

Pandemic Influenza Preparedness Framework

Sharing of influenza viruses &
access to vaccines and other benefits




Webinar on Implementation of Decision WHA72(12)

7 October 2019, 12:00-14:00



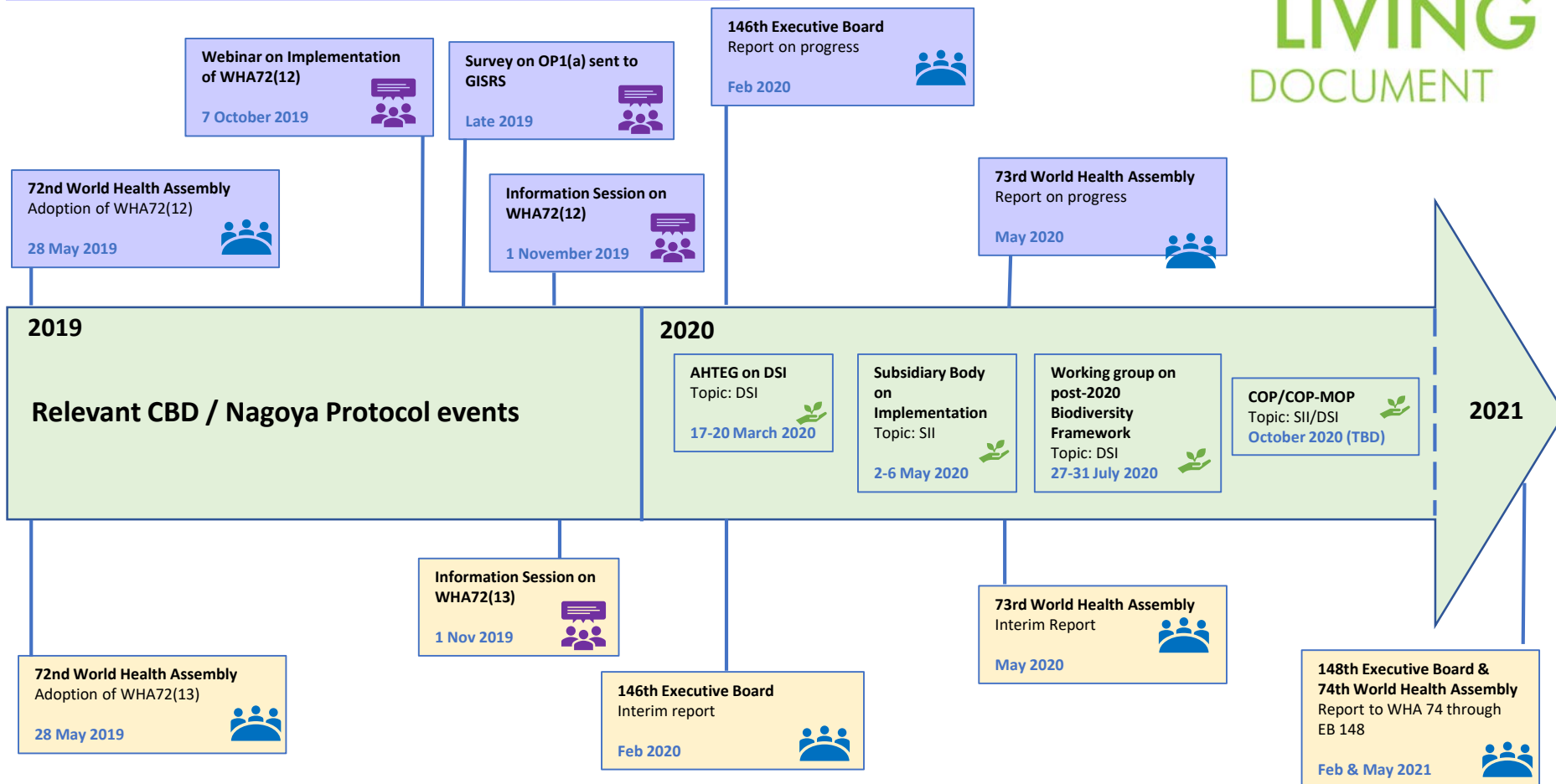
Draft Notional Timeline (as of 1 October 2019)

Legend

-  Governing body meetings
-  Consultations / external inputs
-  CBD/Nagoya events

