranean Region	RCCE	Risk Communications and Community Engagement
DEP	Planning for Deployment	REG	Regulatory Capacity Building
EQAP	External Quality Assessment Programme	RO	Regional Office
EUR	WHO European Region	RRT	Rapid Response Teams
GIP	Global Influenza Programme	SAGE	Strategic Advisory Group of Experts
GISRS	Global Influenza Surveillance and Response System	SARI	Severe Acute Respiratory Infection
GSD	Genetic Sequence Data	SEAR	WHO South-East Asia Region
HAI	Human Animal Interface	SFP	Shipping Fund Project
HLIP	High-Level Implementation Plan	SMTA2	Standard Material Transfer Agreement 2
ICFS	Interim Certified Financial Statement	TAG	Technical Advisory Group
IDP	Institutional Development Plan	TOR	Terms of Reference
ILI	Influenza-like Illness	UNICEF	United Nations Children's Fund
IPPP	Influenza Pandemic Preparedness Planning	US CDC	United States Centers for Disease Control and Prevention
ISID	International Society for Infectious Diseases	US HHS	United States Department of Health and Human Services
ISST	Infectious Substances Shipping Training	VCM	Vaccine Composition Meeting
IVPP	Influenza Virus with Pandemic Potential	WER	Weekly Epidemiological Record
IVTM	Influenza Virus Traceability Mechanism	WHA	World Health Assembly
L&S	Laboratory and Surveillance Capacity Building	WPR	WHO Western Pacific Region
LMIC	Low and Middle Income Countries	WHO	World Health Organization
MS	Member State		
NIC	National Influenza Centre		

IMPLEMENTATION OVERVIEW

PIP PC collection

PERCENTAGE OF TOTAL PC RECEIVED BY YEAR OF INVOICE



TARGET
28M
/YEAR



^a In 2012, contributions were made voluntarily

^b Figure includes PSC. PC collection for previous unpaid contributions and 2018 invoices is in process

PIP PC financial implementation

PREPAREDNESS

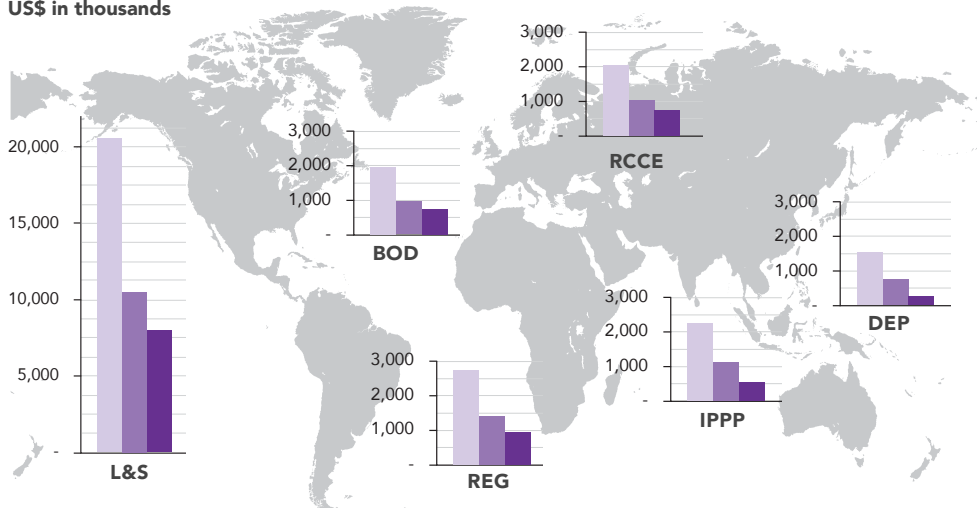
BIENNIAL BUDGET: **\$31M**

FUNDED: **\$16M**

IMPLEMENTED: **\$11.4M**

IMPLEMENTATION BY HLIIP II OUTPUT

US\$ in thousands



PIP SECRETARIAT

BIENNIAL BUDGET: **\$6.8M**

FUNDED: **\$2.8M**

IMPLEMENTED: **\$2.4M**

RESPONSE

TOTAL IN RESERVE
(WITH PSC & 2018
INTEREST): **\$46.7M**

LEGEND

Biennial budget
Funded
Implemented

PIP Framework outcome indicators

OUTCOME

Improved global pandemic influenza preparedness and response through the implementation of the PIP Framework

Indicator	2017 Baseline	2018 Status	2019 Target
% of Member States with zoonotic influenza cases sharing IVPPs with GISRS (N=4)	N/A	75%	N/A
% of PC recipient Member States reporting to FluNet (sustainability indicator) (N=37) ¹	84%	89%	≥85%
% of PC recipient Member States reporting to FluID (N=37) ¹	51%	73%	60%
% of Member States with BOD estimates considered by NITAG (N=19)	N/A	16%	30%
No. of PC recipient Member States that have implemented regulatory approach	0	6	10
% of PC recipient Member States that developed or updated a pandemic influenza preparedness plan (N=40) ¹	30%	35%	60%
% of companies reached to negotiate that signed an SMTA2 (N=32)	34%	38%	50%
% of Partnership Contributions received in the year of invoice (N=\$28M)	N/A	54%	100%

PIP Biological Materials^a shared

PIP BMs RECORDED IN IVTM



FROM 1 SEPTEMBER 2017 TO
31 AUGUST 2018:

184 VIRUS SUBTYPES RECORDED:
A(H1), A(H3), A(H5), A(H7), A(H9)



TOTAL SINCE 1 DECEMBER 2012:

844 PIP BMs RECORDED

^a For definition of 'PIP Biological Materials', see PIP Framework Section 4.1

SMTA2

SMTA2 WITH VACCINE & ANTIVIRAL MANUFACTURERS

Large / multi-national
manufacturers

>75M

pandemic production



Medium-sized
manufacturers

>5M and <75M

pandemic production



Small
manufacturers

<5M

pandemic production



>400M
DOSES

SMTA2 WITH DIAGNOSTIC MANUFACTURERS & ACADEMIC AND RESEARCH INSTITUTIONS



10M

TREATMENT COURSES OF
ANTIVIRALS



250,000

DIAGNOSTIC KITS



NEW:

25M

SYRINGES



66

SMTA2 WITH ACADEMIC
& RESEARCH INSTITUTIONS



29

BENEFIT-SHARING OFFERS
ACADEMIC & RESEARCH
INSTITUTIONS

PIP Framework governance

On 11-13 April and 17-19 October 2018, the PIP Advisory Group held its meetings in Geneva, which included consultations with industry and other PIP Framework stakeholders.



