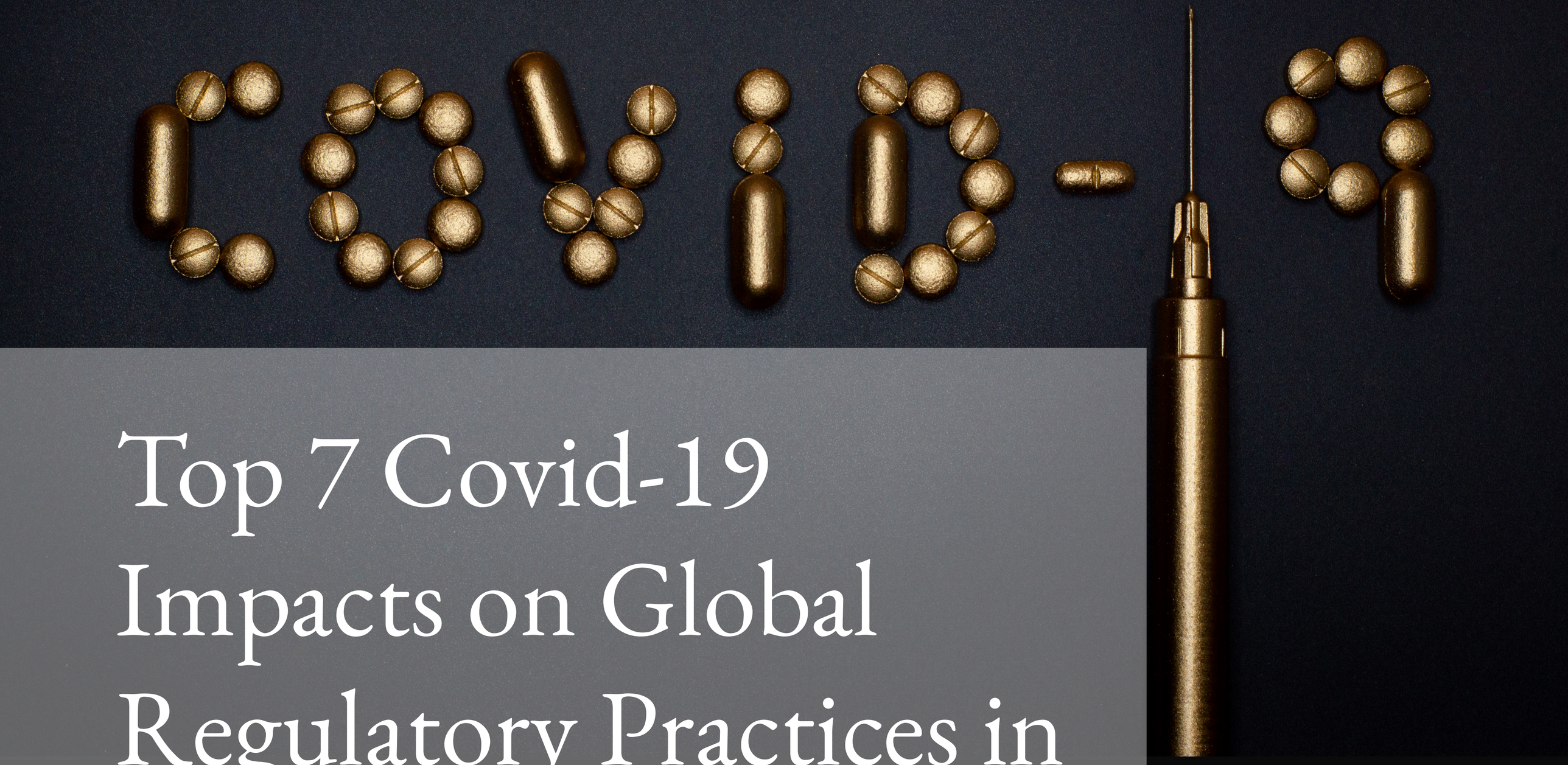


Top 7 Covid-19 Impacts on Global Regulatory Practices in Biotech Industries

WITH DALTON

Peter Pekos

Company Vision

"To make the impossible possible, Dalton Pharma Services uses its scientific and pharmaceutical expertise to bring customer ideas to life. We develop their new drug products, optimize the synthesis of therapeutic candidates, and manufacture them at the highest level of quality."

