

Immunoglobulin Concentrates and SARS-CoV-2 Neutralizing Antibodies



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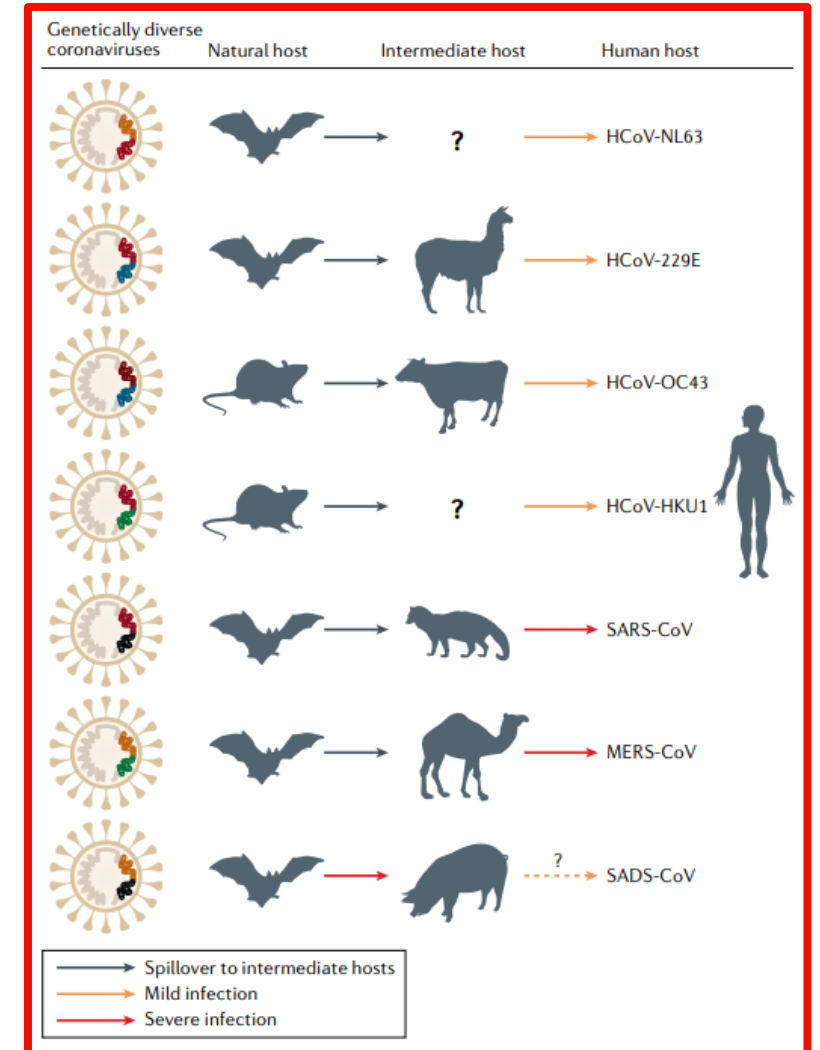
Better Health, Brighter Future

SARS-CoV-2 Pandemic: Unexpected ?



Zoonotic Coronaviruses in Humans

- **alpha**
 - NL63 (ACE as receptor)
 - 229E
- **beta**
 - OC43
 - HKU1
 - **SARS-CoV**
 - **MERS-CoV**
 - **SARS-CoV-2 (ACE as receptor)**



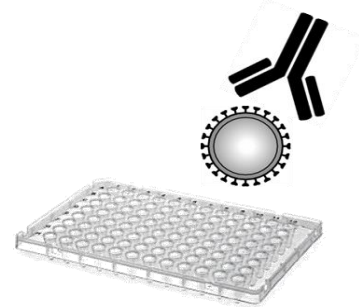
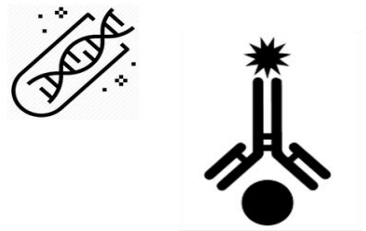
Cross-Binding vs. Cross-Neutralizing Antibodies

