

Country needs and availability of resources for strengthening Healthcare Biotechnology facilities

Presented to

Expert Group Meeting on Strengthening Regional Cooperation in Healthcare Biotechnology and Biomedical Sector

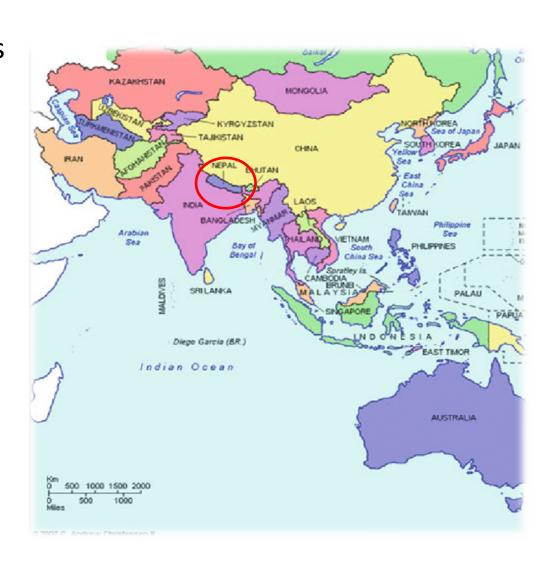
Asian and Pacific Centre for Transfer of Technology (APCTT) of the United Nations Economic and Social Commission for Asia and the Pacific (ESCAP)



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Current status of Healthcare Biotechnology in Nepal

- ✓ There are 6212 healthcare/diagnostic laboratories in Nepal
- Research culture is in <u>early infant stage</u>
- R & D to healthcare biotechnology <u>product to Industry are invisible.</u>
- ✓ Animal/poultry helathcare biotechnology in government laboratory is on scence <u>but not progressive</u> in R & D for new animal healthcare products
- Rresearch institutes work on project basis only rather than a continuous process to launch research products of healthcare.



Current status of Healthcare Biotechnology institutes in Nepal

Government Laboratories

Central Veterinary Laboratory

Ayurved Research Center

Nepal Academy of Science and Technology (NAST)

National Public Health Laboratory (National Reference Laboratory)

Province Public Health Laboratory (#1-7)

Academic institutions

Central Department of Biotechnology- Tribhuvan University

Biotechnology Department – Kathmandu University

Center for Biotechnology – Agriculture and Forestry University

Private Research Laboratory

Hester Biosciences Nepal P. Ltd, Nala, Banepa

Shikhar Biotech, Lalitpur

Bio Vac Nepal P. Ltd , Nala, Banepa etc

Center for Molecular Dynamics (CMDN), Kathmandu

Center for Health and Disease Studies (CHDS), Kathmandu

Needs for healthcare biotechnology

- Establishment of <u>research institution</u> and <u>industries</u> for production.
- ✓ Advanced Instrumentation for <u>upscaling of research output</u> to industry
- ✓ Skilled human resources
- ✓ Public-Private-Partinership and AcademiInda-Industry collaboration
- ✓ Simple and <u>doable projects like ELISA Kit</u> Developments (HIV, Hepatitis, infectious diseases etc.) and its scale up for national need.
- ✓ Huge consumption of imported kits which are to be gradually replaced by national production.
- ✓ National budgetary allocation, bilateral and multilateral cooperation among countries and <u>partnership</u> <u>with EDPs</u> (External doner partners).
- ✓ International <u>technology transfer</u>
- ✓ Outcome based <u>Long-Term research plan</u> (at least 5 years)
- Easy <u>availability of reagents</u>

Priorities for healthcare biotechnology

- ✓ Upgrade the Biotechnology Department of Tribhuvan University as the <u>Center</u> for Excellence
- ✓ Coordination and collaboration with WHO, FAO and others
- ✓ International <u>technology transfer</u>
- ✓ Long term projects (at least 5 years)/Pilot Projects
- ✓ Incubator Programs
- ✓ <u>Instrumentation</u> and <u>human resources</u>.

