Science , Technology and Innovation Regulatory Landscape an Coordination in Uganda

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Summary of Presentation

- A look at the big picture: Macro-economic analysis and national development agenda (Vision 2040 and transformation of Uganda to a middle-income status country.
- Analysis of Uganda's Science, Technology and Innovation ecosystem including functionality, the role of Government of Uganda, Private Sector, Academia, Research and Development units as well as civil society.
- Institutional analysis (organizational development – capacities, gaps, etc.)
- Enabling environment (laws, regulations, incentives, infrastructure, etc.)
- Socio-economic analysis (poverty data, livelihoods, and other Key issues: urbanization, energy, ICT, agricultural transformation, climate change and environment.

Basics

SCIENCE

Search for knowledge and understanding about the physical environment in which they live.

TECHNOLOGY

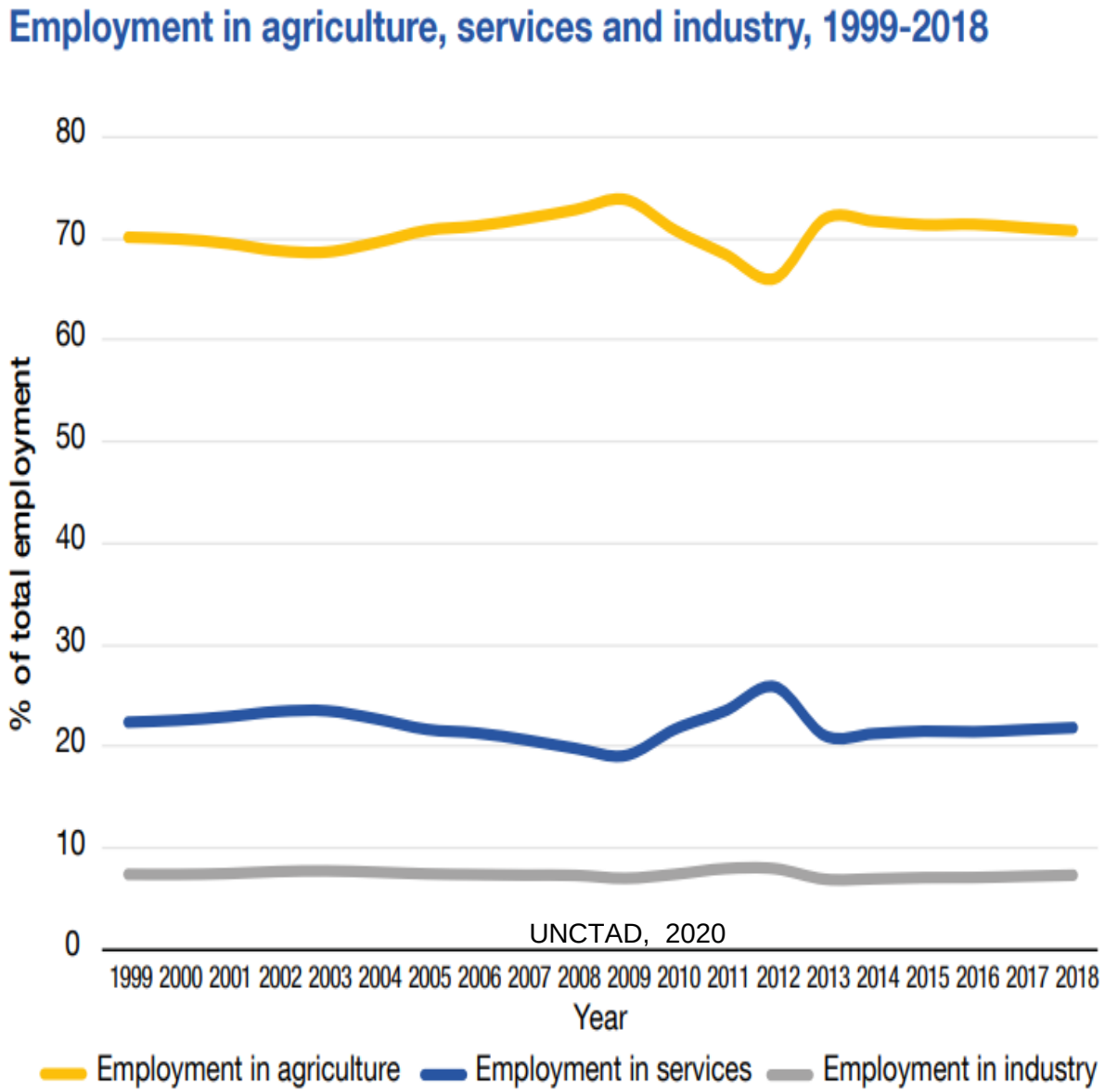
the state of knowledge concerning ways of converting resources into outputs.

INNOVATION

Implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations.

STI and its role in economic development

- STI have been identified as the key drivers for economic growth.
- STI development is an important determinant of progress and transition of countries from agrarian to knowledge-based societies.
- The extent to which a country has embraced and harnessed STI has a direct bearing on its level of development.
- Global recognition of the centrality of STI in the development process motivated countries to closely link STI to economic systems through development of national systems of innovation (NIS).

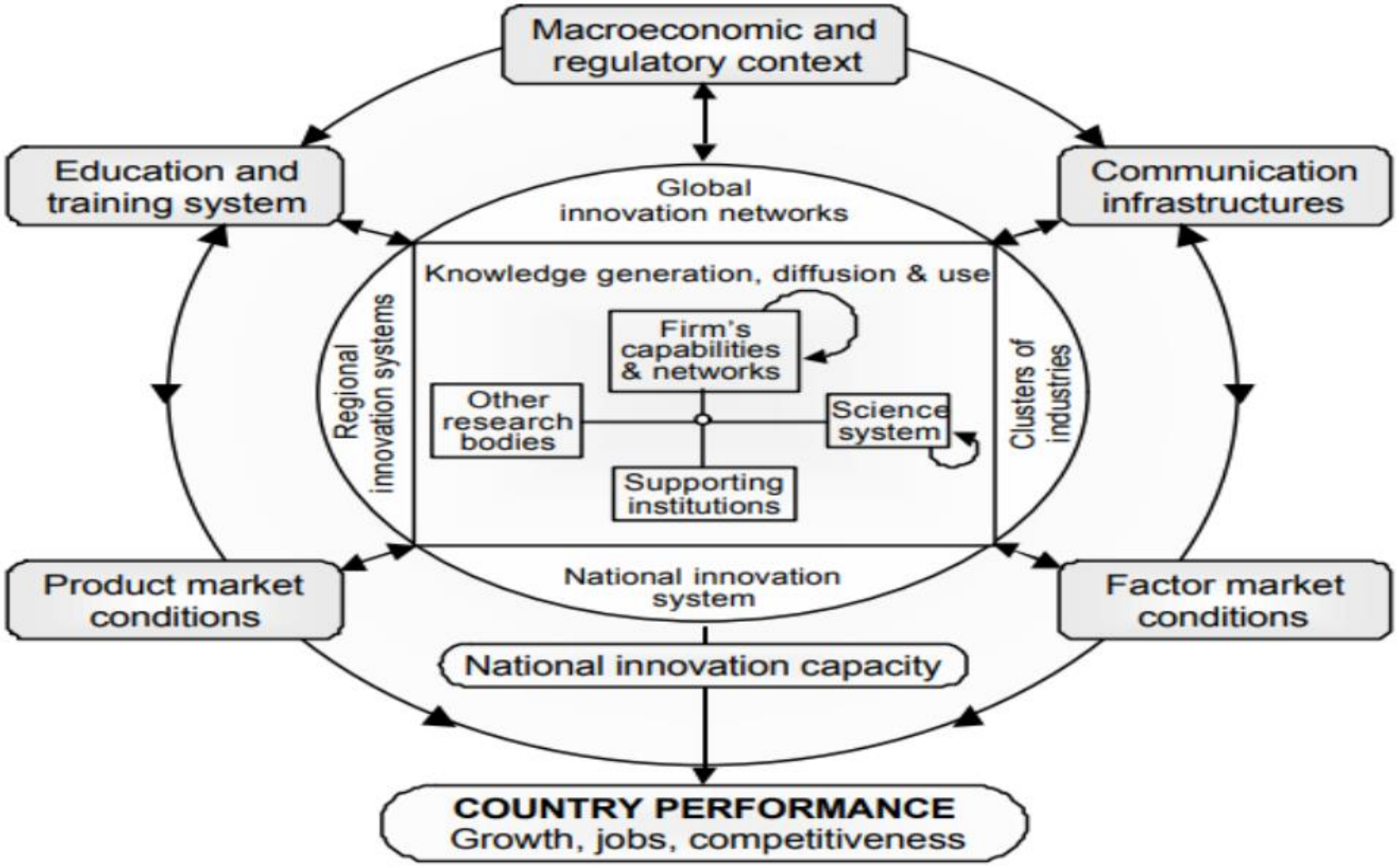


UNCTAD, 2020

New Strategic Direction of UNCST

- Regulation of all aspects of Science Technology and Innovation
- To translate STI Policies into Regulations and Standards to guide the operations of the Entire STI Eco-System
- Homing of Science professional institutions and continuing professional development
- Monitoring and Evaluation of the entire STI ecosystem

