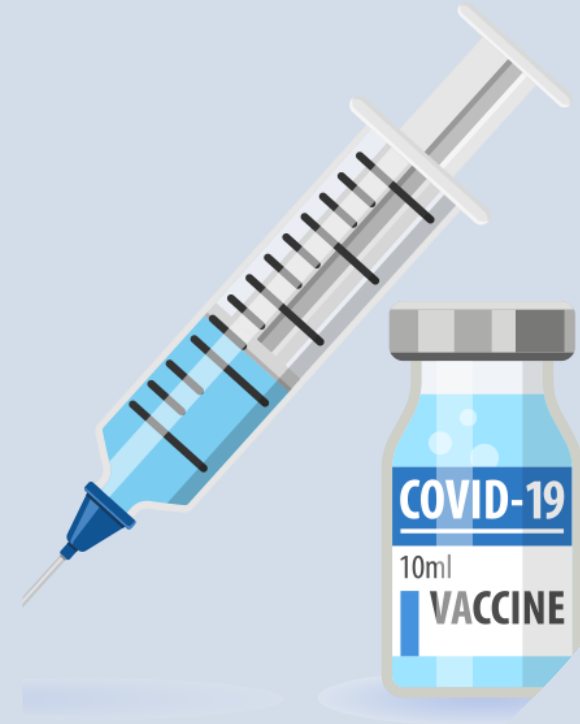


# Pharmacovigilance of Covid19 vaccines **opportunity for collaborations**



Ghita Benabdallah  
CAPM, WHO CC for Strengthening PV practices

16<sup>th</sup> Annual IMSN Virtual Meeting  
November, 8-9, 2021



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# Global context of the covid-19 pandemic

Unprecedented situation

Increasing mortality and morbidity

Very short period of time

Feeling of loss of control

Urgent decision

Media pressure

Large cohort of patients to be treated

No available drugs or vaccines

Special conditions  
Containment

Probabilistic treatments

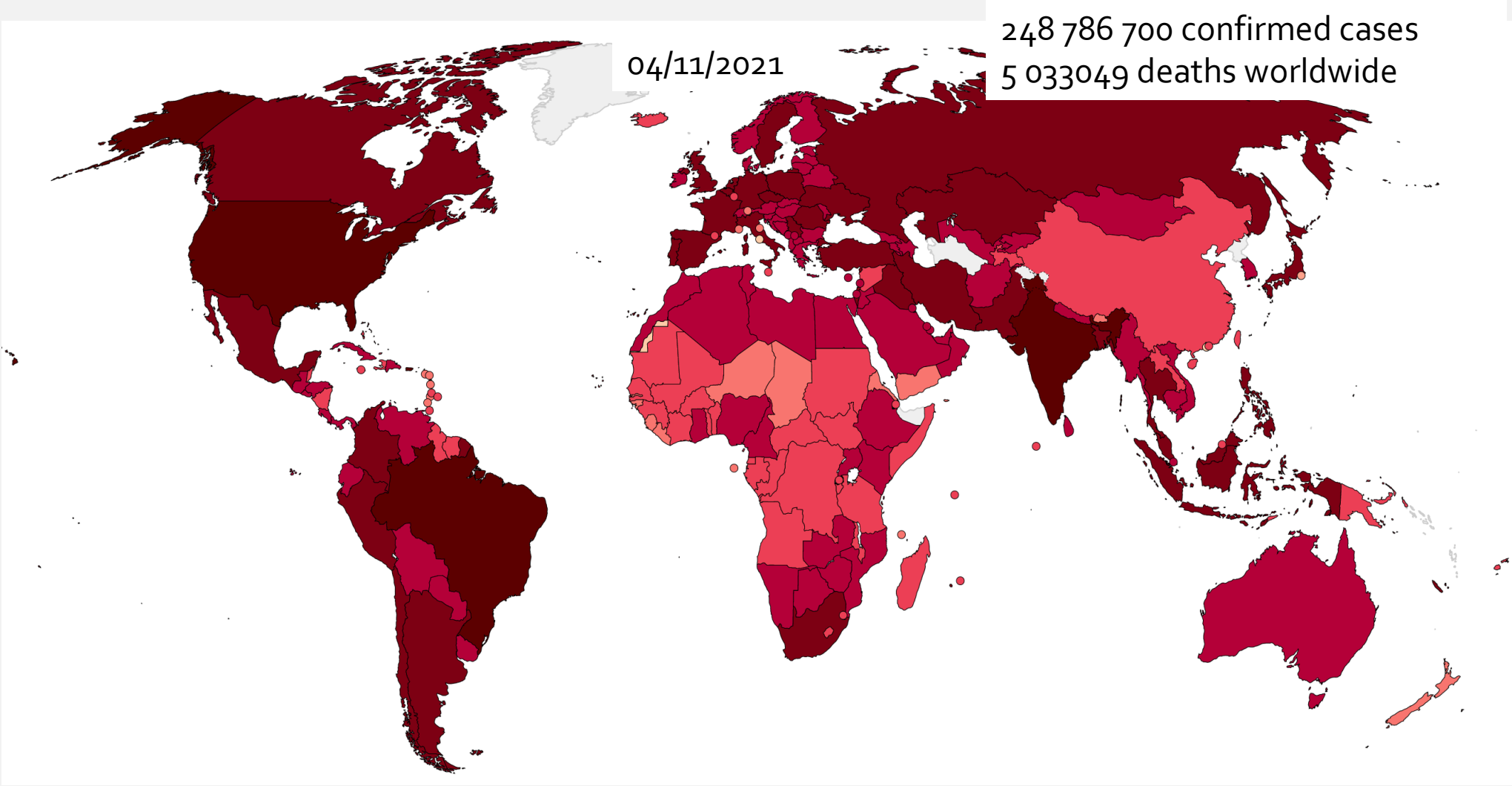
Mortality and morbidity keep on increasing

Response strategy:  
Protective measures

Research and manufacturing of an anti-covid vaccine



# Global context of the covid-19 pandemic



# Global response

## A vital solution: the anti-Covid-19 vaccine

Immunization: main strategy to control the pandemic

- Best option to gain **collective immunity** and **protection against contamination and/or serious forms** of the disease

