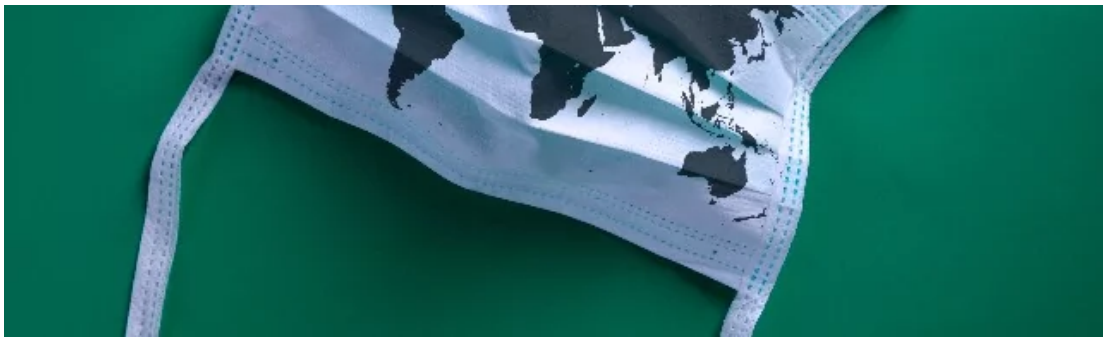
Current Efforts in COVID-19 Vaccine Development

ARTICLE (/drug-discovery/articles) Mar 23, 2020 | By Molly Campbell, Science Writer, Technology Networks



(/tn/editor/molly-campbell)

Molly Campbell (/tn/editor/molly-campbell)

Science Writer

@mollyrcampbell (https://twitter.com/mollyrcampbell)

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CEPI (https://cepi.net/), the Coalition for Epidemic Preparedness Innovations, is a global collaboration between public, private, philanthropic and civil society organizations. The collaboration was created in 2017 upon recognition that a coordinated plan was required to both develop and deploy vaccines in order to prevent future epidemics.

The human population is ever-increasing and aging. We continue to be challenged by emerging *and* re-emerging infectious pathogens. Take the 2014/2015 Ebola outbreak, for example. In their mission statement (https://cepi.net/about/whyweexist/), CEPI say: "Events like the devastating 2014/15 outbreak of Ebola in West Africa—which killed more than 11,000 people and had an economic and social burden of over $53 billion —showed us that very few vaccines are ready to be used against these threats."

CEPI says that the world's response to the Ebola crisis fell "tragically short", adding, "A vaccine that had been under development for more than a decade was not deployed until over a year into the epidemic. That vaccine was shown to be 100% effective, suggesting that much of the epidemic could have been prevented."

Now, the world faces a new challenge: the **COVID-19 outbreak**.

As the disease continues to spread and place extreme pressures on healthcare systems, the economy and general society, one of the key questions circulating is: Will there be a vaccine? And if so, when?

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A definitive answer does not exist at present, but one thing for certain is that there are many efforts underway in this space.

"CEPI has moved quickly and urgently to coordinate with global health authorities and partners to rapidly develop vaccine candidates against the disease," CEPI say (https://cepi.net/covid-19/).

In February of this year, CEPI released a global proposal which invited funding applications for vaccine technology that could potentially be used to develop a vaccine against SARS-CoV-2.

> *"CEPI was set up to accelerate the development of vaccines against emerging infectious threats like COVID-19. One of the ways we're doing this is by bridging the gap between public and private sectors to pool resources and expertise to jump start the vaccine development process." - Richard Hatchett, Chief Executive Officer, CEPI.*

CEPI has provided initial funding to Curevac Inc. (https://www.curevac.com/), Inovio Pharmaceuticals Inc. (https://www.inovio.com/), Moderna Inc (https://www.modernatx.com/)., Novavax Inc (https://novavax.com/)., the University of Hong Kong (https://www.hku.hk/), The University of Oxford (http://www.ox.ac.uk/), and The University of Queensland (https://www.uq.edu.au/) and most recently The Institut Pasteur (https://www.pasteur.fr/en) to develop COVID-19 vaccine candidates. To date, this funding totals $29.2 million. Details on the projects being funded by CEPI in this space are available on the organization's website (https://cepi.net/). Here, we highlight a selection of these projects.

