



Clinical Services Overview

2022

Our Philosophy

Personal

We function as an extension of your team.

Focused

We focus on the minute details of your study, while emphasizing the study objective.

Results

We are committed to achieving your key success metrics on time and on budget.

Our Experience

Pharmaceutical

- Infectious Disease
- Radiopharmaceuticals
- Hematology & Oncology
- Endocrinology & Metabolic
- Obesity

Biotechnology

- Immunology
- Biologics
- Vaccines

Device

- Dual Graft Matrix
- Vascular Graft
- Bone Cement
- Injectables

Our Key Services

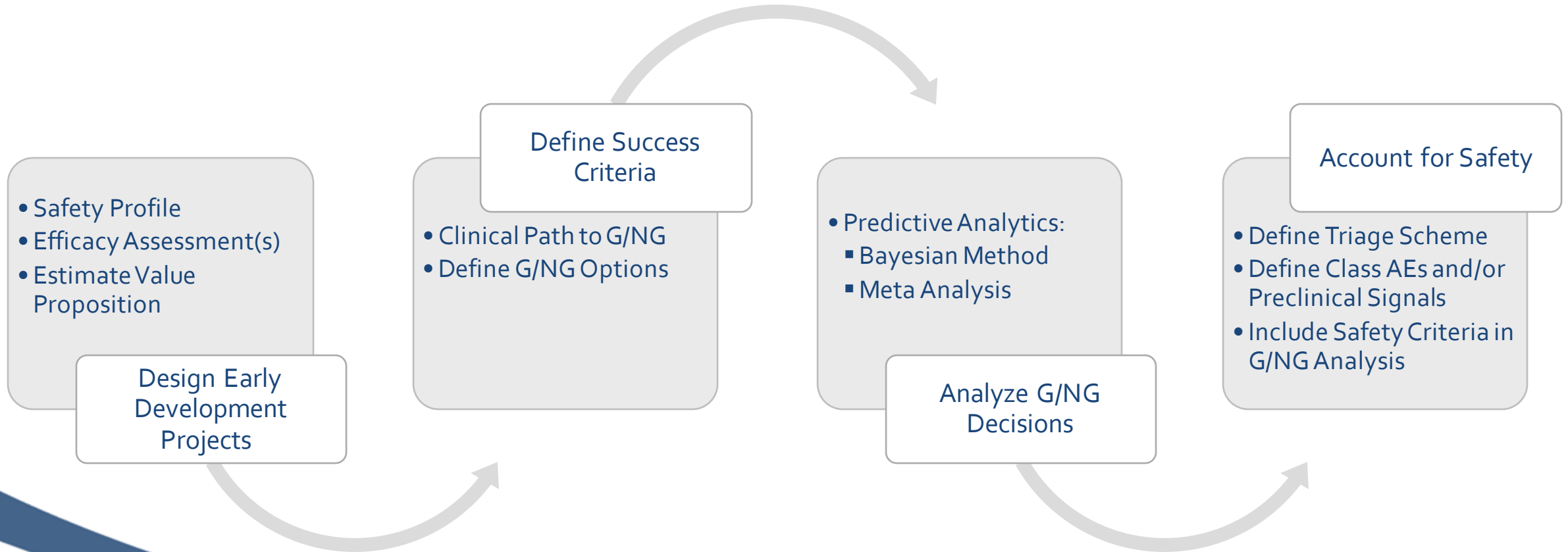
- Regulatory Strategy & Submissions
- Clinical Strategy & Execution
- Drug Safety & Pharmacovigilance
- Formulation Development & Analytical Support
- Project Management
- Site Selection & Management
- Biostatistics & Statistical Programming
- Data Management
- Medical Writing

