Covid-19 Vaccines Risk Management Planning: Stakeholders Experiences and Perspectives

A COVAX Vaccine Safety Working Group Webinar

April 28th 2021
Meeting Norms and Recording Disclaimer

Throughout the workshop, **please ask any questions in the “Q&A” function only.**

During the discussion sessions, please **“Raise Your Hand”** if you want to say something. If called on by the moderator, **you will be unmuted to intervene.** Please **turn on the camera on during your intervention only.**

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For any logistical issue please contact **mireia@wedo-projects.com** or please contact via direct message in Zoom chat **Mireia Manent**

This workshop will be **recorded.** Recording might be shared after the webinar.

Please be mindful of the diverse audience attending the meeting when participating in open discussions.
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| 3:40 pm CET| **Industry Experience & Perspective** | Moderator: Katharina Hartmann (COVAX)  
 Q&A curator: Gabrielle Breugelmans (COVAX) |
|            | Presenters:                    |                                              |
|            | • Sarah Frise (AstraZeneca)    |                                              |
|            | • Jamie Wilkins (Pfizer)       |                                              |
|            | • Marc Ceuppens (J&J)          |                                              |
|            | • Polina Dombure (Gamelaya, Inpharmatics) |                                      |
|            | • Jiayi Wang (Sinvac)          |                                              |
| 4:10 pm CET| **Round table**                | Moderator: Katharina Hartmann (COVAX)  
 Q&A curator: Gabrielle Breugelmans (COVAX) |
|            | Panelists:                     |                                              |
|            | • Shanthi Pal (WHO)            |                                              |
|            | • Nora Dellepiane (former WHO PQ) |                                      |
|            | • Emil Cochino (EMA),          |                                              |
|            | • Helaine Carneiro Capucho (Brazil) |                                      |
|            | • Juan Roldan (Chile)          |                                              |
|            | • Christianah Adeyeye Mojisola (Nigeria) |                                      |
|            | • Corinne Jouquelet-Royer (IFPMA) |                                      |
|            | • Alexander Precioso (DCVMN)    |                                              |
| 4:50 pm CET| **Summary and Closure**        | Shanti Pal (WHO)  
 Jakob Cramer (COVAX) |
| 5:00 pm CET| **End of meeting**             |                                              |
Daniel Brasseur (COVAX)
Katharina Hartmann (COVAX)
Rogério Gaspar (WHO)
Jakob Cramer (COVAX)
Regulators’ Experience and Expectations
Regulators’ Experience and Expectations

Petra Doerr
(WHO)
COVID-19 Vaccines Risk Management Planning - Stakeholders Experiences and Perspectives

28 April 2021

Petra Doerr | Head of Unit | Regulation and Safety
Evolving Science and Regulatory Challenges

• Globalization of markets
• Sophistication of health technologies
• Rapid evolution of regulatory science
• Increasing complexity of supply chains
• Transparency and growing public expectations
• Lack of global regulatory resources

Importance of international cooperation to ensure the safety, quality and efficacy/performance of locally used medical products

Make best use of available resources and expertise, avoid duplication and concentrate regulatory efforts and resources where most needed
WHO Good Reliance Practices - Scope

Regulatory oversight of medical products:
- medicines
- vaccines
- blood and blood products
- medical devices (including in vitro diagnostics).

Addressing all regulatory functions as defined in the Global Benchmarking Tool:
- Regulatory system
- Registration and marketing authorization
- Vigilance
- Market surveillance and control
- Licensing establishments
- Regulatory inspection
- Laboratory testing
- Clinical trials oversight
- NRA lot release

The high-level document will be complemented in a second step by an interactive repository of practical examples of reliance and questions and answers documents.

Principles of Reliance

International cooperation essential to ensure the safety, quality and efficacy/performance of locally used medical products. No regulatory authorities even the best resourced one can do it alone.

Make best use of available resources and expertise, avoid duplication and concentrate regulatory efforts and resources where most needed. Promote a more efficient approach to regulatory oversight, thereby improving access to quality-assured, effective and safe medical products over the entire life-cycle.

The act whereby the regulatory authority in one jurisdiction takes into account and give significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision.

The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions, assessments and information of others.
WHO Good Reliance Practices – Principles

Universality
Applies to all NRAs irrespective of their levels of maturity or resources

Sovereignty of decision-making
NRAs maintain independence, sovereignty and accountability

Transparency
Key enabler to adopting new, more efficient ways of conducting regulatory operations. NRAs to be transparent about their reliance approaches

Respect of national/regional legal basis
Coherent with national/regional frameworks and policies

Consistency
Established for specific and well-defined categories of products and processes

Competency
Build and maintain appropriate competencies and scientific expertise
Application of reliance in Public Health Emergencies

Use of reliance and work-sharing encouraged
WHO Covid-19 vaccines safety surveillance manual encourages reliance, review of risk management plans at regional and WHO prequalification level, pharmacovigilance inspections, etc. https://www.who.int/publications/i/item/10665338400

Facilitation of authorization for use or emergency authorization based on WHO PQs Emergency Use Listing or stringent regulatory authorities approvals

Avoid retesting of vaccines through reliance on the batch release testing from releasing NRAs/NCLs (through the WHO-National Control Laboratory Network for Biologicals)
Thank you

WHO
20, Avenue Appia
1211 Geneva
Switzerland
Regulators’ Experience and Expectations

Emil Cochino
(EMA)
Covid-19 Vaccines Risk Management Planning: Stakeholders Experiences and Perspectives

Presented by Emil Cochino on 28 April 2021
Risk Management Specialist - Human Medicines Division - European Medicines Agency
EMA coreRMP19 guidance, recommendations, requirements

= additional requirements and guidance for the RMP of COVID-19 vaccines

Existing guidance applies*: EU Good Pharmacovigilance Practices: Module V (Risk Management Systems), P I Vaccines, P II Biologicals; EU RMP Template, other vaccine development clinical guidance (e.g. pandemic requirements for influenza vaccines)


coreRMP19 content (1)

