





SONDER

The realization that each random passerby is living
a life as vivid and complex as your own.

Vaccine clinical trials in low-resource settings: perspectives from Uganda, Tanzania and Kenya

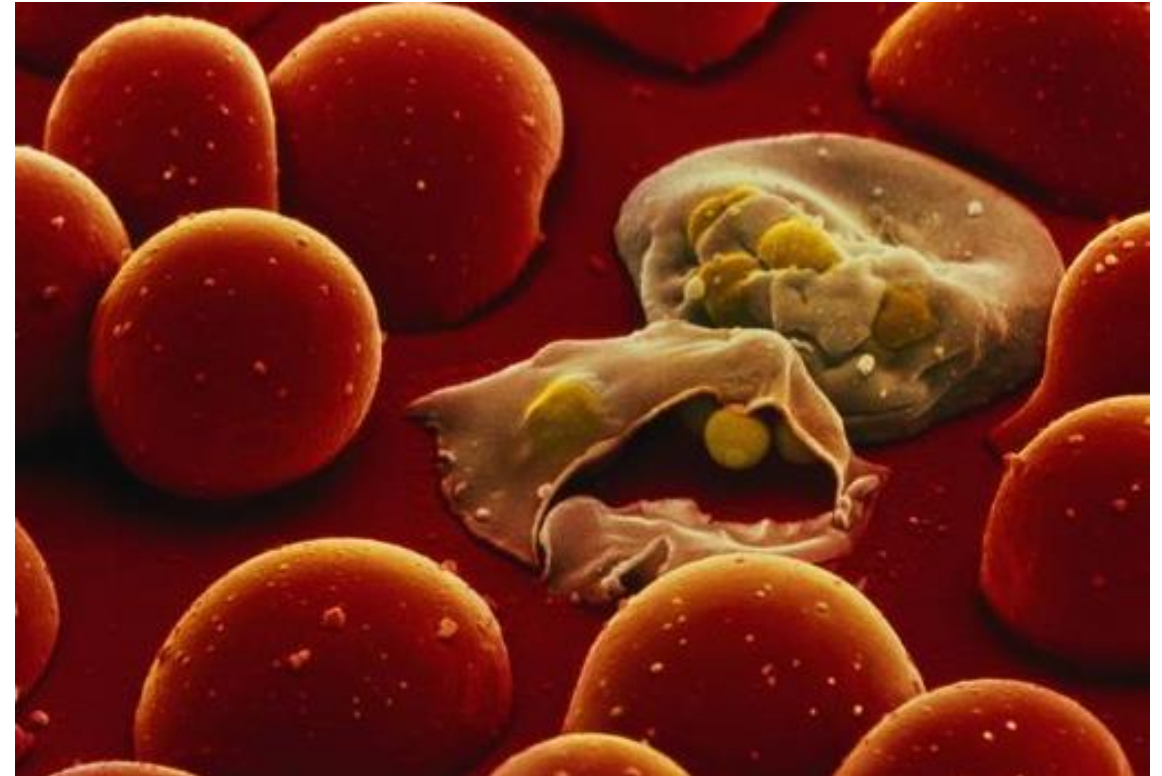
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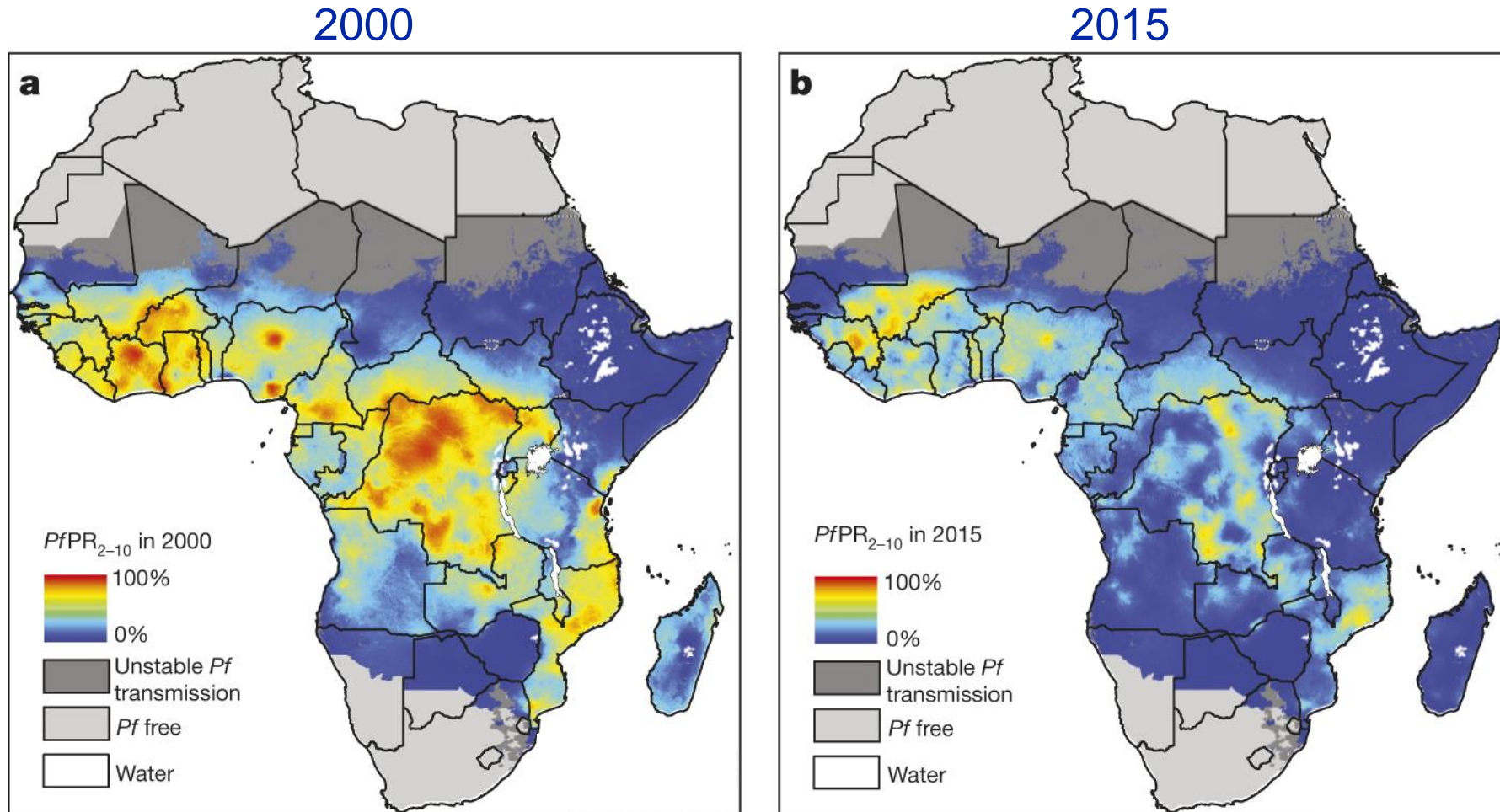
Malaria – an overview

