Model for effective entrepreneur support and start-up formation

It takes an eco-system to build a venture

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Sustainable Biotech Innovation Symposium

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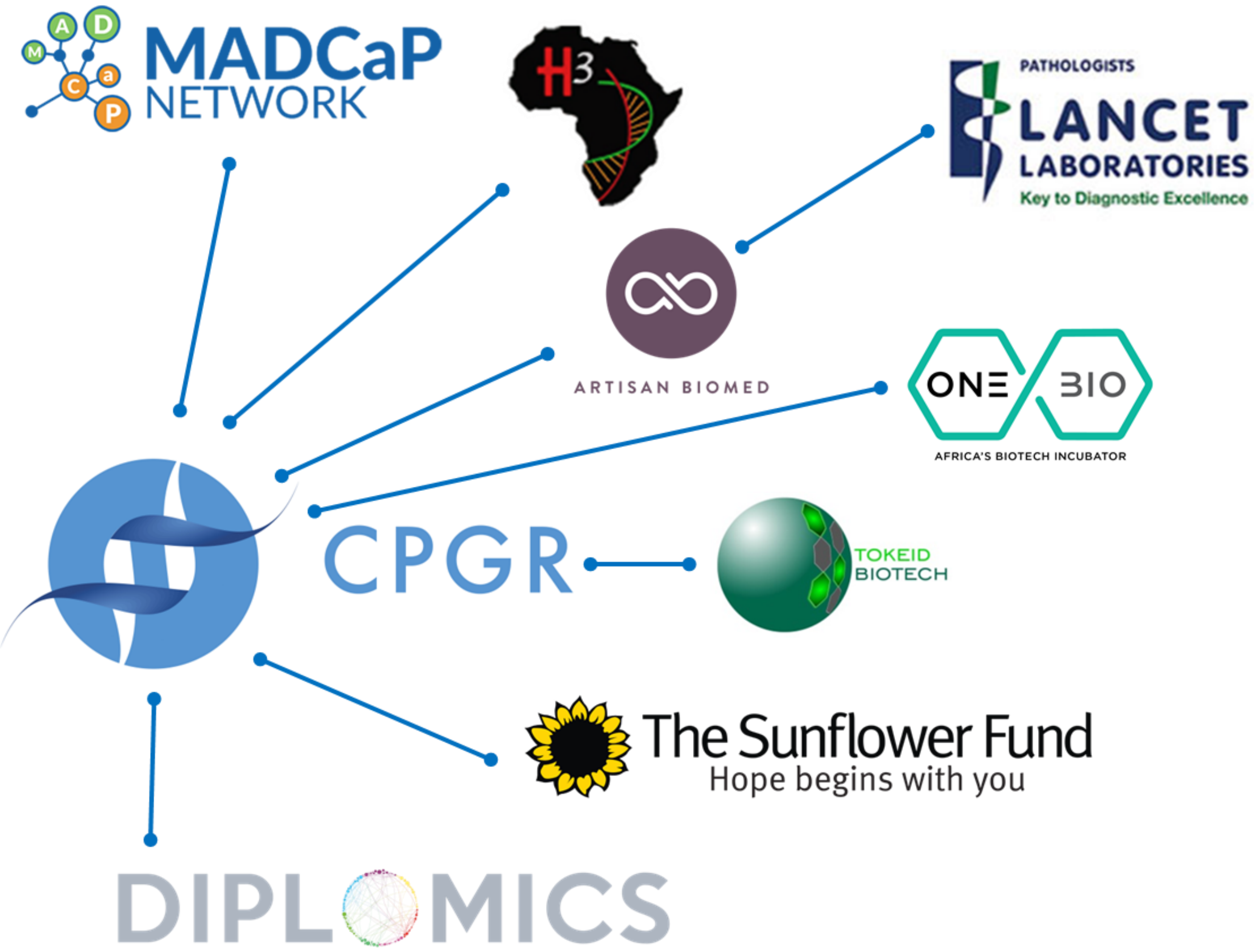
ARTISAN BIOMED

The individual understood

- Brief background
- What is an innovation eco-system?
- Why do we need it?
- What should/could it look like?

Brief background



Empowering the life & medical sciences in Africa

Centre for Proteomic & Genomic Research (CPGR)

Judith Hornby, PhD, MBA
Managing Director (CPGR)

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technology innovation AGENCY
Innovating Tomorrow Together

science & technology
Department: Science and Technology
REPUBLIC OF SOUTH AFRICA

What is an innovation eco-system?

Most innovations fail (start-up perspective)

ecosystem

/ˈiːkəʊsɪstəm/

noun ECOLOGY

a biological community of interacting organisms and their physical environment.
"the marine ecosystem of the northern Gulf had suffered irreparable damage"

- (in general use) a complex network or interconnected system.
  "Silicon Valley's entrepreneurial ecosystem"