On 10 April 2018, the Secretariat held an Information Session on GISRS and the PIP Framework. The session was attended by more than 40 Member States and a wide range of stakeholders. The webcast from the session can be found at: http://www.who.int/influenza/pip/10_April_Info_Session/en/

The Secretariat circulated a draft Analysis on the scope of the PIP Framework as requested by the World Health Assembly in Decision 70(10). This draft was discussed by Member States and stakeholders at the 15-16 October 2018 consultation on the implementation of Decision WHA70(10)8b. The final text was submitted for discussion by the 144th WHO Executive Board in 2019.

IMPLEMENTATION PROGRESS

OUTPUT READING GUIDE

Output name & statement

Biennial budget & funds implemented cumulatively at Output level (excluding PSC)

Milestones: progress updated every six months

Laboratory & surveillance

BIENNIAL BUDGET: **\$20.5M** | IMPLEMENTED: **\$5.2M**

OUTPUT: **National influenza L&S systems contribute to GISRS for timely risk assessment & response measure**

DELIVERABLE A

Risk and severity of influenza, including at the human-animal interface, are routinely assessed

\$2.3M
IMPLEMENTED

MILESTONES

2	PISA trainings completed	→ 43 countries from 3 regions participated
18	Outbreak detection & response trainings	→ 36 countries from 5 regions participated
41	Meetings, workshops, joint investigation & risk assessments	→ 83 countries from 6 regions participated

INDICATORS

Number of risk assessments published

Number of MS reporting to PISA

HIGHLIGHTS

- 54 countries were trained in influenza severity assessment. WHO is supporting countries to establish thresholds, analyse and share their assessments.
- 36 countries are strengthening surveillance and laboratory core capacities, including through trainings for RRT, influenza sentinel surveillance and outbreak investigation.
- 41 human animal interface activities including risk assessments, coordination meetings and trainings were conducted for zoonotic influenza.
- In addition, 9 influenza courses are now available at OpenWHO.org

Funds implemented cumulatively at deliverable level (excluding PSC)

Proportion of funds implemented from the biennial budget

Deliverable name

Indicators: progress updated annually. Results are presented against biennial targets (Baselines are as of 31 December 2017)

Highlights from the latest six-month reporting period

Pandemic Influenza Preparedness Framework | ANNUAL PROGRESS REPORT | 1 January - 31 December 2018

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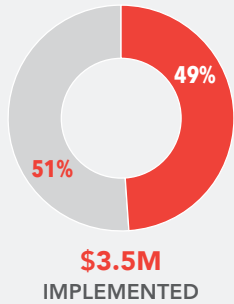
Laboratory & surveillance



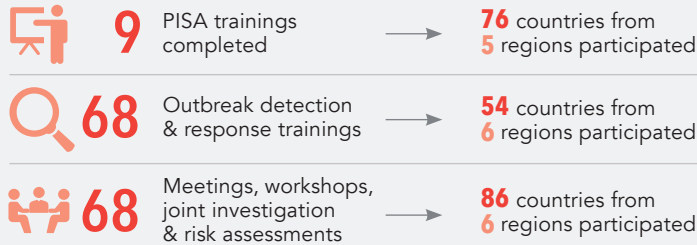
BIENNIAL BUDGET: **\$20.5M** | IMPLEMENTED: **\$8.1M**

OUTPUT: **National influenza L&S systems contribute to GISRS for timely risk assessment & response measure**

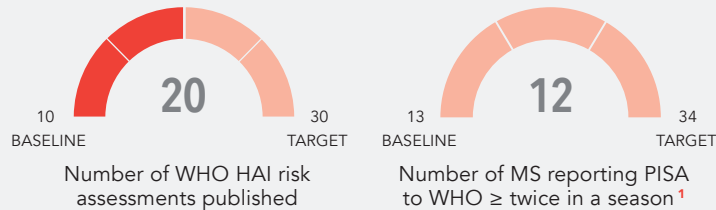
DELIVERABLE A
Risk and severity of influenza, including at the human-animal interface, are routinely assessed



MILESTONES



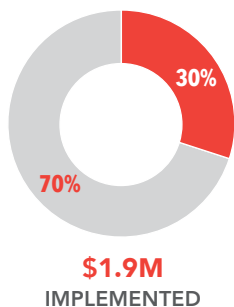
INDICATORS



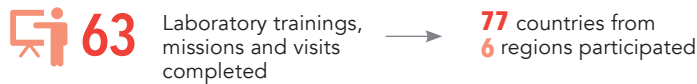
HIGHLIGHTS

- WHO assessed the risk of 8 influenza A subtypes that caused zoonotic infections, including the first documented human A(H7N4) virus infection. Risk assessments were published to support countries in rapidly addressing emerging potential threats.
- 12 countries including 1 PC recipient country reported severity assessments (PISA) to WHO. Another country initiated the process. Conducting severity assessments will inform national preparedness and response during yearly epidemics and future pandemics.

DELIVERABLE B
Quality influenza virus detection capacity is sustained



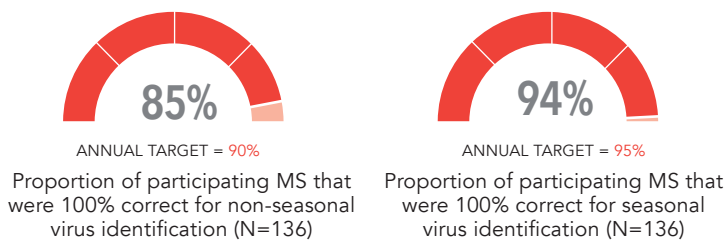
MILESTONES



2018 EQAP status



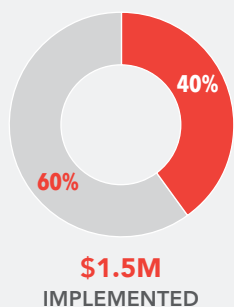
INDICATORS



HIGHLIGHTS

- Of the 136 countries participating in the 2018 EQAP, 116 (85%) correctly identified all non-seasonal viruses and 128 (94%) correctly identified all seasonal viruses.² 77 countries benefited from laboratory training activities. The EQAP and associated training efforts help sustain and improve virus detection capacity.
- GISRS has grown to a network of 145 NICs in 115 countries. This includes NIC Armenia which was newly recognized in 2018. NICs are the backbone of GISRS.

