



A Symbol of Excellence

Clinical Research

Phase IV & Peri-Approval Solutions

Design & Implementation

Observational, Non-Interventional Studies / Phase IV Research

Post-approval observational studies can be used to address questions pertaining to safety surveillance, risk management, and efficacy. Correct study choice and effective execution are paramount to achieving the desired goals.

ICON's Lifecycle Sciences group is experienced in the design and implementation of these studies to collect real-world data with a focus on maximizing the return on investment:

- Non-interventional, Observational Research
- Disease and Product Registries
- Post-Approval Safety-Surveillance Studies
- Phase IV Clinical Trials
- Epidemiologic Studies
- Patient-Reported Outcomes/Quality-of-Life Research
- Health Economic Evaluations
- Scientific and Medical Communications



Patient Registry (Disease or Product)

A Patient Registry is an observational study enrolling individuals with a common characteristic, such as a disease or treatment, and collecting data for varying time periods, frequently several years. The registry data are used to address questions regarding patient outcomes over time as they receive the standard of care from their healthcare provider.

Pregnancy Registries

Similar to a Patient Registry, a Pregnancy Registry observes what happens over time in normal medical practice, but focuses on outcomes data from patients exposed to a product while pregnant.

Safety Surveillance

Safety Surveillance Studies are designed to observe adverse drug reactions associated with a product based on real-world clinical use.

Retrospective Data Analysis

Retrospective data analyses make use of existing data sources such as medical claims or national health surveys. Our researchers are adept at designing and conducting insightful analyses that accommodate the inherent limitations of retrospective data.

Phase IV Clinical Trials

We are uniquely positioned to provide strategic guidance and a comprehensive yet flexible approach to maximize the benefit of these programs.

Development and Validation of Patient Reported Outcomes (PROs)

We provide a full range of customized solutions for all PRO research design needs, from providing strategic recommendations for appropriate PRO measures to developing, testing, and validating an original questionnaire.

Operational Expertise

Our approach is tailored to meet the objectives of multiple stakeholders. Accordingly, ICON's Lifecycle Sciences group offers the full complement of operational expertise from study start to final reporting. Our highly skilled staff implement studies worldwide, providing a cohesive suite of services including:

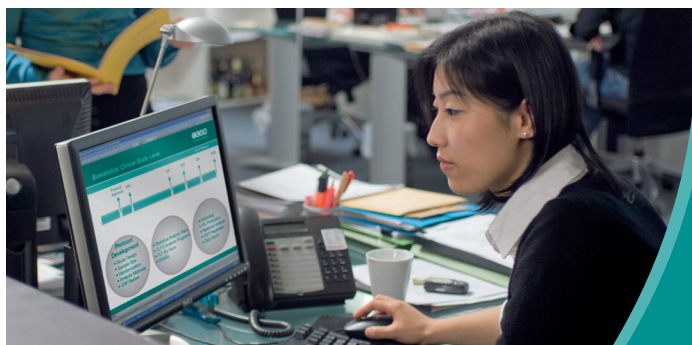
- Study Design
- Study Start-Up, including site identification and recruitment
- Regulatory and EC/IRB Submissions
- Materials Development
- Site Management
- Data Management
- Electronic Data Capture
- Statistical Analysis
- Project Management
- Scientific Advisory Board Communication and Management
- Report Production and Publication Generation

Study Start-up: Site Recruitment and Regulatory Support

ICON's Lifecycle Sciences group is able to address the unique challenges of peri- and post-approval research in order to expedite the study start-up timeline. We believe that developing a relationship with the site early on facilitates rapid site initiation, maximizes retention, and leads to the timely collection of high quality data.

Materials Development

We have substantial experience developing materials to support post-marketing research programs. Our Site Management team works closely with the study's key stakeholders to ensure they meet the study's objectives, are compliant with applicable regulatory requirements, and allow for efficient data collection, analysis, and reporting.



Site Management

ICON's Lifecycle Sciences group leverages considerable experience with remote site management techniques to streamline activities and support sites in a comprehensive yet unobtrusive manner.

