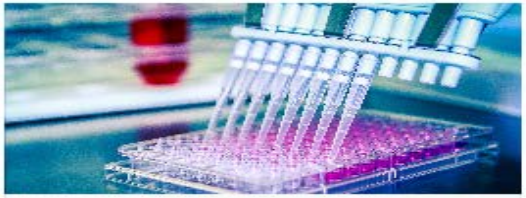
Life technologies services



Customized In Vitro disease modelling for early drug discovery

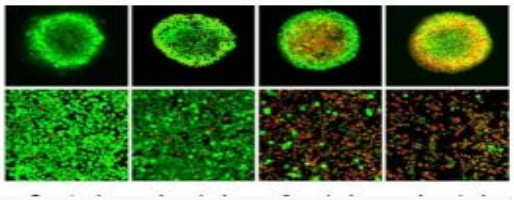
Service no. 1

Industries Based

Service no. 2

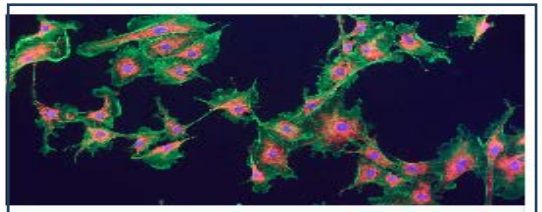
In Vitro ADME & DMPK

Service no. 3



Toxicology and Safety Assessment

Service no. 4



Cell Line Services

Service no. 5

Plant and Agriculture

Service no. 6

Clinical Research Services

Service no. 7

Service no. 1

Customized In Vitro disease modelling for early drug discovery

A

In vitro cell based drug discovery

B

Additional discovery services

1. Cardio vascular diseases

- Cardioprotective studies
- Hypertrophic cardiomyopathy related studies
- Myocardial Infarction based studies
- Atrial fibrillation (AF) (cardiac arrhythmia) based studies
- hERG : Patch-clamp assay
- hERG serum shift assays
- Ion channel trafficking assay
- Action potential duration (ADP) assays
- Cardiac marker detection: Troponin I, II
- Integrated human cardiomyocyte assays
- Hit Identification
- High content imaging- analysis of drug interaction at the sub-cellular level

2. Immunology

- Fibroblast-like synoviocyte activation assay
- Chemotaxis assay: Monocytes
- Chemotaxis assay: Neutrophils
- Conventional Dendritic cells activation assay
- Plasmacytoid Dendritic cells activation assay
- Anti-inflammatory assays
- <u>Immunomodulatory assays</u>

I. Flow cytometry for PK/PD
II. Flow cytometry for CD marker analysis of immunecells
III. ELISpot, to evaluate cellularimmune response
IV. Multiplex cytokine analyses

3. Gastrointestinal disorders

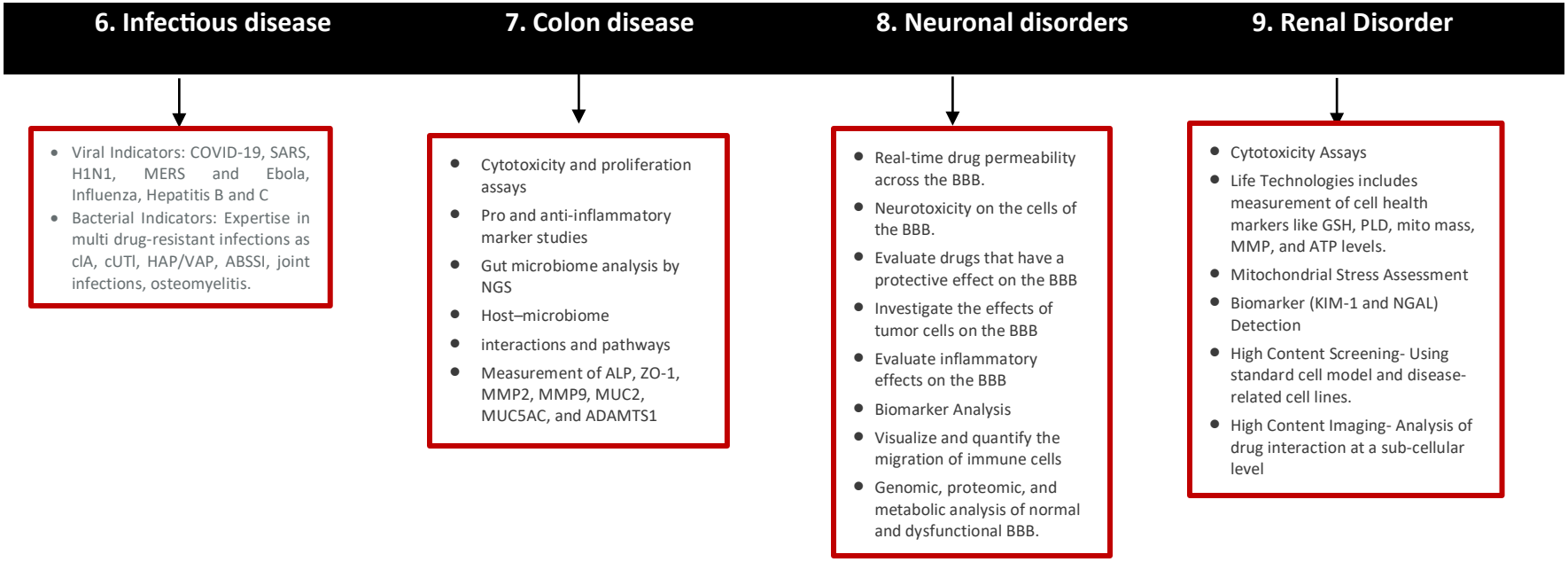
- Acute Pancreatitis
- Ascites
- Biliary Duct Stenosis
- Colorectal Conditions
- Constipation
- Crohn's Disease
- Liver Cirrhosis
- Exocrine pancreatic insufficiency in cystic fibrosis
- GERD
- Intestinal transit modulation
- Inflammatory Bowel Disease
- Irritable Bowel Disease
- Gastroenteritis Infections
- Pancreatic cancer
- Ulcerative Colitis

