# SQN Health EDC

*Fact sheet*

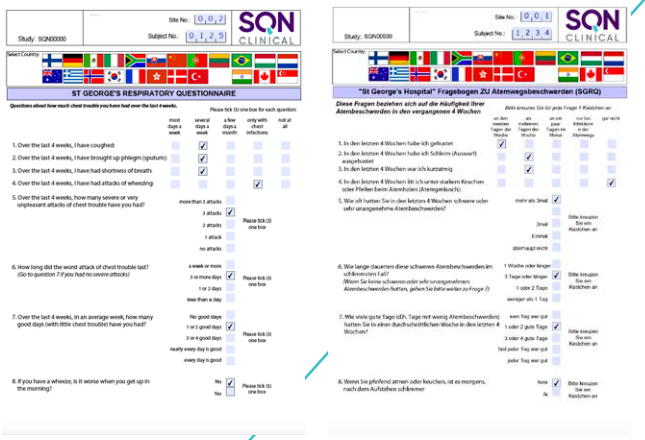
**SQN Health EDC provides an innovative and effective clinical, data management and reporting environment that has been extensively used by global pharma, biotech and other CRO companies to support the simplest and most complex international trial designs. It combines ease of data collection with extensive project management and clinical oversight and consistently delivers high quality data while minimising the risks commonly associated with this process. There will never be the need to compromise your study design because of functional limitations found in other EDC systems.**

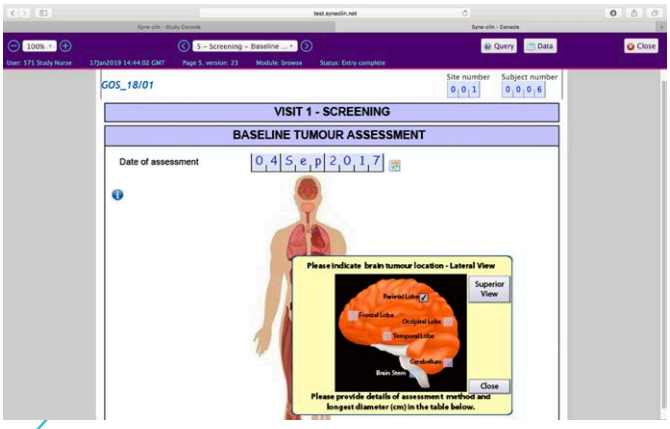
## Intuitive EDC system and processes

Everything about our EDC system is designed to help you run successful trials, mitigating risk and shortening your time to market. Site staff and monitors love it!

The ease of initial set-up means your trial can get underway quickly; six to ten weeks from final protocol is common. This is facilitated by advanced technology using an extensive library of study design and eCRF elements. This library approach is CDISC-based and can incorporate your company and study-specific eCRF components allowing efficient and cost-saving use within and across multiple trials.

Local language is also supported with ease.




## Giving you control and access to your trial data

Real-time access to patient data allows effective safety management. Data-dependent email or SMS alerts provide enhanced oversight and proactive notification of important study events such as Serious Adverse Events etc. Interactive dashboards with drill-down capability gives you the necessary trial oversight even from your mobile and wearable devices.

Personalised and web-based training ensures smooth initiation of trials and includes assessment of user competence and certification. The need for helpdesk support is substantially reduced, aiding continuity of data collection processes and supporting high user satisfaction across the clinical team.

**Our SQN Health EDC will ease the management of your study, including:**

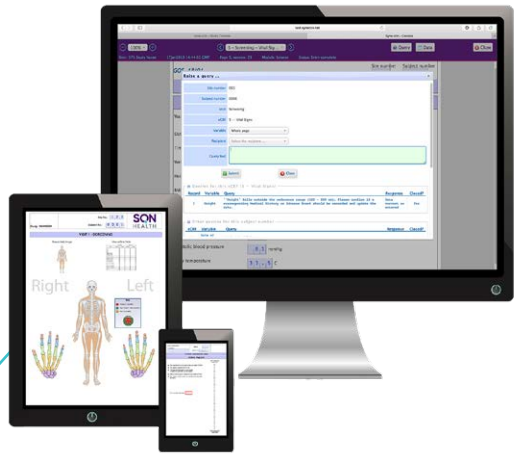
- Reducing risk with real time access to customisable reports
- Integrated query management and oversight
- Integration of ePRO, Diary Cards, IxRS, Laboratory data, Images etc
- Oversight of protocol violators
- Support to SAE expedited reporting and PV integration
- 24/7/365 interactive helpdesk
- Use of mobile devices, including tablets and smartphones
- Support to DSMBs (including Patient Profile reports)
- Real-time data extraction for further review and analysis
- Fully integrated statistical analysis and reporting
- Providing a data package that confidently meets regulatory requirements

