

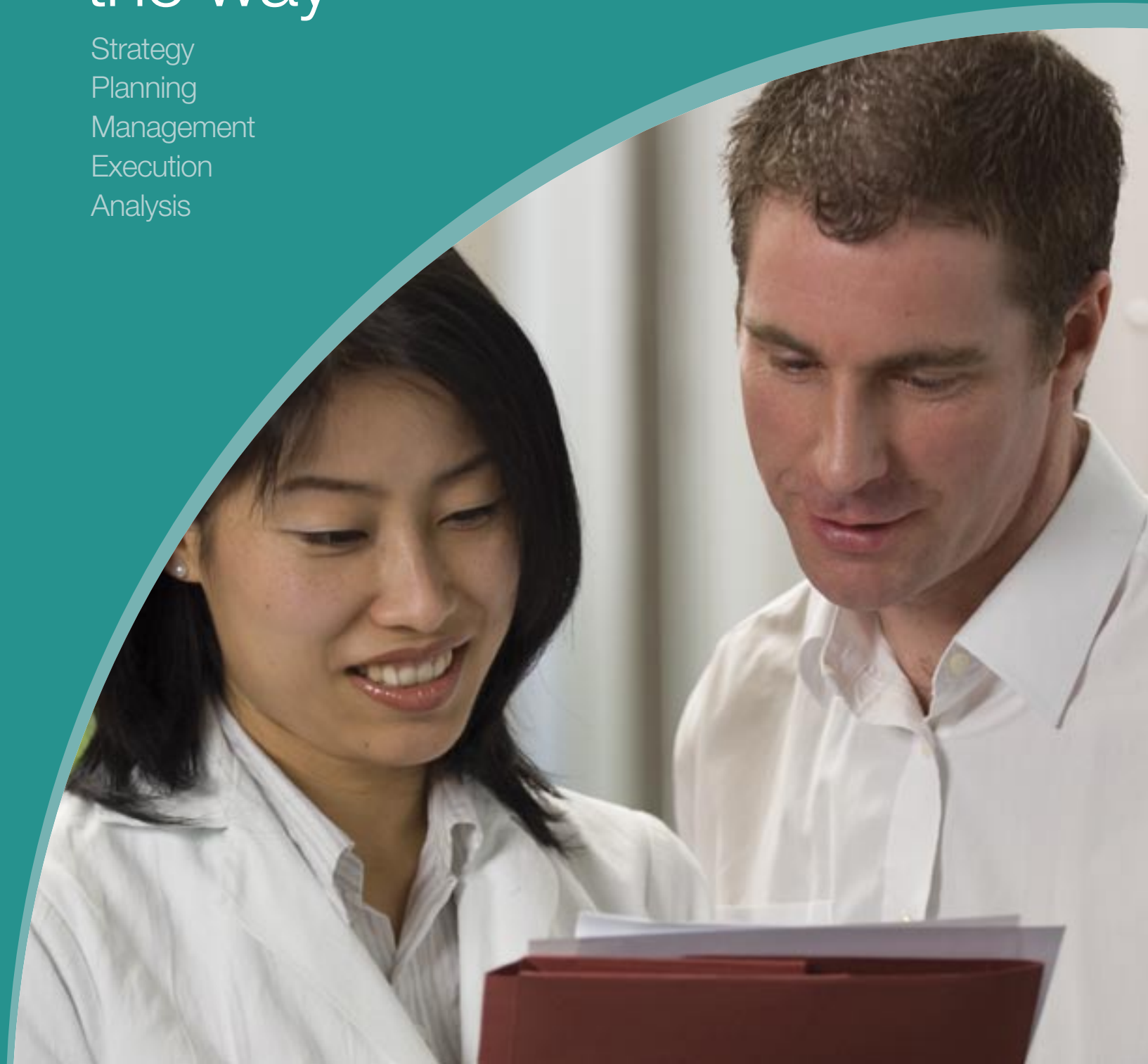


A Symbol of Excellence

Clinical Research

Leading the way

Strategy
Planning
Management
Execution
Analysis



Excellence in Delivery

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

Services

Available separately or as part of a comprehensive clinical program, our integrated Clinical Research services cover a wide range of activities from protocol development and site identification through to completion of study reports.