Disclaimer

This technical report is intended to provide information to quality and regulatory correspondents on the effects of the pandemic on global biotech industries as it relates to regulatory. This technical report should be read in conjunction with the relevant laws, regulations, and guidance's that apply to your situation.

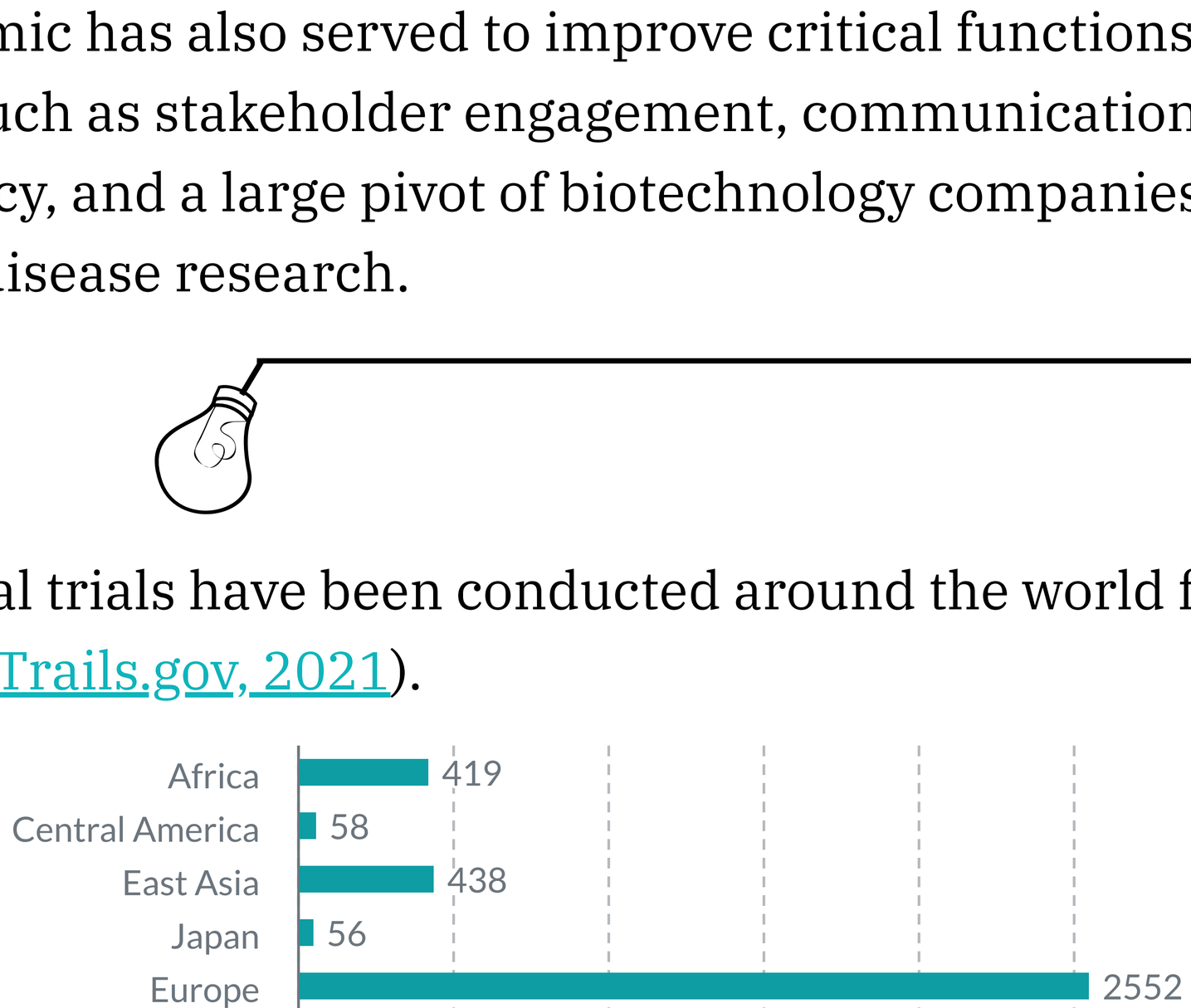
FDA inspected, HC approved, & MRA with EMA