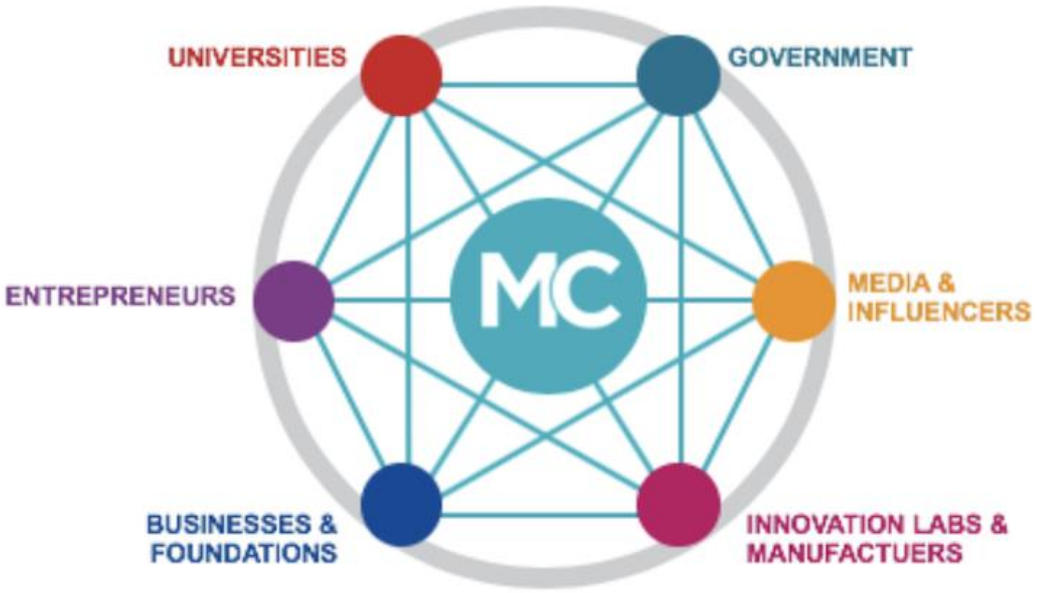
An innovation eco-system may look like this…

HOW DOES IDIA DEFINE AN INNOVATION ECOSYSTEM?

An innovation ecosystem is made up of enabling **policies and regulations**, accessibility of **finance**, informed **human capital**, supportive **markets**, **energy**, transport and communications **infrastructure**, a **culture** supportive of innovation and entrepreneurship, and **networking** assets, which together support **productive relationships** between different actors and other parts of the ecosystem.

https://www.idiainnovation.org/ecosystem

…or this…

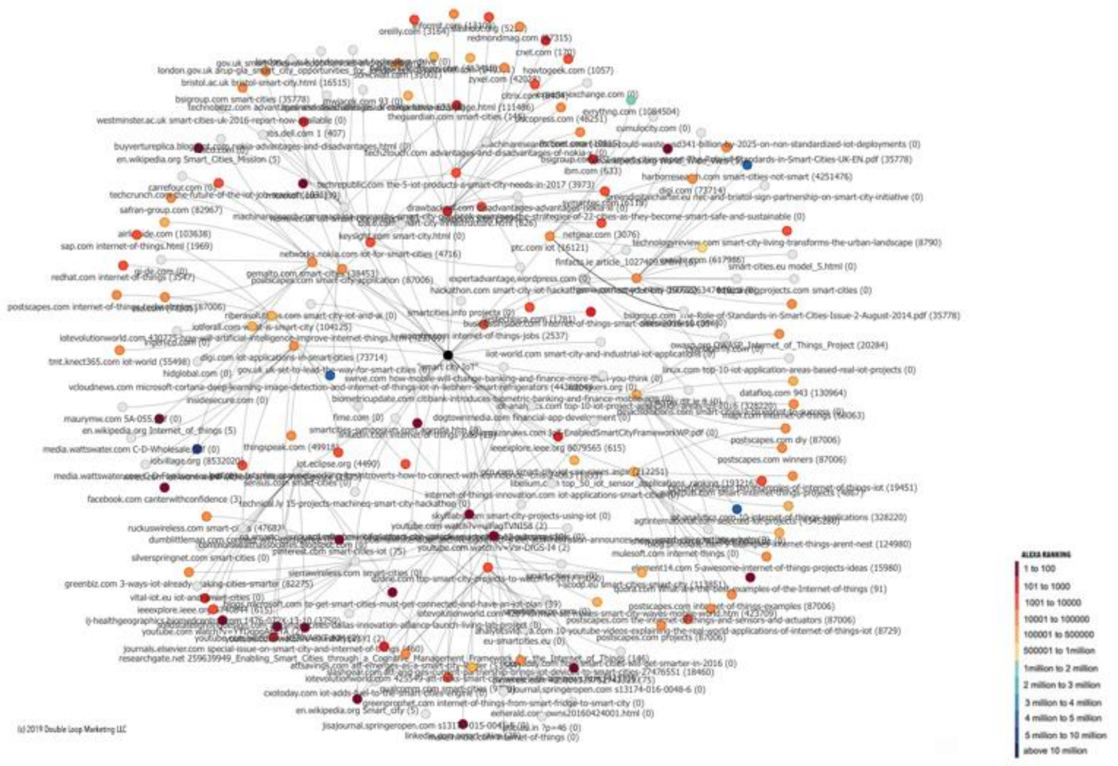


https://masschallenge.org/article/startup-innovation-ecosystem-explained

…or this…

CATEGORY ECOSYSTEM

A high-tech company is competing in the Smart City Internet of Things (IoT) category, and is interested in identifying niche players for potential partnerships. An innovation ecosystem mapping project reveals a number of potential partners.



http://www.marketingjournal.org/the-innovation-ecosystem-new-rules-for-the-future-christian-sarkar-and-philip-kotler/