4. Wound healing

- Proliferation assays
- Cell migration assays: Scratch and cell inserts based
- Angiogenesis assays: Tube formation assay, CAM assay
- Anti-inflammatory assays: Pro and Anti-inflammatory

5. Respiratory disease

- Human Primary cell-based assays- Using 2D and 3D disease-relevant models
- High Content Screening- Using standard cell model and disease-related cell lines.
- Inhalation toxicity test
- Anti-viral studies
- In-vitro 3D respiratory models- for drug testing, inhalation toxicity, viral infections and inflammation studies
- 3D mucociliary tissue model - human-derived nasal/bronchial epithelial cells
- The 3D model derived from basal cells, goblet cells and ciliated cells


6. Infectious disease
Viral Indicators: COVID-19, SARS, H1N1, MERS and Ebola, Influenza, Hepatitis B and C
Bacterial Indicators: Expertise in multi drug-resistant infections as cIA, cUTI, HAP/VAP, ABSSI, joint infections, osteomyelitis.
7. Colon disease
Cytotoxicity and proliferation assays
Pro and anti-inflammatory marker studies
Gut microbiome analysis by NGS
Host–microbiome
interactions and pathways
Measurement of ALP, ZO-1, MMP2, MMP9, MUC2, MUC5AC, and ADAMTS1
8. Neuronal disorders
Real-time drug permeability across the BBB.
Neurotoxicity on the cells of the BBB.
Evaluate drugs that have a protective effect on the BBB
Investigate the effects of tumor cells on the BBB
Evaluate inflammatory effects on the BBB
Biomarker Analysis
Visualize and quantify the migration of immune cells
Genomic, proteomic, and metabolic analysis of normal and dysfunctional BBB.
9. Renal Disorder
Cytotoxicity Assays
Life Technologies includes measurement of cell health markers like GSH, PLD, mito mass, MMP, and ATP levels.
Mitochondrial Stress Assessment
Biomarker (KIM-1 and NGAL) Detection
High Content Screening- Using standard cell model and disease-related cell lines.
High Content Imaging- Analysis of drug interaction at a sub-cellular level

10. Liver disease

- Life Technologies assists in establishing NASH conditions by modulating glucose, fructose, free fatty acids, and lipopolysaccharide (LPS) levels.
- Cytotoxicity assays
- Cytokines analysis: IL-6, TNF-α, MIP-1α (CCL3), MCP-1, IP-10 (CXCL10), IL-8 (CXCL8)
- Expression of profibrotic markers
- Apoptosis marker studies
- Oxidative stress marker studies
- Mitochondrial dysfunction studies
- Cellular lipids and phospholipids estimation by LipidTox staining

11. Stem cells and Degenerative disease

Isolation and Characterization

- Isolation and maintenance of adult tissues and umbilical cord blood/tissue-derived stem cells.
- Characterization of MSCs/AMSCs/HSCs/NSCs by flow cytometry

2D and 3D model-based Differentiation Studies

- Neuronal Differentiation Studies
- Osteogenic Differentiation Studies
- Adipogenic Differentiation Studies
- Cardiomyocytes Differentiation Studies
- Dendritic and other immune cell generation from HSCs/MSCs
- Trans-differentiation studies