About Our Key Services

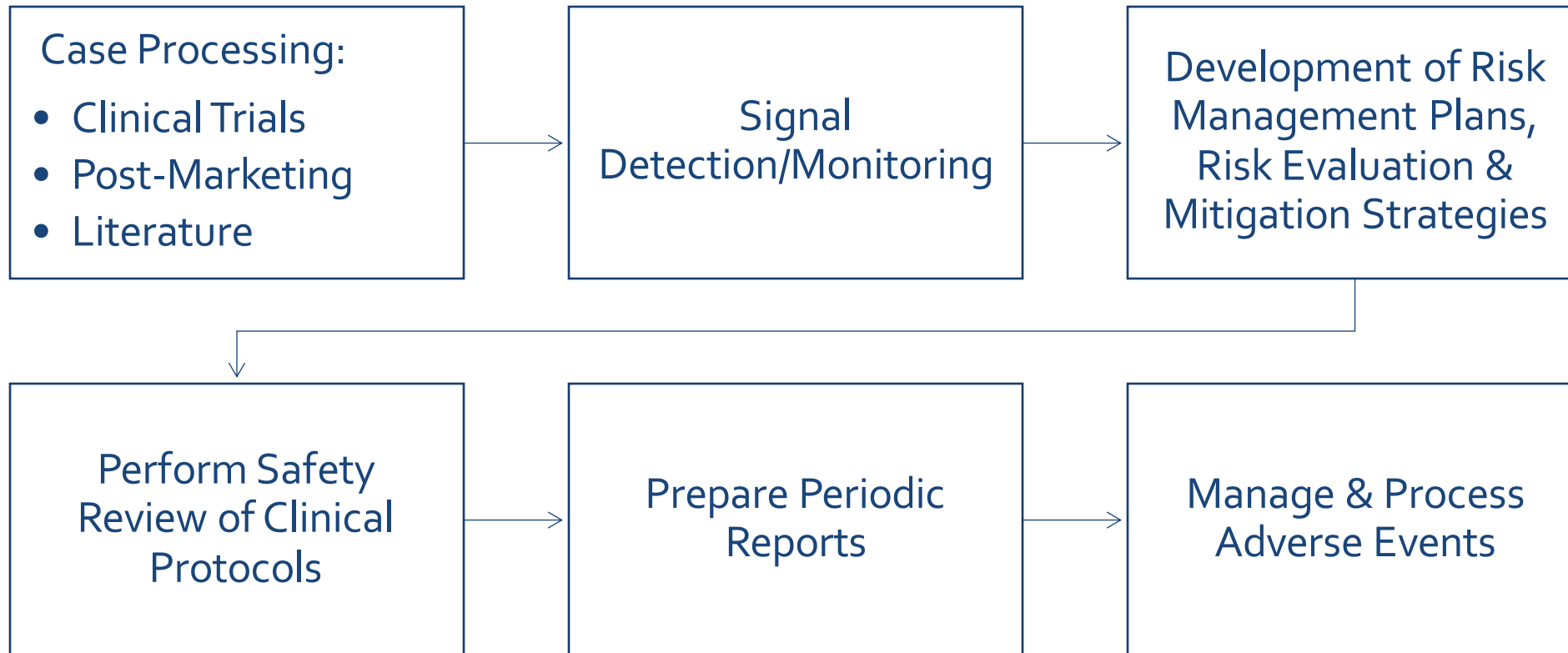
Regulatory Affairs

- Regulatory Strategy development
- Act as regulatory agent with FDA
- Organize pre-IND/IDE, EOP2 Meetings
- IND/NDA/BLA/PMA assembly,
e-CTD submission and management
- Manufacturing sites evaluation for regulatory compliance
- Coordinate import, export and distribution of Clinical Trial Supplies
- Conduct GCP auditing of clinical sites
- Oversee QA review and release of all clinical data

Clinical Development Strategy



Safety & Pharmacovigilance



Formulation & Analytical Services

- Formulation development and analytical support for various clinical phases including FIH studies
- Preclinical formulation development
- High potent and cytotoxic compounds formulation development
- Dosage Forms: Modified release tablet & capsules, Liquid filled hard gelatin, Solution and suspension, Powder for oral solution or suspension
- Parenteral, ready-to-use liquid and lyophilized formulations for IV, IM and SC administration

Site Selection & Management

- Established relationships with sites & investigators
- Proven track record of enrollment success
- Site Feasibility data is updated in real time to ClinSmart's proprietary data base. This means we quickly identify the right research site for the sponsor's needs.
- ClinSmart has a proven record of assisting sites to identify the right subject for the right study. This reduces screen fails and meets or exceeds enrollment expectations.

