

#### Capturing, curating, and consuming data for integrated decentralised clinical trials

ICON has applied its operational and services expertise to develop our third-generation mobile patient engagement and data capture platform, configured to conduct the decentralised clinical trials of today and the future. The ICON Digital Platform is built on a scalable cloud-first framework, hosted on Microsoft Azure. Our platform is modular, fully configurable, and designed specifically to reduce clinical trial burden for patients and sites and increase engagement through one unified platform.

### **Currently offering the following features:**

**Mobile App**: Patient study engagement application, with offline capabilities available for IOS and Android

**eConsent**: Easy to use consent signing workflow in both mobile/remote (eSignature) and on-site (print-to-sign) settings

**eCOA**: Quick configuration and easy to build, eDiary, COA and Patient Reported Outcomes

**Televisit**: Schedule and perform virtual one-on-one patient visits securely via an internet connection on a smart phone, tablet or computer.

**In-Home Services**: Digital, end-to-end in-home solution offering visit management and notifications to support sites, nurses and study managers.

**Tokenisation**: Tokenise patients for inclusion/integration of real world data as evidence in clinical trial reporting/analytics

**Reports and dashboards**: Direct user access to organised task management and meaningful, actionable summary data, through a landing page.

We provide support for all countries and languages enabled on the platform.

ICON has a solid road map, and a multi-year investment commitment for scheduled release of features to broaden and deepen the level of our capabilities.

## Integrating patient, site, and study services for decentralised clinical trials

### Enabling the full breadth of ICON's services through one single platform

- ICON's Concierge Services provide sponsors with outbound and inbound direct support to patients, caregivers and site staff. Through this unique team, we can support stakeholders in both technology and clinical aspects through phone, email and SMS touchpoints, increasing engagement and improving compliance.
- Access to Mapi Research Trust supports and enables digitalisation and validation of rating scales, quality of life questionnaires, as well as other validated instruments.
- Language Services have enabled us to develop a first-ofits-kind library with validation, certification, and translations
  built-in. Using pre-built questionnaires and a visual
  inspection of the final schedule, a study can be effectively
  set up in a fraction of the time it would take on other
  systems, with unparalleled accuracy ensuring a shorter
  time frame to launch a study.
- FIRECREST, ICON's Site Portal hosts just-in-time training and a suite of practical solutions to enable communication and engagement of sites, patients and study team.
- Digitalisation of Accellacare In-Home Services, enabling real-time data capture and access to provide site's oversight.

#### Bringing benefits to your study

#### Speed, scalability and quality data

- A unified experience for patients, sites and sponsors improving operational integration via a common technology platform
- Harmonised integration of all patient and site services required for conduct of decentralised clinical trials
- Streamlined enablement of our wide range of study services via prioritisation of business processes in standard configurations and workflows
- Reduced study start-up timelines via
  - Modern modular architecture enabling flexible, customisable configurability including in-home services, eCOA, patient apps, telehealth, site training
- Enhanced IRB submission and accuracy
  - First-of-its-kind eCOA library with validation, certification, and translations
- Reduced risk through data automation and real-time access
- Global scalability adhering to country specific regulatory standards with MSFT Azure

#### **Built for interoperability**

## API first architecture with FHIR based data storage enables interoperability among key operational systems/tools:

- EDC Systems, Rave and others through custom API's
- IXRS/IRT, Randomisation and Drug Supply
- CTMS systems for payments, subject allocations, study data
- Devices / wearables
- Ability to integrate to various EHR's, like EPIC

### Experience harmonising digital solutions across:



**66**Studies

### Modular components providing flexibility for your specific study

# Modern micro services architecture provides maximum configurability to reduce deployment and study start-up timelines

The platform's **Study Builder** component uses drag and drop functionality, allowing study configurators to build a questionnaire, assessment, or blue-tooth component quickly and easily and storing the designed assessments with built-in quality checks ensuring any out-of-range data are caught upon entry.

The study **Schedule of Activities (SoA) Planner** manages the frequency, schedule, and participant notifications in a user interface that mimics a traditional SoA grid within the protocol, simplifying the preparation of workflows and enabling quick and accurate quality control. Each questionnaire, connected device, or observation can be played and completed seamlessly, whether on the web, tablet, or phone.

The platform is built with modern components allowing it to be released on Android, iOS, and web simultaneously.

Contact us for more information on how the ICON Digital Platform can reduce time in your next decentralised clinical trial.

ICONplc.com/digital-platform