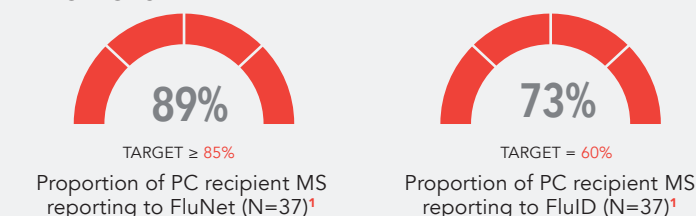
DELIVERABLE C
Countries are supported to consistently report influenza data to global platforms



MILESTONES



INDICATORS



HIGHLIGHTS

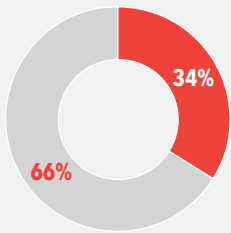
- Of 194 WHO MS, 145 (75%) reported to FluNet and 119 (61%) to FluID. Most of these (≥95%) reported consistently during the influenza season (data not shown). WHO supports all countries to improve and sustain data reporting.
- Of the 37 PC L&S recipient countries, the proportion reporting to FluNet (89%) and FluID (73%) exceeded the annual indicator targets. Consistent reporting facilitates ongoing situation monitoring.
- 3 countries reported to FluNet and 11 reported to FluID for the first time in 2018.



Laboratory & surveillance

DELIVERABLE D

Countries are supported to share timely representative influenza samples with WHO CCs



\$1.1M

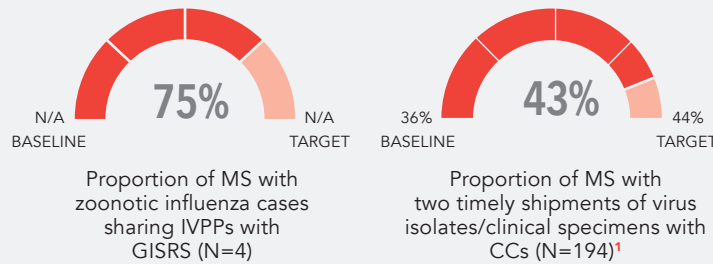
IMPLEMENTED

MILESTONES

10 Trainings on infectious substance shipping completed → **41** countries from **4** regions involved

268 Shipments made using the SFP → **108** countries from **6** regions

INDICATORS

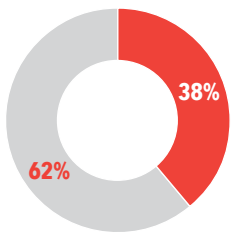


HIGHLIGHTS

- 75% of countries (3 of 4) that reported zoonotic influenza cases to WHO, shared IVPP with GISRS according to WHO guidance.³ WHO systematically follows-up with countries on IVPP sharing.
- 132 countries shared influenza viruses/clinical specimens with WHO CCs at least once.
- Of 194 WHO MS, 84 (43%) shared viruses/clinical specimens with WHO CCs according to WHO guidance (two timely shipments).⁴ This was an increase of 14 countries since last year.
- 108 countries made 268 shipments to WHO CCs. Shipments have doubled since 2014.
- Staff from 41 countries were trained and certified to ship infectious substances to facilitate virus sharing.

DELIVERABLE E

Influenza CVVs, virus detection protocols and reagents, and reference materials are routinely updated



\$93K

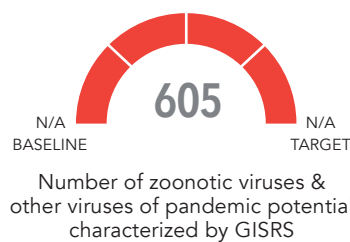
IMPLEMENTED

MILESTONES

15 Protocols and guidance reviewed, including translations

2 Vaccine Composition Meeting consultations completed → **2** new CVVs proposed

INDICATORS



HIGHLIGHTS

- GISRS characterized 605 viruses with pandemic potential. The viruses were of 10 influenza A subtypes and originated from 7 countries. The characterization led to the development of 4 new CVVs to enhance pandemic preparedness.
- WHO updated 4 laboratory protocols⁵ and translated guidance documents into several languages (11 translations) to enable country utilization.

Burden of Disease

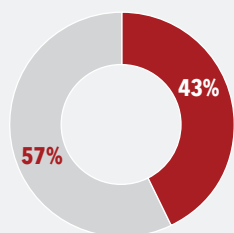


BIENNIAL BUDGET: **\$2M** | IMPLEMENTED: **\$728K**

OUTPUT: **Influenza disease burden estimates are used for public health decisions**

DELIVERABLE A

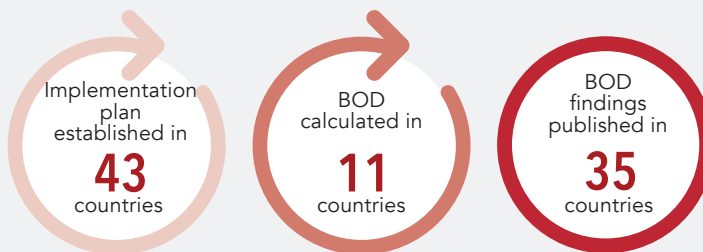
Representative national, regional and global disease burden estimates are available



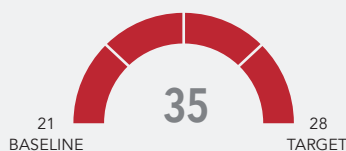
\$396K
IMPLEMENTED

MILESTONE

Number of countries in each burden of disease estimate development stage



INDICATORS



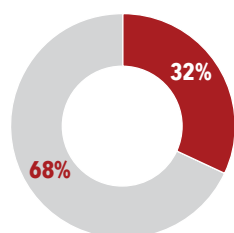
Number of MS with published disease burden estimates based on data collected since 2011¹

HIGHLIGHTS

- In 2018, 14 countries published their BOD estimates bringing the total to 35 globally. The progress made has already exceeded the biennial indicator target highlighting the momentum gained in this area of work in recent years. In addition, 54 other countries have either already calculated or established a plan to estimate their BOD.
- Regional and global BOD estimates help national and international decision-making bodies to take influenza preventive measures. To date, 55 countries including 29 low and middle income countries have shared their data for use in regional or global estimates.
- WHO is trying to develop an influenza burden pyramid tool that can enable countries with limited data to estimate the comprehensive influenza burden.

