

The graphic features a central dark blue circle containing the text 'UIC' in light blue. This circle is surrounded by a yellow ring, which is further enclosed by a red ring. Four thick lines radiate from the center: a yellow line pointing up and to the right, a red line pointing up and to the left, a yellow line pointing down, and a red line pointing down and to the right. The background is a solid light blue.

UIC

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Our Shared Path Forward to the Development of a Vaccine

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Epidemiological Update

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with Dr. Al Edwards
Slide Support & Graphics by
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SOME SIMPLE TRUTHS ABOUT

- PPE > placing a barrier between you and the virus decreases the likelihood of infection
- FACE COVERING/FACE MASKS> think of them as barriers [bandages] for your lungs, i.e., keeping the virus out of your lungs
- Nose & throat are the most likely entry points for the virus to infect you



SOME SIMPLE TRUTHS ABOUT (cont'd)

- HANDS > the most used and therefore the most opportunity for virus contamination
- Decrease the chances of virus invasion by washing with soap & water for 20 seconds or using a hand sanitizer with minimum 60% alcohol content
- Disposable gloves also provide a barrier

https://www.ted.com/talks/alex_rosenthal_and_pall_thordarson_which_is_better_soap_or_hand_sanitizer?language=en



WE'RE ALL IN THIS TOGETHER

- Based on the highly contagious and potentially lethal nature of the virus
- **Your safety depends on me, and my safety depends on you**



WHY PPE VERSUS A DRUG OR VACCINE?

- Currently there are no **proven**, effective therapies
- Barriers, via PPE, are the best choice, at this time



KEEPING UP WITH THE NUMBERS:

- Using the reference numbers for each state can get to state statistics

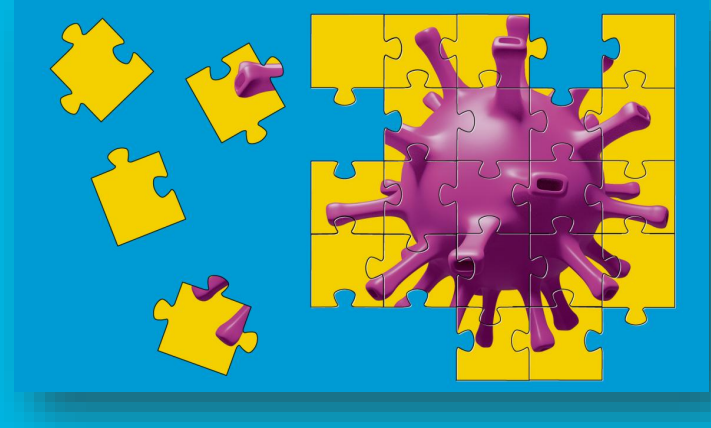
Now Yesterday Search:

USA State	Total Cases	New Cases	Total Deaths	New Deaths	Active Cases	Tot Cases/ 1M pop	Deaths/ 1M pop	Total Tests	Tests/ 1M pop	Source	Proj
USA Total	2,204,639	+21,689	119,069	+786	1,187,263	6,660	360	25,652,670	77,500		
New York	405,715	+576	30,994	+42	288,543	20,856	1,593	3,051,778	156,875	[view by county] [1] [2] [3] [4]	
New Jersey	170,250	+446	12,837	+55	123,450	19,168	1,445	1,131,782	127,422	[view by county] [1]	
California	158,345	+2,744	5,187	+68	110,734	4,007	131	2,937,755	74,351	[view by county] [1]	
Illinois	133,639	+623	6,398	+72	42,239	10,546	505	1,228,341	96,935	[1] [2] [3] [4]	
Massachusetts	105,885	+195	7,665	+18	13,599	15,362	1,112	778,031	112,881	[1]	
Texas	93,575	+2,195	2,061	+45	30,833	3,227	71	1,522,434	52,505	[view by county] [1] [2]	
Pennsylvania	84,083	+394	6,347	+25	20,486	6,568	496	612,700	47,860	[view by county] [1]	
Florida	80,109	+2,783	2,996	+55	61,423	3,730	139	1,461,297	68,038	[view by county] [1]	

<https://www.worldometers.info/coronavirus/country/us/>

THE BOTTOM LINE

- It is still early in the discovery life of this virus
- There are many things we do not know or do not know with certainty
- Expect health authorities to offer changes to our lifestyles
- A 2-5 year plan for changing how we live and what we do
- Is likely in order





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Our Shared Path Forward to the Development of a Vaccine

DIAGNOSTICS:

A brief education on antibody and antigen testing

with Dr. Al Edwards

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COVID-19 Diagnostics

A brief education on Swab & Blood testing for the coronavirus

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TESTING FOR THE CORONAVIRUS

Two types of Tests

- Swabbing, aka, Diagnostic Tests
- Blood Test, aka, Antibody Test



Swab Tests Can be Further Divided into THREE TYPES of TESTS

- All tests detect viral substances from the SARS-CoV-2 virus
- **Molecular** tests detect viral RNA
- **PCR**, aka Polymerase Chain Reaction tests detect viral DNA
- Both Molecular & PCR tests multiply viral DNA so it can be more easily detected
- **Antigen** tests detect the presence of viral proteins



What tests could potentially be used for the screening, diagnosis and monitoring of COVID-19

#EvidenceCOVID

Kile Green, Amanda Winter, Rachel Dickinson, Sara Graziadio, Robert Wolff, Susan Mallett, A. Joy Allen
20th APRIL 2020

<https://www.cebm.net/covid-19/what-tests-could-potentially-be-used-for-the-screening-diagnosis-and-monitoring-of-covid-19-and-what-are-their-advantages-and-disadvantages/>

Swab Tests (cont'd)

- They all answer the same question: *Do I have the virus, NOW?*
- When you have current virus-related symptoms, e.g.,



- Fever
- Cough
- Shortness of breath
- Chills
- Muscle pain
- Recent loss of taste or smell
- Vomiting
- Diarrhea and/or
- Sore throat

Swab Tests (cont'd)

- Why a nasal swab: nose/throat are the most likely ways the virus invades the body
- How: by swabbing the nasopharyngeal passages, i.e.,
- The upper throat area behind nose
- CAUTION: swab insertion can be uncomfortable



Body Immunity / Antibody / Serologic Testing

- Detects the body's response to the virus and NOT viral substances
- When: well after you've had the virus and recovered
- Usually 1 to 3 weeks or more after all your symptoms have resolved
- How: blood sample



FDA STATUS of ALL COVID-19 TESTS

- 120 tests have received Emergency Use Authorization or an EUA
- EUAs are not the same as an FDA APPROVAL
- The majority are Swab Tests: 104 **Molecular** Tests & 1 **Antigen** Test, and
- There are 5 **Antibody** Tests available [on the market] through EUA

HOW EUAs DIFFER FROM FDA APPROVALS:

- APPROVALS are awarded when all required testing has been completed & verified
- They are permanent
- EUAs are temporary “passes” for manufacturers to sell and market their products
- During a **defined emergency**, such as a **pandemic**

HOW EUAs DIFFER FROM APPROVALS (cont'd)

- FDA using its best judgement, places achievable limits on tests and works with test developers
- Allowing the tests use during a public health emergency
- This was done, initially, with the EBOLA virus outbreak in 2013

HOW EUAs DIFFER FROM APPROVALS (cont'd)

- EUAs were started on January 31, 2020, for the SARS-CoV-2 virus pandemic
- EUAs will cease end when the pandemic is no longer an **emergency**
- With all EUA-marketed tests being withdrawn

Home / Medical Devices / Medical Device Safety / Emergency Situations (Medical Devices) / Historical Information about Device Emergency Use Authorizations

Historical Information about Device Emergency Use Authorizations

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This page is intended to provide reference information on EUAs that were previously issued, including revoked EUAs.

