

Format for Submission of Final Report of Completed Project

A. Summary

1. Project title : **National Liver Disease Biobank (NLDB)**
2. Date of start of the project : **30 August, 2016** (as per sanction order)
3. Completion report duration : **30.08.2016 to 29.08.2023**
4. Total cost of the project : **Rs. 22,70,51,182/-** (including revision)
5. Coordinator's detail : **Dr. Chhagan Bihari, Additional Professor,
Department of Pathology and Hematology,
Institute of Liver & Biliary Sciences**

6. Sanctioned objectives and objectives achieved:
(tabular format):

Sanctioned objectives	Objectives achieved
i. To establish an independent national biobank on liver disease research, functioning, testing of cryo preservation, analytical systems and implementation of quality assurance practices.	i. NLDB was established with a cryo-preservation capacity of 5.4 million samples, analytical systems (NGS, MS, and FACS), laboratories for molecular pathology, office premises with reception, and a document record and storage room. NLDB is the first biobank in India, certified by CTR.Net and ISO 20387:2018.
ii. Nationwide capacity building in liver disease research by sharing the services, informatics and strengthening competence and capabilities of stakeholders.	ii. A total of 2,32,013 aliquots from 29,106 liver patients were collected and stored. MOUs with 28 institutes throughout the nation were done. 10964 samples were provided to 135 research projects, while 33584 animal-pathology, 5769 assessments, 5383 FACS, 7213 LCMS, and 9298 NGS were completed. A transient storage facility was provided to 12 researchers; rental storage was provided to 7 institutes; and currently, PIs from 42 institutes are dependent on NLDB services to support their research.
iii. To attain partial sustenance model to deliver the excellence in biobanking services by adopting appropriate model by utilizing the	iii. We adopted the C-CAMP and the academic-industry partnerships model, attaining partial sustenance, and were able to

world-class services and resources.	generate 4.4 crores within a 5-year span utilizing world-class resources.
iv. To undertake biobank-based pilot projects and to expand the biobank-based need and science in India.	iv. NLDB trained 441 scientists and budding scientists. Two joint projects from ICMR (1) and IIT Roorkee (1) were sanctioned. MOU with two training institutes for training in biobanking was done, and advice and support for 3 GOI-funded biobanks were provided. Organized four international symposiums and four workshops in biobanking. 13 awards and global recognition were attained via membership in the apex biobanking societies ISBER, ANRRC, and BBIF, and 13 manuscripts and 8 abstracts were published.

7. Reason for non-achievement of objectives (bullet points only): **None**

8. Infrastructure established (as per sanction order):

Separate area for the National Liver Disease Biobank was designated in the upper basement of Phase 2, ILBS, as different spaces were allocated for (1) cryostorage facility with a capacity of 5.4 million samples (a) LN2 tanks, (b) 80 and -20 freezers, (2) analytical facilities (a) NGS lab, (b) LCMS lab, (c) FACS lab; (3) lab area for molecular and pathology; (4) office premises with reception; and (5) document record/storage room. Biobank Information Management Systems (BIMS) was developed in-house with practical modules and registered via dairy no. 2563/2022-CO/SW under “The Copyright Act 1957”.

Manpower staff: biobank manager (tissue bank manager), IT manager/team lead (senior IT/bioinformatics manager), business development manager, accountant (part-time), senior technical executive, junior technical executive, receptionist (office executive/junior executive), legal advisor (part-time), and junior medical officers were recruited.

