

Partage Sud-Sud d'expériences sur des approches innovantes pour renforcer la surveillance de l'innocuité des médicaments et vaccins.

AEFI Covid 19 Vaccine in Morocco

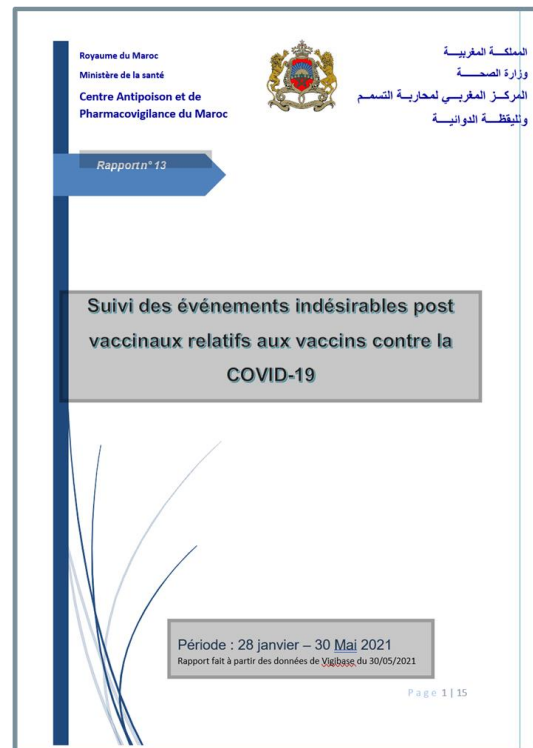


Reports: dissemination and periodicity

A report is shared on a weekly basis with

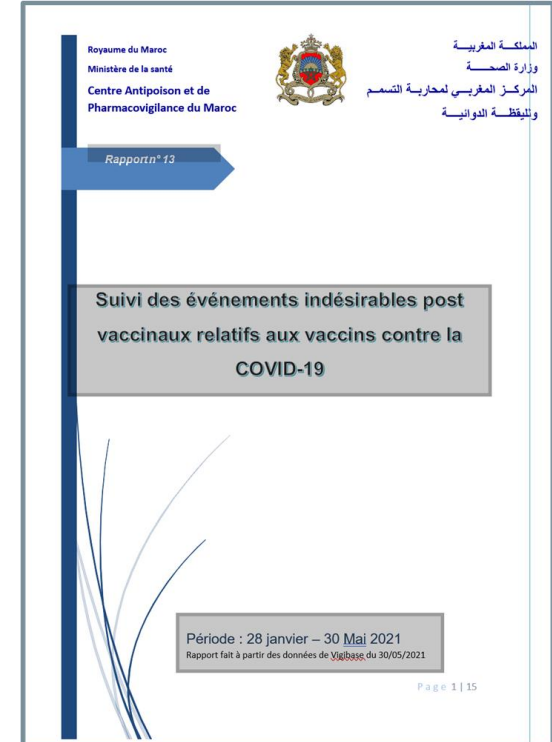
- The health Minister
- The immunization Programme
- The Drug Regulatory Authority
- The WHO Office – Morocco
- The WHO at EMRO