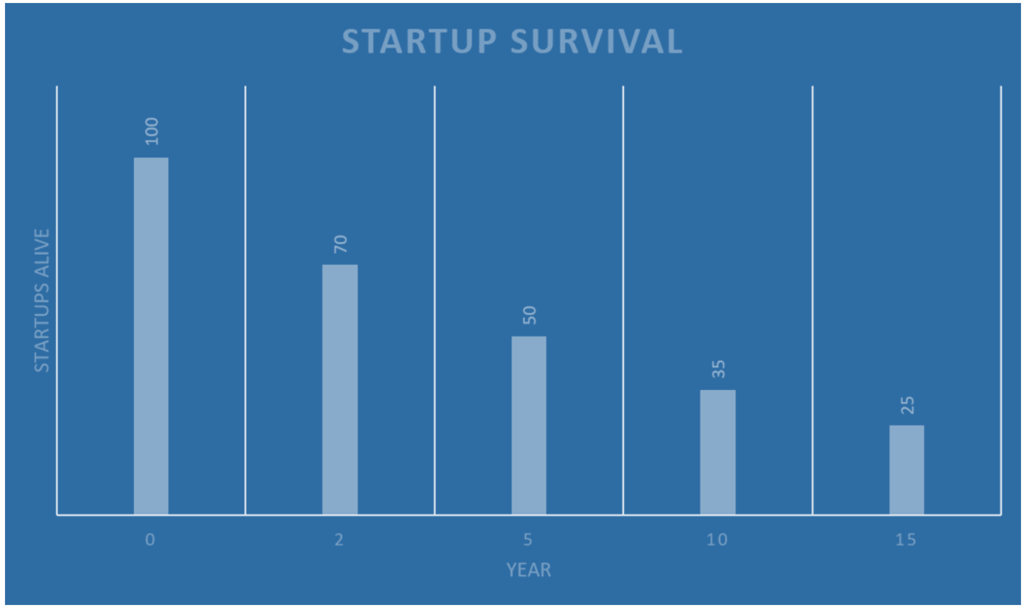
- Complexity (stakeholders & components to consider)
- Inter-connectivity (relations, inter-dependencies)
- Systemic (difficult to control)
- Emergence (difficult to explain, but can – to some extent - predict)

Why do we need an innovation eco-system?

Most innovations fail (start-up perspective)

- Only a small number of startups are successful. Some estimates suggest that 75 percent of venture-backed startups fail. The failure rate of all U.S. companies after five years may be over 50 percent, and over 70 percent after 10 years.

- Other sources cite that 30% of new businesses fail during the first two years of being open, 50% during the first five years and 66% during the first 10. Only 25% make it to 15 years or more.



https://www.entrepreneur.com/article/288769

1. No market need
2. Ran out of cash
3. Not the right team
4. Got outcompeted
5. Pricing/cost issue
6. Poor product
7. Need/lack business model
8. Poor marketing
9. Ignore customers

- Lack of focus
- Lack of motivation, commitment and passion
- Too much pride, resulting in an unwillingness to see or listen
- Taking advice from the wrong people
- Lacking good mentorship
- Lack of general and domain-specific business knowledge: finance, operations, and marketing
- Raising too much money too soon

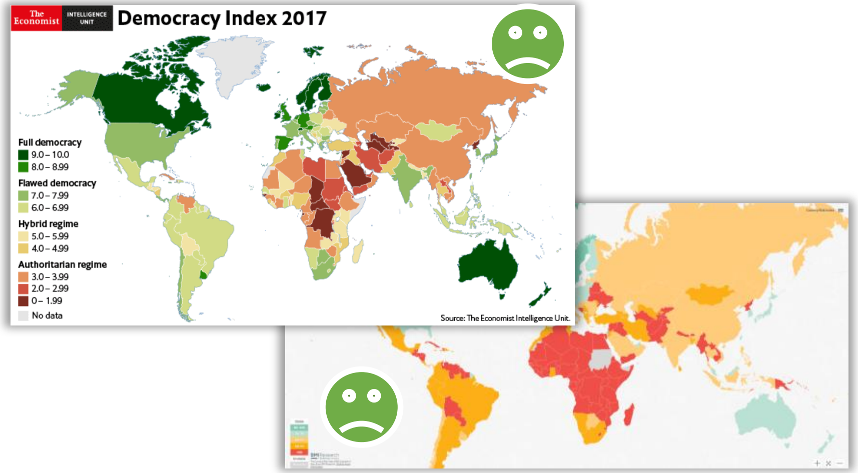
South Africa / Africa perspective

- Distance to other (major) locations (cost, time)
- Economic conditions (challenges, opportunities)
- Market readiness (are there customers?)

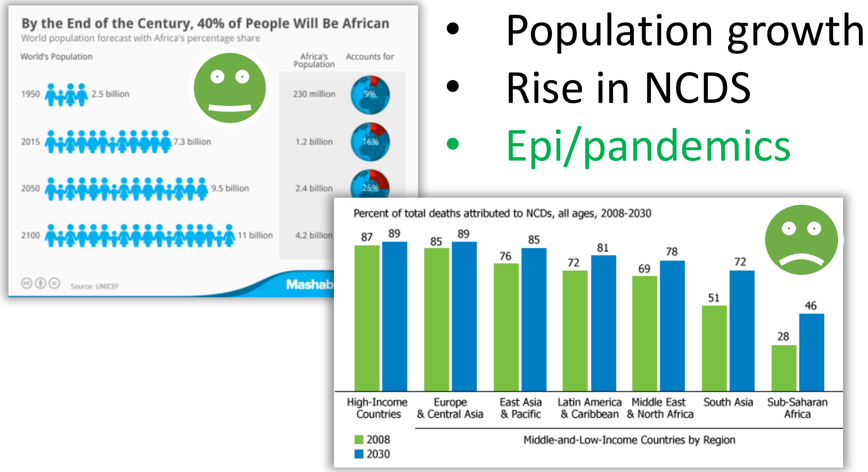
https://www.entrepreneur.com/article/288769

