INSTITUTE OF BIOLOGICAL, BIOCHEMICAL & PHARMACEUTICAL SCIENCES (IBBPS)

DOW UNIVERSITY OF HEALTH SCIENCES

STRATEGIC PLAN

(2024 – 2027)

Pioneering Excellence | Inspiring Innovation

To Heal | To Educate | To Discover


بِسْمِ اللَّهِ الرَّحْمَٰنِ الرَّحِيمِ

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EXECUTIVE DIRECTOR'S MESSAGE

As the Executive Director of IBBPS, I am deeply proud to share our incredible journey in clinical research, a journey marked by innovation, dedication, and a relentless commitment to excellence. Since our founding in 2013, IBBPS has grown into a leading force in bioequivalence studies, clinical trials, analytical testing, and contract research, serving national and international clients with unwavering integrity.

From being the first in Pakistan to conduct Phase I-IV clinical trials to meet the rigorous standards of DRAP as a licensed Contract Research Organization, Bioequivalence & Bioavailability studies provider, and Analytical Laboratory, our team's tireless efforts have paved the way for breakthroughs that elevate patient care and foster advancements in global health.

Yet, as proud as we are of what we have accomplished, our journey has only begun. Today, we stand on the threshold of an exciting new chapter, setting our sights on goals to further amplify our impact on the world stage.

With unwavering determination, we are working toward securing WHO prequalification for our Quality Control Laboratory and CRO by 2025, a prestigious milestone that will bolster our reputation on national and international fronts and allow us to take on high-impact studies that change lives. In partnership with USP, we are also pursuing a groundbreaking initiative to bring purity and impurity standards for APIs and additives to Pakistan—a dream the local industry has held for decades. Expanding our volunteer bed capacity for BE/BA studies is yet another bold step toward fulfilling our commitment to the highest standards of research excellence.

To thrive in an evolving landscape, we are expanding our presence in the global markets and forging stronger bonds with leading pharmaceutical companies, international research organizations, and academic institutions. These partnerships will enable us to undertake a prime role in pioneering research and building a sustainable ecosystem that transcends borders.

Together, we are charting a course for a healthier, more innovative future!

Dr. Izhar Hussain

DIRECTOR'S MESSAGE :

We have established a contract research organization, a bioequivalence studies center, and clinical trial sites to facilitate the pharmaceutical industries. These state-of-the-art facilities comply with the WHO and the International Council of Harmonization (ICH) Standards.

These facilities play a significant role in improving patient health by providing quality research services in Pakistan. We have an experienced and well-trained faculty as per ICH Good Clinical Practice and Good Laboratory Practice guidelines for executing clinical research tasks with a high standard of data integrity using Electronic Data Capturing tools.

In the next three years, I envision the IBBPS extending its services on international forums and becoming a leading Bioequivalence study center & CRO in Pakistan with state-of-the-art and purposely built Clinical Research facilities at Dow University of Health Sciences. The progress and future direction of the IBBPS of DUHS as a leading institution in healthcare research, we are committed to advancing global health through cutting-edge clinical research, innovation, and collaboration.

We will actively pursue strategic international collaborations over the next three years to trigger innovation and share knowledge creation. By fostering working relationships with world-renowned research centers and healthcare organizations, we aim to bring new opportunities to our institute and further enhance our capacity for conducting high-quality clinical trials that address the locally relevant health challenges worldwide.

Our commitment to scientific excellence, ethical standards, and impactful research remains steadfast. Together, we will continue to push boundaries, foster innovation, and improve global health outcomes. I look forward to working with all of you to achieve these ambitious goals and to taking IBBPS of DUHS to new heights in the years ahead.

Dr. Sadia Noor

EXECUTIVE SUMMARY:

This Strategic Plan spans from 2024 to 2027 for the Institute of Biological and Biochemical & Pharmaceutical Sciences (IBBPS) and is the outcome of meticulous strategic planning for the next two years. This plan is crafted to propel the IBBPS towards a heightened level of excellence in clinical research, public health, and service provision. The plan was prepared using a participatory approach by engaging input from the IBBPS technical staff. The valuable contributions of these stakeholders, particularly in the collection of strengths, weaknesses, opportunities, and threats, were an integral part of this process.

With a committed vision of ascending to the forefront as a leading Contract Research Organization (CRO), Clinical Trial Site, Bio-analytical & QC Testing Lab and Bioequivalence Study Center, the IBBPS team is resolute in building upon its current achievements while remaining cognizant of potential challenges and areas for improvement.

Aligned with the purpose statement of the IBBPS-DUHS, five strategic focal goals have been delineated for the advancement of the IBBPS.

1) To become an Authorized USP Reference standard supplier in Pakistan by Q2-2025

   - Establish IBBPS as a trusted supplier of USP reference standards, ensuring a high-quality and reliable pharmaceutical testing center in Pakistan by 2025

2) To Expand Service Offerings by adding new technologies in the Pharma Lab & establishing a microbiology lab by Q2-2027, leading to a 40% increase in the business of the Quality Control Lab.

3) To become a WHO Prequalification Quality Control Lab by Q2-2025 to complement the client's confidence in achieving a greater than 50% increase in the business of Quality Control Lab & BE studies.

4) To Strengthen Research and Clinical Trial Capabilities by Q4-2026 to conduct at least two (02) clinical trial & bioequivalence studies at DUHS.

5) To Enhance Marketing and Global Presence by Q4-2026 in order to grab a place among the Top 50 CROs across the Globe by Q4-2027.

To achieve the above goals, the department is focusing on the global availability of IBBPS-DUHS and enlightening its presence by establishing international collaborations with clients or forums and participating in CPHI as a visitor to nominate the DUHS in promoting clinical research and contributing to the healthcare sector.

ABOUT THE INSTITUTE:

Dow Institute of Biological, Biochemical & Pharmaceutical Sciences (IBBPS) is a Drug Regulatory Authority of Pakistan (DRAP) Licensed Contract Research Organization (CRO) and Bioequivalence Study Center of Pakistan; it is part of a well-renowned and world-class healthcare organization "Dow University of Health Sciences", one of the biggest stakeholders in the country's health care sector.

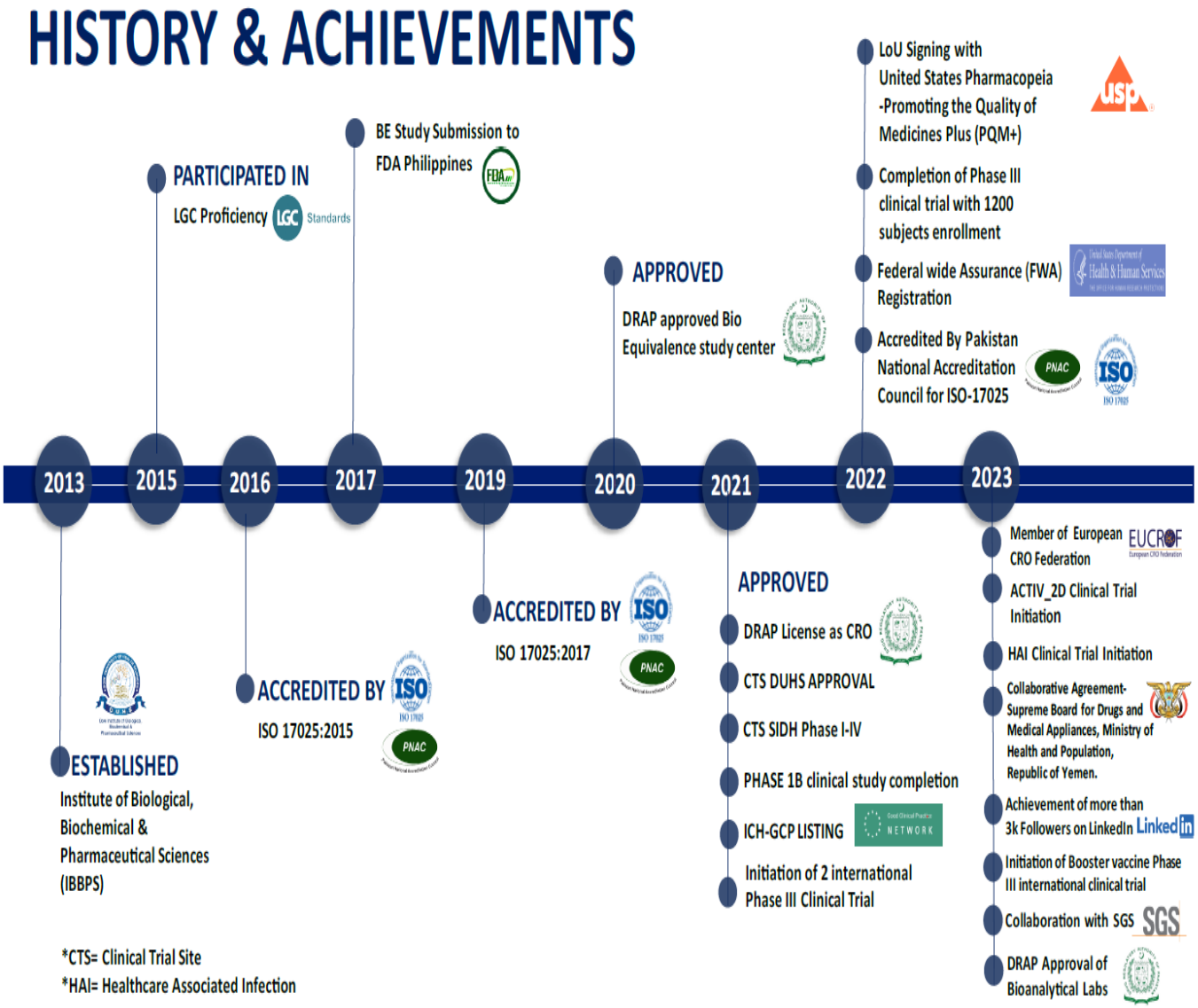
This institute was founded in 2013, and with continuous efforts and hard work of the team, the IBBPS got different licenses from DRAP such as CRO, BA/BE study, and the Bio-analytical laboratory to serve our local and international clients.

IBBPS is a part of tertiary care hospitals, and it is associated with state-of-the-art ISO 17025 PNAC certified Bio-analytical Lab facility, ISO 15189 Certified Diagnostic Lab, Radiology, ICU, Behavioral Sciences, Life Sciences, Animal House for Pre-clinical studies, renal, liver & bone marrow transplantation center, oncology department, and many more facilities available under the umbrella of Dow University of Health Sciences.

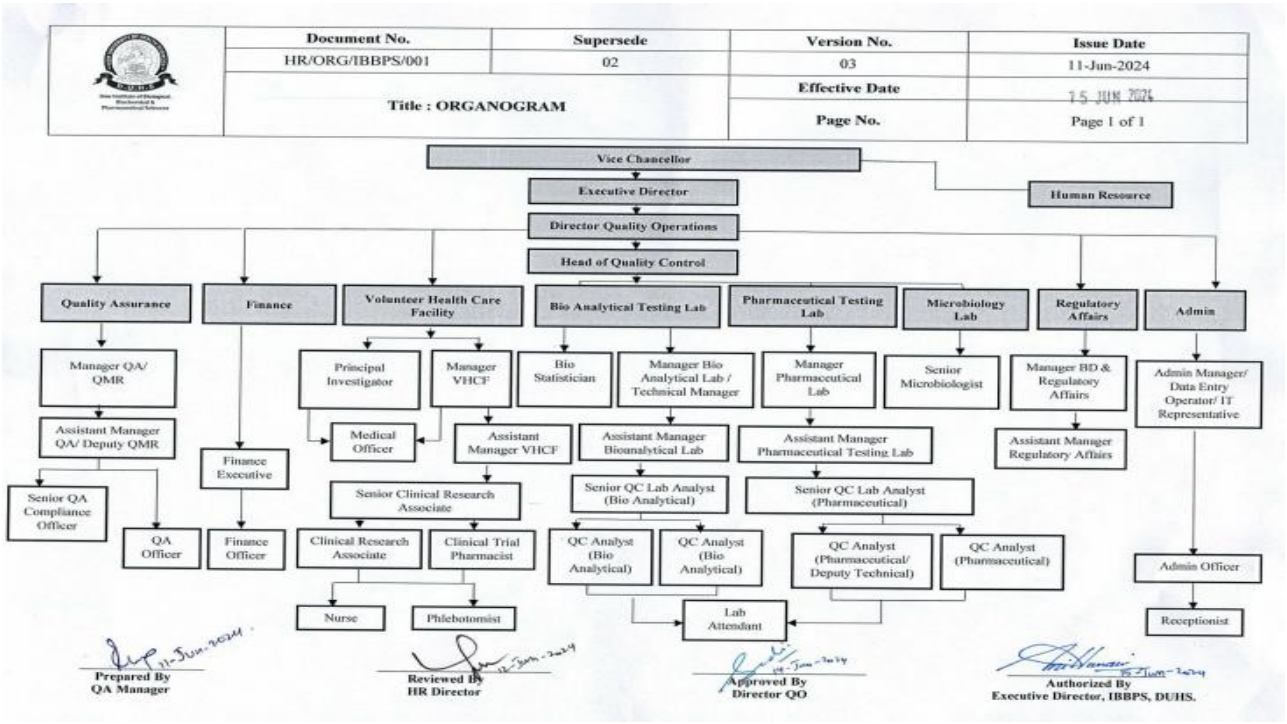
IBBPS has a foreign-trained & experienced clinical and analytical team with deep knowledge of international and national standards to execute the clinical studies at DRAP-approved trial sites located at Dow University Hospital (Ojha campus) and Sindh Infectious Disease Hospital (near NIPA).