Discussed in a weekly meeting with
the Central committee of
Immunization



Report's structure

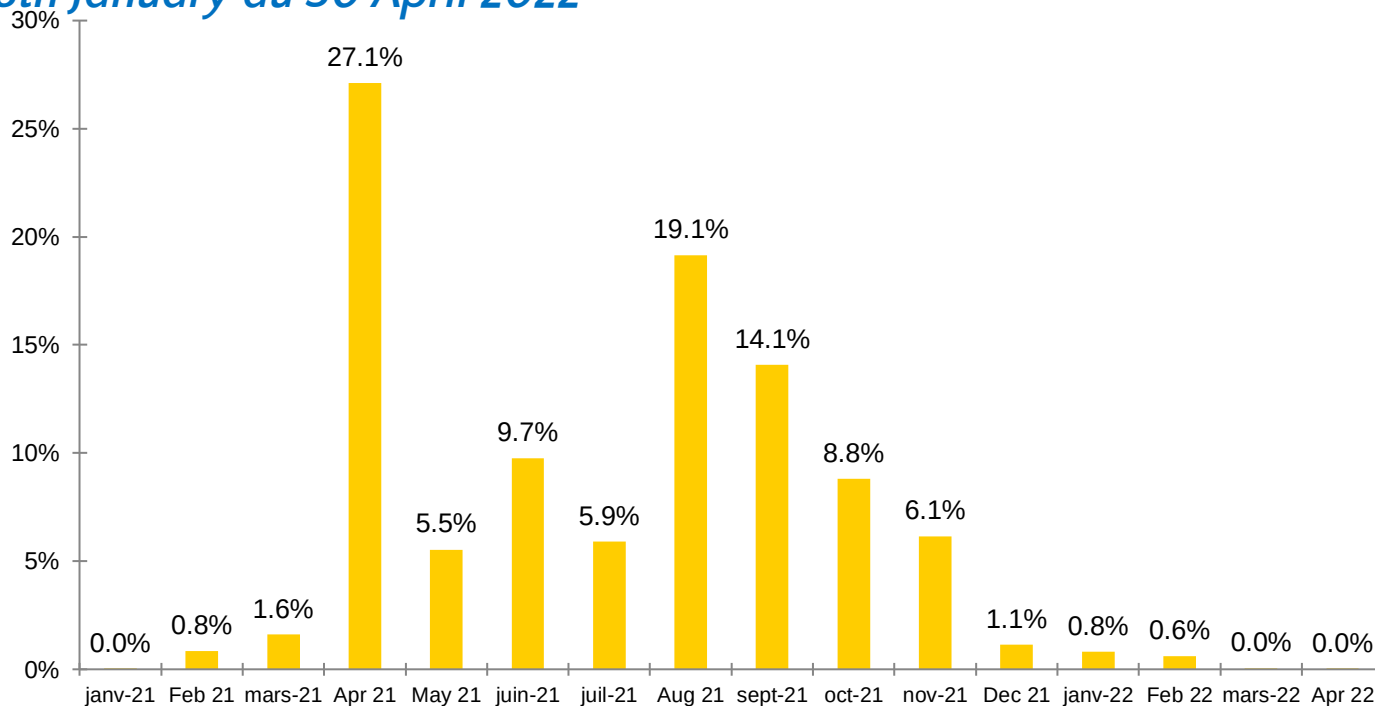
- Vaccination strategy :
 - Vaccines plateforme available
 - Vaccination protocoles
- Results of safety surveillance:
 - Number of vaccinees within the country
 - Region
 - Demographic data
 - Vaccines platforms
 - AEFI reports
 - Number of reports
 - Means of reporting
 - Patient characteristics
 - AEFI analysis : diagnosis , seriousness ..



AEFI reports

36 589 Reports

From 28th January au 30 April 2022



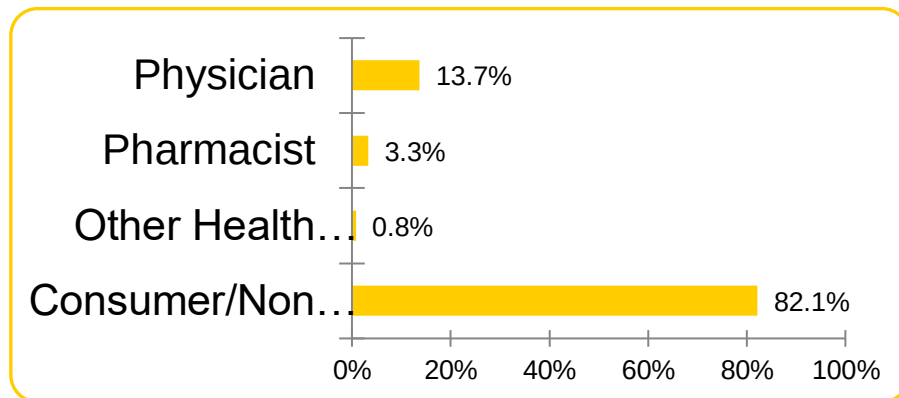
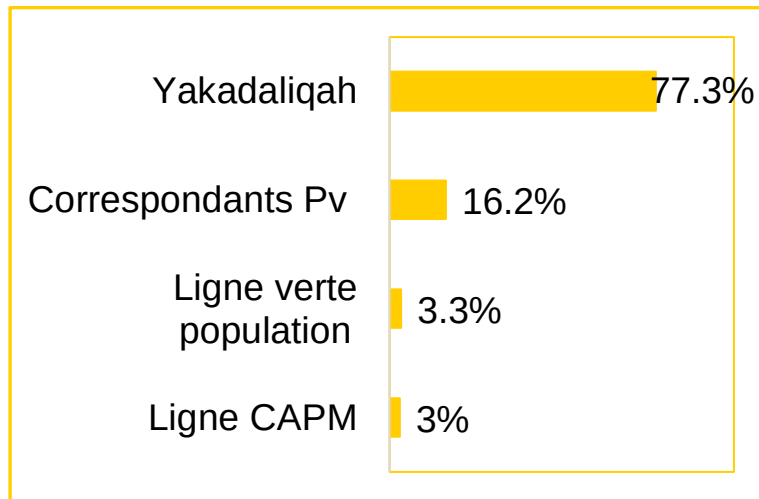
AEFI reports / Vaccine type