The world is complex and ‘messy’, has an effect on start-up endeavours

Politics

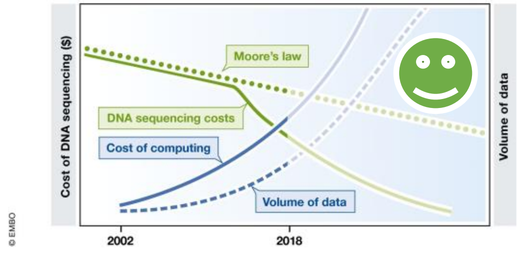


Society



- Population growth
- Rise in NCDS
- Epi/pandemics

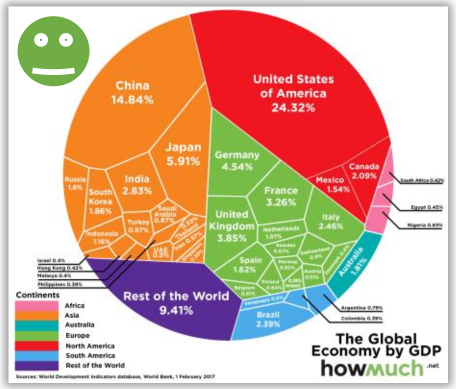
Technology

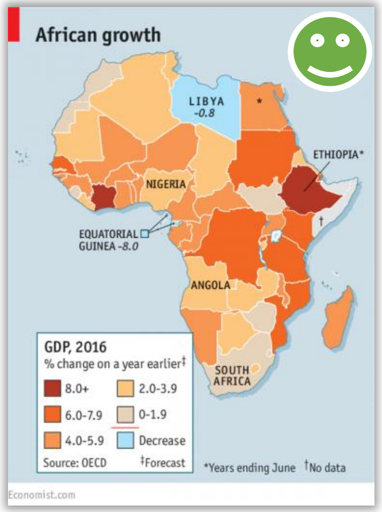


- CRISPR
- 3D printing
- AI

Expo-nential. tech

Economy

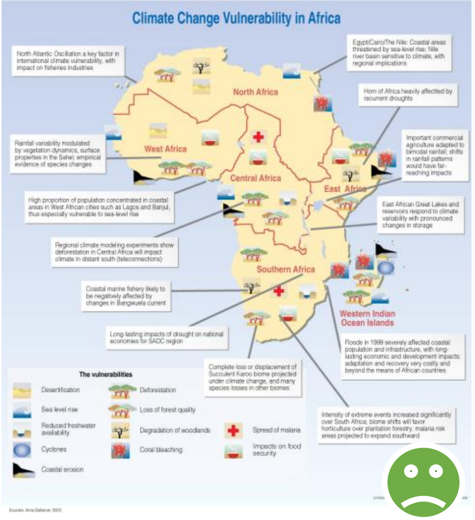




- GERD @ 0,75%

Environment

