

ABSTRACT

For 95 years, ATCC has been compelled by its deep-rooted mission to improve global public health through advancements in science. At its inception in the 1920s, ATCC was regarded as simply a microbe culture collection, a repository of microorganisms scientists could draw from to conduct their research to make discoveries. Today, ATCC provides the world's leading scientists with the largest and most diverse collections of biological materials, including microbe products, cell products, molecular genomics tools, and derivative reagents. As highlighted during the pandemic, having in-country access to key cell lines, pathogens, and reagents is essential for scientific research, innovation, and breakthrough technologies. The pandemic fostered greater global collaborations to expand access to strains, information and biological standards to promote reproducible science. The pandemic also elucidated challenges in some countries without centralized bioresource centers, including import/export regulations, in-country production of high-quality biomaterials, costs for transport, and supply chain disruptions.

The benefits of in-country bioresource centers include 1) establishment of depositories for cells/microorganisms and key biomaterial needed for reproducible science, 2) manufacturing capability to rapid supply of high quality, characterized and authenticated cell lines/organisms/reagents for innovation in medical countermeasure development, and 3) facilitation of the development and validation of biotechnological products and processes which contributes to the growth and competitiveness of biotechnology and related industries in the country and globally.

To that end, ATCC is exploring opportunities to establish a bioresource center with operations in Australia to support Australian government-sponsored, academic, and bio-pharmaceutical life science research and create an ATCC biomanufacturing base of operations within the Asia-Pacific (APAC) region. This center will promote scientific discoveries that provide biological standards, ease of use, regulatory oversight, and a global reach in Australia.

GLOBAL HEALTH EMERGENCY RESPONSES

As evidenced by the COVID-19 pandemic, the ability to acquire, produce, characterize, and distribute key research reagents is paramount to understanding the infectious agent and the initiation of diagnostic, vaccine, and therapeutic development. Bioresource centers are critical to supporting sustained surges in product development and supply chain logistics during outbreaks, epidemics and pandemics. ATCC has successfully supported the needs of the global scientific community during disease outbreaks, including H1N1, MERS, Ebola, and Zika. In addition, ATCC has fostered collaboration and partnerships across global entities to share resources, information, and data to accelerate discoveries and harmonize scientific approaches.

Since **JANUARY 20 20**, ATCC, in collaboration with our government partners, has created a comprehensive catalog of strains and related reagents to support COVID-19 research and development efforts.

To date, ATCC has provided

MORE THAN 300,000 VIALS OF SARS-CoV-2, Surveillance Kits and related coronavirus strains and reagents to **OVER 3,500** RESEARCHERS

At 2,700 INSTITUTIONS in more than **150 COUNTRIES.**

ATCC has acquired, produced, characterized and distributed

MORE THAN 150 STRAINS AND VARIANTS OF

SARS-CoV-2, and worked with vaccine developers to support efficacy studies against emerging variants, and propagated over 100L of virus to support

CHALLENGE STUDIES for vaccine and therapeutic development.

LESSONS FROM GLOBAL HEALTH EMERGENCIES

International Networks are Essential: International collaborations between bioresource centers and key academic and private organizations formed through the pandemic to share information and resources. Although positive, more effort and inclusion is needed for future preparedness.

Public Health Emergency Measures Facilitate Sharing: During the pandemic, the US Government declared a public health emergency which activated a revised agreement for sharing biomaterials. This agreement allowed for the transfer of materials and removed barriers to the commercialization of new products if used for legitimate purposes to rapidly prevent, detect, prepare for and respond to the spread or transmission of SARS-CoV-2.

