AMAREX TAIWAN

美商安美睿生技有限公司

AN EXPERT CRO

Expediting Patient Access to Safe and Effective Clinical Products

Amarex Taiwan, LLC, is a full-service global CRO with the capability and expertise to take your product from laboratory proof-of-concept all the way to marketing approval. We can assist you with the design and execution of clinical trials and the navigation of U.S. FDA, Taiwan FDA and European Medicines Agency (EMA) approval processes.

Our staff truly takes ownership of your products, and strategizes for the best possible approach to achieve your goals. We prefer a consultative approach as the best way to work with our clients and achieve success. We have a tremendous diversity of product development experience:

- All aspects of clinical research
- A broad range of regulatory approval pathways
- A broad range of product types
- A broad range of therapeutic indications

The Amarex Advantage

We can guide you through the entire medical product development and marketing approval process.

Amarex's top leadership, who possess outstanding clinical research expertise, are involved in projects and accessible to clients.

Amarex uses proven, validated technology tools and the most efficient processes to assure quality, compliance and swift project completion.

- Services are available around the world
- Corporate culture that encourages creative thinking, innovation and professional growth
- Corporate culture that fosters staff retention
- Collaborative approach with client interactions
- Expert guidance for study design ensures efficient trial execution and accurate results
- Parallel processing expedites trials to save our clients time and money
- Ongoing review of accumulating study data to enhance trial management decisions
- FDA-audited and ICH compliant systems, processes and SOPs for optimum quality assurance
- Efficient product development processes

Our Core Services

- Product development plan creation
- Study feasibility
- Project management (Phase I-IV, BE/BA, PK/PD)
- Protocol writing
- Site selection and management
- Data management (EDC or paper CRF)
- Clinical monitoring (US, Europe and Asia)
- Safety and Pharmacovigilance
- Biostatistics
- Medical writing
- Clinical study report writing
- Regulatory affairs
- FDA applications (IND, IDE, 510(k), NDI, NDA/505(b)(2), ANDA, BLA, PMA)
- TFDA and European submissions
- U.S. Agent to FDA for correspondence, meetings, presentations, negotiations
- Data Safety Monitoring Committee and Clinical Endpoint Committee management
- Auditing for FDA and ICH compliance (GLP, GCP, GMP, GAP, GTP, GMLP)
- Training seminars
- Consulting: regulatory strategy, statistical methodology, study design, CMC, clinical development plan, clinical research results evaluation, network of regulatory agency consultants, product development assessments, etc.

Voices of Biotech Leaders

"We have worked with Amarex on numerous projects and they consistently deliver high quality reliable service by leveraging a broad array of clinical and regulatory expertise.
What sets them apart from other CROs is a creative entrepreneurial approach to drug development.
They go beyond the technical aspects of clinical trial development and work with the sponsor to drive value and increase chances for success."

Biotech Chief Medical Officer in Maryland

Successful Clinical Product Development

Successful drug development is a collaborative effort between industry and FDA scientists. We provide development strategies and trial designs tailored to your individual needs and goals, and execute those projects with a team of experienced professionals dedicated to their success. Our multi-faceted approach minimizes clinical trial timelines and costs, and streamlines the product approval process.
Five key aspects of the development process are critical for success:

- ***Collaboration***
  Maintain a close collaboration between CRO and Sponsor project team members
- ***FDA Communication***
  View the FDA as a development partner
- ***Strategy***
  Have a complete strategy at the beginning, designed to meet the development goal
- ***Clinical Study Design***
  Have appropriate endpoints and statistical analysis method, use adaptive study design to reduce the time and cost, use trial simulations to assure success
- ***Patient Enrollment***
  Have a trial specific enrollment plan, which includes contingencies

The IND/IDE/510(k) Strategy

A written IND, IDE, or 510(k) strategy document is critical to successful product development and should be designed to reach a specific goal, such as completing:
Early stage proof-of-concept (POC) in order to license rights or sell the product to another company.
All needed safety and efficacy testing to achieve FDA marketing approval.
Some stage of value-added development between POC and marketing approval.
The purpose of the strategy document is to maximize efficiency and aid in fundraising.
Strategy document creation begins with a Gap Analysis to evaluate the product's current development status and identify gaps in the development that need to be filled before submitting a regulatory application. Information about market factors that will impact the product/indication can also be included.
The key elements of the strategy document include:

- Regulatory pathway for product approval
- Regulatory applications required
- List of safety and efficacy studies to be conducted
- Manufacturing solution
- Timeline for each step of the development process