- Droughts
- Extreme weather
- Food security

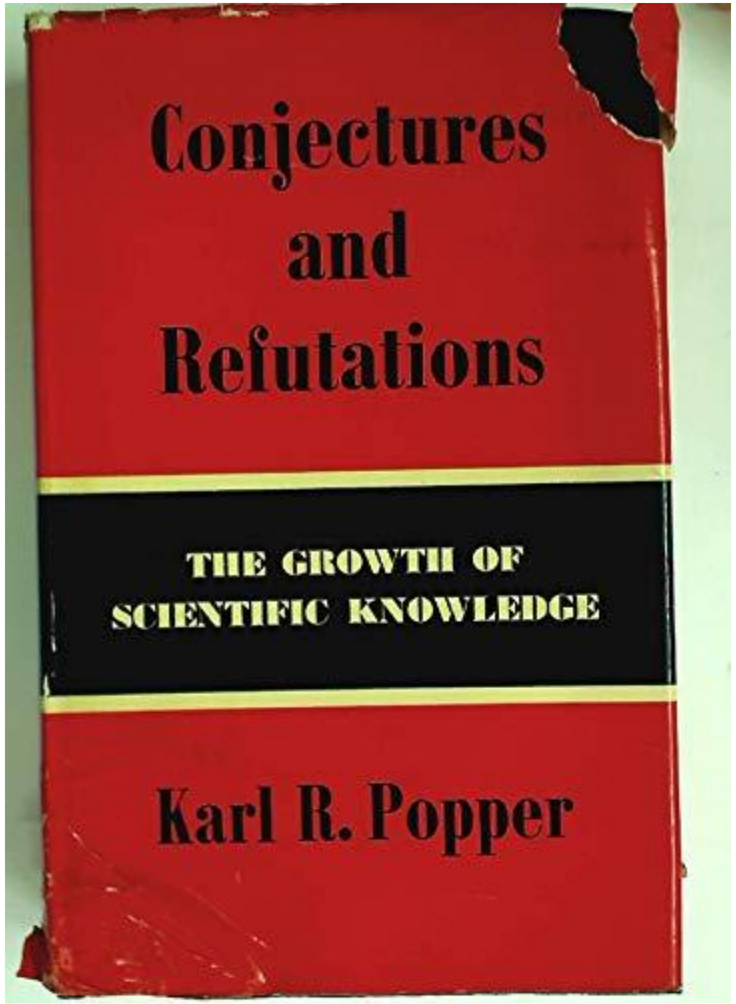


Legal/regulatory

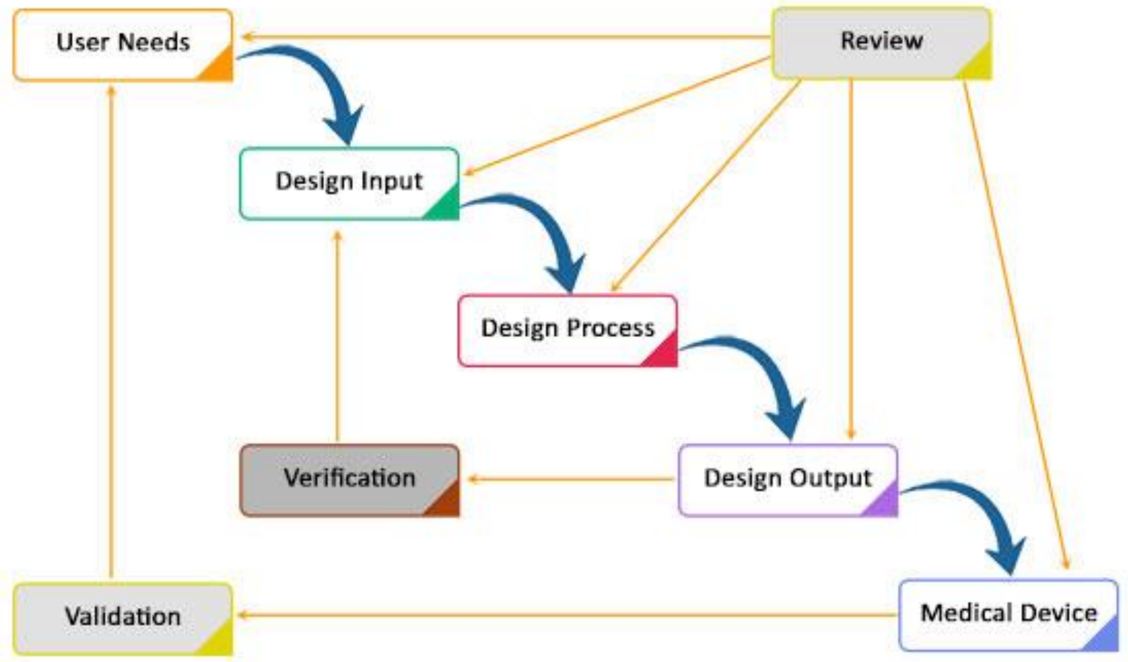
- Import regulations
- Sample transfer
- Data utilisation
- Education (HPCSA)
- Medicine regulations (SAHPRA)
- AI & AI (4IR) impact (automation)

What can a system look like?

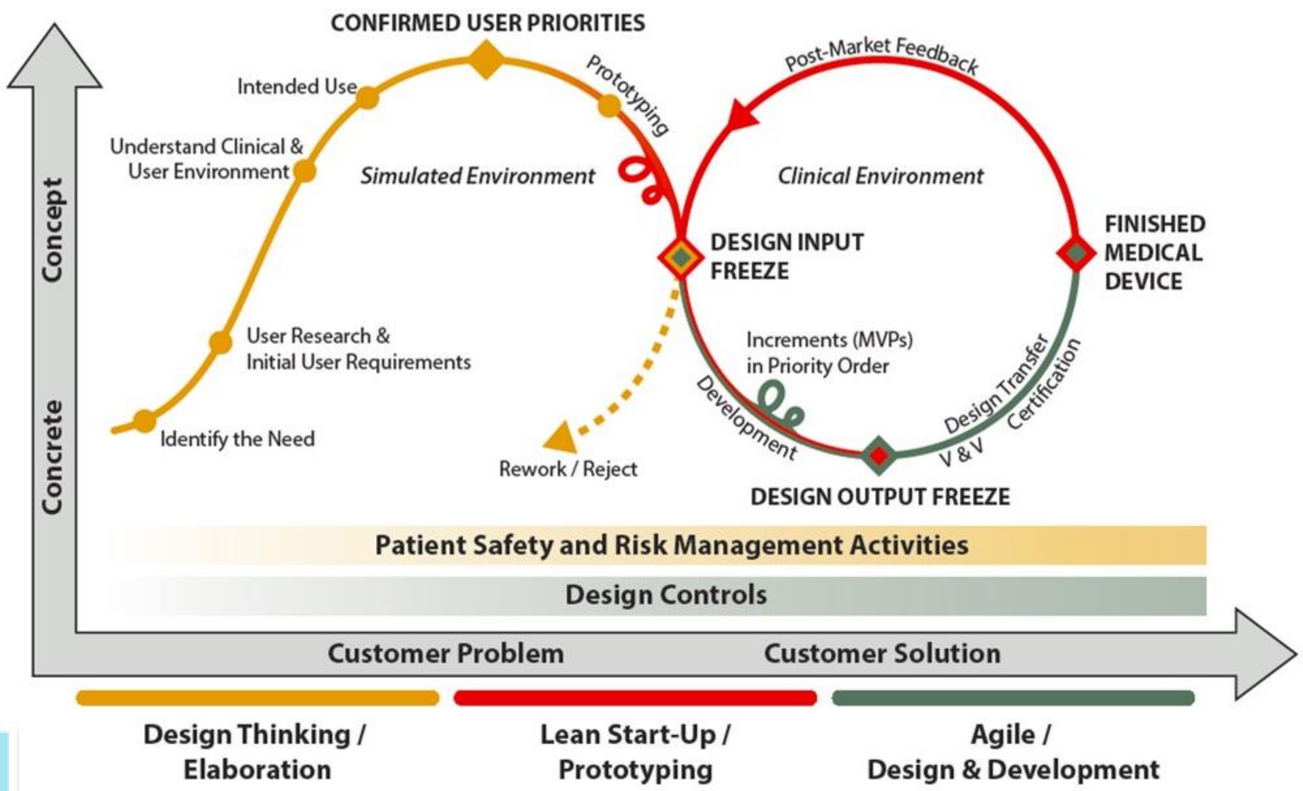
Has a rigorous model for the creation of knowledge…



