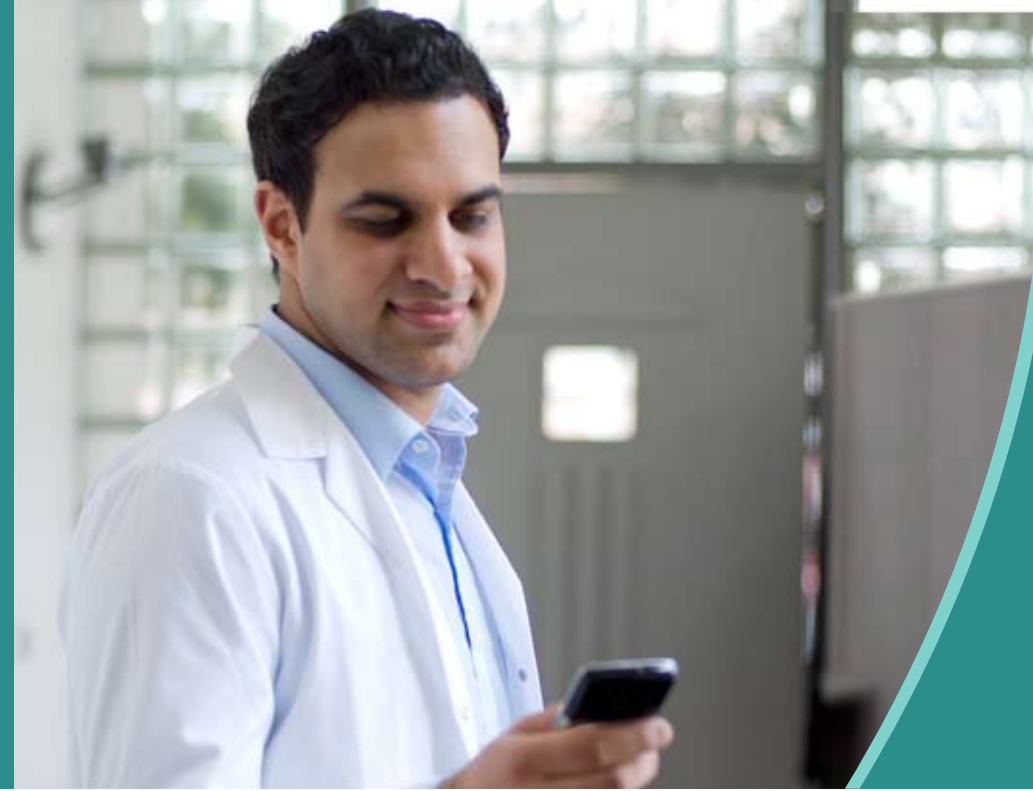




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A Symbol of Excellence

Clinical Research

About ICON Clinical Research

ICON Clinical Research specialises in the planning management, execution and analysis of Phase IIb – IV clinical trials, ranging from small studies to complex, multinational projects.

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ICON has offices located throughout the world. For more information on local offices please visit www.iconplc.com

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Interactive Technologies group

Providing interactive solutions to increase accuracy and efficiency in clinical trials.

ICON's Interactive Technologies group develops, implements, and manages interactive voice and web response systems (IVRS and IWRS) along with cutting edge web technology to increase the accuracy and efficiency of conducting global clinical studies.

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

ICophone™ is our proprietary Interactive Voice and Web Response system (IVR/IWR). Our turnkey solutions are designed to comply with the requirements of 21 CFR Part 11 and are in use with hundreds of global multi-lingual Clinical Trials.

We meet the needs of each clinical trial by offering the following services:

- 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



Randomization

One of the most important elements of a well-run clinical trial is the integrity of the randomization. With ICOPhone™ you are able to automate and simplify the implementation of any complex randomization scheme. We have experience with many different types of randomization schemes, such as dynamic balancing, multiple stratification criteria and dose titration calculations and have the capability of developing your randomization and packaging list as well.

Clinical Supply Management

ICOPhone™ helps to lower trial costs with drug inventory management capabilities. Our system allocates drugs on an as needed basis, keeping sites stocked with only the amount they need based on patient enrollment. This feature is especially critical in trials with drug shortage or high manufacturing costs. Drug shipments can be done as needed, and our systems allow for global tracking and monitoring of supplies.

ePRO

The ICOPhone™ ePRO application offers real-time access to patient data, faster validation of that data and more accurate and reliable data. It reduces the typical implementation time of traditional IVR/IWR systems, enabling studies to reach critical milestones quicker and regulatory submissions to be submitted sooner. In addition increased patient compliance improves the validity of study data, providing more concrete scientific results for clinical studies.

PRO Consulting

Additionally, we have extensive experience in both the design and implementation of Patient Reported Outcomes (PRO) research through ICON's Lifecycle Sciences group. This combination of scientific expertise from Lifecycle Sciences group and the sound technology of ICOPhone™ ePRO with ICON's Interactive Technologies group, allows ICON to offer turnkey PRO services that support client research endeavors and achieve crucial study milestones.

ICOPhone™ Reports

ICOPhone™ provides a reporting application that allows sponsors to securely access real-time web-based reports 24 hours a day. It is provided with a suite of standard reports and the facility to build custom reports as required. It has a built-in filtering capability and the option for the user to export directly into a variety of formats. Common Reports include; Patient Enrollment, Randomization Progress, Drug Inventory & Shipping and Patient Discontinuation.



Seamless System Integration

ICOPhone™ has the ability to integrate with a variety of clinical trial applications, including CTMS, EDC systems, Lab systems and Drug Supply systems. We have experience integrating with many of the well-known applications used today, and can transfer any information collected in our system. This streamlines the clinical trials process, and enables our sponsors to capture data entry and cost efficiencies.

Built to High Standards

Validation

Each IVR and IWR system follows our standard System Delivery Life Cycle (SDLC), which governs the way we build our systems and ensures that quality is built into each step of the process. Each system is fully validated, and ICOPhone™ is 21 CFR Part 11 compliant.

Reliability

ICON built a high level of redundancy for the ICOPhone™ application and is designed to automatically fail-over to a separate secondary location in the event of a disaster. To our sponsors this means that there is no unexpected system downtime, and your data is always protected and safe.

Help Desk

The ICOPhone™ Help Desk is available 24 hours per day, 7 days a week via email or toll-free phone access, and is staffed by ICON employees. We support over 140 languages, and more than 90% of all calls are handled on the first call. Inquiries are reviewed on a monthly basis and monitored randomly to measure quality and determine any trends or common issues.

Excellence in Delivery

ICON's Interactive Technologies group has a proven record of developing and implementing validated IVR and IWR systems with on-time delivery since inception. Our project management is underpinned by comprehensive and consistent processes which conform to ISO9001:200 and our project managers have an average of more than five years experience. They have the expertise to work with sponsors to produce custom IVR/IWR systems that meet study team specifications and help to achieve research goals.

Experience

Having completed over 850 ICOPhone implementations worldwide, we have built a solid foundation in all aspects of electronic trial management solutions. Our systems have managed over 50,000 sites, more than 25,000,000 patient transactions, and have supported over 65 languages in more than 85 countries. We are pioneers of IVR, IWR, and ePRO technology, and have a proven track record of using our technology to help our clients manage their clinical studies.