विज्ञान एवं प्रौद्योगिकी विभाग
DEPARTMENT OF
SCIENCE & TECHNOLOGY

DST@
1971-2021

Impact Analysis of National GLP Program

FOREWORD

Prof. Ashutosh Sharma
Secretary
Department of Science and Technology

The Department of Science and Technology (DST), Government of India, established the National GLP Compliance Monitoring Authority (NGCMA) with the approval of the Union Cabinet on April 24, 2002. On March 3, 2011, India became full adherent to the Mutual Acceptance of Data (MAD) in the OECD. The MAD status has given global recognition to India's non-clinical safety data. It is a matter of honour and pride that Indian GLP test facilities provide non-clinical data to over 50 countries across the globe.

NGCMA will soon be entering the second phase of ten years of recognition of MAD. This Impact Analysis of the National GLP Program, India, critically brings out all the important points of Strengths, Weaknesses, Opportunities and Threats. From the dedication and enthusiasm of the entire team of NGCMA and the critical inputs of the Technical Committee, I am confident the Program is prepared for any assessment and will come out with flying colors.

With continued Government commitment and emphasis on further capacity building, India is destined to be a global leader.

Thanking you,

MESSAGE

Dr. Neeraj Sharma
Scientist 'G' and Head, NGCMA

On behalf of NGCMA, I compliment my team, the technical experts, inspectors and test facilities for bringing the Indian GLP to the highest level of standards and getting recognition by OECD. By virtue of becoming affiliated with OECD, we became a part of the mechanism for solutions and the framing of policies on national and global issues.

It is the endeavor of NGCMA to continuously interact with OECD as well as our technical committee to remain contemporary in quality standards and technological advancements. Frequent interactions with inspectors and with top managements of test facilities has helped us to better assess the real-world situation and carry out timely intervention for corrections and improvements, wherever required.

India is fast becoming a global leader in the pharmaceutical and agrochemical sector. Environment protection has become a focal issue in the health of the human and animal kingdom, as well as the aquatic ecosystem. The National GLP program is playing an important role in policy, planning and implementation of quality systems.

The Chairman, GLP Authority and Secretary, Department of Science and Technology has been a constant source of motivation to all stakeholders.

This impact analysis is designed and conducted with perfection by the Quality Council of India, with which NGCMA has been bonding for over six years. It has provided crucial planning and execution of different operational activities. This report brings out the SWOT analysis and gives a direction for continued efforts towards excellence and perfection.

My best wishes to all the stakeholders.

MESSAGE

Dr. Y. K. Gupta
Chairman, Technical Committee on GLP

Grant of GLP certification by NGCMA under the National GLP Program in 2004 was a milestone. India becoming full adherent to Mutual Acceptance of Data (MAD) in March 2011 was a historical event. This tremendously augmented the credibility and acceptability of Indian data across the globe. This also boosted the confidence of not only the test facilities (TFs) but also different sectors such as pharmaceuticals, pesticides, industrial chemicals, veterinary drugs, feed additives, food additives, cosmetics and others (like medical devices). The spectrum of Indian TFs is wide, involving 8 test items and 9 areas of expertise. The National GLP program has not only helped to create a network of GLP TFs in the country but also generated a large number of highly competent human resources.

The dedicated training of the GLP inspectors and continued capacity building of Indian TFs in emerging areas by the ground team of NGCMA has resulted in upgrading TFs facilities to meet international standards.

This was possible because of the encouragement and guidance by Prof. Ashutosh Sharma, Chairman, GLP Authority and Dr. Neeraj Sharma, Head, NGCMA. I feel proud that the OECD has recognized the Indian contribution and designated Dr. Ekta Kapoor as the Vice Chair of the OECD working group on GLP (for 2021- 22). Special thanks to the Quality Council of India, particularly Dr. Manish Pande who orchestrated this Impact Analysis of National GLP Program. This report not only brings out milestone achievements and its impact in Indian science but also reveals some areas that need to be strengthened.

The collective teamwork of all stakeholders to include policy makers, managers, regulators, TC members, TFs, and sponsors will make India a global leader.

Disclaimer

This report is prepared based on the information collected through several data collection instruments such as surveys, consultation workshops, stakeholders' meetings and secondary research. Due importance has been given to accuracy of data points and information presented in this report.

This report is a general analysis of the GLP Test Facilities in India. QCI and NGCMA encourage case to case basis due diligence before making any business decision.

This report is a publication of the Government of India and can be freely downloaded from the website https://dst.gov.in/ngcma under the section 'What's New'.

About Department of Science and Technology

The Department of Science and Technology (DST) was established in May 1971, with the objective of promoting new areas of Science and Technology and to play the role of a nodal department for organizing, coordinating and promoting Science and Technology activities in the country.

About National GLP Compliance Monitoring Authority

National GLP (Good Laboratory Practice) Compliance Monitoring Authority (NGCMA) was established under the administrative control of the Department of Science and Technology, Government of India, with the approval of the Union Cabinet on April 24, 2002. India was granted a status of full adherence to Mutual Acceptance of Data (MAD) in the OECD's Working Group on GLP w.e.f. March 3, 2011. As a consequence, the data generated by Indian GLP test facilities (TFs) is acceptable in all the OECD member countries and non-member MAD adherent countries. The OECD MAD system is a multilateral agreement which allows participating countries (including non-member MAD adherent economies) to share the results of various non-clinical tests done on chemicals.

About Quality Council of India (QCI)

Quality Council of India is a non-profit autonomous society, which was set up in 1997 by Government of India in setting up organizations in partnership with the Indian Industries to spread quality movement in India by undertaking a National Quality Campaign. The mission of QCI is to lead the nationwide quality movement by involving all stakeholders for emphasis on adherence to quality standards in all spheres of activities primarily for promoting and protecting interests of the nation and its citizens.

ACKNOWLEDGMENT

Dr R.P. Singh,
Secretary General,
Quality Council of India

The Impact Analysis of National GLP Program is an effort to showcase the program's strength in undertaking non-clinical health and environment safety studies in accordance with OECD Principles. The National GLP Program has continuously supported the Indian GLP test facilities to standardize their services according to international norms. The execution of this report is a teamwork of all stakeholders.

We are grateful to the Government of India officials for their guidance and valuable inputs. Our special thanks to,

- Prof. Ashutosh Sharma, Chairman, GLP Authority and Secretary DST, Govt. of India
- Dr. Y.K. Gupta, Chairman, Technical Committee, NGCMA
- Dr. Neeraj Sharma, Head NGCMA and Scientist 'G' DST, Govt of India
- Dr. Eswara Reddy, Joint Drug Controller General of India, CDSCO, Ministry of Health and Family Welfare
- Dr. Sandhya Kulshreshtha, Consultant (Pharma), Central Insecticide Board and Registration Committee, Directorate of PPQ and S, Ministry of Agriculture and Farmer Welfare
- All members of the Technical Committee, NGCMA

We are thankful to Dr. Ekta Kapoor, Member-Secretary, Technical Committee and the nodal point at NGCMA for all technical inputs and support.

The study was anchored by Dr Manish Pande, Director and Head, PAD Division, QCI. His leadership quality is reflected in the extensiveness and accuracy of the report.

Thanks are due to the GLP Certified TFs of India, sponsors and NGCMA inspectors for their active participation in the study through consultations to assess the impact of National GLP Program. We are thankful to Dabur Research Foundation; Eurofins Advinus Limited; Laboratory Animal Research Services (LARS), Reliance Life Sciences Private Limited, and RCC Laboratories India Private Limited for hosting regional consultations for the purpose of this study.

We acknowledge the efforts of pManifold Business Solutions Pvt. Ltd. and its experts for collation and analysis of this study.

Abbreviations

AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care International
CDSCO	Central Drugs Standard Control Organization
CIB	Central Insecticide Board
CMA	Compliance Monitoring Authority
CRO	Contract Research Organization
CPCSEA	Committee for the Purpose of Control and Supervision of Experiments on Animals
DCGI	Drugs Controller General of India
DQ	Design Qualification
DoE	Design of Experiment
DST	Department of Science and Technology
EHS	Environment Health and Safety Program
EEC	European Economic Community
FDA	Food and Drug Administration
FGD	Focused Group Discussion
GLP	Good Laboratory Practice
GOI	Government of India
IAEC	Institutional Animal Ethics Committee
IQ	Installation Qualification
MoU	Memorandum of Understanding
NGCMA	National GLP Compliance Monitoring Authority
OECD	Organization for Economic Cooperation and Development
OQ	Operational Qualification
PPE	Personal Protective Equipment
PQ	Performance Qualification
PPQ and S	Plant Protection Quarantine and Storage
QbD	Quality by Design
QCI	Quality Council of India
SDG	Sustainable Development Goal
TC	Technical Committee on GLP
TFs	Test Facilities

1 EXECUTIVE SUMMARY

1. The National Good Laboratory Practice (GLP) Compliance Monitoring Authority (NGCMA) was established under the administrative control of the Department of Science and Technology (DST), Government of India, with the approval of the Union Cabinet on April 24, 2002. India was granted full adherence to Mutual Acceptance of Data (MAD) status in the Organization for Economic Co-operation and Development (OECD) Working Group on GLP w.e.f. March 3, 2011. As a consequence, the data generated by Indian GLP test facilities (TFs) is acceptable in all the OECD member countries and non-member full adherent to MAD countries.
2. The introduction of NGCMA in the country transformed the culture of the generation of non - clinical data and enabled the Indian test facilities (TFs) to meet the requirements of global non-clinical data as per OECD principles of GLP.
3. Prior to 2004, India was largely dependent on foreign laboratories for generating the non-clinical data causing major foreign exchange burden. More importantly non-GLP data from Indian TFs was an important technical barrier for international acceptance.
4. The journey of Indian GLP certification started in 2004 with four GLP certified TFs. This boosted the credibility of non-clinical safety data from Indian TFs. The demand for GLP data increased resulting in more number of TFs applying for GLP certification.
5. Before India became a full adherent to MAD in the OECD, the Indian TFs had to approach GLP monitoring authorities of countries like The Netherlands, Switzerland, Germany and Belgium for GLP certification, which was cumbersome and expensive. Further, this had limitation of acceptability of data in respective countries and few other countries which recognize that particular country's authority. This limited the global acceptability of the Indian data.
6. A historical milestone was the full adherence of India to MAD in March 2011. This revolutionized the non-clinical testing ecosystem in India. As a result, GLP certified TFs steadily increased and over the years their number has reached 50 as of April, 2020 which are located in 15 states (Figure 1). These TFs are capable of conducting non-clinical studies on all major categories of test items - pharmaceuticals, pesticides, industrial chemicals, veterinary drugs, feed additives, food additives, cosmetics and medical devices.

7 This has been possible due to India becoming a full adherent to MAD in the OECD Working Group on GLP. The robustness of GLP monitoring compliance system in India through NGCMA, cost advantage, shorter turnaround time, and availability of competent inspectors and faster approval process of GLP certification are the factors to create a conducive environment to attract more international business. It is advisable that the potential of Indian TFs should be highlighted strategically in major international forums.

8 To remain contemporary to the needs of the country, NGCMA interacts continuously with Indian and international regulatory authorities. This has resulted in identification of new scopes such as testing of Medical Devices and conducting joint inspections/study audits at the request of the regulators of OECD member countries and MAD adherent countries.

9 In order to achieve the speed and scale to expand the National GLP Program, NGCMA entered into a MoU with Quality Council of India (QCI) on December 31, 2013. The principal objective of this MoU was to establish a mechanism wherein QCI shall support NGCMA for effective implementation of the GLP certification program through a structured approach by managing the operationalisation of the same.

10 For capacity building, NGCMA has regularly organized several residential intensive training programs for GLP inspectors (both basic as well as refresher trainings). Such training programs have been organized in Jaipur, NOIDA, Delhi, Hyderabad, Bengaluru, etc. Further, NGCMA has a mechanism of continuous feedback from TFs, members of technical committee on GLP and lead inspectors of NGCMA to update and harmonize inspectors' understanding on emerging issues.

11 NGCMA hosted the 12th OECD training course for GLP Inspectors in October, 2015 in Hyderabad. In this training course, faculty from OECD and national experts were resource persons. A total of 79 inspectors were trained.

12 Under the collaborative MoU with QCI, NGCMA has conducted more than 100 capacity building programs for academic institutions, national scientific laboratories and GLP TFs in the country. This has created a strong GLP ecosystem of credible data generation in India. The stakeholders strongly opined that a country of the size of India needs many such capacity building activities to be held in a continued manner.

13 QCI, in consultation with NGCMA, has led this 'Impact Analysis Study of National GLP Program'. QCI designed and developed the study in a manner to seek inputs from the important stakeholders namely, sponsors, regulators, GLP inspectors, and members of the NGCMA's Technical Committee on GLP. The responses were collected, collated, analysed and recommendations submitted as the way forward towards strengthening the program.

14 The primary objective of this impact analysis study is assessment of the current GLP TFs and their functioning to ascertain whether the TFs are meeting the expectations of the different stakeholders in terms of quality and scope of activities. In addition, the study would also suggest ways for further strengthening of the GLP ecosystem, so that India not only becomes self-reliant (atma-nirbhar) but also a global leader in GLP quality system.

15 As a part of the impact analysis study, multiple consultative meetings were conducted wherein interactions were held with test facility managements of GLP certified TFs across the country, to understand the impact of the GLP program. It was revealed that there was a fundamental shift in the approach towards the way TFs conducted GLP studies. Some of the process improvements were procurement of high purity chemicals, test animals and cell lines, high end equipment for accuracy and preference to sub-contract work only to GLP compliant facilities.

16 So far, Indian TFs have conducted more than 60,000 non-clinical safety studies. These are valued at INR 7,800 crores (USD 1.3 billion). This is a major step towards self-reliance in development of New Chemical Entities. This program has a significant economic impact, in absence of which the cumulative of these studies would have otherwise gone to GLP TFs outside India for safety assessment of molecules.

17 Among the total GLP studies, 40-50% of studies are undertaken for Indian sponsors.

In the financial year 2018-19, the Indian TFs conducted 12,808 GLP studies. The majority of the studies were conducted in the following two sectors - Pharmaceutical (~70%) and Pesticides (~15%) together contributing to 85%. The other sectors such as food, feed, cosmetics, and industrial chemicals collectively accounted for 15% of the GLP studies.

19 The market valuation of 12,808 GLP studies in financial year 2018-19 was INR 1,465 crores. Of this, the Contract Research Organisations (CROs) accounted for 92% while in-house TFs accounted for 8%. The test item wise analysis showed that pesticide testing in compliance with GLP accounted for a major part (66%) while pharmaceuticals accounted for 22%. All other test items contributed to less than 12%. It is evident that the other sectors of test items need to be encouraged to test their products in compliance with OECD principles of GLP, which will not only ensure human safety and boost consumer confidence but also optimize any idling GLP capacity in India.