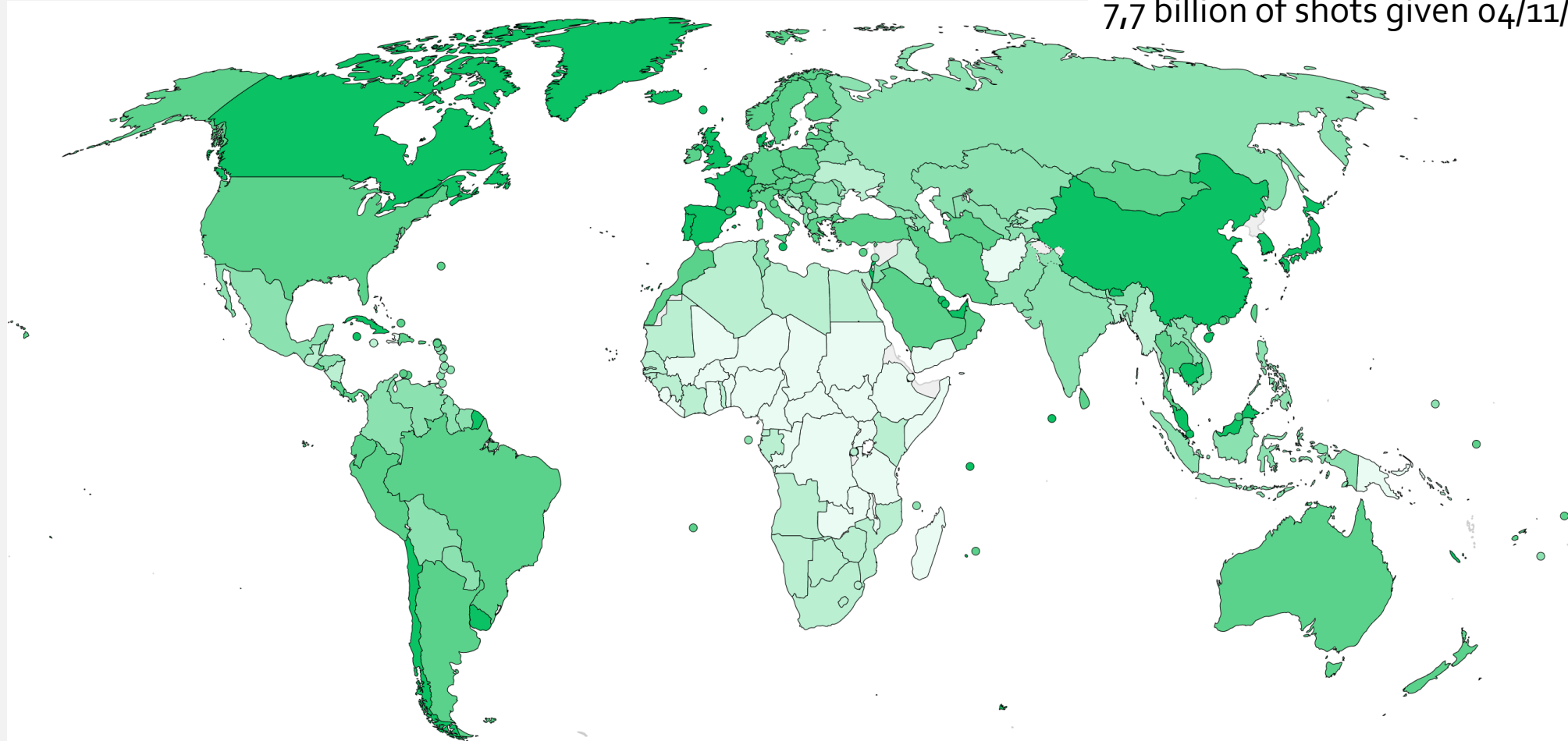


Quick development of **safe and effective vaccines**

- Vaccine safety is based on clinical and pre-clinical data but also on **efficient pharmacovigilance**,
  - **Nevertheless, the anti-covid-19 vaccine, an unprecedented situation**
    - How solid are clinical trials data?
    - Are the countries ready to ensure vaccine safety?
    - Risk Management Plans

# Global context of covid-19 vaccines administered

7,7 billion of shots given 04/11/2021



no data

10

50

100

150

doses per 100 people

# Global context of Pharmacovigilance of covid 19 vaccines

- Not all countries have national PV strategy
  - Factors affecting preparedness of PV systems :
    - Maturity of PV system,
    - Any governmental support
    - Program budget
    - Training facilities
    - Interactive participation of different stakeholders
    - Political stability in the country

# Requirements for global vaccine response

- It is essential that:
  - The anti Covid 19 vaccine is administered to as many eligible people as possible
  - The anti covid-19 vaccines are safely and effectively given
- Each country has a duty to develop a clear vaccination strategy including Risk Management Plan (RMP) to ensure patient safety within its country
- Pharmacovigilance activities should be strengthened, particularly PV of vaccines
- Sharing information with the international Pharmacovigilance program will provide mutual benefit



**safety profile of these news vaccines**



# Time for collaboration

## International level



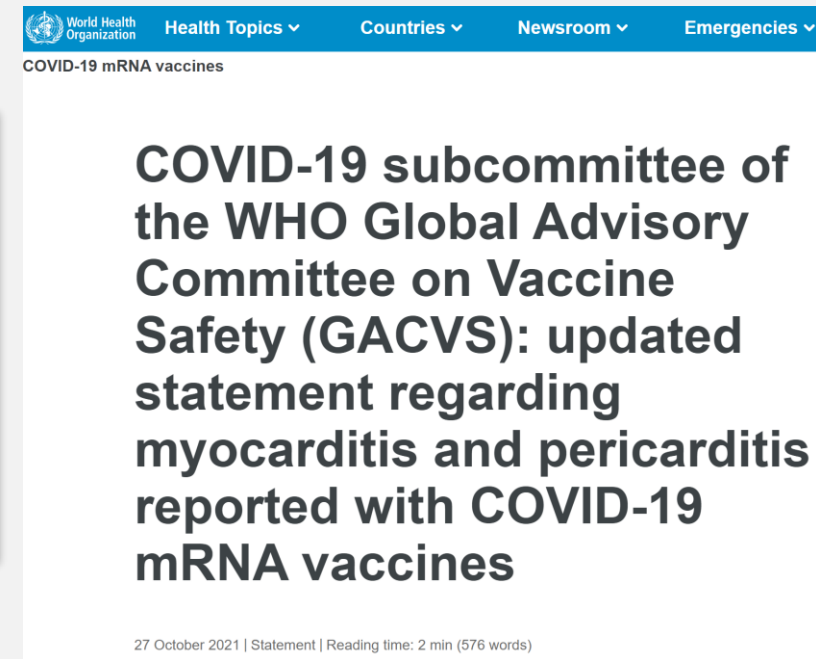
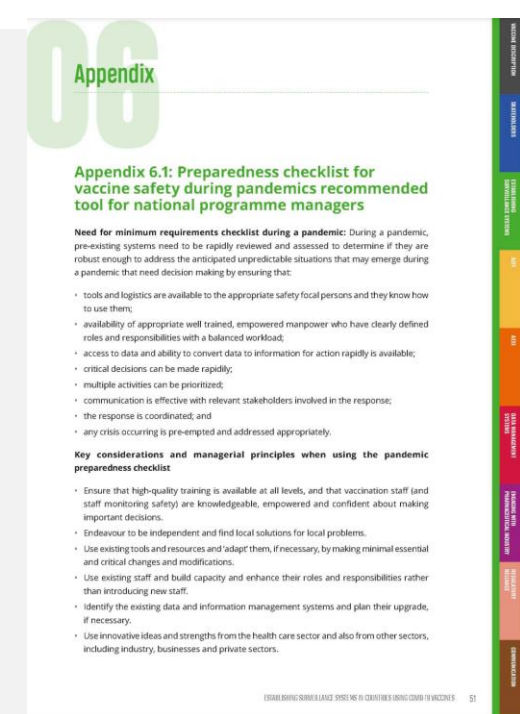
WHO-HQ  
Geneva



