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

Anti-COVID-19 Hyperimmune Globulin (H-IG) will be provided by four manufacturers