

AdvaMed Events & Education

Webinar

CREATING AND IMPLEMENTING A COVID-19 RETURN-TO-WORK PLAN

April 22, 2020

CREATING AND IMPLEMENTING A COVID-19 RETURN-TO-WORK PLAN

- **John de Csepel, MD**, *Chief Medical Officer, MITG, Medtronic*
- **Trang Ly, MD**, *Senior Vice President and Medical Director, Insulet*
- **Susan Van Meter**, *Executive Director, AdvaMedDx*
- **Ambassador Richard Verma**, *Vice Chair & Partner, The Asia Group*
- **Christopher White, Esq.**, *COO & General Counsel, AdvaMed*

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Webinar

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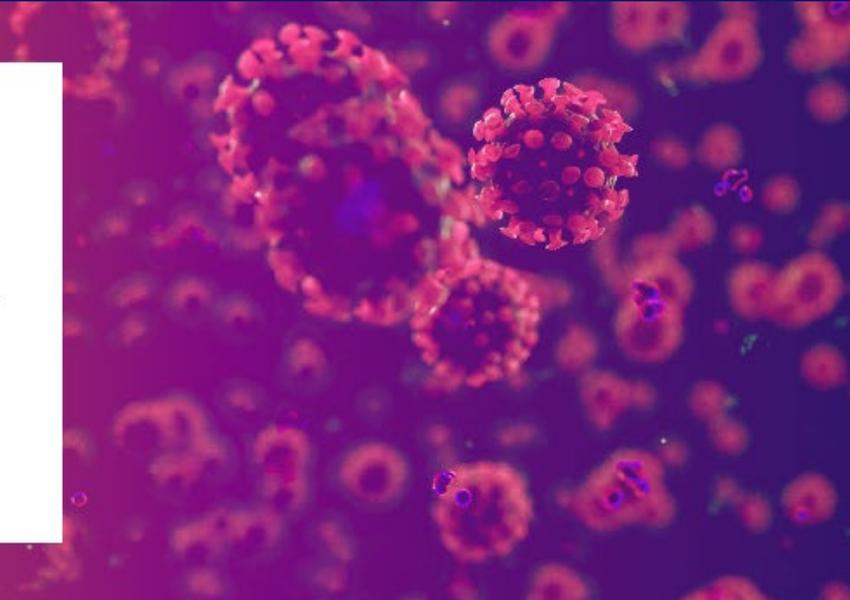
Webinar

Questions?

Please use the Questions/Chat pane of
the GoToWebinar Control Panel

or

Email Pat - pfogarty@advamed.org

A background image showing a microscopic view of COVID-19 virus particles. The particles are spherical and covered in red, spike-like protrusions, set against a dark purple and blue background with a bokeh effect.

COVID-19 MEDTECH RESOURCE CENTER

New Website Now Available!

STAY CURRENT

**Webinar recording and slides will be
available on [MedtechResponds.com](https://www.MedtechResponds.com)**

CURRENT TESTING LANDSCAPE

Diagnosing Symptomatic Patients:

Molecular Tests

- Gold standard to diagnose.
- Sample: nasal/oral swab.
- In labs/hospitals – on high throughput platforms with results for hundreds or tests in 1-4 hours.
- Point-of-care – near patient tests with results in 5-45 minutes.
- About 30 IVD manufacturers collectively producing and shipping about 7 million tests per week with more to come.

Antibody Testing to Determine Potential Immunity:

Serology Tests

- Value depends on disease prevalence.
- Sample: blood draw or finger stick.
- In labs/hospitals – on high throughput platforms with results for 150 tests in 1 hour.
- Point-of-care – small devices with results in minutes.
- 90 test developers on market without FDA authorization.
- IVD manufacturers developing tests. 3 with FDA EUA. Other companies with our EUA.
- AdvaMedDx survey in the field.

Employer Consideration for Return to Work

- Combination of molecular and serological tests to diagnose and monitor workforce.
- Antigen testing to come on line -
 - Immunoassays, can be rapid point-of-care, at lower cost than molecular to diagnose patients potentially even before symptoms appear.
- Social distancing.
- Dependent upon regional health care infrastructure, testing, contact tracing.