# Time for collaboration

## WHO/GACVS

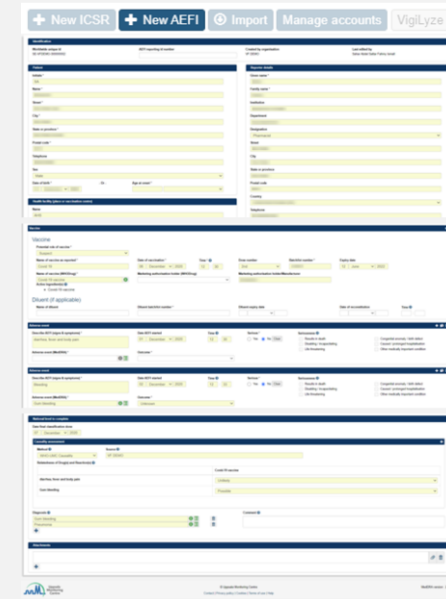
- Global Advisory Committee on Vaccine safety (GACVS): Supports global community
  - Guidelines for countries
  - Experts recommendations
  - Regular reports updates



# Time for collaboration

## WHO/UMC - Database

- Vigiflow adapted to facilitate and make easier sending covid 19 vaccines AEFI and AESI
  - Based on the WHO AEFI reporting form/ inspired by some national AEFI reporting sheets
  - Focused on important data in terms of vaccine pharmacovigilance.
  - one page with several sections (Different languages, French translation/WHO CC Rabat)
  - Training courses organized to display new tools/ French training course by WHO CC rabat
- Adapted Adverse Event coding: selected from a **list of predefined terms**

A screenshot of the 'Adverse event' form in the Vigiflow application. The form is titled 'Adverse event' and has a dark blue header. A red box highlights the 'Select from predefined list' option. The form includes several input fields and checkboxes:

- Name of adverse event as reported**: A text input field.
- Date AEFI started**: A date selection field.
- Time**: A time selection field.
- Serious \***: Radio buttons for 'Yes' and 'No', with a 'Clear' button.
- Seriousness**: A section with checkboxes for 'Results in death', 'Disabling / incapacitating', 'Life threatening', 'Congenital anomaly / birth defect', 'Caused / prolonged hospitalisation', and 'Other medically important condition'.
- Adverse event (MedDRA) \***: A dropdown menu with an information icon.
- Outcome \***: A dropdown menu.

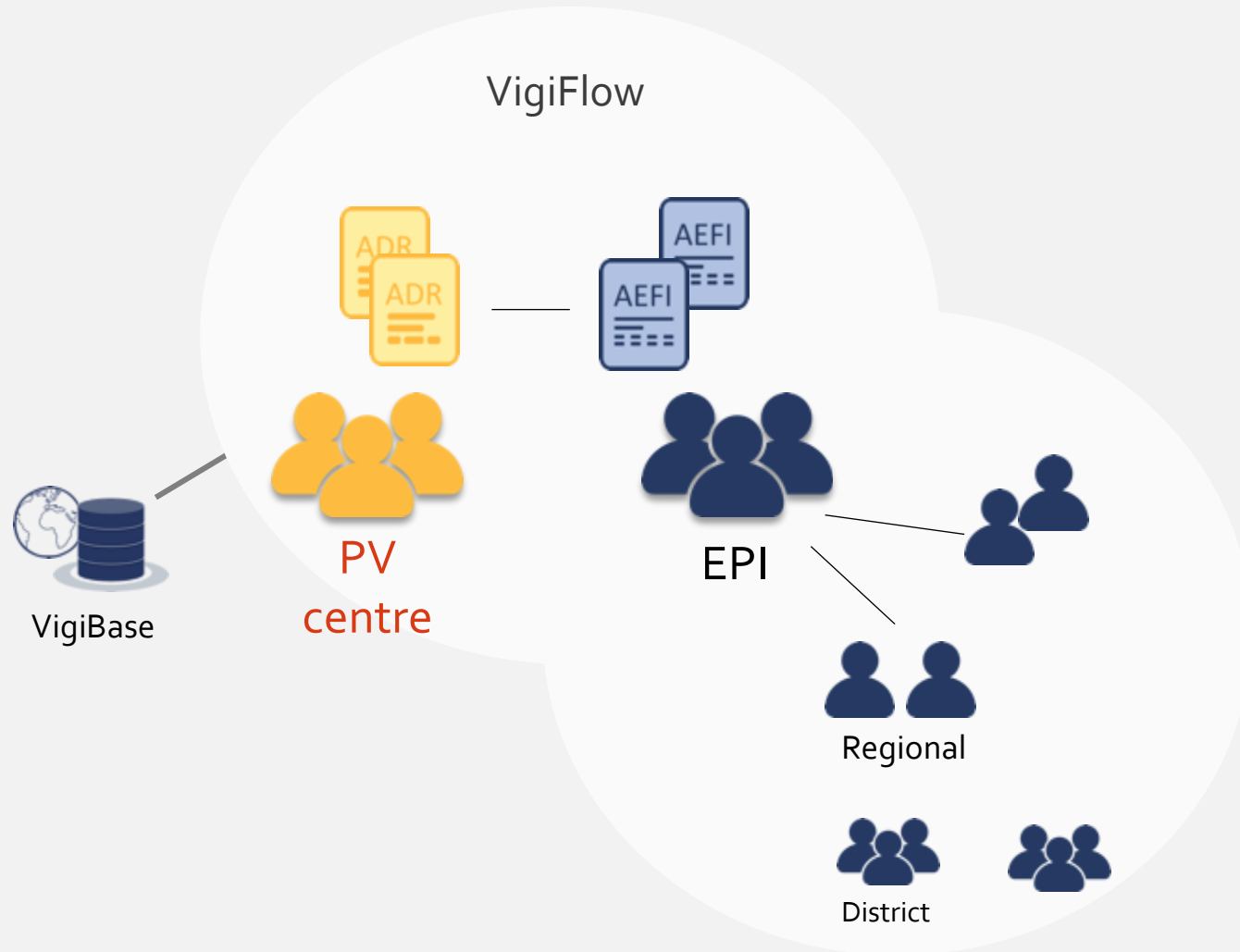
- Database analysis adapted to facilitate national analysis
- Regular publication of **report on COVID-19 vaccines AEFIs - safety profile of vaccines**