Signalling pathways governing stem cells: Notch, Wnt, Hedgehog etc

12. Metabolic disorders

- Cell proliferation studies
- Glucose uptake assay
- Alpha-amylase inhibition assay
- Alpha-glucosidase inhibition assay
- Insulin receptor binding studies
- IGF-R1 receptor binding studies
- Skeletal muscle regeneration assays using stem cells models
- Assays monitoring the protection of human podocytes or freshly isolated glomeruli
- Assays measuring anti-fibrotic effects across different primary cell types
- A comprehensive set of primary islet cell assays covering all relevant aspects of pancreatic beta-cell turnover and function
- Protection/reversal of metabolic stress-induced beta-cell de-differentiation
- Cell-specific primary rat and human beta cell replication (plated or intact islets)
- Cell-specific quantification of beta-cell apoptosis in plated islets
- Insulin secretion studies with rat and human islets

13. Endocrine disruption screening

- Estrogen Receptor (ER) Transactivation
- Androgen Receptor (AR) Transactivation
- Androgen Receptor (AR) Modulation
- Estrogen Receptor-alpha (ER-α) Binding
- Estrogen Receptor beta (ER-β) Binding
- Androgen Receptor (AR) Binding
- Steroidogenesis
- Aromatase Assay

14. Oncology

Cytotoxicity & Proliferation Assays

- SRB assay
- ATP assay
- LDH assay
- Cell cycle
- MTT assay
- Ki67 assay,
- Clonogenic assay

Apoptosis and DNA Damage Studies

- Annexin V/PI assay
- Ao/EtBr assay
- p53 assay
- Caspases assay
- 21 assay
- Comet assay
- MMP - JC1 assay
- Cyt-C assay
- Cell cycle arrest
- NO analysis
- TUNEL assay
- ROS analysis

Angiogenesis and Metastasis Assays

- Cell migration assays
- Scratch assay
- Tube formation assay
- Angiogenesis signaling pathways (HIF1α, TGF-b, VEGF, SMAD, p38, Pi3)

Cancer Signaling Pathway Marker Studies

- C-Jun test
- cAMP assay
- HIF-1 alpha assay
- STAT 1,2,3, & 6 assay
- Phospho-mTOR assay
- Phosphor-Akt (p-Akt) assay
- P53 expression
- Phosphor-ERK assay
- Ca+2 assay
- NF-kappa B/p65
- Phosphor-CREB assay
- EGFR assay
- Akt assay
- P38 activity assay

B

Additional discovery services

1. Microbiome research

- **Whole Genome Sequencing (WGS)**
- **Exome sequencing**
- **RNA sequencing**
- **Pre- implantation screening**
- **Prenatal and postnatal screening**
- **Hybridoma or antibody sequencing**
- **Agriculture and livestock genotyping**
- **Metagenomics**
- **Microbiome analysis**
- **Microbial identification: 16s, 18s and STR sequencing**
- **SNP analysis**

2. Nano particles in drug delivery

- **Particle size analysis**
- **Particle count**
- **SEM**
- **TEM**
- **UV and XRD**
- **Zeta potential**
- **FTIR**
- **Cytotoxicity and other biological applications**

3. Molecular biology-based services

- Cloning, sequencing, and expression service
- gDNA extraction, Reverse transcriptase PCR and Real-time PCR
- RNA extraction, cDNA synthesis, Real-time PCR and Report
- Protein purification service from recombinant Bacteria (His tag) and wild fungi strains
- Labelling services
- DNA fingerprinting service/RAPD
- Mycoplasma detection by PCR
- Endotoxin detection by colorimetry/fluorimetry
- Epigenetics services include methylation, miRNA, and DNA-protein interaction analysis.
- Gene synthesis

I. **Standards Gene synthesis**
II. **ProLongGene**
III. **DNA Fragment**
IV. **SsDNA**
V. **PCR Cloning & Subcloning**
VI. **Mutagenesis**
VII. **Plasmid Preparation**

- Oligo synthesis

I. **Custom DNA Oligos**
II. **Custom RNA Oligos**
III. **qPCR Probes**
IV. **NGS Oligos**

4. Bioanalytical laboratory services

- **Phytochemistry:** Plant extractions, isolation of secondary metabolites and bioactive compounds.
- **Bioanalytical Services:** GC-MS, LC-MSMS, SEM, TEM, HPLC, HPTLC, NMR, X-RD.
- **Biomarker Testing:** Flow cytometry, Immunocytochemistry - Confocal microscopy, ELISA, WB.
- **Immunology Testing:** Immunohistochemical and immunocytochemical assays, ELISA-based assays
- **Next-generation Sequencing:** GWAS studies, SNP detection, RNA seq, Exome Sequencing, CNV Analysis