Vaccine based on weakened version of the flu virus

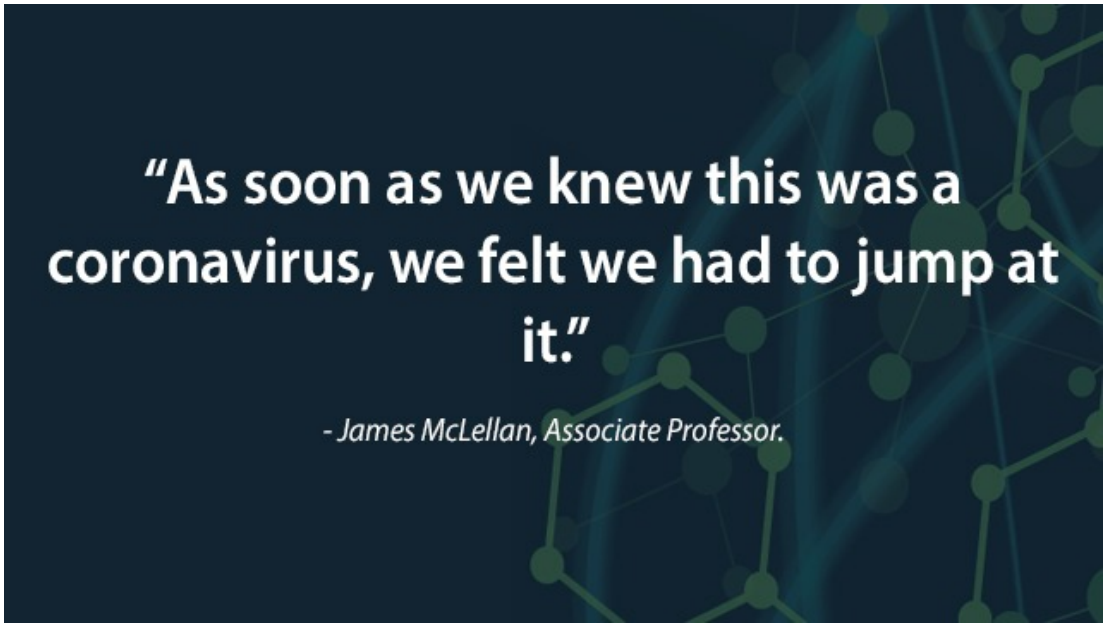
Scientists at the University of Hong Kong have developed a vaccine candidate based on a weakened version of the flu virus. It has been altered to express the surface protein of the SARS-CoV-2 virus; a method previously adopted in vaccine candidate development for MERS. The initial funding from CEPI will enable the University of Hong Kong to undertake preclinical testing of the candidate.

A measles vaccine vector

The Institut Pasteur are facilitating the development of a measles vaccine as a vector (https://cepi.net/news_cepi/cepi-collaborates-with-the-institut-pasteur-in-a-consortium-to-develop-covid-19-vaccine/) from which other recombinant vaccines can be designed to express antigens from other pathogens. "As part of the COVID-19 Task Force set up in January 2020, after our isolation of the coronavirus strains detected in France, the proprietary measles vector (MV) technology was chosen to develop a vaccine against SARS-CoV-2, leveraging our extensive experience with human measles vector technology and an MV-SARS-CoV-1 candidate," commented (https://cepi.net/news_cepi/cepi-collaborates-with-the-institut-pasteur-in-a-consortium-to-develop-covid-19-vaccine/) Stewart Cole, president of the Institut Pasteur.

An ongoing open-label trial

In January, the National Institutes of Health (NIH) and Moderna finalized the sequence for mRNA-1273, a vaccine against SARS-CoV-2. On March 16, the NIH announced (https://www.modernatx.com/modernas-work-potential-vaccine-against-covid-19) the first participant in a Phase 1 study of mRNA-1273. CEPI funded the manufacturing of the first batch of the vaccine, and the open-label trial is anticipated to recruit 45 healthy adult volunteers, providing data on the immunogenicity and safety of mRNA-1273.



