World Health Assembly 2022 resolution on Clinical Trials:
Why?
What is it?
Who for?
When?

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World Health Organization

The World Health Assembly calls for improvements to clinical trials – May 2022

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Key features of the resolution

Calls for governments to acknowledge the central role of RCTs in the health sector, in generating knowledge for decision-making

Calls for national authorities and non-state actors to focus RCTs on the key aspects needed to generate needs-based, high quality evidence

Calls for WHO to develop guidance on design quality, ecosystem strengthening and filling gaps in evidence in under-served groups

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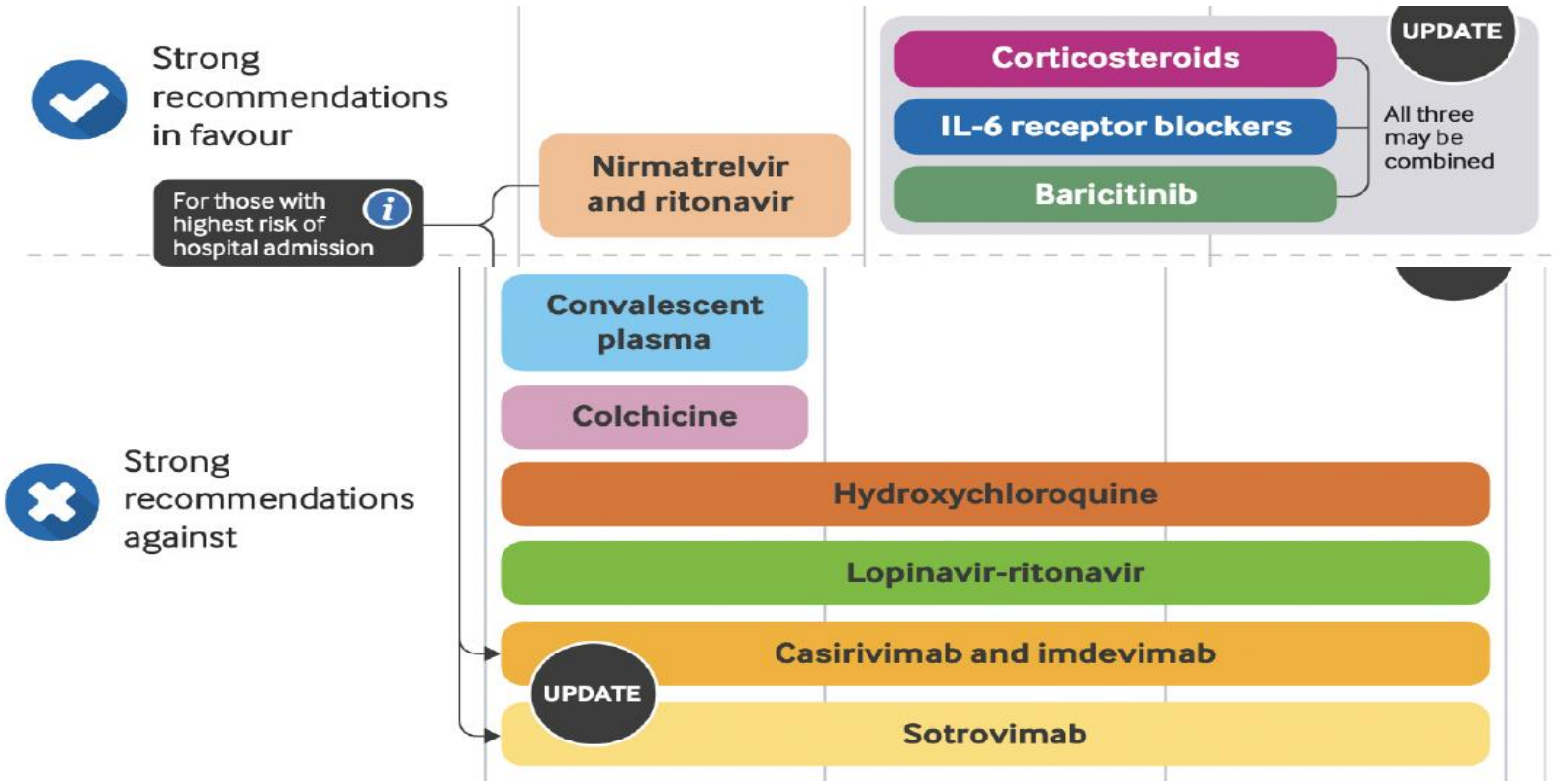
A few large trials generated much useful evidence and changed global practice