LIVING
DOCUMENT




PIP - WHA72(12) implementation milestones and events



NP & PH - WHA72(13) implementation milestones and events

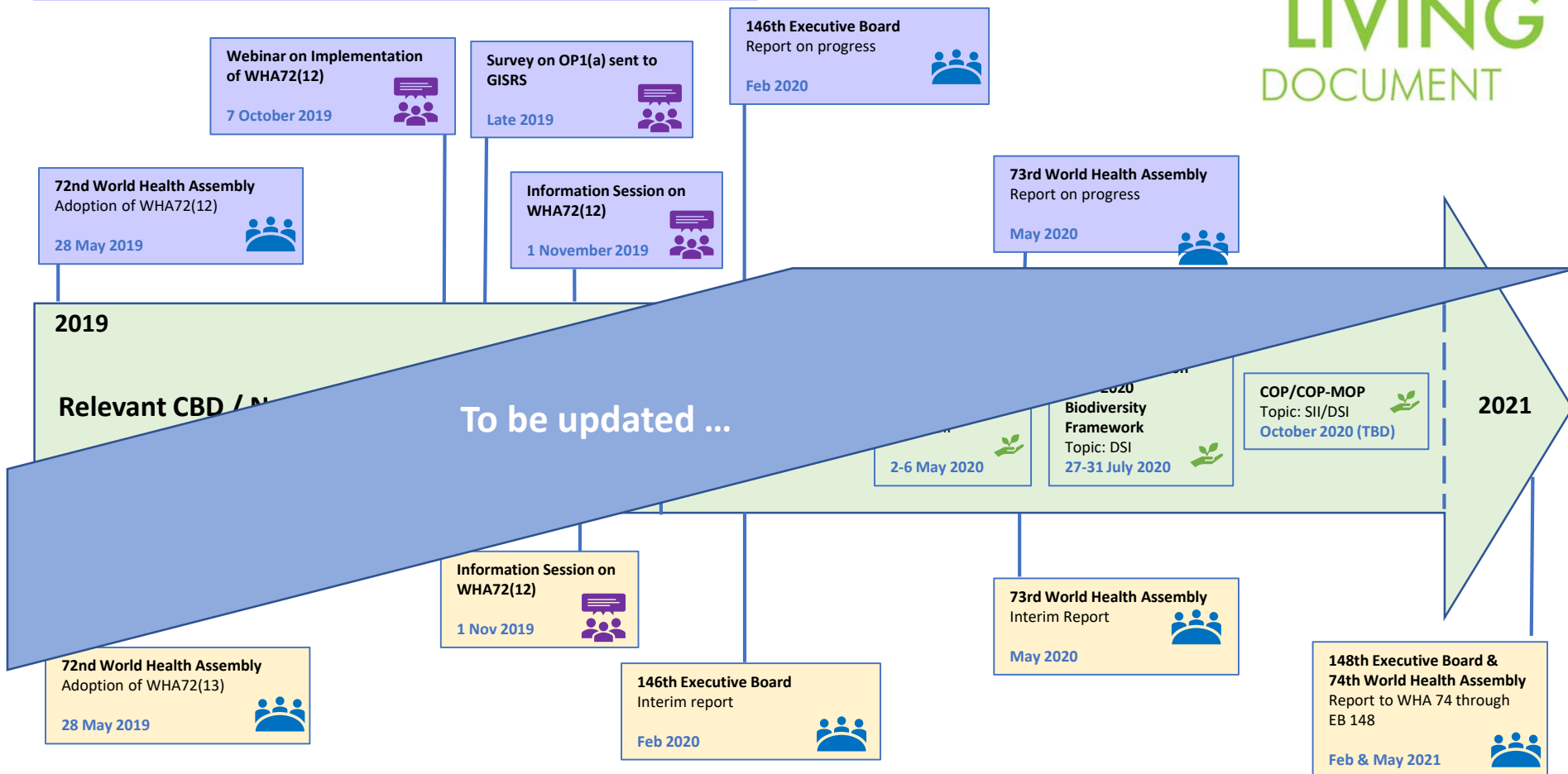
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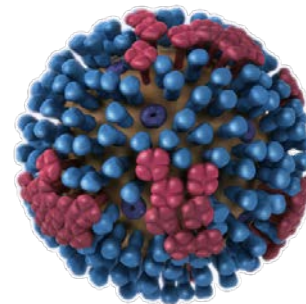
WHA72(12) Implementation Update

- WHO has developed a workplan to address each WHA request, engaging, as necessary and appropriate at all stages, with **relevant key partners**, including:
- ✓ Member States
 - ✓ GISRS
 - ✓ CBD Secretariat, other relevant international organizations
 - ✓ Relevant stakeholders (e.g. manufacturers, civil society, databases & initiatives)
- **Coordinate** across the Organization to ensure harmony and consistency with implementation of decision WHA72(13) on *Nagoya Protocol and Public Health*