The Concept of a National Innovation System



OECD, 1999

Key Elements of Regulation

- Planning and priority setting
- Standards setting
- Permitting
- Monitoring and surveillance
- Enforcement
- Collaborations and Linkages
- Governance

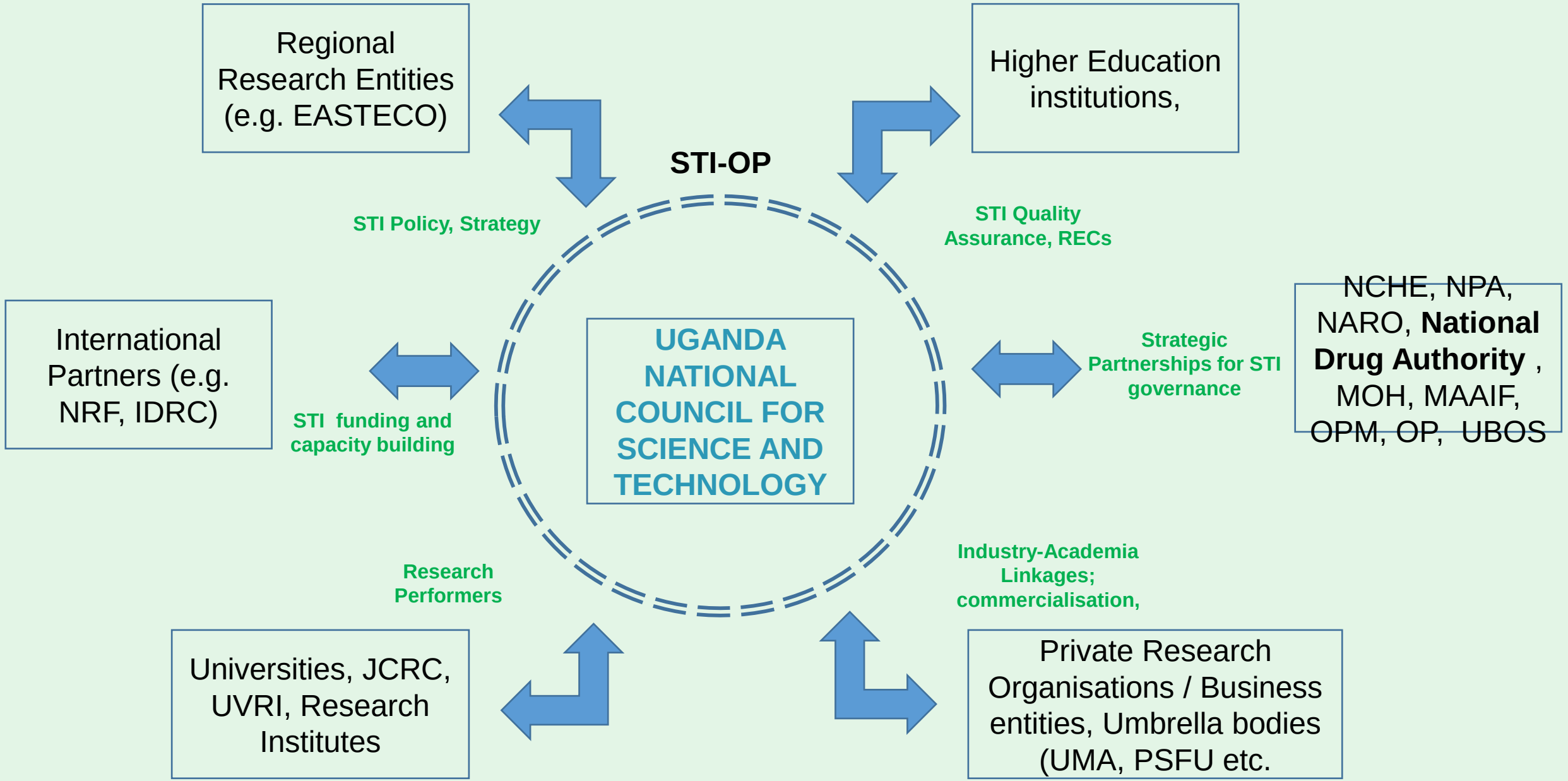
Principles of STI Regulation

- Data-driven interventions
- A Principle-based approach
- A Minimum Regulatory Sand Box
- Outcome-based approach

STI Regulation in Uganda

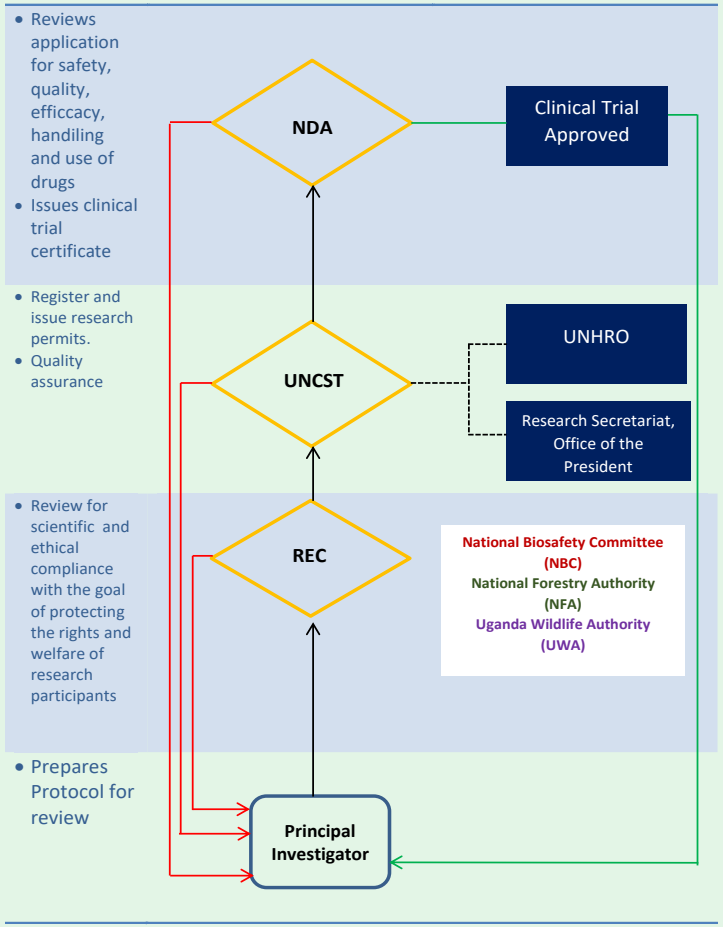
- Rapid STI-led industrial growth and global technological change is affecting Ugandans and straining our natural environment and increasing societal inequalities
- In an age of constant, complex, and disruptive technological innovation, knowing what, when, and how to structure regulatory interventions has become more difficult.
- Regulatory design needs to become more proactive, dynamic, and responsive.
- Has our national regulatory landscape achieved these goals?