- **Today, labs/hospitals run about 150K molecular tests per day. To date, 4.1 million tests performed in U.S.**
- **WH seeks 500K per day / 4.5M per month molecular tests.**
- **What is needed to maximize testing?**
 - Increasing supplies of swabs, transport medium, reagents (chemicals needed to run tests).
 - Bolstering lab infrastructure – including with augmented platforms, manufactured by IVD companies.
 - Maximizing unused lab capacity.

Senate passed legislation last night with \$25 billion for testing; heads to House for expected passage.

ADVAMEDDX MEMBER RESOURCES

COVID-19 IVD TESTING: WHAT WE'RE DOING

April 16, 2020

In vitro diagnostics (IVD) companies are rapidly and dramatically scaling up manufacturing of commercially available COVID-19 IVD tests to meet unprecedented demand.

- Since the outbreak, well over two dozen molecular diagnostics for COVID-19 have received Emergency Use Authorization from FDA for COVID-19 – the first on March 12.
- In the U.S., over 3.3 million COVID-19 diagnostics have been run as of April 16, and demand is great and more are needed.
- Through round-the-clock U.S. and global sourcing and manufacturing, IVD manufacturers' production capacity is on track to reach over 7 million commercial molecular diagnostics per week by the end of April (*disclosed production data).
- Test makers are shipping tests country-wide to meet demand, often with input from government officials, particularly where outbreaks are pronounced.
- Most IVD tests are run by labs and hospitals, typically on high-throughput, automated platforms. Once patient samples are loaded, results typically are provided in 1-4 hours – e.g. of laboratory results display

PATIENT SAMPLE



TRANSFER SAMPLE

IVD PLATFORMS



IVD platforms in small and large clinical labs, like hospital labs, run up to hundreds of tests at once.

IVD platforms have easy to follow and automated workflows and integrated software to perform accurate, reliable diagnostic testing using IVD test kits.

TEST RESULTS



RESULTS

IVD tests on IVD platforms in clinical laboratories deliver results in **1-4 hours**
e.g. of laboratory results display

OBTAIN SAMPLE

- Nasal/oral swab for live virus diagnosis;
- Blood draw/finger stick for antibody testing

TRANSFER SAMPLE

IVD POINT-OF-CARE



IVD Point-of-Care instruments, used in doctors' offices and emergency rooms, can run tests rapidly and almost anywhere.

RESULTS



IVD Point-of-Care tests can deliver results in **5-45 minutes**
e.g. visual results of antibody point of care test

From manufacturing of sample collection devices used by clinicians, testing platforms used by laboratories small and large, and rapid point-of-care tests and platforms, IVD manufacturers are delivering COVID-19 testing.



April 21, 2020

Q&A: In Vitro Diagnostic COVID-19 Testing – Part 1

AdvaMedDx and its member companies are supporting the public health response to the 2019 novel coronavirus (COVID-19) pandemic by expanding the availability of and patient access to diagnostic testing. As of April 21, over thirty commercial diagnostic tests for COVID-19, including rapid, point-of-care tests, have received Emergency Use Authorization (EUA) from the U.S. FDA since the first commercial test received EUA on March 12.

Q. Who are AdvaMedDx's members?

A. AdvaMedDx member companies produce advanced, *in vitro* diagnostic (IVD) tests that facilitate the early detection of disease and guiding of appropriate treatments to improve the quality of patient care and public health. These include tests that are front-line tools in the fight against COVID-19, from diagnosing the infection to guiding treatment decisions for those diagnosed and determining if individuals exposed have potentially developed immunity to the virus. FDA plays an important role, providing oversight of IVD manufacturer test development and manufacturing.

Q. How are AdvaMedDx member companies increasing access to coronavirus testing?

A. IVD manufacturers and laboratories are working around the clock to produce more tests as quickly as possible. Many AdvaMedDx member companies have rapidly developed IVD tests to detect the novel coronavirus, as well as to determine if individuals have been exposed to the virus and potentially have developed immunity. They are continuing to work closely with FDA and other government departments and agencies to facilitate patient access to these tests. To date, there are over 30 commercially available COVID-19 IVDs that have received Emergency Use Authorization from FDA – permitting these tests to be deployed to laboratories, hospitals, and other testing sites. These commercial tests will increase coronavirus testing capacity, speed, and throughput to guide patient care and protect public health.