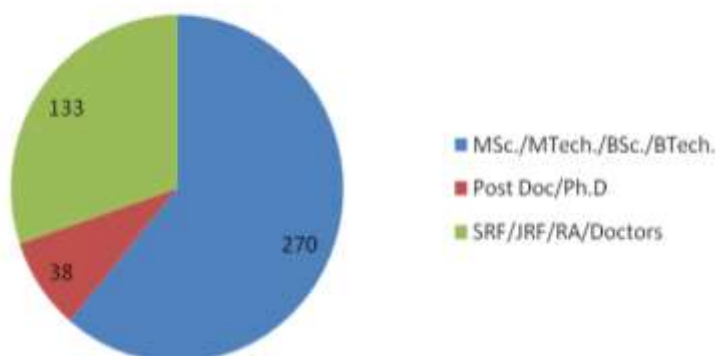
List of equipment installed and working

S.No.	Name of equipment	No.
1	LN2 storage tanks 50,000 (capacity 1.2 & 2ml) with all required inventory system, LN2 supply cylinders & accessories included all accessories & vials	4
2	Controlled Rate Freezer with supply tank of 180 liters with insulated hose and racks	1
3	Cryo shipper holding time 125 days	4
4	Cryo shipper holding time 21 days	4
5	Cryo shipper for airway transportation holding time of 42 days	4
6	Shipping Case	6

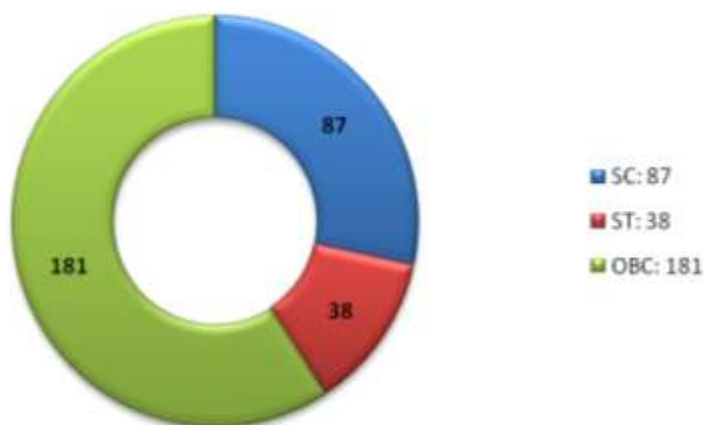
7	LN2 bucket	2
8	-80°C freezers with inventory system boxes, racks (-20°C freezer)	11
9	Lab Freezers	4
10	Sample Pass Box	2
11	Biosafety cabinet	2
12	Microcentrifuge including refrigerated centrifuge with rotors and adapters	1
13	Table top centrifuge with adaptors	1
14	Micro ultracentrifuge	-
15	Labeling machines and barcode readers	2
16	Cryolables	7
17	Computerized support systems, hardware, advanced tissue bank software and website maintenance and networking, cryomonitor software	-
18	CO2 incubator	1
19	RT-PCR	2
20	Grossing Station	1
21	Cryotome	1
22	Microtome	1
23	Tissue Processor	1
24	Embedding Station	1
25	Tissue Microarrayer	1
26	Microscope	2
27	Automated Immunostainer IHC/IF/ISF	-
28	Flow Cytometer with Cell Sorter	1
29	NGS	1
30	Mass Spectrometer (High resolution MS/MS system)	1
31	Table chairs, bench archiving cabins, racks, cabinet stationary, cupboards	-
	Ancillary equipment necessary for daily operations (Gel-Doc system, Multichannel pipettes, Tissue Flotation Bath, Slide warmer, Ph meter, Water bath, Block cabinets, Micro-slide cabinet, Lab freezer, Mini gel tank, Microwave oven, Dry bath with blocks, Hot air oven, Oxygen Meter with sensor & Buzzer, Qubit Fluorometer etc.)	-

9. Manpower trained (as per sanction order, plz include the break up with figures only e.g. number of M.Sc. Students/ JRF/ SRF/ RA and Assistant Professor, etc.): **441**
- **270** students of PhD/M.Sc./M.Tech/B.Tech/B.Sc. trained in biobanking, storage and analytical procedure.
 - **38** students of PhD/Post Doc trained in cell sorting, flow cytometry
 - **133** scientists/M.Sc./JRF/SRF/RA/MBBS for workshop and training in covid-19 biobanking, analysis of covid genome sequencing and associated analytical facilities

Students trained: 441



10. Number of SC/ST/OBC category people trained (Plz provide figures separately for each category):
Estimate representation.



