Our Corporate Philosophy

Vision

Global best-in-class CRO offering comprehensive services along the whole drug development process to pharmaceutical, generics and biotechnology companies.

Mission

Become the preferred CRO partner to pharmaceutical and biotechnology companies globally, by means of scientific competence, timely delivery, quality excellence, cost effectiveness and recognition.

accutest

Our Service Offerings

1. Phase I Bioavailability and Bioequivalence (BA/BE) Services.
2. Clinical Development Services (Phase II - IV and stand-alone services).
3. Biologics and Biosimilars Services.

Regulatory Inspections (Times)

USFDA (31x)

WHO (22x)

EMA (8x)

ANVISA (15x)

DCGI (20x)

MCC (2)

NPRA (3x)

MOH Turkey (1)

and many more...

Phase I Bioavailability and Bioequivalence (BA/BE) Services

Accutest is the partner of choice for global clients looking to execute BA/BE studies on various dosages. The studies are conducted in timely manner with finest cuality and competitive prices.

- Clinical studies from proof of concept to global submission in an ethical, efficient and regulatory compliant manner
- Customized studies for challenging drugs requiring complex design and/or special attention towards safety parameters.
- Specialized solution in pharmacokinetic and statistical analysis.
- Dedicated client specific project management for support and coordination.
- Assistance in seeking regulatory permissions and support including e-CTD complaint dossier submissions and resolution of regulatory queries.

Experience, Infrastructure & Regulatory Track Record

1: Experience and Expertise

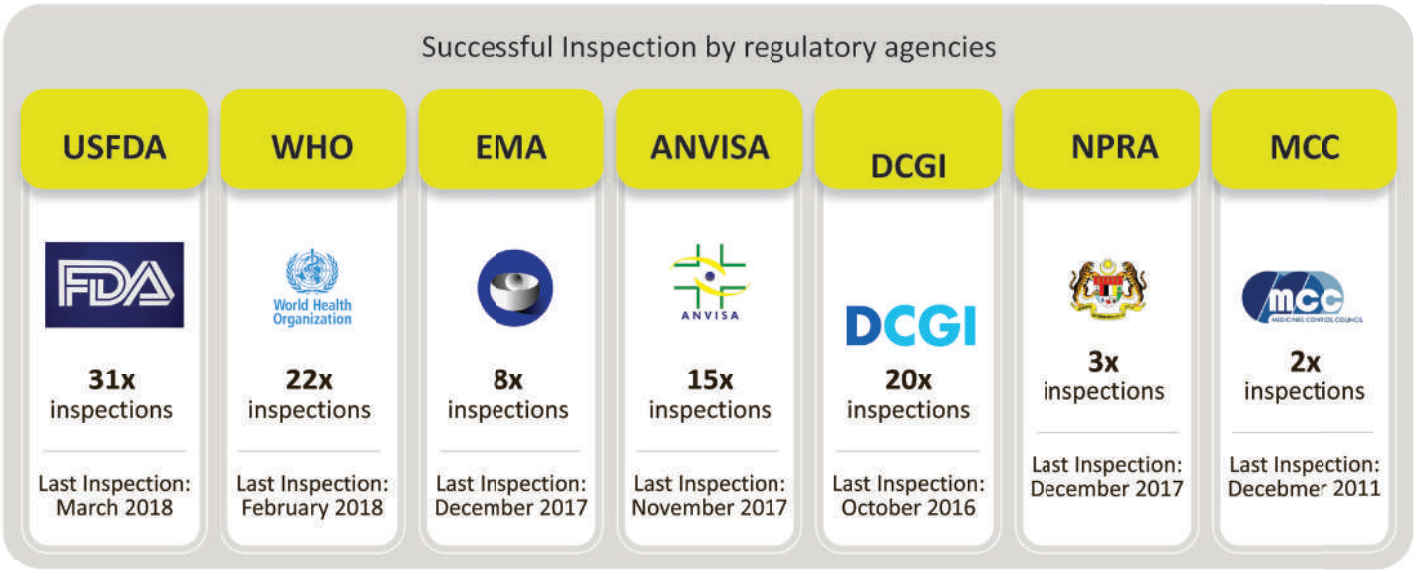
- Vast experience of executing more than 3,000+ studies for different regulatory market
- Assay bank of 700+ Validated bio-analytical Assays
- Database of 37000+ volunteers including female, post-menopausal females and geriatric populations
- Competency in handling complex studies in clinical trial designs (hormones, endogenous substances, elemental formulations and locally administered products) besides oral solid/liquid dosage forms.
- Experienced in handling some of the most challenging assays for hormonal products, nasal sprays with LLOQ of 1.0 pg/mL

2 : State-of-the-Art Infrastructure

- 9 Clinical pharmacology units with 428 beds spread across three cities Navi Mumbai, Ahmedabad and Vadodara
- Pool of latest and highly sensitive LC-MS/MS instruments (37), Including API 6500+ , Xeo TQS coupled with UPLCs
- In-house pathology lab, successfully accredited by CAP and NABL
- Storage facilities for retaining samples at -20*C and -70*C
- Regulatory compliant Archival facility spread across 10000 Sq Ft.

