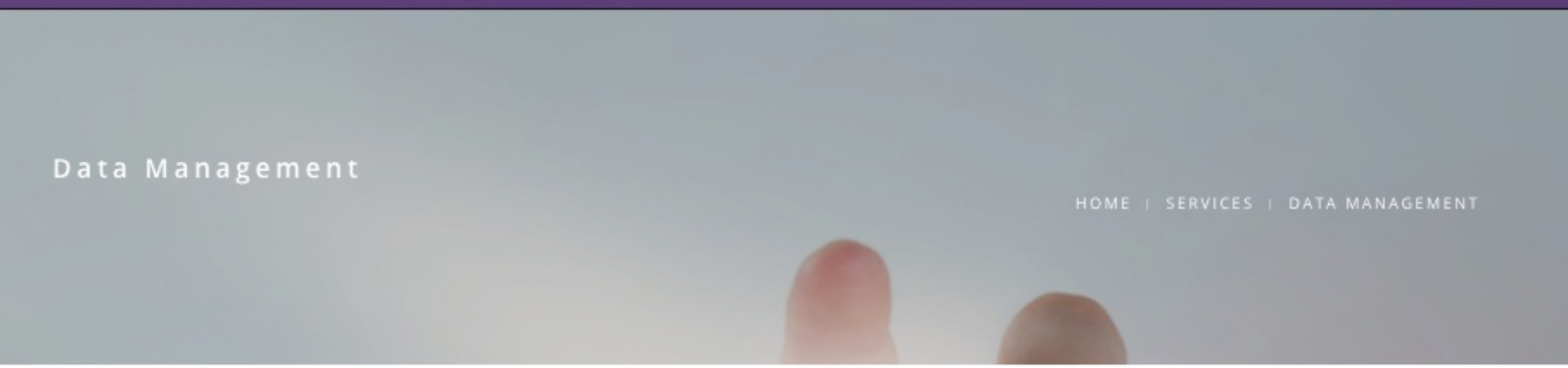


Data Management

Your trial is unique to your needs

Your trial is unique, therefore it is paramount your data management support is flexible to suit your needs – the way your data are collected and managed will impact on the overall quality and efficiency of your trial.

Our world-class data management team and EDC/ePRO technology, supported by effective quality management processes are used to ensure your data are reliable, compliant, secure and delivered on time.

Fully customisable data management services

With an emphasis on quality standards, our team will ensure your study is completed within the shortest possible timeframe, creating a cost-effective solution that refuses to compromise on excellence.

With our help you are assured of:

- Effective patient safety management
- Tailored design of your eCRF/CRF/ePRO and clinical database
- Innovative patient-centric data collection technology
- Full risk management of your data
- Real-time access to all your data at any time
- Processes and data quality that meet QA and regulatory guidelines in every respect

Quality built in

Our team will ensure your study is completed within the shortest possible timeframe, creating a cost-effective solution that refuses to compromise on quality.

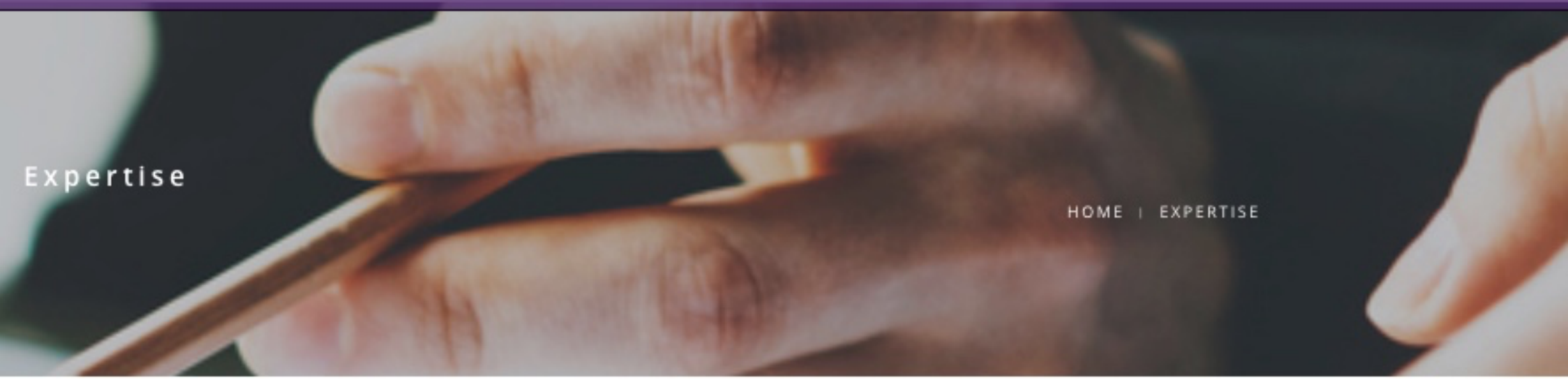
Our staff have strong technical skills and extensive therapeutic experience. We would propose a project team with appropriate experience to meet your trial objectives. No matter how large or complex your trial will be, we will always deliver the highest quality of service on time and within agreed budgets.

Client-specific libraries facilitate rapid database set-up and study initiation as well as accelerated analysis and reporting. CDISC-based processes (CDASH, SDTM, ADaM and define.xml) support the delivery of high quality data.

It just works

By choosing SQN's fully integrated trial management and data management services, trial oversight is greatly enhanced. Easy access to data is available 24/7, providing you with powerful, flexible and real-time reporting of project management and clinical metrics through interactive, personalised dashboards and access to patient data.

