

Making Medicines In Africa

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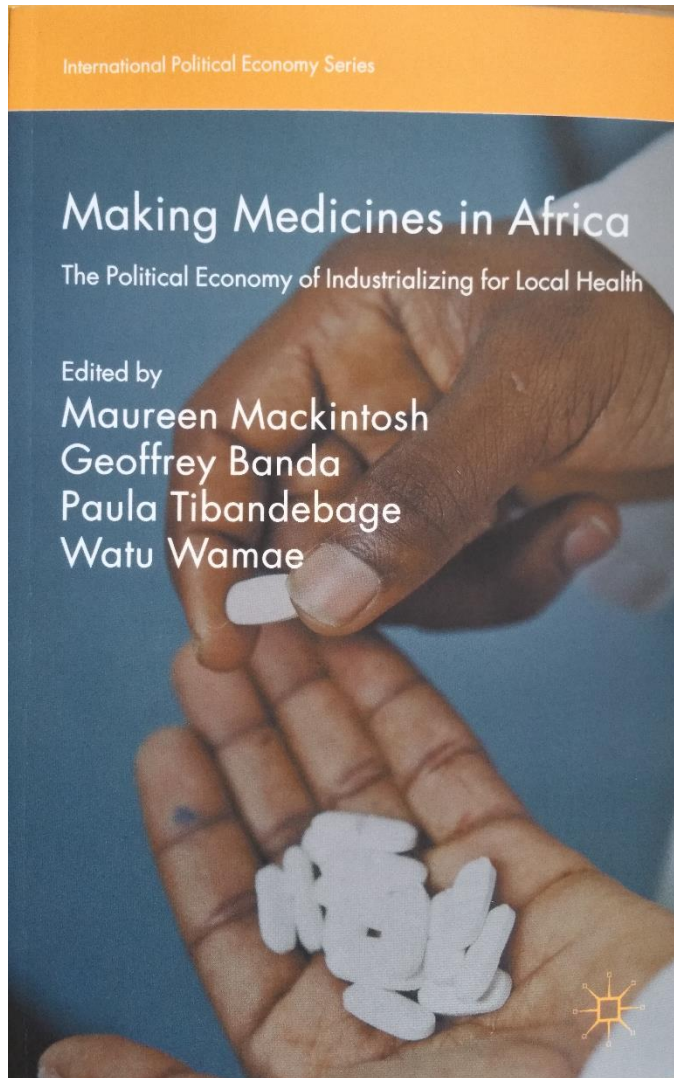


Four Pillars of Medicine

- Small Molecules
- Biologics (vaccines & biological products)
- Medical Devices
- Cell Therapy (Regenerative Medicine)



Making Medicines in Africa



Detailed arguments on the African pharmaceutical industry
Innovation, technological capability upgrading, local health perspective

Part I

Pharmaceutical Industry in Africa
Kenya, Tanzania, Mozambique, Ethiopia, Ghana and Zimbabwe