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"mRNA is an emerging platform. Over the past few years, we have demonstrated its potential in vaccines across more than 1,000 subjects in our clinical trials. This includes successful early-stage (Phase I) clinical trials against five other respiratory viruses (two pandemic influenza strains, RSV, hMPV, and PIV3). Over the last four years, we have started nine clinical trials for mRNA vaccines," Moderna said (https://www.modernatx.com/modernas-work-potential-vaccine-against-covid-19).

The company emphasizes that it is still early in the story, but is preparing for a potential Phase II study under an investigational new drug filing to build on the data from the ongoing Phase I study.

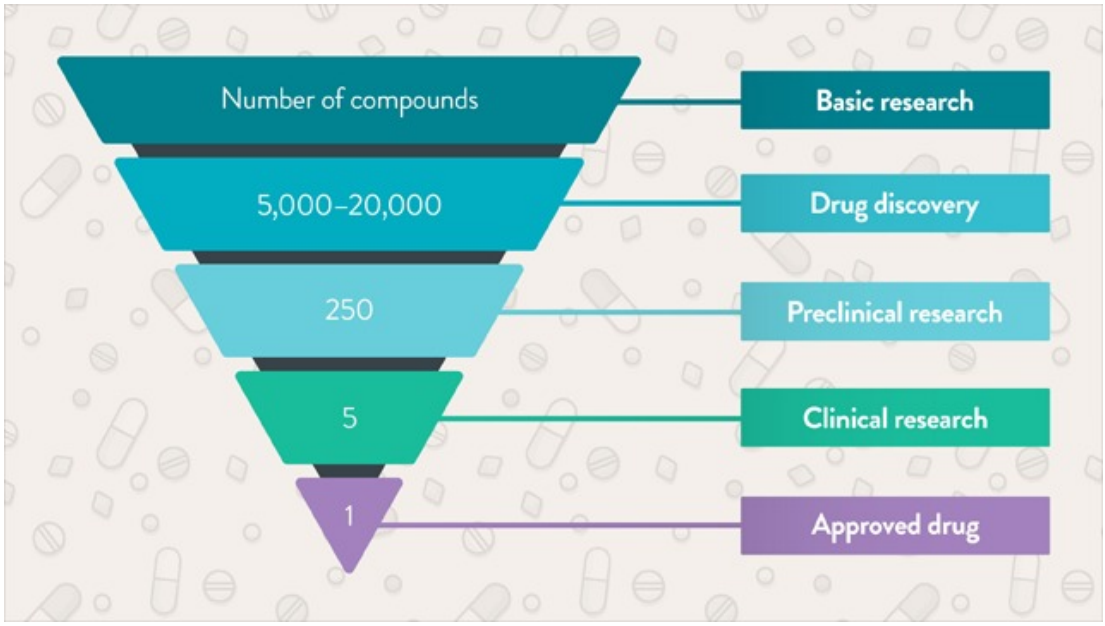
A vaccine candidate already "in the freezer"

Late-stage biotechnology company Novavax develops next-generation vaccines for a variety of serious infectious diseases. The company's COVID-19 vaccine candidates were created utilizing its recombinant protein nanoparticle technology (https://novavax.com/page/8/vaccine-technology.html) to produce antigens derived from the coronavirus spike (S) protein.

Technology Networks spoke with Gregory Glenn, MD, President of Research and Development at Novavax. He said, "In 2012 we generated a very good neutralizing antibody [against SARS]. This was in the freezer, and when the current SARS-CoV-2 popped up we brought it out of the freezer and conducted animal studies. We (and others) have evidence that immunity to SARS could neutralize the virus SARS-CoV-2."

Accelerating vaccine development in critical times

A key pressure point in the development of a vaccine against the COVID-19 virus is time. Considering the continual spreading of the virus and the increasing number of mortalities, time is not a luxury that we possess.



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The clinical development of a vaccine for humans follows the same general pathways as other drugs (https://www.technologynetworks.com/drug-discovery/articles/exploring-the-drug-development-process-331894) and biologics; including testing in pre-clinical models and eventually several phases of human clinical trials to determine efficacy, safety and dosage amongst other parameters. These can take several years to conduct. However, in the current climate, collaborative efforts are underway to fast-track these timelines.

Glenn told *Technology Networks,* "Under normal circumstances the development of a vaccine takes place via a well-structured schedule with set timelines for meetings with the Food and Drug Administration (FDA). In this context, the FDA are really collaborating with us to shorten the typical timeframes for certain conversations. We're hoping to have clinical trial data towards the end of summer that indicates the vaccine is safe and that it triggers a functional immune response."