Constraints

- ✓ <u>Government</u> commitment and investment is <u>not prioritized for healthcare</u> biotechnology products.
- ✓ Government and private laboratories are focused on the <u>disease surveillance</u> component.
- ✓ <u>Negligible human healthcare production</u> and animal healthcare having production category is continuing what it has in previous set up.
- ✓ Limited Government and private institutes though have funding resources but do not have national contribution in healthcare products.
- ✓ Country has yet not taken initiation for healthcare biotechnology products.

Favorables/Opportunities

- Covid-19 compelled the major government laboratories to improve the diagnostic <u>facility with RT-PCR</u> which can be exploited for <u>other infectious diseases</u>.
- ✓ Nepal has <u>unique geography</u> with all sorts of world's climate within the travel of <u>200 km from</u> <u>South to North</u>. So Nepal is a <u>model country</u> to do research for different environmental conditions fitting to respective part of the world.

a) Physiographic Divisions of Nepal

Mt Everest

- ✓ Availability of <u>precious microorganisms to flora and fauna</u> which can be exploited for healthcare biotechnology.
- ✓ Bunch of young generations of <u>Nepali scientists</u> have been on scene who have been <u>trained in</u> <u>different parts of the world</u> who can join the experienced researchers in Nepal.
- \checkmark On March 11, a bill has been approved to carry out Phase-I to Phase-IV clinical trails of vaccines.

Required healthcare biotechnoloty areas

Nepal expects APCTT's members support on the following aspects of the healthcare biotechnology. The enthusiast industry, academia and researchers will make availability of baseline requirements, and expects initial investment and technology transfer.

- Vaccine Production Establishment of a model vaccine company in the region with complete technology transfer from APCTT team as a preparedness for future need of healthcare biotechnology. Appropriate site and supportive human resources are available. Preferably initiation with poultry vaccine industry.
- 2. <u>Drug development</u>- Bioactive compound isolation, screening and drug development from medicinal plants against AMR pathogens using the huge biodivesity in a small land area coverage. Basic laboratory set up is available.
- 3. <u>Diagnostic kits production</u>- There are molecular to immunological researches in universities/ research institutes for diagnostic kits development which need a technical and initial investment to convert them to industrial healthcare products. For instance ELISA, PRC and RDT kits for diseases.

Projects (Specific proposals or requests)

- ✓ ELISA kit and Vaccine candidate development for dengue (an endemic disease).
 - Phase I Dengue VLPs construct preparation using Bioinformatics (Completed)
 - Phase II Construct synthesis and production of VLPs in cell line and assessment for its antigenicity (on going).
 - Phase III Development of ELISA kits and trail on animal model for a Vaccine candidate.
- ✓ Molecular and immunological analysis of infectious diseases circulating in Nepal and their application in diagnosis.
- ✓ Bacteriophage Bank enhancement for the use of the potential bacteriophages against MDR/AMR/XDR pathogens.
- ✓ Anti-snake venom production in collaboration with PPHL.
- ✓ Screening of medicinal plants for bioactive healthcare compounds

Availability of resources for strengthening healthcare biotechnology facilities

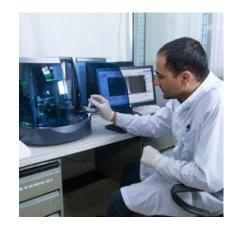
National/Provincial Public Health Laboratory- Comparatively well facilitated



HPLC



Biochem Analyzer



Capillary electrophoresis.



Real Time PCR



Biochemistry. Lab. Divison Polio/JE/Measels program





Endocrinology



Haematology



National Ref. AID/STD

Availability of resources for strengthening healthcare biotechnology facilities

Academic laboratory – Tribhuvan university



Nano drop



PCR.



Real Time PCR



Gel doc



Fragment Analyzer



Illumina MiSeq



Ultra Centrifuge.



