Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

REGN-COV2 Q&A

14-16th October 2020

New trial design

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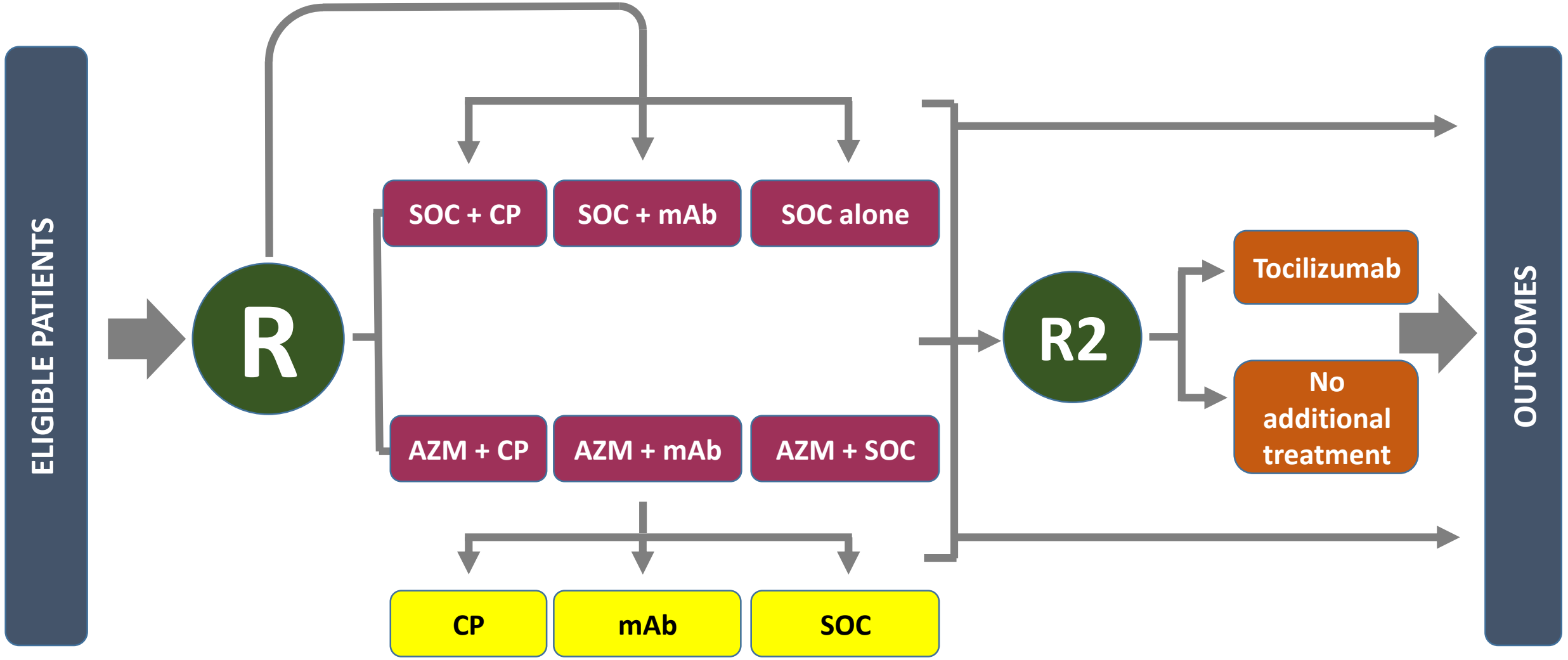