OP1(a) – Influenza virus sharing (1)

WHA request

- *WHO work with GISRS and relevant partners to **collect, analyse and present data on influenza virus sharing** to enable a deeper understanding of **challenges, opportunities and implications for public health***
- *Identify specific instances where virus sharing has been hindered*
- *How hindrances may be mitigated*



OP1(a) – Influenza virus sharing (2)

Phase 1 – Information Collection

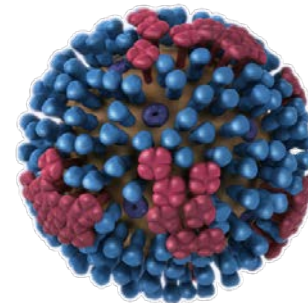
- Develop survey or other mechanisms, as necessary, to gather information on influenza virus sharing from GISRS labs, and other relevant partners and to allow deeper understanding of:
 - Challenges, including instances where virus sharing has been hindered
- Solicit input on:
 - Ideas to mitigate hindrances to virus sharing
 - Opportunities to strengthen virus sharing under GISRS

Phase 2 – Analysis

- Review evidence and information collected
- Develop preliminary findings
- Share with GISRS

Phase 3: Prepare Report for WHA73

1. Summary Document
2. Data Analysis



OP1(b) – ABS legislation & regulations related to influenza virus sharing (1)

WHA request

- *WHO to prepare a report, with input from MS and stakeholders, and in consultation with CBD Secretariat, as appropriate, on:*
 - *Treatment of **influenza virus sharing** in **existing relevant legislation and regulatory measures** – including those implementing Nagoya Protocol*



OP1(b) – ABS legislation & regulations related to influenza virus sharing (2)

Phase 1(a) – Desk Review

Review laws uploaded by **Member States to CBD ABS Clearing House**. Analyze and categorize according to:

➤ **Express consideration of:**

- pathogens
- influenza (including differentiation between seasonal/pandemic influenza)

➤ **Express reference to:**

- PIP Framework
- IHR
- Relevant Nagoya Protocol provisions (arts 4(4), 8(b))



Phase 1(b) – Desk Review

Review Member States' **online legislation databases for ABS legislation** (expressly or impliedly referring to the Nagoya Protocol), using the same categorizing parameters as in Phase 1(a).



Phase 2 – Survey to Member States & Stakeholders *(TBC)*

In close coordination and collaboration with **Chief Scientist Office and CBD Secretariat** contribute to a survey to further build evidence of current state of ABS landscape through a multi-faceted survey.



Report on findings

1. Summary Document
2. Legal Mapping



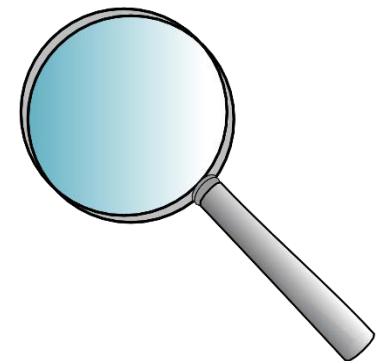
OP1(c): Prototype search engine

WHA request

- *WHO to provide information to allow deeper understanding of search engine*
- **Functioning**, including which databases are searched, the search terms used, how data is processed and presented, and who owns the data;
 - **Usefulness**, including results obtained from piloting the search engine to identify uses of genetic sequence data (GSD) from influenza viruses with pandemic potential (IVPP) and how information generated could potentially be used in the future; and
 - **Limitations**, including what information and data cannot be obtained from the search engine, such as upstream uses of GSD, and where human intervention is needed.

Additional Key Partners

- World Data Centre for Microorganisms (WDCM)
- World Federation for Culture Collections (WFCC)



OP1(d): Awareness-raising

WHA request

→ *Gather information from Member States and relevant stakeholders and explore possible next steps to:*

- *Raise awareness of the PIP Framework among databases & initiatives, data providers & data users;*
- *Promote acknowledgement of data providers*
- *Promote collaboration between data providers and data users*