INTRODUCTION & OVERVIEW

The Dow Institute of Biological, Biochemical & Pharmaceutical Sciences (IBBPS) is a DRAP-licensed Contract Research Organization (CRO) and Bioequivalence Study Centre operating under the prestigious Dow University of Health Sciences (DUHS). As a key player in Pakistan's healthcare sector, DUHS is renowned for its commitment to excellence, innovation, and world-class research standards. IBBPS upholds these values by providing cutting-edge research and regulatory-compliant services, contributing to the advancement of pharmaceutical sciences in the country.



ORGANOGRAM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Effective Date
15 JUN 2024
Page No.
Page 1 of 1
Vice Chancellor
Executive Director
Human Resource
Director Quality Operations
Head of Quality Control
Quality Assurance
Finance
Volunteer Health Care Facility
Bio Analytical Testing Lab
Pharmaceutical Testing Lab
Microbiology Lab
Regulatory Affairs
Admin
Manager QA/ QMR
Assistant Manager QA/ Deputy QMR
Senior QA Compliance Officer
QA Officer
Finance Executive
Finance Officer
Principal Investigator
Manager VHCF
Medical Officer
Senior Clinical Research Associate
Clinical Research Associate
Clinical Trial Pharmacist
Nurse
Phlebotomist
Bio Statistician
Manager Bio Analytical Lab / Technical Manager
Assistant Manager Bioanalytical Lab
Senior QC Lab Analyst (Bio Analytical)
QC Analyst (Bio Analytical)
QC Analyst (Bio Analytical)
Lab Attendant
Manager Pharmaceutical Lab
Assistant Manager Pharmaceutical Testing Lab
Senior QC Lab Analyst (Pharmaceutical)
QC Analyst (Pharmaceutical/ Deputy Technical)
QC Analyst (Pharmaceutical)
Senior Microbiologist
Manager RD & Regulatory Affairs
Assistant Manager Regulatory Affairs
Admin Manager/ Data Entry Operator/ IT Representative
Admin Officer
Receptionist
Prepared By
QA Manager
Reviewed By
HR Director
Approved By
Director QO
Authorized By
Executive Director, IBBPS, DUHS.

ORGANIZATIONAL STRUCTURE

CURRENT STAFF of IBBPS:

Designation	No of Staff
Executive Director	01
Director	01
Managers	06
Head of Quality Control	01
Manager Regulatory Affairs & Business Development	01
Business Development Executive	01
Clinical Research Associate	06
Clinical Research Coordinator	05
Clinical Research Pharmacist	02
Data Entry Operator	02
Finance Executive	01
Pharmacovigilance	01
Medical Officer	02
Data Management & BD Officer	01
Quality Assurance Officer	01
Regulatory Affairs Officer	01
Asst. Manager QC	02
QC Analyst	04
Research Associate	04
Senior Scientist (Microbiology)	01
Lab Attendant	01
Receptionist	02
Messenger	02
Ambulance Driver	01
Total	**50**

QUALITY POLICY

- To provide high-quality services to the customers including clinical research, analytical testing, bioequivalence studies, and other technical testing services, in compliance with QMS procedures, ISO 17025:2017 standards, WHO Prequalification guidelines, and applicable regulatory requirements.
- To achieve customer satisfaction by conforming to customers' legitimate needs, requirements, and intended use.
- To follow good professional practices, maintaining impartiality and confidentiality results in freedom from any influence.
- To ensure Continuous training and improvement programs for the improvement of staff competencies.

FACILITIES:

BIOEQUIVALENCE STUDY CENTRE

The BA/BE facilities of IBBPS are unique in Pakistan as it is part of a leading medical university of Pakistan that can provide one-window services as per WHO, International Council of Harmonization (ICH), and FDA standards.

BIOEQUIVALENCE STUDIES

Bioequivalence "or "BE" means bio-equivalence phenomenon, according to which two medicinal products containing the same pharmaceutical formulation and quantity of the same active ingredient, are considered bioequivalent if they are pharmaceutically equivalent and their bio-availabilities, in terms of rate and extent, after administration in the same molar dose, lie within acceptable predefined limits. The study/assess the bioequivalence of a generic product with the reference product, is termed a bioequivalence study.

BIOAVAILABILITY STUDIES

Bioavailability is the fraction of unchanged drugs reaching systemic circulation after administration by any route. The assessment of the bioavailability of any product is termed a bioavailability study.

The BA/BE Center comprises the following state-of-the-art sections:

Volunteers Healthcare Facility (VHCF):

This facility established spacious rooms and facilities under the supervision of medical doctors as Clinical Research Coordinators and other delegated study staff. VHCF has the following facilities & Services:

- Drug Administration Area.
- Sample Collection Area.
- Dedicated Informed Consent Area.
- Volunteer Confinement Area: Fully air-conditioned rooms with a nurse-calling system.

- A well-equipped access-controlled Pharmacy for the storage of investigational drug products.
- Sample processing room equipped with Refrigerated Centrifuge, -20◦C and -80◦C ultra-low freezers.
- Entertainment Area for the entertainment of subjects i.e. equipped with LCD televisions, indoor games with wi-fi internet access.
- Access control archive room.
- VHCF is also located near a fully equipped Intensive Care Unit (ICU).
- Emergency Management Room
- Availability of ambulance at the study site.
- CCTV cameras for 24 hours. Security and safety monitoring throughout the trial.

Bioanalytical Lab:

The bioanalytical laboratory of IBBPS is established as per the WHO, ICH, DRAP, and FDA guidance and is ISO 17025 PNAC accredited. The lab is equipped with modern technologies. The equipment of the Bioanalytical Laboratory is capable of accurate Quantitation and Quantification of drug molecules in biological matrices. To ensure compliance with Good Laboratory Practices, a well-structured quality management system is in place. The bioanalytical lab is comprised of the following sections:

- Sample receipt desk.
- Plasma Extraction Area.
- LCMS/MS & HPLC Instrumentation lab.
- Wet Lab.
- Chemical storage room.
- Reference Standard storage room.

QUALITY CONTROL LABORATORY:

The Quality Control Laboratory of IBBPS is equipped with sophisticated analytical technologies including Liquid Chromatography, Gas Chromatography, Mass Spectrometry, Elemental Analysis, Atomic Absorption Spectrometry, IR, and Spectroscopy to provide highly sensitive and accurate qualitative & quantitative analytical services to the pharmaceutical industry for the improvement of quality of medicinal products in the country.

Our strengths in assessing existing method validation, identifying gaps, and validation remediation or improvement planning are coupled with vast method optimization experience for many sample types, helping to ensure successful validation as the analytical method development and validation are critical to pharmaceutical development.

The Quality Control lab comprises the following sections:

- Sample Receipt Desk.
- Sample Preparation Area
- Wet Chemistry Lab

- Instrumentation Lab
- Chemical Storage Room
- Reference Standard Storage Room

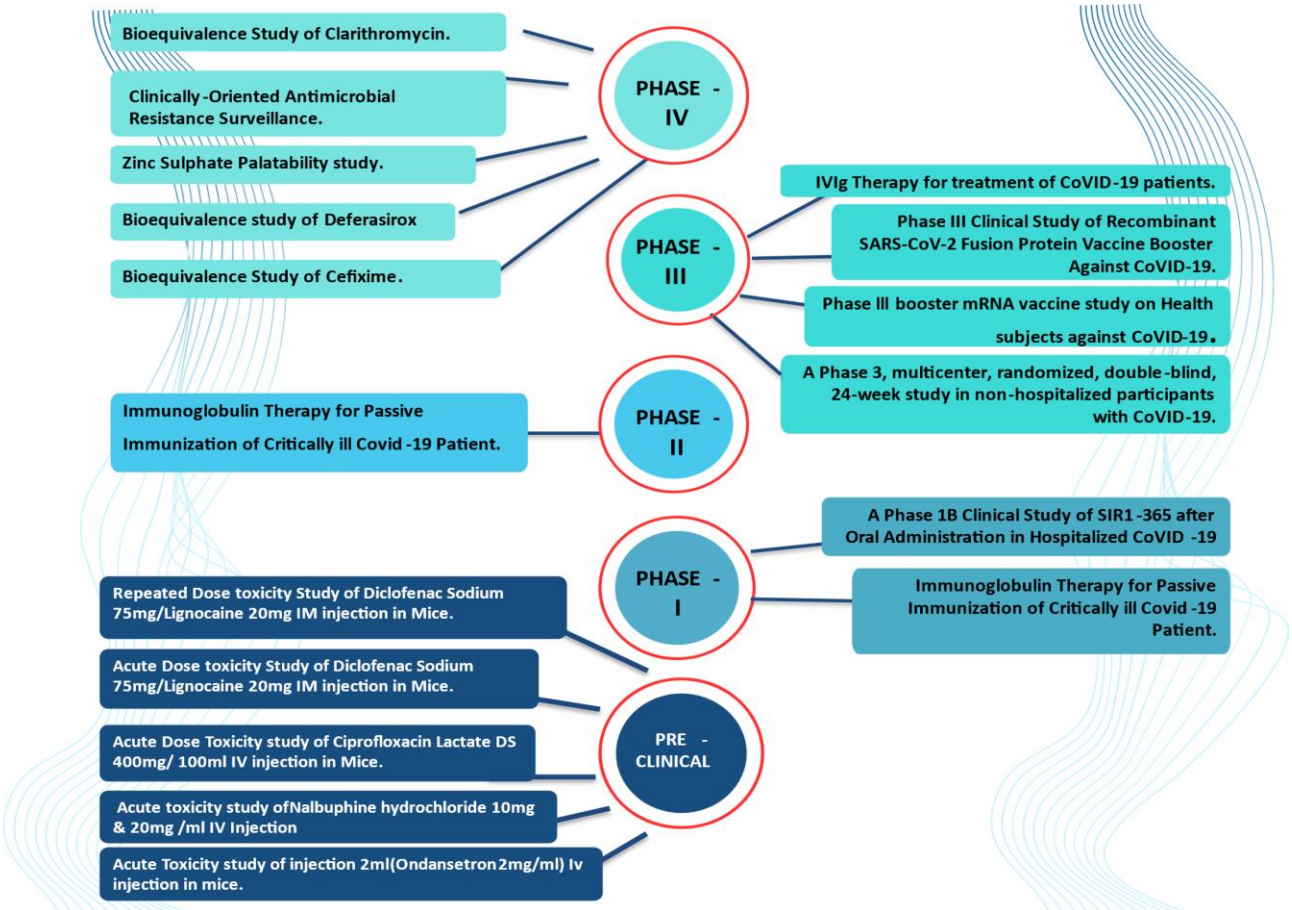
CLINICAL TRIAL SITES:

We offer our clients a flexible, tailored approach to achieving their specific study needs. IBBPS has two (02) Drug Regulatory Authority of Pakistan-approved Clinical Trial Sites to conduct Phase I to Phase IV clinical trials over a wide range of therapeutic areas and medical specialties.