Project Management

- Project plan creation
- Study operations manual creation
- Trial master file maintenance
- Clinical trial setup and initiation
- Project team training and coordination
- Site selection, contracting, and management
- IRB (EC) approvals
- Vendor identification, contracting, and management
- Trial management
- Regularly scheduled communications between project manager and client
- Status reporting
- Project manager continuity policy
- Additional training for project managers in project plan creation, project management systems, and GCP and HIPAA guidelines and requirements

Data Management

- Data management plan (trial specific)
- Case report form (CRF) design (electronic or paper)
- CRF completion instructions
- Database design
- Edit and logic checks
- Database programming (EDC or paper CRF)
- Data collection, entry, and validation
- Database lock and validation
- Data warehousing
- GDPR compliance
- 21 CFR Part 11 compliant computer systems, validated by multiple FDA GCP audits (2010, 2015, 2017)
- Data integrity/protection, with 24/7 monitoring by IT staff
- Custom-designed databases for each clinical trial (EDC or paper CRF)

Performance

We have industry-leading speed for both database setup and database lock.

We provide tables and listings of accumulating data during the treatment phase of a clinical trial to allow the client to conduct ongoing data reviews.

Special-Purpose Database

Our Integrated Safety Database (ISDb) takes multiple databases from multiple clinical trials, for a single product, and makes them uniform so that safety data from all the databases can be analyzed as though it were in a single database. The ISDb is a powerful tool to analyze the safety data of multiple studies, and to rapidly generate safety data for annual IND reports.

WebView Suite

Our proprietary online trial management tool suite (WebView CTMS, WebView IRT, WebView EDC, WebView ePRO, WebView eTMF) works in concert to enhance responsivity to our clients and to ensure successful project implementation, execution, and completion; timeline adherence; and cost control. WebView offers the latest technology for trial management:

- Intuitive navigation interface
- Easy, secure trial data entry for site staff
- Fast & efficient data monitoring and cleaning
- Fully validated and 21 CFR, Part 11 compliant
- 24-hour rapid, secure access to data
- Instant review, revision, and print capabilities
- Real-time notification and access

Biostatistics

- Study sample size calculation
- Statistical analysis plan creation
- Statistical programming
- Analyses and statistical report writing
- Statistical section of protocol
- Adaptive study design statistics
- Statistical simulations of clinical trials
- Integrated summaries of safety and efficacy (ISS/ISE)
- Interim and exploratory analyses
- Statistical analyses presentation and defense before FDA
- Statistical analyses and presentation to DSMC
- Meta-analyses
- Analysis dataset creation and transfer
- Multi-study integrated safety database
- CDISC-compliant databases
- CDISC conversion

Expertise

Expert statistical design and identifying the best method of analysis for a particular protocol are the two fundamental elements to assure an accurate trial outcome. Our statistics team has created hundreds of statistical analysis plans and protocols, and conducted hundreds of trial analyses for many different drug, medical device, and diagnostic products.

Our team began creating adaptive trial designs before the FDA published its guidance on this approach, and uses adaptive designs as often as possible.

Industry Standards

We use industry standards such as ICH E9 guidelines, SAS analysis software, SDTM and ADaM to comply with FDA requirements and preferences.

Clinical Site Monitoring

- Monitoring plan creation
- Site identification and qualification
- Site training and initiation
- Communications with site staff
- Patient recruitment assistance
- Site data and regulatory compliance monitoring
- Site protocol compliance monitoring
- Adverse event follow-up
- Regulatory document management
- Investigational product inventory monitoring
- CRAs are trained in GCP and HIPAA
- CRAs must demonstrate a thorough understanding of Amarex SOPs and they receive protocol specific training for each study they work on
- Site support
- Amarex CRAs maintain regular contact with study sites to keep your study highlighted to the site staff

Medical Writing

Efficiency And Compliance

Amarex uses a two-step process for clinical study report (CSR) writing. First, we produce an ICH-compliant CSR shell before the trial is completed so you can review, edit and approve the format in advance. Second, we provide the first draft CSR two to three weeks after database lock.