Every project is assured our complete focus and is conducted to the highest level of regulatory standards.

- Project Management and Clinical Operations
- Medical and Safety Services
- Data Management
- Biostatistics
- Interactive Technologies
- Lifecycle Sciences

Global footprint

ICON is an International company, with experience in the world's most important regions for clinical research. We speak 19 languages, work across all key regions, and are represented by our 5 divisions in more than 67 locations across the globe.

Quality

We have a framework and philosophy that enables us to maintain a quality culture throughout the organization. It is at the heart of all we do at ICON.

Our Quality Management System is ISO 9001:2000 registered. We were the first global CRO to achieve ISO registration in 1994 and remain the only CRO to have implemented this as standard across all offices and functions.



Clinical Operations group

- Project Management
- Clinical Trial Site Management and Monitoring
- Regulatory Document Processing
- Patient Recruitment
- Contract Management and Investigator Reimbursement

ICON Clinical Research professionals apply their therapeutic, regulatory, and operational expertise to consistently solve the challenges that arise during all clinical projects.

Our core competency is project management, underpinned by comprehensive and consistent processes, which conform to global regulatory requirements and ISO9001:2000, and a culture that is focused on delivering quality information to clients. We are highly responsive and provide customized services, which can be deployed on a stand alone basis or as part of an integrated “full-service” solution. These services can support both global and locally managed projects.

We believe in managing our client relationships as strongly as we manage our studies. Our project teams develop integrated plans involving all stakeholders in the organizations, from project staff to senior management, to ensure that the business relationship succeeds. Ownership and accountability are at the core of communication plans, which provide transparency and understanding throughout the process.

We place the highest importance on delivering quality data on time and on budget. From start-up to completion, performance is monitored regularly and measured against contractual timelines. In addition, project costs are tracked to ensure adherence to agreed budgets.

In an increasingly challenging environment, we have the experience and knowledge to find, recruit, and retain patients in clinical trials. We successfully deliver access to appropriate sites and patients, developing strategies that will minimize the risks inherent in patient recruitment.

Medical and Safety Services group

- Total Product Safety and Medical Call Center
- Clinical Trial Safety Management
- Phase IV and Registry Support
- Post Marketing Surveillance
- Safety Database
- Global Regulatory Reporting
- Safety Signaling and Risk Management
- Medical Oversight, Clinical Development/Consulting
- DSMB Project Management
- Endpoint Management
- Qualified Person for Pharmacovigilance (QPPV)
- Litigation/Drug Recall Services
- Medical and Scientific Writing
- Pharmacovigilance systems implementation and audits

ICON’s Medical and Safety Services group offers safety support across all stages of the product lifecycle by providing efficient drug safety processes, compiling concise drug safety profiles, and developing tailored risk-management strategies.

We provide high-quality, full-service pharmacovigilance within all regions of the world using various models, including low cost and off-shore options, and our Total Product Safety Center (TPSC) can handle every aspect of your marketed product’s needs.

Our global safety team, including more than 300 medical and scientific experts, is located in 5 main safety centers in the Americas, Europe and Asia. This highly experienced team is focused on post-marketing drug safety, pharmacovigilance and risk management and has significant experience in working in all major safety databases, including both commercial and proprietary systems. Our commitment to quality is reflected in excellent audit ratings from internal auditors, sponsors, and major regulatory authorities.

We can provide highly responsive, multi-lingual customized pharmacovigilance services, from small studies to complex multinational projects, which can be deployed on a stand alone basis or as part of an integrated “full-service” solution.



Interactive Technologies group

ICON's Interactive Technologies group develops, implements, and manages cutting-edge voice and web technology to increase the accuracy and efficiency of conducting global clinical studies.

- IVR and IWR Electronic Trial Management
- Electronic Patient Reported Outcomes (ePRO, eDiary)
- Patient Enrollment and Randomization
- Visit Tracking and Patient Management
- Medication and Device Inventory Management
- Data and Platform Integration Capabilities

Working with biotech, pharmaceutical, and medical device organizations worldwide, our team of experts evaluates the needs of each client in order to recommend the right mix of solutions for their studies.

