DRUG REGULATORY AUTHORITY OF PAKISTAN
MINISTRY OF NATIONAL HEALTH SERVICES, REGULATIONS & COORDINATION

QUARTERLY DRAP's NewsLetter

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World Health Organization

Benchmarking of National Regulatory System of Pakistan

May 2023

Figure 1. In response to an invitation from the United States Food and Drug Administration, the Honorable Minister for National Health Services Regulations and Coordination, Mr. Abdul Qadir Patel, and the Chief Executive Officer of DRAP, Mr. Asim Rauf, visited the US FDA. The United States Pharmacopeia (USP) organized the visit.

WHO BENCHMARKING OF NATIONAL REGULATORY AUTHORITY

GBT Functional Teams of DRAP

Drug Regulatory Authority of Pakistan undergoes auditing of the National Regulatory System from 03-12 May 2023 by a team of WHO Regulatory System Strengthening (WHO-RSS).

Background: WHO is mandated by Resolution WHA 67.20 to support countries to strengthen regulatory systems by:

- Building regulatory capacity in Member States consistent with good regulatory practices, and
- Promoting regulatory cooperation, convergence, and transparency through networking, work-sharing, and reliance.

Global Benchmarking Tool: WHO Regulatory Systems Strengthening (RSS) programme has developed a robust tool named as Computerized Global Benchmarking Tool (cGBT) that is used for assessment and benchmarking of the regulatory system of the countries. Through this tool. Through this tool, WHO benchmark the national regulatory system of countries against 268 sub indicators corresponding to nine key regulatory functions. The WHO team evaluates the country's regulatory system using cGBT to identify strengths as well as areas for improvement, and transform its findings into an Institutional Development Plan (IDP).

Global Benchmarking Tool is success story in the field of health regulation, it is simultaneously uplifting the quality of operations and services being performed by NRAs in many countries.

Benchmarking of Pakistan: In 2022, DRAP submitted self-benchmarking exercise to WHO team which was reviewed by the WHO team. WHO conducted an observed audit for Regulatory Inspection in February-2023 followed by formal benchmarking of all 09 functions and an observed audit of pharmacovigilance and laboratory testing in May 2023.

