

ANNUAL PROGRESS REPORT

Proposal ID:BT/PR7403/MED/29/657/2012

S. No.: 50 102/IFD/SAN/2007/2016-2017 dated August, 10 2016.

Project Title- "Setting up the National Biobank facility for clinical and basic research in HCV at ILBS"

1. **PI (Name & Address):**Name: Chhagan Bihari, Associate Professor, Pathology
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2. **Co-PI (Name & Address):**Co-Investigator
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 2. Name: Shvetank Sharma, Associate Professor MCM Department
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 3. Name: Ekta Gupta, Additional Professor, Virology
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 4. Name: Senthil Kumar, Additional Professor, HPB Surgery
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Telephone: 011-46300000
E-mail: sanskriti@hotmail.com
 5. Name: Rakhi Maiwall, Associate Professor, Hepatology
Institute/University: Institute of Liver and Biliary Sciences
Address: D-1, Vasant Kunj, New Delhi-110070
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E-mail:rakhimaiwall02@yahoo.com

3. **Date of start:** October 2016

4. **Duration:** 5 Years

5. **Objective of the proposals:**

- To Establish an Independent National Biobank facility on HCV research, functional testing of cryopreservation and analytical systems and implementation of quality assurance practices in Biobanking.
- Nationwide capacity building in HCV research by sharing the resources and informatics and strengthening competence and capabilities of stakeholders for HCV Research in India.
- To attain partial sustenance model to deliver the excellence in Biobanking services by adopting the C-CAMP like Business and financial model by utilizing the Biobank cryopreservation, analytical services and other resources.
- To undertake Biobank based pilot projects and to develop the Biobanking based need and science in India.

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6. **Methodology** (Experiment work giving full detail of experiment set up, methods adopted, data collected, supported by necessary table, charts, diagrams, photographs).

Experiment set up

Biobank Setup

Biobank is being set up in ILBS phase-2, including offices, processing and storage area, reception and waiting area for the biobank.

Man-power Recruitment

S. No.	Post	Recruited
1.	Biobank Manager (Dr. Birendra Yadav)	Recruited
2.	IT Manager	Under process due to non-joining of selected candidate
3.	Business Development Officer (Mr. Kaustav Mallick)	Recruited
4.	Senior Technical Executive (Mr. Satish Chandra)	Recruited
5.	Junior Technical Executive1 (Ms. Shivani)	Recruited
6.	Junior Technical Executive2 (Ms. Manpreet)	Recruited
7.	Junior Technical Executive3 (Mr. Amit Kumar Rathore)	Recruited
8.	Office Executive (Mr. Inderjeet Kumar Gupta)	Recruited
9.	Part Time Accountant	Selected
10.	Part Time Legal Advisor (Rumita Poddar)	Recruited

Biobank and ILBS have made screening, recruitment and rules committee and biobank staff Selection Committee and selected the best possible man-power for the biobank.

Instruments

S. No.	Items	Status
1.	Liquid Nitrogen Tanks Capacity App. 100000 vialsx2	PNC against tender
2.	Controlled Rate Freezerx1	Purchase order sent
3.	Cryotomex1	Purchase order sent
4.	Semi-Automated Tissue Processorx1	Purchase order sent
5.	Tissue Embedding Station x1	Purchase order sent
6.	ULT Freezer System (-80°C)x2	Purchase order sent
7.	Automated Immunostainer IHC/IF/ISF	3 rd time bid opening
8.	Flow Cytometer with Cell Sorter	4 th time Re-tender
9.	High Resolution MS/MS System (Mass Spectrometer)	PNC on proprietary under process
10.	NGS	PNC against tender
11.	Cryo shippers 35VHCV-11M (qty-4)	Purchased
12.	Cryo shippers CXR500-0 (qty-2)	Purchased
13.	Bio safety cabinet class-II Type A-2 Esco Airstream Class-II Type A-2 biological safety cabinet	Purchased
14.	Semi-automatic Rotary Microtome	Purchased
15.	Micro-Centrifuge with rotors and adapters	Purchase order sent
16.	CO2 Incubator with Accessories.	Purchased
17.	Software hardware, computers	To get best possible we are discussing with various software providers, it has been after instruments as instruments integration with software will be required

Biobank Office Items

S. No.	Items	Quantity
1.	Tables	5
2.	Chairs	9
3.	Computers	4
4.	Printers	1
5.	Work benches	5
5.	Stationary Items	

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LIMS Software

Biobank software is the most important cogwheel in biobanking for management of biological sample with the implementation of barcode systems, Laboratory Information Management Systems (LIMS) and collaborative tools for sharing biological sample collections are required.

- Many software developers demonstrated their softwares which were reviewed by IT Experts, PI and Biobank manager. As per recommendations software developers were asked for quotation to start the tender process. Following members discussed with various software providers- Dr. Chhagan Bihari, Mr. Dinesh Taneja, GM-IT, ILBS; Mr. Sandip, Manager-IT, ILBS; Arindam Basu, Manager Biobank, TMC, Kolkata; Dr. Birendra Yadav, Biobank Manager, DBT-ILBS biobank.
- We extensively studied and took demos of various software providers and following is the comparative

Name	ProS	Cons	Cost	Remarks
Labvantage Nilay Mitra nilaym@labvantage.com	1) Web- based software. 2) Easy to interface with other web-based software eg: HMS system. 3) Multiplelevels of access restrictions can be done but it needs significant IT skills.	1) Support not up to the mark. 2) Not very user friendly 3) Look and feel is very out dated. 4) Prints barcode through 3rd party software. 5) Data mining in challenging. 6) Payment per license which makes it very expensive. 7) Restricted number of users at the same time. 8) Steep learning curve	600000 INR Approx per concurrent license. Yearly 450000 INR Approx support cost.	
Modul-Bio LIMS Laurent Jacotot l.jacotot@modul-bio.com	1) Web- based software. 2) Easy to interface with other web-based software like HMS system and RedCap. 3) Has module to host inventory on institute website for external researchers to search order and track sample delivery. 4) Module available for managing reagents and consumables 5) Invoicing can be done. 6) Data capturing and mining is very easy 7) Data Analysis tools integrated. 8) Multiplelevels of access restrictions can be done easily. 9) End to end solution for translational research institute. 10) Excellent ergonomics. 11) Unlimited number of License 12) Temperature monitoring module available. 13) Highly scalable.	1) The company is based in France with no local vendors or office. This can create complication for purchasing the software. 2) On-site support can be expensive.	78000 Euros = 5538000 INR for unlimited number of license. + 12% support cost after the 1st year.	Cannot comment on support
Openspecimen Srikanth Adiga srikanth.adiga@krishagni.com	1) Web- based software. 2) Easy to interface with other web-based software like HMS system and RedCap 3) data capturing and mining is easy 4) Has module to host inventory on institute website for external researchers to search order and track sample delivery. 5) Unlimited number of License	1) Very high recurring cost. 2) Reagents and consumables management module not available. 3) Prints barcode through 3rd party software. 4) Installation cost is very high for an open source software.	77500 USD = 5153750 INR for unlimited number of License + 15000 USD = 997500 INR support cost.	Cannot comment on support
CloudLIMS Mayuri Pachori support@cloudlims.com	1) Web-based software. 2) No servers required at the institute. Hosted in CloudLIMS server. 3) Overall interface is quite user friendly. 4) Inventorymanagement is included 5) barcode labeling module integrated.	1) Skeptical about data security. 2) Per user license only, no concurrent license available. 3) Integration with other software is difficult. 4) Over a long term period recurring cost will become very high.	For 12 biobankers yearly cost is 26676 USD = 1773953 INR For 5 years with 20 license approx. 35 lacs	
C-DAC Dipak Chaudhari dipakc@cdac.in		Too busy to set up a demo Session. Not their Primary product.		Upgraded version of CA-Tissue. Openspecimen is also upgraded version of CA-Tissue. So functionalities are expected to be quite similar.
Lablynx Contact Person: John Nobles jnobiles@lablynx.com	1) Web-based software. 2) No servers required at the institute. Hosted in Lablynx server.	1) The company is based in USA with no local vendors. Already notified that no onsite support will ever be available. 2) Support team is based in USA with a 10:30 hrs time difference. This may be an issue for future help from support team. We are already facing difficulty in setting up demo session due to this. 3) Skeptical about data security.		Demo to be conducted
Ziath Contact person: David Anstee, Ziath Ltd "Sarveshwar Johri" <Sarveshwar.Johri@ttplabtech.com>	1) Web browser based software 2) Data capturing and mining is very easy 3) Inventorymanagement is included 4) Module available for managing reagents and consumables 5) Rest basic requirements are excellent	1) Parallel licensing is difficult 2) After sales Support is very costly 3) End to end interfacing is the main problem and very costly	30 lacs including the interfacing	Demo appeared too confusing Found to be not a very user friendly