Dr. J. Joseph Kim, Inovio's president and CEO shared an accelerated timeline at the U.S. Coronavirus Task Force meeting in early March. The company began preclinical testing of INO-4800 in January, and plan to conduct

human clinical trials in the U.S. in April (http://ir.inovio.com/news-and-media/news/press-release-details/2020/Inovio-Accelerates-Timeline-for-COVID-19-DNA-Vaccine-INO-4800/default.aspx), which will be shortly followed by testing in China and South Korea. Kim said: "We plan on delivering one million doses by year end with existing resources and capacity."

Moderna attribute (https://www.modernatx.com/modernas-work-potential-vaccine-against-covid-19) their swift advances in developing mRNA-1273 to previous experience in the field: "We were able to leverage our experience in vaccines to move rapidly on design and manufacture of material for the Phase 1 clinical trial. This included our broad understanding of the safety of our platform to date across more than 1,000 subjects."

FDA animal rule approval

One possible option to accelerate the timeline for vaccine development is approval under the Food and Drug Administration's (FDA) Animal Rule (https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/animal-rule-information). The rule was established to facilitate licensure of new products for life-threatening conditions when traditional efficacy trials in humans are unethical or impractical.

(https://cdn.technologynetworks.com/tn/images/body/labmouse1584984116946.jpg)*Credit: Pixabay.*

The rule enables approval of a product based on "adequate and well controlled" animal studies that imply it is "reasonably likely to produce clinical benefit in humans". In these situations, the product sponsor must still demonstrate the product's safety in humans. In November 2015, BioThrax, a vaccine against anthrax, became the first vaccine to receive approval for a new indication via the FDA'S Animal Rule pathway.[1]

Is this a plausible option for vaccine development against COVID-19? Glenn suggests so, for Novavax at least: "One thing that may happen is we make a decision to deploy the vaccine based on animal studies showing that it works. You can get really nice quantitative data from *in vitro* and animal studies that indicate how well the vaccine works," he said.

"Be under no illusion – vaccine development is tough"

It's clear that, as the world faces its worst public health crisis in a generation, scientists are striving full speed ahead on the frontline of vaccine development.

The speed at which the space has progressed in just a few months is no doubt impressive, and the achievements made thus far are not to be underestimated. Hatchett emphasizes (https://cepi.net/news_cepi/cepi-partners-with-university-of-hong-kong-to-develop-covid-19-vaccine/) that the work being undertaken is far from easy: "Be under no illusion – vaccine development is tough. It is complex and costly but CEPI was set-up specifically to overcome these challenges to rapidly develop vaccines against emerging infectious threats like the COVID-19 virus."

He added (https://cepi.net/news_cepi/cepi-partners-with-university-of-hong-kong-to-develop-covid-19-vaccine/): "There are no guarantees of success, but we are working flat out and, if all goes well, hope that a safe and effective vaccine will begin to become available for individuals at greatest risk within the next 12-18 months."

Reference:

1. Beasley, D., Brasel, T. & Comer, J. (2016). First vaccine approval under the FDA Animal Rule. *npj Vaccines.* https://doi.org/10.1038/npjvaccines.2016.13 (https://doi.org/10.1038/npjvaccines.2016.13).

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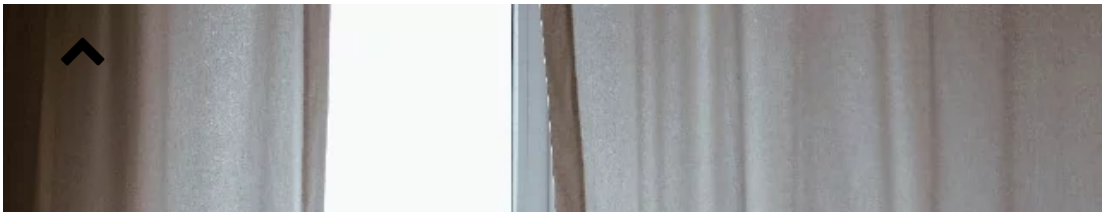

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One in four people on earth are currently in lockdown related to the spread of the novel coronavirus SARS-CoV-2. In this article, we look at some expert advice at how to cope with the impacts of this isolation on your mental health.

