Compassionate Use and/or Emergency use of unproven and registered products during the COVID-19 pandemic: Looking backward, Moving forward

Dr Helen Byomire Ndagije
(BPharm, MBA, MSc Clinical Epidemiology & Biostatics, PhD)
Director Product Safety NDA

September 2021

11th Annual National Research Ethics Conference (ANREC)

Outline

- Compassionate use of investigational drugs
- Looking back
- Challenges in emergency situations
- Present situation
- Moving Forward

National Drug Authority

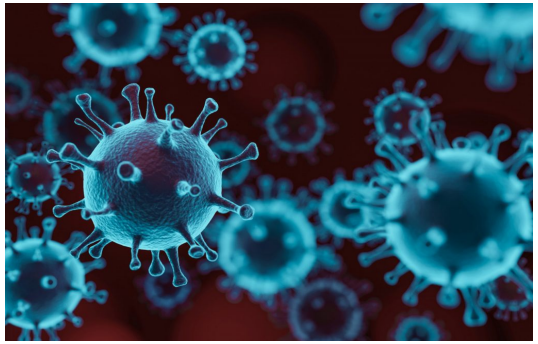
Vision

A Uganda with safe, effective and quality medicines and healthcare products.

Mission

Promoting and protecting public health through the effective regulation of human and animal medicines and healthcare products.

COVID-19 Pandemic



- The COVID-19 pandemic has led to an dramatic loss of human life worldwide

- Increase in research
  - novel therapies
  - use of repurposed drugs
- Rush to use unproven products
- Increase in number of risks
- Need for close attention to medicine regulation

Regulatory Framework

- National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the Laws of Uganda (2000 Edition).
- Section 40 of the NDP&A Act, Cap 206 gives the mandate to authorize drug-related trials by issuing a certificate
- Section 8(4) of the National Drug Policy and Authority Act (NDP/A) (Cap 206) states that: “a drug not appearing on the national formulary may be imported and sold after authorization by the drug authority to meet emergency or extraordinary circumstances”.