- Additional COVID-19 specific topics to be addressed in the safety specification, including missing information and AESI
- Additional topics for discussion as part of Safety Specification, to facilitate discussion with regulators and assessment: e.g. reactogenicity, impact of formulation, management of multiple doses, long term follow-up
- Existing sources to consider for the list of AESI
- When and how to follow and present AESI (i.e. follow-up questionnaires, with periodic reports)
- Methods for signal detection adapted to pandemic use (to be described in RMP)
- Content and periodicity of the Monthly Summary Safety Reports (further developed with the experience of up to four months submissions);
coreRMP19 content (2)

- General recommendation for use of enhanced passive surveillance systems; designs to be avoided
- Use of vaccination cards, stickers for traceability, additional electronic methods (barcode and/or QR codes) to be considered for traceability and risk communication.
- Key elements of PASS design: e.g. rapid start, fast data generation, frequent reports, using results of ongoing EU efforts; considerations on when a PASS should be considered.
- EU projects that are likely to generate useful element for designing and conducting a PASS, or conducting safety surveillance that can be used for regulatory purposes by the MAHs
- Transparency measures: RMP full body and Annex 4 (ADR reports follow-up questionnaires) are published on EMA website for all COVID-19 vaccines
  
NEW INFORMATION MATERIALS ON COVID-19 VACCINES

Standard vaccines compared with covid-19 vaccines

Pharmaceutical quality
Non-clinical research
Phase I
Phase II
Phase III
Scientific evaluation and authorisation
Clinical trials
Large-scale production
Studies after authorisation
Vaccine available for use
NEW INFORMATION MATERIALS ON COVID-19 VACCINES

Standard vaccines compared with covid-19 vaccines

Vaccine available for use

- Pharmaceutical quality
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- Phase III
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- Large-scale production
- Studies after authorisation

Classified as public by the European Medicines Agency
NEW INFORMATION MATERIALS ON COVID-19 VACCINES

Rapid approval processes in the EU

**Early support** for vaccine developers:

EMA provides scientific advice and a dedicated Task Force (COVID-ETF)
Experience with RMP assessment - RR + initial MA application

✓ RMP available only in later rolling reviews submissions, sometimes at the time of the clinical trial data reports generation

✓ One cycle for RMP assessment, two at best (e.g. third rolling review + CMA application)

✓ First four vaccines in EU:
  - Creating precedents while ensuring consistency
  - Accounting for individual CT data submission
  - Sync with CHMP evaluation and PI finalisation (most important risk minimisation activity)
  - Defining the conditions of the MA (imposed studies)

✓ Improving the process from one product to the next = taking parts of the RMP earlier in the RRs: relevance of pre-clinical data; common safety concerns; signal detection during pandemic; defining the AESI; agreeing the monthly summary safety report content requirements; TRACEABILITY tools; studies concepts/synopsis.
EU lessons learned – pre-authorisation

✓ Use 2009-2010 pandemic lessons learned and recommendations


✓ Severe disruption of work environment, travel, medical access = challenges for MAH staff fulfilling PhV obligations, Rapporteurs’ assessment teams, and EMA staff

✓ Flexibility of the EU Network: focused efforts; long assessment hours, weekends included

✓ Early and frequent dialog with Manufacturers: rapid scientific advice, interaction with COVID-ETF, pre-submission meetings

✓ Transparency for requirements and assessment with an enhanced communication to the general public (support confidence in vaccines and assessment process)
Any questions?

Further information

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Send us a question  Go to www.ema.europa.eu/contact

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Regulators’ Experience and Expectations

Helaine Carneiro Capucho
(ANVISA, Brazil)
Regulators’ Experience and Expectations

Brazilian Experience

Helaine Capucho, PhD.
Pharmacovigilance Manager
THE CHALLENGE

NEW DISEASE

UNCERTAINTY

SHORT LIFE-CYCLE TECHNOLOGY

QUICK DISTRIBUTION AND LARGE SCALE

RISK

GREATER NEED FOR SURVEILLANCE

CORONAVÍRUS • COVID-19 • VACINA
VACCINES AUTHORIZED BY ANVISA

SINOVAC/BUTANTAN
Emergency Use Authorization

OXFORD/ASTRAZENECA/FIOCRUZ
Registration

PFIZER
Registration

JANSEN
Emergency Use Authorization

Anvisa, Brazil. Available from https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2021/covid-19-quadro-de-analises-de-vacinas-pela-anvisa?_authenticator=49168e13d276eeb6de2df4a423e2a4eee9c563bc
40,109,657 VACCINATED

FIRST DOSE
27,882,030

SECOND DOSE
12,227,627

78,9% SINOVAC/BUTANTAN
21,1% OXFORD/ASTRAZENECA/FIOCRUZ

Data from April 27, 2021
BRAZILIAN PHARMACOVIGILANCE PROCESS
Risk Management Plan

Executive summary of adverse events

Periodic Benefit-Risk Assessment Reports

International alerts and reports

Reports

Signal Detection

BRAZILIAN PHARMACOVIGILANCE PROCESS

PREMARKETING

POSMARKETING
ADVERSE EVENT FOLLOWING IMMUNIZATION

FLOW REPORTING
ADVERSE EVENT FOLLOWING IMMUNIZATION
FLOW REPORTING

VigiMed

Notificações

Pharmacovigilance Office Anvisa

Comitê de Respostas Rápidas PNI

VigiBase

Uppsala Monitoring Centre/WHO

Signal Detection

Vigilyze

VigiMed

Análise de causalidade

Vacinas

Análise de causalidade

e-SUS Notifica
Agência Nacional de Vigilância Sanitária - Anvisa

VACINA
Vacinas contra a Covid-19 não são intercambiáveis
A Anvisa alerta para que a administração da primeira e da segunda doses da vacina contra a Covid-19 seja realizada com vacinas do mesmo fabricante.