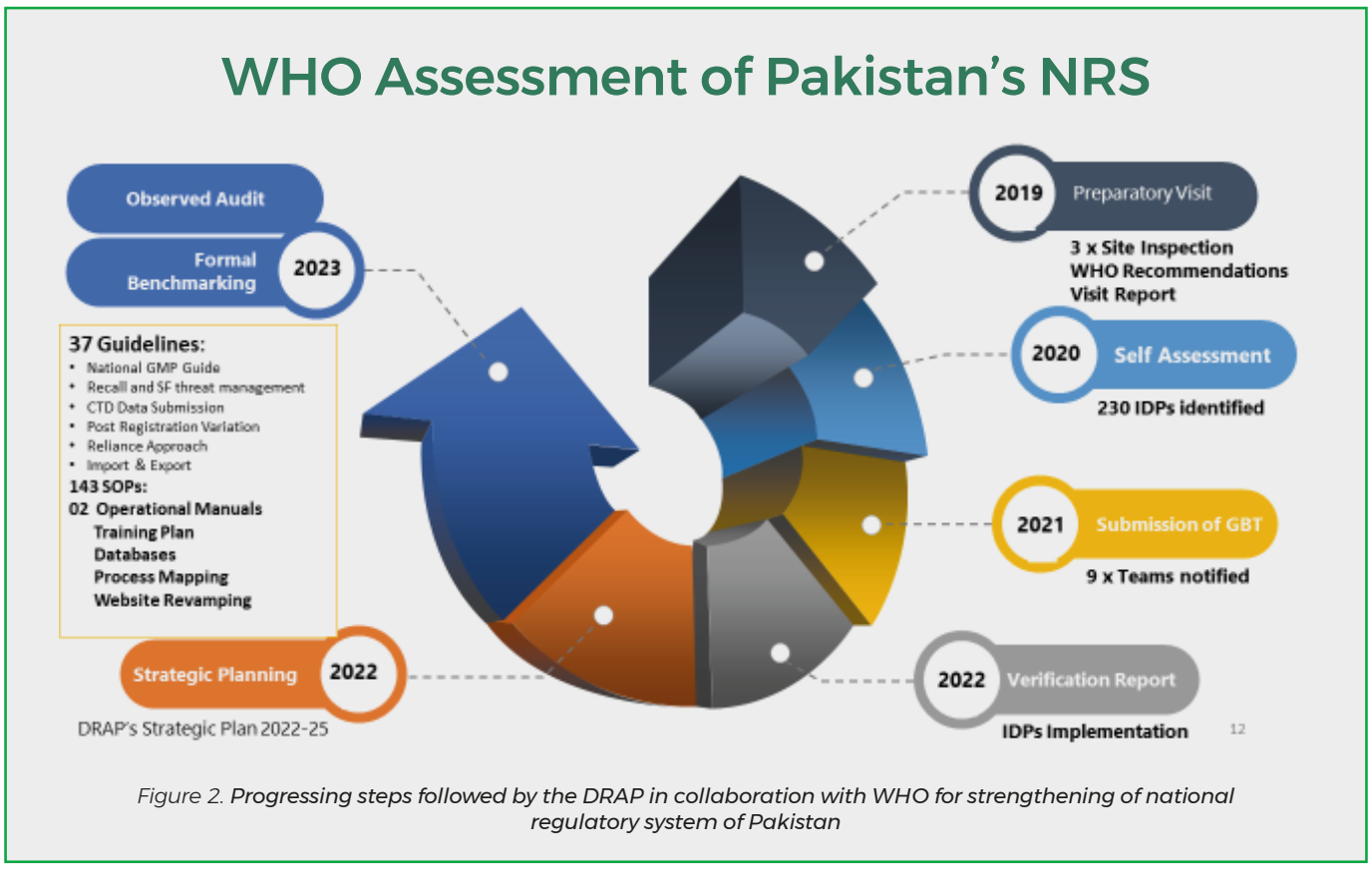


*Figure 2. **Progressing steps followed by the DRAP in collaboration with WHO for strengthening of national regulatory system of Pakistan***

WHO mission comprises 14 Auditors from WHO HQ Geneva, EMRO Office, and the Country office, as well as experts from leading NRAs, participated in the Benchmarking exercise against the WHO computerized Global Benchmarking Tool (GBT). WHO Auditors visited DRAP HQ, Central Drug Laboratory Karachi, and Directorate of Drugs Control Punjab, and Pharmacovigilance Centres to interview Pakistan's regulatory workforce.

CEO DRAP has constituted nine teams among DRAP officers who are working diligently to implement the institutional developmental plan in the national regulatory system. These teams are working in collaboration with respective officers from the drug control administration of all federating units to implement the WHO's recommendations across the country.

DRAP is striving hard to transform regulatory operations are functioning in recommendation with the best regulatory practices.

Dr Alireza Khadem Broojerdi, WHO Team Lead, applauded the progress made by the DRAP and affiliated organizations in recent years. The WHO team provided recommendations for further strengthening the regulatory system and agreed on a roadmap for future collaboration.

CEO DRAP expressed his gratitude and warm regards to Dr. Palitha Mahipala, WR Pakistan, and the entire WHO team on behalf of the Government of Pakistan, DRAP, and the Provincial Drug Control Departments.

Directors of DRAP, Chief Drug Controller Punjab, Director CDL Karachi, and NCLB Islamabad were also present in the concluding session.

Dr. Mahipala, WR Pakistan always comes forward to support in fulfilment of DRAP's mission to provide enhanced access to safe, quality assured and efficacious therapeutic goods for the people of Pakistan. The Government of Pakistan and DRAP highly appreciate his great contribution to the health sectors of Pakistan.

Figure 3. Group photo of WHO Mission with CEO DRAP and his team on the Concluding session of WHO Benchmarking of National Regulatory System of Pakistan, on May 12, 2023 at Islamabad -Pakistan

HIGHLIGHTS OF THE WHO TEAM VISIT TO DRAP

H.E. Dr Palitha Mahipala, WR Pakistan, is welcomed by DRAP's CEO

CEO DRAP receiving WHO RSS Team Lead Dr. Alirerza Khadem

An Overview of Clinical Research Oversight Function in Pakistan

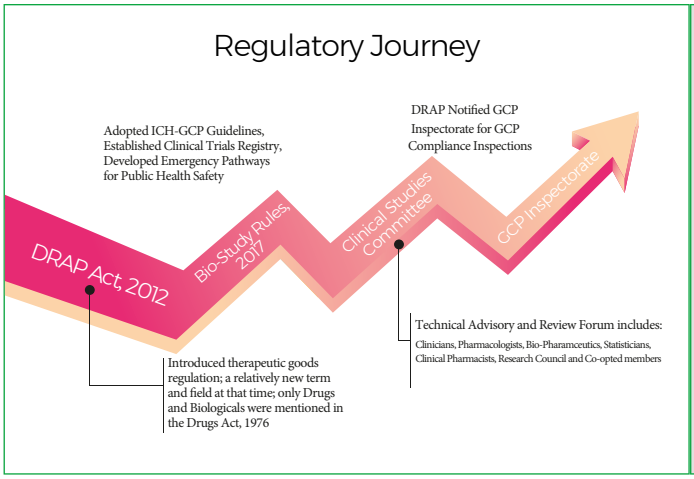
Dr. Obaidullah, Mr. Shafqat Hussain, Pharmacy Services Division DRAP

