

**WEB**INAR

# INICIATIVAS DE INNOVACIÓN EN FH ANTE LA PANDEMIA COVID19

## INVESTIGACIÓN Y EVIDENCIAS CIENTÍFICAS

**DRA. CECILIA MARTÍNEZ**

Secretaria de la SEFH

ORGANIZA:



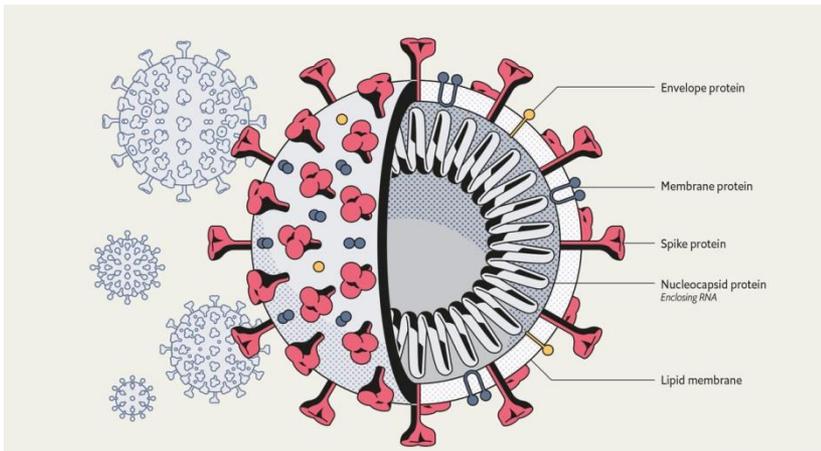
COLABORA:



# INVESTIGACIÓN Y EVIDENCIAS CIENTÍFICAS

*“Actualmente, no existe evidencia de ensayos clínicos aleatorizados que muestren mejoría en los resultados de ningún fármaco de los utilizados en el abordaje para el manejo de pacientes con **sospecha o infección SARS-CoV2 confirmada**, o en **tratamiento profiláctico**”.*

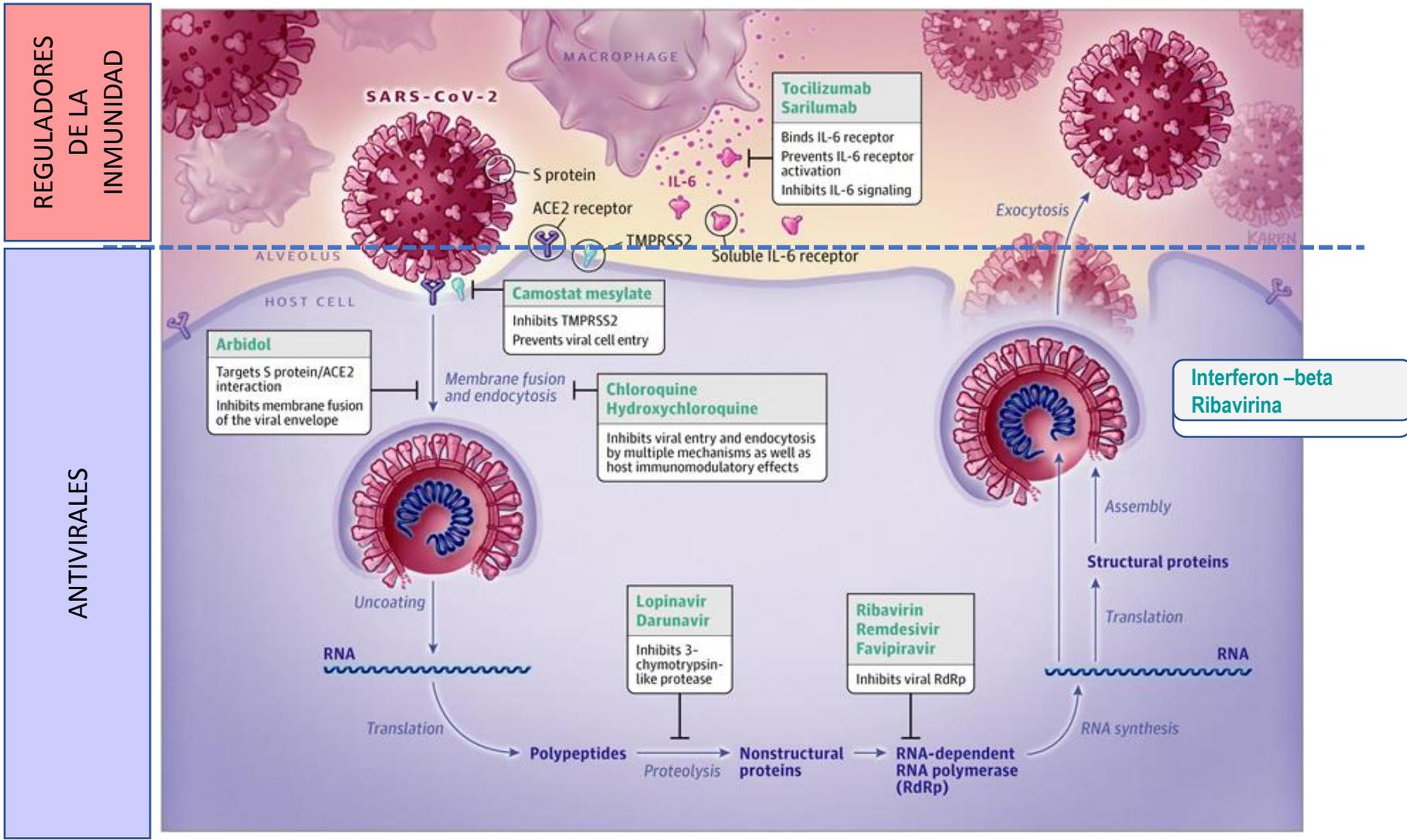
Sanders JM et al. JAMA April 13, 2020. doi:10.1001/jama.2020.6019



