

# Role of iDMC for complex clinical trials

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# Background

- Academic Statistician
- Regularly sit on iDMCs (both academic and industry studies)
- Expertise in complex clinical trials

# The role of a DSMB

- To review accumulating data from patients taking part in a clinical trial on safety (and possibly efficacy)
- To advise the trial sponsor regarding the continuing safety of current and yet to be recruited patients
- To advise the trial sponsor on the continuing validity and scientific merit of the trial

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**without undermining the study's integrity and validity.**

(Chow et al. 2005)

# Implications for iDMC

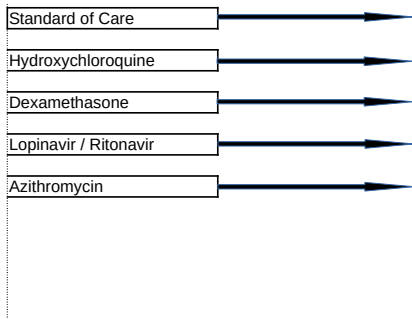
- May be asked to “execute” adaptations decisions



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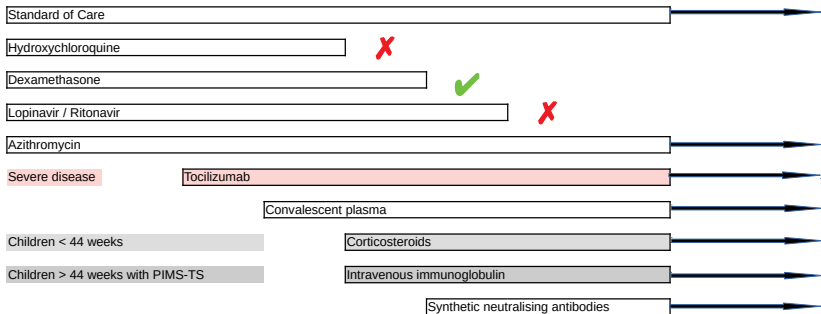
- May be asked to “execute” adaptations decisions
  - $\Rightarrow$  more in a later talk
- Multiple treatments/populations/maturity of data

# RECOVERY when it started



- in hospitalized patients with suspected or confirmed COVID-19 (all ages)

# RECOVERY today



# Challenges for safety monitoring

- Increased risk of spurious findings
- Release of results
- Dependence of decision making
- Expertise of iDMC
- ...

## DSMB models for complex trials



Overarching  
DSMB

Figure: Potential model for iDMCs for complex trials.

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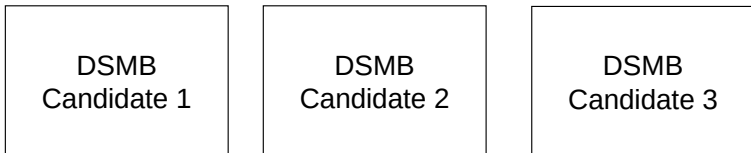


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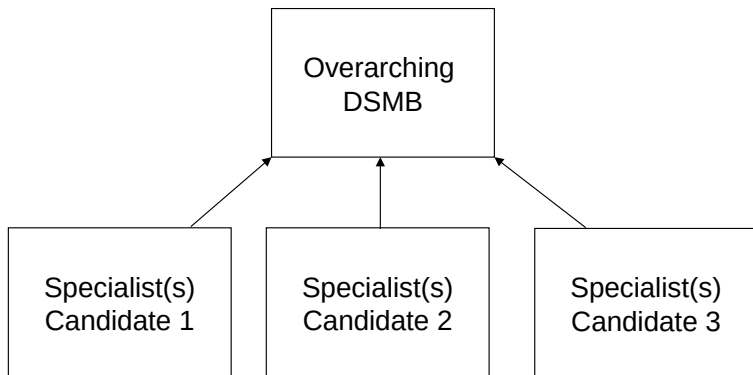


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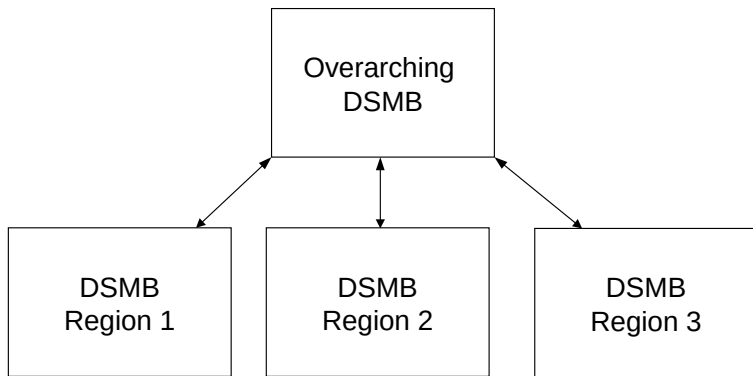


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Evidence could be included

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⇒ Avoid naive pooling due to Simpson's paradox!

# Discussion

- Platforms add organisational complexity
- Adaptive designs add complexities about decision making
- When combining information ensure doing it appropriately

# References

Chow SC, Chang M, Pong A (2005) Statistical consideration of adaptive methods in clinical development. *Journal of Biopharmaceutical Statistics*, **15**(4), 575–591.

Mütze T, Friede T (2020) Data monitoring committees for clinical trials evaluating treatments of COVID-19. *Contemporary Clinical Trials*.