Part II

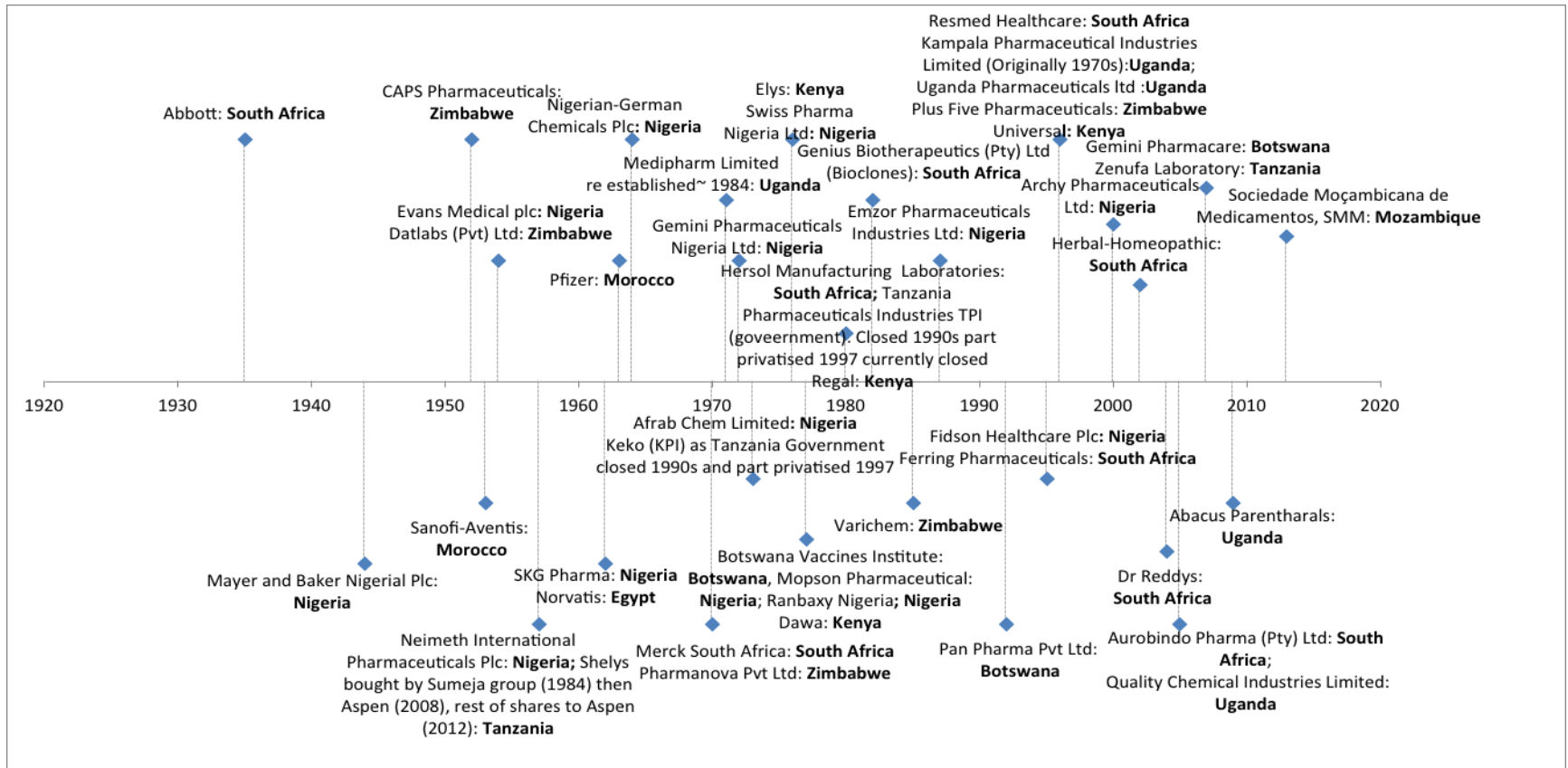
Industrialisation for Health
Health systems as industry policy tools