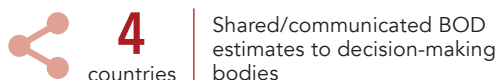
DELIVERABLE B

Disease burden findings are communicated to national and international expert bodies in a format that promotes evidence-based decision making

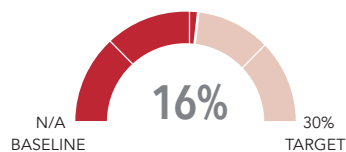


\$332K
IMPLEMENTED

MILESTONE



INDICATORS



Proportion of MS with burden of disease estimates that have been considered by NITAG or other decision-making bodies (N=19)

HIGHLIGHTS

- Four countries reported sharing their BOD estimates with national decision-making bodies. In 3 of these countries, the attention to influenza burden and influenza disease control led to updated initiatives. One country introduced seasonal influenza vaccination policy for risk groups and two countries updated their list of influenza risk groups.
- Monitoring the progress on Deliverable B appears to be challenging. A periodic country survey is under consideration.
- WHO is encouraging countries that calculated national influenza disease burden and used the estimates to influence national prevention and control policy to document the internal process from data to policy, highlighting strengths and challenges.

Regulatory capacity building

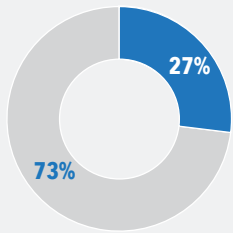


BIENNIAL BUDGET: **\$2.7M** | IMPLEMENTED: **\$952K**

OUTPUT: **Timely access to quality-assured influenza pandemic products is supported**

DELIVERABLE A

National regulatory capacity for pandemic influenza products is strengthened



\$423K

IMPLEMENTED

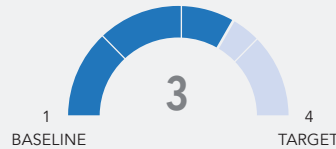
MILESTONES

- 15** Refinements made to WHO Global benchmarking tool

- 1** Country WHO benchmarked
- 1** Country self-benchmarked
- 5** IDP follow-up visits → **5** countries **2** regions

- 11** IDP implementation & technical support activities → **16** countries **6** regions

INDICATOR



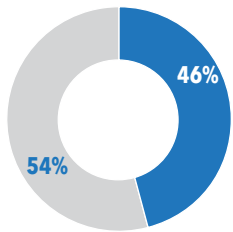
Number of PC recipient MS which strengthened national regulatory capacity to oversee pandemic influenza products

HIGHLIGHTS

- PIP supports 16 countries to strengthen the 3 regulatory capacities critical for pandemic preparedness: regulatory system, marketing authorization and pharmacovigilance.
- Progress has been made against the indicator target; regulatory capacities in 2 countries increased in maturity level based on WHO benchmarking assessments. One of these countries achieved maturity level 3 for all 3 capacities which is a major achievement resulting from PIP support and stakeholder commitment.
- IDP implementation, benchmarking and follow-up visits continued in all 16 countries. All countries attended international workshops at stringent NRAs to improve knowledge and further advance IDP implementation.

DELIVERABLE B

Adoption of regulatory pathways that accelerate approval for use of pandemic influenza products is promoted



\$529K

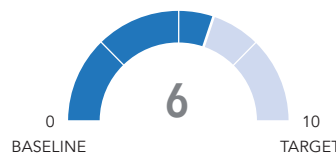
IMPLEMENTED

MILESTONES

- WHO regulatory preparedness guidelines translated to **5** languages

- 5** Workshops/trainings conducted to implement the PIP regulatory guidelines linking national IPPP & NVDP for pandemic influenza vaccines → **42** countries from **6** regions

INDICATOR



Number of PC recipient MS that have implemented a defined regulatory approach that enables timely approval for use of pandemic influenza products

HIGHLIGHTS

- Regulatory pathways to accelerate approval of products during emergencies include PQ and CRP.
- Progress was made against the indicator target with 6 countries implementing their regulatory approach. This included defining and planning the information management and stakeholder coordination required for timely product approval in the broader pandemic preparedness context.
- In 2018, 42 countries targeted by PIP, attended workshops or meetings on accelerated regulatory pathways. This awareness-raising resulted in one country signing the CRP agreement bringing the total to 37 countries/regulatory authorities having a CRP agreement.

Risk Communications & Community Engagement

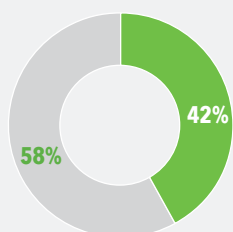


BIENNIAL BUDGET: **\$2M** | IMPLEMENTED: **\$771K**

OUTPUT: **Tools and guidance are available for countries to enhance influenza risk communication and community engagement**

DELIVERABLE A

Countries and front-line responders have access to resources for influenza risk communication, community engagement and social science-based interventions



\$361K
IMPLEMENTED

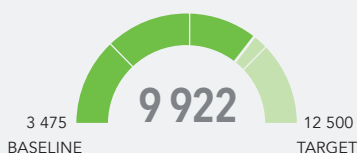
MILESTONES

14 Influenza guidance/courses available on OpenWHO

16 OpenWHO advocacy & marketing events

4 RCCE factors mapped in **5** priority countries

INDICATORS



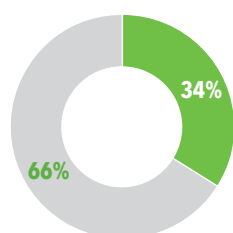
Number of users who completed OpenWHO influenza modules¹

HIGHLIGHTS

- *OpenWHO.org* gained nearly 6,500 new users, making it ahead of schedule to hit the biennial indicator target. OpenWHO now has 14 influenza related modules including "Pandemic Influenza Vaccines - National Deployment and Vaccination Plans."⁶
- A social science intelligence network of partners and research groups activated and tracked community data during outbreaks while a new intelligence mapping tool was tested in 5 countries. Factors mapped include sociocultural, humanitarian and outbreak response.
- A toolkit and guide for rapid sociocultural assessments was tested in 3 AFR countries. These would be quickly used during a pandemic.

DELIVERABLE B

Technical assistance is provided to countries to plan and exercise influenza risk communication and community engagement



\$410K
IMPLEMENTED

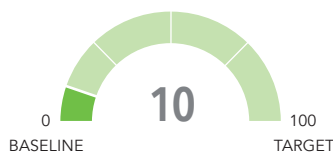
MILESTONES

8 Trainings, missions and other type of technical support provided involving **56** countries from **4** regions

Implementation of global partnerships & networks for effective RCCE capacity



INDICATORS



Number of MS that utilized RCCE support for influenza preparedness or response

HIGHLIGHTS

- RCCE doubled its training missions to include 54 countries from 3 regions.
- Five AFR and EMR priority countries aligned their risk communication capacities within their Pandemic Preparedness Plans by drafting action plans, timelines and responsible units.
- Global RCCE partners have expanded with the addition of OXFAM and Translators Without Borders to increase response strength and skills.
- In 2019, 3 additional WHO regional offices will have RCCE technical focal points to support countries in preparedness planning. This will help roll-out global initiatives and facilitate implementation for country level impact.

