



Global Medical  
Technology Alliance  
Innovating for a Healthier World

# GMTA

Lessons learned from the COVID-19 Pandemic  
IMDRF Presentation – Regulatory aspects  
September 14<sup>th</sup> 2021



# The one thing we have learned...

Access to medical technologies saves lives.



The key Regulatory Question then is Access:

- Disruption to Regulatory Processes
- Global Regulatory Harmonization / Reliance
- Access for novel technologies

# Regulatory Processes: Disruptions and Solutions



## Remote Audits

- Remote sites blocked – remote audits necessary and process developed and deployed, now a working reality.

## Electronic use of Documents

- Acceptance of Electronic signatures
- Acceptance of the Electronic Hague Apostille

## Vigilance activities

- Remote investigations at times
- Consolidated reporting systems

# We have relied on each other

N95 / DS



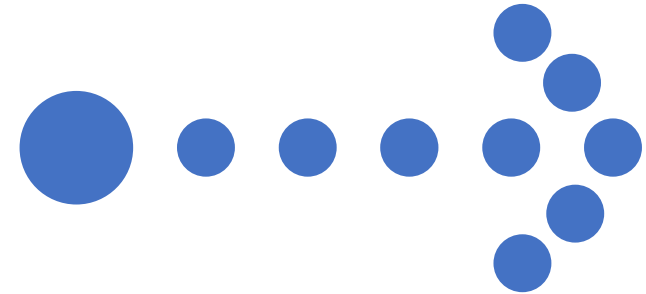
FFP2 / KN95



P2 / KMOEL



They all work –  
Deliver them!



# Access to Novel Technologies

**New  
Technology  
to fight the  
pandemic!**

- **Emergency use Authorisation**
- **Derogation**
- **Emergency Approval...**

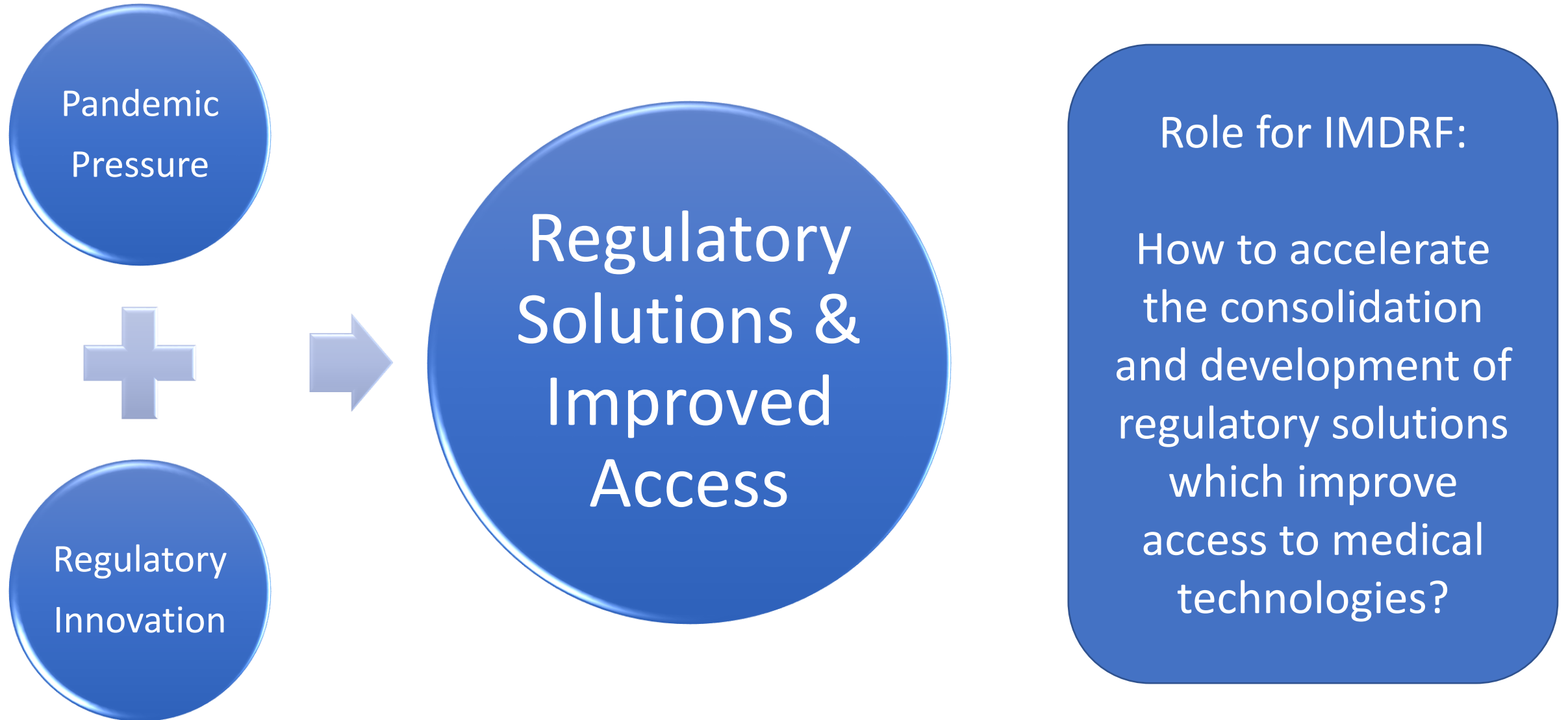
Each Jurisdiction uses:

- A different procedure
- And sets different requirements

For emergency access.

(We can do better)

# Regulatory Systems: Beyond the pandemic





## (Some) Take away lessons from the last 2 years

- Interest in Healthcare collaboration exists and the benefits are understood
- The pandemic / crisis situation showed how complex regulatory systems are worldwide and how making quick changes is difficult
- It identified new tools / processes that proved efficient. This is an opportunity for modernization of our RA system going further
- More harmonization/ reliance between countries is needed to facilitate patients' easier and fastest access to medical device technology
- Collaboration needs to continue beyond the current pandemic situation





# The one lesson we must remember...

Access to medical technologies saves lives ...

... Even when there is no pandemic.