

Boosting International Regulatory Collaboration

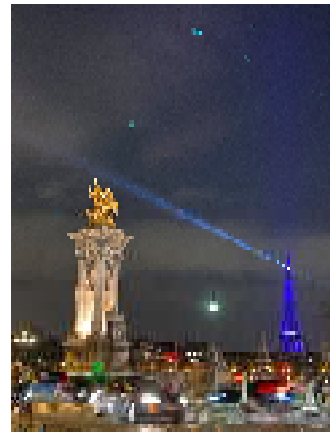
Dr Agnes Saint-Raymond

9 February 2022



Disclaimer

- These are personal views....



- *WHY*
- *WHO*
- *WHAT*
- *HOW*



ICMRA membership (*associate)

<https://icmra.info/drupal/en>

- EMA/EC (chair)
- US FDA
- Brazil ANVISA
- China NMPA
- Health Canada
- India CDSCO
- Japan MHLW/PMDA
- Korea MFDS
- Mexico COFEPRIS
- New Zealand Medsafe
- Nigeria FDA
- South Africa SAHPRA
- Swissmedic
- TGA Australia
- UK MHR
- France ANSM
- Germany PEI
- Ireland HPRA
- Italy AIFA
- Netherlands MEB
- Sweden MPA
- Argentina* ANMAT
- Austria* AGES
- Colombia* INVIMA
- Cuba* CECMED
- Denmark* DKMA
- Ghana* FDA
- Israel* MoH
- Poland* URPL
- Portugal* Infarmed
- Russia* Roszdravnadzor
- Saudi Arabia* SFDA
- Spain* AEMPS
- Ukraine* MoH

WHO Observer

ASR_Feb2022



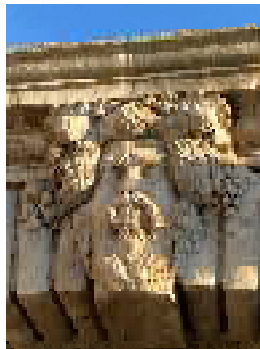
OPEN initiative

- Parallel but different from ACCESS or ORBIS
- Health Canada, Swissmedic, WHO, Japan, Australia TGA
- Participation in Scientific Committee (CHMP) for COVID related medicines
- Parallel reviews – sharing issues and conclusions - as **peers**
- Independent decisions

OPEN evaluation of Vaxzevria (Oxford/AZ) vaccine followed by WHO EUL and within 2 weeks more than 100 approvals across the world

Revolution or Evolution

- What is applicable to Oncology as it is ?



ASR_Feb2022