Planning for Deployment



BIENNIAL BUDGET: **\$1.5M** | IMPLEMENTED: **\$279K**

OUTPUT: **Plans for effective & efficient deployment of pandemic supplies are optimized**

DELIVERABLE A

A common approach to manage global deployment operations is developed and regularly tested with stakeholders and deployment partners

\$150K
IMPLEMENTED

MILESTONES

- 2** PIP Deploy refinements to facilitate planning, allocation and coordination
- 6** Advocacy meetings for a common approach completed → **20** countries / **6** regions

INDICATOR

Annual simulation exercise conducted to test global deployment of pandemic influenza vaccines and other products

HIGHLIGHTS

- To support stakeholders refine pandemic product deployment plans, a PIP Deploy Gaming Exercise was developed to complement the simulation portal developed in 2014-17. The Gaming Exercise offers an immediate learning experience and tests the whole deployment cascade from country request to vaccine administration.
- 2 regional workshops involving deployment simulation exercises are scheduled for February and April 2019, resulting in progress against the indicator target.
- 6 advocacy events were held involving 20 countries and >20 global stakeholders. These events generate requests for support to update deployment plans.

DELIVERABLE B

National deployment planning process is revised and updated

\$129K
IMPLEMENTED

MILESTONES

- 2** Global guidance tools revised
- 3** Trainings, missions, visits & other types of technical support provided to update NVDP → **11** countries / **3** regions

HIGHLIGHTS

- 2 tools were launched to assist countries update their deployment plans; a training package and a set of 10 infographics based on WHO's guidance.⁷
- An *OpenWHO* course based on the WHO guidance was launched. By January 2019, >1000 individuals registered for this course.
- Technical support was provided to 11 countries to update plans and consider the sequence and timelines of deployment actions required in light of other response components. Challenges remain in coordination between regulatory, disease control and emergency response authorities. Future simulation exercises should help bring these stakeholders together.

DELIVERABLE C

Technical assistance to develop policies for sustainable influenza vaccine procurement and production is provided to countries

Deliverable C activities are currently supported by US DHHS through Cooperative Agreement GH14-1420 between US CDC and WHO. PIP funds were not used to date.

Milestone/indicator reporting continues as this Deliverable is within HLIP II scope and PC funds may be used in future.

MILESTONES

Number of countries in each phase of the sustainability assessment process

- 2** Trainings, missions, visits & other types of technical support provided → **42** countries

INDICATOR

Number of MS that have undergone a national analysis of influenza vaccine procurement or production sustainability

HIGHLIGHTS

- Sustainability assessments allow countries to sustain local production (where applicable) and encourage national procurement of seasonal influenza vaccines with the goal of increasing pandemic preparedness.
- The indicator target was achieved with 2 vaccine-producing countries completing assessments, bringing the total to 8 countries. One assessed country has begun implementing recommendations, including developing new national strategies for sustainable influenza vaccine production and use.
- Through 2 meetings, support was provided to 42 countries to introduce the elements of sustainable production and procurement of influenza vaccines and the contribution to national and global pandemic preparedness.

Influenza Pandemic Preparedness Planning

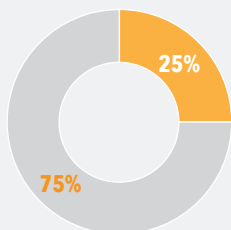


BIENNIAL BUDGET: **\$2.3M** | IMPLEMENTED: **\$557K**

OUTPUT: **National pandemic influenza preparedness & response plans are updated in the context of all-hazards preparedness and global health security**

DELIVERABLE A

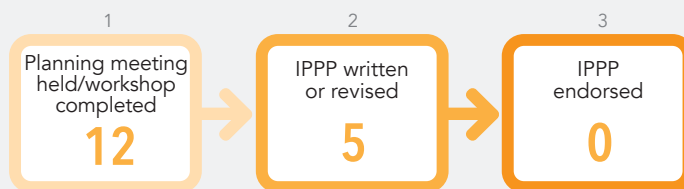
Countries are supported to develop, test and update their pandemic influenza preparedness plan



\$557K
IMPLEMENTED

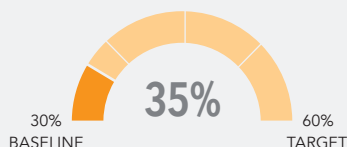
MILESTONES

Number of PC recipient MS currently developing/revising their IPPP

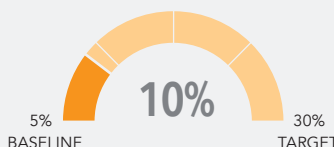


5 IPPP exercises completed in **4** countries **2** regions

INDICATORS



Proportion of PC recipient MS that developed or updated a pandemic influenza preparedness plan since 2014 (N=40)¹



Proportion of PC recipient MS that exercised their pandemic influenza preparedness plan in 2018 (N=40)

HIGHLIGHTS

- 21 PC recipient countries have either written, exercised or are in the process of developing their influenza pandemic preparedness plans. Challenges to IPPP development include competing public health priorities and limited inter-sectoral attention to pandemic influenza preparedness.
- Of 40 PC recipient countries, 14 (35%) now have a plan based on WHO's Pandemic Influenza Risk Management guidance that was published in 2013. Pandemic plans strengthen country operational readiness and catalyze stakeholder commitment and coordination.
- WHO published 3 operational guidance documents to support countries.⁸ Further guidance is under development including a package of exercise scenarios for testing IPPP and a guideline on non-pharmaceutical measures for mitigating the risk and impact of influenza.
- 104 countries, including 20 PC recipient countries, participated in a WHO IPPP survey to identify planning needs. A report is being developed. An analysis of IPPP in context of the IHR (2005) and other disease response plans to provide countries with best planning practices is also being finalized.