Indicateur	Global	Sinopharm	AstraZeneca	Pfizer	Janssen
Number of administrated doses	54 532 286	39 226 530	8 866 853	5 134 283	131 675
AEFI report	36 589	20 138	13 542	1 739	733
Tx/1000 doses	0,67	0,51	1,5	0,33	5,56

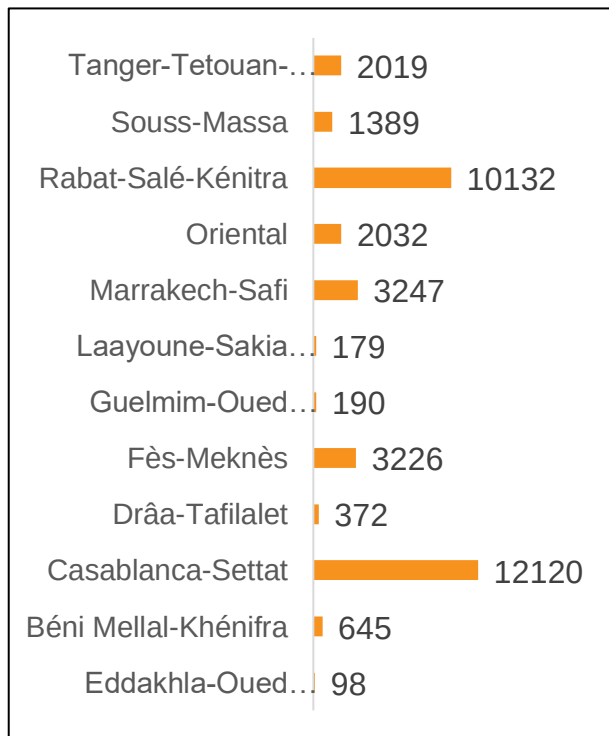
AEFI reports / dose number

Indicators	Global	Dose 1	Dose 2	Dose 3
Number of doses	54 532 286	24 827 666	23 308 068	6 396 552
Number of AEFI	36 589	30 936	5 239	414
Tx /1000 doses	0,67	1,24	0,22	0,06

Reporting means/ Reporter's qualification



AEFI reports /Region



	Number of doses	AEFI	Incidence /1000 doses
Casablanca-Settat	9 709 842	12120	1,24
Rabat-Salé-Kénitra	6 845 008	10132	1,48
Marrakech-Safi	6 414 162	3247	0,50
Fès-Meknès	5 989 445	3226	0,53
Oriental	3 089 390	2032	0,65
Tanger-Tetouan-Al Hoceima	4 626 134	2019	0,43
Souss-Massa	3 847 399	1389	0,36
Béni Mellal-Khénifra	3 632 653	645	0,17
Drâa-Tafilalet	2 397 488	372	0,16
Guelmim-Oued Noun	591 470	190	0,33
Laayoune-Sakia El Hamra	441 071	179	0,43
Eddakhla-Oued Eddahab	164 194	98	0,54
Total	48 769 396	35 670	0,73

