



Global Medical
Technology Alliance
Innovating for a Healthier World

GMTA

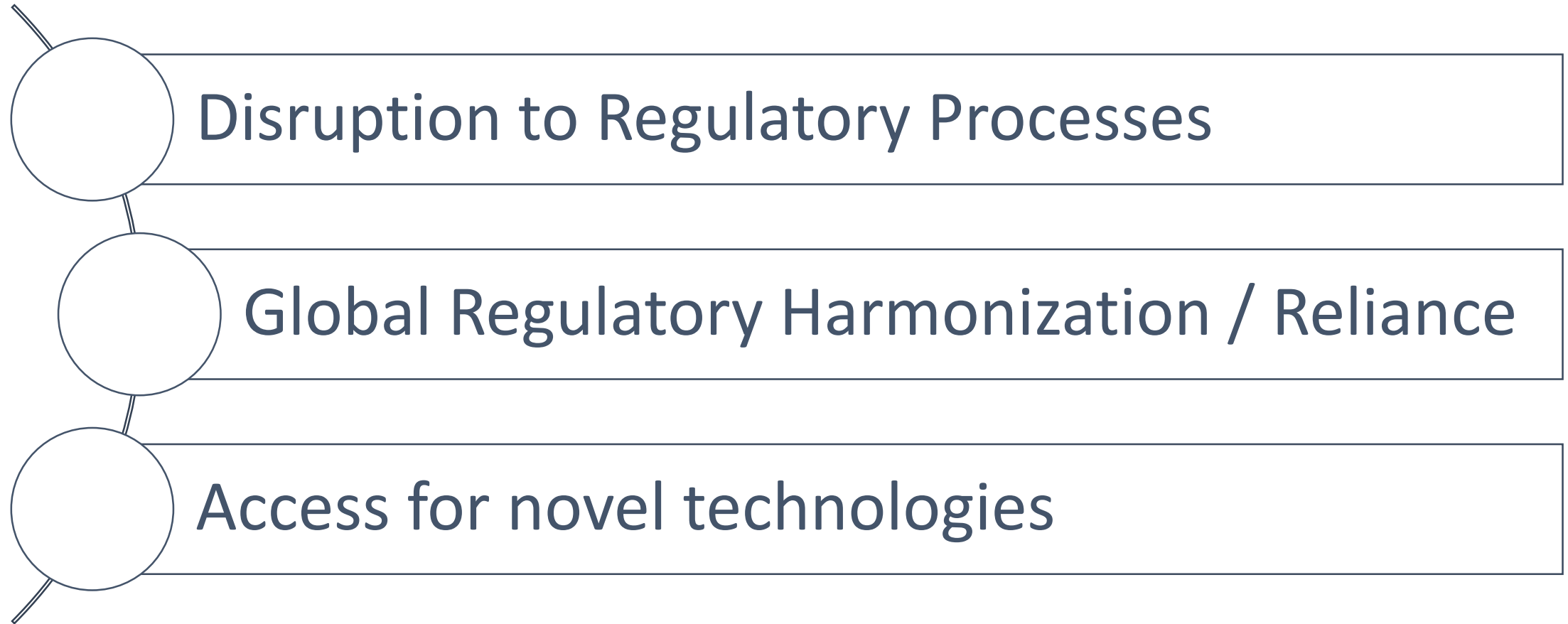
Lessons learned from the COVID-19 Pandemic
IMDRF Presentation – Regulatory aspects
September 14th 2021



The one thing we have learned...

Access to medical technologies saves lives.

The key Regulatory Question then is Access:



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



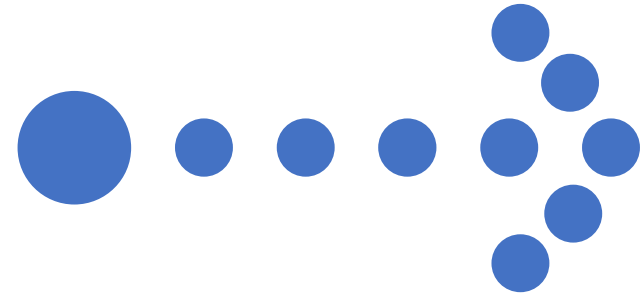
FFP2 / KN95



P2 / KMOEL



They all work –
Deliver them!