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Vivli, the Center for Clinical Research Data, recently issued a press release announcing the launch of the COVID-19 portal, designed to enable the sharing of completed interventional treatment trial data. *Technology Networks* spoke with Julie Wood, Vivli's Director of Strategy and Operations, to learn more about the COVID-19 portal and discover how researchers can access the data within the portal.

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In this article, we review two key questions that remain around the spread of the novel coronavirus SARS-CoV-2.

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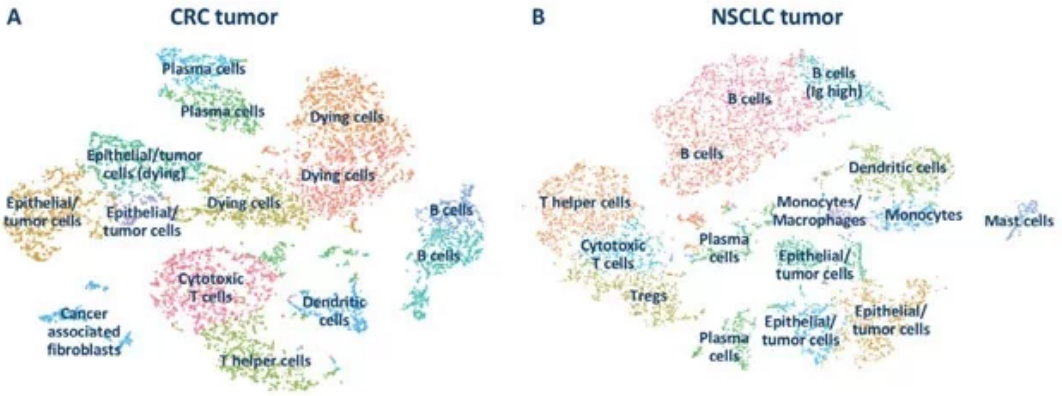

Figure 1. tSNE projections of cells output by Cell Ranger and visualized using the Loupe Cell Browser. Cells are grouped together based on expression profiles. Cell cluster classification was performed by manual curation. A. CRC tumor. B. NSCLC tumor.

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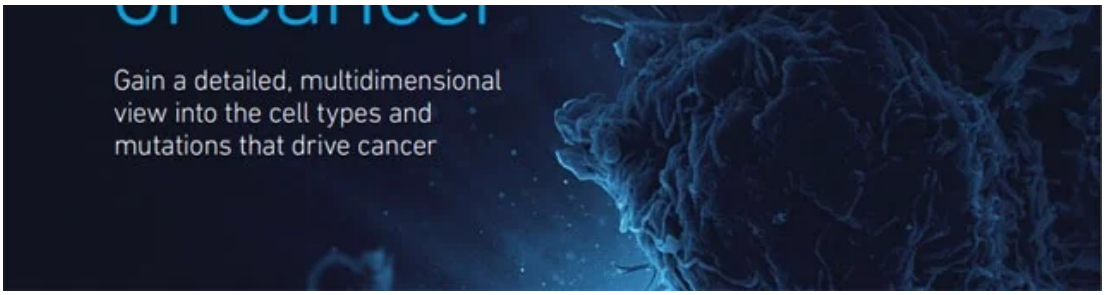