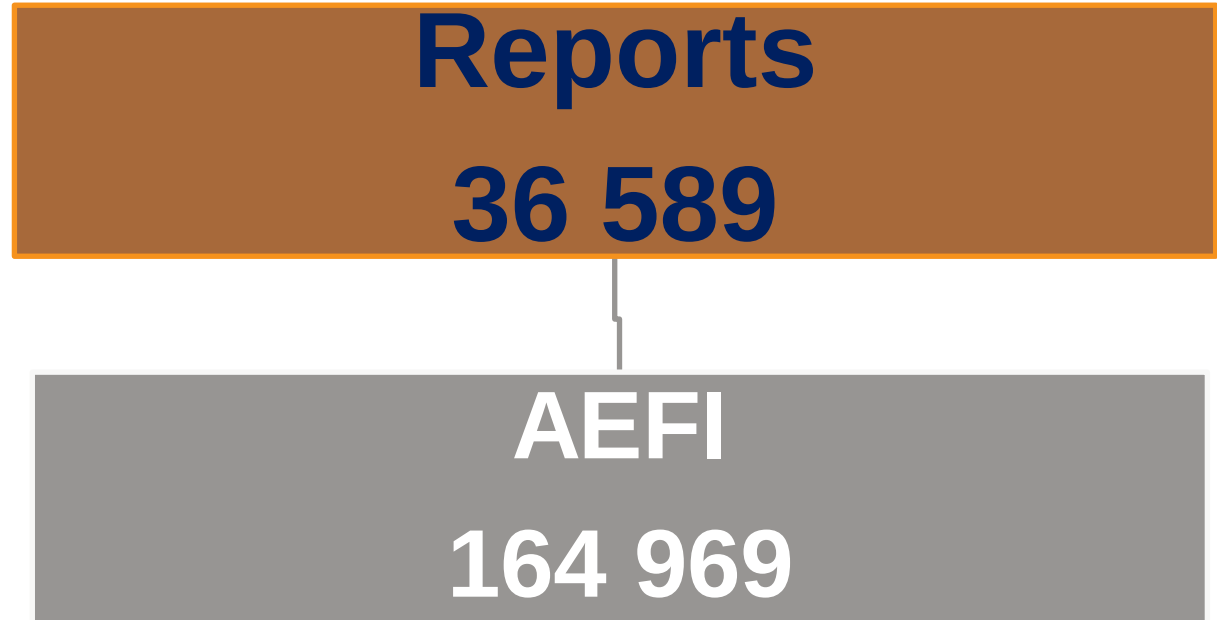
Patient characteristics

Variables	Global (N= 36 589)	Sinopharm (n= 20 138)	Astra Zeneca (n= 13 542)	Pfizer (n= 1 739)	Janssen (n= 733)
Tranches d'âge					
12 to 17 years	606 (1.7%)	165 (0.8%)	14 (0.1%)	419 (26,0%)	7(1%)
18 to 44 years	22092 (61,1%)	15 465 (77.7%)	4814 (35,7%)	1062 (65.8%)	686 (93,6%)
45 to 64 years	8645 (23.9%)	3 465 (17.4%)	4966 (36.8%)	86 (5.3%)	35(4.8%)
65 to 74 years	2168 (6.0%)	309(1.6%)	1734 (12.9%)	13 (0.8%)	0
>75 years	1015 (2,8%)	152(0.8%)	810 (6%)	1(0.1%)	0
Unkown	1600 (4,4%)	336(1.7%)	1138 (8.4%)	29 (1.8%)	5(0.7%)
Gender					
Female	17 676 (49%)	9452 (47,5%)	6980 (51,8%)	766 (47.5%)	302 (41.4%)
Male	18 230 (50,5%)	10406 (52,3%)	6392 (47,4%)	841 (52.1%)	426 (58.4%)
Unkown	170 (0,5%)	52 (0,3%)	107 (0,8%)	6	2

AEFI reports/ age and gender distribution

Variables		Nnumber of AEFI	Incidence %
Age groups	Number of vaccinees		% (vaccinés)
12 to 17 y	2 277 424	642	0.02
18 to 25 y	3 110 923	4 698	0,15
26 to 30 y	2 071 851	5 524	0,27
31 to 40 y	4 280 036	9 725	0,22
41 to 50 y	4 023 562	5 905	0,14
51 to 60 y	3 343 392	4 025	0,11
61 to 75 y	3 0349 324	3 508	0,11
> 75 y	817 288	885	0,10
Gender	Number of doses		% (doses)
Female	26 136 209	17 922	0,068
Male	27 203 638	18 481	0,067

Reported Adverse event



AEFI MedDRA SOC/Vaccine type

System Organ Class-MedDRA	Sinopharm		Astra Zeneca		Janssen		Pfizer	
	Nbre	%	Nbre	%	Nbre	%	Nbre	%
General disorders	15 337	78,0%	9 680	72,6%	622	92,0%	1 285	83,6%
Musculoskeletal and connective tissue disorders	9 360	47,6%	5 334	40,0%	459	67,9%	917	59,6%
Nervous system disorders	7 005	35,6%	4 492	33,7%	319	47,2%	514	33,4%
Gastrointestinal disorders	4 998	25,4%	2 678	20,1%	234	34,6%	371	24,1%
Ear and labyrinth disorders	4 902	24,9%	3 201	24,0%	207	30,6%	376	24,4%
Respiratory, thoracic and mediastinal disorders	4 008	20,4%	1 583	11,9%	99	14,6%	242	15,7%
Psychiatric disorders	3 775	19,2%	1 594	12,0%	162	24,0%	339	22,0%
Metabolism and nutrition disorders	2 698	13,7%	1 312	9,8%	177	26,2%	242	15,7%
Skin and subcutaneous tissue disorders	1 520	7,7%	1 069	8,0%	39	5,8%	120	7,8%
Eye disorders	1 148	5,8%	481	3,6%	34	5,0%	73	4,7%
Infections and infestations	216	1,1%	500	3,8%	2	0,3%	16	1,0%
Vascular disorders	154	0,8%	244	1,8%	2	0,3%	34	2,2%
Cardiac disorders	61	0,3%	179	1,3%	2	0,3%	13	0,8%
Immunisation errors	41	0,2%	26	0,2%	0	0	7	0,5%
Immune system disorders	29	0,1%	41	0,3%	1	0,1%	7	0,5%
Investigations	16	0,1%	16	0,1%	1	0,1%	4	0,3%