sheet

Website Development and Education/ Awareness about biobank

- Domain name www.nldb.in was purchased
- Quotation from vendors received and finalised and development of the website is under the process.
- Logo for the biobank has been designed and registration of the logo is under the process.
- Pamphlets, Catalogues & Information Brochures were made and distribution is under the process.
- Accounts on social media i.e. Gmail, Linked in, Twitter were made. Twitter-twitter.com/NLDB5, Linked in(www.linkedin.com/in/nldb-ilbs-850542151/), Gmail-nldb.ilbs@gmail.com
- Survey Questionnaires prepared.
- For the blood donors which are positive for viral hepatitis C, a counselling

What is Biobank?

A biobank ("bank of life") is a place that stores blood and other human tissue samples donated by patients or healthy donors for research in cancer or other serious diseases. These biospecimens are commonly annotated with information about the patient/donor from whom the biospecimen was taken, including data about their medical conditions and background. However, one of the biobank's top priorities is to protect the privacy and sanctity of the donor's personal and medical information.

What are Biospecimens?

Biospecimens are materials such as urine, fecal, blood, tissue, cells, DNA, RNA, and protein etc. taken from the human body.

Why should I donate?

Biosample donation is a precious gift. The tissue sample taken from you will always be used first and for most to diagnose your condition and to determine the best treatment for you. Sometimes, doctors do not require the whole tissue sample. Donating your tissue sample means that the leftover tissue can be stored for future research.

Will my information remain confidential?

Researchers will not know whose biospecimen they receive. They also can not request for a specific person's bio specimen. Any personal information collected at the time of you donate, your bio specimen will be kept in highly secured environment that can only be accessed by a highly authorized staff.

THE TISSUE PROCESS AND ITS IMPACT

Before surgery, you will be asked for consent to store any leftover tissue

The surgeon removes the tissue during your surgery.

The tissue sample is examined to provide a diagnosis.

Your doctor draws on this information to provide the most suitable treatment.

Any leftover tissue sample is destroyed, unless donated.

Donated tissue samples are kept in the tissue repository for research

Researchers use tissue samples in the development of new drugs and treatments.

This leads to better prevention and treatment of disease to help other patients in future.

YOUR DONATION IS A PRECIOUS GIFT TO HELP OTHER PATIENTS IN THE FUTURE

What Is Tissue Donation?

During surgery, doctors may remove a small sample of tissue to help determine a patient's illness and how best to treat it. Once this is done, any leftovers of the tissue sample are destroyed. But if a patient decides to donate his/her leftover tissue sample, it is stored in a tissue repository. Researchers conducting medical research can then apply to use stored tissue samples in their work.

Why is it important?

Through donated biosamples, researchers can learn valuable information that may help prevent, treat or even cure diseases. This forms an essential step in the research process. It is one of the ways through which we discover new treatments and even

Will my decision effect my care?

The choice to let us use/ keep the left over blood/tissue/other biospecimens from your surgery for future research is voluntary. No matter what you decide to do, it will not affect your medical care.

What will happen if I agree to donate?

The leftover tissue, the additional two to three table spoons of blood and/or other biospecimens like urine, buccal swab, faecal etc., will be stored in the NLDB until the researchers needs them for study. You will not have to go any extra procedure for collections of biospecimens.

What will if I wish to withdraw in future?

If you change your mind in future and you wish to withdraw your permission for storage of the samples and health information and wish that they be destroyed, you may do so at anytime.

What do I need to do to enroll?

If you choose to donate, a member of biobank will approach you with more detail on the biospecimen donation process and will ask you to sign a consent form.

Does my doctor know about this?

Yes, your doctor is aware that NLDB would like to store your leftover specimens. But this does not mean that it is an application to donate. The choice of whether or not donate is yours.

Whom Do I Call if I Have Questions or Problems?

If you have any questions regarding your rights as a participant in this research and/or concerns about the study, or if you feel under any pressure to enroll or to continue to participate in this study, you may contact or ask more questions about the study at any time. Please contact Dr. Birendra Kumar Yadav, Biobank Manager, nldb.ilbs@gmail.com / Ph. +91-11-46300000, Ext. 24814.

Contact us: NATIONAL LIVER DISEASE BIOBANK,
INSTITUTE OF LIVER AND BILIARY SCIENCES,
D-3, VASANT KUNJ, NEW DELHI-110070
Email- nldb.ilbs@gmail.com, www.nldb.in
Tel. +91-11-46300000 Ext. 24813.

National Liver Disease Biobank

DBT
ILBS
Initiative

- Services
- Education
- Research

Disclaimer: This leaflet Services as general information and is not a comprehensive document on Biosample donation. A more detailed Patient Information Leaflet and Consent Form will be provided to potential donors before the donation takes place.

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Committees & Team

Team

- Dr. Chhagan Bihari, PI
- Dr. Birendra Kumar Yadav, Bio Bank Manager
- IT Manager (recruitment under process, as the selected candidate didn't join)
- Mr. Koustav Mallick, Business Development Officer
- Mr. Satish Kumar, Sr. Technician
- Mr. Amit Kumar Rathore, Jr. Technician
- Ms. Shivani Goel, Jr. Technician
- Ms. Manpreet Kaur, Jr. Technician
- Mr. Inderjeet Kumar, Office Executive