Service no. 2

1. Biotech/ biopharma

Large molecules discovery services

- Recombinant DNA Technology
- Cloning and Vector Generation
- Plasmid DNA Preparation
- Mutagenesis
- Antibody Gene Sequencing
- and Reformatting
- Strain Engineering
- **Construction of cDNA, phage, and yeast libraries, as well as plans for high-throughput screening and functional characterization, constitute library generation and evaluation**
- Gene Expression Analysis
- Residual Protein, DNA and Mycoplasma Detection
- Residual Protein, DNA and Mycoplasma Detection
- Protein Sciences
- Protein Expression
- Mammalian Expression Systems
- Insect Cell Expression Systems
- Yeast Expression Systems
- Bacterial Expression Systems
- Protein Purification
- Antibody Purification
- Microbial Purification Capabilities
- Protein Analytics and Characterization
- Protein Stability Analysis
- Protein Conjugation and Labelling

Small molecules

- Contamination & Impurity Testing
- Microbiology testing
- Mycoplasma testing
- Sterility testing
- Pyrogenicity, Endotoxin, and Monocyte activation testing
- Viral safety testing
- Next-Generation Sequencing
- Host cell protein assays
- Process and product related impurities – HPLC-ELSD, HPLC-CAD, HPLC-MS, ELISA
- Residual DNA testing
- Bioactivity & Potency Testing
- Lot & Final Drug Product Release Testing
- Protein Characterization

Biologics testing solutions

- Transmission electron microscopy to detect structure and size of exosomes or nanoparticle
- HPLC assay to quantify amount of drug loading inexosomes/ nanoparticles
- Drug or natural compoundpackaging in exosomes
- Testing the toxicity of new anti-cancer molecules on Cancer stem cell (3D culture)derived from cell lines (MTT Assay)
- MTT assay (cell cytotoxicity assay) in a single cell line with 1 test compound)
- Testing the toxicity of new anti-cancer molecules on primary tumor cells, CTCs (MTTAssay)
- Cancer stem cell characterization using CSC specific markers from a singlecell line

Coveted services

- Development of Murine Hybridoma Cell Lines against an Antigen. Delivery of5 Positive Cell Lines.
- Variety of Antibody Production Methods for Delivery of Purified Monoclonalor Polyclonal Antibodies
- Gene Synthesis, Transformation, and Culturing/Stabilization of Recombinant Producing Protein Cell Lines in Yeast or E.Coli. Functional Validation Available
- Fermentation/Cell Culture Based Production of Recombinant Proteins;Available in ISO 13485/GMP Manufacturing.
- A Range of Affinity Chromatography-Based Purification Options
- Labeling of Antibodies with various Enzymes for use in DiagnosticApplications
- Screening for Matched Pairs from Min. Pool of 5 Antibodies
- Total Development of ISO 13485 Compliant ELISA Kit against any targetantigen. Multiplex ELISA development also available for 2 Antigens.
- Total Development of ISO 13485 Compliant LFS Kit against any targetantigen. Multiplex development also available up to 3 Antigens.
- Exosome isolation from cell culture medium and serum
- Dynamic Light scattering for exosome or nanoparticle size and zeta potentialdetection) (DLS analysis)

- Confocal microscopy to detect cellular apoptosis using AnnexinV
- Generation of mature dendritic cells from monocytes
- PBMC from Human blood 15 million cells (Healthy donor)
- Flow cytometry analysis to detect Ki67 and AnnexinV
- ELISA assay
- Nanoparticle Tracking analysis to detect number ofexosome particle & size in 1 ml sample)

2. Cosmetic industry

- Verify cell lines against the database to identify the non-listed ones
- Perform STR profile testing
- Compare STR profile with donor or database
- Determine the percentage that matches the given sample

Skin Studies

1. **human skin biopsies (Treated vs Untreated)**

- Metagenomics by Next generation Sequencing (NGS)
- Serum lipidsincluding triglycerides
- Vitamins – LC-MSMS
- Calcium
- Blood urea nitrogen
- Creatinine, Elastin and Collagen levels by Q-PCR

2. **In vitro Model for Skin Penetration Study**

- In vitro Skin Penetration Study by using EpiDerm SystemTM
- In vitro Skin Penetration Study by using Strat-M Transdermal Diffusion Membrane System
- In vitro Skin Penetration Study by using Keratinocytes cell line based assays

3. **In vitro Skin Model to test Skin Health**: - In vitro skin models can be used for the following types of Skin Damages

- Matek/ EpiDerm or other 3D culture systems - EpiDerm is a proven in vitro model system for chemical, pharmaceutical and skin care product testing.
- Cultured at the air-liquid interface (ALI), EpiDerm allows for the evaluation of topically applied compounds, chemicals, cosmetic/personal care product ingredients and final formulations

Hair Studies

1. Follicular general health study in Human hair by Anagen Vs Catagen molecular markers quantitative expression (in vivo)

Hair pull Test/ punch biopsy

- 0-5 anagen / telogen hairs extract.