- We have prepared hundreds of clinical study reports
- Our medical writers are familiar with clinical study statistics and ICH guidelines for CSR content and format
- Protocols
- Informed consent forms (ICFs)
- Investigator brochures (IBs)
- Integrated summaries of safety and efficacy (ISS/ISE)
- Articles for publication
- Manuscripts and abstracts

Medical Safety Monitoring/ Pharmacovigilance

- 24/7 serious adverse event (SAE) reporting and medical coverage
- Preparation of narratives, Medwatch and CIOMS reports
- Review of subject eligibility
- Physician review of adverse events, labs, vital signs, ECG's, and other subject safety data
- Site support to answer product and protocol questions
- Study design consulting
- Coding of adverse events and concomitant medications
- Medical review of all clinical trial-related documents
- Amarex physicians with significant clinical research experience provide medical expertise to support subject safety

Regulatory Affairs

- U.S. agent to the FDA
- Regulatory strategy creation and consulting
- FDA applications and submissions: IND, IDE, 510(k), NDA, BLA, PMA, ANDA, orphan drug designation, request for designation, breakthrough therapy, fast track
- New Dietary Ingredient (NDI) applications
- eCTD formatting and submission
- CMC expertise
- International regulatory agency applications
- Adjudication committee management
- GLP, GCP, GMP, GAP audits and certifications
- Clinical research seminars and training
- Global consulting (separate from certification)
- Amarex also provides services for FDA approval of New Dietary Ingredients (NDI) for sale in the U.S.

Auditing

We audit clinical sites (GCP), manufacturing facilities (GMP), agricultural fields (GAP), and laboratory facilities (GLP) to assure complete compliance with FDA and ICH requirements for the development and ongoing production of medical products.

Amarex has undergone several audits by U.S. FDA and TFDA in connection with successful clinical operation and marketing approval applications, and passed each audit without receiving a 483 or any other findings.

Amarex's product development experience includes over 600 projects in all major indications and product types. We have helped 25 products obtain approval from the U.S. FDA.

Therapeutic Indication Experience

- Addiction
- Analgesics
- Antiseptics
- Anti-viral
- Cardiovascular
- Central nervous system (CNS)
- COVID-19
- Critical care
- Dermatology
- Diabetes
- Endocrinology
- Gastrointestinal
- Genetic diseases
- Hematology
- HIV
- Immunology
- Infectious disease
- Metabolic
- Oncology
- Orphan indications
- Pain
- Pediatric
- Respiratory
- Rheumatology
- Smoking cessation
- Urology
- Vaccine
- Wound healing

Product Experience

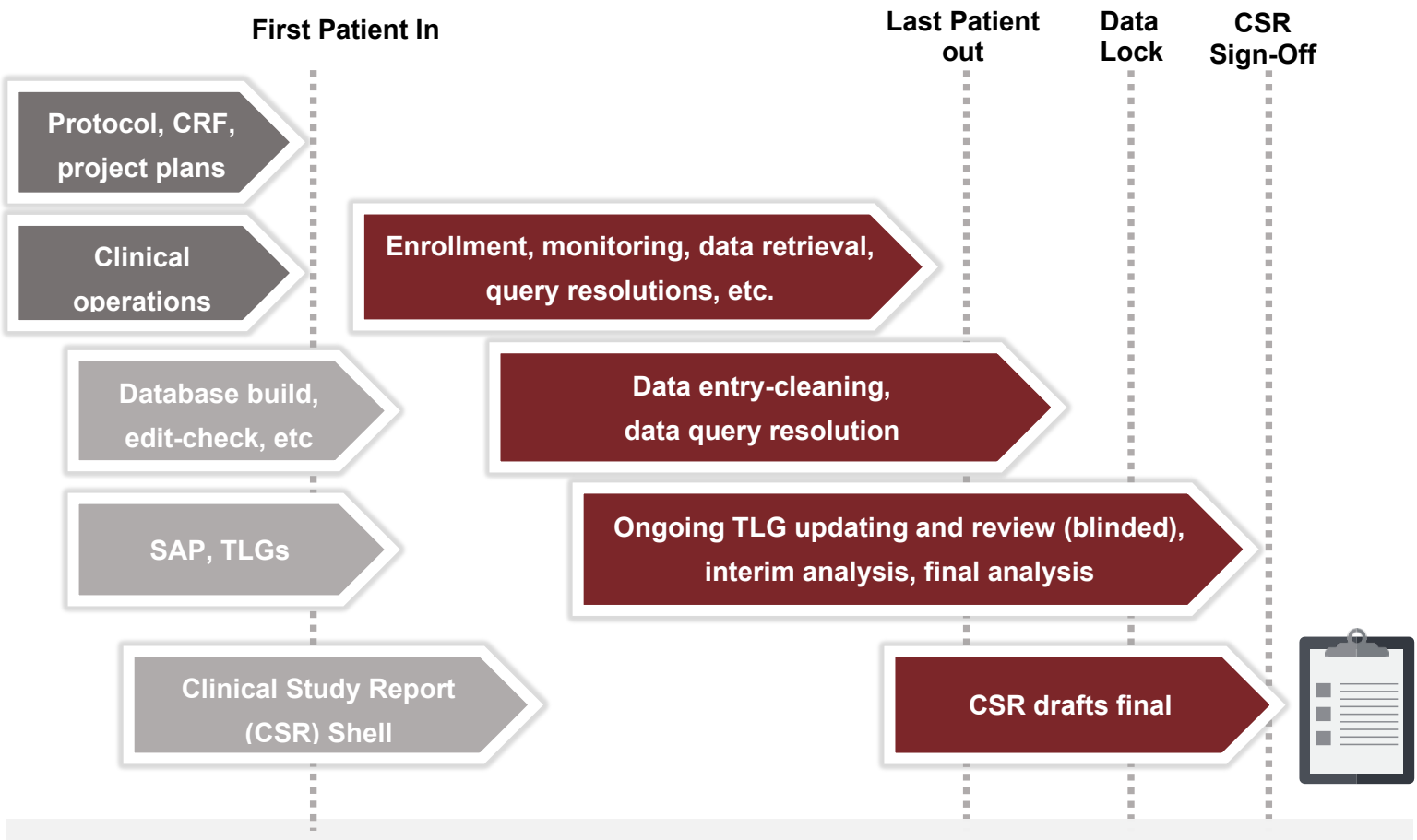
- Biologics
- Diagnostics
- Botanicals / Herbals
- Devices
- Biosimilars and Biobetters
- Pharmaceuticals