→ Development of action plan & activities still in progress



OP1(e): New technology developments

WHA request

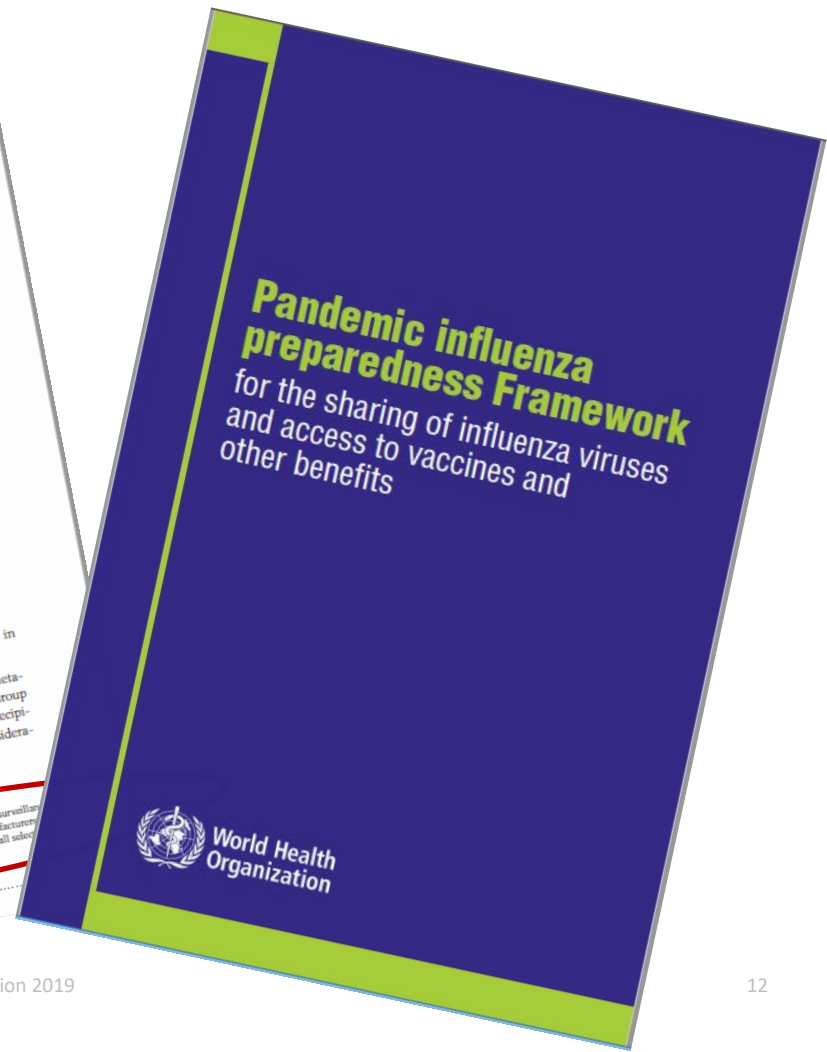
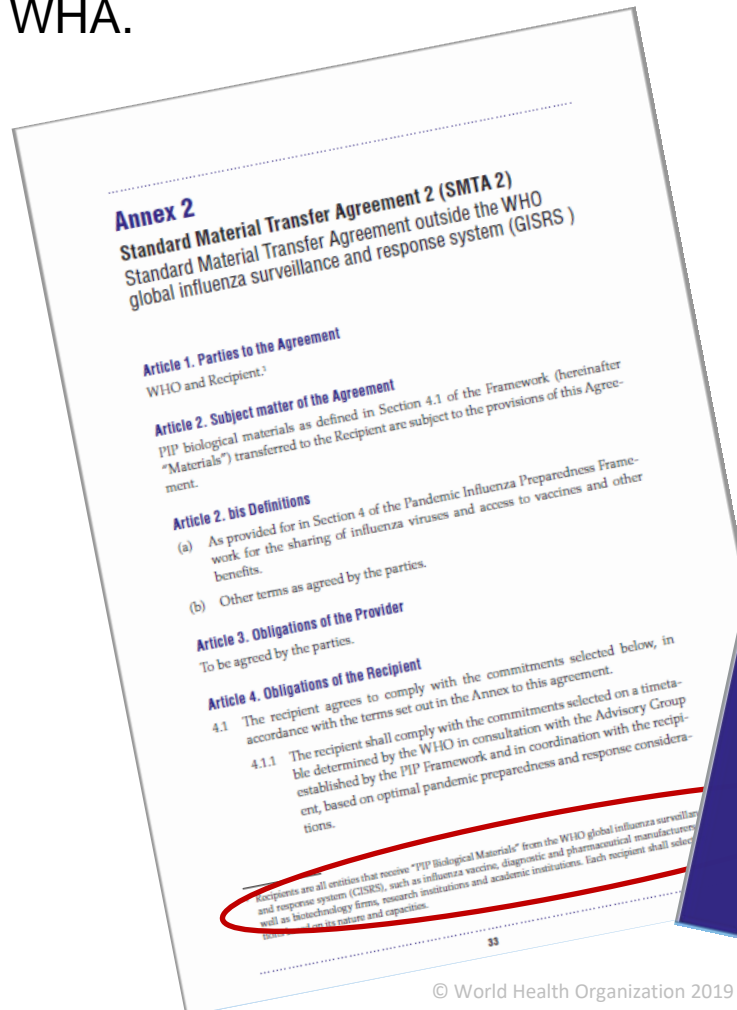
- *WHO to continue providing information on new challenges and opportunities posed by new technologies in the context of the PIP Framework, and possible approaches to them.*
- WHO will continue to its work with partners to gather, develop and share information on relevant new developments.
 - June 2019 – ‘Better global tools’ technical consultation on product research and innovation for influenza prevention, control and treatment.