Follows an iterative development approach (trial & error)…



FDA21 CFR part 820 ISO 13485



- https://www.einfochips.com/blog/medical-device-design-guide-for-medtech/
- https://blog.innokasmedical.fi/blog/applying-design-thinking-lean-start-up-and-agile-methodologies-to-medical-device-design-and-development

Considers all the relevant components underpinning a (successful) innovation…

DOMAIN	Core functions		
DIGITAL	Statistics	Bioinformatics	Data management
Funding & IP	IP	Knowledge transfer	Financing
SCIENCE	Basic & applied research	Education & training	Ethics
WET LAB	Biological assays	Molecular assay	Sample management

Quality management

User needs

Product

Customer needs

Understands the regulatory environment necessary for an innovation…

(1) Discovery & test validation

(A) Discovery

Candidate test developed on training set, followed by lock-down of all computational procedures

Confirmation of candidate omics-based test using:

1. An independent sample set if available (preferred) OR
2. A subset of the training net NOT used during training (less preferred)

(B) Test validation

IRB approval & consultation with the FDA

Define clinical test method

Analytical validation

Clinical / biological validation using blinded sample set

Defined, validated, and locked down test (intended use, assay, computational procedures and interpretation criteria)

(2) Evaluation for Clinical Utility & Use

3 potential pathways (IRB approval & FDA consultation)

Prospective / retrospective study with archived specimens	Prospective clinical trial; test does NOT direct patient management	Prospective clinical trial; test **directs** patient management

IDE needed?