STI Regulatory Outlook

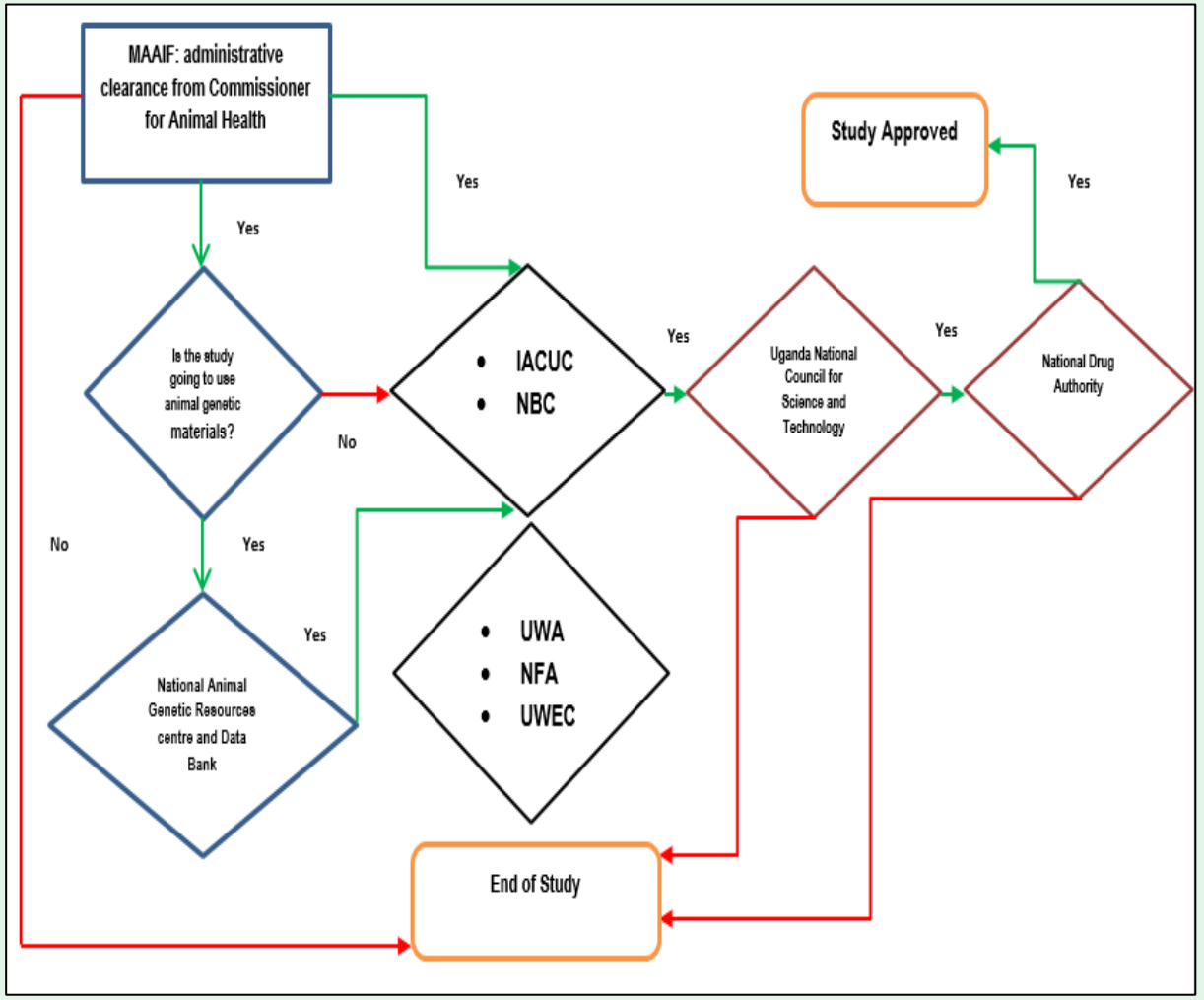


Research Regulatory Process

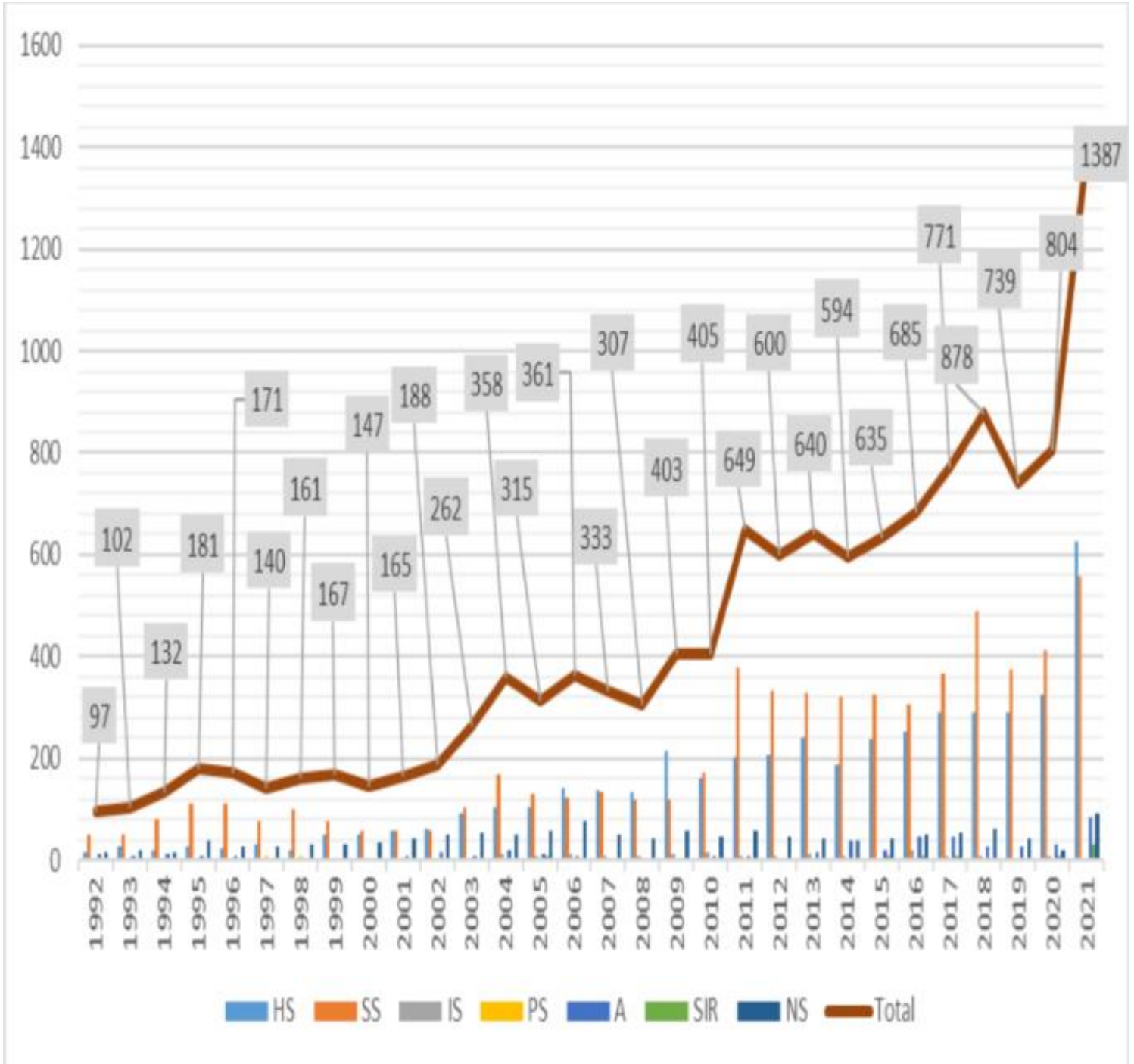
Human subjects



Animal subjects



Research Regulation and Coordination



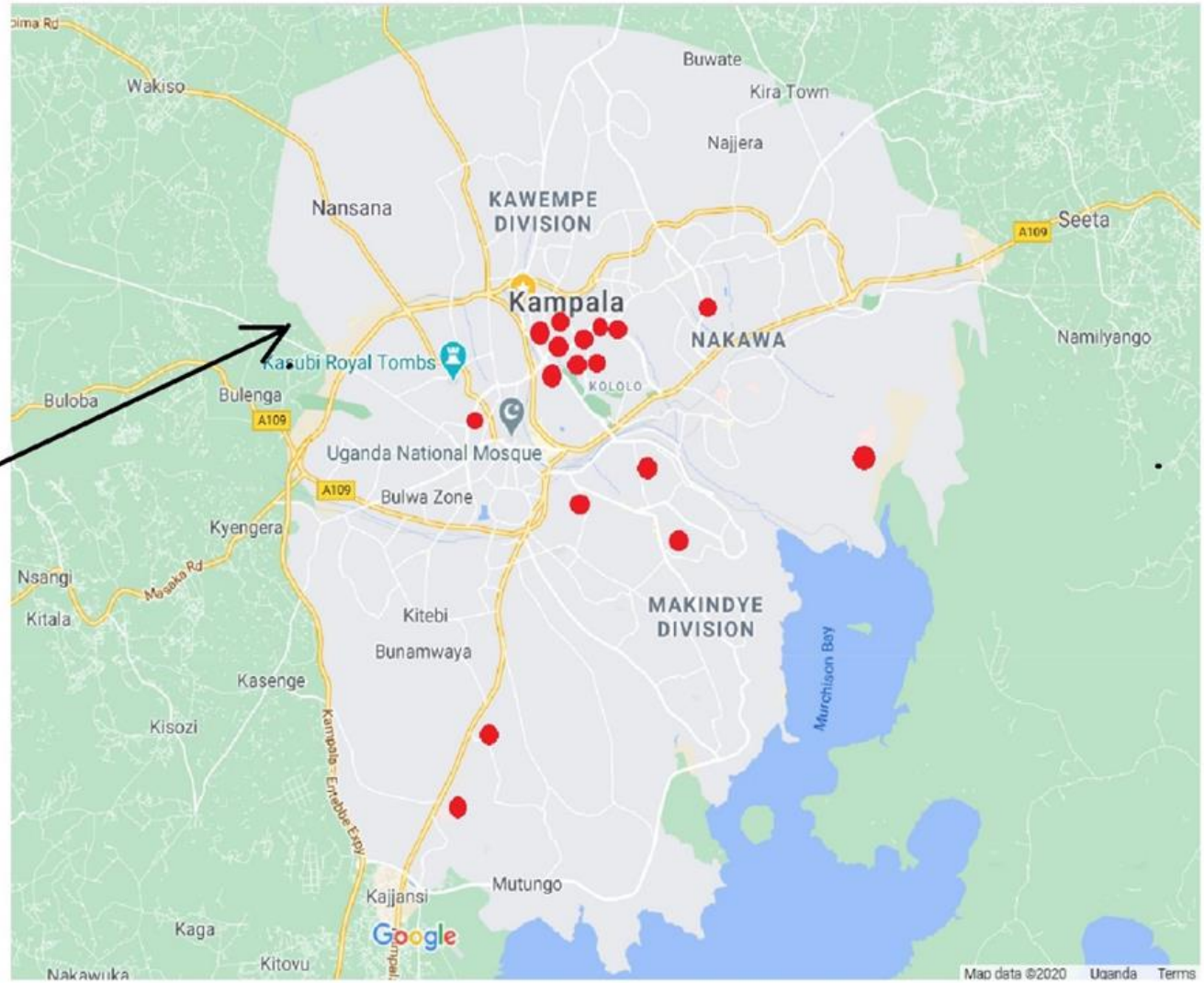
Conduct of Research during COVID-19 Pandemic

- 14 COVID-19 clinical trials reviewed (2020-2021)
- 2 herbal studies reviewed;
- Safety and Efficacy of Covidex Therapy in Management of COVID-19 Patients in Uganda: A Randomized Controlled Clinical Trial;
- A Clinical Evaluation Of Efficacy, Safety Immunogenicity, And Tolerability of Ubv-O1n-a Natural Product In Adult Patients Infected with COVID- 19 in Uganda.
- Over 300 research protocols observed.