- Infectious parasitic disease
 - Majority of cases caused by *Plasmodium falciparum* (>90%)
 - 219 million cases of malaria in 2017
 - 435 000 malaria-related deaths (61% of those were under 5 years)
- Mosquito vector



Source: Albert Bonniers Forlag

Malaria – epidemiology



Source: Malaria Atlas Project

Malaria – prevention

- Insecticide spraying
- Insecticide treated bed nets
- Early diagnosis
- Early treatment

Problem: Malaria parasite resistance to treatments and mosquito vector desensitized to insecticides.



Source: Antonio Mendes/Swiss Malaria Group

Name: RTS,S

Target group: Children aged 5-17 months

Goal: Reduce severe malaria in children <5 years of age



Source: Frederic Courbet

RTS,S malaria vaccine phase III trial
was carried out between March 2009
and January 2014 in 7 African countries
(Burkina Faso, Gabon, Ghana, **Kenya**,
Malawi, Mozambique, **Tanzania**) across
11 clinical trial sites.



Source: Oliver Lassen/Swiss Malaria Group

Understand the researcher and caregiver experience during clinical trials in low-resource settings to identify the associated ethical challenges and their implications for vaccine research design.



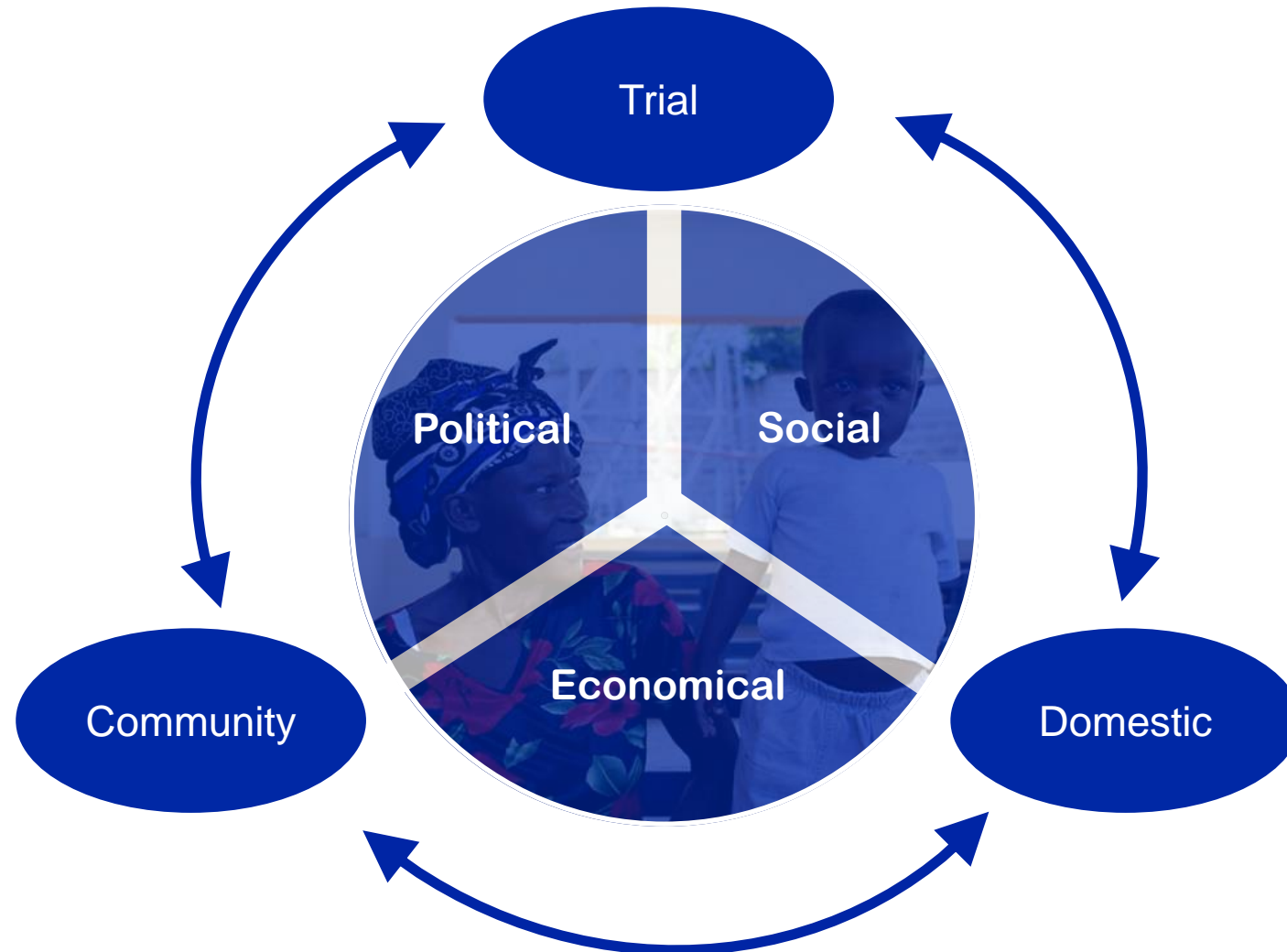


Interviews with caregivers of pediatric participants enrolled in a malaria vaccine clinical trial (n = 78)