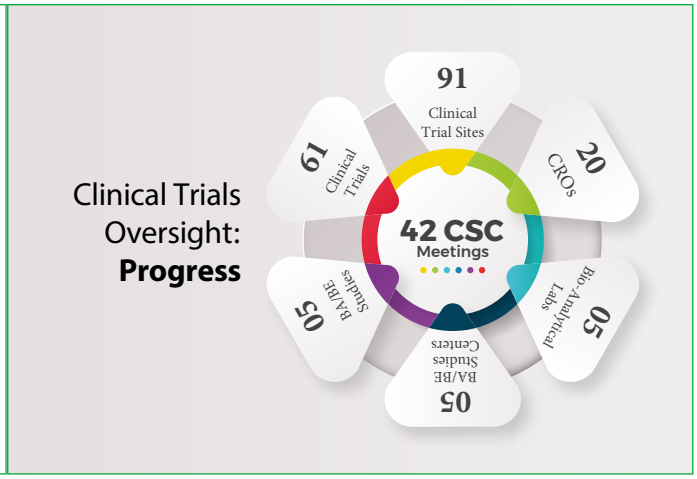
Introduction:

Drug Regulatory Authority of Pakistan (DRAP) regulates the conduct of clinical research related to therapeutic goods in Pakistan under the Bio-Study Rules, 2017. These rules provide a complete regulatory framework for clinical research related to therapeutic goods in the country. As per DRAP Act, 2012, therapeutic goods include drugs or alternative medicines or medical devices, or biological or other related products as may be notified by the Authority.

Regulatory Journey:

After the promulgation of the Bio-Study Rules, 2017, the DRAP has made significant progress in clinical trial oversight and transformed its operation as per international best practices. The Clinical Studies Committee (CSC), DRAP is a statutory forum for regulating clinical trials and National Bio-Ethics Committee (NBC) is the statutory forum for ethical oversight of clinical research in the country. Both committees convene their meetings regularly demonstrating the commitment to ensure promotion of clinical research in the country. During this period, many multi-country and national trials have been granted approval and subsequently monitored as per current ICH-GCP guidelines. Resultantly, trial results have been published in peer reviewed journals and few trials also got appreciation at international level as well.





Boost in Clinical Research:

Clinical Research Section, Pharmacy Services Division evolved in a very short duration. The regulation of clinical research through the Bio-Study Rules, 2017 has resulted in a boost in clinical research activities in Pakistan. Although COVID-19 pandemic was much catastrophic across the globe but at the same time enhanced the research culture in the country, positioning Pakistan as a potential market for clinical researchers and sponsors. During this time like other regulatory functions, DRAP's clinical trials team stood exemplary and worked tirelessly to ensure effective oversight of clinical trials, leading to the approval and availability of safe COVID-19 vaccines. An example is the multicenter, phase 3, double blind, placebo controlled, Randomized Clinical Trial of Recombinant Novel Corona Virus Vaccine (Adenovirus Type 5 vector based COVID-19 Vaccine). On the basis of the trial result, an Emergency Use Authorization (EUA) was approved for trial vaccine by DRAP's Registration Board and latterly EUA was also approved by other regulatory authorities as well. It was a major breakthrough where a trial vaccine got regulatory approval as a therapeutic good nationally and internationally as well. Similarly, various other clinical trials on COVID-19 Vaccines and biologics have been carefully evaluated and approved till now.

Adaptation of International Best Practices:

Various guidance documents and Standard Operating Procedures have been prepared for stakeholders and regulators respectively. Similarly, a manual for CSC operations has also been

prepared and followed in performing its activities by the committee. Aforementioned documents have been prepared as per international guidelines including principals outlined in WHO's Global Benchmarking Tools for National Regulatory Authorities. A gist of such activities is as follows:

a. The Clinical Research Section, DRAP operates under internationally accepted and recognized guidelines, specifically the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use - Good Clinical Practice (ICH-GCP) guidelines.

b. An online Clinical Trial Registry of Pakistan has been launched, providing stakeholders, researchers, and the general public with easy access to information on all DRAP-approved clinical trials. Link of the Clinical Trial Registry is https://ctr.dra.gov.pk/

   https://www.dra.gov.pk/therapeutic-goods/clinical-trials-oversight/clinical-trials-registry/

c. To ensure the safety monitoring of approved clinical trials, an email account has been created (CT_AE.reporting@dra.gov.pk), which is dedicated for reporting of Adverse Drug Reactions (ADR) and Serious Adverse Events (SAE) by sponsors and Principal Investigators (PIs) to DRAP.

d. Regular capacity building of relevant staff dealing with clinical trials oversight and conduction of GCP inspections.