# Time for collaboration

## WHO/UMC - Database

### Include the Expanded Program on Immunization (EPI) in Vigiflow

- The implementation of AEFI reporting in VigiFlow will facilitate collaboration between the EPI / vaccination programs and the PV National Center in terms of vaccine safety monitoring



# Time for collaboration

## WHO/WHO CC, Rabat

- WHO CC Rabat mandated by WHO to share its experience in managing pharmacovigilance of covid 19
- Solicited to train and build capacity in pharmacovigilance of covid 19 vaccines
  - French speaking countries
  - English countries (Africa)
  - Eastern mediteranean region countries
- Solicited to assess PV system of countries to build a road map to PV strategy of covid 19 vaccines
  - Specific coaching in specific areas
- Solicited to build up a regional advisory committee for PV of covid 19 vaccines in EMR countries

# Time for collaboration

## International Committees

- **IMSN –Covid Vaccine Special Interest Group (CVSIG)**
  - Communicate, share experience on Covid-19 vaccines safety issues
  - Make appropriate recommendations for global implementation
  
- **African Advisory Committee on Vaccine Safety (AACVS)**
  - Advisory committee of WHO/AFRO on strategic and policy matters on the safety, vigilance and risk management of vaccines and immunization
  - Covid 19 vaccines: Review and provide guidance and recommendations to the Regional Director on country readiness for safety monitoring and pharmacovigilance of COVID-19 vaccine

The two primary objectives of the **IMSN Covid-19 Vaccine Safety Interest Group** are:

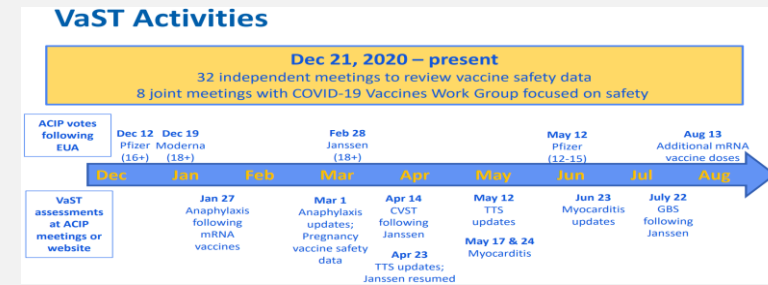
1. To address Covid-19 vaccine safety issues by sharing the experience and learning from member countries on issues being encountered during the vaccine rollout.
2. To make appropriate recommendations for global implementation of safe Covid-19 immunization practices.



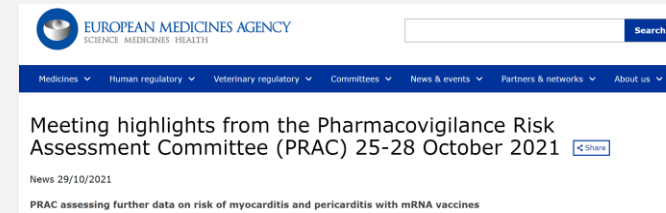
# Time for collaboration

## International Committees

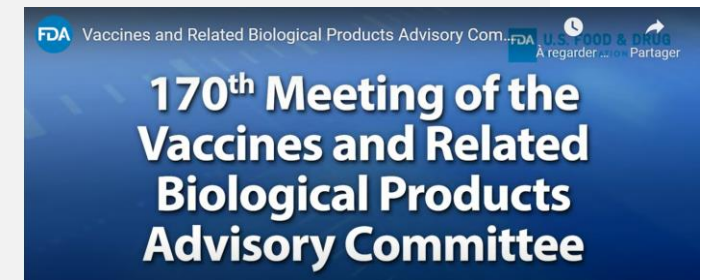
- CDC Advisory Committee on Immunization Practices' (ACIP)
  - COVID-19 Vaccine Safety Technical (VaST) Work Group (subgroup)
    - Provide updates on covid 19 vaccine safety



- Pharmacovigilance Risk Assessment Committee (PRAC)
  - Covid19 EMA pandemic task Force (COVID-ETF)
    - take quick and coordinated regulatory action related to COVID-19 medicines



- FDA Vaccines and Related Biological Products Advisory Committee:
  - Provide independent expert advice on scientific, technical, and policy matters
    - Ex: Discuss request to amend Pfizer-BioNTech's Emergency Use Authorization (EUA) for administration of their COVID-19 mRNA vaccine to children 5 through 11 years of age.





# Moroccan International implication

## Baseline

### Expertise development

- Participation in writing, editing and translating WHO guidelines
- Nomination in the international committees and boards
- Invitation to share experience and to participate in international meetings and trainings

### Launch of Pharmacovigilance Training Course

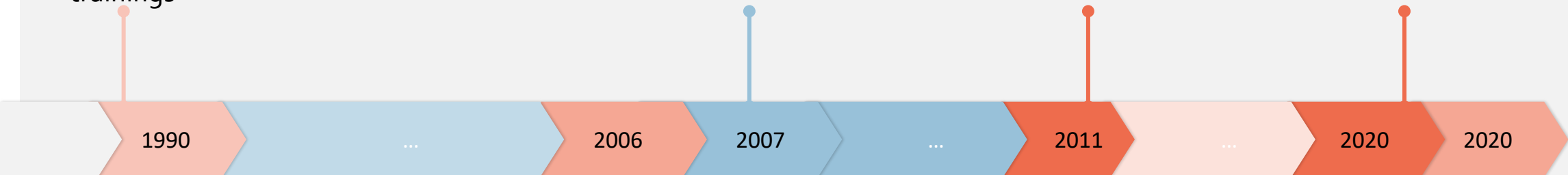
- Run annually for 15 years (2007-2021)
- From onsite version to the online one
- Since 2020: From 2 weeks to 6 weeks
- More than 800 trained HCP across Africa (+Haiti)
- Workshops: PV for SMC, patient safety and ME, ATC/ DDD methodology, PV in PHP

### Nomination as WHO collaborating center

- At both national and international level

### Seizing the opportunity of Covid-19

- Solicited everywhere to train for handling the pharmacovigilance of covid vaccines





# Moroccan experience in the time of covid 19 collaboration



through GACVS:  
developing guidelines

Sept2020

Dec  
2020

2021

# Moroccan experience in the time of covid 19 collaboration

WHO and WHO EMRO:  
**Training of Trainers (ToT)**  
for EMR countries

through GAVSC:  
developing guidelines

## Outcome:

- Pool of trainers competent in PV of vaccines
- Updated knowledge of participants and experience acquired in training activities
- Included in regional pool of experts
- Expected to participate in training in their countries or countries in the region for building capacities for the **Covid-19 vaccine safety monitoring**