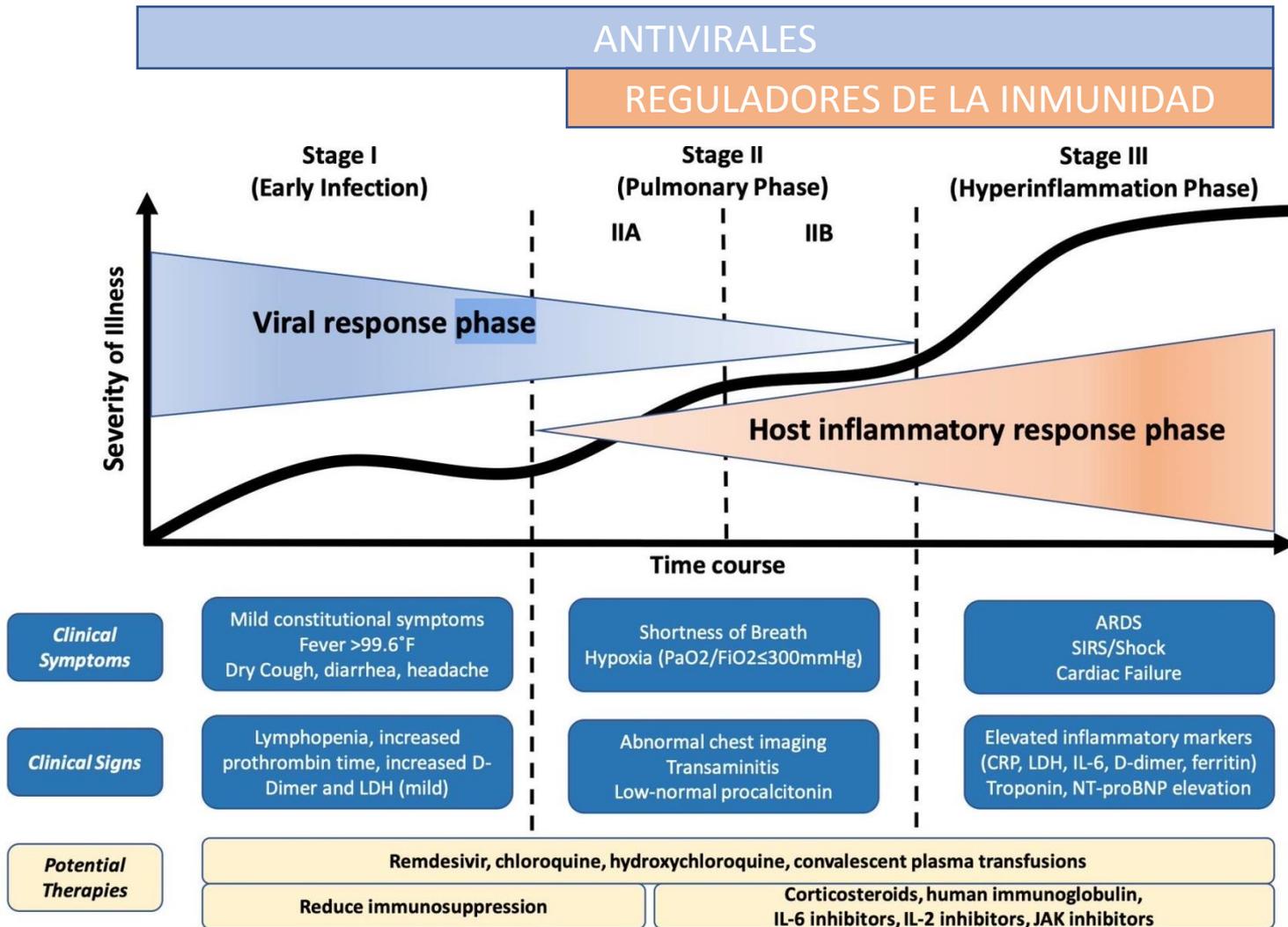
SARS-CoV  
MERS-CoV



SARS-CoV2  
(COVID19)