SQN has a well-earned international reputation as a specialist data management company who can be trusted to meet the biometrics needs of your projects, while working seamlessly with your team and chosen partners.



Our extensive clinical, scientific and technical expertise will support your specific needs.

This expert knowledge and experience will help you in your drive to bring your new pharmaceutical, biotechnology, biosimilar or medical device products to market as efficiently and budget-friendly as possible.

Through stringent quality management and in-depth therapeutic expertise, we will help design and run your trial, adaptively or traditionally, from beginning to end.

Our team covers all areas of your development needs, including:

- Proof of Concept and Phase I trials
- Phase II – III trials
- Late phase and post-marketing trials
- Clinical experience
- Therapeutic expertise
- Data integration and support for ISS/ISE and regulatory submissions
- Consultancy and specialist services

We would be happy to discuss your specific needs in a friendly and engaging way; we believe you will not be disappointed.

Clinical

When you work with SQN you can trust that we have both deep and broad clinical and therapeutic experience and expertise and can gain access to key opinion and thought leaders in many indications worldwide. Your trial becomes faster to start, patients are recruited more reliably and we support your team with expertise and therapeutic knowledge that is trusted to deliver.

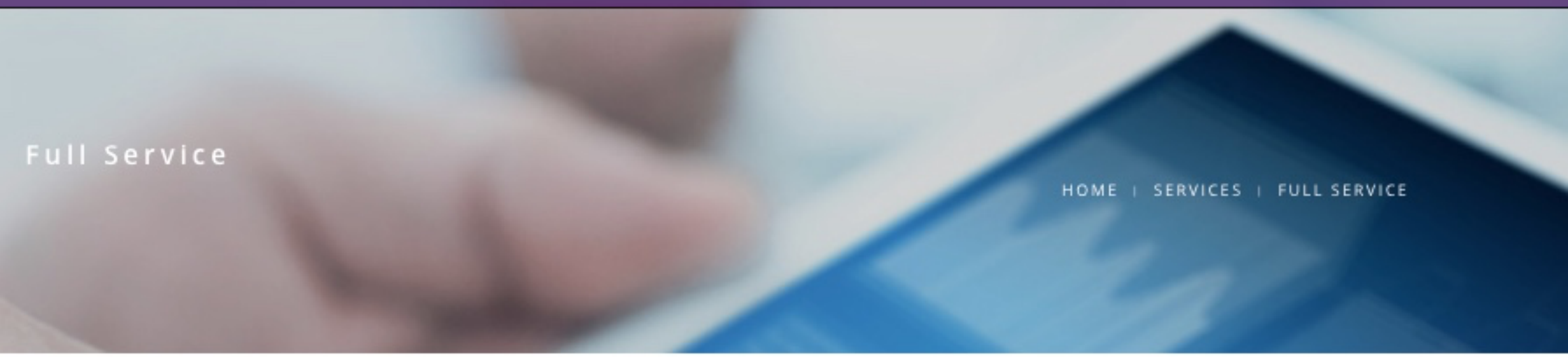
Therapeutic Expertise

Knowing that our people are experienced in relevant therapeutic areas is key in supporting the success of your trial.

Our extensive involvement in local and international clinical trials has supported a significant number of pharmaceutical, biotechnology and medical device companies as well as other CRO organisations. We have been pivotal in many successful NDA's as well as supporting partnering and out-licencing opportunities. Overall this gives us a unique insight into the specific requirements of a wide range of clinical development plans covering a broad therapeutic range.

WINDOW TO OUR THERAPEUTIC EXPERIENCE

To find out more and talk to us about your specific therapeutic requirements, contact us for a summary discussion in the first instance.



Complete Clinical Trials Service

Through our experienced team and extensive national and international network of recognised consultants and specialist clinical and support organisations, you will gain access to a comprehensive range of local and global services to support rapid, focused and effective clinical development.

From the early stages of development planning, study design and feasibility, our strong team of experienced industry professionals focus on providing you with a service based on experience, effective risk management and structured planning. Our supporting integrated technology incorporates risk-based monitoring, adaptive design, real-time project management and clinical oversight reporting, proactively delivering the oversight you need and regulators expect.

International Leadership

Your SQN team is carefully selected according to their experience, therapeutic knowledge and local insight. Through flexible resource management, we make sure you will have an experienced team, with the right skills and knowledge to lead and support your project.

Our state-of-the-art technology supports any local or international language and maximises country and patient trial participation. Effective data collection provides you with highly flexible study design options supported by accurate real-time project and clinical oversight.

With proactive project management and on-demand reporting, our close co-operative, team-orientated service will keep you in touch with your patients and their data 24/7, regardless of your time-zone or location.

The Risk Management Approach

The assessment and management of risk is key to the success of any clinical development programme.

We employ a quality-by-design approach to the conduct of your trial. Together, we determine the critical project success factors and apply risk analysis and management methodologies. This is supported by our Key Performance Indicators (KPI) as well as those we would agree with your company. This, together with our advanced cloud-based EDC system means you will always have your finger on the pulse of your study's status.

There are significant quality and cost benefits in this approach and by incorporating this with a risk-based monitoring strategy ensures visits to site are more focused, efficient and effective.

Why We're Refreshingly Different

Our integrated full service model incorporates the highest level of experience and expertise in each service area. Large and smaller companies alike are finding this approach presents significant added value and cost savings compared with using a single company for all services. Ease of contractual and operational management simplifies the outsourcing process while maximising service quality and reducing development timelines.

We would be delighted to discuss this flexible and effective approach with you in more detail and allow you to see how we, with support from our dependable partners, can maximise the success of your development and project plans.