PIP Framework Secretariat

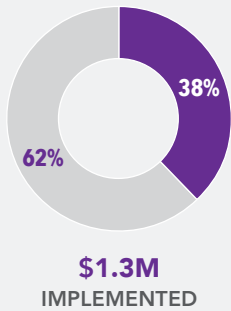
BIENNIAL BUDGET: **\$6.8M** | IMPLEMENTED: **\$2.4M**

OUTPUT: The PIP Secretariat leads, manages and supports implementation of the PIP Framework



DELIVERABLE A

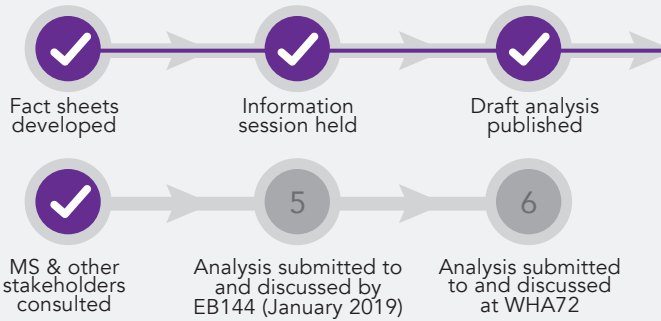
Promote the effective implementation of the PIP Framework in a changing environment



MILESTONES

10 Meetings held and reports submitted to WHO DG or governing bodies to support implementation of section 7 of the PIP Framework

Status of the Analysis requested by WHA 70(10)



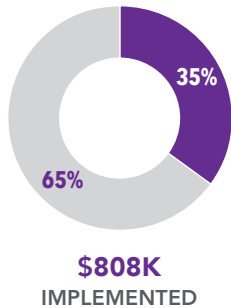
29 Advocacy materials/events completed to promote the PIP Framework to stakeholders

HIGHLIGHTS

- Further to WHA71(11), the final text of the Analysis was published in December 2018 for discussion by EB144.
- WHO worked closely with the PIP AG and WHO CCs to develop the Analysis on the scope of the PIP Framework.
- WHO developed 7 Fact Sheets that concisely present basic information about specific topics related to the Analysis such as biosafety & biosecurity, GSD and databases, and new technologies.⁹
- Several talks and presentations on PIP were provided to Member States, academic institutions, technical gatherings and other fora.

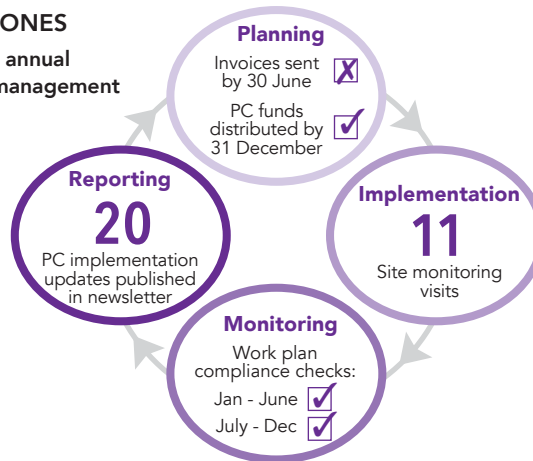
DELIVERABLE B

Collect, implement, monitor and report on the Partnership Contribution

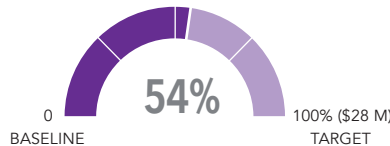


MILESTONES

Status in annual project management cycle



INDICATOR



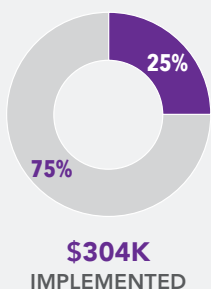
Proportion of Partnership Contributions received in year of invoice

HIGHLIGHTS

- PC invoices were issued in August 2018 and \$15.2M (54%) were received by 31 December 2018.
- Monitoring visits were conducted in all WHO regions. Discussions supported PIP recipient countries to refine implementation plans to focus on programmatic objectives, sustainability and progress against HLIP II indicators.
- 19 'Highlights from the Field' were published in the PIP newsletter to share news about PIP's country impact.
- The HLIP I final report was published to showcase the gains made in pandemic preparedness in 2014-2017.¹⁰ Social media and other fora were used to herald the report's release.

DELIVERABLE C

Negotiate and plan to operationalize the Standard Material Transfer Agreements 2 (SMTA2)

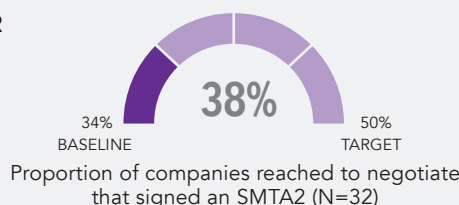


MILESTONES

Number of SMTA2s in negotiation



INDICATOR



HIGHLIGHTS

- 3 SMTA2s were concluded in 2018: one with influenza vaccine manufacturer Takeda (8% donation and 2% reserved pricing), one with influenza diagnostics manufacturer Becton Dickinson (25M syringe donation) and one with Weill Medical College of Cornell University.
- To implement training offers received from academic and research institutions, WHO collaborated with the University of Siena to host a training workshop on Laboratory Quality Management and Biosafety for NICs.¹¹