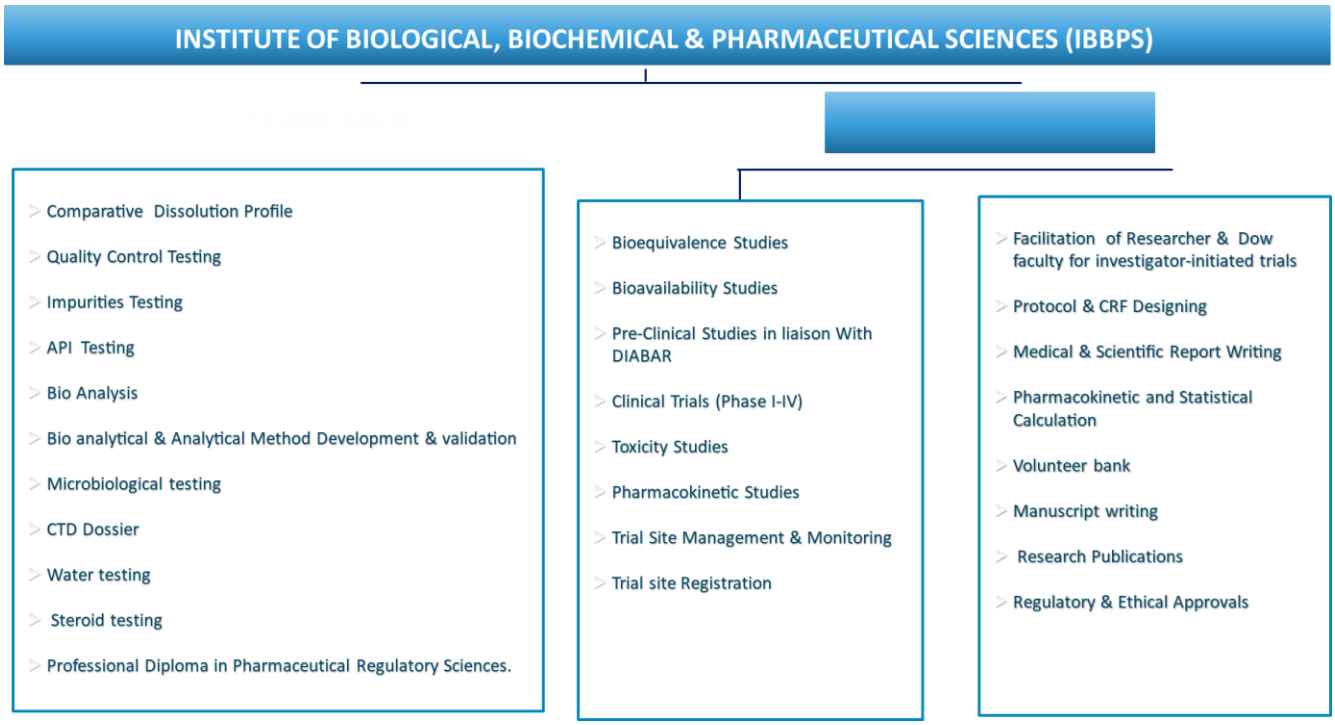
We intend to design, conduct, record, analyze, and publish clinical trials as per ICH-GCP and the Declaration of Helsinki to facilitate the global pharmaceutical industry to bring innovation to the healthcare system.

The DUHS & SIDH&RC Clinical trial sites of IBBPS have conducted the following studies:

Study Experience:



SERVICES


INSTITUTE OF BIOLOGICAL, BIOCHEMICAL & PHARMACEUTICAL SCIENCES (IBBPS)
Comparative Dissolution Profile
Quality Control Testing
Impurities Testing
API Testing
Bio Analysis
Bio analytical & Analytical Method Development & validation
Microbiological testing
CTD Dossier
Water testing
Steroid testing
Professional Diploma in Pharmaceutical Regulatory Sciences.
Bioequivalence Studies
Bioavailability Studies
Pre-Clinical Studies in liaison With DIABAR
Clinical Trials (Phase I-IV)
Toxicity Studies
Pharmacokinetic Studies
Trial Site Management & Monitoring
Trial site Registration
Facilitation of Researcher & Dow faculty for investigator-initiated trials
Protocol & CRF Designing
Medical & Scientific Report Writing
Pharmacokinetic and Statistical Calculation
Volunteer bank
Manuscript writing
Research Publications
Regulatory & Ethical Approvals

CERTIFICATIONS AND ACCREDITATIONS

SECTION I: OVERVIEW OF THE STRATEGIC PLANNING PROCESS

The strategic planning process at Dow Institute of Biological Biochemical & Pharmaceutical Sciences (IBBPS) is designed to propel the IBBPS towards a heightened level of excellence in clinical research, public health, and service provision. It begins with aligning the objectives of IBBPS with the mission & vision of DUHS and setting of the purpose statement of IBBPS. The plan was prepared using a participatory approach by engaging inputs from the IBBPS technical staff. The valuable contributions of these stakeholders, particularly in the collection of strengths, weaknesses, opportunities, and threats, were an integral part of this process.

Key priorities include expand service offerings, WHO Prequalification of Quality Control Lab, expanding the presence in the global markets and forging stronger bonds with leading pharmaceutical companies, international research organizations, and academic institutions, strengthen Research and Clinical Trial Capabilities.

Progress will be tracked through key performance indicators (KPIs) to allow timely adjustments. With a strong focus on sustainability, innovation, and quality research services, the strategic plan ensures IBBPS continued excellence in clinical research for achieving the ultimate objective of patient care.

SECTION II: VISION, MISSION & VALUES

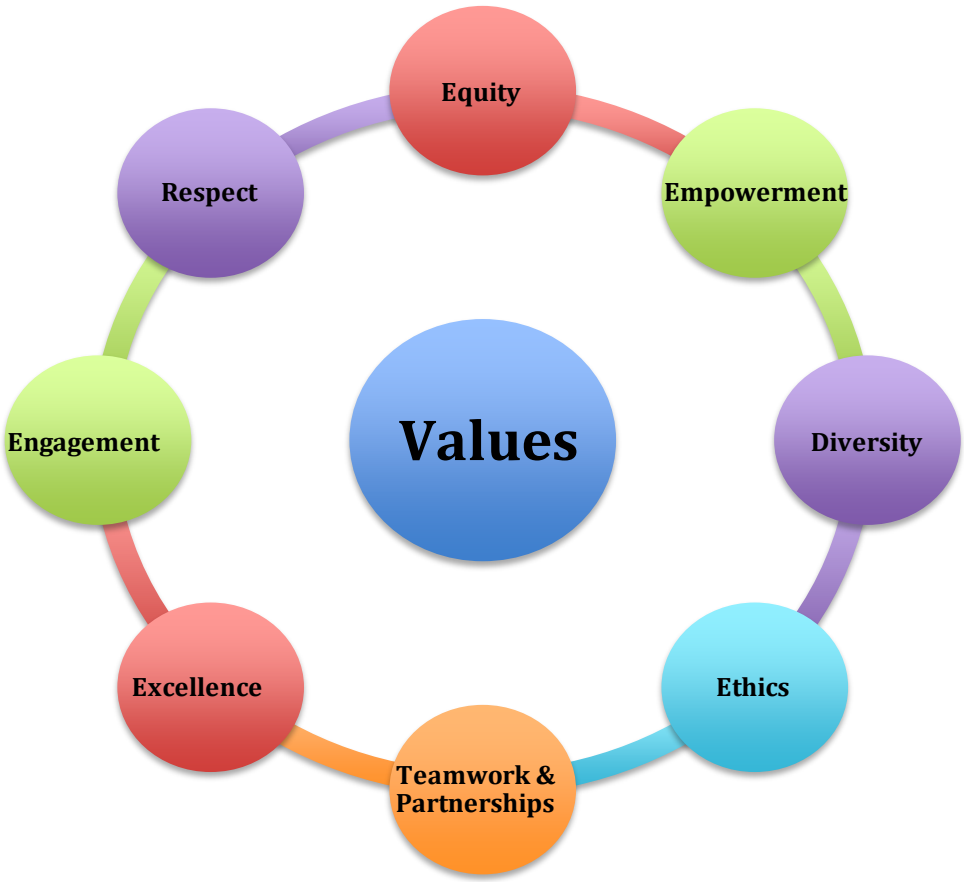
VISION:

To be a pre-eminent academic institution committed to changing and saving lives.

MISSION

Providing outstanding patient-centered education, training, and clinical care informed by cutting-edge research and innovation, generating and disseminating new knowledge.

VALUES



VALUES

Customer Service

- Put patients & students first.

Empathy & Compassion

- Understand before you judge.
- Be concerned for the sufferings & misfortunes of others.

Excellence

- Be the best and commit to exceptional quality and service.

Innovation

- Encourage curiosity, imagine, create, and share.

Teamwork

- Engage & collaborate.

Integrity & Leadership

- Be a role model and influence others to achieve their best. Have the courage to do the right thing.
- Hold yourself and others accountable.

Respect & Collegiality

- Be kind.
- Listen to understand.
- Value different opinions.

STATEMENT OF PURPOSE

We are committed to fostering breakthrough development in health care by enabling our clients to navigate the complexities of drug discovery, development, and commercialization.

SECTION III: ASPIRATIONAL INSTITUTIONS

SYNEOS HEALTH

Syneos Health® is a leading fully integrated biopharmaceutical solutions organization built to accelerate customer success. Syneos Health is currently based in Morrisville, North Carolina, United States. They translate unique clinical, medical affairs, and commercial insights into outcomes to address modern market realities.

Syneos Health® works across more than 110 countries, with a deep understanding of patient and physician behaviors and market dynamics. Syneos Health® uses the latest technologies and applies advanced business practices to speed the customers' delivery of important therapies to patients.

Syneos Health supports a diverse, equitable, and inclusive culture that cares for colleagues, customers, patients, communities, and the environment.

Solutions offered by Syneos Health include:

- Decentralized Clinical Trials Solutions
- Bioanalytical Solutions
- Early Phase
- Phase II-III/Phase IIIb-IIIV
- Late Phase
- Medical Device
- Clinical Data Management
- Clinical Project Management
- Clinical Monitoring
- Drug Safety & Pharmacovigilance
- Site and Patient Access

The rationale to select:

- Syneos Health is one of the top 50 CROs across the Globe.
- Services offered by Syneos Health are quite like the services/solutions offered by IBBPS-DUHS.
- Currently, it's working across 110 countries by taking Syneos Health as an aspirational institute. We will learn how to operate in global markets.

Adopting the collaborative approach of Syneos Health, which focuses on partnering with all stakeholders and delivering diversified services, presents a significant growth opportunity for IBBPS. By embracing this model, IBBPS can strategically expand its network with global clinical trial sites, Principal Investigators, and Contract Research Organizations, strengthening its position as a leader in clinical research.

Furthermore, by adopting Syneos Health's decentralized clinical trial model and advanced data management practices, IBBPS can effectively reach and serve clients in emerging markets. This approach will enable us to conduct more accessible, flexible, and inclusive trials, fostering innovation and improving outcomes in diverse healthcare landscapes.

PAREXEL

Parexel is among the world's largest clinical research organizations (CROs), It is an American dedicated CRO providing the full range of Phase I to IV clinical development services to help lifesaving treatments and leveraging the breadth of clinical, regulatory, and therapeutic expertise, a team of more than 21,000 global professionals works in partnership with biopharmaceutical leaders and sites to design and deliver clinical trials with patients in mind, to make clinical research a care option for anyone, anywhere.

Solutions offered by Paraxel:

- Clinical trial design and development for early phase, phase 2 & 3, and late phase clinical trials
- Clinical data management
- Decentralized clinical trials
- Clinical supply chain management
- Medical writing
- Regulatory affairs consulting
- Pharmacovigilance
- Biostatics

The rationale for selecting:

- Parexel is considered the best CRO in the world.
- Parexel has a presence in all regions of the world with more than 63 offices across Globe.
- In addition, a vast variety of services are offered by Parexel, it also provides all those services that are offered by IBBPS.