Committees

- Technical Advisory Committee for equipments
 - Prof. N.K. Ganguly (Former DG-ICMR), External expert
 - Prof. Puja Sakhuja (GB Pant- Delhi), External Expert
 - Dr. Ekta Gupta (ILBS-Delhi)
 - Dr. Nirupama Trehanpati (ILBS-Delhi)
 - Dr. Shvetank Sharma (ILBS-Delhi)
 - Dr. Chhagan Bihari (ILBS-Delhi)
- Technical Evaluation Committee for equipments
 - Dr. Chinmay K. Mukhopadhyay (JNU-Delhi), External expert
 - Dr. Kalpana Bhargava (DRDO-DIPAS-Delhi), External expert
 - Dr. Gayatri Ramakrishna (ILBS-Delhi)
 - Dr. Meenu Bajpai (ILBS-Delhi)
 - Dr. Rakhi Maiwal (ILBS-Delhi)
 - Dr. Chhagan Bihari (ILBS-Delhi)
- Executive cum-steering Committee, Constituted by DBT
 - Prof. Gagandeep Kang, THSTI, Chairperson
 - Director ILBS/ Director ILBS Nominee, Co-chair
 - Prof. Vijay Kumar, ILBS, Member
 - Prof. Soumitra Das, IISc, Member
 - Prof. Rakesh Agarwal, SGPGIMS, Member
 - Prof. Anoop Saraya, AIIMS, Member
 - Prof. Sanjeev Sachdeva, GBPPGI, Member
 - Prof. CE Eapen, CMC, Member
 - Prof. Anita Mahadeva, NIMHANS, Member
 - Dr. Yogesh Souche, NCCS, Member
 - Dr. Mrinalini Chaturvedi, Cryoviva, Member
 - Mr. Sundeep Sarin, Adviosr DBT, Member
 - Dr. Sandhya Shenoy, Joint Director DBT, Member
 - Dr. Chhagan Bihari, ILBS, Member Secretary

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- **Recruitment Rules Committee:**
 - Dr. Vimal Rai Sharma, Head of Operations (M), ILBS
 - Prof. Seema Alam, Associate Dean, Academics, ILBS.
 - Dr. Chhagan Bihari, Associate Professor (Pathology)
 - Dr. Shvetank Sharma, Associate. Professor (Research)
- **Selection Committee of Biobank Manager & Senior Technical Executive:**
 - Prof. Y.K. Joshi, Chairman
 - Dr. Sudhanshu Vrat, External Expert
 - Prof. Vijay Kumar
 - Dr. Sujata Mohanty, External Expert
 - Dr. Archana Rastogi
 - Dr. Kapil Dev Jamwal
 - Dr. Chhagan Bihari
- **Selection Committee of IT Manager:**
 - Dr. Kashi Nath, External Expert
 - Mr. Dinesh Taneja, ILBS
 - Prof. Y.K. Joshi, ILBS
 - Dr. Sudhanshu Vrat, External Expert
 - Prof. Vijay Kumar, ILBS
 - Dr. Sujata Mohanty, External Expert
 - Dr. Archana Rastogi, ILBS
 - Dr. Kapil Dev Jamwal, ILBS
 - Dr. Chhagan Bihari, ILBS
- **Selection Committee of Business Development Officer:**
 - Prof. Vijay Kumar
 - Dr. Archana Rastogi
 - Dr. Chhagan Bihari
 - Dr. Birendra Kumar Yadav
- **Selection Committee of Junior Technical Executive:**
 - Prof. Vijay Kumar, ILBS
 - Dr. Archana Rastogi, ILBS
 - Dr. Ekta Gupta, ILBS
 - Dr. Chhagan Bihari, ILBS
- **Selection Committee of Office Executive:**
 - Dr. Nirupama Trehanpati
 - Dr. Archana Rastogi
 - Dr. Vijay Kumar
 - Dr. Chhagan Bihari
- **Screening committee for manpower application**
 - Dr. Ekta Gupta
 - Dr. Meenu Bajpai
 - Dr. Kishore Singh
 - Mr. Rakesh

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Documents Prepared with Legal Advisor's Opinion

- **Agreements**
 - Confidentiality Disclosure Agreement (CDA)
 - Collaboration agreement
 - Material Transfer Agreement(MTA)
 - Non-Disclosure Agreement (NDA)
 - Service Agreement
 - Collaboration policy
- **Forms with Legal Advisor's opinion**
 - Application form scheduled
 - Application form unscheduled collection
 - Information & Annexure
 - Informed Consent
 - Hindi
 - English
 - Service requisition form
 - Withdrawal of consent or Data Destruction form
- **SOPs to be reviewed by Core committee**
 - SOP for Administration
 - SOP for Participant and Recruitment Management
 - SOP for Records and Documentation Management
 - SOP for Facilities Management / Operation
 - SOP for Quality Assurance Procedures
 - SOP for Safety
 - SOP for Training
 - SOP for Materials Handling and Documentation
 - SOP for Material Release

Biobank Utilisation Policy for Host Institute

Every potential sample shall be submitted to biobank with blanket informed consent form as a potential biosource.

Students:

1. Student protocol samples will be discounted 75% (standard charges Rs. 200/year/sample)
2. MD/PHD/Research students will not be charged for storage of Biosamples, if they will collect equal number of biosamples and donate to biobank in the common pool.
3. Students will get one week training with certificate on one of instruments Biobank/FACS/NGS/mass spectrometer, if they will facilitate 25 samples to NLDB.
4. Student can get another type of samples in exchange, depending upon the availability (eg. may get PBMC in exchange plasma)

Clinician Scientist: If they donate in the common pool of Biobank with ethical approval and consent

1. Will get 50% ownership of their stored samples (frozen -198°C, FFPE block)
2. Data of their samples will be provided free of cost.

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3. Facility like FACS, NGS, MASS spectrometer, DNA, RNA Isolation will be provided on subsidized rate 50%.
4. Biobank will provide Rs 200 per sample to institute; if the samples are procured by other researchers.
5. Sample exchange can be provided
6. Co-ordinate to develop joint project proposals.
7. Joint authorship, Co-authorships and acknowledgements.
8. Rental basis on 50% subsidized rates.
9. PI/institute who participates in the strengthening process of biobank will be given certificate of participation.
10. Ownership of the biosamples provided by surgeon/PI with NLDB will be as follows:

YEAR	BIOBANK COMMON POOL	SURGEON/PI/ILBS
First	25%	75%
Second	30%	70%
Third	30%	70%
Fourth	35%	65%
Fifth	40%	60%
Sixth	50%	50%

Biobank Utilisation Policy for Non Host Institutes

Students with IRB and Consent

1. MD/PHD/Research students will not be charged for storage of Biosamples, if they will collect two aliquot of biosamples and donate one to biobank.
2. Students will get training with certificate of Biobank FACS/NGS/mass spectrometer, if they will donate 25 samples to NLDB.
3. Samples owned by students and stored at NLDB can be exchanged with other disease type of samples.

Pathologist/Surgeon/PI with IRB approval and consent as a stakeholder for biobank

1. Ownership of the biosamples provided by surgeon/PI with NLDB will be as follows:

YEAR	BIOBANK	SURGEON/PI
First	30%	70%
Second	30%	70%
Third	40%	60%
Fourth	50%	50%
Fifth	50%	50%

2. Free Biobank training for 1 employee.
3. Subsidized rates on analytical equipments by 50%.
4. NLDB also stores samples on revenue share basis (whenever procured by other researchers) as follows:

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Biosamples	Revenue for samples provider *Per sample (INR)	Duration
Plasma	50	Upto five years
FFPE Block	300	Upto five years
Serum	50	Upto five years
Frozen Tissue	300	Upto five years
Formalin Fixed Tissue	100	Upto five years

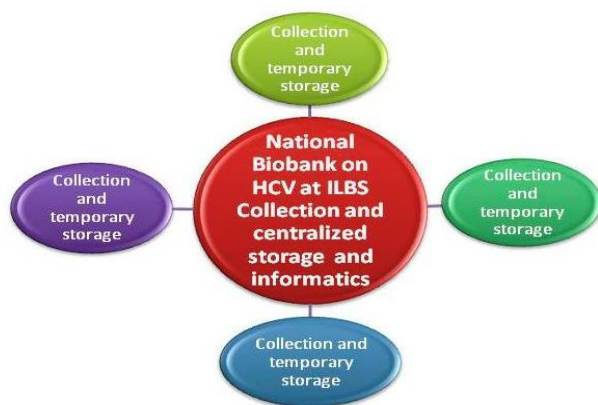
*After five years rates will be revised.