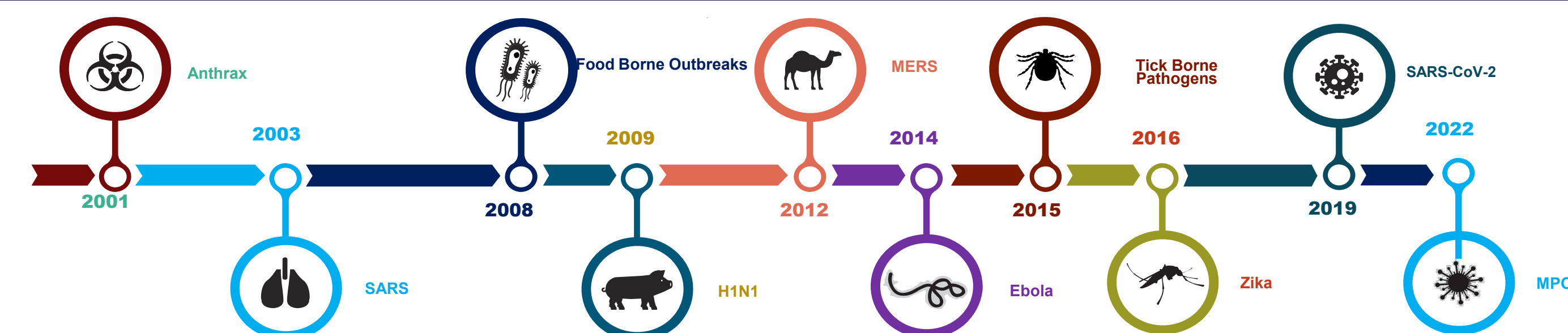
Large Scale, Rapid Biomanufacturing of Standards Accelerate Countermeasures: Surrogate pathogen stocks and product development roadmaps developed for previous infectious disease outbreaks guided the rapid manufacturing of virus stocks and controls.

Supply Chain and Logistics are Stressed, In Country Access to High-Quality Materials and Manufacturing is Vital: Border and transportation lockdowns reduced access to crucial strains and reagents. The ability to locally manufacture critical biomaterials (infectious agents, nucleic acid, inactivated agents) was a differentiator in managing capacity and supply chain and accelerating early-stage diagnostics and countermeasures.



International networks, public health emergency protocols, large-scale biomanufacturing capabilities and reliable supply chain logistics are crucial components of bioresource center operations during an emergency

EVOLUTION



Experience through infectious disease outbreaks, epidemics and pandemics have fostered the evolution of bioresource centers because of the critical role they play in these events.

Strengthening Supply Chains via Biomanufacturing Capabilities: The pandemic has elevated the vulnerability of overreliance on foreign countries to provide offshore active pharmaceutical ingredients (APIs) and other public health measures. An evolution of in-country biomanufacturing is gaining speed in the United States to reduce the threat offshoring imposes on the quality and availability of essential countermeasures.

Pathogen Agnostic and Viral Family Focus on Countermeasure Development: Bioresource centers play a critical role in providing a broad range of biomaterials to support pathogen-agnostic and viral family-focused countermeasures. Prototype pathogen approaches allow for preparedness efforts against the next emerging threat.