Novel Technologies Experience

- Adult stem cell therapeutics
- Botanical derived therapeutics
- Personalized medicine
- DNA, viral, and peptide vaccines
- Gene therapy products
- Molecular probe diagnostics
- Nanotechnology therapeutics
- siRNA and oligo-based therapeutics
- Transdermal patch drug delivery

Parallel Processing: Optimizing Efficiency

We use parallel processing for the conduct of clinical trials. This method reduces study duration, speeds up study closeout, improves study performance and reduces cost.



Quality Assurance

Adherence to requirements and regulations of the U.S. FDA, Canada's Health Products and Food Branch Inspectorate, European Union, ANVISA and other international regulatory agencies is standard practice for Amarex. Our services comply with Good Clinical Practices (GCP) and International Conference on Harmonization (ICH) guidelines (E6).

Expertise + Experience + Processes = Formula for Success

- Majority of our work from repeat business and client referrals
- Degreed operations staff: B.S., M.S., M.D., and Ph.D. scientists
- Top management comprised of clinical research experts who founded Amarex
- Over 95% of our clinical trials maintain project manager assigned at the start of the trial
- Senior statistician with more than 30 years of industry and FDA experience
- Database lock within five days of last query resolved
- Statistical analysis TLGs within 48 hours of database lock
- 100% of IND applications approved
- Flexible and responsive to clients' special needs
- Price competitive without sacrificing performance and quality
- Conscientious of budgets that accurately list the full scope of work to be performed

Client Support Advocate

In addition to being assigned a project manager, you are assigned a client support advocate (CSA) from the business development group. Should a complaint or sensitive request arise that you do not want to route through the project manager, you can speak to the CSA in confidence. The CSA will work with the appropriate senior management staff to address the issue with minimal disruption to the project.

Challenge Resolution

Clinical trials are typically complex, long-term projects. When unexpected challenges inevitably arise, we provide multiple potential solutions based on our expertise in the field of clinical research.

Adaptive Design Trials

Adaptive trial design allows for the recalculation of the sample size and power, or to drop a drug dose, in the middle of a trial. These adaptations can significantly reduce the cost and duration of an ongoing trial.
We have conducted multiple adaptive trials under U.S. IND testing programs. Each adaptive trial has its own special nuances. Our experts understand the pros and cons of adaptive trials, and the special regulatory, design, conduct and analysis challenges of such trials.

Planning for an adaptive trial design requires recognizing the three essential elements of clinical trial design: selection of optimal drug dose, sample size calculation and power calculation. If these elements are not accurately estimated at the study design stage, a trial may fail, even though the product is truly effective.
The concept of adaptive trial design is especially useful for botanical drug product development.

Contact Us

Amarex Taiwan, LLC

2F., No.19-10, Sanchong Rd.,
Nangang District, Taipei 115, Taiwan, R.O.C
T +886 2 26553391
E info@amarextw.com
www.amarextw.com

Amarex Clinical Research, LLC

20201 Century Blvd, 4th Floor
Germantown, MD 20874 USA
T +1 301 528 7000
E info@amarexcro.com
www.amarexcro.com

美商安美睿生技有限公司