20 Of the 50 GLP certified TFs (till April, 2020), 24 TFs (48%) are CROs, thus offering competition in time and cost of conducting GLP studies; 12 (24%) TFs perform only in-house non-clinical safety studies to support their parent manufacturing companies; 14 (28%) TFs perform both CRO and in-house services.

21 Today due to MAD status to NGCMA, Indian GLP TFs are attracting business from 48 countries as shown in the Annexure 6: List of Sponsor Countries.

More and more studies are now being conducted in compliance with GLP and lesser as non-GLP studies. The total number of GLP studies increased 3 times between 2011 and 2018 with a CAGR of 14.7% while the non GLP studies registered a negative CAGR of 4.1%.

23 Notably there are no GLP certified TFs in Madhya Pradesh, Bihar, Jharkhand, Jammu and Kashmir, Ladakh, Kerala, Uttrakhand, Orissa, Chhattisgarh, Sikkim, Daman & Diu, Lakshadweep, Andaman & Nicobar islands and North East states.

24 National Institute of Nutrition (NIN), Hyderabad, National Institute of Pharmaceutical Education and Research (NIPER), Guwahati and Hyderabad are contemplating their animal house/toxicology facilities for GLP certification. For capacity building of scientists and researchers as well as for handholding of these Government institutes, NGCMA organized sensitization workshops in NIPERs - Hyderabad and Guwahati.

25 Within the GLP TFs, for training of new recruits and existing employees of the TFs, in-house training sessions are organized wherein interactive sessions are held with the experienced employees of the organization and external GLP consultants. In addition to the in-house training, continuous training sessions by NGCMA experts have a great impact in the capacity building of TFs. So far, NGCMA has trained 2,268 participants in 41 batches (since 2013).

26 In collaboration with Translational Health Science & Technology Institute (THSTI) and QCI, NGCMA has planned to organize a series of 9 national sensitization workshops "National Series of Sensitization Workshops on Good Laboratory Practice (GLP) for Faculty and Scientists of National Laboratories and Public Funded Institutions". Four workshops in different places have already been conducted and the rest of the workshops have been planned in 2020-21.

27 The feedback on training courses for TFs and the aforesaid national sensitization workshops was exceptionally encouraging. Because of logistical constraints the number of participants had to be restricted. All stakeholders unanimously opined that there should be online training sessions on OECD Principles of GLP.

It is encouraging to note that as on March 31, 2020, about 10 applications for GLP certification have been received of which 7 are from the private sector and 3 are from the Government sector (Institute of Pesticides Formulation Technology (IPFT), Gurugram; National Institute of Malaria Research (NIMR), New Delhi; and Vector Control Research Centre (VCRC), Puducherry).

29 As on March 31, 2020, NGCMA has 28 GLP inspectors (07 Lead, 09 Fellow, 10 Observers and 02 Technical Experts). On an average each inspector conducts around 6-7 inspections annually.

30 Currently, GLP certified TFs in India collectively have the competence to conduct non-clinical health and environmental safety studies on eight types of test items and nine areas of expertise in 28 test systems, including both *in vitro* and *in vivo* studies.

31 Enhanced capacity of Indian GLP certified TFs for conduct of non-clinical studies resulted in an excellent CAGR of 25.5% in the last decade. This was significantly higher than the comparative CAGR of non-GLP studies (1.5%) during the same period.

32 According to GLP certified TFs, substantial investments were made for upgrading their facilities to the level of GLP certification and maintaining them. The pooled investment data of 36 respondent TFs was INR 1144 crore post implementation of GLP standards, as compared to the initial investment of INR 450 crore (details in Annexure 7).

33 The GLP certified TFs have created job opportunities for various profiles such as scientists, managers and technical staff. The 50 GLP TFs have employed about 3,000 people in these key roles. This has also given opportunity to technical and multi-task workers to take care of animal houses and testing facilities. These TFs have also provided practical onsite training opportunities for researchers, students and professionals.

34 As per an estimate, the global GLP service size for pharma, bio-medical and biotech chemicals is 2.5 Bn USD (INR ~19,104 Crores). The GLP service size for Indian Pharma market is estimated to be INR 325 crore in 2019, which is just over 1.7% of the global estimate. This indicates that there is much scope for increasing the capacity of Indian GLP certified TFs in pharmaceutical and all possible areas. It is estimated that approximately 100 such TFs should be created or upgraded to GLP status to meet the increasing demand of Indian stakeholders and also remain viable and competitive in the global scenario.

35 According to the Indian regulators - The Drugs Controller General of India and Secretary, Registration Committee, Central Insecticide Board, the National GLP program has helped in establishing the credibility of Indian TFs by making the data internationally acceptable. They also highlighted that new regulatory norms in the country require GLP certification to be mandatory for submission of data for market approval, which would further require more studies to be done under the ambit of GLP.

36 To sum up, Indian GLP services offer competitive economical advantage. India has been designated the 'Vice-Chair' of OECD's Working Group on GLP, recognising the contribution of the Indian GLP programme. India's leadership in GLP brings a greater recognition of the country's certification of quality for global businesses. This is also a link in the chain to Atma-nirbharta, which is to have structures and processes that are adhered to global standards.

2 HISTORY OF GOOD LABORATORY PRACTICE (GLP)

History is replete with instances where tragedies have occurred due to launch of drugs without adequate quality checks and validation of safety aspects of the drug. Tragedies such as the ill-effect of Thalidomide (drug) consumed by unsuspecting pregnant women and inaccurate data generated by Industrial BioTest Laboratory for the safety of new drugs and cosmetics shocked the consciousness of the medical fraternity.

The subsequent inspection of studies and TFs revealed instances of inadequate planning and incompetent execution of studies, insufficient documentation of methods and results, and even cases of fraud.

These issues were made public in the hearings at the US Congress, and also similar discussions happened in other countries. The world became wary of these issues and prompted countries to introduce tough regulatory measures and came together to put in a robust drug approval process in place.

GLP was first introduced in New Zealand and Denmark in 1972, and later in the US in 1978. A few years later the Organization for Economic Co-Operation and Development (OECD) helped promulgate GLP to many countries.

The OECD put together an expert group to come out with the first set of OECD Principles of GLP. This was an attempt to avoid non-tariff barriers to trade in chemicals, to promote mutual acceptance of non-clinical safety data, and to eliminate unnecessary duplication of experiments.

The expert group's proposals were subsequently adopted by the OECD Council in 1981 through its “Decision Concerning the Mutual Acceptance of Data in the Assessment of Chemicals”. (www.oecd.org).

These interventions are now popularly known as the Good Laboratory Practice (GLP) Principles comprising a set of requirements pertaining to organizational processes and for the studies taken up by the TFs. More emphasis was given on planning, undertaking, monitoring, recording, archiving and reporting of non-clinical health and environmental safety studies.

This new regime focussed on the manufacturer to submit scientific proof to prove efficacy and safety of the drug. It also included full disclosure of all side effects by employing suitable design and test items. This was made a prerequisite for sectors such as pharmaceuticals, agrochemicals, industrial chemicals, cosmetics, food and feed additives.

GLP, a data quality system, should not be confused with standards of laboratory safety - use of appropriate PPEs - gloves, glasses and clothing to handle lab material safely. GLP applies to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs, as well as food additives, feed additives, industrial chemicals and medical devices.

Evolution of National GLP Program, India

Organization for Economic Cooperation and Development (OECD)

The OECD is an intergovernmental organization with 37 member countries, founded in 1961 to stimulate economic progress and world trade. It provides a platform to compare policy experiences, seek answers to common problems, identify good practices, and coordinate the domestic and international policies of its members.

OECD, through its Environment Health and Safety Program, supports the 37 member countries, many partner countries, and other stakeholders to develop and coordinate activities on chemical safety and biosafety on an international basis. Mutual Acceptance of Data (MAD) agreement is one of the most significant developments to meet this objective. MAD is a multilateral agreement which allows participating countries to share the results of various non-clinical tests/ studies done on chemicals. It is based on the concept of "Tested once, accepted for assessment everywhere." The OECD Principles of GLP are published to accomplish this task.

National GLP Program, India

The Department of Science and Technology (DST), Government of India, established the National GLP Compliance Monitoring Authority (NGCMA) with the approval of the Union Cabinet on April 24, 2002. On March 3, 2011, India became full adherent to the MAD in the OECD. The MAD status has given global recognition to India's non-clinical safety data. It is a matter of honour and pride that Indian GLP TFs provide the non-clinical data to over 50 countries.

As a consequence, the non-clinical health and safety studies/ data of such studies generated by Indian GLP test facilities (TFs) is acceptable in 37 OECD member countries and 7 non-member MAD adherent countries. This facilitates the export of chemicals, drugs, pesticides etc. to these countries including developed markets of USA, UK, Australia, Japan, European Union, etc.

The National GLP Program functions through an Apex Body, represented by Secretaries of concerned Ministries/ Departments with the Secretary, DST being its Chairman. This Apex Body oversees that the National GLP Program functions as per OECD Principles of GLP and OECD Council norms. The Apex Body is supported by the Technical Committee on GLP, which is a recommending body of NGCMA on cases of GLP certification and various technical matters concerning GLP.

To meet the increasing demand of GLP compliance monitoring in the country, NGCMA has 28 trained GLP Inspectors (07 Lead, 09 Fellow inspectors, 10 Observers and 02 Technical Experts) from various Government laboratories, Universities and public-funded institutions to evaluate the technical competence of the applicant TF for its compliance to OECD Principles of GLP and OECD Test Guidelines. On an average, the number of inspections carried out annually per inspector is 6-7.

The growth of GLP certified TFs in India has been phenomenal since the inception of NGCMA. NGCMA awarded first GLP certification in the year 2004 to the International Institute of Biotechnology and Toxicology (IIBAT), Padappai, Tamil Nadu.

In the year 2010, before India received MAD status there were only 15 GLP certified TFs. Post MAD (2011-19), this number has grown to 50 TFs registering a 3 fold increase in the number of GLP certified TFs.

MoU: NGCMA and Quality Council of India (QCI)

On December 31, 2013, NGCMA entered into an MoU with QCI. The principal objective of this MoU was to establish a mechanism wherein QCI shall support NGCMA for effective implementation of the GLP certification program. The MoU was continued on February 1, 2019, for another 5 years. The focus of this partnership is:

- To manage the GLP inspections through inspectors approved by NGCMA
- To provide support for organizing relevant and technical meetings to ensure the continued competence of the NGCMA inspectors
- To provide necessary support in organizing various training courses and capacity building programs
- To digitalize the National GLP Program
- To conduct an independent impact analysis of National GLP Program

3 NEED FOR IMPACT ANALYSIS OF NATIONAL GLP PROGRAM

More than 18 years have elapsed since the inception of the GLP Program in India by the Government of India. From a modest start of granting certification to 4 labs in 2004, now the country has 50 GLP certified labs as of April 2020, located in 15 states (Figure 1). These labs are capable of conducting non-clinical health and environmental safety studies in all major categories of test items - pharmaceuticals, pesticides, industrial chemicals, veterinary drugs, feed additives, food additives, cosmetics and medical devices.

Though no systematic study has been conducted in India so far, to objectively assess the impact of the GLP Certification in the pharmaceutical, agriculture and the chemical sector, there is a general perception about it making a positive impact. In order to confirm the impact, it was felt necessary to conduct an objective and detailed study to evaluate the impact of the National GLP program in India after India received MAD status from OECD. The NGCMA and its technical committee deliberated on this and recommended that an impact analysis be conducted by QCI.

The primary objective of this study is to assess the level of impact made by the GLP program on the different stakeholders and sectors. The other important purpose was to understand the scope for improvement and identify capacity building needs so that India establishes its self-reliance and emerges as a global leader in GLP Studies.

The study also aims to come out with data so as to equip the policymakers and planners with details of the impact of the National GLP Program in India and to drive appropriate intervention for enhancing the Program's contribution to the Make in India initiative.

It was recommended that the impact analysis should cover (but not restricted to) the following broad areas:

1. Assessing the reasons of growth of GLP TFs in India
2. Mapping the competitive advantage after India attained full adherent to MAD status
3. Contribution towards the skill development and job creation in various sectors
4. Understanding distribution of CROs vs in-house facilities amongst the TFs
5. Market valuation of GLP studies across sectors and across sponsors
6. Identifying areas of mutual cooperation with the regulators
7. Suggesting the way forward for expansion of National GLP Program

4 METHODOLOGY

The Impact Study report aims to capture the nature and extent of impact of the National GLP program. A questionnaire was prepared to gather the data and responses were collated through a web-based survey tool. The questionnaire was sent to a total of 50 GLP Certified TFs that exist today and 100% of them responded. The entire study was carried out through ten stages using appropriate techniques to capture outcomes of interest.

The methodology adopted for the analysis is summarised below:

Stage 1: Use of Theory of Change

Theory of Change describes how a particular intervention will bring about results. It outlines the causal linkages in an intervention between the shorter-term, intermediate, and longer-term outcomes. Theory of Change is useful for understanding and assessing the impact in complex programs by helping to prioritize outcomes and indicators. It is a comprehensive description and illustration of how and why a desired change is expected to happen in a particular context.

Methodology was developed following a review of theory of change. Impact pathway was considered to develop a conceptual theory of change that formed the basis of the research methods and to capture the likelihood that impacts are occurring through the identified pathways.

Stage 2: Setting objectives of the study

Objectives of the study were set after understanding the plan and undertaking due consultation with the stakeholders. The important stakeholders consisted of NGCMA personnel, senior GLP Inspectors, personnel from Indian Regulatory bodies, key management personnel of QCI, the TC and TF management. Structured interviews of all major stakeholders were held as a part of the study.

The overall objective of the study was to understand the experience of the GLP- certified TFs and to get an idea about the impact of the GLP Program. Specific objectives relate to the quantitative and qualitative analysis of the data obtained through questionnaire and through a detailed interview both individually and in focussed group discussion.

The details of the study design were discussed and finalised by a group of researchers at QCI and a protocol was finalised after a set of interactive meetings. The outline of the study included the mapping of the stakeholders, designing of the questionnaire for each of the mapped stakeholders and developing a structured questionnaire. The prepared draft study design was approved by TC.

Stage 3: Designing the conceptual framework

Keeping in mind the objectives, impact dimensions and indicators, structured feedback was sought on the GLP program with a view to provide areas of opportunity for the program. The research involved administering a structured questionnaire to systematically selected respondents and at times, focused group discussions to gain further insights into qualitative dimensions of the project. The survey instrument was designed on the basis of a measurement framework on which results were reported.

