

## Clinical Pharmacology Center

Pharmaron's Clinical Pharmacology Center (CPC), located in Baltimore, Maryland, focuses on full-service Phase I clinical research. Our experienced team, facility design and geographic location provide operational excellence that ensures precision and integrity for all studies. Our expertise in First-In-Human,  $^{14}\text{C}$ -hADME and vaccine/infectious disease study types, combined with our full suite of clinical pharmacology services, allows our team to rapidly advance drug development programs.

### Capabilities

- 300+ early phase studies completed
- 90+ beds, including 4 FIH and 2  $^{14}\text{C}$ -hADME dosing suites
- 100% HNV recruitment of diverse populations
- CLIA/COLA accredited clinical diagnostic laboratory
- Extemporaneous compounding pharmacy for complex administrations
- ERT-preferred ECG collection site
- Bioanalysis of small molecules, biologics, CGT products and biomarkers
- Biometrics including data management and biostatistics
- Full-service study management, including regulatory affairs, PM, medical writing, clinical monitoring, pharmacovigilance and quantitative pharmacology

### Study Type Expertise

#### Integrated First-In-Human Clinical Studies

- Customized study design consultation based on therapeutic area, study objectives and program goals
- Recruitment of healthy volunteers and patients
- Full-service study management including IND preparation/filing, bioanalysis/biomarker development and dataset delivery
- Exceptional safety oversight and data reporting for rapid dose escalation
- Experience in all therapeutic areas

#### Human $^{14}\text{C}$ -ADME Studies

- $^{14}\text{C}$  ADME/absolute bioavailability within a single protocol
- Customized study design consultation
- $^{14}\text{C}$ -Microtracer, macrotracer and hybrid protocols to meet program goals
- Co-calibrated LSC and AMS to de-risk sample analysis
- Class-leading fully integrated  $^{14}\text{C}/^3\text{H}$  radiosynthesis, animal metabolism, hADME and metabolite identification center of excellence

#### Vaccine/Infectious Disease Studies

- Experienced viral and bacterial challenge study site
- Isolation unit for participant and study separation
- Trial execution and study data analysis led by experienced board-certified infectious disease physician
- Close collaboration with local and nationally recognized academic centers, e.g. University of Maryland Center for Vaccine Development