Nunca existe dúvida, até o momento, a informação sobre intercambiabilidade entre as vacinas utilizadas no Brasil, ou seja, não há dados que sustentem que a troca de fabricantes de vacinas entre a primeira e a segunda dose produza resposta inmunológica ao Sars-CoV-2.

A identificação dessa troca entre a primeira e a segunda dose da vacina deve ser informada às autoridades de saúde.

Sobre o lote em investigação
O lote suspeito – ABV5300 – é fabricado pela AstraZeneca e não é utilizado no Brasil.
THE CHALLENGE

INTEGRATE SYSTEMS USED IN BRAZIL

ANALYZE CAUSALITY QUICKLY

COMMUNICATING RISKS WITHOUT REDUCING ADHERENCE TO VACCINATION
AN OPPORTUNITY

GREATER NEED FOR SURVEILLANCE

A WORLD GOAL

USE OF INFORMATION TECHNOLOGIES IS ACCELERATED

GREATER INVOLVEMENT OF THE POPULATION

DISSEMINATION OF HEALTH INFORMATION

PHARMACOVIGILANCE
Thank you!

farmacovigilancia@anvisa.gov.br

helaine.capucho@anvisa.gov.br
Agência Nacional de Vigilância Sanitária - Anvisa

www.gov.br/anvisa
Regulators’ Experience and Expectations

Juan Roldan-Saelzer
(ISPC, Chile)
Experience on Pharmacovigilance Planning/Risk Management Plans

Engaging the stakeholders in Chile

WHO – COVAX Vaccine Safety WG workshop

Pharm. Juan Roldan-Saelzer, PhD
Head (S) Department National Drugs Agency
Public Health Institute of Chile

April 28, 2021
A reference institution of the State, which promotes and protects population health, strengthening sanitary control through **surveillance, authorization, inspection, research and technology transfer**, complying with high standards of quality and excellence.
Pharmacovigilance Subdepartment

- **Head of subdepartment**
- **Administrative staff**

**Experts Committee on Pharmacovigilance**
- (4 external members):
  - 2 doctors.
  - 2 pharmacists.

**Experts Committee on Vaccines Pharmacovigilance**
- (6 external members)
  - 5 doctors.
  - 1 nurse.
  - Additional experts according to need

**Pharmacovigilance and Cosmetovigilance Section**

**Medicines Information Section**

**Vaccines Pharmacovigilance Section**

**Team:**
- 11 Pharmacists
- 3 pandemic supporting Pharmacists
- 2 administrative staff
Pharmacovigilance activities for COVID-19 vaccines

Participation in:
- Committee for clinical trials and evaluation of adverse events
- Review of medical records for emergency authorization
- External and internal Experts Committee

Routine PV:
Reception and evaluation of spontaneous AEFI Reports

Patient safety survey:
Follow-up of vaccinated people through the email registered in the National Immunization Registry

Evaluation of risk management plans, monthly simplified safety reports, and safety reports
Pharmacovigilance activities for COVID-19 vaccines

- PV Planning
- RMP Evaluation
- Evaluation of monthly simplified Periodic Reports
- AEFI Reception: 7780 reports (04/19/2021)
- AEFI Evaluation and Follow-up
- Feedback of more significative cases

Committee of Experts on Vaccine Pharmacovigilance
Collaborative work with National Immunization Program

https://www.ispch.cl/isp-covid-19/notas-farmacovigilancia/
Pharmacovigilance activities for COVID-19 vaccines

Guidelines for the pharmacovigilance of SARS-CoV-2 vaccines in Chile. Includes information for the submission of RMP

Spontaneous reports received: 7780 reports (04/19/2021)
General application and evaluation process for RMP and s-PSUR of COVID-19 vaccines

**RMP**

- Voluntearily
- Requested

**Pre-authorization stage:**
- Background in the Emergency Use Authorization

**Post-authorization stage:**
- To comply with an emergency use authorization condition

Evaluation by PV-SD (10-12 business days)

- Product:
  - Diffusion of the RMP concept and content in the vaccination authorization process.
  - The issuance of a report with the evaluation results.

- ✔️ Report with conclusions and recommendations
  - ✔️ Internal recommendations: issuance of safety notes, modification of the product's reference safety information, conclusions on the benefit-risk balance, etc.
  - ✔️ The results of the RMP evaluation are shared with the corresponding technical areas and with the Authorization Holder through a technical meeting.
  - ✔️ The approval of RMP is not a requirement for product authorization

**s-PSUR**

- Requested

**Post-authorization stage:**
- To comply with an emergency use authorization condition

Evaluation by PV-SD (10-12 business days)

- Product:
  - The issuance of a report with the evaluation results.
# Strengths, limitations and challenges of the Chilean strategy in PV for Covid-19 vaccines

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<th><strong>Limitations</strong></th>
<th><strong>Challenges</strong></th>
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| - It is useful for monitoring the safety profile of COVID-19 vaccines.  
- Source for signal detection (identify new risks).  
- Contributes to health decision making.  
- Allows to keep the safety information of COVID-19 vaccines up to date.  
- Trained personnel are available to carry out the activity.  | - Complexity of the evaluation (extensive documents with high informative content).  
- Limited human resources and high volume of documents.  
- Heavy workload, requiring exclusivity to perform the activity.  
- Short evaluation times in order to manage the demand of documents susceptible to evaluation.  | - Strengthen staff capacities in regard to the evaluation of this type of documents.  
- To have more professionals available to carry out the activity.  
- Improve the timeliness of document evaluation, as well as making recommended actions as part of the evaluation results.  
- Continuously improve the evaluation process and those derived from its results.  
- Share experiences with other countries in the region regarding the evaluation of these documents.  |
GRACIAS
Regulators’ Experience and Expectations

Mojisola Christianah Adeyeye
(NAFDAC, Nigeria)

Presented by
Prof Mojisola Christianah Adeyeye

At The
COVAX Vaccine Safety Working Group Webinar
28th April, 2021
Outline

- Structure of RMP
- Risk Management Planning
- Requirements for Pharmacovigilance Planning
- Post Authorization Safety Studies
- Requirements for Periodic Safety Update Report/Periodic Benefit Risk Evaluation Report (PSUR/PBRER)
- Need for Risk Management Planning
- Responsibility for RMP and NRA Responsibility
- COVID-19 Vaccine Pre-Authorization Safety Preparedness and Experience
- NAFDAC and International Regulatory Cooperation
- NAFDAC Activities
  - Lessons learnt
  - War Forward
- Conclusion
The RMP consists of seven parts:

- Product overview
- Safety specification
- Pharmacovigilance plan
- Plans for post-authorization efficacy studies (PASS)
- Risk minimization measures (including evaluation of the effectiveness of risk minimization measures)
- Summary of risk management plan
- Annexes
Risk Management Plan (RMP)

Overview

- The **overall aim of risk management** is to ensure that the benefits of a particular medicinal product exceed the risks by the greatest achievable margin.

