SCRIP
CITELINE COMMERCIAL

09 Mar 2022 | **News**

Tech Transfer Roundup: How Can Translational Research Help With The Next Pandemic?

by Joseph Haas

Seven international translational research bodies recommend five actions to help better prepare for future outbreaks. Plus an overview of recent COVID-19-focused collaborations.

Fully two years into the COVID-19 pandemic, biopharmaceutical companies and academic/non-profit research organizations continue to partner on efforts to prevent and combat infections by the SARS-CoV-2 virus. But while the pandemic remains ongoing, a coalition of translational research bodies is using learnings from the COVID-19 experience to propose actions to help with the next pandemic.

Translation Together, an alliance comprising seven translational research organizations across North America, South America, the UK, European Union and Asia-Pacific, published an article on 28 January in *Nature Reviews/Drug Discovery* recommending five ways to better facilitate translational research to yield quicker and more equitably distributed medical solutions to the next global pandemic.

Led by Kanny Wan of the US *National Institutes of Health*'s *National Center for Advancing Translational Sciences* (NCATS), the article's authors note that while development of COVID-19 vaccines occurred in record time, persistent barriers to other aspects of fighting the pandemic became apparent. Translation Together proposes establishment of a global "safe zone" for rapid sharing of precompetitive data; flexible, responsive infrastructure for drug development resources; improved tracking and coordination to avoid duplicative efforts; establishment of adaptive funding mechanisms; and maintaining public health and pandemic preparedness.

"The response [to COVID-19] has led to remarkable scientific advances, but also revealed areas

that can be improved," the authors state. "TT members faced similar bottlenecks and challenges facilitating and coordinating translational efforts, irrespective of regional locations."

In addition to NCATS, Translation Together's membership includes Canada's AdMare Bioinnovations, the UK's *LifeArc*, the European Infrastructure for Translational Medicine (EATRIS-ERIC), Brazil's *Oswaldo Cruz Foundation*, the Japan Agency for Research and Development, and Therapeutic Innovation Australia.

Global Safe Zones For Open Research

While there was some swift dissemination of key COVID-19 research early in the pandemic due to online preprints, matters like publication priorities and intellectual property rights still hampered open data sharing, the authors said. "Sharing both positive and negative data without restrictions is crucial to recognizing opportunities and focusing limited resources toward fruitful research," they asserted.

One success was sharing results of high-throughput screening data for drug repurposing, which was an expeditious way to identify potential treatments, but concerns about IP rights and exclusivity still slowed the process, the article notes. A lack of obvious financial incentives across the spectrum of preclinical research also was a barrier. In clinical development, sharing of data was reluctant and lagging, the authors said.

"Such reactions are unintended products of conventional incentive structures and are not consistent with a collaborative model for translational research," they wrote. To address future pandemics, they recommend the collective research community needs to devise alternative incentive structures for assessing and benchmarking translational research results.

Development Infrastructure, Coordinated Tracking

Supplies and resources for taking translational science into development proved scarce during the pandemic and were quickly exhausted and/or difficult to access, the article notes. Another emerging issue was a lack of ready workforce capable of conducting experiments in biosafety environments. Together, these factors consumed valuable time and effort in the pandemic fight, the authors said.

"Rare successes in preparedness, such as in Brazil (due to their previous experiences with infectious disease outbreaks) highlighted the need to create and maintain established manufacturing facilities in non-pandemic times," they pointed out. Vaccine production capacity limitations hindered the pandemic effort in some regions, particularly in the poorest countries, the article adds.

Tracking and coordination of pandemic-responsive research should help to avoid duplicative efforts, the article says. Translation Together members that had effectively accounted for

existing research, facilities, labs and resources in non-pandemic times were able to mobilize more quickly against the pandemic and avoid duplicative work.

"Also urgently needed is a translational framework for clear coordination across all funding and policy regions to leverage global resources maximally and minimize waste," the authors stated.

Adaptive Funding, Maintaining Readiness

In some regions, existing research funding mechanisms hurt the efficiency and effectiveness of the pandemic effort, with translational research groups often needing to tap emergency funding mechanisms. "Better preparedness must include building flexibility in funding systems and establishing readily accessible emergency funds to accommodate rapidly shifting translational priorities," the authors asserted.