A current list of diagnostic tests that have received FDA EUAs to detect the COVID-19 virus can be found here: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

Q. Will IVD manufacturer COVID-19 tests that have received FDA Emergency Use Authorization (EUA) to diagnose symptomatic patients facilitate faster testing from when the outbreak began?

MODERATED DISCUSSION

RETURN-TO-WORK BEST PRACTICES

Moderator

- **Pat Fogarty**, *VP, Assistant General Counsel & Director, Civil Justice Policy, AdvaMed*

AdvaMed Member Company Medical Officers

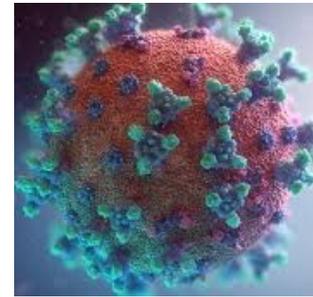
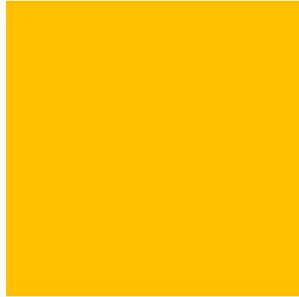
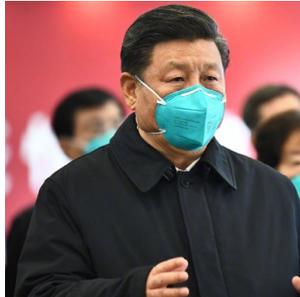
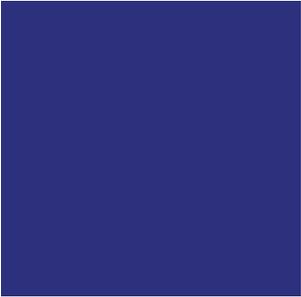
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THE ASIA GROUP

The Race to Recovery in Asia

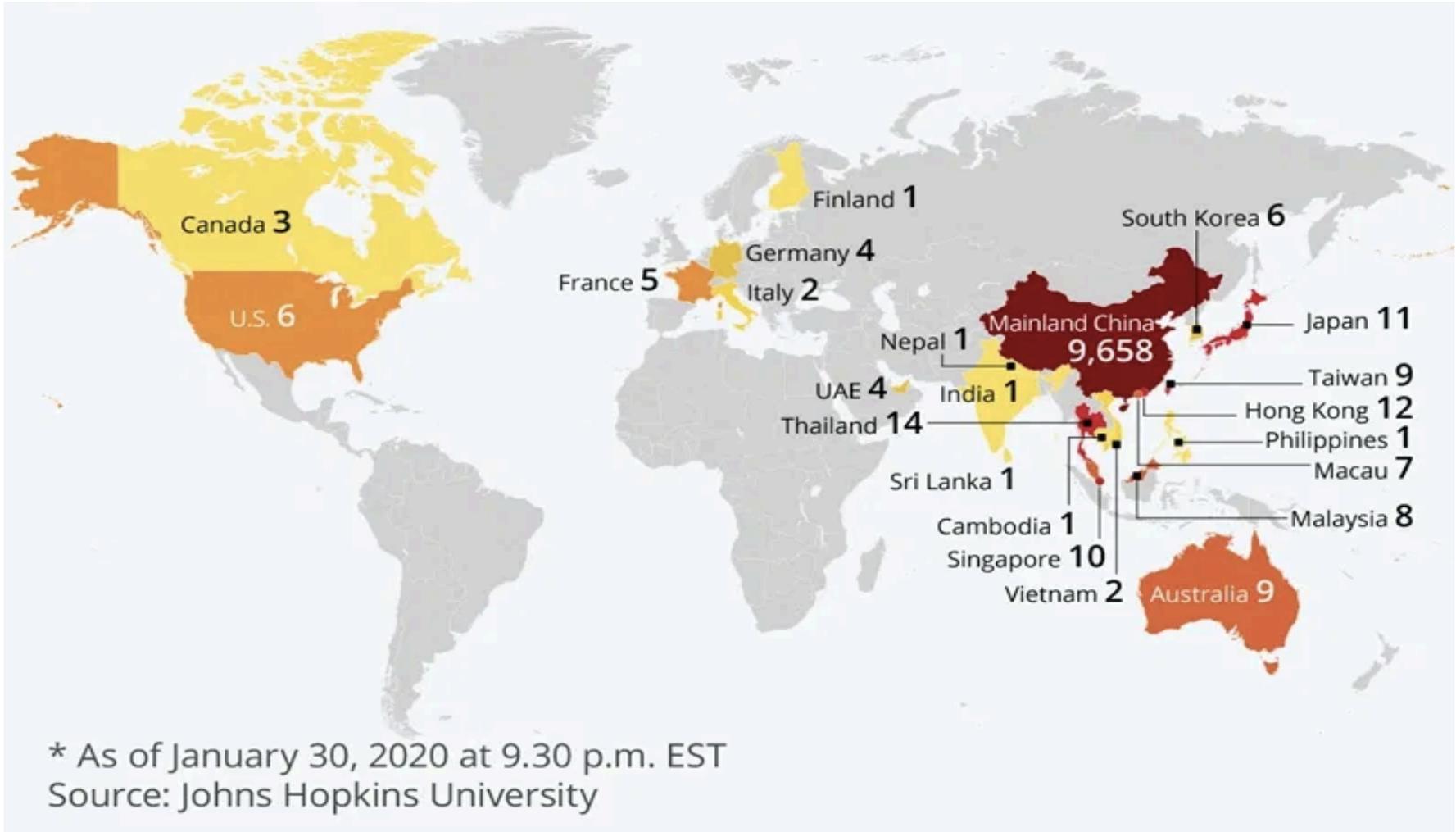
Best Practices for Reopening in a Post-Virus World