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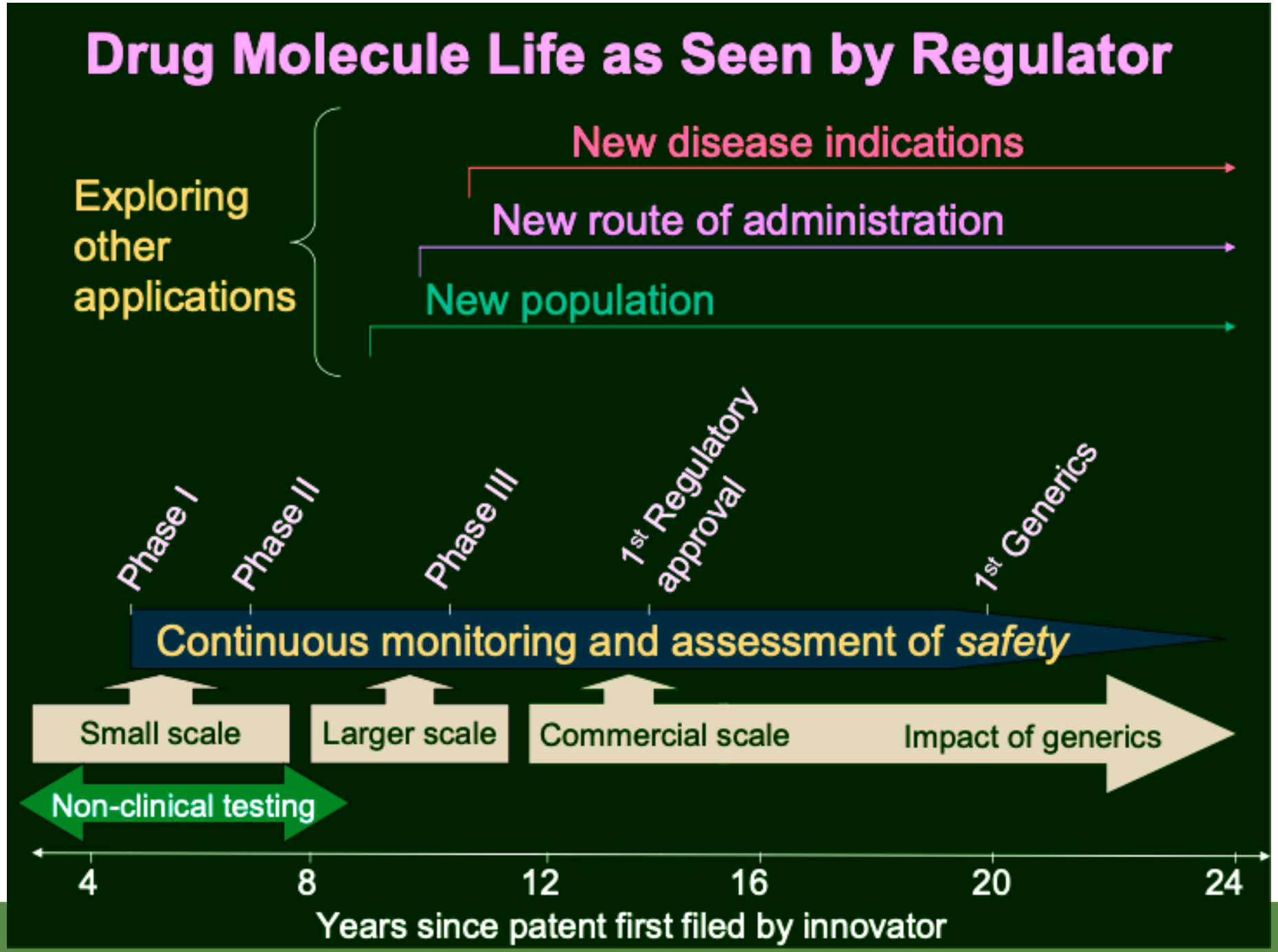
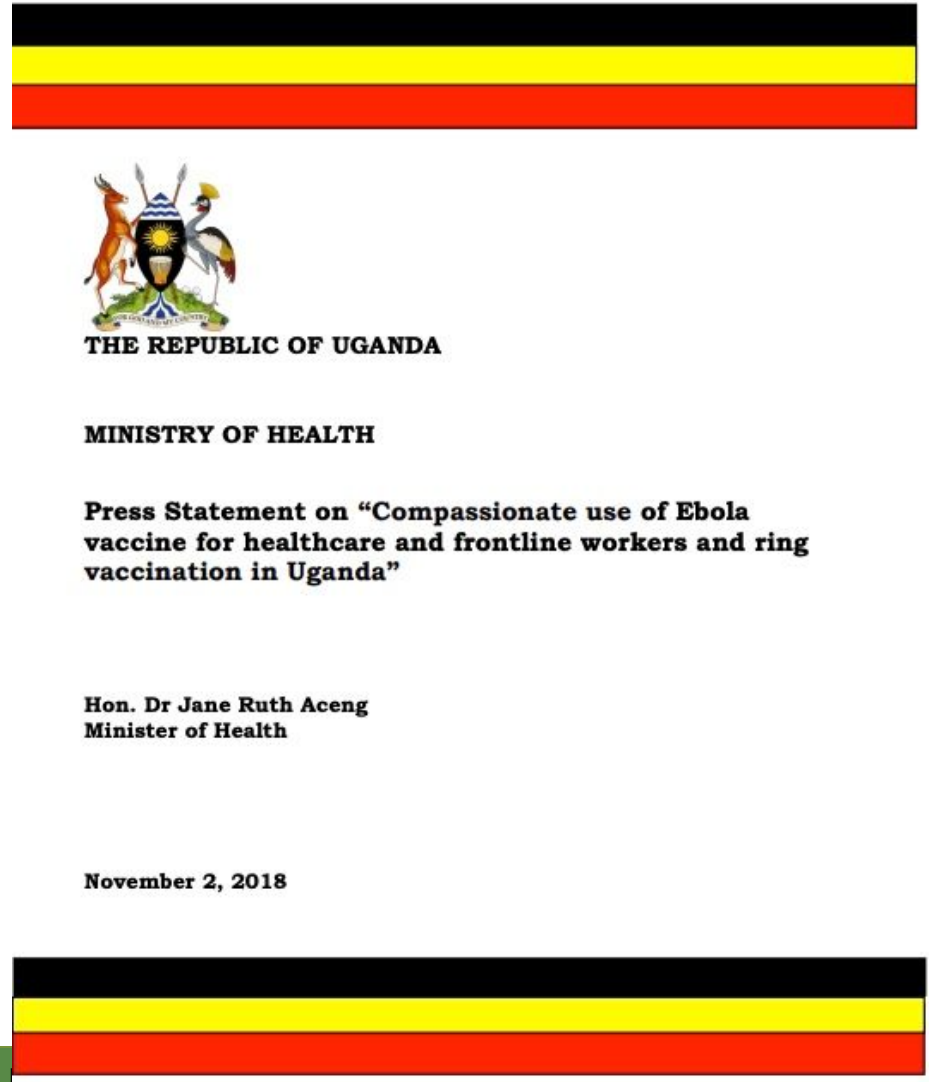