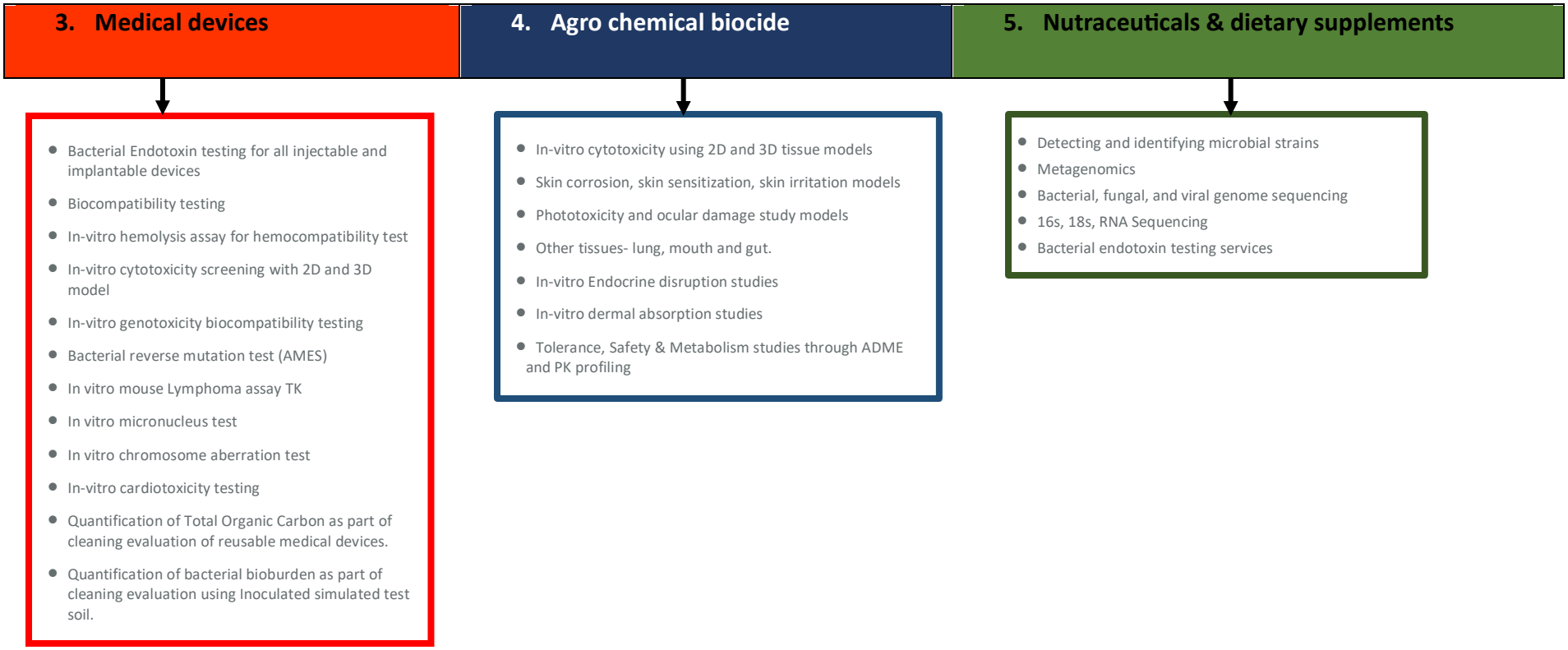
Biopsy of scalp

- Scalp biopsies can be used to confirm a diagnosis of Alopecia
- 4-mm punch biopsy tool to obtain the tissue sample, 2-4 terminal hairs and 1 or 2 vellus hairs

In the hair follicles expression of below factors will be assesd via ELISA/ qRT PCR etc

- Vitamin E and Growth factors
- Keratin protein
- Immunosuppressants TGF-β1
- ATP level
- Beta-1 integrin and p63 (identified as potential markers for hair follicle stem cells)
- Lhx2 gene
- IL-6, IL-10

