

# Accelerating Research

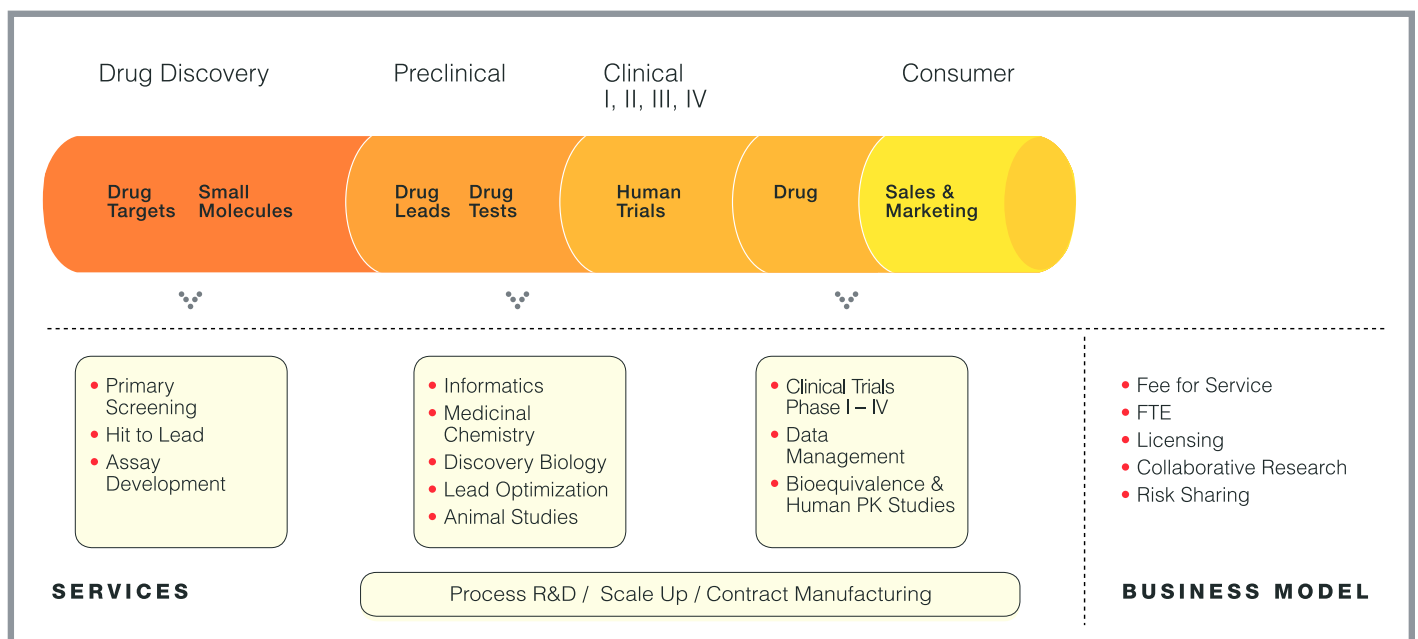
At GVK BIO we offer contract research services that help global pharmaceutical and biotech companies significantly enhance their R&D success.



## Integrated research platform

Our integrated offering allows clients to access multiple outsourcing choices across the research and development value chain. We aim to become preferred partners on collaborative research projects, sharing risks and rewards to jointly create intellectual property. We address a wide spectrum of needs in the following areas:

- Medicinal Chemistry • Informatics • Biology • Process R&D • Clinical Research • BA/BE Studies
- Knowledge Process Outsourcing



# Service areas

## Medicinal Chemistry

Our services meet exacting client needs for organic/ medicinal chemistry and include synthesis of:

- Building Blocks, Scaffolds, Intermediate compounds, Reference compounds
- Specially designed small molecules or analogues for Lead Generation and Lead Optimization
- Pharmacophore based focused libraries generated for a particular target protein
- Compound Libraries
- Lead compounds in grams and kilos (custom synthesis)

Our streamlined project management processes allow our clients to leverage the experience and expertise of our scientists. Our talented teams are versatile enough to synthesize compounds with established chemistry as well as develop novel synthetic routes.