11. Research outcome:

- Publications (**Note: figures only; kindly include only those publications having DBT's acknowledgement as per the sanction order and comes out of this project ONLY**): 13 publications and 8 abstracts
- Patents (**filed and granted separately; kindly also include the patent numbers/reference number**): None, copyright of biobank software via dairy no. 2563/2022-CO/SW
- Technology developed, transferred or commercialized (**Kindly include the name of the company to which the technology has been commercialized**): Utilized high end equipment for contract research through academic-industry partnership with (1)DNA Xperts for genomics/proteomics; (2)Valerian Chem Pvt. Ltd. for Mass Spectrometry; (3)Core Diagnostics for NGS.

- Status of commercialized technology (**whether in market or not; if yes the name of the country**): High end equipment MS, NGS and FACS operational through academic-industry partners in India only.

12. Summary (In two hundred words only)

NLDB was established with world-class labs and equipment for cryopreservation and analytical facilities, office premises, and a record/server room. Manpower was recruited as sanctioned, SOPs, policies, and processes were designed, and biobanking software was developed in-house. For quality assurance, NLDB became the first biobank in India to be certified by ISO 20387:2018 and CTR.Net. 2.35 lakh aliquots of biosamples from 29,106 liver patients were collected and stored via MOUs with 28 institutes throughout the nation and provided 10964 samples to 135 research projects, 33584 histopathology, 5769 assessment, 5383 FACS, 7213 LCMS, 9298 NGS, a transient storage facility to 12 researchers, rental storage for 7 institutes, and research support services provided to PIs from 42 institutes. QC of stored samples and routine audit of processes are done quarterly; logs of storage area and LN2 tank are recorded twice daily; and freezers are monitored 24/7 via an online system. The business-financial models of C-CAMP and academic-industry partnerships were adopted, and partial sustenance was attained, generating 4.4 crores within 5 years as an outcome. MOU with 2 training institutes for training in biobanking and training 441 scientists, two joint projects with South Asian University (ICMR), IIT Roorkee (DST), and advice support for 3 GOI-funded biobanks organized 4 international symposiums in biobanking and 4 workshops; 13 awards and global recognition via membership in the apex biobanking societies ISBER, ANRRC, BBIF; and published 13 manuscripts and 8 abstracts.

13. Grant remaining unspent along with justification: **None (negative balance of Rs. 1,32.95,048/-)**

14. Justification for non-submission of yearly financial documents: **All financial documents were timely submitted**

B. Progress in details (not more 8 pages)

Establishment: A separate area for the National Liver Disease Biobank was designated in the upper basement of Phase-2, ILBS, as different spaces were allocated for (1)cryostorage facility with a capacity of 5.4 million samples (a)LN2 tanks, (b)80 and -20 freezers, (2)analytical facilities (a)NGS lab, (b)LCMS lab, (c)FACS lab; (3)lab area for molecular and pathology; (4)office premises with reception; and (5)document record/storage room.