Global, International STI-related obligations

- Became Party to CBD—8 Sept 1993;
- NEMA is the recognized NFP for the CBD
- Became Party to CPB —30 Nov 2001;
- MWE is the recognized NFP for the CPB
- Acceded to N-KL SP on Liability & Redress —25 June 2014
- Established Competent National Authority for Biosafety
- UNCST is the recognized CAN
- Biological weapons and toxins convention
- (UNSC1540)
- International Health Regulations
- Tokyo Protocol
- WHO Standards
- OIE
- Others….

REGULATION OF RESEARCH
KEY SYSTEMS: RESEARCH ETHICS COMMITTEES

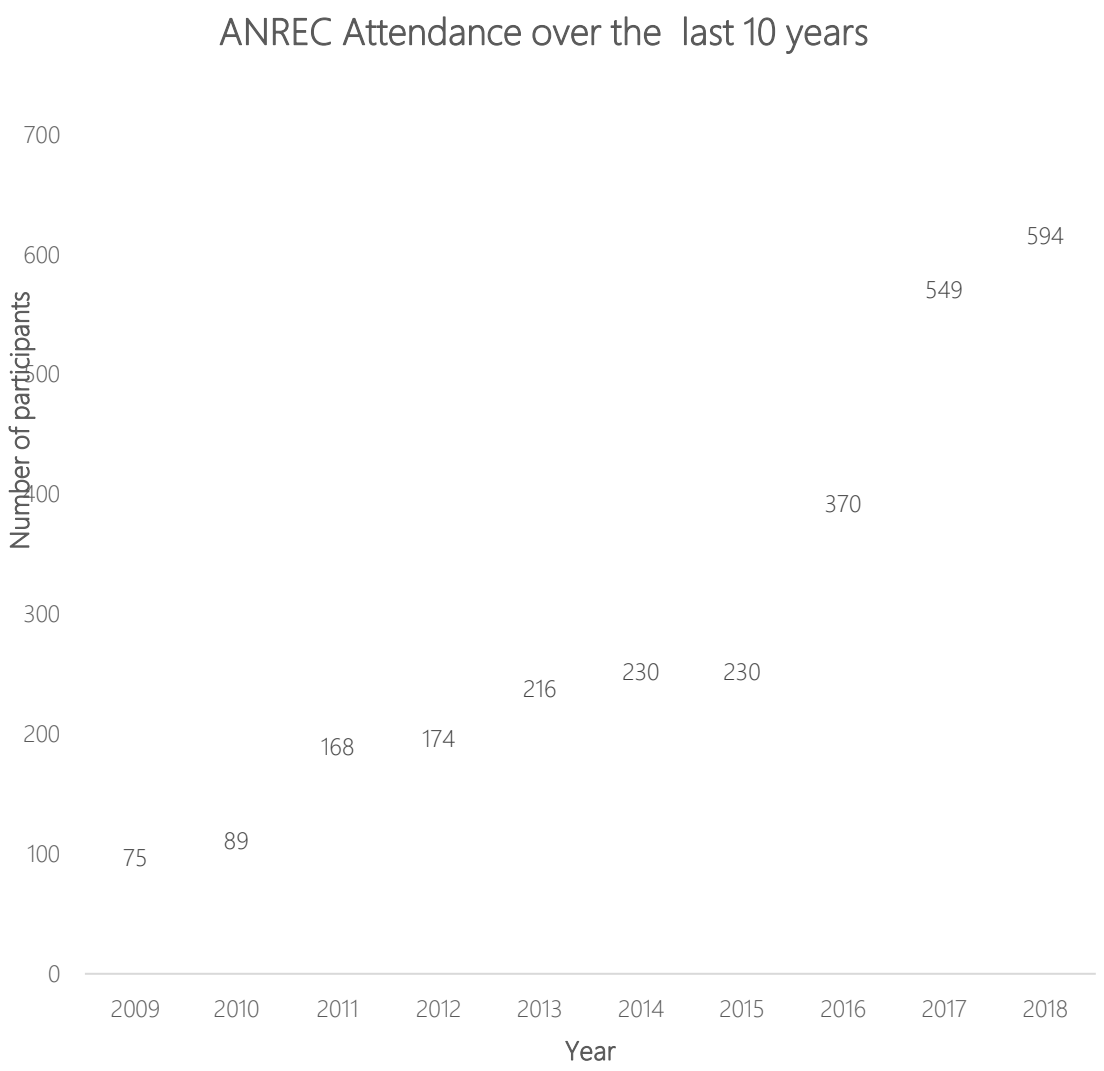


Key systems
Accredited Research Ethics Committees in Uganda

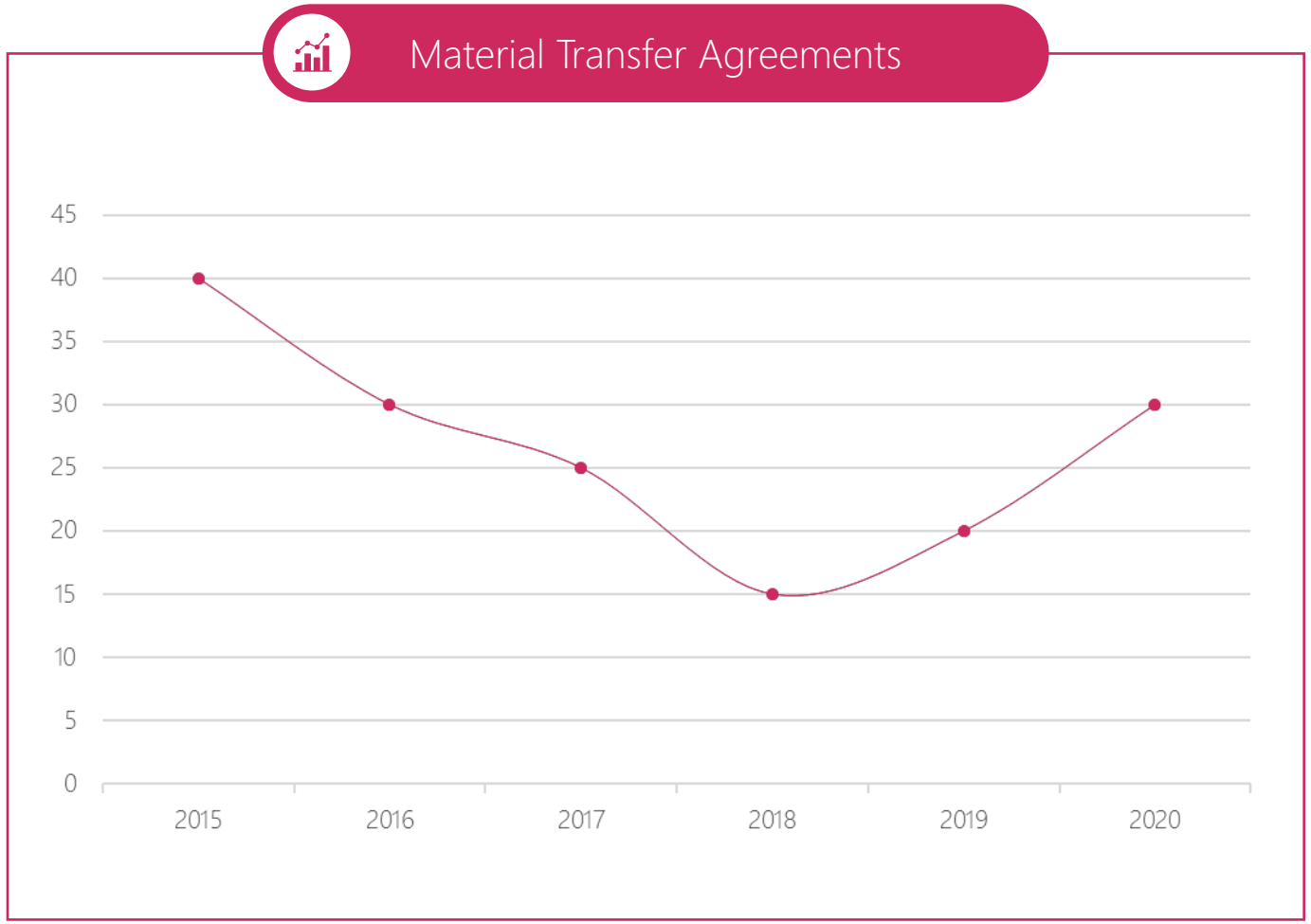
1. National HIV/AIDS Research Committee
2. Uganda Virus Research Institute
3. Joint Clinical Research Centre
4. School of Public Health
5. Mbarara University of Science and Technology
6. School of Medicine
7. School of Biomedical Sciences
8. St. Francis Mengo Hospital
9. TASO Research Ethics Committee
10. School of Health Sciences
11. Mbale Regional Hospital
12. Lacor Hospital
13. Vector Control Division
14. Uganda Cancer Institute
15. St. Francis Hospital Nsambya
16. Makerere University School of Social Sciences
17. Clare International University Research Ethics Committee
18. CURE-Uganda
19. International Health Sciences University
20. Hospice Africa Uganda
21. Gulu University
22. Mild May Uganda Research Ethics Committee
23. Mulago Hospital Research Ethics Committee
24. Uganda Christian University
25. Uganda National Health Laboratory services
26. Infectious Diseases Institute
27. Uganda Heart Institute