The COVID-19 pandemic has created an unprecedented strain on the global health care system and has led to an urgent need for access to health products. As part of the government's broad response to the pandemic, regulatory agencies have implemented innovative and agile regulatory measures. Emphasis has been placed on the importance of regulatory tools, regulatory-driven innovation, and regulatory alignment on a global level to ensure consistency of products and practices, the legality of procedures, and mandates at national levels.

The pandemic has also served to improve critical functions in crisis response such as stakeholder engagement, communication, transparency, and a large pivot of biotechnology companies to pursue infectious disease research.

DID YOU KNOW?

7071 clinical trials have been conducted around the world for COVID-19 (ClinicalTrails.gov, 2021).



DID YOU KNOW?

The Government of Canada has invested more than $1.3B in 29 COVID 19 domestic biomanufacturing, vaccine and therapeutic projects (Health Canada, 2021a).

The pandemic has served to accelerate and introduce many regulatory tools within the health care sector. These changes have capitalized on the strengths of regulatory bodies as well as brought forward opportunities to address key weaknesses in regulatory approaches. As you navigate through this technical whitepaper, consider the following: What learnings has your organization got from the pandemic? What are some opportunities to address key challenges?

Regulatory *Impacts/Changes* (EPR, 2021)

- The pandemic has increased the demand for faster clinical trials. As a result, biopharma companies are adopting various strategies for innovating clinical trials to shorten timelines. Such innovations include introducing new trial designs through adopting a more decentralised approach to collecting patient information and conducting clinical trials. Decentralized clinical trials aim to ease participation for patients by minimizing or eliminating the need to travel to specific study sites. This innovative approach enables greater patient involvement and improves clinical trial diversity, drawing more valuable insights. However, the pharmaceutical industry's biggest challenge will be finding the right technology to support these decentralised study formats. Amidst the pandemic, we have seen that direct patient-provided data is becoming more acceptable to regulators and companies, via wearables or electronic clinical outcome assessments (eCOA). This may be a potential opportunity for this challenge.