Interviews with frontline researchers involved in the phase III RTS,S clinical trial (n = 11)









“Before the research study, when you would visit the government hospital, after the tests they would tell you to go and buy the medicines and sometimes you don’t have the money. But after my child joined the research study, the situation changed. I am grateful as my child was getting malaria tests and given medicines in a sealed bottle not the opened ones.”

Researcher's embodied reality



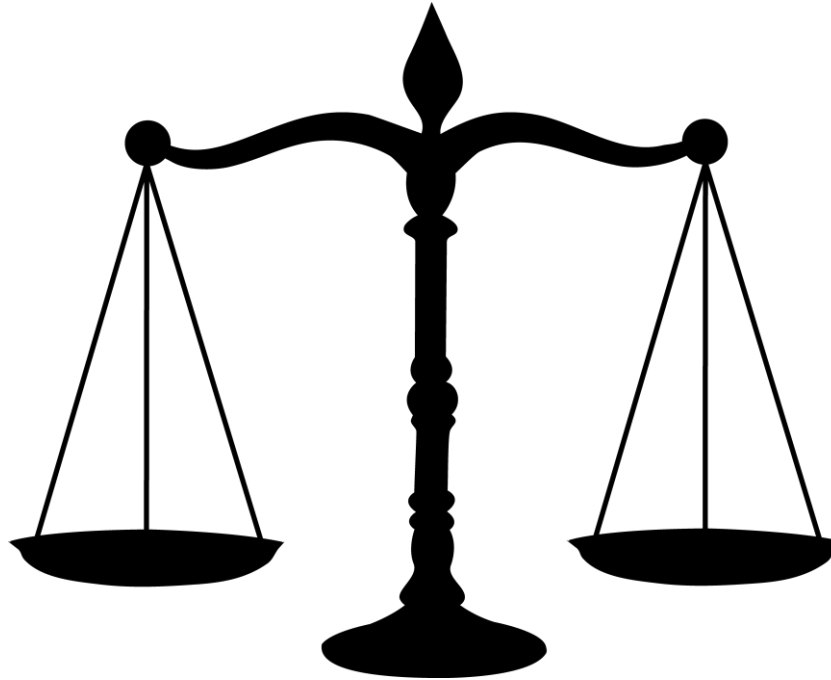
“it is difficult as a person, as a human, as a mother”

- Researcher, Kenya



AUTONOMY

Structural disparity leads to limited autonomy (lack of viable medical options)



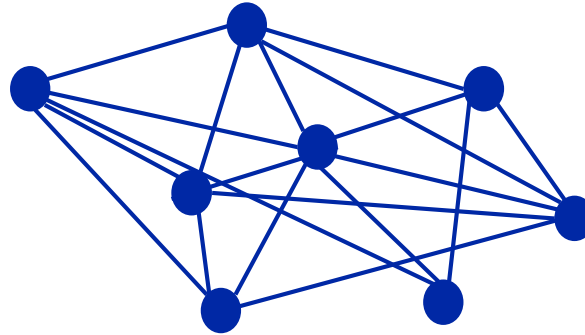
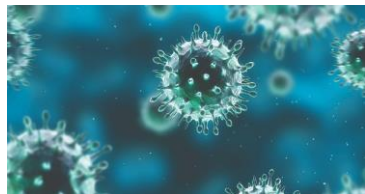
BENEFICENCE

Malaria vaccine an act of beneficence, as is providing medical care and reducing child mortality