3 : Strong Regulatory Expertise

Consistent regulatory track records with more than 100 Successful audits by US FDA, WHO, EMA, ANVISA etc.



100+
Successful audits by Multiple regulators

1,200+
Pivotal Studies for USFDA Submissions

200+
Clients Served across the globe

Clinical Development Services (Phase II - IV and stand-alone services)

Clinical Trials are integral part of drug development. Accutest runs end-to-end services for Phase II to IV clinical trials on small molecules, large molecules and medical devices with fully ICH GCP, complied operations. Accutest is one of the few CRO's providing end-to-end services (protocol writing to CSR submissions) along with stand-alone customized services like clinical data management, medical writing or biostatistics.

Clinical trial feasibility and patient access planning

The clinical study feasibility involves analyzing key regulatory considerations, disease incidences and prevalence and practical implications of conducting clinical trials in a particular geography.

Key Service Areas:

- Study feasibility along with regulatory consultation
- Disease incidence, prevalence and practical implication of conducting study in a specific geography
- Utilizing investigator network & allied functions for effective study planning

  Accessing sites and patient pool for patient recruitment

Clinical Development Services has suuccessfully cleared 4 FDA inspections which included 10 sites.

Project management and planning

Our experienced project management team has successfully executed complex studies by accurately forecasting, identifying and resolving project risks in different therapeutic areas and phases across various geographies. We emphasize both planning and execution and adhere to the highest standards of excellence to ensure high quality and on-time deliverables. The dedicated project manager plays a crucial role while working with SOPs designed for smooth communication and execution of complex studies

Clinical monitoring

Clinical Monitoring is the back-bone and assures the quality of the clinical trials. Our clinical monitoring team works closely with the project management team and the investigators to ensure best in class execution at all stages. Our monitoring team follows industry best practices, local and international regulations. We provide exhaustive training on study protocols, procedures and therapeutic areas including current changes.

Medical writing and scientific communication

Our medical writers have long track records in scientific and/or clinical research areas, ensuring that all medical writing requirements are met in an efficient and timely manner.

- Protocol conceptualization, designing & preparation
- ICF designing
- Review articles, short communications etc.
- Report writing in compliance with ICH E3 guidelines/applicable regulatory submission
- Site specific and country specific reports

Clinical data management and biostatistics:

Clinical Data Management

We offer Clinical Data Management (CDM) services in conjunction with the clinical trials services bundled or as a stand-alone.

Our CDM service offerings are further strengthened by:

- Analyzing data collection requirements
- Identifying and implementing processes and technology solutions
- Tailoring our comprehensive service to match individual requirement
- End to End Clinical Data Management activities for both Paper and EDC studies
- CDASH standards compliant CRF designing
- Use of 21CFR Part 11 Compliant 'MICROSOFT.NET' and OC databases as per requirement
- Proper study planning in timely Go-live, conduct and closeout of the study
- Archival of study data

Statistics and Statistical Programming:

We offer effective solutions for study design, selection of endpoints, defining hypotheses, sample size justification and power calculations across Phase II – Phase IV clinical trials. Biostatistician and Statistical Programming team is experienced in delivering CDISC and SDTM compliant for wide range of therapeutic areas including Pharmacokinetic (PK) and Pharmacodynamic (PD) analyses.

Our Team provides the following range of Statistical Services:

- Review and Development of statistical sections of the Study Protocol
- Generation of Randomization Schedule
- Output generation and Statistical analysis
- Interpretation of results and input to Clinical Study Reports
- Validated software: SAS® 9.2 and WinNonlin 5.0.1 for apt output

Biologics and Biosimilars Services

CMC comparability | Pre-ClinicalComparability | Clinical Comparability

Initial characterization → Process development → Pre-clinical → Clinical → Manufacturing & Marketing