The research team analysed the inputs received from different stakeholders during initial consultation meetings. The questionnaire was further modified to retain the important aspects and a few additional points were added which came up during the stakeholder review in order to align with the objectives of the study. The team then carried out detailed desktop research to co-relate the inputs received in the questionnaire and to integrate the national and global perspective to the study framework.

Stage 4: Evaluation Plan

An impact evaluation plan was prepared in coordination with the team. Evaluation plan was meant to describe the objectives, design, sampling and data collection strategies for the evaluation. It was prepared to define the basis for choosing the impact evaluation methodology and to guide all subsequent steps in the process of implementing the evaluation. It was useful to have a basic understanding of how these aspects are relevant to the overall evaluation and the program itself.

The study was meant to measure results, and so deciding research design was very crucial. The decision generally depends on the available resources, implementation stage of the study, considering baseline evaluation, or endline evaluation. This required a robust research design. Non-experimental design was considered for the study.

4.1. SAMPLING

It was noted that there is high variability in the different TFs in terms of their experience, scope of testing, type of business carried out (national or international, or domestic only, contract research, government and private etc.). It was therefore decided not to conduct the study based on the sample methodology, rather all the 50 TFs were included in the study. The list of respondent TFs is attached in Annexure 1.

In consultation with NGCMA, the research team finalised the data collection plan. It was decided to capture the responses of all the TFs, their sponsors, Indian Regulators, GLP Inspectors, NGCMA officials, members of the Technical committee (TC) etc. For sponsors, the business confidentiality issues were considered and it was decided that only the responses that came voluntarily were to be included in the analysis. In addition to online data collection, it was also decided to meet the TFs in groups for FGD and then individually for specific items. This was done to capture larger issues pertaining to the GLP TF ecosystems such as import facilitation of test systems, clearance for use of large animals etc.

Category 1	No. of TF's interacted
GLP certified TFs	50 (100%)
Sponsors	14 (4 Global + 10 Indian)

Table 1: Interactions with TFs & Sponsors for impact analysis study of National GLP Program

4.2. DATA COLLECTION METHODS

4.2.1 Quantitative

The web-based questionnaires which were designed were submitted to all the TF Managements (TFMs) via their official registered email IDs. For TFs, the questionnaires were primarily directed to the TF Management who in turn forwarded respective parts of the questionnaires to various personnel depending upon whether the query pertained to finance, research, marketing, HR etc. The TFMs responded to the questionnaires after due consultations with their teams. TFMs also shared the contact details of their sponsors. All such sponsors' questionnaires were directly sent from the study team to their official emails and response recorded as per their feedback.

4.2.2. Qualitative

Qualitative methods are effective to understand the process leading to the change. Information about behaviours, values, opinions and relevant unsaid context of a particular

population, from their own perspective, is gathered. It was considered to provide a stronger context so that the results can be easily communicated.

I. **Sampling:** Purposive sampling was used to focus the study on respondents and issues of interest.

ii. **Structuring the study:** Decision was taken with respect to;
   - Techniques relevant for answering the question
   - How to sequence the techniques
   - Level of participation required
   - Preparation of notes based on the technique adopted

iii. **Planning the quality:** Quality control principles had to be considered for the study and hence, time, skills and resources require high level participation. Sufficient checks and balances were put in place so that no alterations of the collected facts at any stage was possible.

Stage 5: Developing and piloting a survey instrument

5.1 DESIGNING THE QUESTIONNAIRE

The questionnaire was tailored to capture various outcomes with an aim to highlight the impact of the National GLP program. Individual meetings were held with each of the stakeholders to explain the content of the questionnaires and to then validate the design of the study.

The respondents of each of the TFs were categorised based on the services that they deliver. For instance, the TFs that only provide CRO services, TFs that only conduct in-house testing, TFs that render services both as CROs and in-house. In addition, other stakeholders such as the NGCMA personnel, senior GLP Inspectors, personnel from Indian Regulatory bodies, key management personnel of QCI, and the TC were also identified as subjects for the interviews.

5.2 TESTING & REFINING THE QUESTIONNAIRE

The survey links were field-tested by engaging various stakeholder categories. The process of disseminating the questionnaire and collecting data was undertaken by ensuring data protection and integrity of the process. The research team pilot tested the questionnaire and reframed certain queries in order to convey the accurate meaning and to produce quality evaluation to gain corresponding information for collation and analysis. It was crucial to confirm the length of the questionnaire and its format so that the survey can yield reliable and consistent results. In certain cases, the team visited the offices of the stakeholders. The final questionnaire was again discussed with NGCMA and TC before putting a wide circulation for soliciting responses.

Stage 6: Field Work and Data Quality

The research team performed a detailed data quality check. All the inputs from the respondents (either verbal, written via email or shared during FGD) were captured and retained as raw data.

Inputs which were ambiguous, were clarified from the respondents either verbally or through email and recorded accordingly. In some instances, the respondents couldn't share some data points because of confidentiality or lack of access.

6.1. FOLLOW-UP SURVEY

In addition to online surveys, six regional consultations were organized to collect additional qualitative inputs and suggestions from participating TFs. The details of these are given in Table 2.

6.2. FOCUS GROUP DISCUSSION

Focus Group Discussions were meant to gain further insights into qualitative dimensions of the project. The FGD aimed to have various stakeholders within the TFs to share additional information in case they had to supplement their submissions that were received through emails. The set up also validated some of the inputs that either had wide variations or were uncannily similar amongst the various TFs to eliminate any bias in the study. The focus group discussions at times gave altogether different perspectives to certain issues when dwelled in detail by addressing key psychological biases.

Stage 7: Data Analysis

Data collected through the online survey and regional consultations was analyzed to quantify the impact of the National GLP Program, India. The data was further used to draw inferences in the form of statistical representation consisting of bar graphs and other time series analysis which is presented in the later part of the report.

Stage 8: Report Writing

The research team took all precautions in collecting and collating the findings. Many of these findings were validated by the TFs and industry experts. The final report in the form of a document consisting of the narrative along with pictorial representation in the form of graph, tables and charts was presented to the TC in one of the specially convened committee meetings. Several suggestions from the TC members were received and all were addressed in the revised draft report. The report has been deliberated by the NGCMA and TC before it got the approval.

Stage 9: Submission to NGCMA

The final report in the hard copy and soft copy was presented to the Head, NGCMA in a specially convened TC meeting in the presence of Dr. Y.K. Gupta, Chairman, TC and other members of the TC.

Stage 10: Dissemination of findings

INTERNAL DISSEMINATION

It provides the basis for organizational learning and enhanced project management. The review provided by the internal team provides a strong background to the study by giving a comprehensive viewpoint about the intricacies of the study.

The internal stakeholders principally comprise of members of the TC comprising senior officials from the Central Insecticide Board, Export Inspection Council, Bureau of Indian Standards, Drugs Controller General of India, Indian Council of Medical Research, Department of Chemicals and Petrochemicals, Department of Pharmaceuticals, Ministry of Environment, Forest & Climate Change, Quality Council of India and NABL.

EXTERNAL DISSEMINATION

It targeted external stakeholders as the results highly depend on how an evaluation has been implemented and how it has been inferred. The final report was therefore focussed on disseminating information to key external stakeholders. The key stakeholders comprise the Department of Science and Technology, Government of India, the OECD Secretariat and most importantly the national and global sponsors.

S. No.	Locations	States covered	Date	No. of Respondents	Stakeholder
1	Delhi	Delhi/ NCR	July 23-24, 2019	→ 21 Respondents from 03 TFs → 03 GLP Inspectors → Regulators → NGCMA	• Dabur Research Foundation • Sun Pharmaceutical Industries Limited • Shriram Institute for Industrial Research • Drugs Controller General of India • NGCMA • GLP Inspectors

S. No.	Locations	States covered	Date	No. of Respondent (TFs)	Stakeholder
2	Lucknow	Uttar Pradesh	September 27-28, 2019	→ 08 Respondents from 02 Govt. TFs	• CSIR - Central Drug Research Institute • CSIR - Indian Institute of Toxicology Research
3	Delhi	Delhi NCR, Rajasthan, Himachal Pradesh, Punjab, West Bengal and Uttar Pradesh	October 21, 2019	→ 06 Respondents from 03 TFs	• Krish Biotech Research Private Limited • PI Industries • Shriram Institute for Industrial Research
4	Bangalore	Karnataka and Tamil Nadu	November 19, 2019	→ 16 Respondents from 10 TFs	• Eurofins Advinus Limited • The Himalaya Drug Company • Syngene International Limited • Bioneeds India Private Ltd. • International Institute of Biotechnology and Toxicology • Vanta Bioscience Limited • Centre for Toxicology and Developmental Research (CEFTE) • Bioscience Research Foundation • GLR Laboratories Pvt. Ltd. • Diligence Bio Private Limited
5	Mumbai	Maharashtra, Goa and Gujarat	6 Dec, 2019	→ 18 Respondents from 16 TFs	• Jai Research Foundation • Zydus Research Centre (Cadila Healthcare Limited) • Torrent Pharmaceuticals Limited: Torrent Research Centre • Sun Pharma Advanced Research Company Ltd. • Meghmani Organics Ltd. • JDM Scientific Research Organization Private Limited

S. No.	Locations	States covered	Date	No. of Respondent (TFs)	Stakeholder
					• GLP Laboratory, Gharda Chemicals Limited • Intox Private Limited • Laboratory Animal Research Services (LARS), Reliance Life Sciences Private Limited • Indian Institute of Toxicology • Sa-Ford • Drug Safety Assessment, Novel Drug Discovery and Development (NDDD), Lupin Limited(Research Park) • PRADO Preclinical Research and Development Organization Private Limited • Accutest Biologics Pvt. Ltd. • Pre-Clinical Department (CRO), Cadila Pharmaceuticals Limited • GLP Testing Facility, Syngenta Biosciences Pvt. Ltd.
6	Hyderabad	Telangana and Andhra Pradesh	27 Dec, 2019	→ 16 Respondents from 06 TFs	• Aurigene Pharmaceutical Services Limited • RCC Laboratories India Private Limited • Vimta Labs Limited • Vivo Bio Tech Ltd. • Edara Research Foundation • Palamur Biosciences Private Limited

Table 2: Consultations conducted for Impact Analysis Study of National GLP Program

5 ANALYSIS

1. KEY FINDINGS

1.1 Geographical distribution of GLP TFs

It is satisfying that NGCMA certified GLP TFs are now spread in almost all geographical locations in the country. This widespread presence is facilitatory in promoting quality science, meeting the requirements of academic institutions, government laboratories and industries for non-clinical testing. The representative map below showcases the GLP certified TFs spread across 15 states in India (Figure 1).

The following states have clusters of GLP TFs:

- Maharashtra (10)
- Gujarat (8)
- Karnataka (8)

The following states/ Union Territories have one TF each:

- Andhra Pradesh
- Delhi
- Goa
- Haryana
- Himachal Pradesh
- Puducherry
- Punjab
- Rajasthan
- West Bengal

However, the following states do not have any certified GLP facilities - Madhya Pradesh, Bihar, Jharkhand, Jammu and Kashmir, Ladakh, Kerala, Uttrakhand, Orissa, Chhattisgarh, Sikkim, Daman & Diu, Lakshadweep, Andaman & Nicobar islands and North East states.

The reason for the cluster of GLP TFs in Maharashtra, Gujarat and Karnataka commensurate with the high number of pharmaceutical industry and national laboratories. Incidentally in the government sector all the three GLP certified TFs are in northern states, two in Lucknow (CSIR-IITR & CSIR-CDRI) and one in Mohali (National Institutue of Pharmaceutical Education and Research).

A vast country like India with over 130 crore population, claiming to be the generic pharmaceutical hub, needs many more such GLP certified facilities both in the private and public sector. The NGCMA has been encouraging the National laboratories in the government sector viz. CSIR-Indian Institute of Chemical Technology (IICT) -

Hyderabad, National Institute of Pharmaceutical Education and Research (NIPER) - Hyderabad, National Institute of Nutrition (NIN) - Hyderabad, National Institute of Malaria Research (NIMR) - Delhi, Vector Control Research Centre (VCRC) - Puducherry, Institute of Pesticides Formulation Technology (IPFT) - Gurugram, to upgrade their facility and come up to the standards of GLP certification.

The report highlights skewing of GLP TFs in Maharashtra, Gujarat and Karnataka which accounts for 50% of the existing TFs. The awareness, hand holding, capacity building and incentives need to be strengthened in other parts of the country to create GLP certified TFs pan India.

Figure 1: *Distribution of GLP certified TFs pan India*

1.2 TYPES OF TFs

A. GLP Certified TFs conducting only in-house Studies

There are 12 GLP certified TFs (24% of total TFs) which are almost fully engaged in conducting studies of the products of their parent/associated companies. As the work load fully occupies their time, they are not able to take up studies from different entities. Some such facilities are Himalaya Drug company, Sun Pharma Advanced Research Centre, Torrent Pharmaceuticals, and others. This initiative provides better quality assurance, reduces the cost of research and development for the company, and increases the ease of monitoring.

B. GLP Certified TFs conducting both in-house and contractual studies

There are 14 TFs (28% of total TFs) that focus on both in-house and contractual studies. The percentage (%) share of the in-house studies performed by such testing TFs ranges from 2% to 95%. This helps the TFs to optimize their resource utilization.

C. GLP Certified TFs functioning as only CROs

There are 24 GLP Certified TFs (48%) which only do contract work. These contracted studies are secured either by competitive bidding or on the basis of their specific expertise. The CROs which differ in their profile in terms of the scope of testing and studies. In case, a sponsor does not get all required type of testing under one roof, the close network of these CROs help the comprehensive study to be undertake.

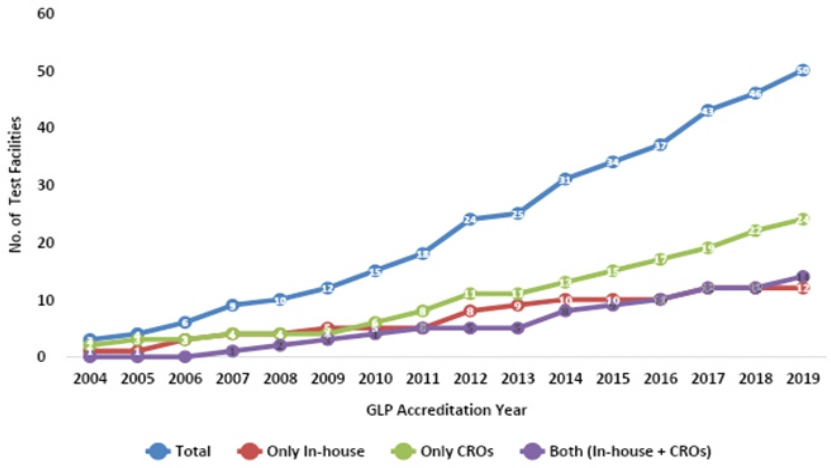

Figure 2: *Number of GLP certified TFs till date*

1.3 Scope Coverage (by types of test items, test systems and areas of expertise)

Indian TFs provide services to conduct specialized non-clinical health and environment safety studies for a range of types of test items, areas of expertise and test systems.