April 21, 2020

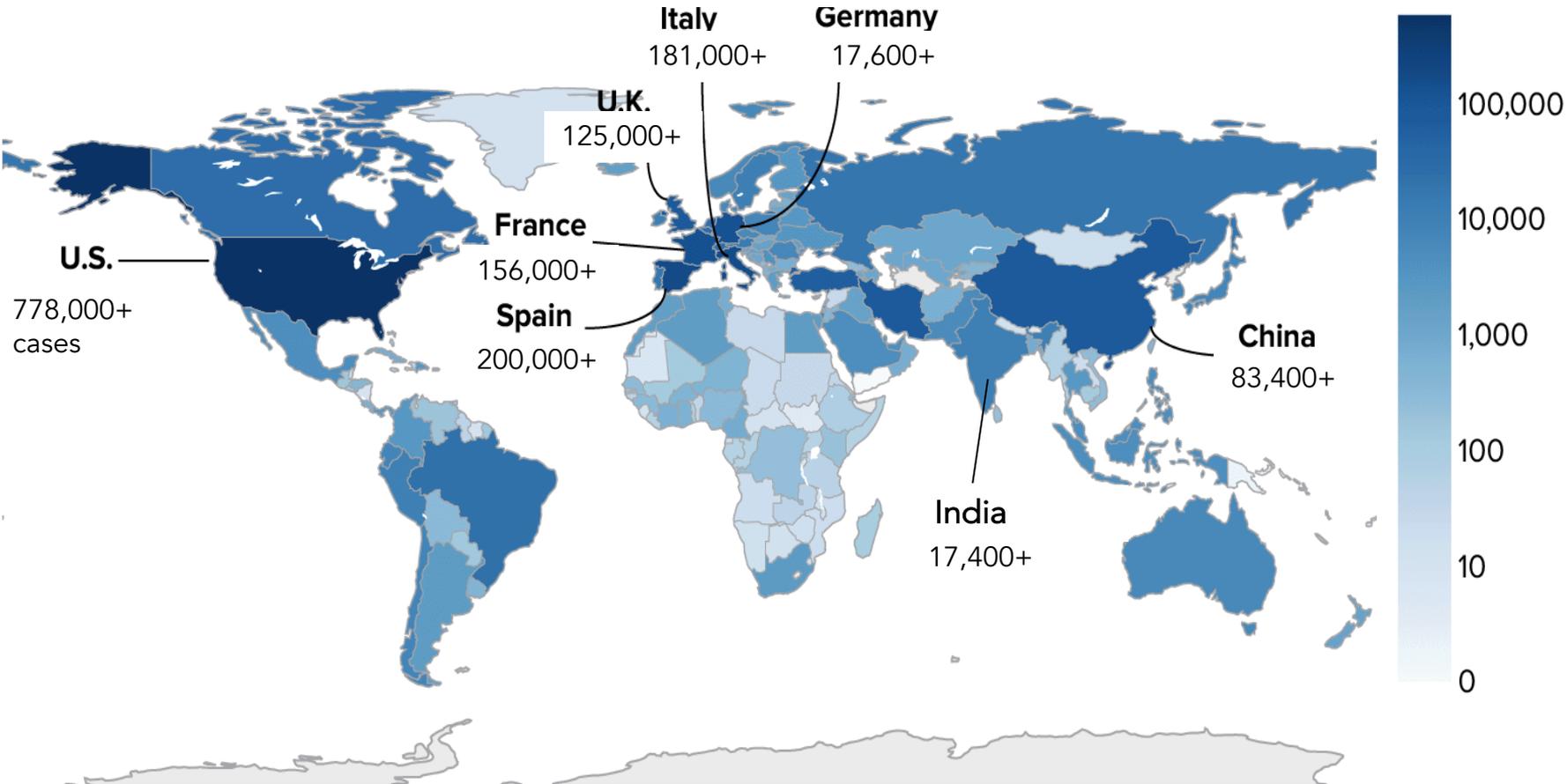
ASIA AS THE EPICENTER OF THE PANDEMIC

Global COVID-19 Cases as of January 30



AMERICA AS THE EPICENTER OF THE PANDEMIC

Global COVID-19 Cases as of April 20



Source: Johns Hopkins University

ASIA AS THE EPICENTER OF RECOVERY

Though **Asia was the epicenter of the COVID-19 outbreak**, countries across the region understand that the crisis presents historic opportunities. COVID-19 is set to **radically transform** the way the global economy operates. Governments and companies that can **transition seamlessly to the “new normal”** stand poised for success.

The Race to Recovery is On and Asia is Out in Front...For Now



Critical Figures

24,601

Daily New
COVID-19 Cases
USA – April 20

12,311

Daily New
COVID-19 Cases
All of Asia – April 20

1.0%

Forecasted GDP 2020
Emerging and
Developing Asia



8.5%

Forecasted GDP 2021
Emerging and
Developing Asia

DIFFERENTIAL RECOVERY RATES WITHIN ASIA

Unpacking the Asian Recovery