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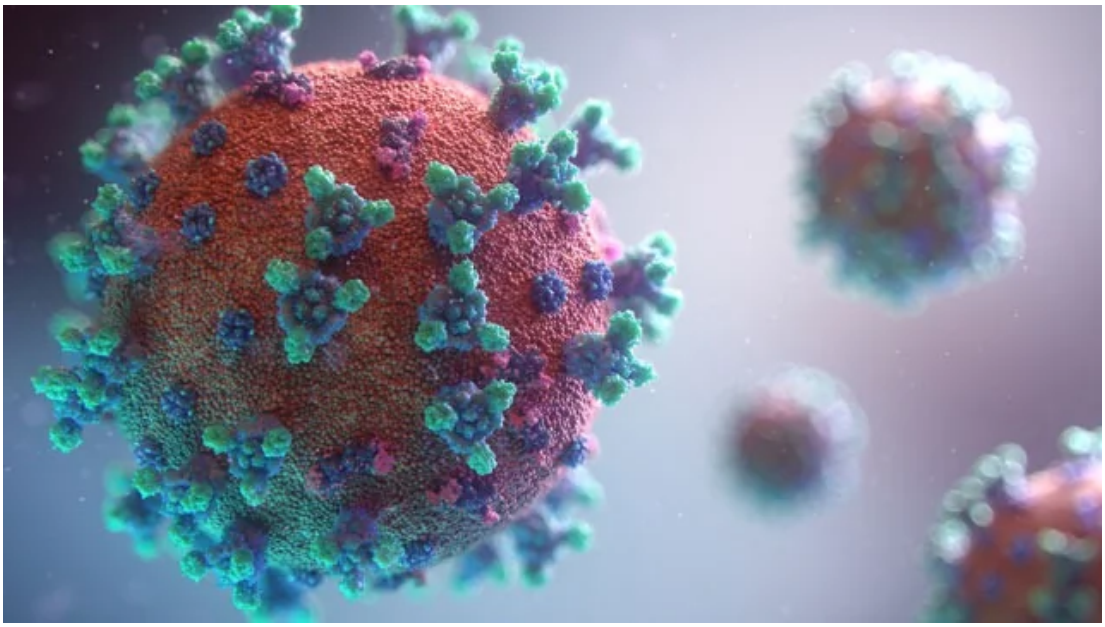

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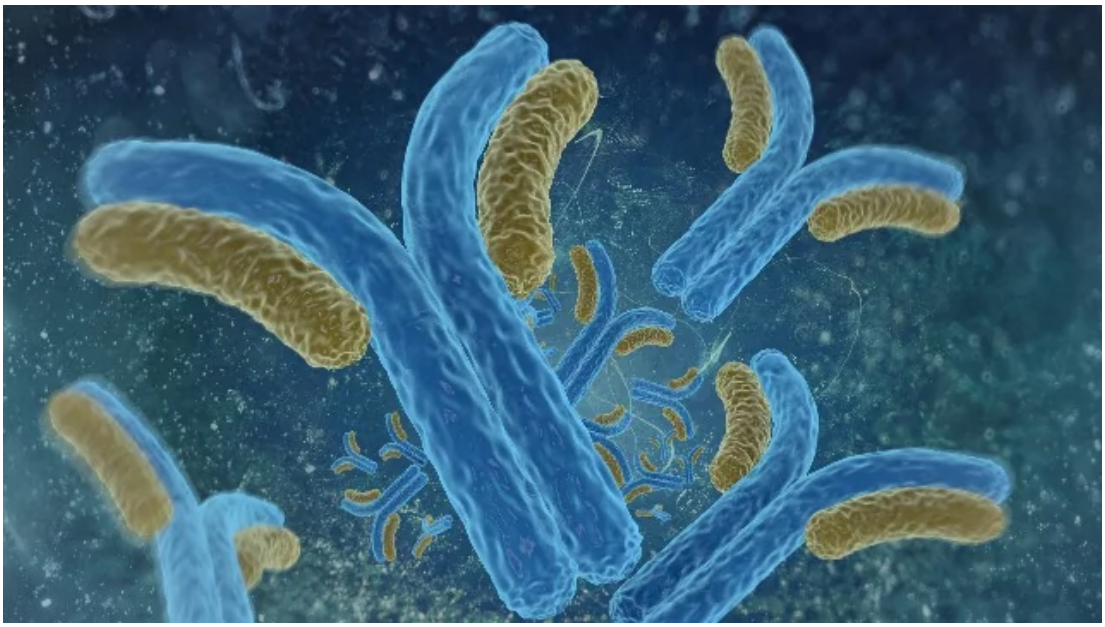

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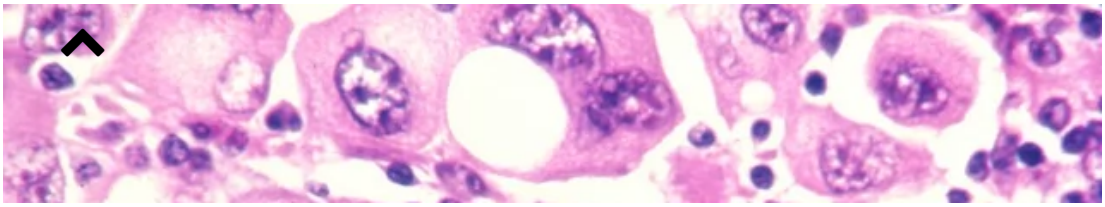