• TFs DISTRIBUTION BY TYPE OF TEST ITEMS

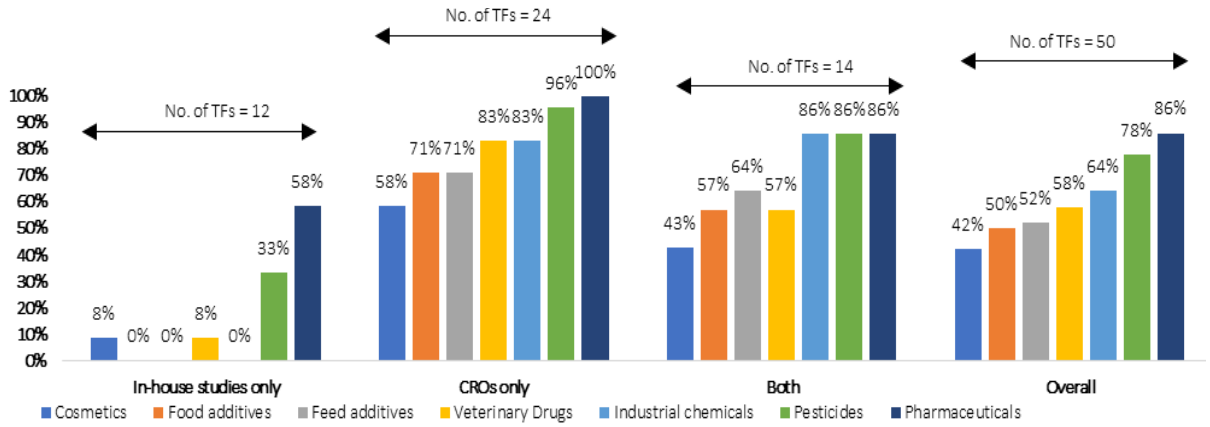

Figure 3: *GLP services offered by Indian TFs based on types of test items*

There are more than 8 types of test items for which Indian TFs are GLP certified. The list is attached in Annexure 2. The types of test items covered by Indian GLP TFs are shown in the graph above.

The top three GLP services offered by Indian TFs by test items are Pharmaceuticals (86%), Pesticides (78%) and Industrial chemicals (64%), where numbers are the percentage of TFs which are testing respective test items. It is noted that in-house TFs are mostly into pharmaceuticals and pesticides (agrochemical) testing. This shows that Indian manufacturers have invested good resources on establishing in-house GLP TFs, thus supporting India's 'Make in India' initiative and saving foreign currency reserves.

Pesticides and pharmaceuticals are the top two test items for which studies conducted by Indian TFs are highly preferred by sponsors. In 2018, pesticides and pharmaceuticals together accounted for 85% of total GLP studies conducted in India, with 70% and 15% respective market share. Industrial chemicals accounted 3.6% share, while feed additives, food additives, cosmetics and veterinary drugs together accounted for less than 3% share. The others, which include medical devices, contribute the remaining 8.4%. It is suggested that NGCMA may take up targeted market development initiatives to increase the number of GLP studies conducted on industrial chemicals, feed additives, food additives, cosmetics, veterinary drugs and other test items.

- **TFs DISTRIBUTION BY AREAS OF EXPERTISE OF GLP CERTIFICATION**

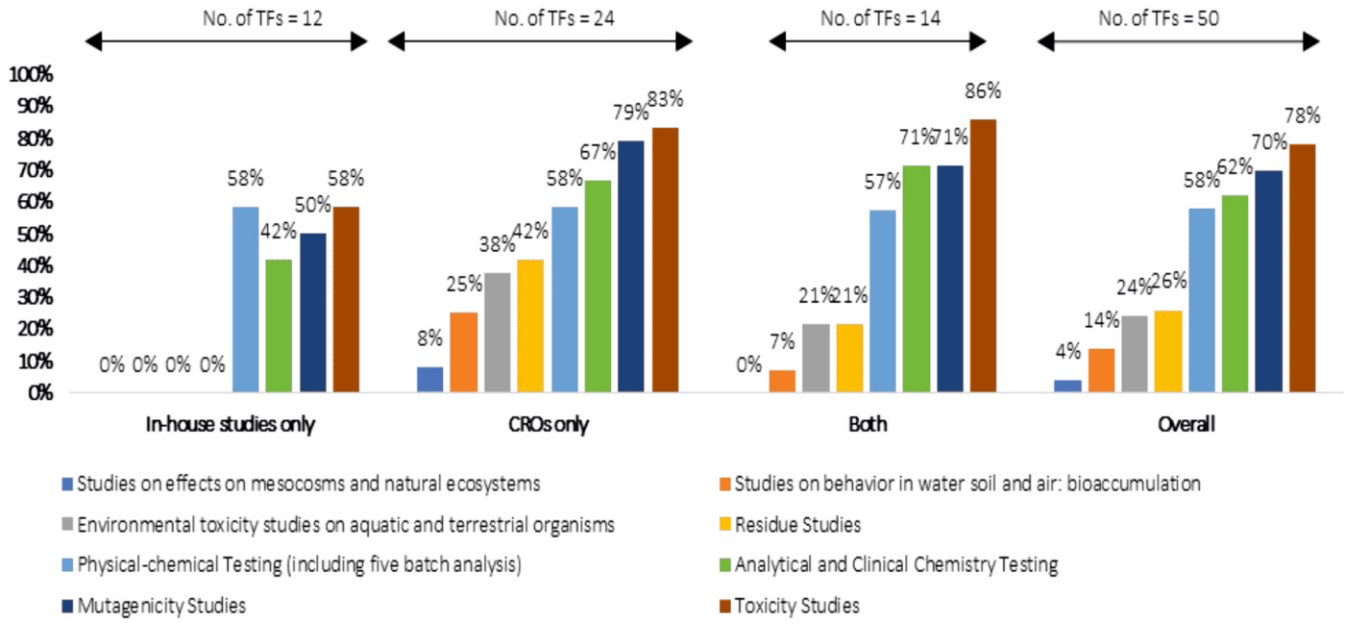

Figure 4: GLP services offered by Indian TFs based on areas of expertise of GLP Certification

The Indian TFs can conduct GLP studies for more than 9 areas of expertise. The list is attached at Annexure 3. Among them, the services under eight areas of expertise covered by Indian GLP certified TFs are shown in the graph above. Apart from this Indian TFs can also provide GLP services for other certification areas like toxicokinetic studies and bio-analysis.

The toxicity studies (78%) is the most preferred area of expertise among the TFs followed by mutagenicity studies (70%), with numbers indicating percentage of TFs that support respective studies. Analytical and chemistry testing is also a preferred area by 62% of the Indian GLP certified TFs.

- **TFs DISTRIBUTION BY TYPE OF TEST SYSTEMS**

Indian TFs are efficient in conducting GLP Studies on a large variety of test systems. Indian TFs are certified for conducting studies on 28 test systems. This list is attached at Annexure 4. The most commonly used test systems are Rat, Rabbit and Guinea pig.

Indian TFs are competent to use a variety of small test systems for GLP studies. TFs have reported some difficulties to conduct GLP studies in large animals due to the approvals from CPCSEA.

1.4 Growth of GLP certified TFs in India

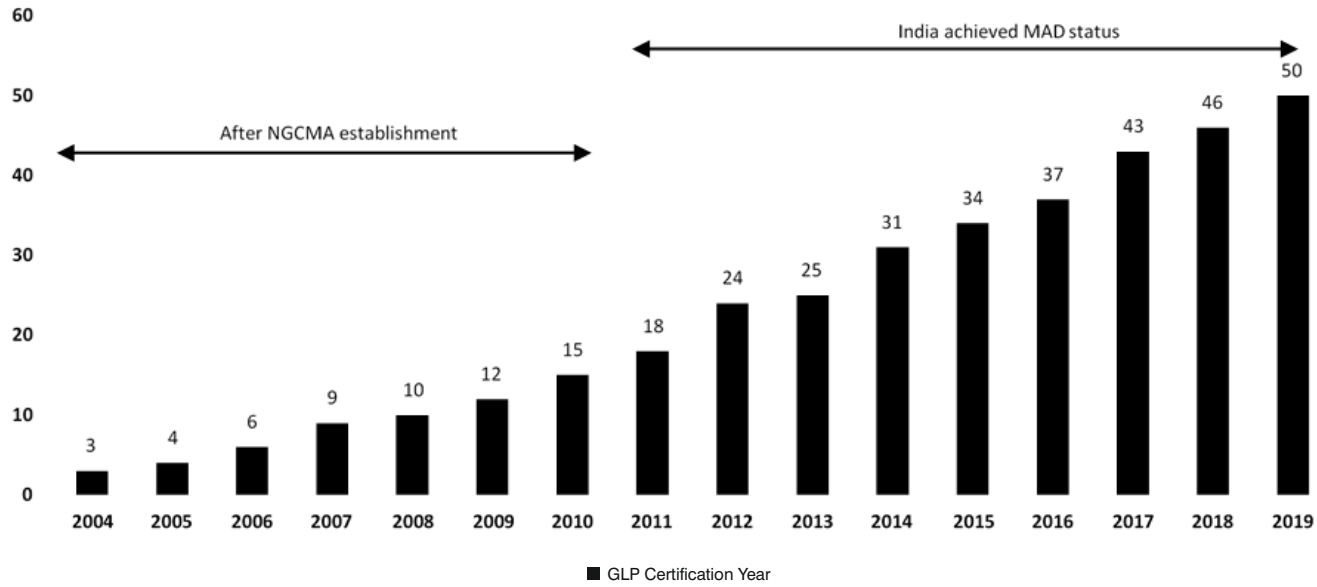

Figure 5: *Historical development of 50 GLP certified labs*

The growth of GLP certified TFs in India has been phenomenal since the inception of NGCMA. NGCMA granted the first GLP certification in the year 2004 to the TF - International Institute of Biotechnology and Toxicology (IIBAT) Padappai, Tamil Nadu.

In the year 2010, before India received the MAD status, there were only 15 GLP certified TFs. Post-MAD status (2011-19) this number has grown to 50 TFs. This is greater than 3 times the total number of GLP certified TFs in the year 2010.

Prior to MAD status some TFs were certified by both, NGCMA and a few OECD countries. The GLP Compliance Monitoring Authorities certifying Indian TFs were mainly from OECD countries: viz., The Netherlands, Switzerland, Germany, and Belgium. However, there was limited business opportunity for Indian TFs. This is because the GLP study(ies) undertaken by the Indian TFs could be submitted to regulators of the above-mentioned countries only.

GROWTH DRIVERS OF NATIONAL GLP PROGRAM

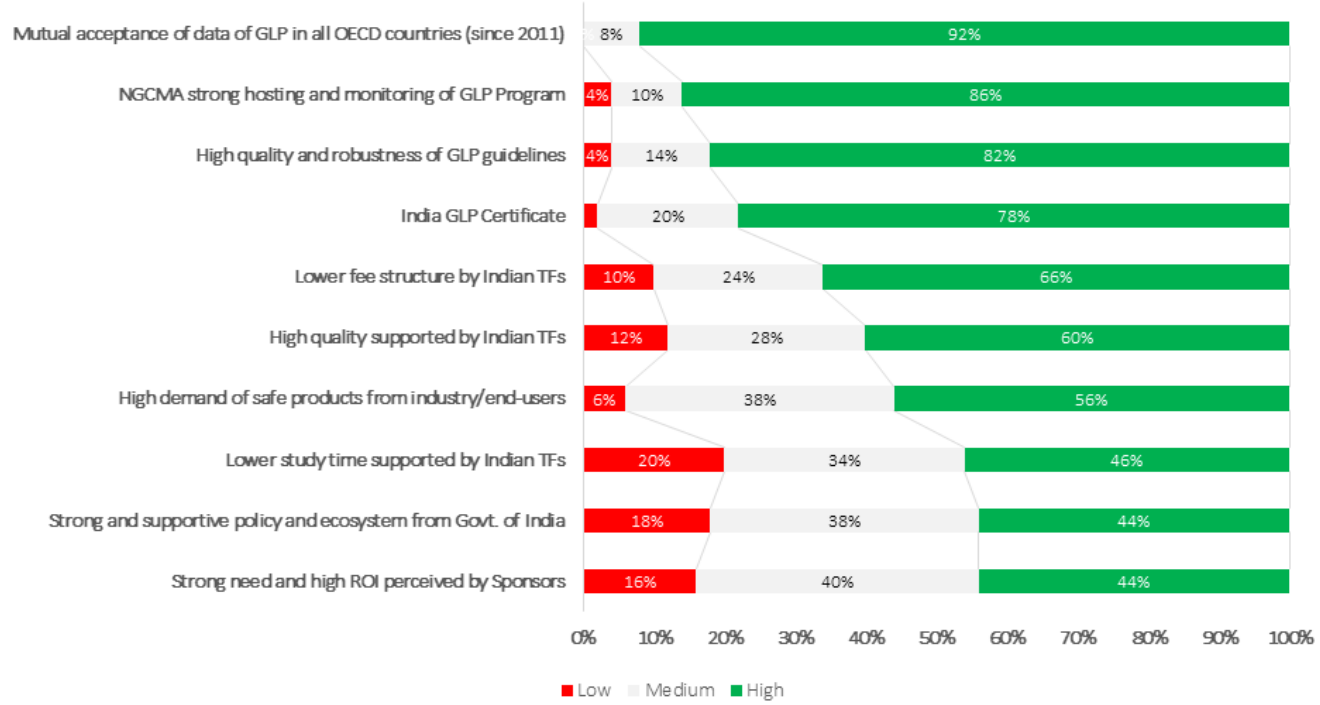

Figure 6: *Growth drivers of National GLP Program*

The Figure 6 shows the list of growth drivers of the National GLP Program. The top three growth drivers as per the TFs are:

1. Mutual acceptance of data in all OECD countries
2. NGCMA's strong hosting and monitoring of GLP program
3. High quality and robustness of OECD guidelines

India's full adherent status to MAD has been a significant milestone for Indian GLP TFs and the overall industry. The 'Tested once – accepted everywhere' objective of MAD plays an important factor for the Indian TFs to expand in the global market - a fact that was agreed by 98% of the respondents from the Indian TFs. The well-established guidelines from OECD together with capacity building and rigour imparted by the NGCMA resulted in the global recognition of the Indian GLP program. The resulting cost and time efficiency of GLP certified Indian TFs has built competitive advantage to attract higher business from both domestic and global sponsors. This growth is further leveraged by a supportive policy ecosystem from Government of India and different regulators, who have now mandated GLP studies for regulatory submission of safety data.