Flow cytometry



Lyophilizer



Agilent HPLC





MilliQ water system. Power backup system

Availability of resources for strengthening healthcare biotechnology facilities

Academic laboratory – Tribhuvan university





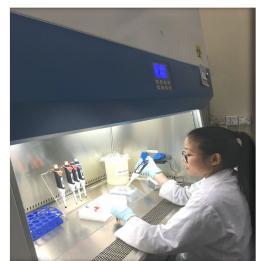




Fermentor

Soxhlet and Rotaevaporator ELISA Plate Reader & Washer

Automatic Nucleic acid extractor







-80° C Freezer



Fluoruscent Microcope.



CDBT-TU Covid Lab

Existing examples of bilateral or multilateral collaborations which have resulted in successful transfer of technologies or establishment of healthcare biotechnology R&D infrastructure in the country.

- CDBT-TU- NIH-U01 project on "Emerging infections: Surveillance, Epidemiology and Pathogenesis" Comprises 5 regions of the world *viz.* USA, China, Hongkong, Nepal and Ethiopia. Skill tranfer in
 - Sequencing skill and bioinformatics.
 - SARS Cov-2 Varient Identification that are circulating in Nepal
 - Team is underway to find the etiology of the Viral FUO (Fever of Unknown Origin) noted in > 90% fever cases.

IFS grant to work on drug development from endolichen Fungi and actinomycetes

- Isolation of bioactive compounds
- Characterization of molecules
- Bio Vac It is a private institute <u>funded by Dutch Private sector investment (PSI)</u> grant as seed money to develop and manufacture poultry vaccines. It is a Nepalese company, and <u>has developed</u> <u>thermostable formulation of Newcastle disease vaccine</u> with Master seed from University of Queensland, Australia. Now the company is at the final process of marketing approval stage.

Model

Research Institute

With most advance instruments
Skilled human resources
(PhD/Post Doc)
For researches on healthcare products

Academic Institutes of Biotechnology

With updated advance instruments
Researchers
(Faculties/Post Doc/PhD/M.Sc.)
For researches on healthcare products

Budgetary Allocation National/International/ conditional grants





National Economy Increment



Medical Biotechnology Laboratory
Implementation of Research Products





With most industrial biotechnology equipment



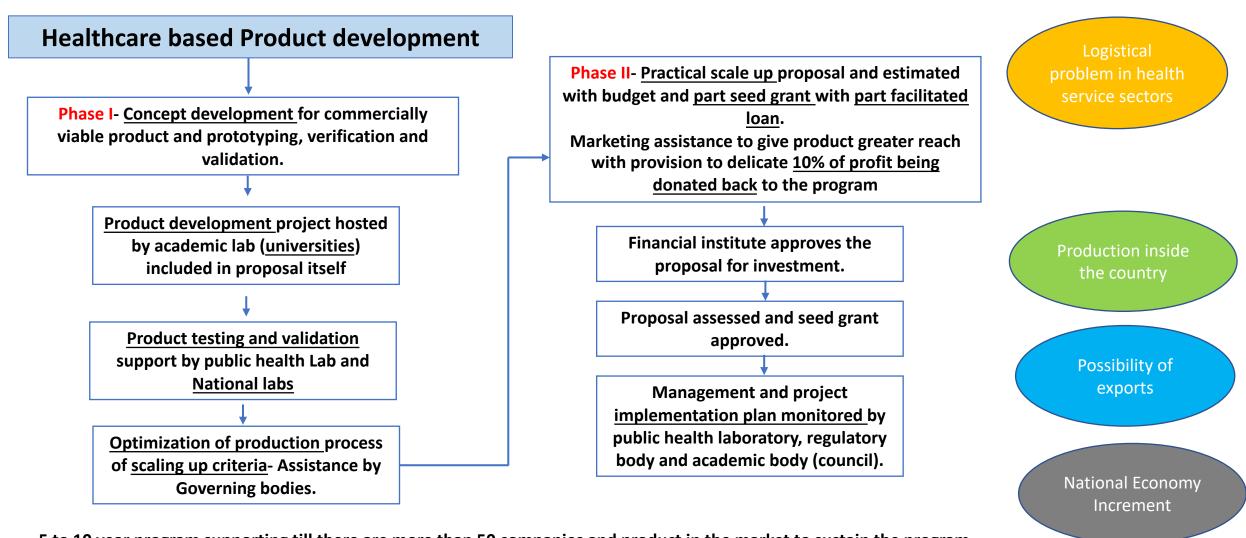
Academia – Industry
Tie up for type production

