Novartis Institutes for
Biomedical Research (NIBR)

Specific aspects of a clinical trial targeting Covid-19

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Early Development Biostatistics

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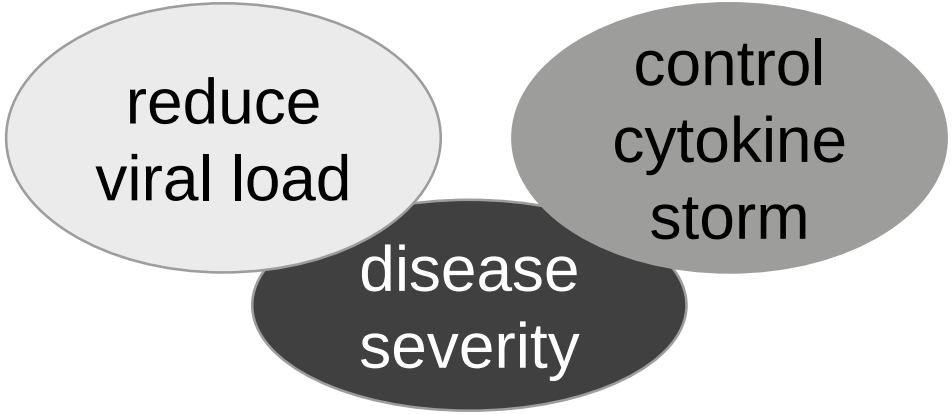
Opportunities



Ph III – compound A

Ph III – compound B

Ph III – compound C

Ph IIa – compound D

Ph IIa – compound E

Pragmatism

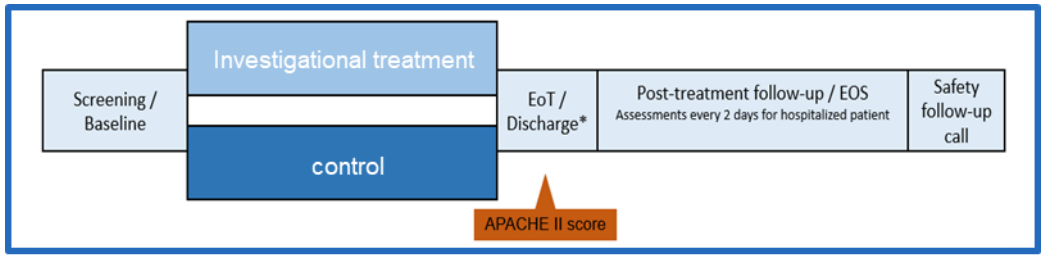
Parallel design

Early discharge opportunity

Established clinical endpoints

Lean CRFs

Remote follow-up



Sparse blood sampling

Estimand reflecting specific situation

EoT: end of treatment
EOS: end of study

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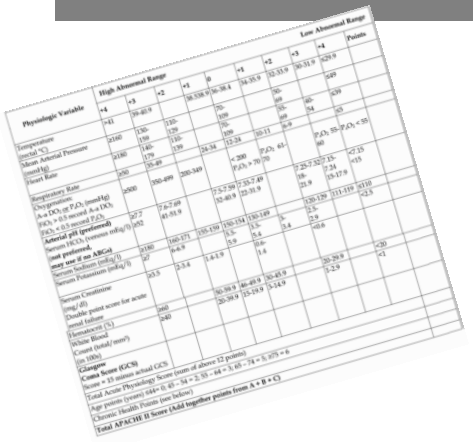
Facts

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



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

PhIII endpoint: includes survival

Estimand considered
- early discharge
- death

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

Aligment with other NVS studies
- Within PhIIa trials
- Across PhIIa and PhIII trials

Collaboration

In society: stay home to protect the vulneralbe

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

...the underlying theme

Within the COVID-19 trial teams:

Be flexible:
- None standard situations
- Unsual 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

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Thank you

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