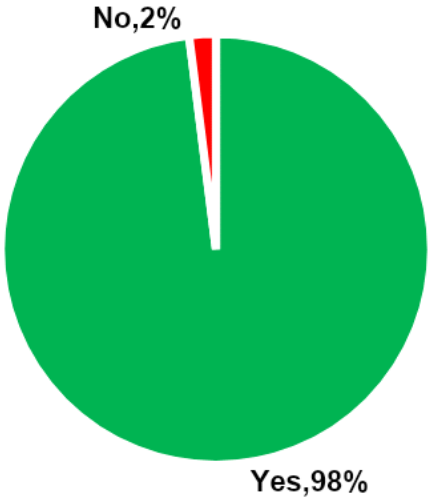

Figure 7: *Applicability of Indian GLP studies for 'Tested Once, Accepted for Assessment Everywhere'*

Some other advantages of the MAD status, as perceived by the Indian TFs are as follows:

- GLP studies from Indian TFs are well accepted by stringent regulators including USFDA, EU regulatory bodies, and others
- The reports that were prepared for submission to Indian regulators have been well accepted by regulators in other countries because of credible documentation, quality and compliance to OECD principles of GLP
- There is recurring business from the same sponsors, including global sponsors, testifying the high quality of data and acceptance by regulators

1.5 Capacity building activities of NGCMA

NGCMA organizes various training programs for the different personnel of TFs to upgrade their skills and knowledge. NGCMA engages its qualified inspectors and external consultants from the industry to deliver different trainings. The overall efforts and quality of NGCMA training programs are well appreciated by all TFs and other stakeholders.

In addition, NGCMA also organises training courses for its GLP inspectors. These include basic level training as well as refresher training, with an aim to have a qualified and experienced pool for GLP inspectors in the monitoring authority.

In the last six years since 2013, NGCMA has organized 41 trainings and have trained 2,268 participants. These participants act as trainers for the larger teams in their respective TFs to strengthen the capacity of the TF personnel.

Table 3: *List of NGCMA's Capacity Building programs*

TYPE OF TRAINING COURSE	TARGET PARTICIPANTS
Sensitization Workshop on GLP	Test Facility Personnel
Training Course for Study Directors	Study Directors
Consultative Meet on GLP	Test Facility Managements
Training Course for Quality Assurance Personnel	Quality Assurance Personnel
Refresher Training of GLP Inspectors	GLP Inspectors
Training Course for Archivists	Archivists
Training Course on Computerized Systems	Test Facility Personnel
Training Course for GLP Inspectors	GLP Inspectors
GLP Inspectors' Conclave	GLP Inspectors
Training Course for Test Item Control Officers	Test Item Control Officers
National workshop series on GLP for faculty and scientists	Faculty and Scientists
Train the Trainer Program on GLP	Faculty
Sensitization Seminar on GLP for Students	Students

2. IMPACT OF NATIONAL GLP PROGRAM

2.1 Employment Generation

The growth of the National GLP Program, India has created strong employment opportunities for various professionals such as scientists, doctors, and students in the field of GLP services. It is estimated that the GLP industry in India employs more than 3,000 workforce across different roles that include Study Directors, Quality Assurance Personnel, Study Personnel, TFM, Archivists, Test Item Control Officers, Faculty, Scientists, and others. This is more than double the workforce engaged beforeIndia received full adherent to MAD status in OECD.

The study directors and quality assurance personnel account for 24% and 8% of the total jobs respectively, showcasing emphasis on the quality management practices adopted by the Indian TFs to provide GLP services to both Indian and foreign sponsors. The workforce breakup of estimated 3,000 people across different types of TFs is shown in Figure 8. This estimate does not take into account the employment generated by the allied services and vendors supporting the TFs.

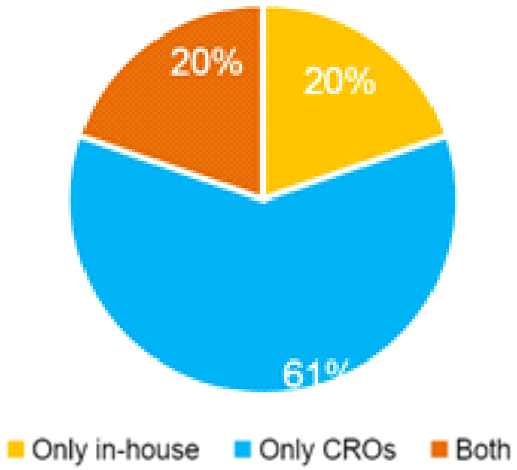

Figure 8: *Employment break-up by types of TFs*

The workload and allocation of duties of the employees in TFs are dependent on the size of the TF and is guided by OECD principles of GLP. Further the qualifications, skills, job roles, and number of study directors and study personnel are also guided by the OECD principles of GLP.

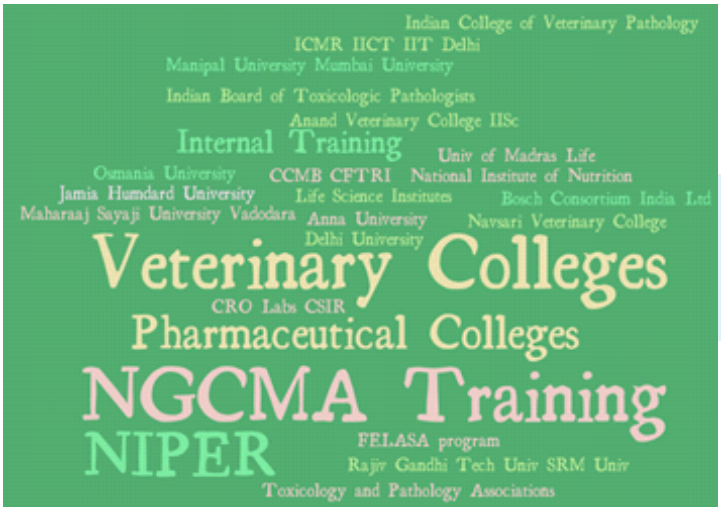

Figure 9:
Institutions identified by TFs for sourcing of skilled resources

The above is a list of some academic and training institutes that are preferred by TFs for recruitment and skill development/ training of the existing employees. In India, there are no specialized institutes to recruit employees for GLP services. The requirement for fresher or junior level resources is generally fulfilled by hiring local talent from colleges and universities, especially veterinary colleges, pharmaceutical colleges, etc. For the recruitment of experienced scientists, hiring is generally done from the industry talent pool with relevant qualification and work experience.

2.2 Capacity Building in GLP Certified TFs

All TFs support the need for continuous training and capacity building of existing workforce. This capacity-building need is currently met through different prevalent methods, namely:

- NGCMA organized trainings, workshops and conferences
- In-house trainings delivered by experienced employees
- Trainings delivered by inviting industry experts or external GLP consultants

In addition, the on-the-job training for conducting GLP studies for different global sponsors and different regulatory requirements has helped the workforce to develop global knowhow.

2.3. Size of GLP Service Industry

Post India becoming full adherent to MAD in OECD, more and more studies are now being conducted in GLP mode. The total number of GLP studies increased 3 times between 2011 and 2018 with CAGR of 14.7%, while non-GLP studies have reduced by CAGR of -4.1% during the same period.

In 2018, about 12,808 GLP studies were undertaken in India as compared to 2,961 in 2010 before India received MAD status, which is 3X growth. Overall, the number of GLP studies has grown 8X in the last one decade (2009-2018) with CAGR of 25.5%. In the same period, the number of non-GLP studies grew by CAGR of only 1.5%, and it has been continuously decreasing in the last few years. In 2018, GLP studies constituted 82% share of total non-clinical safety, health and environmental studies conducted by the Indian GLP certified TFs.

The impact on GLP services industry is studied in below two ways:

a. Number of GLP studies performed per year

b. Business value of studies performed

a. *Number of GLP studies performed per year*

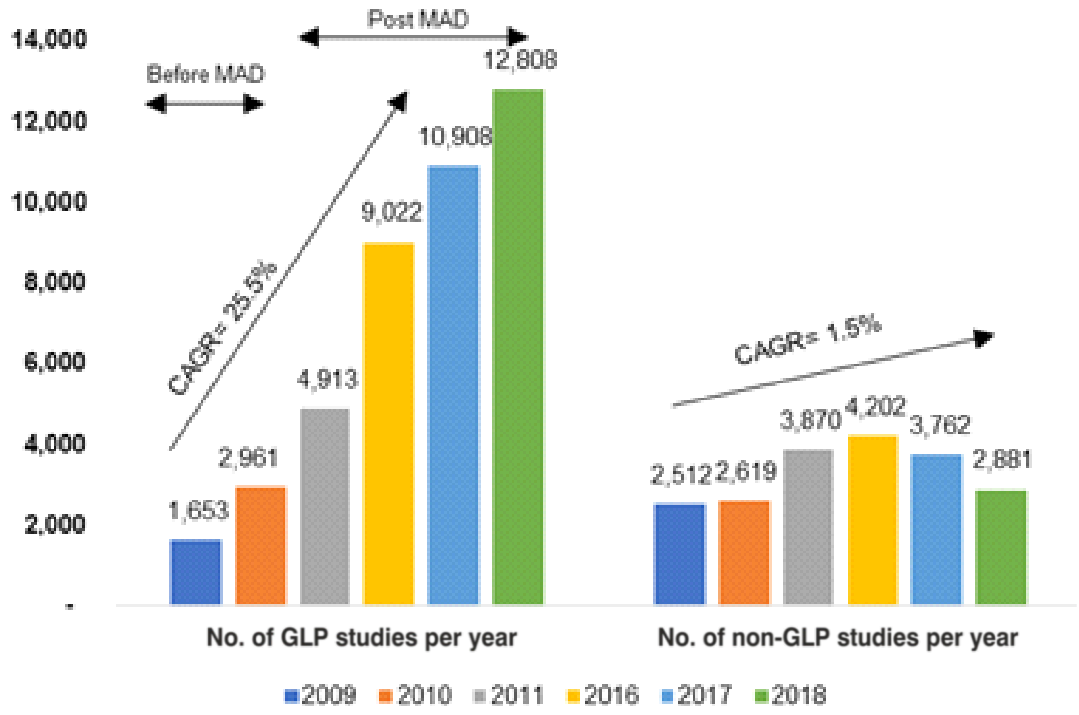

Figure 10: *Number of GLP and non-GLP studies performed per year) - Pre and Post MAD Status*

It is estimated that more than 60,000 GLP studies with INR 7,800 crores (USD 1.3 billion) business value are completed by the Indian GLP TFs. Out of these studies, 40-50% of studies are commissioned at the request of Indian sponsors while remaining are for the foreign sponsors from countries like China, USA, Thailand, Europe, and others.

The distribution of GLP studies by test items is shown below:

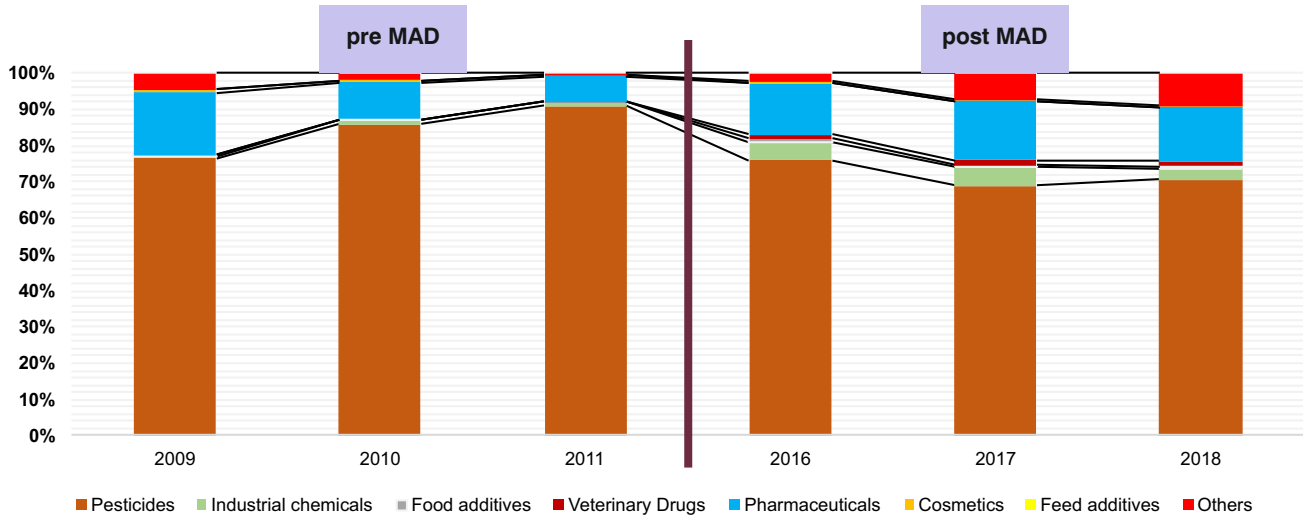

Figure 11: *Distribution (%) of GLP market size by type of Test Items- pre and post MAD status*

b. Business value of GLP studies

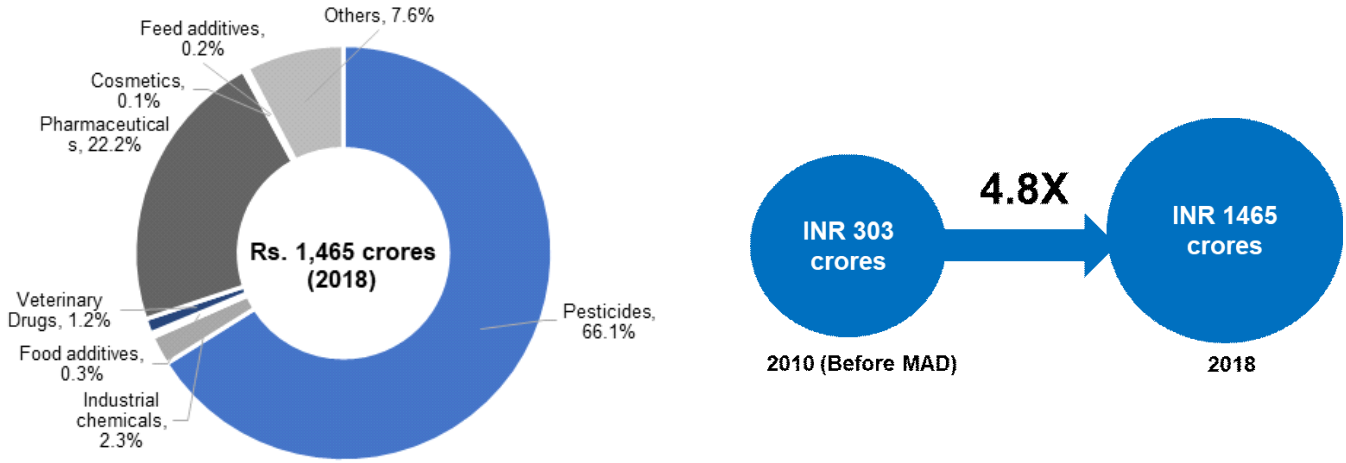

Figure 12: *Business value of GLP services by test items (2018)*

In 2018, the Indian GLP service industry made an estimated business of INR 1,465 crores. The pesticides testing in GLP mode accounted for 66% primary share, while pharmaceuticals accounted for 22%. All other test items contributed to less than 12%. It is evident that other sectors need to be encouraged to test their products in GLP mode which will ensure human safety, boost the consumer confidence and also optimize any idling GLP capacity in India.