Processing Lab1



Processing Lab2



Storage Area



Cryopreservation



Mass Spec facility with 1 lab



FACS facility with 1 lab



Genomics facility with 2 labs



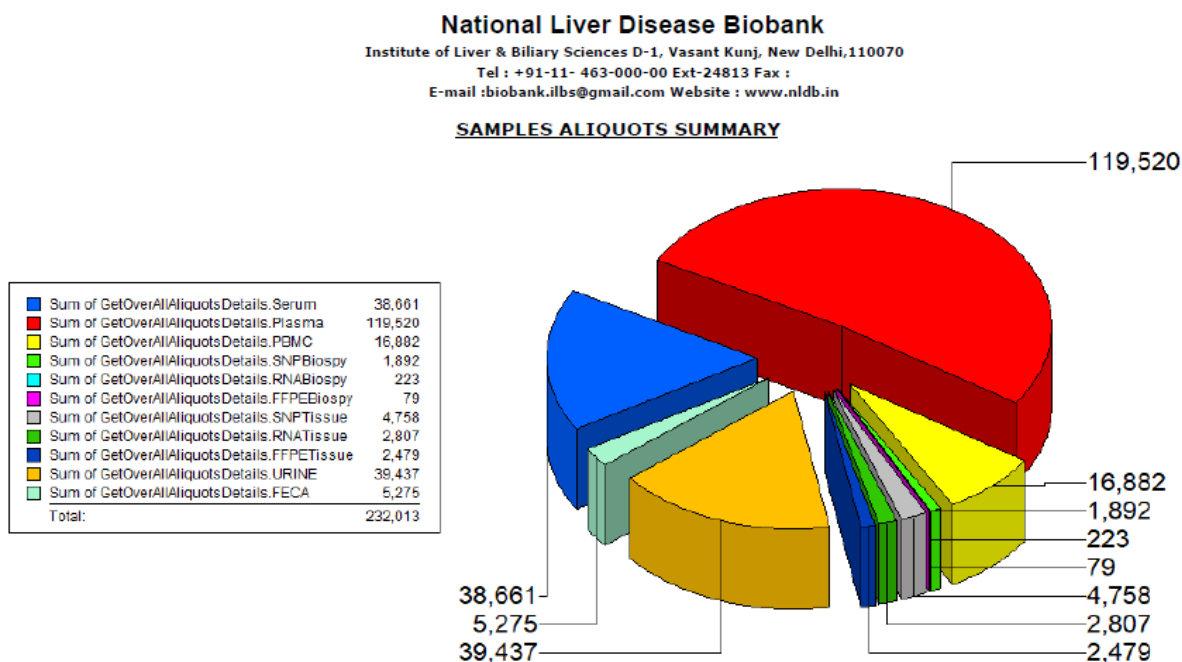
Biobanking software (BIMS)

Manpower: Biobank manager (tissue bank manager), IT manager/team lead (senior IT/bioinformatics manager), business development manager, accountant (part-time), senior technical executive, junior technical executive, receptionist (office executive/junior executive), legal advisor (part-time), and junior medical officers were recruited.

Biobanking Software: Biobank Information Management Systems (BIMS) was developed in-house with practical modules, registered under “The Copyright Act 1957” vide diary no. 2563/2022-CO/SW, and demonstrated to THSTI and AIIMS lab/biobank.

Biosamples:

1. A total of **2,32,013 aliquots from 29,106 liver patients** centrally stored at NLDB by routine decentralized collections from host institute and collaborative hospitals.
2. Provided **10,964 biosamples to 135 research project**



Services:

1. Provided **33,584 animal-pathology, 5,769 pathological assessment, 9,298 NGS, 7,213 Mass Spectrometry** and **5,383 cell sorting work** to researchers from **42 research institutes**.
2. Provided **transient storage facility to 12 researchers** who appealed NLDB in urgent situation for their samples, and **rental storage for 7 researchers/institutes**.

Accreditation and Quality Assurance:

1. **Canadian Tissue Repository Network (CTR.Net)-first biobank in India in 2020**
2. **ISO 20387:2018- first biobank in India in 2021**

ACCREDITATION: First Indian biobank accredited by **ISO 20387 : 2018**



CERTIFICATION: First biobank in India, certified by **Canadian Tissue Repository, Net, Canada**



3. Provided QC for histopathological slides of tumour tissue- regarding necrosis, %tumour, grading, fixation and quality of section.
4. Provided **kit validation for IIT, Kanpur**
5. Provided **kit validation for testing HBV and HCV through our samples for GeneStore India R&D.**
6. Prominent quality assurance methods:
 - a. Daily twice temperature record of cryostorage, storage area and processing lab
 - b. 24x7 monitoring of cryostorage for deviation in temperature
 - c. Three-layer audit of annotation form (medical expert, PI biobank and manager)

MOUs Signed: MOU with 28 hospitals/diagnostics labs for collection of biosamples and two training institutes for providing training in biobanking and analytical facilities.