- **Binding Assays**

- Validation against „gold standard“ NT*:
not widely available, initially

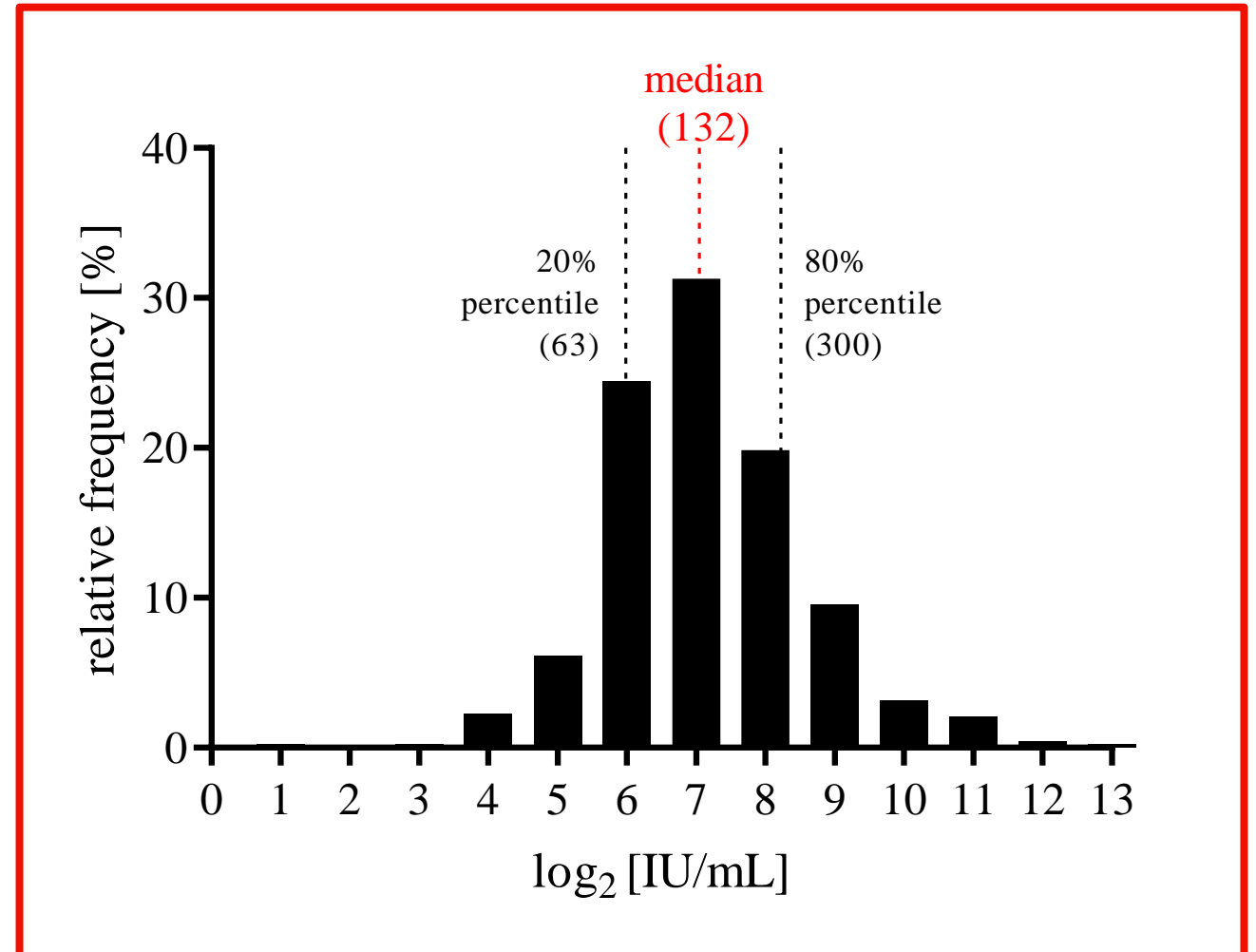
- **Neutralization Assay**

- Biocontainment needed
- Quantification:
relative to a standard preparation

Virus	Infectivity test	Nucleic acid test (e.g. PCR)
Antibody	Neutralization test, gold standard reference	Binding-assay (e.g. ELISA), unclear cross-reactivity
	 <ul style="list-style-type: none">• Biocontainment laboratory, BSL 3• Cell culture• Sterile work bench	 <ul style="list-style-type: none">• More simple diagnostic lab• PoC (?)