It is estimated that CROs accounted for 92% (INR 1,344 crores) market share while in-house TFs accounted 8% (INR 121 crores). 40-50% of the total business is accounted to be coming from foreign sponsors, adding to India's foreign exchange reserves.

As per an estimate, the global market size for the biotech and pharmaceutical CRO service industry across the value chain was USD 38.4 billion in 2018[1]. Out of this, the non-clinical industry market share was only 13.2%. Assuming that GLP studies account 50% of this share, the global GLP service size for pharma, biomedical and biotech chemicals is USD 2.5 billion (INR ~19,104 Crores[1]). India with estimated business value of INR 325 crore from GLP testing services in pharmaceuticals forms lesser than 2% of the equivalent global market share. This indicates that there is much scope for increasing the capacity of Indian GLP TFs in pharmaceuticals and other allied areas.

2.4 Cumulative Capital Investments

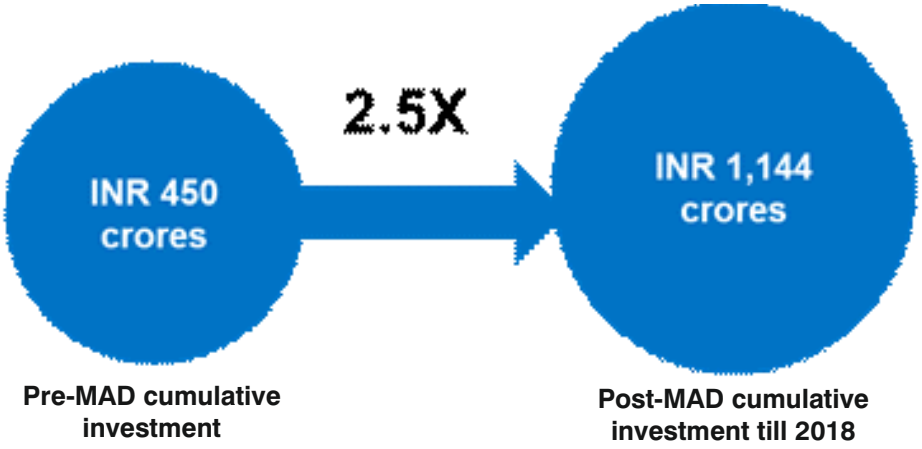

Figure 13: *Cumulative capital investments by TFs*

By 2019, estimated cumulative investment of INR 1,144 crores was made by 36 out of 50 TFs (Annexure 7). This is almost 2.5 times the total investment (INR 450 crores) made by TFs before India received MAD status in 2011. These investments were largely made towards the development of GLP infrastructure that includes setting up new and advanced equipment, animal facilities, software, etc. There are few TFs (like Syngenta Bio-Sciences India Pvt. Ltd., Vipragen Biosciences Pvt. Ltd.) who also received foreign investments through their group holdings however, the quantum of these investments is unknown.

Some TFs like Sun Pharmaceutical Industries Limited, Torrent Pharmaceuticals Private Limited, CSIR-Indian Institute of Toxicology Research and a few more could not provide the data because of difficulty in segregating the financial information related to the TF specifically. In total, 14 TFs could not respond to the investment related questions.

2.5 Development of Allied Services

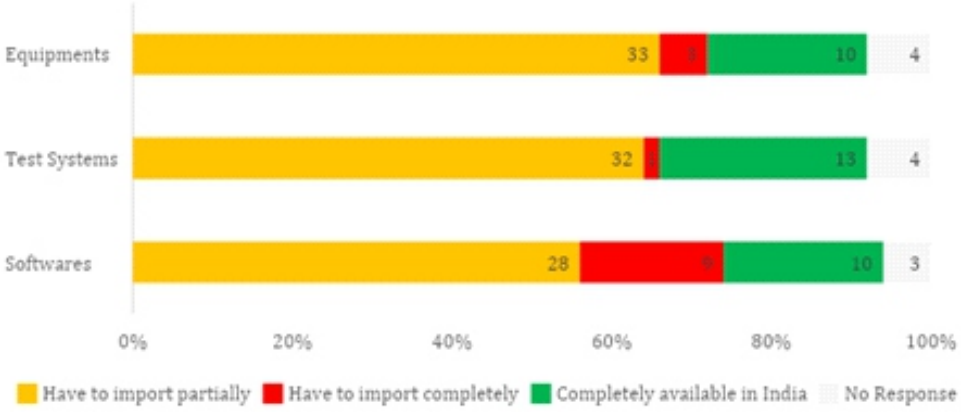

Figure 14: *Opinion on current sourcing of allied services for GLP facilities*

[1]Global Market Research Report CRO Services (Oct 19), Fortune Business Insights
[2] 1 USD = Rs. 70

The National GLP Program also compliments the 'Make in India' initiative by successfully supporting the development of allied services in India. This includes the supply of equipment, test systems, software and other services. About 20-25% of the TFs suggest that these services are completely available in India. For example, hematology analyser, clinical chemistry analyser etc. There are international companies that have established their sales office in India. As a result, there are 60-65% of TFs that are partially dependent on the imports. This is due to the lack of availability of FDA approved online data acquisition systems and sophisticated precision instruments. There are analytical instrument manufacturers in India, but they need product improvements to comply with GLP requirements and quality. India has self-reliance for equipment like housing systems for animals, but for advanced scientific equipment, there is still a dependency on imports. Also, there exists a need for standard software like Scientific Data Management System (SDMS) and Lab Information Management System (LIMS). The growing GLP program in India along with increasing number of TFs provides a good scope for further development of software, GLP equipment, and systems in the country.

2.6 Improvement in vendor quality, support and services

The National GLP Program impacts other industries that are supporting the TFs in conducting GLP studies through standardized supply of animals, equipment, services and materials. Most of the TFs believe that due to the GLP Program and the well stated guidelines, overall quality of supplies, services, and support received from different vendors has improved. The GLP program has led TFs to continuously improve the quality of vendors and support services through vendor assessments, audits and vendor awareness. Stringent vendor assessment/audits are conducted by the TFs to approve the vendors. This has resulted in improved accountability and traceability of the supplies and materials used in the GLP studies. There is an increase in the awareness of vendors on GLP quality system requirements and documentation.

Many vendors have obtained quality certifications for meeting GLP requirements. Few animal suppliers have obtained AAALAC accreditation besides CPCSEA registration.

TFs are increasingly using tools and techniques like Design of Experiment (DoE), Quality by Design (QbD), Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), and others for improving and driving standardization of their vendor supply and services. Further, the vendors are provided training and feedback by the TFs to meet GLP requirements (supply, service, documentation, etc.)

Impact on Quality of Products and Services provided by the Vendors

GLP recommends use of equipment that are compliant to international standards. This has led to increased competition for the supply of quality equipment/instruments. The increased demand for GLP studies has improved animal supply services significantly. The facilities for animal breeding and calibration has improved. There are TFs who have expanded their animal facilities to supply animals to other TFs as well. The use of validated softwares for data recording/capture has increased and there are more providers for the same.

Material availability and services

There is improved availability and more options for higher quality animals and feed. The traceability of calibration of equipment has improved. The local availability of preventive and breakdown services for equipments/ instruments/apparatus has increased

GLP Program has improved vendor quality in the supply of:

1. Test systems/ animals
2. Chemicals
3. Equipment/ instruments (devices, calibrations, machineries, etc.)
4. Software support (computerized systems, automated electronic systems, etc.)
5. Other materials.

The overall quantum and providers have increased post MAD status of India because of the growing GLP industry in India.

2.7 Value addition by GLP quality system

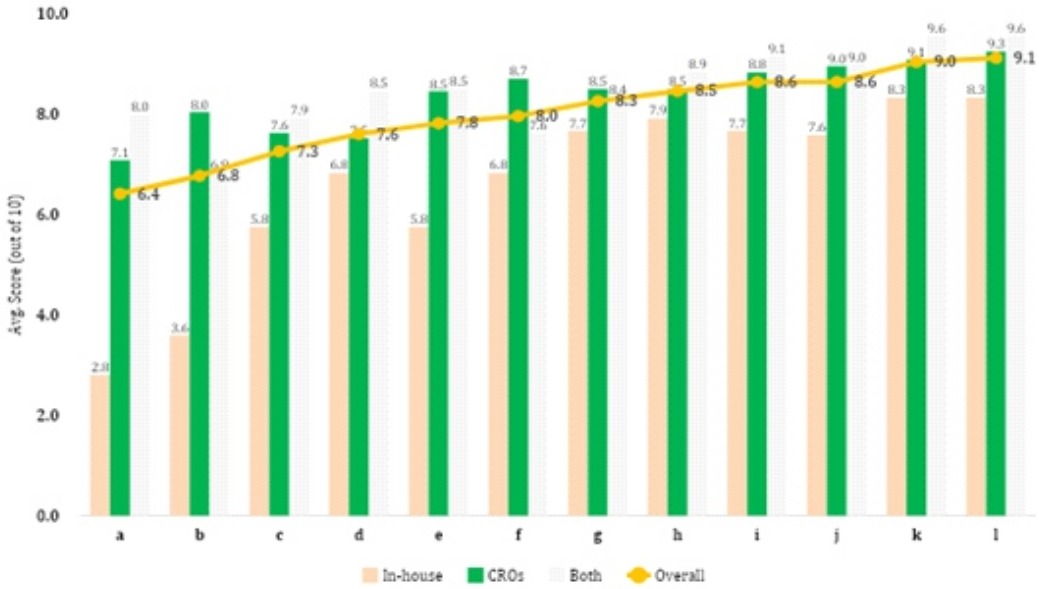

Figure 15: *Value addition by GLP quality system*

DATA LABEL	DESCRIPTION
a	Decrease in number of animals for non-clinical safety studies
b	Increase in business from foreign sponsors
c	Improvement in cost structure for conducting non-clinical safety studies
d	Decrease in time taken for non-clinical safety studies and getting regulatory approvals
e	Increase in types of test items tested and areas of certification
f	Increase in overall revenue from increased number of GLP studies
g	Increase in productivity of overall facility operations and processes
h	Increase in overall infrastructure
i	Increase in skills standardization, human resource, and capacity
j	Improvement in quality of non-GLP studies
k	Increase in overall quality, accuracy of test results and reproducibility of data
l	Brand recognition of TF

The National GLP Program has created a positive impact on following aspects of the Indian GLP certified TFs:

A. Brand Recognition

- The Indian GLP Certified TFs acknowledge that the National GLP program has added more value and recognition to their services. It has helped the organizations to build their brand and trust among both Indian and global sponsors and regulators. It has also created opportunities to provide services in multiple countries.
- GLP certification has become a strong credential in vetting the TFs' quality claims. It is helping TFs to project India as a destination to perform quality research and generate creditable safety data.
- To further enhance quality and meet regulatory requirements, most of the GLP certified TFs are taking additional certification/ accreditation from organizations like AAALAC, NABL, and others.

B. Increase in overall quality, accuracy of test results and reproducibility of data

- The SOPs defined in the GLP Principles have helped to improve the overall quality, test results accuracy, and reproducibility of the data. Other initiatives like NGCMA training/workshops, regular inspection of facilities and systems by NGCMA inspectors and sponsors have also helped to improve and maintain the overall service quality of the TFs. This has resulted in better confidence among the regulators and sponsors for data submitted by the TFs.
- The use of softwares like the Scientific Data Management System (SDMS) and Lab Information Management System (LIMS) has helped to improve the internal processes by automated data archival through these systems.
- The use of calibrated and standardized equipment and machinery has also helped in increasing accuracy and reproducibility of the data.
- GLP also acts as a tool to solve legislative disputes as the evidence/data archived appropriately can be easily retrieved for several years.

C. Improvement in quality of non-GLP studies

The GLP program has strengthened the internal processes of TFs by:

- Writing & Implementing SOPs for different processes
- Improvement in quality of documentation through uniform, prompt, accurate, traceable recording
- Data integrity and data archiving

This has resulted in high-quality research work, data reproducibility, and ease of operations. Further, this has got established as a culture within the TFs for all types of non-clinical studies undertaken by it. As a result, the quality of non-GLP studies has also improved significantly and is almost at par with GLP studies.

> We cannot maintain two different standards to work in the same organization. Therefore, our non-GLP services are almost the same as our GLP services
>
> **- Dabur Research Foundation**

The other important areas which have benefited the TFs are skill standardization, improved infrastructure and equipment, and increased workplace productivity from enhanced planning and utilization.

The global brand recognition of the National GLP program has resulted in an increase in the number of GLP studies being sought by domestic and foreign sponsors across more test items and areas of expertise, and this has led to increased revenue for the TFs.

The OECD guidelines for GLP studies, improved quality eco-system of suppliers and strong coordination as well as monitoring support from NGCMA have allowed Indian TFs to become competitive in cost, also study completion time and uphold strong quality.

More and more foreign sponsors are drawn towards India for GLP studies. This trend is owed to

- Harmonised OECD principles and test guidelines for GLP studies,
- Improved quality eco-system of suppliers
- Strong coordination as well as monitoring mechanism of NGCMA
- Competitiveness of Indian TFs with respect to cost and study completion time.

The TFs have acknowledged that due to the acceptance of the data from India among the OECD countries and the higher result accuracy, the chances to repeat the same study has reduced. This, in turn, has optimised or reduced the requirement of test systems (animals) globally to conduct GLP studies.