Coordinator	Institute	Address
Dr. Harit Kumar Chaturvedi	Max Super Specialty Hospital	New Delhi
Dr. Umang Mittal	Meerut Cancer Hospital, Mithal Cancer Center Enterprises	Meerut, Uttar Pradesh
Dr. P K Tyagi, Dr. K.G. Sanwalia	Muzaffar Nagar District Hospital	Muzaffarnagar, Uttar Pradesh
Dr. Ankur Das Dr. Kaushal	Yatharth Wellness Super-Specialty Hospital & Heart Centre	Noida, Uttar Pradesh
Dr. Vivek Vij	Advanced Institute of Liver and Biliary Sciences Pvt. Ltd.	Delhi
Dr. Shivam Vatsal Agarwal Dr. Deepika Parwan	Sarvodaya Hospital and Research Centre	Faridabad, Haryana
Dr. Prashant Gupta, Director, MS	Sharda Hospital, School of Medical Sciences and Research	Greater Noida, Uttar Pradesh

Dr. S.S. AKHTAR	Jamia Hamdard University	Hamdard Nagar, New Delhi
Dr. Ramesh Garg, Dr. K.D Kavita, Pathology	Saroj Super Specialty Hospital	Rohini, New Delhi
Dr. Rajesh Sharma	Medcon Internationale	Ahmedabad, Gujarat
Dr. Ajay Kumar	King George's Medical University	Lucknow, Uttar Pradesh
Dr. Naval Kishore	Lakshya Cancer Hospital	Lucknow, Uttar Pradesh
Dr. Rishu Srivastava	Prakhar Cancer Hospital	Kanpur, Uttar Pradesh
Dr. Naveen	Divya Cancer Hospital	Gwalior, Madhya Pradesh
Dr. B.R.Srivastava	Cancer Hospital and Research Institute	Gwalior, Madhya Pradesh
Dr. Naveen Agrawal	Dhanwantari Hospital & Research Institute	Kanpur, Uttar Pradesh
Dr. Manish Sharma	Pioneer centre of bioscience for advanced training and research	Ghaziabad, Uttar Pradesh
Dr. Ananda Kumar Soshee	Medical Imaging Solutions	Bengaluru, Karnataka
Modern Diagnostic & Research Centre	Modern Diagnostic & Research Centre Pvt. Ltd.	Gurugram, Haryana
Dr. Charu Garg	RCR Path Labs	Meerut, Uttar Pradesh
Dr. Anita Jain	Valentis Cancer Care Hospital Pvt. Ltd.	Meerut, Uttar Pradesh
Dr. Rishi Gupta	Jagannath Charitable Cancer Hospital	Ghaziabad, Uttar Pradesh
Dr. Nidhi Goyal	Centre for Health Research and Development, Society for Applied Studies	New Delhi
Dr. Udit Dewan	Dewan Histopathology & Diagnostic Centre	Lucknow, Uttar Pradesh
Biobank India Foundation	Biobank India Foundation	New Delhi
Dr. Rohit Jain, MD Pathology	Santokba Durlabhji Memorial Hospital cum Medical Research Institute	Jaipur, Rajasthan
Dr. Prabhsaran Kaur	Institute of Liver and Biliary Sciences	New Delhi
Institute of Liver and Biliary Sciences	Institute of Liver and Biliary Sciences	New Delhi
Dr. Geetanjali Agarwal Joshi	Bhagwan Mahaveer Cancer Hospital & Research Centre	Jaipur, Rajasthan
Dr. VP Singh	Delhi Institute of Technology and paramedical sciences	New Delhi
Training		

Academic-Industry Partnership: NLDB established Academia-Industry Partnership with

1. DNA Xperts Pvt. Ltd.-Mass Spec and NGS for contract research
2. Vproteomics-Mass Spectrometry for contract research
3. Core Diagnostics-NGS

Collaborative Projects ongoing:

1. One joint project from ICMR with South Asian University, titled *“Role of Prostate Tumour Overexpression 1(PTOV1) in Horizontal Transfer of Bioactive Molecules via Exosomes in Breast Cancer Cells and its Clinical implication”*

2. One joint project with from DST with IIT-Roorkee, titled “*Respiratory Virus detection using Advanced Machine-learning enabled Plasmon Enhanced Raman-spectroscopic Nano-sensors*”

Biobanking Advice Support: Provided inputs to three biobanks funded by Government of India,

