**START-UP PROPOSALS**

Start-up business proposals to be evaluated and considered for incubation support at DPSRU Innovation & Incubation Foundation (DIIF).

1. **Personal information**

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**B. Abstract/ Summary of proposal (Maximum 200 words):**

The proportion of population in India which prefers regular medical check-ups voluntarily is infinitesimally small. The primary reason behind this is that a need is not recognized until an overt symptom appears. In a large number of cases, when the diagnosis is done the disease becomes prevalent or damage is done to such an extent that full recovery is not possible. The treatments in advanced stages of a disease are quite expensive. Another reason behind lax attitude towards voluntary diagnosis is the cost involved in undertaking a test. Also, the relatively low presence of health insurance in the Indian market implies that annual preventive check-ups are not something that is seriously considered by the average consumer. Without regular check-ups, the problem is exacerbated.

The rationale for regular testing of kidney function is that in the early stages of kidney involvement the nephrologists can intervene and help in preventing the progression of kidney disease. Strict control of blood sugar and blood pressure can markedly slow down the progression of kidney disease and in some cases, halt it.

People who are at high risk for kidney disease are those with history of hypertension, diabetes, recurrent urinary infections and family history of kidney disease. They should be tested periodically for the presence of protein in the urine as well as the level of toxins in the blood.

**C: Introduction to Ideation**

1. Broad Industry sector (Pharma/Medical Devices/Biotec/Other)

 **: Medical Devices and Biotech**

2. What is your product / service

 **: Diagnostic reagent, diagnostic kits and consultant services**

3. Who is recipient / beneficiary of your product / service?

 **: Mostly hospitals, research institute, diagnostics centers, diabetic and non**

 **diabetic people.**

4. What is the idea/innovation**:**

**“Development of a low cost rapid test of ELISA and LFIA for the Microalbuminuria, an Early Biomarker of Acute Kidney damage (Nephropathy) in diabetic and non-diabetic by urine” (The SwasthKidney kit).**

1. Is it an idea or have you validated any proof of concept?

**: Yes! It is proof of concept and validated on analytical variable. The**

 **evaluation of test strip with more number of clinical samples is to be done**

 **in future and also need to be in professionals shaped.**

1. If you have started any work on it, has it generated any revenue?

**: No. We are currently validating the need and the product by demonstrating the idea or the product before common people, students, professors and professionals in various disciplines like medicine, business etc. We are getting very enthusiastic response for the same.**

5. Any other information on status of your idea / start-up (interms of technology):

* **A lateral flow immunoassay (LFIA) can be used in these areas to have a preliminary indication of kidney problems level which can save both time and money.**
* **LFIAs tests have proven advantages over other detection systems as they are rapid (usu­ally completed in 2–5 min.), portable, disposable and inexpensive, require low sample volume, user friendly format with no require­ment for technical expertise and instrumentation and wide range of samples analysis with no need of processing (in clinical assays –urine, blood, serum, saliva or other body fluids whereas in non-clinical samples – soil, dust, plants or food).**
* **LFIAs have the long shelf life and the fact that refrigeration is not required for their storage.**
* **LFIA are very well adapted for use in developing countries, small ambulatory care settings, remote regions and battlefields.**

6. What is the problem you are trying to solve :

* Above 2 Lakh people die of kidney disease every year in India or roughly 547 every dayor a death every five minutes (TOI).
* In 2000, India (31.7 million) topped the world with the highest number of people with diabetes mellitus followed by China (20.8 million) and United States (17.7 million) in the second and third place respectively. It is predicted that by 2030 diabetes mellitus may afflict up to 79.4 million individuals in India (WHO).
* In India, indigenously made LFIA or ELISA is **not available** for the detection of such potential biomarker protein in urine. However some assays are available commercially which are based on antibody-antigen interaction (imported from other countries) but they are costly, and other technology such as chemical based Urinalysis test strips.
* Early detection is the key to preventing kidney disease.
* There are **no symptoms** in the earliest stages, so it’s vital to test for potential protein on a regular basis.
* Kidney disease can be prevented and/or reversed with treatment if detected early.
* Such diagnostic is tested primarily in diabetes mellitus research and considered to be an early indicator of diabetic nephropathy.
* It has also been used in studies of hypertension, pregnancy (preeclampsia, maternal morbidity, and fetal mortality), non-diabetic renal disease, and the renal effects of various drugs, hormones, and nephrotoxins.
* Concentrations in this range are a warning sign to the physician that protein is spilling into the urine at a level that may place a diabetic patient at risk for kidney disease.