Available Resources:

Clinical Research Section, Pharmacy Services Division has developed resources related to clinical trial operations in the country and are available on DRAP's official website. We encourage and appreciate stakeholders, sponsors, researchers, and the general public to explore the following links and resources to stay informed and engage with the regulatory control of clinical trials in Pakistan

- **The Bio-Study Rules, 2017**

https://www.dra.gov.pk/about-us/legislation/rules/#CTRules

- **Guidance on Clinical Trial Document**

https://www.dra.gov.pk/wp-content/uploads/2022/05/Guidelines-on-Clinical-Trial-Applications-For-Applicants.pdf

- **Online application form and their Checklists:**

https://www.dra.gov.pk/publications/application-forms/#CT

- **Application processing flow charts with time lines**

https://www.dra.gov.pk/therapeutic-goods/clinical-trials-oversight/application-process/

- **List of all approved CTS, CROs, BA/BE Studies Center & Bio-Analytical Laboratories**

https://www.dra.gov.pk/therapeutic-goods/clinical-trials-oversight/cros-and-be-centers/

- **list of Rejected applications for clinical trials is also uploaded regularly.**

https://www.dra.gov.pk/rejected-clinical-trials-applications/

- **ADR/SAE Reporting (Official Email address for reporting):**

https://www.dra.gov.pk/therapeutic-goods/clinical-trials-oversight/serious-adverse-event-in-clinical-trials/

- **ICH-GCP Guidelines for GCP Compliance & Inspection:**

https://www.dra.gov.pk/therapeutic-goods/clinical-trials-oversight/gcp-inspections/

Globally, Clinical Research is multibillion dollars industry and also has huge potential and opportunities for Pakistan. It is direly needed to further develop national clinical research ecosystem by enhancing technical and regulatory capacity as per international best practices and improved clinical research infrastructure. Aforementioned measures will not only improve health care system of the country by introduction of new clinical interventions, the earliest availability of therapeutic goods, evidence based regulatory decisions but will also contribute to the economic wellbeing of the country. DRAP appreciates support of all stakeholder and believe that with our mutual efforts, clinical research network of the country will be further improved and will put Pakistan at international canvass of clinical trials.

Dr Obaidullah,
Chairman Clinical Studies Committee

PICTURE GALLARY

H.E. Mr. Andrei METELITSA, Ambassador for Belarus in Pakistan called upon Mr. Asim Rauf, CEO DRAP in his office at Islamabad.

CEO DRAP Mr Asim Rauf and Vice Chancellor University of Medical Sciences Lt Gen Wasim Alamgir HI(M) discussed the establishment of clinical trial units at Military Hospitals, CMH, and Bio-Analytical Lab in NUMS.

Delegates from the Regulatory Authorities of Kenya, Nigeria, and Ethiopia called upon CEO DRAP Mr Asim Rauf at Pakistan's Engineering and Healthcare Show Lahore.

ڈرگ ریگولیٹری اتھارٹی آف پاکستان
منسٹری آف نیشنل ہیلتھ سروسز ریگولیشنز اینڈ کوآرڈینیشن

سہ ماہی

ڈریپ نیوز لیٹر

جون ۲۰۲۳
والیم ۱
شمارہ ۳

وزیر صحت جناب عبدالقادر پٹیل اور چیف ایگزیکٹو آفیسر ڈریپ عاصم رؤف نے ریاست ہائے متحدہ امریکہ کی فوڈ اینڈ ڈرگ ایڈمنسٹریشن کی دعوت پر امریکہ کا دورہ کیا۔ اس ملاقات کے لیے یو ایس فارماکوپیا نے معاونت کی۔

وزیر صحت عبدالقادر پٹیل کی واشنگٹن میں فوڈ اینڈ ڈرگ ایڈمنسٹریشن کے اعلی عہدیداروں سے ملاقات۔ میٹنگ میں چیف ایگزیکٹیو آفیسر ڈریپ عاصم رؤف بھی موجود تھے۔ ملاقات میں پاکستان کی ڈرگ ریگولیٹری اتھارٹی کی تکنیکی معاونت اور باہمی دلچسپی کے امور پر تبادلہ خیال کیا گیا۔

دورے کے دوران چیف ایگزیکٹیو آفیسر ڈریپ عاصم رؤف نے یو ایس فارماکوپیا کے اعلیٰ عہدیداروں سے بھی ملاقات کی۔

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سیکریٹری منسٹری آف نیشنل ہیلتھ سروسز اینڈ کوآرڈینیشن

مدیر اعلیٰ: عاصم رؤف
چیف ایگزیکٹیو آفیسر ڈریپ

مدیر: ڈاکٹر اختر عباس خاں
ڈائریکٹر لائسنسنگ

کسی بھی سوال، تبصرے یا اپنی قیمتی رائے سے نوازنے کے لیے رابطہ کریں۔
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