2. Hair follicular Bulge stem cell stimulation/activation study by quantified expression of markers (in vitro)


3. Medical devices
Bacterial Endotoxin testing for all injectable and implantable devices
Biocompatibility testing
In-vitro hemolysis assay for hemocompatibility test
In-vitro cytotoxicity screening with 2D and 3D model
In-vitro genotoxicity biocompatibility testing
Bacterial reverse mutation test (AMES)
In vitro mouse Lymphoma assay TK
In vitro micronucleus test
In vitro chromosome aberration test
In-vitro cardiotoxicity testing
Quantification of Total Organic Carbon as part of cleaning evaluation of reusable medical devices.
Quantification of bacterial bioburden as part of cleaning evaluation using Inoculated simulated test soil.
4. Agro chemical biocide
In-vitro cytotoxicity using 2D and 3D tissue models
Skin corrosion, skin sensitization, skin irritation models
Phototoxicity and ocular damage study models
Other tissues- lung, mouth and gut.
In-vitro Endocrine disruption studies
In-vitro dermal absorption studies
Tolerance, Safety & Metabolism studies through ADME and PK profiling
5. Nutraceuticals & dietary supplements
Detecting and identifying microbial strains
Metagenomics
Bacterial, fungal, and viral genome sequencing
16s, 18s, RNA Sequencing
Bacterial endotoxin testing services

Pre formulation services

Single-dose intravenous pharmacokinetic studies, providing solutions, suspensions, creams, emulsions, ointments, gels, and more.

Service no. 3

- Large molecule analysis
- Permeability & Transporters
- Cytochrome P450 induction
- Protein binding
- In Vitro metabolism
- In Vivo Pharmacokinetics
- Drug- Drug interactions
- PK/PD Modelling & Simulations

Bioanalysis quantitation

Sensitive small molecules, light-sensitive, and cytotoxic compounds, conducting bioanalysis in multple bio-matrices for tissue distribution studies.

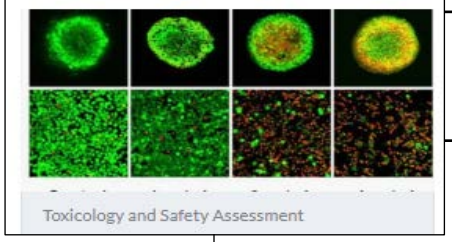
Specific cytochrome P450 (CYP) enzymes and UDP-glucuronosyltransferases (UGTs) inthe metabolism of drugs through reaction phenotyping.

Physico-chemical Assays

- Log D and Log P assessments help in understanding thedistribution and partitioning behavior of compounds
- Providing insights into their potential uptake anddistribution within the body
- Kinetic and thermodynamic solubility studies evaluate the solubility properties of compounds under different conditions,
- Providing critical information for formulation and dosage form optimization.

Metabolite identification & biotransformation

Service no. 4



- Functional mitochondrial toxicity (Seahorse)
- Mitochondrial respiratory complex assay (using permeabilized cells)
- Mitochondrial biogenesis
- Mitochondrial Glu/Gal assay
- HCS mitochondrial toxicity

Multiparametric toxicity

Nephrotoxicity

In vitro cell based screening models

Genotoxicity

Neurotoxicity

- Acute neurotoxicity
- Sub chronic neurotoxicity
- Developmental neurotoxicity
- Behavioral and developmental toxicity
- Safety pharmacology
- NMDA receptor antagonist

Hepatotoxicity & drug induced liver injury

- Using HepG2, HUH7, Hep3B cell lines and human iPSC HepRG spheroid cultures
- Drug-induced phospholipidosis and steatosis
- Lysosomal trapping (lysosomotropic)
- Cholestasis
- Mitochondrial permeability transition

Multiparametric toxicity

- IC50 determination
- Cell loss/death using fluorescent imaging
- Nuclear size and morphology using fluorescent imaging
- Cell membrane permeability using fluorescent imaging

Cardiotoxicity

- functional mitochondrial toxicity (Seahorse)
- hERG safety screening using Invitrogen's Predictor™ hERG fluorescence polarization assay kit
- 3D microtissue-based cardiotoxicity assay using human iPSC – CM (cardiomyocytes) spheroid cultures

Ocular toxicity

- Electroretinography (ISCEV, custom protocols, and VEP)
- SD-OCT enables anterior and posterior imaging and retinal layer segmentation.
- Pachymetry (corneal thickness)
- Digital fundus photography/video
- CSLO provides 3D images using infrared and tomography modes.
- Fundus autofluorescence
- Fluorescein angiography (FA)
- Indocyanine green angiography (ICG)
- Vitrectomy
- Aqueous/vitreous humor collections and biomarker quantification
- Slit-lamp bio microscopy
- Indirect and direct ophthalmoscopy
- Gonioscopy
- Streak retinoscopy
- Draize test
- Ocular reflexes