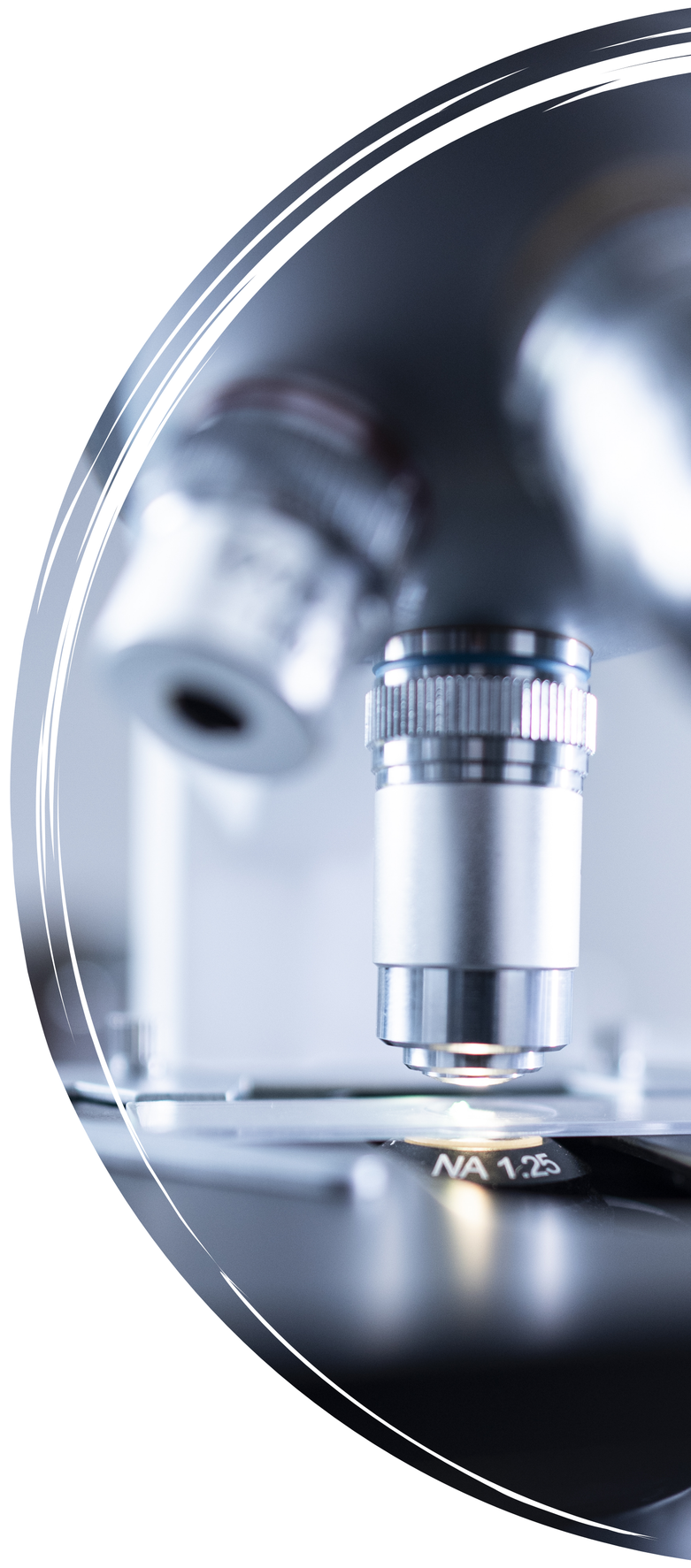
- The pandemic has increased the demand for expedited regulatory reviews. As a result, biopharma companies are turning to regulatory information management (RIM) technology to help automate the more tedious, repetitive regulatory reporting activities with artificial intelligence (AI) and machine learning (ML).

- Accelerated drug approval processes have also been driven by existing expedited regulatory tools such as:
  - Rolling reviews for vaccines
  - The EU's conditional marketing authorisation (CMA)
  - The US FDA's pre-investigational new drug (IND) meetings, with flexibility around the non-clinical information to be included to accelerate the review and start of studies
  - Canadian interim orders

  (Health Canada, 2021b), (Cavaleri et al., 2021)

  NOTE: all these temporary regulatory pathways help expedite authorizations for COVID-19-related drugs and vaccines without compromising patient safety.

- Enhanced collaboration between governments, industry, and big techs. Changes in manufacturing and supply chain are driving the need for new regulatory approaches. Increased collaboration amongst biopharma companies is expected to ensure consistent and expedited delivery of drugs and vaccines to the public. Many pharma companies will need to leverage their partners instead of manufacturing the products themselves. Dalton Pharma Services is a leading cGMP contract service provider of integrated drug discovery, development and manufacturing services to the pharmaceutical and biotechnology industries. Contact us today.

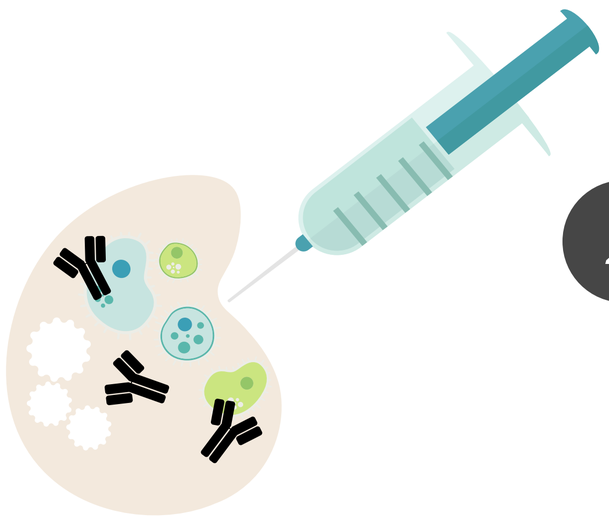


- As COVID-19 is expected to have prolonged economic implications, patients' financial situations may change, altering the drug coverage by the government for COVID-19 related treatment.