  - Dynamic document that should be updated throughout the life cycle of medicinal product(s).

Safety Specifications

- Current knowledge about the **safety profile, benefits and the risks** of the vaccine or medicinal product,

- Key information on **plans for studies** and other activities to gain more data on missing information,

- Plans for **risks minimization and assessment** of effectiveness
Requirements for Pharmacovigilance Planning

There is need to focus PV planning in the following areas:

- **Specific activities for collection, compilation, assessment and reporting of AEFI to NRA**
- **Monthly safety summaries** in addition to routine PSURs
- **Post-authorization safety studies**
- **The establishment of sentinel sites**, as part of active surveillance system for COVID-19 vaccine safety
- **Provision of educational materials and implementation of technology-driven tracking system** of vaccine administered e.g., barcode stickers
Requirements for Pharmacovigilance Planning

Monthly safety summaries should include:

- A summary of vaccine distribution (number of doses, locality of distribution)
- Global numbers (with country of origin) and analysis of AESIs reported in individuals following immunization, following the Brighton Collaboration recommendations for COVID-19 vaccines
- Numbers of deaths and relevant case histories, including observed over expected analysis
- In addition to 6 months PSUR/PBRER, a monthly safety summary focusing on AESI should be submitted or more frequently as the situation requires

Other requirements defined in the regional annex

- Challenges such as large volume of reports of adverse events following immunization (AEFIs) associated with a mass vaccination campaign should be considered and reflected in the planning document
Post Authorization Safety Studies (PASS)

- PASS should be considered and reflected in RMP if planned clinical trials and routine activities do not provide enough information for the complete characterization of important identified and potential risks.

Further studies to consider under PASS include:
- A study to further investigate the safety in pregnant women and pregnancy outcomes.
- Study in pediatrics and young children who were not studied on during clinical trials.
- Effectiveness studies are key in this section of the RMP.
- It is recommended that the MAHs make use of the existing/established efforts that could provide brand-specific data reliably and timely.
Requirements for PSUR/PBRER

- Periodic Safety Update Report/Periodic Benefit Risk Evaluation Report shall be submitted to the Agency immediately upon request or in accordance with the following:
  - Where a medicinal product has been on the market, the following periodicity shall apply:
    - For new drug molecules, at least every six (6) months for the first two (2) years, annually for the following three (3) years, and every five (5) years, at the time of renewal of license.
  - For products already being marketed elsewhere, existing PSUR/PBRER shall be submitted to the Agency not later than thirty days after submission of documents requesting for Certificate of Registration in Nigeria.
  - For listed medicinal products (provisional registration), the Certificate of Registration holder shall submit a PSUR/PBRER every six (6) months for the two (2) year listing period.
Each vaccine manufacturer/MAH should be responsible for submitting PSUR/PBRERs for its own products to the Agency according to the following timelines:

- Within **70 calendar days** of the data lock point (day 0) for PSUR/PBRERs covering intervals up to **12 months** (including intervals of exactly 12 months); and

- Within **90 calendar days** of the data lock point (day 0) for PSUR/PBRERs covering intervals in excess of **12 months**;

- PSUR/PBRER reporting should be linked to the risk management systems of the medicinal product
Need for Risk Management Planning

- The uptake of COVID-19 vaccines once authorized is anticipated to be very high which may lead to a high volume of suspected adverse reaction reports and other safety data.

- Passive and active safety monitoring are integral to the evaluation of efficacy and safety of vaccines.

- Prompt detection and evaluation of new information on the benefit-risk balance of these vaccines, timely communication and a high level of transparency will be key to protect public health and ensure the public’s trust in the vaccines and in the regulatory system.
Responsibilities for RMP

An applicant/marketing authorization holder is responsible for:

- Having an appropriate risk management system in place
- Ensuring that the knowledge and understanding on the product’s safety profile, following its use in clinical practice, are critically reviewed.
Responsibilities for RMP...

- Should monitor pharmacovigilance data to determine whether there are new risks or whether risks have changed or whether there are changes to the risk-benefit balance of medicinal products

- Should designate a qualified person responsible for pharmacovigilance (QPPV) (or a global QPPV for international vaccine manufacturers) for monitoring its safety; and to clearly present the contact information and qualifications of the QPPV to the NRA
NRA Responsibilities

- Clear guidance and requirements for PV
- Contribute to regional annex for RMP to establish criteria for study site selection
- Provide oversight for study implementation
- Guidance to MAH on requirements for routine communication of study findings, adhoc communications for urgent emerging issues
  - Implement a coordinated routine communication plan with stakeholders
- Ensure a national committee is ready to review any national PASS data
COVID-19 Vaccine Pre-Authorization Safety Preparedness and Experience

- Collaboration with all relevant stakeholders NPHCDA, NCDC, WHO, UNICEF, AUDA NEPAD, MHRA, CDC, etc
- Multi-Agency Technical Working Group established to enhance planning and safety surveillance
- Development of the COVID-19 Vaccine Regulatory preparedness plan
- Deployment of the AEFI form on the Med Safety App
- Training of health workers on the use of Med Safety App
- Deployment of PV focal persons and champions for the Med Safety App to the field to monitor vaccination and upload reports real time
COVID-19 Vaccine Pre-Authorization Safety Preparedness and Experience...