Part III

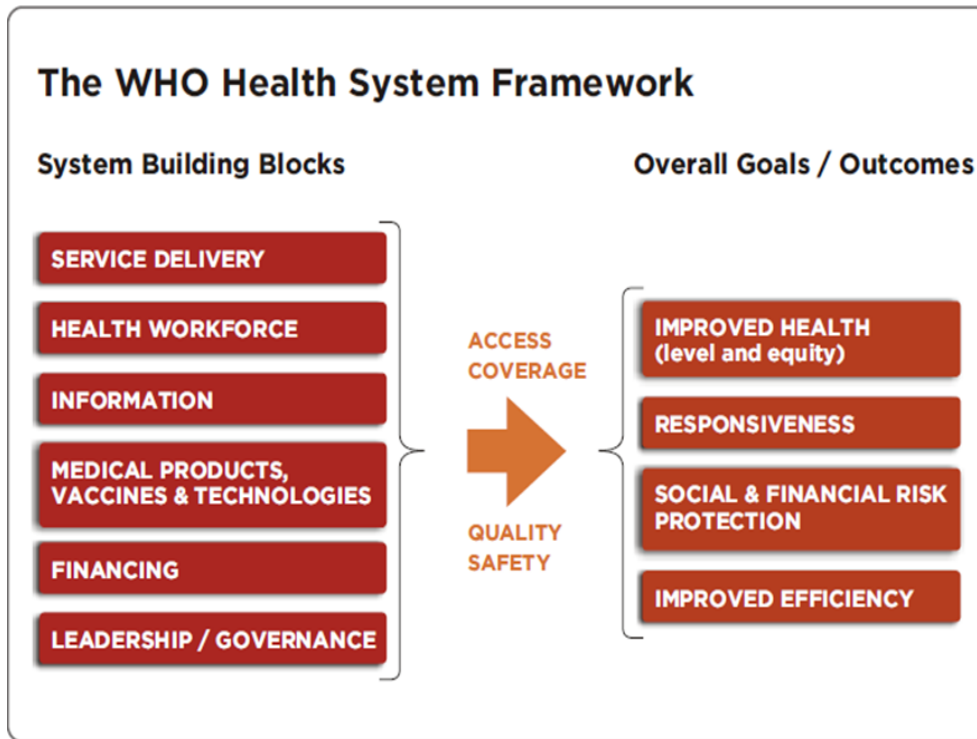
Industrial Policies and Health Needs
Pricing, Standards, Innovative Procurement, Industry Associations and Finance and Incentives



Establishment of African Pharma Companies



Health System Building Blocks (WHO, 2009)



- Frustration
 - What works in health systems strengthening?
 - Should Africa depend on Global Value Chains only?
- Missing cog
 - Where is Local Industry?
 - What about building local capabilities?
 - What role in medical technologies supply security?
 - Focus on finance and not building local capacity and capabilities?
- Global Health Initiatives
 - Have not sustainably improved national health systems (Samb et al, 2009)



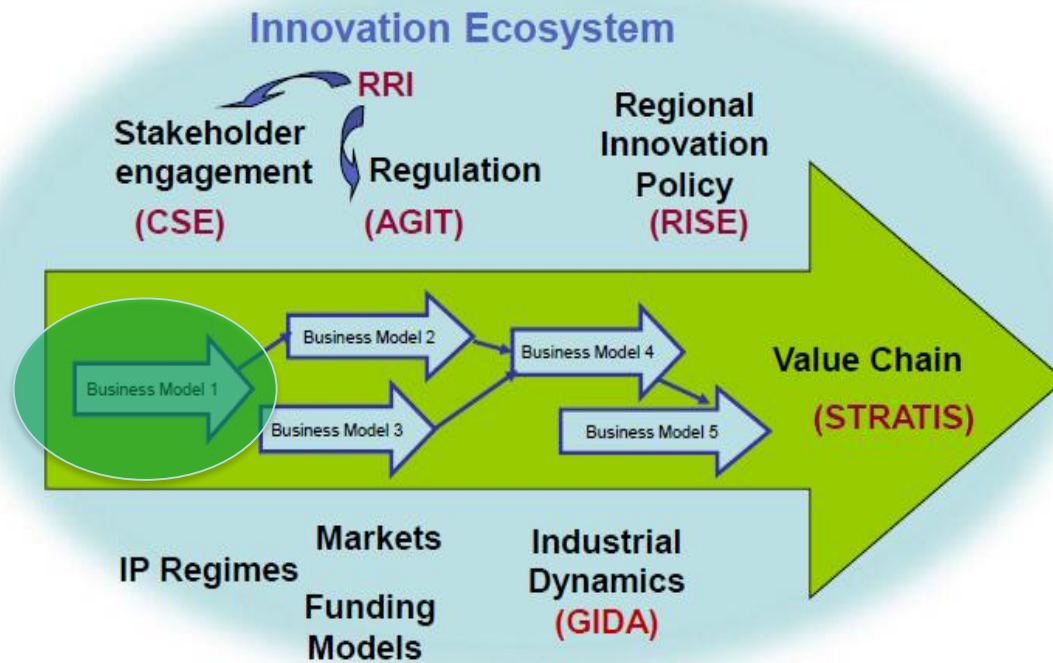
WHO: A health system "consists of all organisations, people and actions whose primary intent is to promote, restore or maintain health".