Sept2020

Dec  
2020

2021

# Moroccan experience in the time of covid 19 collaboration

WHO and WHO EMRO:  
**Training of Trainers (ToT)**  
for EMR countries

**UMC training course** online:  
Use of new  
Vigiflow/ vigilyze  
tools/french

through GAVSC:  
developing guidelines

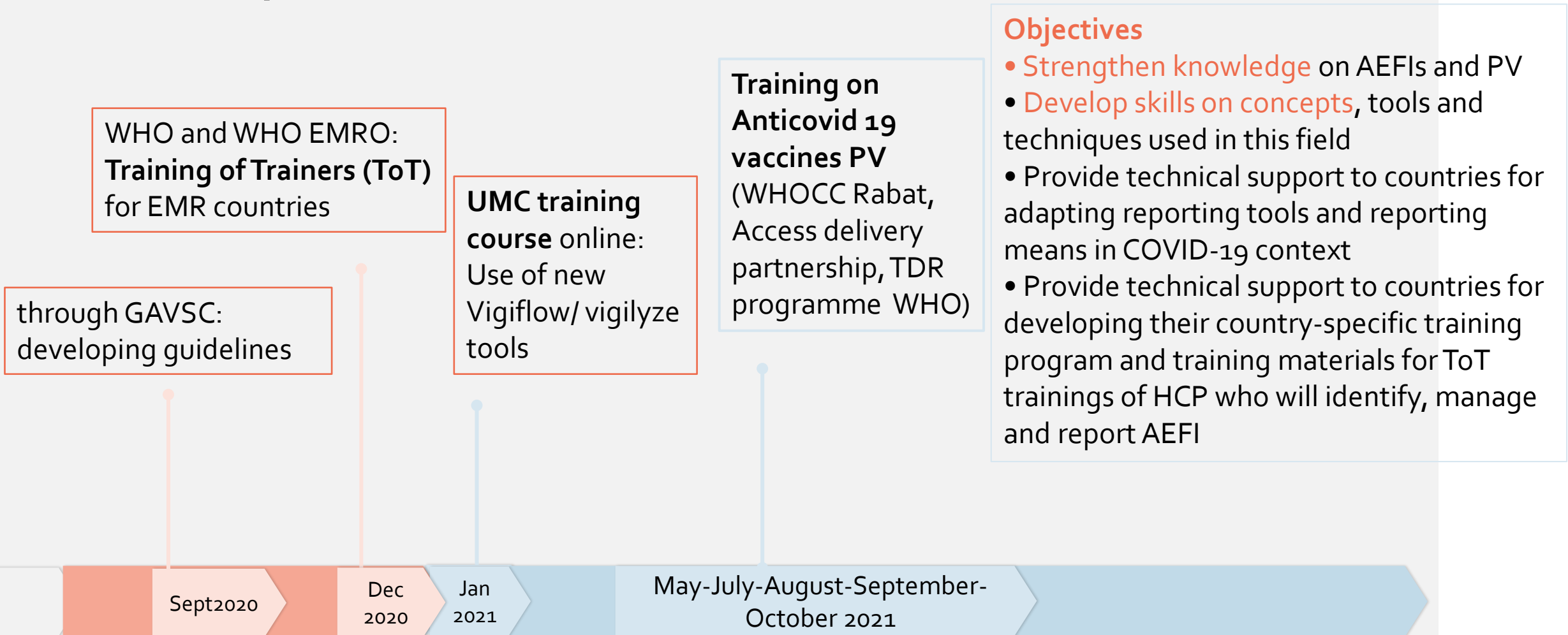
Sept2020

Dec  
2020

Jan  
2021

2021

# Moroccan experience in the time of covid 19 collaboration



# Moroccan experience in the time of covid 19 collaboration

WHO and WHO EMRO:  
**Training of Trainers (ToT)**  
for EMR countries

**UMC training course** online:  
Use of new  
Vigiflow/ vigilyze  
tools

**Training on Anticovid 19 vaccines PV**  
(WHOCC Rabat,  
Access delivery partnership, TDR programme WHO)

through GAVSC:  
developing guidelines

## PROGRAM

- |  |   |
|--|---|
| DAY 1<br>Generalities on<br>Pharmacovigilance  | <ul style="list-style-type: none"> <li>• Extent of the problem and contributing factors</li> <li>• Pharmacovigilance globally</li> <li>• National Pharmacovigilance centers and systems</li> <li>• Adverse reaction definition and classification</li> <li>• Concept, tools and technics used in pharmacovigilance</li> </ul> |
| DAY 2<br>Notions of Vaccine-<br>vigilance      | <ul style="list-style-type: none"> <li>• Importance of vaccination and overview of the different types of vaccines</li> <li>• Adverse Event Following Immunization (AEFI)</li> <li>• Vaccine safety institutions and mechanisms</li> <li>• WHO Support for Covid-19 surveillance</li> </ul>                                   |
| DAY 3<br>Notions of Vaccine-<br>vigilance      | <ul style="list-style-type: none"> <li>• Reporting forms, means of reporting and reporting flow</li> <li>• Investigation</li> <li>• Causality assessment</li> <li>• Databases and signal detection</li> <li>• Communication and crisis management</li> </ul>  |
| DAY 4 :<br>Anti Covid-19<br>vaccines and AEFIs | <ul style="list-style-type: none"> <li>• Different types of anti-Covid-19 vaccines</li> <li>• Specificities of anti-covid-19 vaccines vigilance</li> <li>• Strategies implemented in response to the immunization campaign</li> </ul>   |
| DAY 5 :<br>Case studies                        | <ul style="list-style-type: none"> <li>• AESI : Adverse Event of Special Interest</li> <li>• Thromboembolic events</li> <li>• Anaphylactic reactions</li> <li>• Declaration of death case</li> <li>• Immunization errors</li> </ul>   |