Key systems ct'd : The Annual National Research Ethics Conference (ANREC)

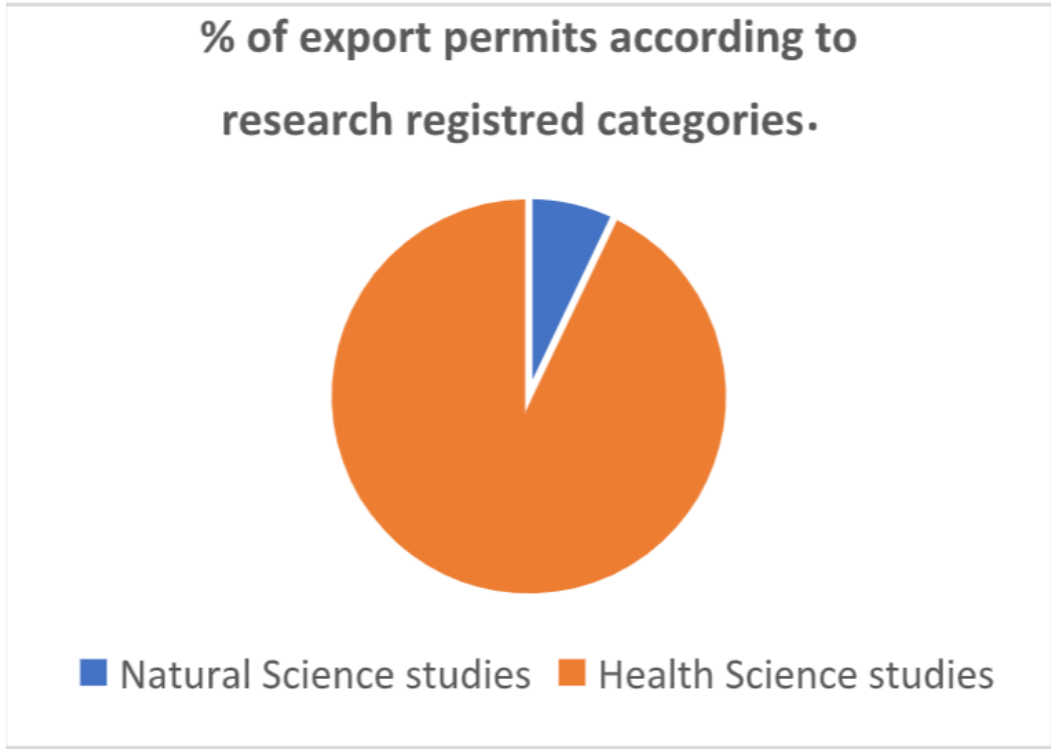
- The Annual National Research Ethics Conference (ANREC) has been recognised globally since its inauguration in 2009. Held 11 conferences which have led to compliance and better research policies.
- Objective is to share experiences and discuss contemporary issues affecting the conduct of research involving human and participants in Uganda and the Region.
- UNCST recognized 7 outstanding individual contributions of Ugandan men and women towards the protection of human research participants in Uganda and for the advancement of bioethics for national development.



MATERIAL TRANSFER



UNCST Database, 2022



Reason for export

a. Quality assurance
b. Insufficient capacity within the country for the tests
c. Future research
d. Collaboration

National Biosafety and Biosecurity systems

Competent Authority for Biosafety in Uganda –Cartagena Protocol-

- Approves research, development, testing and use of Genetically engineered organisms (GMOs) in Uganda.

- Ensures safety of genetic engineering to human health, animal health and the environment during research, development, testing and use of GMOs.

- Ensures enforcement of necessary measures to avoid adverse effects on the environment, biological diversity, human health, animal health and on socioeconomic conditions arising from genetic engineering and its products.

Uganda's Experience with GM Crops of Confined Field Trials

Cotton – resistance to cotton ball worm

Cotton – resistance to herbicide

Cassava – resistance to brown streak virus

Cassava – resistance to cassava mosaic virus

Banana - resistance to black sigatoka disease

Banana – resistance to banana bacterial wilt

Banana bio-fortified vitamin A and Iron

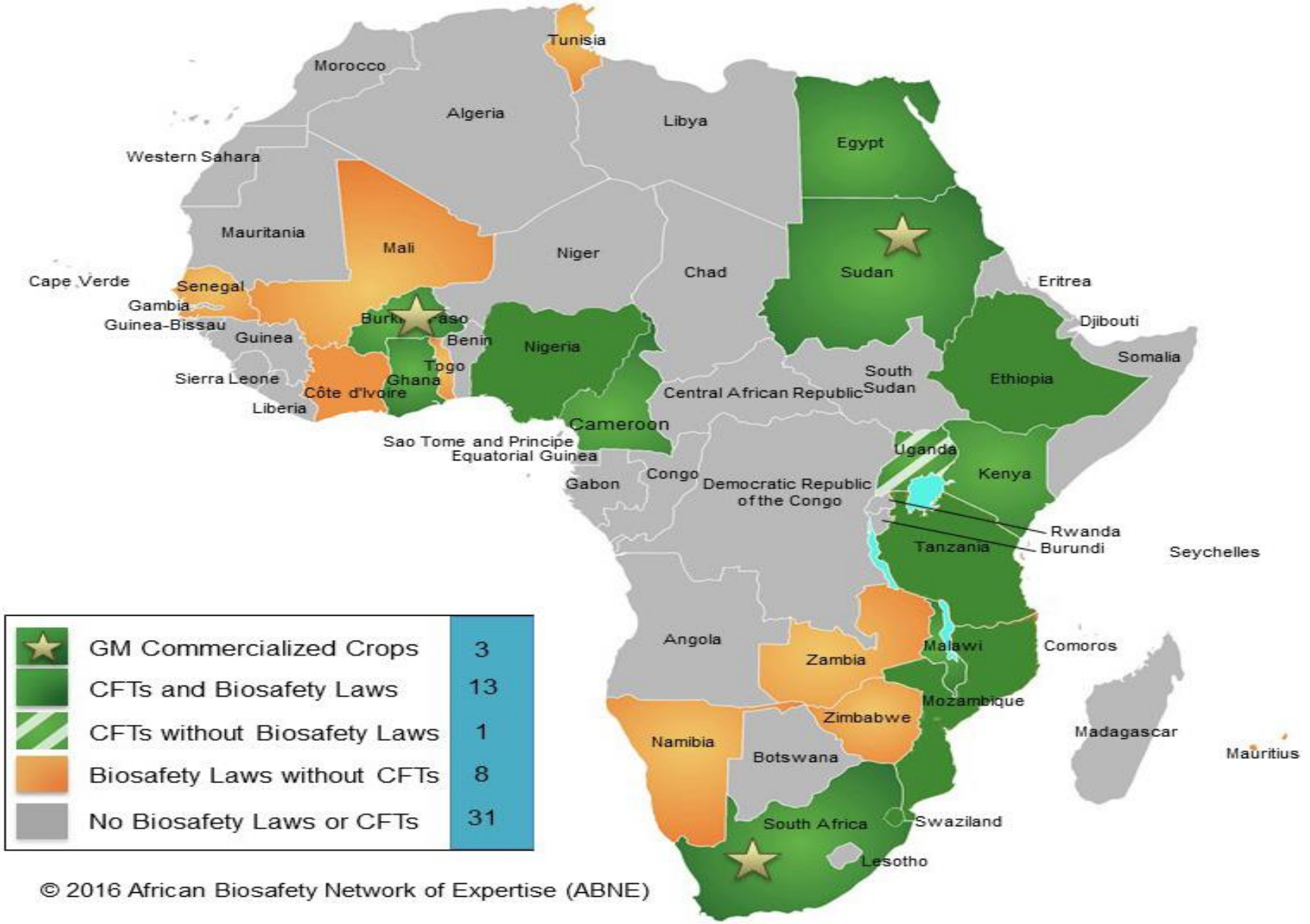
Potato- resistance to late blight

Cotton – resistance to ball worm

Cotton – resistance to herbicide

Maize – Resistance to water stress

Map showing Adoption of GM crops in Africa



Biosecurity elements

- Approval of laboratory establishments;UNCST has assisted in establishment and inspected biosecurity laboratories handling dangerous pathogens involving select agents inclusive of Marburg, Ebola to ensure that the agents are handled safely.