5. Samples owned by Hospital/PI and stored at NLDB can be exchanged with other samples from common pool.
6. PI/institute who participates in the strengthening process of biobank will be given certificate of participation.
7. Industrial usage will be charged as per the biobank standard charges and 30% of the revenue will be shared with the institutes/hospital.
8. Facilitate joint project/co-authorship, acknowledgement as per standards.

Methods Adopted

- We have adopted Decentralised sample collection, centralised storage and centralised informatics model for our National biobank facility.
- Marketing and ads (spreading awareness about bio bank in other hospitals and to other doctors).
- Official Contact to directors of Government & Private Hospitals.
- We proposed our objectives to different hospitals in Delhi and we are in continuous contact to collaborate for sample collection.
 - Brochures are provided for institutes/hospitals, doctors, donors and patients.
 - Awareness through
 - ❖ Personal Visit to doctors
 - ❖ Email
 - ❖ Phone/Mobile.
- Model of National Biobank Delivery

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Model of Delivery

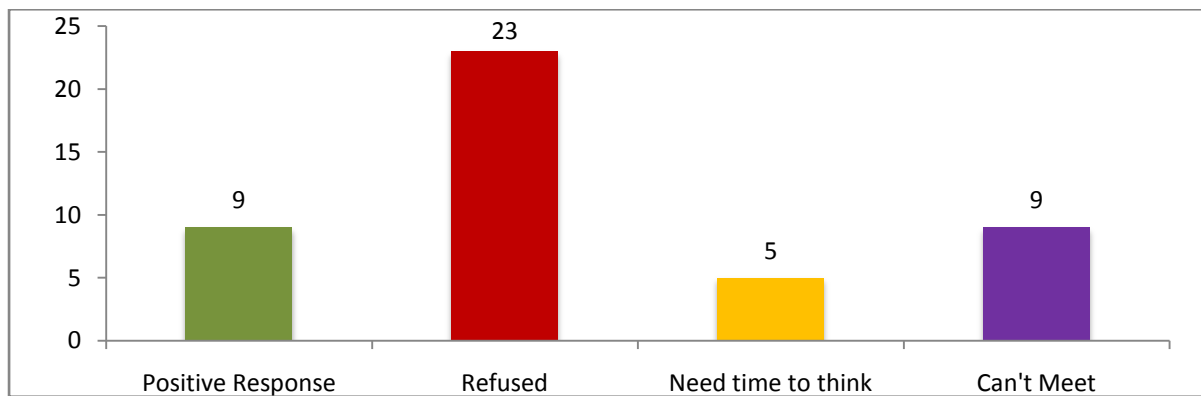
Sharing the Resources

- 46 Doctors were visited personally in 22 Hospitals/Institute in Delhi & NCR.

List of hospitals/doctors visited by person				
S. No.	Hospital name	Name of doctor	Address	Comment
1	Baba saheb ambedkar	Dr. Suyasha vyas Dr. Priyanka singh Dr. Ila sharma Dr. Amita chawala	Rohini, new delhi	No response
2	Saroj hospital	Dr. P k bhardwaj (ms)	Rohini, new delhi	No response
3	Pt. Madan mohan malviya	Dr.praveen singh Dr.mala vinayak Dr.sharmila mishra	Malviya nagar, New delhi	Ready to help but no liver surgery. Want to collaborate through proper channel We send biopsy tissue to m.a. Medical college.
4	Pushpavati singhanian hospital	Dr.k.r.vasudevan	Saket, new delhi	Doctor not present
5	G.b.pant hospital	Dr.s.saluja Dr.sanjeev sachdeva	New delhi	No response Want to collaborate through proper channel
6	L.n.j.p.hospital	Dr.p.n.agarwal	New delhi	Want to collaborate through proper channel
7	Fortis hospital	Dr.ajitabh srivastava	Gurugram	No response
8	Artemis hospital	Dr.giriraj singh bora	Gurugram	No response
9	Paras hospital	Dr.rajnish monga	Gurugram	Doctor not present
		Dr.anukalp prakash	Gurugram	Doctor not present
10	Alchemist hospital		Gurugram	Hospital closed
12	Fortis hospital	Dr.(col.)Ms paul	Vasant kunj, new delhi	Need time to think
13	Medicity, the medanta	Dr.pramod nath	Gurugram	No response
		Dr.randeep wadhawan		No response
				No response
				No response
		Dr. S.I. Jain		Interested to send hcv patients to nldb.
		Dr.sunita kakkar		Interested to make a

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				network but not interested to store samples at nldb.
14	Army hospital(r&r)	Dr. Puja misra	New delhi	Interested to make a network but not interested to store samples at nldb.
		Dr.k.b.mishra		No response
15	Charak palika hospital	Dr.col.k.j.singh	Moti bagh, new delhi	Want to collaborate through proper channel
				Doctor not present
17	Northen railway hospital	Dr.rajani bhalla	New delhi	Want to collaborate through proper channel
18	R.m.l. Hospital	Dr.sharad c.khorwal	Connaught place, new delhi	No response
19	G.t.b.hospital	Dr.m.b.shankhwar	New delhi	Want to collaborate through proper channel
		Dr.sharad verma		Doctor not present
				Want to collaborate through proper channel
20	Safdurjung hospital	Dr.nirupma p.khan	New delhi	Need time to think
21	Mahendra hospital	Dr.a.s.chawla	New delhi	Want to collaborate through proper channel
				No department of gastrology
22	Sukhmani hospital		New delhi	No department of gastrology



Response on personal visit

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2. 113 Doctors were contacted 46 Hospitals/Institute in Delhi and other States through Email.