In Vitro Diagnostics (IVD)

Content current as of: 06/16/2020

Regulated Product(s)
Medical Devices

Test	Date**	Letter of Authorization	Fact Sheet for Healthcare Providers	Fact Sheet for Patients	Labeling (PDF)
DPP COVID-19 IgM/IgG System (Chembio Diagnostic System, Inc.)	04/14/2020	[Authorization]	[Healthcare]	[Patients]	[Labeling]

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/historical-information-about-device-emergency-use-authorizations>

Helpful FDA Video on Tests

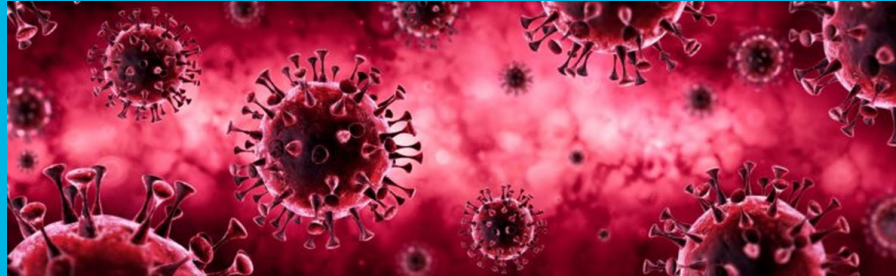
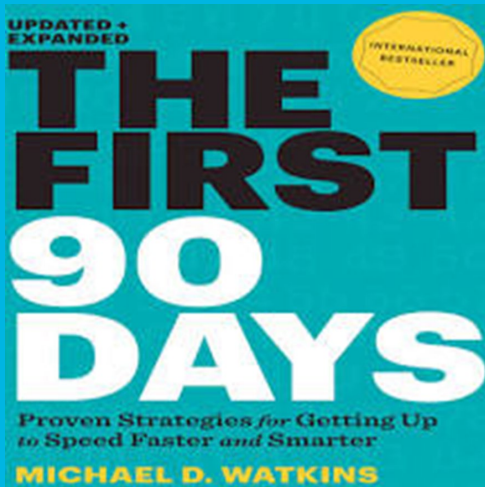


https://www.youtube.com/watch?v=5hu7_xlsCRg

https://www.ted.com/talks/cella_wright_how_do_virus_tests_actually_work



Sars-Cov-2/Covid-19 Therapeutics and Vaccines



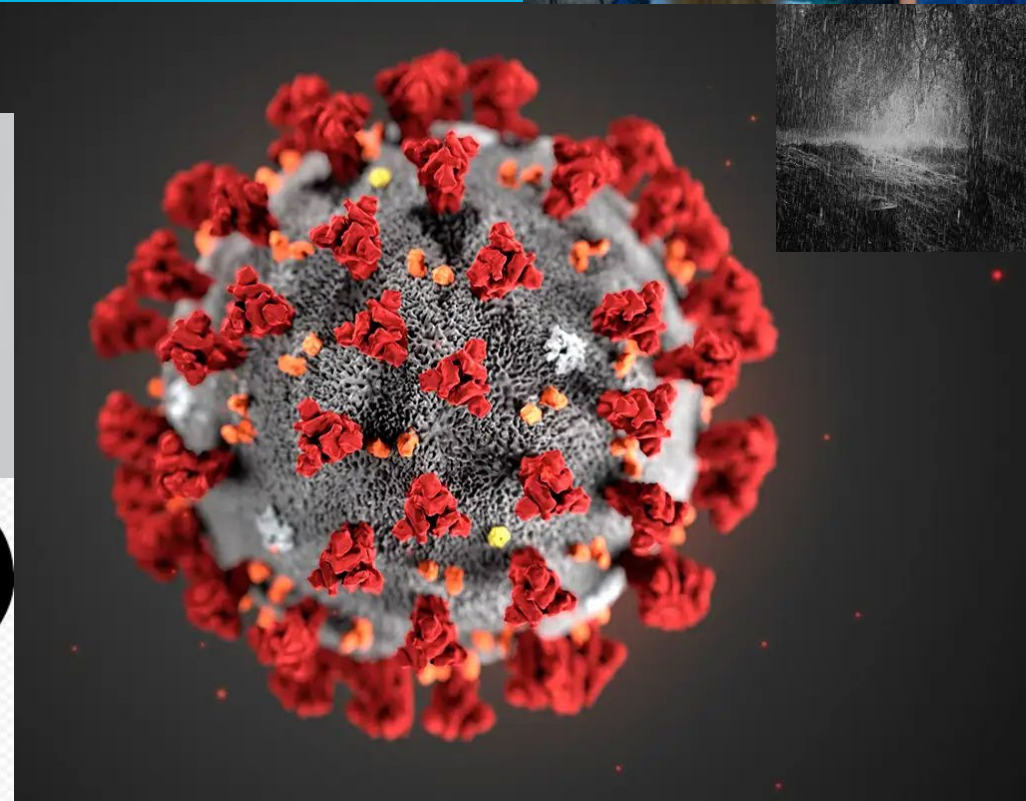
by

Thomas Kanyok, BS Pharm, PharmD, RPh



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Where We Are Now



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Therapeutics

Anti-virals and Anti-inflammatories

There are currently no FDA approved therapeutics but a number of products have been made available through EUA

Clinical Trials

- Operation Warp Speed (OWS)
 - <https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html>
- <https://www.recoverytrial.net/>
 - Chloroquine/Hydroxychloroquine
 - Dexamethasone
- National COVID-19 Convalescent Plasma Project
- SOLIDARITY World Health Organization (WHO).
 - > 100 countries have joined SOLIDARITY to evaluate high-profile treatment candidates for COVID-19 including hydroxychloroquine
- Interleukins cytokine storm: Tocilizumab and sarilumab IL-6 inhibitors, anakinra IL-1 inhibitor.

Other countries

- Avigan (favilavir) in China, Italy and Russia
- Veklury (remdesivir) in Japan.