Makerere University , College of Veterinary Medicine Animal Resources and Biosecurity , Uganda Wildlife Authority.

- A database of Select agents was developed in accordance with international health regulations, 2005.

- Accredited Institutional Biosafety Committees at Uganda Virus Research Institute, Uganda Cancer Institute and National Agricultural Research Organisation

Legal Framework and Guidance Documents

1. **Guidelines for research in Humans:** To ensure the rights, interests, values and welfare of research participants and their communities.

2. **Guidelines for research in Animals:** To promote humane and responsible use of animals for scientific purposes in research and teaching.

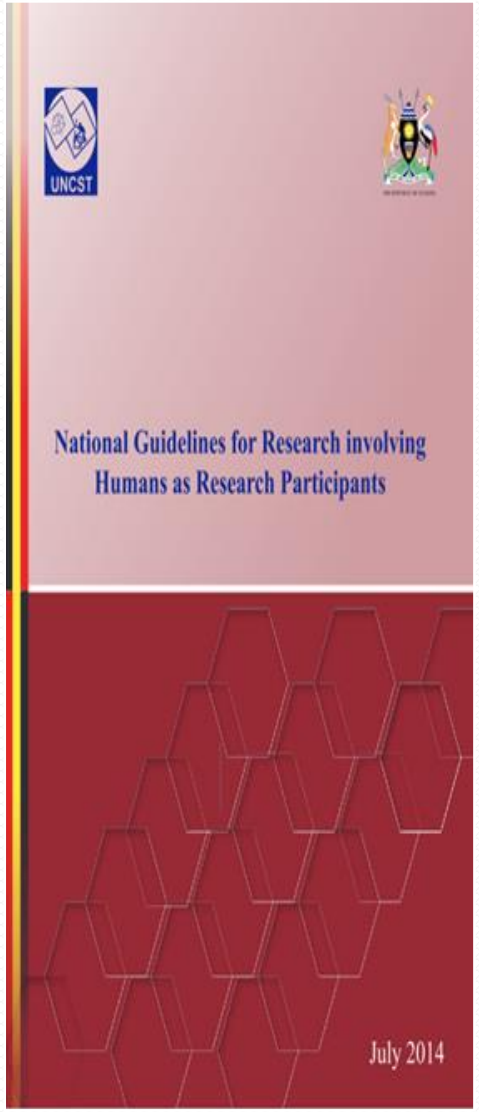
3. **Biobanking Guidelines:** To establish a coherent regulatory framework for establishment, operation and accreditation of the biobanks.

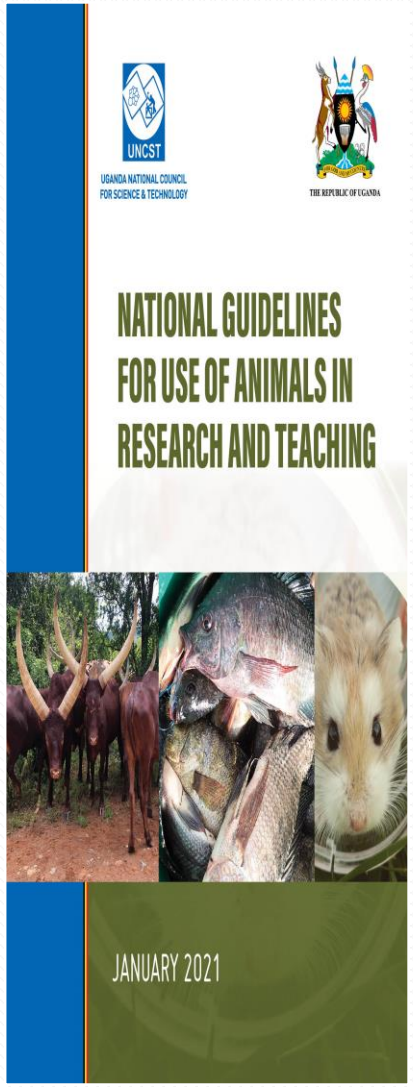
4. **National Biotechnology and Biosafety Policy**: To provide a framework for safe application of biotechnology in order to contribute to Uganda's economic growth and transformation.

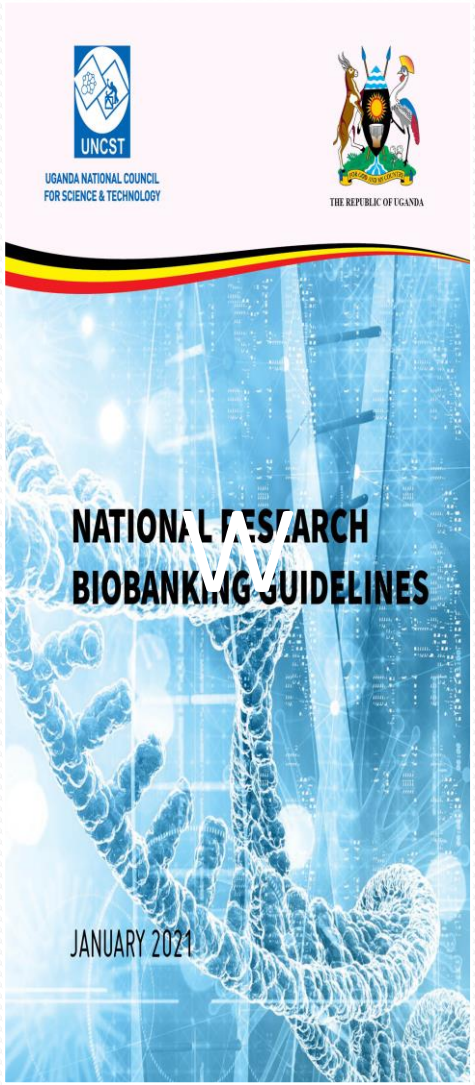
5. NDA Guidelines for Conduct of Clinical Trials in Uganda , 2019.

6. NDPA ACT , Cap 206 and UNCST ACT, Cap 209

7. MAAIF Policies on Animals
8. National guidelines on confinement and containment of genetically modified organisms
9. **International Guidance** : ICH –GCP, CIOMS , AVAREF –WHO**.**


UNCST
National Guidelines for Research involving
Humans as Research Participants
July 2014


UNCST
UGANDA NATIONAL COUNCIL
FOR SCIENCE & TECHNOLOGY
THE REPUBLIC OF UGANDA
NATIONAL GUIDELINES
FOR USE OF ANIMALS IN
RESEARCH AND TEACHING
JANUARY 2021