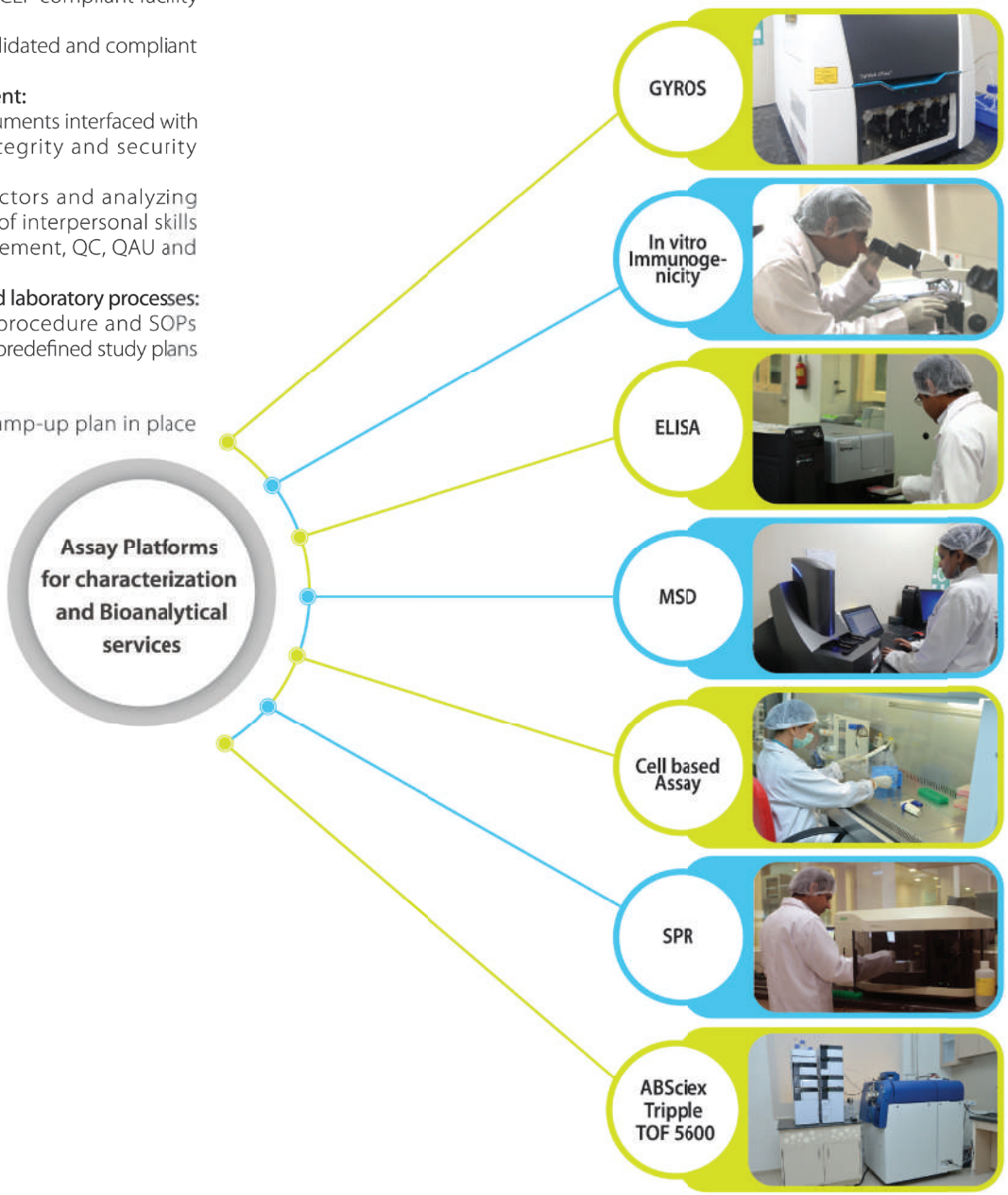
AREA	ASSAY FORMATS	ACTIVITIES
Characterization Services	LCMS/ MS, HPLC, SDS- PAGE, DLS RT PCR, 2D GEL Electrophoresis SPR Flow cytometry and Luminex	Intact mass, peptide mapping, di - sulfide bonding, N and C terminal sequencing and PTM - Glycosylation, Phosphorylation and acylation. Purity, Particle Size and Surface Charge Host cell DNA and Protein Impurities in Formulations Binding Kinetics and Biomolecular Interactions Surface Marker analysis and Multiplexing Biomarker assay
Bioanalytical Services	ELISA GYROS MSD Bioassays	Development and validation of bioanalytical methots for biomarkers, Pharmacokinetics and Immunogenicity assessments including functional bioassays for Potency enaluations and detecting neutralizing antibodies Biosimilarity Demonstration
Other Services	Critical reagent production	Transfection and gene expression studies Polyclonal and monoclonal antibody production purication & labeling Analytical cell banking and mycoplasma testing Statistical analysis & report writing

GLP and GCLP compliant Bio-analytical services for pre clinical and clinical development of biologics




Key Differentiator

1) **Global credibility:**
   - DCGI approved, GLP and GCLP compliant facility
2) **Latest technology:**
   - Equipped with qualified, validated and compliant high end instruments
3) **Thorough data management:**
   - Major data acquisition instruments interfaced with Watson LIMS for data integrity and security
4) **Experienced team:**
   - Cross trained study directors and analyzing scientists with high levels of interpersonal skills
   - Dedicated sample management, QC, QAU and archivist personnel
5) **Well defined and established laboratory processes:**
   - As per the documented procedure and SOPs
   - Activities performed under predefined study plans and study protocols
6) **Active growth plan:**
   - Business continuity and ramp-up plan in place



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