Operation Warp Speed (OWS)

- Collaboration of several US federal government departments including the **Department of Defense, Health and Human Services** and its subagencies, Agriculture, Energy and Veterans Affairs and the private sector.
- Within OWS, the US National Institutes of Health (NIH) has partnered with more than 18 biopharmaceutical companies to accelerate development of drug and vaccine candidates for COVID-19 in a collaboration dubbed Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV).
- So far, the effort has yielded 14 vaccine candidates from more than 100 that are in development. Some of those are in clinical trials now.
- Those 14 will be further narrowed down to seven candidates, and the most promising of those will get further testing and clinical trials.
- Operation Warp Speed has also been working with multiple companies to quickly manufacture a vaccine and to develop solutions for distribution of that vaccine once it is ready. This includes tools such as pre-filled syringes, vials and containers.
- **May 21: HHS announced up to \$1.2 billion in support for AstraZeneca's candidate vaccine, developed in conjunction with the University of Oxford. The agreement is to make available at least 300 million doses of the vaccine for the United States, with the first doses delivered as early as October 2020 and Phase 3 clinical studies beginning this summer with approximately 30,000 volunteers in the United States.**

RECOVERY

Randomised Evaluation of COVID-19 Therapy



- This United Kingdom based national clinical trial aims to identify treatments that may be beneficial for people hospitalised with suspected or confirmed COVID-19
- Principle Investigator - Peter Horby, Professor of Emerging Infectious Diseases and Global Health
- A range of potential treatments have been suggested for COVID-19 but nobody knows if any of them will turn out to be more effective in helping people recover than the usual standard of hospital care which all patients will receive. The RECOVERY Trial is currently testing some of these suggested treatments:
 - Lopinavir-Ritonavir (commonly used to treat HIV)
 - Low-dose Dexamethasone (now only recruiting children)
 - Azithromycin (a commonly used antibiotic)
 - Tocilizumab (an anti-inflammatory treatment given by injection)
 - Convalescent plasma (collected from donors who have recovered from COVID-19 and contains antibodies against the SARS-CoV-2 virus).
- Data from the trial are regularly reviewed so that any effective treatment can be identified quickly and made available to all patients. Please see our news page for results that RECOVERY has already found. The RECOVERY Trial team will constantly review information on new drugs and include promising ones in the trial.

Chloroquine/Hydroxychloroquine

- ‘We have concluded that there is no beneficial effect of hydroxychloroquine in patients hospitalised with COVID-19. We have therefore decided to stop enrolling participants to the hydroxychloroquine arm of the RECOVERY Trial with immediate effect. We are now releasing the preliminary results as they have important implications for patient care and public health.
- ‘A total of **1542 patients** were **randomised to hydroxychloroquine** and **compared with 3132 patients randomised to usual care alone**. There was **no significant difference in the primary endpoint of 28-day mortality (25.7% hydroxychloroquine vs. 23.5% usual care; hazard ratio 1.11 [95% confidence interval 0.98-1.26]; p=0.10)**. There was also no evidence of beneficial effects on hospital stay duration or other outcomes.
- ‘These data **convincingly rule out any meaningful mortality benefit of hydroxychloroquine in patients hospitalised with COVID-19**. Full results will be made available as soon as possible.
- **16 June 2020 FDA pulls EUA for hydroxychloroquine/chloroquine**

Dexamethasone

- In March 2020, the RECOVERY (Randomised Evaluation of COVID-19 thERapY) trial was established as a randomised clinical trial to test a range of potential treatments for COVID-19, including low-dose dexamethasone (a steroid treatment). Over 11,500 patients have been enrolled from over 175 NHS hospitals in the UK.
- On 8 June, recruitment to the dexamethasone arm was halted since, in the view of the trial Steering Committee, sufficient patients had been enrolled to establish whether or not the drug had a meaningful benefit.
- A total of 2104 patients were **randomised to receive dexamethasone 6 mg once per day (either by mouth or by intravenous injection) for ten days** and were compared with 4321 patients randomised to usual care alone. Among the patients who received usual care alone, 28-day mortality was highest in those who required ventilation (41%), intermediate in those patients who required oxygen only (25%), and lowest among those who did not require any respiratory intervention (13%).
- **Dexamethasone reduced deaths by one-third in ventilated patients (rate ratio 0.65 [95% confidence interval 0.48 to 0.88]; p=0.0003) and by one fifth in other patients receiving oxygen only (0.80 [0.67 to 0.96]; p=0.0021). There was no benefit among those patients who did not require respiratory support (1.22 [0.86 to 1.75]; p=0.14).**
- Based on these results, **1 death would be prevented by treatment of around 8 ventilated patients or around 25 patients requiring oxygen alone.**

Convalescent Plasma – Mayo Clinic

Early Safety Indicators of COVID-19 Convalescent Plasma in 5,000 Patients J Clin Invest 2020 Jun 11 Michael J Joyner et al.

- Background: **Convalescent plasma** is the only antibody based therapy currently available for COVID 19 patients. It **has robust historical precedence** and **sound biological plausibility**. Although promising, convalescent plasma has not yet been shown to be safe as a treatment for COVID-19.
- Methods: Thus, we analyzed key safety metrics after transfusion of **ABO compatible human COVID-19 convalescent plasma in 5,000 hospitalized adults with severe or life threatening COVID-19, with 66% in the intensive care unit**, as part of the US FDA Expanded Access Program for COVID-19 convalescent plasma.
- Results: The incidence of all serious adverse events (**SAEs**) in the first four hours after transfusion was **<1%**, including mortality rate (0.3%). Of the 36 reported SAEs, there were 25 reported incidences of related SAEs, including mortality (n = 4), transfusion-associated circulatory overload (TACO; n = 7), transfusion-related acute lung injury (TRALI; n = 11), and severe allergic transfusion reactions (n = 3). However, only 2 (of 36) SAEs were judged as definitely related to the convalescent plasma transfusion by the treating physician. **The seven-day mortality rate was 14.9%**.
- Conclusion: Given the deadly nature of COVID 19 and the large population of critically-ill patients included in these analyses, the mortality rate does not appear excessive. These **early indicators suggest** that transfusion of **convalescent plasma is safe in hospitalized patients with COVID-19**.

Avigan (favilavir)

15 March 2020, the drug was approved in China for SARS-CoV-2

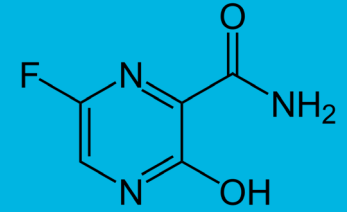
Zhejiang Hisun Pharmaceutical

Toyama Chemical (Fujifilm group) approved in Japan for influenza in 2014

Broad spectrum anti-viral mechanism of its actions is thought to be related to the selective inhibition of viral RNA-dependent RNA polymerase.