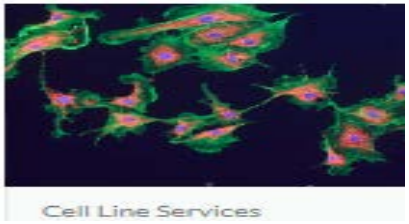
Dermal toxicity

- In vitro irritation using 3D reconstructed human epidermis models (OECD 439)
- In vitro skin corrosion using 3D reconstructed human epidermis models (OECD 431)
- Phototoxicity assay using BALB/c-3T3 cells
- Skin sensitization assay using KeratinoSens cell line (OECD 442D)
- Skin sensitization by directing peptide reactivity assay (OECD 442C)

Embryotoxicity

- Developmental and reproductive pathology
- Specialized neurobehavioral testing
- Functional assessments cover growth, pulmonary, neurobehavioral, reproductive, and immunological development.
- Toxicokinetic evaluations, including induction studies
- Juvenile toxicity testing in rodents and nonrodent species
- Screening Information Data Sets (SIDS)
- Hormone assays
- Male reproductive assessments in rodents and nonrodents
- Behavioral tests encompass pre/postnatal and multigenerational studies, assessing activity, learning, and memory.
- Range of developmental immunology tests that can be added to pre-and postnatal and multigenerational studies
- Endocrine disruptor screenings (in vivo and in vitro)
- Skeletal measurements include bone size, geometry, density using micro-CT, pQCT, X-ray, and DXA in pre/postnatal studies.
- Sperm/oestrous cycle analyses
- Neuro-histomorphometry
- Genomics

Service no. 5



Cell surface validation marker service	Cell immortalization service	Custom immortalized cell line development service	Custom host cell line development	Epigenetic induction of cell growth service

B cell - CD1C, CD28, CD79, CD80, CD86, CR1, FCGR2A, ITGA3, MS4A1, NT5E
T cell - CD4, CD8, CD3, CD6, CD40LG, CTLA4, FAS, TNFRSF4
Natural killer (NK) cell - CD2, CD7, CD96, CD244, CD247, IL12RB1, KLRs, NCAM1
Macrophage/monocyte - CD33, CD63, CD69, CD70, CD74, DPP4, IL1R2, ITGA1, TNFRSF8
Platelet - ITGA2B, ITGB3M SELP
Dendritic cell - CD1A, CD40, CD83, CD86, CD209, IL3RA, ITGAX
Granulocyte - C5AR1, CEACAM8, FCER1A, FCER2, FCGR3A
Endothelial cell - ENG, ICAM2, MCAM, NOS3, PECAM2, TEK, VCAM1, VWF
Epithelial cell - CD1D, EPCAM, KRT8, KRT18
Smooth muscle cell - MYH9, MYH19, MYOCD
Fibroblast - ALCAM, COL1A1, COL1A2
Human Mesenchymal Stem Cells - CD44, CD90, CD105, CD106, CD166, and Stro-1
Human-induced Pluripotent Stem Cells - 5T4, ABCG2, Activin RIB/ALK-4, Activin RIIB, Alkaline Phosphatase/ALPL, B18R, E-Cadherin, Cbx2
Human Haematopoietic Stem Cells - Sca-1, CD27, CD34, CD38, CD43, CD48, CD117 and CD150
Human Embryonic Stem Cells - OCT4, SOX2, and NANOG
Human Limbal Stem cells - α9 and β1 integrins, α-enolase, and connexin-43

- SV40T antigens are widely used for most cell types
- hTERT is commonly used for most cell types
- EBV Genes are used for B Cells
- HPV16-E6/E7 is used for Keratinocytes
- Adenoviral E1A is used for epithelial cells from a broad range of rat tissues
- CDK4 is used for Bronchial epithelial cells
- P53-siRNA is used for a wide variety of cell types
- cMyc is used for Prostate epithelial cells

- Tissue sourcing
- Primary cell isolation
- Cell Immortalization
- CRISPR/Cas9 Based KO and KI or other genetic modification

GMO Protein Testing in Plants:
Cry1Ac, Cry2Ab, CP4 EPSPS, VIP3A

DNA Fingerprinting

Zygosity in Cotton

GMS Testing in Cotton

Genomic DNA extraction from plant

Service no. 6

Plant and Agriculture

mRNA isolation from leaf and seed

Sample preparation for ELISA (plant samples like tomato, potato)

Double Haploid Line Development (DH)

TY Genes in Tomato

Bioefficacy Testing

Service no. 7

1. Investigator & trial facilitation service `
2. Feasibility service
3. Site management service
4. Monitoring service
5. Quality assurance service
6. Regulatory service
7. Medical writing
8. Insourcing service
9. Post marketing surveillance
10. Statistical service
11. Non industry sponsored clinical trial solutions