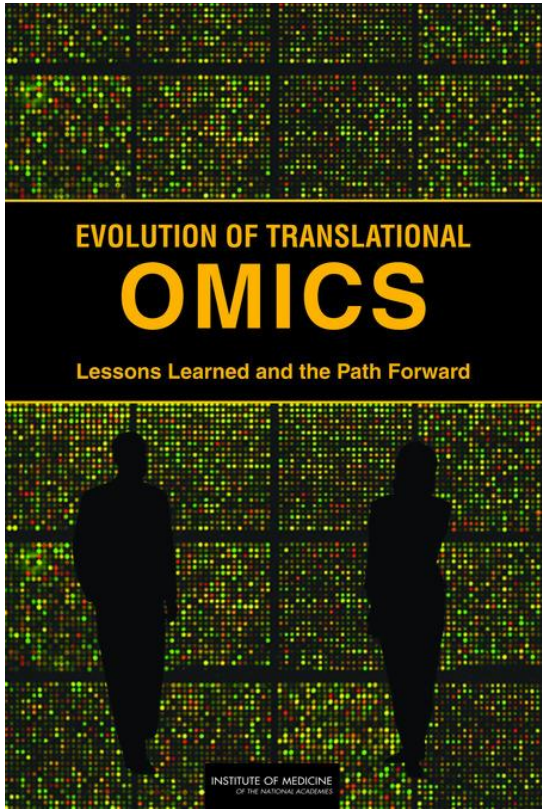
No	No	Yes

FDA approval / clearance or LDT process for Clinical Test

Additional high quality evidence to evaluate clinical utility of test

Practice guidelines & reimbursement

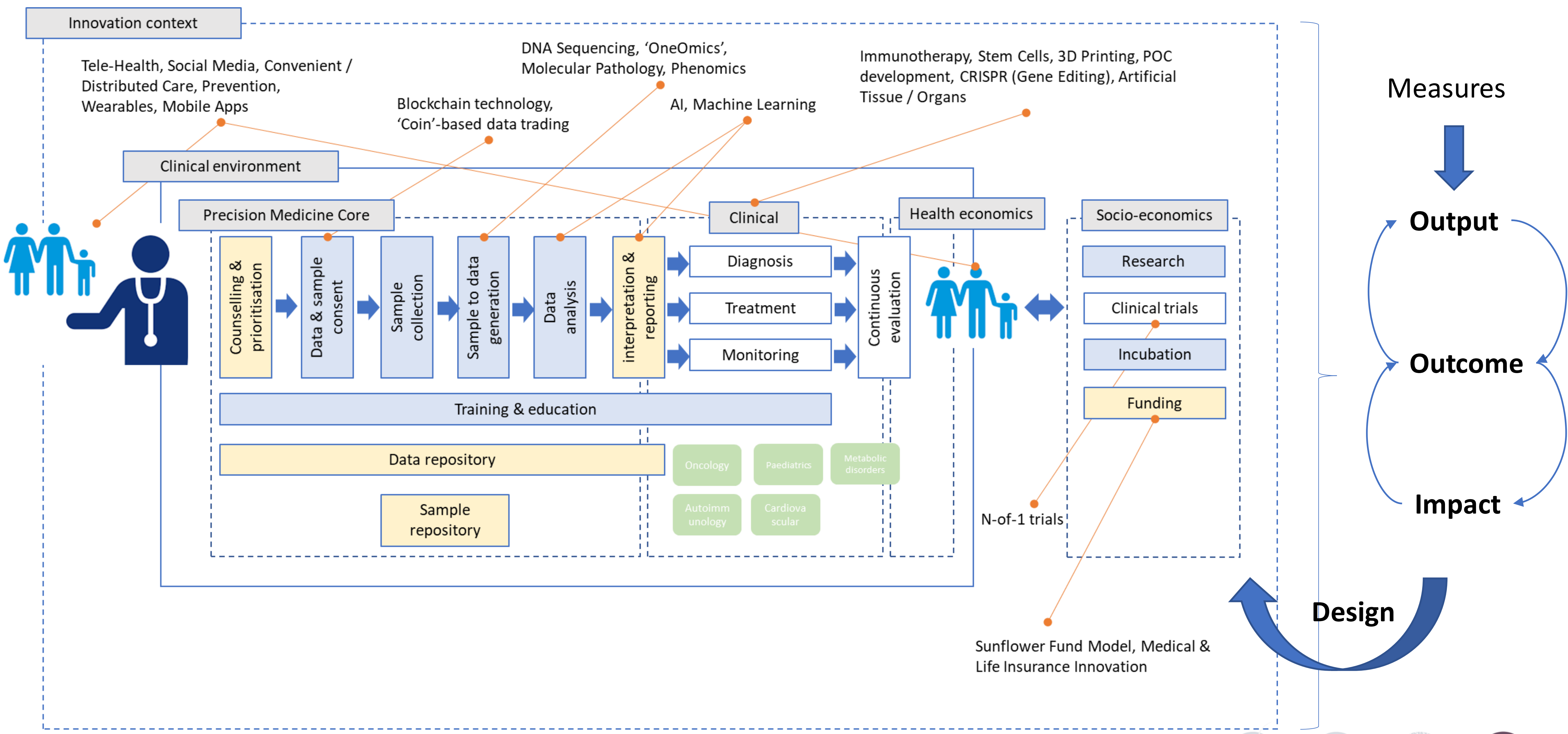
Clinical use



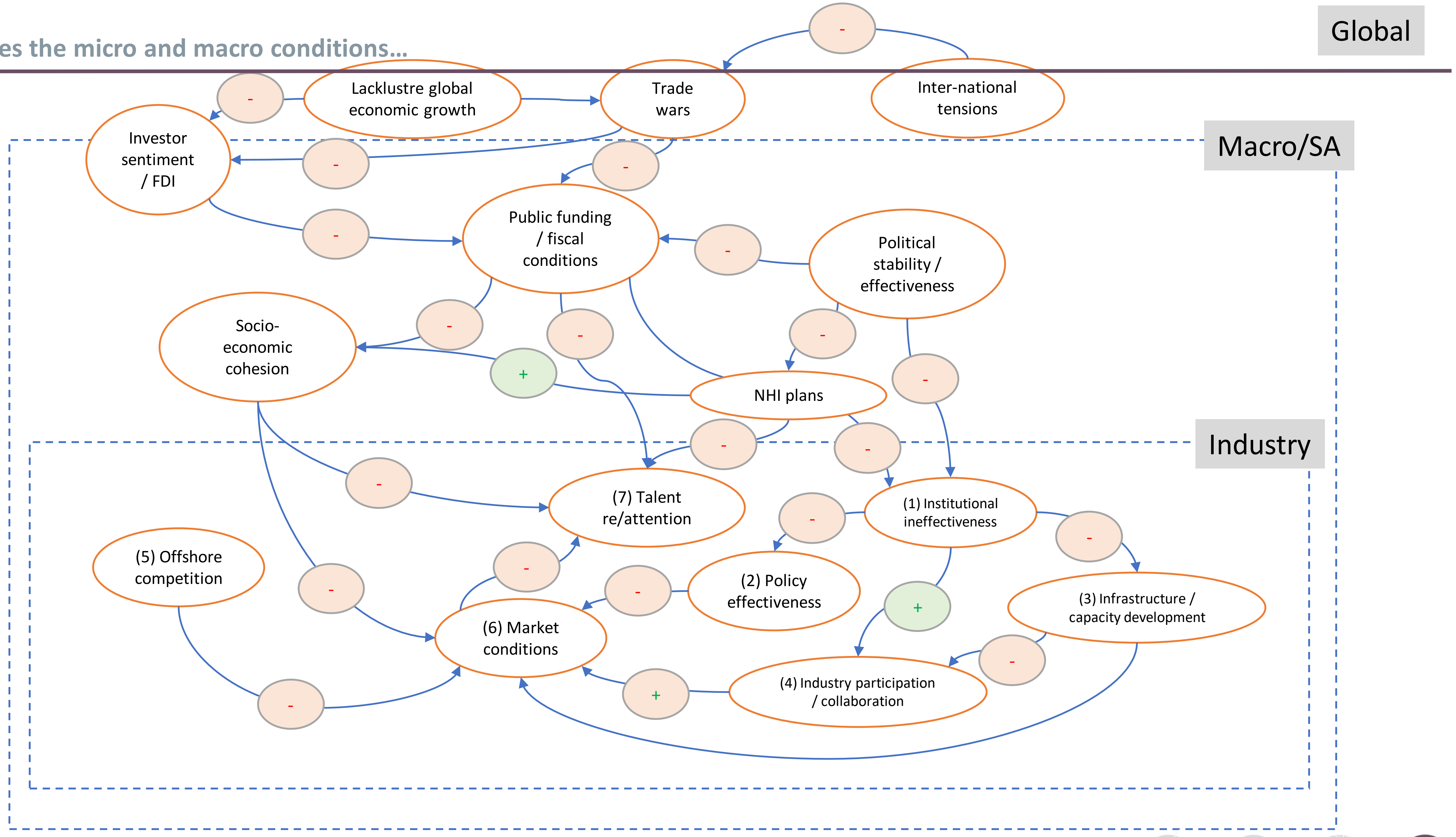
FDA, Food & Drug Administration; IDE, Investigational Device Exemption; LDT, Laboratory Developed Test; dotted box = CLIA Certified Laboratory; CLIA, Clinical Laboratory Improvement Amendments