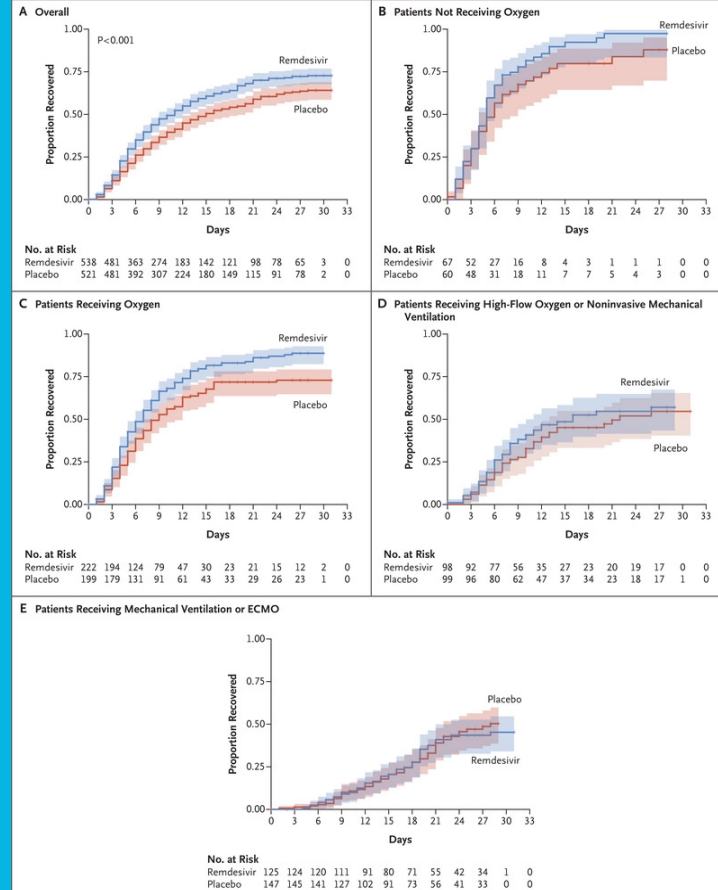
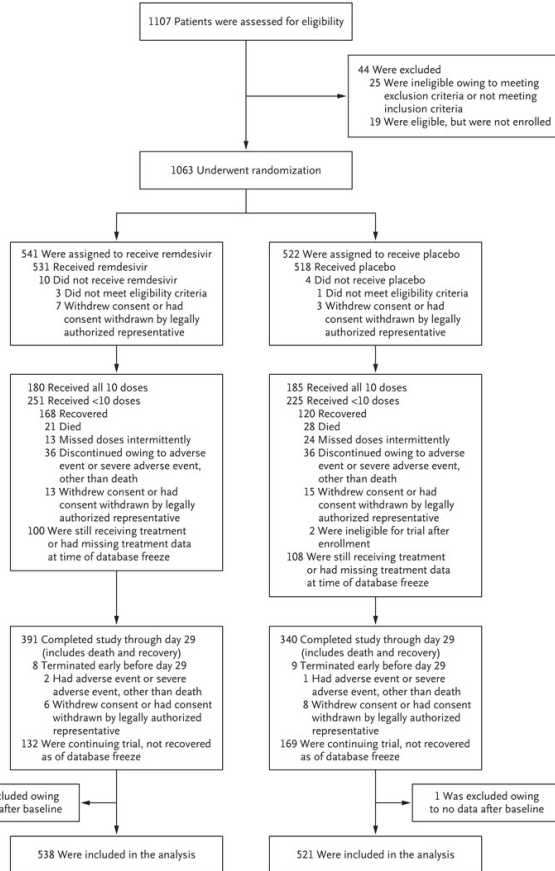
Has reportedly shown efficacy in treating the disease with minimal side effects in a clinical trial involving 70 patients. The clinical trial is being conducted in Shenzhen, Guangdong province.

US Department of Defense developed favipiravir in partnership with MediVector, Inc. as a broad-spectrum antiviral and sponsored it through FDA Phase II and Phase III clinical trials, where it demonstrated safety in humans and efficacy against the influenza virus. Was developed to replace Tamiflu (oseltamivir). **However, animal experiments show the potential for teratogenic effects.**



Veklury (remdesivir)

Preliminary Report NEJM May 22, 2020 John H. Beigel, M.D. et al., ACTT-1 Study Group Members*



Tom Kanyok, BS Pharm, PharmD, RPh

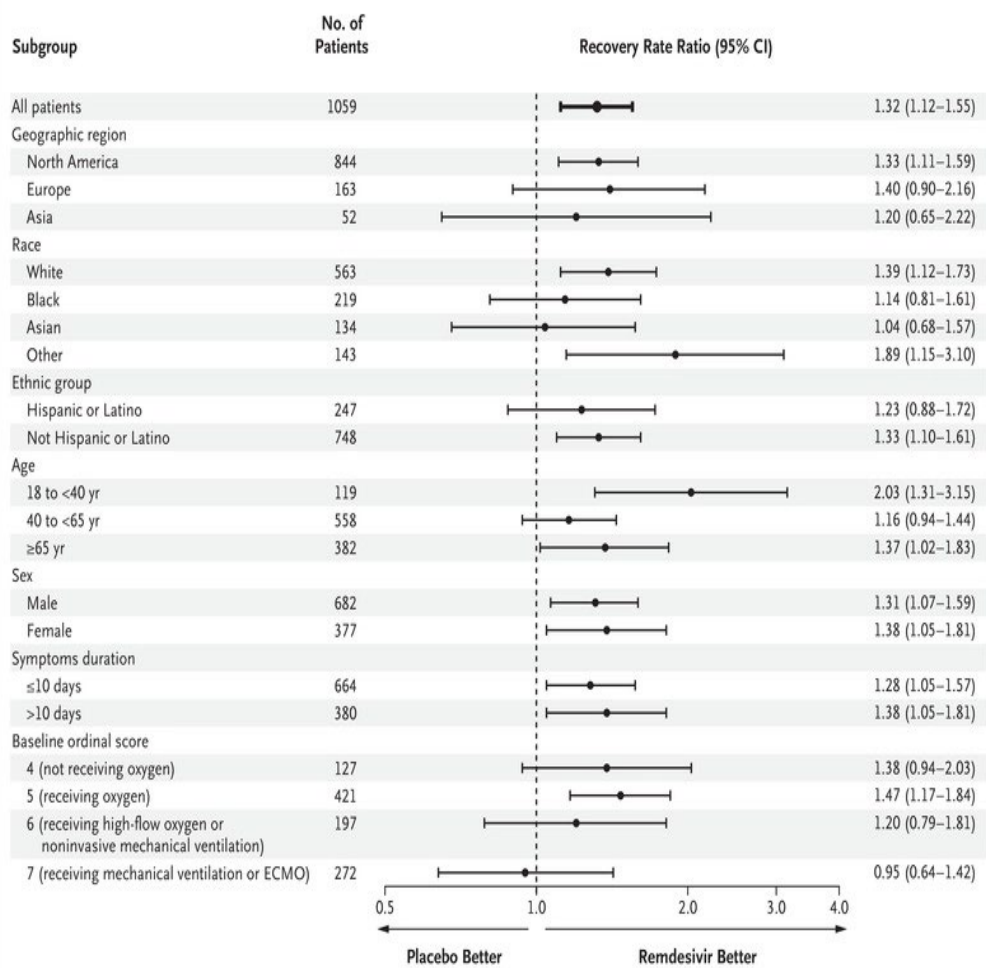
Table 2. Outcomes Overall and According to Score on the Ordinal Scale in the Intention-to-Treat Population.^a