Data Management

Our Data Operations team has extensive post-approval research experience, ensuring that data management systems meet appropriate data quality standards. Our strategy is to provide enhanced but flexible and reliable options for data capture and management while maximizing data quality.

Electronic Data Capture (EDC)

We have extensive experience creating, deploying, and maintaining EDC solutions. This breadth and depth of experience allows us to quickly identify and efficiently implement the right solution for each study.

Statistics

ICON's Lifecycle Sciences group statistics professionals are renowned for advancing methodologies for observational data analysis. They work closely with the project team during the study design and materials development phase.

Project Management

Our highly skilled project managers are experienced in providing strategic and operational guidance and leadership throughout the project. Efficient, consistent communication and information flow are critical to project success, and an essential element of a professional partnership.

Global Full Service Capability

As peri- and post-approval studies vary considerably in terms of scope, objectives, and regulatory requirements, ICON's Lifecycle Sciences group is in a unique position to leverage varied and broad capabilities as a part of a large, global CRO.

In order to conduct global post-approval studies, we can use internal expert resources to provide comprehensive and cost-effective solutions. Additional services include:

- Global Regulatory and Local Language Support
- IVRS / IWRS, including ePRO
- Clinical Data Management
- Clinical Operations: global, flexible placement of CRAs
- Medical Monitors and Pharmacovigilance
- Central Laboratory Services
- Medical Imaging

Case Studies

Challenge:

A global pharmaceutical company asked us to design an orphan disease registry to be conducted exclusively in Europe to collect data on the treatment selection criteria used by physicians. The client also wanted to utilize safety data from the observational study, in addition to clinical trial data, to enhance their submission to the FDA for marketing approval of their product.

Solution:

- Designed a registry that met critical organizational needs for real-world post-approval treatment data, as well as safety outcomes to support the sponsor's clinical development program
- Developed all registry materials including the study protocol, CRFs, and other site-related documents and associated translations
- Managed all regulatory and IRB/Ethics Committee submissions
- Performed on-site data monitoring
- Managed EDC website developer
- Facilitated safety data reporting with sponsor pharmacovigilance group
- Generated the statistical analysis plan and analyzed the data
- Developed study publications



Challenge:

The client asked us to take over a series of ongoing programs that had moved into long-term extension. We were asked to develop a strategy for managing multiple global studies across several therapeutic areas that was process driven and cost effective. This served as the foundation for a collaborative partnership in outsourcing future long-term extension programs.

Solution:

- Provided strategic project management to utilize in-house resources for site management activities and field CRAs for source document verification
- Coordinated global resources to ensure that all study activities were of high quality and completed efficiently
- Developed training material for a 'SWAT' team of CRAs to be able to conduct on-site monitoring visits with minimal training
- Served as single point for site contact available in each country/region
- Tracked all CRFs and query responses
- Collected and tracked amendments/regulatory documentation
- Managed study supplies
- Ensured that all database lock timelines were met
- Managed all regulatory and IRB/Ethics Committee submissions
- Trained sites (new staff only) on an as-needed basis
- Facilitated safety data reporting with sponsor's pharmacovigilance group

Expertise you can trust

ICON Clinical Research is a division of ICON plc which specializes in the planning, management, execution and analysis of Phase IIB-IV clinical trials, ranging from small studies to complex multinational projects.

Innovation, high quality solutions and excellent customer service are the foundations of ICON's Lifecycle Sciences group. We provide comprehensive and strategic support to our clients throughout the project lifecycle with three distinct yet complementary departments: Health Economics & Outcomes Research, Statistics & Data Operations, and Project Operations which support our highly strategic, flexible and high quality delivery of projects. We view our clients as strategic partners and understand that each interaction our team has is an opportunity to build upon and strengthen relationships, drive business results, and ensure quality. Our customer-focused model allows our team to be proactive, identifying and implementing solutions while providing an exceptional level of client service.

We have a commitment to quality in all communications and deliverables, and in today's rapidly changing environment, one constant is the depth, breadth, and commitment of our staff.

About ICON plc

ICON plc is a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries. The Company specializes in the strategic development, management and analysis of programs that support clinical development - from compound selection to Phase I-IV clinical studies. ICON currently has over 7,000 employees, operating from 71 locations in 38 countries.

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