Emerging learnings *from the pandemic*

1 Product sourcing and procurement: The limited ability to produce locally, and export restrictions on active pharmaceutical ingredients (API) or over-the-counter medication have significantly impacted the supply chain amidst the pandemic. We must rethink and transform the pharmaceutical supply chain strategy by identifying alternate suppliers to mitigate regulatory risks and allow for rapid adaptation to market needs (Deloitte, 2020).

Now is the time to identify and collaborate with relevant biopharma companies, like Dalton, to share capabilities that include the supply chain.



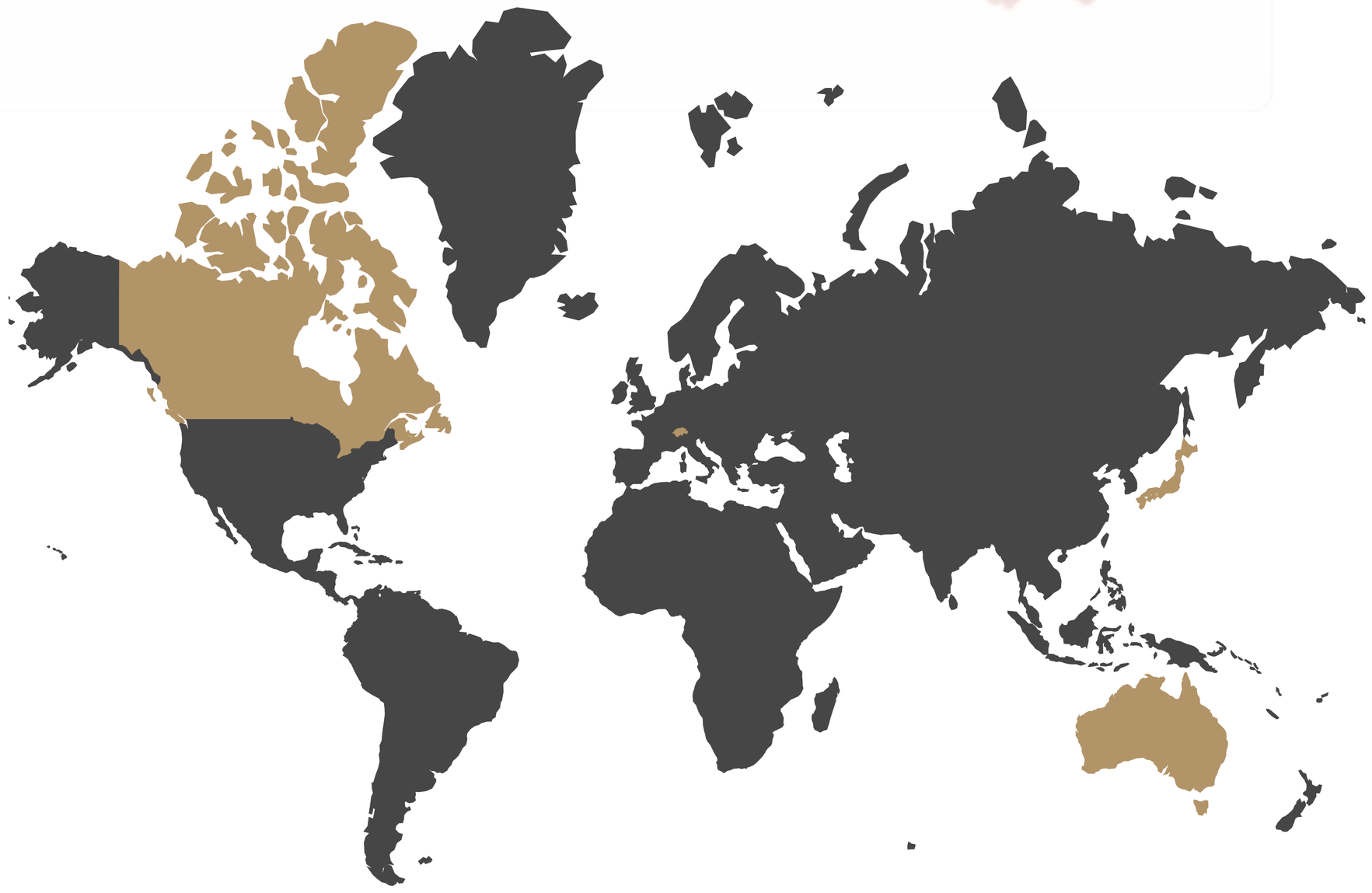
2 Amidst the pandemic, it became evident that different public health authorities were in misalignment on the decisions of which vaccines would be approved in their respective jurisdiction. This case exemplified the need to ensure improved coordination and communication with national health bodies.