	Overall ^b		Ordinal Score at Baseline							
			4		5		6		7	
	Remdesivir (N=538)	Placebo (N=521)	Remdesivir (N=67)	Placebo (N=60)	Remdesivir (N=222)	Placebo (N=199)	Remdesivir (N=98)	Placebo (N=99)	Remdesivir (N=125)	Placebo (N=147)
Recovery										
No. of recoveries	334	273	61	47	177	128	47	43	45	51
Median time to recovery (95% CI) — days	11 (9–12)	15 (13–19)	5 (4–6)	6 (4–8)	7 (6–8)	9 (7–11)	16 (NE–10)	22 (NE–12)	NE–NE	28 (NE–22)
Rate ratio (95% CI) [†]	1.32 (1.12–1.55 [P<0.001])		1.38 (0.94–2.03)		1.47 (1.17–1.84)		1.20 (0.79–1.81)		0.95 (0.64–1.42)	
Mortality										
Hazard ratio (95% CI)	0.70 (0.47–1.04)		0.46 (0.04–5.08)		0.22 (0.08–0.58)		1.12 (0.53–2.38)		1.06 (0.59–1.92)	
No. of deaths by day 14	32	54	1	1	4	19	13	13	13	19
Kaplan–Meier estimate —% (95% CI)	7.1 (5.0–9.9)	11.9 (9.2–15.4)	1.5 (0.2–10.1)	2.5 (0.4–16.5)	2.4 (0.9–6.4)	10.9 (7.1–16.7)	15.2 (9.0–25.0)	14.7 (8.7–24.3)	11.3 (6.7–18.8)	14.1 (9.2–21.2)
Ordinal score at day 15 (±2 days) — no. (%)[‡]										
Patients with baseline and day 15 score data — no.	434	410	60	51	196	161	71	77	101	115
1	99 (22.8)	76 (18.5)	22 (36.7)	15 (29.4)	54 (27.6)	45 (28.0)	13 (18.3)	7 (9.1)	10 (9.9)	8 (7.0)
2	158 (36.4)	127 (31.0)	25 (41.7)	21 (41.2)	95 (48.5)	66 (41.0)	28 (39.4)	27 (35.1)	6 (5.9)	10 (8.7)
3	11 (2.5)	6 (1.5)	7 (11.7)	4 (7.8)	4 (2.0)	2 (1.2)	0	0	0	0
4	23 (5.3)	20 (4.9)	1 (1.7)	3 (5.9)	12 (6.1)	7 (4.3)	4 (5.6)	4 (5.2)	6 (5.9)	6 (5.2)
5	34 (7.8)	40 (9.8)	3 (5.0)	5 (9.8)	14 (7.1)	6 (3.7)	2 (2.8)	7 (9.1)	15 (14.9)	22 (19.1)
6	16 (3.7)	14 (3.4)	1 (1.7)	0 (0)	1 (0.5)	3 (1.9)	6 (8.5)	6 (7.8)	7 (6.9)	5 (4.3)
7	60 (13.8)	72 (17.6)	0 (0)	2 (3.9)	12 (6.1)	12 (7.5)	5 (7.0)	13 (16.9)	43 (42.6)	45 (39.1)
8	33 (7.6)	55 (13.4)	1 (1.7)	1 (2.0)	4 (2.0)	20 (12.4)	13 (18.3)	13 (16.9)	14 (13.9)	19 (16.5)
Odds ratio (95% CI)	1.50 (1.18–1.91 [P=0.001])		1.51 (0.76–3.00)		1.31 (0.89–1.92)		1.60 (0.89–2.86)		1.04 (0.64–1.68)	

^a P values and confidence intervals have not been adjusted for multiple comparisons. NE denotes not possible to estimate.

[†] Recovery rate ratios and hazard ratios were calculated from the stratified Cox model; P values for these ratios were calculated with the stratified log-rank test. Recovery rate ratios greater than 1 indicate a benefit for remdesivir; hazard ratios less than 1 indicate a benefit for remdesivir.

[‡] The ordinal score at day 15 is the patient's worst score on the ordinal scale during the previous day. In the remdesivir group, 103 patients did not have ordinal scale scores for the day 15 visit at the time of the data freeze (11 with mild-to-moderate illness and 92 with severe illness). In the placebo group, 109 patients did not have ordinal scale scores for the day 15 visit at the time of the data freeze (12 with mild-to-moderate illness and 97 with severe illness). Two patients died 15 days after randomization and are included in the ordinal scale scores but not in the estimate of mortality by day 14. Scores on the ordinal scale are as follows: 1, not hospitalized, no limitations of activities; 2, not hospitalized, limitation of activities, home oxygen requirement, or both; 3, hospitalized, not requiring supplemental oxygen and no longer requiring ongoing medical care (used if hospitalization was extended for infection-control reasons); 4, hospitalized, not requiring supplemental oxygen but requiring ongoing medical care (Covid-19–related or other medical conditions); 5, hospitalized, requiring any supplemental oxygen; 6, hospitalized, requiring noninvasive ventilation or use of high-flow oxygen devices; 7, hospitalized, receiving invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO); and 8, death. Odds ratios and P values were calculated with the use of a proportional odds model. Odds ratio values greater than 1 indicate a benefit for remdesivir.



SIDP recommendations - Remdesivir

Recommendation for Hospitalized Patients with Severe COVID-19:

- The COVID-19 Treatment Guidelines Panel (the Panel) recommends the investigational antiviral agent remdesivir for treatment of COVID-19 in hospitalized patients with $SpO_2 \leq 94\%$ on ambient air (at sea level) or those who require supplemental oxygen **(AI)**.
- The Panel recommends remdesivir for treatment of COVID-19 in patients who are on mechanical ventilation or extracorporeal membrane oxygenation (ECMO) **(BI)**.

Recommendation for Duration of Therapy in Patients with Severe COVID-19 Who Are Not Intubated:

- The Panel recommends that hospitalized patients with severe COVID-19 who are not intubated receive 5 days of remdesivir **(AI)**.

Recommendation for Duration of Therapy for Mechanically Ventilated Patients, Patients on ECMO, or Patients Who Have Not Shown Adequate Improvement After 5 Days of Therapy:

- There are insufficient data on the optimal duration of therapy for mechanically ventilated patients, patients on ECMO, or patients who have not shown adequate improvement after 5 days of therapy. In these groups, some experts extend the total remdesivir treatment duration to up to 10 days **(CIII)**.

Recommendation for Patients with Mild or Moderate COVID-19:

- There are insufficient data for the Panel to recommend for or against remdesivir for the treatment of patients with mild or moderate COVID-19.