REGN-COV2

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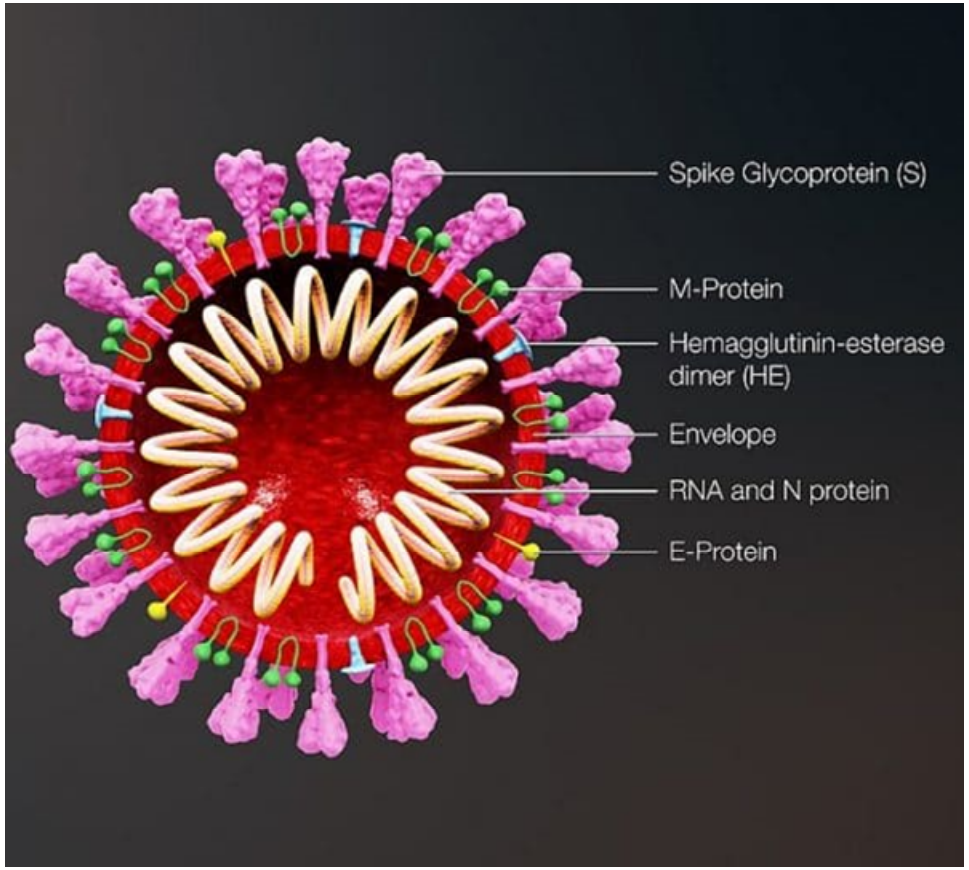
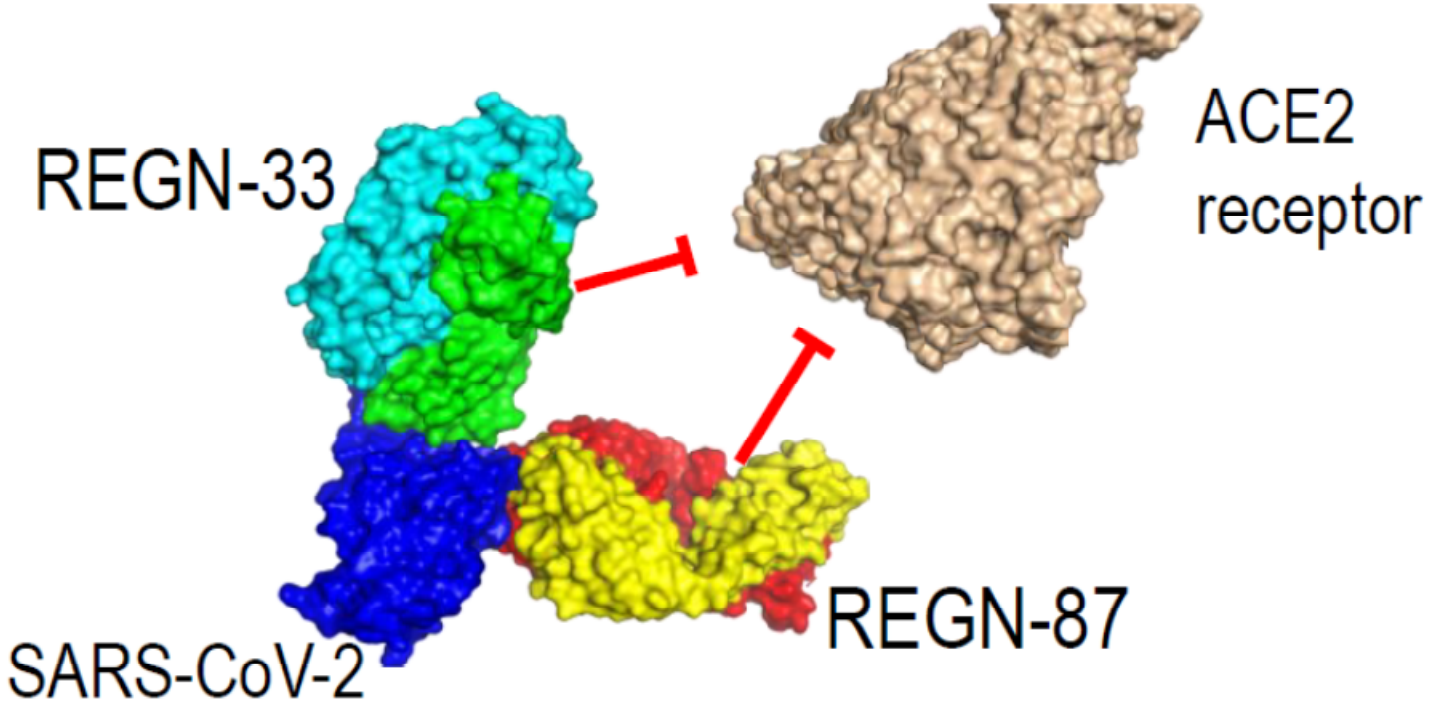
- Several companies are now producing monoclonal antibodies (mAbs) against SARS-CoV-2 “spike” protein