2.8.Global sponsors of Indian TFs

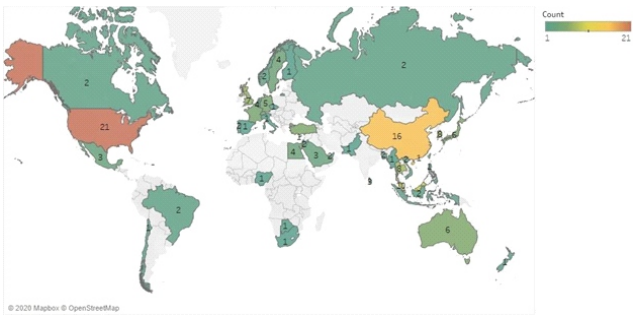

Figure 16: *Global outreach of India GLP Services*

Due to India becoming full adherent to MAD, the ease of doing business for GLP studies has significantly improved among OECD member and non-member MAD adherent countries. Indian TFs provide GLP services to sponsors from 48 countries (Annexure 6). The global outreach of GLP services from Indian TFs is shown in Figure 16.

80% of CROs are doing business with sponsors from Europe and 40% with those from the USA. Such a high percentage of GLP studies being conducted by the Indian TFs for these two most regulated markets indicates global acceptance of the quality and credentials of Indian TFs.

2.9 Comparison of GLP service levels of Indian TFs

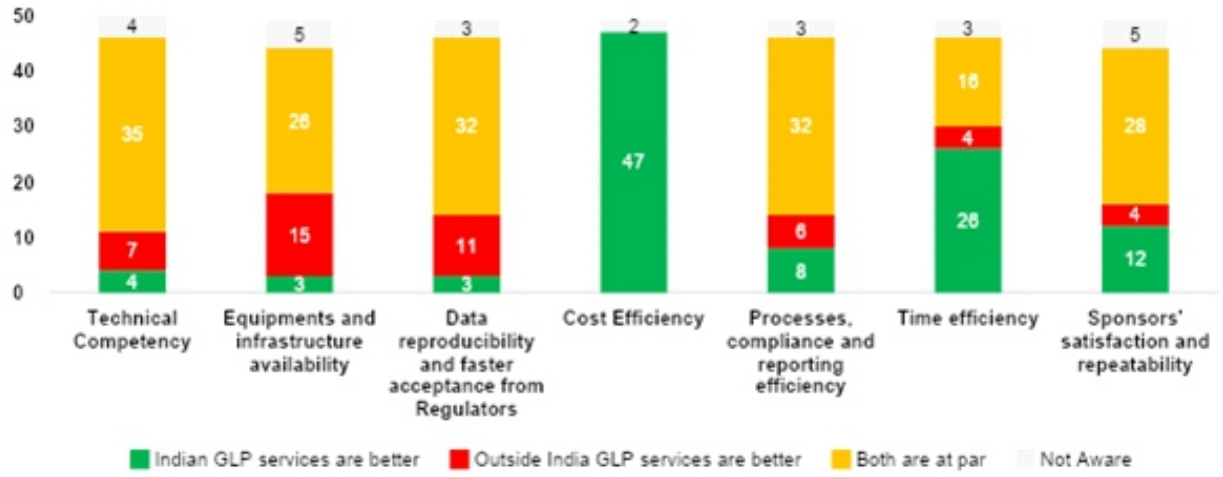

Figure 17: *Value addition by GLP quality system*

The above chart provides perception of Indian TFs for their delivered GLP services in comparison to their counterparts outside India on following metrics:

- **Technical competency:** 35 out of 50 (70%) Indian GLP certified TFs believe that their technical competence is at par with foreign TFs. This is an indication of the presence of well-qualified scientific manpower and other resources in India.
- **Equipment and infrastructure availability:** 26 out of 50 (52%) Indian TFs agree that their equipment and infrastructure availability is at par with foreign TFs.
- **Data reproducibility and faster acceptance by regulators:** 32 out of 50 (54%) Indian TFs agree that data reproducibility and faster acceptance of safety data by regulators is at par with foreign TFs. However, there were 11 (26%) Indian TFs who rated foreign TFs higher on this parameter. This may also be because of certain reservations among the sponsors and global regulators. Such challenges can be addressed by active participation of Indian TFs together with NGCMA in targeted global markets and showcasing Indian TFs' leadership and credentials.
- **Cost efficiency:** There is almost a unanimous view that Indian TFs have cost efficiency advantage over foreign TFs. This is because of the availability of well-qualified and trained personnel in India at a lesser cost. It has been conveyed that the cost of performing a GLP study outside India costs 2 to 3 times more to the sponsor.
- **Process compliance and reporting efficiency:** 32 out of 50 (64%) TFs agree that process compliance and reporting efficiency of the Indian TFs is at par with foreign TFs. However, 8 TFs believe that Indian TFs perform better on this parameter when compared to foreign TFs. It is felt that the use of the latest technologies and more automation by Indian TFs can help to further improve compliance efficiency.
- **Time efficiency:** A majority of Indian TFs, 26 out of 50 (52%) believe that time efficiency for conducting GLP studies of the Indian TFs is better as compared to foreign TFs. Another 16 (32%) Indian TFs believe this to be at par with foreign TFs. It is important to mention here that higher resourcing and better coordination along side with follow-ups have helped Indian TFs to build time competitiveness.

- **Sponsor satisfaction and repeatability:** 28 out of 50 (58%) Indian TFs agree that the sponsor satisfaction and repeatability is at par for both Indian and foreign TFs. 12 (24%) Indian TFs believe that sponsor's satisfaction and repeatability is better than foreign TFs.

This perception resulting from Indian TFs on their service levels is vetted with some key Indian and global sponsors. Most of them have rated Indian TFs GLP services 'at par' or 'better' than foreign TFs. These sponsors generally take GLP services from Indian GLP TFs for pesticides and pharmaceuticals.

National GLP Program: High Recall Value

The Indian GLP TFs recognise the National GLP Program for its integrity, expertise, traceability, reliability and acceptance of data.

This shows that the National GLP Program, India is recognized for its quality, cost and time efficiency and has very strong potential to build global leadership with increased share of GLP services.

Figure 18. *Attributes of National GLP Program as perceived by TFs*

2.10. Sustainable Development Goals

SDGs Impacted by National GLP Program

There are 17 Sustainable Development Goals (SDGs) defined by the United Nations (UN) member states. Out of these 17 SDGs, the National GLP Program contributes to 7 SDGs as per as the details given below:

Table 4: SDG Mapping of National GLP Program, India

SDG GOAL	TARGET	DESCRIPTION AND RELEVANCE
SDG 2 Zero Hunger	Target 2.4	By 2030, ensure sustainable food production systems and implement resilient agricultural practices that **increase productivity and production,** that help maintain ecosystems, that strengthen **capacity for adaptation to climate change, extreme weather, drought, flooding. and other disasters** and that progressively improve land and soil quality
	Target 2.6	Increase investment, including through enhanced international cooperation, in rural infrastructure, agricultural research and extension services, technology development and plant and livestock gene banks to enhance agricultural productive capacity in developing countries, in particular, least developed countries
SDG 3 Good Health and Well Being	Target 3.8	Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and **access to safe, effective, quality and affordable essential medicines** and vaccines for all
	Target 3.9	By 2030, substantially **reduce the number of deaths and illnesses from hazardous chemicals and air, water, and soil pollution and contamination**
	Target 3.11	Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all
SDG 4 Quality Education	Target 4.4	By 2030, substantially **increase the number of youth and adults who have relevant skills, including technical and vocational skills, for employment, decent jobs and entrepreneurship**
SDG 8 Decent work and economic growth	Target 8.3	Promote development-oriented policies that support productive activities, **decent job creation, entrepreneurship,** creativity, and innovation, and encourage **the formalization and growth of micro-, small- and medium-sized enterprises,** including through access to financial services
	Target 8.4	Improve progressively, through 2030, global resource efficiency in consumption and production and endeavor to **decouple economic growth from environmental degradation,** in accordance with the 10-year framework of programs on sustainable consumption and production, with developed countries taking the lead

SDG GOAL	TARGET	DESCRIPTION AND RELEVANCE
SDG 9 Industrial innovation and infrastructure	Target 9.5	Enhance scientific research, upgrade the technological capabilities of industrial sectors in all countries, in particular developing countries, including, by 2030, encouraging innovation and substantially increasing the number of research and development workers per 1 million people and public and private research and development spending
SDG 11 Sustainable cities and communities	Target 11.5	By 2030, significantly reduce the number of deaths and the number of people affected and substantially decrease the direct economic losses relative to the global gross domestic **product caused by disasters, including water-related disasters,** with a focus on protecting the poor and people in vulnerable situations
SDG 12 Responsible consumption and production	Target 12.4	By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil to minimize their adverse impacts on human health and the environment
	Target 12.5	By 2030, substantially reduce waste generation through prevention, reduction, recycling, and reuse
	Target 12.9	Support developing countries to strengthen their scientific and technological capacity to move towards more sustainable patterns of consumption and production

6 RELATED DISCUSSIONS

1. Sponsors' opinion on National GLP Program

As a part of the methodology of this Impact Analysis Study, 14 sponsors (10 Indian and 4 global) were interviewed for their feedback on GLP services provided by Indian TFs and their future outlook. All sponsors felt that Indian GLP TFs developed very well post MAD status and there is a huge growth potential to attract increased foreign sponsors.

They appreciated the procedures and activities of NGCMA and Government of India in building a supportive ecosystem to facilitate the industry's competitiveness and environment safety.

Indian TFs are providing excellent support to the sponsors for filing marketing applications and smooth product registrations in India and other countries.

The presence of a network of GLP TFs providing high quality services at competitive cost has helped their business growth.

Quality of services from Indian TFs is deemed at par with foreign TFs. High satisfaction was expressed on accuracy of tests results and quality of the data generated by the CROs.

The time competitiveness of Indian GLP certified TFs in conducting non-clinical health and environmental safety studies has helped them to advance to clinical studies in a timely manner.

The sponsors expressed satisfaction on the technical competency, knowledge, skills, and professionalism of Indian TFs. There was a recommendation to drive periodic training programs to facilitate more global exposure.

2. Sponsors' opinion on Indian Regulators

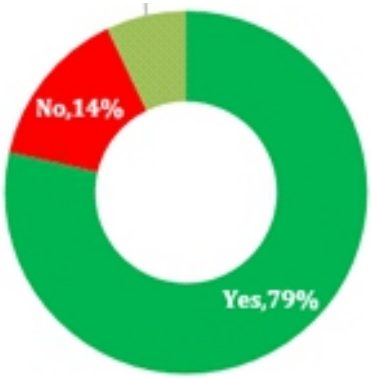

Figure 19: *Sponsors' opinion on mandating GLP studies by Regulators*

Most of the sponsors supported the opinion that similar to European Union's REACH initiative, Indian Regulators should also mandate GLP studies for regulatory submissions.

3. Opinion of Indian Regulators on National GLP Program

Indian Regulators greatly acknowledged the contribution of National GLP Program in developing overall quality consciousness in non-clinical research across the value chain. The CDSCO and CIB have made GLP studies mandatory in India for registration purposes of pharmaceuticals and pesticides respectively. As Regulators, they recognize following positive impacts from the National GLP program:

- GLP certification has helped to speed up the approval process for non-clinical safety studies. The GLP studies usually have very low rejection rates.
- The data generated by GLP TFs is considered accurate and reliable.
- NGCMA undertakes effective GLP compliance monitoring and has robust and transparent processes.

The regulators mentioned that the Clinical Trial Rules, 2019 would give further impetus to India to undertake newer molecular drug discovery and develop new biosimilar molecules. This will further push the demand for more GLP studies and increase the number of GLP certified TFs in India, thus making GLP studies more affordable and accessible for manufacturers of all levels.

Considering the global scope there is a potential for the country to become the global market leader of non-clinical GLP testing. It is estimated that approximately 100 such laboratories should be created or upgraded to GLP status to meet the increasing demand of Indian stakeholders and also to remain viable and competitive in the global scenario.

4. Challenges faced by TFs

There are certain challenges faced by the TFs while performing GLP studies in India. Some of these issues may not come directly under the purview of NGCMA but are important to address to realize the full potential of the National GLP Program.

Import of test systems and the acquisition of test license

- The processes for obtaining import licenses and customs' clearance for certain test systems and samples of testing for testing purposes can be re-aligned for preventing loss of opportunities in terms of valuable business.
- There are complicated rules for import of biological samples used as *in-vitro* test systems (skin/ tissues, soil etc.)
- The import of bigger test systems such as dogs poses greater challenges

Availability of quality test systems and other support resources

- There is some difficulty in obtaining high-quality animals from Indian suppliers. This problem is largely resolved for small animals (mice and rats) but still exists for large animals.
- The availability of quality non-rodent test systems is the biggest challenge in performing GLP studies in India. It significantly reduces the scope of the package to be submitted to regulatory agencies for novel drug development.
- There is considerable time-lapse in procurement of critical reagents, chemicals and related resources.

Technically trained manpower and software support

- There is a need for better support from Indian vendors for equipment and software. This has improved over years, but there is still more to be done to strive for leadership.
- The recruitment of skilled human resources continues to pose a challenge. It takes long years to train the staff for non-clinical safety studies.

Regulatory Approvals

- The clearance of higher animal protocols by CPCSEA, at times, takes longer than expected, resulting in loss of business from foreign sponsors.
- The current regulatory norms for use of bigger test systems such as dogs and primates are tedious.

5. Challenges faced by the research team

Citing the OECD observation on Impact Assessment, the research team too faced the challenges of employing the most suitable techniques appropriate to register the impact assessment of the Indian GLP program. The focus of the study was to first, understand what this impact assessment activity is trying to achieve and, second, the data and other resources that can be assembled as there was no empirical data available. To further elaborate the challenges faced by the team were :

- The data received by the researchers was mostly based on the calculations and assumptions of the TFs.
- The researchers were not privy to the accounting books of the TFs and the information has been received on good faith.
- All the data received was in response to the questionnaire that was circulated electronically which was best supplemented by the Focussed Group Discussion across the various TFs.