Seed Implementation funding

Academia Promotion

Project Modality - Multiphase grant structure

Academia- Private association for <u>initial Research and development inside university</u>
Mandatory enroll criteria for <u>early career and graduate student in the project</u>



5 to 10 year program supporting till there are more than 50 companies and product in the market to sustain the program from 10% R&D funding given back by the companies.

Country needs and of resources for strengthening Healthcare Biotechnology facilities

- 1. For establishing healthcare biotechnology institutes
 - Needs [Medical Biotechnology course for M.Sc./PhD and Research Laboratories]
 - Priorities [Healthcare based PhD and Post Doc. Programs with projects]
 - Constraints [Funding resources]
- 2. Facilities regarding
 - human resource development
 - o R&D focus
 - technical capacity

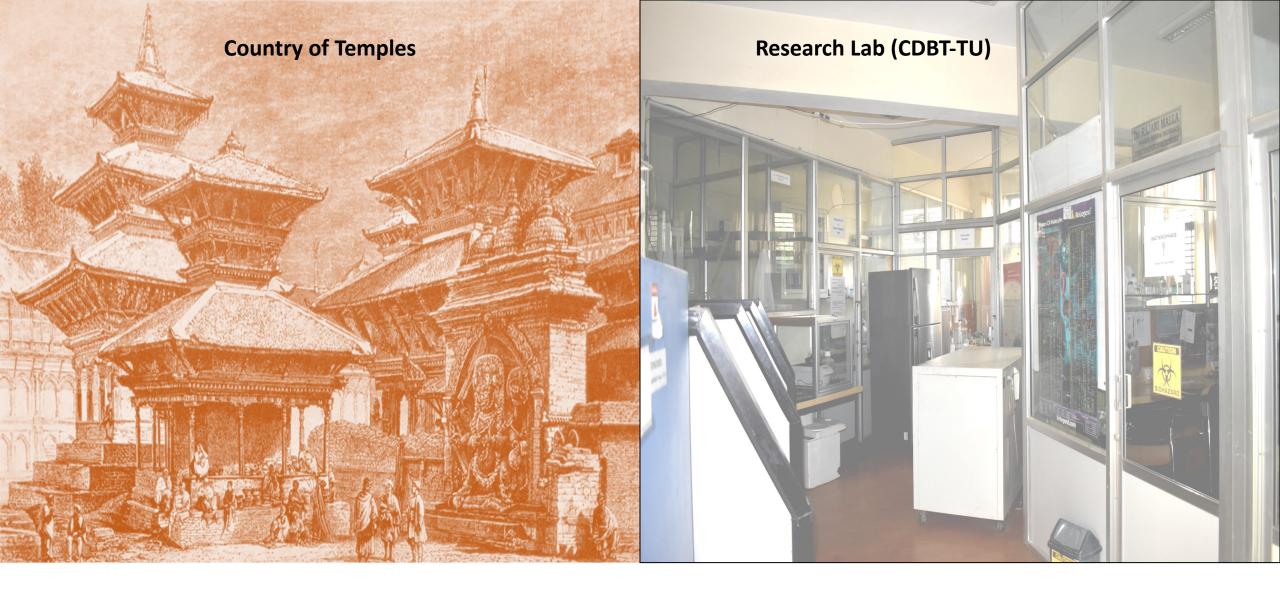
Academic and

Ressearch institutes, and industries

- Investment
 Academia-Industry model
- business models
 Academia for pilot procucts to industry model

In broad spectrum

- Needs [Culture of research to be transferred]
- Priorities [Higher academic courses]
- Constraints [Expensive instrument and country policy]



THANK YOU