Asian Country	Days for Cases to Double	COVID-19 Cases to Date	2020 GDP (%)	2021 GDP (%)
China	70 days	83,817	1.2	9.2
South Korea	47 days	10,674	1.3	2.3*
Taiwan	27 days	420	1.8*	2.5*
Vietnam	26 days	276	4.8	6.8
Thailand	22 days	2,765	- 4.5*	2.5*
Malaysia	20 days	5,389	0.5*	5.5*
Philippines	15 days	6,259	2.0*	6.5*
Indonesia	11 days	6,760	2.5*	5.0*
India	8 days	17,656	1.9	7.4
Japan	8 days	10,751	2.0*	3.0
United States	13 days	759,687	- 5.9	4.7

THE CURRENT OPERATING ENVIRONMENT

Current Regional Dynamics

1. The Early Leaders are Open for Business but Focused on Preventing a Second Wave
2. Steady Climbers Aim to Contain First Wave and Scale Production
3. Shift from “Total” to “Targeted Lockdowns” as First Wave Progresses
4. Essential vs. Non-Essential Sectors Change – Challenges and Opportunities
5. Second Wave Fears Drive Regional Uncertainty
6. Domestic Interests Shape Investment and Business Landscape

Asia's Business Landscape Remains in Flux



WHERE ARE WE HEADING?