International collaborations have been pivotal to approach harmonisation of regulatory requirements and many regulatory agencies are increasingly becoming involved in national policy agreements to contribute to better alignment to help to strengthen regulatory capacity and increase drug availability:

- EMA has opened its scientific discussions to regulators from non-EU countries. As of December 18, 2020, Health Canada is participating in the pilot phase of the European Medicines Agency's (EMA) "Opening our Procedures at EMA to Non-EU authorities (OPEN)" project.

(Health Canada, 2021c)

OPEN makes it possible for trusted regulatory authorities outside of the European Union to collaborate with EMA. At this stage, regulators from Australia, Japan, Switzerland, and the World Health Organisation are also participating in OPEN (EMA, 2021).



As part of this pilot, these trusted regulatory authorities will be able to:

1 Participate in EMA's assessment process for COVID-19-related medicinal products, including vaccines. This initiative will promote overall transparency and contribute to public trust in vaccines and therapeutics,

2 Contribute to discussions involving the Committee for Medicinal Products for Human Use (CHMP), and

3 Contribute to discussions involving the Emergency Task Force concerned with the rolling review of COVID-19 applications. (EMA, 2021)

Another global initiative is the International Coalition of Medicines Regulatory Authorities (ICMRA). This global coalition of regulatory authorities, including the World Health Organization (WHO) as an observer, provides strategic leadership to address current and emerging regulatory and safety challenges in human medicines.