## Informatics

Our Informatics division analyzes data to transform biological patterns into knowledge and ultimately, successful products and services. Our services span Curation, Cheminformatics and Bioinformatics. Information from more than 125 journals and patents has been curated into rich databases. This includes chemical activity, biological activity, toxic information and pharmacological information for a large number of compounds. Key advantages are:

- Available in searchable formats such as Oracle, XML, ISIS/Base and can easily be exported to relevant formats.
- A total of over a million compounds and three million SAR points covering a large number of targets
- Easy querying using a combination of structure, numeric and textual fields
- Structure, sub-structure and molecular similarity based query
- Pharmacophore hypothesis, analogue (3D- QSAR) or structure based drug design (virtual screening) for enhanced potency and selectivity
- Similarity and Diversity analysis with a focus on chemical library design

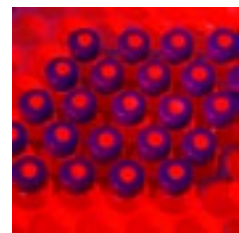
## Process R&D

We offer services in the areas of process development, analytical development, quality and IP management. We also provide process scale up services through our Kilo lab and manufacturing facilities.

Our accomplished teams have expertise in synthetic chemistry, characterization, impurity profiling and documentation. They work in state-of-the-art facilities with cutting edge equipment and analytical infrastructure.

## Biology

Our Biology services complement our existing services in Informatics and Medicinal Chemistry and complete our services in Discovery Research. We offer comprehensive pharmacological profiling, which encompasses services including primary screening, selectivity and ADME. DMPK, efficacy and safety evaluations in appropriate animal models are also available. Our offerings include a panel of validated assays and models for determination of the biological activity of NCEs. We have established a state of art facility that includes a cell biology lab, a radioisotope lab and biochemical lab for compound profiling. Our team comprises of highly skilled and qualified personnel with relevant pharma industry experience



# Service areas

## Clinical Research

We offer integrated or stand alone full service contract research support for Phase I to IV clinical trials across broad therapeutic areas.

Our services include:

### Clinical Operations

- Protocol & Statistical Design
- Medical Writing
- Site Feasibility
- Medical Monitoring
- Regulatory Affairs
- Quality Assurance

### Data Management

- Project Management
- Case Record Form Design
- Statistical Analysis Plan
- Statistical Analysis and Report
- Data Validation

## Knowledge Process Outsourcing

We provide comprehensive information and knowledge in the field of intellectual property and patenting. We offer an eclectic mix of IP-trained professionals proficient in chemical, biotechnological, pharmaceutical and other scientific and engineering disciplines; rendering our high quality services at a cost-effective value. Our team is proficient in providing high-end services utilizing Delphion, MicroPatent, and other patent databases. We have specific expertise handling structure and sequence searches using STN.

Our services cover the entire framework required for filing of patents including:

- Patent Search
- Prior art
- State-of-the-art Infringement
- Validity
- Patent Writing
- Patent Drawing
- Patent Proofreading
- Claim Analysis
- File History Analysis

## BA/BE

We offer integrated or stand alone services in the areas of Clinical, Bioavailability and Bioequivalence studies. Our services include selection of a suitable study design, protocol and ICF preparation, interaction with Independent Ethics Committee, selection and care for subjects, pharmacokinetic and statistical data evaluation, integrated report preparation and safe archiving of study-related data.

Our state-of-the-art Bioanalytical laboratory includes four clinics of 30, 34, 40 and 40 beds with dedicated areas for phlebotomy. With a continuously updated list, we offer highly selective and sensitive validated methods for assay of drugs, metabolites and endogenous compounds from biological matrices using HPLC and LC/MS/MS techniques. A strong SOP driven culture ensures compliance with all statutory and mandatory requirements.