The African Pharmaceutical Industry

- Dates back to 1930s
 - pharmaceutical technology, managerial and industry capabilities
- Not meeting continental medicines supply needs
 - finance one of the major challenges
- Importance of local production
 - sustainable supply and rapid response to emergencies
 - growing recognition of *health-industry complex* for local health systems strengthening and promoting industry development
 - local health security - a key component of national security
- Funding challenge - not a simple access to finance issue!
 - financial systems architecture: set up to support commerce and trade
 - finance capability: the who, what, where, when, how and why of finance
 - policy frameworks: purposive crafting of policy to reduce local production costs



STRATIS Framework



Regenerative Medicine Manufacturing challenges

- At manufacturing level need to solve
 - technological/engineering challenges on equipment,
 - media [huge COGS driver],
 - product and process optimisation,
 - shelf-life management
- Develop and optimise:
 - quality control tests
 - and tools for potency assays ex-factory and before therapy.



Challenges of “Emerging Technologies”

- Entrepreneurship

- SMEs
- Business Models

- Development of capabilities

- Firm and sectors
- Pathways to market and Purposively assisting the Development of Markets

- Funding risky stages of enterprises

- Role of innovative procurement
- De-risking early stages of enterprise growth

- Which innovation system?

- Purposeful crafting of innovation systems that strategically promote local manufacture of medicines



What Capabilities should be developed?

Capability	
Organisational	Organisational capabilities including project capabilities subset. Economies of scale and scope. Project capabilities critical for project based firms.
Dynamic	Embodied in strategic management capabilities of resource identification, selection and deployment. Recruitment of middle layer management and efficient resource allocation.
Technological	Expressed as functional capabilities - taking product from lab to patient's bedside. R&D, translation, production activities, process development and optimisation, regulatory approval, sales and marketing, distribution and re-imburement <ol style="list-style-type: none">Investment capability [Pre-Investment and project Execution]Production capability [process, product and industrial engineering optimisation]Linkages within the economy [intra and inter-firm linkages]The ability to develop own standards as well as adopt and adapt to industry product and process standards. Standards can be organisational, regulatory, process or product.
Finance	Knowing type and sources of finance and matching with financing requirement, and repayment expectations. Project finance capability and resources burn rate.
Innovation	Innovation, knowledge and learning capabilities. The skills, resources, knowledge and experience (tacit or explicit), which may be embodied in technology, artefacts or institutional memory.