What is Compassionate use ?

- Compassionate use (CU) is a program that is intended to provide potentially life-saving experimental treatments to patients suffering from a disease for which no satisfactory authorized therapy exists and/or who cannot enter a clinical trial (WHO)

- For many patients, these programs represent their last hope.



THE REPUBLIC OF UGANDA

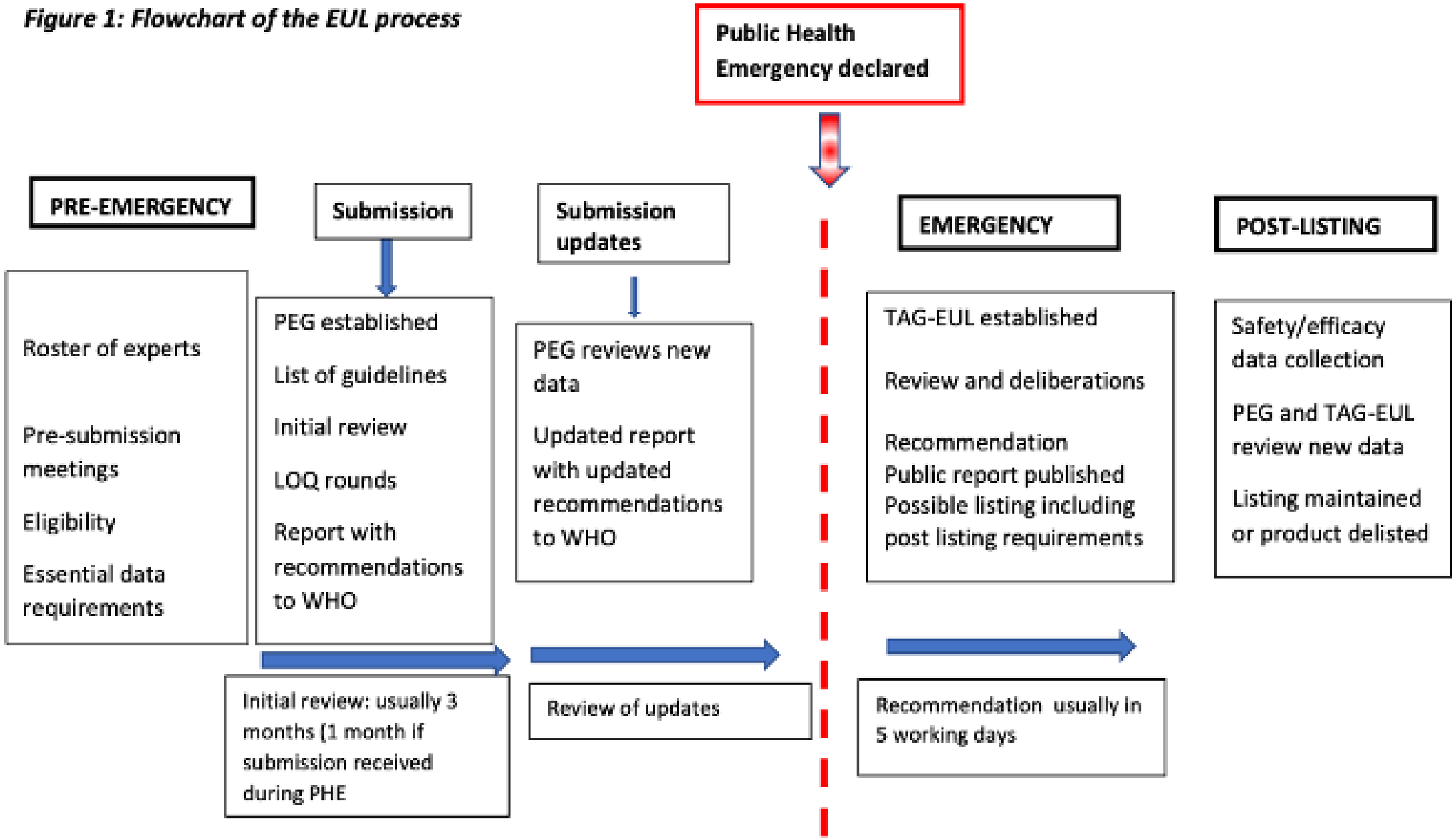
MINISTRY OF HEALTH

Press Statement on "Compassionate use of Ebola vaccine for healthcare and frontline workers and ring vaccination in Uganda"

Hon. Dr Jane Ruth Aceng
Minister of Health

November 2, 2018

Figure 1: Flowchart of the EUL process



What is Emergency Use Authorisation?

- A mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic.
- Involves the use of unapproved medical products, or unapproved uses of approved medical products in an emergency
- No adequate, approved, and available alternatives.

Compassionate use for Investigational/Unregistered Products -UG

- Recombinant vesicular stomatitis virus–Zaire Ebola virus (rVSV-ZEBOV)
- ZMapp (a monoclonal antibody cocktail)
- Remdesivir (GS-5734) (an antiviral drug, has since been granted EUA for COVID-19 in a number of countries)
- REGN3470-3471-3479 (a monoclonal antibody cocktail)
- mAb 114 (a monoclonal antibody currently approved in the US as Ansuvimab for Ebola Treatment)
- Favipiravir (an antiviral drug)

Compassionate use vs Emergency use

COMPASSIONATE USE
is available to :

- qualified registered treating healthcare professional at
- Licensed health unit for
- patients who meet **inclusion** and **exclusion** criteria and provide informed consent;
- product is considered investigational

- EMERGENCY USE LISTING/ AUTHORISATION

- to treat patients with serious or life-threatening (eg COVID-19)
- use of product is part of the practice of medicine.