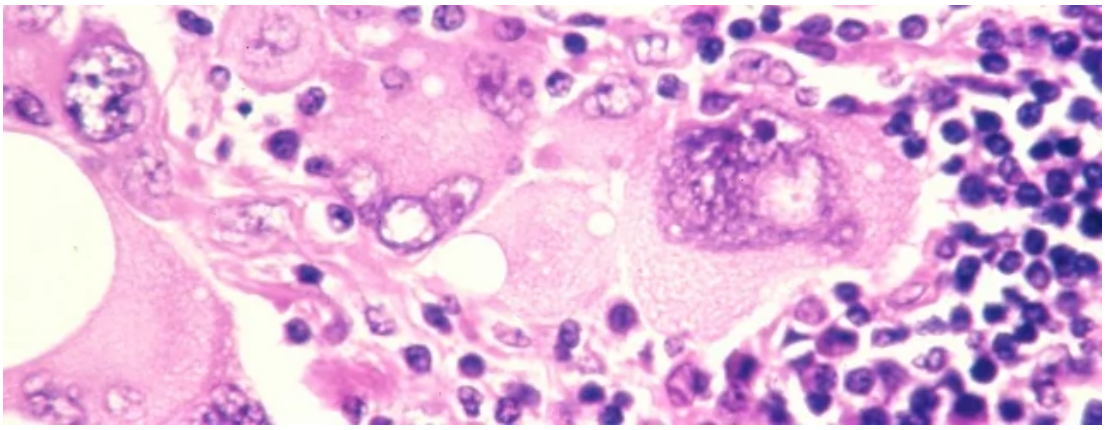

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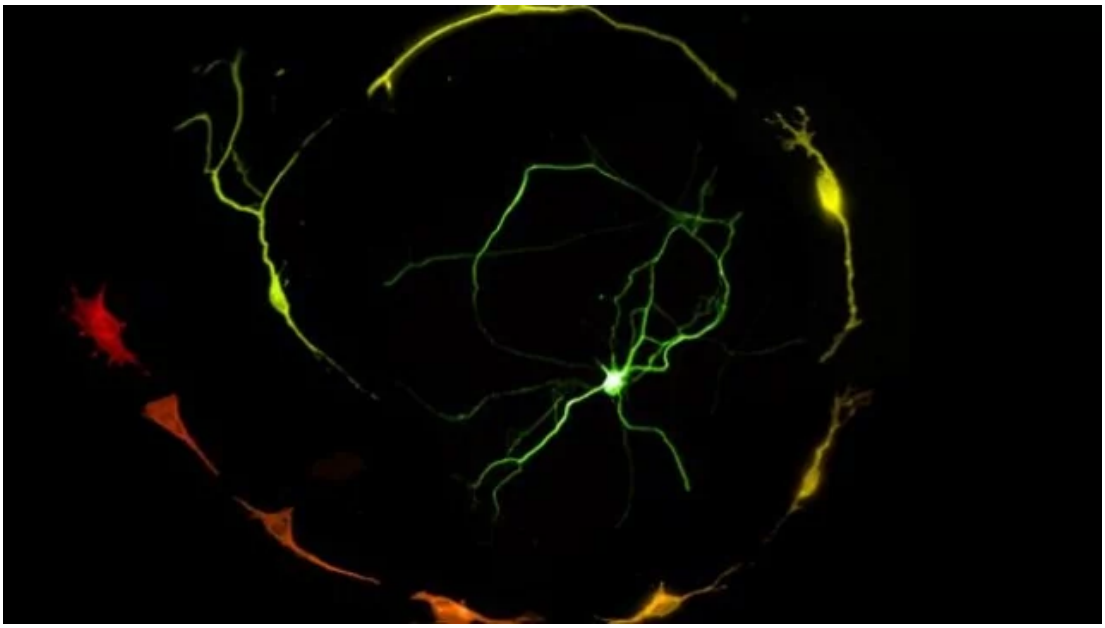

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