Endnotes

- ¹ Indicator baselines were first published in HLIP II in March 2018. Baseline data have since stabilized and 7 were updated. The changes are reflected in this report.
- ² World Health Organization. Detection of influenza viruses by reverse transcription polymerase chain reaction: WHO external quality assessment programme summary analysis, 2018. *Weekly Epidemiological Record*. 2019; 94:5 (<https://www.who.int/wer/2019/wer9405/en/>, accessed 19 February 2019).
- ³ Operational Guidance on Sharing Influenza Viruses with Human Pandemic Potential (IVPP) under the Pandemic Influenza Preparedness (PIP) Framework. Geneva: World Health Organization; 2017 (https://www.who.int/influenza/gisrs_laboratory/ivpp_sharing_guidance/en/, accessed 19 February 2019).
- ⁴ Operational Guidance on Sharing Seasonal Influenza viruses with WHO Collaborating Centres (CCs) under the Global Influenza Surveillance and Response System (GISRS). Geneva: World Health Organization; 2017 (https://www.who.int/influenza/gisrs_laboratory/seasonal_sharing_guide/en/, accessed 19 February 2019).
- ⁵ WHO information for molecular diagnosis of influenza virus. Geneva: World Health Organization; 2018 (https://www.who.int/influenza/gisrs_laboratory/molecular_diagnosis/en/, accessed 19 February 2019).
- Protocols updated:
- Annex 2. B. Protocol 2: Real-time RT-PCR one-step duplex for the detection of Influenza type A subtype H1pdm09 and subtype H3 ([Page 29](#))
 - Annex 2. D. Protocol 1: Real-time RT-PCR assays for the detection of seasonal influenza viruses and H5N1 influenza viruses ([Page 34](#))
 - Annex 2. D. Protocol 2: Real-time RT-PCR for the detection of A(H5) gene ([Page 39](#))
 - Annex 2. D. Protocol 3: Real-time RT-PCR procedures for the detection of influenza A, influenza B, A(H1N1), A(H3N2), A(H5N1), A(H7N9), A(H9N2) viruses ([Page 41](#))
- ⁶ Pandemic Influenza Vaccines: National Deployment and Vaccination Plans. Geneva: World Health Organization; 2018 (<https://openwho.org/courses/ndvp-en>, accessed 19 February 2019).
- ⁷ Guidance on Development and Implementation of a National Deployment and Vaccination Plan for Pandemic Influenza Vaccines. Geneva: World Health Organization; 2012 (https://www.who.int/influenza_vaccines_plan/resources/deployment/en/, accessed 19 February 2019).
- ⁸ Guidelines published in 2018 to support countries' pandemic influenza preparedness
- A checklist for pandemic influenza risk and impact management: building capacity for pandemic response. Geneva: World Health Organization; 2018 (https://www.who.int/influenza/preparedness/pandemic/influenza_risk_management_checklist_2018/en/, accessed 19 February 2019).
 - Essential steps for developing or updating a national pandemic influenza preparedness plan. Geneva: World Health Organization; 2018 (https://www.who.int/influenza/preparedness/pandemic/essential_steps_influenza/en/, accessed 19 February 2019).
 - A practical guide for developing and conducting simulation exercises to test and validate pandemic influenza preparedness plan. Geneva: World Health Organization; 2018 (https://www.who.int/influenza/preparedness/pandemic/simex_influenza_preparedness_plans/en/, accessed 19 February 2019).
- ⁹ Information related to the development of the Analysis on seasonal influenza and GSD under the PIP Framework can be found here: http://www.who.int/influenza/pip/Documents_WHA70108b/en/.
- ¹⁰ Pandemic Influenza Preparedness Framework: Partnership Contribution High-Level Implementation Plan I. Final Report 2014-2017. Geneva: World Health Organization; 2018 (https://www.who.int/influenza/pip/partnership_contribution/hlipi_final_report/en/, accessed 19 February 2019).
- ¹¹ For more information on the training workshop see: https://www.who.int/influenza/Sienna_Workshop_Report.pdf?ua=1

ANNEX A: FINANCIAL REPORT

**Table A.1:
Partnership Contribution received from each manufacturer
2012–2018**

CONTRIBUTORS	TOTAL CONTRIBUTIONS (US\$)
Glaxosmithkline (GSK)	40 909 080
Sanofi Pasteur	39 569 520
Hoffmann - La Roche and Co. Ltd.	39 960 031
Novartis	15 292 743
Medimmune	7 246 929
Seqirus	7 215 830
Kaketsuken (K M Biologics)	3 611 092
The Research Foundation for Microbial Disease of Osaka University (BIKEN)	3 596 419
CSL Limited	2 667 745
Denka Seiken Co. Ltd.	2 589 088
Kitasato Daiichi Sankyo Vaccine Co. Ltd.	1 936 830
Green Cross Corporation	1 642 357
Shanghai Institute of Biological Products Co., Ltd.	556 575
Sinovac Biotech Ltd.	556 575
Becton Dickinson and Company (BD)	326 432
Beijing Tiantan Biological Products Co. Ltd.	262 223
Fluart Innovative Vaccines LTD	307 379
Baxter International Inc.	209 205
Changchun Institute of Biological Products Co., Ltd. CNBG	208 231
Omninvest Vaccine Manufacturing, Researching & Trading Ltd.	149 443
S K Bioscience	122 678
Alere Inc.	117 159
Saint-Petersburg Scientific Research Institute of Vaccines & Sera	86 815
Focus Diagnostics, Inc.	83 844
Adimmune Corporation	65 543
Qiagen	61 512
Serum Institute of India Ltd.	35 623
DiaSorin Molecular LLC	29 692
China National Biotec Group	20 000
Vabiotech	12 761
Cadila Healthcare Ltd. (R&D Center)	15 170
Government Pharmaceutical Organization (GPO)	13 045
Princeton Biomeditech Corporation	10 591
Institute of Vaccines and Medical Biologicals (IVAC)	10 591
Cepheid	10 591
Takeda Pharmaceuticals Internatioanl GmbH	37 580
Fast Track Diagnostics	13 045
Quidel Corporation	8 136
NPO Petrovax Pharm	10 246
Indevr, Inc.	7 439
Medicago Inc.	7 439
Response Biomedical Corporation	5 417
Nanotherapeutics	5 337
Nanosphere Inc.	4 984
PT Bio Farma (Persero)	4 984
Protein Sciences Corporation	4 944
UMN Pharm INC.	2 799
Lanzhou Institute of Biological Products	2 173
Grand Total with PSC	\$169 623 865 (\$152 551 038, net of PSC)

**Table A.2:
Fund allocation and expenditure for staff and activities
1 January - 31 December 2018**

OUTPUT	DELIVERABLE	2018-19 Approved budget	Funds distributed for 2018	Expenditure 2018	Implementation on 2018 funds distributed (%)	Balance funds
Laboratory & Surveillance	Risk and severity of influenza are routinely assessed	7 085 481	3 681 103	3 498 855	95%	182 248
	Quality influenza virus detection capacity is sustained	6 264 851	3 189 426	1 877 710	59%	1 311 716
	Countries are supported to consistently report influenza data to global platforms	3 675 876	1 931 088	1 486 825	77%	444 263
	Countries are supported to share timely representative influenza samples with WHO CCs	3 251 976	1 668 988	1 110 968	67%	558 020
	Influenza CVs, virus detection protocols and reference materials are routinely updated	247 998	123 999	93 477	75%	30 522
	Total for L&S	20 526 182	10 594 604	8 067 835	76%	2 526 769
Burden of Disease	Representative national, regional & global disease burden estimates are available	932 179	486 090	396 245	82%	89 845
	Disease burden findings are communicated to national and international expert bodies in a format that promotes evidence-based decision making	1 034 179	497 090	331 597	67%	165 493
	Total for BOD	1 966 358	983 180	727 842	74%	255 338
Regulatory Capacity	National regulatory capacity for pandemic influenza products is strengthened	1 588 750	794 375	422 964	53%	371 411
	Adoption of regulatory pathways that accelerate approval for use of pandemic influenza products is promoted	1 142 750	631 375	529 049	84%	102 326
	Total for REG	2 731 500	1 425 750	952 013	67%	473 737
Risk Communication & Community Engagement	Countries and front-line responders have access to guidance, tools and interactive resources for risk communication, community engagement, and social science-based interventions for influenza	850 852	425 426	361 184	85%	64 242
	Technical assistance for risk communication, community engagement & social science-based interventions provided to countries to facilitate influenza interventions & address vaccine hesitancy	1 210 291	605 146	410 582	68%	194 564
	Total for RCCE	2 061 143	1 030 572	771 766	75%	258 806