Complexity theory

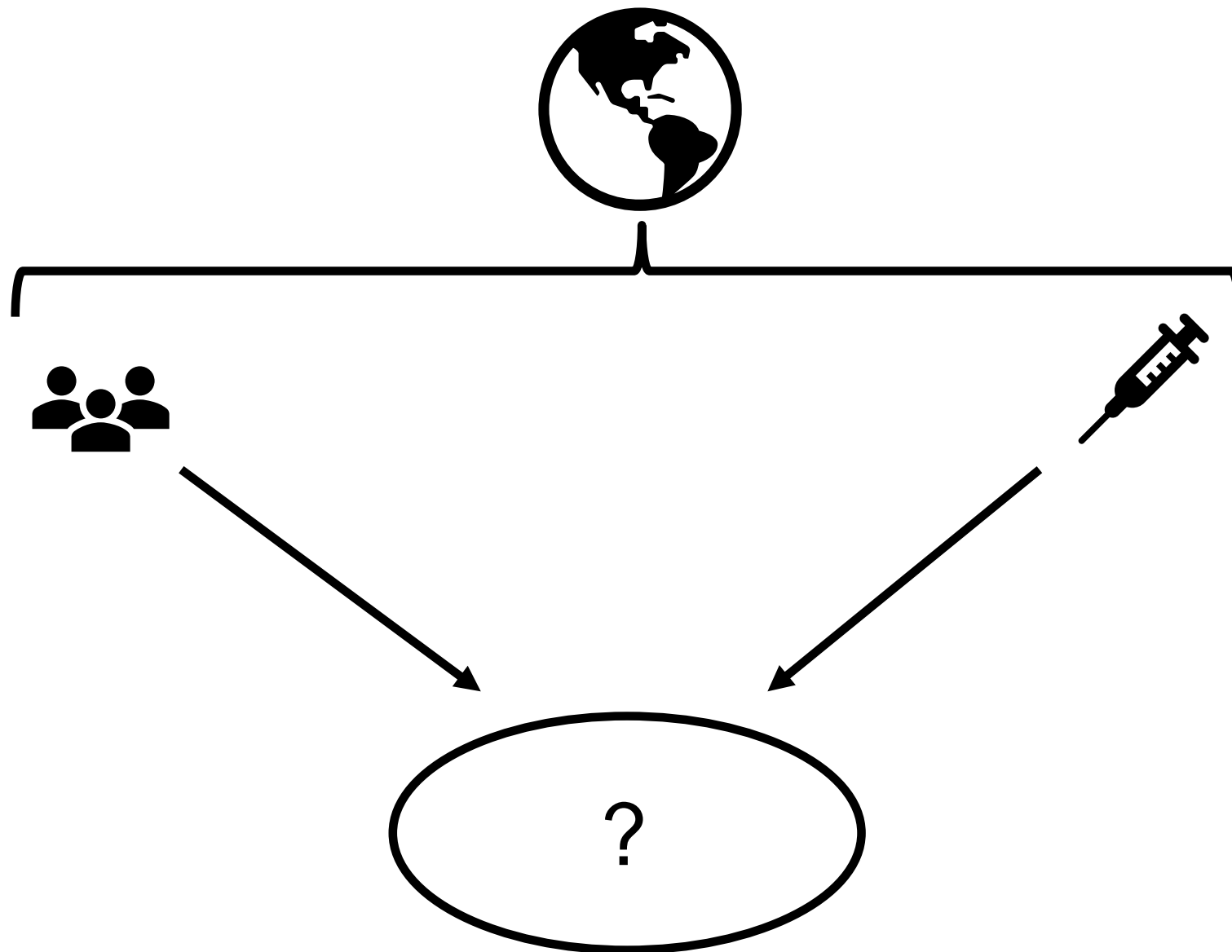
Complex adaptive systems (CAS) describe systems that have components of unpredictability, non-linearity, iteration, interdependence and emergence.