1. Investigator & trial facilitation service

- Referrals to Relevant Studies
- Clinical Research Primers & GCP Training
- Clinical Trials Process Training/Overview
- Standardized Site SOPs
- Assistance with Site Coordinator Staffing
- Assistance with Patient Recruitment
- Facilitation & Coordination of Regulatory Docs
- Site Pre-Qualification & Initiation Pre-Calls or Visit
- Contract Negotiations & Management

2. Feasibility service

- Investigator/Site interest
- Patient population to determine capacity and speed of enrollment
- Possible confounding factors in patient recruitment
- Availability of referral networks
- Investigator/Site experience in conducting similar trials
- Successful patient recruitment techniques
- Retrospective assessment of enrollment and retention in similar studies
- Availability of qualified site personnel
- Availability of equipment/facilities required to successfully conduct the trial
- Impact of study procedures on Standard of Care
- Additional sponsor requirements

3. Site management service

- Provide study coordinator to work with the site (hospital or medical institution) / Principal Investigators to support the principal investigator (PI) in ethics committee submissions, patient recruitment, and follow-up.
- Our assigned study coordinator assists the site in creating the project's specific working documents.
- Set up the clinical trial process to meet specific project requirements.
- Supppprt the sites to achieve overall project deliverable from the sites' perspective

4. Monitoring service

- Develop study management plan based on our project management capability.
- Conduct and write reports for the feasibility, initiation, interim monitoring, and site close visits.
- Discuss patient recruitment strategies and retention plan with site staff.
- Perform site visit according to monitoring plan and work with data management team to ensure data quality.
- Work with pharmacovigilance team to provide accurate safety information.

5. Quality assurance service

- Provide Audit Support for clients and assist them in preparing for site inspection.
- Assist CRAs and project managers to ensure that GCPs and compliance with regulatory requirements are maintained.
- Provide periodic internal audits to ensure that our standards are maintained.

6. Regulatory service

- Insight on local regulatory environments.
- Smooth transitions from exploratory to confirmatory stages of investigational drugs.
- Expedited submissions for possible acceleration of the developmental process.
- Facilitated approval of applications to conduct clinical trials of new drugs.
- Responses to regulatory body requests for information.
- Support for and participation in meetings with regulatory bodies.
- we provide crucial links to major regulatory authorities and are skilled in the preparation, coordination, and management of complex multinational submissions and meetings.

7. Medical writing

- Prepare documents for clinical trials, post-marketing clinical studies, clinical trial plan protocols, informed consent forms, case report forms, investigator's brochures, etc
- Assist in preparing clinical trial dossiers (CTDs)
- Work in conjunction with the pharmacovigilance team to prepare in relation to periodic safety reports
- Assist in preparing manuscripts, articles, etc.
- Translate medical information from and into English and to other languages

8. Insourcing service

- Provide flexible resourcing to meet your needs
- Provide full Odisha coverage (East Zone,INDIA)
- Provide flexible contract and resource allocation tailored to your needs

9. Post marketing surveillance

- Comparative head-to-head studies with equivalence or non-inferiority endpoints
- Non-randomized observational studies and patient registries
- Special safety studies to fulfill phase 4 regulatory obligations
- Observational marketing research
- Post-marketing safety update reports for regulatory submission
- Exploratory statistical analyses of data from marketing authorization clinical trials
- Awareness building, medical education and publication support
- Post Marketing Literature Surveillance
- AE Monitoring & Reporting Services

10. Statistical service

- Comprehensive data analysis plans, including sample size determinations, detailed descriptions of statistical methodologies, program specifications, and mock examples of all deliverables.
- Preparation and generation of randomization plans.
- Preparation of customized analysis programs thoroughly tested and validated according to documented procedures.
- Interpretation of study results and writing support for study reports and manuscripts.
  Integrated efficacy and safety analysis for regulatory submissions.
- Adaptive design consultation to help lower development costs and reduce time to market.

11. Non industry sponsored clinical trial solutions

- Literature review
- Study design
- Development of clinical protocol
- Preparation of essential documents
- Regulatory support and guidance
- Preparation of regulatory paperwork
- eCRF design and build
- Investigator Selection and Qualification
- Investigator Site staff training
- SOP development for Investigator site
- Laboratory selection, qualification, and training
- IMP handling and storage
- Study monitoring and project management
- Medical safety monitoring, DSMB
- Pharmacovigilance
- Patient e-Diary
- Data management
- Clinical Study Report writing
- Manuscript writing and publication support
- Biological Sample storage and retrieval
- Audits and compliance support