Our portfolio of electronic trial management solutions includes: ICOPhone, ICOPro, and ICOWeb. ICOPhone is a proprietary Interactive Voice and Web Response Application (IVR/IWR) that has been used in more than 650 studies to date. ICOPro is an electronic Patient Reported Outcomes (ePRO) application that uses ICOPhone technology and has been proven to increase subject compliance and increase the quality of our clients' PRO data. ICOWeb is a reporting application that allows sponsors to securely access real-time web-based reports 24 hours a day.

To date, ICON Interactive Technologies systems have managed over 35,000 sites, more than 500,000 patients, and have supported over 50 languages in more than 65 countries. We are pioneers of IVR, IWR, and ePRO technology, and have built up a proven track record of using technology to help our clients manage their clinical studies.

Lifecycle Sciences group

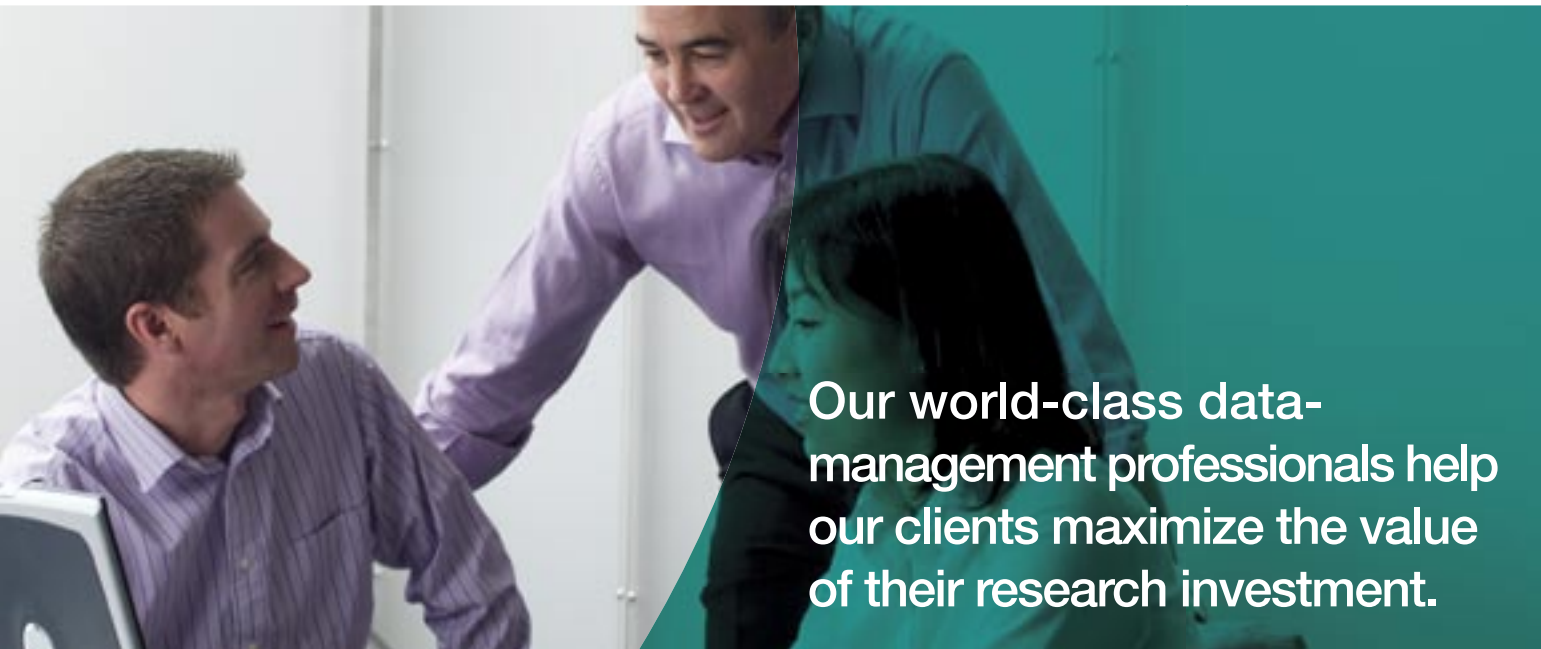
ICON's Lifecycle Sciences group specializes in strategic consulting, as well as the development, management and analysis of observational research throughout the product lifecycle.