Over the Horizon Outlook in Key Asian Markets

EARLY LEADERS

China, Taiwan, South Korea, and Vietnam

- Health authorities are focusing on locking in gains + preventing a second wave
- Production gradually returning as companies adopt contagion SOPs
- Governments shifting to export-oriented posture – both in terms of medical equipment and PPE, but also more broadly within the manufacturing sector

STEADY CLIMBERS

Thailand, Malaysia, and Philippines

- Public health interventions are steadily flattening the COVID-19 curve
- National or regional lockdowns likely to ease in time barring second wave reversals that remain possible
- Companies are already looking to scale up opportunities for manufacturing

BASECAMP + BACKSLIDERS

Indonesia, India, Singapore, and Japan

- Countries in lockdown under enhanced restrictions or seeing restrained government action despite rising cases and possibility of contagion
- Health authorities focused on limiting contagion and grappling with health and political challenges of a rising caseload
- Companies working to maintain essential production and preparing for a wider range of contingencies and possible policy reversals

PREPARING TO RE-OPEN: A DECISION-MAKING FRAMEWORK

Companies must develop and align operational and GR strategies for re-opening and advance tailored approaches within distinct market environment in Asia. A one-size fits all approach will not work in this diverse and dynamic region.

Key Steps

1

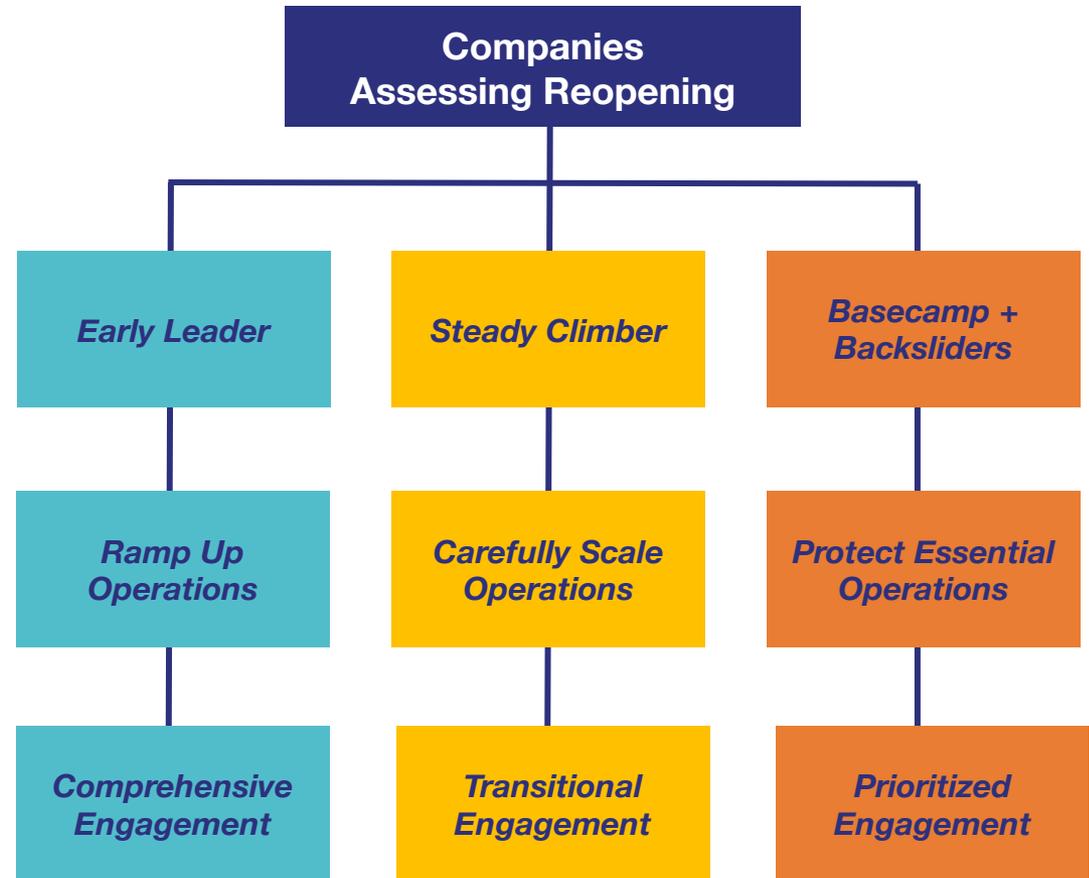
Determine Market Environment

2

Develop Operational Procedures

3

Drive Tailored GR Strategy



MARKETS IN FOCUS: CHINA AND INDIA

China Emerges an Early Leader After Initial Outbreak



After COVID-19, Focus on Reopening Economy

- FDI down 25% just in February; this was on top of a trade war, and an already slowing economy
- Businesses began opening in February. New protocols abound
- Priority is to restart manufacturing; services are secondary
- Traffic congestion and pollution in many parts of China have returned to January 1st levels