- Planned the conduct of enhanced/targeted passive surveillance of COVID-19
- Planned the pilot testing of the Traceability system using the COVID-19 Vaccine introduction
- Developed the CEM protocol for active surveillance for COVID-19 vaccine monitoring
- Inaugurated the National Expert Committee on AEFI Causality Assessment
- WHO at the continental level has built the capacity of the National Expert Committee on AEFI Causality Assessment in Nigeria (NAFDAC and NPHCDA).
  - All these efforts are geared towards ensuring appropriate safety monitoring, causality assessment and adequate information sharing on safety concerns on COVID-19 vaccines.
NAFDAC and International Regulatory Cooperation

- Pre-vaccine roll out regulatory meetings - International Coalition of Medicine regulatory Authorities (ICMRA)
- Pre-vaccination World Health Organization meetings, workshops
- The imminent arrival of COVID vaccines has created an urgent demand for a strong, coordinated, multi country approach to safety monitoring
- Post-vaccination AEFIs, AESIs sharing among ICMRA members
- The African Union Smart Safety Surveillance (AU 3S) coordinated by AUDA NEPAD and MHRA as technical partner is one such co-operation.
  - Four countries National Regulatory Authorities namely: Nigeria, Ghana, Ethiopia and South Africa are participating in the programme
NAFDAC and International Regulatory Cooperation

- ** Capability trainings on data collection tools** for Adverse Events Following Immunization (AEFIs), signal detection and management, safety communication and risk benefit assessments have been conducted across the four countries.

- **Landscape assessment** of the safety surveillance system was also conducted to identify key gaps and mitigation strategies

- **AU-3S Joint Signal Management Group** has been established with participants from the four countries as members

- **Aggregated safety data** harvested from the Med Safety App from the four countries provides source of data for signal detection
  
  - This provides continental approach to safety monitoring and signal management.
NAFDAC Activities (Examples)

- General awareness education on use of COVID-related commodities
- Debunking unproven claims for cures of COVID-19 and (Ongoing)
  - Press releases
  - NAFDAC and Your Health

- Guidance for some regulatory processes and Outcomes
  - COVID-related clinical trials (Therapeutics, Cohort event Monitoring)
  - Therapeutics submissions and approvals (Sanitizers: 26-----250) companies; therapeutics – Remdesivir (Compassionate ground permit)
  - Medical Devices – testing kits, face masks,
    - Manufacturing of personal protective equipment (PPEs)
      - Approved the first Nigerian-made medical face mask and protective gown
  - Herbal medicines’ submissions (Over forty submissions and fifteen Listing approvals)
  - Guidance on COVID-19 vaccines preparedness – first NRA in Africa
NAFDAC Activities (Examples)

- Training of Traceability Technical Working Group by GS1 Technical officers
- Development of In-Country track and trace plan
- Pre-NAFDAC approval of COVID vaccine studying of SRAs assessment reports
- Vaccine Committee review of COVID vaccine dossiers

- Monitoring of Adverse Events Following Immunization
  - *Med Safety App (launched November 2020)*
  - *GS1 technology-driven traceability (launched October 2020)*
  - *Training and deployment of personnel for field safety monitoring (1st quarter 2021)*
Challenges with Routine/Expected Pharmacovigilance Activities

- Despite the deployment of the Med Safety App, a large number of AEFIs are not reported particularly when they are considered mild or non-serious.

- **Downloading and use of the App** still a challenge even with literate users. Sustained awareness and sensitization required.

- **AEFI reports are mainly received from urban and semi-urban areas with good network coverage.** There are few AEFI reports from rural areas due to poor internet penetration and low levels of literacy with the ownership and use of smartphones.

- **Undue reliance on other sister agencies** to support data collection at the periphery leading to delays.

- **Poor transmission of investigation forms for serious AEFIs from the States to the National**
Lessons learnt

- Targeted multi-stakeholder engagements is a very important factor to continually detect and report AEFIs during and post vaccination.
- **Trainings** to improve implementation of Policy (NPC staff and all PV stakeholders on Covid-19 vaccines roll-out).
- **Electronic data collection tools fully deployed** (e-Reporting and Med Safety App)

- Increase in number of AEFI reports during on-field sensitization and vaccine monitoring however, **post-exposure studies required to monitor effectiveness of vaccines**

In summary,
- Capacity strengthening, electronic data collection tools, online platforms for direct ADR reporting alongside local, national and international stakeholder engagement is critical towards strengthening systems for PV in Nigeria.
Way Forward

- Awareness Creation, Intense sensitization and Enlightenment campaigns
  - Social media
  - Radio and Television
  - Community sensitisations

- Sustained Implementation of country plans
- Increased vaccination via tackling vaccine hesitancy in the populace
- Safety monitoring of medical products (medicines and vaccines) and reporting of ADRs/AEFIs associated with the use of medicines and vaccines using electronic and online reporting tools.
- Monitoring of effectiveness of PV interventions
Conclusion

- Safety monitoring of COVID-19 vaccines is key to characterizing the full safety profile of the vaccine

- Collaboration between the NRA and vaccine manufacturer/MAHs is critical

- Adequate minimization measures put in place in the RMP should be well implemented in conjunction with the NRA oversight
Thank You
Industry Experience and Perspective
Industry Experience and Perspective

Sarah Frise & Jamie Wilkins
(Astra Zeneca) (Pfizer)
Covid-19 Vaccines Risk Management Planning: Stakeholders Experiences and Perspectives

Industry Experience & Perspective
28th April 2021

Jamie Wilkins, Pharm.D., Pfizer Worldwide Safety
Sarah Frise, MSc, Ph.D., Head of Risk Management, Astra Zeneca
WHO Risk Management Plan (RMP) Preparation & Submission: A matter of perspective
Global Risk Management Submission Requirements:

EMA: RMP Plus
- GVP V revision 2 template
- Routine PV
- Bi-weekly meetings
- Monthly sPSUR (summary report)
- Traceability (EU)
- Numerous PASS (& different)

MHRA: RMP Plus
- Detailed description

US FDA: Pharmacovigilance Plan (PVP)
- Based on E2B
- Routine PV
- Action Plan for Safety Issues
- Observational Studies

WHO: RMP
- Based on GVP V rev 2 template
- Regional Annex

2. MHRA guidance: PV and RM requirements for COVID-19 vaccines in the UK (not published)
A number of uncertainties initially:

- Process for review/approval? Who/What/How?
- RMP documentation for WHO- approach and strategy?
- Length of review?
A core organizational stance on information contained within major regulatory Risk Management Documents:

- Identified Risks
- Potential Risks
- Missing Information
- Routine PV
- Studies

Organizational position on elements to include in core risk management documents vs. appropriate information for addendum

Provides ability to quickly mobilize for submissions; formatting may differ based on regulatory requirements however, content is consistent.
Challenges and Opportunities

Potential Challenges

- Unknown requirements
- Co-existing products in certain countries (COVAX supply vs. approved/authorized product via typical process)
- Additional requests and clarifications from WHO
- Implementation of pharmacovigilance in LMICs

Potential Opportunities

- Unique perspective during pandemic
- Innovative methods of implementing requirements
- Global knowledge sharing
- RMP structure for LMICs
- Flexibility and agility
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Industry Experience and Perspective

Marc Ceuppens
(Janssen)
COVID-19 Vaccines Risk Management Planning: Stakeholders Experiences and Perspectives

The Janssen Experience

Marc Ceuppens, MD – Janssen Global Medical Safety – 28/04/21

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Background

- Format
  - Core Risk Management Plan
    - Support development EU-RMP, US PV Plan, meet Local Country requirements (Addenda)
  - Learnings from Ad26.ZEBOV vaccine

- Accelerated development
  - Evolving knowledge COVID-19
  - AESI: Identification, case definition and background incidences
  - Parallel development with Phase 3 trials conduct
  - Addressing ‘Missing Information’ and further risk characterisation through PA(S)S program
Challenges

- Exposure data
  - Product specific
  - Stratification age – gender – racial/ethnic origin
- Reliable background incidences for Observed/Expected calculations
- Meeting multiple country expectations
  - The rapid development of new and updated COVID-19 vaccine-specific local/regional regulatory guidance
  - Local epidemiology data (population exposure, concurrent disease, ...)
  - AESI selection
  - PA(S)S requirements
  - Post-marketing periodic reporting
- PA(S)S set-up and roll-out
- Assessing effectiveness risk minimisation tools
  - Monitoring and reporting AEFIIs through local surveillance
Thank You

Nelly Velez, *The World Among Us*
Artwork from Gilda’s Club

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Industry Experience and Perspective

Polina Dombure
(Inpharmatis)
Sputnik V (Gam-Covid-Vac)
Risk Management Plan preparation
Success and Challenges

28.04.2021
By Dr. Polina Dombure, CEO, Inpharmatis Group
Collaboration

- National Research Center of Epidemiology and Microbiology n.a. N.F. Gamaleya is the world’s leading research institution founded in 1891
- The Center successfully created the world’s first Ebola virus vaccine. A MERS vaccine is currently in advanced stages of clinical trials. Both vaccines are based on the human adenovirus vector platform used for Sputnik V
- The Center runs one of the world’s only “virus collection” and has its own vaccine production facility
- Sovereign Wealth Fund of Russia established in 2011
- RDIF has played a key role in fighting COVID-19 in Russia. The Fund has selected and funded the most promising testing system (COVID-19 SmartAmp), drug (Avifavir) and vaccine (Sputnik V) for COVID-19
- RDIF is supporting the development of Russia’s COVID-19 vaccine by the Gamaleya Center
- RDIF has the exclusive license for the sale and manufacture of Sputnik V vaccine in international markets
- 20+ years of proven experience operating in the EU, Russia and CIS region
- Partnership with leaders in pharmaceutical and medical device industry - proven compliance with high-quality standards
- Consulting for RDIF & Gamaleya on Sputnik V from the beginning – providing high level scientific and medical expert advice
- EMA / WHO Rolling Review Procedures for Sputnik V vaccine
- Global Pharmacovigilance Set Up fulfilling the requirements EU, WHO and acting as EU QPPV, as well as centralised management of all safety data for Sputnik V vaccine

Developer of Vaccine

© Inpharmatis 2021

Authorised for production and distribution outside of Russia

Global Pharmacovigilance for Sputnik V
Inpharmatis Role

• Regulatory support in WHO & EMA Rolling Review Procedure
• Global Pharmacovigilance provider for Sputnik V vaccine
• Global ADR collection / Case Processing / Case Submission
• Global Pharmacovigilance database management
• Global Literature Search
• Aggregate Report Preparation
• Signal Detection
• CMO, CRO and local PV partners management & support
• Medical Information Management
• Regulatory Intelligence etc.
Sputnik V Product Presentation
Sputnik V short overview

SARS-CoV-2

Glycoprotein S

VACCINATION REGIMEN:
Component 1 Component 2

0 21 DAYS

Component 1 rAd26-S
Component 2 rAd5-S

10^{11} viral particles (vp) per dose for both rAds
Sputnik V Short Overview:
Advantages of heterologous prime-boost immunisation

- Boosting of the primary immune response is important for a long-lasting immunity
- Prime immunization induces anti-vector immunity which affects efficacy of the boost immunisation
- Heterologous prime-boost immunisation might overcome anti-vector immunity
- rAd26 and rAd5 are distinct vector serotypes with a low probability to induce cross-serotype immunity
Phase III Results
Phase III: Interim Report

**Primary Endpoint**
- Proportion of trial subjects with COVID-19 disease developed

**Secondary Endpoint**
- The percentage of trial subjects with mild, moderate, severe, and extremely severe COVID-19

**Secondary Endpoint / Immunogenicity**
- Percentage of trial subjects with a fourfold or more increase in the titer of SARS-CoV-2 glycoprotein-specific antibodies
- Interferon gamma concentration in T-cells after repeat stimulation with the SARS-CoV-2 glycoprotein
- Geometric mean virus-neutralizing antibodies titre
- **Secondary Endpoint / Safety**: Incidence and severity of adverse events (including adverse events of a particular interest) in the study subjects
The efficacy of the Sputnik V vaccine is 91.6% (95% CI: 85.6-95.2), based on the interim analysis of 78 confirmed COVID-19 cases: 16 cases in the vaccine group (n=14964) and 62 cases in the placebo group (n=4902). Calculation was based on the analysis of data of volunteers who received both doses of the vaccine or placebo.