REGN-COV2

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- REGN-COV2 is a mixture of two monoclonal antibodies (mAbs: REGN10933 and REGN10987)

- These are fully human antibodies directed against spike protein

- Two different antibodies mean that if virus mutates its spike protein such that one antibody doesn't bind so well, the other antibody probably still will

Safety of REGN-COV2

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- REGN-COV2 mAb has been given to >1000 patients so far in early phase trials
  - No serious adverse reactions
  - Minor infusion reactions do occur during infusion

- Other trials ongoing in other clinical scenarios e.g. outpatient, prophylaxis
  - Preliminary results from outpatient trial suggest more rapid reduction in viral load and symptoms compared to placebo

It’s good enough for him…

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Welcome to the BBC

LIVE Trump receives treatment as new cases emerge

REGN-COV2 site setup

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1. Local PIs need to complete online training and confirmation form
   - They should ask other staff involved at site to also do this, but not require before site activation

2. Pharmacy need to be ready to support new arm
   - Review Pharmacy Manual on website (V3.0) and complete local risk assessment to determine where mAb will be prepared
   - Confirm staff details to RECOVERY team so user accounts on Cenduit websystem can be created (Cenduit user guide on website)
   - Indicate when they will be ready to:
     1. Receive drug
     2. Support allocation to a trial participant

Administration

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- REGN-COV2 is reconstituted in 250 mL bag of normal saline and infused over 60 minutes via a 0.2-0.22 micron low protein binding filter
- Does not necessarily require administration by research staff
- Observations and beginning, middle and end (as for blood product)
- Infusion should be stopped if reaction occurs
  - Reaction should be treated symptomatically
  - If severe, infusion should be abandoned
  - Otherwise can be restarted at half the original rate on medical advice

Preparation

- There is nothing in the SPS national guidance (https://www.sps.nhs.uk/wp-content/uploads/2016/12/mAb-Products-5th-Edition-2015.pdf) that states where mAbs should be prepared. The choice of preparation area and therefore isolator should be determine by the product.
- A risk assessment using nationally recognised tools and advice was sought from Regional QA. In their opinion, in the absence of evidence/lack of data due to how new these mAbs are, they would suggest that operator protection should be provided, as well as microbiological protection of the final product.
- This is not a licensed mAb and there is very little data on the occupational exposure and potential impact on the staff preparing
- MAbs should be prepared in line with SPS yellow cover document on a campaign basis with clean down between this product and another drug, to reduce or minimise the risk of product cross contamination.

Spill Kit

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- REGN-COV2 is not cytotoxic
- The components contained within a cytotoxic spill kit can be used to clean up a monoclonal antibody spill
- If sites have a non-cytotoxic spill kit which covers monoclonal antibody spills or a specific monoclonal antibody spill kit, then they can use those kits instead