Realising the potential of
synthetic biology for health

UK Centre for Mammalian Synthetic Biology



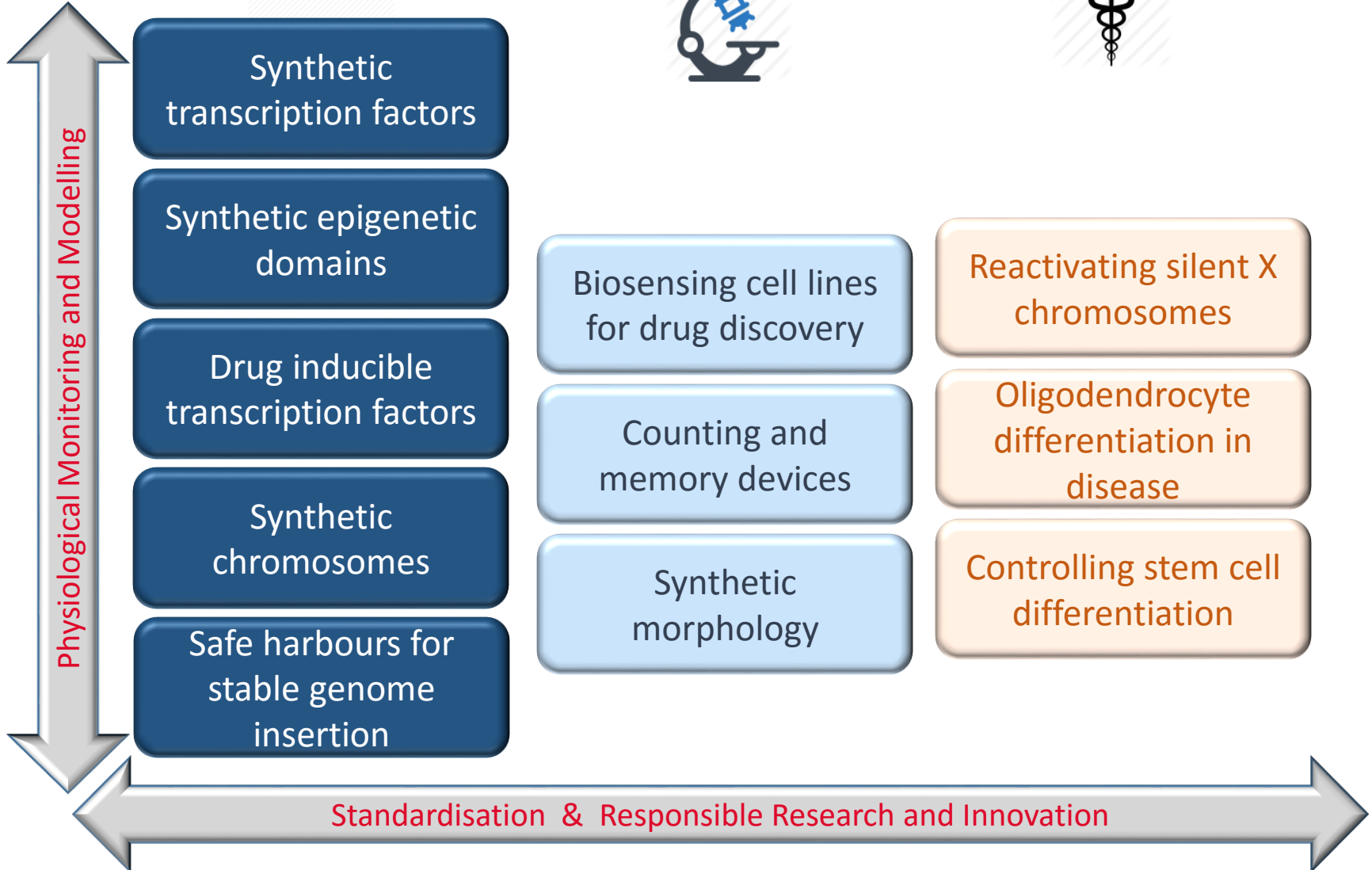
To pioneer the development of the underpinning tools and technologies needed to realize the full potential of synthetic biology for mammalian biology and medicine.