1. AIIMS, Jhajjar, Haryana
2. National Institute of Cancer Prevention and Research-ICMR, Noida, UP
3. Brain Biobank at National Brain Research Centre, Manesar, Haryana

Conferences: NLDB organized:

1. Two international symposiums (India’s first in biobanking field), one biobanking workshop and one IHC Workshop
2. 3rd International Biobanking Symposium 2023 in Feb, 2023
3. Organizing task force-chair- ISBER annual conference in Seattle, USA from May,23
4. “Biobanking workshop 2022”, 27th and 28th July 2022
5. 2nd Co-organized of Biobanking International Symposium, February 22, 2022
6. Round table discussion topic “Improving trust in Biobanking” ISBER 2021
7. 1st Biobanking International Symposium, February 20,21, 2020
8. Workshop in Biobanking at NLDB, ILBS, February 20 2020
9. NLDB-ISBER open forum, India, February 21, 2020
10. First symposium cum workshop biobanking, Feb 2019

Membership:

1. Membership of Asian Network of Research Resource Centres (ANRRC), ISBER was joined. ISBER make easy for us to connect biobanking community and make our biobank update with recent development in this field.
2. Manager, NLDB designated as a member of ISBER Hybrid Task Force to organizing future ISBER conference Post Covid. Hybrid task force was responsible to work on organizing the ISBER conference -2022 in Atlanta, USA.
3. Member of task force to develop a toolkit for Biobank Regional Ambassadors.
4. Member of ISBER organizing committee -2021 -present
5. Member of ISBER Education & Training committee 2021 -present
6. Member of the Scientific Committee and Jury Members in Young Scientists’ Conference (YSC) at India International Science Festival (IISF 2019)
7. Technical Specification Committee member of ICMR automated National Bio-bank facility 2020-Present

Awards:

1. ILBS Received Biobank Pioneer Award 2023 from Biobank India Foundation
2. NLDB Manager selected as “Program task force Chair-ISBER 2023”
3. PI, Biobank received Biobank India Foundation Award for Outstanding Achievement in Biobanking-2022
4. “Australian Biospecimen Network newsletter-2022” published the summary of NLDB-International Biobanking Symposium
5. BBIF an Indian Biobank society designated Manager, NLDB as “Regional Director” for North Indian region
6. Invited speaker and Session Chair, ISBER -2022, Atlanta, USA
7. Biobank Manager received “ISBER-Special service award”
8. ISBER an apex biobanking society designated Manager, NLDB as a “Regional Ambassador” for the Indo Pacific Rim in 2019 and reselected in 2020, 2021 and 2022.
9. Special service award for BBM, ISBER-2021
10. Invited speaker, ISBER-2021
11. Moderator for a round table discussions (topic: Improving trust in biobanking), ISBER-2021
12. ISBER-2021 conducted virtually
13. Invited Speaker, ISBER -2018, Dallas, Texas, USA

Training: 441 students/scientists were trained in biobanking and associated analytical facilities

Publication: Published 13 manuscript and 8 abstracts

Covid Biobank:

1. ICMR designated NLDB as one of the 16 trusted biorepositories across the country to store and share covid biosamples for research purpose.
2. A separate area in biobank was allotted for sample processing and storage space for -80C ULT freezer. Separate room with limited access is used for VTM sample processing.
3. Clinical trial: NLDB assisted in clinical trial by providing the robust biobank facility, and involved in clinical CoViD-19 patients’ clinical trial and collect biosamples, process, and create databases.
4. SOPs/Policies and annotation forms for the collection of these biosamples were designed
5. NLDB add-on CoViD biobank collected 41,427 aliquots of CoViD aliquots from 32,217 CoViD patients and provided 3129 samples to 8 research projects (2719 academia + 410 industry), 72serum, 250 saliva, 20 PBMC, 610 urine, 527 plasma, 750 NPS and 200 post-vaccine plasma and 700 NPS+OPS samples to researchers

Funds Generated: NLDB was able to generate Rs. 4,38,51,000/- till 29 August 2023, and as per the project mandate, this amount will be utilized for operational expenses to support the existence of biobank in long run.