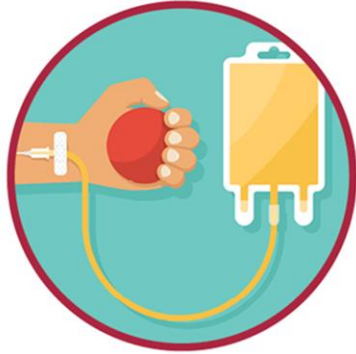


# Hyperimmune Globulin



## Convalescent Plasma Donation

- Patients who have recovered from COVID-19 donate their plasma. This convalescent plasma contains antibodies that could help the immune system fight the new coronavirus.
- The level of antibodies in this plasma varies from donor to donor.

## Creation of Hyperimmune Globulin

- Convalescent plasma is sent to manufacturing facilities.
- Plasma is pooled and processed to remove or inactivate viruses, and purified to create a “hyperimmune globulin”
- This serum contains a reliably consistent amount of antibodies.

## Plasma Collection



- Use existing source of plasma from partner companies
- Target multi regional approach
- Requires HA consultations



## Analytics and manufacturing

- Serological /Neutralisation assay
- Small scale batches CT: CSL/ Takeda
- Commercial batches: tbc



## Clinical Trial

- randomized trial in hospitalised COVID-19 patients
- NIH/NIAID collaboration 4 manufacturers
- 500 patients
- sponsor: University of Minnesota
- IND holder: NIH

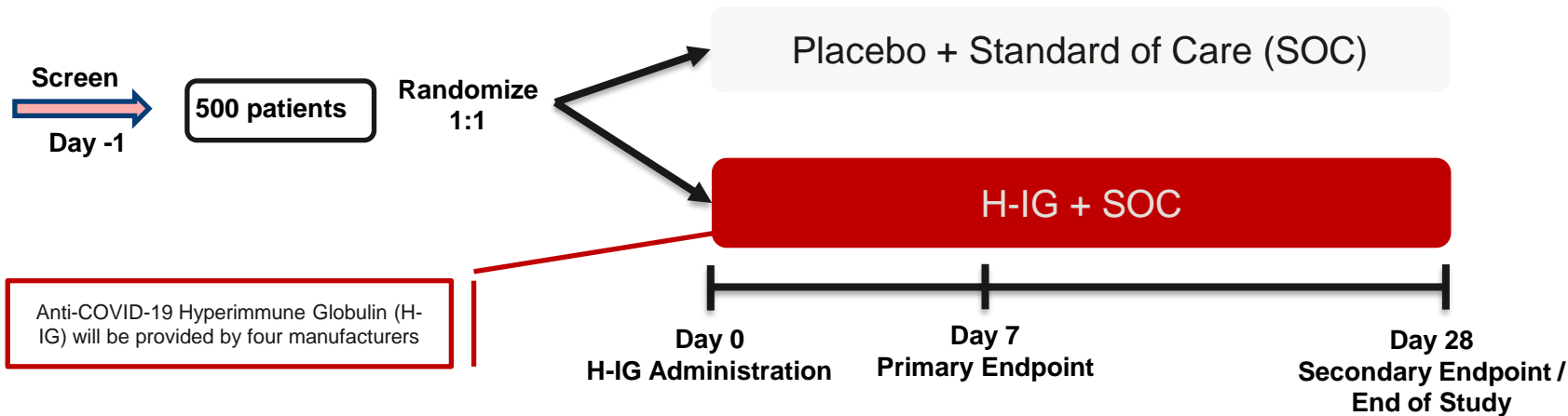


## Filing

◇EUA  
CMA



# Protocol INSIGHT #013



**Study set-up:** randomized (1:1) placebo + SOC (including Remdesivir): H-IG in addition to SOC (including Remdesivir), single infusion, single dose level