SARS-CoV-2 Neutralization

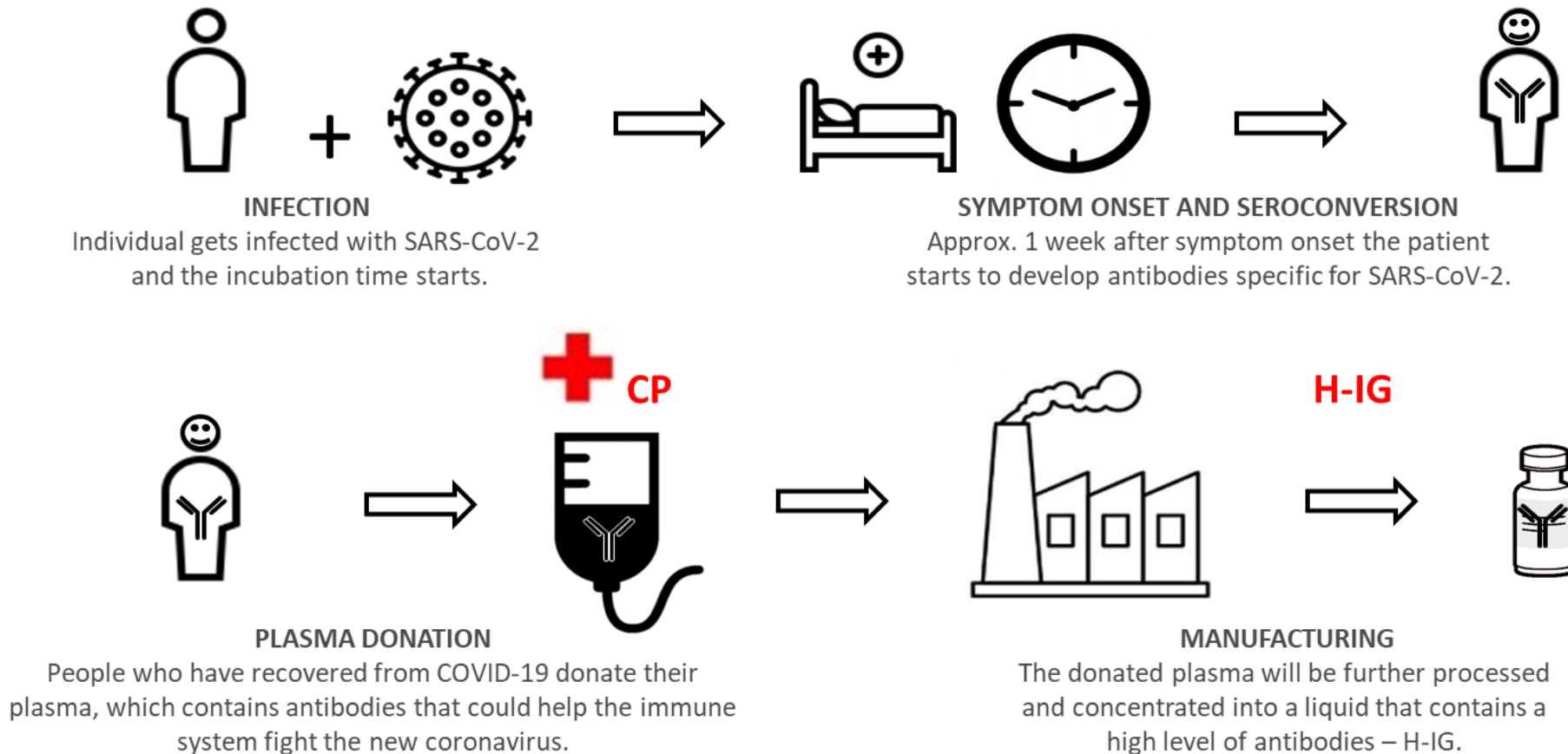
- 438 plasma donations
- Quantitation:
international units / ml
→ comparator for vaccinees



COVID-19: Antibody-Based Therapies



- Convalescent Plasma (CP)
- Hyperimmune Globulin (H-IG)