Parexel is a well-structured CRO with a strong presence across various regions and an extensive network of sites worldwide. It supports sponsors globally by providing regulatory consultation, clinical trial supply, and logistics management. By adopting a similar model, IBBPS can offer tailored services to meet the local needs of clients and sponsors, making Pakistan an attractive destination for global sponsors.

Moreover, Real World Evidence (RWE), derived from Real World Data (RWD), is a key focus for Parexel, bridging the gap between drug developers and Key Opinion Leaders (KOLs). IBBPS can establish its own Real World Data sets by collaborating with DUHS faculty and utilizing the electronic medical records (EMR) already implemented at DUHS. This initiative will position IBBPS to attract interest from global sponsors, demonstrating its commitment to advancing research through robust, data-driven insights.

SECTION IV: STRATEGIC GOALS

Goal 1: **To become an Authorized USP Reference Standard Supplier in Pakistan by Q2-2025.**

Objective 1: Agreement with USP to become a local Distributor in Pakistan by Q3-2024

Objective 2: Market awareness of local USP distributors by Q1-2025

Goal 2: **Expand lab services with new technologies to drive growth and improve quality control.**

Objective 1: Establish the Medical Devices Testing Lab for European Conformity CE Marking Body. (Notified Body for NANDOS Countries) by Q2-2026.

Objective 2: Expansion of the scope of the Pharmaceutical Testing lab by adding new technologies by Q2-2025.

Objective 3: Establishment of a Microbiology Lab to support Pharma industry by Q2-2027.

Goal 3: **Achieve WHO Prequalification to enhance client confidence and drive business growth.**

Objective 1: Scope Enhancement of ISO 17025:2017 accreditation for IBBPS Lab by Q2-2024.

Objective 2: Participation in Proficiency Testing by LGC UK every year.

Objective 3: Achieving WHO Pre-Qualification Status through Successful Inspection by Q4-2024.

Objective 4: Development and Implementation of a Software-Based Digitalized Environment for the Quality Control Lab by Q4-2024.

Goal 4: **Enhance research and clinical trial capacity to conduct trials and bioequivalence studies.**

Objective 1: Training (GxP, TCPS2, ACRP & Lead Auditor ISO 17025) of IBBPS Team till Q3-2025.

Objective 2: Training of technical team from International BE Study Centers of Jordan or Malaysia by Q2-2026.

Objective 3: To initiate and prepare registries for disease data at DUHS by Q4-2026.

Objective 4: To facilitate DUHS investigators to provide scientific support by Q3-2025.

Objective 5: Create awareness of Bioequivalence Studies, Preclinical studies, and clinical studies among all stakeholders by doing at least 02 conferences/ year.

Objective 6: Establishment of purposely built facilities of IBBPS at the same place by Q3-2027.

Goal 5: Strengthening marketing and global presence to position among the top 50 CROs worldwide.

Objective 1: Participation in at least 02 international conferences or exhibitions every year.

Objective 2: WHO Prequalification of IBBPS CRO till Q4-2026.

Objective 3: To connect with 10 international clients for multicenter trials per year.

Objective 4: Expansion of Clinical Trial Network with at least 03 Hospitals in the region and collaboration with at least 02 International Clinical Trial Sites till Q3-2025.

Objective 5: Become an approved Bioequivalence study center/ CRO in Malaysia NPRA as it is a PIC/s member country & GCC till Q2-2026.

Objective 6: Be listed or registered with 04 International CRO Associations & forums to enhance the presence of IBBPS on influential platforms of target markets (i.e. North America, Europe & China) by Q1 2026.

OBJECTIVES, OKRs & KPIs

<table>
<tr><td colspan="8">Goal 01: To become an Authorized USP Reference Standard Supplier in Pakistan</td></tr>
<tr><td colspan="8">Goal Statement: Establish IBBPS as a trusted supplier of USP reference standards, ensuring high-quality and reliable pharmaceutical testing center in Pakistan by 2025</td></tr>
<tr><td colspan="8">Objectives & Key Results (OKRs)</td></tr>
<tr><td colspan="8">Objective 1: Agreement with USP to become a local Distributor in Pakistan by Q3-2024</td></tr>
<tr><th>Objective</th><th>Key Results</th><th>KPI</th><th>Measurement Method</th><th>Target</th><th>Person Responsible</th><th>Resource Requirement</th><th>Timeline</th></tr>
<tr><td rowspan="4">Agreement with USP to become a local Distributor in Pakistan by Q3-2024</td><td>KR1: Approval from VC by Q2-2024</td><td>KPI 1: Approval from VC for establishment of specific reference standard storage area by Q2-2024.</td><td rowspan="2">Physical availability of the storage area</td><td>Readiness of Storage Area</td><td>Director Office</td><td rowspan="4">Human Resources:
Full-time Business Executive
Full-Time Project Manager

Equipment:
01 Pharmaceutical Refrigerator
01 (-20°C) freezer
03 Laptops
Temp & Humidity Monitoring System
Air conditioners
UPS
Backup Power Supply

Space:
Space is available to maintain operations for around 2 to 3 years. Infrastructure will be required</td><td>Completed in Q3- 2024</td></tr>
<tr><td>KR2: Familiarize ourselves with the specific requirements outlined by the United States Pharmacopeia (USP) for becoming a supplier of reference standards</td><td>KPI 2: Establishment of specifically designated area for storage of USP reference standards by Q3-2024</td><td rowspan="3">IBBPS as USP RS Distributor</td><td>Head of QC</td><td>Completed in Q3- 2024</td></tr>
<tr><td rowspan="2">KR3: Development & approval of Layout for Storage Area</td><td>KPI 3: Agreement with USP to become a local distributor in Pakistan by Q4-2024.</td><td rowspan="2">Signed agreement with USP</td><td>Director Office</td><td>Q1 – 2025 Initiated</td></tr>
<tr><td>KPI 4: Development & approval of Layout for Storage Area by Q4-2024</td><td>Director Office</td><td>Completed in Q3- 2024</td></tr>
<tr><td colspan="8">Objective 2: Market awareness of local USP distributors by Q1-2025</td></tr>
<tr><th>Objective</th><th>Key Results</th><th>KPI</th><th>Measurement Method</th><th>Target</th><th>Person Responsible</th><th>Resource Requirement</th><th>Timeline</th></tr>
<tr><td>Market awareness of local USP distributors by Q1-2025</td><td>KR1: Consolidate the list of required reference standards as per the demand by Q1-2025</td><td>KPI 1: Information from Industry for RS import data in Pakistan for the last three years by Q1-2025.</td><td>Positive growth of the business</td><td>Identification of Potential Clients</td><td>Regulatory & BD</td><td>Human Resources:
Full-time Business Executive
Full-Time Project Manager

Equipment:
01 Pharmaceutical Refrigerator
01 (-20°C) freezer
03 Laptops
Temp & Humidity Monitoring</td><td>Q1 – 2025 initiated</td></tr>
</table>

	KR2: Intimate to Pharma Industry and raise Material request to USP	KPI 2: Market awareness as local USP distributors by Q1-2025	Positive growth of the business	Awareness among the Pharma industry that IBBPS is RS distributor	Regulatory & BD	System Air conditioners UPS Backup Power Supply **Space**: Space is available to maintain operations for around 2 to 3 years. Infrastructure will be required	Q1 – 2025 initiated
	KR3: Involve the Marketing Dept in initiating different strategies to catch the market in the presence of available competitors	KPI 3: Advertise in local industry for the availability of reference standards by Q1-2025	Availability of high demand standards at IBBPS-Reference standard bank	Awareness among the Pharma industry that IBBPS is RS distributor	Regulatory & BD		Q1 – 2025 initiated

Goal 02: Expand lab services with new technologies to drive growth and improve quality control.							
Goal Statement: To expand service offerings by adding new technologies in the pharma lab & establishing a microbiology lab by Q2-2027, leading to a 40% increase in the business of the quality control lab.							
Objectives & Key Results (OKRs)							
Objective 1: Establish the Medical Devices Testing Lab for European Conformity CE Marking Body. (Notified Body for NANDOS Countries) by Q2-2026							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
Establish the Medical Devices Testing Lab for European Conformity CE Marking Body. (Notified Body for NANDOS Countries) by Q2-2026	KR1: Understand the regulatory requirements for medical device testing labs set forth by the European Union's Medical Device Regulation (MDR).	KPI 1:Preparation of Feasibility Assessment Report, Availability of technical data with reference to international requirement of testing by Q4-2024	Submission of Feasibility Report to the top Management Evaluation of technical Bids and selecting the equipment	Feasibility Report submission	Regulatory & BD Head of QC	**Human Resources:** 02 Managers 02 Assistant Managers 03 Sr. QC Analyst 02 QC Analyst 02 QA Officer **Equipment:** 02 HPLC 01 UFLC 01 Dissolution apparatus (18 baskets with autosampler) 01 Particle size counter Equipment required for Medical Device testing. 01 TOC Analyzer 01 QTOF with HPLC 01 Vacuum Manifold 01 Refrigerated Centrifuge 01 Drying Oven	Q2-2026

						01 Muffle Furnace 01 Microbalance 01 Stability or Climatic chamber 02 Incubator 01 Auto clave 01 PCR with Kit **Space:** Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for Stability chamber Lab. Space for Microbiology Laboratory	

Objective 2: Expansion of the scope of the Pharmaceutical Testing lab by adding new technologies by Q2-2025							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
Expansion of the scope of the Pharmaceutical Testing lab by adding new technologies by Q2-2025	KR1: Perform a gap analysis and prepare a list of the required lab equipment	KPI 1:Submission of URS by Q4-2024	Evaluation of technical Bids and selection of the equipment	Need Assessment	Regulatory & BD & Head of QC	**Human Resources:** 02 Managers 02 Assistant Managers 03 Sr. QC Analyst 02 QC Analyst 02 QA Officer **Equipment**: 02 HPLC 01 UFLC 01 Dissolution apparatus (18 baskets with autosampler) 01 Particle size counter Equipment required for Medical Device testing. 01 TOC Analyzer 01 QTOF with HPLC 01 Vacuum Manifold 01 Refrigerated Centrifuge 01 Drying Oven 01 Muffle Furnace 01 Microbalance 01 Stability or Climatic chamber 02 Incubator 01 Auto clave 01 PCR with Kit **Space**: Space to Build purposely builds a facility of	Completed
	KR2: Preparation of URS & submit to Procurement.	KPI 2:Preparation of Tender documents by Q1-2025		Tender Publication	Regulatory & BD & Head of QC		Q1-2025 initiated
	KR3: Equipment Placement at IBBPS QC Lab	KPI 3:Installation of equipment by Q2-2025	Addition of new tests in the Service list by Q3-2025.	Upgradation of service offering	Regulatory & BD & Head of QC		Q2-2025 Not Initiated

		KPI 4: Capacity building of staff by Q2-2025	Evaluation of technical Bids and selection of the equipment	Scope enhancement	Regulatory & BD & Head of QC	IBBPS to provide all services to clients under the same roof. Space for Stability chamber Lab. Space for Microbiology Laboratory	Q2-2025 Not Initiated
Objective 3: Establishment of a Microbiology Lab to support Pharma industry by Q2-2027							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
Establishment of a Microbiology Lab to support Pharma industry by Q2-2027	KR1: Structural requirement Assessment	KPI 1:Approval by Vice Chancellor by Q2-2025	Establishment of lab	Scope enhancement	Director Office	**Human Resources:** 02 Managers 02 Assistant Managers 03 Sr. QC Analyst 02 QC Analyst 02 QA Officer **Equipment**: 02 HPLC 01 UFLC 01 Dissolution apparatus (18 baskets with autosampler) 01 Particle size counter Equipment required for Medical Device testing. 01 TOC Analyzer 01 QTOF with HPLC 01 Vacuum Manifold 01 Refrigerated Centrifuge 01 Drying Oven 01 Muffle Furnace 01 Microbalance 01 Stability or Climatic chamber 02 Incubator 01 Auto clave 01 PCR with Kit **Space**: Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for Stability chamber Lab. Space for Microbiology Laboratory	Q4-2024 Completed

