SONY

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Sony Biotechnology's range of fully automated cell sorting systems enable better:

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- Cytokines, and T and B cell analysis
- Single cell epigenomics of COVID-19 receptor expression
- Sorting of antibody-producing B cells for therapeutic antibody candidates

SH800 cell sorter

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THWARTING A PANDEMIC:

COVID-19 VACCINE STRATEGIES

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Sony Biotechnology Inc. is committed to supporting the research community in its mission to accelerate scientific knowledge about the SARS-CoV-2 virus and develop a much-needed cure or novel vaccine. Flow cytometry is an indispensable tool in this research, and Sony's microfluidics-based cell sorters are ideal high throughput and gentle isolation of cells for studies ranging from therapeutic monoclonal antibody discovery and immune repertoire analysis to single cell transcriptome analysis for the investigation of virus pathology. Sony's instruments – which include the MA900 Multi-Application Cell Sorter and SH800 Cell Sorter – are already being used for ground-breaking projects in this fast-moving field, including immune cell profiling, cytokine, and T and B cell analysis, single cell epigenomics and sorting of antibody-producing B cells for therapeutic antibody candidates.

Get answers faster with Sony's flow cytometry solutions – Sorting Made Simple™

THWARTING A PANDEMIC:
COVID-19 VACCINE STRATEGIES

It typically takes 5-20 years to develop a vaccine, but researchers are racing to develop one for COVID-19 within a much shorter timeframe due to the seriousness of the pandemic. To win this race, researchers must develop a vaccine that does not cause additional health problems, that provides long-term protection to prevent re-emergence of the virus in years to come, and that protects older people who may mount a weaker immune response. Several types of vaccines are currently in development, including deactivated viral vaccines, viral vector vaccines, RNA and DNA vaccines, and protein-based vaccines. Much work remains, but the number of agencies, pharmaceutical companies, and governments working on a potential COVID-19 vaccine is encouraging.

TYPICAL VACCINE DEVELOPMENT: 5-20 YEARS

1-10 YEARS			2-3 YEARS	2-4 YEARS		1+ YEARS
TARGET ID, PRECLINICAL TRIALS • Academic and governmental scientists identify natural or synthetic antigens that might help prevent or treat a disease. These may include virus-like particles, weakened viruses, or other pathogen-derived substances. • Researchers use tissue culture or cell culture and animal testing to broadly assess the safety and immunogenicity of the candidate vaccine.	**INVESTIGATIONAL NEW DRUG (IND) APPLICATION** • The sponsor company submits the IND. They describe the manufacturing and testing processes and the proposed study, and summarize preclinical laboratory reports.	**PHASE 1** • This first attempt to assess the candidate vaccine in humans involves a small group of adults, usually between 20-80 subjects. • Researchers assess the safety of the candidate vaccine and determine the type and extent of immune response that the vaccine provokes in humans.	**PHASE 2 / PROOF OF CONCEPT** • A larger group of several hundred individuals participates in Phase 2 testing. Some of the participants may belong to groups at risk of acquiring the disease. • The goals of Phase 2 testing are to study the candidate vaccine's safety, immunogenicity, proposed doses, schedule of immunizations, and method of delivery.	**PHASE 3** • Successful Phase 2 candidate vaccines move on to larger trials involving thousands to tens of thousands of people. • Vaccine safety, efficacy, and dose are confirmed.	**BIOLOGICS LICENSE APPLICATION (BLA) TO THE FDA** • Identity, purity, impurity, potency and quantity are demonstrated by analytical testing. • Analytical testing includes chromatography, electrophoresis, immunological assays, microbial analysis, and various stability tests. • The FDA will inspect the factory where the vaccine will be made and, if satisfied, approve the labeling of the vaccine.	**POST-MARKETING SURVEILLANCE** • Various surveillance schemes including Phase 4 trials, the Vaccine Adverse Event Reporting System, and the Vaccine Safety Datalink are used to monitor vaccine safety post-licensure.