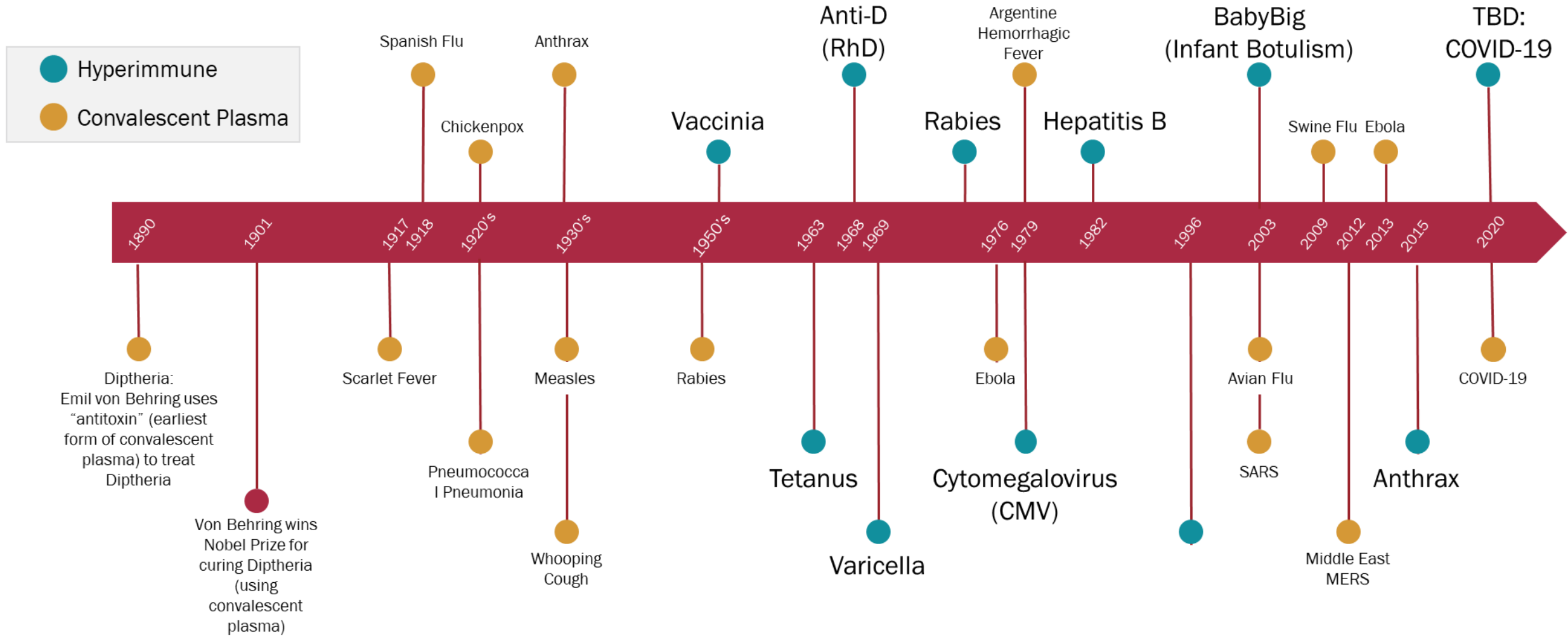
COVID-19: Antibody-Based Therapies



Same origin, but different

- **Convalescent Plasma**
 - Availability: immediate
 - Safety: tested for viruses
 - Potency: variable
 - IgM, IgG ...
- **Hyperimmune Globulin (H-IG)**
 - Availability: later
 - Safety: high safety margins
 - Potency: consistent & stable
 - IgG

COVID-19: Antibody-Based Therapies





CoVIg-19 PLASMA ALLIANCE

CoVIg-19 PLASMA ALLIANCE

Working Together to Fight COVID-19 with Immunoglobulin (Ig) Therapy



Alliance participants

1. FOUNDERS

CSL Behring



2. MEMBERS



octapharma

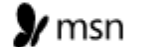
3. CONTRIBUTORS



4. SUPPORTERS



Uber Health





What is the CoVig-19 plasma alliance?



Purpose:

Develop and deliver a **non-branded hyperimmune globulin (H-Ig)** for COVID-19

By working together we can...

