

## National model for replicating benchmarking of basic research investigations in govt institutes: a case for ministries of science and technology and health and family welfare

"Good Laboratory Practices (GLP)" enshrined under the OECD guidelines provide an excellent framework in raising the bar in research productivity in our country. Ironically, none of the publically funded labs in the country have adopted these norms for basic research investigations. If these norms are adopted it may result in enhancing the quality standards, increase credibility, efficiency and transparency of research and diagnostic facilities. This is the first time that the Neuroscience Research Lab at PGI Chandigarh was awarded National Award by Quality Council of India for implementing quality principles voluntarily. This innovation has led to a system dependent technical and managerial procedures facilitating research audit and document control, improving purchase and accounting procedures as well as human resources besides delivery of patient care diagnostic services.

The conventional system of running research labs in India is based on no established or uniform method of management relying on individual preferences and experiences. Unfortunately, even the individual medical institutes do not define modules of running research facilities unless mandated by GMP requirements defined by regulatory authorities. This happens in the case of clinical trials where patient's safety and care is involved. These trials have been presumably halted due to questionable data and lack of back traceability of information. The ability to bring clinical level safety at the pre-clinical (basic research investigation) level makes this innovation unique transparent and credible for effective clinical translation. This can stimulate knowledge economy and attract huge investments from around the globe.

The current quality systems in Neuroscience Research Lab encourages goal driven, self proposed monthly master schedule of activities in consultation with the study director, using the combination of Standard Operating Procedures (SOPs), Data Recording Sheets (DRSs) and master schedules. The Quality Assurance (QA) conducts periodical audit of the progress, compliance and reproducibility of experiments giving a new lease to research output. The data generated is filed in a defined format using a mandatory raw book, master code, calibrated instruments (with IQ, OQ, PQ), log sheets with continuously regulated infrastructure and room environment providing back up for each facility (including power outage). This data and samples (if any) are archived in defined shelves or freezers as the case may be so that research productivity and quality is enhanced. The electronic repository of entire data is maintained in dedicated servers secured by physical installation of firewalls.

The entire system in the research facility operates under a moral obligation for biannual external audit by senior quality assurance experts which includes proficiency testing. This innovation encompasses periodic training of research personnel and staff to not only engage in academic activities but also bio waste management, sanitation, fire extinguisher safety, first aid, animal handling, and development of IQ (Intelligence quotient), SQ (Spiritual quotient), EQ (Emotional quotient) through periodic orientation programs which are essential for mentoring of independent neuroscience research leaders for tomorrow.

This innovation aims to enhance the reproducibility and error reporting of

research data and sustain quality system in research practices, thereby facilitating a higher sincerity of purpose for research in medical institutes in India. This system also seeks to bridge the credibility chasm that exists between data generated from India and that from the West, because of which the best research from India is rarely taken seriously. The frequency and quality of research papers from this research facility provide for an innovation which has improved the credibility of research generated from this research facility. This is expected to boost discovery and innovation thereby accelerating translational research.

Implementation of this concept has led to benchmarking of research projects which are usually considered a soft activity in medical institutes of India, thereby enabling reliable translation of bench to clinic. This innovation has led to a system dependent technical and managerial procedures facilitating research data reproducibility, audit control and document control.

It is a perfect time for new Ministers of Science and Technology and Health and Family welfare to take note of this and consider instructing the funding agencies like DST, DBT, ICMR, DAE, DRDO under them to demand quality systems to be implemented in labs before releasing tax payer's money to them for research and development. Neuroscience Research lab can be converted into a national reference laboratory to mentor this activity.

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**Akshay Anand**  
Editor in Chief