Goal 03: Achieve WHO Prequalification to enhance client confidence and drive business growth.							
Goal Statement: To become a WHO Prequalification Quality Control Lab by Q2-2025 to complement the client's confidence for achieving greater than 50% increases in the business of Quality control lab & BE studies.							
Objectives & Key Results (OKRs)							
Objective 1: Scope Enhancement of ISO 17025:2017 accreditation for IBBPS Lab by Q2-2024							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
Scope Enhancement of ISO 17025:2017 accreditation for IBBPS Lab by Q2-2024.	KR1: Adding new impurities test for EG & DEG in Raw & finished drug product by Gas Chromato-graphy	KPI 1:Availability of validated test method by Q2-2024	Satisfactory Assessment by PNAC team Extended scope status update on PNAC website	Validation of ATM	QA & Head of QC	**Human Resources:** 02 Managers 02 Assistant Managers 03 Sr. QC Analyst 02 QC Analyst 02 QA Officer **Equipment**: 02 Safety Chemical storage cabinet HVAC System LIMS Software needs to develop Data Management System WinNonlin Software **Space**: Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for Chemical Storage. Space for Lab & QC record Room	Q2-2024 Completed
		KPI 2:Applied for the scope extension in PNAC and added GC EG & DEG tests by Q2-2024		Application submission to PNAC	QA & Head of QC		Q2-2024 Completed
		KPI 3: The scope of GC testing was included in the last inspection by Q2-2024		Addition of impurities in ISO 17025 Scope	QA & Head of QC		Q2-2024 Completed
		KPI 4: The lead & technical assessor have submitted the audit report to PNAC by June 2024			QA & Head of QC		Q2-2024 Completed
Objective 2: Participation in Proficiency Testing by LGC UK every year							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
Participation in Proficiency Testing by LGC UK every year.	KR1: Participation in both rounds of PT test offered by LGC UK	KPI 1:Participation in LGC, UK round PH-088 & PH-089 (One HPLC Assay and three impurities tests in Peppermint oil.) with satisfactory results by June 24	Satisfactory PT results	Successful Participation in PT	Head of QC	**Human Resources:** 02 Managers 02 Assistant Managers 03 Sr. QC Analyst 02 QC Analyst 02 QA Officer **Equipment**: 02 Safety Chemical storage cabinet HVAC System	Q2-2024 Completed

		KPI 2: Participation in DTL, Punjab round PT/ILC-005 Results satisfactory. (Analysis by UV, FTIR, DT, Weight variation & Sterility test) with satisfactory results by February & November 2024		Successful Participation in ILC	Head of QC	LIMS Software needs to develop Data Management System WinNonlin Software **Space**: Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for Chemical Storage. Space for Lab & QC record Room	Q2-2024 Completed
		KPI 3: Participation in PT program at the Industrial Analytical Center, HEJ, KU. (Assay, dissolution, Diameter, DT, Friability, Hardness, weight variation & FTIR) by Oct-2024		Successful Participation in IAEC	Head of QC		Q2-2024 Completed
Objective 3: Achieving WHO Pre-Qualification Status through Successful Inspection by Q4-2024							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
Achieving WHO Pre-Qualification Status through Successful Inspection by Q4-2024	KR1:QMS Document preparation for the Inspection	KPI 1:Review of existing approved QAQC procedures in consultation with WHO consultant by Q3-2022	LIF acceptance by WHO PQT Team	GAP Assessment	QA & QC Manager	**Human Resources**: 02 Managers 02 Assistant Managers 03 Sr. QC Analyst 02 QC Analyst 02 QA Officer **Equipment**: 02 Safety Chemical storage cabinet HVAC System LIMS Software needs to develop Data Management System WinNonlin Software **Space**: Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for Chemical Storage.	Completed
		KPI 2:Revision of procedures to comply with WHO standards. Q2-2023		Implementation in QMA as per WHO	QC Head & QA Manager		Completed
		KPI 3:Prepare lab information file (LIF) to comply with WHO requirement for the application of WHO prequalificati on by Q3-2023		Readiness of LIF for Submission	QC Head & QA Manager		Completed
		KPI 4:Submission of Lab Information File (LIF) to the WHO		LIF submission to WHO	QC Head & QA Manager		Completed

		Office by Q4-2023				Space for Lab & QC record Room	
Achieving WHO Pre-Qualification Status through Successful Inspection by Q4-2024	KR2: Inspection by WHO Inspectors.	KPI 5:Assessment of LIF by WHO and reply of query when required by Q3-2024	Successful Inspection of QC Lab	Initial Review by WHO PQT	QC Head & QA Manager		Completed
		KPI 6: Response to WHO queries in consultation with WHO consultant by Q3-2024		Query response Submission to WHO PQT	QC Head & QA Manager		Completed
		KPI 7: Pre-Assessment by the WHO technical team		WHO PQ of IBBPS Lab	QC Head & QA Manager		Q1 - 2025 Initiated/A waiting WHO inspection
		KPI 8: Expected WHO inspection by Q1-2025			QC Head & QA Manager		

Objective 4: Development and Implementation of a Software-Based Digitalized Environment for the Quality Control Lab by Q4-2024

Objective	Key Results	KPI	Measurement Method	Target	Person Responsible	Resource Requirement	Timeline
To create a software-based digitalized environment in the Quality Control Lab by Q4-2024	KR1: [Key result 1]	KPI 1: Development of LIMS software by Q2-2024	100% implementation of Laboratory Information Management System	GAP Assessment	QC Head ICT Directorate & RG & BD	**Human Resources:** 02 Managers 02 Assistant Managers 03 Sr. QC Analyst 02 QC Analyst 02 QA Officer **Equipment**: 02 Safety Chemical storage cabinet HVAC System LIMS Software needs to develop Data Management System WinNonlin Software **Space**: Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for Chemical Storage. Space for Lab & QC record Room	Completed
		KPI 2: Development of BRD for LIMS in HMIS by Q3-2024		URS Preparation	QA & QC Manager QC Head ICT Directorate & RG & BD		Completed
		KPI 3: Integration of HPLC results from Shimadzu HPLC to HMIS software. Q2-2025		Integration of QC lab	QC Head ICT Directorate		Completed
		KPI 4: Purchase of an internationally acceptable and global quality standards compliant software by Q4-2024		Implementation of LIMS in the LAB	QC Head		Q2-2025
		KPI 5:Online Conversions of all Laboratory operations by Q4-2024		System generated reporting system implementation	QA & QC Manager QC Head ICT Directorate & RG & BD		Initiated & planned to complete by Q2-2025

Goal 04: Enhance research and clinical trial capacity to conduct trials and bioequivalence studies							
Goal Statement: To strengthen research and clinical trial capabilities by Q4-2026 to conduct at least two (02) clinical trial & bioequivalence studies at DUHS.							
Objectives & Key Results (OKRs)							
Objective 1: Training (GxP, TCPS2, ACRP & Lead Auditor ISO 17025) of IBBPS Team till Q3 -2025							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
Training (GxP, TCPS2, ACRP & Lead Auditor ISO 17025) of IBBPS Team Q3 -2025	KR1: Preparation of the Training Plan	KPI 1: GCP Certification of all clinical operation staff by Q4-2024.	Submission of Training certificates Implementation of training in routine activities	Need Assessment	Manager Clinical Operation Manager VHCF	**Equipment:** Clinical Trial Management Software – To monitor trial progress, data collection, and regulatory compliance. Medical Equipment – Including diagnostic equipment for clinical trial procedures (e.g., ECG, blood pressure monitors, etc.). Data Management Systems – For handling patient data, clinical trial results, and regulatory documentation. Pharmaceutical Manufacturing Equipment – For conducting bioequivalence studies, including dissolution testers and analytical equipment. **Space:** Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for Clinical Trial site. Space for archive room as per WHO & ICH requirements. Space for additional Beds for Bioequivalence studies Space to Build purposely builds	Q3-2024 Completed
	KR2: Availability of Resources	KPI 2: ACRP & TCPS Certification of at least 02 members of clinical operations per year to enhance the credentials of research team by Q3-2025		Training Plan	Manager Clinical Operation Manager VHCF		Q3-2025 Initiated
	KR3: Training Budget	KPI 3: ISO 17025 Assessor Training of QA/QC/Regulatory Managers by Q3-2025		Execution of Training	Manager QA Manager Regulatory		Q3-2025 Initiated
	KR4: Necessary Approvals						Q3-2025 Initiated

						a facility of IBBPS to provide all services to clients under the same roof.	

Objective 2: Training of technical team from International BE Study Centers of Jordan or Malaysia by Q2-2026							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
Training of technical team from International BE Study Centers of Jordan or Malaysia by Q2-2026	Only 01 Foreign Trained staff	KPI 1: List the top 10 BE centers available in Jordan and Malaysia by Q4-2024	MOU signing with BE center for training by Q4-2025	Foreign Training of Staff	Manager Regulatory & BD	**Equipment**: Clinical Trial Management Software – To monitor trial progress, data collection, and regulatory compliance. Medical Equipment – Including diagnostic equipment for clinical trial procedures (e.g., ECG, blood pressure monitors, etc.). Data Management Systems – For handling patient data, clinical trial results, and regulatory documentation. Pharmaceutical Manufacturing Equipment – For conducting bioequivalence studies, including dissolution testers and analytical equipment. **Space**: Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for Clinical Trial site. Space for archive room as per WHO & ICH requirements. Space for	Q4-2024 Initiated
		KPI 2: Cost comparison to be made by Q2-2025			Manager Regulatory & BD		Q4-2025 Initiated
		KPI 3: Training budget to be approved by Q3-2025			Manager Regulatory & BD		Q3-2025

						additional Beds for Bioequivalence studies Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof.	
Objective 3: To initiate and prepare registries for disease data at DUHS by Q4-2026							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
To initiate and prepare registries for disease data at DUHS by Q4-2026	KR1: Clinical Operations to develop Disease Registries (including Rare and Prevalent Diseases) with oncology team by Q4-2025	KPI 1:Initiate work with Dow investigators/ Consultants on Disease Registry by Q4 2024	Align the investigator and the research team for developing a clinical trial registry First draft to be prepared by Q4 2026	Establish Effective communication among Investigators	Manager Clinical Operations	**Equipment**: Clinical Trial Management Software – To monitor trial progress, data collection, and regulatory compliance. Medical Equipment – Including diagnostic equipment for clinical trial procedures (e.g., ECG, blood pressure monitors, etc.). Data Management Systems – For handling patient data, clinical trial results, and regulatory documentation. Pharmaceutical Manufacturing Equipment – For conducting bioequivalence studies, including dissolution testers and analytical equipment. **Space**: Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for Clinical Trial site. Space for archive room as per WHO & ICH requirements. Space for additional Beds for Bioequivalence studies	Initiated with Oncology, ER and Gastro dept
		KPI 2:Prepare proforma with oncology by November 2024		Initiation of Clinical Trial Registry			
		KPI 3:Onboard internal stakeholders for the implementation of the registry by Q2- 2025					
		KPI 4:Select and purchase software for the registry by Q2 2025		Identification Software for Registry			
		KPI 5:Onboard societies for the endorsement of registries by Q3-2025		Implementation of Clinical Trial registry			Not Initiated, to be done by Q4-2026
		KPI 6:Continuous monitoring and evaluation of registry data in each month					
		KPI 7:Develop the first annual report on the registry by Q4 2026					Not Initiated, to be Done by Q4-2026

						Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof.	
Objective 4: To facilitate DUHS investigators to provide scientific support by Q3-2025.							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
To facilitate DUHS investigators to provide scientific support by Q3-2025.	KR1: To identify the investigators or Researchers, who need support in conducting research by Q2-2025	KPI 1:To discuss with investigators their challenges and identify training needs & and provide data analysis support, manuscript writing, or publication, or other research-related services to the DUHS investigators by Q4-2024.	The number of services provided to researchers	At least 01 Publication / Year	Manager Clinical Operations	**Equipment**: Clinical Trial Management Software – To monitor trial progress, data collection, and regulatory compliance. Medical Equipment – Including diagnostic equipment for clinical trial procedures (e.g., ECG, blood pressure monitors, etc.). Data Management Systems – For handling patient data, clinical trial results, and regulatory documentation. Pharmaceutical Manufacturing Equipment – For conducting bioequivalence studies, including dissolution testers and analytical equipment. **Space**: Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for Clinical Trial site. Space for archive room as per WHO & ICH requirements. Space for additional Beds for Bioequivalence studies Space to Build purposely builds a facility of IBBPS to provide	Q3-2025 Initiated for Urology, Neurosurgery & OICD dept.

						all services to clients under the same roof.	
Objective 5: Create awareness of Bioequivalence Studies, Preclinical studies, and clinical studies among all stakeholders by doing at least 02 conferences/ year							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
Create awareness of Bioequivalence Studies, Preclinical studies, and clinical studies among all stakeholders by doing at least 02 conferences/ year.	KR1: Arrange 02 seminars or awareness session/campaign on Bioequivalence study by Q4-2025	KPI 1:Identify different platforms for awareness sessions on bioequivalence /clinical studies by Q1-2025.	Representation of IBBPS on Local forums	Participation in at least 02 local conferences & awareness sessions	Manager Reg & BD	**Equipment**: Clinical Trial Management Software – To monitor trial progress, data collection, and regulatory compliance. Medical Equipment – Including diagnostic equipment for clinical trial procedures (e.g., ECG, blood pressure monitors, etc.). Data Management Systems – For handling patient data, clinical trial results, and regulatory documentation. Pharmaceutical Manufacturing Equipment – For conducting bioequivalence studies, including dissolution testers and analytical equipment. **Space**: Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for Clinical Trial site. Space for archive room as per WHO & ICH requirements. Space for additional Beds for Bioequivalence studies	Q1-2025 Initiated
		KPI 2:Meeting, Plan, and finalizing the platform for the awareness session by Q2-2025	Meeting Reports	Meeting with at least 10 Pharma / Q	Manager Reg & BD		Q4-2025

						Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof.	