From 15 to 21 days after the first dose, efficacy was 73.6% (p=0.048).

The efficacy of the Sputnik V vaccine is comparable within different age and sex groups.
Phase III Interim Safety

The safety study included 21,862 volunteers, who received at least one dose of vaccine or placebo.

During the study among 21,862 volunteers (who received at least one dose), 70 episodes of SAE not related to COVID-19 were recorded in 68 volunteers: in 45 volunteers from the vaccine group and 23 volunteers from the placebo group.

No one of registered SAEs was associated with vaccination.

There were no vaccine-related deaths reported.

There were 3 SAEs reported in the vaccine group 3 days after administration: renal colic, deep vein thrombosis, and extremity abscess (third finger). SAE was diagnosed on the basis that in all three cases the event required hospitalization for study participants. No association was found between SAE and the vaccine administration.

The most common adverse events were influenza-like illness and local reaction. During the study, among volunteers 60+, 3 episodes of AEs grade 3 or more, not associated with vaccination, were recorded: in the vaccine group an exacerbation of urolithiasis and acute sinusitis, in the placebo group an influenza-like illness. All these AEs were resolved without consequences.

Based on 21,862 volunteers data (who received at least 1 dose). No one of registered SAEs was associated with vaccination. Most post-vaccinal systemic and local reactions (93·96%) were mild.
Conclusions

Interim analysis of Sputnik V phase 3 trial in participants aged 18 years or older showed:

• Vaccine is effective in preventing symptomatic COVID-19 cases with 91.6% efficacy after day 21 from the Dose 1.

• Vaccine induces robust humoral and cellular immune response.

• Vaccine has a good safety profile.

• More than 8 million doses of Sputnik V have already been administered to the public.

• Vaccine has EUA in 62 countries.
Sputnik V Safety Profile To Date
Sputnik V Safety Profile

Summary of the safety profile

The safety assessment was carried out in the framework of three clinical studies of the safety, tolerability and immunogenicity of the Sputnik V vaccine for the prevention of the new coronavirus infection (COVID-19), in healthy male and female volunteers and in healthy volunteers of 60 years and older. Safety assessments in these studies were performed in a similar manner and included assessment of AE incidence, vital signs, the results of instrumental studies, physical examination, and laboratory parameters (full blood count, biochemical blood test and urinalysis).

Adverse events specific to the vaccine use identified in clinical trials of the Sputnik V vaccine, as well as studies of other vaccines based on a similar technological platform, can be predominantly mild or moderate, can develop in the first or second days after vaccination and are resolved within 3 consecutive days. The following short-term general reactions: short-term flu-like syndrome, characterized by chills, fever, arthralgia, myalgia, asthenia, general malaise, headache and local (soreness at the injection site, hyperemia, swelling) may develop more often than others.

The prescription of non-steroidal anti-inflammatory drugs (NSAIDs) is recommended for fever after vaccination. Such reactions as nausea, dyspepsia, decreased appetite, and sometimes an increase in regional lymph nodes can occur less frequently. Some patients may develop allergic reactions, a short-term increase in the level of hepatic transaminases, creatinine and creatine phosphokinase in the blood serum.

Most of the adverse events reported in clinical studies resolved without consequences. Laboratory abnormalities of immunological parameters had no clinical significance and did not require additional diagnostic procedures and therapy.
# Sputnik V Safety Profile

<table>
<thead>
<tr>
<th>System/Region/Adverse Event</th>
<th>100 AE episodes</th>
<th>300 AE episodes</th>
<th>500 AE episodes</th>
<th>Total</th>
<th>Median</th>
<th>95% CI</th>
<th>95% CI</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gastrointestinal disorders</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>91</td>
<td>0.6</td>
<td>24</td>
<td>115</td>
<td>0.6</td>
<td>0.342</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>71</td>
<td>0.5</td>
<td>22</td>
<td>92</td>
<td>0.5</td>
<td>0.330</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>69</td>
<td>0.5</td>
<td>20</td>
<td>89</td>
<td>0.4</td>
<td>0.289</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal discomfort</td>
<td>49</td>
<td>0.3</td>
<td>15</td>
<td>55</td>
<td>0.2</td>
<td>0.187</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>29</td>
<td>0.2</td>
<td>9</td>
<td>32</td>
<td>0.2</td>
<td>0.065</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Organ system total</strong></td>
<td>135</td>
<td>2.3</td>
<td>92</td>
<td>443</td>
<td>2.0</td>
<td>0.042</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Nervous</strong></td>
<td>81</td>
<td>0.6</td>
<td>17</td>
<td>100</td>
<td>0.5</td>
<td>0.074</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory</strong></td>
<td>64</td>
<td>0.5</td>
<td>16</td>
<td>80</td>
<td>0.4</td>
<td>0.200</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Skin</strong></td>
<td>138</td>
<td>0.9</td>
<td>28</td>
<td>166</td>
<td>0.8</td>
<td>0.039</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Upset stomach</strong></td>
<td>58</td>
<td>0.3</td>
<td>10</td>
<td>67</td>
<td>0.3</td>
<td>0.034</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Injury, poisoning, and procedural complications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Decreased appetite</strong></td>
<td>59</td>
<td>0.6</td>
<td>19</td>
<td>100</td>
<td>0.5</td>
<td>0.074</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Visual disturbance</strong></td>
<td>52</td>
<td>0.1</td>
<td>9</td>
<td>57</td>
<td>0.1</td>
<td>0.045</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory system</strong></td>
<td>50</td>
<td>0.3</td>
<td>10</td>
<td>60</td>
<td>0.3</td>
<td>0.034</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Infections and infestations</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Decreased appetite</strong></td>
<td>59</td>
<td>0.6</td>
<td>19</td>
<td>100</td>
<td>0.5</td>
<td>0.074</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Increased appetite</strong></td>
<td>16</td>
<td>0.1</td>
<td>5</td>
<td>21</td>
<td>0.1</td>
<td>0.025</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory system</strong></td>
<td>48</td>
<td>0.3</td>
<td>14</td>
<td>60</td>
<td>0.3</td>
<td>0.034</td>
<td></td>
<td></td>
</tr>
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<td><strong>Infections and infestations</strong></td>
<td></td>
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</tr>
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<td>16</td>
<td>0.1</td>
<td>5</td>
<td>21</td>
<td>0.1</td>
<td>0.025</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory system</strong></td>
<td>35</td>
<td>0.3</td>
<td>10</td>
<td>55</td>
<td>0.3</td>
<td>0.044</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory system</strong></td>
<td>29</td>
<td>0.2</td>
<td>4</td>
<td>33</td>
<td>0.2</td>
<td>0.107</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
4. The findings are presented as the number of subjects with reported AEs and the percentage of the safety population in a given group.
5. Enlarged lymph nodes, lymphadenopathy
6. Notice in use
Global Pharmacovigilance System for Sputnik V
Key Safety Data of SPUTNIK-V Vaccine