**7. What experiments you will like to do? :**

**Objective 1:** To prepare immunogen and enzyme conjugate of biomarker (MAU).

**Objective 2:** Enzyme conjugate (MAU-HRP) preparation.

**Objective 3:** To develop assays (ELISA) and check their immunoreactivity and optimal

 loading for further displacement analysis and different assay validations.

**Objective 4:** Checkerboard Assay and coating of antibody to microtitre plates.

**Objective 5:** To evaluate the assays for their displacement and different assay validations for

 analytical variables like; sensitivity, specificity, precision, accuracy, recovery,

 precision and correlation coefficient etc.

**Objective 6:** To synthesize, stabilize and characterize colloidal gold nanoparticles.

**Objective 7:** To develop one steps, rapid specific and cost effective; colloidal gold labeled

 based rapid lateral flow immunoassay for MAU.

 8. What will be requirement to get idea conceptualized:

 **: Workstation, internet facility, Labs, Animal house, seeds money for**

 **Infrastructures (instruments).**

**D. Start up plan**

1. Who are the targeted founders / co-founders / promoters?

 **: Promoter-1. Dr. Dinesh Kumar. Ph.D.**

 **: Promoter-2. Mr. Swapnil Chauhan (MBA 2017-19, IIM Ahmadabad)**

1. Specify role of each promoter-1. **: Technical supports.**

 promoter-2. **: Strategy and business development.**

1. Since how long you have been working together on this idea? : **Lifelong.**
2. **E: On Your Business Idea**
3. **What is your financial viability plan for your start-up / idea:**
* Expecting a first year adoption rate of 50% and an annual check-up frequency, we expect 30 million individual units to sell at the ₹30 tag.
* Making a similar assumption for adoption rate among diabetics and an expected purchase frequency of 4 times a year (based on frequency of purchase of the bundled product- glucometer refill strips), we expect 120 million units to sell at the ₹25 tag.
* Hence the projected first year revenue: ₹ 3.9 billion (₹30 x 30 million + ₹25 x 120 million)
1. **What are the sources of funds from self or other co-founders or anticipated**

 **from incubation centre:**

: DBT and ICMR. We are planning to propose the idea in other incubation centres like CIIE IIM Ahmadabad, online crowd funding platforms etc.

1. **Anticipated competition and current industry position with respect to your idea**

: No manufacture of similar products in India is available currently thus we are at a unique advantage of being the first mover.

1. **Uniqueness of your start-up with respect to product / service:**

Yes! Immunochromatographic (ICG) test strip has practical advantages both in clinical and basic sciences, and has been widely used as a popular diagnostic tool in clinical chemistry for other detecting tumor markers, hormones, viruses, bacteria, and parasitic antigens as well as for the detection of drug and toxins. Therefore, the test has become convenient and speedy due to a novel concept of ICG that depends on the transportation of a reactant to its binding partner immobilized on a membrane surface. This recently developed technique, often called strip assay or lateral-flow assay, is based on an immunochromatographic procedure that utilizes antigen antibody properties and provides a rapid detection of an analyte. It combines several benefits, including a user-friendly format, short assay time, long-term stability over a wide range of climates, and cost effectiveness. These characteristics make it ideally suited for on-site screening by unskilled persons.

1. **How do you view your idea/technology with respect to sustainability:**

The opportunity before the idea is ample both in terms of its novelty and also the potential market size to operate. Thus the idea is sustainable from business, technology and environment perspective.

**Business sustainability:** According to Wild et al. the prevalence of diabetes is predicted to double globally from 171 million in 2000 to 366 million in 2030 with a maximum increase in India. It is predicted that by 2030 diabetes mellitus may afflict up to 79.4 million individuals in India, while China (42.3 million) and the United States (30.3 million) will also see significant increases in those affected by the disease.  The advantage of innovation is very simple, near-patient, decentralized, point-of-care, and on-site rapid testing is emerging as a tool for more efficient diagnosis and patient evaluation.