American Chamber of Commerce Survey Finds

- **40%** of companies would maintain planned investments
- **25%** would cut investments
- **33%** said it was too early to determine impact

India Tackles First Wave with National Lockdown



Lockdown Extended But Some Restrictions Lifted

- India has extended its lockdown through May 3, but allowed certain key sectors resume operations starting April 20
- Health officials will allow these business to operate outside COVID containment zones/ hotspots. Inside, no relief for industry
- The lockdown measure has already raised unemployment to 14.5 percent
- Manufacturing PMI fell - 54.5 to 51.8 in March



Manufacturers Navigate Dynamic Environment

- Home Ministry is constantly shifting list of essential and non-essential sectors
- Local restrictions on travel coupled with limitations on e-commerce reduces incentives for manufacturers to restart ops

CASE STUDY: NAVIGATING CHINA'S NEW NORMAL

Following the initial outbreak, China adopted aggressive containment efforts that flattened the curve, though health officials are watching for signs of a second wave. Businesses must now comply with strict government health requirements.

1 Determine Market Environment

China is an Early Leader: China was one of the first countries to emerge on the other side of the curve and is a bellwether market for other economies across the globe grappling with the global pandemic. Continued outbreak risk and imported cases may challenge economic normalization.

U.S. Retailer



Reacted swiftly to sweeping gov't lockdown measures, closing brick-and mortar stores while ramping up online presence.

Foreign Manufacturer



Identified risks to supply chain bottlenecks due to lockdown restrictions and bolstered production in other markets.

2 Develop Operational Procedures

Full-Spectrum Operations With Precautions: Beijing has mandated that all businesses impose temperature checks and supply face masks, but companies are also implementing additional precautionary measures that are location-specific as full operations come online.



Gave clear internal guidelines in early shift to online workflow to avoid disruption, formulated health precautions on a location-specific basis during reopening period.



Modeled operational procedures to local guidelines, provided checkups and masks for workers. Disinfected plants and other facilities.

3 Drive Tailored GR Strategy

Comprehensive Engagement: Companies recognize that continued engagement with stakeholders is critical in keeping business plans up-to-date with rapidly-changing local guidelines. As immediate COVID-19 restrictions recede, companies are shifting to longer-term policy efforts.



Emphasized COVID-19 compliance to local leaders while shifting focus of engagement toward post-virus growth strategy.



Recognized potential delays for reopening while working with local authorities to ensure domestic sales can continue amid decline in overseas demand.

CASE STUDY: PROTECTING ESSENTIAL OPERATIONS IN INDIA

India has extended its lockdown through May 3 and continues to see an uptick in COVID-19 cases. In this environment, companies are advancing targeted engagements to maintain essential production and showcase workforce safety measures.

Key Steps

U.S. Power Company

Indian IT Service Companies

1 Determine Market Environment

India is at Basecamp: India is still in the early stages of its COVID-19 response and cases are still rising. Essential v. non-essential sectors shift and the possibility of further restrictions and reversal remains high in the coming weeks, especially in key states that house manufacturing clusters.



Recognized quickly that GOI was likely to extend lockdown and sought exemptions for select facilities that align with GOI goals.



Understood that IT services may not necessarily be included in essential list, requiring quick and steady engagement.

2 Develop Operational Procedures

Protect Essential Operations and Workforce: The Ministry of Home Affairs has detailed basic standard operating procedures for manufacturers looking to reopen. But companies are preempting these by taking steps to ensure worker safety and production in critical facilities.



Set up company-sponsored travel to plant to limit movement. Social distancing maintained throughout the production line.



Though GOI allows operations with 50% staff, companies returning in a phased manner – starting with 15 to 20%. Hiring firms to sanitize offices.

3 Drive Tailored GR Strategy

Targeted Crisis Engagement: Companies must conduct proactive government engagements to ensure essential operations continue and communicate steps taken to protect workers. Central and state-level outreach is key.



Prioritized GR engagement on continued operations for highest-value manufacturing facility, not all facilities. Coordinated with Invest India, DPIIT, + state govts.