Micheel, C. M., Nass, S. J., & Omenn, G. S. (Eds.). (2012). *Evolution of translational omics: lessons learned and the path forward*. National Academies Press.

How are we going to reach this goal (through integrating all the relevant parts)?

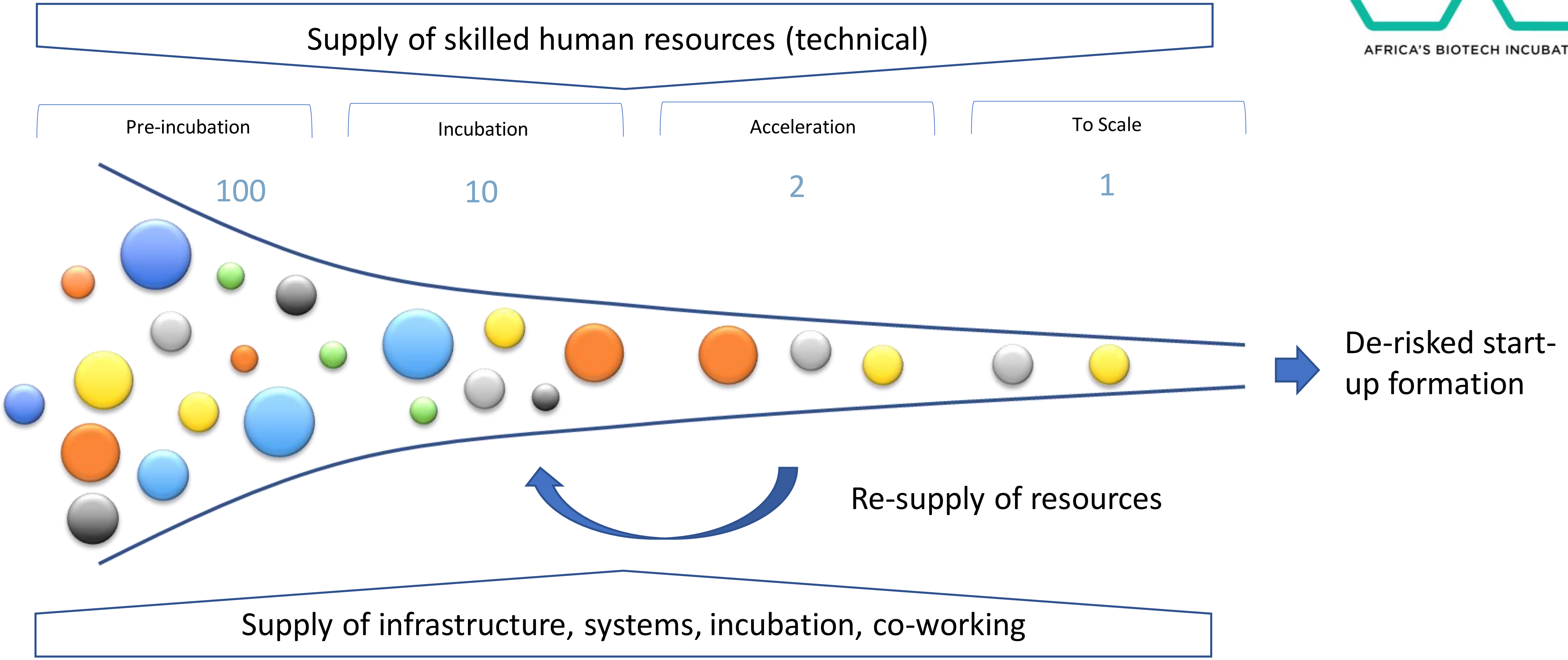


Appreciates the micro and macro conditions…



Understands risk and duration inherent to succeeding with an innovation...

ONE BIO
AFRICA'S BIOTECH INCUBATOR



CPGR, DIPLOMICS, other labs

Has a way to address these issues…

- 5000 sqm building
- Within range of current location, new building

- 1,200 to 1,500 sqm in space
- High-throughput laboratory in a novel innovation-supporting environment

- Aim is to achieve co-location scenario with other companies/organisations by the end of 2020

- Create a more vibrant innovation ecosystem, together with partners

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