Vaccines and SARS-CoV-2

COVID-19 vaccine development pipeline gears up AsherMullard The Lancet Volume 395, Issue 10239, 6–12 June 2020, Pages 1751-1752

	<u>Developer</u>	<u>Properties</u>	<u>Development status</u>
mRNA-1273	Moderna and NIAID	mRNA vaccine	Phase 2
BNT162	BioNTech and Pfizer	mRNA vaccine	Phase 1/2
INO-4800	Inovio Pharmaceuticals	DNA vaccine	Phase 1
AZD1222	University of Oxford and AstraZeneca	Adenovirus vaccine	Phase 2b/3
Ad5-nCoV	CanSino Biologics	Adenovirus vaccine	Phase 2
Unnamed	Wuhan Institute of Biological Products and Sinopharm	Inactivated virus	Phase 1/2
Unnamed	Beijing Institute of Biological Products and SinoPharm	Inactivated virus	Phase 1/2
PiCoVacc	Sinovac	Inactivated virus, plus adjuvant	Phase 1/2
Unnamed	Institute of Medical Biology and Chinese Academy of Medical Sciences	Inactivated virus	Phase 1
NVX-CoV2373	Novavax	Protein subunit	Phase ½
	J&J, Merck and Pfizer		Pre-clinical



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History of Vaccines and the Importance of the FDA Process

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Can a vaccine for SARS-Cov-2 be produced and approved in record time?

<https://www.nytimes.com/interactive/2020/06/09/magazine/covid-vaccine.html>

In the history of medicine, rarely has a vaccine been developed in less than five years. Among the fastest to be developed was the current mumps vaccine.

Currently there are no approved DNA vaccines or RNA vaccines.

Vaccine development for a new pathogen traditionally takes many years or even decades.

The process includes:

- Small-scale manufacturing
- Phase 1
- Phase 2
- Phase 3 clinical trials
- Regulatory approval and large-scale manufacturing

Goal is to compress these timelines considerably without compromising safety

What Can We Learn from the Shingrix Vaccine Development Timeline?

S. Albert Edwards, PharmD LTD

Founder & President

eSubmissions University

fdaexpert@gmail.com

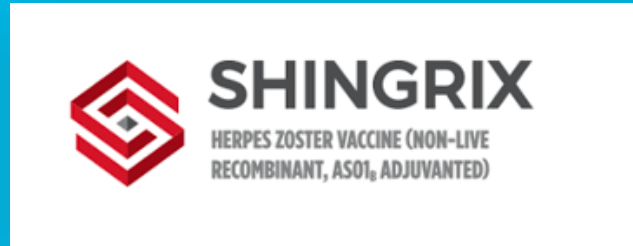
(847) 945-4750

www.esubmissionsuniversity.com



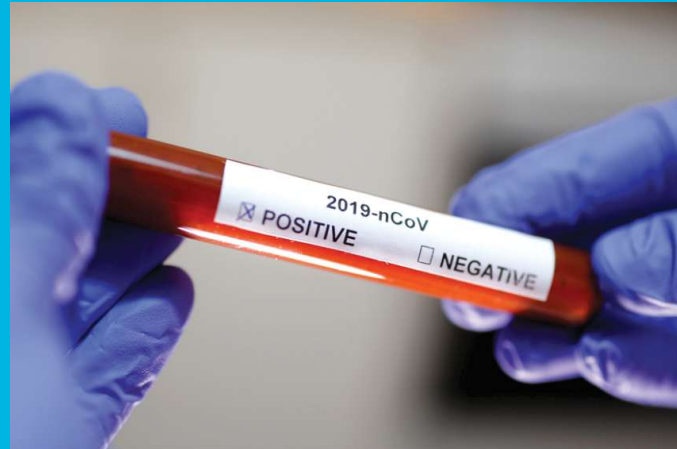
SHINGRIX VACCINE DISCOVERY:

- Dr. Abbas Vafai, University of Illinois College of Medicine at Rockford, 1990-97
- Discovered glycoprotein on the surface of the virus/causes shingles/confers immunity
- Along with Dr. R. J. Cohrs, University of Colorado, Denver, co-discoverer
- But, next-what I think we all want from a coronavirus vaccine.....



WHAT I THINK - we all want from a vaccine

- SAFE, i.e., free of major health-related side effects, and safe for the old and the young
- POTENT, i.e., giving us immunity for a number [4-6?] years
- EASY to take, i.e., a small, quick shot, just below the skin or a drop under the tongue



WHAT I THINK - we all want from a vaccine (cont'd)

- INEXPENSIVE & EASY to manufacture, so that **everyone** [including other nations & populations in the world] can get it, quickly, and finally
- Heat-stable [most vaccines require refrigeration or other temperature controls]



WHAT I THINK - we all want from a vaccine (cont'd)

- Honestly, this is a 'tall order'
- Even for the industrialized, highly science-oriented countries of our planet
- There are many virus details that we still need to discover!
- Ed Yong, “Why the Coronavirus Is So Confusing”, The Atlantic, 4/29/2020



<https://www.theatlantic.com/health/archive/2020/04/pandemic-confusing-uncertainty/610819/>

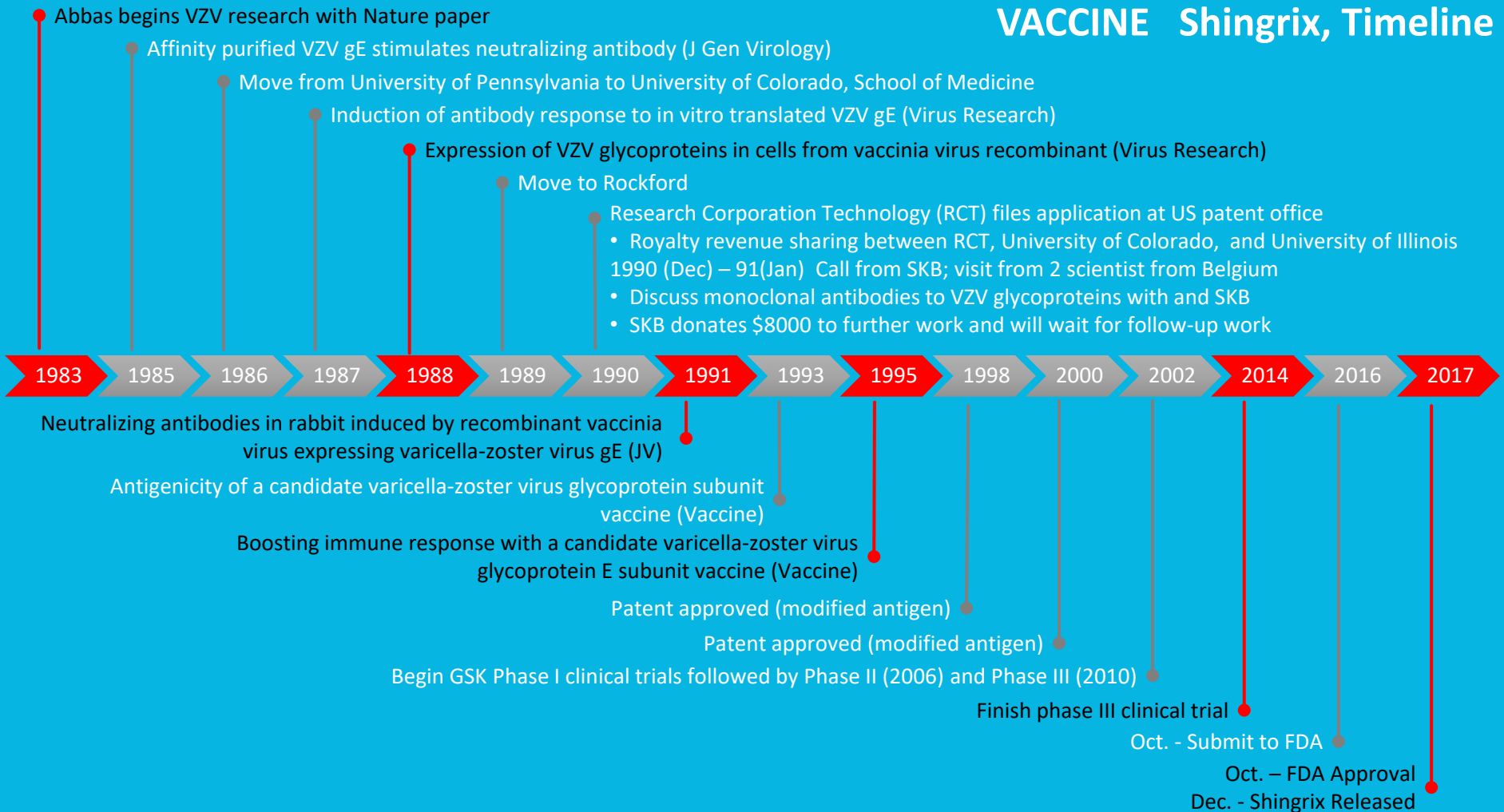
COMPLETE Vaccine Development Timelines:

Are impossible to locate – Why?

Both manufacturers/developers and FDA
[by regulation]

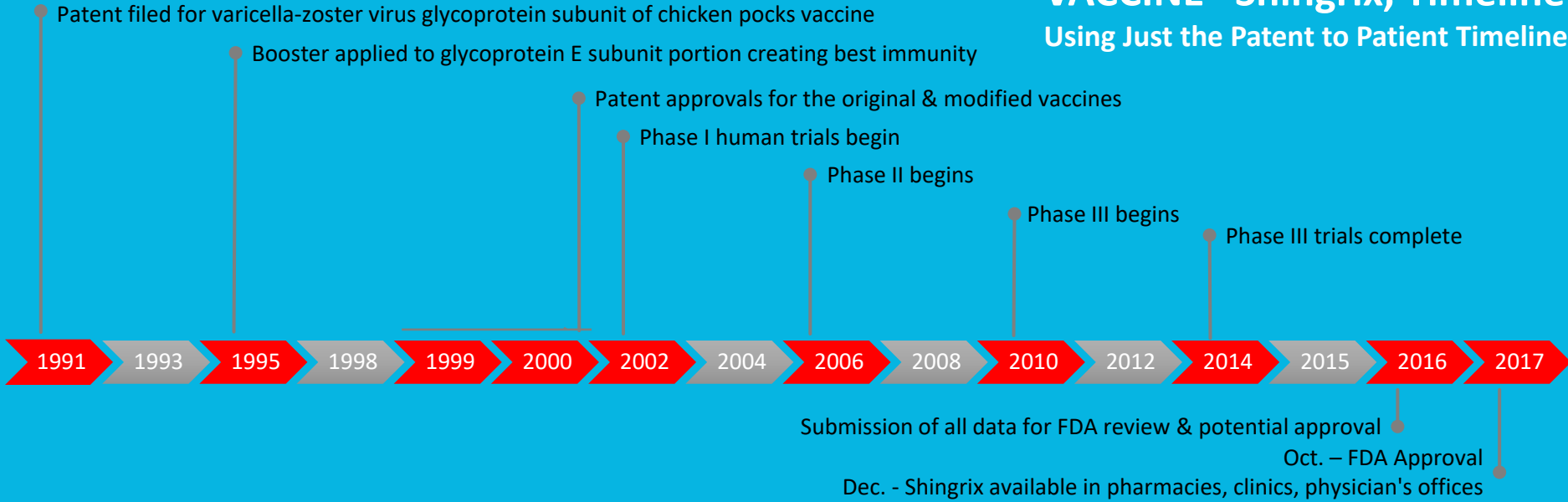
Keep the early research dates and filings
confidential

VACCINE Shingrix, Timeline



VACCINE Shingrix, Timeline

Using Just the Patent to Patient Timeline



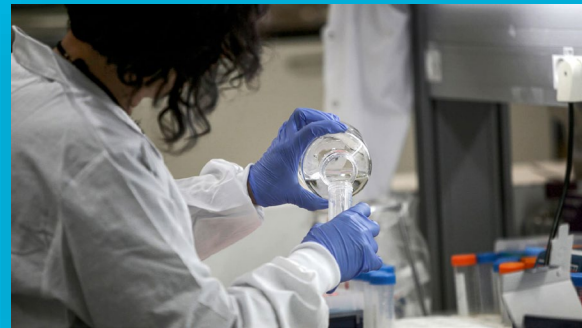
At this point, I do not want you to be turned off by this 26 year timeline!

FURTHER INFO ON THE PHASES OF CLINICAL TRIALS:

[https://www.fda.gov/patients/drug-development-process/step-3-clinical-research#The Investigational New Drug Process](https://www.fda.gov/patients/drug-development-process/step-3-clinical-research#The_Investigational_New_Drug_Process)

ASSUMPTIONS TO SHORTEN THE VACCINE TIMELINE

- NO coronavirus patents, since it is needed on a world-wide, urgent basis
- Save approximately 9 years from Shringrix timeline
- The immunity producing virus segment will be found & perfected in 1 year
- Time from Phase I to II human trials can be compressed to 2 years
- Phase III trials will then begin at year 3.5, assuming no issues with SAFETY



ASSUMPTIONS TO SHORTEN THE VACCINE TIMELINE (cont'd)

- Knowing that the vaccine will be used world-wide populations
- Phase III trials will likely take 4 years to complete
- Why: widely divergent populations in various countries will need testing
- US is mix of many of the world's populations-SAFETY
- Phase III Trial data will also depend on the availability of not only the test vaccine but also the various patient populations throughout the world



ASSUMPTIONS TO SHORTEN THE VACCINE TIMELINE (cont'd)

- Assuming efficacy, i.e., lasting immunity to SARS-CoV-2, 4-6 years?
- Results would be ready for review by FDA and other world-wide Regulatory Authorities at year 8
- **A vaccine would then likely be available in about 9 years**
- **Yes, this at odds with media predictions and speculations**



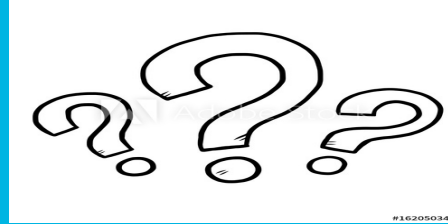
ASSUMPTIONS TO SHORTEN THE VACCINE TIMELINE (cont'd)

- Can the timeline be further shortened?
- Testing fewer of the world's populations
- Going with a much shorter “lasting immunity” time, e.g., 1-2 years
- This would necessitate more frequent, REPEAT, vaccinations
- Testing smaller numbers of patients > SAFETY?
- One cannot *'rush the science'* and come out with a premiere vaccine!