Access to Novel Technologies

**New
Technology
to fight the
pandemic!**

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

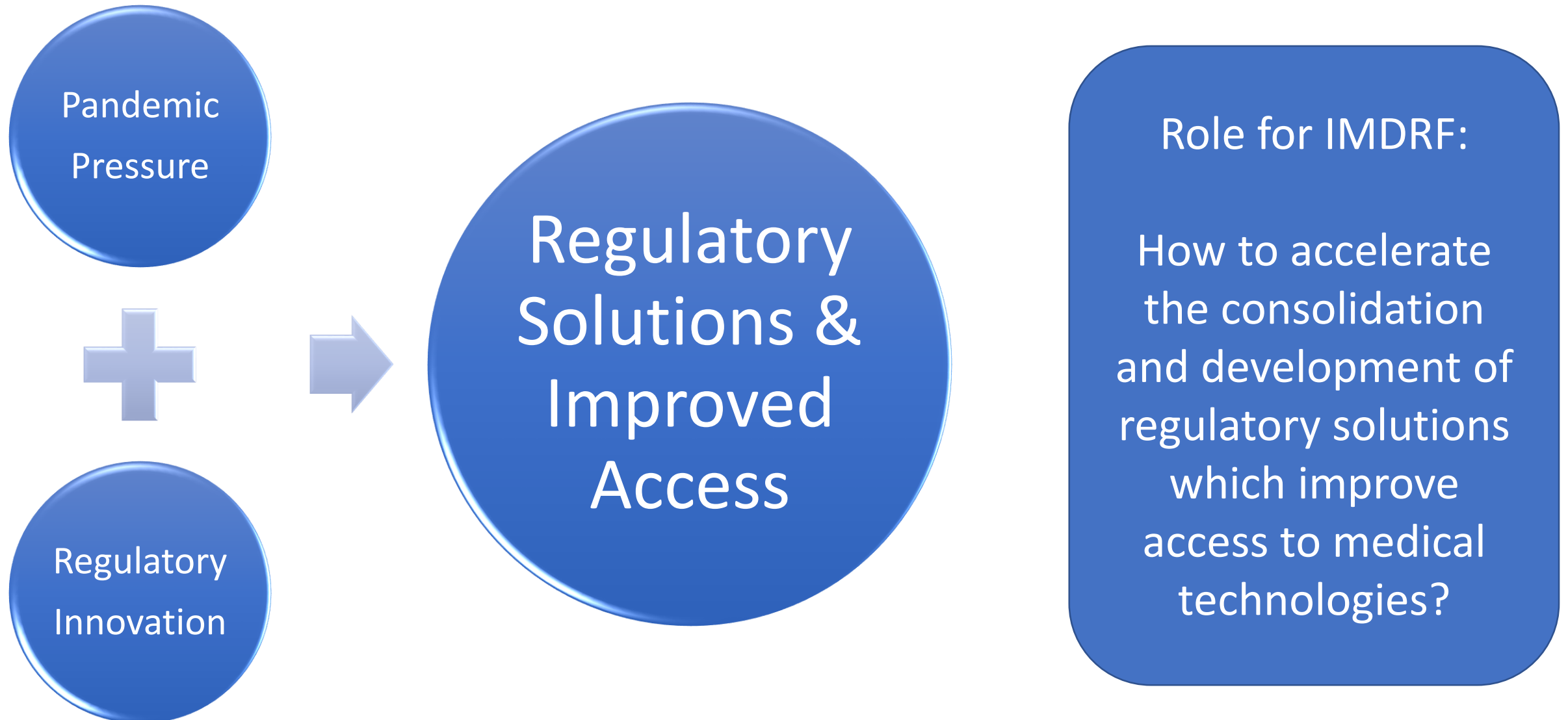
Each Jurisdiction uses:

- 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.