**Technological sustainability:**  Technological innovations based on lateral flow assays have enabled a move to bring testing closer to the patient and provide a simple, easy-to read, rapid, and convenient diagnostic method. Secondly, being semi-quantitative, Microalbuminuria concentration can be predicted without using any costly instrument and hence it is more user- friendly. The feasibility to execute such diagnostic tests at a location far from the laboratory would be highly utilitarian as regards the pace and economic costs. The ICG assay or simple form strip assay has been in use for a while. Further advancements in the technology and methods concerned to assays will help great deal in the mentioned idea as well.

**Environment sustainability:** Current alternatives are the expensive tests in the laboratories which consume large quantity of electricity and chemicals to carry out tests. Product such as SwasthKidney will prevent such high costs on the environment and provide a green solution.

**7. Target Market (customer segments) identification; Market size and trends; how much market share you can gain over next 3 years:**

The potential consumers of SwasthKidney are primarily the over 62 million diabetics in India. *(Kaveeshwar S.A., 2014)\** Possible consumers for the kidney may also include hypertension patients, 31.5 million in rural and 34 million in urban populations. *(Gupta, 2004)\*\**

Another major segment of the Indian population that can be included in the potential market for SwasthKidney is pregnant women who may want to use the kit in order to detect complications such as preeclampsia. This market may be quantified using the birth rate in India (19.3births/1000 population). Thus, one may assume around 25.5 million births per year.

SwasthKidney will thus cater to a market of 120 million Indians (making conservative assumptions for overlaps in the above-mentioned segments).

\* Kaveeshwar S.A., C. J. (2014). The current state of diabetes mellitus in India. *Australasian Medical Journal*.

\*\*Gupta, R. (2004). Trends in hypertension epidemiology in India. *Journal of Human Hypertension*.

**F: Strategy**

1. What if you do not get incubation support from DIIF:

**We'll propose the idea to other incubation centres like CIIE IIM Ahmadabad, Atal Incubation Centres, online crowd funding platforms etc.**

1. What if you get incubation support from DIIF:

**Acknowledge DIIF in Patents also provide the student dissertation/ training and employment.**

1. How do you plan to scale up your start-up:

**Start manufacturing on large scale with collaboration with innovation labs, industry bodies and corporate entities.**

1. What are the challenges you are facing now and you foresee in next 2 years:

 **1). Drug and manufacturing license**

**2). Animal House facilities and foresee in next**

**2 years:** SwasthKidney is an innovation and hence does not have direct competitors. This said, diagnostic laboratories are the current service providers for the service that SwasthKidney proposes to provide.

**G. Requirements**

1. Infrastructure required (workstation/office space/lab facility/internet facility/ Labs/Animal house):

 **: Workstation, office space, internet facility, Labs, Animal house, seeds money for**

 **infrastructures (instruments).**

1. Justification of infrastructure required 1

 **:** Workstation for **Kit development,** Office space for **administrative work,** internet

 facility for **online E-Commerce to be online product promotion,** Lab facility for **R & D** and Animal housefor **in house antibody production.**

1. Requirement of meeting room (Frequency of meetings being held /month):

**Rarely or may not be required.**

1. Funds required upto 2 years: Minimum 25 lakhs
2. Assistance required upto 2 years: **Guidance from experts in the relevant field and also business experts to introduce and then scale the product in the market.**
3. H. Expected milestones (every 6 months):

**Months 1-6:**

* 1. Setup the lab and other infrastructure.
	2. Develop a fully functional minimum viable product (MVP).
	3. Conduct market surveys and hence market research to solicit views from potential customers with or without product demonstrations.

**Months 7-12:**

1. Refine the product based on expert comments and findings from the market research.
2. Private beta testing of the product.
3. Apply for medical and manufacturing license.

**Months 13-18:**

1. Follow up and respond to the fulfillment requirements by the licensing authorities.
2. Public beta testing of the product.
3. Gain market validation.

**Months 19-24:**

1. Key hiring for the startup (tentative)
2. Formulate and implement a marketing plan.
3. Launch the product online and offline (limited regions initially).
4. Collaborate with not-for-profits and for-profits business entities to increase the reach of the product.