- Disease & Product Registries
- Safety Surveillance Studies
- Large Simple Trials
- Quality of Life Research
- Health Economics & Outcomes Research
- Statistical Analysis & Epidemiology

We have set a high standard for patient registry development and execution by understanding and meeting the growing demands of global regulators and commercial markets. Our clinical development teams have supported registries ranging from 45 to over 2,000,000 patients. Our expertise in late-stage drug development offers sponsors complete program support, including registry strategy and design, operations, regulatory guidance, data analysis, and reporting.

We have advanced the science of outcomes research, while ensuring that our research remains accessible to providers of care. Indeed, we use our foundation in health economics and patient-reported outcomes to help pharmaceutical companies, medical device manufacturers, hospitals, payors, and managed-care organizations deliver more cost-effective and patient-focused care through rigorous research and responsible communication.

We work hard to ensure a solid return-on-investment for our clients' outcomes research initiatives. We take pride in our robust publication track record, not only for its volume, but also for its strategic benefit to our clients and to the healthcare community.



Our world-class data-management professionals help our clients maximize the value of their research investment.



Providing comprehensive, high-quality, and timely deliverables, produced by experienced statisticians and programmers.

Data Management group

- Flexible Data Solutions
- Standardization and CDISC Compliance
- Project Management
- EDC and Technology Integration

ICON's Data Management group delivers high-quality, cost-effective solutions to ensure the successful management and delivery of clinical trial data.

Our team leads the way in the use of technologies and standards. Our data managers are proficient in the use of technologies including Rave®, InForm™, Oracle® RDC, Oracle Clinical™, Clintrial, ePro solution, optical scanning and work flow systems.

Our experience and understanding of Electronic Data Capture (EDC) processes and systems enables us to provide the optimum solution for each project. We offer a full range of EDC services that can be combined to meet virtually any need. Our expert certified resources work with customers internally and externally to ensure each trial is developed to the highest standards using the latest technologies in the marketplace for clinical trials.

Our Data Managers are also trained in the use of the latest standards including CDISC. We employ these standards to enable efficient review, processing transmissions and submission of data to the regulatory authorities. We continue to build an impressive portfolio of experience in the use of the various CDISC models including SDTM and ADaM.

Biostatistics group

- Design and Analysis of Clinical Trials
- Statistical Consulting
- Data Standardization (CDISC) and Integration
- Adaptive and Bayesian Designs
- DSMBs and Risk-Benefit Analysis

ICON's Biostatistics group provides services for clinical development plans, study design, statistical analyses, and regulatory support.

Our team of experienced statisticians and programmers produces comprehensive, high-quality, timely analysis and reporting of study results. We have extensive knowledge of experimental design, statistical methodology, and global regulatory requirements. This enables us to give advice on all aspects of the design, sizing, and conduct of a study to ensure that all designs and analysis methods fully conform to the latest regulatory standards and guidelines.

In the past 5 years, our biostatisticians and programmers have supported over 500 Phase I-IV clinical trials, involving 125,000 patients across all major therapeutic areas, including CNS, cardiology, gastroenterology, metabolics, oncology, and infectious diseases. Members of our global team have an average of 12 years' experience and 40% have a Ph.D. in biostatistics.

ICON's global team of Biostatisticians have supported **36 studies involving DSMBs** and have generated over **100 CDISC** compliant (SDTM) datasets in the past year. We have also been involved in over **25 adaptive design studies**, including sample size re-estimation, changing hypotheses, and combining phase II/III.



A Symbol of Excellence

ICON is a global provider of outsourced development services to the pharmaceutical, biotechnology, and medical device industries. We specialize in the strategic development, management, and analysis of programs that support Clinical Development – from compound selection to Phase I-IV clinical trials including:

- Clinical Research
- Central Laboratories
- Contracting Solutions
- Drug Development and Regulatory Support
- Phase I Clinical Trial Development
- Medical Imaging



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