It also will be vital to capture and maintain current anti-pandemic momentum to be better prepared for future outbreaks, they said. Initiatives that could help toward this goal include: development of easy-to-access drug-repurposing platforms; expansion of screening libraries to include a broader range of agents with suspected antiviral activity; development of a pipeline of Phase II-ready candidates for rapid clinical evaluation; and building stockpiles of approved drugs with regulatory exemptions for cross-referencing of master files already in place to benefit pandemic response.

Recent COVID-19 Pandemic-Related Transactions:

- *Virios Therapeutics, Inc.* announced a collaboration on 28 February with Utah's *Bateman Horne Center (BHC)* to explore the role of combination antiviral therapy in long COVID, otherwise known as post-acute sequelae of COVID-19. The partners will evaluate IMC-2, a novel, proprietary combination of valacyclovir and celecoxib that combines two specific and synergistic mechanisms of action, purposely selected to inhibit herpes virus activation and replication.

- *Sunshine Biopharma Inc.* unveiled an alliance on 25 February with the *University of Arizona* to advance novel PLpro inhibitors discovered by University of Arizona and *University of Illinois, Chicago* researchers. At Arizona, the research will focus on determining the in vivo safety, pharmacokinetics and dose-selection properties of three university-owned PLpro inhibitors, followed by efficacy testing in MA10 mice infected with SARS-CoV-2. Molecules showing efficacy in infected mice will advance to human trials.

- Drug-repurposing specialist *Cantex Pharmaceuticals, Inc.* said on 23 February that it will team with *Harvard University*'s *Wyss Institute for Biologically Inspired Engineering* to develop azeliragon, a small molecule clinical candidate for inflammatory lung diseases including COVID-19. Cantex plans to conduct a Phase II trial to test azeliragon in hospitalized patients with severe COVID-19, as well as Phase II trials in other pulmonary inflammatory diseases

including chronic obstructive pulmonary disease and steroid-refractory asthma. Azeliragon previously has been tested for Alzheimer's disease and diabetic nephropathy, where it showed high levels of safety in Phase III clinical trials involving more than 2,000 patients. (Also see "*Alzheimer's Rollercoaster: Azeliragon Misses Endpoints, But Responding Subgroup Identified*" - Scrip, 13 Jun, 2018.)

- *Ena Respiratory* and the *COPD Foundation Inc.* announced a partnership on 23 February to develop INNA-051 in people with chronic lung diseases. Phase II studies to confirm the pan-antiviral potential of INNA-051 are expected to begin soon and include a randomized COVID-19 post-exposure antiviral prophylaxis study and an influenza challenge pre-exposure prophylaxis study.

- *Everest Medicines Limited* licensed global development and commercialization rights on 14 January to a series of viral 3C-like protease inhibitors discovered by Singapore's *Experimental Drug Development Centre* (EDDC) as potential COVID-19 oral antiviral treatments. EDDC gets an undisclosed upfront payment and can realize clinical and commercial milestone payments, as well as royalties on net sales. Clinical trials evaluating lead candidate EDDC-2214 are expected to begin later in 2022.

- *Tonix Pharmaceuticals Holding Corp.* unveiled a partnership with *Kansas State University* on 4 January to work on keeping mRNA vaccines for COVID-19 stable at a wide range of temperatures using the university's zinc nanoparticle technology, which could replace lipid nanoparticle technology employed in current COVID-19 vaccines.

- *BiondVax Pharmaceuticals Ltd.* signed definitive agreements on 22 December with the *Max Planck Innovation* and the *University Medical Center Göttingen*, both in Germany, to collaborate on the development and commercialization of COVID-19 nanosized antibodies (NanoAbs). NanoAbs have demonstrated strong neutralization at very low concentrations of major variants of concern including Alpha, Beta, Gamma and Delta in in vitro studies. Based on in silico studies, they also were expected to neutralize the Omicron variant.

- *BioVaxys Technology Corp.* signed a sponsored research collaboration on 7 December with *Ohio State University* to further develop the biotech's haptenized viral antigen platform to create a broadly reactive pan-sarbecovirus vaccine. The second COVID-19-focused partnership between BioVaxys and Ohio State, it will leverage the biotech's proprietary haptenized viral antigen platform to create a broadly reactive pan-sarbecovirus vaccine composed of hapten-modified S-spike protein from SARS-CoV-2 and a hapten-modified S-protein from SARS-CoV-1.