- **Accelerate** plasma collection and medicine development activities
- If approved, **increase supply and availability** to more people

What is the CoVig-19 Plasma Alliance?

An unprecedented partnership of 13 leading plasma companies with deep experience in discovering, developing, and producing plasma-derived therapies formed to meet the challenge of COVID-19.

In just months, the **Alliance has made remarkable progress**

- Developed virological analytics to quantify the active principle for H-Ig, i.e. virus neutralizing antibodies
- Established the processes to collect convalescent plasma
- Manufactured the H-Ig
- Initiated clinical phase 3 trial

CoVig-19 PLASMA ALLIANCE

WHO'S IN?

COVID-19 Survivors Needed Now!

CoVig-19 PLASMA ALLIANCE

Working Together to Fight COVID-19 with Immunoglobulin (Ig) Therapy



CoVig-19 Plasma Alliance Announces Topline Results from NIH-Sponsored Clinical Trial of Investigational COVID-19 Hyperimmune Globulin Medicine

April 2, 2021



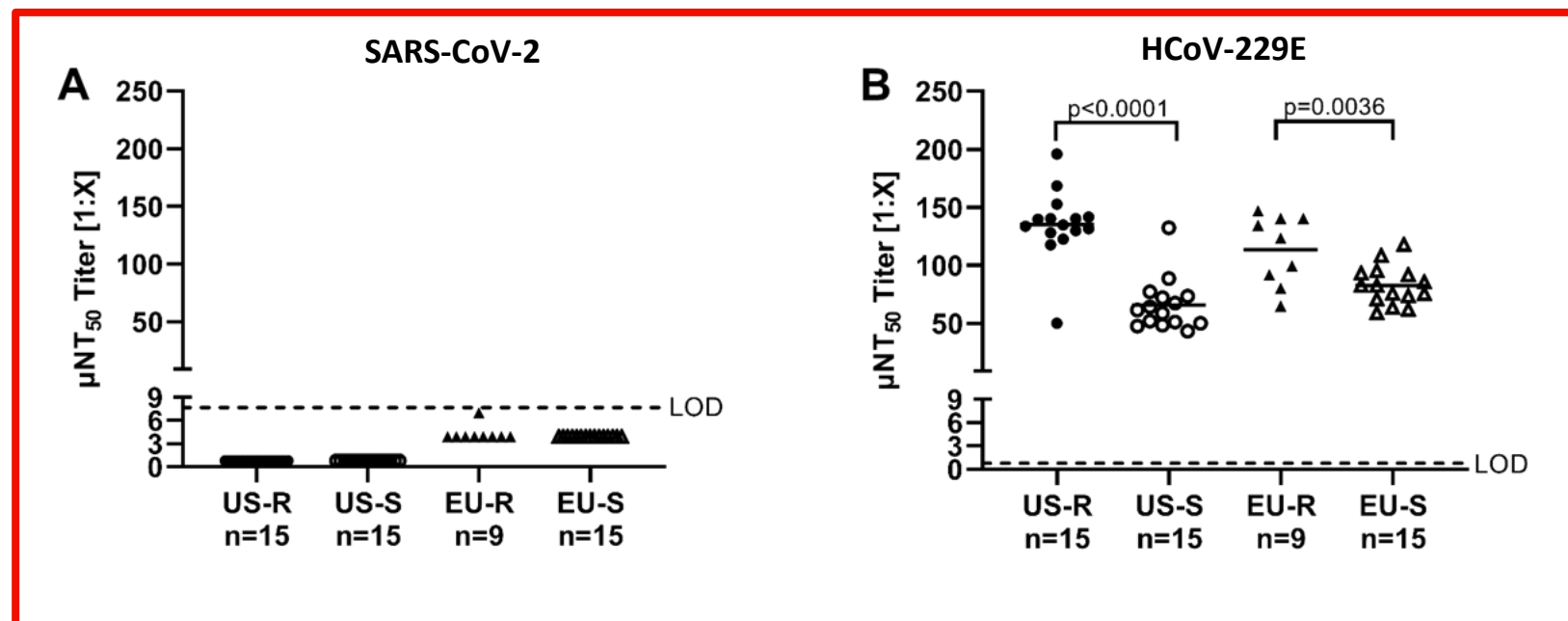
CoVig-19 PLASMA ALLIANCE

Working Together to Fight COVID-19 with Immunoglobulin (Ig) Therapy

- *Phase 3 Inpatient Treatment With Anti-Coronavirus Immunoglobulin (ITAC) Clinical Trial Sponsored and Funded by the National Institute of Allergy and Infectious Diseases (NIAID), Part of the National Institutes of Health (NIH), Did Not Meet Its Endpoints to Show Efficacy in Adults Hospitalized With COVID-19*