UNCST
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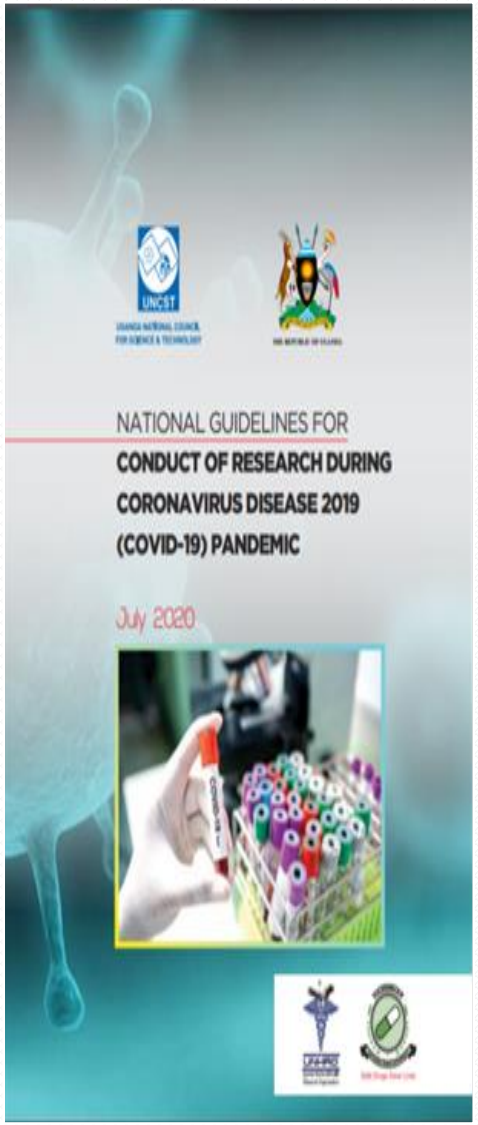
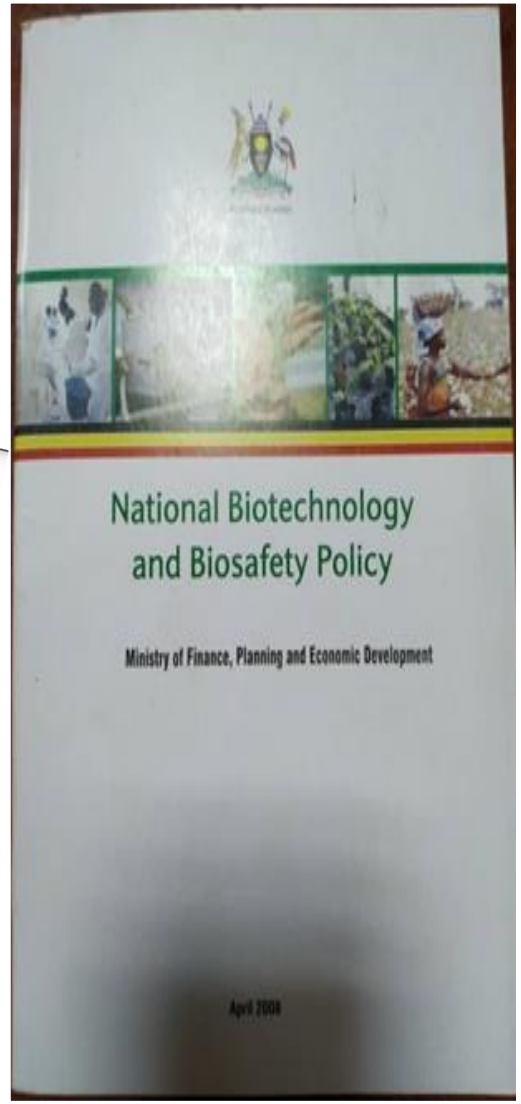
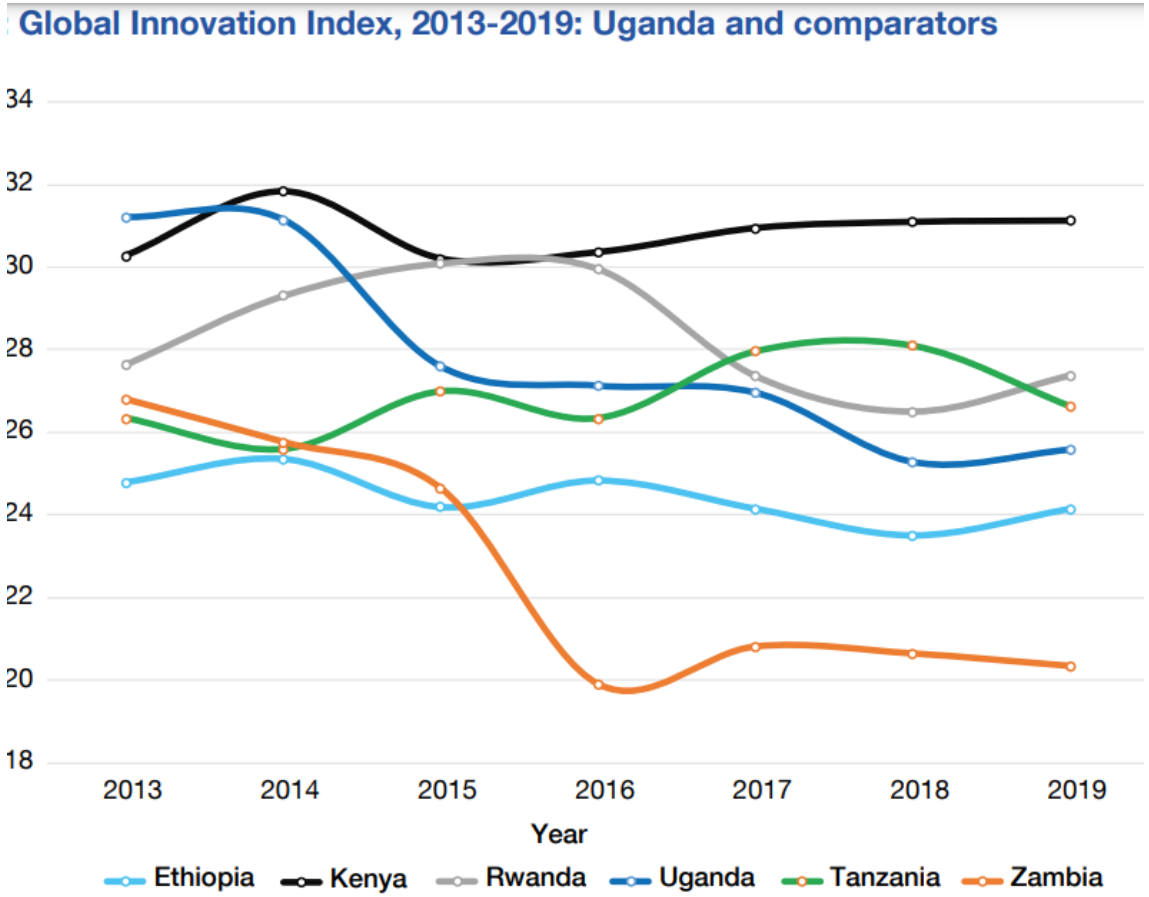
THE REPUBLIC OF UGANDA
JANUARY 2021


UNCST
NATIONAL GUIDELINES FOR
CONDUCT OF RESEARCH DURING
CORONAVIRUS DISEASE 2019
(COVID-19) PANDEMIC
July 2020

Policy Landscape



Innovation comparators



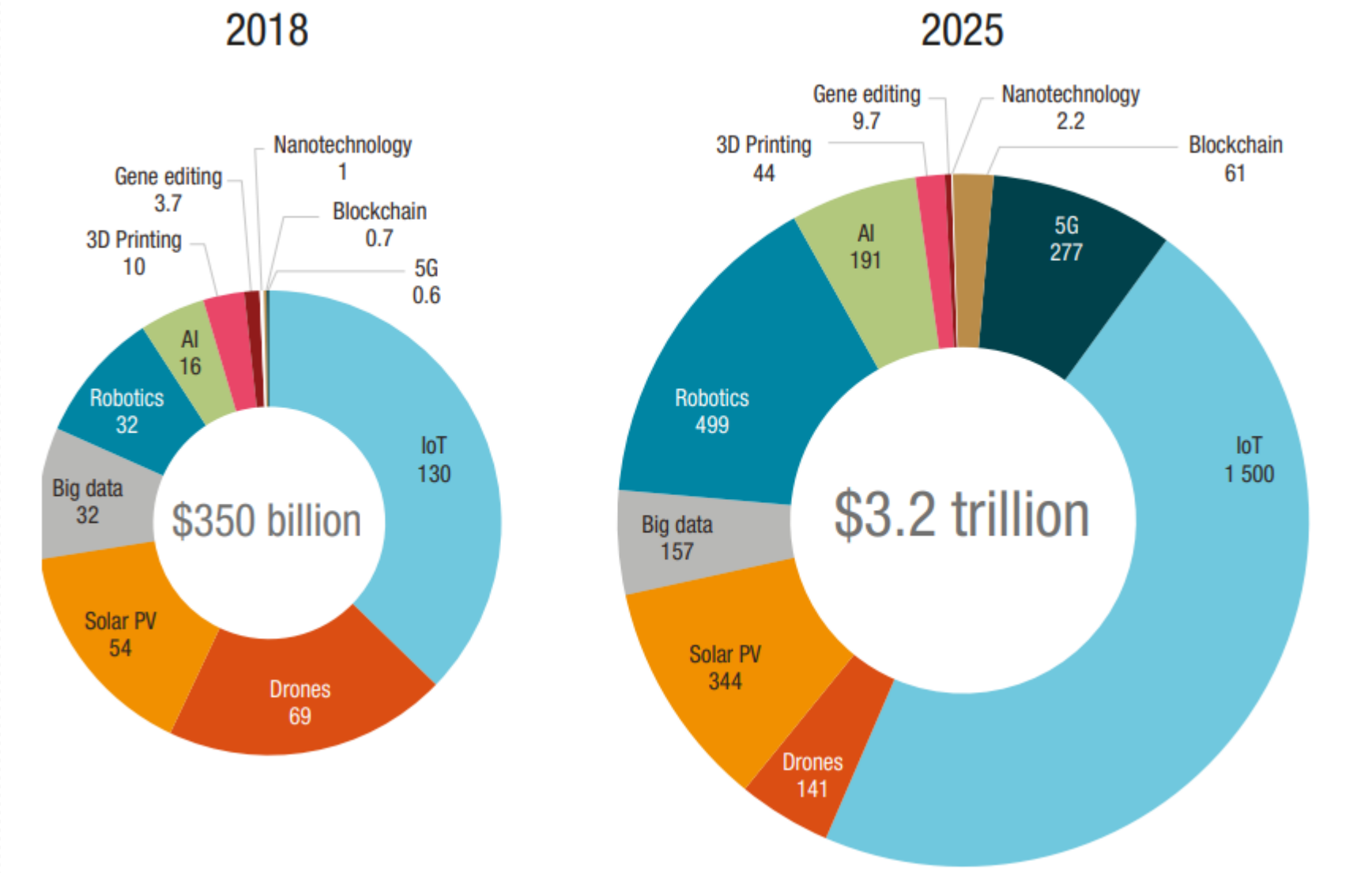
UNCTAD, 2020

Strengths			Weaknesses		
Code	Indicator name	Rank	Code	Indicator name	Rank
1.2	Regulatory environment	59	2.1.1	Expenditure on education, % GDP	111
1.2.3	Cost of redudancy dismissal	18	2.2.1	Tertiary enrolment, % gross	124
2.2.3	Tertiary inbound mobility, %	18	2.3.3	Global corporate R&D investors, top 3, mn US$	41
3.2	General infrastructure	56	2.3.4	QS university ranking, top 3	74
3.2.3	Gross capital formation, % GDP	33	3.1.1	ICT access	127
4.1.3	Microfinance gross loans, % GDP	23	5.1.3	GERD performed by business, % GDP	89
5.1.2	Firms offering formal training, %	42	5.1.5	Females employed w/advanced degrees, %	124
5.2	Innovation linkages	56	6.2.3	Software spending, % GDP	121
5.2.1	University-industry R&D collaboration	63	7.1.2	Global brand value, top 5,000, % GDP	80
5.2.3	GERD financed by abroad, % GDP	45	7.3	Online creativity	128
5.3.4	FDI net inflows, % GDP	43	7.3.3	Wikipedia edits/mn pop. 15–69	128
6.1.4	Scientific and technical articles/bn PPP$ GDP	65			
6.2.1	Labor productivity growth, %	49			
6.3.1	Intellectual property receipts, % total trade	50			