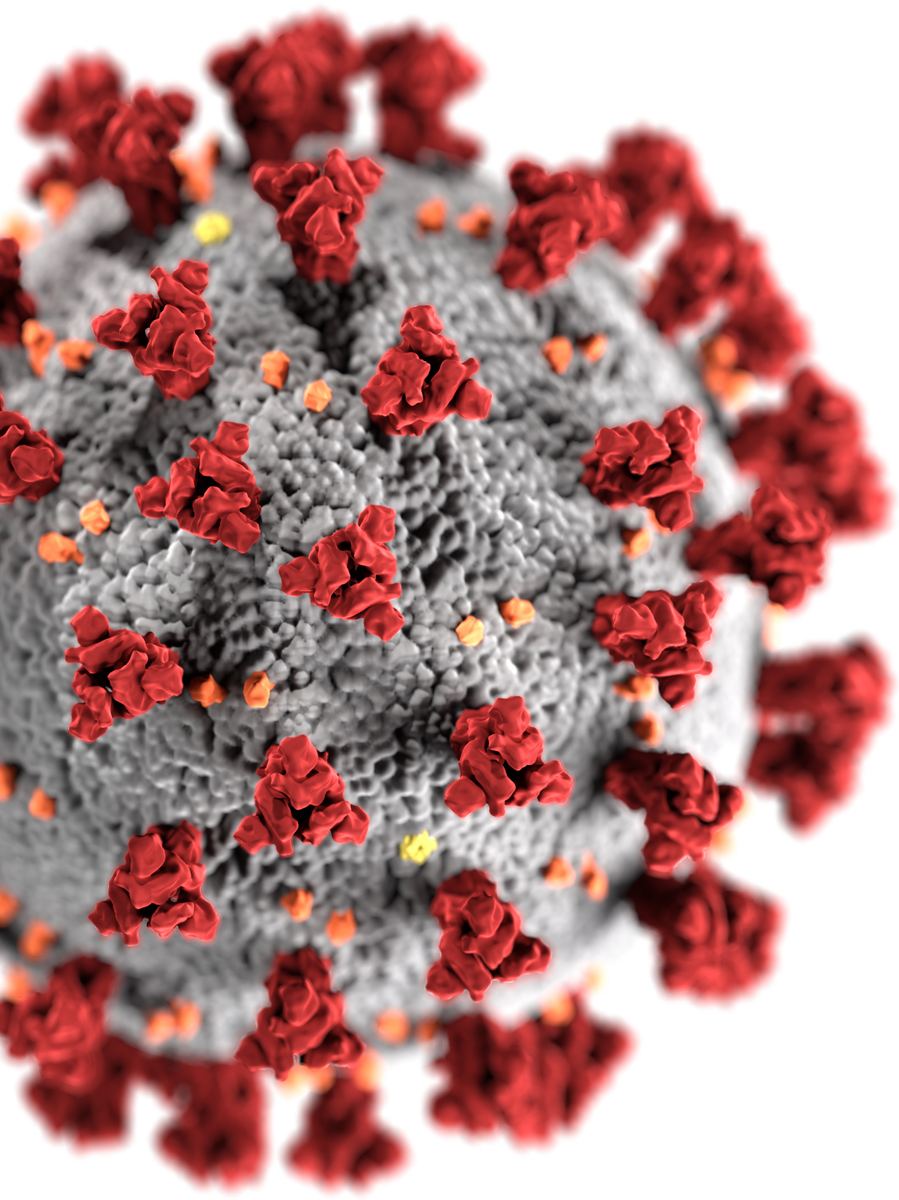
Many trusted regulatory authorities, including Health Canada, play an integral role in setting ICMRA's strategic directions. In response to the COVID-19 pandemic, the ICMRA has expanded its scope of work to provide a global approach for aligning the approaches of regulators to COVID-19 treatments and vaccines.

DID YOU KNOW?

International Coalition of Medicines Regulatory Authorities (ICMRA) is a voluntary, executive-level, strategic coordinating, advocacy, and leadership entity of regulatory authorities that work together to (ICMRA, 2021):

Address current and emerging human medicine regulatory and safety challenges globally, strategically, and in an ongoing, transparent, authoritative, and institutional manner	Provide direction for areas and activities common to many regulatory authorities' missions
Identify areas for potential synergies	Wherever possible, leverage existing initiatives/enablers and resources

Dalton's Services



Investors will reward and finance innovation, ingenuity, and willingness to take risks more than ever before. As a result of the pandemic, companies that shifted their focus to infectious disease research may have more opportunities to pursue new classes of therapeutics and novel areas of research. At Dalton, we offer both contract drug development and manufacturing services ranging from early-stage research and development through to developing material for both clinical trials and commercial production. As a CDMO, we enhance our customers production efforts through expertise from highly qualified chemists and researchers to accelerate the end-to-end process, while ensuring regulatory standards are met throughout. Given that Dalton is Health Canada approved and an FDA inspected facility, quality control is essential to meeting these strict regulatory standards for pharmaceutical manufacturing.

We deliver fully integrated solutions with emphasis on speed, flexibility, and quality.

We are experts in:

- Custom Synthesis
- cGMP API Manufacturing
- Formulation Development
- API Process Development
- Sterile Filling Services
- Accelerated Stability

For more information on services we provide, visit our website.

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