DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

IMDRF International Medical Device Regulators Forum

IMDRF/DITTA Joint Virtual Workshop

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What to learn from COVID 19?

Emergency Use Diagnostics: An IVD Developer's Perspective

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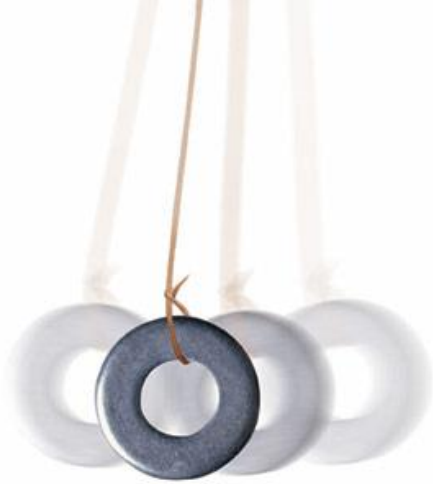
Roche Diagnosticsitle

Roche Diagnostics
SARS-CoV-2 Diagnostics Portfolio[1]
Comprehensive portfolio of tests and digital solutions

	Clinical Labs		Near Patient	
Molecular solutions	• TIB MOLBIOL LightMix® Modular SARS-CoV-2	*Launched*	• **cobas**® SARS-CoV-2 & Influenza A/B	*Launched*
	• **coba**s® SARS-CoV-2	*Launched*		
	• **cobas**® SARS-CoV-2 & Influenza A/B	*Launched*		
Immunology solutions	• Elecsys® Anti-SARS-CoV-2	*Launched*	• SARS-CoV-2 rapid antibody	*Launched*[3]
	• Elecsys® Anti-SARS-CoV-2 S[2],	*Launched*	• SARS-CoV-2 rapid antigen	*Launched*[3,4]
	• Elecsys® Anti-SARS-CoV-2 antigen	*Launched*	• SARS-CoV-2 rapid antigen (saliva/nasal)	*Launched*[3]
	• Elecsys® IL-6 Test to diagnose cytokine release syndrome	*Launched*	• SARS-CoV-2 & Influenza A/B rapid antigen	*In-development*[3]
Digital solutions	• Viewics LabOps COVID-19 for efficiency improvements	*Launched*	• NAVIFY Remote Monitor[4]	*Launched*
			• v-TAC[5] digital algorithm for blood-gas	*Launched*
			• iThemba Life COVID-19	*Launched*

[1] Not all products are available in all countries; [2] S=spike protein; [3] external distribution partnership; [4] US only; [5] v-TAC=venous to arterial conversion

Developer Challenges



- Compressing years of **development** into months
- Clinical and Regulatory
  - **Access** to specimens/virus
  - Lack of clarity in regulation**, divergent emergency regulatory mechanisms** around the world
  - **Local clinical studies** in some markets
- Scaling **production** in a short period of time
- **Capacity** of clinical labs
  - Dependent on installed base of analyzers on which tests will run
  - Availability of trained staff under CLIA
  - In some cases, can produce faster than labs can run the test
- Availability of **consumables** needed to collect specimens or run tests (e.g., swabs, PPE)
- Access to **Real World Data** on specific tests in some markets

COVID-19 is draining regulatory resources worldwide

- **>7,600** entries of COVID-19 trials in WHO International Clinical Trials Registry Platform (ICTRP)*
- **1,031** test kits commercially available or in development for the diagnosis of COVID-19 listed in the FIND database*

Sheer volume of innovation

- About **75% of regulatory authorities** struggle to perform all core functions consistently well and depend often on better resourced authorities in other countries**
- Even well-resourced regulators are putting non-COVID-19 related product submissions on the back burner

Lack of regulatory capacity

- Ensuring access to new generations of products and cumulative innovation around the evolving science **of the novel virus** is critical

Evolving science of the new virus

**Source: Global regulatory agility during covid-19 and other health emergencies, https://www.bmj.com/content/bmj/369/bmj.m1575.full.pdf

*Site visited January 18, 2021

IMDRF regulators have shown regulatory agility during pandemic

Country	Emergency Pathway?	Timeline*	Normal timeline*	Reliance Model?
Australia	Yes	1-2 weeks	5-6 months class 3	Yes
Brazil	Yes	2-3 weeks	3 months class 3	Yes (MDSAP only)
Canada	Yes	5 days - 2 months	12 months class 4	Yes
China	Yes	1-3 days (beginning)	6-8 months class 3, excluding clinical study timeline	No
EU	No	Self-declaration of conformity	Self-declaration of conformity	No
Japan	Yes	2-5 weeks	1 year for class 3	Yes (MDSAP Pilot only)
Russia	Yes	2 weeks	50 working days (official review) class 3, excluding clinical trials and supplement request	No
Singapore	Yes	3 days -3 weeks	8 and 11 months class C&D via abridged path	Yes
South Korea	Yes	2-8 weeks (beginning)	80 working days (official review) class 3, excluding supplement request	No
US	Yes	1 day – 3 months	6-8 months class II de novo	Yes (MDSAP only)

*Timelines reflect review timelines based on observations, estimation

Lessons Learned (So far. . .)

- **Prioritize** based on what is needed at each pandemic phase
- Leverage **regulatory reliance and convergence** models to avoid duplication
  - Premarket authorizations
  - Clinical evidence
  - MDSAP
- Practice **regulatory agility** during & beyond the pandemic, including:
  - Risk-calibrated pre-market authorizations
  - Implement remote audits in place of physical inspections
- Further develop agile regulatory concepts and practices to optimize use of regulator and industry resources, and speed patient access to innovative technologies
  - Consider development of a common **emergency use pathway** globally
- Improve access, leverage **real world data** to monitor performance and bring products to full market authorization

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Thank you!