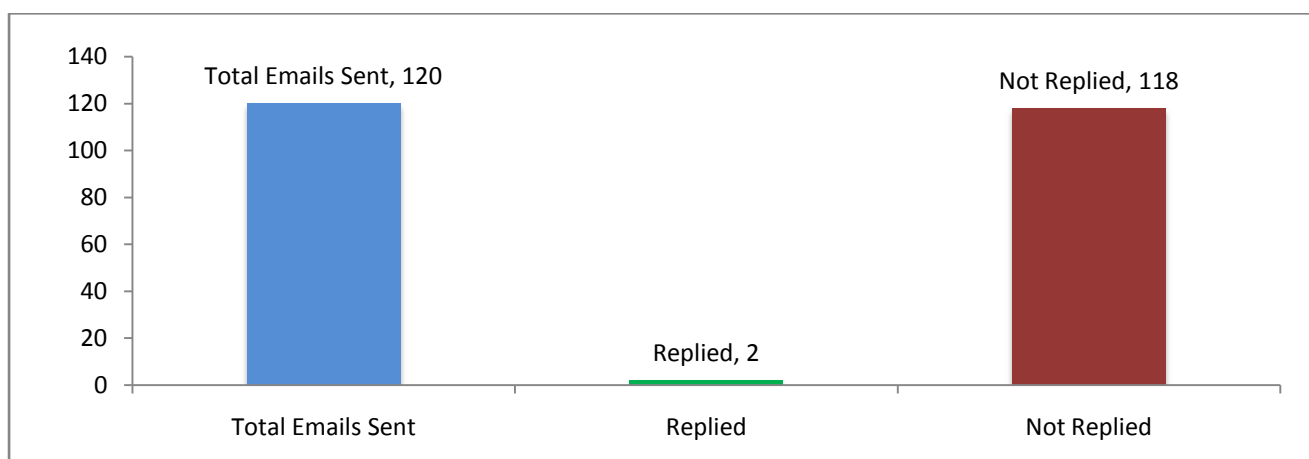
List of Doctors Contacted by Email				
S. No.	Hospital	Address	Doctor Name	Email ID
1	AIIMS	New Delhi	Dr.A.S.Saraya Dr.Umesh Kapli Dr.P.K.Garg Dr.Vineet Ahuja Dr.Govind K.Makharia Dr.Shalimar Dr.Baibaswata Nyak Dr. Lalit Dar	Ansaraya@yahoo.com Umeshkapil@yahoo.com Pgarg10@hotmail.com Vins_ahuja@hotmail.com Govindmakharia@gmail.com Drshalimar@yahoo.com Baibaswata@yahoo.com Lalitdar@gmail.com
2	M.A.M.College	New Delhi	Dr.Lovenish Kumar Dr.P.N.Agarwal Dr.N.S.Hadke Dr.A.K.Sarda Dr.R.K.Jindal Dr.Sanjeev Kumar Tudu Dr.Pawan Indra Lal Dr.Sudhir Kumar Jain Dr.Chandra Bhushan Singh Dr.Pawan Lal Dr.Rajdeep Singh Dr.Sushanto Neogi Dr.Anubhav Vindal Dr.Deepak Ghuliani	Drlovenish@yahoo.com Pnagarwal@hopmail.com Nshadke@yahoo.com Aksarada@rediffmail.com Rkjindsal@vsnl.com Drtudugnt2015@gmail.com Profplal@gmail.com Sudhirkumar11@gmail.com Drchandrabhushansingh@gmail.com Pawanlal@yahoo.com Rajdeep.mam@gmail.com Sushantoneogi@gmail.com Anubhav.vindal@gmail.com Drdeepakghuliani@gmail.com
3	Safdarjung	New Delhi	Dr.Rajini Gaiind Dr.Monorama Deb Dr.Balvinder singh Arora Dr.Jagdev Kaur Dr.Vindu Amitabh Dr.Rashmi Arora Dr.Leelavathi Dawson Dr.Mukul Singh Dr.Charanjeet Ahluwalia Dr.Amit Kumar Yadav Dr. Pushpa Rani Dr. Ratan Gupta Dr M.K. Sen	Rgaiind5@hotmail.com Monoramad@yahoo.com Arorabalvinder007@yahoo.com Jagdevbal08@gmail.com Vamitabh@yahoo.com Arorarashmi@hotmail.com Dawsons_home@yahoo.com Drmukulsingh@gmail.com Charanjeetahluwalia@rediffmail.com Amityadav7284@yahoo.com Pinkey.2809@gmail.com Ratangupta100@yahoo.com Drmksen@yahoo.com
4	AIIMS	Patna, Bihar	Dr.Manoj Kumar Dr.Anil Kumar Dr.prashantkumar Singh Dr.Surya Vikram Dr.Sushmita Das Dr.Sayan Bhattacharya	Drmanojk@aiimspatna.org Dranilk@aiimspatna.org Drprashants@aiimspatna.org Drsuryav@aiimspatna.org Drsushmitad@aiimspatna.org Drsayanb@aiimspatna.org
5	AIIMS	Jodhpur, Rajasthan	Dr.Jiwan DR.Vijay Lakshmi Nag Dr.Anuradha Sharma Dr.Ravish Kaur Gadepalli Dr.Mahendra Lodha Dr.Ram Karan Chaudhary	Drjivishnoi@gmail.com Nag@aiimsjodhpur.edu.in Sharmaa@aiimsjodhpur.edu.in Gadepallir@aiimsjodhpur.edu.in Lodham@aiimsjodhpur.edu.in Chaudhary@aiimsjodhpur.edu.in
6	Artemis	New Delhi	DR.Giriraj Singh Bora Dr.Ramdip Ray Dr.T.Krishan Thusoo Dr.Shayam Sunder Mahansaria Dr.Paritosh S.Gupta Dr.Anshuman Kaushal Artemis Hospital Dr.Anil Khetarpal	Giriraj.bora@artemishospitals.com Ramdip@artemishospitals.com Tkthusoo@gmail.com Drmahansi@gmail.com Paritoshg@artemishospitals.com Anshuman.kaushal@artemishospitals.com Liver.gastro.surgery@hotmail.com Anilkpl@artemishospitals.com

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7	FORTIS	New Delhi	Dr.(Col.)MS Paul Dr.Pramod Nath Dr.Randeep Wdhawan DR.Ajitabh Srivastava	Ms.paul@fortishealthcare.com Pramod.nath@srl.in Randeepwadhawan@fortishealthcare.com Ajitabh.srivastava@fortishealthcare.com
8	FORTIS	Faridabad	Dr. Nalini Bansal	Drnalinibansal@yahoo.com
9	Dr Ram manoharlohia Hospital	New Delhi	Dr. Sunil Saxena Dr. Sarit Dr. A.K. Gadparde Dr. Rajnish Mr. Anil Kumar	Sunilsaxena883@yahoo.co.in Doctorsarit@gmail.com Drgadpade@yahoo.com Docrajnish11@gmail.com Ddarmhl@gmail.com
10	Balaji Action	New Delhi	Dr. Naveen Aggrawal Dr. Pinky Yadav Dr. Parveen	Drnagarwal@actioncancerhospital.com Drpinky72yadav@yahoo.com Drparveenmangal@gmail.com
11	Acharya Tulsi R.C.C.	Bikaner, Rajasthan	Dr.Shankar Jhakhar Dr.Jitendera Kumar Nangal	Drsjakhar@gmail.com Drijitendranangal@gmail.com
12	Max Hospital	Gurugram	Dr.Geeta Arya Dr.Rajneesh Shrivastava	Geeta.arya@maxhealthcare.com Drrcshrivastava@rediffmail.com
13	Max Hospital	Saket, New Delhi	Dr. Sahar Qureshi Dr. Poonam Das	Sahar.qureshi@maxhealthcare.com Pdas@maxhealthcare.com
14	S.G.T.Medical College		Dr.Priti Aggarwal	Pritidragarwal2@gmail.com
15	B.L.K.Hospital	New Delhi	Dr.Rashika	Drrasikasetia@blkhospital.com
16	G.T.B.Hospital	New Delhi	Dr.Sharad Verma	Sharad.verma83@nic.in
17	KGMU	Lucknow	Dr. Neha Nigam	Nehanigamdoc26@gmail.com
18	Guru Tegh Bahadur	Dilshad Garden , Delhi	Dr.Sunil Kumar Dr. P. Ram	Msgtbh@nic.in Parmeshwar1968@gmail.com
19	Sanjay Gandhi Memorial Hospital	Mangolpuri ,Delhi	Dr. Mukesh Yadav	Dr.yadavmukesh@gmail.com
20	Lalbahadurshastri Hospital	Khicripur , Delhi	Dr. Yogesh Kushwaha(Ykushwaha@hotmail.com
21	Loknayak Hospital	Jawaharlal Nehru Marg, New Delhi	Dr. Naresh Kumar Dr. Mohan Lal	Nareshdr114@yahoo.com Ashokmital@yahoo.com
22	Deendayalupadhyay Hospital	Hari Nagar, Delhi	Dr. Uma,	Meumak@yahoo.com msdduh@yahoo.co.in
23	Pandit Madan Mohan Malviya Hospital	Malviya Nagar, New Delhi	Dr. Sunil	Sharma_sunil16@yahoo.com
24	Baba Saheb Ambedkar Hospital	Rohini, Delhi	Dr. Shweta	Vivekrana1965@gmail.com
25	Chacha Nehru Bal Chikitsalaya	Geeta Colony, New Delhi	Dr. Medha Goyal Dr. Samiksha	Medhagoel@hotmail.com Sdublish@gmail.com
26	Bhagwanmahavirhospital	Pitampura, Delhi	Dr. Daljeet Kaur	Drdaljeet@yahoo.com
27	Maharishi Balmiki Hospital	Poothkhurd, Delhi	Dr. Rajiv Singhal	Msbmh@nic.in
28	Babujagjivan Ram Memorial Hospital	Jahangirpuri, New Delhi	Dr. Avinash Kumar	Msbjrmh@yahoo.co.in
29	Arunaasaf Ali Hospital	Rajpur Road, New Delhi	Dr. Javed	Drjavedsalam99@yahoo.co.in
30	Suchetakripalini Hospital	Panchkuian Road, New Delhi	Dr. H.R. Singh Dr.Vivek Suman	Dhrhsingh.10@gmail.com Drviveksuman@gmail.com
31	Bara Hindu Rao Hospital	New Delhi	Dr. Nikhara	Dvinodnikhara@hotmail.com
32	Dr. Hedgewar Arogya Sansthan	New Delhi	Dr. Arjun Singh	Arjun_singh_15@yahoo.co.in
33	Apollo Hospital	Sarita Vihar, Delhi	Dr. Neera Trivedi Ms. Pushpa Rawat	Neera_k@apollohosptals.com Pushpa_r@apollohosptals.com
34	Moolchand Hospital	Lajpat Nagar, Delhi	Dr. Madhu Handa	Madhu.handa@moolchandhealthcare.com