## Rapid set-up and deployment

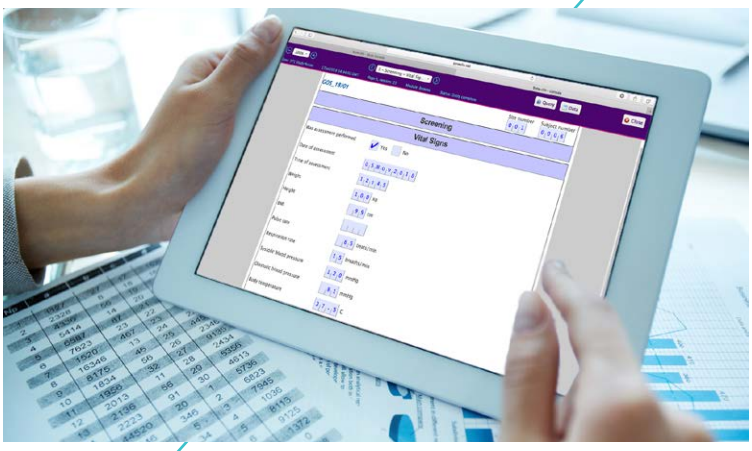
An extensive library of functional and validated eCRF components is a unique feature of our EDC system. This allows us to produce an advanced interactive eCRF within a few days that allows an early, yet extensive eCRF review against the trial protocol by the clinical, statistics and data management teams, dramatically improving the eCRF quality and time to study start.

For many sponsors, we have developed an eCRF library that reflects their unique trial and development needs.

With standard mapping, all data are CDISC compliant, delivering data standards that meet regulatory needs from a data collection, analysis, reporting and submission perspective.




## Your trial your way




Our efficient and structured trial set-up process is also flexible to meet your specific needs.

Interactive eCRFs available early on in the process ensure that the SQN EDC system reflects the detailed needs as defined by the study protocol and allows for easy review and modifications in the case of protocol amendments, etc. The rapid interactive development process significantly reduces the time from final protocol to first patient first visit.

Any data or process that is specific to your study can be accommodated, incorporating innovative eCRF data collection forms and real-time reports that focus on your study-specific outcomes. You get what you want with no need to compromise.

## Sophisticated, yet simple to use

The ergonomically designed eCRFs are intuitive to use and easy to complete. Frequently, sites become frustrated with overly complex and slow EDC systems, this is not the case with our approach.

Deployment at site is simplicity itself with support from experienced staff and training/support processes.

Plus:

- eCRF forms and completion guidelines can be presented in multiple languages and switched interactively when needed.
- Patient reported outcomes (ePRO), such as questionnaires, can be incorporated, again using local language options.
- Adaptive study designs can be accommodated.

## Quality of data

The quality of your data is paramount, and our system delivers this to the highest level.

This includes:

- Field level validation checks at point of data entry maximises data quality at the point of origin.
- Fully integrated clinical, data management, PV and coding systems (MedDRA, WHODrug or your own specific dictionaries).
- Powerful integrated validation, query management and reporting delivers dependable data with appropriate scientific oversight.

Proactive management of data reduces the number of queries and significantly accelerates database lock and reporting.

## About SQN Clinical

Established in 1996, SQN Clinical entered the clinical research industry and quickly became an established leader in biometrics. The last two decades have seen significant changes in clinical trial processes as technology has come to the forefront, driving processes in every sector.

At SQN we have driven and innovated the change in trend from paper to electronic data capture (EDC) solutions and from assessing the tools in the marketplace we quickly established that for a large amount of therapeutic areas, these were not flexible enough to fulfil the evolving needs of clinical research and so we created SQN Health – our ecosystem of tools and solutions to facilitate the shift to a digital world in healthcare.

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|  **Statistics** |  **ISS/ISE CDISC data integration** |  **Data management** |
|  **CRF/eCRF Design** |  **Trial management and advanced data analytics** |  **ePRO and patient centric data** |
|  **EDC systems deployment** |  **Clinical Services** |  **Medical writing** |