Objective 6: Establishment of purposely built facilities of IBBPS at the same place by Q3-2027							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
Establishment of purposely built facilities of IBBPS at the same place by Q3-2027	Allocation of Land	Approval of allocated space by VC by Q3-2024	Physical takeover of Land	Land allocation approval	Director Office & PD	**Equipment**: Clinical Trial Management Software – To monitor trial progress, data collection, and regulatory compliance. Medical Equipment – Including diagnostic equipment for clinical trial procedures (e.g., ECG, blood pressure monitors, etc.). Data Management Systems – For handling patient data, clinical trial results, and regulatory documentation. Pharmaceutical Manufacturing Equipment – For conducting bioequivalence studies, including dissolution testers and analytical equipment. **Space**: Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for Clinical Trial site. Space for archive room as per WHO & ICH requirements. Space for	Q3-2024 Completed
	Layout Finalization	Signing of the Finalized Layout by Q4-2024	Approved Layout	Layout approval	Director Office & PD		Q4-2024 Completed
	Tender Allotment & Construction	Handing Over to IBBPS from PD by Q4-2025	Facility Availability	Purpose Built facility	Director Office & PD		Initiated Q4-2025

						additional Beds for Bioequivalence studies Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof.	

Goal 05: Strengthening marketing and global presence to position among the top 50 CROs worldwide							
Goal Statement: To enhance marketing and global presence by Q4-2026 to grab a place among the top 50 CROs across the globe by Q4-2027							
Objectives & Key Results (OKRs)							
Objective 1: Participation in at least 02 international conferences or exhibitions every year							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
Participation in at least 02 international conferences or exhibitions every year.	KR1: List down the International conferences, and the opportunities of Business expansion.	KPI 1: Participation in 02 international conferences per year till Q4-2027 in the target market regions to represent IBBPS Services and attract partnerships with global CRO. (shortlisted conferences are discussed in BP)	Participated in Conferences held during the year 2023-2024	Participation in 02 Conferences / Year	Manager Regulatory & BD	**Human Resources:** 02 Business Development Executive to be hired. 06 additional CRCs will be required for each Clinical Study Project. 03 CRA will be required for each clinical study project. 01 Project Manager will be required for each clinical study project. 01 Regulatory Affairs Officer will be required for each clinical study project. 03 Administrative staff will be required for each clinical study project 01 Statistician **Equipment**: Office related equipment **Space**: Global Conference & Exhibition Participation Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof.	Completed for 2024 & initiated for 2025 & 2026 (Drug Information Association & Bio International Convention 2025)

						Space for archive room as per WHO & ICH requirements.	
Objective 2: WHO Prequalification of IBBPS CRO till Q4-2026							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
WHO Prequalification of IBBPS CRO till Q4-2026	KR1: Preparation of CRO Master file.	KPI 1: Request Letter Submission for Technical Assistance by WHO PQT by Q2-2025	Acceptance of CRO Master file	Readiness of CRO Master File	Manager Regulatory & BD & Manager Clinical Operations & VHCF	**Human Resources:** 02 Business Development Executive to be hired. 06 additional CRCs will be required for each Clinical Study Project. 03 CRA will be required for each clinical study project. 01 Project Manager will be required for each clinical study project. 01 Regulatory Affairs Officer will be required for each clinical study project. 03 Administrative staff will be required for each clinical study project 01 Statistician **Equipment**: Office related equipment **Space**: Global Conference & Exhibition Participation Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for archive room as per WHO & ICH requirements.	Q4-2026 Initiated
	KR2: Readiness of QMS as WHO Guidelines	KPI 2: Submission of CRO Master file to the WHO Prequalification team by Q4-2025.		CRO Master file submission to WHO			
Objective 3: To connect with 10 international clients for multicenter trials per year.							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
To connect with 10 international clients for multicenter	KR1: Coordination through email for collaborations.	KPI 1:Establish connection with 10 international clients to offer	Project feasibility	Secure at least 02 Global Clinical trial projects	BD Officers	**Human Resources:** 02 Business Development Executive to be	Q4-2026 Initiated Two MoUs finalized with inter-

trials per year.	KR2: Review Trial registries for the insight of ongoing & upcoming CT.	research services including BA/BE, Multicenter trials, Animal studies (Toxicity & PK/PD Studies) by Q4-2025, and MoU signing with at least 04 of them by Q4-2026 for future clinical trial projects			BD Officers	hired. 06 additional CRCs will be required for each Clinical Study Project. 03 CRA will be required for each clinical study project. 01 Project Manager will be required for each clinical study project. 01 Regulatory Affairs Officer will be required for each clinical study project. 03 Administrative staff will be required for each clinical study project 01 Statistician **Equipment**: Office related equipment **Space**: Global Conference & Exhibition Participation Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for archive room as per WHO & ICH requirements.	national clients in Q3-2024. DT&CRO Trial 360
	KR3: Approaching more than 10 International Clinical Trial clients through Digital platforms by Q4 2025		NDA signed with international clients		BD Officers		

Objective 4: Expansion of Clinical Trial Network with at least 03 Hospitals in the region and collaboration with at least 02 International Clinical Trial Sites till Q3-2025.

Objective	Key Results	KPI	Measurement Method	Target	Person Responsible	Resource Requirement	Timeline
Expansion of Clinical Trial Network with at least 03 Hospitals in the region and collaboratio	KR1: Submission of Clinical Trial Site application to DRAP.	KPI 1: DRAP audit for 03 Trial sites of DUHS by Q4-2024	Signed MOU with Hospitals	Application submission to DRAP	Regulatory Officer	**Human Resources:** 02 Business Development Executive to be hired. 06 additional CRCs will be	Q3-2025 Shifa Inter-national Islamabad Signed MOU with NUS & PHRI (Canada)

n with at least 02 International Clinical Trial Sites till Q3-2025.	KR2:MOU with hospitals	KPI 2:Coordination with at least 15 International Clinical Trial sites by Q3-2025 and secure collaboration with at least 03 sites.		Collaboration with at least 04 CTS of the Country	BD Officers	required for each Clinical Study Project. 03 CRA will be required for each clinical study project. 01 Project Manager will be required for each clinical study project. 01 Regulatory Affairs Officer will be required for each clinical study project. 03 Administrative staff will be required for each clinical study project 01 Statistician **Equipment**: Office related equipment **Space**: Global Conference & Exhibition Participation Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for archive room as per WHO & ICH requirements.	Welcome Foundation CAMO-NET
	KR3: Identification of an international Clinical Trial for a Multicenter trial	KPI 3:Collaboration with at least 04 local clinical trial sites.			BD Officers		

Objective 5: Become an approved Bioequivalence study center/ CRO in Malaysia NPRA as it is a PIC/s member country & GCC till Q2-2026.

Objective	Key Results	KPI	Measurement Method	Target	Person Responsible	Resource Requirement	Timeline
Become an approved Bioequivalence study centers/ CRO in Malaysia NPRA as it is a PIC/s member country & GCC till Q2-2026.	KR1: Understanding of Regulatory Framework for Listing & Registration of PIC/s NPRA.	KPI 1:Application Submission to NPRA Malaysia to be listed as approved BE/ CRO by Q3-2025 to attract the clients for BE studies.	Listed in NPRA & PICS	NPRA inspected CRO	Regulatory Officer	**Human Resources:** 02 Business Development Executive to be hired. 06 additional CRCs will be required for each Clinical Study Project. 03 CRA will be required for each clinical study project. 01 Project Manager will be required for each clinical study project. 01 Regulatory Affairs Officer will be required	Q4-2026 Initiated
		KPI 2: Application Submission to Gulf Cooperation Council, be listed as approved BE/ CRO by Q2-2026 to attract clients for BE studies.		GCC inspected CRO	Regulatory Officer		Q4-2026 Initiated

		KPI 3:Coordination to get listed with Euro Asian Economic Union by Q4-2025 for CRO Registration		Euro Asian Economic Union Inspected CRO	Regulatory Officer	for each clinical study project. 03 Administrative staff will be required for each clinical study project 01 Statistician **Equipment**: Office related equipment **Space**: Global Conference & Exhibition Participation Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for archive room as per WHO & ICH requirements.	Q4-2026 Not Initiated
Objective 6: Be listed or registered with 04 International CRO Associations & forums to enhance the presence of IBBPS on influential platforms of target markets (i.e. North America, Europe & China) by Q1 2026							
Objective	**Key Results**	**KPI**	**Measurement Method**	**Target**	**Person Responsible**	**Resource Requirement**	**Timeline**
Be listed or registered with 04 International CRO Associations & forums to enhance the presence of IBBPS on influential platforms of target markets (i.e. North America, Europe & China) by Q1 2026	KR1: List of Potential CRO Federations	KPI 1:Secure membership of North American CRO Council, Europe, and China CRO federations/Associations by Q1-2026.	Get the membership of the CRO association	Membership with at least 01 CRO association	Manager Regulatory & BD Director Office	**Human Resources:** 02 Business Development Executive to be hired. 06 additional CRCs will be required for each Clinical Study Project. 03 CRA will be required for each clinical study project. 01 Project Manager will be required for each clinical study project. 01 Regulatory Affairs Officer will be required for each clinical study project. 03 Administrative staff will be required for each clinical study project 01 Statistician **Equipment**: Office related equipment **Space**:	Q1-2026 initiated
		KPI 2: Business development team building by Q2-2026 in the North America, Europe & China		Availability of BD officer in North America, Europe & China	Manager Regulatory & BD Director Office		Q1-2026 initiated

						Global Conference & Exhibition Participation Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. Space for archive room as per WHO & ICH requirements.	

