Specific aspects of a clinical trial targeting Covid-19
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Opportunities

- **reduce viral load**
  - Ph III – compound A
  - Ph III – compound B
  - Ph III – compound C

- **control cytokine storm**
  - Ph IIa – compound D
  - Ph IIa – compound E

- **disease severity**
Pragmatism

Parallel design
Established clinical endpoints
Lean CRFs
Remote follow-up
Sparse blood sampling

Estimand reflecting specific situation

- Investigational treatment
- Control
- Screening / Baseline
- EoT / Discharge
- Post-treatment follow-up / EOS
  Assessments every 2 days for hospitalized patient
- Safety follow-up call
- APACHE II score

EoT: end of treatment
EOS: end of study
Facts

APACHE scores applied in intensive care units (ICU), several versions exist

PhIIa endpoint: used to predict survival probability at EoT in ICU

Estimand considered
• early discharge
• death

PhIII endpoint: includes survival

Choice of endpoint driven by restrictions on sample size
Challenges

«moving targets»:
• Expected recruitment
• Daily reality at the sites
• Standard of care
• Endpoints: from 7- to 9-point scale

Early development specific
• Limited drug availability
• Non-standard primary endpoint

Short timelines:
5 weeks from internal approval to FPFV

Alignment with other NVS studies
• Within PhIIa trials
• Across PhIIa and PhIII trials
Collaboration

In society: stay home to protect the vulnerable

At home: within the (much) closer «community»

...the underlying theme

Within the COVID-19 trial teams:

- Be flexible:
  - None standard situations
  - Unusual requirements
  - Be available

Split tasks

Everyone takes responsibility

External interaction:

- Very close collaboration between Global and Local NVS teams
- Rapid feedback from HAs
- Close communication with sites
Thank you