No SARS-CoV-2 Neutralization by Intravenous Immunoglobulins Produced from Plasma collected before the 2020 Pandemic *

- 229E Coronavirus potent neutralization
- SARS-CoV-2 no neutralization



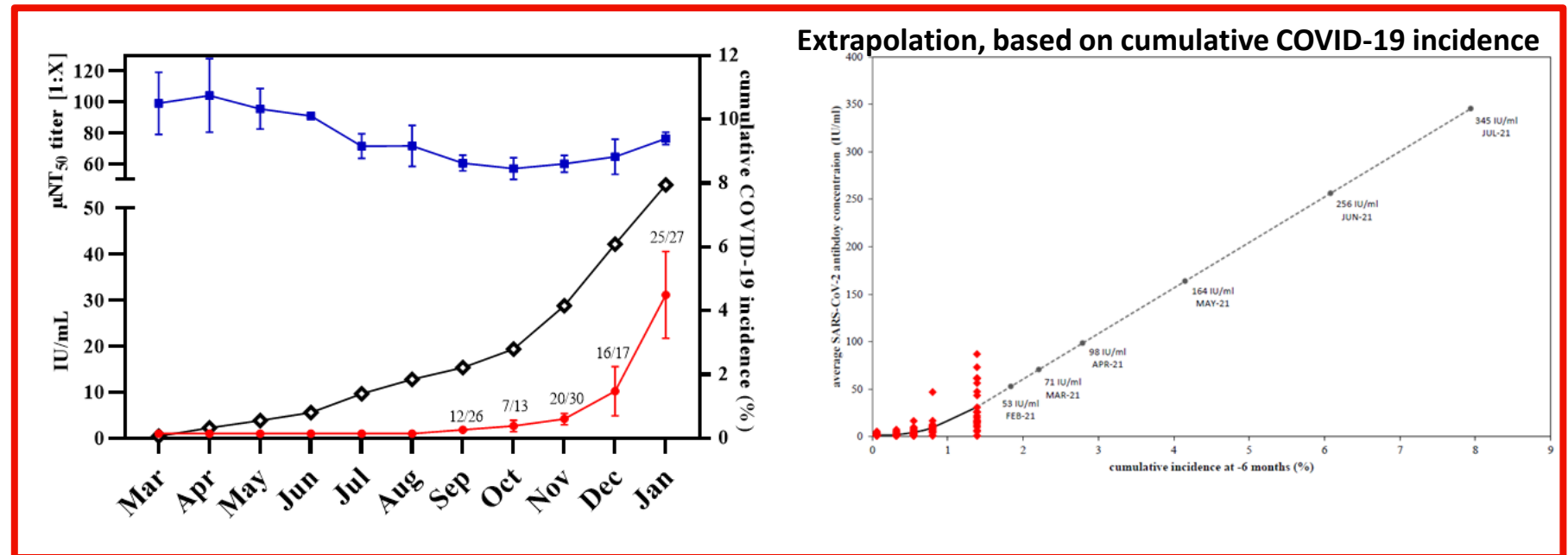
Rapidly Increasing SARS-CoV-2 Neutralization by Intravenous Immunoglobulins Produced from Plasma Collected During the 2020 Pandemic *

- 229E Coronavirus: stable

- **SARS-CoV-2:
increasing**

- **Cumulative
post COVID-19**

- **Vaccination ?**



- **SARS-CoV-2 has been / is another pandemic virus challenge**
From past experience with coronaviruses, we should have been prepared.
- **Next challenge ?**
A question of when, not if.
- **Seroconversion of the world's population is ongoing**
Driven by post-COVID-19 initially, by vaccination now.
- **Plasma increasingly contains SARS-CoV-2 antibodies, and so do IG products.**

THANK YOU !

Any Questions ?