Engaged GOI and state govts to secure exemption. Now trying to ensure IT products are considered essential to facilitate continued work from home

LOOKING BEYOND RE-OPENING

“What People Thought was a Global Supply Chain, was the Chinese Supply Chain”

Supply chain diversification away from China was already happening

- Wages were climbing; Trade war stoked greater concerns on cost/stability
- Consumers more discerning
- But – you can move your factory – you still need your inputs for that factory – and these are still coming from China

Diversification of supply, durability and redundancy in supply will be key

- Low cost and quality will be still be huge drivers – but these will not be the sole drivers any longer.

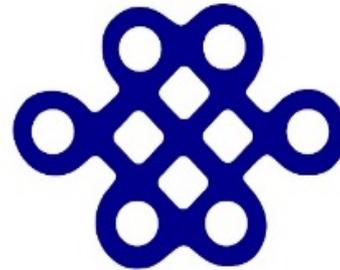
What is strategic and imperative to a country’s security and livelihood will take on new meaning and likely to require domestic sourcing and new frameworks

- Agreements and understandings will have to be developed in advance to ensure a reliable flow of medical goods before the next crisis hits
- Production is only one element – shipping and logistics also must have redundancy.
- Nationalism will put greater pressure on companies to bring production back home....new technologies and efficiencies may make that possible.

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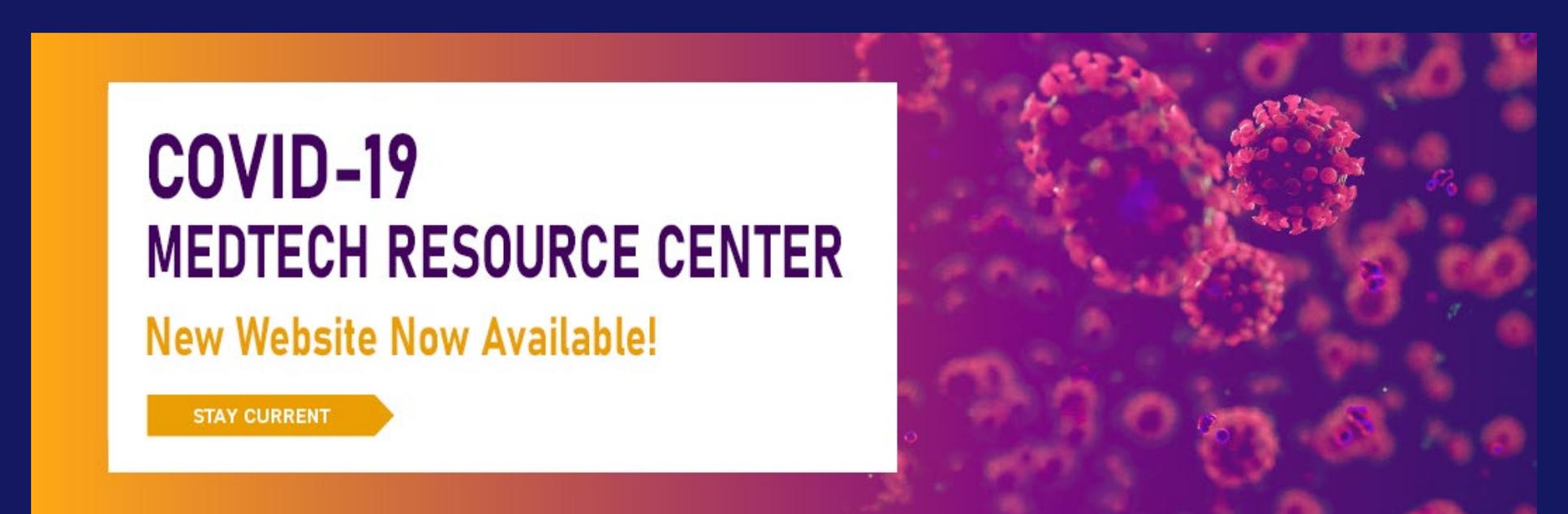


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The background of the top section features a dark purple and blue gradient with numerous 3D-rendered COVID-19 virus particles. These particles are spherical with a textured, bumpy surface, resembling the characteristic appearance of the virus. They are scattered across the frame, with some appearing larger and more detailed than others, creating a sense of depth and movement.

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