SECTION V: RESOURCE PLANNING FOR ACHIEVING STRATEGIC GOALS

STRATEGIC GOALS	RESOURCES		
	Human Resources	Equipment	Space
GOAL 1: To become an Authorized USP Reference standard supplier in Pakistan by Q2-2025	○ Full-time Business Executive ○ Full-Time Project Manager	○ 01 Pharmaceutical Refrigerator ○ 01 (-20°C) freezer ○ 03 Laptops ○ Temp & Humidity Monitoring System ○ Air conditioners ○ UPS ○ Backup Power Supply	○ Space Available to maintain operations for around 2 to 3 years. ○ Infrastructure will be required
Total Budget Required for Goal -1: 17.5M PKR/ Year	Budget Required: 2.5 M PKR/ Year	Budget Required: 10 M PKR/ Year	Budget Required: 05 M PKR/ Year
GOAL 2: Expand lab services with new technologies to drive growth and improve quality control.	○ 02 Managers ○ 02 Assistant Managers ○ 03 Sr. QC Analyst ○ 02 QC Analyst ○ 02 QA Officer	○ 02 HPLC ○ 01 UFLC ○ 01 Dissolution apparatus (18 baskets with autosampler) ○ 01 Particle size counter ○ Equipment required for Medical Device testing. ○ 01 TOC Analyzer ○ 01 QTOF with HPLC ○ 01 Vacuum Manifold ○ 01 Refrigerated Centrifuge ○ 01 Drying Oven ○ 01 Muffle Furnace ○ 01 Microbalance ○ 01 Stability or Climatic chamber ○ 02 Incubator ○ 01 Autoclave ○ 01 PCR with Kit	○ Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. ○ Space for Stability chamber Lab. ○ Space for Microbiology Laboratory
Total Budget Required for Goal -2: 55.4M	Budget Required: ○ 14 M PKR/ Year	Budget Required: ○ 22.62 M PKR/ Year	Budget Required:

PKR/ Year			18.8 M PKR/ Year
GOAL 3: Achieve WHO Prequalification to enhance client confidence and drive business growth.	○ Same as Above	○ 02 Safety Chemical storage cabinet ○ HVAC System ○ LIMS Software needs to develop ○ Data Management System ○ WinNonlin Software	○ Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. ○ Space for Chemical Storage. ○ Space for Lab & QC record Room.
Total Budget Required for Goal -3: 24.8M PKR/ Year	**Budget Required:** Already covered in the above goal.	**Budget Required:** 16 M PKR/ Year	**Budget Required:** 18.8 M PKR/ Year
GOAL 4: Enhance research and clinical trial capacity to conduct trials and bioequivalence studies	○ 02 Business Development Executives to be hired. ○ 06 additional CRCs will be required for each Clinical Study Project. ○ 03 CRA will be required for each clinical study project. ○ 01 Project Manager will be required for each clinical study project. ○ 01 Regulatory Affairs Officer will be required for	○ Office-related equipment. ○ IT support ○ Electronic Data-capturing Tool ○ Sink Clock ○ Interactive Response Technique ○ Temp & Humidity Recording System. ○ Refrigerated centrifuge. ○ Equipment required for a particular study project. ○ Fire Suppression system.	○ Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof. ○ Space for Clinical Trial site. ○ Space for archive room as per WHO & ICH requirements. ○ Space for additional Beds for Bioequivalence studies

	each clinical study project. ○ 03 Administrative staff will be required for each clinical study project ○ 01 Statistician		○ Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof.
Total Budget Required for Goal -4: 38.4M PKR/ Year	**Budget Required:** ○ 16.6 M PKR/Year	**Budget Required:** ○ 3 M PKR/ Year	**Budget Required:** 18.8 M PKR/ Year
GOAL 5: Strengthening marketing and global presence to position among the top 50 CROs worldwide	○ Same as above	○ Office related equipment	○ Global Conference & Exhibition Participation ○ Space to Build purposely builds a facility of IBBPS to provide all services to clients under the same roof.
Total Budget Required for Goal -5: 23.8M PKR/ Year	**Budget Required:** Already covered in the above goal.	**Budget Required:** 5 M PKR/ Year	**Budget Required:** 18.8 M PKR/ Year

SECTION VI: IMPLEMENTATION AND MONITORING OF STRATEGIC PLAN

Goal 1: To become an Authorized USP Reference standard supplier in Pakistan by Q2-2025	
Key results	• Approval from VC by Q2-2024 • Development & approval of Layout for Storage Area by Q4-2024 • Consolidate the list of required reference standards as per the demand by Q1-2025. • Familiarize ourselves with the specific requirements outlined by the United States Pharmacopeia (USP) for becoming a supplier of reference standards. • Signing of Agreement with USP by Q4-2024.
Review Frequency	Quarterly review meetings will be held to assess the progress on each goal. Mid-year review to revisit timelines and necessary action for resource management. An annual review will be at the end of each year to align directions toward goals.
Responsibility	Head of QC, Regulatory & BD, and Director Office

GOAL 2: Expand lab services with new technologies to drive growth and improve quality control.	
Key results	• Understand the regulatory requirements for medical device testing labs set forth by the European Union's Medical Device Regulation (MDR) by Q4-2024 • Determination of the technical capabilities and expertise required to conduct testing for different types of medical devices by Q2-2025 • Identify the accreditation process for testing labs seeking to become Notified Bodies under the Medical Device by Q1-2025 • Perform gap analysis and prepare a list of lab equipment required by Q4-2024. • Approval from higher management and VC by Q2-2024 • Preparation of URS and MR & submit to Procurement by Q4-2024. • Structural requirement Assessment for Microbiology Lab by Q3-2025 • Resource and Utility need Assessment for Microbiology Lab by Q2-2025 • Layout Finalization for Microbiology Lab by Q4-2025 • Civil work completion for Microbiology Lab Q4-2026

Review Frequency	Monthly review to rule out the challenges. Quarterly review meetings will be held to assess the progress on each goal. Mid-year review to revisit timelines and necessary action for resource management. An annual review will be at the end of each year to align directions toward goals.
Responsibility	Head of QC, Regulatory & BD, and Director Office

GOAL 3: Achieve WHO Prequalification to enhance client confidence and drive business growth.	
Key results	• Lab Information File (LIF) submission to the WHO Office by Q4-2023. • QMS Document Readiness for the Inspection by Q2-2024 • Participation in Proficiency Testing by LGC UK by Q1-2024 • ISO 17025 Audit & Accreditation & Adding new impurities test for EG & DEG in Raw & finished drug product by Gas Chromatography by Q2-2024 • LIMS Implementation at Lab by Q4-2024 • Laboratory Readiness for the Inspection by Q2-2024 • Inspection by WHO Inspectors by Q2-2025
Review Frequency	Monthly review to rule out the challenges. Quarterly review meetings will be held to assess the progress on each goal. Mid-year review to revisit timelines and necessary action for resource management. An annual review will be at the end of each year to align directions toward goals.
Responsibility	Head of QC, Regulatory & BD, and Director Office

GOAL 4: Enhance research and clinical trial capacity to conduct trials and bioequivalence studies	
Key results	• Development & implementation of Clinical Trial Registries, (including Rare and Prevalent Diseases) by Q4-2024 • Coordination & Finalization of Jordan & Malaysia BE centre for training of IBBPS BE Centre staff by Q4-2024

	• Establishment of connection with DUHS Alumni & To identify the investigators or Researchers, who need support in conducting research Q4-2025. • GxP, TCPS2, ACRP & Lead Auditor ISO 17025 training Plan & execution of training • Identification of Potential Clinical Trial Sites by Q1-2025
Review Frequency	Quarterly review meetings will be held to assess the progress on each goal. Mid-year review to revisit timelines and necessary action for resource management. An annual review will be at the end of each year to align directions toward goals.
Responsibility	Clinical Operations, BD Executive & Director office

Goal 5: Strengthening marketing and global presence to position among the top 50 CROs worldwide	
Key results	• List down international conferences and the opportunities for Business expansion Q2 & Q4 of every year till 2027 • Participation in International conferences till Q4-2027 • Preparation of CRO Master file by Q2-2025. • Readiness of CRO QMS as WHO Guidelines by Q3-2025 • Clinical Trial Site registration application submission to DRAP • 02 Conferences to create awareness of Bioequivalence Centre by Q2-2025. • Prepare a List of Potential Underdeveloping Countries Regulatory Authorities Q2-2025. • Create liaison with the Underdeveloping countries' Regulatory Authorities. • Visit of Underdeveloped countries Q4-2025 • Establish an understanding of the Regulatory Framework for Listing & Registration of PIC/s NPRA by Q3-2025 • Identification & Liaison with Potential CRO Associations across the Globe by Q1-2026
Review Frequency	Monthly review to rule out the challenges. Quarterly review meetings will be held to assess the progress on each goal. Mid-year review to revisit timelines and necessary action for resource management. An annual review will be at the end of each year to align directions toward goals.
Responsibility	Clinical Operations, Regulatory & BD, Quality Assurance

SECTION VIII: LIST OF APPENDICES

No.	DESCRIPTION
A	LIST OF EXISTING RESEARCH PROJECTS
B	SWOT ANALYSIS
C	TOWS MATRIX

APPENDIX A: LIST OF EXISTING RESEARCH PROJECTS

Project Name	International/ Local	Sponsor (country)	Focus Area
A Multi-center, Randomized, Blinded, Placebo-controlled, Phase 3 Clinical Study to Evaluate the Efficacy, Safety, and Immunogenicity of SARS-CoV-2 Bivalent mRNA Vaccine (LVRNA021) as Booster in Participants Aged 18 Years and Older who Completed Primary/1 Booster Dose(s) of SARS-CoV-2 Vaccination	International	AIM Vaccine Co. Ltd.	COVID-19
A Clinically Oriented Antimicrobial Resistance Surveillance Network for Healthcare-associated Infections (ACORN-HAI)	International	National University of Singapore / Welcome Trust	Hospital Acquired Infection
Anticoagulation for Stroke Prevention in Patients with Recent Episodes of perioperative Atrial Fibrillation aft er noncardiac surgery - The ASPIRE -AF trial	International	PHRI Hamilton Health Research. Canada	Non-cardiac surgery
ACTIV-2d/A5407) A Phase 3, multicenter, randomized, double-blind, 24-week study of the clinical and antiviral effect of S-217622 compared with placebo in non-hospitalized participants with COVID-19	International	Shionogi & Co. Ltd	COVID-19 oral antiviral trial (non-hospitalized)
An open-label, single-dose, randomized, two-period, 2x2 crossover bioequivalence study of Perispa (Eperisone HCl) Tablet 50 mg	Local	Platinum Pharmace uticals (Pvt.) Ltd	Bioequivalence Study
An open-label, single-dose, randomized, two-period, 2x2 crossover bioequivalence study of Fixitil-T D.S 400mg Tablet (Cefixime).	Local	Tabros Pharma (Pvt.) Ltd.	Bioequivalence Study

An open-label, single-dose, randomized, two-period, 2x2 crossover bioequivalence study of Amlodipine Tablets 10mg	Local	AGP	Bioequivalence Study
An open-label, single-dose, randomized, two-period, 2x2 crossover bioequivalence study of Clarithromycin Suspension 250mg/5ml (70ml)	Local	Medisure	Bioequivalence Study
An open-label, single-dose, randomized, two-period, 2x2 crossover bioequivalence study of Cefixime Suspension 100mg/5ml (60ml)	Local	Medisure	Bioequivalence Study
A Clinically Oriented Antimicrobial Resistance Surveillance Network for Healthcare-associated Infections (ACORN-HAI) (Next Phase)	International	National University of Singapore / Welcome Trust	Hospital Acquired Infection

APPENDIX B: SWOT ANALYSIS:

STRENGTHS	WEAKNESSES
RESOURCES: 1. Qualified & GCP Certified Staff. FACILITIES: 2. Associated with Tertiary Care Hospitals: * Dow University Hospital Ojha * Civil Hospital Karachi * SIDH & RC Volunteer Healthcare facility. 3. Well Equipped Bio – Analytical Lab (HPLC, LCMS, GCMS, Atomic). 4. Experience of International Trials Phase I – IV. 5. Animal House for Pre-Clinical Toxicological Studies. LICENSE & ACCREDITATION: 6. DRAP Approved Bioequivalence Study Centre. 7. DRAP Approved Clinical Trial sites for Phase 1 to 4. 8. DRAP Approved Contract Research Organization. 9. DRAP Approved Bioanalytical Lab 10. Listed with ICH-GCP Network 11. US Human & Health Services FWA Registered. 12. Partner member of European CRO Federation EUCROF. 13. ISO 15189 accredited Dow Diagnostic Research and Reference Laboratory (DDRRL). 14. Legacy of DUHS. 15. Being a GOVT Organization, we have an edge over our competitors.	GLOBAL REACH: 1. Less reach to top profile clients in the fast-growing contract research organizations & clinical trials across the Globe. 2. Socio-Economic Factor. 3. Inflation rate / Dollar rate fluctuation. LOCAL REACH: 4. Awareness of IBBPS in local Pharma Industries for BA/BE, CRO, Clinical trials & Analytical Testing. 5. Less number of International Accreditation. 6. Less Marketing & Business Development Activities. 7. Regulatory Constraints. 8. Manual quality management system, which causes human errors. 9. Lack of clinical research culture-oriented PIs (Principal investigators) at DUHS. 10. Delayed Approval Mechanism of IRB, especially for commercial research projects. 11. Less define SOPs of IRB. 12. Minimum number of IBBPS staff Publication due to the unavailability of separate research funds. 13. Complex and prolonged Procurement mechanism, no involvement of end-user in tender committee to finalize the purchase decisions, especially in work order finalization. 14. Employee Retention/ 6 months service contracts. 15. Longer Lead time for any activity in the Quality Control Lab. 16. Employee Promotion policies are not implemented at DOW.