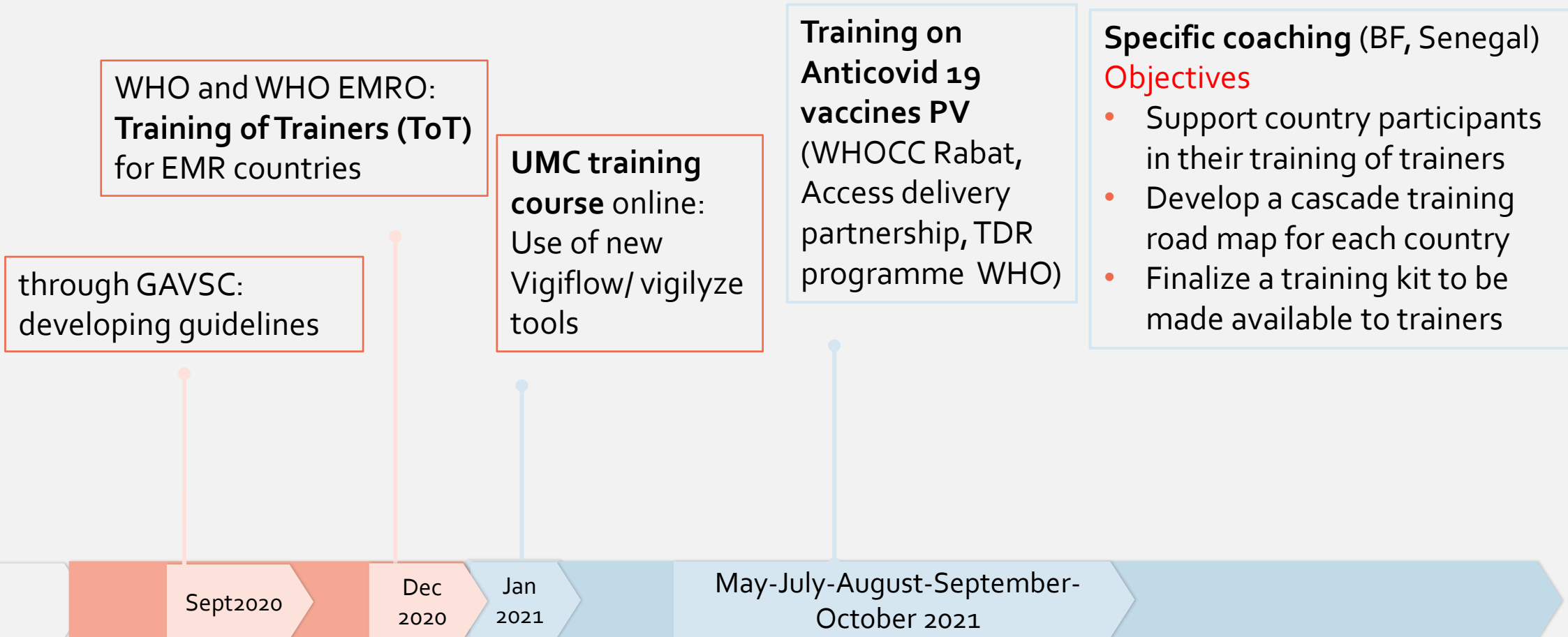
Sept2020

Dec  
2020

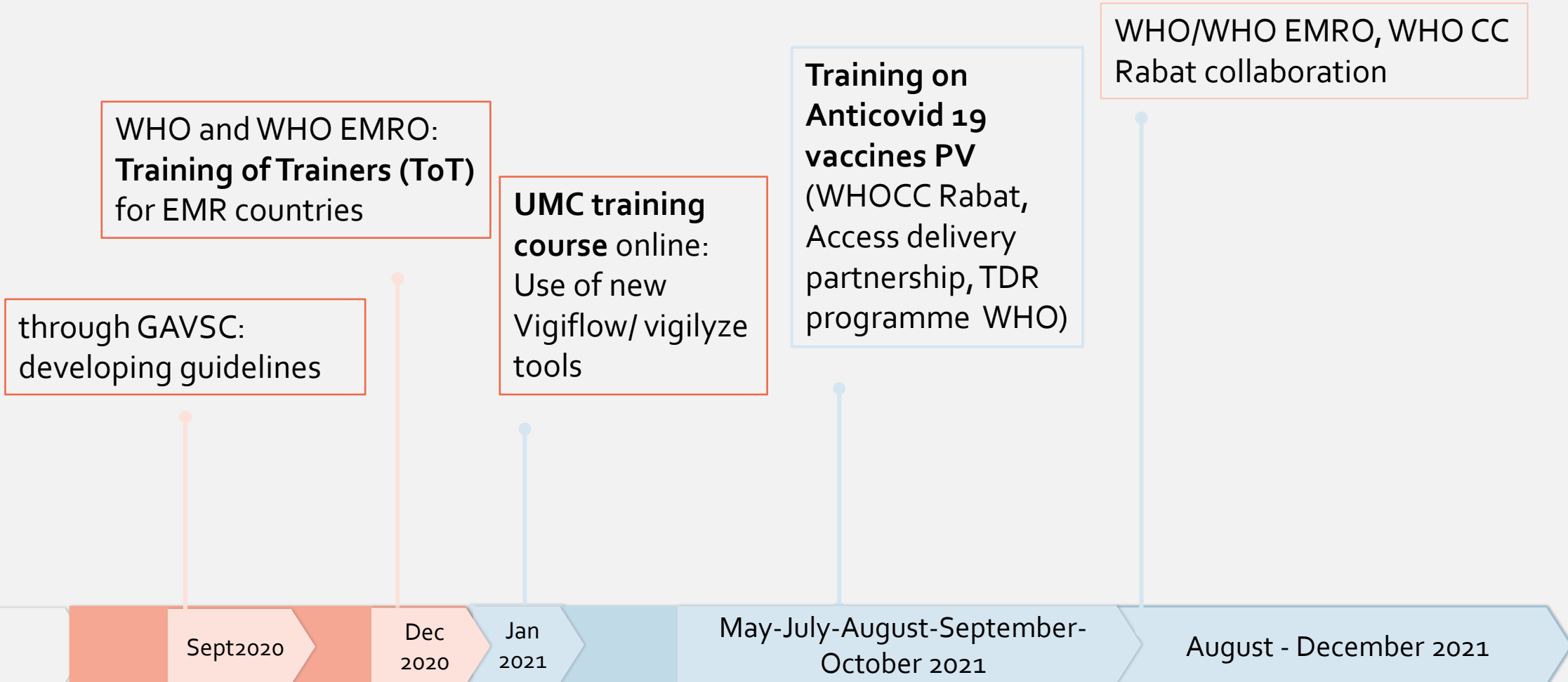
Jan  
2021

May-July-August-September-  
October 2021

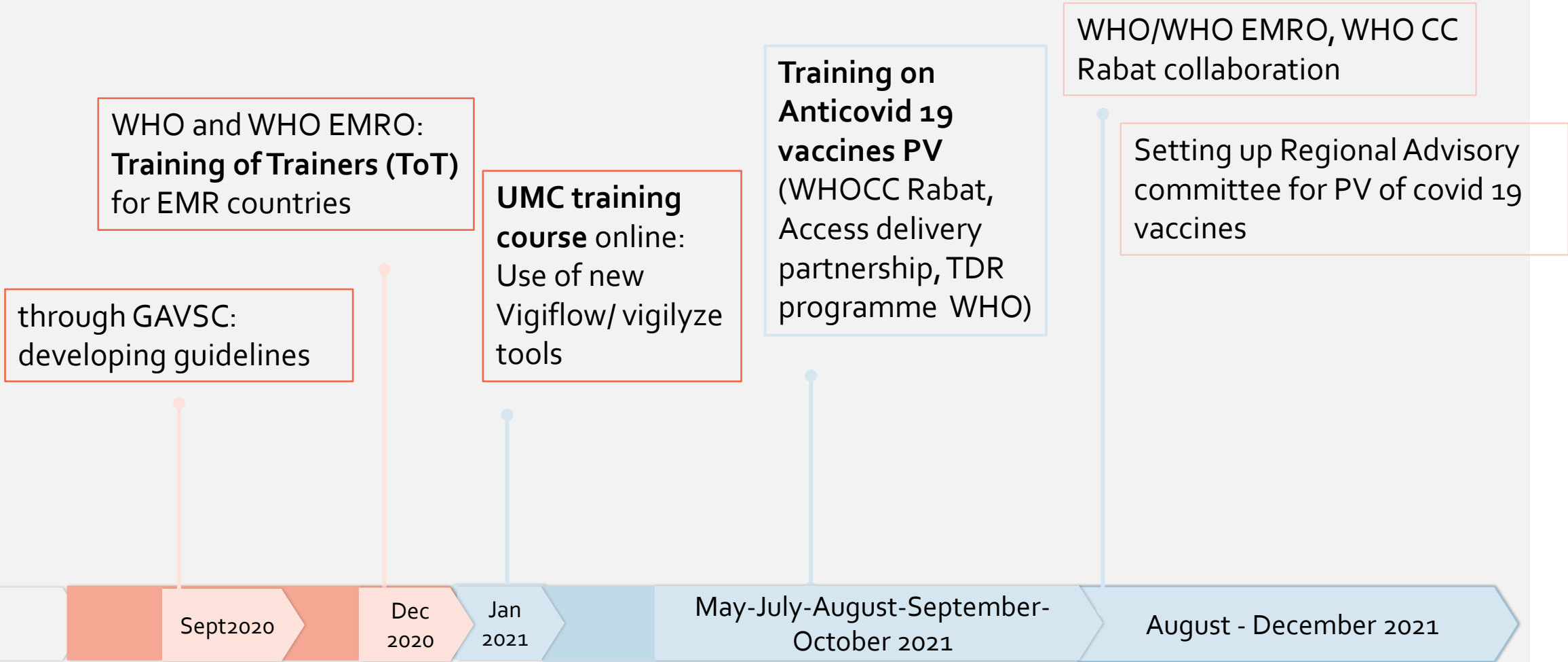
# Moroccan experience in the time of covid 19 collaboration