Immunization errors

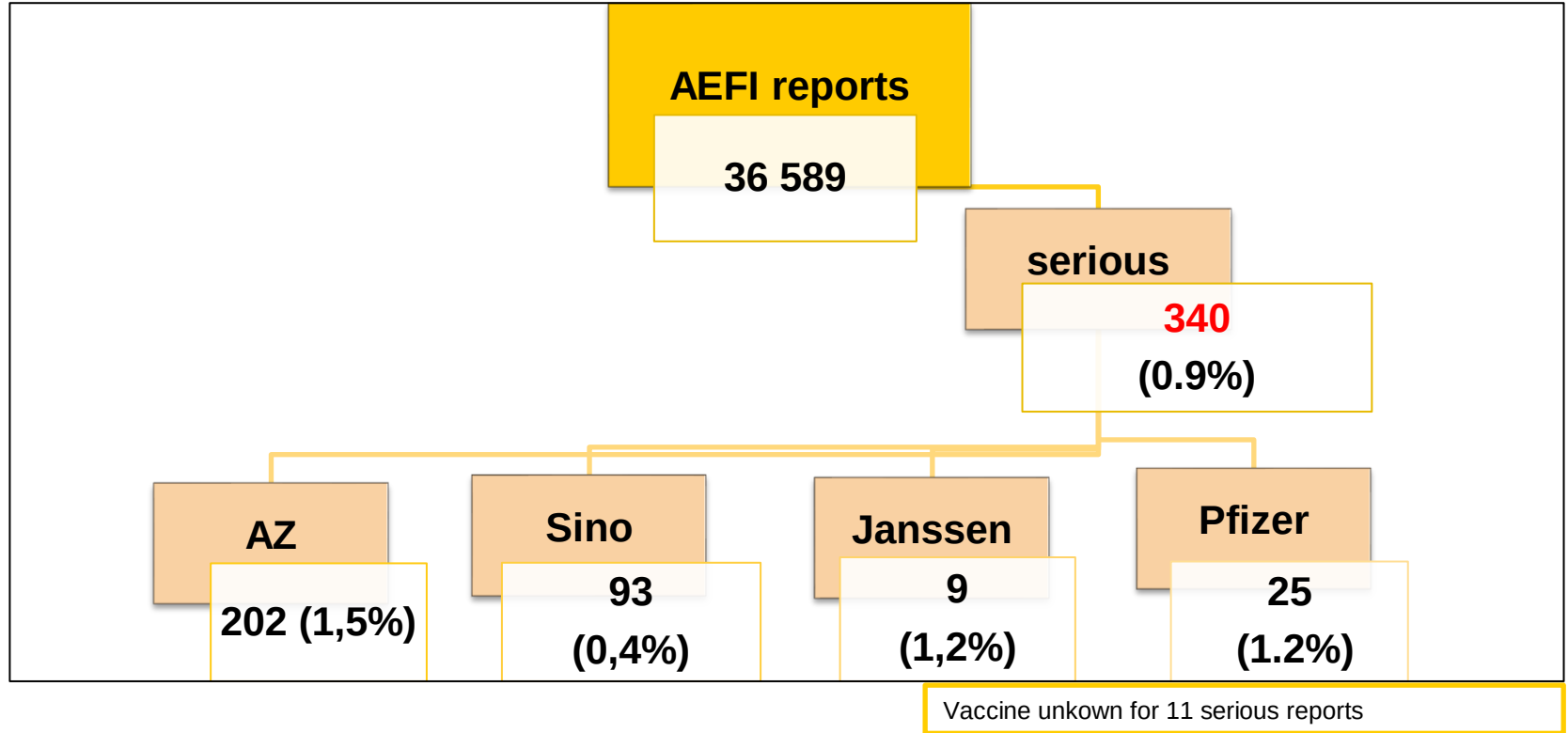
Astrazeneca : 18 cases

Type of errors	Symptomatic errors (4)	Asymptomatic errors
Indication error		
Administration to pregnant women		3
Administration to Breastfeeding Women		2
Wrong schedule of administration		
2 doses at the same time	Palpitations (1)	5
Non-observance of the interval between doses	Tachycardia (1), Dyspnea	4
Manipulation error	Pain in the eye Keratitis (1) Inflammation in the eye (1)	

