Ethics and research

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Overview

- International clinical trial governance
- Standard of care / prevention: comparator arm in COVID-19 vaccine trials
- Research methodology – evolving or novel trial designs
- Post-trial access

International clinical trial governance: equity considerations

How should large, simple, global platform trials be governed?

Top-down trial design and implementation or bottom-up?

Ethics review: international ethics review vs local ethics review

Standard of care / prevention: comparator arm in COVID-19 vaccine trials

- The use of an authorized active comparator as a control ensures that those who are assigned to the active comparator arm are assured access to a safe and efficacious intervention. To conduct active comparator trials, the developer of an authorized vaccine may donate/sponsor their vaccine for use as the comparator.
- But what are the ethical implications if a developer refuses to allow their authorised product to be used as an active comparator?

Research methodology – evolving or novel trial designs

- the need to capacitate REC members and regulators to appreciate the ethical issues that evolving or novel trial designs raise
- Rapidly evolving public health contexts necessitate evolving or novel trial designs.
- For example, the COVID-19 pandemic has seen a proliferation of research methodologies, including adaptive trials designs, the use of real world evidence, different types of placebo-control trials, and synthetic or external controls.
- REC members need to be capacitated to oversee such research or we risk critically important and legitimate research being held back or methodologically unsound and potentially unethical research being approved.

Conclusion

- Ethics should be integrated into the wider research ecosystem so that ethical reflection becomes an integral component of the entire research endeavour value chain – from research conception to commercialisation.