WIPO (2022)

Technology landscape: Frontier technologies

- Frontier technologies are converging through the increasing use of digital platforms to produce new combinatory technologies, accelerating the pace of change across multiple sectors.
- Precision agriculture using satellite and drone mapping can be utilized to better manage the development and use of irrigation, fertilizer, and pesticide systems while working towards increasingly sustainable outcomes.



UNCTAD's Technology and Innovation Report 2021

- The “frontier technologies” are a group of new technologies that take advantage of digitalization
- and connectivity which enable them to combine to multiply their impacts (AI), IoT, big data, block chain, 5G, 3D printing, robotics, drones, gene editing, nanotechnology and solar photovoltaic (Solar PV).
- Readiness

STI Funding Landscape

- The STI sector was created in March, 2017 as it was critical for Government to explicitly provide a platform for planning, budgeting and general discussion of issues relating to STI
- The STI sector budget for FY2019/20 was Ug shs 205.823billion (bn). This increased to 237.5bn in FY2020/21 and increased slightly in FY 2019/2020 to 0.5% in FY 2020/21
- Precision agriculture using satellite and drone mapping can be utilized to better manage the development and use of irrigation, fertilizer, and pesticide systems, while working towards increasingly sustainable outcomes.

New STI Sector Outlook: Focus Areas / Value Chains

Pathogen Economy

[Innovations targeting disease control, vaccines, diagnostics, therapeutics]

Mobility Industrial Value Chain

[develop, make, sell, use sustainable mobility solutions; manufacture of vehicles, motorbikes, bicycles]

Industry 4.0+

[Innovations in electronics, AI, cyber security, robotics, big data, IoT, additive manufacturing]

Aeronautics and Space Science

[space exploration, earth observation, aeronautics, satellites]

Infrastructure Innovations

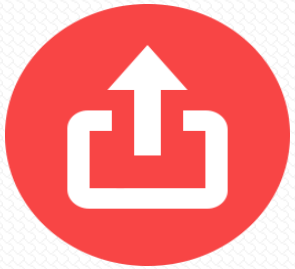
[innovations in engineering systems, energy, railway, roads, airports, nanotechnology, minerals]

Productivity Acceleration

[Technology transfer, appropriate mechanisation, automation, connectivity, PDM innovations]

Import Substitution

[Protection of new and infant industries, production of quality domestic goods and services]



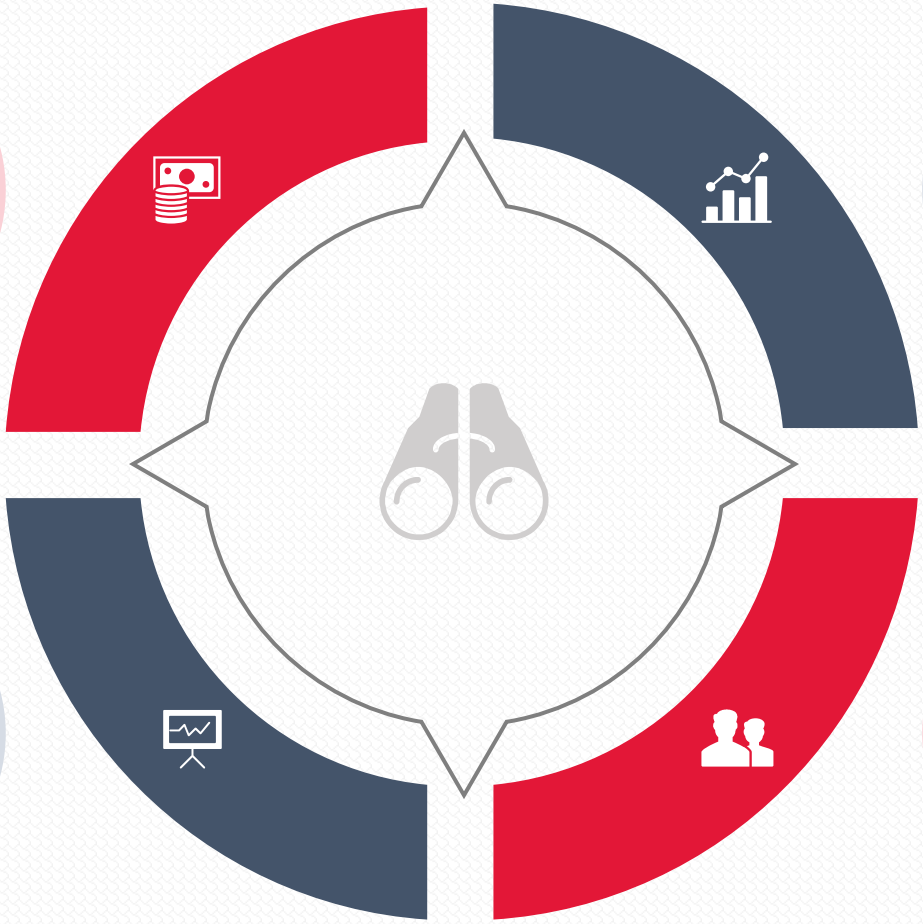
Export Targeted STI

[Commercialisaiton of innovations, national framework to foster competitiveness]

- **Demographic changes** – Uganda typically has a fast-growing/youthful populations – which will increase the supply of labour and depress wages, reducing the incentives for automation.
- **Lower technological and innovation capabilities** – Uganda has few skilled people; dependent on rainfed agriculture which tends to be slower to take advantage of new technologies.
- **Slow diversification** – Uganda typically innovate by emulating industrialized countries, diversifying their economies, and absorbing and adapting new technologies for local use,
- **Weak financing mechanisms** – Whereas evidence shows an increase in research performance, expenditure on R&D has remained relatively low but these are still relatively low.
- **Intellectual property rights and technology transfer** – Stringent intellectual property protection will restrict the use of frontier technologies that could be valuable in SDGs related areas such as agriculture, health and energy.

Some Gaps in STI Regulation

Physical Sciences Regulation



Chemical Sciences Regulation
Chemical Information Management, Chemical Technology, Cheminformatics,, Computational Chemistry, Crystallography

Biological Sciences Regulations
botany. zoology. genetics. Microbiology. sport and exercise science., molecular biology, biophysics, and biochemistry. biotechnology.

Space Science Regulations

Regulatory Gaps

- Research diffusion. Ugandan research is highly cited and internationally visible, although overall productivity remains low. 84% of published papers are produced as a result of international collaborations, and citations level are above the G20 average.
- Even with the ambition to link research with national priorities, demand for research from the government and the private sector is limited. Knowledge exchange activities are only undertaken by a handful of research organisations, and the links with the private sector and civil society remain undeveloped.

Regulatory Gaps

- Absence of Genetic Engineering Regulatory Law
- Absence of Laboratory Infrastructure for specialized testing
- Emerging technologies: Gene therapy, gene editing
- Limited capacity in some areas especially artificial intelligence systems, 4th Industrial revolution elements

Way Forward

- Need to recalibrate STI Sector Regulatory regime
- Strengthening of partnerships and coordination for better STI outcomes
- Capacity building for STI across the different sector
- Governance reforms
- Funding and support
- Need for enabling laws especially the biotechnology law
- Reviewing existing policies to match new trends
- Continuous capacity building and systems development
- Investment in 4^{th}, 5^{th} Industrial revolution capabilities

References

- OECD (1999), A Report for the Organisation fo European Economic Development. Available at https://www.oecd.org/science/inno/2101733.pdf
- UNCTAD (2020), Science, Technology and Innovation Policy Review of Uganda, A Report for the United National Commission on Trade and Development; Available at https://unctad.org/webflyer/science-technology-and-innovation-policy-review-uganda
- WIPO (2022), Uganda Ranking of the Global Innovation Index., 2021. Available at https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2021/ug.pdf