Pharmacologic Treatments for Coronavirus Disease 2019 (COVID-19) JAMA. Published online April 13, 2020. doi:10.1001/jama.2020.6019



*J Heart Transplantat. March 25<sup>th</sup> 2020. DOI: 10.1016/j.healun.2020.03.012*





## Flooded by the torrent: the COVID-19 drug pipeline

The world is rushing to test potential COVID-19 treatments. But do we really need so many trials? Asher Mullard reports.



The coronavirus disease 2019 (COVID-19) drug pipeline is not growing at quite the same speed as the pandemic. But its rate of expansion is nevertheless cause for pause. In the months since COVID-19 has spread, researchers have launched more than 180 clinical trials of everything from repurposed antivirals and immunomodulators to unproven cell therapies and vitamin C. A further 150 trials are preparing to recruit patients.

For pandemic preparedness experts, this begs crucial questions. "Do we need 300 trials? Is that a good use of resources?" asks Daniel Bausch, director of the UK Public Health Rapid Support Team and infectious disease expert at the London School of Hygiene & Tropical Medicine. "I would probably say we don't."

There are good reasons to build up a full pipeline of COVID-19 drugs. Up to 90% of new entrants into clinical trials never make it to approval, and so investigators want to have as many shots on goal as possible. Scientific understanding of COVID-19 is also changing so quickly that it makes sense to keep options open. But other motives, including public relations and financial gain, might also be in play. "During a crisis, some people will go out of their way to sacrifice their lives, and others will hoard medicines and be complete jerks. On institutional levels, we have the same span of good actors and bad actors," says Bausch.

And in the absence of comprehensive trial coordination mechanisms, signs of disarray are emerging. "The scale of these trials is too small, and the variation in terms of how they are being run is too large," says John-Arne Ratttinger, chief executive of the Research Council of Norway and proponent of a more

collaborative approach. "These trials aren't really designed to answer the questions that need to be answered." Clinical trial literature, moreover, is riddled with drugs that looked promising in small trials only to prove ineffective in bigger, more rigorous studies.

"Do we need 300 trials? Is that a good use of resources? ..."

Mentad Parsy, chief medical officer at Gilead, agrees. "We are seeing that the level of evidence on some of the therapeutics that are out there is not great. Given how broadly some of these agents are being used, this may impact our ability to actually detect signals with other molecules", he explains.

The research community faces a tricky dilemma, with little time for reflection. "On the one hand, we want to be coordinated. On the other hand, we don't want to spend too much time getting coordinated because the pace of this thing is so rapid," explains Parsy. "Everyone's doing their best", he adds.

"The most important things to get right are primary outcomes, inclusion and exclusion criteria, and standard of care," says Bin Cao, a pulmonology and critical care specialist at the China-Japan Friendship Hospital in Beijing. Cao helped to coordinate some of the first trials of COVID-19 drugs in China. Getting the standard of care right for these trials was particularly important, he adds, when systems were overwhelmed and so little was known about the disease.

WHO has now taken steps to provide greater coordination through its Solidarity trial, a study of four therapeutic approaches for hospitalised patients with confirmed

COVID-19. These consist of Gilead's RNA polymerase inhibitor remdesivir, the antimalarials hydroxychloroquine and chloroquine, the HIV protease inhibitors lopinavir and ritonavir, and lopinavir and ritonavir in combination with the immunomodulatory agent interferon beta-1a. First results could be available within 12-16 weeks, insiders say.

Not only will the umbrella trial test multiple drugs at scale, but it also seeks to align the research community behind key clinical trial design features that can make the most of incoming data. By enrolling patients from around the world, the Solidarity trial might be able to answer questions more quickly than standalone trials can. Already, 70 countries have committed to joining up. Countries with the least developed health-care infrastructures can follow a backbone protocol, whereas those with better capabilities will launch "daughter" trials that will collect additional data.

"I like the Solidarity trial", says Zhi Hong, chief executive officer of the biotech firm BioSciences and former head of infectious disease research and development at GlaxoSmithKline. Although the trial is not double-blind, that is acceptable



La investigación clínica es una *prioridad* en el ámbito *internacional*, y los esfuerzos en investigación se están llevando a cabo en *red* para compartir toda la información relevante y los resultados publicados a este respecto.