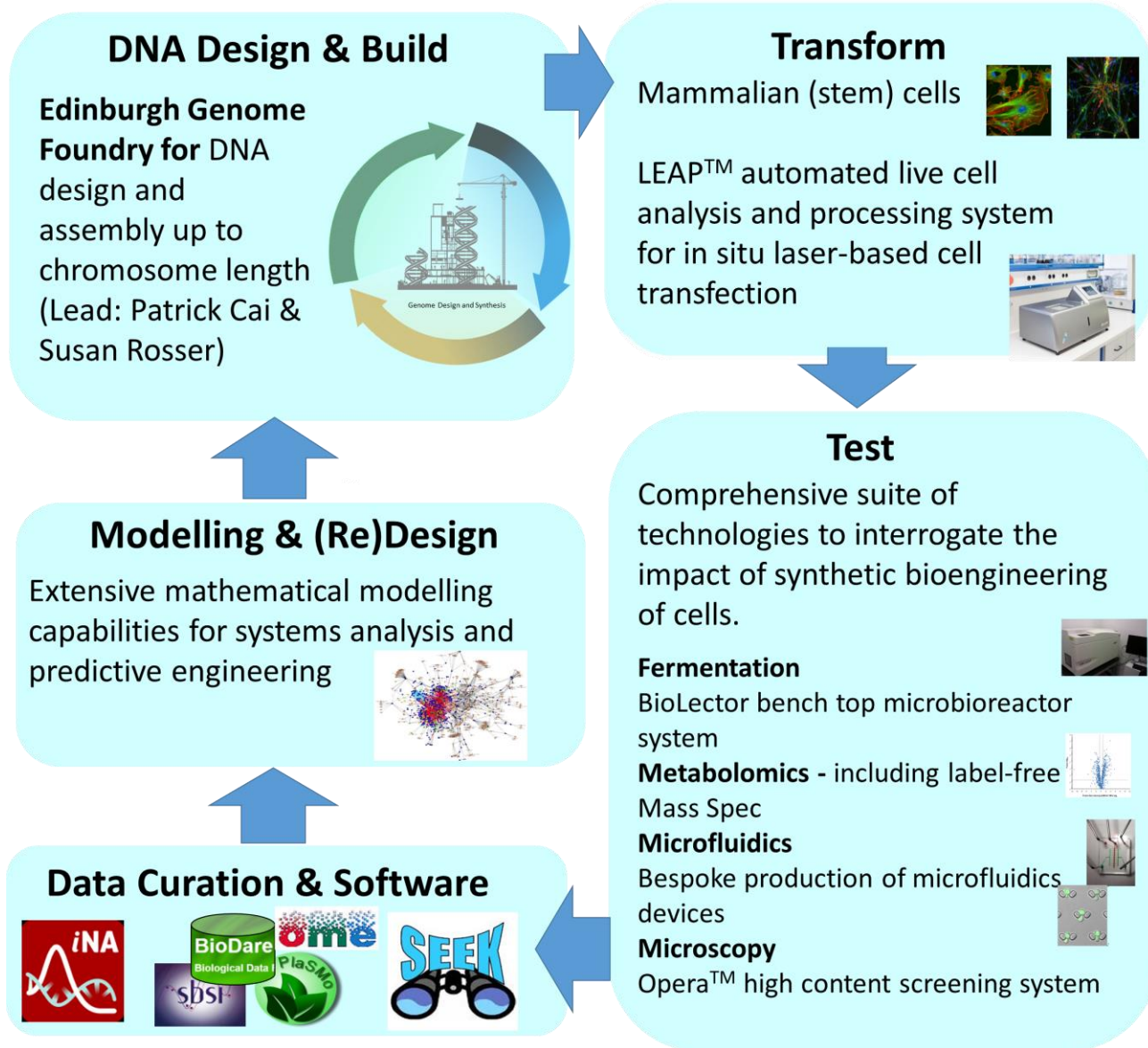


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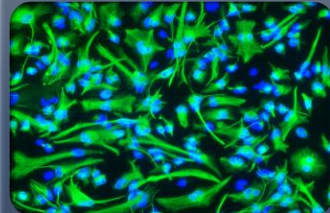
Biosensors & Diagnostics

Cells engineered to produce a more informative read-out useful for drug assays and for *in situ* sensors.



Epigenetics Drug Discovery

New models and targets for drug discovery in this rapidly developing field of medicine.



Regenerative Medicine

Predictable, tuneable control of cell lineage for drug discovery, cell therapy and tissue repair.



Biomanufacturing Industry

Optimising production yields of next-generation biologics in CHO and *E. coli*.

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