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35	Sir Ganga Ram Hospital	Rajinder Nagar, Delhi	Dr. Shalini Chawala	Chawlashalini9@gmail.com
			Dr.Sunita	Drsunitasunda@gmail.com
36	St. Stephens	Tis Hazari, Delhi	Dr. Vijay Kataria	Dr.vijay@katarias.in
37	Diagno India	Gurugram	Dr.Anita Vaidya	Anitavaidya@hotmail.com
38	BLK Hospital	Rajinder Nagar, Delhi	Dr. Gurbachan Singh	Gurbachan.singh@blkhospital.com
39	Dang Lab		Dr. Nanin Dang	Drdangsoffice@gmail.com
40	Lal Path Lab		Dr. Atul	Atul.thatai@lalpathlabs.com
41	Super Religare Lab		Dr. Rashmi	Rashmi.talwar@srl.in
42	Apollo Lab		Mr. Abhimanu	Cssingh@apollohospitals.com
43	Patel Chest		Dr. Madhu Khanna	Madhukhanna@hotmail.com
44	Sir Ganga Ram Hospital	Rajinder Nagar, Delhi	Dr Chand Watal	Chandwatal@gmail.com
45	Sequence Referral Laboratory		Dr. Sonu Panwar	Drsonupanwar187@gmail.com
46	Airport Hospital	New Delhi	Dr. Sanjay K Mattoo	Aphopalam@gmail.com



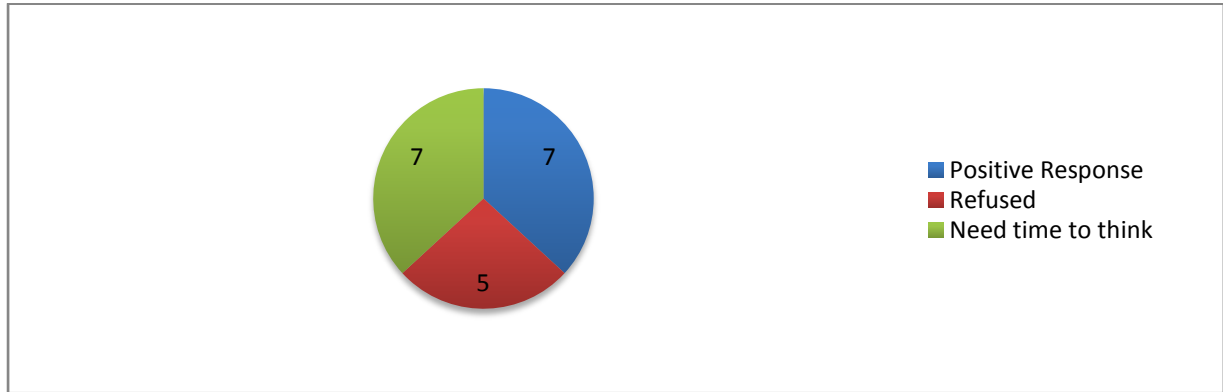
Doctors contacted via Email

3. 19 Doctors were contacted by phone from 18 Hospitals/Institute in Delhi and other States.

List of Doctors Contacted by Phone				
S. No.	Hospital Name	Name of Doctor	Address	Comment
1	Army (R&R)	Dr. K.J. Singh	New Delhi	Interested for collaboration
2	Balaji Action	Dr. Naveen Aggrawal	New Delhi	Positive Response
3	B.L.K. Super Speciality	Dr. Rashika	New Delhi	Needs time to think
4	KGMU	Dr. Neha	Lucknow	Interested for collaboration
5	Fortis	Dr. Nalini Bansal	Faridabad	Positive Response
6	AIIMS	Dr.Jiwan	Jodhpur, Rajasthan	Positive Response
7	Acharya Tulsi R.C.C.	Dr.Shankar Jhakhar	Bikaner, Rajasthan	No Response
8	Medicity, The Medanta	Dr. Sunita Kakkar	Gurugram	Interested in biobank networking
9	Fortis	DR Pramod nath	New Delhi	We will discuss with high authority
10	Cellugen Biotech Pvt.Ltd.	Dr Anubhav Pandey	Gurugram	We will discuss with high authority
11	Cryoviva biotech	DR Vikas verma	Gurugram	Refused
12	Dahiya medical centre	Dr Sanjeev kumar dahiya	Gurugram	Refused
13	Max healthcare	Dr. Geeta arya,microbiologist	Gurugram	We will discuss with high authority

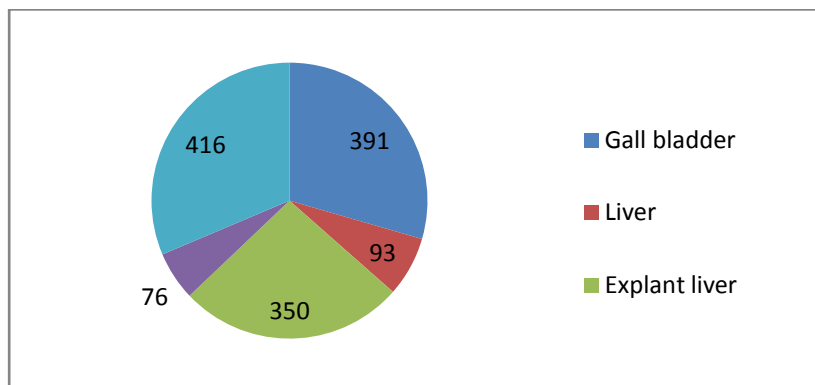
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		Dr .Rajneesh shrivastava	Gurugram	Refused
14	Diagno India	Dr. Anita vaidya,pathologist	Gurugram	Time needed for think
15	Rockland hospital	Dr. .sushma barde	Manesar, Gurugram	Time needed for think
16	SGT Medical college	Dr. Priti agaarwal,MICROBIOLOGY	Gurugram	Time needed for think
17	GTB Hospital	Dr. Nirupama p khan	New Delhi	Want to collaborate through proper channel
18	Diagno india	Dr. sonal saxena	Gurugram	Refused