# Moroccan experience in the time of covid 19 collaboration

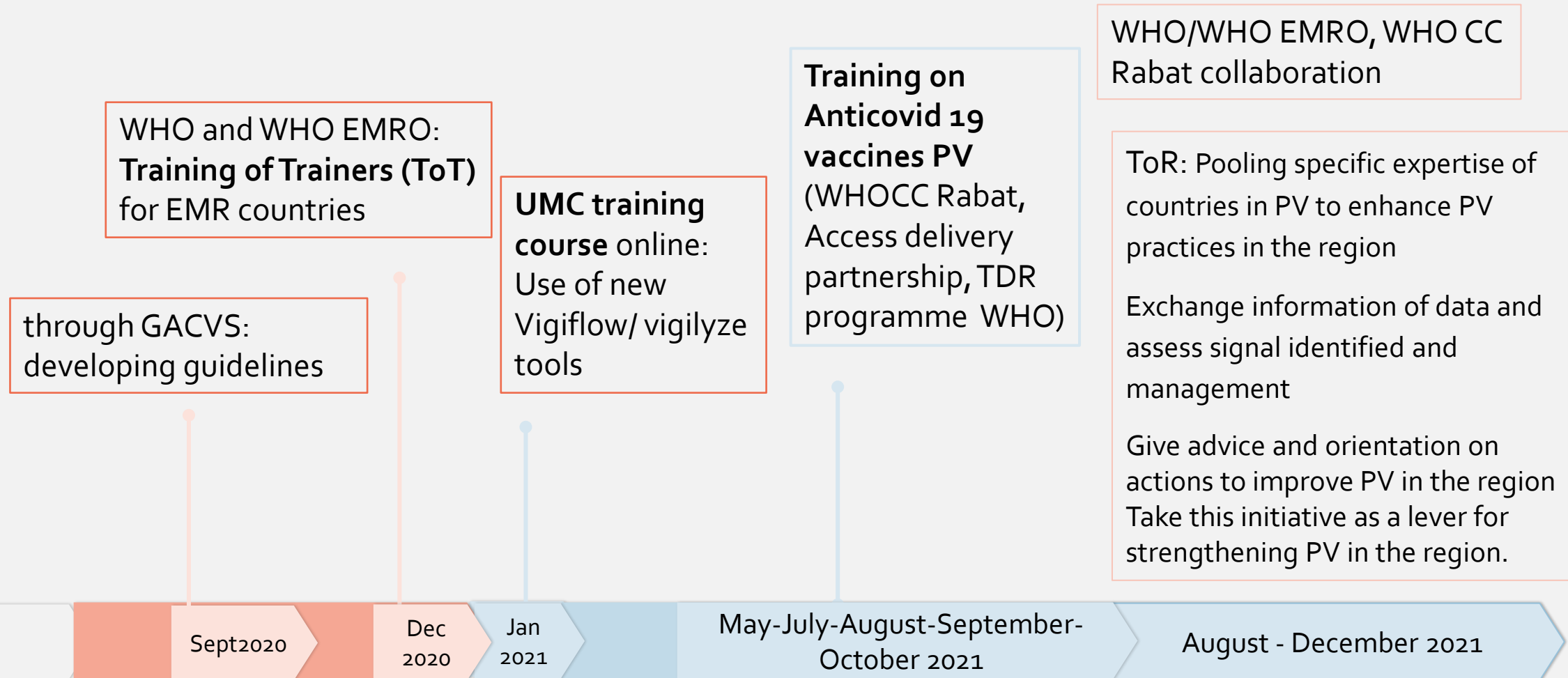


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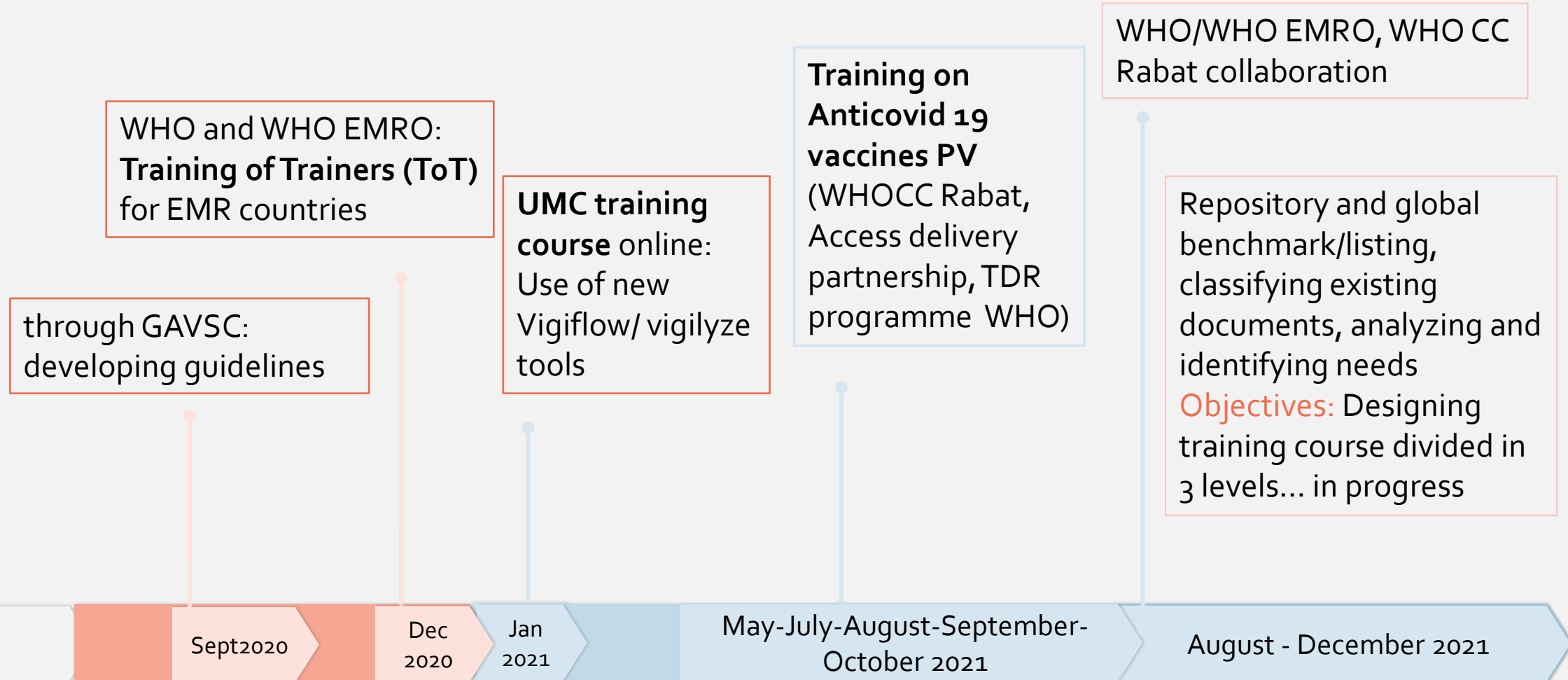




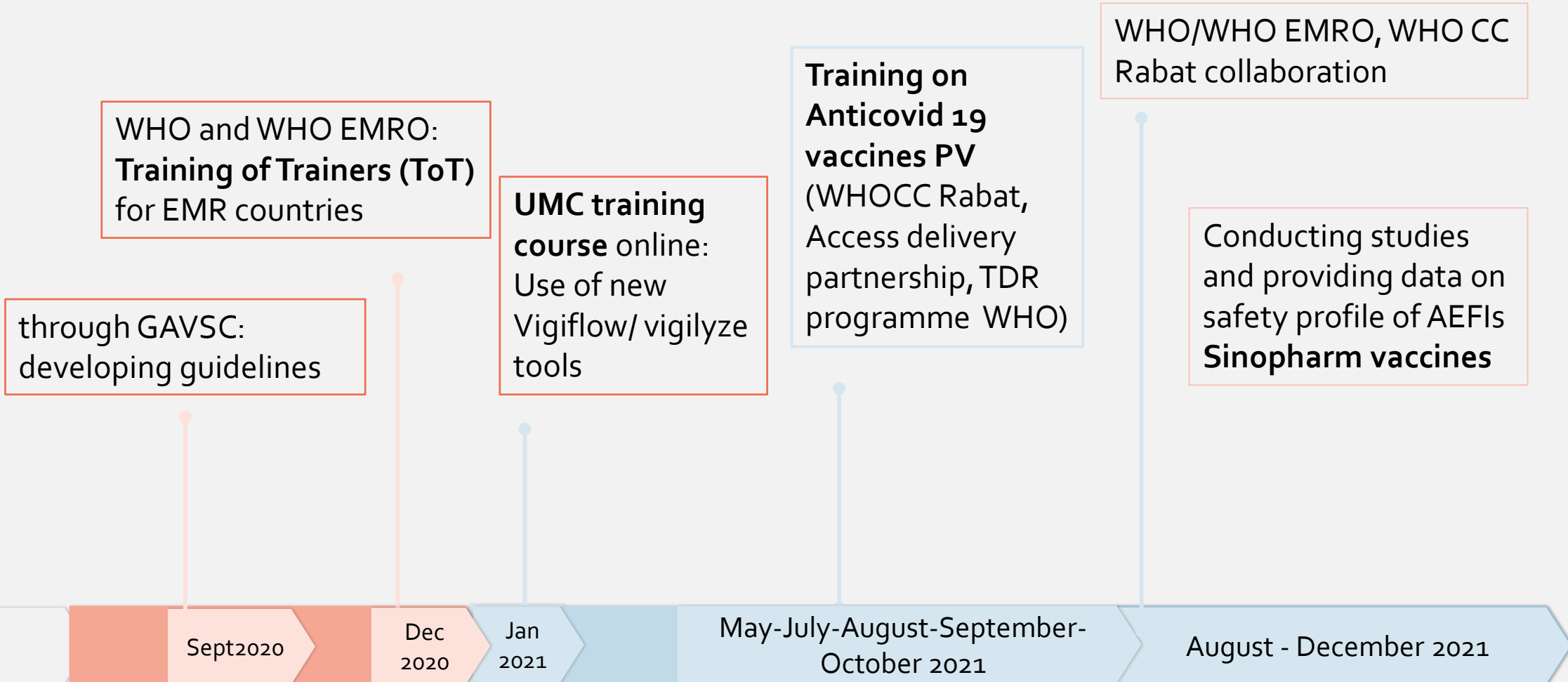
# Moroccan experience in the time of covid 19 collaboration



# Moroccan experience in the time of covid 19 collaboration



# Moroccan experience in the time of covid 19 collaboration



## Moroccan data on PV of Covid 19 vaccines

Indicator	Global	Sinopharm	AstraZeneca	Pfizer	Janssen
Number of doses	47 623 193	34 173 454	8 765 099	3 436 277	112 271
Number of cases	33 448	18 434	12 794	1 147	676
rate /1000 doses	0,70	0,54	1,46	0,33	6,02

January 28<sup>th</sup> – October 31<sup>st</sup>, 2021

# Conclusion



- Countries are forced to face the covid 19 pandemic and vaccination campaign so they have to take this opportunity to lay the foundations of PV for the long term and use collaborating centres and committees for increasing knowledge, expertise and strategies.