Sinopharm: 4 cases

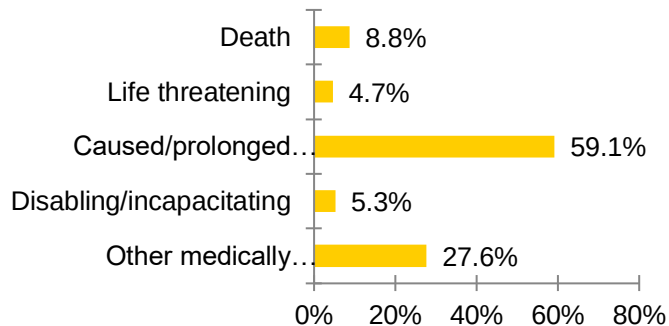
Type of errors	Symptomatic errors	Asymptomatic errors (4)
Indication error		
Administration to pregnant women		1
Administration to Breastfeeding Women		1
Wrong schedule of administration		
2 doses at the same time		1
Non-observance of the interval between doses		1 (after 3 days)
Manipulation error		

Serious AEFI

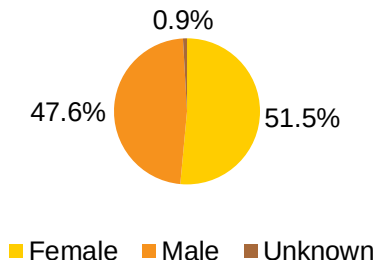


Serious AEFI

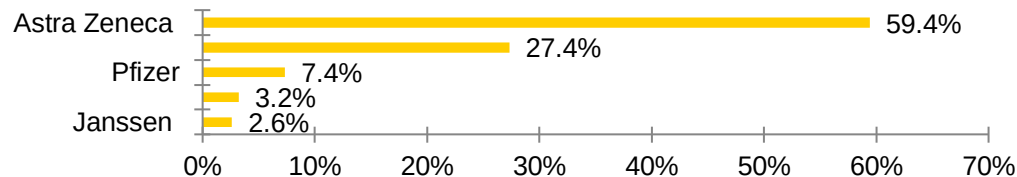
Seriousness criteria