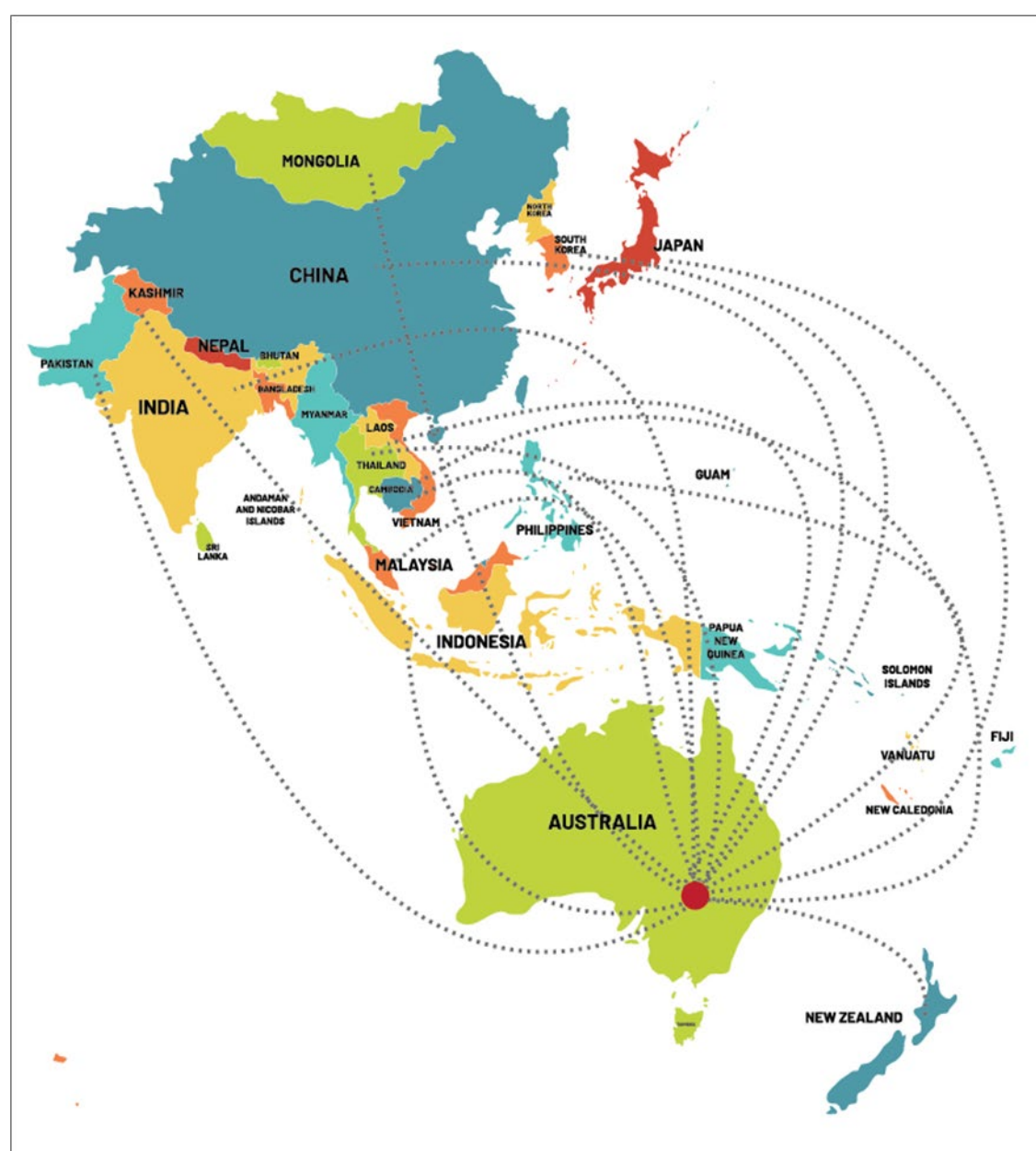
Data-Driven Information is Critical: Sequence analysis became critical during the pandemic. ATCC participated in working groups to ensure consistency among bioinformatic pipelines, which are fundamental to SARS-CoV-2 surveillance efforts. A bioresource center plays a critical role in providing sequence-verified viral stocks to support data-driven public health responses.

THE OPPORTUNITY IN THE ASIA PACIFIC

Establishing ATCC in Australia following ATCC's acquisition, production, authentication, and distribution model will:

- Support the growing biotech industry in Australia and foster biotech startup success
 - Improve access to ATCC products and services in the APAC region
 - Facilitates the production of biomaterials that are critical for the region's public health risks
- ATCC in the region is especially important for rapidly evolving pandemics:
- Provides a strong bio-surveillance opportunity building on existing platforms/partnerships
 - Provides worldwide sharing of data and materials following international agreements
 - Provides an innovation ecosystem evolution around the biorepository through the attraction of entrepreneurs, researchers, and startups focused on infectious disease countermeasures and translational products.

ATCC in Australia and APAC Region



ATCC in Australia would allow for more accessibility in the APAC region and would enable Australia's biotech growth, academic research, and clinical study development.

SUMMARY

The benefits of in-country bioresource centers are multifaceted and will improve the response rate to future outbreaks and pandemics. Bioresource centers support and facilitate research and product development for the region served. Facilitating the development and validation of biotechnological products and processes significantly contributes to the growth and competitiveness of biotechnology and related industries in the country and globally. Proactive surveillance of emerging pathogens will be supported by storing diverse microbial strains. Biomanufacturing capabilities will allow for both pandemic preparedness and response by establishing the agile and rapid supply of well-characterized cell lines, microorganisms, and other biological materials for drug discovery, development, and testing.

An ATCC presence in Australia will ease access to essential biological samples, expediting R&D in Australia. As a global leader in biomaterials, ATCC can immediately broaden the accessibility to imported and exported samples in the APAC region. Such access to biological samples would remove significant quarantine red tape, allowing for faster and better research. A bioresources center would enable Australia's biotech growth, academic research, and clinical study development. As well as attract investment and partnerships, helping to position Australia as a global leader in biotechnology and life sciences. In summary, ATCC will continue to explore collaboration with Australia to establish a bioresource center focused on improving global health.

ACKNOWLEDGEMENTS



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