	17. No Policy for Annual Health Assessment of Existing Employees. 18. Unavailability of exclusive Services of DDRRL for the clinical trial. 19. Unavailability of Disease Data Directory at DUHS. 20. Less interdepartmental networking that causes delays in trial feasibility submission 21. Weak Implementation of Clinical Trial registry at DRAP, academic/commercial trials are not registered at CTU/IBBPS.
OPPORTUNITIES	**THREATS**
1. Medical Devices Testing Lab for European Conformity CE Marking Notified Body (NANDOS Countries). 2. To cater to more clinical trials, a patient data registry and a Clinical trial registry will help to catch more trials. 3. A high patient pool helps to catch International and national businesses for clinical research work. 4. Certified Paid Training in Clinical research-related fields will help in capacity building. 5. Participation in CPHI will develop business contacts with international Clients. 6. Scope enhancement for ISO 17025 by adding more tests. 7. Collaboration with Pharmaceutical Industries. 8. Collaboration with International Forums. 9. WHO Pre-Qualification and PIC/s (Pharmaceutical Inspection Cooperation Scheme) Certification. 10. Scope of Bioequivalence Studies in Exporting Under Developing & LMIC/s. 11. Support to Yemen Regulators will help in business expansion and open a new window for business. 12. Fast-growing Oncology Clinical Trial market in Pakistan.	1. NUMS Entry in the market for BE studies. 2. New CROs & CTUs are entering the market all over Pakistan, the major competitor in the CRO market is IQVIA. 3. Volatile economy and political instability of Pakistan. 4. Reluctance of Pharma industries for BE studies. 5. DRAP Planning to revert the Phases I & II trial approvals 6. Delayed Regulatory Approvals of BE studies or Clinical Studies by DRAP. 7. Lack of Interest in clinical research from Local Pharma & Biological Industries. 8. Insurance Providers are unavailable in Pakistan for clinical trials and BE studies.

13. Addition of New Clinical trial sites such as Malir Chest Clinic, Lyari General Hospital, Dept. of Family Medicine Chanesar Goat, etc. in the IBBPS-DUHS Network. 14. Database for Safety Reporting. 15. Collaboration with International CROs and the Pharma industry of Pakistan.	

APPENDIX C: TOWS MATRIX

	OPPORTUNITIES	THREATS
	1. Medical Devices Testing Lab for European Conformity CE Marking Notified Body (NANDOS Countries). 2. To cater to more clinical trials, a patient data registry and a Clinical trial registry will help to catch more trials. 3. A high patient pool helps to catch International and national businesses for clinical research work. 4. Certified Paid Training in Clinical research-related fields will help in capacity building. 5. Participation in CPHI will develop business contacts with international Clients. 6. Scope enhancement for ISO 17025 by adding more tests. 7. Collaboration with Pharmaceutical Industries. 8. Collaboration with International Forums. 9. WHO Pre-Qualification and PIC/s (Pharmaceutical Inspection Cooperation Scheme) Certification. 10. Scope of Bioequivalence Studies in Exporting Under Developing & LMIC/s. 11. Support to Yemen Regulators will help in business expansion and open a new window for business. 12. Fast-growing Oncology Clinical Trial market in Pakistan.	1. NUMS Entry in the market for BE studies. 2. New CROs & CTUs are entering the market all over Pakistan, the major competitor in the CRO market is IQVIA. 3. Volatile economy and political instability of Pakistan. 4. Reluctance of Pharma industries for BE studies. 5. DRAP Planning to revert the Phases I & II trial approvals 6. Delayed Regulatory Approvals of BE studies or Clinical Studies by DRAP. 7. Lack of Interest in clinical research from Local Pharma & Biological Industries. 8. Insurance Providers are unavailable in Pakistan for clinical trials and BE studies.

	13. Addition of New Clinical trial sites such as Malir Chest Clinic, Lyari General Hospital, Dept. of Family Medicine Chanesar Goat, etc. in the IBBPS-DUHS Network. 14. Database for Safety Reporting. 15. Collaboration with International CRO's and the Pharma industry of Pakistan.	
	SO	ST
RESOURCES: 1. Qualified & GCP Certified Staff. FACILITIES: 2. Associated with Tertiary Care Hospitals: * Dow University Hospital Ojha * Civil Hospital Karachi * SIDH & RC Volunteer Healthcare facility. 3. Well Equipped Bio – Analytical Lab (HPLC, LCMS, GCMS, Atomic). 4. Experience of International Trials Phase I – IV. 5. Animal House for Pre-Clinical Toxicological Studies. LICENSE & ACCREDITATION: 6. DRAP Approved Bioequivalence Study Centre. 7. DRAP Approved Clinical Trial sites for Phase 1 to 4.	1. New Market opportunity in such a way to showcase the state-of-the-art licensed facility and to have oncology trials. 2. Database for safety Reporting to be developed to capture cases of the tertiary care hospital 3. Seek more international accreditation to get a feather in cap for the trial site & lab 4. Medical Devices Testing Lab for European Conformity CE Marking Notified Body (NANDOS Countries) 5. WHO Pre-Qualification and PICs (Pharmaceutical Inspection Cooperation Scheme) Certification will give us an advantage in future to get more business nationally and internationally. 6. Certified paid training will be offered to the GCP trained staff for capacity building. 7. Add more test services by using a well-equipped lab to collaborate with the pharmaceutical industry 8. Scope enhancement for ISO 17025:2017 to get more certifications.	1. By adding civil Hospital as a New trial site will give an edge as compared to other CTU available in Pakistan. 2. EUCROF annual Subscription & ICH - GCP Subscription need to be continued in the future for availing and establishing new business relationships with international clients. 3. New Product development to be promoted to revoke the DRAP decision 4. Audit Assessment Annually 5. Trained staff to be retained through offered paid training & creating a backup of everyone. 6. Scope of tests needs to be enhanced further with Updated technologies in the equipped lab, so that the political situation can't affect it.

8. DRAP Approved Contract Research Organization. 9. DRAP Approved Bioanalytical Lab 10. Listed with ICH-GCP Network 11. US Human & Health Services FWA Registered. 12. Partner member of European CRO Federation EUCROF. 13. ISO 15189 accredited Dow Diagnostic Research and Reference Laboratory (DDRRL). 14. Legacy of DUHS. 15. Being a GOVT Organization, we have an edge over our competitors.	9. Awareness session conducted for the scope of BE Studies 10. Conduct BE studies for the products that will be registered in Yemen 11. Participation in international forum & conferences to develop business contacts to fetch international sponsors for conducting international trials (I-IV) esp. oncology trials 12. Creating awareness among international clients about animal houses and bringing preclinical studies for new product development at DUHS. 13. More clinical trials with more lab testing can be offered to fetch new international clients. 14. Affiliation with international organization & institutes through DUHS alumni by using the legacy of DUHS. 15. Clinical Trial registry and patient or disease data registry to be prepared in DUHS will support the CTS for conducting prospective and Retrospective studies 16. Having the government set up a new clinical trial site to be added, such as Malir chest clinic, Lyari General hospital, Dept of Family medicine Chanesar Goth, Gambat etc. in IBBPS-DUHS Clinical Trial Network.	7. International clients need to be sought for BE studies 8. Advocacy with Regulator & Govt./Industries Stakeholders by Conferences & Workshops to create awareness on pre-clinical studies, develop local pharma and biological industry to involve in research activities, and DRAP to expedite the processes. 9. Self-created registries and databases will increase the research work 10. Being a government organization, we need to create pressure for DRAP to expedite the approval process.
WEAKNESSES	**WO**	**WT**
GLOBAL REACH: 1. Less reach to top profile clients in the fast-growing contract research	1. Participation in international forums & exhibitions to promote services offered by IBBPS and catch more business	1. Marketing campaign to be established within creating awareness, especially through

organizations & clinical trials across the Globe. 2. Socio-Economic Factor. 3. Inflation rate / Dollar rate fluctuation. LOCAL REACH: 4. Awareness of IBBPS in local Pharma Industries for BA/BE, CRO, Clinical trials & Analytical Testing. 5. Less number of International Accreditation. 6. Less Marketing & Business Development Activities. 7. Regulatory Constraints. 8. Manual quality management system, which causes human errors. 9. Lack of clinical research culture-oriented PIs (Principal investigators) at DUHS. 10. Delayed Approval Mechanism of IRB, especially for commercial research projects. 11. Less define SOPs of IRB. 12. Minimum number of IBBPS staff Publication due to the unavailability of separate research funds. 13. Complex and prolonged Procurement	opportunities from international clients. 2. All clinical trials, BE, and CRO agreement to be kept in dollars or in foreign currency to avoid effects of exchange rates or inflation rates on department earnings. 3. Advocacy with Regulator & Govt./Industry Stakeholders by Conferences & Workshops to create awareness on pre-clinical studies, develop the local pharma and biological industry to involve in research activities, and DRAP to expedite the processes. 4. More accreditation to be achieved to get a top profile customer 5. Well-defined reporting timeline communicated to the stakeholder 6. Software and digitalization of system to be planned 7. Data scientists to establish the importance of data 8. Networking for clinical trials with all HODs. 9. Increasing the number of international clinical trials will develop pressure in the IRB to create a new approval mechanism for the IRB 10. Staff to be asked for publication will be compulsory for staff availing paid training 11. International requirements need to be escalated to all stakeholders (IRB, Procurement department, HR) 12. Paid training to be offered long-term contract to be in place for employee retention 13. A well-defined reporting timeline needs to be defined	the international client 2. Target the international market to establish the inflation rate and the dollar fluctuations 3. Awareness session and webinars for Pharma clients for BE studies 4. Worked for getting more international accreditation to get recognition on the international level. 5. Work in collaboration with the DUHS marketing dept 6. Interpersonal relations with regulatory authorities and different pharma to work for community benefit. 7. Smoothly, the development of HIMS and work to create a paperless environment 8. Contact the DUHS alumni in different countries 9. Providing opportunities for IBBPS staff to conduct research at the department level. 10. Work in close coordination with the procurement department 11. Career growth and development of all employees. 12. Lab needs to work on their test activities smoothly and frequently. 13. Implementation of the Promotion policy is mandatory

mechanism, no involvement of end-user in tender committee to finalize the purchase decisions, especially in work order finalization. 14. Employee Retention/ 6 months service contracts. 15. Longer Lead time for any activity in the Quality Control Lab. 16. Employee Promotion policies are not implemented at DOW. 17. No Policy for Annual Health Assessment of Existing Employees. 18. Unavailability of exclusive Services of DDRRL for the clinical trial. 19. Unavailability of Disease Data Directory at DUHS. 20. Less interdepartmental networking that causes delays in trial feasibility submission. 21. Weak Implementation of Clinical Trial registry at DRAP, academic/commercial trials are not registered at CTU/IBBPS.	14. International requirements need to be escalated to all stakeholders (IRB, Procurement department, HR) 15. Annual health Assessment of employees before participating in trial. 16. Service agreement finalization with DDRRL 17. Redcap will be used to develop a directory for the disease database. Diseases data directory, Development & accessibility of it to the concerned stakeholders 18. Strong market campaign to be made through the international forum 19. Mechanism to be established for all academic & commercial research, CT, Observational studies in clinical trial registries.	14. Due to DUHS legacy and the government sector, we are pioneers of data compared to other competitors, we need to develop an international-level data directory that can be accessible to all departments 15. Annual meetings with other CROS to discuss these issues and come up with the solution simultaneously.