OP2 – PIPF Annex 2, Footnote 1 Amendment (1)

WHA decision

- Revise PIP Framework, Annex 2, Footnote 1, with effect from the closure of the 72nd WHA.



OP2 – PIPF Annex 2, Footnote 1 Amendment (2)

Amended Footnote Text

- “Recipients are receivers of “PIP Biological Materials” from the WHO global influenza surveillance and response system (GISRS), such as manufacturers of influenza vaccines, diagnostics, pharmaceuticals and other products relevant to pandemic preparedness and response, as well as biotechnology firms, research institutions and academic institutions. Recipients shall select from among the commitments identified in SMTA2 Article 4.1.1 (a) to (c) based on their nature and capacities; those that are not manufacturers shall only have to consider contributing to the measures set out in SMTA2 Article 4.1.1(c).
- Any manufacturer that enters into any contracts or formal agreements with recipients or GISRS laboratories for the purpose of using PIP Biological Materials on the manufacturer’s behalf for commercialization, public use or regulatory approval of that manufacturer’s vaccines, diagnostics, or pharmaceuticals shall also enter into an SMTA2 and select from among the commitments identified in Article 4.1.1 (a) to (c) based on their nature and capacities.”



OP2 – PIPF Annex 2, Footnote 1 Amendment (3)

WHO has taken the following steps to implement this decision:

- *Revise the GISRS PIP Biological Material (PIPBM) Shipping Notice*: In 2011, WHO developed notice to be included in all shipments of PIPBM to alert recipients that acceptance of such Materials would trigger benefit sharing obligations under the PIP Framework. The document has been revised in close collaboration with GISRS and will start being used very soon. An online version will be uploaded.
- *Revise SMTA2 templates*: Templates for the three categories of SMTA2 have been updated and signatories of existing agreements are being contacted to inform them of the amendment and its applicability to their agreement.
- *Revise the PIP Framework text and 'purple book'*: Process to publish revised PIP Framework booklet under way. Anticipate availability of new publication in all WHO languages by the end of 2019.
- *Update the PIP webpage*: PIP webpage updated to inform of the amendment.



Next steps

- 1 November 2019 Information Sessions for Member States on implementation of WHA decisions:
 - WHA72(12) (PIP Framework)
 - WHA72(13) (Public Health Implications of the Implementation of the Nagoya Protocol)
- Secretariat will report on progress to WHA73 (May 2020), though EB146 (February 2020).
- Complete OP2 steps outlined above

Key links

- Decision WHA72(12): [http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72\(12\)-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72(12)-en.pdf)
- Decision WHA72(13): [http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72\(13\)-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72(13)-en.pdf)
- PIP Framework webpage: <https://www.who.int/influenza/pip/en/>
- PIP Progress Report Jan 2018 – June 2019:
https://www.who.int/influenza/pip/partnership_contribution/pip_progressreport_30jun2019.pdf?ua=1
- Analysis: Approaches to seasonal influenza and genetic sequence data under the PIP Framework:
https://www.who.int/influenza/pip/Analysis_WHA70108b/en/
- Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications. Study by the Secretariat:
https://www.who.int/influenza/Nagoya_Full_Study_English.pdf
- CBD Access & Benefit-sharing Clearinghouse: <https://absch.cbd.int/>



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PIP Framework Secretariat

Infectious Hazard Management
Health Emergencies Programme
email pipframework@who.int

<http://www.who.int/influenza/pip/en/>

Thank you
谢谢
Merci
Спасибо
شكراً
Gracias