Alumni
Exchange



Where are we going?

Prevention and Contact
tracing best tools we have
until there is a vaccine



COLLEGE
OF PHARMACY

Planning for the future – the new normal



THANK YOU!



Doctors



Hospital Staff



Nurses



First Responders



Pharmacy Staff



Police



Fire Fighters



EMTs



Delivery Drivers



Restaurant Workers



Truck Drivers



Grocery Employees

THANK YOU

- To our pharmacists/colleagues in retail pharmacy, outpatient clinics, emergency rooms, and ICUs who are on the 'front lines' of this pandemic
- As well as, ALL 'FRONT LINERS' who are doing their daily jobs with exposure to the coronavirus!

BACKUP SLIDES



Phase

Sample size

Objectives

Small sample size
(healthy volunteers)



Test the safety of a new medicine



Test for side effects

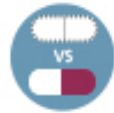


Define the right dose

Larger sample size
(including those with the condition or disease)



Test for its effects in the short term

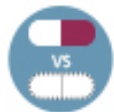


Compare a new medicine against an existing treatment/ placebo



Monitor side effects

Larger sample size
(including those with the condition or disease)



Compare a new medicine against an existing treatment/ placebo



Test for side effects



See if it's better

Phase 1

A phase of research to describe clinical trials that focus on the safety of a drug. Usually conducted with healthy volunteers, and the goal is to determine the drug's most frequent and serious events and, often, how the drug is broken down and excreted by the body.

Phase 2

A phase of research to describe clinical trials that gather preliminary data on whether a drug works in people who have a certain condition/disease (that is, the drug's effectiveness). For example, participants receiving the drug may be compared to similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short term adverse events are studied.

Phase 3

A phase of research to describe clinical trials that gather more information about a drug's safety and effectiveness by studying different populations and different dosage and by using the drug in combination with other drugs. These studies typically involve more participants.

1

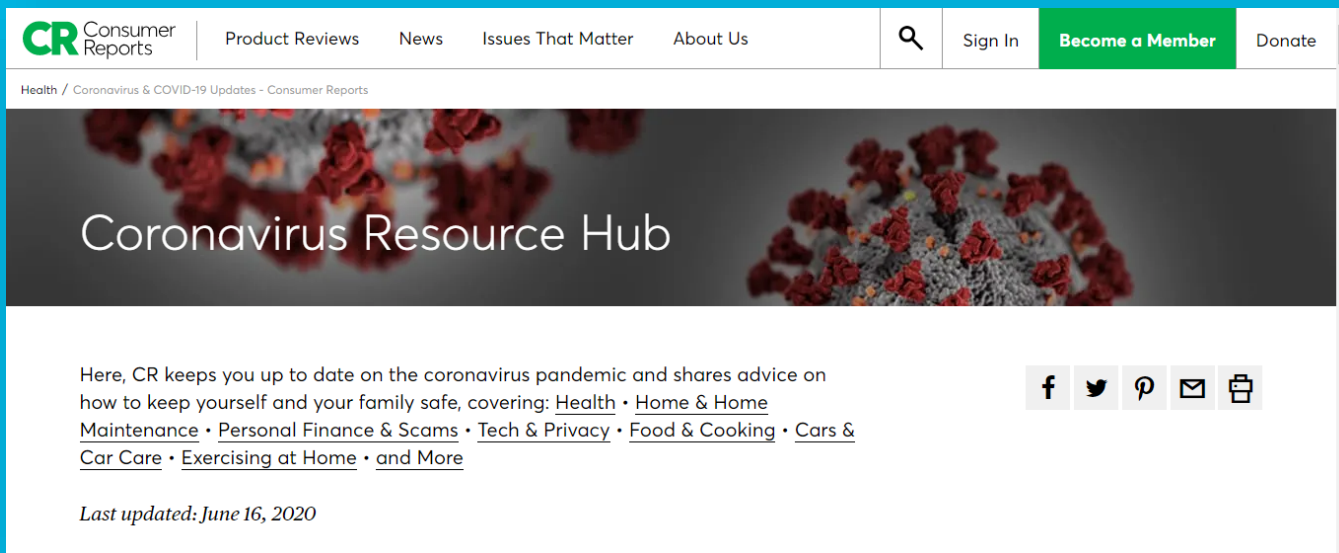
2

3

HOW DO I STAY INFORMED?

CR.org/covid19

<https://www.consumerreports.org/coronavirus/coronavirus-covid-19-updates/>



The screenshot shows the top navigation bar of the Consumer Reports website. It includes the CR logo, links for Product Reviews, News, Issues That Matter, and About Us, a search icon, Sign In, a green 'Become a Member' button, and a Donate link. Below the navigation bar is a breadcrumb trail: Health / Coronavirus & COVID-19 Updates - Consumer Reports. The main content area features a large image of a coronavirus particle with the text 'Coronavirus Resource Hub' overlaid. Below the image, there is a paragraph of text: 'Here, CR keeps you up to date on the coronavirus pandemic and shares advice on how to keep yourself and your family safe, covering: [Health](#) • [Home & Home Maintenance](#) • [Personal Finance & Scams](#) • [Tech & Privacy](#) • [Food & Cooking](#) • [Cars & Car Care](#) • [Exercising at Home](#) • [and More](#)'. To the right of this text are social media sharing icons for Facebook, Twitter, Pinterest, Email, and Print. At the bottom left of the content area, it says 'Last updated: June 16, 2020'.

footnote: Consumer Reports, page 11, June, 2020

IS TAKEOUT FOOD SAFE?

In general, yes, assuming prevention of food borne contamination by

- Gloves, masks, hairnets, and hand-washing by restaurant staff
- Pickup food best; avoid proximity to other people
- Transfer food to a plate, reheat it, wash hands before eating

footnote: Consumer Reports, page 19, June, 2020

YOUR CAR & THE CORONAVIRUS

- Most car interiors can be disinfected with 70+% isopropyl alcohol
- Recondition leather surfaces with a conditioner after alcohol use
- Fabric surfaces can be scrubbed with a small amount of water & laundry detergent
- NO bleach, peroxide, or ammonia-may damage non-glare coatings

footnote: Consumer Reports, page 53, June, 2020

AT THE GAS PUMP

- Gloves or a paper towel for any key pressing and using the pump/handle
- After the fill-up, wash hands or use hand sanitizer

footnote: Consumer Reports, page 53, June, 2020

GOING TO THE DENTIST

- Only urgent or emergency dental procedures
- For example: pain, bleeding, swelling
- For Illinois: <https://dph.illinois.gov/covid19/community-guidance/oral-and-dental-care-guidance>
- See CDC Dental Guidance, updated, May 19, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/dental-settings.html>

COVID-19 TESTING COSTS

- Cost of actual test is -0-
- Cost of any work-up, e.g., chest X-ray, office visit, are determined by your routine health insurance coverage

Thank You

Questions?