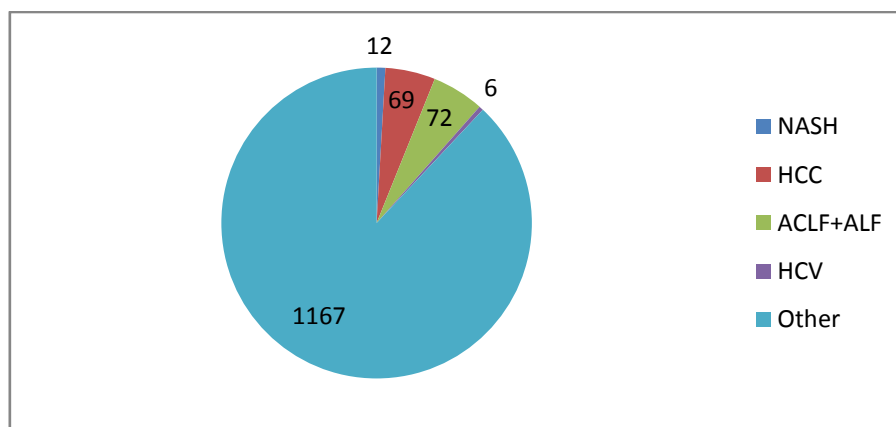


Potential available source for biosamples

- Formalin Fixed Tissue Samples from 1326 patients were identified in ILBS and all samples were linked with their demographical, clinical and pathological data.



Types of samples



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7. Interim modification of objectives/methodology (with justification). *NA

8. Summary on progress (during the period of report) vis-a-vis time schedule.

		First Year			
		Quarter 1	Quarter 2	Quarter 3	Quarter4
Proposed	Call for material suppliers and installation experts for cryopreservation setup				
Achieved			Started		
Proposed	Ordering/tendering for Cryopreservation equipments				
Achieved					
Proposed	Establishment and installation of Cryopreservation infrastructure				
Achieved					
Proposed	Call for material suppliers and installation experts for Analytical equipments				
Achieved					
Proposed	Ordering/tendering for Analytical equipments				
Achieved					
Proposed	Establishment and installation of Analytical infrastructure				
Achieved					
Proposed	Recruitment for Tissue Bank staff started				
Achieved					

Call for material suppliers and installation experts for cryopreservation setup was made in second quarter. Ordering/tendering for Cryopreservation equipments (Liquid Nitrogen, - 80°C deep freezer) were completed in third and fourth quarter. Establishment and installation of Cryopreservation infrastructure will be started and we expect it to be completed by the second quarter of second year. Call for material suppliers and installation experts for Analytical equipments were started in third quarter. Ordering/tendering for Analytical equipments were started and completed in third and fourth quarter. Establishment and installation of Analytical infrastructure will be started and we expect it to be completed by the mid quarter of second year. Six cryoshippers, Bio safety cabinet, Semi automatic Microtome and CO2 incubator with accessories were purchased third and fourth quarter. Posts for the Biobank were advertised in second quarter; candidates were interviewed in Third quarter and selected in fourth quarter. *(Suitable candidate not found for the post of IT Manager and Recruitment will be completed in First quarter of second year).

9. Detailed analysis of Results indication contributions made towards increasing the state and knowledge in the subject.

- a. Spreading awareness about bio bank in other hospitals and doctors.
- b. Spreading awareness with help of pamphlets.
- c. Brochures are provided for institutes/hospitals, doctors, donors and patients
- d. We proposed our objectives to different hospitals in Delhi and NCR through:
 - Personal Visit to doctors by our staff.
 - Emails were sent with Information and brochures about our biobank.
 - Clinicians were also contacted via Phone/Mobile personally.
 - We have also selected different conferences to set up our awareness stall and to make participants conscious about the biobank.
- e. We are getting positive response for collaboration from following institutes/hospitals/doctors:
 - i. Army Research &Referral Hospital
 - ii. Shri Balaji Action Medical Institute
 - iii. BLK Super Speciality Hospital
 - iv. Medanta-The Medicity
- f. Logo



Logo of the NLDB has been designed and registration is under process. The purpose of our logo is to give a visual representation of the Biobank. Our logo serves the purpose of supporting our entity name and the products and services we provide.

- g. The following Biobank agreements, Forms and documents were prepared with the help of legal advisor. Confidentiality Disclosure Agreement (CDA), Collaboration agreement, Material Transfer Agreement (MTA), Non-Disclosure Agreement (NDA), Service Agreement, Collaboration policy, Application form scheduled, Application form unscheduled collection, Information & Annexure, Informed Consent (In both Hindi & English), Service requisition form and Withdrawal of consent or Data Destruction form. Biobank is still under development in India and our agreements and documents prepared with legal advice would be used by upcoming biobanks in India.
- h. We have contacted many clinicians, pathologists, Blood bank head and microbiologists from different hospitals in Delhi and NCR. We were able assess clinician's point of view regarding sample collection, Transpiration, Process and Storage of biosamples from different centres. We also sensitised biobanking concept and scope in different hospitals and Institutes.

10. Conclusions summarizing the achievements (Not more than 150 words).

Biobank has been established at ILBS by the name of National Liver Disease Biobank. This includes offices, reception, and processing and storage area. Office furniture & Accessories were purchased and set up of the office was completed. Laboratory for processing, de-identification, labelling of biosample has been set up. All biobank staff has been selected except IT Manager. SOPs, Consent and other Forms and Agreements were prepared. Logo for the biobank has been designed, Domain www.nldb.in was purchased and development of the website is under process. Biosample release committee and biobank ethical committee are under review. Order & Tender of cryopreservation systems and Analytical equipments were made. Six cryoshippers, Bio safety cabinet, Semi automatic Microtome and CO2 incubator were purchased. LIMS software specifications were identified and quotations were invited for tender process. Formalin Fixed Tissue Samples from 1341+ patients were identified as biosample source. We proposed our objectives to different hospitals in Delhi and NCR and got positive response for collaboration.

11. Applied value of the project: Rs. 22.32 cr

12. Research work which remains to be done under the project.

Project Work
Second Year
Establishment and installation of Cryopreservation infrastructure
Establishment and installation of Analytical infrastructure
Verification Cryopreservation and Analytical functional facility of Biobank and Operations
Establishment and implementation of Standard Operating Procedures
Quality assurance
Third Year
Establishment and implementation of Standard Operating Procedures
Quality assurance
Collection and storage of samples from institute other than host institute
Validation of stored samples for scientific usage
Participation of researchers stakeholders
Fourth Year
Quality assurance
Collection and storage of samples from institute other than host institute
Validation of stored samples for scientific usage
Participation of researchers stakeholders
Training programme
Business Development
Fifth Year
Quality assurance
Collection and storage of samples from institute other than host institute
Validation of stored samples for scientific usage
Participation of researchers stakeholders
Training programme
Business Development

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Third quarter of the second year will be for (i) Verification and validation of functional cryopreservation (ii) analytical facility (iii) development of SOPs, establishment after external review and implementing. It will be standardized by the first half of third year.