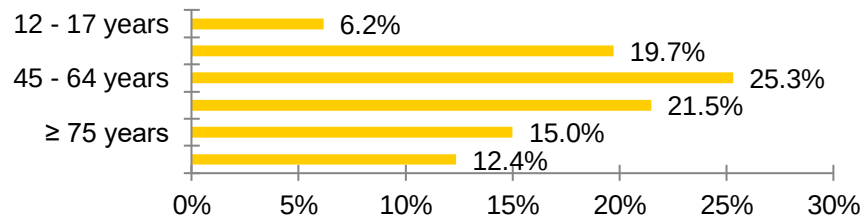
Patient sex



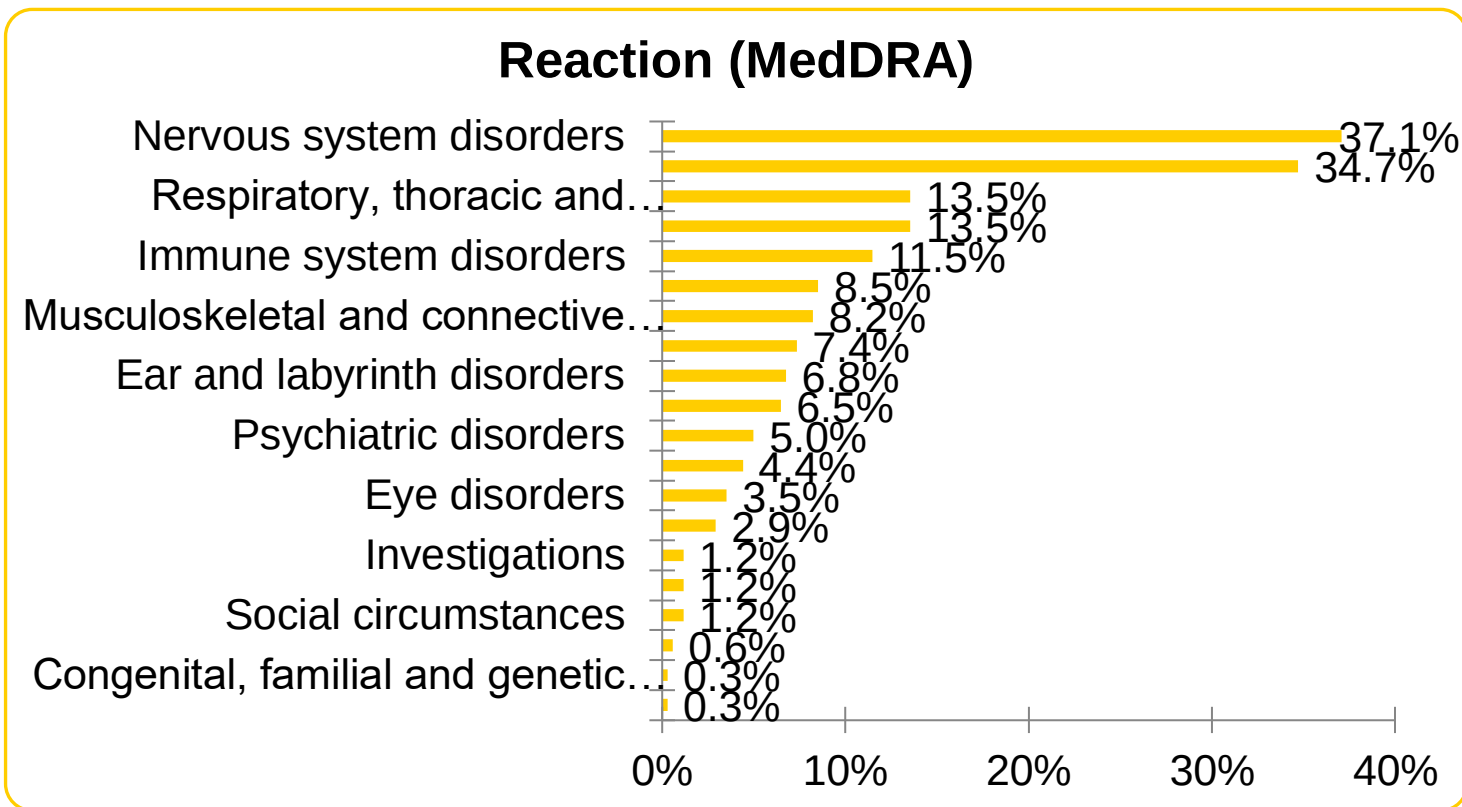
Vaccine type



Patient age

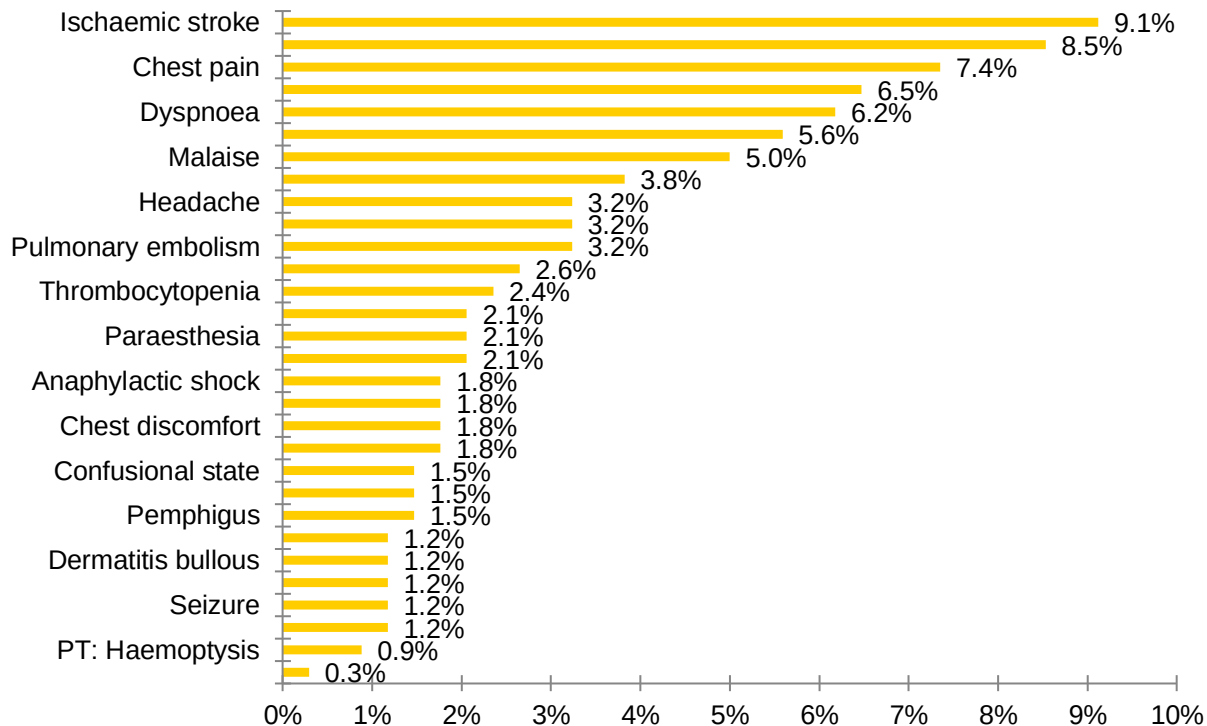


Serious AEFI

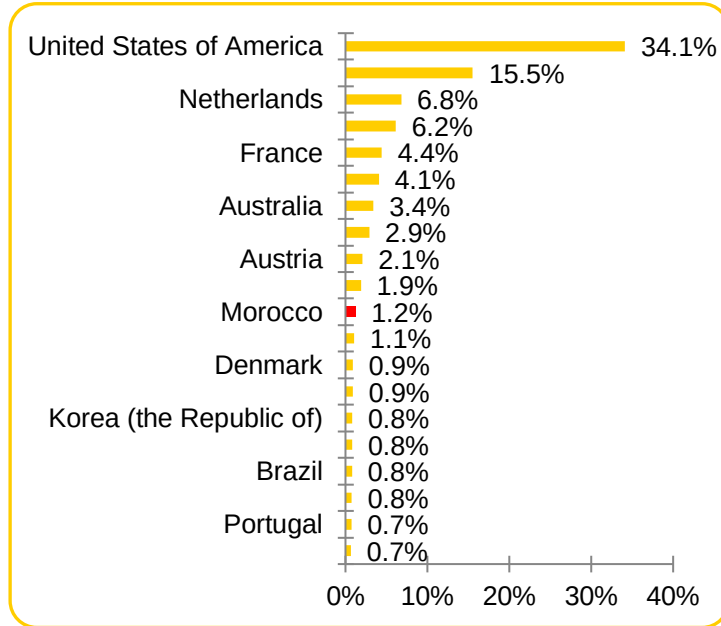


Serious AEFI

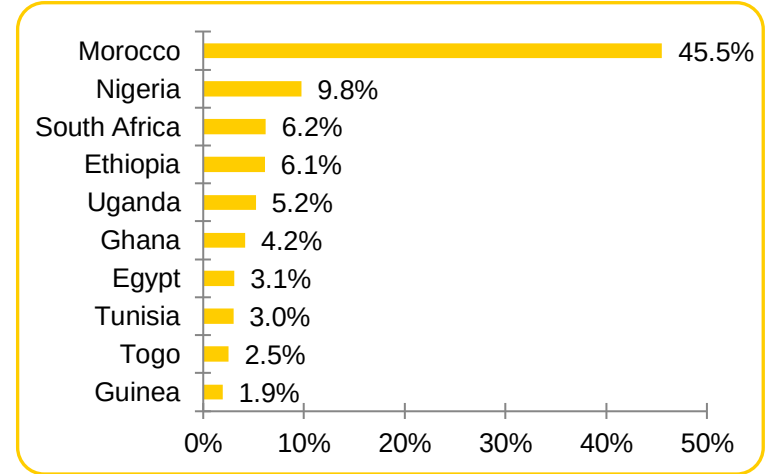
Reported preferred terms (MedDRA)



Top countries reporters



Worldwide/covid vaccine data



African Region



Conclusion

- The covid 19 vaccination campaign worldwilde is an **opportunity to strengthen any existing pharmacovigilance system** or to put in place an efficient one in when it is lacking, to enhance the awareness of the culture of reporting.
 - Each country regardless of the level of performance of its pharmacovigilance system has the duty to develop a clear vaccination strategy including Risk Management Plan (RMP) and Pharmacovigilance activities should be strengthened
 - Each country should share its data in the WHO Database (Vigibase) to participate in the international effort to define the safety profile of anti-Covid 19 vaccines.