7 SUGGESTIONS: STRENGTHENING THE NATIONAL GLP PROGRAM

GLP certified TFs in India have the potential to tap the existing global CRO business opportunity for non-clinical safety studies. During interactions with various stakeholders including the TFs, Regulators, Sponsors and Inspectors, the following suggestions were made to expand the footprints of the current program:

1. Increasing the scope of GLP certification
    - To include more types of test items to be tested under GLP namely
        - AYUSH products
        - Cell therapy products
        - Stem-cells
        - Biotech products
        - Nano materials
2. Capacity building programs
    - Use the latest techniques like webinars, online training courses, etc.
    - Increase the frequency of the training programs
    - Training sessions may be organized zone-wise to cater to wider geographies
    - Develop and publish NGCMA's training videos on the web portal, so that the GLP TFs can use them as training resource for their in-house trainings
    - Create an online forum (an app-based platform) where queries asked by the TFs can be immediately responded by the experts
    - Invite international GLP experts to deliver workshops and seminars online and offline
    - Provide on-line training programs and professional certifications by NGCMA to enhance GLP labs required various role-based skill sets for both existing and new professionals.
    - Organize brainstorming sessions between NGCMA GLP Inspectors and TFs to harmonize understanding of GLP principles
    - Increase the scope of training to other disciplines such as drug metabolism, safety pharmacology, bioinformatics, or technical report writing according to the regulatory requirement and other relevant fields
    - Increase coordination with other government and private institutions to conduct various training programs especially for young professionals on analytical skills, non-clinical safety studies, documentation and regulatory requirements

3. Ease of norms for importing test items
    - GLP certified TFs to be exempted from having import permits for importing test samples (pesticides/ research molecules)
    - Simplified procedures to fast track approvals of importing test items
4. Government may develop an online system for GLP and compliance monitoring including:
    - Digitization of the GLP certification for transparency and fastening of the approval process
    - For learning and capacity building through Webinars and online training modules
5. The government may take steps to bring all certifying agencies like CIB, National Accreditation Board for Testing and Calibration Laboratories (NABL), ISO etc., under one roof for non-clinical safety testing.
    - Better coordination between members departments to ensure the ease of business for Indian TFs
    - Data generated by the GLP certified TFs may be accepted by all the Government agencies in India
    - For medical devices, NGCMA and CDSCO could develop a common process for approval for GLP certified TFs
    - Mandating GLP studies for all the regulatory approvals is desirable
    - Simplification of procedures for animal ethics approval.
6. Incentivising allied services such as the animal facility, quality animals and equipment availability for strengthening the GLP certification eco-system.
7. Establishing technical and educational institutes to start specialized courses on quality systems especially GLP for students to support the industry

8 TESTIMONIALS ON NATIONAL GLP PROGRAM

The Indian GLP program has ensured that the Indian non-clinical contract research industry has achieved and sustained its due place as a competitive, reliable support and regulatory solution provider to the Indian and international pharma, agro-chemical and chemical industries.

-GLR Laboratories Pvt. Ltd.

The Indian GLP (NGCMA) meticulously lays out the program for the growth of Indian CRO's. The Indian GLP program (NGCMA) is transparent and at par with international regulations.

-Bioscience Research Foundation (BRF)

The role played by NGCMA in creating a monitoring system in India, achieving the MAD status and providing monitoring and certification for TFs in India is commendable.

- Eurofins Advinus Ltd

The GLP program is helping the facilities to a great extent. GLP facilities not only enhance their knowledge through such capacity building programs, but these programs also help in ensuring different facilities are on the same page. People from our facility who have attended such programs have always praised these sessions, and in fact, the other TFs personnel also look forward to attending these sessions.

- GLP Test Facility, Sun Pharmaceutical Industries Limited

The National GLP program has enabled the acceptability of data generated by Indian GLP TFs across OECD countries. Appreciate the approachability of NGCMA and active participation in developing harmonized GLP ecosystem in the country.

- Syngene International Limited

The quality of the guidelines made it easy to identify or implement a new type of study in the laboratory. I greatly appreciate the openness in communication on the process and training of people that we needed in terms of certification that we can use with our customers.

- Natural Remedies Pvt. Ltd.

The National GLP program has brought various changes among the testing laboratories in India. The acquisition of the GLP certificate improved the infrastructure and quality of laboratories. The supply of quality laboratory animals has a great impact on the results of studies. The accuracy of data from devices is ensured by regular calibrations. Indian scientific community is becoming more knowledgeable than before due to continuous training programs organized by NGCMA. The national GLP program has encouraged commercial suppliers to comply with international standards. Overall, the National GLP program ensures quality science and service in India.

- Diligence Bio Pvt. Ltd.

9 LIST OF ANNEXURES

Annexure 1- List of Respondent Test Facilities

S. No.	List of Test Facilities
1	Accutest Biologics Pvt. Ltd.
2	Ana Laboratories
3	Anthem Biosciences Pvt. Ltd.
4	Aurigene Pharmaceutical Services Limited (Formerly called as Aurigene Discovery Technologies
5	Bioneeds India Private Limited
6	Bioscience Research Foundation
7	Centre for Toxicology and Developmental Research
8	CSIR- Central Drug Research Institute
9	CSIR-Indian Institute of Toxicology Research
10	Dabur Research Foundation
11	Diligence Bio Pvt. Ltd.
12	Drug Safety Assessment, Novel Drug Discovery and Development
13	Edara Research Foundation
14	Eurofins Advinus Limited
15	GLP Test Facility, Sun Pharmaceutical Industries Limited, Gurugram, Haryana
16	GLP Test Facility, Sun Pharmaceutical Industries Limited, Gurugram, Haryana
17	GLR Laboratories Private Limited
18	Indian Institute of Toxicology (IIT)
19	Indofil Industries Limited
20	International Institute of Biotechnology and Toxicology
21	Intox Pvt. Ltd.

S. No.	List of Test Facilities
22	Jai Research Foundation
23	JDM Scientific Research Organisation Private Limited
24	Jubilant Biosys Limited
25	Krish Biotech Research Pvt. Ltd.
26	Laila Nutraceuticals Research & Development Centre
27	Lambda Therapeutic Research Ltd.
28	Meghmani Organics Ltd.
29	National Toxicology Centre, NIPER, Mohali
30	Natural Remedies Private Limited
31	Palamur Biosciences Private Limited
32	PI Industries , R & D Centre
33	PRADO Preclinical Research & Development Organization Pvt. Ltd.
34	RCC Laboratories India Pvt. Ltd.
35	Reliance Life Sciences Pvt. Ltd.
36	Ross Lifescience Pvt. Ltd.
37	Ross Lifescience Pvt. Ltd.
38	sa-FORD (A Division of Sharon Bio-Medicine Ltd.)
39	Sipra Labs Limited
40	Sun Pharma Advanced Research Company Limited, Vadodara, Gujarat
41	Syngene International Limited
42	Syngenta Bio-Sciences India Pvt. Ltd.
43	The Himalaya Drug Company R&D Center
44	Torrent Pharmaceuticals Limited
45	Toxicology Centre, Shriram Institute for Industrial Research
46	Vanta Bioscience Limited
47	Vimta Labs Limited
48	Vipragen Biosciences Pvt. Ltd.
49	Vivo Bio Tech Limited
50	Zydus Research Centre

Annexure 2- List of Types of Test Items

S. No.	Test Items
1	Pharmaceuticals
2	Pesticides
3	Industrial Chemicals
4	Veterinary Drugs
5	Feed Additives
6	Food Additives
7	Cosmetics
8	Others - Medical Devices

Annexure 3- List of Areas of Expertise

S. No.	Areas of Expertise
1	Physical-chemical Testing (Including Five Batch Analysis)
2	Toxicity Studies
3	Mutagenicity Studies
4	Environmental Toxicity Studies on Aquatic and Terrestrial Organisms
5	Studies on Behavior in Water, Soil and Air; Bioaccumulation
6	Residue Studies
7	Studies on Effects on Mesocosms and Natural Ecosystems
8	Analytical and Clinical Chemistry Testing
9	Others • Absorption, Distribution, Metabolism, Excretion (ADME) Studies • Bioanalysis • Biochemical Characterization • Biocompatibility Studies • Bio efficacy studies on Household insect pests in the laboratory as per WHOPES and other Standard protocols • Drug Metabolism and Pharmacokinetic (DMPK) Studies • Efficacy Studies/Bioassays • Hemocompatibility Studies • Implantation Studies • in vitro Bioassays • Maximum Tolerated Dose (MTD) Studies • Method Development • Method Validation • Safety pharmacology • Viral Clearance Studies

Annexure 4- List of Test Systems

S. No.	Test Systems
1	Rat
2	Mouse
3	Rabbit
4	Guinea Pig
5	Dog
6	Goat
7	Cell lines
8	Plasma and Tissues
9	Human Lymphocytes
10	Reconstructed Human Epidermis (Episkin)
11	Melanoma/ Carcinoma/ Tumor cell
12	Cornea
13	Bacterial Strains
14	Fish
15	Bird
16	Mosquito
17	Silkworm
18	Earthworm
19	Housefly
20	Honeybee
21	Daphnia
22	Lemna
23	Algae
24	Cockroach
25	Chironomus Larvae
26	Yeast
27	Mould
28	Analytical instruments

Annexure 5: Process of GLP Certification

Annexure 6: List of Sponsor Countries and Regions

S. No.	Country Name	Number of TFs doing business
1.	USA	21
2.	China	16
3.	Malaysia	10
4.	Korea	8
5.	Thailand	8
6.	UK	7
7.	Australia	6
8.	Japan	6
9.	Singapore	6
10.	Turkey	6
11.	France	5
12.	Germany	5
13.	Belgium	4
14.	Egypt	4

S. No.	Country Name	Number of TFs doing business
15.	Israel	4
16.	Sweden	4
17.	Switzerland	4
18.	Europe	3
19.	Mexico	3
20.	Saudi Arabia	3
21.	Sri Lanka	3
22.	Taiwan	3
23.	Bangladesh	2
24.	Brazil	2
25.	Canada	2
26.	Indonesia	2
27.	Jordan	2
28.	Netherlands	2
29.	Norway	2
30.	Portugal	2
31.	Russia	2
32.	UAE	2
33.	Vietnam	2
34.	Botswana	1
35.	Chile	1
36.	Cyprus	1
37.	Czech Republic	1
38.	Finland	1
39.	Hong Kong	1
40.	Italy	1
41.	Myanmar	1
42.	New Zealand	1
43.	Nigeria	1
44.	Pakistan	1
45.	Philippines	1
46.	South Africa	1
47.	South America	1
48.	Spain	1

Annexure 7: Investment in Test Facilities upgradation

S. No.	Test Items	Cumulative Investments made before GLP (INR Crores)	Cumulative Investments made as on Oct 19 (INR Crores)
1	Accutest Biologics Private Limited	30.0	30.5
2	Anthem Biosciences Pvt. Ltd	15.0	20.0
3	Aurigene Discovery Technologies Limited	2.4	2.4
4	Bioneeds India Private Limited	2.2	8.8
5	Bioscience Research Foundation	25.0	75.0
6	Cadila Pharmaceuticals Limited- Pre-Clinical Department (CRO)	20.0	20.0
7	Centre for Toxicology and Developmental Research (CEFTE)	1.0	5.0
8	Dabur Research Foundation	30.1	51.6
9	Diligence Bio Pvt. Ltd.	2.0	2.0
10	Drug Safety Assessment, NDDD, Lupin Research Park	25.0	50.0
11	Edara Research Foundation	10.0	12.0
12	GLP Test Facility, Sun Pharma	3.0	6.0
13	GLR Laboratories Private Limited	0.7	1.3
14	Indian Institute of Toxicology	1.0	5.0
15	Indofil Industries Limited	5.0	5.0
16	International Institute of Biotechnology And Toxicology (IIBAT)	4.9	5.1
17	Intox Pvt. Ltd. Pune	2.3	7.8
18	Jubilant Biosys	5.6	10.0
19	Krish Biotech Research Private Limited	10.1	30.2
20	Meghmani Organics Ltd.	4.2	4.5
21	Natural Remedies Private Limited	3.0	3.0
22	Palamur Biosciences Pvt. Limited	8.0	10.0
23	PI Industries RandD Center	33.0	64.0
24	Preclinical Research and Development Organization Pvt. Ltd (PRADO)	2.0	5.0
25	RCC Laboratories India Private Limited	25.0	40.0
26	Ross Lifescience Pvt. Ltd.	3.0	4.5
27	sa-FORD	Not available	9.8
28	Sipra Labs Ltd	80.0	100.0

S. No.	Test Items	Cumulative Investments made before GLP (INR Crores)	Cumulative Investments made as on Oct 19 (INR Crores)
29	The Himalaya Drug Company	12.5	38.8
30	Torrent Pharmaceuticals Ltd, Torrent Research Center	Not available	60.0
31	Toxicology Centre, Shriram Institute For Industrial Research	15.0	0.0
32	Venus Medicine Research Center	20.0	65.0
33	Vimta Labs Limited- Preclinical Division	10.7	215.0
34	Vipragen Biosciences Private Limited	3.0	7.0
35	CSIR- Indian Institute of Toxicology Research	10.0	20.0
36	Zydus Research Centre (Cadila Healthcare Limited)	25.0	150.0
	Total	**449.6**	**1,143.3**
37	CSIR-Central Drug Research Institute	Not available	Not available
38	Eurofins Advinus Limited	Not available	Not available
39	GLP Laboratory, Gharda Chemicals Ltd.	Not available	Not available
40	Jai Research Foundation	Not known	Not known
41	JDM Scientific Research Org. Pvt. Ltd.	Not available	Not available
42	Laboratory Animal Research Services	Not available	Not available
43	Laila Nutraceuticals Research and Development Centre	Not available	Not available
44	Lambda Therapeutic Research Limited	Not available	Not available
45	National Toxicology Centre	Not available	Not available
46	Sun Pharma Advanced Research Company Limited	Not available	Not available
47	Syngene International Limited	Data difficult to extract	Data difficult to extract
48	Syngenta Biosciences Pvt. Ltd.- GLP Testing Facility	Not available	Not available
49	Vanta Bioscience Limited	Not available	Not available
50	Vivo Bio Tech Ltd.	Not available	Not available

Annexure 8: List of Technical Committee Members

S. No.	Name	Designation
1	Prof. Y.K. Gupta	Chairman
2	Dr. Sandhya Kulshrestha	Co- Chairperson
3	Plant Protection Adviser	Member
4	Director, Export Inspection Council of India, Department of Commerce	Member
5	Secretary General, Quality Council of India (QCI)	Member
6	Director General, Bureau of Indian Standards (BIS)	Member
7	Drugs Controller General of India	Member
8	Representative, Department of Fertilizers	Member
9	Director General, Indian Council of Medical Research (ICMR)	Member
10	Representative, Department of Chemicals and Petrochemicals	Member
11	Representative, Department of Pharmaceuticals	Member
12	Representative, Ministry of Environment, Forest and Climate Change	
13	Representative, National Accreditation Board for Testing and Calibration Laboratories (NABL)	Member
14	Dr. Ekta Kapoor, Scientist 'E', NGCMA, Department of Science and Technology	Member-Secretary

The woods are lovely dark and deep, But I have promises to keep, and miles to go before I sleep, and miles to before I sleep……...

By Jawaharlal Nehru

National GLP Compliance Monitoring Authority
Department of Science and Technology
Ministry of Science and Technology
Technology Bhavan, New Mehrauli Road, New Delhi-110 016
www.dst.gov.in/ngcma