SMALL-SCALE CLINICAL TRIALS MATERIAL → MANUFACTURING SCALE-UP, VALIDATION → LARGE-SCALE MANUFACTURING

COVID-19 VACCINE STRATEGY: 1 TO 2 YEARS

1-2 YEARS		
TARGET ID, PRECLINICAL TRIALS, IND FILING	**PHASE 1,2,3 CLINICAL TRIALS** • Safety / dose selection / efficacy	**EMERGENCY USE AUTHORIZATION (EUA) APPLICATION** • The EUA facilitates the availability and use of medical countermeasures needed during public health emergencies.

MANUFACTURING SCALE-UP, VALIDATION → LARGE-SCALE MANUFACTURING

Normally, vaccine development is a lengthy and expensive process, and failure rates are high. However, for COVID-19, a "pandemic paradigm" is necessary, with multiple overlapping steps.

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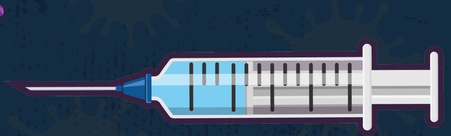
Multiple Targets, Multiple Efforts

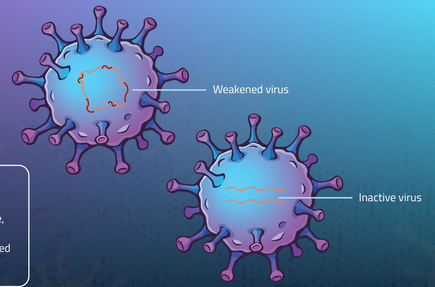
Since detecting SARS-CoV-2 in late 2019, numerous groups began working towards potential vaccines. By mid-2020, more than 100 vaccine projects were in development, with several supported by the nonprofit Coalition for Epidemic Preparedness Innovations (CEPI). By early June 2020, there were at least 10 candidate vaccines undergoing clinical evaluation, and at least nine in Phase 1 or 2 human trials.



Virus Vaccines

- Scientists make weakened viruses by introducing mutations to viral RNA.
- Inactivated viruses become non-infectious following treatment with chemicals or heat.

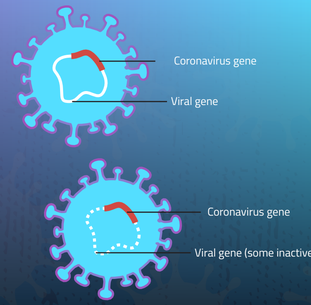
Vaccine candidates in human trials as of late May 2020:
- Sinovac, inactivated vaccine, Phase 1
- Sinopharm Group, inactivated vaccine, Phase 1/2



Viral Vector Vaccines

- Scientists weaken viruses such as measles or adenovirus and then modify them to carry genetic information for SARS-CoV-2 proteins.
- These viral vectors may replicate or be modified to make them incapable of replicating.

Vaccine candidates in human trials as of late May 2020:
- CanSino Biologicals, nonreplicating vector (two different vaccines), Phases 1 and 2
- University of Oxford/AstraZeneca, nonreplicating vector, Phase 1/2
- Shenzhen Geno-Immune Medical Institute, nonreplicating vector, Phase 1/2



Nucleic Acid Vaccines

- Composed of DNA or RNA encoding viral proteins, such as the spike (S) or membrane (M) proteins.
- RNA is often encased in lipids so that it can enter cells.

Vaccine candidates in human trials as of late May 2020:
- Inovio Pharmaceuticals, DNA vaccine, Phase 1
- Moderna/NIAID, RNA vaccine, Phase 1/2
- BioNTech/Pfizer, RNA vaccine, Phase 1/2

Protein Vaccines

- Protein subunits, such as S proteins or M proteins, or portions of subunits are mixed with adjuvants for injection.
- Empty viral shells lacking genetic information provoke a strong immune response, but are difficult to manufacture.

Several in preclinical development