DOES NOT

- require approval by an Ethics Committee

Challenges of the previous EBV outbreak

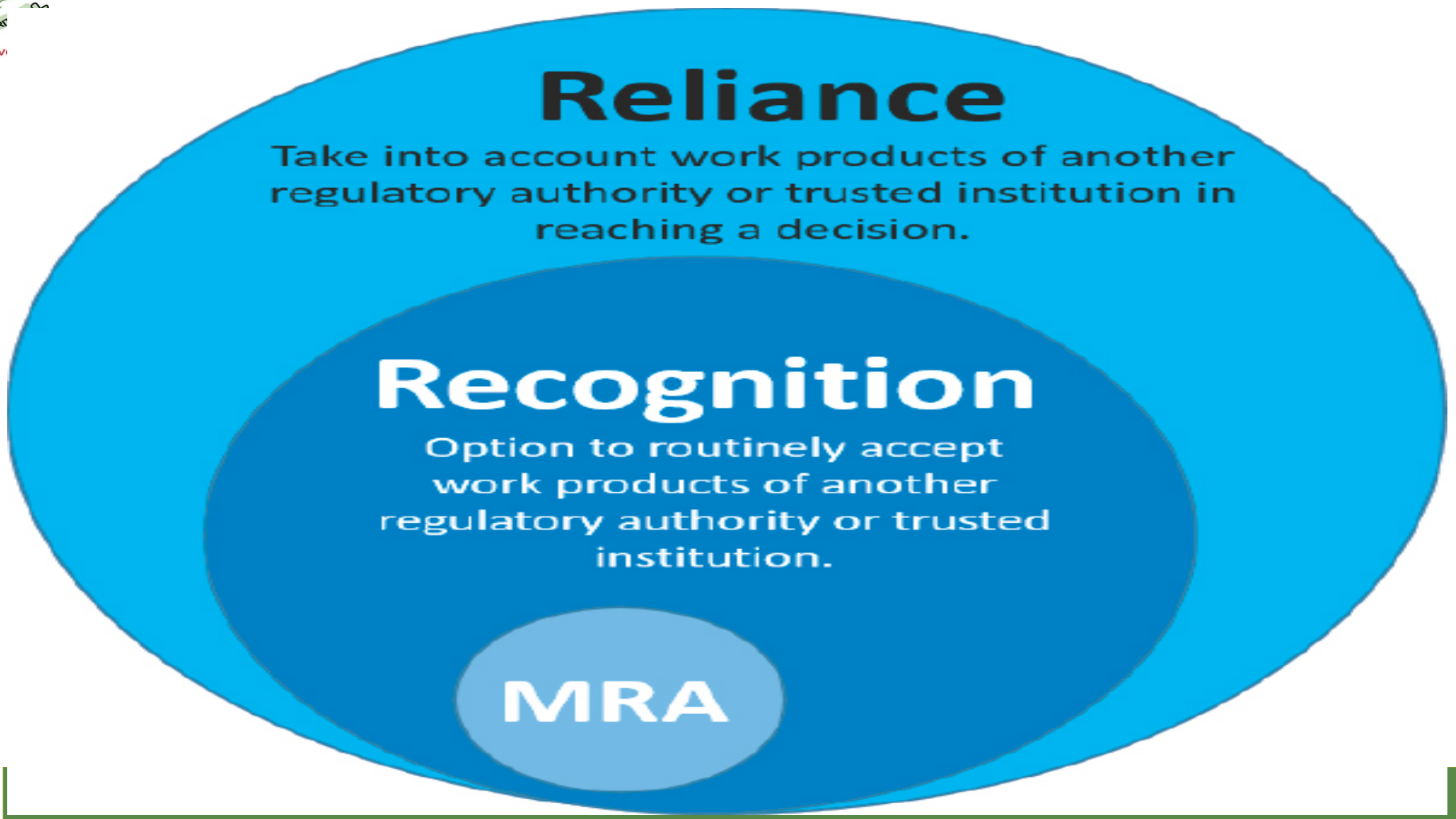
- Allocation of experimental therapeutics available in limited quantities.
- Lack or use of adaptive clinical trial designs.
- Ethical considerations of therapeutics access relative to vulnerable populations (Pregnant or lactating women or children are often excluded from phase I and phase II safety trials of potential new therapeutics or vaccines, frequently leading to decreased access to promising treatments).
- Challenges of informed consent to ensure that vulnerable patients (consented in a culturally appropriate manner)

Lessons from the Current Covid-19 Pandemic

The current pandemic has been characterized with;

- Information sharing platforms and fast publishing of information like the Cytel COVID-19 tracker https://www.covid19-trials.com/
- Complex Trial Designs like Involves complex study designs eg basket, umbrella, and platform trial designs. Basket trials investigate the safety/efficacy/effect of an IMP or combination of IMPs across a variety of populations like Platform trials test several IMPs in one or multiple populations in a highly dynamic design.

Reliance and Recognition mechanisms:



Looking Forward

- Strengthening of legal framework
- REC review and oversight: representation in major health facilities to assess that the wellbeing and integrity of patients receiving the intervention are protected.
- Strengthen technical capacity: This is to swiftly review and approve clinical research especially for abridged trials during the pandemic.
- Improve local research and development
- Community engagement
- Monitoring the intervention:

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Thank you