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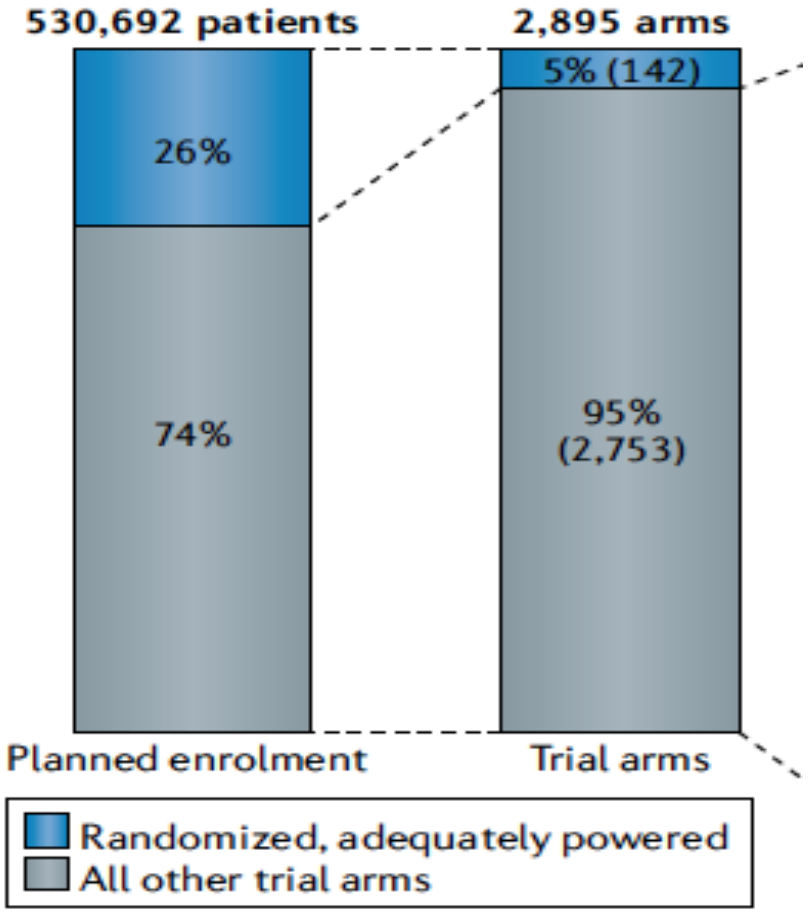
1000s of trials were low quality



Ref: Nat Rev Drug Discov . 2021 Apr;20(4):254-255. Bugin & Woodcock.

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WHO guidance on best practices for clinical trials

- Design and implementation
- Strengthening the clinical trial ecosystem
- Addressing underserved populations
- Roles of different stakeholders

What will this add?

- Focus on streamlining, key features needed for reliably informative evidence
- Removing excessive bureaucracy
- New models for coordinated approvals
- Better international coordination, prioritization, links with policy
- Support capacity development initiatives

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Who are the audience?

- Member States
- National authorities (research funders, ethics, regulatory)
- Non-state actors including clinical researchers (private and public sector)

When will it be available?

- Draft for consultation Q3 2023

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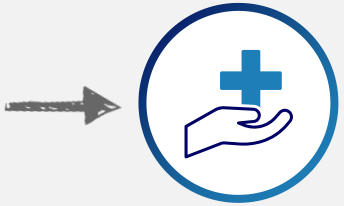
African Vaccines Regulatory Forum

AVAREF (African Vaccine Regulatory Forum) connects regulators and ethics committees from African countries

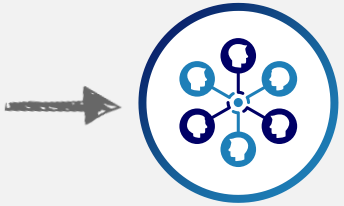
All 55 countries in Africa are members of AVAREF.
AVAREF aims to **harmonise** regulatory practices, **strengthen** collaboration, **build** capabilities and **shorten** timelines to country decisions through joint-review processes

AVAREF offers and facilitates **three main services to PDPs**, using (fromQ4 2023) a fees for services model



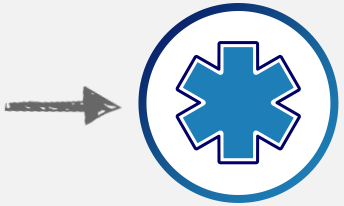
Clinical Trial scientific advice

- Platform for PDPs to engage with experts from across Africa to obtain regulatory and ethical advice about the design of clinical trial in African countries



Multi-country review of Clinical Trial application

- Facilitated joint-reviews for PDPs willing to conduct clinical trial in multiple African countries, coordinating regulators and ethics committee for timely and efficient review



Emergency Use Authorisation facilitation

- Facilitated multi-country technical workshops and joint-reviews for PDPs willing to obtain EUA in multiple African countries using the WHO EUL recommendation for candidate vaccines

All services are available for vaccines, medicines and medical devices, for products addressing a public health emergency, a neglected disease, an unmet medical needs, or involving a novel technology

Visit AVAREF **website** to view guidance, templates and tools

Subscribe to our **newsletter**

Contact AVAREF Secretariat for information and enquiry: maigad@who.int ; rodgersj@who.int

As baseline mapping of clinical trial capabilities proceeds, elements of a possible self-assessment toolkit emerge

- National clinical trial legislation and regulation
- Maturity of NRA/ERC for trial oversight
- Role of national health research authority
- Availability and allocation of clinical trial funding
- Institutional capacity for clinical trials
- Links between evidence and trials ecosystems
- Efficiency and quality of clinical trial reporting
- Clinical trial networks
- Clinical trial initiatives

?Country clinical trial capability self-assessment toolkit

?Inform capacity development for clinical trials

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Thank you

For queries or specific follow-up calls please contact WHA758@who.int

Website Implementation of the resolution on clinical trials (who.int)

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