Site Selection & Management

- Feasibility Questionnaire
- Pre-Qualification Visits
- IRB Submission Support
- Preparation of Pre-Study Site Documentation
- Investigator Meeting Support
- Site Initiation and Monitoring Visits
- Study Close-Out Visits
- Ongoing Site Management
- Sponsor/Site Liaison
- Risk Based Monitoring

Biostatistics & Statistical Programming

- Development of Statistical Analysis Plan
- Sample size & power calculations
- Randomization code design & execution
- Pharmacokinetics analysis
- Coordinate Data Management & Statistics
- Perform interim & final statistical analyses
- SAS programming
- Topline results within 5 days after database lock

Data Management

- eCRF Design and Database Validation
- Data Management Plan
- Development of Electronic Validation Rules & Edit Checks
- CRF Completion Guidelines
- Manual Listing Review (Safety & Data)
- Query Management
- Medical Coding
- Vendor Data Reconciliation
- SAE Reconciliation

Medical Writing

- eCTD Modules (Common Technical Documents for Regulatory Submission)
- Scientific posters and papers
- Clinical manuscripts to support marketing & journal publications
- Protocols / Synopses, Specialty Charters, and Study Reports
- Integrated Clinical Trial Reports
- Early & full clinical development plans

Imaging Lab

- Partnership with European-based imaging lab that has over 20 years of experience in radiopharmaceuticals & molecular imaging
- Turn-key solutions for PET, SPECT, radiological and MRI imaging
- Site set-up: training for investigators and site staff, phantom measurements, system calibration, nuclide logistics
- Image data management (collection, QA)
- Advanced image analysis (reading protocols, remote reading: RECIST, PERCIST, advanced endpoints)

Project Management

- Develop & maintain timeline & budget
- Ensure efficient use of resources
- Oversee risk management & contingency planning
- Set up & maintain communication with sponsor, sites, vendors
- Lead scheduled team meetings
- Create repository for project documents
- Establish & maintain project deliverables

Recent Projects and Publications

Our Recent Projects

- Covid-19 Therapeutics
- Radiotherapeutics
- Acute Stem Cell Transplantation (ASCT)
- Hypophosphatemia
- Cannabis use disorder treatment
- Anti-plaque dental study for Dept. Of Defense (DOD)

Recently Published ClinSmart Studies

- Covid-19 Therapy: "Efficacy and safety of CD24Fc in hospitalised patients with COVID-19: a randomised, double-blind, placebo-controlled, phase 3 study" *The Lancet*, March 11, 2022
- Anemia: "Effects of Iron Isomaltoside vs Ferric Carboxymaltose on Hypophosphatemia in Iron-Deficiency Anemia: Two Randomized Clinical Trials" *Journal of the American Medical Association (JAMA)*, February 4, 2020
- Anti-Plaque: "Four-day plaque regrowth evaluation of a peptide chewing gum in a double-blind randomized clinical trial" *Clin Exp Dent Res.*, 2020

Tools and Certifications

Information Technology

- Cloud and On-premise hybrid configuration of Microsoft servers
- All servers are backed up fully and incrementally using Jungle Disks Cloud Backup.
- All servers have Disaster Recovery Restore by Acronis.
- Secure SonicWALL VPN Tunnel for any remote connections to on-premise servers.
- Malwarebytes Business Endpoint Security and Administration
- Microsoft Teams, Office365, SharePoint and OneDrive for Business utilized for business productivity and collaboration.



WBE, WOSB, MBE

Your Business Advantage – working with a Diverse Supplier

- Federal Tax Incentives
- Promote Diversity
- Reduce Overall Costs
- Increased Profits
- Encourage Innovation



Our Clients



Why ClinSmart?

- Serving clients since 2008 in a range of therapeutic areas
- Successful Regulatory outcomes
- On time & on budget
- Experience in pre-IND through post marketing submissions
- Direct communication, less bureaucracy
- Repeat clients
- Meet your company's Supplier Diversity Initiatives by working with ClinSmart, a certified WBE, WOSB, and MBE



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We look forward to working together!