OUTPUT	DELIVERABLE	2018-19 Approved budget	Funds distributed for 2018	Expenditure 2018	Implementation on 2018 funds distributed (%)	Balance funds
Planning for Deployment	A common approach to manage global deployment operations is developed and regularly tested with stakeholders and deployment partners	814 100	407 050	149 997	37%	257 053
	National deployment planning process is revised & updated	614 100	307 050	128 941	42%	178 109
	Technical assistance to develop policies for sustainable influenza vaccine procurement and production is provided to countries	103 500	51 750	-	0%	51 750
	Total for DEP	1 531 700	765 850	278 938	36%	486 912
Influenza Pandemic Preparedness Planning	Countries are supported to develop, test and update their pandemic influenza preparedness and response plan	2 252 617	1 129 559	556 854	49%	572 705
	Total for IPPP	2 252 617	1 129 559	556 854	49%	572 705
	Total for Preparedness Outputs	31 069 500	15 929 515	11 355 248	71%	4 574 267
	PSC (13%) on Preparedness Funds In process for 2019 distribution ^a Undistributed funds ^b		4 733 331	1 476 182		3 257 149 13 789 581 8 157 996
PIP Secretariat	Grand Total for Preparedness	31 069 500	20 662 846	12 831 430	62%	29 778 993
	Promote the effective implementation of the PIP Framework in a changing environment	3 303 591	1 390 769	1 220 858	88%	169 911
	Collect, implement, monitor & report on the Partnership Contribution	2 294 792	977 584	807 719	83%	169 865
	Negotiate and plan to operationalize the Standard Material Transfer Agreements 2 (SMTA2)	1 210 583	474 338	343 542	72%	130 796
	Total for PIP Secretariat Output	6 808 966	2 842 691	2 372 119	83%	470 572
	PSC (13%) on Secretariat Funds In process for 2019 distribution ^a Undistributed funds ^b		677 637	308 375		369 262 2 368 115 1 547
	Grand Total for PIP Secretariat	6 808 966	3 520 328	2 680 494	76%	3 209 496
	Response funds					45 798 449
	Annual interest earned on response funds for 2018					928 587
	Grand Total for Response Funds	-	-	-	-	46 727 036
	Grand Total for PIP PC	37 878 466	24 183 174	15 511 924	64%	79,715,525^c

^a Funds are being distributed for 2019 work plan implementation.

^b Undistributed funds include Partnership Contributions received after funds for 2018 work plans were distributed.

^c Includes Response Funds (US\$ 46,727,036) which will only be used at the time of a pandemic.

Fig. A.1: Interim certified financial statement as of 31 December 2018



Pandemic Influenza Preparedness (PIP) – Secretariat, Preparedness and Response

Interim Financial Statement as at 31 December 2018 (expressed in US dollars)

	<u>Secretariat - 10%</u>	<u>Response - 30%</u>	<u>Preparedness - 70%</u>	<u>Total</u>
Opening Balance - 1 January 2018	3,089,290	38,236,561	24,966,024	66,291,875
Revenue				
Receipts from:				
Becton Dickinson and Company (BD)	1,500	4,050	9,450	15,000
Beijing Tiantan Biological Products Co.Ltd	2,699	7,287	17,003	26,989
Cadila Healthcare Ltd (R&D Center)	245	663	1,546	2,454
Denka Seiken Co. Ltd.	41,711	112,618	262,776	417,105
Fast Track Diagnostics	245	663	1,546	2,454
Fluart Innovative Vaccines LTD	7,361	19,874	46,372	73,607
GlaxoSmithKline (GSK)	539,783	1,457,413	3,400,631	5,397,827
Government Pharmaceutical Organization (GPO)	245	663	1,546	2,454
Hoffmann-La Roche and Co Ltd	662,460	1,788,642	4,173,498	6,624,600
Kaketsuken	61,339	165,615	386,435	613,389
Kitasato Daiichi Sankyo Vaccine Co. Ltd.	29,443	79,495	185,489	294,427
Medimmune	208,617	563,266	1,314,286	2,086,169
NPO Petrovax Pharm	245	663	1,546	2,454
Research Foundation for Microbial Diseases of Osaka University	61,339	165,615	386,435	613,389
Sanofi Pasteur	810,100	2,187,270	5,103,630	8,101,000
Seqirus	343,679	927,933	2,165,176	3,436,788
Shanghai Institute Of Biological Products Co., Ltd.	7,361	19,874	46,372	73,607
Sinovac Biotech Ltd	7,361	19,874	46,372	73,607
SK Bioscience	12,268	33,123	77,287	122,678
Takeda Pharmaceuticals International GmbH	2,699	7,287	17,003	26,989
Total received	<u>2,800,700</u>	<u>7,561,888</u>	<u>17,644,399</u>	<u>28,006,987</u>
Interest	-	928,587	-	928,587
Total Revenue	<u>2,800,700</u>	<u>8,490,475</u>	<u>17,644,399</u>	<u>28,935,574</u>
Expenditure				
2018	2,680,494	-	12,831,430	15,511,924
Balance as at 31 December 2018	<u>3,209,496</u>	<u>46,727,036</u>	<u>29,778,993</u>	<u>79,715,525</u>

I certify that the above statement reflects correctly the revenue and expenditure recorded in the WHO Global Accounting System.


Jane Stewart
Director Accounts

20 February 2019



**Statement of Financial Performance-by Donor/Award Entity : 'WHO' , From date : '01-JAN-2018
, To date : '31-DEC-2018' , Award Number : '60478'**

Sum of Expense	
Expense Type	Total (USD)
Staff Costs	1,880,804
Equipment, Vehicles and Furniture	17,470
Contractual Services	170,626
Travel	256,288
General Operating Costs	46,931
Programme Support Costs (PSC)	308,375
Total	2,680,494

**Statement of Financial Performance-by Donor/Award Entity : 'WHO' , From date : '01-JAN-2018'
, To date : '31-DEC-2018' , Award Number : '61722'**

Sum of Expense	
Expense Type	Total (USD)
Staff Costs	3,825,140
Medical Supplies and Materials	587,985
Equipment, Vehicles and Furniture	23,943
Contractual Services	3,429,879
Travel	1,939,951
Transfers and Grants	1,122,163
General Operating Costs	426,189
Programme Support Costs (PSC)	1,476,182
Total	12,831,430

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PIP Framework Secretariat

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www.who.int/influenza/pip/en