Then the quality practice implementation with the suggestions and inputs from the user's experts will be started and they will go along the Biobank programme. Biobank will start collecting and storing the samples once the SOPs, policies and quality practices are implemented and the collection will be started from the beginning of Year-3 Biobank will caters biosamples across the country. Biobank will start validating the stored samples in middle of the third year and then samples will be available for customers, researchers, collaborators. The training programme will be started from the fourth year to prepare the human resources in the field of cryopreservation in India and Simultaneously Biobank will develop a business model for its sustenance by academic and industrial collaborations and liaisons. To summarize in first and second year the infrastructure for cryopreservation and analysis will be established, third year will be dedicated for the quality assurance in the Biobank operation in fourth and fifth year there be focus on the HR development and business development of Biobank. But the operational, collection, storage, processing, sharing and sustenance model will expect to be started from the beginning of third year.

13. Scope for future work

The establishment of National Liver Disease Biobank is an important step towards establishing national liver disease research programmes. Following would be the scope of future work in the field of liver disease biobank

Biobank ethical committee and Sample release board is to be defined with due deliberation with SSACC/ core committee meeting

Collaboration: Our plan is to collect biosamples from different parts of India for which request will be made to different hospitals for collaboration. We will sign MOU with willing hospitals/institutes and biobank will help them, in providing collection devices, SOPs, manuals for the standard collection, quality control and training.

Joint proposal: Biobanks are precious source of samples and data for the development of commercial products in both public and private sectors. Several biotechnologies companies and research institutes needs bio-resources to develop applications in the performance and capabilities in healthcare and medicine. We will propose joint project proposal with industry for development of new products.

Counselling: We will facilitate patients counselling services for patients referred by hospitals, diagnostic laboratories and blood banks. It would help to diagnose and treatment of individuals with liver diseases, allowing them to get into care and treatment sooner.

Consultancy: Biobank will serve as consultancy agency for developing and designing, providing necessary documents, framework for new biobank

Manpower training course: Biobank will develop capacity of human resources in the country by training paramedical and medical staffs. We will also start a diploma/certificate courses for medical students, laboratory technicians, life science students, doctors and researchers etc.

Welfare of biobank personnel: We will provide bonus, Employee Provident Fund, Perks, Earned leaves, employees and their family's health insurance and incentives etc. to biobank personnels.

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QC centre: We will start quality control and certification center for other biobank. Biobank accreditation requirements will be set up to insure that quality assurance and quality control procedures in biobanks.

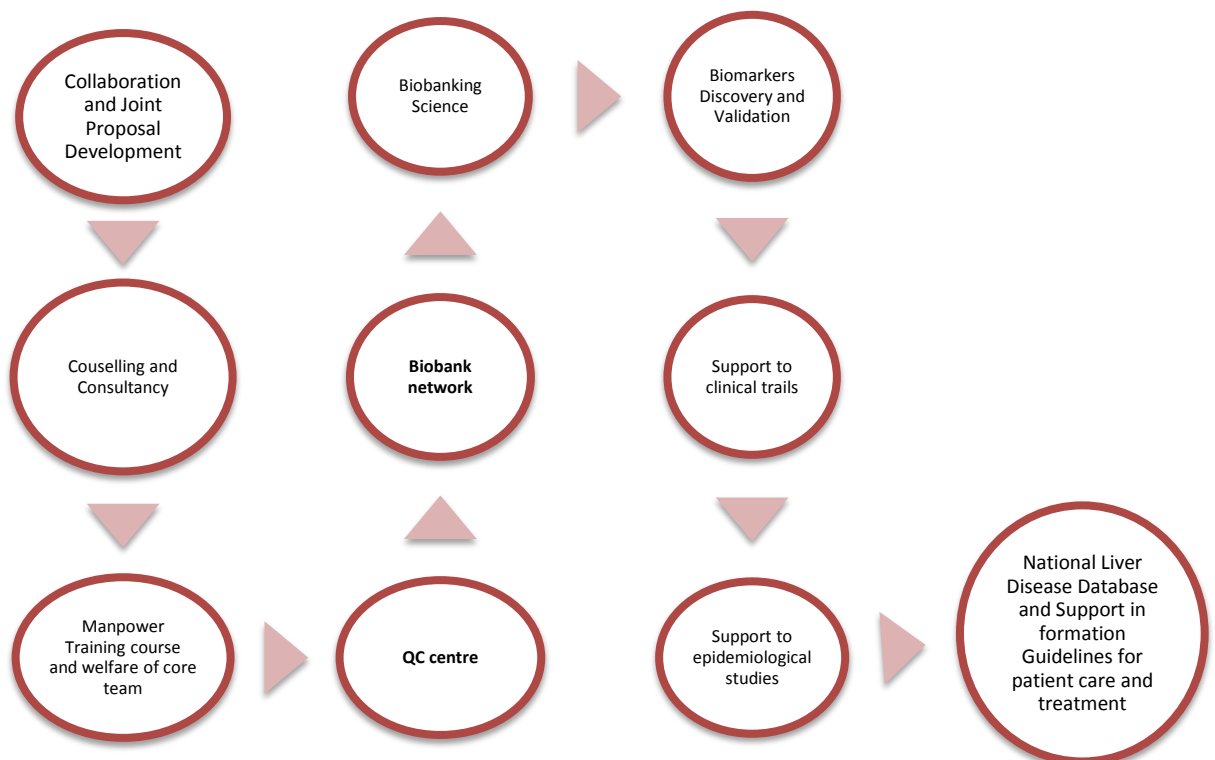
Biomarker Validation: By the collection of high quality patient samples with patient clinical, pathologic and outcome data, we will help in the biomarker discovery and validation.

Biobank network: We will make biobank network in India, which will accelerate research and save time by providing good quality of samples from each part of country.

Biobanking based science: We will be role model in the biobanking science by providing biosample, education, training, counselling, and consultancy.

Clinical trial: Biobank resources are important tools in clinical trial. Each clinical trial sample needs to collect, processed, storage space, create databases, develop sample collection protocols. NLDB will help in clinical trial by providing their robust biobank facility.

Epidemiological study: Biobanks are a key resource in unravelling the association between genetic background, lifestyle and environmental determinants of the incidence, natural course and treatment response for various complex diseases and health traits. Biobanks are goldmines for epidemiological research, provided that they are set up properly, enable multicentre collaboration, and are available for use by all serious epidemiology groups.



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14. Any patents applied for: **NO**

15. Likelihood of product/process development with time frame.

	5th Year	6th Year	7th Year	8th Year	9th Year	10th Year
Biobanking						
Training & Certifications						
Industrial Collaboration & New Project Development						
New Biomarker discovery						
Quality Control Centre for Biobank						
Liver Database Development						
National Programme Development						

14. Any patents applied for: NO

15. Likelihood of product/process development with time frame.

	5th Year	6th Year	7th Year	8th Year	9th Year	10th Year
Biobanking						
Training & Certifications						
Industrial Collaboration & New Project Development						
New Biomarker discovery						
Quality Control Centre for Biobank						
Liver Database Development						
National Programme Development						

Date _____

Name & Signature

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