- Key safety data are based on the following study:
  - Randomized Double-Blind Placebo Controlled Clinical Trial of Efficacy, Immunogenicity and Safety of the Gam-COVID-Vac Vaccine against the SARS-CoV-2 Infection (The Lancet 2021 Feb 20)

- 21963 subjects were randomized in a ratio of 3:1 vaccine group / placebo group.
- Safety Analysis - 19,866 volunteers (14964 vaccine / 4902 placebo).
- A total of 16,795 AEs were registered during the study
  - 6670 (44%) vaccine
  - 1328 (27%) placebo

- RMP was developed by Gamaleya according to Eurasian Union & Russian Federation Requirements
- Global RMP was developed according to EMA’s requirements by Inpharmatis
Sputnik Roadmap

Vaccine development by Gamaleya
  • Complete*

First clinical trial
  • Jun-2020

First registration
  August 2020
  • Complete
    (Russia)

Emergency Use License
various territories worldwide

EMA / WHO application
  • Ongoing

Rolling Review by EMA / WHO expected by end June 2021

*Current ongoing development of lyophilisate form and nasal form
Challenges with RMP Development

- Market entry from Russian Federation
- Eurasian Union GVP requirements are very similar to European GVP requirements
- Many on-going Clinical Trials around the world, including with another vaccine
- Many Emergency Use Authorizations in the world
- Many CMOs around the world for Sputnik V
- Data derived from other vaccines / PRAC recommendations should be considered (e.g., thrombosis events)
- Daily received new information from the market that requires urgent processing, centralization, analysis and conclusions requiring urgent RMP update
- Different RMP or RMP-like expectations (format, frequency) globally
Our Conclusions and Recommendations

• RMP for COVID-19 vaccines is a “live” document, that must be updated on almost monthly basis

• Global RMP must be managed according to the highest regulatory standards despite possible deviations in expectations of various Regulators

• Safety profile and measures for risk management must be reviewed on daily basis and RMP is not the best document for the management of such task

• Guidance from EMA, WHO and other Regulators is highly appreciated

• Harmonisation of safety data with other vaccine manufacturers is needed
Thank you for your attention

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Fax  +371 6721 0501
Industry Experience and Perspective

Jiayi Wang
(Sinovac)
Covid-19 Vaccines Risk Management Planning: Stakeholders Experiences and Perspectives

Jiayi Wang  PV Supervisor

科兴控股生物技术有限公司
SINOVAC BIOTECH LTD.

2021年4月28日星期三
SINOVAC COVID-19 vaccine obtained Conditional Marketing Authorization in China on 5th February 2021 and obtained EUA in many Countries/Regions worldwide, as of now.

SINOVAC is in the process of answering the Second List of Questions focusing on RMP for Emergency Use Listing (EUL).

SINOVAC has submitted RMP to EMA for Obtaining an EU marketing authorization.
Post-approval challenges

AEFI Collection in Countries/Regions outside China

- Sign Pharmacovigilance Agreements with local agents or MOH/DOH
  Usually take a couple of days. Not in a timely manner.
- AEFI reporting with CIOMs Form (Serious and Non-serious)
  Time consuming with huge volume of reports under mass vaccination
  Changed to Excel Spreadsheet for Non-serious AEFI
- AEFI reporting from Countries/Regions with immature PV system
  Not available. Need to figure out a way to get more AEFI information
让中国儿童使用国际水平的疫苗
让世界儿童使用中国生产的疫苗

科兴以“为人类消除疾病提供疫苗”为使命，致力于人用疫苗及其相关产品的研究、开发、生产和销售，为我国乃至全球的疾病预防控制提供服务。
Round table
Panelists

- Petra Doerr (WHO)
- Shanthi Pal (WHO)
- Nora Dellepiane (former WHO PQ)
- Emil Cochino (EMA)
- Helaine Carneiro Capucho (Brazil)
- Juan Roldan (Chile)
- Mojisola Christianah Adeyeye (Nigeria)
- Corinne Jouquelet-Royer (IFPMA)
- Alexander Precioso (DCVMN)

Moderator

Katharina Hartmann

Q&A curator

Gabrielle Breugelmans
Summary and conclusions
Shanti Pal (WHO)

Jakob Cramer (COVAX)
Thank you