AEMPS, 22 Abril, 2020

NIH U.S. National Library of Medicine  
*ClinicalTrials.gov*

233 Estudios de intervención  
395 Estudios (intervención + observacionales)

# LA SEFH EN SU APUESTA POR LA INVESTIGACIÓN

## REGISTRO ESPAÑOL DE RESULTADOS DE FARMACOTERAPIA FRENTE EL COVID-19



## ESTUDIO QUINAVID

ENSAYO CLÍNICO PARA LA EVALUACIÓN DE QUIMIOPROFILAXIS CON  
HIDROXICLOROQUINA DE LA COVID-19 EN PROFESIONALES SANITARIOS



Estudio de intervención  
(pendiente de autorización por AEMPS)





51

## Estudios Clínicos autorizados por AEMPS

Fase I-II  
 23  
 Fase III-IV  
 29

28  
activos

8  
profilaxis

43  
tratamiento

Hidroxiclороquina  
Mefloquina

Sarilumab  
Tocilizumab  
Siltuximab  
Roxilitinib  
Remdesivir

Selinexor  
MSC  
Defibrotide  
Pembrolizumab  
Corticoides...

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**Ensayo clínico aleatorizado, controlado y abierto para la evaluación de la eficacia y seguridad de la quimioprofilaxis**

- ➔ 9 centros (3+4 pendientes)
- ➔ Aleatorización a 3 ramas (2:2:1)  
Mínimo de 861:861:430, 2163 sujetos en total
  - ➔ D. carga, 200 mg/24h 1 semana +200 mg/72h semanas 2,3,4
  - ➔ D. carga, 200 mg/48h 1 semana +200 mg/72h semanas 2,3,4
  - ➔ Brazo control: sin quimioprofilaxis
- ➔ Intentar establecer que dosis bajas son eficaces en la reducción de la tasa de infección



## Información sobre investigación clínica sobre la COVID-19

Fecha de publicación: 22 de abril de 2020

La Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) ha recibido un gran número de solicitudes de diferentes tipos de estudios clínicos. Los ensayos clínicos tienen un espacio propio en el que se publican sus características, el Registro Español de estudios clínicos, ([REec](#)). Sin embargo, los estudios observacionales no disponen de su espacio propio y se considera importante que estén accesibles también para establecer colaboraciones y sinergias entre grupos de investigación. [Estos estudios son tramitados por la AEMPS](#) de acuerdo con su normativa propia.

Además de los ensayos clínicos, la investigación clínica también se desarrolla a través de estudios observacionales con medicamentos es decir, investigaciones en las que se recogen datos de salud de los pacientes con el fin de analizar el uso, la seguridad o la efectividad de los medicamentos en el contexto de la asistencia sanitaria real, sin intervenir en la práctica clínica. Esto convierte a ambos métodos en complementarios para extraer mucha información relevante del tratamiento con los diferentes medicamentos.

AEMPS, 22 Abril, 2020

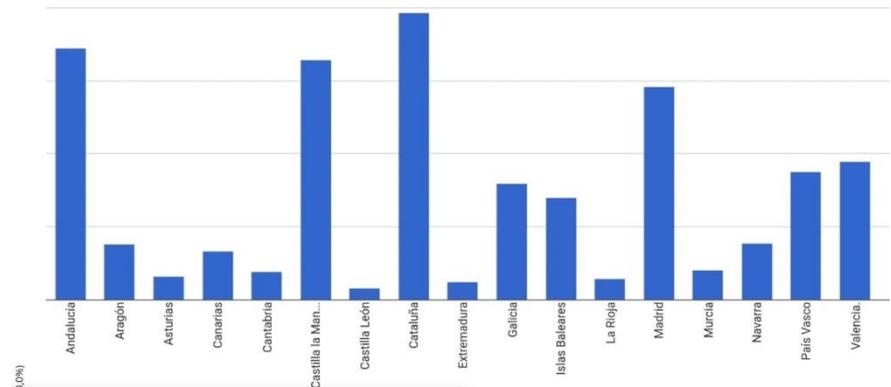
# REGISTRO ESPAÑOL DE RESULTADOS DE FARMACOTERAPIA FRENTE EL COVID-19



➔ 132 centros (+6)

➔ 4000 registros

➔ 682 investigadores registrando en RedCap



## AGRADECIMIENTOS

INVESTIGADORES COORDINADORES y además

Emilio Alegre, Laila Abdelkader, Marta Rodríguez, Caridad Pontes, Dolores Fraga, Vicente Faus



# WEBINAR

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COLABORA:



# LA SEFH EN SU APUESTA POR LA INVESTIGACIÓN



**CIENTÍFICAMENTE VÁLIDA**

**ECONÓMICAMENTE SOSTENIBLE**

**CON ACCESO Y TRANSPARENCIA  
PARA LOS SOCIOS**

**DE CALIDAD**

ORGANIZA:



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