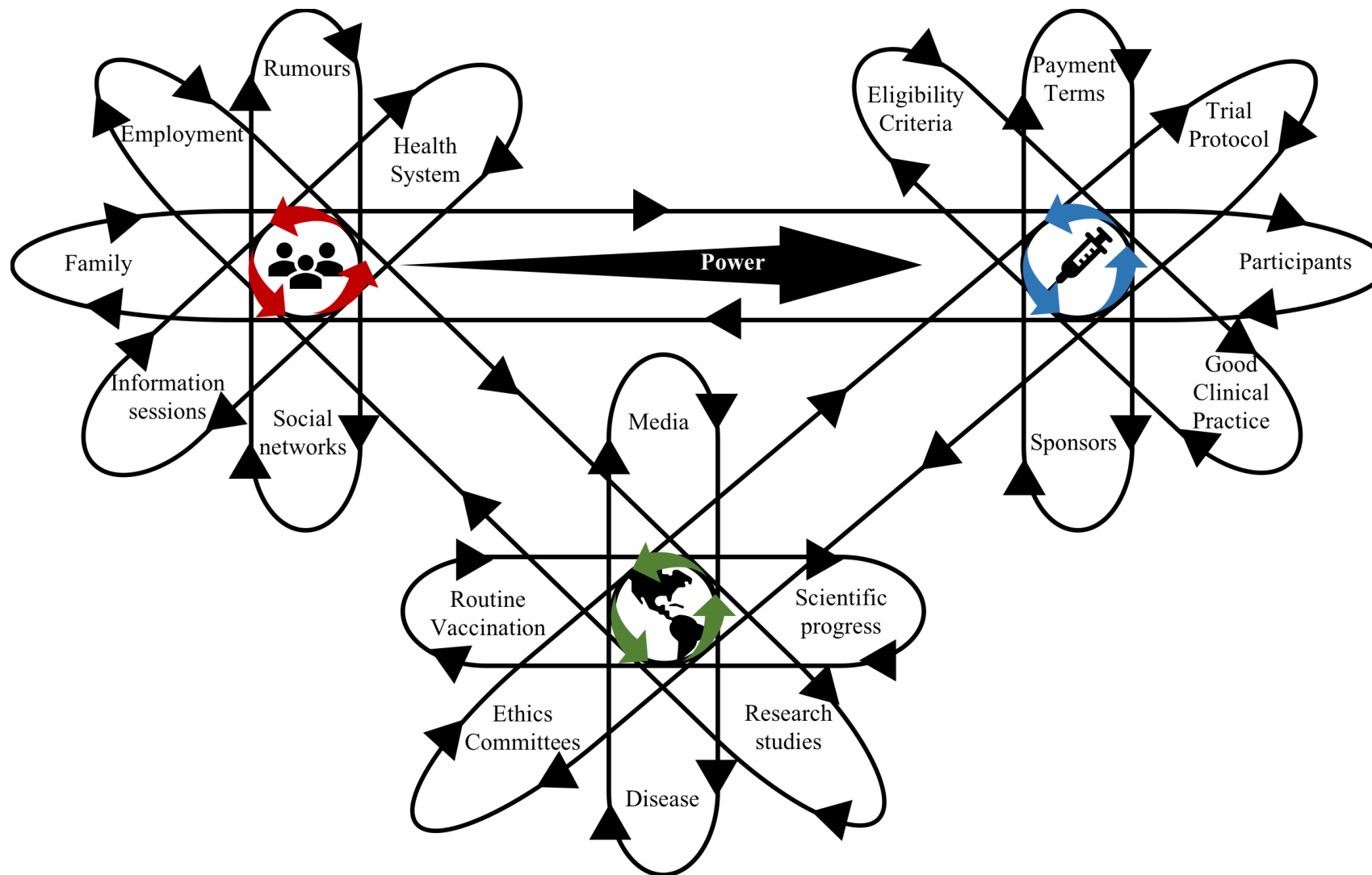
A CAS is a system with a history that impacts the current state and the direction of its evolution, a system that has many concurrent interactions which are characterized by feedback loops and is open to the external environment.



Outcomes



Outcomes





1) Recognize the role of the frontline researchers and the tools they need to build trust with caregivers and the community

2) Identify ways in which to support front line researchers in a way that is appropriate for the context and its structural capacity

3) Develop collaborative partnerships with local stakeholders to reduce structural inequities and foster sustainable health system strengthening

Vaccine clinical trial design



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