Biomarker Services

Biomarkers are critical tools in drug discovery and development. They serve as surrogates for assessing the activity of candidate therapeutics, and can be indispensable tools for validating targets, proving the mechanism of action and predicting therapeutic efficacy, as well as alerting for potential toxicity. The ability to develop biomarkers in animal models and then translate them to the clinic can greatly accelerate candidate development and decrease timelines.

Biomarkers are an important component of our service offering. Our comprehensive global portfolio supports clients every step of the way, from novel biomarker identification, to animal models and testing, through safety assessment and clinical support. Our knowledge and expertise allows us to assist with the discovery of biologically and scientifically relevant biomarkers, as well as the measurement and interpretation of their changes within the test system relating them to the drug development program. Scientific excellence is ensured by a synergy between experts in multiple areas, adding value to the preclinical studies. In addition to our portfolio of GLP-compliant markers, qualified assays can also be rapidly validated for GLP compliance.

Services include:
- Therapeutic Area Expertise
- Behavioral Assessments
- Physiological and Functional Assessments
- Biomarker Identification and Assay Development
- Fluid- and Tissue-Based Assays
- Imaging Capabilities

Therapeutic Area Expertise
Charles River provides a comprehensive range of biomarker services in key therapeutic areas and toxicological indications. From early discovery stages to clinical support, our scientists have the expertise to relate biomarkers to every stage of a drug development program. In addition to several sites dedicated as therapeutic area centers of excellence, we employ multidisciplinary teams of experts in oncology, inflammation, immunology, infectious disease, ocular disease, metabolism, and disease of the cardiovascular, renal, respiratory, and central nervous systems.
Behavioral Assessments
Our behavioral markers support drug development mainly in the central nervous system (CNS) and musculoskeletal areas in a range of large and small animal species. Both quantitative and qualitative assessments play an integral role in many of the in vivo efficacy and safety studies offered by our global discovery and preclinical facilities. Our team uses a unique toolkit of translational technologies (e.g., fine motor kinematic analysis and touch screen testing) and the latest validated models (e.g., chronic social defeat) to measure a full spectrum of traits beyond general behavior, from learning and memory to reflexes, pain, strength, and depression.

Physiological and Functional Assessments
Physiological and functional markers span across multiple species and therapeutic areas, including, but not limited to, the cardiovascular, respiratory, ocular, renal and central nervous systems. Offered in a number of our discovery and preclinical facilities, these qualitative assessments are typically included in our efficacy and/or safety studies, and are designed to meet regulatory requirements, as applicable. Many of these assessments are available in stand-alone specialty studies and can be integrated into repeat-dose toxicology studies to reduce animal use. Our team uses a combination of sophisticated equipment (e.g., jacketed telemetry) and humane techniques (e.g., wireless transmission and group housing) to collect data on brain/neuronal activity, retinal function, intraocular pressure, blood pressure, respiratory rate, tidal and minute volume, heart rate, and ECG parameters.

Biomarker Identification and Assay Development
The identification and use of predictive biomarker assays has become an integral part of the drug discovery and development process. Our capabilities span a range of diseases and include identification and validation of biomarkers, development of quantitative assays in primary cells and disease tissue, pharmacodynamic and disease models, safety assessment studies and efficacy and translational medicine markers in the clinic. Our team is experienced in the evaluation of a number of standard and novel readouts, including proteomic, genomic, phosphoprotein, and epigenetic markers.

Fluid- and Tissue-Based Assays
The biomarker scientists and clinical and anatomic pathologists at Charles River work with multiple platforms to offer full method development, optimization, qualification and validation. All assays can be performed in accordance with GLP regulations. In addition, assay qualification for support of early drug discovery studies can be tailored to a sponsor’s requirements. Our assay development services are fully supported by core capabilities in clinical and anatomic pathology, clinical sample analysis and immunology- and chromatography-based assays.

Imaging Capabilities
Imaging has the potential to dramatically increase the efficiency of lead candidate selection by providing earlier and more highly predictive data, compared with traditional methods. Imaging is also well suited for facilitating translation between preclinical testing and clinical evaluation of drugs. Furthermore, imaging methods are more easily applied than traditional methods in the newer, more realistic models of human disease that are becoming increasingly prevalent.

Our scientific and technical staff included a number of imaging specialists at our sites in Canada and Finland offering a broad range of small and large animal imaging capabilities including MRI, PET, SPECT, DXA, micro-computed tomography and optical coherence tomography. In addition, we have access to one of few available cyclotron particle accelerators in the industry.